

THE NATIONAL QUALITY FORUM

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STEERING COMMITTEE ON
NATIONAL VOLUNTARY CONSENSUS STANDARDS
FOR PATIENT OUTCOMES

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MEETING

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TUESDAY
APRIL 20, 2010

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The Patient Outcomes Steering
Committee met in Salon 1 in the Marriott
Bethesda Hotel, 5151 Pooks Hill Road,
Bethesda, Maryland, at 10:00 a.m., Joyce Dubow
and Lee Fleisher, Co-Chairs, presiding.

MEMBERS PRESENT:

JOYCE DUBOW, MUP, Co-Chair
LEE FLEISHER, MD, Co-Chair
RUBEN AMARASINGHAM, MD, MBA, Member
LAWRENCE M. BECKER, Member
E. PATCHEN DELLINGER, MD, Member
ANNE DEUTSCH, PhD, RN, Member
BRIAN FILLIPO, MD, MMM, FACP, Member

LINDA GERBIG, RN, MSPH, Member
EDWARD F. GIBBONS, MD, Member
LINDA GROAH, RN, MSN, CNOR, FAAN, Member
PATRICIA K. HAUGEN, member
DAVID HERMAN, MD, Member
DAVID S.P. HOPKINS, MS, PhD, Member
DIANNE V. JEWELL, PT, DPT, PhD, CCS, Member

DAVID A. JOHNSON, MD, FACP, FACG, FASGE,
Member

IVER JUSTER, MD, Member

MEMBERS PRESENT (Cont'd):

BURKE KEALEY, MD, FHM, Member

PAULINE McNULTY, PhD, Member

LEE NEWCOMER, MD, MHA, Member

VANITA K. PINDOLIA, PharmD, BCPS, Member

AMY K. ROSEN, PhD, Member

BARBARA J. TURNER, MD, MSED, MA, FACP, Member

BARBARA YAWN, MD, Member

ALSO PRESENT:

HEIDI BOSSLEY, MSN, MBA, SENIOR DIRECTOR,

PERFORMANCE MEASURES

HELEN BURSTIN, STAFF

HAWA CAMARA, STAFF

SARAH FANTA, STAFF

SEAN O'BRIEN, MD, CONSULTING STATISTICAL

REVIEWER

REVA WINKLER, MD, MPH, PROGRAM CONSULTANT

SEAN O'BRIEN, MD, Consulting Statistical
Reviewer

NQF STAFF:

HEIDI BOSSLEY

HELEN BURSTIN

HAWA CAMARA

SARAH FANTA

REVA WINKLER

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

10:09 a.m.

CO-CHAIR DUBOW: Good morning,
everybody. I am Joyce Dubow, Co-Chair.

CO-CHAIR FLEISHER: I am Lee
Fleisher, the other Co-Chair.

CO-CHAIR DUBOW: We are a little
bit late, and we will go around the room,
introduce ourselves, declare whether we have
any conflicts, and then we will review the
agenda for the next two days.

We would very much appreciate it
if the name tags could be directed toward us
so that everybody gets called by the proper
name, and also, please, when you introduce
yourself, if you were Chair of one of the
Technical Panels, please also let us know that
so that we will know who is who.

I am Joyce Dubow from AARP.

CO-CHAIR FLEISHER: I am Lee
Fleisher from the University of Pennsylvania,
Chair of Anesthesia.

1 DR. WINKLER: I am Reva Winkler.
2 I am a Project Consultant to NQF.

3 MEMBER AMARASINGHAM: I am Ruben
4 Amarasingham. I am a physician at Parkland
5 Health and Hospital System.

6 MEMBER JOHNSON: David Johnson, a
7 gastroenterologist from American College of
8 Gastroenterology, and I was the GI TAP Chair.

9 MEMBER JUSTER: Iver Juster from
10 Outcomes and Informatics at ActiveHealth
11 Management. No disclosures.

12 MEMBER AMARASINGHAM: No
13 disclosure.

14 MEMBER JOHNSON: David Johnson, no
15 disclosure.

16 MEMBER KEALEY: I am Burke Kealey.
17 I am a hospitalist for HealthPartners
18 Integrated Delivery System in Minneapolis, and
19 also an officer of the Society of Hospital
20 Medicine. No disclosure.

21 MEMBER McNULTY: Hi. I am Pauline
22 McNulty from Johnson & Johnson. No

1 disclosures.

2 MEMBER GERBIG: Hi. I am Linda
3 Gerbig from the Association of Perioperative
4 Registered Nurses. No disclosures.

5 MEMBER BECKER: Hi. I am Larry
6 Becker. I am the Director at Xerox
7 Corporation, and I am also on the Board at The
8 NQF.

9 MEMBER TURNER: Good morning. I
10 am Barbara Turner, American College of
11 Physicians. No disclosures.

12 DR O'BRIEN: Hi. I am Sean
13 O'Brien. I am a statistician at Duke Clinical
14 Research Institute, and I am here as a
15 consultant for NQF as a fiscal reviewer. DCI
16 is involved with measures to do with STS. So
17 when those are discussed, I will not be here
18 as a consultant for NQF.

19 MEMBER FILLIPO: Hi. I am Brian
20 Fillipo, the Vice President for Medical
21 Affairs at Bon Secoeur, St. Mary's, and I have
22 no disclosures.

1 MEMBER YAWN: Barbara Yawn, family
2 physician, health services researcher, and I
3 was Chair of the TAP, Pulmonary TAP, and I
4 have no disclosures.

5 MEMBER HAUGEN: Pat Haugen,
6 consumer, National Breast Cancer Coalition.
7 No disclosures.

8 MEMBER PINDOLIA: Vanita Pindolia,
9 pharmacist, Henry Ford Health System in
10 Detroit, Michigan, medication management
11 programs, and I have no disclosures.

12 MEMBER GROAH: Linda Groah, CEO of
13 APRN, and I have no disclosures.

14 MEMBER JEWELL: Dianne Jewell. I
15 am a physical therapist representing the
16 American Physical Therapy Association. I was
17 the Chair of the Bone and Joint TAP, and I
18 have no disclosures.

19 MEMBER DEUTSCH: Anne Deutsch. I
20 am a clinical research scientist, Rehab
21 Institute of Chicago. No disclosures.

22 MEMBER NEWCOMER: Lee Newcomer

1 with United Health Group, and I run the cancer
2 and cells divisions there. I chaired the
3 Cancer TAP, also the former Chairman, Park-
4 Nicollet Health Services in Minneapolis.

5 MEMBER HOPKINS: David Hopkins,
6 Director of Quality Measurement, Pacific
7 Business Group on health. I have no conflicts
8 to disclose.

9 MEMBER DELLINGER: Patch
10 Dellinger, Professor of Surgery and Chief of
11 General Surgery at the University of
12 Washington. I chaired the IV TAP. I don't
13 think I have any disclosures relevant to here.
14 I have consulted for almost every
15 pharmaceutical firm that makes any antibiotics
16 over the years, but I don't think that is
17 relevant to what we are doing here.

18 MEMBER ROSEN: Amy Rosen. I am
19 health services researcher at Boston
20 University, School of Public Health and School
21 of Medicine, and also at the VA.

22 MS. CAMARA: Hawa Camara, analyst

1 at NQF.

2 DR. BURSTIN: Good morning,
3 everybody. I am Helen Burstin, Senior Vice
4 President at NQF.

5 MS. BOSSLEY: good morning. I am
6 Heidi Bossley, Senior Director for Quality
7 Measures at NQF.

8 CO-CHAIR DUBOW: Are there any
9 Committee members on the phone? Is Shelley?
10 Okay.

11 (Off-mike introductions.)

12 MS. FANTA: Hi. Sarah Fanta,
13 research analyst with NQF.

14 CO-CHAIR DUBOW: Are there any
15 members of the public on the phone who would
16 like to introduce themselves, please? We
17 heard a few of you. Rita?

18 DR. GALLAGHER: Hi. It is Rita
19 Munley Gallagher with the American Nurses
20 Association.

21 CO-CHAIR FLEISHER: Bruce, are you
22 there?

1 CO-CHAIR DUBOW: I thought we
2 heard somebody else this morning.

3 DR. PATTON: Mary Patton from the
4 Association of American Medical Colleges.

5 DR. HALL: Bruce Hall from the
6 American College of Surgeons.

7 CO-CHAIR DUBOW: Okay, thank you
8 very much.

9 DR. WINKLER: Welcome, everyone.
10 The last six months since we met in October
11 has been a very busy and intense time. As you
12 all participated in, we had two conference
13 calls in March to evaluate an initial set of
14 12 measures, and I am going to give you the
15 results of all of that, but at the same time,
16 numerous conference calls and meetings were
17 held with the Technical Advisory Panels
18 preparing for this meeting.

19 So thanks to everybody for your
20 participation. But let's go on to what
21 happened in the past, so we know where we are.

22 Out of the 12 measures that you

1 evaluated over the conference calls in March
2 and 17th and 24th, you recommended eight of
3 them to go forward for endorsement.

4 Six of the measures were
5 recommended straight out for regular
6 endorsement, and they are the Intensive Care
7 In-Hospital Mortality Rate, as well as the
8 Intensive Care Length-of-Stay measure paired
9 with the ICU.

10 The complication rate for ICD and
11 the 30-day readmission for PCI, and then the
12 composite measure for AMI discharge care
13 transition, and also the heart failure
14 discharge care transition composite measure.

15 So a majority of the Committee
16 members recommended that these go forward for
17 endorsement.

18 Any questions from anybody on the
19 Panel? Okay, now you did recommend that two
20 of the measures go forward for time limited
21 endorsement, and these are the two measures
22 around pulmonary rehabilitation. The first is

1 the health related quality of life, and the
2 second is functional capacity. Any questions
3 about those?

4 We have had conversations with the
5 developers of these two measures, and they are
6 in agreement with doing the testing of these
7 measures within the 12-24 month time frame
8 that NQF requires. So that is where we are.

9 MEMBER YAWN: Is it 12 or is it
10 24?

11 DR. BURSTIN: Twelve months is our
12 new policy. This project hit it smack dab in
13 that transition point. So I think we will
14 allow them to go up to 24 months, but
15 preferable, the sooner the better, and they
16 know that.

17 MEMBER YAWN: That is good. I was
18 just going to make a complete 24 months.

19 DR. WINKLER: So any other
20 questions on that? Okay.

21 The four measures that were not
22 recommended -- but I will tell you that those

1 were close-ish, but these were the individual
2 measures that are part of composites. The
3 majority of -- About half the Committee really
4 only recommended these measures for the
5 composite only, and then a goodly -- and then
6 several more not at all.

7 So as stand-alone measures, these
8 four were not recommended, but they are part
9 of the composite, which you did recommend.

10 Questions on that?

11 Okay, so that is where we are.

12 Given that --

13 MEMBER JUSTER: So they are still
14 going to be reported?

15 DR. WINKLER: These measures are
16 part of the composite. Correct. Just but you
17 did not recommend them as stand-alone,
18 independent measures.

19 Given that this is sort of a
20 decision endpoint, we would like the
21 opportunity for public comment on them.

22 CO-CHAIR DUBOW: We will have

1 public comment in just a minute. I just want
2 to remind you what happens to our
3 recommendations. Do you want to explain that?

4 DR. WINKLER: Sure. What is going
5 to happen next is we have drafted a report
6 that describes the discussions and the
7 evaluation of these 12 measures. We are
8 finalizing it to be released for public
9 comment in May. All right?

10 We expect to get feedback from NQF
11 members as well as members of the public at
12 large. Those comments will be collated and
13 organized by measure.

14 We will also be asking comments on
15 the measures not recommended, and then we will
16 be coming back to you sometime in June,
17 probably around the third week of June, to
18 look at those comments to see how -- This is
19 feedback for your decisions, to see if it
20 changes your mind, gives you a different way
21 of thinking about things, brought up issues
22 you hadn't considered, whatever.

1 This is sort of an opportunity to
2 get feedback on the decisions you made, and
3 at that time make any revisions which you feel
4 might be necessary based on those comments.

5 After that, the revised draft
6 report will be sent to NQF members for voting.
7 This is planned for the month of July, and
8 then the results of voting will go to the
9 Consensus Standards Approval Committee in
10 August.

11 The Consensus Standards Approval
12 Committee of CSAC is a subcommittee of the
13 Board of Directors whose charge is to look at
14 the process of evaluating and recommending
15 these measures as well as the measures
16 themselves on behalf of the Board. Then the
17 Board endorsement is scheduled for September.

18 So that is where we are going to
19 go with these measures going forward. So your
20 role is not finished with them totally. We
21 will want to come back with you after the
22 comment period to get your feedback and

1 consideration of those comments.

2 MEMBER HOPKINS: So that report
3 you referred to is going to encompass
4 everything, not just the measures that we
5 already voted on, but everything that we are
6 looking at today?

7 DR. WINKLER: What we are going to
8 do is put --

9 MEMBER HOPKINS: Just these?

10 DR. WINKLER: What we are going to
11 do is put these out in two ways. A couple of
12 reasons: It gets a group of them out forward
13 and faster. It is a little easier on
14 audiences to digest that number of measures.
15 So we are releasing them as two publications.

16 You are right. Down the road
17 where final-final comes together, they will
18 get packaged together, but for right now --

19 MEMBER HOPKINS: The other
20 question: Are we going to see that draft
21 report before it goes out?

22 DR. WINKLER: Yes. We are

1 planning on sending it to you. We didn't
2 think you wanted it like last Thursday when it
3 was ready, with everything else. So I will be
4 happy to send it to you tonight or tomorrow
5 night. Absolutely, we will be sending it to
6 you for your comments, but we didn't want to
7 over -- You have plenty right now. We want to
8 give you a chance to take a breather.

9 CO-CHAIR DUBOW: I just want to
10 remind you that the measures that we don't
11 recommend are also included in the four and
12 subject to public comment as well. So that
13 you can see, we will have the opportunity to
14 gauge public response on all of the measures.

15 MEMBER HOPKINS: So the results
16 that you just told us, what got voted for,
17 what didn't, that came out of our voting
18 survey. This is the first time we have heard
19 what those results are.

20 DR. WINKLER: The reason it took a
21 long time is some of you voted conditionally.
22 You recommend with conditions. I had to sort

1 through all those conditions with the measure
2 developers and figure out whether they
3 responded and whether your vote ultimately
4 became a yes or a no. That took a while.
5 That takes a while. So, yes.

6 We also have -- I just finished
7 them -- the summaries with the actual votes.
8 Those will be available. Again another thing
9 to circulate to you; didn't think you wanted
10 it last week, and we will be sending those to
11 you as well. they will be part of the
12 information that is also posted. So it is in
13 view for everyone on how the votes came out,
14 not by individual but in the aggregate for the
15 committee.

16 CO-CHAIR DUBOW: If there are no
17 more member comments, we are now open to
18 entertaining comments from the public.

19 MEMBER GIBBONS: I have a comment.

20 CO-CHAIR FLEISHER: Please
21 identify yourself.

22 MEMBER GIBBONS: Ted Gibbons from

1 Seattle, Washington.

2 CO-CHAIR DUBOW: We can't hear
3 you.

4 MEMBER GIBBONS: This is Ted
5 Gibbons from Seattle, Washington.

6 CO-CHAIR DUBOW: Are you speaking
7 on a speakerphone?

8 MEMBER GIBBONS: No. I am on a
9 headset.

10 CO-CHAIR DUBOW: It is really
11 breaking up. It is very difficult to hear
12 you.

13 MEMBER GIBBONS: Okay. I am
14 sorry. Why don't you go ahead then. I will
15 forgo my comment.

16 CO-CHAIR DUBOW: Ted, again we are
17 going to listen very carefully. Ted?

18 MEMBER GIBBONS: I will not
19 comment. Thanks.

20 CO-CHAIR DUBOW: Okay.

21 DR. WEINER: Thank you. I am Dr.
22 Weiner from SCAI, and I just want to raise

1 some concerns over the PCI readmission
2 measures. We have been on record now almost
3 four occasions opposing the current measures.

4 I think with now the passage of
5 the Patient Protection Affordable Care Act,
6 there are even new wrinkles that, I think,
7 need to be considered as part of this measure.

8 In the Hospital Readmission
9 Reduction Program, there are actually now
10 penalties for readmissions to hospitals, and
11 that represents in the first year
12 approximately a one percent cut across the
13 board for hospitals who fail to meet the
14 measure.

15 DR. GALLAGHER: This is Rita
16 Gallagher. We cannot hear you at all.

17 DR. HALL: This is Bruce Hall from
18 the American College of Surgeons. Yes, we are
19 not hearing anything on the call.

20 CO-CHAIR DUBOW: Okay, hold on a
21 minute. We are trying to sort that out. Can
22 you hear us? Guess not. We are going to try

1 something else. Just a minute. Thank you.

2 DR. WEINER: I will start again,
3 just for the benefit of the folks on the
4 phone.

5 I am Dr. Bonnie Weiner from SCAI.
6 I am an interventional cardiologist, and we
7 have been on record now on multiple occasions
8 being opposed to the proposed PCI readmission
9 measure, and I don't know that we should go
10 through all of the details, but certainly, the
11 concern evolves around attributable
12 readmission.

13 Now with the passage of the
14 Patient Protection and Affordable Care Act,
15 there is even a bigger issue, I think, which
16 reflects on the potential for penalties as
17 part of the Readmission Reduction Program,
18 which represents about a one percent across
19 the board cut to hospitals who don't meet an
20 approved measure that will unfairly penalize
21 hospitals with cath labs as opposed to
22 hospitals that are potentially not at risk for

1 that one percent risk, because they don't
2 happen to have a cath lab.

3 So I think that is an unfair
4 advantage -- unfair disadvantage to hospitals
5 who are providing high quality care and high
6 value and high technical types of care for
7 cardiovascular patients.

8 It is also important to recognize
9 that in the Act there are specific exclusions
10 for readmissions that are unrelated to the
11 prior discharge, and that has been one of our
12 big concerns about the way the current measure
13 is designed, that it does not attribute the
14 readmissions to the PCI; and because this is
15 a measure that is specifically termed related
16 to the procedure as opposed to the disease
17 state that the PCI is treating, it seems
18 unreasonable to us to expect the PCI hospital
19 physicians and system to be accountable for
20 readmissions that are unrelated to
21 complications of that procedure or the process
22 of that procedure.

1 As we have looked at the data,
2 there is a significant number of the
3 readmissions within the 30 days after PCI that
4 are not attributable to the PCI procedure
5 itself, and we don't believe that that is
6 being compensated for appropriately, the way
7 the measure is defined.

8 Finally, if this were to go
9 forward, we think that, first of all, the 30-
10 day is the wrong window for PCI, because there
11 is a lot of noise beyond the first seven to 14
12 days that, again, is mostly unrelated to the
13 PCI procedure. But if it is going to go
14 forward in its current form or any form, we
15 think this should be a time-limited measure,
16 because we think there is a lot to be learned
17 about how to better define what is
18 attributable and not attributable to the PCI
19 procedure itself. Thank you.

20 DR. NEWCOMER: Just a question.
21 You mentioned that there is a lot of
22 admissions after the PCI not related to. What

1 were your criteria to deciding what was and
2 what wasn't, and just give me a rough
3 percentage of how many were not related.

4 DR. WEINER: Sure. I don't have
5 the exact numbers in front of me, but it could
6 be as much as 30 percent. A good example is
7 somebody who has a PCI who then comes back in
8 to get their hip replaced or has a routine
9 screening colonoscopy, because it happens to
10 be their time to get a yearly colonoscopy.

11 So there is a lot of those
12 diagnoses that are captured within the 30
13 days. There is no question, if somebody has
14 a breathing event after a PCI and he needs a
15 colonoscopy or an EGD, that would be an
16 attributable risk, I think, because of the
17 drugs we use and all the things that go on
18 around the PCI. But for the routine screening
19 ones, we have no mechanism to really sort that
20 out from a coding standpoint. You know,
21 there's a lot of attributable risks.

22 MEMBER JOHNSON: I am a

1 gastroenterologist. We don't admit people for
2 a colonoscopy or endoscopy. So they wouldn't
3 even be on the screen.

4 DR. WEINER: Oh, I mean, for some
5 of the states, that is true. But I think for
6 a lot of the states, they do get captured
7 because of billing issues as inpatient
8 procedures.

9 CO-CHAIR FLEISHER: And also you
10 would not be doing the rectal surgery within
11 30 days of a PCI. Where is your data from
12 that you actually gave us that 30 percent
13 unrelated? The measure specifications have
14 been provided to you by CMS?

15 MR. HARDER: There should be the
16 top 100 codes in a chart at the end.

17 CO-CHAIR FLEISHER: So you are
18 saying it is from CMS data that you are --

19 MR. HARDER: Right.

20 CO-CHAIR DUBOW: Are there any
21 other questions? Dr. Johnson, did you have a
22 question?

1 MEMBER JOHNSON: Just a comment.
2 We actually have very specific guidelines and
3 consensus recommendations. So we never do a
4 procedure, unless it is an emergency, within
5 30 days, as far as any type of screening or
6 routine elective stuff; because Plavix is non-
7 negotiative for 30 days. A non-drug alluding
8 stent, 30 days you can stop it, but we don't
9 do -- and I am a past President of the
10 College, and I was involved in all these
11 guidelines.

12 So I will tell you that that just
13 seems to be a very, very minute scope of the
14 patients you are talking about.

15 DR. WEINER: And again, there's
16 100 codes, and I happened to pick those couple
17 off the top of my head. There are certainly
18 others. There are dialysis codes that are
19 used, and again we are not talking about
20 somebody who has acute renal failure and needs
21 dialysis because of a complication related to
22 contrast.

1 We can't sort out the sort of
2 chronic dialysis patient who gets sick for
3 other reasons, you know, two weeks later, and
4 winds up getting admitted, and the code of
5 dialysis is used as part of that admission.

6 That is why we think there is so
7 much noise in the measure. In order to
8 attribute it to the PCI procedure itself, we
9 need a lot more information, a lot more
10 granularity about how those codes are being
11 used, and to not subject the hospitals to the
12 potential of the one percent penalty across
13 the board for all their DRG reimbursements
14 just because we are not very good at defining
15 what those attributable risks are up front.

16 DR. GALLAGHER: This is Rita
17 Gallagher again. I am on the measure
18 development team. Would it be okay if I made
19 a comment about why we approached it this way?

20 CO-CHAIR DUBOW: Please.

21 DR. GALLAGHER: Okay. The
22 challenge -- You know, we didn't design it so

1 that every -- We didn't design to account for
2 tightly related -- readmissions that were
3 related to the procedure just by the AMI going
4 into heart failure. The all cause relation
5 measures inside the group of four don't take
6 a narrow view.

7 Then the challenge is, I think,
8 NQF has seen in other measures like APR DRG
9 readmission measure where you try to look at
10 pairs of inpatient diagnosis and procedures,
11 and then a readmission diagnosis like heart
12 failure, and then readmission, and is this
13 related or not, not just to the procedure but
14 to the hospital around the procedure.

15 So this is a measure that measures
16 not just the procedure, but the person's
17 experience of hospitalization and discharge,
18 coordination of care, follow-up, medication
19 reconciliation, and there are a lot of things
20 around that care that may not be related to
21 the interventional cardiologist's actual
22 technical expertise in the procedure that do

1 affect the possibility a patient is
2 readmitted, and we actually want to capture
3 the, quote/unquote, "aspect readmissions"
4 relative -- looking across the spectrum of
5 hospitals and seeing which hospitals had
6 relatively high readmission rates.

7 We know there are going to be some
8 readmissions that are unavoidable. We just
9 know that. We are not trying to get to sort
10 identify preventable readmissions and then get
11 those down to zero. We are looking at a
12 relative performance of readmission for
13 hospitalization and the follow-on care for the
14 whole episode of the care of the patient, and
15 that is why it does not try to parse out is
16 this closely or tightly related to the actual
17 execution of the procedure.

18 I just want to comment. I am not
19 sure what the breakdown is for doing that, but
20 that again is as relative performance relative
21 to peers. It doesn't require or demand that
22 only particular kinds of readmissions are

1 counted relative to the condition or procedure
2 for which the patient was originally
3 readmitted.

4 DR. WEINER: Just two comments.

5 One is I think what you say is true if we were
6 talking about disease state treatment, but we
7 are not. This is labeled specifically as a
8 PCI readmission measure, not an acute coronary
9 syndrome, not an acute MI readmission. It is
10 specifically targeted at the procedure, and to
11 not make the readmission related to the
12 procedure, if you are going to call it that,
13 I think, is disingenuous.

14 The second thing is that the law
15 specifically says that the readmissions need
16 to be attributable to the prior admission. So
17 to just sort of ignore that and say this is,
18 you know, somehow relative, when we don't even
19 know what the right benchmarks are at this
20 point, I think, is again a reason to at most
21 make this a time-limited measure so we can
22 gain that information, and at worst something

1 that we should really go back to the drawing
2 board and think about again.

3 MEMBER GIBBONS: Well, this is one
4 of the previous TAP folks here today. Can I
5 make a comment about that?

6 I actually saw this as the measure
7 developer's perspective, and I think that,
8 although I highly respect the intervention
9 opinion on this, I think it is important,
10 though, that it is disingenuous to say that
11 this is only related to the PCI procedure.

12 This is related to the disease
13 states in the PCI with all the results and the
14 need for the PCI and the complex medical
15 conditions that are associated with
16 individuals who need PCI.

17 So this is actually looking at the
18 global perspective of the medical care, is not
19 meant to reduce the readmission rate to zero,
20 but to look at patients that can be examined,
21 reevaluated and reduced by an individual
22 institution looking at their own experience.

1 So I think that to say that this
2 is only related to the PCI operator is
3 actually is actually a very small part. This
4 is looking at the condition that results from
5 the PCI and the management of the patients who
6 have just had the PCI.

7 CO-CHAIR DUBOW: We heard that you
8 support the position of the measure developer,
9 and then missed a lot of what you said. If
10 you could send us a quick overview, just so
11 that the record is very clear, it would be
12 very helpful. An e-mail to one of the staff
13 would be great. We did get the thrust, but
14 not the nuance.

15 MEMBER GIBBONS: I'm sorry. I am
16 actually on a microphone, but --

17 CO-CHAIR DUBOW: Okay. Well, I'm
18 sorry about the technical issue, but just to
19 ensure that we have your view, it would be
20 useful if you could just dash a quick e-mail
21 to staff, just so that we can have it recorded
22 properly.

1 Are there any other questions?

2 Otherwise, we have another public comment.

3 MR. HARDER: Hi. My name is Joel
4 Harder. I am the Director of Quality
5 Initiatives.

6 I am asking the measure developer
7 -- I know that Lein is here -- if she could
8 step up and ask us -- and inform us if this
9 should be used for the Hospital Reduction
10 Program per the legislation, or not.

11 CO-CHAIR FLEISHER: Is that
12 question relevant to our decision?

13 DR. HAN: Yes. I don't think we
14 should comment on the health reform bill yet.

15 MR. HARDER: It will be relevant
16 to the comment period by the public, and I
17 would like the transcript to reflect upon this
18 information.

19 CO-CHAIR DUBOW: But I am not sure
20 that Lein is in a position to be responding on
21 behalf of CMS. So I don't think it is a
22 question that she is in a position to respond

1 to. So it is fair game if you want to raise
2 it, but I don't think that we have anybody
3 here who can respond to it.

4 These regulations haven't been
5 written, and we just don't have the
6 information yet.

7 DR. HAN: And we have to work on
8 how we are going to carry out those things in
9 the health care reform bill, and I don't think
10 that we are right now ready to answer that
11 question. We have to work on that first. But
12 I do have two responses to what you have
13 raised.

14 One is that this is a hospital
15 level measure. So we are not specifically
16 focusing on the physician or the surgeon who
17 performs this procedure. It is the whole
18 management of patients. It is the whole --
19 the system result of the measure. So I just
20 want to remind you that it is a hospital level
21 measure.

22 The other thing is that I think,

1 if you want to talk about the health care
2 reform bill, we are talking about excess
3 readmission here. So it is not shooting at
4 zero, but it is excessive readmission here.

5 CO-CHAIR FLEISHER: So may I ask,
6 in relation to your first comment, so is this
7 really more of an episode of care. The
8 initial comment here was about this is a
9 procedure, but it really sounds like the
10 procedure represents an episode of care. Is
11 that how you are defining it?

12 DR. HAN: How do you define
13 episode of care?

14 CO-CHAIR FLEISHER: In other
15 words, is it really just somebody happens to
16 have a PCI and, therefore, that episode of
17 care really --

18 DR. HAN: Inside a hospital?

19 CO-CHAIR FLEISHER: Yes.

20 DR. HAN: I think it is even --
21 because readmission, we talk about 30 days.
22 So you have that discharge, too. How do you -

1 - you know, the whole care after. I mean
2 discharge planning, that kind of process.

3 I think, if that is the episode of
4 care you are talking about, yes.

5 CO-CHAIR FLEISHER: Yes, I am. So
6 it is just not about the actual procedure.

7 DR. HAN: It is not one thing. We
8 are talking about from patient perspective,
9 that you got hospital, and you were readmitted
10 in 30 days. I think the whole package of the
11 hospital. That is my point.

12 CO-CHAIR FLEISHER: Thank you for
13 that clarification.

14 DR. HAN: Okay, thank you.

15 MEMBER PINDOLIA: I think that you
16 just said what several of us have been talking
17 about is quite important, that this is a
18 person. So we talk about patient centered
19 outcomes, not a 15 or a 30 or a 50-minute
20 window of time in that patient's life, and
21 ignore all of the rest of the things that are
22 happening around them.

1 So I really also strongly support
2 the idea that this is a patient centered
3 measure, and the patient comes in with many
4 things, and to ignore the fact that people
5 choose what happens to that patient in the
6 hospital, regardless of what the patient may
7 think at that moment, so they choose and do
8 the procedure. They choose to give them this
9 medicine or that medicine.

10 I just think that we need to look
11 at a patient centered measure, and it is --
12 You have hospital care of that patient, and
13 you need to keep remembering that.

14 CO-CHAIR DUBOW: Okay. Are there
15 any other public comments?

16 MR. HARDER: Yes. I would like to
17 continue.

18 CO-CHAIR DUBOW: Please.

19 MR. HARDER: I just want to let
20 the Steering Committee understand that this is
21 also an inpatient and outpatient population,
22 and that in the outpatient population the

1 patient comes in for this procedure and gets
2 discharged sometimes the same day, is the
3 trend right now, and that 30-day window is
4 fairly long, in our view, for the
5 cardiovascular related readmissions that we
6 are very, very interested in, and this isn't
7 Nurse Sky's. This was evaluated by the TAP
8 PCI Registry Steering Committee, which is
9 where the patient population is coming from.

10 We really feel that, you know, for
11 this to be of best interest to the PCI patient
12 population, these are issues that we want to
13 see in this measure.

14 CO-CHAIR FLEISHER: Other
15 comments?

16 CO-CHAIR DUBOW: Are there any
17 comments from the public on the phone? Okay.
18 Thank you very much. Thank you both.

19 CO-CHAIR FLEISHER: Any comments
20 from the committee? No.

21 CO-CHAIR DUBOW: Thank you. So we
22 are now going to do the diabetes measures?

1 The intro, right. Sorry.

2 DR. WINKLER: Joyce wants to stay
3 on time. Got it.

4 Just to kind of start the day and
5 the work we have ahead of us is there is
6 another group of measures that we are going to
7 be discussing in the next two days. There are
8 28 measures. All right?

9 They are in a variety of areas, as
10 we have listed them out. We will be
11 discussing them as we did on the phone, but
12 this way we have a slightly different dynamic
13 with being face to face.

14 Measure developers are here with
15 us. So what we will do is, much as we did on
16 the phone, discuss them. We have tried to
17 bunch them into groups, but a lot of the
18 agenda and the order of discussion has to do
19 with availability of those developers and some
20 of the logistics behind that.

21 So this is what we are going to do
22 today. Next slide: What happens with this

1 outcome is similarly, but about a month to six
2 weeks behind the first group, this will also -
3 - we will write the draft report. We will
4 share it with you. The comment period will be
5 in July, the voting in September, and the
6 Board endorsement in October.

7 So we want them about a month
8 apart, so you know where this is going, but
9 they will follow the same pathways.

10 One of the things that the Co-
11 Chairs asked, briefly before we get started,
12 was a review of the decisions this Committee
13 made in October when we set sort of the
14 planners for this project around what are
15 outcomes.

16 Just as a reminder of what we
17 included, there was discussion as these
18 measures were evaluated by the various
19 Technical Panels of what are outcomes? Is
20 this really an outcome measure? Where are
21 those boundaries?

22 If you recall, this group cast it

1 relatively broadly, and just as a review:
2 Measures of patient function, symptom, health
3 related quality of life were in, as well as
4 intermediate clinical outcomes, the
5 biochemical and physiologic, which we have
6 seen some of each; patient experience is an
7 outcome measure, as well as measures around
8 knowledge, understanding, motivation and
9 adherence or health behaviors.

10 The next: Service utilization as
11 a proxy for outcome, I think, is for the
12 readmission measures or ED visit measures or
13 some of those sorts of measures fall into.

14 Then there is nonclinical -- or
15 non-mortality, clinical morbidity associated
16 with a disease control or condition, and then
17 adverse events or complications are outcomes,
18 and then sort of traditional mortality is,
19 obviously, an outcome.

20 So these are the parameters that
21 you all agreed on would be our definition or
22 our scope of what the meaning of outcomes is.

1 So the question does come up in a couple of
2 the measures, whether it fits under this group
3 or not.

4 Some of the measures are composite
5 measures, and they seem to have a mixture of
6 process and outcome, and because of the
7 outcome component, these measures are being
8 considered under this project.

9 So it is within the purview of
10 this Committee to determine that a measure
11 just does not fit under the definition, if you
12 so choose. The TAPs discussed some of these
13 and offered their opinions as well for you to
14 consider.

15 So are there any questions? This
16 is a sort of reminder/follow-up before we
17 start launching into things.

18 CO-CHAIR DUBOW: Just to keep this
19 in mind and to keep this slide handy, because
20 I think it is going to -- I think we are going
21 to need to refer to it, to remind ourselves
22 about the parameters that we set for the

1 definition of outcomes.

2 David, did you want to say
3 something?

4 DR. HOPKINS: Yes. I think
5 another way to look at this is we sort of set
6 out for ourselves the concept of what we
7 consider to be a full dashboard of outcome
8 measures, and at some point in this meeting I
9 hope we have the opportunity to sort of
10 revisit how well we did at filling up the
11 dashboard. That is probably at the end and
12 not the beginning.

13 CO-CHAIR DUBOW: Right. And,
14 Reva, please remind me. The report will
15 include research recommendations. Is that
16 right?

17 DR. WINKLER: Yes. The report
18 includes any recommendations that you make
19 that accompany it, and whether they are
20 research or whatever. We had three
21 recommendations with the last group of
22 measures.

1 There is also the second part of
2 this project which, because we need to get
3 through the measures, we aren't going to spend
4 as much time, but we will get back to, and
5 that is on the gaps, filling the gaps in the
6 kinds of measures.

7 We have been asking to the
8 Technical Advisory Panels for their
9 recommendations. We are using this as the
10 framework, so that for each of the various
11 conditions that have been considered, do we
12 have a measure? If not, what kinds of
13 measures would be desirable to fit into each
14 of them?

15 That is sort of an ongoing process
16 as we go through the rest of this, and it is
17 another part that, at the very end of all of
18 this, will get packaged together. But you
19 will have an opportunity to weigh in and
20 review that as well.

21 We are trying to break this down
22 into digestible pieces, but it is still an

1 awful lot of information to manage right now.
2 So while we will take notes on anything that
3 you raise during the discussion, we will save
4 the focus discussion on the gaps to a later
5 time when we don't have this work to deal
6 with.

7 CO-CHAIR DUBOW: I think there is
8 another overarching issue that we will have to
9 deal with, and that is the concept of best in
10 class, which NQF supports. We have a few
11 measures that appear to be duplicative, but
12 not entirely. On occasion they use a
13 different data source, for example.

14 So we are going to have to come to
15 grips with, I think, the help of the staff to
16 determine how to handle those measures. Do we
17 endorse two measures that are seemingly very
18 similar or do we make a decision about a
19 preferable data source, for example? So I
20 think we just need to keep that in mind, too.
21 Barbara?

22 MEMBER YAWN: And I had a question

1 related to the data source for some of the
2 measures before. They were based all on CMS
3 data, and so when I voted, I made it
4 conditional that they only be applied to CMS
5 data. I am not sure that I understand, when
6 the measure is released, what is said about
7 it; because it does change the way I would
8 vote on some of these.

9 If they are going to use something
10 else than CMS data, I may be quite
11 uncomfortable with some of these measures
12 being applied.

13 DR. BURSTIN: This is an
14 interesting discussion. We have had lots of
15 discussions about this, since you raised it on
16 our conference call. Thank you, David. And
17 it is really an important question.

18 The issue at this point is the
19 fact that these measures include risk models
20 that have been explicitly done on the basis of
21 patients over age 65 in that population. I
22 think we strongly want to move toward getting

1 to the point where we have measures that allow
2 us to, in fact, have a different risk model or
3 a companion risk model, and we are trying to
4 think through what those next steps would be.

5 I think the idea that you would
6 take a risk model developed for an over 65
7 population and just assume it would work in an
8 under 65 population, I think, is difficult.
9 That is where --

10 I'm sorry. The second issue is
11 just, for some of the populations like, for
12 example, Medicare Advantage, I guess the issue
13 more so is I think the risk model probably
14 would still work, but the data availability,
15 I think, becomes the bigger issue.

16 So that is our understanding of
17 it. Any other discussion would be very
18 welcome.

19 CO-CHAIR DUBOW: Just with respect
20 to that, I thought we had, in certain cases,
21 made a recommendation to the developer that
22 the developer work on making the measure

1 applicable to the missing population.

2 MEMBER YAWN: And you got the
3 responses from them.

4 DR. WINKLER: Right. At this
5 point, they would agree that the approach can
6 be applied to other populations, assuming you
7 have the appropriate data, and that the risk
8 model would have to be adjusted.

9 So they are not saying you can't
10 use it, but it is not something you can pull
11 off the shelf and just plug in for another
12 population.

13 MEMBER HOPKINS: So I still have
14 my question. Why can't the measure be
15 represented as applying to a population of
16 people over 65 years old, and not specific to
17 a segment of the Medicare population?

18 MEMBER YAWN: I mean, I would have
19 no problem with that. I just have a problem
20 with saying this measure is approved, and it
21 just seems like, okay, if you are 50 and you
22 have this, it should also include you. That

1 bothers me a great deal. So that is why I
2 said some of my conditional approvals.

3 CO-CHAIR FLEISHER: Sean, did you
4 want to make a comment as someone who reviewed
5 these measures from a methodologic standpoint?

6 DR. O'BRIEN: I would say that
7 some of the qualities of the measure you have
8 to consider have to do with the reliability of
9 the data elements and the data capture, and it
10 is hard to really define that just in general
11 without reference to a specific population
12 and a specific source of the data.

13 So I think, for creating
14 scientific acceptability, it is helpful to
15 define the source.

16 CO-CHAIR DUBOW: On the other
17 hand, or in addition, we need to make a
18 decision about whether we stand on principle
19 and not recommend a measure that otherwise has
20 great merit for that particular population,
21 and I would remind you, David, that virtually
22 all people over 65 are Medicare beneficiaries.

1 I think maybe under three percent
2 aren't. So it is a pretty encompassing --

3 MEMBER HOPKINS: Everybody is not
4 fee for service. That is my point.

5 CO-CHAIR DUBOW: Well, just fee
6 for service. Yes, well, I think there are --
7 I mean, on one of the measures I have a
8 question about that, too. I think that is
9 fair. But just hearing you talk about
10 Medicare versus everybody over 65 --

11 Okay. All right. So we need to
12 make these decisions about how finely we cut
13 this thing. But I think that CMS should
14 receive this opinion from the Steering
15 Committee, certainly. So I think that is
16 legitimately included in the report.

17 MEMBER YAWN: But there may be
18 groups other than CMS that choose to grade
19 hospitals and other things on some of these,
20 like the PCI measure. We have a whole lot of
21 people less than 65 getting those measures
22 now.

1 CO-CHAIR DUBOW: Well, that is the
2 under 65 issue.

3 MEMBER YAWN: Yes, that is. That
4 is what I say. I think there are two issues
5 here. One is does it only apply to the CMS
6 group that we have data for, and the other is
7 can it apply to all ages? I think, yes, we
8 have to separate them, but it seems to me that
9 the age one -- You can't just ask a
10 statistician about the age group, because it
11 has to do with the medical condition.

12 CO-CHAIR DUBOW: We have made
13 those distinctions, I think. I think the
14 staff is clear on them.

15 DR. BURSTIN: I do think we ought
16 to continue to follow up with CMS, because I
17 think David's point about why you would
18 exclude just to keep a service based on a data
19 availability issue is not a methodologic
20 concern. It is an issue of data availability.
21 If the data was available for those other
22 plans, I don't -- You know, the model will

1 specify for those under 65, not for those in
2 fee for service. I agree. We will follow up
3 with CMS on that.

4 CO-CHAIR FLEISHER: So one of my
5 questions would be: If we endorse this model
6 for the fee for service, do you have to
7 actually go back to NQF to get it endorsed for
8 Medicare Advantage or --

9 DR. BURSTIN: We will try to work
10 those issues through before we put it out for
11 comment.

12 CO-CHAIR FLEISHER: Great.
13 Perfect.

14 MEMBER GERBIG: But is it correct
15 that, once a measure is approved, it is
16 available for any payer to use or can a
17 measure be limited to only a 65 or older?

18 My understanding was, once it is
19 approved, it is available to anyone to use.

20 DR. BURSTIN: This is, again, this
21 e-mail exchange David and I had, that in some
22 ways that almost becomes like an off-label use

1 for FDA. It is pretty analogous.

2 It hasn't been tested on that
3 population. Do you really want to use that
4 drug with the potential risks and issues
5 involved in using it? I think, you know, if
6 the measure is specified for over 65, I think
7 those who choose to use it for under 65 could
8 potentially have some issues on their hands,
9 and I think it would not be wise, although I
10 think we would like to work with the measure
11 developers in general to bring forward
12 measures that allow us to have risk models to
13 get as broad a population as possible.

14 CO-CHAIR DUBOW: In other words,
15 there is not an NQF police department, and you
16 know, this is a voluntary process all around,
17 maybe not at CMS, but it sort of is. But we
18 won't go into that. But the point is that NQF
19 specifies these measures and then trusts that
20 they will be used appropriately.

21 CO-CHAIR FLEISHER: So to say,
22 Helen, that somebody is using an NQF endorsed

1 measure, that would not be NQF endorsed.

2 Did we want to comment on best in
3 class?

4 DR. BURSTIN: Best in class, we
5 have to come to as get to those issues. I
6 mean, I think the thing from our perspective
7 always is evaluate the measure in front of you
8 exactly as it should be, based on the
9 criteria, and then after you have evaluated
10 that measure, I think it is appropriate to
11 look toward whatever is already endorsed and
12 make a decision on whether it actually adds
13 something to the portfolio or is it really
14 sort of just -- using the FDA analogy, is it
15 just another sort of "me, too," kind of --

16 CO-CHAIR DUBOW: And that is a
17 criterion in the measure evaluation list. So
18 we have that to assess as part of our work.
19 Okay. Are we --

20 CO-CHAIR FLEISHER: We are on
21 time. We are going to go into the diabetes
22 measures. We are actually going to -- Reva is

1 going to go over the measures, but we are
2 going to take them out of order in that we are
3 going to do the single measure first, the
4 HbA1c, and then we will do the two composite
5 measures second.

6 DR. WINKLER: So Hawa is going to
7 bring that up. All right.

8 CO-CHAIR DUBOW: Is the measure
9 developer here, by the way?

10 DR. WINKLER: There he is.

11 DR. BURSTIN: Is anybody from
12 Minnesota Community Measurement on the line?
13 Dan? Anybody?

14 CO-CHAIR DUBOW: All right.

15 DR. WINKLER: Let me just -- I am
16 just trying to find it. Okay.

17 NQF has endorsed a set of diabetes
18 measures for pretty close to its entire
19 existence. Within the group of endorsed
20 measures, there are a large number of outcome
21 measures. Hemoglobin A1c levels, blood
22 pressure levels, LDL levels are measures that

1 are endorsed by NQF for years.

2 Currently within the portfolio we
3 have, in terms of Hemoglobin A1c control
4 outcome measures, we have endorsed the measure
5 that is poor control, which is Hemoglobin A1c
6 greater than 9, and most recently we have also
7 endorsed the measure of Hemoglobin A1c less
8 than 8.

9 This is another of sort of a set
10 of measures from the same measure developer on
11 Hemoglobin A1c outcome measures, and this is
12 for patients 18 to 65 years of age with either
13 Type I or Type II diabetes with a Hemoglobin
14 A1c level less than or equal to 7 percent.

15 This measure focuses in on a
16 narrower population than the other measures,
17 the other outcome measures that we have
18 endorsed. I think this one is one for
19 selected populations.

20 So the numerator for this is the
21 most recent Hemoglobin A1c level performed
22 during the year of 7 percent. The applicable

1 population is aged 18 to 65 years. This is a
2 younger population. The other diabetes
3 measures apply to patients up through age 75.

4 This is a more aggressive
5 management target, and the -- go ahead and
6 scroll down, Hawa. It is not a process
7 measure. It is an outcome measure. It is an
8 intermediate outcome measure.

9 The Diabetes Technical Panel did
10 review this measure, and they felt that again
11 it was -- They rated it high on importance:
12 Outcomes for diabetes, large population,
13 getting them under good control. Appropriate
14 intermediate outcomes do reflect long term
15 outcomes.

16 So the only issue was, because
17 this is a narrower population and it is an
18 aggressive outcome target, has the population
19 been managed sufficiently enough to be
20 appropriate for that lower level and more
21 aggressive target? So that was rated highly.

22 On the scientific acceptability,

1 they rated it generally highly again. The
2 measure is based on administrative data. They
3 were concerned that there might be some
4 exclusions not addressed, particularly
5 patients experiencing frequent hypoglycemic
6 episodes because of the aggressive target,
7 people who have occupational risks for which
8 you wouldn't want to have them experience
9 those episodes, patients who are already on
10 multiple medications and kind of maxed out on
11 treatment and are realizing that for this
12 measure not doing the Alc does count against.
13 So it is not -- patients who haven't had the
14 test done are included in the numerator.

15 They again rated the usability of
16 this measure highly. It is a straightforward
17 intermediate outcome measure similar to the
18 others, and feasibility is good. These
19 measures are already in use and use the same
20 methodology.

21 So that is the measure before you,
22 and I don't think Dr. Greenfield is here as

1 the TAP Chair. Is he?

2 DR. BURSTIN: Shelley, are you on
3 the line?

4 MEMBER PINDOLIA: Reva, I have a
5 question. I still don't quite understand what
6 is the difference between this measure and the
7 current NCQA HEDIS measure for HbA1c less than
8 7? It is just the age?

9 DR. WINKLER: Ben, correct me if I
10 am wrong, but age is the primary difference.

11 MEMBER PINDOLIA: So it is 18 to
12 75 for the current one, and this is 18 to 65?

13 DR. WINKLER: That is correct.

14 MEMBER PINDOLIA: And that is the
15 only difference?

16 MR. HAMLIN: This measure was just
17 recently revised, actually. We have been
18 collecting the less than 7 for a couple of
19 years now. We added the additional age
20 exclusion plus some cardiovascular and other
21 comorbid exclusions as well for this
22 particular population, given the new studies

1 in the coordinated events trial.

2 So we further restrict this with
3 management exclusions for cardiovascular
4 patients. I don't have the exact list in
5 front of me, but it restricts the age as well.
6 It is trying to target the younger, healthier
7 population, particularly, for active
8 management.

9 MEMBER JUSTER: The previous
10 measure was 7 or 8, because I thought it was
11 eight?

12 MR. HAMLIN: The previous measure
13 actually was 7. It was not restricted. The
14 8 was just recently introduced last year
15 during the review when we also further
16 restricted the 7 population.

17 MEMBER JUSTER: And, Ben, two
18 questions for you. Does the current NCQA
19 measure -- is it less than or equal to or is
20 it less than?

21 Second, are the regular HEDIS
22 measures -- If somebody didn't have the test,

1 are they considered the same as a person who
2 failed the -- In other words, they are both
3 not numerator?

4 MR. HAMLIN: Yes. If the value is
5 not present, they are included in the
6 numerator, but they don't get credit for the
7 numerator. So they get dinged.

8 I believe it should be less than
9 or equal to 7.

10 MEMBER JUSTER: Okay.

11 CO-CHAIR FLEISHER: Barbara?

12 MEMBER TURNER: I'm curious what
13 the unit of analysis is here. Is it a plan or
14 is it a provider's panel, and are they looking
15 at the main controls, so it is okay that you
16 have -- you know, expect a certain number of
17 outliers that are going to be in your panel?

18 MR. HAMLIN: This is applied to
19 both the provider population and in the health
20 plan population for both a diabetes
21 recognition program providers and for the
22 health plan.

1 The unit of analysis is the last
2 measurement taken during the measurement year,
3 which is our 12-month period from January to
4 December. We have done testing in the past
5 for these lab values of those relevant to, if
6 you will, the most reliable data for that
7 measurement period. If it was done multiple
8 times over the year, it would not deviate from
9 the mean. Generally, the last value is as
10 close as you are going to come.

11 We do have further -- The approach
12 is all in retrospective claims based approach
13 with the health plan population. So --

14 MEMBER TURNER: Right. I just
15 have a follow-up question. Do you have a
16 minimum end per provider that you would insist
17 on having to be able to have stable estimates,
18 and have you looked at or thought about a
19 change, so if you have somehow a high risk
20 population, most of them coming in with Alc's
21 of 10, you get credit for getting them down
22 below 8 as opposed to getting dinged because

1 they are at 9?

2 MR. HAMLIN: Right. Yes. For the
3 Diabetes Recognition Program, there is a
4 minimum of 25 patients that meet these
5 criteria, and this also -- It is important to
6 understand that in both of these programs,
7 this is one of the three HbA1c measures. So
8 you look at the greater than 9, the less than
9 8, and the less than 7, and you get credit for
10 wherever your patient falls in that
11 population.

12 It is more the proportion of
13 patients we expect to see below 7 versus below
14 8 versus above 9, and the Diabetes Recognition
15 Program weighting is skewed to that fact, as
16 is the performance score for the health plan
17 population.

18 So we do expect to see -- And
19 basically, we expect to see a certain
20 proportion to fall within these certain
21 parameters, and the weighting for the Diabetes
22 Recognition Program takes that into account.

1 CO-CHAIR FLEISHER: David?

2 MEMBER JOHNSON: The question, I
3 guess, is just in the unforeseen consequences,
4 and I am not familiar with the Hemoglobin Alc
5 as a gastroenterologist routine measurements.
6 That is not what we do. But what happens to
7 the people that are poorly compliant in
8 situations where the doctors taking care of
9 them have the staff, and the patient's
10 understanding and the educational levels? I
11 could see a drift away of avoiding poorly
12 compliant patients just so you don't get
13 pulled out as a bad provider here of this
14 measure.

15 MR. HAMLIN: Right. I am sure
16 that there is a certain amount of gaming of
17 the system, if you will, for selecting
18 populations. But in general, since we are
19 looking at this primarily in the health plan
20 population, you know, with 7 million providers
21 and even more millions of patients, it is one
22 of the factors of life that we have to take.

1 We are basically looking for the
2 overall population. This is reported as a
3 reasonable rate by plan. So it is the entire
4 plan population; and in the Diabetes
5 Recognition Program, you know, you have a
6 small end population, you can select patients.

7 It is a continuous selection
8 process. You are supposed to select 25 charts
9 with the criteria, remove the ones that are
10 not appropriate, select an additional 25, and
11 go through that process. You know, I can't
12 control the way providers select their charts
13 for patient reporting in that program at this
14 point.

15 So there are certain assumptions
16 that there may be some selection bias there as
17 well.

18 CO-CHAIR FLEISHER: Lee?

19 MEMBER NEWCOMER: I just want to -
20 - Kind of reading through the measure, this
21 looks only at patients less than 7, and your
22 comment about range between 7 and 8, and 9 and

1 above, there are other measures that do that.
2 This one does not.

3 I just want to quality. This
4 stands alone at less than 7 only?

5 MR. HAMLIN: Right.

6 MEMBER NEWCOMER: Because we will
7 be looking at one shortly.

8 MR. HAMLIN: Right. The greater
9 than 9 and the less than 8 have already been
10 endorsed as individual measures themselves.
11 So we are looking to add to both this as an
12 individual measure of less than 7 as well as
13 a component of our composite measure for
14 diabetes.

15 CO-CHAIR FLEISHER: So, in fact,
16 this is very similar to some of the previous
17 measures in that we could endorse this
18 independently or as a part of a composite.

19 MR. HAMLIN: We prefer the former.

20 CO-CHAIR DUBOW: This is right now
21 being considered as a standalone measure.

22 CO-CHAIR FLEISHER: David?

1 MEMBER HOPKINS: I don't
2 appreciate looking at this measure as a
3 standalone, because I think it absolutely goes
4 with the other two.

5 Then I have a question for NCQA
6 and NQF. Does this replace the existing
7 endorsed less than 7 measure?

8 DR. BURSTIN: There is no endorsed
9 measure. It has never been endorsed.

10 MR. HAMLIN: We are using HEDIS
11 for several years. Now we are seeking
12 endorsement with this new refined measure.

13 MEMBER HOPKINS: Well, I think it
14 is part of a suite with the 7, 8 and 9.

15 DR. WINKLER: You could have the
16 option of recommending it that way. Recommend
17 that the measure is going to be an independent
18 measure, but it should be used with the other
19 two measures, because you do get a better
20 holistic view of the population.

21 MEMBER JOHNSON: What would be the
22 rationale for keeping it standalone?

1 MR. HAMLIN: You know, really, I
2 don't know as a full standalone measure to
3 really speak to that. We generally use it
4 combined with the other HbA1c measures. I
5 would imagine that, if a provider wished to
6 use this measure as a standalone measure just
7 to understand what proportion of the
8 population was under 7, if they were doing a
9 different program -- We have our own programs.
10 We know that a number of our measures are used
11 in other programs, particularly with the ones
12 that NQF endorsed.

13 I do see value in keeping a lower
14 level for HbA1c target, if you will, in the
15 younger and healthier population. Generally,
16 if the measure doesn't get endorsed as a
17 standalone, it is harder to make justification
18 for inclusion in the composite use.

19 All of our other measures that are
20 currently in the composite are NQF endorsed as
21 individual indicators.

22 CO-CHAIR FLEISHER: Dianne?

1 MEMBER JEWELL: You have already
2 answered my question. Thank you.

3 CO-CHAIR FLEISHER: Barbara?

4 MEMBER YAWN: And this is 65 and
5 younger. Is that correct?

6 MR. HAMLIN: Eighteen to 65, yes.

7 MEMBER YAWN: And the average
8 person at 65 has how many chronic conditions?

9 MR. HAMLIN: I couldn't speak to
10 that right now in particular.

11 MEMBER YAWN: About three on
12 average. So do you really -- You know, I
13 believe 65 is young. I am not sure I believe
14 it is unhealthy. I am concerned about the
15 age, of 7, and the data that is coming out
16 about the side effects and the problems we are
17 causing between ages 50 and 65 to patients who
18 we are trying to push down to 7.

19 So I am concerned about the upper
20 age limit of this, and perhaps you could tell
21 us what the data is on the upper age limits
22 and the risks to those people.

1 MR. HAMLIN: Yes. Actually, you
2 know, the upper age of 65 was -- I mean,
3 despite the fact that that population is
4 actually getting younger and healthier every
5 year, it was selected because of the fact that
6 we do a retrospective claims based approach
7 for our measures.

8 The DOPSI, you know, in the
9 primary program, the health plan HEDIS
10 population, we are looking at a retrospective
11 approach. So we have to draw certain
12 parameters around the population. The
13 reduction of range to get it into the
14 commercial Medicaid only, we have two product
15 lines that we collect for this measure.

16 That was why that age limit was
17 selected. The additional comorbids that we
18 added, the cardiovascular disease and other
19 comorbid conditions that also excluded
20 patients in this population, would suggest
21 your other point of the ones who are not
22 healthy at 65, would also be removed from the

1 measure.

2 CO-CHAIR FLEISHER: We have that
3 on the screen, just in case anyone is looking.

4 MEMBER YAWN: If I could see that.

5 DR. BURSTIN: I'm sorry. It is
6 also on your thumb drive. I think it is page
7 55 of the diabetes -- Slide 60 of the diabetes
8 risk file.

9 I just want to point out that,
10 although the denominator is up to age 65,
11 there are a very large number of exclusions to
12 specifically get at the comorbidities, and
13 that figure should speak to the specifics of
14 the comorbidities rather than the
15 generalities.

16 MEMBER YAWN: Yes. And that is
17 great. I saw the cardiovascular.

18 MR. HAMLIN: Right. We have
19 chronic renal failure, dementia, and the other
20 ones you will see there as well. We are also
21 looking at this -- I mean, again, this, of
22 course, we have taken a retrospective claims

1 approach primarily.

2 We are looking now to further
3 refining these definitions through, obviously,
4 electronic health record environment and new
5 coding that are going to be available, but
6 right now with the approach that we have and
7 the data we have collected in the last couple
8 of years for this measure, these seem to be --
9 and our expert panels and the TAP agreed that
10 this was sort of a reasonable comorbid list to
11 include. This has all been through codes as
12 well. So there are complete code lists.

13 CO-CHAIR FLEISHER: I think B.J.
14 was next, and then Amy.

15 MEMBER TURNER: Thanks. So I
16 think pretty much the evidence of the value of
17 pushing Alc down to this level is for people
18 who have an estimated survival of at least 10
19 years to 20 years.

20 There are lots of people who have
21 those conditions that are not exclusions, like
22 cancer, etcetera, and their list would have to

1 be much more comprehensive, and it would
2 actually have to be much more evidence based.
3 This seems like a somewhat random selection of
4 folks with, say, cardiovascular risk.

5 So please explain to me why you
6 need to apply this across the board without
7 having a much better sense of what someone's
8 estimated life span is.

9 MR. HAMLIN: Well, again it was
10 the -- You know, the criteria that are
11 outlined here were the sort of best judgment
12 from the expert panel and from us on the
13 appropriate exclusions for this population,
14 given the evidence for driving Alc.

15 Obviously, the folks who are
16 primarily who are on microvascular and
17 macrovascular with long term complications for
18 driving Alc down -- you know, I can't speak to
19 the cancer at all at this point. I don't have
20 the background to provide you there.

21 MEMBER TURNER: That is the point,
22 I think.

1 MR. HAMLIN: Right.

2 MEMBER TURNER: I mean, this is
3 the thing. It is very -- well, myopic is a
4 bad word to use here. But it is very limited,
5 and the evidence right now, the adverse
6 consequences of pushing somebody down to that
7 level, is just emerging right now.

8 You have two perfectly reasonable
9 measures, the 9 and the 8, to be able to get
10 people to improve their care and continue to
11 strive, but to push people to a level where
12 you don't really know there is a benefit for
13 them, because they may not be living that
14 long, and they may certainly be getting side
15 effects that you can't capture with the kind
16 of claims data that you use, seems to be
17 having significant unintended consequences.

18 MR. HAMLIN: Well, you know, I
19 would disagree. There is actually evidence to
20 show that moving certain patient populations
21 who have a diagnosis of any kind of cancer may
22 be inappropriate. I do agree that there are

1 probably specific diagnosis of cancer or
2 perhaps current treatment regimens that might
3 want to exclude them from the population, but
4 I don't believe the evidence shows that
5 someone who has a diagnosis of breast cancer
6 that is, you know, Stage 1 should not be
7 managed well and actively if they are also
8 diabetic.

9 MEMBER NEWCOMER: There is
10 evidence to look at age and look at
11 complication rates for hypoglycemia as you
12 age. Is there any evidence on that?

13 MR. HAMLIN: Interestingly, when
14 we first -- When we filtered this data and
15 when we collected the first year data, we had
16 forgotten to address certain restrictions on
17 the age around our patient population. When
18 the data came in on the first two years,
19 actually the over 65 -- the 65 to 75
20 population actually had better A1c rates than
21 the other two populations combined.

22 So it was one of those areas where

1 we still feel like it is an inappropriate
2 population to measure through our approach.

3 However --

4 MEMBER NEWCOMER: Well, what is
5 the evidence in the medical literature? What
6 we are trying to drive to here is we know that
7 hypoglycemia is a definite consequence of this
8 kind of tight control. Does that vary from
9 age population to age population in the
10 literature?

11 For instance, can a 20 to 30-year-
12 old tolerate that better than a 50 to 65-year-
13 old? Do we know?

14 MR. HAMLIN: We don't know the
15 exact parameters around what ages would
16 tolerate the aggressive management better than
17 others at this point, but again the experts
18 felt that 65 was a reasonable cutoff for
19 active management, given the new trials that
20 just came out.

21 MEMBER NEWCOMER: So we are
22 talking about an opinion versus any evidence.

1 That is all we are trying to clarify here.

2 MR. HAMLIN: Yes.

3 MEMBER NEWCOMER: Okay.

4 CO-CHAIR FLEISHER: Okay. Amy?

5 MEMBER ROSEN: I just wanted to
6 follow up on that, that this measure is not
7 risk adjusted, and given the concerns, I am
8 wondering why risk adjustment was not
9 considered, and something like age and gender
10 could easily be folded into some type of
11 measure like this. If not, risk adjusted, at
12 least some stratification could be done.

13 I also had some concern about the
14 denominator in that you are using claims data,
15 but oftentimes somebody may come in with
16 multiple problems, and a diagnosis of diabetes
17 might not get on the claim. So that won't be
18 in the denominator.

19 I wondered if you had thought
20 about looking at pharmaceutical claims as a
21 way of getting a more comprehensive
22 denominator, and also had you looked at the

1 reliability of the medical record review or
2 the automated laboratory data.

3 I know from my experience that,
4 depending on where you look in the medical
5 record, you may get different values of a
6 particular test. So I just wondered what kind
7 of guidelines there are in looking for that
8 particular numerator that people might follow,
9 so that you get a consistent reading from all
10 the different providers.

11 MR. HAMLIN: To your first point,
12 we don't actually risk adjust any of our
13 effectiveness of care measures. We only risk
14 adjust currently our cost of care measures for
15 HEDIS. That is being examined right now,
16 whether we need additional risk adjustment
17 strata applied to more of our effectiveness of
18 care measures, but that is a long way off at
19 this point.

20 We do validate and verify our data
21 collection methodologies. So before a measure
22 can make it into the HEDIS population, we do

1 do both a claims and a medical record review
2 validation study.

3 So we have looked at the
4 reliability of the claims against the medical
5 record and what turns up in the medical record
6 versus what is available through electronic
7 claims.

8 To your third point, we do
9 actually include pharmacy as an identifier for
10 diabetes denominator. It is a visit with a
11 diagnosis or a number of ambulatory
12 prescriptions for anti-diabetic agents. So
13 that is included as part of the identification
14 criteria.

15 CO-CHAIR DUBOW: The
16 stratification issue?

17 MR. HAMLIN: The stratification --
18 We don't risk adjust or stratify the majority
19 of our -- We don't risk adjust any of our
20 HEDIS measures. We don't stratify the
21 majority of our measures at this point, but it
22 is something that we are looking into as we

1 move forward, whether that is something that
2 we should be asking additional data elements
3 from the plans.

4 CO-CHAIR DUBOW: But you do
5 stratify in a way by payer.

6 MR. HAMLIN: Yes. We do stratify
7 a commercial Medicare product, yes.

8 MEMBER ROSEN: That is not what I
9 am suggesting.

10 CO-CHAIR DUBOW: I know, but it is
11 a form of stratification.

12 MR. HAMLIN: Right. We do report
13 all these three separately. So the commercial
14 population, the Medicare population, the
15 Medicaid population all are reported
16 separately. For this one, it would just be
17 commercial and Medicaid.

18 CO-CHAIR FLEISHER: Do we have any
19 new topics that need to be covered?

20 MEMBER AMARASINGHAM: I just have
21 one question. If a person -- If a provider is
22 trying to get a patient below 7 and the

1 patient was experiencing hypoglycemic effects,
2 how is that accounted for or is the patient
3 excluded? I didn't see that in exclusions.

4 MR. HAMLIN: It is not at this
5 time. If a provider is -- You know, again,
6 these measures are guidance. They are not
7 absolute. We don't expect a provider to go
8 against the best clinical practices for
9 managing individual patients.

10 This is a whole population
11 approach that we are looking at. So, you
12 know, we are not trying to tell physicians
13 they have to manage them down to this certain
14 level. They have to use their better
15 judgment.

16 CO-CHAIR FLEISHER: Vanita?

17 MEMBER PINDOLIA: Hi. I just had
18 one comment, again to have NCQA consider
19 combining these with a Hemoglobin Alc 8 and 9
20 measure. The reason is that, just looking at
21 state of Michigan and, I am sure, other
22 states, how the HEDIS measures are being used

1 -- the five large HMOs, they are really just
2 going after those less than 7, even though it
3 is not NQF endorsed.

4 The Blue Cross/Blue Shield

5 Michigan PGIP program for physician incentive
6 only targets if you got them less than 7.
7 They don't even consider the 8 or 9. So there
8 seems to be a misconception of less than 7 is
9 good for everybody, and by putting them all as
10 individual, they are getting to pick and
11 choose, and it might lead to some major
12 patient negative outcomes.

13 MEMBER AMARASINGHAM: I would like
14 to underscore that. I also think that, even
15 among providers and plans, I think there is
16 variation in sort of the baseline Hemoglobin
17 Alc in the population. So if a plan or a
18 provider had a higher proportion sort of in
19 the 8, 9 range, I think this measure could be
20 interpreted as getting everybody down to 7,
21 which could have a lot of unintended
22 consequences.

1 So I think it has to be a suite of
2 measures.

3 CO-CHAIR DUBOW: Excuse me. If
4 somebody on the phone has -- Everybody on the
5 phone should be on Mute.

6 CO-CHAIR FLEISHER: David, a new
7 topic?

8 MEMBER HOPKINS: No, no. I was
9 actually going to move approval of this
10 measure as part of a suite that would comprise
11 less than 7, 8 and 9, less than or equal to,
12 I think, and that is not a composite, by the
13 way, if I understand the term composite.

14 So we are using a different term
15 here, which is suite, which means it is three
16 distinct reported measurements that are
17 reported together.

18 CO-CHAIR FLEISHER: So we actually
19 need David to comment, because that has not
20 been proposed. All that has been proposed is
21 your suite of pairing in a composite.

22 DR. WINKLER: Well, actually, this

1 is the purview of the Steering Committee, to
2 do what has been done many times in the past
3 at NQF. That is, we called them pairs when
4 there were two. I don't know what you want to
5 call them when it is three, you know,
6 whatever. But the concept is not a new one.
7 It is an old one, and it is independent of how
8 the measure was developed or might be used.

9 If you feel that your
10 recommendation for endorsement, that these
11 should go together as a whatever you want to
12 call it group, suite -- and what we do is it
13 will be put out for comment that way. We will
14 tag the other two measures to it.

15 When we put it out for vote, it is
16 this and this and this, and you are voting on
17 it as a group, so that they are an entity that
18 rises and falls together.

19 MEMBER HOPKINS: That is my
20 motion.

21 CO-CHAIR FLEISHER: Quick comment,
22 B.J.?

1 MEMBER TURNER: So we have to
2 respond to that motion, up or down vote?

3 CO-CHAIR FLEISHER: Well, do we
4 want to go to public comment first? Are there
5 any public comments before we move for a vote?

6 MR. HALL: This is Bruce Hall from
7 the American College of Surgeons. I have a
8 couple of questions.

9 MEMBER NEWCOMER: You are not
10 entertaining the motion. Is that right?

11 CO-CHAIR FLEISHER: Not quite yet.
12 Who on the phone is speaking?

13 MR. HALL: It is Bruce Hall,
14 American College of Surgeons.

15 CO-CHAIR FLEISHER: Do you want to
16 comment first?

17 MR. HALL: I have a couple of
18 questions for the developer essentially on
19 reliability and feasibility.

20 I saw that they provided a sample
21 set of calculations that was roughly 550
22 patients. I was wondering if they had any

1 sense of how many practices can meet that
2 sample size? I did not see any other
3 commentary on the reliability of the patients
4 between providers. So I was wondering if
5 there is any information on that.

6 Then on the topic of feasibility,
7 I see that they have made an estimate of how
8 many hours of data collection would be
9 required from both administrative folks and
10 the medical record review.

11 I was wondering if there has been
12 any discussion of the cost and the burden that
13 is created.

14 MR. HAMLIN: I have to make one
15 correction. The sample size of 550 is a
16 recommended sample size for the medical record
17 review approach. This is a paired measure we
18 call a hybrid approach where you use a -- you
19 select a sample, and do medical record review
20 to collect the data elements such as HbA1c
21 levels where they are not available just
22 directly in claims data.

1 Our normal for the other measures
2 is 411, but because of the additional
3 exclusions applied to this measure, we had to
4 up that sample size. That is applied to plans
5 only, not to medical -- individual providers
6 or medical groups.

7 The provider sample size is 25, as
8 we said before. So there is a difference in
9 the two methodologies for which product each
10 measure is used in.

11 As far as the cost burden, again
12 as we collect the data through this hybrid
13 methodology of claims versus the medical
14 record approach, we annually review the
15 variation and performance among plans that are
16 reporting as admin only -- the integrated
17 delivery systems generally have this through
18 electronic data -- versus the medical record
19 approach, and we look at the rates, the
20 variation of rates among the plans and then
21 the variation of rates plan year to year and
22 try and move that to a claims based approach

1 whenever possible.

2 Unfortunately, this is not one
3 that is possible at this current time.

4 CO-CHAIR FLEISHER: Okay. Other
5 comments?

6 DR. JEWELL: Hi. I am Kay Jewell.
7 I am a physician, a consultant in Wisconsin,
8 and I have two disclaimers. One is I am a
9 consultant with one of the drug companies that
10 has diabetes related products, but I also have
11 a conflict -- well, influence in some work I
12 do with consumers.

13 I have two points relative to the
14 selection and the exclusion of the age 65. If
15 that was selected, as I understand, a couple
16 of years ago immediately after advance and
17 reported and published, it was a reaction to
18 concern of unintended consequences, and it has
19 not been reviewed, and the actual evidence for
20 excluding a 65-year-old person who doesn't
21 have comorbidities from achieving a A1c of
22 less than 7 -- I don't believe that there is

1 evidence for that as a risk factor and is an
2 issue for hypoglycemia.

3 In fact, just like your data of
4 the over 65, that they are actually doing
5 better at getting Alc's, and we aren't seeing
6 large numbers of problems that have been
7 reported; and in fact, the NHANES data from
8 2003-4 -- it is the less than 65-year-olds.
9 Sixty-eight percent of them are achieving less
10 than 7 percent in 2003-4 versus 48 percent for
11 those less than 65.

12 So the data would suggest that the
13 elderly are not having a problem with this,
14 especially if you have a way to exclude the
15 comorbidities.

16 The other concern: There also has
17 to be a way for the physician to be doing the
18 individual assessments. The ADA and the
19 Endocrine Society do recommend an individual
20 assessment, and looking at the comorbidities,
21 and do not use age all alone as a criteria for
22 not achieving good control, and there has to

1 be some room for individual physician
2 assessment.

3 Hypoglycemia, as far as the data
4 that I have looked at, what they have
5 identified -- and this did come up at the TAP;
6 Dr. Hellman talked about it, that it wasn't
7 age per se that was the issue for hypoglycemic
8 events. It was things like frequency of
9 testing and attention to testing, and
10 hypoglycemic awareness, which is probably
11 different.

12 That is one of the issues and
13 concerns about including this population, is
14 that we are going to have all this
15 hypoglycemia, because it is an age issue. I
16 don't think the evidence is there.

17 In terms of looking at the long
18 term effects, there are two issues of long
19 term effects that come at 15 to 20 years for
20 cardiovascular, but there are also short term
21 effects for a 65-year-old.

22 There are short term effects in

1 terms of retinopathy, and eye disease can be
2 achieved within five to eight years. There is
3 also risks in terms of -- impact in terms of
4 infection, infection control, and neuropathy.
5 Neuropathy is an early issue, and a very, very
6 important patient outcome pain issue.

7 MEMBER NEWCOMER: How do those
8 differ from a population at 8 or less?

9 CO-CHAIR FLEISHER: I think,
10 actually, we need to move on, because we have
11 multiple measures. Unless anyone feels
12 strongly, I would just like to comment that
13 the TAP endorsed this measure as a standalone
14 measure. Would you like to comment, Reva, on
15 the TAP?

16 DR. WINKLER: In general, they
17 felt that this measure narrowed a population.
18 There were some more questions that you
19 raising with it. Was it narrowed
20 appropriately and enough to worry about the
21 adverse consequences, but you know, they
22 generally supported the measure.

1 CO-CHAIR FLEISHER: So I have
2 actually heard a motion. I assume Lee was
3 going to second it.

4 MEMBER NEWCOMER: I wasn't,
5 actually.

6 CO-CHAIR FLEISHER: You weren't?
7 Well, what I have heard is several either
8 endorse the measure standalone, endorse the
9 measure as part of a triplet, endorse it as
10 part of a composite, or not endorse it. So I
11 wanted to defer to Reva to see how we will
12 vote.

13 DR. WINKLER: I would recommend
14 voting each of those independently, and we
15 will see where it leads us. Is there a
16 logical -- You know, do you feel it should be
17 a standalone measure, yes or no? Then the
18 next one: Do you feel -- Would you recommend
19 it as part of the three-group, yes or no?
20 That way, rather than split the committee.

21 CO-CHAIR FLEISHER: And by hands?
22 So I guess it is a show of hands with regard

1 to the committee, with regard to a standalone
2 measure. All those in favor of a standalone
3 measure.

4 MEMBER NEWCOMER: I need some help
5 before we do that. One question on the
6 standalone measure. Do we have evidence that
7 the hemoglobin elastin-7 has -- that we
8 understand what its long term side effects are
9 for all populations? Was there evidence
10 talked about that in the TAP?

11 I understand for certain
12 populations, it clearly benefits. That is
13 indisputable.

14 DR. WINKLER: They certainly
15 discussed it. It varied between some evidence
16 and a lot of opinion.

17 DR. NEWCOMER: So just tell me
18 about the sum evidence for this large a
19 population.

20 DR. WINKLER: I can't speak to the
21 details.

22 DR. NEWCOMER: Okay. Thanks.

1 DR. BURSTIN: I would just refer
2 you again to the TAP summary. They really did
3 spend quite a bit of time on this measure, and
4 they specifically felt that in general the
5 evidence wasn't there for Hemoglobin Alc less
6 than 7 for all patients, but they did
7 specifically indicate, at least in what they
8 said, that they thought that the no risk
9 adjustment beyond exclusions was okay, and
10 they specifically wanted to be sure that Stage
11 4 and 5 CKD was out, which it is.

12 So that is all we can share,
13 unfortunately. I am not sure if Shelley has
14 joined us yet on the phone.

15 CO-CHAIR FLEISHER: Before we
16 vote, David, do you want to introduce yourself
17 and any disclosures?

18 MEMBER HERMAN: My name is David
19 Herman. I am from the Mayo Clinic. No
20 disclosures.

21 CO-CHAIR FLEISHER: So I guess we
22 are calling the vote. All those who would

1 like to endorse this measure as a standalone
2 measure, please raise your hands.

3 Abstentions? No.

4 DR. WINKLER: No? That is
5 everybody?

6 CO-CHAIR FLEISHER: One
7 abstention. Okay. Second vote: As part of
8 a group of measures, including 7, 8 and 9.

9 MEMBER TURNER: Point of
10 clarification. I don't know what that means.
11 I don't understand how you operationalize it.
12 Does it mean 25 percent have to be under 7,
13 and 50 percent have to be under -- How do you
14 do that? I am just wondering how you
15 operationalize it.

16 DR. BURSTIN: I think there is
17 really two issues. I think what you have just
18 said is on its own, you wouldn't, for example,
19 want public reporting of Hemoglobin A1c less
20 than 7 for selected populations on its own.

21 You then have an opportunity when
22 we get to the composite to say, okay, maybe

1 not on its own, but maybe in the composite.
2 I think the third issue that was brought up
3 was that, since we have already endorsed the
4 less than 8 and the greater than 9, I guess
5 one other possibility would be to indicate
6 your support potentially for Hemoglobin A1c
7 less than 7 should only be publicly reported
8 with the other two levels. That is what, I
9 think, was --

10 MEMBER TURNER: It doesn't help me
11 understand what it means. In other words, is
12 it the goal to have 90 percent of your
13 population under 7? Well, then how do you --
14 You said it was weighted, and I am trying to
15 understand what weighting means. No?

16 DR. BURSTIN: I think there is
17 some confusion between the Diabetes
18 Recognition Program, which is not on the
19 table, which is weighted and scored. Some of
20 that will come up during the composite
21 discussion, because I think some of the
22 weighting is pretty similar to what we were

1 literally just talking about in terms of
2 publicly reporting the measure.

3 Would you want to see the rates of
4 those three levels for a given practice or
5 whatever the case may be publicly reported,
6 even if you didn't feel comfortable seeing Alc
7 less than 7 on its own. That is all.

8 MEMBER NEWCOMER: Is this measure
9 actually that, and wouldn't we vote on that
10 measure alone, because the next measure does
11 ask for 8, 9 and 7.

12 CO-CHAIR FLEISHER: But it
13 includes multiple other criteria.

14 MEMBER NEWCOMER: So we are voting
15 on would we like to see 7, 8, 9 standing
16 alone?

17 CO-CHAIR FLEISHER: Correct.

18 MEMBER AMARASINGHAM: Here is my -
19 - With respect to this suite of measures, sort
20 of representing all three, what is the
21 implication for the provider, though?

22 For example, if the provider's

1 baseline was, before they even saw the
2 patient, 40 percent had a Hemoglobin Alc
3 greater than 9, then what would it mean in the
4 subsequent year to represent the proportions;
5 because you don't have an anchor period.

6 So I am just trying to understand
7 what is the purpose of the reporting? Is it
8 to kind of reflect the provider's performance
9 or to say this is sort of the baseline
10 population?

11 DR. BURSTIN: It is intended to
12 reflect the population.

13 MEMBER NEWCOMER: I would answer
14 that as yes. The first year would be baseline
15 performance. The subsequent years would be
16 performance. So it is just a measure. All we
17 are doing today is saying this is an
18 acceptable measurement, and how it is used is
19 going to vary from person to person.

20 CO-CHAIR DUBOW: I think we need
21 to be clear that NCQA has to go along with --
22 If this is a recommendation to NCQA -- It was

1 submitted as a standalone measure. So we need
2 to -- This vote is going to reflect the
3 recommendation.

4 MR. HAMLIN: The reason it is a
5 standalone measure is because the other two
6 are already endorsed. It is the one left
7 over.

8 MEMBER YAWN: The only advantage I
9 see of it being part of the suite is you get
10 to exclude some people. Now do I think it is
11 the right ones, and do I have any evidence?
12 No. That is the only thing that I can see
13 that is positive. Rather than just saying,
14 okay, we are going to do 7, 8 and 9, and have
15 no exclusions for 7, this gives you some
16 exclusions for 7, and that is the only
17 advantage I can see of thinking about putting
18 it out there.

19 Doesn't mean I am going to vote
20 for it. I am just saying I think that is what
21 we have to think about.

22 CO-CHAIR FLEISHER: Quickly,

1 because we do need to move on.

2 MEMBER PINDOLIA: I think the
3 other advantage is how it is used out in the
4 public. Once NCQA approves, the HEDIS
5 measures are used to give payer incentives.
6 They are used to have measurements of this
7 health system is better than this one, and to
8 have a trio, at least you can see overall, and
9 you are not being forced to draw everyone less
10 than 7. So there is another use.

11 MR. HAMLIN: My only one concern
12 with putting it in a trio is that the greater
13 than 9 and less than 8 do not have these
14 exclusions applied. So they apply to
15 different populations.

16 So there is some variance in those
17 populations. The population of the greater
18 than 9 and less than 8 are 18 to 75 with no
19 additional comorbidity exclusions. The less
20 than 7 is. So --

21 DR. BURSTIN: Just to be clear,
22 just a point of process, you have already made

1 the initial assessment of should it be a
2 standalone measure. No. Your only options at
3 this point are potentially to put this back to
4 NCQA with a recommendation or even a condition
5 saying the only way the Steering Committee
6 would approve Alc is if it was always reported
7 with 8 and 9.

8 That is really your only
9 opportunity at this point. They haven't
10 submitted to you a suite of 7, 8 and 9. So at
11 this point it would be your recommendation
12 back to them indicating less -- and this is
13 just a possibility -- less than 7 would be
14 fine as long as it is reported with the other
15 two levels. That could be a condition or
16 recommendation.

17 CO-CHAIR FLEISHER: David, would
18 it be acceptable, can we defer that vote until
19 we talk about the composite? Do you want to
20 vote now?

21 MEMBER HOPKINS: Well, there is a
22 different problem, because you've got two

1 composites, and I believe they are in
2 competition with each other.

3 CO-CHAIR DUBOW: So let's wait on
4 that.

5 CO-CHAIR FLEISHER: So the vote on
6 the second motion which Helen described of
7 going back to NCQA and actually suggesting
8 this be developed into a measure with all
9 three. How many vote -- No?

10 DR. BURSTIN: No, sorry. Don't
11 want to confuse things. They wouldn't
12 actually develop anything. I think the issue
13 would be this Steering Committee has indicated
14 not as a standalone. The Steering Committee
15 could potentially put forward a motion saying
16 you would conditionally approve Hemoglobin Alc
17 only if it is always reported with the other
18 two levels.

19 It is just a reporting issue. It
20 is not combining it into a composite, which is
21 the later discussion.

22 CO-CHAIR FLEISHER: So how many

1 vote yes for that?

2 DR. WINKLER: Fifteen.

3 CO-CHAIR FLEISHER: Noes? So we
4 have four noes. Abstentions? Okay.

5 MS. BOSSLEY: Barbara walked out
6 of the room.

7 CO-CHAIR DUBOW: Oh, okay. If
8 Barbara walked out, we didn't get her vote.
9 Okay.

10 CO-CHAIR FLEISHER: Okay. Anybody
11 else not vote? Well -- Do people want five
12 minutes?

13 CO-CHAIR DUBOW: We have to finish
14 this.

15 DR. WINKLER: The decision was to
16 -- The next measure will be the composite
17 measure submitted by NCQA, which is the
18 comprehensive diabetes care measure. This is
19 measure 29, and this is essentially a
20 composite measure, the percentages measures.

21 This is 18 through 75 with
22 diabetes related to the following, and you can

1 see the components of the composite. Ben,
2 correct me if I am wrong. The most recent
3 version I saw of this did not have two blood
4 pressure controls. Correct?

5 MR. HAMLIN: Yes. If you
6 downloaded this from your online site, we were
7 having technical issues getting the updates in
8 there. So, yes, it does not include 130 over
9 80. We were having trouble saving our changes
10 after the TAP.

11 CO-CHAIR FLEISHER: So what is the
12 current one? The current measures includes?

13 MR. HAMLIN: The current one
14 measure includes everything you see here
15 except for the less than 130 over 80, because
16 the TAP asked us if we would remove that from
17 consideration.

18 CO-CHAIR FLEISHER: And keep just
19 the one?

20 MR. HAMLIN: Keep the one, 140
21 over 90, yes.

22 CO-CHAIR FLEISHER: Great. Thank

1 you.

2 DR. WINKLER: This is a composite
3 measure that includes these components, all of
4 these components with the exception of the
5 Hemoglobin A1c less than 7 currently endorsed
6 by NQF, and also the blood pressure control
7 less than 130 over 80, which is not included
8 in the most recent version.

9 What we need to go to, Hawa, is
10 the table that talks about the weightings and
11 how this composite is put together.

12 MEMBER NEWCOMER: There is an
13 asterisk behind the Hemoglobin less than 7.
14 Is that because it is not in the current NCQA?
15 Is that what the asterisk stands for?

16 DR. WINKLER: No. Because it is
17 not currently NQF endorsed, and your actions
18 have relevance to what is going on here.

19 MEMBER NEWCOMER: Okay, thanks.
20 So do you have that one, Helen?

21 DR. BURSTIN: Right.

22 DR. WINKLER: Okay. One of the

1 things, when this was initially presented to
2 the TAP is these weightings were not
3 available, and so they re-met by conference
4 call last Thursday to take a look at how these
5 measures are combined.

6 These are the criteria as well as
7 the points given. This is the table for the
8 recognition program. So the meeting 75, I
9 think, is more an implementation issue, but
10 the methodology for combining each of the --
11 all of these measures is really a two-step
12 methodology; whereas, you get credit if you
13 meet the criteria, and then you get that many
14 points, and then the sum of the points.

15 So the final score is your total
16 number of points. How a user or implementer
17 might then use those points to display or
18 publicly report, I think -- NCQA does it one
19 way, which isn't necessarily the only way that
20 it might be done, and that was the discussion
21 on the TAP.

22 Again, as you will find with most

1 of the composite measures that we will be
2 discussing over the next couple of days, the
3 weightings and the choice of how many points
4 and things like that are somewhat arbitrary,
5 but based on the developer's value system
6 around what is important in the care of
7 patients around this condition with their
8 Technical Panels.

9 MEMBER NEWCOMER: So we need to
10 clarify again. This is not part of what we
11 are voting on today, though. Is that correct?

12 DR. WINKLER: This is what you are
13 voting on today. This is the composite
14 measure. The weighting -- the criteria and
15 the points, not the recognition part.

16 MEMBER NEWCOMER: I didn't see
17 that in our documents.

18 CO-CHAIR FLEISHER: Bur the
19 weights were endorsed by --

20 DR. WINKLER: They haven't been
21 endorsed, not by NQF.

22 CO-CHAIR FLEISHER: No, by the

1 TAP.

2 DR. WINKLER: The TAP liked the
3 weights, yes. when they reviewed them, they
4 supported them, and suggested that this was a
5 good composite of diabetes care, that the
6 weightings made sense. They made clinical
7 sense, and they supported the measure going
8 forward.

9 MEMBER KEALEY: So what does the
10 rejection of the less than 7 that we just did
11 -- what does that do to this?

12 DR. BURSTIN: Nothing. So the NQF
13 composite framework requires that all the
14 measures within a composite be individually
15 evaluated. They don't -- to be, rather,
16 standalone or only as part of a composite.

17 So you have now indicated the Alc
18 measure can only be as part of this composite
19 or as NCQA agrees in that pairing other
20 measure, but it is fine here, if you agree it
21 is acceptable as part of a composite.

22 MEMBER KEALEY: And if we like

1 everything but the less than 7, is there any
2 ability to parse that apart or --

3 DR. BURSTIN: You would have to
4 again make those issues discussions back and
5 forth with NCQA.

6 MEMBER YAWN: It is not a percent.

7 MEMBER AMARASINGHAM: But it would
8 actually -- I assume, Helen, that that would
9 actually mean we would turn down the measure,
10 but suggest a change, because we couldn't
11 approve the measure with the composite.

12 DR. BURSTIN: The measure being a
13 composite.

14 CO-CHAIR FLEISHER: Vanita?

15 MEMBER PINDOLIA: I just had a
16 question on the point system. How does that
17 work? It is all or nothing? So let's say you
18 have 16 percent greater than 9. You get zero
19 points?

20 The way this is going to be used,
21 I know in the state of Michigan and I know in
22 other states, it is going to be used for the

1 physician incentive programs, and this is
2 going to look so nice, because it is going to
3 composite all of them together.

4 So all of a sudden, you have 16
5 percent. You get zero. So you are down to 90
6 right away. Is that -- or is there a grading?
7 The 10 will become a 9 to 8, and the 7 to 6.

8 MR. HAMLIN: The total points add
9 up to 100. If you can make 75 points, you
10 achieve the SEQ ADA physician recognition for
11 diabetes care, but that is -- This is the
12 points, yes.

13 MEMBER PINDOLIA: But the points -
14 - I am just wondering like for the 10, the 5,
15 the 20 -- is it a 10 or a zero, a five and a
16 zero? You either are there or you are not, or
17 is it --

18 MR. HAMLIN: Yes, for each
19 category. If you meet the criteria, then you
20 get the points or not. Yes, sorry.

21 CO-CHAIR FLEISHER: Okay, David
22 and Ruben.

1 MEMBER HOPKINS: So I have a point
2 of order. Since NQF now has a requirement
3 that we consider measures that are best in
4 class, and since we have another type of
5 composite measure that gets at many of the
6 same things in a different way, I think it is
7 important that we have the opportunity to
8 review both before voting on either. I don't
9 know how you want to do that.

10 DR. BURSTIN: Since there are
11 different components, I think it would be
12 helpful to finish our discussion of this
13 measure and not necessarily vote, but then
14 come back after the discussion of both
15 composites.

16 CO-CHAIR FLEISHER: Yes.

17 MEMBER HOPKINS: Three different
18 approaches.

19 MEMBER DELLINGER: If I am
20 understanding correctly, the less than 7 here
21 comes without the restrictions that were on
22 the less than 7 that we just finished

1 discussing, because it doesn't say that
2 anywhere here.

3 DR. BURSTIN: It says for special
4 populations.

5 MEMBER DELLINGER: Oh, okay.
6 Thank you.

7 MEMBER AMARASINGHAM: The question
8 I have: This was clearly -- This was only
9 developed by expert opinion. There is no
10 empiric evidence to suggest these percentages.
11 So one question I have is could this be
12 proposed as a one-year time-limited, only
13 because I am curious what is the underlying
14 population in the United States where it
15 actually achieved this.

16 MR. HAMLIN: This is actually --
17 This was actually developed through expert
18 consensus but based on four years of data
19 collection in the DRP, and this was just
20 reviewed last year. It is based on four years
21 of data collection.

22 MEMBER AMARASINGHAM: So do you

1 have a histogram or a distribution for how
2 this would look, like if you got 80 percentile
3 on this, what does that mean?

4 MR. HAMLIN: If you meet the --
5 Sorry, for the recognition? I am not
6 understanding your question.

7 MEMBER AMARASINGHAM: Do you have
8 a histogram of points?

9 MR. HAMLIN: Not with me, no, but
10 they were just reviewed in 2009, and what they
11 did is they looked at the data for each of
12 these years and the weighting that came in
13 from each of the provider offices that were
14 seeking recognition. Then the experts
15 basically judged that, yes, this weighting was
16 still valid and usable and appropriate for
17 this population.

18 CO-CHAIR DUBOW: This measure has
19 been in use for a long time. It doesn't
20 really qualify for time-limited endorsement.
21 That is not what that process would do.

22 MEMBER NEWCOMER: Lee. I will

1 just make a comment. When we do come to
2 voting, I would like to say that I like the
3 measures and would strongly endorse them, but
4 I would also amend, if it is possible, to get
5 that criteria off the table.

6 What is important here is that you
7 measure what is happening to a diabetic
8 patient. You have a number of excellent
9 measures there, and they are well thought out.

10 What kind of criteria table you
11 might use to determine what is, quote, "good"
12 diabetic care and other is nothing more than
13 expert opinion, as already stated, and doesn't
14 meet a good evidence standard.

15 These other measures, though, do
16 meet evidence standards, and what is important
17 is to report them.

18 CO-CHAIR FLEISHER: So when you
19 say criteria table, do you mean the weighting?

20 MEMBER NEWCOMER: The point system
21 that is there.

22 CO-CHAIR FLEISHER: The weighting

1 only?

2 MEMBER NEWCOMER: People could
3 come up with 1,000 different point
4 combinations, and they would only be opinion
5 based. However, everything on that left tab
6 is very good evidence based and are excellent
7 measures to follow diabetic control.

8 MEMBER YAWN: Well, you are going
9 to see another composite measure that takes
10 those, and it just says yes or no. So you
11 have to have 100 percent of all of them to get
12 credit for anything, and I am going to tell
13 you, it is a real bear to try to deal with 100
14 percent.

15 So I am not saying those
16 percentages are right. I don't like only 60
17 percent of the eye, for example. That seems
18 really low to me. But I think that at least
19 they are trying to get at the concept of
20 nobody is going to be perfect, and this at
21 least gives you some --

22 MEMBER NEWCOMER: I think you also

1 made my point, that you don't think 60 percent
2 is right.

3 CO-CHAIR FLEISHER: Helen would
4 like to address the weighting system, and then
5 we can go to the other measure. So let's let
6 Helen talk.

7 DR. BURSTIN: Again, all these
8 measures with the exception of Alc less than
9 7 have already been endorsed by NQF. So these
10 are ones people can go ahead and report on
11 right now. That is not an issue.

12 The only thing that is new here,
13 in addition to the discussion we just had
14 about Alc less than 7, is the idea of bringing
15 in a composite. Again, in our definition a
16 composite is combining multiple measures into
17 a single score.

18 So by needing a single score,
19 you've got to have some scheme that will bring
20 them together. They could have -- whatever
21 the case may be. They based on expert opinion
22 this series of weights to get at what they

1 thought was most important.

2 Again, we could certainly go back
3 to NCQA, ask for further details about the
4 logic of it, but there is a requirement that
5 we have to get to a single score. So unless
6 it is an all or none composite, we've got to
7 have some formula to get at that.

8 CO-CHAIR FLEISHER: A quick
9 comment. Then I would like to look at the
10 next measure.

11 MEMBER DELLINGER: A question:
12 Are the percents in the center column there --
13 are those what have already been endorsed?

14 DR. BURSTIN: No. Those are
15 thresholds that are not the issue. The issue
16 is more -- So the actual clinical measures on
17 the left have been endorsed, yes -- or right,
18 whatever.

19 MEMBER AMARASINGHAM: I know that
20 we have been saying that these measures have
21 been endorsed, but it is not insignificant
22 that there is new criteria.

1 DR. BURSTIN: No, that is the new
2 measure.

3 MEMBER AMARASINGHAM: That is what
4 I am saying. So I think --

5 DR. BURSTIN: That is just
6 weighting.

7 MEMBER AMARASINGHAM: Right.

8 DR. BURSTIN: Essentially that
9 creates the weights --

10 MEMBER AMARASINGHAM: But the
11 weighting is very important.

12 DR. BURSTIN: The weighting is
13 critical, and we want you to take a critical
14 eye to it and see if it makes sense. Yes.

15 CO-CHAIR FLEISHER: So that is
16 what we will or will not vote on, but let's go
17 to the second measure.

18 DR. HALL: This is Bruce Hall. I
19 am on the phone. I have a quick question. Is
20 the weighting available? I am trying to
21 follow the discussion and the materials, and
22 I just cannot find this information.

1 MR. HAMLIN: It is not there.

2 DR. HALL: Okay. Thank you.

3 CO-CHAIR FLEISHER: Okay, and we
4 haven't opened this up for public comment.

5 DR. HALL: This is Bruce Hall. I
6 am not the developer -- as you may know,
7 representing the college. But I am having a
8 hard time following the discussion. How could
9 any weighting scheme, whether it is an equal
10 weighting scheme or any other weighting scheme
11 -- how could that possible be submitted on the
12 reliability of that composite if it hasn't
13 already been in practice a long time, or the
14 interpretability of those scores if they
15 hadn't been in practice a long time?

16 CO-CHAIR FLEISHER: Thanks, Bruce,
17 for that comment. We are going to move on to
18 the second measure.

19 DR. WINKLER: The third diabetes
20 measure is submitted by Minnesota Community
21 Measurement. This is an optimal diabetes care
22 measure. It is an all or none composite that

1 has five components, and we have it up there.

2 These are patients looking at the
3 Alc level, the LDL level, the blood pressure,
4 the tobacco use or nonuse, and the daily
5 aspirin use.

6 So this is on a patient level data
7 collection. How many patients have hit all
8 five of the targets. So this includes
9 patients 18 to 75 with diabetes who meet all
10 of them. The Hemoglobin Alc is less than 8.
11 The LDL is less than 100. The blood pressure
12 is less than 130 over 80. They don't smoke,
13 and -- this is the most recent revision -- for
14 patients over the age of 41, daily aspirin use
15 unless there are contraindications.

16 So it is a five-part measure that,
17 at a patient level, if you hit all five, you
18 get credit for it.

19 MEMBER JUSTER: Clarification.
20 Wasn't this recently revised so it was a daily
21 aspirin if you have cardiovascular disease or
22 is it still at age 41 or above?

1 DR. WINKLER: Actually, we had --
2 Like I say, yesterday we got a --

3 CO-CHAIR DUBOW: It is. It is.

4 DR. WINKLER: Yes.

5 CO-CHAIR DUBOW: Thank you.

6 DR. WINKLER: Now but because they
7 have made revisions that came in in the last
8 day or two, the most recent one says daily
9 aspirin for age 41-plus, use unless
10 contraindicated. That is the most recent one
11 that I got.

12 CO-CHAIR DUBOW: The material that
13 we got --

14 DR. WINKLER: Right, and this came
15 in like at four o'clock yesterday.

16 CO-CHAIR DUBOW: Okay. But it
17 does make the distinction that I've mentioned.

18 DR. WINKLER: Is someone from
19 Minnesota on the phone? Excellent.

20 CO-CHAIR DUBOW: Because the
21 Chairman of the TAP is not here, does somebody
22 -- one of the staff want to just summarize

1 what the TAP -- their review, please?

2 DR. WINKLER: Yes. The TAP
3 generally was concerned about a couple of
4 aspects of it. When this was first presented,
5 the revisions to the aspirin component had not
6 been made, and there had been recent evidence
7 to show the adjustment wasn't needed. So we
8 had to wait for the changes that they have
9 made.

10 It was felt that the Alc target of
11 less than 8 was reasonable. The LDL was less
12 than 100. Those are aligned with current re-
13 endorsed NQF measures. So everything is fine.
14 I think the biggest issue centered around the
15 blood pressure target of 130 over 80. There
16 were concerns, particularly, of most recent
17 publications that actually were coming out the
18 week the TAP met that this blood pressure
19 target was of concern.

20 So that element of it was probably
21 the major focus of the TAP's discussion and
22 their concern with this measure.

1 MEMBER NEWCOMER: Reva, what was
2 the concern? The data was showing it was too
3 aggressive?

4 DR. WINKLER: Yes. Right. I
5 think it was the most recent ACCORD trial, not
6 showing benefit of aggressive blood pressure
7 management for that population.

8 MEMBER HOPKINS: What is their
9 response?

10 MEMBER NEWCOMER: Yes, have they
11 modified it since then?

12 DR. WINKLER: Has Minnesota
13 modified it? No.

14 MEMBER NEWCOMER: They have not.
15 Okay.

16 MEMBER YAWN: I am also bothered
17 by the 41 without evidence of cardiovascular
18 disease. I do not believe that is evidence
19 based, and for women it is 55, not 41. So I
20 know that we have the one that says
21 cardiovascular disease, but the update is the
22 41-plus.

1 MS. PITZEN: No, that is not
2 correct. We just wanted to make a
3 clarification as the measure developer, if we
4 could.

5 Hi, this is Collette from
6 Minnesota Community Measurement. We actually
7 did work on this process, and the aspirin
8 component is justification for cardiovascular
9 disease, irregardless of age.

10 DR. JEWELL: Of what type of
11 cardiovascular disease?

12 MS. PITZEN: We have a defined
13 list of vascular disease, cardiovascular and
14 peripheral vascular.

15 DR. JEWELL: Thank you.

16 MS. PITZEN: Thank you.

17 MEMBER NEWCOMER: So if the
18 developer is on the line, are you intending to
19 change the blood pressure recommendations or
20 do they stay the same?

21 MS. PITZEN: I can answer that.
22 We constantly are reviewing the evidence and

1 the guidelines. A year ago we revised our A1c
2 target that was less than 7 to less than 8,
3 and recently, based on the ADA standard and
4 our expert guideline changes, we did change
5 the aspirin component, and we would expect to
6 be reviewing the blood pressure evidence as it
7 emerges, and pulling our group together again
8 to decide if we need to change that component.
9 The evidence coming out is similar.

10 CO-CHAIR FLEISHER: So, Helen, can
11 you comment? What happens if they change it
12 after we endorse it?

13 DR. BURSTIN: If there is a
14 significant or material change to the measure,
15 it would come to NQF as an ad hoc review. We
16 would together experts to review the change
17 and make a determination if it made sense.

18 I mean, again, literally, the
19 studies came out the day the TAP was meeting.
20 So I think they were able to go back and do a
21 revision on the aspirin one, but I think it is
22 not clear they have been able to in literally

1 real time.

2 Let me just look up the date. The
3 ACCORD trial was March 14th.

4 CO-CHAIR FLEISHER: Comments?
5 B.J.?

6 MEMBER TURNER: So with moving
7 targets on a lot of these variables, to have
8 them all glommed together and have to meet
9 them all seems like a pretty crude hammer to
10 me. And I know that there is a lot of
11 variability across racial groups.

12 I guess this is Minnesota, but I
13 come from Philadelphia where we have a lot of
14 African Americans where blood pressure control
15 is much more difficult. You have to have four
16 drugs sometimes to be at that level, and the
17 side effects are much more significant, too.

18 There is a lot of concern about
19 diastolic hypotension. We don't have any
20 information about that here. So I think,
21 within some of these, especially the
22 hypertension and aspirin we are really

1 focusing on here, there are concerns and
2 questions at this point.

3 I think, to have them all glommed
4 together and you pass/fail is not a very
5 sensitive measure, given that there is a lot
6 of instability in the measure segments.

7 CO-CHAIR FLEISHER: Other
8 comments? Questions for the developer?

9 MEMBER PINDOLIA: Just a question
10 on the non-tobacco user piece. Can you just
11 provide clarification. Is this purely the
12 number of patients as a non-tobacco? How
13 about if they are in a smoking cessation
14 program?

15 MS. PITZEN: Collette. This is
16 non-tobacco use.

17 MEMBER PINDOLIA: So it is just
18 you have to be a non-tobacco user. So if you
19 have someone who is currently smoking and is
20 trying to quit, that doesn't count as a
21 positive?

22 MS. PITZEN: That is correct.

1 CO-CHAIR FLEISHER: Comments?

2 Lee?

3 MEMBER NEWCOMER: I will just
4 offer the counter-view, that the thinking in
5 Minnesota was that, since these patients -- if
6 you get all five, you are going to get a much
7 bigger bang for your buck in terms of delayed
8 outcomes and complications. That is why they
9 put the five together.

10 MEMBER YAWN: And the one they
11 don't pay attention to is eyes.

12 MEMBER NEWCOMER: Right.

13 CO-CHAIR FLEISHER: Okay, are
14 there any other questions regarding this
15 particular measure, rather than comments on
16 the appropriateness?

17 MEMBER AMARASINGHAM: I guess one
18 question is can we endorse the measure with
19 the requirement that it be revised to meet the
20 core guidelines?

21 DR. BURSTIN: It could certainly
22 be something where the measure could be

1 provisionally -- conditionally approved based
2 on the potential for them revising the blood
3 pressure measure, in particular. But again,
4 that is one option for you.

5 DR. WINKLER: But realize that
6 until they do, it is a No vote.

7 MEMBER ROSEN: I think, given the
8 lack of attention to different risk groups,
9 from what I have heard about the measure, is
10 really very insensitive to the needs of the
11 diabetic population, and it is really a very
12 heterogeneous group rather than homogeneous.
13 So I have a concern about that.

14 CO-CHAIR FLEISHER: Comment from
15 the developer, or response?

16 MS. PITZEN: I don't have
17 understand the last comment and what it meant.

18 MEMBER ROSEN: Well, you are just
19 -- As Barbara Turner said, you are just kind
20 of lumping in these five intermediate outcome
21 or process measures and applying it to all
22 patients with diabetes, when in fact patients

1 with diabetes have very different levels of
2 risk and need.

3 So I don't think it is very
4 sensitive to that.

5 MEMBER NEWCOMER: Although the
6 evidence shows -- You know, we have had our
7 debate about blood pressure, but the evidence
8 shows that all diabetics would, in fact, have
9 better outcomes with these measures. So I
10 don't think it discriminates in that sense at
11 all.

12 MS. PITZEN: Well, the other
13 thing, as a developer I think we would like to
14 just comment that, actually, as it is
15 preventive, it does meet all evidence, and we
16 wanted to be clear that Collette said earlier
17 that, in fact, we have an eye to the new
18 evidence preventive stuff. We review it. We
19 will study the blood pressure in the studies,
20 and it is among other studies, and I think it
21 is important to improvement to review all
22 evidence, not just base a change on one study,

1 and the 130 over 80 is supported in ADA
2 guidelines.

3 MEMBER TURNER: I don't think we
4 want to go into a long discussion about blood
5 pressure cut points, but I do think that there
6 is enough of a discussion going on in the
7 world that you can't be dogmatic about the 130
8 over 80 is the measure we have to use for
9 everyone.

10 CO-CHAIR FLEISHER: Thanks. I
11 would actually ask Helen or Rita to give us
12 some help in how we should proceed with
13 talking about the two measures, as well as
14 what else we need to do as far as voting for
15 the individual criteria.

16 DR. BURSTIN: Sure. Just to make
17 the point, as we were talking about earlier in
18 terms of trying to -- You know, these are
19 essentially competing composites. I don't know
20 if one could imagine a world with both of
21 them.

22 You would have to make that

1 determination, but what we would ask you to do
2 is actually we want you to go through the
3 formal process of voting on each of the
4 criteria for each of them, and then make an
5 assessment of what you would like to move
6 forward, because we really do want to be able
7 -- You know, the measures, in and of
8 themselves, have to pass the criteria, and
9 then you can make a determination of the next
10 steps in terms of whether there is one that is
11 best in class.

12 MEMBER YAWN: Could I ask the
13 developer why the Minnesota measure does not
14 include eye exams?

15 MS. PITZEN: At the time this
16 measure was developed, and we have quite a bit
17 of history back to 2003, it was felt that the
18 intermediate outcomes of controlling enough
19 the LDL and blood pressure would prevent
20 potential complications down the road from
21 occurring. So we did not include that process
22 measure as part of our composite.

1 MEMBER YAWN: My comment would be
2 that is nice down the road maybe 10 years, but
3 it may not be nice for people between the time
4 you start and 10 years down the road, because
5 they already have eye disease.

6 CO-CHAIR FLEISHER: Iver, and then
7 I would like to move to taking the vote. Last
8 comment.

9 MEMBER JUSTER: And, actually, I
10 suppose the same comment could be made for
11 nephropathy screening.

12 CO-CHAIR FLEISHER: Okay. So we
13 are going to actually discuss the measure we
14 just discussed. So we will start with the
15 Minnesota measure, and Reva will take us
16 through voting on each of the criteria.

17 DR. WINKLER: Just as we did with
18 the other measures in the first group, we do
19 need to have the Committee's final assessment
20 on how well the measure meets the criteria for
21 importance to measure and report, scientific
22 acceptability of the measure properties,

1 usability and feasibility.

2 I will draw your attention to the
3 handy dandy little cheat sheet provided at
4 each place of those criteria. But having this
5 sort of data helps as the measure moves
6 through the process to kind of provide summary
7 evidence for the various audiences going
8 forward to help determine how things are going
9 to go.

10 CO-CHAIR FLEISHER: Can we put the
11 TAP's recommendations for these?

12 DR. WINKLER: The TAPs only looked
13 at the sub-criteria. They did not vote on the
14 overall criteria. That is your -- That is a
15 Steering Committee role. But how they felt on
16 the sub-criteria are listed here as well.

17 All right. So we are looking
18 right now at the Minnesota Community
19 Measurement composite measure, optimal
20 diabetes care. So what we are looking for is
21 your -- the Committee's assessment on
22 importance to measure and report. This is a

1 yes/no vote.

2 So do you want to do it? Do you
3 want me to do it?

4 CO-CHAIR FLEISHER: All those that
5 vote Yes?

6 DR. WINKLER: Eighteen.

7 CO-CHAIR DUBOW: Noes?

8 DR. WINKLER: Three.

9 CO-CHAIR FLEISHER: Abstain? One.

10 DR. BURSTIN: And people could
11 actually refer to that little handout. It
12 would be helpful, because again we are asking
13 you to do an overall assessment of importance
14 based, in fact, on the three sub-criteria of
15 the impact to the condition, if there is a
16 known gap in care and the relation -- and the
17 third piece of that would be evidence, and I
18 guess that would be potentially part of what
19 people are voting on. So to be clear.

20 DR. WINKLER: So the next
21 criterion is scientific acceptability of this
22 measure as it is specified, the properties of

1 this particular measure, and there are
2 multiple sub-criteria around the
3 specifications, reliability, validity, their
4 exclusions, risk adjustment, meaningful
5 differences, comparability and approach to
6 disparity.

7 You can see the recommendations of
8 the TAP in terms of those sub-criteria. So
9 the Steering Committee will provide the
10 overall rating for that criterion.

11 MEMBER YAWN: Sorry. Can I ask
12 just what about -- In scientific
13 acceptability, I don't see a place for gaps.

14 DR. BURSTIN: That is under
15 importance to measure and report. You have
16 already voted on that.

17 MEMBER YAWN: Thank you.

18 DR. BURSTIN: You are welcome.
19 This is really the scientific acceptability of
20 the measurement properties, its reliability,
21 its validity, the precision of the
22 specifications. That is not the evidence.

1 You just did that one.

2 MEMBER HOPKINS: So do we have the
3 data on reliability and validity or did the
4 TAP -- The TAP looked at it and said it was
5 complete?

6 DR. BURSTIN: Yes.

7 CO-CHAIR FLEISHER: So those who
8 vote Yes for this criterion? No?

9 CO-CHAIR DUBOW: No.

10 DR. WINKLER: Give me a second.
11 Importance actually is a threshold criteria.
12 You voted Yes. So we can move forward. I you
13 had voted No, we would stop.

14 Okay. So on scientific
15 acceptability, the voting is: Completely
16 adheres to the criteria; partially adheres to
17 the criteria; minimally adheres; or not at
18 all. Okay?

19 How many would favor completely
20 meets the criteria for this measure? I am
21 seeing one.

22 MEMBER NEWCOMER: Clarify again

1 what we are voting on.

2 DR. WINKLER: This measure as
3 specified completely meets the criteria as
4 listed and laid out by NQF for scientific
5 acceptability of the measure properties, this
6 measure as specified. Would that be
7 partially?

8 So we try it again. How about
9 completely? Anybody to vote for completely?

10 How about partially? All right.
11 Twenty-one. Okay.

12 How about minimally? I knew there
13 was at least one. Okay. And abstentions? I
14 don't believe so. I think we've got
15 everybody. All right.

16 The next topic is usability of
17 this measure. The usability criteria focused
18 around distinctive or added value, how well it
19 is harmonized with other measures, and
20 provides added value as a new measure to
21 NQF's portfolio. Okay?

22 How many think it adheres to the

1 criteria completely? Six?

2 Partially? Thirteen.

3 How about minimally? Two.

4 Abstain? No.

5 Okay. The last criterion is
6 feasibility, and this is what is the burden,
7 what is the cost, what does it take to
8 generate the information, particularly around
9 how well it is amenable to use by electronic
10 sources, moving into EHRs, whether exclusions
11 require different data sources, potential for
12 inaccuracies or errors.

13 MEMBER NEWCOMER: Are the comments
14 up there relative to feasibility or are they
15 more relative to usability?

16 DR. WINKLER: Right. Well,
17 sometimes we would get -- It gets to be a
18 messy discussion sometimes.

19 So the vote for feasibility. How
20 many think it meets the criteria completely?
21 Fifteen.

22 Partially? Five.

1 Minimally? One, two. Two.

2 Abstentions? Zero. Okay.

3 CO-CHAIR FLEISHER: Do you want to
4 do the other one?

5 DR. WINKLER: Yes. I think it
6 would be confusing to do the overall? I think
7 you need your recommendation.

8 DR. BURSTIN: This is a little
9 unusual. I think the simplest thing is let's
10 rate the criteria. Then you could see the
11 criteria as you have rated them head to head,
12 and then make your assessment, I think, would
13 make the most sense.

14 So let's do the other one, same
15 game. Let me explain that, actually, because
16 the logic is we would only -- I'm sorry.

17 I think the issue is we would only
18 do the head to head comparison if, in fact,
19 both meet our criteria. So we need to
20 establish that first, and then we will come
21 back and do the assessment.

22 DR. WINKLER: Now we are going to

1 turn our attention -- Hawa, do you have the
2 table up? Great -- to the NCQA composite. If
3 you recall, it had the numerous process and
4 outcome measures, I believe, on that page.

5 All right, so important to measure
6 and report. This is a yes/no criterion. So
7 how many would say, Yes, it is important to
8 measure and report? A unanimous 22.

9 All right. Scientific
10 acceptability of the measure properties as
11 specified, and that includes the composite
12 methodology of the weighting and the points.
13 All right?

14 So how many feel it meets the
15 criterion for scientific acceptability
16 completely? Okay.

17 Partially? That is 17.

18 Minimally? Four.

19 Anybody else? Not at all? No?

20 Okay.

21 In terms of usability of this
22 measure -- What?

1 MS. BOSSLEY: I think it is five
2 for partial, because we should have 22 voting.
3 I meant minimal. I'm sorry.

4 DR. WINKLER: No, there is five --
5 I was going to say, there were six, not even
6 five. All right. Given we did so well with
7 that one, let's try usability.

8 How many would say it meets the
9 usability criteria completely? Four.

10 Partially? Fifteen.

11 And minimally? One, two, three.

12 MEMBER PINDOLIA: Can I change my
13 vote to a higher one?

14 DR. WINKLER: You were partial?

15 DR. BURSTIN: So you want to go to
16 Completely?

17 MEMBER PINDOLIA: Yes.

18 DR. WINKLER: Okay. So you are
19 14. We can do that. Five-fourteen-three.
20 All right.

21 Feasibility criteria: Completely?
22 Eleven.

1 Partially? Eleven.

2 Minimally? Is there anybody still
3 on minimally? No? It should be everybody.
4 Right? Okay. All righty.

5 CO-CHAIR FLEISHER: Okay. Helen?

6 CO-CHAIR DUBOW: Heidi is doing
7 it.

8 CO-CHAIR FLEISHER: So next do you
9 suggest voting on each individually, Helen?

10 CO-CHAIR DUBOW: If you give me
11 just a second, I will give you a summary of
12 what you said.

13 MS. PITZEN: Hello?

14 DR. BURSTIN: Sorry. We are just
15 compiling results. You haven't missed
16 anything. Just give us a moment.

17 DR. WINKLER: Okay. I have -- I
18 can tell you. So let me start first with the
19 all or none. It is not pretty.

20 CO-CHAIR FLEISHER: While they are
21 putting this up, I just would propose -- Does
22 anybody feel these are competing versus non-

1 competing measures? In particular, does
2 anyone feel that they both could be endorsed,
3 because they are non-competing? David, do you
4 want to make a comment?

5 MEMBER HOPKINS: I feel they are
6 competing, and I feel that there is a property
7 of the Minnesota measure that really hasn't
8 been highlighted. It is, in fact, a patient-
9 centered perspective measurement, and we have
10 so few measures that are formulated this way.
11 I just think it is really important for people
12 to think about that.

13 It is about the whole patient
14 getting the care and with the results that are
15 important to that individual. So I strongly
16 favor that measure.

17 CO-CHAIR FLEISHER: Iver?

18 MEMBER HOPKINS: I think the flip
19 side of that is I do find that in the other
20 measure the need for weighting invites
21 arbitrariness, and there just is no way to
22 scientifically validate the weights.

1 MEMBER JUSTER: There is a
2 compelling case to be made for all or nothing
3 measures or 80 percent or more measures or
4 whatever you want to call them. I don't know
5 if there is space to say something about -- I
6 might be happier voting yes if this measure
7 was harmonized or it included the retinal exam
8 and screen for nephropathy.

9 So it is sort of a great idea
10 "and" kind of thing. Is there space for that
11 sort of thing?

12 CO-CHAIR FLEISHER: Patchen?

13 MEMBER DELLINGER: Just in terms
14 of how we describe things, we are calling the
15 Minnesota measure an all or none. It is all
16 or none for individual patient, but the
17 measure is the percent of patients who meet
18 the all or none criteria.

19 CO-CHAIR FLEISHER: Brian?

20 MEMBER FILLIPO: I also am in
21 strong support of all or none criteria. I
22 think there are patient centered, although I

1 think this specific collection of indicators
2 is just not granular enough, and not risk
3 adjusted. So I don't think that this
4 particular one is good.

5 CO-CHAIR FLEISHER: Do you make a
6 comment, Joyce?

7 CO-CHAIR DUBOW: I was just
8 repeating something I heard at the table and
9 that is whether, in fact, these are two
10 measures, because they set different levels of
11 achievement, the all or none measure as
12 opposed to one that is one of gradation and so
13 whether, in fact, these represent two
14 measures.

15 On the other hand, if the idea is
16 to represent to the public, for example, to a
17 patient what is good diabetes care, then we
18 have a different cut. But the issue is
19 whether we have the opportunity to make room
20 for both or whether we need to take a cut on
21 it.

22 CO-CHAIR FLEISHER: Patricia?

1 MS. HAUGEN: Yes. I just wanted
2 to comment. If you look at usability, it is
3 that is this understandable to the public, and
4 can it be used in decision making? I think
5 that speaks to the Minnesota measurement
6 where, although it is the percentage that
7 there is some clarity in this, I think one
8 issue of composite measures from a patient
9 perspective is how you really understand the
10 intricacies of it, and can I make a decision
11 or does it inform me? I think this one has
12 some clarity to it that, from a patient
13 standpoint, would make it usable.

14 CO-CHAIR FLEISHER: Barbara?

15 MEMBER YAWN: But I am going to go
16 back to you say it is patient-centered. It is
17 patient-centered as long as you don't care
18 about their eyes or their kidneys. But
19 there's -- Well, outcomes are identifying
20 early eye disease, and being able to prevent
21 blindness. I think that is very significant.
22 So I am concerned about those lack. I

1 understand the simplicity.

2 CO-CHAIR FLEISHER: So I would
3 actually ask Reva, for example, would we ever
4 endorse a measure but say we believe that
5 there is -- from either a research or a gap in
6 care perspective, these two are not -- have
7 been ignored, and it should be included in
8 another measure to be developed over the next
9 year? Would that be reasonable?

10 DR. BURSTIN: There is only so
11 much you can do in terms of conditions on a
12 measure. The measure that is before you, not
13 conditions, but that would be essentially
14 rejecting and asking a different measure to
15 come back.

16 You can potentially ask for
17 harmonization of the individual components, if
18 that is something you would feel more
19 comfortable with. That is something, I think,
20 within your purview, but I think adding
21 components to the composite couldn't be done
22 at this point.

1 I mean, for example, this issue of
2 the blood pressure control -- There are, you
3 know, the aspirin measure. I think there are
4 potentially conditions that could be placed on
5 it, if you feel it is important, and that is,
6 in fact, we do -- although I am not sure we
7 should, we do specifically have criteria for
8 composite measures, and harmonization of the
9 components is an important aspect. So just
10 another consideration.

11 MEMBER AMARASINGHAM: Can I ask a
12 quick question? When we vote on the all or
13 none measure then, will there be an option
14 about the condition with respect to the ACCORD
15 trial guidelines in harmonizing the blood
16 pressure?

17 DR. BURSTIN: Yes.

18 CO-CHAIR FLEISHER: So we will
19 include that in the vote, conditional pending
20 blood pressure, as one of the options. Then
21 secondly -- Okay, do you want to propose what
22 the condition would be, so that when we vote,

1 we know what the condition is?

2 MEMBER AMARASINGHAM: I am not
3 familiar with the specifications of the ACCORD
4 -- you know, what the results were from the
5 ACCORD trial with respect to this. So I guess
6 I would say that they should reflect the
7 results of the ACCORD trial, which I believe -
8 -

9 CO-CHAIR FLEISHER: It is the
10 interpretation.

11 MEMBER AMARASINGHAM: Right, but
12 at least a review of it.

13 DR. BURSTIN: Right, and I think
14 it would be reasonable for you potentially ask
15 that they respond back, for example, why the
16 blood pressure -- I mean, I think their
17 response we have heard on the telephone was
18 that it was one study. They had looked at the
19 full view of the evidence.

20 I think the concern is, as I
21 recall from the TAP, and I did just pull up
22 the study, is I think the issue was the fact

1 that there is possible harms associated with
2 a lower blood pressure, and that was the issue
3 they really homed in on. It wasn't just an
4 issue of the fact that it didn't significantly
5 reduce the bad outcomes from cardiovascular
6 disease, but that there were signals of
7 possible harm with intensive blood pressure
8 control, including a rate of serious adverse
9 events that were significantly higher in the
10 intensive therapy group compared to the
11 standard therapy group. That was the issue
12 they are really homing in on, was the safety
13 issue.

14 CO-CHAIR FLEISHER: So can we
15 actually say conditional and then reviewing
16 and responding to the TAP's concerns, and that
17 would be what I would propose as the
18 condition, so that they could either change it
19 -- approve it by either changing the blood
20 pressure or responding appropriately, and
21 there's multiple other levels in which this
22 needs to be approved. Okay?

1 MEMBER PINDOLIA: I'm sorry. I
2 have been trying to read the results. I was
3 trying to figure out exactly how many people
4 are meeting these five, and out of their
5 119,000 patients submitted, 19 percent met all
6 five targets with a range of 45 percent to
7 below one percent.

8 So does that mean below one
9 percent physicians are considered to be not
10 practicing properly or is it they just have a
11 negatively selected patient population or in
12 an urban area or --

13 MEMBER NEWCOMER: It simply means
14 they had a 99 percent opportunity for
15 improvement. That is all it means.

16 MEMBER YAWN: Not when they get
17 paid.

18 MEMBER PINDOLIA: Right. Not when
19 there is going to be incentives applied to it
20 and not when there is going to be -- just
21 because you have higher smokers, because you
22 don't have an opportunity to even have smoking

1 cessation.

2 DR. BURSTIN: The measure is
3 titled optimal care, just to recall that. It
4 is inherently a different construction. I
5 just want to be clear. That is actually how
6 it is titled.

7 MEMBER HERMAN: And the developers
8 are on the phone, and they could tell you
9 that, when they have looked at it, it is not
10 stratified by one group or another. I mean,
11 there are some clinics that should really be
12 doing a whole lot better, but are doing very,
13 very poorly. So there is not a bias within
14 this that we can detect.

15 MEMBER PINDOLIA: That could be
16 used like to then have -- like how is that
17 going to be used? It is just a reporting or
18 there going to be actual them saying what does
19 your practice need or what is it missing? Is
20 there processes to help improve those?

21 CO-CHAIR FLEISHER: So I am going
22 to call the vote.

1 MEMBER NEWCOMER: There has to be
2 a comment here. If we are still looking
3 between the two measures -- We are not then?
4 Okay. All right.

5 My comment: The difference
6 between the two measures --

7 CO-CHAIR FLEISHER: Do you want to
8 go through the criteria, Reva?

9 DR. WINKLER: On the optimum care,
10 the ONM measure, you said it was important.
11 It partially meets the scientific
12 acceptability criteria, partially meets the
13 usability criteria, and completely meets the
14 feasibility criteria.

15 Compared to the NCQA composite of
16 the multiple measures: Yes, it is important,
17 partially meets the criteria presented for
18 acceptability, partially meets the criteria
19 for usability, and partially meets the
20 criteria for feasibility.

21 MEMBER YAWN: So the only variant
22 is really the feasibility.

1 CO-CHAIR FLEISHER: And the
2 scientific acceptability.

3 DR. BURSTIN: Can you go back?

4 MEMBER NEWCOMER: There is a key
5 difference in philosophy between these two
6 measures. The first measure, the five
7 aggregates strives toward as best performance
8 as you can possibly get. Ultimately, your
9 goal is to get as close to 100 as you can.

10 The other is about minimal
11 performance. It is more like meeting test
12 standards. If you get to your 15 percent, you
13 can move on to the next measure and improve
14 it, my point being, if you take a look from a
15 clinical standpoint, I think measure one says
16 we are going to try harder to get to total
17 perfection.

18 The second measure is more about
19 passing the test, and for that reason I would
20 favor the first measure.

21 CO-CHAIR FLEISHER: But realize,
22 you just actually advocated that you could

1 have both..

2 MEMBER NEWCOMER: You certainly
3 could.

4 CO-CHAIR FLEISHER: I mean you
5 could actually endorse both measures of what
6 I am hearing, and actually say did you pass
7 the test, and did you have a perfect score,
8 which are two different criteria.

9 DR. BURSTIN: Just one other
10 point. Since they obviously are so close in
11 terms of your ratings, there is really not a
12 whole lot of light between them as you
13 actually look at the ratings of them.

14 You are still fairly early in this
15 process. So, again, there is also nothing
16 wrong with potentially putting them both out
17 for comment and allowing us to get what is
18 usually a very -- I assume we will get a
19 fairly robust response on this, the set of two
20 measures, is one potential idea.

21 CO-CHAIR DUBOW: I like that idea
22 a lot. I also think that it is possible that

1 these two measures appeal to two different
2 interests: One, the patient who, obviously,
3 wants optimal care and is going to be very,
4 very interested. It is intuitively easier to
5 understand whether you have got everything you
6 should get, and in only one measure. The
7 Minnesota Community measure absolutely does
8 that.

9 On the other hand, it seems to me
10 that the NCQA measure does have some value
11 from a clinical perspective, ticking off the
12 items, because you are knowing whether you are
13 getting past some predetermined threshold.

14 So it feels to me as though there
15 is the potential here for having our cake and
16 eating it, too, in that there is one measure
17 that really will resonate with patients, and
18 a second one that may have some more salience
19 for the clinical audience.

20 CO-CHAIR FLEISHER: And that may
21 get back to the question of what is your
22 population in the clinic. If the population

1 is highly motivated, then you may be able to
2 achieve optimal care. If the population is
3 much less motivated, then a measure that says
4 you are doing certain things and can you
5 actually pass a test, given a less motivated
6 population? may be important.

7 Last comment, and then we are
8 going to vote.

9 MEMBER HOPKINS: So Joyce's
10 comment reminds me of our recent debate about
11 the -- and the Board's debate about NQF
12 expectations for use of measures, and I
13 believe where it sits is public reporting --
14 what we call accountability and quality
15 improvement, and the important word there is
16 "and."

17 So I personally favor the first
18 measure for public reporting, and I do not
19 favor the second, because it is too low a bar.

20 CO-CHAIR FLEISHER: It requires
21 the patient to be involved.

22 MEMBER YAWN: I am still going to

1 argue that optimal care doesn't mean the
2 process measures for some outcomes are ignored
3 while the process measures for others, like
4 Hemoglobin A1c which is a process -- it is an
5 intermediate outcome, just like having an eye
6 exam is an intermediate outcome. It is not
7 optimal care, in my opinion, but you have all
8 said you think it is.

9 CO-CHAIR FLEISHER: So we are
10 actually going to vote, I think, yes or no on
11 Minnesota, followed by yes without conditions,
12 yes with conditions that they respond to the
13 TAP regarding the blood pressure issue, no,
14 and then a second comment with regard to
15 potential gap in care unless we just rather we
16 would endorse that they evaluate in the future
17 including issues of retinopathy and
18 nephropathy. Would that be fair? Okay.

19 MEMBER HOPKINS: And the Minnesota
20 one has the condition that they look at the
21 blood pressures.

22 CO-CHAIR FLEISHER: That is a

1 minimum. That is the second. So the first
2 one is the NCQA, which is a simply yes or no.
3 I'm sorry. I made the mistake in the order.
4 Yes, my fault.

5 CO-CHAIR DUBOW: Oh, okay.

6 CO-CHAIR FLEISHER: Okay. I was
7 looking at that and remembered. So we
8 discussed NCQA first. All those in favor of
9 endorsing the NCQA measure?

10 MEMBER NEWCOMER: We can do more
11 than one?

12 CO-CHAIR FLEISHER: Yes.

13 CO-CHAIR DUBOW: We can. We can
14 do more than one. Yes, we can. Sure.

15 DR. BURSTIN: We can do more than
16 one, because at this point all you are doing
17 is approving it to move for the membership.

18 CO-CHAIR DUBOW: What was that?

19 DR. WINKLER: I got 13.

20 CO-CHAIR FLEISHER: This NCQA is
21 not with conditions.

22 DR. WINKLER: Okay. Thirteen,

1 okay.

2 CO-CHAIR FLEISHER: All those who
3 vote No?

4 DR. WINKLER: Eight.

5 CO-CHAIR FLEISHER: Okay.

6 DR. WINKLER: Are there any
7 abstentions?

8 MEMBER ROSEN: I just wondered if
9 we could, for the NCQA one, have a condition
10 that we get some sort of more empirical
11 evidence as to the way they system has been
12 used.

13 CO-CHAIR FLEISHER: Is that a
14 condition or just a comment, because I didn't
15 hear any -- We voted Yes without conditions.
16 It is a comment.

17 MEMBER ROSEN: It is a comment.

18 CO-CHAIR FLEISHER: Okay. We need
19 to vote. For those who voted Yes, is it vote
20 Yes without conditions -- well, that is what
21 I heard. No?

22 DR. WINKLER: I hadn't heard the

1 conditions. The question, I think, Amy just
2 brought up was if -- your comment, you would
3 like to see more data, but does that mean
4 that, if they don't produce it, then you vote
5 no?

6 MEMBER ROSEN: I am concerned
7 about the weighting and how the criteria were
8 developed for the weighting. So if they can
9 produce more evidence on that, that --

10 MEMBER NEWCOMER: We have already
11 been told there isn't any. So they aren't
12 going to be able to do it.

13 MEMBER ROSEN: It is just clinical
14 judgment that something is a 20 versus a 10.
15 Expert opinion, and in my mind that is not
16 good enough. So, okay.

17 CO-CHAIR FLEISHER: Well, you
18 voted Yes or No?

19 MEMBER ROSEN: I voted No.

20 CO-CHAIR FLEISHER: You voted No.
21 Okay. So then we can just give that comment.

22 Okay. Next is Minnesota. So now

1 -- Oh, are there any abstentions?

2 DR. WINKLER: There would have to
3 be. We need 22.

4 DR. BURSTIN: Were there any
5 abstentions on that vote?

6 DR. WINKLER: Oh, Barbara is out.

7 CO-CHAIR FLEISHER: So we will get
8 it when she comes back.

9 Okay. Minnesota: So we have Yes
10 without any conditions. Remember there is the
11 issue of the ACCORD trial. So anybody vote
12 Yes without any conditions?

13 DR. WINKLER: One, two. Two.

14 CO-CHAIR FLEISHER: Yes with the
15 conditions that they evaluate the ACCORD trial
16 and respond regarding the appropriateness of
17 their blood pressure criteria?

18 DR. WINKLER: Fourteen.

19 CO-CHAIR FLEISHER: No?

20 DR. WINKLER: Four. Any
21 abstentions? No? And Vanita. One.

22 CO-CHAIR FLEISHER: Okay.

1 MEMBER YAWN: And also Barbara.
2 She is not here.

3 CO-CHAIR FLEISHER: And a simple -
4 - Do we need a Yes or No that we would like
5 them to look at nephropathy or retinopathy or
6 are people willing -- So we don't vote on
7 that. We just suggest?

8 Is it the will of the committee
9 that they look at that for any future measure?
10 Okay. Thank you.

11 DR. BURSTIN: Could you go over
12 the final votes, Reva?

13 DR. WINKLER: The final votes were
14 Yes for the measure as is; with two Yes with
15 the condition that they respond to the blood
16 pressure, the ACCORD trial, and come back to
17 this committee. That was 14. Noes were four.

18 I think what is going to happen
19 is, when they come back, we will probably have
20 to re-vote it.

21 I think there is time for us to
22 get that back so that it isn't left unresolved

1 and hanging. I think the better we can get it
2 resolved, it would be useful.

3 CO-CHAIR DUBOW: All right. I
4 think we are done with the diabetes measures.
5 Is that right?

6 Okay, the first one is always
7 harder. That was very difficult. Now we have
8 to make a decision. I can't imagine that some
9 people don't want to take a five-minute break,
10 but it is also close to lunch. So maybe we
11 can combine -- Okay, we are checking on lunch.
12 I was going to suggest that we take a quick
13 break, bring our food back and -- It is not
14 there? Okay. So it will be at one. Well,
15 can everybody manage 20 minutes? No?

16 CO-CHAIR FLEISHER: So why don't
17 we just have Reva actually go over the
18 measure?

19 CO-CHAIR DUBOW: Yes. Well, what
20 we have been asked to do is to -- We are back
21 to talk about the cross-cutting measures, and
22 we were going to hit the BTE measure first, if

1 that is okay. But if you want to introduce
2 all of the cross-cutting measures, Reva, that
3 is what we should try for. But we will start
4 with that one.

5 Okay. So we are about to start
6 our discussion on the cross-cutting measures.
7 We will stop at one, and next time build in a
8 little bit of a break.

9 DR. WINKLER: So we are going to
10 do this one first. The first one we will be
11 looking at is a measure that is the proportion
12 of patients with a chronic condition, and they
13 are listed in there, multiple chronic
14 conditions, that have a potentially avoidable
15 complication during an entire calendar year.

16 I think it is important -- I hope
17 you have had a chance to kind of read the Word
18 document that came along with the measures
19 talking about the background of the
20 development of these measures as part of the
21 Prometheus Project.

22 The potentially avoidable

1 complications is a concept that these are
2 being built around. There are numerous
3 measures -- we are going to see three others -
4 - around more shorter term acute events, but
5 this is the cross-cutting for chronic
6 conditions, looking at avoidable
7 complications.

8 Some of them include readmission.

9 Some of them include types of care required
10 for things like DVTs and sort of other kind of
11 complication type measures, as well as
12 utilization type things such as readmission or
13 ED visit or all of these sorts of things.

14 So that is the measure, and I
15 guess having read that background piece will
16 help better understand the Bridges to
17 Excellence folks' approach and, as I said,
18 this is all part of the Prometheus payment
19 system. So that is the first one.

20 The second one is the Medicare
21 Health Outcomes Survey, the physical
22 components summary score. This is -- The

1 measure steward is NCQA. This is a patient
2 survey tool. It is in use in the Medicare
3 population. It is based on the SF-36 -- I
4 think the A version -- but this is a measure
5 that has been around a long time.

6 What we gave you, in addition to
7 the submission were the links to their very
8 extensive website that has the tool and the
9 current results and a lot of the research that
10 has been done around it, those sorts of
11 supporting documents.

12 The third one is another measure
13 from NCQA, the care for older adults. This is
14 a three-part measure that includes results for
15 advanced care planning, functional status
16 assessment, and pain screening. But these are
17 three parts with each one reported as an
18 individual measure and with individual
19 results.

20 So those are the three cost-
21 cutting measures we are going to be looking at
22 on the next go-round.

1 CO-CHAIR DUBOW: Okay. We have --
2 We are going to do the BTE measure first. So,
3 Francois, will you join us at the table? We
4 have the developer with us, and if you would
5 like to make some opening remarks, that would
6 be just fine.

7 MEMBER NEWCOMER: This is the 2209
8 measure?

9 CO-CHAIR DUBOW: Sorry. This is
10 the -- Right.

11 MR. DeBRANTES: Well, yes, thank
12 you. I don't know if, Reva, there was an
13 opportunity to send out the PowerPoint slides.

14 DR. BURSTIN: It is on the PDF.

15 CO-CHAIR DUBOW: So let's just
16 find it. Do we have it? Just bear with us
17 for a minute. No?

18 CO-CHAIR FLEISHER: I don't see
19 it.

20 CO-CHAIR DUBOW: Well, she will
21 pull it up.

22 MR. DeBRANTES: All right. Thank

1 you, and I apologize for those not having been
2 sent, I guess, on time.

3 What I wanted to do is to
4 summarize a little bit what our approach has
5 been in devising this comprehensive
6 complication of care measure and, obviously,
7 be in a position to answer questions that any
8 members of the Steering Committee might have.

9 As Helen mentioned, there are
10 others like this coming up a little later. So
11 they are all constructed essentially the same
12 way, although this one measure is around
13 chronic conditions, in particular. The other
14 ones are around acute medical conditions.

15 We have been through four TAPs. I
16 would say that the grade we have gotten from
17 the four TAPs are highly variable as, by the
18 way, are potentially avoidable complication
19 rates. So I think it is well consistent and
20 probably speaks to, I think, both the
21 definitions around the measures and the
22 challenge that they represent for most

1 physicians.

2 Just a couple of words on where
3 this all came from which, as Helen mentioned,
4 is a by-product of our work around creating
5 episodic care payment, and in doing so, part
6 of our charge has been to determine the extent
7 to which we can identify care that is
8 appropriate, right for patients, versus things
9 that might happen in a patient's life that are
10 caused by what we have come to call
11 potentially avoidable complications.

12 What is important in these
13 definitions and in this measure is that we
14 think about this as truly a patient centric
15 measurement. So this isn't about an
16 individual physician or an individual
17 hospital. This is about a patient.

18 In some instances, that patient
19 might have asthma but with comorbid
20 conditions, or that patient might have
21 diabetes with comorbid conditions.

22 We don't try to parse out the

1 diabetes from the asthma, from the COPD, more
2 than to think about the patient as a whole,
3 and to determine the extent to which the
4 patient has had one or more avoidable
5 complications during the course of their
6 episode, which we define in the case of
7 chronic conditions as being one year.

8 So I think one of the -- bringing
9 back some of the comments that we got from the
10 first TAP we went through, which I think was
11 pulmonology, there was a significant pushback
12 that the measure wasn't tightly linked to COPD
13 or asthma. That is because we don't think
14 about this from a provider centric
15 perspective.

16 We think about this from a patient
17 centric perspective, and a patient with COPD
18 often has comorbid conditions. So the extent
19 to which they are hospitalized for one of
20 their comorbid conditions as opposed to their
21 core condition, we consider that a potentially
22 avoidable complication, because what we are

1 trying to do is to create a measure that looks
2 at and evaluates the system of care around the
3 patient and creates accountability for the
4 system, not necessarily individuals but anyone
5 within the system, and creates co-
6 responsibilities for all the providers that
7 manage and co-manage, whether they do it
8 consciously or unconsciously, or don't do it,
9 but are supposed to be co-managing the
10 patients.

11 So the potentially avoidable
12 complications are essentially divided into
13 three parts, and maybe we will skip to that
14 section so that folks can understand it.

15 Well, let me just quickly go
16 through this. So we have gotten lots of help,
17 actually -- and this is just a few examples;
18 there is a larger summary in the Word document
19 that was sent out.

20 We have had a fair amount of
21 support from AHRQ, CMS, HC Health Partners,
22 other organizations, ACC-related physicians,

1 in really doing and looking at this issue of
2 what can you consider to be typical care
3 versus care associated to potentially
4 avoidable complication, and all this help from
5 physicians across the country has been baked
6 into these definitions. Next slide.

7 So the six chronic conditions that
8 we have studied are the six that are listed
9 here: Diabetes, coronary artery disease,
10 congestive heart failure, COPD, diabetes, and
11 hypertension.

12 Importantly, this measure, as you
13 have looked at the definition, is really for
14 patients below the age of 65. So I want to
15 make sure that that is clear. We are not
16 including patients above the age of 65, which
17 often happen to have multiple, multiple
18 chronic conditions, mostly because we haven't
19 studied patients above the age of 65.

20 We study patients below the age of
21 65, and so that is what this measure is
22 intended to look at, is accountability in the

1 management of patients under the age of 65 in
2 commercial populations. Next slide.

3 So here is the way an episode of
4 care is defined. The reason why I bring this
5 up is because we count avoidable complications
6 during the period of time that is defined
7 around this episode. In this instance, it
8 happens to be one year.

9 So a chronic care episode is
10 looked at as being a one-year episode. We
11 look at it usually in a calendrical fashion so
12 that it is tied to the benefit year. It is
13 tied to contracts. It is tied to a whole
14 bunch of other things.

15 The claims that are analyzed as
16 part of any effort around measurement using
17 claims are really distinguished between two
18 types of claims, professional services, labs
19 and other ancillary services and drugs --
20 outpatient based claims, if you will -- versus
21 inpatient based claims.

22 So these come in two different

1 streams, and we accumulate them together. As
2 we look at an episode of care during the
3 course of a year, we classify events,
4 services, as either being typical -- so those
5 are the ones that are illustrated on this
6 chart as blue -- versus potentially avoidable,
7 and we will get into the definitions of what
8 we consider to be potentially avoidable.

9 I emphasize potentially, because
10 we don't pretend that any of these are
11 completely avoidable, but potentially
12 avoidable and should, therefore, be worked on.

13 Inpatient stays and ED visits, in
14 our definitions, are mostly potentially
15 avoidable complications for these patients
16 with chronic conditions. Next slide.

17 So the way you arrive at the
18 measure and the measure definitions and the
19 accounting around the measure is really using
20 claims data. So all claims data come into --
21 this is just an illustration of a funnel.
22 Some get excluded. Why? Because they are not

1 at all relevant to that patient's condition,
2 and cancer is an example. Then the balance
3 get sorted between typical services versus
4 potentially avoidable complications or
5 services associated to potentially avoidable
6 complications.

7 The measure that we are proposing
8 here, and with the three that will follow, is
9 counting these events, so counting events that
10 are associated to avoidable complications.

11 Next slide.

12 So just to give you a sense of the
13 size of the database, the sample sizes of the
14 patient cohorts that we have analyzed through
15 our effort, very large amounts of patients.
16 So four million in total, 172,000 patients
17 with diabetes. We do not suffer in our
18 analysis from small sample size problems. We
19 have very adequate sample sizes to do severity
20 adjustments and other analyses.

21 MEMBER YAWN: Lower age limit?

22 MR. DeBRANTES: Excuse me?

1 MEMBER YAWN: Lower age limit?

2 MR. DeBRANTES: Lower age limit
3 depends on the condition. For the most part,
4 it is 18, except for pediatric asthma.

5 MEMBER YAWN: Well, I assume that
6 will go down to two or three.

7 MR. DeBRANTES: So in a snapshot,
8 you can see that, out of the total 650 or so
9 patients with these chronic conditions, about
10 72 percent during the course of a year had one
11 or more potentially avoidable complications.
12 Again, these can be associated to either the
13 core condition, comorbid conditions or patient
14 safety issues, and I will get into that.

15 There is a huge amount of regional
16 variation, as you can imagine, for rates of
17 potentially avoidable complications by
18 condition. This is just a snapshot. We
19 ranked all of the states into deciles, and
20 then we ranked the states by decile, so that
21 you have a decile distribution here with the
22 min, the max, and kind of the average.

1 I think what is important is that
2 -- and we see this not just in these chronic
3 conditions but also in the acute medical
4 hospitalizations -- is that there is more
5 distribution, I would say -- or there is a
6 wider variation on the top end of the decile
7 distribution than there is on the lower end,
8 again not surprising, but it does tell us, I
9 think, clearly, in our analyses that a
10 significant percentage of these avoidable
11 complications can, in fact, be avoided;
12 because you have -- The variation is not
13 explainable by severity of patients.

14 So adjusting for the severity of
15 patients, you have these significant
16 variations in rates of hospitalizations and
17 emergency department visits by patients.

18 When we actually look at the
19 distribution of these patients across the
20 country, unsurprisingly and related to your
21 prior discussion, patients in Minnesota on
22 average have far fewer rates of potentially

1 avoidable complications than patients in, say,
2 Arkansas, and I am not passing judgment on one
3 versus the other more than I do think that
4 there is a relationship between low rates of
5 potentially avoidable complications and good
6 systems of care. Next slide.

7 So rates of potentially avoidable
8 complications fall into three categories.
9 Type 1 are avoidable complications that are
10 associated to the patient's core condition; so
11 diabetes, for example.

12 The second would be related to
13 comorbid conditions. So a patient with
14 diabetes also has asthma. If they are
15 hospitalized for their asthma, we will
16 consider that a potentially avoidable
17 complication.

18 The third one are avoidable
19 complications that are associated to patient
20 safety issues, and an adverse drug event is a
21 classic example of such a potentially
22 avoidable complication.

1 When we look at the distribution
2 of those types of avoidable complications by
3 disease category, the vast majority of
4 avoidable complications come from Type 2,
5 which is comorbidities and patient safety
6 failure. Far fewer come from the core
7 condition.

8 I think this speaks to the
9 critical importance of this measure and its
10 contribution to the field of accountability,
11 because what we see is that, when you are
12 looking at the tight scope of a measure,
13 asthma or COPD, and you are trying to
14 determine the extent to which that asthma or
15 that COPD is being controlled appropriately,
16 we find that on average, yes, although there
17 are avoidable complications. But what seems
18 to be forgotten are the comorbid conditions of
19 the patient, and that is what is driving a lot
20 of these avoidable complications.

21 So if we make this move from a
22 solid measurement of individual physicians to

1 as more systems measurement of surrounding the
2 patient and understanding whether or not the
3 system is, in fact, working to the benefit of
4 the patient, we have to look far broader than
5 just the tight Type 1 potentially avoidable
6 complication.

7 Some further scopes again -- and
8 these now start relating back to dollars,
9 because we do look at dollars quite
10 extensively in our work. So that both the
11 volumes or the frequency of avoidable
12 complications, but also the costs associated
13 to these avoidable complications are highly
14 skewed toward PACs of Type 2, so associated to
15 comorbid conditions with 255 out of \$400
16 million. So lots and lots of dollars being
17 spent in this population on avoidable
18 complications. Next slide.

19 This is just somewhat of a top 10,
20 if you will or close, of top drivers of
21 potentially avoidable complications for each
22 one of these chronic conditions.

1 Emergency room visits, as you can
2 see, are a significant driver, but then again
3 the acute flare-ups of the core condition,
4 UTIs, cardiac dysrhythmias, pneumonia, lung
5 complications.

6 So these are the things that most
7 of you who practice know that, when patients
8 hit the hospital at the emergency department,
9 this is what they present with. This is what
10 we see as avoidable complications.

11 The reality is that, if the
12 patients are fundamentally managed as a
13 whole, I do think that we can legitimately say
14 these numbers should go down, and without
15 holding the system accountable for them, then
16 it ain't going to happen.

17 We do have relatively robust
18 severity adjustment built into each one of
19 these measures, and this is just an
20 illustration of how that severity adjustment
21 works.

22 So if you've got the population

1 severity index that varies, that is going to
2 have an impact on their rate of potentially
3 avoidable complications, and you can
4 recalculate the rates of potentially avoidable
5 complications severity adjusted to the patient
6 population, so that when you are using this
7 for comparative performance purposes, it is
8 fully severity adjusted.

9 MEMBER TURNER: Which measure is
10 it?

11 MR. DeBRANTES: Excuse me?

12 MEMBER TURNER: Which measure are
13 you using -- the severity level?

14 MR. DeBRANTES: The severity
15 adjustment is based on a -- Excuse me? Well,
16 we used some of it, but it is really a
17 relatively standardized linear multi-variable
18 linear regression model.

19 DR. RASTOGI: So we created the
20 risk adjusted models for each of the six
21 conditions, and then calculated for every
22 patient their severity score, and then for the

1 whole population you can calculate a severity
2 index.

3 So then you compare one health
4 plan to the other health plan or one employee
5 base to the other employee base, whatever is
6 their population. Their constituent base, we
7 will call it as one, and then each other
8 population we can look at the sum total of the
9 severity scores of individual patients with
10 that condition.

11 So it is all based on a linear
12 regression model like Francois was mentioning.

13 MEMBER TURNER: So I am just
14 trying to figure out what the inputs are into
15 the severity model.

16 MR. DeBRANTES: Well, resource use
17 and cost of care as an initial input.

18 DR. RASTOGI: Yes. So diagnosis
19 scores, pharmacy goes into it. Procedures go
20 into it. Quite a bit of the services that are
21 there, they all go into the severity
22 adjustment, and it is all part of the measure

1 development.

2 We have included all the variable
3 lists in the measure submission.

4 CO-CHAIR FLEISHER: Amita, would
5 you introduce yourself, please?

6 DR. RASTOGI: Yes. I am Dr.
7 Amita Rastogi. I am Medical Director with
8 BTE, work with Francois.

9 MEMBER HOPKINS: Can somebody
10 explain why the risk adjustment didn't work
11 inversely on this slide? If coefficient B is
12 higher severity -- am I interpreting that
13 right? -- then why wouldn't you downward
14 adjust their PAC rate?

15 DR. RASTOGI: If it is higher
16 severity?

17 MR. DeBRANTES: No, it is the
18 opposite. It is lower severity. So the index
19 work in the opposite way, but yes.

20 DR. RASTOGI: No, that is exactly
21 right.

22 MR. DeBRANTES: This is actual

1 calculated severity index.

2 MEMBER HOPKINS: So lower index is
3 higher severity.

4 MR. DeBRANTES: Right. You can do
5 it either way.

6 MEMBER TURNER: Has this been
7 published anywhere?

8 MR. DeBRANTES: Yes. Actually, we
9 have published it in a couple of journals, and
10 we have one new paper that is in review now
11 with HCR.

12 CO-CHAIR FLEISHER: Did you do any
13 head to head comparisons of this severity
14 index model against some of the other more
15 established ones?

16 MR. DeBRANTES: Well, we are doing
17 it now, and Rand is actually conducting that
18 study right now.

19 CO-CHAIR DUBOW: Okay. We are
20 going to have a discussion of the measure
21 itself as soon as we grab lunch. We are going
22 to hear from Sean, because Sean is going to

1 give us his -- Is that okay, Sean? We are
2 going to get lunch. Don't go away. You can
3 get lunch, but don't leave. Don't leave.

4 So is 20 minutes adequate? Can we
5 manage? We can eat in here. We are going
6 to eat in here. Okay. Thank you.

7 (Whereupon, the foregoing matter
8 went off the record at 1:05 p.m.)

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19

1 are going to start with that, and we are also
2 going to have -- We have a screen shot of the
3 vote of the various Work Groups, Reva?

4 CO-CHAIR FLEISHER: It is on here.

5 CO-CHAIR FLEISHER: We have them.

6 Okay. So let Sean give us his take on the
7 methodology first. Okay?

8 DR. O'BRIEN: I was just trying to
9 figure out what my take is, based on talking
10 to Amita who was filling me in on very useful
11 information.

12 I basically reviewed the measure
13 based on what was provided in the measure
14 submission, and then poking around in the web
15 a lot and found an extensive amount of
16 research looking at all kinds of aspects of
17 the validity and reliability and the science
18 underlying the method.

19 Most of the work that is there is
20 dealing with modeling of the evidence in the
21 form of case rates and estimation of cost. So
22 I think my impression is that, although the

1 modeling is extensive, the modeling is
2 focusing on cost rather than the frequency of
3 PACs per se.

4 So that, to the extent that the
5 models exist, they may have been optimized for
6 one endpoint, and they are being applied to a
7 different endpoint. So there would be a
8 question of to what extent would results get
9 there if you had a custom model specific to
10 the endpoint of PACs, the binary yes/no
11 occurrence, rather than the cost of an
12 episode.

13 So I guess I will just continue,
14 because I definitely have questions.
15 Typically, when you are adjusting for an event
16 rate, you want to adjust for factors that were
17 present at the beginning -- you know,
18 intrinsic risks to the patient that are
19 present at the beginning of the care episode,
20 and not adjust for factors that are influenced
21 by the care providers that you are assessing.

22 My impression of the documentation

1 is that there are some variables in there that
2 are actually things that are going on during
3 the course of that episode. At least, that is
4 a point that could be clarified. I may have
5 been reading that incorrectly.

6 I guess it seemed like a dramatic
7 amount of variation between the states, which
8 is good news. I just would want to be careful
9 to understand how the units that are being
10 measured are entering their data, and could
11 there be variations in the data collections,
12 the number of diagnoses that are being filled
13 in or present upon admission, indicators,
14 anything like that that might be an
15 alternative explanation for such very wide
16 variation.

17 The mechanics of the severity
18 adjustment: In my review I wrote that I
19 wasn't clear that there was a severity
20 adjustment for that PAC rate, that basically
21 they are going to -- PAC rates are calculated
22 as not relative values.

1 They say in their documentation,
2 for example, a health plan would report that
3 60 percent of its plan members with a given
4 chronic condition incurred PACs in the study
5 time window. So they are just reporting
6 absolute percentage like that. That has not
7 been -- It doesn't sound like it is adjusting
8 for the severity.

9 CO-CHAIR FLEISHER: Sean, we just
10 heard they did. So is there --

11 DR. O'BRIEN: Well, so that is
12 what I was trying to work through. To the
13 extent that it is adjusted, I am not quite
14 clear on the mechanics. So I can't really
15 comment on that.

16 CO-CHAIR FLEISHER: But just
17 before you finish that point, Francois, yes or
18 no with regard to risk adjustment?

19 MR. DeBRANTES: Yes. So the
20 severity adjustment model is done using
21 dollars, absolutely, and it turns out a
22 severity index, both at the individual patient

1 level and then rolls it up at the population
2 level, which at that point allows you to
3 determine the relative severity, for example,
4 of a diabetic population versus any of the
5 other chronic conditions.

6 You can look at the severity of
7 sub-cohorts within the total population
8 studied and determine the differences in the
9 severity index and adjust the PAC rate for
10 that. And we are, in fact, doing that, for
11 example, with some payers in New Jersey and in
12 other parts of the country.

13 The variation that exists in our
14 developmental database has been replicated
15 when we studied other databases, although
16 again we see striking differences in rates of
17 potentially avoidable complication from system
18 to system and plan to plan, using the exact
19 same methodology; and it is not, at least for
20 us, explainable by -- We haven't been able to
21 explain that from differences in
22 documentation.

1 If it is there, it is likely to be
2 standard noise across more than specifically
3 focused in one location versus another, but
4 unknown. That is a limitation of any claims
5 dataset. You are going to have some amount of
6 noise in it, and that is what we exclusively
7 use for this measure, is claims data.

8 DR. O'BRIEN: I guess -- The
9 mechanics of the severity adjustment aren't
10 clear to me. I think what I maybe understand
11 is that you -- Basically, each patient, you
12 are going to have some weighted average of the
13 risk factors that are present --

14 MR. DeBRANTES: That is right.

15 DR. O'BRIEN: For each factor that
16 is present, you add on a certain amount and
17 calculate that patient's severity score, and
18 now you can, for a population, calculate the
19 average severity score of that population or
20 you can calculate the sum of the severity
21 scores, and you can concur, okay, relative to
22 some maybe benchmark population or rough edge

1 population, is this hospital, is this plan
2 more severe or their case mix more severe
3 compared to the benchmark population or less
4 severe. You can quantify that by the ratio.

5 This cohort that we are interested
6 in measuring has an average severity of 2
7 compared to the benchmark as one. So they are
8 twice as severe as the benchmark.

9 Now how you take that result now
10 and you see that this population that you are
11 measuring has a PAC rate of 70 percent --
12 their severity is double the benchmark
13 population. Now how do you take that 70
14 percent PAC rate and adjust it for the fact
15 that their predicted -- their average severity
16 score was twofold compared to the national
17 population? To me, that it is not clear.

18 DR. RASTOGI: You just --

19 MR. DeBRANTES: You use the
20 factor. Use the factor, and you apply the
21 severity factor to the PAC percentage.

22 CO-CHAIR FLEISHER: Are we taking

1 -- Do we want to take questions right now or
2 do you want to continue your critique?

3 MEMBER TURNER: So can we clarify
4 just a touch more. So what goes into this is
5 just dollars, though? The severity adjustment
6 is just dollars?

7 MR. DeBRANTES: Is all kinds, yes.

8 MEMBER TURNER: Okay. And so if
9 somebody for some reason has a physician who
10 does lots of testing on them and does lots of
11 MRIs, they are going to have more dollars.

12 MR. DeBRANTES: That has nothing
13 to do with it.

14 MEMBER TURNER: Okay. So what
15 dollars do you look at?

16 MR. DeBRANTES: Because it is not
17 about the total dollars consumed by a patient.
18 It is about their risk factors, and their risk
19 factors are the types of comorbidities they
20 might have based on, for example, the drug
21 regimen or the types of office visits they
22 have had.

1 So it is about risk factors of
2 patients, not about --

3 MEMBER TURNER: But it is not
4 disease diagnosis based. It is dollars
5 attached to disease? I am still trying to get
6 it straight.

7 MR. DeBRANTES: It is code based.
8 I mean, I guess all that is relatively -- I
9 guess, maybe not relatively well explained in
10 the document, but it is -- For every patient
11 population, you've got specific code sets that
12 define the risk factors, and there is a
13 comprehensive list of all the risk factors.

14 MEMBER TURNER: Okay. Diabetes
15 and hypertension.

16 MR. DeBRANTES: That is correct.

17 MEMBER TURNER: Okay, I am getting
18 it.

19 MR. DeBRANTES: So if you go
20 through the spreadsheets, you've got a
21 comprehensive list of all the risk factors for
22 each population, and those risk factors are

1 calculated population by population.

2 So based on the relative profile
3 of a given population, you are going to have
4 a risk profile for that population and the
5 individuals within that population, which is
6 going to give you your severity index.

7 MEMBER TURNER: I missed the
8 dollars part. That's the thing.

9 MEMBER ROSEN: So I understand
10 what you are saying, are you saying that we
11 then have this risk profile, and you look at
12 the PACs, P-A-Cs that the patient has, and
13 they will determine what the cost will be?

14 MR. DeBRANTES: Well, we certainly
15 look at cost, but the measure as presented is
16 counting the total number of potentially
17 avoidable complications, not the dollars
18 associated to them.

19 MEMBER ROSEN: Right.

20 CO-CHAIR FLEISHER: I guess where
21 people are getting confused is we all -- many
22 of us are used to an Alex Hauser or Charleson

1 or some sense of comorbidities. Are you using
2 that or not? Is it just a simple question
3 that can be --

4 MR. DeBRANTES: No.

5 DR. RASTOGI: The comorbidity
6 index like Charleson index is approximately
7 similar.

8 CO-CHAIR FLEISHER: Right.

9 DR. RASTOGI: Because these are --
10 Quite a few are outpatient, and we saw only
11 six percent of the PACs was anything to do
12 with hospital. Ninety-two percent-plus was on
13 outpatient care. So we couldn't do
14 Charleson's index.

15 MEMBER TURNER: I mean, there's
16 tons of outpatient --

17 MR. DeBRANTES: Yes. So I am
18 going to go back to -- our not-for-profit
19 organization was primarily funded for the
20 development of a program, and we decided
21 specifically not to use any commercial
22 application as a matter of policy, so that we

1 could put our work in the public domain at no
2 cost.

3 CO-CHAIR DUBOW: Barbara.

4 MEMBER YAWN: Is there a clear
5 distinction between a PAC and something you
6 use for risk adjustment, because where I am
7 concerned is could PACs be calculated in the
8 risk adjustment and then for -- of course, you
9 would expect them to add more PACs?

10 MR. DeBRANTES: That is an
11 excellent question, and I think it is what
12 distinguishes this approach from all the
13 current episode approaches, is that we do not
14 specifically exclude all potentially avoidable
15 complications prior to looking at risk
16 factors.

17 So risk factors are purely
18 designed and evaluated on the typical services
19 of the patients, excluding all potentially
20 avoidable complications. Otherwise, you get
21 into the circularity of --

22 MEMBER YAWN: You try to avoid

1 that.

2 MR. DeBRANTES: Exactly. Exactly.
3 So risk factors are risk factors that exclude
4 completely potentially avoidable
5 complications.

6 MEMBER YAWN: Thank you.

7 CO-CHAIR DUBOW: Iver.

8 MEMBER JUSTER: So at the bottom
9 of all this, would the intuitive idea be that
10 you have two populations now, and one of them
11 has a twice as high risk. So you would expect
12 them to have twice as high PAC?

13 MR. DeBRANTES: That is correct.

14 MEMBER JUSTER: Okay.

15 CO-CHAIR DUBOW: Amy?

16 MEMBER ROSEN: A couple of
17 comments. One is that it is difficult to
18 separate out from a diagnosis code or
19 something present on admissions is also a
20 complication. There has been a lot in the
21 literature on that, and that is why present on
22 admission codes have been introduced in the

1 private sector.

2 I am just wondering if you have
3 looked at that, because you really don't know
4 if something is a complication or present on
5 admission.

6 My big concern also is that how
7 are the PACs determined? Was this by a
8 clinical panel that determined whether or not
9 a potentially avoidable complication was
10 related to the index condition? How did you
11 come up with this list of potentially
12 avoidable complications, because there is a
13 literature, you know, on this, starting with
14 all these complication screening programs and
15 some of the patient safety indicators from
16 AHRQ are certainly important complications of
17 care.

18 So there is one out there. AHRQ
19 has also done preventable hospitalization.

20 MR. DeBRANTES: Absolutely.

21 MEMBER ROSEN: There are a lot of
22 episode groupers.

1 My third point is that there are a
2 lot of episode groupers out there. Have you
3 checked your methodology comparing yourself to
4 the reviews or the -- But it would be really
5 important to see how you have conceptualized
6 these components as your measure, whereas some
7 others have been doing it all along.

8 MR. DeBRANTES: Sure.

9 MEMBER ROSEN: And what is the
10 contribution of your measure?

11 MR. DeBRANTES: Sure. Well, none
12 of the others use potentially avoidable
13 complications. So I think that is a clear
14 distinction, which is why we are here, and in
15 fact, we are working with Ingenix now so that
16 they can incorporate our definitions of
17 potentially avoidable complications into the
18 ETGs.

19 The issue of PLA applies mostly to
20 the potentially avoidable complication
21 measures that we are going to be looking at
22 later this afternoon around MI, pneumonia,

1 and stroke. In our submission for those acute
2 medical events, we do specify that conditions
3 that are present on admission would not be
4 counted as potentially avoidable complications
5 for the reasons that you specified.

6 When reviewing the patients in
7 chronic conditions, PLSA is a nonissue,
8 because the ED visit itself is a potentially
9 avoidable complication, and you would expect
10 a patient who has diabetes admitted for an
11 emergency department visit for, say,
12 hypoglycemia to have a PLA diabetes. So it is
13 not as applicable an issue on chronic care
14 avoidable complications as it is on the
15 inpatient ones and, certainly, for the
16 inpatient ones we do exclude PLA for the
17 reasons that you mentioned.

18 Then I think your other point
19 about harmonization, I think, is what you were
20 pointing at. Absolutely. We have
21 incorporated in our definition of avoidable
22 complications all of the existing ones to

1 date.

2 So again this afternoon when we go
3 through MI, stroke and pneumonia, you will see
4 that CMS defined hospital condition or defined
5 PSIs -- all those are included as potentially
6 avoidable complications. So we use those
7 definitions and incorporate them.

8 We do take, and make no excuse for
9 it -- quite the contrary -- We do take a very
10 liberal view of potentially avoidable
11 complications. So our list is far, far
12 broader than what you will find at CMS, AHRQ,
13 or anywhere else, and that is on purpose.

14 MEMBER JOHNSON: Francois, how did
15 you establish that the relationship between
16 risk and complications was linear? Then how
17 do you assure that it is linear across all
18 disease states when you are looking at
19 multiple disease states? So you go up by a
20 factor of two times risk. Does it equate to
21 two times the complication 50 percent
22 reduction and --

1 MR. DeBRANTES: Oh, you mean in
2 the industry?

3 MEMBER JOHNSON: -- and is that
4 consistent across everyone of your
5 extrapolations when you look at multiple
6 diseases?

7 MR. DeBRANTES: Yes. So don't
8 know, and you know, when you do something like
9 severity adjusting a rate of potentially
10 avoidable complication, you have to make a
11 decision.

12 In this instance, the decision
13 that we made is, believe it or not, keep it
14 simple. So is it linear? I don't think so.
15 Again, the population that we studied is
16 commercially insured.

17 So that is a more -- It certainly
18 is a more homogeneous population than you
19 would get if you took like, for example, an
20 non-payer dataset, and you might come to some
21 different conclusions in non-payer dataset.

22 In the commercial insured

1 population, I think it is -- you know, the
2 linearity is more of a reasonable assumption,
3 and is it perfect? No, by no means. I just
4 don't -- You know, there is no such thing as
5 perfection in severity adjustment. So you try
6 to do something that is fair and reasonable,
7 explainable, I think, to physicians and
8 hospitals, so that when you hold them
9 accountable, there is an understanding of the
10 methodology.

11 CO-CHAIR FLEISHER: So can I ask:
12 It sounds like it is not really risk adjusted.
13 Sounds like you are going to actually present
14 absolute rates with a severity index that the
15 hospital could risk adjust, because it doesn't
16 sound like you would be presenting risk
17 adjusted rates, or am I missing something?

18 MR. DeBRANTES: No, you are not
19 missing. You are correct.

20 CO-CHAIR FLEISHER: Okay.

21 MR. DeBRANTES: And back to the
22 conversation this morning about the Minnesota

1 Community Measurement measure on diabetes
2 which, by the way, Bridges to Excellence uses
3 as its top level of performance in the country
4 as we recognize physicians -- there is no
5 severity adjustment.

6 The purpose is to count events. I
7 want to relate a comment that we had during
8 the discussion with the stroke PACs with the
9 TAP. There was a comment about comas, in
10 particular, and I am bringing it up, because
11 of the 400-odd potentially avoidable
12 complications, six of them were comas.

13 The point from the neurologists
14 was that, you know, in many instances coma is
15 unavoidable for patients with stroke. I asked
16 a relatively basic question, which is -- not
17 being a clinician myself, which is: Can you -
18 - Are comas always on unavoidable for patients
19 with stroke?

20 Of course, the answer is no. So
21 we don't call these absolutely avertable
22 complications for very specific reasons. We

1 call these potentially avoidable
2 complications. The purpose is let's start
3 counting these things. Let's start
4 understanding the system that exists or
5 doesn't exist around patients, and let's work
6 to reduce them.

7 You know, we don't think that you
8 can get to zero. None of us think we can get
9 to zero, but we could probably get from 90
10 percent to 45 percent. I know that bothers a
11 lot of people, but I think it bothers the
12 patient a lot more when something happens.

13 DR. O'BRIEN: I feel like I have
14 heard two different answers to the question of
15 whether it is risk adjusted or not. So I am
16 confused about that. But I would just say
17 that, based on what is in the measure
18 submission, which may be what we should go on,
19 there is not written down the mechanics of
20 actually taking an observed percentage and
21 adjusting it up or down to account for the
22 risk. It just indicates -- there is not

1 amounts and values to say the purpose of risk
2 adjusting PAC rates.

3 There is a model that has been
4 validated for the purpose of predicting costs
5 and, to the extent that it is applied -- I
6 know there is all kinds of statistical and
7 nonstatistical reasons for decisions when you
8 are developing a measure, but it seems like
9 ideally developing a model that is
10 specifically for this event would be the
11 preferable way to do it.

12 This seems like kind of a non-
13 standard approach to take, basically, a model
14 that is for cost, and then multiply your
15 observed PAC rate up or down by the ratio of
16 this population's predicted cost relative to
17 something else -- I think there's pitfalls
18 with that approach based on where I have seen
19 similar approaches in another context.

20 The question is, if you have
21 extreme variation between the units in these
22 predicted costs, which we may expect, to what

1 extent will you result maybe be driven by what
2 you are getting on the denominator? Your
3 predicted costs rather than observed results,
4 I think, would be appropriately rated.

5 I assume that didn't make sense.

6 MR. DeBRANTES: No, no, your point
7 is well taken. I think the decision is do you
8 apply some severity adjustment to these rates
9 of potentially avoidable complications or not?
10 In this instance, we have taken the
11 methodology we have developed around severity
12 adjustment and said you can apply that
13 methodology -- whether it is the best or not
14 is clearly subject to opinion -- and you can
15 apply that methodology to severity adjusting
16 the PAC rate.

17 CO-CHAIR DUBOW: Okay. Any other
18 discussion? Perhaps we can see how the sub-
19 group voted on this measure.

20 MS. BOSSLEY: Can everyone read
21 that or should we kind of summarize?

22 CO-CHAIR DUBOW: Why don't you do

1 that?

2 MS. BOSSLEY: Okay.

3 DR. BURSTIN: Tell them where it
4 is, too.

5 MS. BOSSLEY: It starts first on
6 page 83 of your PDF -- 82, actually. That is
7 where the important section starts.

8 In general, for importance the
9 four people who reviewed this measure thought
10 that it did completely meet the importance
11 criteria for the gap. There is evidence, and
12 it does meet a priority.

13 For scientific acceptability --
14 and for anyone who was on the Work Group, feel
15 free to jump in and add any comments. I am
16 just going to provide high level.

17 For scientific acceptability,
18 again you were asked to get in on the sub-
19 criteria. So for the specifications and the
20 reliability, the four felt that it completely
21 met the criteria.

22 For validity, we had a split

1 between completely and partially. Then when
2 you go down and look at exclusions, looking at
3 the risk adjustment that was provided, meaning
4 whether you can actually determine meaningful
5 differences based on how it is specified,
6 there of you felt it was completely, one
7 partially, and also we had one minimally for
8 meaningful differences.

9 Comparability, again four of you
10 felt that it was completely met. Disparities,
11 we had a mix between completely, partially,
12 not at all, and did not apply.

13 Then for the next one, usability:
14 This is where we are looking at harmonization,
15 does the measure bring added value, is it
16 understandable?

17 For understandable, two felt it
18 completely met the sub-criteria. Two felt it
19 partially met it.

20 Harmonization: Three of you felt
21 that it completely did. One said Not
22 Applicable, because there wasn't any other

1 measure other than what you have before you.

2 Then whether there was added
3 value, all four felt it completely met the
4 sub-criteria.

5 Then the last in feasibility,
6 again we are looking at can the data be
7 produced as a by-product of care? Is there
8 electronic means to collect it?

9 Looking at exclusions, do you need
10 additional data sources or not? Inaccuracies
11 within the data and implementation? Pretty
12 much everyone felt that it was completely
13 meeting the criteria except for the
14 inaccuracies piece, and that was two for
15 completely and two for partially.

16 So very few ratings of minimal or
17 not at all.

18 CO-CHAIR DUBOW: Is there anybody
19 on the Sub-Work Group who is able to talk
20 about the understandable piece of it under
21 usability? Does anybody from the Sub-Group
22 remember that particular?

1 I am just interested in why this
2 is not considered understandable. I mean,
3 what I always consider under this category is
4 public reporting piece and how consumers will
5 understand this, and this one feels to me so
6 unbelievably understandable that it exceeds
7 the grade that it could get, because --

8 MS. BOSSLEY: I am wondering if
9 the first comment that says very useful with
10 the managed care population for which there is
11 an assigned primary care physician or group,
12 less useful with insured population where
13 there is not a PCP. I mean, Lee, I think you
14 were on the group.

15 CO-CHAIR FLEISHER: Yes. Well, I
16 am not sure about that first one, but I think
17 when you put a rate starting at 89 percent and
18 that it can be both preventable -- potentially
19 preventable and potentially not preventable,
20 I think that is one of the concerns people
21 have.

22 if I remember some of the comments

1 from the other TAPs, it is, you know, if you
2 get into an accident or certain other
3 conditions -- certain conditions that you
4 can't -- There are certain preventable --
5 certain PACs that may not be preventable, but
6 you have grouped them into large buckets, and
7 that is why is some concern, especially at an
8 89 percent rate. People would think that you
9 could get to a zero percent rate, which I
10 agree, that is why you have articulated that
11 you might get from 85 to 45, but I think if it
12 was released to the public, it may or may not
13 be understandable in that regard, because of
14 the wide capture of PACs.

15 MR. DeBRANTES: Can I respond to
16 that? Again, I think this was discussed
17 earlier in the Community Measurement effort
18 where you can go on the website and see rates
19 of 45 to one percent compliance, and in
20 Minnesota people understand that. It might be
21 shocking to many, but they do understand it.

22 I don't think -- It doesn't seem

1 to me as if everyone is thinking, oh, there
2 numbers should all be at 100 percent, more
3 than there is variation, and there is a big
4 difference between 45 percent and one percent
5 or 85 percent and 45 percent.

6 CO-CHAIR DUBOW: I would just add
7 that these measures, when reported well, have
8 some context, and there is some help to the
9 user in understanding how to interpret the
10 measure.

11 So you don't just slap up a bunch
12 of numbers without providing some kind of
13 guidance. In that context, I think that these
14 kinds of measures are eminently understandable
15 to the public who want to avoid complications.
16 It really relates to the patient-centeredness
17 part of this approach.

18 MEMBER JUSTER: As one committee
19 members, I think my main concern was just --
20 which was not an easy thing for me to do --
21 was pretend I am an uninformed consumer, and
22 I am having -- I am living in this world with

1 ever shortening sound bites that are -- you
2 know, that the news programs are trying to get
3 me to understand something in nine seconds.

4 So I am competing with this, and
5 the things that I might -- and I am sure there
6 will be some consumer testing, because I
7 really like this measure, but I would need to
8 know, for example, it really isn't expected to
9 be 100 to zero, like everybody who has a heart
10 problem should be taking a statin unless they
11 can't. That should be -- There should be zero
12 noncompliance there.

13 Here, I am being expected to
14 understand that it won't reach zero. So then
15 I am going to say, okay, well, if it shouldn't
16 reach zero, what should it reach, because the
17 whole thing about variation might just go
18 right over my head.

19 Also, I would want to know that
20 these were adjusted -- these took into account
21 characteristics that people had before they
22 were measured that they came into the

1 measurement period with, all sorts of things,
2 three or four little sound bites that might be
3 digestible.

4 Then for the more curious reader,
5 I guess there would be more, but these
6 considerations would be true for any public
7 testing, I think.

8 MEMBER McNULTY: Sure. I thought
9 it was completely useful. I was really
10 comfortable with it, and to sort of make that
11 point even more clear, I put it in front of my
12 86-year-old mother with chronic heart failure
13 and asked her if she understood it, and she
14 immediately understood what that measure
15 meant, and it was very easy for a consumer.

16 I happen to recognize that first
17 comment as being my comment. So I can speak
18 to the other side of it, which is, when I look
19 within the provider community, the ease with
20 which it would be to move that number to drive
21 toward perfection.

22 I happen to come from not a

1 system, a hospital system that employs
2 relatively few physicians, and in this world
3 that we are measuring here that really does
4 take a group of people. It takes a system to
5 manage these patients.

6 So when I look at the usability
7 with my provider hat on, I realize that when
8 I am going to get in my world is a constant
9 push-pull between physicians and independent
10 practice, emergency departments, specialists
11 who are not aligned, and hospitals, all saying
12 not my fault, I did my part.

13 That doesn't mean that it is not a
14 good usable measure from a patient's point of
15 view, a consumer point of view. It is very
16 understandable. It is a very different
17 measure and takes us to a level of
18 accountability that we have not been pushed to
19 before.

20 MEMBER YAWN: From a group of
21 providers' perspective -- and I will not claim
22 this as mine, but when I asked a little bit

1 about this concept, they said, as soon you say
2 potentially avoidable complications, you have
3 just employed all the attorneys in town.

4 That was their take on it, is
5 until we have malpractice reform, doing this
6 kind of thing is of concern to them. Now I am
7 not saying that makes it right. I am just
8 telling you that that was what -- and when we
9 put it out for public comment, I expect to
10 hear those comments of, if it was potentially
11 avoidable, somebody should have avoided it
12 and, by golly, I am going to sue, because it
13 happened to me. So just another perspective.

14 CO-CHAIR DUBOW: Any other
15 comments?

16 MEMBER DELLINGER: You could
17 rephrase it as possibly avoidable. Seriously,
18 I mean, you know, I do a lot of work in
19 surgical infection, and we have a lot of very
20 well proven process measures that we do
21 infection risk, but never take it to zero.

22 So we say a surgical site

1 infection is potentially preventable if the
2 right antibiotic wasn't given at the right
3 time, if the patient wasn't kept warm, if
4 blood sugar wasn't controlled perioperatively.
5 But we have things we can really measure, and
6 with administrative data you can't possibly do
7 that.

8 This would feel better to me if it
9 said possibly preventable complications.

10 CO-CHAIR FLEISHER: Have you seen
11 some New England Journal papers' titles.

12 MEMBER YAWN: No, it is a legal
13 word.

14 CO-CHAIR DUBOW: Okay. Well, we
15 have -- Francois, I don't know if you want to
16 entertain that.

17 MR. DeBRANTES: Well, just to
18 mention that our Board Chair, Alice Gosfield,
19 is a relatively well known health care lawyer
20 who has represented physicians and hospital
21 systems for a long, long time, and is robustly
22 published.

1 I think it is an issue that we
2 have actually debated extensively, and she
3 feels very strongly that the use of
4 potentially actually is a very good protection
5 for physicians against aggressive attorneys.

6 CO-CHAIR DUBOW: Okay. I think we
7 need to bring this to a close, because we need
8 to move on. So, Reva, would you help us
9 navigate the vote, please?

10 DR. WINKLER: Yes. As before, we
11 need to vote on the criteria, the four main
12 criteria as well as your final recommendation.

13 CO-CHAIR DUBOW: Excuse me. Is
14 there anybody in the public who wants to make
15 a comment? On the phone? Is there somebody?

16 DR. HALL: Bruce Hall from
17 American College of Surgeons.

18 CO-CHAIR DUBOW: Okay.

19 DR. HALL: I am just looking
20 again for the reliability and distinction
21 between providers. I have asked those
22 questions several times this morning, but I

1 just don't see that information presented.

2 MR. DeBRANTES: So is the question
3 about --

4 CO-CHAIR DUBOW: Reliability among
5 providers.

6 MR. DeBRANTES: Well, we can
7 certainly tell where the avoidable
8 complication came from, and this is a measure,
9 as we say in the submission, that is designed
10 not at the individual physician level. So I
11 want to be clear about that and reiterate it.
12 This is not an individual physician
13 performance measurement.

14 MEMBER HOPKINS: Could you verify
15 what is the unit of measurement?

16 MR. DeBRANTES: We think practice,
17 certainly a medical group, hospital, a health
18 system, health plan. But if you are talking
19 about physicians, I think the lowest unit of
20 accountability would be the practice.

21 CO-CHAIR DUBOW: This is a comment
22 from George Isham who is the Medical Director

1 and Chief Health Officer of HealthPartners in
2 Minneapolis. I am not going to read the whole
3 thing, but he says:

4 "The comprehensive complications
5 of care measure developed by Prometheus
6 Payment as part of their payment reform model
7 holds a promise to change the locus of quality
8 accountability and stimulate the type of
9 patient centeredness expressed in the IOM
10 reports. Use of these measures does not
11 necessarily need to be tied to payment, but
12 they can be used as a performance measure on
13 their own to ascertain effectiveness of
14 transitions and coordination of care.

15 "Prometheus potentially avoidable
16 complications encourage providers to look
17 beyond what they do and engage them in the
18 accountability of what happens to the patient.
19 For example, cardiologists managing a patient
20 with congestive heart failure are held
21 accountable not only for the PACs related to
22 the patient's CHF, but for PACs related to

1 comorbidities.

2 "HealthPartners believes that, by
3 endorsing measures like Prometheus PACs, the
4 National Quality Forum will help move the
5 current provider focused health system into
6 one that is patient centered, and that is why
7 we support the endorsement of PACs as
8 comprehensive complications of care as a
9 performance measure."

10 Now, Reva, would you please walk
11 us through the measure?

12 DR. WINKLER: Okay. As before, we
13 will go through the four criteria, and then
14 the recommendation.

15 So the first one is for this
16 measure, the importance to measure and report.
17 This is a yes/no vote.

18 So how many vote that this
19 important to measure and report? Everybody,
20 and how many everybodies are there? It is
21 Sean who is missing.

22 MEMBER NEWCOMER: You missed one.

1 DR. WINKLER: Okay. So scientific
2 acceptability of the measure properties. This
3 is where we will vote completely, partially,
4 minimally, or not at all, your assessment of
5 how well this measure conforms to the criteria
6 under scientific acceptability of this
7 measure's properties.

8 All for completely? One, two,
9 three, four, five.

10 Partially? Thirteen.

11 Minimally? Four.

12 Not at all? No. Do we add up
13 right. Okay, that's 22. Great.

14 Now on the usability criteria,
15 completely? Fifteen.

16 Partially? This is usability now,
17 partially. Four.

18 Minimally? One.

19 Not at all?

20 You didn't vote. Okay, add one,
21 all right. I am still missing one.

22 MEMBER NEWCOMER: I am a partial.

1 DR. WINKLER: Okay. So you are
2 the partial. Okay. So I got 16 complete,
3 five partial, one minimal. Okay.

4 The last one is feasibility.
5 Completely? Fourteen.

6 Partially? Eight. That's it.

7 CO-CHAIR DUBOW: Now we have to
8 vote up or down.

9 DR. WINKLER: Right.

10 CO-CHAIR DUBOW: So I guess it is
11 just all those in favor of this measure?

12 DR. WINKLER: Correct, going
13 forward.

14 CO-CHAIR DUBOW: Going forward for
15 public comment and for endorsement.

16 DR. WINKLER: All in favor?
17 Nineteen, I think.

18 No? Four?

19 CO-CHAIR DUBOW: Wait a minute.
20 It doesn't add.

21 DR. WINKLER: No, it doesn't.
22 Barbara changed her vote. Right? Okay. So

1 it is 18 yes, and four no.

2 CO-CHAIR DUBOW: Okay. So this
3 measure is recommended by the Committee.

4 Okay, now we have two NCQA
5 measures, and the measure -- Is Sue Miller --
6 I'm sorry -- Milner on the phone?

7 MS. MILNER: Hi. This is Sue. I
8 am here.

9 CO-CHAIR DUBOW: Okay. Great. So
10 let's start with the HOS measure.

11 MEMBER NEWCOMER: What number is
12 that, please?

13 MS. MILNER: I'm sorry. Which one
14 are you starting with? The health outcomes
15 survey measure?

16 CO-CHAIR DUBOW: Yes, please.
17 Lee, that is measure number --

18 MS. MILNER: Judy Ng? Judy, are
19 you on the phone?

20 DR.NG: Yes, I am on the line.

21 CO-CHAIR DUBOW: What number is
22 this? Number 6? Okay, sorry.

1 Do we want to -- Reva, do you want
2 to tell us anything about this measure, or the
3 measure developer?

4 DR. WINKLER: Well, I was going to
5 say, the summary pretty much describes what is
6 going on with this measure. This is a survey
7 measure. It uses essentially the reference
8 Rand Health Survey, the VR-12 as sort of an
9 underlying instrument behind it.

10 This is a measure that has been
11 used in the HEDIS program, I believe just in
12 the Medicare patient population. There are
13 scales that provide essentially two summary
14 measures. One is the physical component
15 summary score, and then the mental summary
16 score. So there are sort of two results from
17 the implementation of this survey measure.

18 CO-CHAIR DUBOW: I have a question
19 about this measure. I have a recollection
20 that this was once fielded in the fee-for-
21 service population. I see that it is
22 restricted to the Medicare Advantage

1 population.

2 Is there a reason? Is CMS here?

3 I don't know. I know -- Hasn't this been used
4 in fee-for-service Medicare before?

5 DR. NG: This is Judy from NCQA.

6 It has been piloted in fee-for-service. I
7 think it was about 10 years ago, and I think
8 essentially what happened was it was found to
9 be a bit too expensive to perform in fee-for-
10 service, because --

11 CO-CHAIR DUBOW: We are having
12 trouble hearing you. You are fading in and
13 out.

14 DR. NG: Okay, hold on. Let me
15 take off my speaker. Is this better? Okay.

16 Yes, it has been piloted in the
17 fee-for-service study before. For a number of
18 reasons, I believe mainly related to cost, CMS
19 decided not to go ahead and leave it in the
20 fee-for-service population and restrict it
21 just to Medicare.

22 CO-CHAIR DUBOW: But there is

1 nothing, in and of itself, that would be
2 peculiar to the Medicare Advantage population.
3 Is that correct?

4 DR. NG: That is correct.

5 MEMBER HOPKINS: To further your
6 point, it actually applies to chronic
7 populations, and why would you restrict it
8 anymore than that? This one doesn't have to
9 tie to age. I don't understand why --

10 CO-CHAIR DUBOW: Well, it actually
11 used to be called a health of seniors measure,
12 but you know, I just -- If it is a cost issue
13 for the implementer, that doesn't speak to the
14 measure properties, and I just wondered about
15 that. Is there discussion?

16 Do the folks from NCQA want to say
17 anything about this measure? Would you like
18 to add anything to what Reva mentioned?
19 David?

20 MEMBER JOHNSON: I just had a
21 question. As with any survey, it is subject
22 to who fills it out, and what is the

1 anticipation of how this is going to be used?
2 You give it to a patient, and the people that
3 are happy are going to fill it out, and the
4 people that are very angry are going to fill
5 it out, but the vast majority of people are
6 going to say I don't need to do this.

7 CO-CHAIR DUBOW: There is some
8 experience with this measure already. Can you
9 tell us a little bit about that? This measure
10 is used in Medicare, in the Medicare Advantage
11 program already.

12 MEMBER JOHNSON: Again, I am just
13 subject to a lot of surveys, and it is the
14 people who fill them out have either one
15 extreme or the other. It is the in-betweens
16 that are the majority that typically say I
17 don't need to do this.

18 CO-CHAIR DUBOW: Do we have data
19 on the response?

20 DR. NG: Yes. The response has
21 gone from 8 over 60 to 80 percent.

22 CO-CHAIR DUBOW: You know, CMS --

1 Well, I guess CMS. NCQA drives other measures
2 from this survey. So this, in addition to
3 being a functional status measure, also has
4 embedded in the survey instrument -- I don't
5 know -- flu and a couple of other measures
6 that come out of this. It is in here
7 somewhere.

8 DR. NG: The measure covers
9 osteoporosis -- and there are a number of
10 items on comorbidities.

11 CO-CHAIR DUBOW: And that is
12 probably an aside, because what we are really
13 considering here is the functional status
14 measure.

15 DR. NG: There's other measures, I
16 believe, are endorsed separately.

17 CO-CHAIR DUBOW: Yes. Right.

18 MEMBER JEWELL: Right. So this
19 may just be my mental fatigue from having read
20 so much over the last several days of this
21 material, but how -- What are the score cut
22 points for deciding better, worse?

1 I am not familiar with the FS-36
2 in its original form. So I know what the
3 population norms are. I know different
4 population important differences that
5 distinguish between better, no different,
6 etcetera. So is that in here, and I just
7 missed it or can you provide some
8 clarification about how do you decide who is
9 better and who is not?

10 DR. NG: The better or worse
11 things actually are based on national norms.
12 I think at this moment they are the norms for
13 the 1998 U.S. general population for that
14 particular age group.

15 MEMBER JEWELL: Were the
16 instruments in this version or with the
17 original SF-36? Maybe that is why I am
18 confused?

19 DR. NG: I think it was the basic
20 norm as well as -- They have been working here
21 with a 12-item instrument using this version,
22 and I believe it would be 1991.

1 MEMBER DELLINGER: My only comment
2 on this is, if you look on page 9 of the
3 document that we were given here, it says that
4 out of 187 MAOs, two had mental health better
5 than expected -- that is one percent; 10 worse
6 than expected -- that is five percent; zero
7 had physical health either better or worse
8 than expected.

9 So this distinguishes nothing.
10 This is a useless instrument.

11 DR. NG: I think part of what is
12 happening with that is the way the risk
13 adjustment is being done. They might actually
14 be risk adjusting for a lot of the factors,
15 and that is what we are actually looking into
16 right now.

17 DR. TURNER: I think it is
18 excellent information to have, with the onus
19 of understanding the case mix of your
20 population, but I guess I have been always
21 wondering about the research that shows a lot
22 of these measures are meetable by the care

1 that you give.

2 I mean just that it is a small
3 portion of how your mental health is. What is
4 going on with your health care? There are so
5 many other factors in terms of where you live
6 and your socioeconomic status.

7 So I am just curious what you
8 would use this for or is it just to inform
9 your study and your sites about the case mix
10 that they take care of?

11 CO-CHAIR DUBOW: Sue, do you want
12 to respond to that, or maybe CMS would respond
13 to it. Come to the table, please.

14 DR. HALIM: This is Shaheen Halim
15 from CMS. The mental health score and the
16 physical health scores are actually used in
17 some of our health plan performance metrics
18 that are shown on the Medicare options compare
19 site. So I just wanted to point out that use.
20 That is -- It is being publicly reported in
21 that website.

22 CO-CHAIR DUBOW: I thought the

1 question was what could be done by the plan to
2 improve the scores.

3 DR. HALIM: Oh, I see.

4 MEMBER TURNER: Do you have any
5 data that getting those data allow the plan to
6 actually change the scores of their patient
7 populations, because that is -- because they
8 are usually so multi-factorial -- what makes
9 your mental function, etcetera -- that it is
10 a little piece of the pie.

11 DR. HALIM: Right. I don't have
12 that information. Perhaps NCQA can comment on
13 how it is being used in quality improvement
14 activities.

15 CO-CHAIR FLEISHER: So can I just
16 ask. Does CMS use it as a -- just reporting
17 it or as a performance measure, because if NQF
18 chooses to endorse it, then it can go for a
19 performance measure. If NQF doesn't choose to
20 endorse something, given the current -- my
21 understanding of what is in the bill and the
22 language, then what happens?

1 DR. HALIM: I can't speak to that,
2 but I do know that it is used as part of a
3 composite -- a set of composite measures that
4 are shown on Medicare --

5 CO-CHAIR FLEISHER: Are those
6 composite measures endorsed?

7 CO-CHAIR DUBOW: That is what CMS
8 does. But I think that nothing compels CMS to
9 use NQF endorsed measures, although the
10 legislation does -- Well --

11 DR. BURSTIN: The current status
12 of it is that NQF is they will have to look
13 toward NQF for standards when they are
14 available. I think the issue here has not
15 endorsed any functional status measures to
16 date. So they have not been available. So
17 they will have to use others.

18 This has been viewed as a --
19 Actually, as part of the work that the Measure
20 Prioritization Committee of doing, functional
21 status rose to the top of the list as being a
22 pretty significant measurement gap.

1 CO-CHAIR DUBOW: Right. The new
2 legislation does say that the Secretary should
3 give preference to NQF endorsed measures.

4 MEMBER HOPKINS: And says
5 functional status is important.

6 CO-CHAIR DUBOW: Yes, is a key
7 issue. I would point out that in the long
8 history of this measure, and it has been
9 around for a really, really long time, that
10 the HOS group at CMS has tried to respond to
11 that question that you have raised by
12 publishing guidance on what plans could do to
13 improve the functional status of their
14 members.

15 So there is some literature on
16 this by way of guidance, but obviously, we see
17 not a whole lot of variation in the reporting
18 performance, perhaps because of the way the
19 measure is risk adjusted.

20 MEMBER HOPKINS: Is somebody
21 addressing that issue?

22 CO-CHAIR DUBOW: I heard Sue say

1 that they are looking at the risk adjustment.

2 Is that right, Sue?

3 DR. NG: This is Judy speaking.

4 CO-CHAIR DUBOW: I'm sorry, Judy.

5 DR. NG: That is correct. We are
6 looking at it right now, for the same reasons
7 that the outlier is showing up.

8 CO-CHAIR FLEISHER: But we have to
9 vote on the current risk adjustment.

10 CO-CHAIR DUBOW: I was just going
11 to ask, what is the timing on your
12 reevaluation?

13 DR. NG: Until, I believe it is,
14 the end of the summer, but it is an issue that
15 we could revisit even at that point.

16 MEMBER HOPKINS: Can this
17 committee carry something over that long? I
18 am curious.

19 DR. WINKLER: It is not going to
20 match the timeline of this project. The
21 question is, is there another avenue within
22 NQF to potentially look at the measure and,

1 you know -- unclear at this point, but
2 probably will be.

3 DR. BURSTIN: We would also have
4 to go back to NCQA and really find out. Even
5 if the risk adjustment, the work, is done by
6 July, when will we actually have results.
7 These they will bring to us. We always have
8 the option of doing an ad hoc review if
9 something changes significantly, if it is
10 endorsed.

11 CO-CHAIR FLEISHER: What if it is
12 not endorsed?

13 DR. BURSTIN Then they would have
14 to wait for another opportunity to resubmit
15 it.

16 DR. NG: It is possible that it
17 could be done earlier than that, considerably
18 less time.

19 CO-CHAIR DUBOW: Dianne.

20 DR. JEWELL: I am still struggling
21 with trying to figure out what this measure is
22 for. I hear where everybody is interested in

1 having functional status measures, but I don't
2 know what this measure is supposed to tell me.

3 DR. HERMAN: I would second that.
4 If it is an outcomes measure, there should be
5 something that we can do to change it, and I
6 haven't heard anything that shows that you can
7 do anything to change it. So if it is
8 supposed to be an outcomes measure, there has
9 to be kind of the before and the after.

10 DR. JEWELL: Right. And again,
11 maybe I just am not seeing all the detail that
12 is in front of me, but as it is described
13 right now, it sounds to me more just like a
14 status check, like how is the health of the
15 population that we happen to be looking in on.

16 CO-CHAIR DUBOW: No. This is a
17 two-year measure. This follows a cohort over
18 two years, and it is to change from expected.
19 It is a two-year --

20 DR. JEWELL: Okay. So then if
21 that is what I understood the first time, I am
22 wondering how valid it is to talk about the

1 change in expected in a score like this, when
2 you are talking about norms that are validated
3 with a different instrument.

4 DR. HERMAN: Or if there is no
5 change over the two-year period.

6 DR. JEWELL: What does it mean?
7 Yes.

8 CO-CHAIR DUBOW: Judy? Sean, do
9 you have any insight?

10 DR. O'BRIEN: I think the outcome
11 of the measure is reporting patients that
12 don't deteriorate, that maintain their status
13 or improve. So, basically, they are using the
14 same measure baseline and two years later
15 comparing them.

16 MEMBER NEWCOMER: And it is that a
17 function of health care or a function of --

18 CO-CHAIR DUBOW: Barbara?

19 MEMBER TURNER: Well, but there
20 are things that you can do to improve the
21 mental health of the community, like perhaps
22 recognizing depression and beginning to treat

1 it, which we do very badly as a health care
2 sort of a system -- I guess we are.

3 So there are some things like that
4 that can be done, but is this the measure to
5 do it when they have such a small change and
6 so few outliers. It bothers me that this is
7 not a good measure for assessing how we are
8 currently doing in giving us room to improve.

9 So that is my biggest concern.

10 CO-CHAIR DUBOW: So I heard some
11 interest in deferring -- is that the right
12 word? -- to hear how NCQA proposes to modify
13 the risk adjustment, to see whether we could
14 see more discrimination?

15 DR. TURNER: I think that is a
16 great idea, and I also suggest, if they have
17 any data that helps us understand that health
18 care delivery has something to do with that or
19 whether we can parse out our contributions
20 that we should be responsible for and if we
21 make a difference; because I think it is a
22 great thing.

1 CO-CHAIR DUBOW: Wait a minute.

2 We need some guidance from Reva and Helen
3 about whether we can -- what we can do to move
4 that sentiment into reality.

5 DR. BURSTIN: It sounds like the
6 first thing we should do is just ask for
7 additional clarification from NCQA, the
8 additional analysis they can provide. When is
9 the schedule for testing? And I think we will
10 have to -- I think we are asking people on the
11 phone to make sort of off the cuff assessments
12 of when things will be ready. I really want
13 to go back to the NCQA leadership and be able
14 to do that.

15 I think it would be helpful to get
16 a full set of what the issues are. The issue
17 Barbara just raised is a complicated one.
18 Oftentimes we don't always know exactly what
19 health care interventions affect outcomes, and
20 yet if we think they are worthy and important
21 outcomes, we still go ahead and put them
22 through.

1 So I think that may be a harder
2 lift for NCQA to really respond to.

3 CO-CHAIR FLEISHER: So, Helen, if
4 we vote no, will we get a chance to relook at
5 this. If we vote yes conditionally, and they
6 don't -- We can defer?

7 CO-CHAIR DUBOW: We are not asking
8 -- What we are exploring here is the
9 possibility of not taking a vote, so that we
10 can go back and ask NCQA a series of questions
11 to give us some better clarity. Based on
12 those answers, we could vote by email. Okay?

13 So let's just take a couple of
14 minutes to flesh out what we want to know.
15 One of the things is that we want to know
16 about their plans to reexamine the current
17 risk adjustment method to see whether they are
18 going to come up with something that will be
19 more discriminating with respect to the
20 results. That is the first item I hear. Is
21 that right? Okay.

22 The second is some data around--

1 MEMBER TURNER: Any influence that
2 say depression interventions or something on
3 a large population, anything that we can do.

4 CO-CHAIR DUBOW: Yes. This is not
5 a new measure. This has been used. I mean,
6 we have those data, by the way. You know they
7 went back -- I can't remember.

8 It goes all the way back to the
9 early 2000s or the late '90s, I think. So we
10 saw some stuff here about change in
11 performance, and some of the literature that
12 they provided us also discussed that, if you
13 click on some of those links. They have a
14 whole website. So that is one thing. Dianne,
15 you want to add to the list?

16 MEMBER JEWELL: Yes. I just need
17 some direction about what constitutes
18 meaningful change, so that you can fall into
19 one of these categories or not, and how that
20 has been determined and validated. That is
21 really my point about validation. I didn't
22 articulate very well the last time. Even

1 standard error change.

2 DR. O'BRIEN: They have extensive
3 documentation on the web on this, and it was
4 all provided with the submission.

5 MEMBER JEWELL: Okay. So if I
6 need to, I will do that.

7 CO-CHAIR DUBOW: All right. So we
8 have Dianne's point.

9 DR. O'BRIEN: Can I add a couple
10 to the list? Things I noticed is that one of
11 the questions that I was asked to address to
12 my view is whether the risk model adjusts for
13 factors that reflect disparities in care.

14 This is a measure that does adjust
15 for socioeconomic status and race and goes
16 back. So it definitely does. So whether that
17 is right or wrong or if it is not exactly
18 consistent with the current NQF criteria for
19 evaluating risk adjustment measures, it is a
20 relatively limited set of risk factor
21 adjustments.

22 So for adjusting, there is a

1 mortality model. There is an MCS model and
2 PCS model. That's the mental and the physical
3 component scores. The two component score
4 models basically only adjust for socioeconomic
5 variables. They do not adjust for baseline
6 measurements -- you know, they don't adjust
7 for your baseline MCS score or any other
8 factors and may be associated with the
9 likelihood you will be able to maintain your
10 current health status.

11 You know, the methodology was
12 extensively and rigorously tested from all
13 kinds of perspectives. I mean, it is clear
14 that this is a long history, lots of
15 publications, and really a lot of work went
16 into it.

17 Looking at it, I couldn't tell
18 whether fit of the models they are proposing
19 were assessed in terms of calibration and
20 looking at calibration within the subgroups.

21 The last point was that, in terms
22 of this discriminating performance, I saw the

1 same results that you raised. I thought the
2 PCS was less discriminating. I mean, there
3 were outliers for the -- actually, for the
4 physical. One appeared to more underpowered
5 than the other.

6 CO-CHAIR DUBOW: More
7 discrimination, but not a lot. That has been
8 pretty consistent over the years as well.

9 MEMBER JUSTER: Since we are
10 measuring compared to themselves, is the role
11 of risk adjustment when the outcome is a
12 difference between time one and time two may
13 not --

14 CO-CHAIR DUBOW: That is the
15 point.

16 MEMBER JUSTER: And left to
17 myself, I have a chronic disease, I am simply
18 going to deteriorate.

19 CO-CHAIR DUBOW: Do you want to
20 add something to that, Judy?

21 DR. NG: It is --

22 CO-CHAIR DUBOW: We cannot hear

1 you. Okay. I think it adjusts itself,
2 because it is the same person.

3 MEMBER AMARASINGHAM: I am not
4 sure of that, though. Let me just make sure
5 I understand that. I mean, you can still risk
6 adjust for the likelihood of something
7 happening to a patient. So for example, you
8 can risk adjust for the likelihood of a
9 readmission in the future for a patient. It's
10 still the same patient.

11 MEMBER JUSTER: I am not saying
12 don't risk adjust. I am just saying --

13 MEMBER AMARASINGHAM: But I think
14 risk adjustment is still important. Don't
15 take risk adjustment out of the table.

16 CO-CHAIR DUBOW: Amy?

17 MEMBER ROSEN: I just want to
18 raise maybe what Sean was thinking about, too,
19 is kind of the clumping of using the summary
20 components, summary scores for MCS and PCS and
21 whether that is important in thinking about
22 the lack of variation in the outcomes, whether

1 looking more specifically at some of the
2 domains of the summary scores might be more
3 effective in picking up more variation. Just
4 as a thought statistically in terms of moving
5 us more forward.

6 CO-CHAIR DUBOW: I would like to
7 just add -- I mean, this is almost a
8 rhetorical question about the issue of
9 restricting this to the Medicare Advantage
10 population and whether there is something
11 intrinsic about this particular measure that
12 justifies that, excluding the fee-for-service
13 population.

14 I expect the answer to be no, but
15 I would just like it on the record. So are
16 there any other questions? It sounds as
17 though there is consensus around deferring a
18 decision on this measure, on the HOS measure,
19 until we get some feedback from NCQA, the
20 measure developer. Okay.

21 DR. PAGE: Joyce, this is Karen
22 Page, NQF.

1 CO-CHAIR DUBOW: Hi, Karen.

2 DR. PAGE: I just want to address
3 a question that came up about whether you need
4 to risk adjust if you are using -- or
5 comparing difference to the patient's own
6 baseline.

7 The question that comes up is
8 that, depending on what your baseline is,
9 there may be different opportunities or
10 probability of improvement. So if that is the
11 case, so say someone -- whether you are the
12 higher end, to begin with, and you have
13 greater chance of improving or if you are the
14 lower end and you have greater chance of
15 improving, the idea is that there is a
16 different mix of patients that is starting at
17 the different levels. There is a variable
18 probability of changing, but in risk
19 adjustment it is something to at least
20 consider.

21 CO-CHAIR DUBOW: Thank you, Karen.

22 MEMBER HOPKINS: My process

1 question was is that going to happen in the
2 time frame of this committee?

3 CO-CHAIR DUBOW: Is what going to
4 happen?

5 MEMBER HOPKINS: Whatever is
6 taking place. We are deferring decision, but
7 I would like --

8 DR. WINKLER: We can ask NCQA and
9 get a response within the time frame. What
10 that response will then set you up to do will
11 be the next step. You may not be able to act
12 or do anything within the time frame remaining
13 of the project, depending on what the response
14 is.

15 MEMBER HOPKINS: So I am trying
16 to figure out how this gibes with the decision
17 we made on the Minnesota measure where it was
18 conditionally approved. Seems like we are not
19 treating things the same way.

20 DR. BURSTIN: It sounds like
21 people don't feel like we have enough even to
22 make that decision or even say what the

1 conditions are. There is enough outstanding
2 questions that I have the sense people aren't
3 ready to make that choice. If people feel
4 ready to make that choice, that's another
5 option, but I think the bigger issue is when
6 is this testing going to be done? Would you
7 want to see the updated tested measure before
8 you make that decision?

9 CO-CHAIR DUBOW: Dianne.

10 MEMBER JEWELL: Can I just
11 clarify? This measure -- I infer references
12 I have seen in the reference list that this
13 measure has been around for a while. Has it
14 been around for a while in the Medicare
15 Advantage?

16 CO-CHAIR DUBOW: Yes.

17 MEMBER JEWELL: But the
18 reliability testing that is reported is only
19 with the veteran's group? Did I understand
20 that properly?

21 CO-CHAIR DUBOW: Is that correct,
22 NCQA?

1 MEMBER JEWELL: What is in the
2 reliability section, at least in the measure
3 application form, refers to extensive testing
4 in the Veterans Affairs study with that
5 population, and I just am not clear the extent
6 of the testing in other groups.

7 DR. PAGE: I believe this has been
8 tested in both veterans and elderly groups.

9 CO-CHAIR DUBOW: Thank you.

10 MEMBER HOPKINS: Joyce, what I am
11 struggling with is the core of this survey is
12 SF-36, probably the most widely tested survey
13 instrument in the world. So if we get through
14 this process and don't even have NQF
15 endorsement of SF-36, something is wrong.

16 MEMBER JEWELL: This isn't the SF-
17 36.

18 MEMBER HOPKINS: It is embedded in
19 this thing.

20 MEMBER JEWELL: But it is not the
21 SF-36.

22 CO-CHAIR DUBOW: Okay. You know

1 what. Let's take a vote to defer, because we
2 need to move on, everybody. We are late. We
3 are way behind. So I think, as Lee suggests,
4 that we take a vote.

5 All those in favor of deferring
6 consideration of this measure until we have
7 answers to the questions we just identified,
8 please raise your hand.

9 Okay. So we all agree, and we
10 will defer consideration. We will be hearing
11 from NQF staff. Keep an eye out for the
12 email.

13 We now have the last cross-cutting
14 measure for our consideration, and that is
15 care for older adults, advance care planning,
16 functional status assessment, pain screen.
17 Again, it is an NCQA measure.

18 Reva, do you want to introduce us
19 to the measure?

20 DR. WINKLER: Sure. This is
21 measure 007. It is care for older adults. So
22 percentage of adults 65 years and older who

1 receive the following during a measurement
2 year: advance care planning, functional
3 status assessment, and pain screening. Each
4 of these are reported individually, though
5 they are part of this measure.

6 MEMBER HOPKINS: Page reference is
7 25.

8 CO-CHAIR FLEISHER: Thank you.

9 CO-CHAIR DUBOW: Yes, and it is
10 OT2-007-09.

11 DR. WINKLER: This is not a
12 composite measure. It has multiple parts
13 embedded in it -- or it is not submitted as a
14 composite measure. Let me put it that way,
15 and we have endorsed similar measures that are
16 sort of multi-part, if you will, like this.

17 CO-CHAIR FLEISHER: So there would
18 be one person who voted? Is that --

19 DR. WINKLER: Yes. Not a lot of
20 participation for the group that looked at
21 this one. So whoever was the one person,
22 thank you very much for stepping up.

1 MEMBER HOPKINS: Reva, this one
2 raises a fundamental question. How did it get
3 through the screen for outcomes measures? It
4 is not an outcome measure in any sense of the
5 word.

6 DR. WINKLER: What screening are
7 you referring to exactly?

8 MEMBER HOPKINS: I thought this
9 was the Patient Outcomes Steering Committee.
10 Wasn't that the first slide that you showed?
11 Where does it fit on that slide? This is a
12 total process measure.

13 DR. WINKLER: And the Steering
14 Committee is welcome to make that
15 determination and act that way.

16 MEMBER NEWCOMER: So, Mr.
17 Chairman, let's emulate the lawyers and ask
18 for a summary judgment to dismiss, because it
19 really isn't an outcomes measure.

20 CO-CHAIR DUBOW: Is there anybody
21 who wants to entertain this measure?

22 MEMBER TURNER: I had one

1 question. I mean, I think we still have to
2 consider process measures, because that moves
3 the bar in the right direction, but -- am I
4 wrong? Advance care planning? I am reading
5 the wrong thing. Am I?

6 CO-CHAIR DUBOW: No, you are not.
7 You are not.

8 MEMBER TURNER: I think they are
9 processes. I think process measures can be
10 outcome measures.

11 CO-CHAIR DUBOW: Excuse me. This
12 is an important discussion.

13 MEMBER HOPKINS: Instead of saying
14 I assess the functional status, report what it
15 is.

16 MEMBER TURNER: Meaning what was
17 the pain, not pain screening. What was the
18 pain?

19 MEMBER HAUGEN: From a patient
20 standpoint, the fact you do something isn't
21 meaningful. It is what you do with that
22 information, and then do I improve it. So

1 just the fact I do things -- I just don't
2 think that is even comes close to
3 accountability.

4 MEMBER PINDOLIA: You know, there
5 is NQF measure number 0553 for medication
6 review. That is why they didn't include it in
7 the three.

8 I did vote, but I think I wrote it
9 after the due date. So I did vote, but I
10 guess it didn't get counted, because I was a
11 little late. Sorry about that. But it says
12 that the 0553 has already been NQF endorsed,
13 and that is why they didn't include that in
14 here, and they included the other three senior
15 outcome measures.

16 Is there any data? Is 0553 any
17 different than these or what they are looking
18 for? It is on page -- It is under 3(c),
19 distinctive or additive values in other NQF
20 endorsed measures.

21 CO-CHAIR FLEISHER: So, Helen,
22 within the context of this discussion, so if

1 the committee -- Somebody has proposed a
2 potential measure. So the question is, if we
3 say no, do we say no, because we don't believe
4 it should be endorsed or, no -- do we also
5 have a right to say, no, it is not an outcome
6 measure and, therefore, it should not be
7 brought forward? You are winding your eye.
8 So that means --

9 DR. BURSTIN: It is very late in
10 the process, and I think our understanding was
11 all these measures were looked upon against
12 this list of what we decided up front were
13 broad topical areas that could -- Some of
14 these aren't the classic outcomes. You had a
15 fairly broad list up front of what you
16 considered outcome measures.

17 So we made that initial
18 assessment, I thought, with you guys,
19 actually, to specifically include these kinds
20 of -- that this measure was included, because
21 it actually fit patient experience.

22 MEMBER HOPKINS: But back to that

1 discussion, we weren't talking about somebody
2 assessed those things. We were talking about
3 the measure was measuring those things. That
4 is the distinction I would make.

5 MEMBER JEWELL: The comparable
6 conversation that we had in the fall related
7 to another measure, was the gate velocity
8 measure that I had raised a question about.
9 The response I got was that in its current
10 specification, because it was the question,
11 did the physical therapist assess gate speed,
12 yes or no, that that was by definition a
13 process measure, and that that wasn't relevant
14 to this conversation, and that in order to
15 make it relevant, it would need to be
16 respecified to reflect some set of values
17 against which you would hope the patient would
18 match, like the Alc measures.

19 So using that logic, I concur that
20 this --

21 MEMBER TURNER: So with that
22 analogy, what would be the advance care

1 planning outcome? They stayed alive or they
2 didn't stay alive or they -- I am just saying
3 that you do want to have -- You do want to
4 have the process evaluated.

5 MEMBER JEWELL: And I don't
6 disagree with you philosophically. I think it
7 is a matter of where does it best belong. I
8 guess I do have a little bit of a concern
9 about integrity of process by virtue of other
10 measure submitters.

11 I think we need to be as clear as
12 we can be that the rules are applied the same
13 way all the time. So if other groups thought
14 they had measures -- and I speak to this more
15 from the bone and joint TAP. We got no
16 measures. I can imagine there was a whole
17 wealth of process measures that would have
18 been relevant in the same logic that you are
19 arguing.

20 So for me, it is both a
21 consistency of approach issue as well as just
22 a definition issue.

1 CO-CHAIR DUBOW: David raised that
2 point earlier this morning in a sidebar
3 conversation, and I think that argument has
4 merit. But I do think we need to be, to
5 Barbara's point, very clear that it doesn't
6 fit into our definition, because that is the
7 standard that we will be judged by, and any
8 action we take needs to be justified on the
9 basis of the fact that it doesn't meet our
10 definition.

11 This is the definition that we
12 advertised, and I suppose if we decide that it
13 doesn't, then the measure is not considered
14 but without prejudice.

15 MEMBER BECKER: So, Joyce, just a
16 question. So I think these are important
17 things, whether they are process or outcome.
18 So if we decide not to go forward, is there a
19 place where these get posited so they can get
20 accepted -- reviewed, accepted, not accepted,
21 because I think advance care planning is an
22 important thing to do. You know, if we just

1 pocket veto these things and they fall into an
2 abyss, then I don't think we are doing --

3 CO-CHAIR DUBOW: Is there a shared
4 decision making -- Nothing? Is there any
5 other place to give this --

6 CO-CHAIR FLEISHER: So actually,
7 getting back to Barbara's comment, if advance
8 care planning is considered an outcome, if
9 they have a plan, then it doesn't matter if
10 the others are process measures, from the
11 previous discussion, as long as one of the
12 components is an outcome.

13 So the question is -- and I think
14 it is a great question that Barbara asked --
15 Is there anything that -- If you create a
16 plan, is that an outcome versus a process.

17 CO-CHAIR DUBOW: Having a plan.

18 CO-CHAIR FLEISHER: Having a plan.

19 MEMBER AMARASINGHAM: But I think
20 the reason to have a plan for the outcome is
21 that your end of life is better. Now we don't
22 know -- how that is defined is very murky, but

1 that is the whole reason for advance care
2 planning. I still think it is a process
3 measure.

4 CO-CHAIR DUBOW: No, it is having
5 a plan that reflects your preferences.

6 MEMBER AMARASINGHAM: Right. So
7 that decisions can be better made at the end
8 of life.

9 CO-CHAIR DUBOW: No. That reflects
10 your preferences.

11 MEMBER AMARASINGHAM: For the end
12 of life.

13 MEMBER JEWELL: Well, by saying it
14 reflects your preferences, to me that sounds
15 like an intermediate outcome. That is not how
16 this measure is specified. So then we are
17 respecifying the measure on behalf of the
18 developer. So that is a whole 'nother issue.

19 MEMBER ROSEN: Only because it is
20 -- the advance care planning is specified with
21 CPT codes. So we are not really asking the
22 patient what happened. We are looking at the

1 data.

2 MEMBER JOHNSON: Can we get back
3 to the slide? Just put the slide back up, the
4 one we just had, what we are charged to do.

5 There are a couple of
6 circumstances here that we need to consider.
7 One, this was accepted for this task force to
8 review. So it is -- It got into the queue
9 where other people would have not had these
10 process measures maybe go forward. Is that
11 right?

12 CO-CHAIR FLEISHER: Reva, did
13 anything get rejected by the staff to say it
14 was not -- it would not be reviewed? So if
15 somebody submitted -- because if not, then
16 that is a dangerous statement to make. So we
17 should just have clarification. Did staff
18 perform triage?

19 DR. WINKLER: Well, the problem
20 is, staff had the same discussion you are
21 having, with a variety of opinions, actually,
22 and applying that as criteria is harder than

1 you think. So the default was to keep it
2 rather than let it -- and let the Steering
3 Committee make that decision.

4 MEMBER JOHNSON: So nothing was
5 turned down? My point is just that --

6 DR. WINKLER: It was just one or -
7 - you know --

8 MEMBER JOHNSON: The second point
9 is: I am 100 percent, this is a process
10 measure, but if you look up and read what we
11 said in bullet 1, patient function, symptoms,
12 health related quality, I think we are really
13 trying to talk about changes in, rather than
14 measurement of.

15 If you just measure something, and
16 in the first bullet I think that is still a
17 process measure. It is not an outcome. You
18 haven't defined a change, which is what an
19 outcome is.

20 So I think, if I were submitting
21 this measure and I read your first bullet
22 point, I would say, well, we fit right into

1 that.

2 CO-CHAIR DUBOW: I want to ask the
3 measure developer. NCQA, can you tell us why
4 you submitted this measure as an outcomes
5 measure, please? It goes to the question that
6 you raised, David.

7 DR. PAGE: Yes. I believe that we
8 had discussions with staff and felt that, you
9 know, in terms of measure call and where this
10 measure might be most appropriate, you know,
11 this was where we ended up.

12 CO-CHAIR DUBOW: Okay, thank you.
13 If there is no further discussion,
14 I think we need to call the vote, and it seems
15 to me that we ought to have the vote on the
16 basis of whether we consider this -- before we
17 vote on -- Well, we could do it up or down,
18 but I think we should vote on whether we
19 consider this a process measure, because it is
20 out of scope. Right.

21 MEMBER PINDOLIA: Hold on. Before
22 we vote, I think my question still hasn't been

1 answered. There's four components for senior
2 care of what they are trying to do. They only
3 included three, because one of them was
4 already NQF endorsed, and that was the
5 medication review, number 0553 that they put
6 in there.

7 Is that considered an outcome
8 measure, because if that was, then you can't
9 say these three aren't. But if that wasn't,
10 then maybe that is what those should go to,
11 whatever those are called.

12 DR. PAGE: I believe that was
13 endorsed under a separate measure development
14 call.

15 CO-CHAIR DUBOW: It was.

16 DR. PAGE: And perhaps Helen knows
17 exactly what.

18 CO-CHAIR DUBOW: But that doesn't
19 matter, because the scope of those projects
20 was different. The criterion in the other
21 project wasn't was it outcome or process.

22 MEMBER PINDOLIA: That is what I

1 wanted to know. Was it or not?

2 CO-CHAIR DUBOW: No, it wasn't.

3 So now we are going to vote. All
4 those who believe this measure is in scope for
5 this committee, please raise your hands.

6 Okay. Then out of scope?

7 CO-CHAIR FLEISHER: In or out of
8 scope. Out of scope is now. So it is 21.

9 CO-CHAIR DUBOW: So I think this
10 does not indicate anybody's preference or
11 opinion about the measure itself.

12 DR. BURSTIN: Let's try to find a
13 home for it, so it doesn't fall into an abyss.

14 CO-CHAIR DUBOW: Right.

15 MEMBER AMARASINGHAM: I guess one
16 question is: Can our committee make a
17 recommendation to NQF, because I think, even
18 when we were thinking about this last fall and
19 we were going out and talking to other
20 methodologists, one of the things I mentioned
21 to them is we are not looking for process
22 measures. But that is equally vitally

1 important, and there should be some forum or,
2 hopefully, there will be a forum at NQF where
3 that is considered.

4 Now, of course, advance care
5 planning is critical.

6 CO-CHAIR DUBOW: Right. This
7 actually fits into one of the six NPP
8 priorities, as a matter of fact.

9 DR. BURSTIN: We are planning to
10 have a palliative care project beginning in
11 November. So at the latest, it is six months
12 away.

13 DR. O'BRIEN: I was wondering
14 about the Brandeis CMS evaluation of
15 management for heart failure, MI, and
16 pneumonia. Those are arguably processes of
17 care.

18 CO-CHAIR DUBOW: Okay. So we have
19 now completed our consideration of the cross-
20 cutting measures, and we are now going to
21 infectious disease.

22 CO-CHAIR FLEISHER: Okay. So we

1 have ordered joe for the entire panel, could
2 do jumping jacks to get us back on track. Do
3 people want to take two minutes to stretch?
4 Why don't we do that. So take two minutes to
5 stretch while we get the next set of measures
6 up, and we will start.

7 (Whereupon, the foregoing matter
8 went off the record at 2:52 p.m. and went back
9 on the record at 2:57 p.m.)

10 CO-CHAIR FLEISHER: Okay. We
11 actually will get Francois back to the table.
12 This is not you? Okay. No, no,no. We are
13 going to start with your measure.

14 CO-CHAIR DUBOW: Under ID,
15 pneumonia.

16 CO-CHAIR FLEISHER: So, you know,
17 I am used to surgeons asking docs, you have a
18 7:45 heart start time, and I am used to
19 calling them at 7:15 and asking where they
20 are.

21 So we are going to start. So,
22 B.J., we would like to start. So we have

1 already actually had a lot of these
2 discussions. I want to keep this going.

3 DR. WINKLER: Just by way of
4 introduction to this set of measures,
5 hopefully, we can be a little bit efficient,
6 because one measure is very similar to the
7 measure we talked about earlier today about
8 the PACs, and Francois is back to talk about
9 that.

10 The next three measures for ID are
11 very similar to a heart failure, AMI measures
12 from Brandeis that we already talked about in
13 March. So the methods are the same. The
14 issues should be very much the same. So,
15 hopefully, we can perhaps be a little more
16 efficient in our conversation, without redoing
17 things we have already gone over and over
18 again.

19 So the first measure we are going
20 to talk about -- and we need to go down to 22,
21 Helen -- is the proportion of pneumonia
22 patients that have potentially avoidable

1 complications during the index day or the 30-
2 day post-discharge measure.

3 So this is brought to you from
4 Francois and company, who created a whole
5 suite of measures. This is a measure focusing
6 in on patients who are hospitalized with
7 pneumonia who then have -- again, same
8 methodology, identifying the PACs -- either
9 during their hospitalization or within the 30-
10 day time frame immediately after
11 hospitalization. It is measure 22.

12 CO-CHAIR FLEISHER: But the
13 difference is there was one --

14 CO-CHAIR DUBOW: It is measure 13.

15 DR. WINKLER: Oh, you are right.

16 CO-CHAIR FLEISHER: So we have
17 moved down from the one year to a 30-day, an
18 important point.

19 DR. WINKLER: Right, and it is
20 focusing in on patients whose primary
21 discharge diagnosis was pneumonia. Correct,
22 Francois?

1 MR. DeBRANTES: That is right. So
2 primary discharge diagnosis is pneumonia and
3 potentially avoidable complications, just like
4 in the definitions for chronic illness,
5 include readmissions or ED visits, encounters
6 related to the pneumonia. That would be Type
7 1; Type 2 related to comorbid conditions; type
8 3 related to patient safety issues.

9 When you look at the distribution
10 of the potentially avoidable complications for
11 this type of measure, it is more concentrated
12 around complications that occur related to the
13 index condition and patient safety issues,
14 mostly stuff that happens during the hospital
15 stay.

16 There was a fair amount of
17 discussion during the TAP for pneumonia, and
18 I have to admit, not being a physician and
19 Amita not being around, I was not able to
20 answer a lot of their clinical questions, and
21 I also clearly was not very articulate in my
22 answers; because it didn't seem as if anyone

1 on the TAP actually understood what I was
2 talking about.

3 CO-CHAIR FLEISHER: Barbara, were
4 you the Chair?

5 MEMBER YAWN: No. I was on
6 pulmonary, but this TAP is infectious disease.

7 CO-CHAIR FLEISHER: Yes, this was
8 under infectious disease.

9 MEMBER YAWN: I don't know why,
10 but it was.

11 CO-CHAIR FLEISHER: Right.

12 MR. DeBRANTES: So, for example,
13 you know, we do specify -- I tried to explain
14 a couple of times -- that if a patient comes
15 in and has something present on admission --
16 we had that conversation earlier -- then,
17 obviously, it is not going to be counted as a
18 potentially avoidable complication.

19 We got into circular discussions
20 around the severity adjustment, not dissimilar
21 to what we had earlier.

22 CO-CHAIR FLEISHER: Francois, why

1 don't we get the TAP comments, ask for more
2 comment form the TAP's perspective, the
3 concerns about this measure or what they
4 thought about this measure.

5 MEMBER DELLINGER: I think we had
6 trouble understanding a lot of it, and the
7 issues -- Francois, it helps me reflecting
8 reasonably well the conversation -- and some
9 of them are put up in the material here on
10 page 71.

11 There was concern over -- For
12 instance, thoracentesis was considered a PAC,
13 and yet it is indicated if a patient has
14 pleural fluid and the question of empyema.
15 There are a lot of things included as PACs
16 that seemed to us like necessary components of
17 care.

18 CO-CHAIR FLEISHER: Amita, do you
19 want to address?

20 DR. RASTOGI: So being a thoracic
21 surgeon, I agree with you that thoracentesis
22 is an important part of care, but empyema

1 itself should not happen, and sometimes the
2 codes are picked up by empyema, and sometimes
3 it is picked up by the procedure code.

4 The idea is that we can't avoid
5 all empyema after pneumonia, but these are all
6 potentially avoidable complications that we
7 are talking about, and we want to restrict the
8 number of empyemas that happen, just like we
9 want to restrict the number of dates that
10 happens in patients who are hospitalized.

11 So all these systems are
12 potentially avoidable, and you are not
13 expecting a zero percent rate. So that was
14 the premise by which we were going with most
15 of the definitions.

16 MR. DeBRANTES: So similar to your
17 other measures.

18 MEMBER DELLINGER: Personally,
19 empyema is one of the understood complications
20 of pneumonia. It is the way in which some
21 pneumonias even present. It is really -- and
22 you know, we could go down to reach another

1 one. I am not even sure we had -- I guess we
2 had similar complete lists of the PACs, but
3 there was concern about that.

4 DR. RASTOGI: And the fact that
5 you said it is a complication, that itself --
6 you know, you said it.

7 MR. DeBRANTES: So here is -- and
8 I thought one that occurs naturally in the
9 course of the disease. And I think this is
10 the debate that we are having in the field,
11 obviously, because we are instrumenting our
12 program in quite a number of communities
13 around the country, and it is something that
14 we are having in the field and, I think, very
15 useful and instructive to this committee;
16 because instead of -- In fact, we don't --
17 There is no finger pointing or accusations or
18 malfeasance or anything else in any of our
19 implementations.

20 Instead, there is robust
21 discussion within the physician and the
22 hospital community around what truly can be

1 done to try to avoid some of these PACs, and
2 I have difficulty -- and this is a difficulty
3 inherent in any measure that relies solely on
4 administrative claims data, is that sometimes
5 you cannot parse the ones that are truly
6 avoidable from the ones that aren't.

7 So our position has been, if the
8 answer to the question is they can never be
9 avoided, and I mean never -- so not one
10 percent, two; they can never be avoided --
11 then we will remove those definitions from
12 PACs.

13 If even one percent can be
14 avoided, then we will include them, because if
15 you don't, then you are sending a signal that
16 says it is not important to count. We think
17 that it is important to count. So that is the
18 only point we are trying to make, and I
19 understand the emotional and philosophical and
20 other issues associated to it.

21 Our position has been let's count,
22 and let's figure out collectively the extent

1 to which we can impact these numbers.

2 CO-CHAIR FLEISHER: Dianne.

3 MEMBER JEWELL: So perhaps this is
4 just I need some clarification about the way
5 things are indicated. I would agree that an
6 empyema, by way of example, that occurs
7 because a patient is out in the community with
8 unattended pneumonia is a different thing than
9 an empyema that occurs because of --

10 MEMBER TURNER: They didn't have
11 the right antibiotic.

12 MEMBER JEWELL: Right. But what I
13 also can appreciate is perhaps there is not,
14 to use your word, parse. There is not a way
15 to easily identify what presents on admission
16 versus not.

17 So I am asking the question: Is
18 that the problem or is it that, really in your
19 mind, those things aren't different?

20 MR. DeBRANTES: I don't believe --
21 At least in our definition, that should not be
22 the problem, because we are very clear that

1 elements that are present on admission would
2 be excluded from counting as PACs. So that
3 should not be a problem.

4 MEMBER PINDOLIA: Except it will,
5 of course, because not all of us can tell you
6 that was present on admission. But I am going
7 to take another tack, and that is the public
8 health perspective.

9 I would like to believe that we
10 might be able to get people to come in so they
11 aren't out in the community with an unattended
12 pneumonia, and that I as a physician should
13 take responsibility for that also.

14 Perhaps that is different being a
15 primary care physician than some people who
16 are, you know, a thoracic surgeon, but I think
17 that that is a potentially avoidable
18 complication, because that patient should have
19 known to come in earlier. We should have made
20 access available to them.

21 Now I can't change all of it, but
22 there might be something I can do about it.

1 So I think we have to be very careful and not
2 think too narrowly about health systems the
3 way they currently exist, because they are
4 really not very good. We all know that.

5 CO-CHAIR FLEISHER: Okay. Other
6 comments? So, Patch, I am just curious. Is
7 there any present on -- I mean, what I am
8 hearing in Francois' response and your
9 question, are there inclusion or exclusion
10 criteria that could be applied, or certain CPT
11 codes that maybe should not be in this measure
12 that would satisfy some of your comments or
13 concerns?

14 MEMBER DELLINGER: Well, I am not
15 a CPT or ICD-9 expert. I couldn't possibly --
16 The numbers mean nothing to me. I need the
17 labels or the descriptions. I understand what
18 Francois is saying. I think that is
19 reasonable. That was the biggest concern, I
20 think, that the group had with this.

21 You know how to use this. It
22 seems everyone will have PACs. All systems

1 will have PACs. I guess the issue becomes
2 what is the range of PACs, and is there a way
3 to change that.

4 CO-CHAIR FLEISHER: Lee?

5 MEMBER NEWCOMER: I think this
6 measure I am going to compare to a coffee
7 table book. It is designed to start a
8 conversation rather than to actually weight or
9 rank anything, because of all the issues that
10 are described, you could get into that level
11 of detail with every single PAC.

12 So if we think about it in that
13 term, that this is simply a conversation
14 starter and an internal measure for how we
15 could get better or we could look at other
16 systems and find that they have better
17 measures, find out what they do to get ours
18 better. But you can't make it perfect. It
19 will not happen.

20 CO-CHAIR DUBOW: But I think -- I
21 don't know if you are trying to narrow the use
22 of this measure. I hope I am not hearing you

1 say that this is for QI and not for public
2 reporting.

3 MEMBER NEWCOMER: Actually, that
4 is probably exactly what I am saying.

5 CO-CHAIR DUBOW: Ah. Well, then I
6 would disagree, because I think that this
7 measure has, again as I observed about the
8 other measure, I think this has salience for
9 a patient.

10 I think that it may very well be -
11 -- I think that the value, actually, is that
12 it is good for QI, and it does simulate
13 improvement, because it will stimulate that
14 conversation. But, by golly, this is very
15 useful for a patient to be looking at
16 performance, because it is absolutely
17 understandable.

18 MEMBER HOPKINS: And to ask why?

19 CO-CHAIR DUBOW: And to ask why --
20 Well, to ask why or you say never mind.

21 MEMBER NEWCOMER: And to follow --
22 Can we follow that empyema example as maybe

1 why we are thinking differently about this?

2 I might be at Harbor General in
3 L.A. where a lot of people simply don't have
4 primary care and can't access and are not
5 going to be on antibiotics, and get empyemas,
6 or I could be at your general hospital in
7 Nebraska where the doctors are using the wrong
8 antibiotics, and empyemas are showing up.

9 Those are quite different
10 scenarios, and I would not want to, as a
11 consumer, assume that those two hospitals are
12 exactly the same. They aren't. Same bag, but
13 for much different reasons.

14 So it is a good conversation
15 starter, but for us to say to a consumer
16 hospital X is better than hospital Y based on
17 these measures, I think, is a big stretch.

18 CO-CHAIR FLEISHER: That actually
19 gets to how these measures are being utilized.
20 Although I realize we all have that in the
21 back of our mind and the doc well has
22 emphasized that on several occasions, it still

1 -- Public reporting is different than pay for
2 performance.

3 I know that may change. So the
4 question is --

5 MEMBER NEWCOMER: But we are not
6 talking about either one of those. We are
7 talking about a consumer using the
8 information.

9 CO-CHAIR DUBOW: But it is -- I
10 think the difference is that what, obviously,
11 I inferred correctly then, that -- but,
12 unfortunately -- that Lee was suggesting that
13 these are good quality improvement measures
14 that should be used internally and not
15 publicly reported.

16 Obviously, a criterion that we
17 have at NQF is that these measures be used for
18 both quality improvement and public reporting,
19 and we have a disagreement. I believe that
20 this meets that test.

21 MEMBER NEWCOMER: Maybe not. I
22 don't mind them being publicly reported at

1 all, but I don't think they should be touted
2 as a consumer measure that absolutely
3 distinguishes a difference between one system
4 and another. Whether they are public or not
5 doesn't bother me one bit. It is a coffee
6 table conversation started.

7 CO-CHAIR FLEISHER: So do you have
8 any comment -- Well, go ahead, Larry.

9 MEMBER BECKER: So I absolutely
10 think they ought to be out there in the public
11 domain. They ought to be out there. I mean,
12 there's any number of measures from cardiac
13 measures to hospital mortality that make
14 differences in systems, and people make real
15 decisions about those.

16 So if there are potentially
17 avoidable complications that one hospital more
18 of those than another, then consumers ought to
19 know that, and they ought to be making their
20 decisions about that.

21 It may be with the specificity
22 anybody would like, because it is not about

1 their specific decision, but we know it is
2 about systems care. it is not necessarily
3 about individual things.

4 So putting this information and
5 having systems react to that and get
6 themselves better because they are motivated,
7 because the data is public, is hugely
8 important.

9 CO-CHAIR FLEISHER: Helen, do you
10 want to comment at all on this discussion? I
11 am going to put you on the spot, Helen.

12 DR. BURSTIN: What do you want me
13 to say? There is nothing else to say. I
14 mean, I think the issue is just that NQF
15 endorsed measures are intended for both,
16 potentially QI as well as public reporting.
17 It just is what it is.

18 CO-CHAIR FLEISHER: Barbara?

19 MEMBER YAWN: I just have a
20 question about -- You said this was for people
21 whose primary diagnosis was pneumonia.

22 MR. DeBRANTES: Discharge.

1 MEMBER YAWN: I know. Yes, the
2 primary discharge. That is what I am going to
3 get to. We all know that DRG, you rearrange
4 the diagnoses, so you get paid the most. Does
5 this remove some very important pneumonias
6 from this, and is there any way -- and I don't
7 know that there is an easy way to say, well,
8 we don't want pneumonias acquired in the
9 hospital; we want one that they had when they
10 got in. Have you thought that through? You
11 probably have.

12 MR. DeBRANTES: Yes. It is people
13 who -- This excludes patients who got
14 pneumonia while in the hospital. It is for
15 people who -- if you get pneumonia during the
16 hospital, you actually use a PAC.

17 MEMBER YAWN: Right. No, that is
18 a hospital acquired, but there are people who
19 come in primarily for pneumonia, but because
20 you get a higher DRG, they are coded as
21 something else as the primary diagnosis.

22 DR. RASTOGI: We don't want to use

1 the DRG codes in identifying our triggers.
2 They are using the principal diagnosis code.
3 So we deduct the DRGs from our trigger
4 definition.

5 MR. DeBRANTES: Partially for that
6 reason.

7 DR. RASTOGI: And we have given
8 the triggers which are, but we then specified
9 the AHRQ defined community acquired
10 pneumonias, and if the principal diagnosis was
11 that, that is what --

12 MEMBER YAWN: Okay. No, I wasn't
13 worried about the in and out of the hospital
14 so much as just rearranging an order.

15 CO-CHAIR FLEISHER: Other
16 comments, new comments on new topics, because
17 I would like to actually move to start voting
18 on the criteria. No comments? Reva, take it
19 away with a vote.

20 DR. WINKLER: So first going
21 through the criteria for this measure,
22 importance. It is a yes/no vote. So

1 important to measure and report. Everybody
2 who say yes. I don't see any No votes. Okay,
3 zero.

4 Scientific acceptability of this
5 measure: Completely? Partially? Ten.

6 Minimally? There's got to be one.
7 There you go. All right.

8 Usability: Completely?
9 Seventeen?

10 CO-CHAIR FLEISHER: Hands up
11 again.

12 DR. WINKLER: Okay, 16 that time.
13 Partially? This is usability,
14 partially. Five.

15 Minimally? I'm still missing one.
16 Not at all? Okay. Seventeen for
17 complete. Okay.

18 Feasibility: Completely?
19 Eighteen.

20 Partially? Four. Okay, that
21 should be it. All right.

22 CO-CHAIR FLEISHER: Okay. Next is

1 a vote --

2 DR. WINKLER: Recommend the
3 measure.

4 CO-CHAIR FLEISHER: --
5 recommendation. Is there any conditions, just
6 before? Okay. So either recommend Yes or No.

7 So, Yes? I get 20.

8 CO-CHAIR FLEISHER: No? Two.

9 Abstain? There should be none.

10 Very good. Okay.

11 Next we have three from Brandeis,
12 and this should be very similar to our
13 discussions the last time while I was walking
14 around San Juan. So I may have missed part.
15 They didn't know that? I was walking around
16 old San Juan. So, Reva?

17 MEMBER YAWN: Did you go in any of
18 the breweries there?

19 CO-CHAIR FLEISHER: No. I was
20 actually in Starbucks.

21 MEMBER YAWN: Okay. Too bad.

22 DR. WINKLER: Okay. Is Dr.

1 Tompkins with us? Oh, there you are. Sorry.
2 Missed you. So we do have the developers. We
3 have Chris on the phone with us.

4 Essentially, this is the same
5 group of three measures that we have discussed
6 for heart failure and we have discussed for
7 AMI.

8 So measure 003 is the 30-day post-
9 hospital pneumonia discharge ED visit measure.
10 So that is the first one. The second one is
11 measure 004, which is the 30-day post-
12 pneumonia discharge E&M service visit measure.
13 Then the last one, 005, is the 30-day
14 pneumonia discharge care transition composite
15 measure.

16 The methodology for these measures
17 is the same as we have seen with the AMI and
18 the heart failure. These are just applied to
19 patients with -- correct me if I am wrong --
20 primary diagnosis of pneumonia at discharge.
21 Correct?

22 DR. TOMPKINS: Correct.

1 CO-CHAIR FLEISHER: Well, once
2 again we will get PACs here.

3 DR. TOMPKINS: Once again, just
4 like with the VA, MI and the heart failure,
5 this began with the same -- many of the same
6 parameters as the existing CMS readmission
7 measures.

8 So it has the same definition of
9 what the cohort is, as currently seen in the
10 mortality and the readmission measures. It
11 has the same 30-day window, uses actually the
12 CMS readmission rate measure as one of its
13 components, and then asks the two additional
14 questions: Were there an emergency department
15 visit before any readmission, and was there an
16 evaluation and management visit that occurred
17 before either a readmission or an emergency
18 department visit, if any occurred?

19 CO-CHAIR FLEISHER: Patch, any
20 comments from the TAP?

21 MEMBER DELLINGER: I think the ID
22 TAP was basically content. They had lots of

1 questions, and the only issue that really
2 stood out was the rating on the composite
3 measure, which is arbitrary, and is that the
4 right weighting. There, of course, is not an
5 answer to that, I guess.

6 CO-CHAIR FLEISHER: Any other
7 comments? David?

8 MEMBER JOHNSON: The question is
9 what are you comparing it to? Do you have a
10 standardized index of people with the same
11 disease that haven't been hospitalized? Is
12 that your baseline comparison or -- Reporting
13 a number could sound fairly onerous, but if
14 you knew the likelihood of someone going to
15 the ER with disease acts or comorbidities,
16 what would be the -- Would that be the
17 baseline comparison?

18 DR. TOMPKINS: Well, the general
19 framework is to look at people who just came
20 home out of the hospital. So the issue of
21 people in the community who haven't been in
22 the hospital is a separate reference

1 population.

2 The way these measures are
3 constructed, it is using the nomenclature that
4 is referred to as predicted over-expected. So
5 there is a risk adjustment model that predicts
6 the number of these events, of likelihood of
7 these events, and then for the reporting
8 purpose, for any given hospital, it is the
9 extent to which it is predicted or, you might
10 say, loosely speaking, observed rates differ
11 from what is expected based on the risk
12 adjusted value.

13 CO-CHAIR FLEISHER: David?

14 CO-CHAIR DUBOW: I just said we
15 had been through all of that.

16 MEMBER HOPKINS: But since we are
17 all together, I would like to put two pictures
18 on the screen, page 67 -- Okay? This is the
19 unadjusted data for pneumonia readmission
20 rates: Very wide distribution, huge
21 variability. Right?

22 Now please go to page 68 and see

1 what the risk adjustment algorithm has done to
2 that distribution, and in so doing it has
3 eliminated at least 50 percent of the
4 outliers.

5 Now, you know, some will argue
6 that, well, they should never have been
7 identified as outliers in the first place,
8 because it didn't take into account the size
9 of the hospital and so on and so forth. But,
10 really, how is the public being served by this
11 kind of scrubbing of the original data so that
12 in the end little or no variation remains?
13 That is my question.

14 CO-CHAIR FLEISHER: Chris, do you
15 want to comment?

16 DR. TOMPKINS: Well, I think that
17 a few weeks ago it was when we were talking
18 about this, right? I think that, to some
19 degree, part of your business was you said
20 that you were going to formulate either the
21 Steering Committee, NQF or somebody who was
22 going to communicate back to CMS about the

1 advisability of using this particular
2 technique for outcome measures, and that is
3 separate from whatever I did. Right? Our
4 measure borrowed the existing thing.

5 Philosophically, there -- The problem is that
6 outcome measures have a lot of noise, and
7 systematically, in general, there are three
8 ways in which you can try to deal with that.
9 One is to try to increase the amount of time,
10 the number of events. You can increase the
11 number of measures, which is my preferred
12 philosophy.

13 This one, unfortunately, blends
14 hospital-specific information with the growing
15 mean, which is what a lot of people don't
16 like. It results in discounting or granting
17 a lot of -- or giving a lot of deference to
18 the outlier status that is assumed to be
19 noise.

20 MEMBER HOPKINS: And it is not the
21 only part of such risk adjustment. That is
22 the point.

1 DR. TOMPKINS: Right, and just for
2 people who are following it, the risk
3 adjustment, as it was occurring earlier and
4 today, is typically thought of as the ability
5 to use information such as the patient's
6 comorbidities and so forth, to set an
7 expectation.

8 This is rolled into what they
9 refer to as a risk standardized method, which
10 is hierarchical modeling that combines the
11 individual and the group averages together.

12 CO-CHAIR FLEISHER: So this --
13 Would you like to comment from CMS?

14 DR. HAN: Is this the readmission,
15 not the one that --

16 DR. BURSTIN: Yes.

17 CO-CHAIR FLEISHER: Just the
18 readmission rates.

19 DR. HAN: CMS raised did raise
20 this issue when the measure was developed. So
21 this is what we understand, the narrow
22 distribution after you risk adjusted.

1 First, we understand from the
2 developer, the readmission rate is very high.
3 It is like one out five. I am talking about
4 a general AMI, heart failure, pneumonia. So
5 it is like -- It is a bad thing across the
6 board. It is really bad to have one out of
7 five. So then we thought, that's fine.

8 The other thing is that we
9 understand also from the developer, risk
10 adjustment for comparing hospitals or
11 profiling hospitals, there are certain factors
12 we don't risk adjust them away. So this risk
13 adjustment model, we have case mix in the risk
14 adjustment model.

15 So what we were told is that
16 readmission is very particular. Maybe the
17 system factors play bigger role in the
18 variation of the hospital performance on
19 readmissions.

20 So that is the reason why that we
21 got everybody is bad. So that is quite
22 narrow, very close to each other, and system

1 factors play a bigger role. So that is why we
2 were told that you can see the R-square is
3 very low, because, you know, we purposely not
4 to risk adjust system factors. That may tell
5 you the variation.

6 I am not sure that I explained it
7 well, because this is what we understand.

8 MEMBER HOPKINS: I think,
9 actually, she probably right, but the last
10 measure we just approved was not giving people
11 a bye for system factors.

12 CO-CHAIR FLEISHER: So, Lein, will
13 you comment, because we could spend probably
14 the next two days debating this issue. So one
15 option is to continue debating it. The other
16 option is to call for a vote or a consensus
17 that we ask NQF to continue evaluating the
18 appropriateness of hierarchical models, but we
19 defer to NQF to bring this up in other panels,
20 and then --

21 MEMBER NEWCOMER: So my only new
22 comment is that, going to the second

1 methodology makes the nation assume that one
2 out of six is a normal, because that is what
3 you have done. You have tightened that around
4 and said one out of six is normal, but if you
5 look at the preceding draft best practice,
6 seven percent of hospitals are able to get to
7 zero.

8 My point is that we should not
9 accept the .15 as normal. We should be
10 driving to zero.

11 CO-CHAIR FLEISHER: And to be
12 honest, if you look at all the data on central
13 line infections, we no longer accept what was
14 the average.

15 MEMBER NEWCOMER: But we are
16 encouraging that in this.

17 CO-CHAIR FLEISHER: So the
18 question is, are you saying we shouldn't
19 endorse this measure? This measure is
20 actually already endorsed. So can I ask --
21 Amy?

22 MEMBER ROSEN: I want to get back

1 to the ER measure.

2 CO-CHAIR FLEISHER: Well, I just
3 want to -- Does anybody have any other
4 comments with regard to risk adjustment in the
5 model?

6 MEMBER AMARASINGHAM: Well, I
7 think the comment that is probably important
8 is we have accepted this risk adjustment
9 methodology for the other measure, the other
10 composite measure.

11 So I think it is important for all
12 the decisions we make that we are consistent,
13 and if we have already set a precedent, I
14 think I would be hard pressed to kind of go
15 against that on almost an equivalent measure.
16 But I do think that we should bear in mind how
17 we voted on the prior measure, which is we
18 accepted the composite but not the standalone
19 measures.

20 CO-CHAIR FLEISHER: Okay. So I am
21 just asking. Is there general consensus that
22 -- Do you want to ask NQF to reevaluate the

1 hierarchical model in light of this
2 discussion?

3 MEMBER HOPKINS: Yes.

4 CO-CHAIR FLEISHER: How many
5 people think that NQF -- just a statement?

6 CO-CHAIR DUBOW: Well, it is not
7 exactly NQF. It is CMS.

8 CO-CHAIR FLEISHER: It is CMS.

9 CO-CHAIR DUBOW: Isn't it?

10 DR. BURSTIN: Well, I think this
11 is a bigger issue than we are going to be able
12 to sort of swallow today. I think we have
13 heard it. The committee has clearly
14 indicated. I think those tables are
15 incredibly compelling, in a way, but I have
16 not seen it before, David. So I do think this
17 is something we need to think about.

18 For now, though, that is the
19 current endorsed measure that is not up for
20 decision making today. It is part of a
21 composite, just like it was on the first two.

22 CO-CHAIR FLEISHER: Thank you. It

1 sounds like in the report there will be a
2 statement with regard to our concerns about
3 risk adjustment. So new topics?

4 MEMBER AMARASINGHAM: Well,
5 actually -- I think Amy was first. Go ahead.

6 CO-CHAIR FLEISHER: Sorry, Amy.
7 New topic.

8 MEMBER ROSEN: Conceptually, I
9 have some concerns about readmission as an
10 outcome measure, and I think it is an outcome
11 measure, and I think that being admitted to an
12 ER, you know, within 30 days after
13 hospitalization is as much dependent on the
14 outpatient care one gets as the hospital care,
15 and I don't see that taken into account here.

16 I think, conceptually, an ED
17 measure is very different than a readmission
18 measure. I think oftentimes it has to do with
19 an availability of primary care and
20 accessibility.

21 So I don't know how that is taken
22 into account in this particular measure. So

1 I raise that concern.

2 CO-CHAIR FLEISHER: So, Patch, I
3 will just take chair prerogative. When we
4 vote, we will actually vote similar to our
5 previous time where it could be endorsed only
6 part of the composite, just to --

7 MEMBER DELLINGER: -- because
8 there is a composite measure which measures
9 E&M and gives you credit for E&M and deficit
10 for an ED visit.

11 CO-CHAIR FLEISHER: Right. So it
12 is identical. Chris, do you want to comment?

13 DR. TOMPKINS: Well, I think that
14 the last comment about the composite is
15 correct. This is a care transitions measure.
16 It is saying when people leave the hospital.
17 I don't think anyone is going to say that,
18 when somebody left the hospital, that the
19 hospital is solely responsible for everything
20 that happens. The idea is to say that the
21 hospital is part of the system.

22 CO-CHAIR DUBOW: This is a care

1 coordination measure.

2 CO-CHAIR FLEISHER: Right. So we
3 will have the option to endorse each measure
4 separately or endorse it only in the context
5 of care or not endorse it -- in concert with
6 a composite -- excuse me -- or not endorse it.

7 MEMBER AMARASINGHAM: I think what
8 I would like to do for the committee is just
9 restate our case for why we thought it needed
10 to be considered together, and that is because
11 there may be cases where a hospital does quite
12 well on the readmissions, but maybe the ED
13 measure or the post-acute care measure doesn't
14 do so well.

15 I mean, you need to consider all
16 of that, because there's very innovative
17 models out there that I am familiar with, and
18 that was the rationale for the composite, is
19 for us to stem the measures previously, and I
20 am not sure we would want to have different
21 sets of criteria for the different measures.

22 CO-CHAIR FLEISHER: Thank you.

1 Any new comments? Okay, time to vote on the
2 four criteria. Reva?

3 DR. WINKLER: Okay. We are going
4 to start with the ED visit measure, which is
5 003, and so, as before, importance to measure
6 and report. It is a yes/no vote. So all
7 agree it is yes, ED visit measure --

8 CO-CHAIR FLEISHER: Just a
9 clarification. So if we vote no, can we put
10 it in the composite?

11 MEMBER NEWCOMER: Can you do two
12 yeses? Can you vote for it and put it in the
13 composite?

14 DR. BURSTIN: Yes.

15 DR. WINKLER: Right. But right
16 now we are just doing the criteria and how
17 this particular measure individually addresses
18 the --

19 DR. BURSTIN: This is a standalone
20 vote.

21 DR. WINKLER: Yes -- addresses the
22 criteria. then the recommendation will have

1 those multiple components.

2 MEMBER JUSTER: Not just as a
3 standalone vote. We do -- Should we just be
4 voting no right now?

5 DR. WINKLER: The integrity of the
6 measure itself, not how well you think it is
7 going to work as a standalone measure. Right.

8 CO-CHAIR FLEISHER: So if you
9 believe it should be in the composite, you
10 should vote yes for importance. Is that
11 correct?

12 DR. BURSTIN: You should vote
13 whatever you think. I think the reality is
14 just rate this measure as it stands by
15 criteria. You will have the opportunity to
16 make the decision of whether overall you want
17 it as a standalone or -- you will get the
18 chance to talk about it in the composite
19 shortly.

20 CO-CHAIR DUBOW: We are voting on
21 this measure.

22 DR. WINKLER: Right. So the

1 importance to measure and report for a measure
2 of ED visits within 30 days after hospital
3 discharge for pneumonia. Important to measure
4 and report, Yes? I get 19.

5 No? Three. Oh, I can't add. I'm
6 sorry.

7 Okay, scientific acceptability of
8 this measure as specified. Does it meet the
9 criteria completely? I see zero.

10 Partially? I don't see any
11 others. So, okay, all 22 for partially.

12 Usability: Does it meet the
13 criteria completely, how many? Five? Okay.

14 Partially meet the usability
15 criteria? Fourteen.

16 And minimally meet the criteria?
17 One. Is that right? No, I've only got 20.
18 There is a No. Did everybody vote? You voted
19 no? Okay, so you are a No. Does it still add
20 up?

21 MS. BOSSLEY: That is right.

22 DR. WINKLER: All right, the last

1 one is feasibility. Completely? I get 20.

2 MS. BOSSLEY: And 21.

3 DR. WINKLER: Okay, 21.

4 MEMBER HOPKINS: Is this measure
5 for fee for service, Medicare only? Is it one
6 of those?

7 CO-CHAIR FLEISHER: Chris?

8 DR. TOMPKINS: The empirical
9 estimations that we gave you are for fee for
10 service only. There is no reason conceptually
11 why it couldn't be used by anybody who is a
12 payer or even a cafeteria delivery system. If
13 you had information on all the covered
14 services, you could implement it.

15 DR. WINKLER: Okay.

16 CO-CHAIR DUBOW: We only had 21.

17 DR. WINKLER: I was just going to
18 say, feasibility: Did somebody have a
19 partial? Okay, there is one.

20 CO-CHAIR FLEISHER: We are missing
21 one usability.

22 DR. BURSTIN: In case everybody is

1 wondering, we have finally, in fact, ordered
2 those little handheld voting devices. They
3 are on their way, finally. We will see if
4 that is better or worse.

5 CO-CHAIR FLEISHER: So now vote on
6 the measure. Do you want to standalone for
7 each of them?

8 DR. WINKLER: We have only just
9 done the ED visit measure. Right.

10 CO-CHAIR FLEISHER: So go through
11 the other two.

12 DR. WINKLER: So do you want to do
13 the recommendations for this particular
14 measure?

15 CO-CHAIR FLEISHER: Yes. So
16 recommendations. The options are: Yes as a
17 standalone; yes, but only as part of a
18 composite measure; or no.

19 DR. WINKLER: Only as a
20 standalone.

21 CO-CHAIR FLEISHER: Okay, just up
22 or down. Yes as a standalone? Who votes yes?

1 DR. WINKLER: Eight. No for a
2 standalone measure? Thirteen is what I get.

3 MEMBER HOPKINS: I didn't vote. I
4 didn't understand what measure. The one on
5 the screen is --

6 DR. WINKLER: This is the ED visit
7 measure. You do? Okay, so that is nine.
8 Nine yes, 13 no as a standalone measure.

9 CO-CHAIR FLEISHER: Okay, next.

10 DR. WINKLER: So next we will go
11 to the pneumonia, which is the E&M visit
12 measure. Okay? You know the discussion.

13 Is there any discussion about the
14 E&M measure before voting on the criteria?
15 Okay. So I take it you want to do -- all
16 right.

17 So importance to measure and
18 report on a measure of follow-up care
19 afterward, yes or no. Yes? Twenty-one, and
20 Barbara is not here. So 21, okay. That makes
21 the No zero.

22 Okay. Scientific acceptability of

1 the measure properties: Completely meets the
2 criteria, how many? Zero.

3 Partially meets the criteria?
4 Twenty-one, okay.

5 Usability: completely meets the
6 criteria? One.

7 Partially meet the criteria?
8 Eighteen.

9 Minimally meets the criteria?
10 There is one.

11 And not at all meet the criteria?
12 Is that you?

13 MEMBER HOPKINS: I have looked in
14 this section under this measure. It is old
15 409, right?

16 CO-CHAIR FLEISHER: So you are
17 abstaining or not?

18 MEMBER HOPKINS: I am happy to
19 abstain.

20 DR. WINKLER: Okay. Abstain. So
21 feasibility: Completely meets the criteria?
22 I get 14.

1 Partially meet the criteria?

2 Seven.

3 Minimally meet the criteria?

4 Barbara is out. Okay. Great. That's it.

5 All right. So the last one is the
6 recommendation as a standalone measure. Yes?

7 DR. TOMPKINS: Just to connect a
8 couple of dots. The mediocre scoring on --
9 The partial on scientific acceptability and
10 the sort of mediocre on usability -- is that
11 wound up in this question about the
12 hierarchical modeling? That is what I
13 thought. I just didn't want go unspoken about
14 that, that it was something else that was
15 major going on.

16 DR. WINKLER: Okay. So we are
17 back. We are voting on recommendation of this
18 measure as a standalone measure. We will get
19 to the composite.

20 All in favor of it as a standalone
21 measure? This is the E&M visit after
22 pneumonia discharge. Four. I am getting four

1 yeeses.

2 CO-CHAIR FLEISHER: And No?

3 DR. WINKLER: And No: Seventeen.

4 CO-CHAIR FLEISHER: Barbara is not
5 here.

6 CO-CHAIR DUBOW: So that is
7 correct.

8 DR. WINKLER: Fine, so that is
9 everybody.

10 All right. So the next discussion
11 is around the composite measure, which brings
12 together the currently endorsed readmission
13 measure with the ED visit measure and the E&M
14 service measure, with the same weightings as
15 we saw previously in the other two measures.
16 It is a -4 for readmission, -2 for ED, and a
17 +1 for the E&M service. So it is all the
18 same, no changes.

19 CO-CHAIR FLEISHER: Did you want
20 to have a separate discussion? I had thought
21 we -- Any new points? Okay.

22 So importance: Yes?

1 DR. WINKLER: It is unanimous. So
2 that is 21. Barbara is still out. Right?

3 Okay. So scientific
4 acceptability: Completely meets the criteria?
5 Two.

6 Partially meets the criteria?
7 Nineteen. Okay.

8 All right. Usability: Completely
9 meets the criteria? I am seeing none.

10 Partially meets the criteria? Is
11 that everybody? Okay. So it is 21.

12 Feasibility: Completely?
13 Thirteen.

14 Partially? Eight. That's it.

15 Okay, so the next is the
16 recommendation on the composite measure going
17 forward. Are there any conditions?

18 CO-CHAIR FLEISHER: None.

19 DR. WINKLER: Bless you.

20 MEMBER HERMAN: We did talk about
21 a condition when these went through the TAP,
22 is that should this always be tied to an E&M?

1 We talked about the carriers, and there is a
2 lot of places that are doing this through home
3 visits and things that are not tied to an E&M.

4 DR. WINKLER: And for those of you
5 who put that in your comments, you got a No on
6 the measure and the composite.

7 MEMBER HERMAN: Right, but --

8 DR. WINKLER: But it still passed.

9 MEMBER HERMAN: Yes.

10 DR. BURSTIN: Although I was
11 actually going to raise the same thing, not so
12 much for the composite, but I do think it is
13 important, particularly for Brandeis and CMS,
14 to consider the fact that I think this measure
15 would have done better as a standalone, if in
16 fact that issue had been addressed.

17 I think that is partially the
18 reason why it had difficulty, because it
19 excluded all the innovation of people, in
20 fact, using a nurse telephone or something
21 like that, when you wouldn't capture it as a
22 physician E&M visit.

1 MEMBER JOHNSON: Is there any way
2 that you co-adjust for utilization of ERs in
3 a given area, because if certain areas -- and
4 this came up before in the discussion of
5 coverage -- it is a standard. Somebody calls
6 after the office is closed, go to the ER, as
7 opposed to management interventions that may
8 preclude going to the ER, and whether or not
9 that ER actually led to a hospitalization.

10 The utilization of the ER -- is
11 that variance part of this? How do you
12 balance that as far as what standards are for
13 people that call after hours?

14 DR. TOMPKINS: Well, I mean, we
15 would lose a lot of points on feasibility if
16 we tried to capture things like telephone
17 calls and information about whether the
18 primary office, doctor's office, was closed
19 when the ER visit occurred.

20 So there is always a trade-off
21 here. This -- as I said before, it is a
22 profound system, and where the system breaks

1 down is going to ding you somehow, and if the
2 primary care doctor's offices tend to be
3 closed and the ED is the only thing that is
4 open, then that system would tend to look
5 worse because of that.

6 If the system wants to improve in
7 some way, it ought to do its own engineering
8 to figure out why it is that it is either
9 below average or less than it thinks it ought
10 to be. So issues like access to alternatives,
11 I think, is part of the game here, and gain.
12 That is the opportunity for gaming.

13 MEMBER JOHNSON: But I guess, if
14 it is a system that is unified as opposed to
15 a hospital when you've got independent
16 providers. Then it is not really a system. It
17 is just a -- It is an organization of
18 dysfunctional participants.

19 DR. TOMPKINS: Well, you know,
20 we've turned a corner here, and ACO is the
21 great acronym of the day, and people are
22 asking how is it that we can have a fragmented

1 system look more like a system.

2 Measures like this are intended to
3 profile the system performance, and leave it
4 to the professionals to figure out where the
5 deficiencies are that could best make their
6 score improve.

7 CO-CHAIR FLEISHER: So calling for
8 a vote. All those in favor of the measure --
9 The composite?

10 DR. WINKLER: It is unanimous.

11 CO-CHAIR FLEISHER: Okay. I guess
12 we are now going to call for any public
13 comment on the measures that we have discussed
14 today, since this morning.

15 DR. GALLAGHER: This is Rita
16 Gallagher from the American Nurses
17 Association.

18 There is no specific comment on
19 the measure as discussed, but really a
20 reminder that consideration of patient
21 outcomes in the absence of consideration of
22 the processes and/or structures by which those

1 outcomes arose is problematic.

2 CO-CHAIR DUBOW: Thank you, Rita.

3 Anybody else?

4 We are due for a 15-minute break.

5 That means we have this afternoon before we

6 eat dinner, we need to finish the

7 cardiovascular and the surgery measures.

8 So you are getting 10 minutes. We

9 are going to start again at four, and we are

10 going to start with the BET measures to take

11 advantage of the fact that we have the

12 developer with us today.

13 (Whereupon, the foregoing matter

14 went off the record at 3:50 p.m. and went back

15 on the record at 4:05 p.m.)

16 CO-CHAIR DUBOW: We are eating at

17 six o'clock, because nobody wanted hang time

18 in the Marriott, and Heidi has, obviously,

19 worked that for us. Then the bus will come

20 and bring you back at -- We are leaving at

21 7:30, but maybe we will make it earlier.

22 Tomorrow morning we are starting

1 promptly at 8:30, and food will be here. So
2 the buses will get you. You will be picked up
3 at 8:10, and good luck to you in coming
4 downtown at rush hour to be here. I said good
5 luck.

6 This is the David Johnson dinner
7 at six o'clock. Okay. Let's get started,
8 guys.

9 CO-CHAIR FLEISHER: So we are
10 going to start the cardiovascular measures,
11 and we are going to start -- Amita, do you
12 want to join us at the table. Why don't you
13 start with the Bridges to Excellence measures,
14 and then we will go to the STS and then the
15 SVS measure.

16 Do we have the TAP Chair?

17 CO-CHAIR DUBOW: Dr. Gibbons.

18 CO-CHAIR FLEISHER: Dr. Gibbons,
19 are you still on the line?

20 MEMBER GIBBONS: This is Ted
21 Gibbons.

22 CO-CHAIR DUBOW: Are you there?

1 CO-CHAIR FLEISHER: Great.

2 MEMBER GIBBONS: I have been here
3 all day.

4 CO-CHAIR FLEISHER: Fantastic.
5 Dr. Gibbons, if you would like to vote on any
6 of the measures, I guess you can send an email
7 to Reva.

8 MEMBER GIBBONS: I will send an
9 email. Fantastic.

10 CO-CHAIR DUBOW: Thank you.

11 CO-CHAIR FLEISHER: Greatly
12 appreciated. So I guess, Reva, do you want to
13 start with a brief introduction of the two
14 measures, and then --

15 DR. WINKLER: All right. The
16 first two measures we are going to talk about
17 are very similar to ones we have already done.
18 These are more of the Bridges to Excellence
19 measures with PACs.

20 The first one is the proportion of
21 patients hospitalized with AMI that have a
22 potentially avoidable complication during the

1 index stay or in the 30-day post-discharge
2 period.

3 So the methodology is the same.
4 The approach is the same. The number is OT1-
5 030-09.

6 CO-CHAIR FLEISHER: Ted, do you
7 want to -- Any comments from the TAP?

8 MEMBER GIBBONS: Well, the TAP had
9 differing approaches or at least different
10 takes on the AMI or stroke avoidable
11 complications.

12 The AMI had very few controversies
13 -- There was some feedback that weren't
14 controversial, but really reflects some of the
15 questions that were posed earlier, primarily--

16 CO-CHAIR FLEISHER: We are losing
17 about every other word.

18 MEMBER GIBBONS: I'm sorry. Can
19 you hear me now?

20 CO-CHAIR FLEISHER: Yes.

21 MEMBER GIBBONS: I'm sorry. I am
22 on a land line. It is actually connected with

1 wires and walls.

2 The stroke issues related to the
3 understanding that some of the adverse
4 outcomes of stroke may be occurring -- I think
5 those group of issues have kind of been
6 discussed earlier. I don't know that there
7 were -- what are seen as complications of care
8 are actually part of the -- process --

9 CO-CHAIR FLEISHER: Thank you.
10 Amita, do you have any comments or responses
11 to the concerns of the TAP?

12 DR. RASTOGI: No. Dr. Gibbons
13 commented very well. Francois is not here
14 right now, but what he mentioned to me was the
15 same thing, comorbid considered as part of the
16 care process of stroke and cancer, and I kind
17 of basically thought that it is important to
18 count it, even if it happens, because in the
19 end we want to reduce the number of PACs. So
20 it is a complication that could be part of
21 more discussion.

22 MEMBER GIBBONS: Yes, but I think

1 that the discussion really homed on the global
2 access to care and the early recognition of
3 stroke, and trying to reduce the morbidity
4 associated with stroke y focusing on the
5 global process.

6 CO-CHAIR FLEISHER: So were you on
7 the line or were you available to the TAP so
8 that the comments after -- I was just
9 wondering if the TAP got the responses from
10 Bridges to Excellence and what the TAP thought
11 of the responses.

12 MEMBER GIBBONS: Yes, the
13 discussion that took place on the responses
14 really focused on really some of the same
15 issues, such that they weren't meant to
16 penalize individuals institutions that took
17 care of high risk stroke, but really to
18 reflect the process of care and reduction of
19 potentially avoidable complications.

20 CO-CHAIR FLEISHER: Comments from
21 the Steering Committee?

22 MEMBER AMARASINGHAM: I just had a

1 question. I assume the risk adjustment
2 methods are essentially the same as before,
3 and I guess my same question that I had
4 before, which is: These risk adjustment
5 methods which appear to me novel have not been
6 tested in head to head comparisons with other
7 risk adjustment methods yet. Right? That is
8 being done by Rand?

9 DR. RASTOGI: That is right, and
10 as Francois mentioned, you know, the PAC rates
11 are developed, and then the severity index is
12 there. If folks feel strongly about it, they
13 can adjust it for the severity index, but that
14 is basically what it is.

15 Rand currently has taken our
16 models and are giving it a complete make-over,
17 so to say, testing the models and doing all
18 kinds of analyses and subgroup analyses. So
19 that is a different project completely.

20 MEMBER AMARASINGHAM: I guess the
21 question would be, because it does appear to
22 be sort of novel approach to do this, and I

1 recognize the challenges with data collection
2 which requires this approach, what will we do
3 if Rand concludes that it is inferior to other
4 risk adjustment approaches?

5 DR. RASTOGI: At this point, I
6 don't think it is a matter of whether it is
7 inferior or superior. It is just finding a
8 risk adjustment approach. Right? So at this
9 point, the PAC percentages that we are
10 calculating with the patients, that
11 calculation is there. Whether they are
12 severity adjusted depends on the users,
13 whether they want to use it or not.

14 So the emphasis is more than
15 counting the PAC rate. That is the idea
16 behind it.

17 MEMBER AMARASINGHAM: The only
18 thing that concerns me -- I love the approach,
19 and I think what Prometheus is great, but the
20 reason I had to vote no on the other cases is
21 because there is an element of a leap of faith
22 here about this risk adjustment method. It is

1 not a typical approach, and it hasn't been
2 validated against other approaches.

3 MEMBER PINDOLIA: I wonder if the
4 other approaches have been validated in this
5 type of a measure, though. Yes, they may have
6 been done for a long time, and most of us who
7 use Charleson now, but it has been done for a
8 long time, but it is really not a very great
9 measure, and some of the others that have been
10 used maybe don't work terribly well for this
11 particular situation. So --

12 MEMBER AMARASINGHAM: Well, I
13 agree. You know, with any measure you want
14 some sort of reproducibility and triangular
15 validation. So if you had multiple measures
16 that are pointing to the same result, even if
17 they are inferior but there are somewhat all
18 pointing to the same result, then you feel
19 like you are on stronger ground.

20 MEMBER PINDOLIA: I agree. Yes.

21 CO-CHAIR FLEISHER: Okay.

22 MEMBER TURNER: So one of the

1 axioms of the panels when we were reviewing
2 the statistics in papers is how they developed
3 the models.

4 I understand the p value driven
5 models, and that is exactly what it looks like
6 it is. You only include things that are in
7 there with a p value that is less than .25,
8 and then you use stepwise modeling, which is
9 also a no-no, from our point of view, the
10 reason being that you should have clinical
11 input to try to decide which variable is
12 important, not p values, and not let the
13 program decide what variables to be in there.

14 So it makes me feel much more
15 uncomfortable about the risk model if that is
16 the way it was developed, because it doesn't
17 really have a clinical mind behind it.

18 MEMBER HOPKINS: Do just a
19 question of philosophy. Because clinicians
20 think that the factor is important, is that
21 sufficient, even though you put it to a
22 statistical test and find that it isn't?

1 DR. TURNER: Yes, because there
2 are a lot of factors that affect each other,
3 even though it is not obvious by itself, that
4 a p value is like, let's say, age may not be
5 significant in the model, but it has an
6 important affect modification on other things
7 that you are concerned about, like the
8 diseases.

9 So it in itself isn't
10 independently predicted, but the way other
11 important variables that are in the model are
12 interpreted has to have age in the model to
13 correctly understand them.

14 The other thing is that the power
15 of this is that you have really big databases.
16 I mean, you've got lots of ability to include
17 a whole host of variables, and I think that is
18 where you have the opportunity to really
19 include a lot of the key predictors and not
20 let the machine decide what is in there.

21 MEMBER HOPKINS: Can I ask Sean to
22 comment on this, as the expert on risk

1 adjustment. I thought it was right to use
2 statistics to demonstrate what is significant
3 or not in a risk model.

4 DR. O'BRIEN: Yes, and I think you
5 can find that clinicians do not always know
6 exactly what is going to predict. There are
7 all kinds of surprises, and the surprises
8 aren't always just spurious associations.
9 They are real things that are uncovered by the
10 data that are not uncovered by clinicians.

11 On the other hand, depending on
12 the size of the data, what outcome you are
13 studying, the variable, selection procedures
14 can be highly unreliable in the sense that if
15 you did the exercise in choosing variables and
16 you repeat it again in a different dataset
17 that based on the same population, you may get
18 entirely different predictors in the model.

19 I think it is acceptable, although
20 based on a little bit of error. You are not
21 going to choose the variables perfectly, but
22 one consideration. As these models become

1 published and codified and accepted as the
2 model. Other people will come along and want
3 to do a different approach, and we say, no, we
4 have endorsed this model, but there's
5 variables in the model that are partly
6 haphazard.

7 So you might think you don't know
8 exactly what the important predictors are,
9 because there is some uncertainty in the
10 approach that basically takes the potential
11 variables that you think are important and
12 just leaves them in the model and then adjusts
13 for them is another possible approach to doing
14 it. So not relying so much on variable
15 selection is an option that I think some
16 statisticians would support.

17 CO-CHAIR FLEISHER: Amita, did you
18 want to comment?

19 DR. RASTOGI: I would like to give
20 a little bit of feedback on that, because as
21 a -- you know, I am not a biostatistician, but
22 as a physician, I was concerned about the

1 reliability of each variable that went in.
2 And as you will see, each model that was
3 developed -- we've got 21 UCLs now. Each
4 model that was developed for each part of that
5 portion or part of that episode was very
6 carefully calculated for input variables that
7 are specific to that particular episode.

8 So AMI variables are not the same
9 as pneumonia variables, and they are not the
10 same as stroke variables. There are certain -
11 - and you will see that in the expanded
12 trigger in the all-codes workbook. Each one
13 of them was specifically tailored for that
14 particular episode, from input from the
15 physicians who helped us develop it.

16 MEMBER TURNER: No. I think that
17 is great. What I have trouble with is when
18 you take your risk factor variables that your
19 experts give you and then you enter it into
20 the model using stepwise regression, and drop
21 them out based on a p value.

22 I thought also another thing about

1 what you do is you enter classes of variables
2 into the model and see how they affect it, and
3 I like that, too. I just feel like this is a
4 very -- It is very important to not allow the
5 modeling to be too specific to the data that
6 you have, for the reasons we just heard.

7 CO-CHAIR FLEISHER: Barbara, and
8 then I have a comment.

9 MEMBER YAWN: I would have been a
10 lot more concerned if the p value that had
11 made them remove it had been .05. When you
12 start getting to .25, then I think that I am
13 much less concerned.

14 I think then you may have the best
15 of both worlds, which is trying to look at
16 some ability to do more than use our opinions,
17 which, of course, are wonderful, but we are
18 somewhat narrow minded occasionally about, you
19 know, I see family medicine, so cardiology
20 must look just like family medicine or things
21 like that.

22 So I was pleased that there was,

1 in my opinion, this combination of the
2 clinical significance and then some very broad
3 statistical significance. I mean .25 is
4 really -- you know.

5 MEMBER TURNER: So to make all of
6 us happy, did you do this in multiple datasets
7 and find that the same variables were, in
8 fact, selected?

9 DR. RASTOGI: There was a
10 bootstrap validation process that was
11 followed, and it was run 200 times, and then
12 the variables that they selected 80 percent of
13 the time were the ones that were finally
14 chosen.

15 MEMBER TURNER: This is the same
16 data, but that is good.

17 DR. RASTOGI: Yes. And then to
18 your point, what we have now -- These programs
19 are now available as an automated function,
20 and each health plan can develop it from
21 scratch on their own data.

22 So they don't have to use the

1 coefficients and the variables that we select,
2 just the EEGs and all. When I was with
3 Ingenix and I developed the EEG regression
4 models, you publish the coefficients every two
5 years, every three years. Right? Then
6 everybody has to adopt it, or at 3M. You
7 know, the publish the coefficients every so
8 often, and everybody has to use that as the
9 industry norm.

10 Here it gives the capability for
11 each health plan to choose the variables that
12 are selected for that population. So it runs
13 from scratch, but they have to have a minimum
14 sample size for that to go. So we give them
15 scoring one, scoring two, scoring three
16 logics, which is all part of the automated
17 programs.

18 So from usability point of view,
19 the needed criteria are friendly, and the
20 HealthPartners has run it, and they have
21 really -- You know, I was talking to Chad
22 Hines just the other day, and they have really

1 enjoyed working with it.

2 CO-CHAIR FLEISHER: So, Amita,
3 just so that we understand. So we are
4 endorsing a measure using PACs over a time
5 period. The risk adjustment seems to evolve
6 over time, and that is -- or it can be -- In
7 other words, getting back to your question,
8 Ruben, if you go with Rand and find that the
9 risk model should be tweaked, would you come
10 back and actually say the risk model should be
11 different, although the basic measure stays
12 the same?

13 DR. RASTOGI: Reva, I will throw
14 that question back to you, whatever you
15 recommend.

16 DR. WINKLER: Essentially,
17 whenever there are significant changes in a
18 measure specifications, measure developers are
19 expected -- it is too strong to say obligated,
20 but to tell us that that is what they have
21 done and that may, depending on what those
22 changes are, prompt an ad hoc review. Is that

1 right, Helen?

2 DR. BURSTIN: That is correct.

3 CO-CHAIR FLEISHER: So it sounds
4 like, if we endorse this measure, that if the
5 risk model changes, then you would actually be
6 obligated to come back.

7 MEMBER AMARASINGHAM: I think I
8 would amend my word on the previous one.

9 CO-CHAIR FLEISHER: You can do
10 that. Amy, comment?

11 MEMBER ROSEN: I want to make a
12 comment on the risk adjustment methodology, in
13 that typically we don't include treatments or
14 -- I think it is listed up there as various
15 types of services, in the risk adjustment
16 model, because those are very subject to
17 physician practices.

18 So that is just a thought I want
19 to throw out there in terms of, if you are
20 thinking about doing it, perhaps now including
21 that in the risk adjustment model.

22 CO-CHAIR FLEISHER: Are those

1 measured during the episode of care, like
2 before?

3 DR. RASTOGI: That is right, and
4 some of the services that you mentioned like
5 durable medical equipment and all were
6 deliberately put in partly because they were
7 used as surrogate measures for the patient's
8 condition.

9 It is very hard to put in a
10 diagnosis code to say that they are wheelchair
11 bound, you know. So the DME was kind of a
12 surrogate to suggest that the patient was a
13 little more debilitated than another person.

14 So these were the type of
15 procedure or CPT codes that were put in.

16 CO-CHAIR FLEISHER: You almost
17 have an expert group who wants to help you
18 with your risk model, or at least see the Rand
19 paper when it is ready.

20 MEMBER ROSEN: One thing I want to
21 comment on is we are focusing a lot on the
22 risk adjustment, but I am concerned about the

1 PACs. Do you have -- What I am confused about
2 is exactly how they get defined for each
3 disease or each chronic condition and each
4 different type of disease.

5 Are there different PACs for
6 stroke, different PACs for AMI, and how does
7 that get determined? Who determines that? Is
8 there a clinical expert panel that meets? Is
9 there some kind of Delphi process that happens
10 or how does that work?

11 DR. RASTOGI: Yes. Some of it is
12 detailed in the document which Francois kind
13 of circulated called History of PAC
14 Development. So there were working groups
15 that were appointed for different ECIs which
16 gave their input, and then in some of the ECIs
17 where I got more input, I worked with the
18 physicians one to one, back and forth,
19 sometimes with a panel, sometimes with
20 individual physicians, to get the right
21 coding, circulated the documents to work with
22 them to get the input and feedback. So that

1 is how these came to be.

2 MEMBER ROSEN: I am sorry that I
3 missed that.

4 CO-CHAIR FLEISHER: Not a problem.

5 MEMBER ROSEN: It still makes me a
6 bit worried thinking about it, because you can
7 get a group of -- As you all know probably,
8 you can get a group of physicians in a room,
9 and you know, the next day another group of
10 physicians will come out with exactly the
11 opposite.

12 So to some extent, it is much
13 better that we are able to see both clinical
14 and empirical testing of outcomes that one
15 develops. So that is in the ideal world.

16 CO-CHAIR FLEISHER: Thank you.
17 Sean?

18 DR. O'BRIEN: At this time, I have
19 got one comment for the PAC measures and one
20 that is specific to AMI.

21 The one that applies to AMI is
22 that looks like patients undergoing CABG are

1 excluded, and it seems that is a factor that
2 is definitely under the control of the
3 provider and may be why certain types of units
4 or hospitals who promote CABG may have
5 different outcomes. You may adjust that away.
6 I guess I will stop there.

7 DR. RASTOGI: Yes. You may have
8 episode, but it is a very short episode. It
9 only has 30 days-plus and discharge period,
10 and patients who had to have CABG -- we
11 thought of them as slightly different than the
12 rest of the population with AMI, something to
13 the effect that mortalities are excluded, you
14 know.

15 We have to know that up front
16 going in, but we are looking at these PACs
17 only at patients with AMI who didn't have a
18 surgical intervention.

19 CO-CHAIR FLEISHER: Any other
20 comment?

21 DR. O'BRIEN: The second comment
22 is that there is a component endpoint which is

1 useful, but if you look at that, the later
2 statement in the submission basically says it
3 is a percent of patients. You capture
4 patients that have a PAC.

5 Then if you really want to un-PAC
6 it and know what is considered a PAC, you have
7 to go to the Excel file and look through all
8 these codes. There is not really any English
9 language, concise statement of what are all
10 the PACs that go into the PAC, and I think for
11 interpretation and reporting and transparency,
12 it is important to have kind of a more
13 understandable statement of what you are
14 measuring.

15 DR. RASTOGI: That is exactly
16 right, and I think Francois and Joyce already
17 talked, and they are going to write a one-
18 pager for each of these measures, so that for
19 public comment it becomes a little bit easier
20 to understand.

21 CO-CHAIR DUBOW: A crib sheet
22 version, I would guess.

1 CO-CHAIR FLEISHER: Yes. Any
2 other comments? Ted, do you have any other
3 comments, having heard this discussion, from
4 the perspective of the Steering Committee --

5 MEMBER GIBBONS: I just want to
6 comment that I think it points up the fact
7 that we need to keep reexamining how the risk
8 adjustment might change over time, but I think
9 that many of the --

10 CO-CHAIR FLEISHER: We are losing
11 you again.

12 MEMBER GIBBONS: I'm sorry. Many
13 of these comments really reflect the fact that
14 we have to keep track of how it evolves over
15 time. I haven't heard any comments that
16 depart significantly from the TAP discussion.

17 CO-CHAIR FLEISHER: Yes, thank
18 you. So are we ready to vote? Any other
19 comments? Any public comment? Hearing none--

20 DR. WINKLER: Okay, we will vote
21 the measures independently, so separately the
22 AMI, and then we will follow with the strokes.

1 So the first one we are going to
2 talk about is the AMI measure. So everybody
3 got that clear? So the first criterion is the
4 importance to measure and report. It is a
5 yes/no. How many say Yes? It is unanimous.
6 Okay. So that is 22.

7 All right, scientific
8 acceptability of the measure properties:
9 Completely meet criteria, how many? All those
10 for completely? Ten.

11 Partial? Twelve. Okay. That is
12 everybody.

13 All right, usability: Completely?
14 Completely for usability: Ten.

15 Partially? So everybody else?
16 Yes, it is everybody else.

17 All right, feasibility:
18 Completely? Fifteen.

19 Partially? Seven. that's it.

20 MEMBER JOHNSON: Never let it be
21 said that you don't get your exercise.

22 DR. WINKLER: It's lovely. Thank

1 you so much. So recommendation: Are there
2 any conditions?

3 CO-CHAIR FLEISHER: First, anybody
4 want to propose any conditions on the
5 recommendation? No. Okay, so it is a simple
6 yes or no vote. Those voting Aye?

7 DR. WINKLER: Twenty-one.

8 CO-CHAIR FLEISHER: No?

9 DR. WINKLER: Okay. One No. That
10 means no abstentions. Okay.

11 So now we move on to the stroke
12 measure, the same measure with the PACs for
13 stroke.

14 Importance to measure and report:
15 Yes? I am getting 19. So it is 19.

16 No? You are abstaining. Barbara
17 is gone. Okay, so you are going to 20, and
18 there is one abstention, and Barbara is out of
19 the room. Okay.

20 CO-CHAIR FLEISHER: Can you turn
21 the microphone off for Barbara?

22 DR. WINKLER: Okay. So for

1 scientific acceptability of the measure
2 properties, how many think it completely meets
3 the criteria? This is the stroke PAC measure,
4 completely meets criteria. Four.

5 Partially? Seventeen, and that is
6 everybody.

7 Usability: Completely? Four.

8 Partially: Seventeen. Yes, it is
9 everybody else.

10 Feasibility: Completely meets?
11 Fourteen.

12 Partially? Seven. That is
13 everybody.

14 So now the recommendation.

15 CO-CHAIR FLEISHER: Any
16 conditions? No. Okay. Those voting Yes?

17 DR. WINKLER: Yes for the measure?
18 Okay, so it is 20 Yes. Amy, your vote is a
19 No? Okay.

20 CO-CHAIR FLEISHER: So next could
21 we have the STS measure? I know we have Bruce
22 on the line.

1 DR. WINKLER: Bruce isn't from
2 SVS.

3 CO-CHAIR FLEISHER: No, Bruce --
4 He is next, ACS.

5 DR. WINKLER: Were we expecting
6 anybody?

7 CO-CHAIR FLEISHER: But Sean
8 should be able to -- Are you the methodologist
9 on the STS measures?

10 MEMBER GIBBONS: Yes.

11 CO-CHAIR FLEISHER: Okay.

12 CO-CHAIR DUBOW: Do we have anyone
13 from STS on the phone?

14 MS. HAN: This is Jane Han.

15 DR. WINKLER: Do we have the
16 measure up? This is a composite score of
17 endorsed measures for coronary artery bypass
18 from STS. This measure is a combination of
19 outcome and process measures that have been
20 endorsed by NQF for a while, several years,
21 actually.

22 So this measure presents a

1 composite methodology for combining these
2 measures into a single score. And that is
3 kind of what it is.

4 CO-CHAIR FLEISHER: That is it.
5 Do we have any comments from the TAP?

6 DR. WINKLER: They liked it.

7 CO-CHAIR FLEISHER: They liked it.
8 Okay. Sean, any comments? Any questions?

9 DR. WINKLER: One thing, I asked
10 Amy to take a look at this measure as a
11 methodologist to see if she had any comments
12 about the composite methodology.

13 CO-CHAIR FLEISHER: Just tell us
14 if you do vote no.

15 MEMBER ROSEN: So this -- It is
16 kind of interesting after sitting here
17 listening to some of the comments. But this
18 measure -- The composite includes both process
19 and outcome measures. So I want people to be
20 aware of that.

21 So we have -- So that is okay, but
22 just so that you know, we have the mortality

1 and morbidity measures as well as the
2 perioperative process of care measures and the
3 operative care measure. So those are all
4 included in the composite. The composite is -
5 - It is fine with me, but I just wanted to
6 point that out.

7 The composite is not weighted,
8 which is different from the other composites
9 we have seen, and again I kind of like that
10 myself, because I think that the weighting
11 schemes that we have seen here are really just
12 clinically based and isn't evidence of
13 empirical testing.

14 So as far as I am concerned,
15 weighting them equally is good, and I think it
16 is important to -- in thinking about a
17 composite measure, to think multi-
18 dimensionally, and I think looking both at
19 processes of care in relation to CABG surgery
20 is quite relevant.

21 What that does, however, on the
22 other side of it is that we lose focus on what

1 the specific outcome measures might be,
2 because we are looking multi-dimensionally.

3 So overall, I thought that there
4 was really adequate empirical testing as well
5 as clinical oversight, and that the developers
6 did a very nice job in putting the composite
7 measure together.

8 So maybe I should go to my room
9 now.

10 DR. SHAHIAN: This is Dave Shahian
11 from STS. Could I respond to the comments?

12 CO-CHAIR FLEISHER: Sure.

13 DR. SHAHIAN: Just wanted to point
14 out that, although we do roll up those process
15 and outcome measures to a single score, that
16 when we present the scores, they are presented
17 individually as well, and the providers are
18 also given a granular view of where they
19 failed specifically in the all or none process
20 measures to help them to inform their
21 performance improvement activities.

22 So we provide both the overall

1 score, but also a very detailed drill-down to
2 the component level.

3 MEMBER ROSEN: That is absolutely
4 correct, and I guess the thing that is
5 somewhat puzzling is this is used at the
6 provider level as well as the practice group
7 level and at the hospital level, and I don't
8 know to what extent comparing providers has
9 been tested statistically in terms of what
10 panel size providers would need.

11 It is very different to compare
12 providers versus hospital level measures.

13 DR. SHAHIAN: Well, let me just
14 comment on that. We base these scores on what
15 we call an STS participant. Now in the vast
16 majority of cases, an STS participant is a
17 hospital with a cardiac surgery program.

18 There are, however, instances in
19 which there may be, for example, two large
20 cardiovascular surgery groups within a
21 hospital that may decide to independently
22 contract with STS to have their results

1 measured and computed using the STS
2 methodology. But the unit of analysis is an
3 STS participant.

4 CO-CHAIR FLEISHER: Okay. Joyce
5 had a comment?

6 CO-CHAIR DUBOW: Well, I have a
7 question. That is interesting that it is an
8 STS participant. It means that that person
9 has to participate in the registry.

10 DR. SHAHIAN: That is correct.

11 CO-CHAIR DUBOW: There is a fee?

12 DR. SHAHIAN: That is correct.

13 CO-CHAIR DUBOW: Isn't that
14 correct?

15 DR. SHAHIAN: That is correct.

16 CO-CHAIR DUBOW: But that wasn't
17 my point.

18 CO-CHAIR FLEISHER: The percent of
19 people who participate in the registry is --

20 DR. BURSTIN: Over 90 percent.

21 CO-CHAIR FLEISHER: So 90 percent
22 of all CABGs, I think, are in the registry.

1 Correct? Sean?

2 CO-CHAIR DUBOW: Okay. But my
3 question has to do with my understanding that
4 the reporting of this measure is wrapped up in
5 the measure that we would be endorsing or
6 recommending for endorsement, because -- and
7 this is a question. I am just trying to get
8 it out.

9 That is unusual. We don't
10 normally -- This has the star. If you read
11 the presentation, this has the three stars
12 with 77 percent of physicians or STS
13 participants falling into the two-star
14 category, as I recall.

15 So that essentially this measure,
16 as I understand it, encompasses the way this
17 stuff is reported, the results are reported,
18 as well. Is that correct?

19 DR. SHAHIAN: Well, do you want me
20 to respond to that?

21 CO-CHAIR DUBOW: Please.

22 DR. SHAHIAN: That is the way we

1 submitted it, although each provider is also
2 given a numerical score, both overall and for
3 each of the four domains of the composite. So
4 one could use that numerical score.

5 Most of our providers have found
6 it useful to also have this star rating, which
7 we have developed and which has shown itself
8 to be fairly consistent among providers over
9 time, and also to correlate fairly well with
10 the performance in each of the individual
11 domains.

12 So, yes. I guess the answer to
13 your question is, yes, we did submit this
14 along with the star rating, because that is
15 the way it has been operationalized.

16 CO-CHAIR DUBOW: Okay. So as I
17 recall, the reporting is at the 99 confidence
18 interval, and I think that is what I remember
19 reading. But my question is whether the
20 ratings themselves are publicly available or
21 is it just the stars?

22 In other words, if a reporter

1 wanted to take the numeric values, would those
2 be available?

3 DR. SHAHIAN: I don't know whether
4 that has been in our discussions or if it was
5 Consumer Union and for our own internal
6 reporting.

7 One of the concerns we have, and I
8 have seen this, is that external entities
9 sometimes take numerical scores and do funny
10 things with them that they were never intended
11 to do. They may take, for example, the
12 patients that we categorize into three groups
13 and they may try to change them into some
14 other weighting system that may not be
15 appropriate.

16 So I would have a little bit of
17 concern about that. You know, we've spent an
18 awful lot of time doing pilot studies using
19 this three-star system. We have been using it
20 in practice now for over three years. We know
21 how it works, and we think it is sound, both
22 theoretically and in practice.

1 I guess my concern would be to put
2 numbers out there which somebody could
3 irresponsibly and incorrectly use.

4 CO-CHAIR DUBOW: Not to beat a
5 dead horse, I think we ought to consider --
6 You know, I think this is -- I would ask the
7 staff if this is not unusual, that we buy into
8 a reporting approach in addition to the
9 measure itself. I don't remember another
10 measure like that. So I wonder whether we
11 ought to separate them or whether we can
12 separate them. I don't know.

13 MEMBER AMARASINGHAM: Well, I am
14 just curious whether it is like some of the
15 Medicare measures that we have debated, that
16 they were validated deriving data on the
17 Medicare population. We are saying that this
18 was sort of derived and validated on STS.

19 CO-CHAIR DUBOW: We don't tell
20 Medicare how many stars to attach to a
21 hospital.

22 CO-CHAIR FLEISHER: So I would ask

1 David, so if this committee based -- One of
2 the potential votes is to endorse this on the
3 condition that the star rating not be part of
4 it. If that condition is required, would the
5 measure developer accept that?

6 DR. SHAHIAN: Well, I would think
7 we would want to seriously think about that,
8 and I would not want to make that decision
9 right now, because as I said previously, we
10 would be concerned about misuse of the raw
11 numerical data. So I think that is something
12 we would want to take under consideration.

13 CO-CHAIR FLEISHER: Okay. Well,
14 thank you. We will take that into
15 consideration as we go.

16 DR. SHAHIAN: Sean O'Brien who
17 worked with us and was very instrumental in
18 helping to develop it -- I realize that he is
19 an awkward position there today, but perhaps
20 for informational purposes you might ask his
21 opinion about the question we have been
22 discussing.

1 CO-CHAIR FLEISHER: So as your are
2 squirming in your seat, Sean, do you have a
3 comment?

4 DR. O'BRIEN: Personally, I think
5 NQF should go in the direction of endorsing --
6 All the aspects of reliability and validity
7 and usefulness can only be assessed in a
8 particular context. A measure has to be used
9 for a particular purpose. It needs to be
10 particular.

11 I think that, even if you want to
12 basically have a more broad description of
13 what you are endorsing, demonstrating that it
14 is useful in at least one particular
15 application is helpful.

16 So I think you can either take
17 this as an example of the usefulness of the
18 measure or you could decide to actually make
19 that example part of what is being endorsed,
20 either way. But I think it is a demonstration
21 of how it has been used in practice, and it
22 has actually been well accepted and used by a

1 lot of groups.

2 CO-CHAIR FLEISHER: Anne?

3 MEMBER DEUTSCH: I just want to
4 add that I actually like that they put effort
5 into making it more understandable potentially
6 to consumers. It helps us interpret the
7 information perhaps a little bit more, and so
8 what is an important difference.

9 One of the projects I do, we show
10 some people in senior centers some quality
11 measures that Medicare has put out, and we ask
12 them to interpret it, and some people say, oh,
13 only five percent difference, that is nothing.
14 Other people say, oh, five percent difference,
15 that is important.

16 So this, I think, actually helps
17 potentially people to interpret the data and
18 what is an important difference.

19 CO-CHAIR FLEISHER: Okay. New
20 comments? David?

21 MEMBER HOPKINS: I have some
22 questions and some comments.

1 So first question is for NQF: All
2 four of these elements, the individual
3 measures within the composite, have been
4 endorsed. Is that correct?

5 DR. BURSTIN: Correct.

6 MEMBER HOPKINS: Okay. Second
7 question for the developer: Did I understand
8 that the weighting of these four elements is
9 equal, is 25 percentage?

10 DR. SHAHIAN: Well, we did not
11 weight them, but by virtue of the variation in
12 each one of the individual domains, they were
13 standardized, and by virtue of that the
14 mortality measure does end up carrying more
15 weight within the composite. But we did not
16 start out by saying we want more mortality to
17 be weighted more heavily. It is purely a
18 function of the standard deviations.

19 MEMBER HOPKINS: Okay. So what
20 are the weights for these?

21 DR. SHAHIAN: Sean, do you want to
22 comment on that?

1 DR. O'BRIEN: We first
2 standardized each domain's score at a common
3 standard deviation, and then we applied equal
4 weights to those standardized scores. So in
5 that respect, the weights are one, one, one,
6 one, actually one-fourth, one-fourth, one-
7 fourth, and one-fourth.

8 MEMBER HOPKINS: Okay.

9 DR. O'BRIEN: Now it is also true
10 that there is no such thing as no weight. Any
11 weighting system, even if it is equal
12 weighting, has implications, and I think we
13 strived to make the implications by weights --
14 to understand them internally, and to publish
15 them and basically make them apparent.

16 Part of some of the implications,
17 as basically he is explaining, is that on the
18 original raw scale of mortality you have equal
19 weighting on the standardized scale, but that
20 implied unequal weighting on some other scale.
21 It is not possible to have equal weighting on
22 every single scale. If you have equal

1 weighting on one scale, you have unequal
2 weighting once you standardize them. So it is
3 a situation that has no solution.

4 So what we did is we basically
5 described the implications, and one percentage
6 point difference improvement on the mortality
7 scale for the mortality domain would
8 essentially increase a provider's score on the
9 composite about the same amount as an eight
10 percentage point increase in the morbidity
11 domain.

12 MEMBER HOPKINS: And how about the
13 use of IMA?

14 DR. O'BRIEN: Did you have the
15 numbers in front of you? I think it is
16 somewhere around 15 percent.

17 MEMBER DELLINGER: So what you are
18 saying is a difference of one is one standard
19 deviation for each of the elements?

20 DR. O'BRIEN: Well, I was saying a
21 one percentage point -- the difference between
22 a two percent mortality rate and a three

1 percent morality rate is going to have a
2 certain impact on your measure performance.

3 MEMBER DELLINGER: But you rate
4 one standard deviation away from the median as
5 the same in each of the four areas. Is that
6 what you are saying?

7 DR. O'BRIEN: Right. Well, we
8 took -- Each member has -- You calculate a
9 score, and we rescaled each score at a common
10 standard deviation. The way you do that is
11 you divide each score by its standard
12 deviation.

13 MEMBER BECKER: Could I ask -- Is
14 that methodology you just described
15 transparent and available to everybody?

16 DR. O'BRIEN: Yes.

17 DR. SHAHIAN: This was published
18 in detail three years ago. I think you have
19 the PDF of that.

20 CO-CHAIR FLEISHER: Sure. We want
21 to keep moving. Go ahead.

22 MEMBER HOPKINS: So, I'm sorry. I

1 have a printed version. I don't know where it
2 is in this package. Page 14 of something
3 shows a really interesting analysis of -- and
4 this is related to star ratings, actually --
5 of the stability of the star ratings.

6 I look at that, and I say only
7 half remained where they were. I appreciate
8 the fact that they didn't go down two levels
9 or up two levels. Page 79 in this one? Thank
10 you. But they changed by one, half of them.

11 Considering the fact that this is
12 built on 99 percent or 98 percent confidence,
13 to me, that suggests that there is something
14 screwy about weighting these particular
15 measures altogether.

16 I don't know how else to interpret
17 that. Sean, maybe you have a better way to
18 interpret it, but I thought that was really
19 unstable, and I question the scientific
20 acceptability of the composite.

21 DR. O'BRIEN: Well, I think if you
22 take this in context to other measures that

1 are out there and being used, it is actually
2 a measure that has a fair amount of precision.
3 We compared the outlier status when we are
4 classifying hospitals based on the same
5 rigorous Bayesian probability, just using
6 mortality, and there is basically no
7 discrimination.

8 Mortality is a measure that is
9 well accepted, widely used, and it basically
10 did not discriminate nearly to the extent that
11 the composite does. Now part of the reason
12 why the second year, when you are comparing
13 what you see in one year and the second year,
14 is that in the second year you also -- based
15 on this 99 percent probability.

16 Now a few of us said the second
17 year, do we believe that hospital was above
18 average or not. You know, based on a 50
19 percent criterion, you are really going to see
20 a situation where hospitals where you are 99
21 percent certain in the first year that they
22 are above average, and now we think they are

1 below average.

2 Basically, our best bet, you know,
3 is that these hospitals remained above
4 average. We weren't 99 percent certain. We
5 went from being 99 percent certain to slightly
6 below 99 percent certain, but we still made it
7 then 95 percent certain, 90 percent certain.
8 So in that respect, I think it was still in
9 okay shape.

10 CO-CHAIR FLEISHER: We need to
11 move on. Is there any last new comment?

12 MEMBER HOPKINS: I just want to
13 make a final comment on the issue that -- I
14 think it was Joyce brought up. If you are
15 going to tie the star rating system as
16 proposed and it is built on 99 percent
17 confidence, I can't in good conscious vote for
18 that as --

19 CO-CHAIR FLEISHER: You will have
20 a chance.

21 MEMBER HOPKINS: Okay. I'm just
22 making a statement for others to think about.

1 I think the consumer should decide
2 on what level of certainty they want, and
3 certainly not that level. It is out of step
4 with every other measure I can think of.

5 DR. O'BRIEN: We have -- Dave
6 Shahian can speak to this, but the Society of
7 Thoracic Surgeons got a lot of input from
8 users of the measure and addressed the topic
9 of using basically custom developed
10 probabilities other than 99 percent for some
11 applications, and you don't need to be 99
12 percent certain.

13 There's discussions of multiple
14 payers about whether this particular system
15 was working for them, and the feedback was
16 universally positive. So that level of
17 probability was working for the users to the
18 extent that they were able to tell.

19 The users are participants who are
20 receiving these as internal feedback report
21 and they are third party payers who are
22 gathering, basically, their data, voluntarily

1 reported them to the Society for Thoracic
2 Surgeons.

3 CO-CHAIR FLEISHER: Other issues
4 unrelated to the star rating? B.J.?

5 MEMBER TURNER: Just an
6 observation, that we are giving these guys a
7 pass, which I think is fine on process
8 measures, like prescribing a certain drug.
9 I'm just saying that, if that is the way we
10 get them in, then I am all for it. So that is
11 one point.

12 I would appreciate when we are
13 going to this more discrimination in telling
14 us about the exclusions, because it just says
15 whatever, contraindications to XY, and I am
16 trying to make sure that this is really
17 covering the bases. So in the future I would
18 like to know more about what you call an
19 exclusion.

20 CO-CHAIR FLEISHER: Dianne.

21 MEMBER JEWELL: So, actually, I
22 was going to point to this measure as a nice

1 example of how measure developers can specify
2 a composite that is outcome and process based,
3 and that is part of the issue, is we really
4 need the measure developers to be able to well
5 specify what their intent is, and then we also
6 have to be consistent in our scope.

7 I think those are -- That is what
8 we have done here. We are not passing
9 anybody. We have been clear about our scope,
10 and we have been clear about integrity of
11 process, and we are clear that the measure
12 developers have given us something that
13 reflects both of those things appropriately.

14 CO-CHAIR FLEISHER: Thank you. So
15 time to vote.

16 DR. WINKLER: All right. Four
17 criteria and then the recommendation. So for
18 composite measure for CABG, procedure.

19 CO-CHAIR FLEISHER: This is
20 criteria voting.

21 DR. WINKLER: So, importance to
22 measure and report: Yes?

1 CO-CHAIR FLEISHER: Uniform.

2 DR. WINKLER: Okay. So it is 22.

3 All right. Scientific

4 Acceptability of the measure properties:

5 Completely meets criteria for scientific

6 acceptability?

7 CO-CHAIR FLEISHER: Well, I think
8 you need to vote -- I think you could place it
9 in either. If you do not believe it is
10 scientifically valid, then it should be voted
11 partial or none.

12 DR. O'BRIEN: Currently, it is
13 reported as the actual number along with the
14 confidence interval. In addition to that,
15 there is a star.

16 MEMBER HOPKINS: That is important

17 CO-CHAIR FLEISHER: Do you want to
18 clarify that?

19 MEMBER HOPKINS: That is the
20 number in the confidence interval and the
21 star.

22 MEMBER AMARASINGHAM: But it is an

1 important point, in that I think it addresses
2 the original concern.

3 CO-CHAIR FLEISHER: So we will --
4 according to the group up here, we will say
5 that the star rating is part of usability, and
6 therefore, we do not include that in the
7 scientific acceptability. Is that okay, to
8 make a comment as part of the voting?

9 MEMBER HOPKINS: What we are
10 voting on has only the star rating?

11 CO-CHAIR FLEISHER: No, no, no.
12 No, what I am saying is that we will, as part
13 of the definition of our voting, say that we
14 consider the star rating part of usability and
15 not scientific acceptability. We will put
16 that condition on our -- So if you vote, you
17 will know that it has this comment that goes
18 forward up the chain.

19 DR. BURSTIN: It is specifically
20 under the usability section for this
21 discrimination.

22 CO-CHAIR FLEISHER: Go ahead.

1 DR. WINKLER: Okay. For
2 scientific acceptability, completely meets the
3 criteria? I get 15.

4 Partially meets criteria? Five.

5 Minimally? -- Oh, you have six?
6 Okay, I missed one. All right.

7 Usability: All right, completely
8 meets? I get a zero.

9 Partially? Fifteen, okay.

10 Minimally? Three.

11 Not at all? One -- I am still
12 missing one. It was 17 on the partial? Okay.

13 Now feasibility: Completely meets
14 criteria? Eight.

15 CO-CHAIR DUBOW: Withdraw one?

16 DR. WINKLER: Whose?

17 CO-CHAIR DUBOW: Mine.

18 DR. WINKLER: I didn't count you
19 yet. Okay, Partially? Twelve.

20 Minimally? That should be one.

21 Okay.

22 CO-CHAIR FLEISHER: And you must -

1 - You must be part of the registry to get this
2 data as opposed to other measures.

3 DR. O'BRIEN: Dave, feel free to
4 answer the registry conclusive -- we think 90
5 percent of the hospitals in the U.S. have a
6 marginal cost, separate from the fact we
7 already are collecting this data, getting all
8 kinds of reports. So the additional cost of
9 doing this composite is -- you know, there is
10 no additional cost.

11 MEMBER HOPKINS: That is fine if
12 you want to report at the hospital level. If
13 you want to report at the surgeon level, what
14 then?

15 DR. SHAHIAN: We don't calculate
16 this at the surgeon level.

17 CO-CHAIR FLEISHER: But this could
18 not be calculated independently of joining the
19 registry?

20 DR. SHAHIAN: That is correct.

21 MEMBER AMARASINGHAM: When you use
22 the 90 percent, though, you know, a lot of

1 hospitals don't perform bypass surgery. So
2 does that 90 percent include 90 percent of
3 those that perform bypass surgery or 90
4 percent of U.S. hospitals?

5 DR. SHAHIAN: Ninety percent of
6 the hospitals that -- Yes, about 90 percent of
7 the hospitals that perform cardiac surgery are
8 in the registry.

9 MEMBER YAWN: Yes. It is nowhere
10 near 90 percent of hospitals that perform
11 cardiac surgery.

12 MEMBER GERBIG: Will it continue
13 to be correct that surgeons can join.
14 Surgeons and hospitals can join, but hospitals
15 on their own cannot submit?

16 DR. SHAHIAN: No. A hospital can
17 be an STS participant. A surgical group can
18 be an STS participant, and in rare cases an
19 individual surgeon, and that is very rare.

20 Most commonly, it is a hospital
21 submitting its entire cardiac surgery results,
22 but occasionally it is a large surgical group.

1 CO-CHAIR FLEISHER: Okay. Now for
2 the vote. Any conditions that anyone wants to
3 put on the vote? Do you want to propose your
4 condition? Yes or no?

5 MEMBER KEALEY: I am still
6 confused by the star system. I don't quite
7 get it, why it has to be there.

8 CO-CHAIR FLEISHER: Well, that --
9 So you can propose that it is approved without
10 the star system? Are you proposing that?

11 MEMBER KEALEY: I am hoping that
12 maybe they can explain it one more time so I
13 can understand what exactly this is. I
14 thought it was just the stars, but then it
15 sounded like the numbers are being reported,
16 and so it is an either/or thing.

17 DR. SHAHIAN: The problem is that
18 the numbers for many people would be very
19 difficult to interpret, and as a way of making
20 the measure more usable for the general
21 public, we calculated what we believe to be a
22 very responsible system for differentiating

1 truly superior programs, programs that are
2 clearly having an issue, and the large
3 percentage of programs, about 75 percent, that
4 are statistically indistinguishable.

5 They may vary in certain
6 characteristics in certain domains, but it is
7 very hard to distinguish them statistically.
8 Frankly, it is our belief, and we have had
9 many external observers comment as well, that
10 this is pretty consistent with how we view
11 things clinically, that there are a few truly
12 superior places, a few programs, 10-15
13 percent, that are operating suboptimally, and
14 then the vast majority operating at a very
15 high level and not able to be distinguished
16 from one another statistically.

17 We think that works. It helps --

18 CO-CHAIR FLEISHER: I think we
19 have the point.

20 MS. HAUGEN: Just a comment from a
21 consumer standpoint. You know, one star, two
22 stars, three stars, I think, would be

1 interpreted as good, better, best, not as ---
2 I mean, one star here is below the mean, which
3 means it is poorer than what -- at least the
4 minimum we should be able to expect. That is
5 how I interpret this.

6 I don't know how this -- whether
7 this would be translated by the public on its
8 own in accordance with what the data is really
9 telling us, what the statistics are telling
10 us. So that is, I guess, a concern I have.

11 As you look at this -- I mean, the
12 layperson thinks, if they got one star, that
13 is pretty good, maybe not as good as the
14 third, but where I am maybe that is pretty
15 good, and that is not what this is telling
16 you.

17 DR. SHAHIAN: We never -- There
18 is no STS publication of any kind that has
19 ever said good, better, best or we would very
20 definitely state that, that one star is an
21 underperforming program.

22 MEMBER HAUGEN: Yes. I am just

1 saying -- I am taking it from saying the
2 layperson that looks at this -- I am not
3 saying that you have done that. But if you
4 look at this in isolation, that is the way
5 this type of mechanism -- and maybe there is
6 a different way of visualization, because
7 people will visualize this and interpret this
8 in that way. That is my perspective.

9 CO-CHAIR FLEISHER: Okay, thank
10 you. Any public comment before we vote?
11 Okay. I am going to take Chair prerogative
12 that we vote the measure as is, vote the
13 measure with the condition that the star
14 system not be part of the measure, the
15 endorsed measure, and vote against the
16 measure.

17 CO-CHAIR DUBOW: I just wonder
18 whether we should ask the developer whether --

19 CO-CHAIR FLEISHER: We did, and he
20 said maybe. He said he would have to go back.

21 MEMBER AMARASINGHAM: I think, if
22 you vote for the condition, you should vote

1 recognizing that it could get rejected.

2 CO-CHAIR FLEISHER: If we vote for
3 the --

4 MEMBER AMARASINGHAM: It means
5 that progress on this measure might be --

6 CO-CHAIR FLEISHER: Do we want to
7 vote -- Are you proposing we vote that they
8 respond to this and we re-vote, if they say
9 no?

10 CO-CHAIR DUBOW: No. I think what
11 we could do is -- I think we could express --
12 I think we could have an up or down vote on
13 the measure as it is currently presented, and
14 express some concern about the fact that this
15 reporting mechanism is tethered to the measure
16 itself.

17 My guess is that there is some
18 sentiment that the reporting mechanism is less
19 than ideal, doesn't sound as though it has
20 been tested among all users, just professional
21 users, but that the measure itself clinically
22 has a great deal of validity and importance.

1 So I would prefer to express some
2 concern rather than to see the measure go
3 down.

4 CO-CHAIR FLEISHER: Okay. So does
5 anybody -- Sean, you want to make a comment?

6 DR. O'BRIEN: I think a can of
7 worms was opened by accident that didn't need
8 to be opened, and worms could be put back in.

9 In the submission form that I
10 wrote, it says the STS CABG composite score.
11 Now the STS CABG composite score is the
12 backbone for the star rating system.

13 It is used by the Society of
14 Thoracic Surgeons, but I think everyone would
15 be very happy if there was a vote made on the
16 STS CABG composite score as a submitted
17 measure, and then no one needs to discuss the
18 star. You are happy to have implementation
19 issues be a separate implementation issue.
20 Let it be a separate implementation issue, and
21 you don't need to specify we don't like the
22 star rating system, we do like it, and it is

1 a separate issue.

2 CO-CHAIR FLEISHER: Yes. Okay.

3 Yes, David?

4 DR. SHAHIAN: I would just want to
5 know what the implications of that were,
6 because we have worked very hard to create the
7 star system, to have it in operation for
8 several years, and if this vote means that the
9 star system has no NQF endorsement, then I
10 think we would want to come back and talk to
11 you about that.

12 DR. O'BRIEN: I don't think anyone
13 is going to be -- It is going to be that the
14 STS CABG composite score is endorsed, and that
15 is going to be what is desirable.

16 CO-CHAIR FLEISHER: Is that --

17 DR. O'BRIEN: I suspect that you
18 wouldn't be in a law suit against STS if six
19 months from now that the score itself was not
20 publicly reported. This score --

21 DR. SHAHIAN: You know, it makes
22 it really awkward for the STS, which reports

1 this and is going to report it publicly using
2 the star rating -- It makes it very awkward
3 for us to try to explain, well, the STS
4 composite score is endorsed, but the star
5 rating system, which is what you are seeing,
6 isn't endorsed. That is very awkward.

7 CO-CHAIR FLEISHER: Okay. So what
8 I am hearing is a proposal to have two
9 separate votes. One is to endorse the measure
10 as written and, two, to separately vote on the
11 star system; and the measure developer can
12 deal with -- There is still public comment.
13 there is still responses, and there is still
14 CSAC. Is that what you are proposing, Joyce?

15 CO-CHAIR DUBOW: I think what Sean
16 is proposing makes sense. If we endorse a
17 measure with the STS score, that seems to be
18 the guts of the methodology. The reporting is
19 -- we have not taken -- We don't -- So I think
20 that whatever STS decides to do on reporting -
21 - So just severing the two seems to be
22 acceptable to Sean. I think he proposed it.

1 CO-CHAIR FLEISHER: Then do we
2 vote on --

3 CO-CHAIR DUBOW: No, no.

4 CO-CHAIR FLEISHER: Well, the
5 question is would we then not vote or vote,
6 vote on the reporting mechanism, since we have
7 suggested that we don't endorse reporting
8 mechanisms?

9 MEMBER YAWN: Can't we just make a
10 comment? I mean, we vote it up or down as --
11 not the reporting, just the measure, and then
12 re have every right to make a comment saying
13 we don't like the star system, we don't
14 believe it is as transparent as they think it
15 is. End of story.

16 CO-CHAIR FLEISHER: And we will
17 take a simple vote on that to give the
18 strength of that.

19 MEMBER HOPKINS: As a separate
20 question we haven't dealt with.

21 CO-CHAIR FLEISHER: Yes.

22 MEMBER HOPKINS: So, Reva, the

1 measure we re voting on is just a simple
2 measure. Right? The STS composite? Are we
3 voting on it exclusively as a measure of
4 hospital performance or more generally that
5 could be applied to physicians, if they were
6 willing? That is my question.

7 DR. WINKLER: This is submitted at
8 the practice -- of either the group practice
9 or hospital level. It was not submitted as an
10 individual surgeon measure, and that is what
11 we are evaluating it for.

12 MEMBER HOPKINS: I'm just trying
13 to understand the implications. No one could
14 take it -- Even STS couldn't take it and apply
15 it to an individual surgeon, if they wanted to
16 and say it was an endorsed measure.

17 CO-CHAIR FLEISHER: The latter
18 half is the important condition. They could
19 do it, but it wouldn't be endorsed.

20 MEMBER HOPKINS: I understand the
21 restriction. We haven't heard it. I
22 understand sample size issues, but --

1 CO-CHAIR DUBOW: The measure
2 developer didn't propose it.

3 MEMBER HERMAN: And most places,
4 when they look at it, do do it by the
5 individual surgeon level, because if you have
6 an issue with your measure, you have to have
7 a place where you can go.

8 CO-CHAIR FLEISHER: And actually,
9 cardiac surgery is a group sport, because it
10 is a team, the ICU, the ward care, the nursing
11 care, the perfusionist. So let's vote.

12 So we are going to vote on
13 endorsing the measure at the practice level or
14 hospital, yes or no, simple vote. Then you
15 are separately going to vote as just a simple
16 recommendation, and the strength of that
17 recommendation with regard to the star rating.

18 So how many vote yes for this
19 measure?

20 DR. WINKLER: It is everybody.

21 CO-CHAIR FLEISHER: Okay.

22 Secondly, how many people vote that the star -

1 - the implementation using the star system --
2 how many people vote that they should
3 reconsider that? I don't know if you want to
4 propose --

5 MEMBER AMARASINGHAM: A
6 clarification. It is going to be reporting
7 with the star system, the point estimate and
8 the confidence interval? That what my
9 understanding was. Right, Sean?

10 CO-CHAIR FLEISHER: The reporting
11 actually is the point estimate --

12 CO-CHAIR FLEISHER: It would be
13 everything in the form right now.

14 DR. O'BRIEN: Dave Shahian should
15 speak up, but I think that the idea -- It
16 sounds like STS is interested in receiving
17 endorsement for the whole package -- sorry,
18 for the star rating system. So it sounds like
19 there is -- can the endorsement apply to the
20 star rating system as well?

21 DR. SHAHIAN: Well, we would
22 report the point estimate and confidence

1 intervals. We will continue to use the star
2 rating, and you know, what you decide to do in
3 terms of a recommendation is fine, and we will
4 certainly take a look at it, but we have so
5 much experience with this now that I think we
6 will likely continue it.

7 CO-CHAIR FLEISHER: So I am not
8 even going to take a vote. I am going to
9 propose, unless anybody disagrees, that there
10 will be a comment that significant concern was
11 expressed by the committee of the utilization
12 of the star system for implementation, and
13 just leave it at that.

14 That doesn't say significant
15 concern was expressed. Anybody disagree with
16 that statement? That doesn't mean some people
17 endorsed it. Okay.

18 Let's go to the final measure --
19 What?

20 DR. WINKLER: Well, actually, we
21 have three more.

22 CO-CHAIR FLEISHER: No, no, no,

1 but I mean the final cardiovascular measure on
2 post-operative stroke or death after carotids.

3 DR. WINKLER: Is somebody from the
4 Society of Vascular Surgeons with us?

5 SVS REPRESENTATIVE: Yes, Josh --

6 DR. WINKLER: Thank you. Okay.
7 So this measure, which is 0T1-011-09 -- This
8 is the percentage of patients without carotid,
9 neurological, retinal symptoms as a baseline,
10 within 12 months immediately preceding their
11 carotid endarterectomy who then experience
12 stroke or death after undergoing the
13 procedure.

14 CO-CHAIR FLEISHER: The year is
15 the pre-op period.

16 DR. WINKLER: Right. That
17 establishes the baseline.

18 CO-CHAIR FLEISHER: I thought it
19 was 30 days.

20 DR. WINKLER: I wanted to say it
21 is, too. I have to go look.

22 CO-CHAIR FLEISHER: Can the

1 developer comment? What is the post-operative
2 surveillance for stroke?

3 SVS REPRESENTATIVE: It was
4 intended to be in hospital.

5 CO-CHAIR FLEISHER: In hospital?
6 Thank you.

7 DR. WINKLER: During
8 hospitalization.

9 CO-CHAIR FLEISHER: In fact, that
10 was the comments from the TAP.

11 MEMBER YAWN: Could we ask how
12 long is an average stay in the hospital.

13 CO-CHAIR FLEISHER: Two days. Two
14 days, I'm sure. So, Barbara, we need the
15 microphone, but the question was how long do
16 they stay in the hospital, and is that an
17 appropriate measure?

18 If I remember the comments from
19 the TAP, there were some comments. So, Ted,
20 are you still there?

21 MEMBER GIBBONS: yes, I am.

22 CO-CHAIR FLEISHER: Can you

1 comment?

2 MEMBER GIBBONS: Yes. I think we
3 were thinking that the likely time of
4 observation should be longer than the in-
5 hospital stay, because the time may need to be
6 extended. The recognition of the stroke is of
7 paramount importance, because these are
8 individuals who enter surgery asymptomatic.

9 CO-CHAIR FLEISHER: Okay.

10 Comments? Barbara?

11 MEMBER YAWN: Do we have data on
12 what is the rate of stroke within 24 or 48
13 hours and within 30 and 60 days?

14 DR. HERMAN: Yes, we do.

15 MEMBER YAWN: Okay.

16 CO-CHAIR FLEISHER: Was there
17 concern from the TAP that this was acceptable
18 with this short a time frame?

19 MEMBER GIBBONS: I think, in terms
20 of the ability to define it based on stent
21 data, that that would be --

22 If I could comment, one of the

1 major concerns in the TAP was the differences
2 in the evolution of practice patterns for
3 carotid disease being treated with stenting
4 versus surgical endarterectomy, and that the
5 decision to do so was increasingly made, and
6 justifiably so, by the surgeon, who may not
7 only be involved with direct surgical
8 endarterectomy but with the placement of the
9 stent in collaboration with interventional
10 radiology or interventional cardiology, and
11 that the measure itself may need to be
12 revisited as the practice pattern changes
13 fairly quickly over the next few years.

14 CO-CHAIR FLEISHER: Other
15 comments?

16 MEMBER PINDOLIA: I'm sorry. I
17 don't see that figure in there. I still don't
18 see 24 hours post, 48 hour or 30 days post.
19 It just has in the hospital is 1.3 percent,
20 and then 1.7 percent, but it doesn't have the
21 extrapolation of how far out DC.

22 CO-CHAIR FLEISHER: Any other

1 comments, because we have a public comment.

2 No? Please.

3 DR. JEWELL: -- and that one of
4 the issues is who is making the assessment and
5 the determination that there has been a
6 stroke, that sometimes the reliability of the
7 surgeon making the diagnosis is not the same,
8 and the studies have shown that you get
9 different rates, depending on who you have
10 making the diagnosis and whether they are
11 using a standardized scale or whether it is a
12 neurologist or an internist making the
13 diagnosis, and that this as an outcome measure
14 from a consumer perspective makes a difference
15 who is making the diagnosis to report the
16 outcome.

17 CO-CHAIR DUBOW: Do we have a
18 reaction from the developer? Could the
19 developer respond to that, please?

20 SVS REPRESENTATIVE: Yes, thank
21 you. First, let me just respond to the
22 question about the percentage of strokes that

1 occur within 30 days, that occur in the
2 hospital.

3 In our registry it is about 94
4 percent. So that it does -- In-hospital data
5 really captures quite well the stroke rate,
6 post-operative stroke rate, and our concern
7 was that the data would be unreliable at the
8 30-day time point.

9 In terms of the question about who
10 is making the assessment, there have been
11 studies that show that, if a patient is in a
12 randomized trial or a neurologist sees the
13 patients that the rate of detection of small
14 strokes is higher. However, hospitals are
15 incented to record post-operative stroke,
16 because it increases the complexity of the
17 patient and, therefore, the billing.

18 Other measures that currently are
19 in existence at CMS, such as their measure 166
20 which is stroke after cardiac surgery or after
21 coronary bypass -- there is no specification
22 made in that measure at all about how the

1 stroke is measured. In fact, it isn't even
2 well defined. So at least by current
3 measures, we think we are meeting the same
4 standard.

5 MEMBER AMARASINGHAM: Let me just
6 make sure I understand it. Are you suggesting
7 that there is an incentive to up-code?

8 SVS REPRESENTATIVE: Yes.

9 MEMBER AMARASINGHAM: So that is a
10 legal --

11 CO-CHAIR DUBOW: You are
12 accurately coding.

13 SVS REPRESENTATIVE: Accurately is
14 what I mean.

15 MEMBER NEWCOMER: His point was
16 that hospitals had a legitimate reason to
17 search for legitimate strokes because they
18 would be up-codes. So there should be a
19 higher capture rate, is all, not that they are
20 defrauding.

21 CO-CHAIR DUBOW: No, I think it
22 responds to the question, that there is an

1 incentive to capture them properly.

2 MEMBER FILLIPO: But the hospital
3 can't code it until the physicians document
4 it, that it is a stroke. I mean, the coder
5 can't go through and say it is a stroke. I
6 mean, the physician has to document that it is
7 a stroke.

8 MEMBER DELLINGER: But it is a
9 Medicare rule, but the hospital can certainly
10 prompt the physician to make sure the
11 diagnosis is made. They can query the
12 physician. That is certainly done in my
13 hospital.

14 MEMBER FILLIPO: Absolutely.

15 DR. JEWELL: Except now you have
16 the opposite incentive. If it is going to be
17 reported as an outcome and be a negative, then
18 it goes against how much difference are you
19 going to get for the DRG.

20 CO-CHAIR DUBOW: Well, look, I
21 thought your question was whether these
22 strokes were going to be properly reported.

1 The response was that indeed there is every
2 incentive for them to be reported properly,
3 because there is an incentive to do it. So
4 that seems to answer the question that you
5 posed.

6 DR. JEWELL: The TAP brought it
7 up, that there would be the counter-incentive
8 as well.

9 CO-CHAIR DUBOW: Okay.

10 MEMBER KEALEY: I was just going
11 to say, this creates the other side of the
12 coin, and as frequently we see, there is
13 competing interests with payment and accurate
14 diagnosis. I see this in health grades all
15 the time with how thorough these document
16 post-op issues, because they will be seen as
17 complications and make you look bad, but they
18 might improve your payment. What do you do?

19 MEMBER NEWCOMER: Your hospital
20 administrator has an easy answer for that.

21 I want to comment about the
22 denominator. It simply says carotid

1 endarterectomy, but there is very high
2 interoperative variation in the indication for
3 this test -- or for this procedure, and we
4 don't adjust for that anywhere that I can see.

5 I am a little worried about that
6 denominator being so vague that we won't get
7 a decent result. So I would argue against the
8 scientific validity of that measure.

9 MEMBER DELLINGER: Well, it is not
10 every carotid endarterectomy. It is carotid
11 endarterectomy in a patient who has had no
12 logic symptoms for 12 months before the
13 operation.

14 MEMBER NEWCOMER: You can't tell
15 that from the coding. Well, I guess you can
16 with the G code. Okay.

17 CO-CHAIR FLEISHER: Barbara?

18 MEMBER YAWN: I'm fascinated by
19 the fact that people believe, with apparent
20 great accuracy about the ability to say this
21 patient has been totally asymptomatic, but
22 they don't think that they can reliably

1 identify strokes in 30 days.

2 I'm sorry. That doesn't wash with
3 me at all, and I would be very interested in
4 60 and 90 days out and what those data are,
5 too, because if these were truly asymptomatic
6 patients, you do something and now they have
7 a stroke in the next year, they should be at
8 quite low risk for that.

9 CO-CHAIR DUBOW: But the measure
10 we have before us is short frame measure --

11 MEMBER YAWN: I understand.

12 CO-CHAIR DUBOW: -- and we just
13 heard that that accounts for 90 percent of the
14 strokes under these circumstances. So --

15 MEMBER YAWN: Up to 30 days, yes,
16 we heard that.

17 CO-CHAIR DUBOW: Right. So that
18 is the measure we have before us.

19 MEMBER YAWN: I understand. I am
20 just suggesting there might be reasons not to
21 vote in favor of it.

22 MEMBER KEALEY: Is that a

1 different -- The 94 percent is kind of a
2 national average. At a place where they don't
3 do them so well, suddenly that becomes 80
4 percent. So is this a differentiated that we
5 are automatically getting rid of?

6 CO-CHAIR FLEISHER: Okay. Lee,
7 last comment.

8 MEMBER NEWCOMER: Sorry, but could
9 the developer tell me on how they would choose
10 these carotid endarterectomies? What is the
11 criteria for this patient being an operative
12 candidate? It is not there.

13 SVS REPRESENTATIVE: Really, that
14 underscores why this measure is so important,
15 because neurologists and surgeons together
16 make decisions to recommend this surgery or
17 perhaps in the future stenting when that is
18 approved for asymptomatic patients, based on
19 the severity of this analysis and all the
20 other factors that would influence morbidity
21 and, therefore, the outcome has to be really
22 good.

1 That is why we think it is so
2 important to keep track of this, even at the
3 in-hospital level, which would provide the
4 consumer, I think, with great data that is
5 just simply not available now.

6 MEMBER NEWCOMER: I am going to
7 argue this surgery is a morbidity, and you
8 could definitely have your post-op morbidity
9 decline by operating nothing but healthy
10 carotids -- I mean, to be extreme. I just
11 can't find validity.

12 CO-CHAIR FLEISHER: It is time to
13 vote on the criteria.

14 DR. HALL: Are you ready for
15 public comment?

16 CO-CHAIR FLEISHER: We opened it
17 up. Is there other public comments?

18 DR. HALL: This is Bruce Hall. I
19 just had a question on the measure
20 specification. Again, it is a question I have
21 asked repeatedly during the day.

22 I do not see data on reliability.

1 The measure developers talk about information
2 like this. We do see rates from about 4.1
3 percent, a 3.8 percent and so on. I know
4 those numbers may differ in different
5 situations.

6 A great proportion of the
7 hospitals across the country are going to do
8 a significant number of these cases, to the
9 degree that they can be reliably assessed on
10 this outcome that is probably going to be
11 under 3 percent.

12 Furthermore, the measure is
13 supposed to be eligible for provider physician
14 level as well. How do we know what the
15 reliability distinctions between physicians
16 and how many physicians do enough of these
17 cases to be reliably judged?

18 CO-CHAIR FLEISHER: Okay, thank
19 you, Bruce. Reva, do you want to go over
20 criteria?

21 DR. WINKLER: All right. For the
22 criteria, for this measure of stroke after

1 carotid endarterectomy: Importance to measure
2 and report: Yes? All those that say yes?
3 All but Barbara and Lee. Okay.

4 So how many No? There they are.

5 So that's 20. All right.

6 MEMBER YAWN: That is as
7 specified.

8 DR. WINKLER: Scientific
9 acceptability of this measure as specified:
10 Completely meet the criteria? Two, okay.

11 Partially meet the criteria?
12 Nine.

13 Minimally meet the criteria?
14 Nine.

15 CO-CHAIR FLEISHER: Doesn't meet
16 the criteria, two.

17 DR. WINKLER: Definitely on the
18 low end.

19 Usability: Completely meet the
20 criteria? I see zero. I'm sorry, David. So
21 one.

22 Partially meet the criteria of

1 usability? Thirteen.

2 Minimally meet the criteria of

3 usability? Six. That's 20.

4 Not at all? Two, okay.

5 Feasibility: completely meets the

6 criteria? Three.

7 Partially meets the criteria?

8 Twelve.

9 Minimally? Five.

10 Not at all? Okay. All right.

11 CO-CHAIR FLEISHER: Call for a

12 vote. Any conditions? No. Those in favor of

13 the measure?

14 DR. WINKLER: Five.

15 CO-CHAIR FLEISHER: Those opposed

16 to endorsing the measure?

17 DR. WINKLER: Seventeen. That's

18 everybody.

19 CO-CHAIR FLEISHER: Thank you.

20 Okay, last two measures as the day continues.

21 Bruce, you are still there, obviously. We are

22 on to the two ACS measures.

1 The risk adjusted colorectal
2 surgery outcomes measure. Was that one of the
3 other times?

4 DR. WINKLER: Yes, it actually
5 was.

6 CO-CHAIR FLEISHER: It was done in
7 the GI TAP?

8 DR. WINKLER: Yes.

9 CO-CHAIR FLEISHER: David, did you
10 -- Was David the Chair of that?

11 DR. WINKLER: Yes.

12 CO-CHAIR FLEISHER: David, do you
13 have any comments on that measure from the
14 TAP's perspective?

15 MEMBER JOHNSON: The measure was
16 viewed favorably.

17 CO-CHAIR FLEISHER: Not on mike.

18 MEMBER JOHNSON: The measure was
19 overall viewed favorably. It was defined
20 need, and the only question was the
21 participation in the Ethnoscript database, and
22 that there was a mechanism to account for

1 participants that maybe weren't participating
2 in the Medscript database. So that the
3 developer addressed that and provided a
4 pathway for that. So overall, the impression
5 was favorable.

6 CO-CHAIR FLEISHER: So just to
7 recognize that, unlike the STS measure, the
8 ACS measures -- the hospital does not have to
9 be a participant in the registry.

10 Any questions? Patch?

11 MEMBER DELLINGER: Yes. The STS
12 criteria are very rigorous and not that easy
13 to do. So I am quite -- sorry, NSQIP. NSQIP
14 criteria are very strict. I am quite curious
15 as to how a non-NSQIP hospital could get
16 measured by this NSQIP criteria.

17 CO-CHAIR FLEISHER: Bruce, I know
18 you have answered this before. Would you --
19 but not for the whole Steering Committee. Do
20 you want to address that?

21 DR. HALL: Sure. Thank you. I
22 have been on the call all day, and I have

1 appreciated hearing all of the discussion up
2 to this point.

3 The measure before you is a very
4 parsimonious measure. It is specified with a
5 small number of data points, and it is
6 specified with a subset of colorectal -- and
7 also a small number of outcome endpoints. So
8 any implementation of the measure would be
9 accompanied by education about how each of
10 those risk factors or outcomes is defined and
11 applied, but the measure before you is a very
12 parsimonious model, and we have given very
13 specific estimates of what we think the
14 reporting value would be.

15 MEMBER JOHNSON: The other point
16 that was recognized is that, although the
17 NSQIP participants weren't necessarily uniform
18 100 percent, the people that were doing the
19 colorectal surgery represented 85 percent of
20 the eligible surgeries already. So the
21 majority of surgeons were already
22 participating.

1 CO-CHAIR FLEISHER: Other

2 comments? David?

3 MEMBER HOPKINS: The measure as

4 stated is for what level of measurement?

5 Hospital, group, physician?

6 DR. HALL: Institutional.

7 MEMBER HOPKINS: Hospital only.

8 CO-CHAIR DUBOW: Page one, the

9 summary provides the level of analysis, thanks
10 to Heidi.

11 CO-CHAIR FLEISHER: Other

12 comments? Public comment? Reva?

13 DR. WINKLER: Okay. So importance

14 to measure and report on a measure of

15 colorectal surgery; so importance to measure

16 and report, Yes? Is that everybody? Is there

17 anybody voting no? Okay, good. All right.

18 Scientific acceptability of the

19 measure properties for this measure as

20 specified: Completely meets criteria?

21 Eleven.

22 Partially meets criteria? Eleven.

1 That is everybody.

2 Usability: Completely meets
3 criteria? Criteria for usability. Eleven,
4 completely.

5 Partially? Eleven. So that is
6 everybody. Okay.

7 The last one is feasibility:
8 Completely meets feasibility criteria? Seven.

9 Partially? Thirteen.

10 Minimally? Two. Okay.

11 CO-CHAIR FLEISHER: Conditions
12 before we vote? None. Hearing none, all
13 those in favor of endorsing this measure? It
14 is unanimous.

15 DR. WINKLER: Okay, great.

16 CO-CHAIR FLEISHER: Thank you. We
17 have one measure left. This is a similar
18 mini-NSQIP measure. It is risk adjusted care
19 mix adjusted elderly outcomes measure
20 developed by the American College of Surgery.
21 It was discussed extensively at the TAP, and
22 essentially, this is a mixed group of surgical

1 procedures similar to the previous measure.

2 It was actually -- Bruce had explained the way
3 that non-NSQIP hospitals could actually
4 calculate it, because I believe there is only
5 two criteria for risk adjustment. So it is
6 relatively simple. Did I get that right,
7 Bruce?

8 DR. HALL: It is a very small
9 set. I think there are -- In total, if you
10 include demographics and what-not, you are
11 talking about half a dozen factors.

12 CO-CHAIR FLEISHER: Right.

13 CO-CHAIR DUBOW: Could you tell
14 me if this includes hip fractures?

15 DR. HALL: Yes, that was a
16 particular question during the TAP. So at
17 first NSQIP approaches, multi-trauma and
18 severe trauma patients are not eligible to
19 take part in NSQIP, but isolated trauma such
20 as fall from standing or slip from standing
21 that might be associated with a hip fracture,
22 which is relative to this population, would be

1 included.

2 So the way to think about it in
3 the shorthand, it is just that, if you fall
4 from standing and fracture your hip, you would
5 meet it. If you fall off the roof of your
6 house and fracture a hip, then you are out.

7 CO-CHAIR DUBOW: Okay.

8 CO-CHAIR FLEISHER: The TAP
9 actually felt, as far as gap in measures or
10 future research, that a hip fracture measure
11 independent of this measure should be
12 developed, and they actually felt that quite
13 strongly. So that -- Based on Joyce's
14 question, if the Steering Committee also
15 agrees with that, we will -- no, not as a
16 condition -- a recommendation. Yes, Dianne?

17 MEMBER JEWELL: Actually, no. I
18 would ask, given that the Bone and Joint TAP
19 received no measures for consideration, and
20 hip fracture is one of the specific conditions
21 that is identified, I think it would be a
22 helpful message to send that we really want a

1 specific hip fracture measure.

2 CO-CHAIR FLEISHER: So the
3 question to Bruce -- I don't know if in NSQIP
4 or if NSQIP could work with the orthopods to
5 develop such a measure.

6 DR. HALL: Well, I will just
7 reemphasize that this measure before you is
8 based on the standard approach. So it does
9 include, you know, at least the portion of the
10 population that I described to you.

11 NSQIP does not approach severe
12 trauma patients. There is a quality registry
13 within the American College of Surgery, the
14 trauma QIP, the TQIP which does more severe
15 injury patients.

16 I don't know if I am speaking out
17 of turn -- I don't think so, but certainly,
18 the College would be happy to use the TQIP
19 resources and to work with orthopedics in the
20 future to that end, but I don't think that is
21 feasible as a condition for the measure that
22 is in front of you.

1 CO-CHAIR FLEISHER: No, no, no. I
2 think what is being asked, Bruce, is that hip
3 fracture, similar to colorectal -- we may want
4 to pull out, and we are asking that you
5 consider developing a hip fracture specific
6 measure very similar to colorectal in the
7 general measure, given its public health
8 importance and Medicare issues. Barbara?

9 MEMBER YAWN: And I think that the
10 idea of hip fractures only from standing or
11 sitting is really a subset of the non-major
12 trauma hip fractures. I mean, some of us were
13 walking and went down one step and fractured
14 something, not --

15 DR. HALL: Again, that would be
16 included. If it is not a fall from height,
17 that would an included case.

18 MEMBER YAWN: Okay. So your
19 measure is broader than you suggested.

20 DR. HALL: I was trying to give a
21 shorthand. So the fall from standing or
22 walking, that is in; fall from height, off a

1 roof, that would be out.

2 CO-CHAIR FLEISHER: So the other
3 Barbara.

4 MEMBER TURNER: I am interested in
5 the breadth of surgical conditions that are
6 being covered, and the fact that some
7 institutions may have -- I don't know --
8 mostly neurological procedures, and other
9 institutions might have thoracic CNS things.

10 CO-CHAIR FLEISHER: Right. So
11 that actually was one of the major concerns of
12 the TAP.

13 MEMBER TURNER: And?

14 CO-CHAIR FLEISHER: Bruce, comment
15 on how you judge the severity of surgery, so
16 to speak.

17 DR. HALL: Certainly. So first of
18 all, there is a full CPT list of
19 specifications for the measure, and that is
20 submitted. I'm sure you are not looking at it
21 at the moment. But the concern about
22 standardizing across surgical procedures is a

1 very insightful one.

2 The approach we have taken to that
3 is that we have dropped all of the CPT codes
4 that are eligible for this measure into
5 clinically related buckets based on their CPT
6 coding. So in other words, two colorectal
7 surgeries that are different versions or, for
8 instance, would be in the same clinical
9 bucket.

10 So we have identified roughly 135,
11 136 if you include the category of "other,"
12 clinical buckets that all the CPT codes fall
13 into, and then each of those buckets is run as
14 an initial regression against the outcome.

15 We take the results of that
16 initial regression and generate a scale of
17 risk score. That scale of risk score
18 effectively gives you a measure of the
19 endogenous risk of that procedure.

20 So a urologic procedure all by
21 itself, all other things equal, has a very
22 different risk than a hip fracture or a

1 colorectal procedure. But each procedure
2 bucket is given its own scale of risk score,
3 and those scores are then used in re-
4 regression in conjunction with the other risk
5 adjustment variables and in conjunction with
6 the relative value units of scientific code.

7 So what that gives us is an
8 ability to standardize across procedures. So
9 if one institution did a procedure that had
10 endogenous the lowest and another institution
11 has high risk procedures by definition, then
12 we control for that mix.

13 That is why the measure is
14 referred to not just as patient risk adjusted
15 but also case mix adjusted for the
16 institution.

17 CO-CHAIR FLEISHER: Sean -- Well,
18 you reviewed this, but let B.J. finish.

19 MEMBER TURNER: Well, just to
20 respond. The same issues come up with how
21 many populations you have looked at, your case
22 mix stratification approach. Is it just one -

1 - same idea as we went through with the
2 severity of illness measure issues.

3 DR. HALL: So the measure in front
4 of you has been developed using historical
5 NSQIP data, even though participation in NSQIP
6 is not required to fulfill the measure. So
7 all of the coefficients and the reliability
8 assessments and so on are all developed from
9 historical NSQIP data.

10 CO-CHAIR FLEISHER: Okay, Sean, do
11 you have any comments? You did review this?

12 DR. O'BRIEN: Yes, I did review
13 it. In terms of my comments, I didn't see
14 much in the way of assessing calibration of
15 the model. They assessed calibration with a
16 Hosmer-Lemeshow statistic, but they also
17 commented that with such a large sample size,
18 a significant Hosmer-Lemeshow test p value,
19 which would ordinarily indicate lack of fit,
20 is not meaningful, because no model is
21 actually literally a perfect fit. So often
22 Hosmer-Lemeshow is just a measure of how large

1 your sample is. But even when you have --
2 when the Hosmer-Lemeshow is not meaningful,
3 there's other ways to assess calibration
4 graphically.

5 Typically, very often you will
6 report comparisons of the observed to expected
7 outcomes within subgroups or by deciles of
8 predicted risk, and I was curious to know if
9 the developers had done those types of
10 analyses.

11 Because the populations for these
12 two measures are relatively broad, assessing
13 fit, not just globally, that also important
14 subgroups would be warranted, and also this
15 will be in the DRG group, since the DRG
16 basically entered into the model is a two-step
17 estimation procedure where they estimate --
18 you know, they basically get an estimate for
19 each DRG, but that goes into the model in the
20 second stages, kind of a linear term where you
21 are basically assuming that, if you have a --
22 You have a continuous variable, and basically

1 you are making linearity assumptions. So it
2 would be worth assessing that.

3 CO-CHAIR FLEISHER: Bruce?

4 DR. HALL: thank you. Thank you,
5 Sean. Your remarks are always very well
6 thought out. So in fact, we have given up --
7 Internally, we have given up using the HL fit
8 statistics for exactly the reasons that we saw
9 and the reasons that you reiterated.

10 So in fact, we do for all of our
11 models perform fit curves where we describe --
12 we actually evaluate fit within that
13 graphically, and that helps us to know where
14 we are on the fit.

15 We provided the HL fit, the 50-50
16 codes it seems that many times people look
17 for. We have publications that have already
18 been published, as well as an additional
19 publication under review that specifically
20 evaluates the additional value of using scale
21 of risk from CPT codes, and I appreciate you
22 said DRG codes, but we are referring to CPT

1 codes.

2 We find that in all cases in
3 applications like this, the application of
4 scale of risk scores derived from CPT codes
5 dramatically improves the fit.

6 So we did not submit any graphical
7 pictures of the fit codes for this model. We
8 would be happy to do that. We did not know
9 that would be the question, but we do do that.
10 that is our normal approach nowadays.

11 CO-CHAIR FLEISHER: Any comment?

12 DR. O'BRIEN: No. An unrelated
13 comment, and I may have missed some of the
14 discussion. But the models are highly
15 parsimonious, and I understand the need to
16 reduce the reporting burden.

17 This measure is going to be
18 implemented beyond NSQIP, but the criterion
19 for assessing the performance of the model has
20 to do with reducing or eliminating or reducing
21 to the extent possible bias due to
22 differential case mix across the sites.

1 So you might think about treating
2 a larger model as a gold standard and using
3 that model to assess the extent to which case
4 mix does vary, and the extent to which
5 different case mix would produce bias, and
6 then to what extent does a three-variable
7 model or a six-variable model succeed at
8 removing the bias that you think may be there
9 based on what you have estimated from your
10 larger model, just any way to validate the use
11 of a three-variable or six-variable model.

12 DR. HALL: Thank you, Sean.

13 Actually, in this month's American College of
14 Surgeons we have a publication that evaluates
15 the five-variable models with a specific
16 procedural grouping, and as you have said,
17 this is a topic that we continue to
18 investigate. So we certainly agree with your
19 remarks that these are important aspects to
20 continue to investigate.

21 CO-CHAIR FLEISHER: Can you send
22 that to Reva, if you get a chance, a copy of

1 that?

2 DR. HALL: Sure thing.

3 CO-CHAIR FLEISHER: David?

4 MEMBER HOPKINS: Just a question.

5 So this measure is for over 65. Does NSQIP
6 have in its armamentarium an under 65 measure
7 that parallels this?

8 DR. HALL: We have not submitted
9 an under 65 measure that is otherwise
10 specified the same. We developed this measure
11 in conjunction with consultation with CMS
12 leadership, because they were particularly
13 interested in the unique burdens and risks
14 that the over 65 population has. So that is
15 why we have taken this approach.

16 I don't know that there is any
17 reason to preclude making a similar model for
18 an under 65 population, but we have made the
19 argument that the over 65 population carries
20 uniquely increased risk and uniquely increased
21 risk of morbidity after these surgeries.

22 CO-CHAIR FLEISHER: So, David, I

1 assume we -- One potential request is that
2 this be looked at in the future.

3 MEMBER HOPKINS: Sure.

4 CO-CHAIR FLEISHER: Patch?

5 MEMBER DELLINGER: This is -- I
6 think this is a great model, but I really fail
7 to see how this could be applied to a non-
8 NSQIP hospital.

9 DR. HALL: Dr. Dellinger, the CPT
10 codes that would be eligible for data
11 collection are specified. The number of cases
12 that would need to be evaluated over the
13 course of the year, I believe, is
14 approximately 180 cases, and so a hospital
15 could sample 15 cases a month.

16 The risk adjustment model gave a
17 very parsimonious, fewer than half a dozen,
18 risk adjustment variables. So any
19 implementation would again be accompanied by
20 education about how those fields are defined,
21 and then whether the hospital was
22 participating in NSQIP or not, the data for

1 their cases would just be submitted to
2 whatever organization was doing the
3 implementation.

4 The models would be applied, and
5 the evaluations would be returned to those
6 institutions.

7 CO-CHAIR FLEISHER: Yes, B.J. We
8 have seven minutes to dinner.

9 MEMBER TURNER: So I think -- I am
10 curious. Do you report your results in age
11 strata, because although you say the over 65,
12 66 is like a kid compared to 98. So I am
13 wondering whether -- or how you report or
14 address the issue of age in your model.

15 DR. HALL: We don't report it in a
16 stratified manner, but it is included as a
17 variable that we can use for risk adjustment.
18 So even within -- Even given the fact that the
19 entire population is over 65. So we don't
20 report out 65 to 70, 75 to 80 and so on.

21 MEMBER TURNER: But you do adjust
22 for how old they are?

1 DR. HALL: Within the group.

2 CO-CHAIR FLEISHER: Other

3 comments. Amy?

4 MEMBER ROSEN: I have a comment on
5 functional status. If a hospital doesn't have
6 NSQIP, then they have to go in and look at the
7 medical records for that? I just want to be
8 clear on that in terms of usability or
9 feasibility.

10 DR. HALL: This question also came
11 up during the TAP, and actually, again because
12 we do have 250 or 270 hospitals around the
13 country that use that same variable, our
14 experience within the program is variable is
15 actually pretty easy found within nursing
16 assessments of the patient, that this is an
17 access that the nursing that the nursing
18 assessment does usually cover. So that might
19 not be immediately obvious, but that is our
20 experience.

21 CO-CHAIR FLEISHER: Okay, public
22 comment? Hearing none-- Yes, from CMS.

1 DR. HAN: I think I have more just
2 a question about the implication of NQF
3 endorsement here. Am I correct to assume that
4 NQF endorsed measures, sort of like public
5 available, is transparent, because from CMS
6 point of view that we interested -- We are
7 going to -- We are interested in using
8 measures the NQF endorsed.

9 So for example, the STS measures
10 that I have this question. What is the
11 implication of you endorse the composite
12 methodology, but you put it aside, the
13 question of the star system?

14 So does that mean that CMS has --
15 there is a transparency of the methodology.
16 We can use the measure, but CMS can decide how
17 we are going to do the star system, how we are
18 going to report? I would like to know what
19 STS's concern is. That is a separate thing.
20 Right?

21 CO-CHAIR FLEISHER: Yes. But ay
22 issues with this measure, we can try to

1 address that separately, or do you want to
2 wait for Helen?

3 DR. WINKLER: The question on that
4 is, again I think what this committee was
5 saying was the actual implementation where you
6 determine stars and whatever is separate from
7 the measure. Even though STS has wrapped them
8 together, the recommendation of this committee
9 is that they really should be looked at
10 separately.

11 DR. HAN: Okay. So the same thing
12 applies to the ACS measures, that I think it
13 was David asking, you know, how he -- he
14 wonders how this measure can be used outside
15 of NSQIP.

16 So CMS is interested in the
17 measure, but when we implement it, CMS will
18 have some authority to require hospital to do
19 that. So it is the methodology that we are
20 interested in. It is not the implementation.
21 So just want to remind you, when you vote on
22 this measure.

1 CO-CHAIR FLEISHER: I am sure,
2 though, during the comment period, the
3 American Hospital Association, in particular
4 -- I am sure we will hear from Nancy Foster or
5 others about the burden.

6 DR. HAN: That is the -- Okay.

7 CO-CHAIR FLEISHER: So I think the
8 TAP, from what I am hearing, the TAP -- Excuse
9 me, the Steering Committee can comment that we
10 are concerned about burden, and that public
11 comment regarding potential burden of this
12 measure would be important before endorsement
13 at the next level. Is that a fair comment to
14 add, unless anybody disagrees with that
15 comment?

16 MEMBER YAWN: That goes to
17 feasibility and usability.

18 CO-CHAIR FLEISHER: Separate from
19 endorsement, because we can endorse a measure
20 but say --

21 MEMBER YAWN: But say we think
22 there is a feasibility issue.

1 CO-CHAIR FLEISHER: So let's vote
2 on those components of feasibility. So if you
3 are concerned about that, you should vote
4 lower on feasibility and usability.

5 MEMBER AMARASINGHAM: One question
6 for my own edification as an internist. What
7 is the number of hospitals that are
8 participating in this group?

9 CO-CHAIR FLEISHER: Small. You
10 hear it. Two hundred thirty-eight, Bruce?

11 DR. HALL: Two hundred seventy.

12 CO-CHAIR FLEISHER: Two hundred
13 seventy, and that actually is the -- out of
14 5,000. It is actually the major concern of
15 why, at least I have heard, the College is
16 looking at other ways to do this, because --
17 We are a NSQIP hospital, and the burden is
18 large, and the costs are large, although
19 interestingly, the STS costs are probably
20 very similar.

21 So let's vote on -- It is not low.
22 The cost is low, but the burden to collect.

1 So can we vote on the importance?

2 DR. WINKLER: All right. Let's
3 vote on importance for this measure, which is
4 a measure of outcomes of mixed surgeries for
5 patients over 65. So importance, yes or no.
6 Yes? Is anybody voting No? Okay, so that's
7 good.

8 Scientific acceptability:
9 Completely meets the criteria? No.

10 Partially? That's everybody.

11 CO-CHAIR FLEISHER: No.

12 DR. WINKLER: No? Anne? Amy?
13 You are a minimum. Okay.

14 All right, usability: Completely?
15 That is zero.

16 Partially? Twelve, I think.

17 Minimally? Ten. Okay.

18 Feasibility: Completely? Zero.

19 Partially? 10.

20 Minimally? 11. Okay.

21 So recommendation on the measure?

22 CO-CHAIR FLEISHER: Okay.

1 Recommendation of the measure. Now recognize
2 we will have a strong comment that they should
3 get public comment regarding the usability of
4 this measure.

5 DR. WINKLER: It is going to
6 happen, no matter what.

7 CO-CHAIR FLEISHER: But that we
8 have concerns about implementation.

9 MEMBER TURNER: And a lot of
10 statistical issues that we were discussing.

11 CO-CHAIR FLEISHER: Well, that is
12 separate. So are there any conditions that
13 anybody wants on the measure? Okay.

14 All those in favor of the measure?
15 Did anybody vote No? Is there any No? No.
16 Okay. So 22 to zero.

17 So, Bruce, thank you. The one
18 comment, Bruce, is Dianne is going to be
19 talking with you, because the TAP and the
20 Steering Committee both feel there should be
21 a separate hip fracture.

22 Any comments?

1 CO-CHAIR DUBOW: No, but we are
2 going to reconvene tomorrow at 8:30. Your
3 shuttle will pick you up at 8:10, and we are
4 eating here, for those of you who decided to
5 do that, at six.

6 MS. BOSSLEY: Right. And we do
7 have at least one person going back to the
8 hotel now and taking a cab. So if anyone
9 wants to do that, we will get enough. I guess
10 it is just Amy right now.

11 CO-CHAIR FLEISHER: So one quick
12 question. Because many of us assume that it
13 was a four o'clock end time, but we are
14 further -- those of us who took the train. Do
15 other people have like strict deadlines? So
16 is the goal to -- if we finish at three, will
17 people need to leave early? If we finish at
18 2:30, will they need to leave early?

19 (Whereupon, at 6:03 p.m. the
20 steering committee was adjourned.)

21
22

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