

NATIONAL QUALITY FORUM
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SURGERY ENDORSEMENT MAINTENANCE 2010
STEERING COMMITTEE

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WEDNESDAY
MAY 4, 2011

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The Steering Committee convened,
in the A. Philip Randolph Room at the Embassy
Suites DC Convention Center, at 900 Tenth
Street, Northwest, at 9:00 a.m., Arden M.
Morris and David Torchiana, Co-Chairs,
presiding.

PRESENT:

ARDEN MORRIS, Co-Chair, MD, MPH, FACS
DAVID TORCHIANA, Co-Chair, MD
NASIM AFSAR-MANESH, MD
HOWARD BARNEBEY, MD

JAMES E. CARPENTER, MD
ROBERT R. CIMA, MD, MA, FACS, FASCRS
CURTIS D. COLLINS, PharmD, MS,
BCPS AQ-ID
PETER W. DILLON, MD, MSc
RICHARD P. DUTTON, MD, MBA
STEVEN FINDLAY, MPH

PAULA R. GRALING, DNP, RN, CNS, CNOR
VIVIENNE HALPERN, MD, FACS
EILEEN KENNEDY, *
RUTH KLEINPELL, PhD, RN, FAAN
JOHN MORTON, MD, MPH, FACS
DENNIS W. RIVENBURGH, MS, ATC, PA-C
TERRY ROGERS, MD

CHRISTOPHER SAIGAL, MD, MPH, FACS
NICHOLAS J. SEARS, MD
ALLAN SIPERSTEIN, MD

PRESENT (CONT.)

RENAE STAFFORD, MD, MPH, FACS

CAROL WILHOIT, MD, MS

CHRISTINE S. ZAMBRICKI, CRNA, MS, FAAN

NQF STAFF PRESENT:

HEIDI BOSSLEY

HELEN BURSTIN, MD, MPH

ALEXIS FORMAN

MELINDA MURPHY, RN, MS

JESSICA WEBER

ALSO PRESENT:

SKIP ANDERSON

SUSANNAH BERNHEIM

JOHN BOTT

DALE BRATZLER *

LAURA EATON *

SUSAN FITZGERALD

JEFFREY GEPPERT *

LAURA GROSSO *

JANE HAN *

WANDA JOHNSON *

TIM KRESOWIK *

VICTORIA LYNCH *

KRISTYNE McGUINN

PATRICK ROMANO

DAVID SHAHIAN

DAVID SHAPIRO

JEFFREY SILBER *

DONNA SLOSBURG

SUSAN WHITE *

* Present via telephone

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

9:00 a.m.

CO-CHAIR MORRIS: Good morning.

Hi, everybody. Thanks so much, again, for participating in the Steering Committee. It's nice to see you all here today.

What we are going to do right now is just, basically, welcome and introduction, very similar to last time. And I would like to just go around the table and have everybody introduce themselves, say where you are from. Then, we also need to verbally state whether we have any disclosures of conflict of interest or bias.

I will start. I am Arden Morris. I am the Chief of Colorectal Surgery at the University of Michigan, and I have no conflicts of interest.

CO-CHAIR TORCHIANA: I am David Torchiana.

I am happy to be here today, and I

1 want to add my thanks to all for coming.

2 I am formerly a cardiac surgeon.

3 I was Chief of Cardiac Surgery at Mass
4 General, and I am now the head of the
5 physicians' group there. No conflicts.

6 MS. FORMAN: Alexis Forman,
7 project staff.

8 MEMBER AFSAR-MANESH: Nasim Afsar.

9 I am an internist and with the Department of
10 Neurosurgery and the Associate Medical
11 Director of Quality and Safety at UCLA Medical
12 Center. I have no conflicts.

13 MEMBER SAIGAL: Chris Saigal. I
14 am a urologist at UCLA. No conflicts.

15 MEMBER HALPERN: Vivienne Halpern,
16 Chief of Vascular Surgery at the Carl T.
17 Hayden Phoenix VA Medical Center. No
18 conflicts.

19 MEMBER CIMA: Bob Cima. I am a
20 colorectal surgeon and Vice Chair of the
21 Department of Surgery for Quality at the Mayo
22 Clinic, Rochester. I have no conflicts.

1 MEMBER WILHOIT: Carol Wilhoit,
2 Quality Improvement Medical Director for Blue
3 Cross/Blue Shield of Illinois. And I have no
4 conflicts.

5 MEMBER BARNEBEY: I'm Howard
6 Barnebey, an ophthalmologist from Seattle. I
7 have just joined the Committee a week ago.
8 So, some understanding and sympathy will be
9 appreciated.

10 (Laughter.)

11 And I have no conflict of interest
12 to report.

13 MEMBER GRALING: Good morning.

14 I am Paula Graling. I am the
15 Clinical Nurse Specialist of Perioperative
16 Services here in town at INOVA Fairfax
17 Hospital, and I have no conflict.

18 MEMBER RIVENBURGH: Dennis
19 Rivenburgh. I am a physician assistant with
20 St. Anthony's Primary Care and Co-Chair of the
21 Quality and Safety Committee of St. Anthony's
22 Hospital. And I have no conflicts of

1 interest.

2 MEMBER COLLINS: Hi. Good
3 morning.

4 Curtis Collins, Clinical
5 Pharmacist, Infectious Diseases, at the
6 University of Michigan. No conflicts.

7 MEMBER ZAMBRICKI: Hi. I'm
8 Christine Zambricki. Good morning. I am a
9 nurse anesthetist and I am Deputy Executive
10 Director of the American Association of Nurse
11 Anesthetists.

12 And I reported a potential
13 conflict when I agreed to participate. That
14 is that I sit on an advisory board to a
15 surgical information systems company.

16 MEMBER STAFFORD: Hi. I am Renae
17 Stafford. I am the Director of Surgical
18 Critical Care at the University of North
19 Carolina in Chapel Hill.

20 The only potential conflict is I
21 am a member of the Quality Committee at SECM,
22 and I am also a member of the American College

1 of Surgeons.

2 MEMBER KLEINPELL: Good morning.

3 Ruth Kleinpell. I am a Professor
4 of Nursing at Rush University Medical Center
5 in Chicago and also a nurse practitioner. And
6 I have no conflicts.

7 MEMBER SIPERSTEIN: Allan
8 Siperstein. I chair Endocrine Surgery at the
9 Cleveland Clinic. I have no conflicts.

10 MEMBER ROGERS: Terry Rogers, CEO
11 of the Foundation for Health Care Quality in
12 Seattle. And I have no conflicts.

13 MEMBER CARPENTER: Good morning.
14 Jim Carpenter. I am the Chair of
15 Orthopedic Surgery at the University of
16 Michigan. I have no conflicts.

17 MEMBER FINDLAY: Hi. Good
18 morning.

19 I am Steve Findlay. I am a Senior
20 Health Policy Analyst at Consumers Union. I
21 am a consumer representative on this panel,
22 and I have no conflicts to report.

1 MEMBER DUTTON: Rick Dutton. I am
2 a former trauma anesthesiologist in Baltimore,
3 now the Executive Director of the Anesthesia
4 Quality Institute in Chicago. I have no
5 conflicts.

6 MEMBER DILLON: Peter Dillon,
7 Chair of Surgery at Penn State, and I have no
8 conflicts.

9 MS. BOSSLEY: I have two
10 microphones. I don't know what to do.

11 (Laughter.)

12 Heidi Bossley, Vice President of
13 Performance Measures at NQF.

14 MS. WEBER: Jessica Weber, NQF.

15 MS. MURPHY: Melinda Murphy, NQF.

16 CO-CHAIR MORRIS: All right.

17 Thank you, everyone.

18 We are just going to next talk
19 about our expectations and the process for the
20 meeting. This will be very familiar for most
21 of you, maybe not all of you.

22 Basically, our plan here is to

1 start, as you will see on your agendas, by
2 talking about initially a recap of the work to
3 date, which Alexis and Melinda will lead.

4 We will talk about how to use our
5 remote controls appropriately to vote.

6 And we will talk about the Phase I
7 measure followup. There were a lot of things
8 about the Phase I measures that we wanted to
9 get more information about, and there are some
10 votes that we postponed until we received more
11 information. So, that has happened in the
12 interim.

13 We will start by talking about
14 Measure 0300 and get the additional
15 information from CMS that we were looking for
16 last time.

17 And, then, we will determine
18 whether or not our conditions are satisfied.
19 We won't vote on this measure quite yet.

20 We will, then, go to the list on
21 page 2 of the agenda and sequentially vote on
22 those measures. We will not represent the

1 measures. So, those of you who are
2 responsible for each of these individual
3 measures won't necessarily need to represent
4 unless the group feels that it would be
5 beneficial prior to voting.

6 As you can see, our agenda is
7 really full for today. We will try to be
8 efficient with time, but, on the other hand,
9 the reason that we are all here in person is
10 to have a discussion. So, if we need to do
11 that, we certainly will.

12 We also have -- is it time to open
13 the meeting? Okay. So, it is time to open
14 the meeting to the public.

15 Before we do, Dr. Morton, would
16 you just introduce yourself to the group?

17 MEMBER MORTON: I am John Morton.
18 I am an Associate Professor from Stanford
19 University.

20 CO-CHAIR MORRIS: Thank you.

21 So, we are going to open it to the
22 public now, and we have several folks on the

1 line and in person. So, we would like to ask
2 you to introduce yourselves.

3 MS. SLOSBURG: Good morning.

4 I am Donna Slosburg with ASC
5 Quality Collaboration. I guess I should have
6 told you I am a measure developer.

7 MS. MURPHY: And those on the
8 phone, anyone on the phone?

9 MR. BRATZLER: Dale Bratzler.

10 MS. MURPHY: I am sorry. Say your
11 name again, please. It did not come through
12 well.

13 MR. BRATZLER: Dale Bratzler.

14 MS. MURPHY: Hi, Dale.

15 Anyone else on the phone?

16 (No response.)

17 CO-CHAIR MORRIS: Let's see, I
18 think that that's about it, and it is time to
19 recap. So, already we are ahead of schedule.
20 This is great.

21 (Laughter.)

22 MS. MURPHY: Okay. So, for the

1 recap, what we want to do is just quickly
2 repeat some of the information from the last
3 meeting. And we will start with the project
4 purpose.

5 Again, when you are looking at the
6 measures, you are looking at endorsement or
7 continuation of measures for quality
8 improvement and public reporting, and all
9 these measures are around surgical patient and
10 surgical procedures.

11 As part of this, there is a
12 maintenance review of the surgery standards
13 that were endorsed prior to June of 2008.
14 There are some specific things that you looked
15 at last time, asked for last time, that you
16 will want to do again during Phase II. We
17 will point those out as we look at the
18 criteria.

19 So, for the Phase I measures, the
20 first part of the agenda is to resolve any
21 outstanding issues. You will recall that
22 there were some requests that you made at the

1 time of the last in-person meeting that were
2 resolved. The majority of them were resolved
3 to your satisfaction during the March 31st
4 call, and there is one that we will hear more
5 about today.

6 Then, you will be making
7 recommendations related to related and
8 competing measures that you considered in
9 Phase I and make endorsement recommendations
10 for the measures, the 20 measures that you
11 considered in Phase I that you determined met
12 the four criteria that would make them
13 eligible for consideration for endorsement.

14 And, then, we will move to the
15 Phase II measures, where you will be
16 evaluating 38 measures against the measure
17 evaluation criteria, as you did for the Phase
18 I measures. And you will, again, make
19 recommendations related to related and
20 competing measures.

21 And what we talked about a bit
22 earlier this morning is that you might not be

1 ready to make final recommendations about
2 related and competing measures, particularly
3 Phase II, depending on where we are in the
4 work by that point in the day tomorrow and,
5 again, to make endorsement recommendations.

6 So, I want to just quickly run
7 through the criteria.

8 Importance to measure and report
9 is the first criteria. And, remember, these
10 are in a hierarchical fashion, and you make
11 determinations about importance before you
12 move to any of the others, with the
13 understanding that, if it is not important to
14 measure and report, you probably don't want to
15 even look at the other pieces with the
16 exception of those measures that you might
17 determine are topped-out.

18 And for those measures, if you
19 determine that they are not important to be
20 continued for endorsement because they are
21 topped-out, you will want to look at the other
22 criteria in order to make a determination

1 about whether or not they should go into an
2 inactive status. You would not want to move
3 a topped-out measure into an inactive status
4 where it could be reactivated if you did not
5 feel that it met all the other criteria.

6 So, for those measures, once you
7 make the determination it's not important, and
8 it is not important based solely on the fact
9 that it is topped-out, we will still go
10 through the other criteria.

11 And for the measures that are
12 undergoing maintenance, a couple of the things
13 that you will be looking for, in particular,
14 is whether or not they have identified what
15 the performance gap was and, within the
16 performance gap, have they stratified it so
17 you can see where disparities may be that
18 might need to be further addressed? So, you
19 are going to be looking for data, for numbers,
20 as well as the citations.

21 In scientific acceptability, there
22 is the list of things you are looking for with

1 respect to scientific acceptability with the
2 fundamental piece being, are the measures
3 reliable; are they valid? So, within that,
4 you are going to look at the testing that has
5 been done for reliability and validity, and,
6 again, looking at the other pieces of the
7 information around scientific acceptability.

8 For usability, if the extent to
9 which the audience that is to receive the
10 output of the measure can understand the
11 results and will find them useful, and some of
12 you on the Work Groups will recall that there
13 were some discussions about some of the
14 measures in terms of what is the utility to
15 the public and how would you convey that
16 information to the public. So, those are
17 questions that you will answer as you think
18 about usability.

19 Also looking at, are the measures
20 harmonized? And again, whenever we are
21 looking at related and competing measures,
22 what do new measures add in terms of value to

1 the measures that are already endorsed and
2 availability?

3 And with the maintenance review
4 considerations, one important piece is, are
5 the measures that have been endorsed over time
6 being publicly reported? And if not, what are
7 the plans for public reporting, just as you
8 did in Phase I?

9 Feasibility. Is the information,
10 the data required to compute the measure
11 available? Can it be retrieved with relative
12 ease, not a lot of additional burden? And can
13 it be implemented?

14 So, you are looking for
15 information, data that is generated as part of
16 the process, the care process, information
17 that is available electronically. If there
18 are exclusions, do you have to go someplace
19 other than the data source for the measure
20 elements proper to get the information about
21 the exclusion? If so, that is an additional
22 burden.

1 What are the susceptibilities to
2 inaccuracies? And given all of the
3 information about where the data comes from,
4 can the strategy that is recommended for use
5 in collecting it actually be implemented?

6 So, then, in the course of rating
7 those criteria, the first one, as I said, was
8 importance. That is a yes/no rating.

9 The other criteria are evaluated
10 based on the level to which they meet the
11 criterion, either completely, partially,
12 minimally, not at all, or it is not
13 applicable. And you will get some more
14 information as you look at how you are going
15 to use the tool.

16 So, Jessica is going to give you
17 information about the voting, but do you want
18 to do that now or do you want to do it in a
19 bit?

20 MS. WEBER: We can do it now.

21 MS. MURPHY: Okay.

22 MS. WEBER: So, everyone should

1 have the voting tool that they had last time.
2 So, to vote, you press the number of your
3 choice and then Send. And make sure you aim
4 it towards me, so that it picks up the vote.

5 (Laughter.)

6 So, we can go ahead and do a
7 demonstration, if you want. I will leave the
8 measure up that we are going to vote on first,
9 and you should have 60 seconds to put your
10 vote in, once I start the timer.

11 It will be on the screen to my
12 right, and it should give a live tally of how
13 many votes we have.

14 (Whereupon, a voting demonstration
15 was performed.)

16 We should have 19. Okay, great.

17 All right. Thanks.

18 MS. MURPHY: Alexis?

19 MS. FORMAN: As Melinda and Dr.

20 Morris indicated, we will start off with
21 outstanding issues from Phase I. We will
22 begin with a brief introduction from the

1 measure developer for Measure 0300.

2 The Committee suggested changing
3 the measure from 6:00 a.m. to 24 hours. CMS
4 had to go back to their expert panel to
5 provide that suggestion. So, we will hear
6 results from that meeting and if they are able
7 to make their modification.

8 Then, following that discussion,
9 as Dr. Morris indicated, we will make final
10 recommendations on 15 of the Phase I measures.
11 And unless someone indicates we need to
12 discuss some of the measures, we will just go
13 straight to the voting.

14 As Melinda indicated, we will then
15 go into Phase-I-related and competing
16 measures. And we will have a brief discussion
17 on each of those measures.

18 This slide is just to indicate we
19 pulled four measures from a current project
20 that is going on, the Pediatric Cardiac
21 Surgery Project. We brought them over for
22 competing and related, which we will have a

1 discussion on tomorrow at 1:30 during our
2 Phase-II-related and competing discussion.

3 These measures are related to two
4 of our maintenance measures, 0339, pediatric
5 heart surgery mortality, and 0340, pediatric
6 heart surgery volume. So, we will discuss
7 that in more detail tomorrow.

8 CO-CHAIR MORRIS: Great. So, this
9 is the appropriate time, is it Dale, to --

10 MS. MURPHY: Yes.

11 CO-CHAIR MORRIS: Okay. For Dale
12 Bratzler to go ahead and talk with us about
13 the additional information regarding Measure
14 0300.

15 MR. BRATZLER: All right. Can you
16 hear me okay?

17 CO-CHAIR MORRIS: It is actually
18 real quiet. Is there a way to turn up the
19 volume? Dale, we can barely hear you. So, we
20 are going to work on the volume here.

21 MR. BRATZLER: All right. Let me
22 know if you are having trouble.

1 Can you hear me?

2 CO-CHAIR MORRIS: Anybody who
3 cannot hear him?

4 Okay. Dale, why don't you go
5 ahead and proceed?

6 MR. BRATZLER: All right. We will
7 get going, everyone.

8 After the last meeting, as you
9 know, the Committee asked us to take the
10 measure back and consider some changes to the
11 measure. And the primary change that was
12 requested at the time was that we look, rather
13 than the previous performance metric, which
14 the data element was collected 6:00 a.m. blood
15 sugar or blood sugar that was collected closer
16 to 6:00 a.m., that we collect the blood sugar
17 at 24 hours.

18 We took the discussion back to two
19 different groups. First, I think many of you
20 are aware that the Society of Thoracic
21 Surgeons has published a practice guideline
22 series on blood glucose management during

1 adult cardiac surgery. It was published in
2 the annals of Thoracic Surgery in 2009 and
3 provides evidence-based recommendations for
4 blood sugar control in cardiac surgery
5 patients.

6 So, we had a conversation with
7 several of the authors of that guideline.
8 Then, we met with the Surgical Care
9 Improvement Project Section Technical Expert
10 Panel, who invited Dr. Tony Furnary, and I
11 believe Dr. Richard Engelman was also on the
12 call, both authors on the STS, to participate
13 with the Technical Expert Panel.

14 So, let me just highlight just a
15 couple of things. First, there is still
16 strong support for the measure. We feel that,
17 based on the conversation with the Technical
18 Panel and STS, that there is strong evidence
19 to support glucose control in cardiac surgery
20 patients.

21 Secondly, when you look at the STS
22 guideline, they make explicit Class 1A

1 recommendations around glucose control. I
2 will just read the one recommendation that is
3 relevant here.

4 "Patients with and without
5 diabetes with persistently-elevated blood
6 sugar should receive IV insulin infusions to
7 maintain the serum glucose less than 180
8 milligrams per deciliter for the duration of
9 their ICU care."

10 Again, they gave it a Class 1A
11 recommendation.

12 So, after discussions with the
13 Technical Panel, what we were trying to figure
14 out was a way to capture some information
15 about blood sugar control in the ICU without
16 too much burden for the hospitals. So, the
17 recommendation of the Technical Panel, along
18 with representatives of the Society of
19 Thoracic Surgeons, is that we simply ask the
20 hospital to capture a data element that looks
21 at whether any of the blood sugars between 18
22 and 24 hours were greater than 180 milligrams

1 per deciliter.

2 So, we would only look at a single
3 timeframe. We would not look at two days, as
4 we have in the past.

5 The feeling of the Committee, and
6 particularly the input of STS, is that by 18
7 to 24 hours after surgery the blood sugars
8 should be controlled, and the Class 1
9 recommendation is that those blood sugars be
10 below 180.

11 And so, I know Tori Lynch and
12 Wanda Johnson are on the call. They can
13 perhaps give you a little better description
14 of the data elements that we are testing. But
15 it would simply look at whether any blood
16 sugars in that timeframe, 18 to 24 hours after
17 surgery end time, were greater than 180
18 milligrams per deciliter.

19 Wanda, do you want to add any
20 comments?

21 MS. JOHNSON: The only thing that
22 we also added is, if there was no blood sugar

1 documented between 18 and 24 hours after
2 anesthesia end time, that they would record
3 the highest one between 12 and 18 after, just
4 in case there were no blood sugars at the 18-
5 to-24-hour mark.

6 MR. BRATZLER: So, that is our
7 recommendation for the changes. That met the
8 approval of our Technical Expert Panel and,
9 again, had a great deal of input from the
10 Society of Thoracic Surgeons, the guideline
11 panel that gave the Class 1A recommendation
12 for blood sugar control.

13 CO-CHAIR MORRIS: Does the group
14 feel as though our conditions are satisfied?

15 MEMBER CIMA: I just want to
16 clarify a couple of things. First of all,
17 that was not Class 1A evidence they cited.
18 They cited, "All patients with diabetes
19 undergoing cardiac surgical procedures should
20 receive an insulin infusion in the operating
21 room and for at least 24 hours postoperatively
22 to maintain serum glucose levels less than

1 180." That is evidence Level B. So, just to
2 make sure we are clear on what they said.

3 MR. BRATZLER: But look at
4 Recommendation No. 7.

5 MEMBER CIMA: I am looking at the
6 paper right now. The recommendation is not a
7 Class 1.

8 MR. BRATZLER: I read it. I read
9 it.

10 MEMBER CIMA: I have it right here
11 in front of me.

12 MR. BRATZLER: Yes, well,
13 Recommendation No. 7, I read it verbatim.
14 "Patients with and without diabetes with
15 persistently-elevated blood glucose should
16 receive IV insulin infusions to maintain serum
17 glucose less than 180 milligrams per deciliter
18 for the duration of their ICU care. Level of
19 evidence A."

20 MEMBER CIMA: Well, if you look at
21 the second page of that recommendation, which
22 I mean I am reading it right now also, Level

1 4, management of hyperglycemia using insulin
2 protocols in the perioperative period,
3 recommendations Class 1B.

4 So, "All patients with diabetes
5 undergoing cardiac surgical procedures should
6 receive an insulin infusion in the operating
7 room for at least 24 hours postoperatively to
8 maintain serum glucose levels less than 180
9 milligrams per deciliter (level of evidence
10 equals B)."

11 MR. BRATZLER: But, yes, so I see
12 what you are reading, but that, again, looks
13 at the perioperative period which includes the
14 operating room, which is not what we look at.
15 We only look at the postoperative care in the
16 ICU. So, Recommendation No. 7 is where we
17 based our --

18 MEMBER CIMA: It says for at least
19 24 hours postoperatively. I just want to
20 clarify that. It says that right there,
21 postoperatively for 24 hours.

22 MR. BRATZLER: Well, exactly, but

1 so does Level 7, or Recommendation No. 7 is
2 during the ICU stay. So, that is all we look
3 at. We do not look at interoperative control.

4 MEMBER CIMA: Okay. So, the only
5 issue is, what does it mean? Why are they
6 going from 200 to 180 now?

7 MR. BRATZLER: Basically, because
8 we felt like we should align with the
9 published guideline. We, frankly, always try
10 to do that. We always try to make sure that
11 we incorporate guideline recommendations for
12 our performance metrics.

13 MEMBER CIMA: Now what if the
14 patient -- there are exclusions here for
15 patients on inotropes. Is that going to be an
16 exclusion built into it or are they just
17 saying any patient?

18 MR. BRATZLER: No, it is all
19 patients. And you're absolutely correct. We
20 recognize that inotropes drive the blood sugar
21 up, but that is all the more reason that those
22 patients need to have IV insulin infusions to

1 keep their blood sugars controlled.

2 As was pointed out by the STS
3 Committee, the inflection point for mortality,
4 morbidity, and infections goes up once the
5 sugars are in excess of 180, whether it is
6 induced by inotropes or whether they have
7 diabetes. So, it is for all patients. We
8 don't exclude patients on inotropes.

9 MEMBER CIMA: The only thing I am
10 a little confused about is that you are saying
11 that patients -- it says in item 7.1, it says,
12 "Patients with and without diabetes with
13 persistently-elevated serum glucose should
14 receive an IV insulin infusion." So, that's
15 Level A evidence.

16 But the question is, so
17 persistently-elevated, does that mean that you
18 are saying that all ICU patients need to have
19 an insulin infusion to make sure or is it
20 patients that are persistently elevated? I
21 mean, because the question here is you are
22 saying you want to introduce a measure where

1 you have to put everyone on an insulin
2 infusion to make sure they are on insulin for
3 24 hours or you are saying they have had a
4 blood sugar greater than 200, which may not
5 correspond to persistently elevated.

6 The question is here, is exactly
7 what are you talking about; what do you want
8 us to do? So, are you saying that everyone
9 has to be on insulin infusion or everyone has
10 to be on it even when the evidence says it is
11 persistently elevated, not a single evaluation
12 point?

13 MR. BRATZLER: Right, right.

14 Well, the recommendation for the Committee was
15 that the blood sugars between 180 -- I mean,
16 sorry -- between 18 and 24 hours should be 180
17 or less. And so, we don't require anybody to
18 be on insulin infusion. I will make that
19 every clear. We don't look at how patients
20 are treated. We allow the hospital to control
21 the blood sugar any way. And if the patient's
22 blood sugars are less than 180, there's no

1 need for any intervention at all.

2 But the recommendation of the
3 Committee was simply that the hospital record
4 the highest blood sugar between 18 and 24
5 hours. And we looked to see whether or not it
6 was greater than 180 milligrams per deciliter.

7 MEMBER CIMA: So, if they check it
8 one time and it is 200, that is the first
9 time, they are going to get penalized, and,
10 then, they start the insulin drop
11 appropriately? I mean I am just concerned
12 about the language. It is persistently
13 elevated. You are looking at a one-time
14 measure.

15 MR. BRATZLER: Right, I understand
16 your point completely. I think it would be a
17 rare case that somebody would check for the
18 first time a blood sugar 18 hours after
19 cardiac surgery, but --

20 MEMBER CIMA: No, but, then, if it
21 is --

22 MR. BRATZLER: -- I understand

1 your issue.

2 MEMBER DUTTON: Arguably, if the
3 first time they check it is 18 hours after
4 surgery, they should be dinged because that
5 would be out of compliance with --

6 MEMBER CIMA: No, but what if is
7 fine multiple times and, then, one time it is
8 not? I mean, which one are you going to take?
9 Say they have two of them, and one is higher
10 and the next one within 24 hours is lower
11 because they have adjusted the insulin.

12 MEMBER DUTTON: It seems to me
13 that there is going to be a tradeoff here
14 between the burden of data collection and the
15 ability to assess the measure, to figure out
16 if we are actually doing the right thing.

17 MEMBER CIMA: That's the point.
18 Is it a good way of measuring it? Should we
19 say evidence of attempting to maintain
20 insulin? I am just saying it is a very
21 difficult measure to meet by many hospitals
22 that are keeping them on insulin drips. And

1 also, the way it is written is difficult to
2 manage.

3 You know, the data suggests not a
4 single blood sugar level. The data, all the
5 data suggest persistent elevation over a
6 period of time. This is not a good measure
7 for measuring that.

8 MEMBER KLEINPELL: Well, you know,
9 last time we had a lot of discussion how, as
10 it was raised before, with a 6:00 a.m. focus,
11 that a lot of hospitals were, in fact, putting
12 patients on intensive insulin therapy in order
13 to meet that 6:00 a.m. measure.

14 So, now we are moving to 18 to 24
15 hours, which, again, is more comprehensive,
16 you know, definitely better than just the 6:00
17 a.m. But I think we also have to look at
18 unintended consequences.

19 You know, we talked before about
20 some people potentially gaming the system to
21 try to get that 6:00 a.m. within normal
22 values, and, then, maybe not adhering to

1 looking at the value and how that varies over
2 time.

3 I think the change is definitely,
4 again, more comprehensive, but I guess
5 feasibility may have to be considered. I
6 guess we won't know until we really see this
7 in practice.

8 Is there any data with respect to
9 longitudinal monitoring of glucose that you
10 have that would relate that many patients are
11 within the range by 18 to 24 hours?

12 MR. BRATZLER: I personally don't
13 have, we don't have any of that data from the
14 SCIP project. I believe that Tony Furnary's
15 group and others do have considerable data on
16 that particular topic. I would have to defer
17 to them.

18 You know, I think one of the
19 issues that we struggle with here is that we
20 all recognize, as with the current measure,
21 with the 6:00 a.m. measure as it exists
22 currently, occasional cases will fall out even

1 with appropriate care. We understand that.

2 We have never, never ever said
3 that the target of performance on the measure
4 is 100 percent. So, we haven't tried to build
5 the performance measures to address every
6 possible rare clinical exclusion to the
7 performance measure.

8 So, I think it is possible that a
9 single blood sugar between 18 and 24 hours
10 could pop up above 180 and a case might fail.
11 I guess that is a possibility. And we
12 recognize that.

13 We know from cardiac surgery data
14 that 50 to 60 percent of all cardiac surgery
15 patients are hyperglycemic postoperatively.
16 So, it is a big population of the cardiac
17 surgery group that should receive insulin
18 therapy, and it has to do with the prevalence
19 of diabetes and the use of inotropes, and all
20 the other things that happen to these very
21 large operations that are occurring to these
22 patients.

1 So, that was the recommendation of
2 the Committee with a great deal of input from
3 the Society of Thoracic Surgeons' Committee,
4 also.

5 You know, we talked about it. I
6 know this group has talked about it. We have
7 talked about it before.

8 Ideally, we would capture every
9 single blood sugar and calculate a daily
10 average, but that simply isn't feasible.

11 MEMBER DUTTON: So, Dr. Cima, you
12 are concern is that a single value doesn't
13 accurately reflect that integral over time?
14 Or that the rate at which it doesn't reflect
15 it is high enough to invalidate the measure?

16 MEMBER CIMA: Well, I just think
17 their own literature says that it needs to be
18 a trend of persistently elevation. And that
19 is GSS, despite how you may want to parse the
20 words. But, certainly, it is better than two
21 days at two separate times at 6:00 a.m. It is
22 a better measure, but I just think it is not

1 really directing at what the literature and
2 the scientific evidence support, which is
3 better glucose control over a period of time.

4 I think in the ICU setting, as
5 they physicians who care for these patients,
6 you can have a patient on an insulin drip and
7 have them at 150 for six hours straight and
8 check another blood sugar and it is 200 for no
9 reason. I think that is what people feel,
10 that they are really tightly controlling these
11 people.

12 And there is evidence in the
13 literature, Class 1 evidence, that says
14 extremely tight control in ICU patients and
15 cardiac surgical patients increases their risk
16 for death and sepsis. So, it works both ways.

17 And the data says a trend and
18 persistent elevation. We are looking for a
19 single marker in critically-ill patients who
20 are on inotropes who have had major
21 interventions, who are ill patients coming in.
22 The vast majority have diabetes, as was

1 mentioned. I think it is not the ideal
2 measure for it.

3 Now does that invalidate it? I
4 think it is better than it was, but I still
5 think it doesn't meet the scientific evidence
6 that is available now, that it is a persistent
7 elevation of blood glucose levels greater than
8 180 that have been shown to increase the risk
9 of infection and mortality. It is not a
10 single value.

11 CO-CHAIR MORRIS: Okay. So, our
12 role right now is to determine whether or not
13 our condition was satisfied.

14 Dale, would you please repeat the
15 numerator statement for the group?

16 MR. BRATZLER: So, the numerator
17 would be patients having cardiac surgery whose
18 blood sugars -- so, what we do is we capture
19 the highest blood sugar between 18 hours and
20 24 hours. So, it would be those patients who
21 had a blood sugar that was 180 or less in the
22 18-to-24-hour timeframe, recorded as their

1 highest sugar.

2 MEMBER HALPERN: So, are you
3 saying that somebody is looking at all the
4 sugars anyway?

5 MR. BRATZLER: They are looking at
6 those between 18 and 24 hours. They only
7 capture one. They just look at the chart for
8 that timeframe.

9 MEMBER HALPERN: So, why aren't
10 they, then, looking at the average, if they
11 are looking at them all anyway?

12 MR. BRATZLER: Well, that would
13 require them to capture them all. We don't do
14 that. So, this just lets them glance at the
15 lab or the glucometer records and capture a
16 single value.

17 MEMBER HALPERN: Okay. Well,
18 then, I go back to Dr. Cima's point. If they
19 look at it and they see the majority of the
20 glucose, all of them except one is high, is
21 that really a good measure? Because you do
22 have, if you force people to overtreat and

1 they become hypoglycemic, again, there's
2 consequences to that.

3 MR. BRATZLER: I completely
4 understand that. But, again, I want to make
5 it very clear. We have never, never ever
6 promoted intensive insulin therapy, never,
7 with this performance measure. As we have now
8 or as it was in the past, we have never
9 promoted it.

10 The clinical endocrinologists
11 published guidelines about a year ago focused
12 on all ICU patients, not just cardiac surgery.
13 That recommends for all ICU patients blood
14 sugars be maintained between 140 and 180.
15 That is the national recommendation for ICU
16 patients. The STS guideline is consistent
17 with that, that the blood sugar simply be
18 maintained less than 180.

19 So, believe me, I understand the
20 comments about unintended consequences, and I
21 have made it very clear in multiple forms that
22 we do not promote intensive therapy. So, what

1 we are trying to do is figure out a way to
2 capture reasonable control of blood sugar in
3 a timeframe after surgery when most, the
4 expert panel, the STS felt that by 18 hours
5 the blood sugars should be reasonably
6 controlled.

7 MEMBER CIMA: I have a question,
8 then, hypothetical. If at 18 hours the blood
9 sugar is 150, well, but let's say, for
10 clinical reasons, they do. And, then, at 18
11 and a half hours it is 200. And, then, at 19
12 hours it is 150 because they corrected it. Do
13 we fail them?

14 MR. BRATZLER: Yes, the case would
15 fail as recommended.

16 MEMBER CIMA: So, is that the
17 clinical, is that what you want? You want us
18 to be treating that as opposed to the clinical
19 circumstances? Is that what you are asking?

20 MR. BRATZLER: So, I understand
21 the point, and that is why I made the point.
22 We understand that sometimes patients who

1 receive appropriate care fail the measure. We
2 understand that. The target is not 100
3 percent. It is high, and right now the
4 national average around the current measure is
5 in the 90 percent range, but some cases still
6 have blood sugars that are elevated.

7 So, again, I am just reflecting
8 the conversation of the Committee to try to
9 balance this combination of data burden with
10 having a measure that is reasonable and
11 consistent with the guideline.

12 CO-CHAIR MORRIS: Dr. Martin?

13 MEMBER MORTON: I was going to say
14 that I think the proposal is a step forward.
15 It is something that is different from what
16 was encountered before. I think all of us
17 reflected some of the frustration we see in
18 clinical practice in having to meet an
19 arbitrary 6:00 a.m. time. So, I think the
20 proposal is really a step forward in that it
21 is capturing it within a more reasonable
22 timeframe.

1 I think the other point is that we
2 all agree that blood sugars should be
3 controlled after surgery. I don't think
4 anybody has a quibble about that.

5 I think the one point here is
6 whether or not a single time point is
7 reflective of the entire post-op glycemic
8 state of the patient. I think that is really
9 the question. I guess I think that is one
10 that is a little hard to figure out. There is
11 always a balance of trying to get as much data
12 as possible as well as having the parsimony to
13 get things actually done.

14 But I think the proposal is a step
15 forward, where we don't have that arbitrary
16 6:00 a.m. time.

17 MR. BRATZLER: So, I guess I am
18 going to ask the question, what would be
19 enough data? Should we say two or more blood
20 sugars greater than 180?

21 I mean, what we are trying to
22 avoid is extensive data collection, data

1 points. We have used metrics like this for
2 data abstraction in the past where the
3 abstractor can scan a record, and if they see
4 a number that is above a threshold, they stop
5 looking. They don't have to look anymore.

6 So, once we go to two or three
7 data points, then we start to require them to
8 look at every single sugar that occurred
9 during that timeframe.

10 MEMBER CIMA: Could you do
11 something like 18 to 24 hours, if there is a
12 blood sugar greater than 200, was there a
13 correction and another blood sugar within four
14 hours that was less than the goal? I mean,
15 could you look at it that way? So, it is a
16 two-tiered system.

17 I agree with John; I think this is
18 a much better measure in the sense it is more
19 realistic in the sense of what we are trying
20 to achieve. But could you say, within 18 to
21 24 hours, if it is less than 180, fine, we're
22 done. If it is above 180, was there an

1 intervention to correct it in a reasonable
2 time period and bring it down below 180?

3 MR. BRATZLER: Well, I am going to
4 defer to you or Tori to think about the
5 mechanism of capturing that. It would require
6 additional data elements for sure.

7 MS. LYNCH: Right, and as we look
8 forward to EHRs, how would you write that? If
9 you found a level higher than 180, you would
10 then look for an entry for a correction? And
11 you would then look for an entry for a
12 controlled value.

13 To me, it is a matter of hospital
14 data abstraction burden. But, yes, we can
15 write specifications to address that.

16 MR. BRATZLER: We can certainly
17 explore it.

18 MEMBER SIPERSTEIN: I would just
19 like to echo the comments that, yes, this
20 measure I think is moving in the right
21 direction. One of my concerns is that these
22 measures are not just passive observations of

1 a best clinical practice, but the
2 institutions, quote, "study for the test".
3 So, it does influence practice pattern.

4 And you could very easily see some
5 practice patterns evolve that are no good.
6 So, if you get one blood sugar that is 179 at
7 18 hours, are you going to quit measuring it
8 for the next six hours? I mean institutions
9 are going to do things to game the system, and
10 I think it is important, as Bob has hinted, to
11 craft the measure so that it really is
12 encouraging a best clinical practice, you
13 know, somewhat analogous to the normothermia
14 measure, in that after surgery that if you may
15 not meet the temperature requirements, at
16 least you have tried.

17 In this way, I agree that some
18 type of two-tiered measure where you do go
19 just above the threshold, and you have
20 demonstrated success/attempt to correct, then
21 that would mean that the institution is moving
22 towards or doing their best to institute a

1 best practice.

2 CO-CHAIR TORCHIANA: I just had a
3 thought pursuing this same line, because the
4 idea of just checking one sugar and then not
5 checking another until 24 hours and 30 minutes
6 sounds too, it is a little too cynical to
7 support a practice like that.

8 But what if there were a sugar
9 that was greater than the threshold, whether
10 that is 180 or 200, and that is the trigger?
11 And, then, if there are other sugars prior to
12 24 hours that are below the threshold, it
13 basically gets erased? So, the trigger
14 creates a tension, and only if the subsequent
15 sugars up to 24 hours remain elevated does the
16 measure actually become a failed glucose
17 control. And you don't have to look for the
18 intervention. The intervention would be
19 implicit in the lower sugar.

20 MR. BRATZLER: I think that would
21 be easier to do.

22 CO-CHAIR MORRIS: I think what we

1 are doing here is adding additional
2 conditions, which is absolutely fine, but
3 Melinda please correct me if I am wrong. So,
4 that is something that we are sort of talking
5 about as a group, putting additional
6 conditions on this before we would vote on it.

7 MS. MURPHY: And that is fine, but
8 it will make a difference. We will not be
9 able to vote on it today because, again, I am
10 going to make the assumption that they will
11 need to go back to their technical panel to
12 have this discussion. So, we are talking
13 about it moving out some period of time.

14 CO-CHAIR MORRIS: Okay.

15 MR. BRATZLER: For just a
16 specification change, we can figure out a way
17 to communicate via email with the panel. So,
18 we can expedite the discussion.

19 CO-CHAIR MORRIS: Okay. I think
20 that sounds fine.

21 Anything else that anybody wants
22 to say about whether the conditions were

1 satisfied on Measure 0300 before we move on to
2 voting on the other measures?

3 (No response.)

4 All right, let's go to page 2 of
5 the agenda. The next measure is 0114, risk-
6 adjusted postoperative renal failure.

7 We had a lot of discussion about
8 this previously. Does the group wish to have
9 this represented or do you folks believe that
10 you are ready to go ahead and vote?

11 (No response.)

12 Okay, let's go ahead and vote.

13 Okay. So, the first question is,
14 do you recommend this measure for endorsement,
15 yes or no?

16 (Vote.)

17 Are we all set?

18 That is 17 votes for yes, two for
19 no, and three abstain. So, we do recommend it
20 for endorsement.

21 Sorry. One for no, one for
22 abstain. Yes, I definitely need eyes in the

1 back of my head more than ever before.

2 Measure No. 0115, risk-adjusted
3 surgical re-exploration, is there a desire
4 among the group to redescribe this measure or
5 to represent this measure?

6 MEMBER CIMA: Did we talk about
7 this one last time? I forgot. I don't
8 remember it.

9 CO-CHAIR MORRIS: I am blanking,
10 my memory is blanking out on this one as well.
11 Did we actually talk about it?

12 MEMBER FINDLAY: So, we punted on
13 all these. Why, again? Could you remind us
14 why?

15 MS. MURPHY: The items that are
16 here that you are looking at right now, each
17 had some condition or request for additional
18 information from the Committee to the
19 developer. And, then, on the 31st of March --

20 MEMBER FINDLAY: Right.

21 MS. MURPHY: -- those conditions
22 were discussed in terms of whether or not they

1 met the request requirement of the Committee.

2 And the ones that you are looking
3 at on the 31st all met the conditions that
4 were requested. So, now the last piece, the
5 last step, is to vote on whether or not you
6 would now, having that condition satisfied,
7 are ready to vote on a recommendation for
8 endorsement.

9 MEMBER DUTTON: I believe most of
10 the STS ones, the issue was disparities,
11 right? Presenting disparity data, which they
12 did on the phone.

13 MS. MURPHY: And what you see on
14 the screen up here in the shaded box is what
15 the condition was, how the developer
16 responded, and what the action of the
17 Committee was. So, in each case, what you are
18 going to see projected is what your condition
19 was, the response, and your determination.

20 (Vote.)

21 CO-CHAIR MORRIS: Okay. So, the
22 voting is completed. There are 19 votes for

1 yes, none for no, and one abstain.

2 The next measure is Measure 0116,
3 anti-platelet medication at discharge.

4 As Melinda pointed out, the
5 conditions will come up in the shaded box.

6 There are a number of conditions,
7 and during our conference call we agreed that
8 they were met. I think it is time to go ahead
9 and vote. Does anybody want to discuss
10 further?

11 (No response.)

12 Okay.

13 (Vote.)

14 There are 20 votes for yes, none
15 for no, and none for abstain.

16 Measure No. 0118, anti-lipid
17 treatment at discharge.

18 Again, this is around disparities.
19 Anybody want to discuss it?

20 (No response.)

21 Okay.

22 (Vote.)

1 Can everybody hit their button one
2 more time on their remote?

3 (Vote.)

4 Twenty votes for yes.

5 Measure No. 0119, risk-adjusted
6 operative mortality for coronary artery bypass
7 graft.

8 And again, you can see in the
9 shaded box the conditions.

10 Is everybody ready to vote?

11 (No response.)

12 Okay.

13 (Vote.)

14 Nineteen votes for yes, one vote
15 for no.

16 The next measure is Measure 0120,
17 risk-adjusted operative mortality for aortic
18 valve replacement.

19 Again, we are looking for
20 information on disparities, and we will go
21 ahead and vote.

22 (Vote.)

1 Nineteen votes for yes, one vote
2 for no.

3 Measure No. 0121, risk-adjusted
4 operative mortality for mitral valve
5 replacement.

6 Again, questions about
7 disparities, and we will go ahead and vote.

8 (Vote.)

9 Okay, could everybody hit the
10 button on their remote one more time?

11 (Vote.)

12 Nineteen votes for yes, one vote
13 for no.

14 Item No. 0122 is risk-adjusted
15 operative mortality for mitral valve
16 replacement and coronary artery bypass graft
17 surgery, and we will go ahead and vote.

18 (Vote.)

19 Let's go ahead and hit the buttons
20 one more time. This is sounding familiar.

21 (Vote.)

22 Okay. Nineteen votes for yes, one

1 vote for no.

2 Measure No. 0123, risk-adjusted
3 operative mortality for aortic valve
4 replacement and coronary artery bypass graft.

5 Okay, we will go ahead and vote again.

6 (Vote.)

7 And that's 20 votes for yes.

8 Measure No. 0129 was risk-adjusted
9 prolonged intubation, ventilation.

10 And our conditions were
11 consideration of a change in the time limit to
12 less than 24 hours and data on disparities.
13 We, in the conference call, believed that our
14 conditions were met.

15 Does anybody want to discuss this?

16 MEMBER ROGERS: Yes. This is
17 Terry. I would just like to make one comment.

18 I am still opposed to 24 hours.
19 Notwithstanding the complexity of many
20 patients in surgery, I think that 24 hours
21 gives some leeway and latitude. So that, if
22 you actually had a sloppy method of addressing

1 people postoperatively, it gives you too big
2 a window, in fact, to practice that
3 sloppiness. So, I would just register that
4 comment.

5 CO-CHAIR MORRIS: Thank you.

6 Anybody else?

7 (No response.)

8 Okay. Let's go ahead and vote
9 then.

10 (Vote.)

11 It says 15 votes for yes, four
12 votes for no, and one abstain.

13 One of the issues that arose in
14 our last discussion that we kept coming back
15 to was the issue of topped-out measures,
16 measures in which the criteria had essentially
17 been met to an extensive degree, maybe not 100
18 percent, but pretty close to it. And this was
19 one of those measures.

20 We will need to, basically,
21 determine how we want to deal with that
22 because several of these measures may be

1 topped-out or approaching being topped-out.
2 I guess if they are approaching it doesn't
3 count, but if they are topped-out, then we
4 need to make a decision about whether we want
5 to continue to endorse them in the maintenance
6 measures.

7 Is there more?

8 MS. MURPHY: So, the discussion at
9 the time of the last in-person meeting was
10 that performance was at or above 90 percent,
11 but there was discussion that the Committee
12 felt that compliance should be closer to 100
13 percent.

14 So, the remaining question is, do
15 you feel that, based on the information that
16 you have here, that it should remain in an
17 active status until it gets closer to 100
18 percent?

19 MEMBER HALPERN: You are talking
20 about the intubation one still?

21 MS. MURPHY: Right.

22 MEMBER HALPERN: The intubation

1 one that we were just talking about a second
2 ago. Because you have the sterna wound
3 infection up on there, I think it is confusing
4 people.

5 MS. MURPHY: Yes, this is where
6 the discussion was. So, you're right, this
7 had the voting for the other one, but what you
8 need to be looking at is the information that
9 reflects the discussion.

10 MEMBER HALPERN: Certainly, if
11 they keep it at 24 hours, I think we should
12 get closer to 100 percent.

13 MS. MURPHY: And that is not at
14 issue. I mean it is as specified. So, that
15 would remain.

16 MEMBER FINDLAY: So, at the last
17 meeting we had, did we, in fact, move any
18 measures? I don't recall moving any measures
19 to inactive status. We did? How many?

20 MS. MURPHY: There were not any
21 that were recommended to move to inactive
22 status. There was discussion of a few of them

1 that could potentially be candidates for
2 inactive status. But, really, the inactive
3 status -- and, actually, I am going to let
4 Heidi speak to this, if she is willing to do
5 so -- is a new approach that NQF is taking,
6 and is still working that through.

7 But the draft guidance out at this
8 point is that you might determine that a
9 measure could be moved to an inactive status
10 only on the condition that it is important to
11 measure, it meets all of the criteria, but the
12 performance is so high that you would not
13 expect that there would be a huge opportunity
14 cost to increase it beyond the performance
15 level at the time.

16 MS. BOSSLEY: Right. So, I think
17 what you will want to look at is not only is
18 it topped-out at the top, you want to look at
19 the variation. You also want to look at the
20 disparities data, if they are able to provide
21 it, because if you see there is an issue with
22 the disparities, you may very well determine

1 that you don't want to use the inactive status
2 here.

3 The one caveat I will say is this
4 status is going to the NQF Board for their
5 consideration because it does need to be
6 approved since it is a new endorsement status.
7 That will happen next week.

8 So, if you do decide that you want
9 to use this and it is appropriate for any of
10 these measures, we will caveat it with "if the
11 Board approves it". And, then, if they do
12 not, then we will bring it back to you. And,
13 then, we will have to figure out what your
14 next step will be.

15 But, again, we don't want to
16 remove endorsement from measures that may be
17 very appropriate to continue to surveil, to
18 look at over perhaps a periodic time period.
19 So, this was our way of acknowledging that
20 these are still evidence-based measures. They
21 meet all the criteria except they don't show
22 any disparities, there is no variation, that

1 type of thing.

2 CO-CHAIR MORRIS: So, just to
3 really clarify, measure that are really good
4 measures that we are concerned providers
5 potentially may not attend to any further if
6 they come off of the active list. If they are
7 still in inactive, they would be easily
8 reinstated.

9 MEMBER FINDLAY: So, at the
10 deliberations next week, is NQF going to
11 create a process for the Committees, this one
12 and others, to move measures to inactive
13 status, which might include a number of steps
14 that you would take to do that?

15 MS. BOSSLEY: Right. So, right
16 now, what we are thinking is anytime measures
17 that come up for maintenance, because it would
18 only be applicable to --

19 MEMBER FINDLAY: Right.

20 MS. BOSSLEY: -- measures that are
21 currently endorsed, it will be brought to the
22 Committee as a potential option.

1 The other thing that we are
2 building in is the ability to continue to
3 capture this updated specifications on those
4 measures. Because if we do think it is
5 important for periodic surveillance, that type
6 of thing, we will continue to have that on our
7 website and available for individuals.

8 So, that is our preliminary
9 thinking at the moment. Whether that would
10 mean more in the way of guidance to the
11 Steering Committees, we are developing that
12 now. And again, your discussion will help us
13 with that. So, we appreciate it.

14 MEMBER FINDLAY: So, there is a
15 broader context here that there is a lot of
16 pressure at NQF and also at CMS and in other
17 venues to remove topped-out measures. That
18 happened in the hospital value-based
19 purchasing final rules in the last week or
20 two, where there was pressure put on CMS to
21 remove four or five of the measures, and they
22 did so.

1 So, I guess I would say that we
2 ought to be paying more attention to that and
3 build it into the process. I guess today and
4 tomorrow, if we have the option, if there are
5 measures that look to be topped-out, then we
6 have the option of sort of punting on them
7 until there's clarification. Correct?

8 MS. MURPHY: I am not sure what
9 you meant by punting. You have the
10 opportunity --

11 MEMBER FINDLAY: Well, put it
12 aside not to vote, not to take a vote at this
13 time.

14 MS. MURPHY: Or what you have the
15 opportunity to do is go ahead and vote --

16 MEMBER FINDLAY: And, then, ask
17 for --

18 MS. MURPHY: Right. But you would
19 vote, you would first make the
20 determination --

21 MEMBER FINDLAY: Right.

22 MS. MURPHY: -- that it remained

1 important and it met all of the criteria. So,
2 you would go through all of that process and,
3 then, because of the level of performance,
4 which is the only kind of measure that is
5 deemed to be important, and it is going to
6 have the opportunity to move to an inactive
7 status.

8 MEMBER FINDLAY: Right.

9 MS. MURPHY: You would recommend
10 that occur contingent upon approval by the NQF
11 Board for that designation.

12 MEMBER FINDLAY: Thanks.

13 CO-CHAIR MORRIS: So, the question
14 for us with this measure, we voted on it, and
15 that part is done. But the question is, do we
16 want to recommend that it move to inactive
17 status? Do we think that it is topped-out?

18 MEMBER ROGERS: Well, one of the
19 reasons that it might top out is that the
20 threshold is too generous. I mean, hopefully,
21 one learns from these. This is what we are
22 all about. What we are trying to do is change

1 behavior. And if we have a threshold that is
2 so generous that nobody's behavior is going to
3 change, then putting it on inactive status is
4 not doing justice to the reason we have it to
5 begin with.

6 So, I would think that, harkening
7 back to I think 24 hours is way too generous,
8 and it is set up as sort of a surrogate for
9 other issues. For instance, if more of your
10 patients require or if enough of your patients
11 require more than 24 hours, should maybe they
12 have been operated on to begin with? I mean
13 that is one question.

14 And secondly, to keep it at this
15 because it might lead to premature extubation
16 makes no sense to me at all. I mean you
17 extubate when you need to extubate.

18 But the way it is set up, I don't
19 think we are learning anything from this.
20 Just putting it on inactive status doesn't get
21 us where we need to be. It is sort of
22 shuffling it under the rug. We need to have

1 a threshold that actually delineates or
2 discriminates between, and helps people look
3 at their behavior. It makes them change. And
4 24 hours for me just doesn't cut it.

5 CO-CHAIR TORCHIANA: If I could
6 comment on this one, we talked about this on
7 the call. It is an interesting measure. I
8 would say that the reasons why patients are
9 intubated for more than 24 hours after heart
10 surgery are multi-factorial.

11 The one that is most obvious is to
12 get at the anesthetic technique, and an
13 anesthetic technique that results in prolonged
14 somnolence and delayed extubation is probably
15 not a good practice.

16 But patients also sometimes stay
17 intubated because of hemodynamic instability⁷
18 or hemorrhage. The thinking, at least on the
19 call that I was on, was that this might be
20 augmented by an average time to extubation for
21 non-outlier patients, which would be a good
22 measure of the anesthetic approach and the

1 approach to the care of the patient. And,
2 then, the greater than 24 hours intubation
3 would become more of a surrogate measure for
4 the issues like hemodynamic instability or
5 operating on the wrong patient, somebody who
6 has already been on a ventilator for a month
7 when they go to the operating room, for
8 example. And having those two together might
9 complement and solve some of the problems that
10 we are concerned about with this measure.

11 CO-CHAIR MORRIS: As a group, we
12 voted to endorse the measure.

13 I hear what you are saying, Terry,
14 about that the fact that you would like for
15 the measure to be a better measure. In terms
16 of whether we believe that it should -- but we
17 voted to endorse it as a group. Do we think
18 that it is premature, then, to put it on
19 inactive status?

20 MEMBER ROGERS: Yes, I really like
21 David's approach. That way, at least it
22 discriminates. You learn something about the

1 group who maybe should have been intubated
2 earlier, and you learn something about the
3 other group who, say, had complications. To
4 lump them all together I think doesn't do
5 service to either one of those groups.

6 So, maybe a message we can give
7 back to STS is to help us maybe craft another,
8 if that is something we can recommend, to
9 address that very issue that David brought up.

10 MS. MURPHY: So, then, the
11 recommendation is that this remain in an
12 active status, that it be endorsed, and that
13 STS get a recommendation that they develop a
14 companion measure. Okay.

15 CO-CHAIR MORRIS: That sounds
16 good.

17 Let's move on to -- oh, is there
18 more?

19 MR. SHAHIAN: Dave Shahian from
20 STS. I came in late because I had travel
21 problems this morning.

22 Could I just ask for some

1 clarification as to what you are looking for?

2 I understand you are asking for a change in
3 the measure, which I thought had been
4 endorsed. So, could I just ask for some
5 specifics?

6 CO-CHAIR MORRIS: We are asking
7 for development of a companion measure.

8 Go ahead.

9 CO-CHAIR TORCHIANA: Yes, I think,
10 David, not a change in the measure, but a
11 companion measure that might get at the
12 question of anesthetic in postoperative
13 practice, such as median time to extubation
14 for those not intubated for greater than 24
15 hours, something in that mode.

16 Because there is a concern that
17 this measure was described as a sloppy measure
18 that allows for a lax practice, that allows
19 for patients who ought to routinely be
20 extubated before 24 hours remaining intubated
21 for a longer period of time than is
22 appropriate.

1 MR. SHAHIAN: So, you are asking
2 for a new additional measure?

3 MS. MURPHY: Yes.

4 MR. SHAHIAN: Thank you.

5 MEMBER DILLON: When does this
6 measure come up for review again? In three
7 years? So, would it be a fair statement that
8 the likelihood of this being passed three
9 years from now, certainly in its current
10 state, is probably highly unlikely, given the
11 concerns in that?

12 Because what I am trying to set up
13 is a timeline or an expectation for the
14 development of a new measure.

15 MS. MURPHY: So, your additional
16 recommendation is that this companion measure
17 be brought forward at the next time this is
18 brought forward for maintenance review?

19 MEMBER DILLON: Yes.

20 CO-CHAIR MORRIS: Okay. The next
21 measure, 0130, risk-adjusted deep sterna wound
22 infection rate.

1 This condition was also around
2 data regarding disparities. Let's go ahead
3 and vote.

4 (Vote.)

5 Nineteen votes for yes, one
6 abstain.

7 Measure No. 0131, risk-adjusted
8 stroke/cerebrovascular accident.

9 And our conditions were data
10 regarding disparities; also, the time period
11 in which the cases were eligible for inclusion
12 in the numerator, and exclusion of patients
13 with a prior stroke. And STS responded, and
14 we considered that to be sufficient.

15 Any other discussion of this?

16 (No response.)

17 Let's go ahead and vote.

18 (Vote.)

19 Could everybody hit their button
20 one more time?

21 (Vote.)

22 That's 20 votes for yes.

1 The next measure is Measure 0300
2 that we have spent some time talking about.
3 We decided that the conditions were not
4 entirely satisfied, is that correct? Not
5 entirely satisfied; we asked for more
6 conditions.

7 Let's move on to Measure 1501,
8 risk-adjusted operative mortality for mitral
9 valve repair.

10 So, our conditions were that we
11 wanted clarification whether this is simply
12 open-chest procedures, and the response was
13 that it applies to all mitral valve repairs.
14 And, then, we asked for data on disparities.

15 Any discussion?

16 (No response.)

17 Okay, let's vote.

18 (Vote.)

19 Please hit your buttons one more
20 time.

21 If there is somebody that
22 consistently notices that, after they hit

1 their button, the vote is over, please come up
2 and see us. Maybe there is a battery change.

3 (Vote.)

4 Twenty-one votes for yes, and no
5 votes for no or abstain.

6 Do we have 21? Do we have 21?

7 Okay.

8 The next measure is 1502, risk-
9 adjusted operative mortality for mitral valve
10 repair and coronary artery bypass graft
11 surgery.

12 Again, we wanted further data on
13 disparities. Let's go ahead and vote.

14 (Vote.)

15 Twenty-one votes for yes, none for
16 no or abstain.

17 So, we are done with that portion.
18 Now it is time for us to move on to discussion
19 of Phase-I-related and competing measures and
20 the Steering Committee recommendation for
21 endorsement. It is, yes, time to move on to
22 that discussion.

1 Was Alexis going to talk about
2 this? Were you going to talk about --

3 MS. MURPHY: So, this activity is
4 a new piece of work with NQF. And it is
5 looking at, again, where we have a number of
6 measures that are related and the extent to
7 which those measures can be harmonized,
8 assuming that they both are important or
9 whatever number are important.

10 And when you are looking at
11 related measures, you are looking at they may
12 have the same measure focus or they may have
13 a different measure focus but the same
14 population or care setting. So, they are not
15 looking at the same focus and the same
16 population. The relationship does not put
17 them in competition one with the other.

18 So, the first question to answer,
19 while you are looking at the measures, is, are
20 they, in fact, truly, as you see them, related
21 measures that should be looked at, then,
22 further in terms of harmonization, where it is

1 appropriate to harmonize, where there are
2 unintended differences that could, in fact,
3 lend themselves to harmonization?

4 And, then, you are looking at
5 whether or not the measures are competing.
6 Are they, in fact, looking at the same measure
7 focus and the same population, such that you
8 want to or we should be looking at whether or
9 not we should have two measures that are
10 looking at the same focus in the same
11 population, and whether or not one of those
12 measures is a best measure. This goes to the
13 best-in-class question.

14 So, what we have got are a set of
15 measures that you will look at in terms of
16 here what you see on the screen is the measure
17 related to a database for cardiac surgery.
18 This is Measure 0113 that you have evaluated
19 in Phase I.

20 And a related measure is another
21 STS measure looking at participation in a
22 database for general thoracic surgery.

1 And, then, the third measure is
2 the one that Helen mentioned to the group when
3 the group met in March in terms of a generic
4 database.

5 So, those are the ones that you
6 are now looking at in terms of related or
7 competing measures.

8 The threshold question that the
9 group discussed at its in-person meeting was
10 the question -- and I think this was also
11 discussed during the conference call -- was
12 the question about clearly and certainly at
13 the time of initial endorsement of measures
14 related to participation in database. It was
15 at a time whenever there were few measures,
16 when there needed to be a mechanism through
17 which information could be collected in order
18 to learn about performance.

19 And one of the issues that the
20 group discussed is whether or not that time
21 had gone by and whether or not the information
22 that now provides data for measures that are

1 drawn from a database supplant the need for a
2 measure that says participation in a database.

3 So, there are two questions, and
4 Dr. Cima is not happy?

5 (Laughter.)

6 MEMBER CIMA: No. I am trying to
7 clear that up.

8 MS. MURPHY: He's concentrating?
9 Okay. So, you can address it either way. You
10 can take the discussion of should there be
11 measures around participation in a database,
12 any database? And if the answer to that is
13 yes, then it is probably good to go on to the
14 next part of taking a look at these measures
15 in terms of harmonization and competing
16 measures.

17 CO-CHAIR MORRIS: One of the
18 things that we are thinking about here that
19 has come up in multiple conversations in the
20 group was the precedent this will set because
21 there are more and more databases being
22 developed, regional databases, national

1 databases. And there is more interest in
2 looking at data in secondary databases for
3 quality improvement and accountability.

4 So, we are not making a final
5 decision here, but we are making some
6 important preliminary decisions that likely
7 will be discussed and revisited many times in
8 the future.

9 And there are number of different
10 ways to handle this. I think that the first
11 question, as Melinda said, the first question
12 that we should probably discuss is whether we
13 think that participation in any sort of
14 systematic database should be essentially
15 mandated, so any sort of database should be
16 mandated.

17 Anybody want to open that up?

18 MEMBER HALPERN: Well, I will tell
19 you that your Board certification in surgery
20 now depends on you having some sort of
21 database, you know, some sort of quality
22 control of yourself. So, it essentially

1 forces you already to participate in a
2 database.

3 CO-CHAIR MORRIS: Do we mandate
4 that hospitals participate in databases?

5 MEMBER ZAMBRICKI: I was trying to
6 remember the measures for cardiothoracic
7 surgery. Are there any that do not include a
8 requirement for comparing a performance
9 against a database? Because that was one of
10 the issues you brought up. Is this already
11 included in the other individual measures? Do
12 you see what I am saying?

13 CO-CHAIR MORRIS: Yes, I think
14 that they are all within the STS database. Is
15 that right?

16 Okay. All of the measures were
17 within the STS database. And so, one of the
18 questions that arose was, is it appropriate
19 for us to mandate that hospitals participate
20 in the STS database?

21 MEMBER ZAMBRICKI: Yes, and I
22 thought we had decided, no, that it had to be

1 some type of a database, multi-hospital. So,
2 I thought that that was the change for those
3 individual measures, that it could not dictate
4 STS database.

5 MS. MURPHY: But I think what we
6 got was clarification that the measures, while
7 it is clear that they say the information for
8 those measures that is presented in terms of
9 performance was drawn from data in the STS
10 database, that participation in the STS
11 database was not a requirement of the measure.

12 MEMBER ZAMBRICKI: Right.

13 MS. MURPHY: And there was
14 discussion around what might you then have to
15 do in order to put that data together. But in
16 none of those measures, in the measures
17 themselves, none of those require
18 participation in the STS database.

19 MEMBER ZAMBRICKI: Do they require
20 participation in a database?

21 MS. MURPHY: And we are talking
22 now about the measures using data derived from

1 the database. We are not talking about these
2 measures.

3 MEMBER ZAMBRICKI: Correct.

4 MS. MURPHY: And so, say your
5 question.

6 MEMBER ZAMBRICKI: Well, I am just
7 wondering, is it duplicative to have a measure
8 that just calls for participation in a
9 database if the individual measures for
10 performance include in the measurement of that
11 measure the necessity to be participating in
12 a database? So, by nature of the fact that
13 you are submitting information on those
14 measures, you must be already participating in
15 a database. Does that make sense? In which
16 case, we wouldn't need any of these because
17 anyone submitting a cardiothoracic measure
18 would be participating in a database, if I am
19 understanding it correctly.

20 MS. MURPHY: And that is the
21 threshold question. The issue, though, is
22 that they would not necessarily be

1 participating --

2 MEMBER ZAMBRICKI: Right.

3 MS. MURPHY: -- in the STS
4 database.

5 MEMBER ZAMBRICKI: Right.

6 MS. MURPHY: But they would have
7 to be able to derive, to collect and have all
8 of the information for computing the
9 performance against the measure.

10 MEMBER HALPERN: I think also
11 saying you are participating in the database
12 makes you have to compare yourself to others,
13 as opposed to just creating your own database.
14 So, I think it is a separate issue.

15 MEMBER MORTON: That is the same
16 point I was going to make. There is a real
17 utility in participating in a national
18 registry where you can benchmark against other
19 people, rather than just having a home-grown
20 registry.

21 MEMBER DILLON: Yes, but I agree
22 with Christine that, if we are to focus just

1 on the particular measures, by that happening
2 people are going to have to participate in a
3 database. They will have to be comparing
4 themselves because our measures will require
5 that, particularly as they evolve in their
6 complexity.

7 So, I am not sure that we have to
8 say, you know, it is mandatory that you have
9 to participate in a database. We are going to
10 say you have to submit these measures. How
11 you get these measures and how you wish to
12 compare yourselves to others, as required by
13 the measure, is up to, should be up to the
14 institution. Because, otherwise, how many
15 databases -- you know, where does it stop?
16 How many databases do we tell people that they
17 apply to?

18 MEMBER HALPERN: But are the
19 measures actually saying that you have to
20 compare yourself? I don't think they are
21 actually saying that. They are saying that
22 you need to collect this data, but it is not

1 really saying that you have to compare
2 yourself.

3 MEMBER MORTON: I would kind of
4 err on the side of being explicit rather than
5 implicit in the registry. I know what you are
6 saying, Peter, but it is possible people could
7 interpret it in a way where they don't
8 participate in a national registry. So, I
9 would rather be explicit about it.

10 MEMBER FINDLAY: What is the
11 burden of that, this measure, on providers, on
12 collection of the data, on anything? It a
13 yes-or-no question, essentially.

14 CO-CHAIR TORCHIANA: Well, there
15 is a history here that Dr. Shahian may want to
16 comment on as well. So, the STS database is
17 overwhelmingly the most ubiquitous benchmark
18 database in the country for cardiac surgery.
19 But there are two very important other
20 databases that are highly respected, the
21 Northern New England database, which was a
22 spontaneous effort among New England

1 hospitals, and, then, the mandatory New York
2 State reporting system, both of which had long
3 lives and have been very effective. And they
4 use all the same concepts. The comorbidities
5 and the outcomes overlap, but are non-
6 identical.

7 And certainly, everyone involved
8 in the STS database would acknowledge that
9 institutions in New York State that are in the
10 New York State database, and from a mandatory
11 requirement by New York State government, or
12 those that are voluntarily in the NNE, are
13 doing a good job of doing a benchmark quality
14 assurance.

15 And so, that is why this language
16 I think ought to be ambiguous, that it is in
17 a dataset where you are benchmarking against
18 other institutions.

19 David, do you have anything to add
20 to that?

21 MR. SHAHIAN: No, I think you have
22 covered it correctly. We are now at about 95

1 percent participation nationally. The only
2 programs that don't participate are basically
3 those in northern New England or New York.

4 When the measures were initially
5 adopted, we were well below that level, and
6 this was an attempt, using a structural
7 measure of quality, to drive participation in
8 a national registry.

9 For all practical purposes, given
10 the pressure to report the hard outcomes that
11 we now report, you are correct that de facto
12 you must belong in a systematic cardiac
13 surgery registry or you basically can't exist
14 in cardiac surgery in the United States today.

15 Now, having said that, that is not
16 true for the general thoracic, where I would
17 say a large percentage of general thoracic
18 surgery in this country is conducted in
19 programs where there is no participation in a
20 systematic database.

21 So, the measure for cardiac
22 surgery, do what you feel is correct. I don't

1 think it is going to change the status quo
2 because we are at a point in cardiac surgery
3 right now where you can't survive without
4 being in a registry.

5 CO-CHAIR TORCHIANA: If I could
6 just make one other comment on this, the
7 requirement presupposes the existence of an
8 effective organization to do the data analysis
9 and benchmarking. And requiring institutions
10 to participate in an organization that doesn't
11 do that effectively is probably not a wise
12 thing to do.

13 CO-CHAIR MORRIS: That sort of
14 gets to your question about what is the cost
15 to the hospital or provider.

16 MEMBER MORTON: I had a question
17 maybe for the STS representative about, isn't
18 there a requirement to give reimbursement to
19 participating in STS at this point for a lot
20 of the payers?

21 MR. SHAHIAN: Many payers do
22 actually require this, either for

1 participation in their plan, certainly for
2 premium status of various sorts. So, yes,
3 that is correct.

4 And did somebody want to ask about
5 the cost of participation? Was that a
6 question? Yes?

7 MEMBER FINDLAY: Yes, the burden
8 and cost.

9 MR. SHAHIAN: Certainly. The
10 average cost to a participant, and a
11 participant is typically either a hospital or
12 a large surgical group, the cost is
13 approximately \$3,000 a year. On top of that,
14 you have software costs which range anywhere
15 from about \$10,000 for a very, very good
16 program anywhere into the hundreds of
17 thousands for all the bells and whistles. But
18 you can do it for about \$10,000 software cost.
19 The major cost, as in all registries, is the
20 cost of data collection. We estimate one FTE
21 for every 500 cases entered.

22 MEMBER CIMA: I mean that is a

1 major issue that was brought up even at my
2 institution. It is getting to, like Peter was
3 saying, how many do you do?

4 We have four full-time abstracters
5 for the STS database at the Rochester campus.
6 We have abstracters in Florida and Arizona.
7 Basically, the decision at Florida was, well,
8 we were also paying for an abstracter for
9 NSQIP. The multi-specialty NSQIP came out.
10 So, we are going to stop participating in the
11 STS. We are going to use the cardiac surgery
12 NSQIP.

13 So, there is this dynamic, as we
14 have mentioned multiple times, the burden of
15 data abstraction and participation in
16 different databases. I mean the cost to
17 actually submit the data is relatively mild in
18 medical terms, \$10,000 maybe. But
19 abstracters, trained abstracters, a full-time
20 FTE can run into the multiple tens of
21 thousands, if not, with benefits and
22 everything, \$100,000 a year. So, you have to

1 get some real value out of it.

2 If they can do 15 cardiac cases
3 for the NSQIP sample as opposed to doing 40
4 STS ones, because they have a requirement to
5 do all, I believe, in STS, and I am not 100
6 percent, people are making their cost/benefit
7 thing. It is a huge number. As it becomes
8 more and more burdensome, it is going to
9 become more and more of an issue.

10 MEMBER DUTTON: To get back to the
11 fundamental question, I think there is value
12 to participating in a registry above and
13 beyond simply counting your cardiac mortality
14 or anything else. And for less-involved
15 specialties than cardiac surgery, they are at
16 a much more primitive point that David
17 mentioned of having very low participation in
18 national or aggregate benchmarking.

19 CO-CHAIR MORRIS: This sort of
20 gets back to what Dr. Halpern was saying.
21 That is that participating in a registry means
22 that you are comparing yourself to other

1 hospitals, and that is kind of the bottom
2 line; whereas, the other measures that we
3 voted on just mean that you are measuring
4 those items.

5 So, do we believe that we want to
6 advocate for essentially endorsing that
7 hospitals belong to a registry where they are
8 comparing themselves to other hospitals?

9 MEMBER SIPERSTEIN: Yes, I think
10 we have had the discussion before. I think
11 everyone is on the same page in that
12 registration makes sense. I think most
13 hospitals realize that, yes, there are going
14 to be resources that need to be put towards
15 this end.

16 The difficulty has to do with
17 multiple similar, quote, "competing" sources.
18 And obviously, if you are participating in
19 multiple registries, you are diluting
20 resources that could be better spent in
21 different areas.

22 CO-CHAIR MORRIS: Okay. Sorry.

1 So, the decision here I think is, are these
2 measures competing? Are they related? If
3 they are related, should they be harmonized?
4 So, competing versus related is a decision
5 that we have to make here.

6 MEMBER ROGERS: I'm sorry, I just
7 have one other comment or question. If we
8 move towards a mandate, which it sounds like
9 we are inching towards, that normally carries
10 with it some sense of authority or
11 jurisdiction, i.e., punishment if you don't
12 belong. I am not sure that we actually own
13 that kind of --

14 MS. MURPHY: And I don't think
15 that that is what it is trying to do, and that
16 is not what this question is trying to go to.

17 MEMBER ROGERS: Okay.

18 MS. MURPHY: The threshold
19 question is, does endorsement continue for a
20 measure that speaks to participation in a
21 database?

22 MEMBER ROGERS: Okay. Because I

1 heard the "mandate" word two or three times.

2 I just wanted to -- right.

3 CO-CHAIR MORRIS: I think that
4 this question is trying to go there, but we
5 don't necessarily have to help it.

6 (Laughter.)

7 MEMBER ROGERS: Okay.

8 MEMBER CIMA: A question that
9 arises, though, from this is, what I remember
10 the discussion was with STS last time was,
11 yes, it comes from the STS database, the data
12 to support that there is a performance gap and
13 whatever, and that there is also these are our
14 measures.

15 But, then, the question became,
16 and then they said, well, it is all on the
17 web. People can go to our website and
18 download the way of doing it so that you get
19 the number, the risk-adjusted number. It is
20 basically saying, if we endorse a measure
21 designed that way, yes, you don't have to
22 participate in STS, but you have to follow

1 STS's rules in how they adjust their risk
2 adjustment for whatever it is.

3 That is where I fundamentally had
4 the problem last time. Because what if there
5 is a different risk adjustment model used by
6 a different nationally-qualified clinical
7 database registry? Should we say you can
8 participate in that one, but for this specific
9 measure you have to use the rules and the
10 methodology outlined by the STS that we have
11 endorsed.

12 Even though you participate in
13 this measure, you participate in a nationally-
14 qualified clinical dataset that comes up with,
15 that evaluates cardiac surgery, but just
16 doesn't happen to use the same methodology,
17 you still have to use that methodology. That
18 is where you get into the problem.

19 If you are going to say we need to
20 harmonize, then you have to harmonize the
21 measures and say that the methodology for the
22 measurement is identical or standard, so that

1 you don't have to use the STS methodology.
2 Where risk adjustment is very different, very
3 important in cardiac surgery, they have a
4 different risk adjustment than maybe NSQIP
5 has.

6 So, we are saying, yes, you can go
7 to the web and do it, but what that means is
8 I've got a person in my hospital that has got
9 to do the NSQIP dataset and, then, I have to
10 take our raw data, I have to go to the STS
11 dataset. I have to get their methodology. I
12 have to redo it, then submit it to you.

13 That is a data burden, and that is
14 what we have to clarify here. Are we saying
15 you participate in a dataset and, then, the
16 measures could come from STS, but they can't
17 use the STS risk adjustment because that
18 means, in essence, you have to do what they
19 are doing. That is picking a winner.

20 MEMBER SAIGAL: I agree with that
21 point, although there is some benefit to
22 homogenous reporting of data across all these

1 datasets. These are the best minds in the
2 field in NSQIP and the STS. If there are
3 differences in their models, maybe an
4 appropriate thing is to have them come with
5 their measures and debate that, why one is
6 better than the other, when they are putting
7 their measures forward.

8 MEMBER CIMA: So, then, you are
9 saying, either way, let's say at the end of
10 that debate A wins versus B. Then, you have
11 to say we are letting you participate in
12 database. We say that is fine for that
13 measure. But, at the end of the day, that
14 data really doesn't count; you have to use
15 somebody else's. You have to use their
16 methodology.

17 What's the purpose of doing that
18 then? Then, you are saying: well, then, why
19 are you paying for this? You should just do
20 that.

21 MEMBER SAIGAL: Well, I am saying
22 you can agree with one of the developers that

1 their model is stronger, and I think that it
2 is an appropriate thing for us to do, to have
3 data nationally be collected in a similar way
4 and be comparable.

5 MEMBER HALPERN: I think, if I get
6 you right, what you are trying to say is, if
7 one database actually has a better model, then
8 all databases should move toward that model.

9 MEMBER CIMA: I think that is a
10 different discussion, though, than measurement
11 development. We are being asked to develop a
12 mortality, you know, risk-adjusted mortality
13 for aortic valve replacement, AVR 0120.
14 Although it based on STS risk-adjustment
15 methodology, so if you use your NSQIP to
16 report your risk-adjusted operative mortality
17 for mitral valve, is that sufficient? Or do
18 you have to say I collected that data, I have
19 done it, and now I have to go back and use the
20 free, publicly-accessible data methodology on
21 the STS website to reprocess my data and re-
22 administer and then resubmit it? That is what

1 I am saying, there is a difference.

2 CO-CHAIR MORRIS: Okay. Dr. Cima,
3 thank you.

4 I think that I agree that that is
5 sort of a nuance, the discussion about whether
6 other databases should move toward one best
7 model, and we talked about those nuances as
8 well previously, but that is sort of outside
9 of what we are trying to accomplish for right
10 now.

11 Dr. Shahian, did you have
12 something to add?

13 MR. SHAHIAN: Yes, just a point of
14 fact. I have served as an advisor to NSQIP
15 for the last four years. I serve on their
16 Measurement Committee, their Policy Advisory
17 Committee.

18 There is no NSQIP cardiac surgery
19 model. There is no competing model. I work
20 very closely with Cliff Ko, who directs it.
21 We work in a complementary fashion. They have
22 no desire to get into cardiac surgery. They

1 do not have a cardiac surgery module. They do
2 not plan a cardiac surgery model.

3 And feel free to call them anytime
4 to check on that.

5 MEMBER CIMA: Well, Allan and I
6 sit on the Joint Commission NSQIP Board, and
7 in the multi-specialty there's cardiac surgery
8 in it.

9 MR. SHAHIAN: There is also
10 prostatectomy and laminectomy and
11 neurosurgery. These are not models designs
12 for cardiac surgery. These are generic risk
13 models. They were never intended to be used
14 for something as specialized as this.

15 And they are actually phasing out
16 that model as they bring in specialties.
17 Specific models in general surgery, but they
18 have no plans to do so for cardiac surgery.

19 MEMBER CIMA: But, right now, they
20 are reporting on that. You can participate in
21 a multi-specialty and have cardiac surgery
22 patients included in that.

1 MR. SHAHIAN: Well, you can
2 include anybody you want, but the risk models
3 are so generic they would be, in our opinion,
4 of little value.

5 MEMBER HALPERN: That actually
6 comes up on vascular because I have noticed
7 that in NSQIP predicted mortality of certain
8 cases, like, for instance, an infected aortic
9 graft, their predicted mortality of the
10 patient that was involved was 2 percent, which
11 is ridiculous.

12 MEMBER CIMA: Well, I am not
13 supporting one or the other, but I am just
14 saying, as Dr. Shahian just pointed out, in
15 his opinion and the STS's opinion, it is not
16 any good.

17 But we are asking whether or not
18 participating in a national database, a
19 systematic database, is appropriate. That is
20 the question at hand here, not whether or not
21 one is better than the other.

22 So, there is a national

1 clinically-recognized database that does have
2 cardiac surgery data in it. Whether you agree
3 with the modeling or not is a different
4 question.

5 My point is this: should a
6 hospital, then, also need to participate in
7 STS or can they use the cardiac, fulfill the
8 requirement for cardiac surgical patients if
9 they participate in NSQIP?

10 MR. SHAHIAN: The question begs
11 credulity. Nobody is using NSQIP for cardiac
12 surgery. It was not designed for cardiac
13 surgery.

14 You may choose to use it, but you
15 would be alone, essentially, in the country.
16 I can't say anything else. It is a matter of
17 fact.

18 MEMBER MORTON: Just as kind of a
19 historical point, NSQIP went through a high-
20 risk model just to look at certain cases.
21 That is being phased out, but they are going
22 to come up with surgery-specific models. I

1 agree, right now, I guess there is not a plan
2 to do something around cardiac, but I don't
3 think it precludes that they will.

4 But, in just reading the measure
5 and talking here, it seems fairly agnostic.
6 It doesn't say that it has to be STS. Am I
7 reading that correctly?

8 So, I think the main point all of
9 us want to have here is that we do believe it
10 ought to be collected. We believe it ought to
11 be benchmarked. It ought to be risk-adjusted.

12 Does it have to be STS? I think
13 that is the only question that is out there
14 because STS seems to have the preponderance of
15 the hospitals, but there can be other datasets
16 that come up.

17 So, I think, from my sense, I am
18 fine with it as long as it is not exclusionary
19 to just STS.

20 MEMBER DILLON: But doesn't it
21 become focused, aren't we, then, directing it,
22 if we approve this, because of the

1 stewardship?

2 MEMBER MORTON: I don't know.

3 That is a good question. I don't know.

4 MEMBER CARPENTER: Isn't the
5 question at hand whether these are competing
6 measures? I mean these have all been
7 approved. We are not asking whether to
8 approve these or not. Whether these are
9 competing, and in that competing, make us have
10 to select one versus the other. I would
11 suggest that these are not competing, that
12 these are related, that they are different
13 patient populations. Obviously, the measure
14 on the right is a much more generic measure
15 for a hospital, and every hospital can meet
16 that in a variety of ways, and that these are
17 not, as listed there, competing, and really
18 have nothing to do with a lot of the
19 discussion that has been which database is
20 actually used.

21 And so, I would suggest that,
22 unless someone thinks that they are competing,

1 and we should discuss that, that we call these
2 related and move on with that.

3 CO-CHAIR MORRIS: Does everybody
4 agree to call these related rather than
5 competing? Dr. Cima, do you agree?

6 So, another issue that we have
7 here, then, is that since 0113 is a
8 maintenance measure, and Dr. Shahian said that
9 there's more than 95 percent participation,
10 and that if you don't participate,
11 essentially, you're alone, should this become
12 an inactive measure?

13 MEMBER DUTTON: Yes, I think I
14 suggested that last time. I think in many,
15 many specialties and disciplines this is a
16 very important measure. I mean the number of
17 anesthesia practices reporting anesthesia data
18 is less than 5 percent right now. So, there
19 is a huge opportunity in other specialties,
20 but in this case they have topped it out.

21 CO-CHAIR MORRIS: Anybody else?

22 MEMBER ZAMBRICKI: I think that

1 that is a good point because isn't part of the
2 intention that these measures will be publicly
3 reported and the public can make judgments
4 about quality based on the result of a
5 measure? So, in a simple way, a lot of people
6 would get credit for quality in the public's
7 eye, when it may actually be the status quo.

8 CO-CHAIR MORRIS: Any other
9 thoughts on 0113 and whether we would
10 recommend that it go to an inactive status?

11 MEMBER WILHOIT: Another
12 perspective on this would be that the rate is
13 95 percent, which means that 5 percent aren't
14 participating, and do you want to draw
15 attention to that 5 percent? Is that an
16 issue?

17 Because it is not the rate that is
18 reported; it is the individual facility or
19 practice. Does this practice, does this
20 hospital participate in the registry, not that
21 the rate is 95 percent.

22 MEMBER STAFFORD: Do we know what

1 the number is combined for all of the
2 databases that are out there? So, if it is 95
3 percent for STS, of that 5 percent gap, how
4 much of that are those that belong to the New
5 England Consortium and the New York State
6 databases?

7 CO-CHAIR MORRIS: With the
8 language of the measure, they would still be
9 adherent to the measure.

10 MEMBER ZAMBRICKI: But it sounded
11 like, from the STS representative, the
12 compliance is about 100 percent if you include
13 the New England database and the New York,
14 from what he was saying earlier.

15 CO-CHAIR MORRIS: Does anybody
16 disagree with recommending that this move to
17 inactive status?

18 (No response.)

19 Okay.

20 MS. MURPHY: So, then, what we can
21 do is vote for retaining endorsement with the
22 caveat that it would be on inactive status if

1 the Board of Directors approves that, the
2 status.

3 MEMBER MORTON: Can I ask what
4 that means practically? Is it like double-
5 secret probation when you go to inactive?

6 (Laughter.)

7 What does that mean?

8 MS. MURPHY: It means that it
9 would be set with measures that would not be
10 expected to be monitored and reported on --
11 because, remember, this is a public reporting
12 piece -- on the same frequency, but that it
13 could be brought back into an active status
14 and, then, reported upon without having to go
15 through all of the process.

16 MEMBER HALPERN: When you say not
17 with the same frequency, does that mean they
18 still get monitored at some frequency?

19 MS. MURPHY: One, it is voluntary
20 and there is the expectation that there would
21 be some monitoring of it, but periodically --
22 there would not be an expectation on the part

1 of NQF to have, unless the Board of Directors
2 specifies something, to have a specific
3 interval during which it is reported upon.

4 MS. BOSSLEY: Right. This is
5 where it gets challenging because we don't
6 control the implementation. We are not
7 necessarily involved in the implementation and
8 the reporting of these measures.

9 So, anything that does go into
10 inactive status, in the same as anything that
11 is endorsed, other than us saying this meets
12 our criteria, that is an influencer on who
13 implements and uses these measures. But,
14 beyond that, we can't say with all certainty
15 that any measure that is endorsed will be used
16 and reported.

17 So, inactive, in that way, I think
18 that is something that the Committee needs to
19 balance as well. When you do have a measure
20 that moves into inactive you are sending a
21 message, still valid, still reliable, still
22 important, topped-out, that may actually move

1 a measure off of implementation programs. I
2 think that is part of what you need to look
3 at, is what are the unintended consequences of
4 that. With this measure, I don't think that
5 is an issue. You may have a few coming
6 forward that you would need to address that.

7 MEMBER KLEINPELL: Well, I have a
8 question. When a measure is moved to inactive
9 status, is there some rationale then provided,
10 so that when people go there, they see the
11 reason that we are putting it inactive is
12 because there is 95 percent to near 100, if
13 you include all of them? So that they know we
14 are not saying this is not important anymore.

15 MS. BOSSLEY: So, this is part of
16 the messaging that we are still figuring out
17 because we are new to the maintenance piece of
18 this. We want to be able to message, when
19 removal of endorsement occurs, what was that
20 reason. We want to be able to say why it
21 moved into inactive status.

22 So, we are currently figuring out,

1 what is that? What is the level of detail?
2 But, again, inactive would clearly state it
3 meets all the criteria except it is topped-
4 out, yes.

5 MEMBER STAFFORD: So, if you are
6 still working on the language, should we even
7 be talking about this at this point? Because
8 you are now asking us to discuss and vote on
9 something that may change, and we have just
10 spent a whole lot of time talking about this.

11 And so, if we don't know what the
12 message is going to be based on our vote, then
13 it really doesn't seem like the right thing to
14 do at this time.

15 MS. MURPHY: Can I respond?

16 MS. BOSSLEY: Sure.

17 MS. MURPHY: We provided
18 information about inactive status in terms of
19 the draft. And that is one of the reasons why
20 you would caveat a decision. But within the
21 information about inactive status, it provides
22 for the fact that the measure focus continues

1 to be important, that it meets the criteria
2 based on evidence of scientific acceptability,
3 usability, feasibility, and that the only
4 issue is that it is topped-out.

5 So, that part of the criteria I
6 don't think is at issue or would be expected
7 to be changed by the Board.

8 MS. BOSSLEY: Right. I mean we
9 have put the inactive status proposal out for
10 comment and received comment from the
11 membership. In general, it is supportive. I
12 don't anticipate that the Board will have an
13 issue with it.

14 So, in that way, we feel that it
15 is probably in the best interest of your time
16 to at least consider it now, rather than have
17 you come back on a conference call and do it.
18 But we are taking a bit of a chance asking you
19 to do this. We are also doing it with another
20 committee as well.

21 With the language, though, on the
22 website, let me be clear, all your documents

1 that go out for comment and in the report will
2 clearly explain what you have proposed and
3 what your recommendation is. Nothing else on
4 the website will change.

5 The measures stay endorsed until
6 this final review is done. It goes through
7 the Consensus Standards Approval Committee,
8 and, then, it goes to the Board.

9 That gives us until November or so
10 to figure out the language that actually goes
11 on the website with these measures that are
12 inactive. So, I think we are okay. I mean,
13 from a staff perspective, we feel comfortable.
14 And so, the question is, if you all feel
15 comfortable having that conversation today,
16 but we don't think that there will be an issue
17 going to the Board.

18 MEMBER MORTON: Can I ask a
19 question? I am just curious what Dr. Shahian
20 has to say about it. Will this have an impact
21 on anything going on in cardiac surgery if we
22 go to making this measure inactive?

1 MR. SHAHIAN: No, I don't think
2 this will have any impact because the measure
3 is derived from database participation or,
4 essentially, required if you want to have a
5 cardiac surgery program.

6 The only thing I would worry about
7 was the comment that was made, what is the
8 message we are sending? I am a little
9 concerned about that. But I leave that to
10 your good judgment.

11 MEMBER DUTTON: Success, that is
12 the message. You've done it. You've got
13 everybody.

14 MR. SHAHIAN: Well, as long as
15 everybody understands, as long as the rest of
16 the world understands that, I think it is all
17 in how it is presented.

18 CO-CHAIR MORRIS: Maybe the name
19 could be changed from inactive to successful.

20 (Laughter.)

21 MS. BOSSLEY: We have had I can't
22 say how many high achievement, emeritus. We

1 don't know the right name.

2 (Laughter.)

3 Any suggestions are welcome.

4 MEMBER COLLINS: I have a
5 question. On these inactive states and for
6 measures that are topped-out, is there a
7 concern with regressing, regression? High
8 rates of compliance, 95-plus, it is not such
9 a big deal here, but I see measures we will
10 talk about in the future where I think it is,
11 where if you go back to 90, 80 percent, you
12 know, some even lower rates, that is a real
13 concern.

14 Have there been similar scenarios
15 where things have been moved to inactive, the
16 Committee has determined it is topped-out,
17 and, then, you have seen a regression?

18 MEMBER AFSAR-MANESH: Well, I know
19 this is not really up for discussion at this
20 point, but it would be very interesting, as
21 this gets developed by the staff, that perhaps
22 there is an infrequent reporting component

1 built in. And again, maybe for this one it
2 doesn't need to be as frequent, but for some
3 of the other ones, again, that are coming up
4 today, something that looks at it on an annual
5 basis, or whatever frequency seems reasonable,
6 so that it is inactive, but still there is
7 some feedback loop. So that, if it slipping,
8 we would know about that.

9 MS. BOSSLEY: They are all really
10 good points, those things that we have been
11 trying to figure out because no one knows what
12 the potential impact of this is. So, this is,
13 again, where we need to balance because we do
14 not control who implements/reports out all of
15 this. That is not within NQF's purview.

16 But, as we move toward electronic
17 systems, we are hoping that this actually can
18 be much easier. Especially with some of these
19 measures, I think once you have an electronic
20 system, you will be able to poll this and be
21 able to surveil it periodically. But it is
22 one of those things we honestly don't know the

1 answer to yet, and we will have to continue to
2 monitor with it, work with CMS, HHS, and
3 others, to figure out what we can do to
4 assist.

5 CO-CHAIR MORRIS: Okay. So, we
6 essentially agreed as a group that there is an
7 inactive or emeritus or some other label for
8 Measure 0113, we agree that it should go
9 there.

10 We should move on to Measure 0134.

11 MS. MURPHY: We should vote.

12 CO-CHAIR MORRIS: Do we need to
13 officially vote? Oh, okay, we are going to
14 officially vote.

15 Do you recommend this measure for
16 endorsement?

17 MS. MURPHY: And the caveat here
18 is it will also say "and moved to inactive
19 status".

20 MEMBER DUTTON: So, we are
21 recommending it be moved to inactive status,
22 what this really should say?

1 MS. MURPHY: As an endorsed
2 measure.

3 CO-CHAIR MORRIS: Endorsement does
4 not preclude inactive. In fact, it has to be
5 endorsed to move to inactive.

6 (Vote.)

7 Please hit your button again.

8 (Vote.)

9 It is 20 votes for yes and one
10 abstain.

11 The next measure is 0134, surgery
12 patients who received appropriate venous
13 thromboembolism prophylaxis within 24 hours
14 prior to surgery to 24 hours after surgery end
15 time.

16 And again, we are going to see
17 measures that are potentially related versus
18 competing here.

19 Oh, I'm sorry, did I misread that?
20 I'm sorry. Yes, I am getting ahead of myself.
21 I apologize.

22 Coronary artery bypass graft using

1 internal mammary artery, 0134.

2 MEMBER DUTTON: Why does STS have
3 two of these measures? What is the
4 difference?

5 CO-CHAIR MORRIS: That is what we
6 are supposed to be talking about here.

7 MR. SHAHIAN: I think the
8 difference is simply, is mainly the
9 exclusions, and 0134, actually, what you
10 probably have in your paperwork, our staff
11 discovered a slight error, which I hope will
12 be corrected.

13 But the appropriate exclusions
14 list should not include the IMA is not a
15 suitable conduit. When this was discussed
16 recently on a call, we agreed to eliminate
17 that exclusion. So, the exclusions that are
18 considered valid are previous cardiothoracic
19 surgery and released on a radiation emergent
20 or a salvage procedure or the absence of LAD
21 disease.

22 So, again, it is mainly the

1 exclusions. I think 0134 is the measure that
2 is being put forward.

3 MEMBER WILHOIT: The endorsed
4 Measure 0516 was endorsed four years ago?
5 Wouldn't that be up for review again by now if
6 it is four years old? I was confused by the
7 date on that.

8 MS. HAN: This is Jane Han from
9 STS. May I answer that question?

10 Measure 0516, actually, it was
11 first introduced in 2008 and it received time-
12 limited endorsement. And so, Heidi Bossley is
13 there, and she can probably speak from an NQF
14 perspective.

15 But it was reviewed by the CSAC
16 last July, July 2010, and received final
17 endorsement or full endorsement as a result of
18 that discussion.

19 The reason why, as Dr. Shahian
20 explained, the exclusions are listed
21 differently, which we will have corrected, but
22 the other difference is that 0516 is at the

1 physician-level while 0134 is at the hospital-
2 or facility-level. I don't think we have any
3 problems combining them into a single one.

4 The reason why we have a
5 physician-level measure is for PQRI. So, I
6 don't what happened in 2008. It was before I
7 started here. But I think it was submitted as
8 a separate measure with the same
9 specifications just for that reason.

10 Does that make sense?

11 CO-CHAIR MORRIS: Yes. Thank you.

12 Would the group like to recommend
13 that they be harmonized?

14 (Chorus of yeses.)

15 Okay. Anything else?

16 Dr. Shahian, do you want to say
17 anything?

18 MR. SHAHIAN: No.

19 MS. MURPHY: So, we would not vote
20 on the measure as it exist today because you
21 have just recommended that it be harmonized.
22 So, you would be voting on something that is

1 going to be overtaken very quickly.

2 CO-CHAIR MORRIS: Okay. The next
3 measure, 0218. Now we are going to talk about
4 surgery patients who received appropriate
5 venous thromboembolism prophylaxis within 24
6 hours prior to surgery to 24 hours after
7 surgery end time.

8 MEMBER CARPENTER: I can make a
9 couple of comments because I have looked at
10 this.

11 We have been through one of these
12 measures, the 0218, last time, and we voted to
13 endorse that. That is specific to selected
14 surgical patients, and there is a list of
15 diagnoses that apply in their measure.

16 The other measure, the previously-
17 endorsed measure from the Joint Commission, is
18 medical and surgical patients, essentially all
19 patients over the age of 18, as I read it.

20 So, it is a much broader inclusion criteria.

21 The 0218 is a subset of the patients included
22 in 0371. So, that is one difference.

1 The other difference is what is
2 considered VTE prophylaxis. In my
3 understanding, the 0371 measure includes any
4 documented VTE prophylaxis measure or
5 technique, medication or mechanical
6 prophylaxis, versus the 0218, which requires
7 really the chest position guideline measures
8 primarily to meet the criteria.

9 So, the 0371 is not restricted to
10 any one individual set of guidelines. There
11 are competing guidelines, chest positions,
12 which is based on DVT prophylaxis. There is
13 one from the orthopedic surgery group which is
14 based on symptomatic PE, which differ from the
15 chest position guidelines.

16 So, those are some of the
17 differences. It is a smaller, it is a subset
18 of the bigger group, and it is a more
19 specified degree of what is acceptable
20 prophylaxis.

21 There is some controversy over
22 what is acceptable prophylaxis, and those two

1 groups have not been able to work out
2 mutually-standardized prophylaxis guidelines.
3 So, there are sort of competing guidelines at
4 this point.

5 MEMBER HALPERN: Correct me if I
6 am wrong, but I think some of the controversy
7 arises from bleeding versus clotting risks,
8 the risk of bleeding into recently surgical
9 spaces and the detrimental effects of that.

10 MR. BRATZLER: Yes, this is Dale
11 Bratzler.

12 I need to correct something here.

13 MEMBER HALPERN: I can't hear you.

14 MR. BRATZLER: I was the Chair of
15 the Technical Expert Panel for the NQF/Joint
16 Commission VTE measures that are being
17 discussed here, the competing measure.

18 The surgical population is
19 explicitly excluded from that measure. That
20 measure focuses only on medical issues. So,
21 this measure focuses on surgical patients,
22 based on the HACCP guidelines, which gives

1 procedure-specific Level 1 recommendations for
2 VTE prophylaxis.

3 The populations do not overlap
4 with the Joint Commission measure. We worked
5 carefully to make sure that they did not
6 overlap.

7 And the reason that the NQF-
8 endorsed Joint Commission VTE measure allows
9 any forms of prophylaxis is because for
10 medical patients there are almost no
11 guidelines that are explicit about which forms
12 of VTE prophylaxis are appropriate for medical
13 patients.

14 So, I chaired that Technical
15 Expert Panel and know the Joint Commission
16 measures very well. And I can tell you
17 without question that the SCIP population is
18 excluded from those measures.

19 MEMBER STAFFORD: Dale, we are
20 sitting here looking at Measure 0371, which is
21 the Joint Commission measure, and it includes
22 surgical patients, both in the numerator as

1 well as the denominator. It says, "Medical
2 and surgical inpatient discharges. If surgery
3 and incision time is greater than 24 hours of
4 admission, patients must have documentation of
5 prophylaxis within 24 hours of hospital
6 admission."

7 That is the measure that was
8 endorsed in May of 2008.

9 MR. BRATZLER: And I am telling
10 you that, if you look at the denominator
11 specifications, the SCIP population is
12 excluded.

13 MEMBER STAFFORD: No.

14 MEMBER CIMA: Well, in our
15 document it says, "Denominator, all patients".

16 MEMBER STAFFORD: That is correct.

17 MR. BRATZLER: Well, I can tell
18 you that, if you look at the ICD-9 codes, the
19 SCIP population, we worked carefully to make
20 sure that the two measures did not completely
21 overlap. So, they don't overlap. The SCIP
22 population is not included in the Joint

1 Commission measures.

2 MEMBER DUTTON: Yes, on page 22,
3 it does list SCIP as an exclusion.

4 MR. BRATZLER: And the reason is
5 that there is a large number of surgical
6 patients that don't fall under the SCIP
7 population for which there aren't explicit
8 recommendations around VTE prophylaxis or
9 others. They are hospitalized and they have
10 some surgery.

11 But the SCIP population, the SCIP
12 measure that you are discussing now only
13 reflects those operations for which there are
14 published Level 1A recommendations for VTE
15 prophylaxis. And that is the big difference
16 between the Joint Commission and the CMS
17 measure. The Joint Commission measure looks
18 essentially at hospitalized patients. Did
19 they get prophylaxis or did they have
20 documentation of a reason to not get
21 prophylaxis, whether they are medical or
22 surgical? But the SCIP population is excluded

1 from the Joint Commission measure.

2 MEMBER STAFFORD: Perhaps even
3 more of a point to harmonize these, because I
4 would say that most hospitals and most
5 surgeons are doing this for all of their
6 patients, whether they are in the SCIP
7 population or not.

8 MR. BRATZLER: And I understand
9 that point. Perhaps there is a way to do it,
10 but the difference here is that we look at the
11 appropriateness of prophylaxis based on
12 surgical procedure in the SCIP population;
13 whereas, the Joint Commission measure only
14 looks at whether any form of prophylaxis was
15 given at all.

16 You know, there just aren't many
17 people out there that would recommend TED hose
18 for hip replacement surgery or other things.
19 That is the big difference in the
20 specifications of the measures.

21 The Joint Commission measure does
22 not look at appropriateness, and that is the

1 big difference for the SCIP measure. It looks
2 at appropriateness.

3 CO-CHAIR MORRIS: So, Measure 0218
4 is really for the SCIP population, it sounds
5 like; whereas, the other measure specifically
6 excludes the SCIP population.

7 Jim, I want to hear what you have
8 to say. So, I am not trying to push us ahead,
9 but we will need to decide whether we want to
10 endorse 0218 and, then, request harmonization
11 from the other measure.

12 MEMBER CARPENTER: What I was
13 going to say, I think I understand that better
14 with Dale's clarification. Because I don't
15 think we have all the details in what we were
16 presented, and the Joint Commission makes it
17 particularly hard to follow their algorithms.
18 If you ever look at those, you just give up
19 pretty quickly. And some of the tables are a
20 little hard to find.

21 So, I think that clarification is
22 helpful, and perhaps they are not the same

1 group of patients. They are really more
2 related.

3 I guess having different criteria
4 for different groups of patients for data
5 collection/extraction does complicate that
6 process. And if there is an opportunity for
7 harmonization, that would be an advantage.

8 You do lose potentially some of
9 the appropriateness. As we discussed before,
10 we did endorse that, but there is controversy
11 and guidelines do change with time. So, there
12 may be an opportunity for harmonization here.

13 MEMBER SIPERSTEIN: I just want to
14 comment, having had the pleasure of just re-
15 reviewing the chest guidelines, it is a very
16 thick tome. Part of the reason is it is not
17 a simple algorithm. And subset of patients in
18 whom there are data to make more specific
19 recommendations exist, but there are also
20 large groups of patients where we really are
21 working in the realm of generalities.

22 So, I can understand the concept

1 that, where the data exists to be more
2 prescriptive about types of VTE prophylaxis,
3 even the chest guidelines, there are menus
4 given for each of these categories, not a
5 single treatment. It may make sense, where
6 there is data, yes, to be more prescriptive,
7 and where there is not data, to simply be more
8 general in terms of recommending some type in
9 the absence of more definitive data.

10 MR. BRATZLER: Yes, so I think you
11 have highlighted why there are two separate
12 measures. And again, I chaired the panel fore
13 the Joint Commission. That is really the
14 population.

15 We are focused on the hospitalized
16 population, medical patients, surgical
17 patients that don't fall under the SCIP
18 population. A hospital can pass with any form
19 of prophylaxis or documentation of a reason
20 not to use prophylaxis.

21 The SCIP measures are very
22 procedure-specific. In the development of the

1 denominator, we went through every ICD-9 code,
2 now ICD-10 code, to define which patients
3 would fall into the population of the
4 denominator for each type of surgery. And,
5 then, the menu, the menu that you mentioned
6 from the chest guidelines, is the appropriate
7 menu that is used to put the patient in the
8 denominator for each type of surgery.

9 CO-CHAIR MORRIS: Okay. Thank
10 you.

11 Are we ready to vote on whether to
12 endorse 0218? Anybody want to say anything
13 else about it?

14 (No response.)

15 All right. Let's go ahead and
16 vote. Be sure you aim at Jessica.

17 (Vote.)

18 Is there somebody missing?

19 Please press your buttons one more
20 time.

21 (Vote.)

22 Okay. Seventeen votes for yes,

1 two votes for no, one abstain.

2 Our next decision is whether we
3 want to request that this be harmonized,
4 whether we want to request that the other
5 measure be harmonized with this measure.

6 Are we actually voting on that or
7 just discussion it?

8 MS. MURPHY: It is not a voting --

9 CO-CHAIR MORRIS: It is not a
10 vote? Okay.

11 MS. MURPHY: But it would be a
12 recommendation from the --

13 MEMBER RIVENBURGH: It sounds like
14 that is no, since they are defined by
15 different populations. And the reason they
16 are defined as different populations is that
17 the standards are different or the guidelines
18 are different.

19 CO-CHAIR MORRIS: In that case,
20 what I would like to request is just that this
21 be clarified a little bit more when it comes
22 back up for review. Are the populations

1 actually different?

2 Jim, did you have anything to add?

3 MEMBER CARPENTER: No.

4 CO-CHAIR MORRIS: So, the next
5 measure is Measure 0360, esophageal resection
6 mortality rate, risk-adjusted.

7 And this was to be evaluated with
8 0361, right? I think we are talking about
9 whether to harmonize.

10 MS. MURPHY: Yes. So, this is
11 looking at 0360 and 0361, mortality and
12 volume, in comparison to the Leapfrog measure,
13 which combines the two into a single measure.

14 And the question here is not
15 whether it competes, but, rather, is there an
16 opportunity to take 0360 and 0361 and in some
17 way, through combining them or otherwise
18 harmonizing with the Leapfrog measure, and it
19 was endorsed just in last September.

20 CO-CHAIR MORRIS: One of the
21 issues that came up in our discussion of this
22 was that volume is more predictive of

1 mortality than mortality is because the volume
2 can be so low in some centers. So, that
3 should be part of our discussion here.

4 MS. MURPHY: Go ahead and have
5 that discussion, whatever they want to do.

6 CO-CHAIR MORRIS: All right. I
7 guess what we should really discuss here is,
8 do we want for these to be harmonized before
9 we actually vote on them?

10 MEMBER HALPERN: Yes.

11 CO-CHAIR MORRIS: Anybody disagree
12 with that?

13 MEMBER WILHOIT: I think there's
14 reasons not to harmonize. I mean for the
15 point you just raised of volume being an
16 important measure. And if you look at the
17 Leapfrog measure, as best as I can figure out
18 from the details that are here, it is all a
19 calculation.

20 And so, you have no direct
21 measurement. You are not quite sure what you
22 are getting. All you get is the bottom line.

1 And if mortality is less
2 predictive than volume, I like seeing the
3 numbers rather than just seeing a calculation.

4 CO-CHAIR MORRIS: Anybody else
5 want to respond to that?

6 (No response.)

7 I think that mortality has a lot
8 of street credibility. And therefore, it is
9 important in that way. It probably should be
10 measured. If it is measured as a completely
11 separate entity, that can be deceptive.

12 Is it possible to have a volume
13 measure and, then, to have a mortality measure
14 that is harmonized with volume as a separate
15 -- can we make that recommendation?

16 MS. MURPHY: Yes.

17 CO-CHAIR MORRIS: What do you guys
18 think about making that recommendation?

19 MEMBER WILHOIT: And the
20 recommendation there being to harmonize 0360
21 and 0361, but keep them separate from the
22 Leapfrog measure? I think that has a lot of

1 credibility, to do that.

2 MS. BOSSLEY: This is Heidi.

3 I mean one option is to recommend
4 that they be paired, which means that they are
5 endorsed as two separate measures, but should
6 be implemented and used together, which is, I
7 think, what you are trying, where you are
8 headed with those two.

9 MS. MURPHY: And when they were
10 initially endorsed, they were endorsed to be
11 reported as pairs.

12 MS. BOSSLEY: So, I think you just
13 want to continue that endorsement.

14 CO-CHAIR MORRIS: Any other
15 discussion of this? Carol, do you feel
16 satisfied by that?

17 MEMBER WILHOIT: That would sound
18 good to me.

19 CO-CHAIR MORRIS: Okay. All
20 right, let's go ahead and vote.

21 (Vote.)

22 Please aim your hand-helds at

1 Jessica and vote one more time.

2 (Vote.)

3 Okay. That is 20 votes for yes,
4 no noes, and no abstains.

5 I think what we are going to do
6 now is, it's 11:19, yes, we will take a break.
7 Maybe is five minutes too short? A 10-minute
8 break? And, then, we will come back.

9 Yes?

10 MEMBER CARPENTER: Let's finish
11 this because they are a pair.

12 CO-CHAIR MORRIS: Oh, I'm sorry.
13 Oh, I beg your pardon. I'm sorry about that.
14 This is what having no eyes in the back of my
15 head leads to.

16 On 0361, let's go ahead and vote.
17 Please just go ahead and vote twice.

18 (Laughter.)

19 (Vote.)

20 That's 20 votes for yes, no noes,
21 and no abstains.

22 And now a 10-minute break,

1 assuming nothing else pops up behind me. So,
2 we will see you back here at 11:30.

3 (Whereupon, the foregoing matter
4 went off the record at 11:20 a.m. and resumed
5 at 12:40 a.m.)

6 CO-CHAIR TORCHIANA: Could we get
7 underway again, please?

8 Okay. Before we get to
9 consideration of candidate measures, Melinda
10 has a comment to make on the prior discussion.

11 MS. MURPHY: This is just
12 finishing up the discussion that you just had
13 with respect to the esophageal resection
14 measures.

15 What we will do, what we need to
16 do is be able to get you the full
17 specifications, probably in the form of the
18 measure evaluation for the Leapfrog measure,
19 so that you can look at that in terms of best
20 measure evaluation against the two that you
21 just recommended for endorsement. And we will
22 get that out to you, and we will have that

1 discussion on a conference call, when we talk
2 about the other related and competing
3 measures.

4 CO-CHAIR TORCHIANA: So, the
5 consideration of candidate measures will begin
6 with a presentation by the measure developers.

7 And I would ask that we try to be
8 quite concise in this, so that we can actually
9 get to some of the measures before our lunch
10 break at 12:40.

11 And so, I am going to follow the
12 order that is on the agenda and begin with the
13 Society of Thoracic Surgeons. I think we have
14 eight or nine developers. So, we will start
15 with the STS.

16 David, are you going to be the
17 presenter?

18 MR. SHAHIAN: Yes, and I can be
19 quite concise.

20 This is a measure designed to
21 promote the use of beta blockade in the
22 preoperative cardiac surgery patient.

1 Cardiac surgery entails some
2 manipulations of the heart, fluid shifts,
3 electrolyte shifts, use of
4 cardioplegic/cardiopulmonary bypass, and a
5 number of other unique features that result in
6 a particularly high incidence of postoperative
7 atrial fibrillation which can be quite a
8 morbid complication and certainly a costly
9 complication.

10 The use of preoperative beta
11 blockade primarily for this purpose has been
12 a longstanding ACCAH Class 1 indication.
13 There are now more than 60 randomized trials,
14 excuse me, 30 randomized trials that show on
15 average a 60 percent reduction in
16 perioperative atrial fibrillation with the use
17 of preoperative beta blockade.

18 There are other reasons to
19 consider beta blockade in the cardiac surgery
20 patient, including one study by Bruce Ferguson
21 based on several hundred thousand patients in
22 the STS database showing a slight reduction in

1 mortality in patients with ejection fractions
2 over 30 percent, substantiated by two smaller
3 observational studies. There are 10
4 randomized trials showing a reduction in the
5 incidence of postoperative VT and DF.

6 This is a measure where we have
7 considerable room remaining. There is a gap
8 and there is variability in performance. We
9 have in our more recent iterations recognized
10 the fact that there are patients for whom
11 preoperative beta blockade may not be
12 possible, for reasons of hemodynamic
13 instability, for example. And we now allow
14 such exclusions if they are documented in the
15 medical chart.

16 An audit of this measure is
17 included as part of a routine audit, and our
18 auditors have found that there is agreement
19 between the use of contraindications and what
20 is available in the chart to document those
21 reasons in over 95 percent of cases. So, that
22 seems to be working.

1 Now there may be some concern due
2 to the fact that the recommendations have
3 changed in general surgery. There has been a
4 move away from routine preoperative beta
5 blockade.

6 A little bit different situation.
7 First of all, most of the studies that have
8 shown concern have been studies in which fixed
9 dose agents have been used a very short time
10 before the procedure and without titration,
11 which is clearly not the appropriate way to do
12 it. Very salutary results have been found
13 where patients have been titrated to an
14 optimal heart rate, and the agents have been
15 started well in advance.

16 So, I don't think that the
17 concerns in --

18 CO-CHAIR TORCHIANA: David, if I
19 could ask you to be just a little more high-
20 level?

21 MR. SHAHIAN: I'm done.

22 CO-CHAIR TORCHIANA: We have a

1 bunch of these to get through.

2 Any comments on the beta blocker
3 at discharge that seems pretty self-
4 explanatory?

5 MR. SHAHIAN: This is
6 preoperative, I think we are doing.

7 CO-CHAIR TORCHIANA: No, I am
8 saying there is a second STS measure.

9 MR. SHAHIAN: Oh, yes.

10 CO-CHAIR TORCHIANA: Any comment
11 on that one?

12 MR. SHAHIAN: The same reasoning,
13 except to say that virtually all, by
14 definition, cardiac surgery patients would
15 qualify for one of the ACC/AHA recommendations
16 for secondary prevention for use in patients
17 that have MI, unstable angina, heart failure.

18 So, there are compelling reasons,
19 not the least of which is long-term survival
20 in a number of studies, to support this
21 measure.

22 CO-CHAIR TORCHIANA: Thanks very

1 much.

2 The next measure is from CMS, and
3 I believe Dale on the telephone is going to be
4 presenting as the developer.

5 MR. BRATZLER: Yes, this is Dale.
6 Let me pull up my notes.

7 This is the conversation about the
8 beta blocker measure? I want to make sure I
9 have got the right one.

10 CO-CHAIR TORCHIANA: Yes, the beta
11 blocker measure, surgical patients on beta
12 blocker prior to admission.

13 MR. BRATZLER: Right. So, the
14 denominator for this measure is restricted to
15 patients undergoing surgery who are on beta
16 blockers prior to arrival. So, the American
17 College of Cardiology, the American Heart
18 Association have, it is a Class 1A
19 recommendation continuing beta blockers in
20 patients who take beta blockers at home.

21 So, the denominator population for
22 this performance measure is patients having

1 surgery who take a beta blocker at home. We
2 recently recommended some mild changes to the
3 performance specifications to improve the
4 measure and to reduce some of the data burden.

5 So, the change to the measure now
6 is that the post-op length of stay is greater
7 than or equal to two days. And we look to see
8 if the patient received a beta blocker on the
9 day prior to surgery or the day of surgery.

10 So, no longer are we requesting a 24-hour
11 timeframe. We just simply say, did the
12 patient get the beta blocker either the day
13 before or day of surgery, and, also, did they
14 get a beta blocker on either post-op day 1 or
15 post-op day 2?

16 One of the problems with the
17 measure in the past is that the hospitals
18 could pass the performance metric by simply
19 giving a single dose before surgery. And now,
20 you know, the real focus of the guideline is
21 to continue beta blockers in patients who take
22 them at home. So, now we will look to see,

1 did they get a dose the day of the day before
2 surgery, and if they are in the hospital for
3 greater than two days, did they get dose on
4 either post-op day 1 or day 2?

5 CO-CHAIR TORCHIANA: Thank you.
6 Could you also say a word on the measures on
7 the next page of the agenda, hair removal,
8 complication rates following arthroplasty, and
9 readmission rates?

10 MR. BRATZLER: Yes. So, I cannot
11 speak to either the arthroplasty or the
12 readmission rates. We don't have
13 responsibility for that measure.

14 The hair removal measure, I think
15 this has been discussed before. This is a
16 measure that I think there has been some
17 discussion about approaching very high rates
18 of performance. The performance measure
19 basically looks at whether the patient had no
20 hair removal at all for certain operations or
21 use of either depilatories or clippers rather
22 than razors.

1 I can tell you, I don't have the
2 data right in front of me, the national
3 performance rates on the measure are extremely
4 high. I am pretty sure Wanda has access to
5 that data, and I know there has been some
6 discussion about whether this is a, quote,
7 "topped-out" measure or not.

8 CO-CHAIR TORCHIANA: Okay. Thank
9 you, Dale.

10 It has been suggested to me that
11 Laura Grosso from Yale University might be the
12 developer for the other two CMS measures. Is
13 she present?

14 (No response.)

15 All right, let's move on, then, to
16 the next category, which would be AHRQ.
17 Please cover all the potential measures on
18 this list, if you can, whoever is here from
19 AHRQ.

20 MR. BOTT: Yes. My name is John
21 Bott. I work under contract onsite with AHRQ.

22 In one minute or less, yes, these

1 are a number of AHRQ quality indicators. They
2 are derived from electronic administrative in-
3 patient claims datasets.

4 And these are measures that are
5 annually updated as far as coding, user input,
6 refinements, to stay contemporary with the
7 field of measurement. They are freely
8 available to the public in terms of the
9 software and the documentation, which feeds
10 into users being able to provide continued
11 input into the measure.

12 And real quickly, just to
13 apologize for the late arrival of the
14 citations to the measures, as we were in the
15 process of updating the citations for all
16 measures and we have since prioritized those
17 in the NQF maintenance process. And we
18 appreciate NQF's allowance for that late
19 arrival of those updated cites.

20 And there are several others, when
21 we talk about the RQIs, who are here in person
22 as well as on the phone from the RQI team that

1 will probably be much more responsive to the
2 more technical questions than myself.

3 CO-CHAIR TORCHIANA: Thank you.

4 I skipped Ingenix, the patients 18
5 years of age or older on a beta blocker. Is
6 Laura Eaton on the phone from Ingenix?

7 MS. EATON: Yes, I am. Can you
8 hear me?

9 CO-CHAIR TORCHIANA: We can hear
10 you fine.

11 MS. EATON: Can you hear me?

12 CO-CHAIR TORCHIANA: We can hear
13 you fine.

14 MS. EATON: Oh, okay. All right.
15 Thank you.

16 Yes, I guess I will be short. I
17 wanted to point out that we at Ingenix are
18 aware of the STS registry measures that NQF
19 currently endorses, and we believe that they
20 are very good measures. Our hope is not to
21 replace the STS measures, but to actually just
22 be as a companion measure that would be added

1 value.

2 We feel that we created value in
3 three important ways via the different data
4 sources. We use claims data, and pharmacy
5 claims data are highly good at capturing
6 prescriptions filled. And we believe that our
7 measure will be good at capturing patient beta
8 blocker use.

9 We also feel that we look at a
10 different aspect of care and measure a
11 different part of the care process and
12 communities. Since the STS measure uses
13 registry data, it is supposed to be considered
14 more provider-centric as when it is capturing
15 more about physicians' prescribing behaviors.
16 Our measure, it is a patient-centric which we
17 are capturing information about a patient's
18 prescription-filling behavior.

19 And, then, finally, our measure
20 uses administrative claims data, as I
21 mentioned previously. This type of data is
22 routinely collected for reimbursement, and it

1 is not voluntarily reported, and, thus, could
2 provide less-biased performance results.

3 Our measure also brings to the
4 table health plans as a user. This
5 administrative claims data is routinely
6 collected by them, and it could benefit from
7 using this measure.

8 I would also like to say that our
9 measure does not require participating or
10 using our proprietary database. Our
11 proprietary database is used solely to test
12 and create the measure. We put all of our
13 NQF-endorsed measures out in the public domain
14 for anyone to use and apply to their own
15 databases.

16 At the last Subcommittee meeting,
17 there was some question about the low CABG
18 volume that we were picking up. And I just
19 wanted to say that I went back and looked at
20 the data.

21 There was a problem with some of
22 the code, the programming code. It had to do

1 with we were trying to exclude CABG patients
2 who were readmitted to an acute or non-acute
3 care facility within seven days.

4 And it turns out that more than
5 half of our qualified CABG members were being
6 excluded from the analysis because of a bug in
7 the code. So, it drastically brought up our
8 numbers. Initially, we were reporting about
9 731 patients, and now that denominator is
10 2,303 patients. And so, we ended up with a
11 new compliance rate of approximately 91.5
12 percent.

13 CO-CHAIR TORCHIANA: Thank you.

14 MS. EATON: I just wanted to make
15 sure that I brought that to the Committee's
16 attention because it was of great concern at
17 the last meeting.

18 CO-CHAIR TORCHIANA: Thank you.

19 The next set of measures are from
20 the ACS Quality Collaboration. We have two
21 representatives here.

22 MS. SLOSBURG: Good morning.

1 I am Donna Slosburg. I am the
2 Executive Director of the ASCQC, and this is
3 Dr. David Shapiro with me.

4 I am going to take a little
5 different track. I just wanted to make sure
6 that he is aware about the ambulatory side.

7 The collaboration was formed in
8 2006 to develop standardized measures for the
9 ASC specifically. It is a group of management
10 companies, professional association, and
11 accrediting bodies.

12 Something that is a little
13 different is that the consensus was that our
14 measures needed to be within the scope,
15 influence, and control of the ASC. We didn't
16 limit these to any particular patient
17 population to allow all ASCs to participate.

18 I also wanted everyone to
19 understand that we have tried to harmonize our
20 measures. However, you need to take into
21 account that ASCs are different than in-
22 patient hospitals. The code set for billing,

1 hospitals use ICD-9; ASCs use CBTs. The claim
2 format, hospitals use UBO-4s; ASCs use
3 CMS-1500s. And our patient population is
4 typically ASA 1 or 2. So, they are already,
5 in our minds, risk-adjusted.

6 To date, just so everybody is
7 aware, CMS has not implemented a quality
8 reporting system for ASCs. So, all the work
9 that we are doing is basically voluntary
10 reporting. We also have public reporting on
11 our website on our measures. And ASCs were
12 not included in the EMR incentive program.

13 We are presenting three measures
14 today for maintenance. Two are process
15 measures, and they are in accordance with the
16 surgical site prevention guidelines, IV
17 antibiotic timing and appropriate surgical
18 hair removal. I am sorry, the IV antibiotic
19 is tomorrow. And, then, our third measure is
20 hospital transfer admission. It is an
21 outcomes measure.

22 We did harmonize the IV antibiotic

1 and the hair removal measure with the SCIP
2 measures as best as we could. And we do have
3 our results and our data from about 1300 ASCs
4 on our website. It is out there for other
5 ASCs to benchmark, and there's about 5200 ACSs
6 in the country, but, again, these 1300 are
7 doing this voluntarily.

8 David, do you have any comments?

9 MR. SHAPIRO: No. Thank you again
10 for having us here to present these three
11 measures for maintenance with you today.

12 I think Donna touched on the two
13 probably most important aspects of why we
14 would like you to consider our measures in
15 possibly a slightly different light than you
16 might others.

17 One is that they really are
18 important to the ASC industry. This is a
19 voluntary project that we have undertaken
20 without to date any federal requirement for
21 quality reporting, and we have done so with
22 your help. And I want to, again, thank you

1 for endorsing the measures that you have in
2 the past.

3 The measures really do warrant
4 continued attention from us. Within our
5 industry, they may not meet all the
6 statistical criteria that we would like
7 eventually to be able to apply to them by
8 furthering our data-gathering techniques.

9 And the other thing is just a
10 general comment on the ASC industry, which we
11 are glad to talk more about in specific
12 relation to our measures. But, in many
13 instances, although we do comparable services,
14 we are, for reasons including those that Donna
15 Slosburg mentioned and others, we are
16 comparable, but not identical to the HOPDs.

17 So, I think when we start talking
18 about harmonization of our measures, we will
19 be able to give you a little bit more
20 background as to why we have been in some
21 cases unable to harmonize to the extent that
22 even we would like to harmonize our measures

1 with already-existing ones for other sites of
2 service. So, I will wait until we discuss our
3 measures, but, again, I want to thank you for
4 your support in the past and hope that we
5 continue to be able to work together on these
6 measures and move forward.

7 Thanks.

8 CO-CHAIR TORCHIANA: Thank you.

9 The Society for Vascular Surgery?

10 They will not be in until 1:30. Okay.

11 American College of Cardiology
12 Foundation, followup assessment of stroke or
13 death after carotid. They were going to be
14 attending the meeting.

15 No one here from the ACC?

16 (No response.)

17 Okay. Children's Hospital of
18 Pennsylvania, of Philadelphia, rather.

19 (No response.)

20 The same outcome.

21 I think that's it.

22 Any other developers that have

1 measures for consideration?

2 (No response.)

3 No. So, let's, then, go back to
4 the agenda.

5 MS. GROSSO: Excuse me. This is
6 Laura Grosso calling from Yale University.

7 They called for our measure a
8 while ago. I am actually on the train. I am
9 presenting on Measures 1550 and 1551. I am
10 wondering, I was expecting to give the summary
11 at 3:45. Would it be okay to give a brief
12 summary when I am there at 3:45?

13 CO-CHAIR TORCHIANA: I think that
14 would be fine.

15 MS. GROSSO: Okay. Great. Thank
16 you.

17 CO-CHAIR TORCHIANA: Okay. So,
18 let's now go back to the agenda, top of page
19 3, Measure 0127, preoperative beta blockade.
20 We will start with the lead reviewer, Paula
21 Graling.

22 MEMBER GRALING: Okay. I am

1 speaking for Work Group A, and we had just a
2 few comments related to this measure.

3 It is a part of the STS CABG
4 composite score. We felt that there was very
5 strong evidence to support the measure and
6 that we could see a clearly-demonstrated
7 performance gap.

8 We did have some concerns related
9 to the contraindications. And actually, STS
10 provided us with an additional document that
11 helps to update those concerns.

12 Feasibility was certainly still a
13 question. We recognize that the cost of data
14 extraction or a data extraction manager is
15 present, as we have spoken about several of
16 the other measures before. And we do
17 recognize that there is some possible
18 opportunity for harmonization as we consider
19 all of the beta block measures that come
20 before us.

21 And that's really it.

22 CO-CHAIR TORCHIANA: Any other

1 discussion on this measure?

2 (No response.)

3 Hearing none, if we could vote,
4 first, on importance?

5 (Vote.)

6 Thank you.

7 I have to read it out. Twenty-
8 one, yes; zero, no.

9 So, scientific acceptability. We
10 now have a more complex vote here: 1 through
11 4, completely, partially, minimally, not at
12 all.

13 (Vote.)

14 What is our numerator here? Is it
15 21?

16 If everyone could press again?

17 (Vote.)

18 Sixteen, completely; five,
19 partially; no, minimally; no, not at all.

20 Usability, the same scale.

21 (Vote.)

22 We are still shy one vote.

1 Seventeen, completely; four,
2 partially.

3 If I could ask the staff, who
4 might be more knowledgeable in the technology
5 here, if we just keep submitting votes until
6 we hit 21, will that unload or overload or
7 confuse the system, if everyone just keeps
8 voting until we hit 21?

9 MS. WEBER: No, it should be fine.

10 CO-CHAIR TORCHIANA: Okay.

11 MS. WEBER: It only counts each
12 vote once.

13 CO-CHAIR TORCHIANA: So, let's do
14 that. Just keep hitting your votes until we
15 hit 21. We might save 20 seconds a vote here.

16 So, feasibility?

17 (Vote.)

18 Seventeen, completely; four,
19 partially.

20 Let's see if we can get it under
21 10 seconds this time and have a new record.

22 Does this measure meet all the NQF

1 criteria for endorsement? We are back to a 1,
2 2, 3 vote here.

3 (Vote.)

4 Wow! Okay. Are we done with that
5 one?

6 Twenty-one, yes; zero, no.

7 Okay. So, we are done with that
8 measure.

9 And, Paula, you have 0284?

10 MEMBER GRALING: Yes, that one,
11 also.

12 Measure 0284 is surgery patients
13 on beta blockers prior to admission who
14 received a beta blocker during the
15 perioperative period. This is a CMS SCIP
16 measure, and you will recognize it. It is not
17 just limited to CABG. It is, indeed, surgery
18 patients.

19 Some of our original questions
20 related to the timing of the perioperative
21 period, and I think Dr. Bratzler discussed
22 that in terms of looking at from day of

1 surgery to post-op day 2.

2 We also had a question about the
3 denominator definition. You will notice in
4 the definition that laparoscopy is identified
5 in those lists, and we wondered why
6 laparoscopes were just pulled out of that
7 denominator. And perhaps he can address that
8 for us.

9 Finally, there were some questions
10 related to the collection methodology. It
11 talked about getting the information from the
12 medical record, and we wanted some clarity
13 about paper versus electronic, or both.

14 And, then, finally, they did a
15 nice job in terms of listing the disparities
16 at the back of the application, but perhaps
17 that they could address some of their
18 disparity comments.

19 CO-CHAIR TORCHIANA: So, there was
20 quite a bit of discussion about this measure
21 on the call.

22 I will point out that this is only

1 for patients who were on beta blockers prior
2 to admission. That confused me a little bit
3 when I was thinking about it.

4 Is there any discussion that you
5 would like to bring here?

6 MEMBER MORTON: Yes, I just wanted
7 to chime in about the laparoscopic part of
8 things. We have had this discussion
9 previously about prophylaxis for VTE and
10 everything else, but I think it just reflects
11 kind of older ideas about laparoscopy, but, as
12 we look now, one of the most common iterations
13 is for bariatric surgery, where a lot of
14 patients may be actually on beta blockade
15 prior to surgery, hypertension occurring in
16 about 70 percent of those patients.

17 So, I would highly suggest making
18 sure that laparoscopy is not excluded from
19 this, particularly vis-a-vis the bariatric
20 surgery laparoscopic patients.

21 MS. JOHNSON: I believe Dr.
22 Bratzler signed off. I can tell you -- this

1 is Wanda Johnson from OSMQ -- the laparoscope
2 exclusion is being removed, starting with
3 January 2012. And so, that exclusion will not
4 be counted with this measure.

5 We do only collect chart-
6 abstracted measures. Currently, we are in the
7 process of updating specifications, so that
8 they can be collected via EHRs.

9 MEMBER WILHOIT: One question that
10 I had is the denominator is defined in terms
11 of surgery patients on beta blocker therapy
12 prior to arrival, but prior to arrival is not
13 defined. Is that a year ago, a month ago, a
14 day ago, a week ago? And I couldn't find a
15 definition, and it seemed like it would make
16 a big difference.

17 CO-CHAIR TORCHIANA: I think that
18 was discussed on the call. Could one of the
19 developers comment?

20 MS. JOHNSON: Sure. In the data
21 element, beta blocker current medication,
22 which is how the abstractors determine whether

1 it was considered a prior to arrival, it has
2 to be listed as a home or a current
3 medication. It must be documented that they
4 were on it prior to arrival, that it wasn't
5 started while they were in the hospital.

6 And if it is taken for a non-
7 cardiac reason, then they would answer "no" to
8 current medication. So, they wouldn't be in
9 the denominator.

10 CO-CHAIR TORCHIANA: I guess I
11 would throw in that the other discussion that
12 occurred on the call was the vagueness of the
13 criteria around what constituted a
14 perioperative beta blocker, and I think that
15 the vagueness in terms of what the dose, route
16 of administration, et cetera, would mean.

17 I think the way that discussion
18 was resolved was that greater specificity just
19 resulted in greater complexity and measurement
20 burden, and that just the threshold of was a
21 beta blocker administered was the only way to
22 do this simply.

1 MEMBER HALPERN: But she just said
2 that it was for non-cardiac reasons. So, how
3 is that determined?

4 MS. JOHNSON: It has to be
5 documented that it was non-cardiac for them to
6 answer no. That is just one of the outs that
7 we allow them to have. Say they were taking
8 it for migraines. It has to be documented
9 that it was for a non-cardiac reason, taken at
10 home, and, then, they could answer no to beta
11 blocker current medication, and they wouldn't
12 be in the measure denominator.

13 MEMBER HALPERN: So, what if they
14 were just taking it for hypertension, because
15 those patients often also have co-existing
16 cardiac disease?

17 MS. JOHNSON: They would answer
18 yes, and they would be considered for this
19 measure.

20 MEMBER AFSAR-MANESH: Just to add
21 on to what Dr. Torchiana was saying, one of
22 the problems that I had with this measure was

1 that overall just having a beta blocker on in
2 the peri-op period hasn't been shown to be
3 beneficial if it is not titrated to a certain
4 heart rate. And I understand that, for
5 measurement purposes, that is going to be a
6 lot more difficult to capture, but perhaps at
7 a future date, as we move towards EHRs, the
8 measure developers can think about how to
9 include that. Because if we do want to
10 improve the quality of care, just having
11 metoprolol at a low dose on isn't really going
12 to be beneficial if it is not titrated.

13 MS. JOHNSON: We will take the
14 recommendations to the Technical Expert Panel.
15 We do have an exclusion. As you know, they
16 are bradycardiac, so the heart rate less than
17 50. Then, they would answer that there is a
18 reason for not administering a beta blocker
19 and would get excluded.

20 But, yes, titration is something
21 that we can address with the TEP.

22 CO-CHAIR TORCHIANA: Any other

1 discussion before we vote?

2 MEMBER WILHOIT: The one other
3 thing would be a recommendation to -- some of
4 the things that have just been discussed don't
5 seem to be in the writeup in terms of
6 excluding patients who are on a beta blocker
7 for other than cardiac reasons, exclusion for
8 bradycardia. Those are not listed as
9 exclusions. It seems like those are pretty
10 important and should be.

11 MS. JOHNSON: It is because they
12 are listed in the data element, reasons for
13 not administering. We will try to do a better
14 job of getting those exclusions spelled out,
15 instead of just listing the data element.

16 CO-CHAIR TORCHIANA: Okay. So,
17 the first vote is importance to measure.

18 Remember, just keep pushing the
19 button until it gets to 21.

20 (Vote.)

21 Did someone leave the room? I
22 don't think so.

1 Twenty-one in favor.

2 The second vote is scientific
3 acceptability. Here we are voting on the 1-
4 to-4 scale.

5 (Vote.)

6 Ten, completely; ten, partially;
7 one, minimally.

8 Usability, on the 1-to-4 scale.

9 (Vote.)

10 Twelve, completely; nine,
11 partially.

12 Feasibility, on the 1-to-4 scale.

13 (Vote.)

14 There is definitely one in here
15 that is not working.

16 Twelve, completely; nine,
17 partially.

18 Does the measure meet all the NQF
19 criteria for endorsement, yes, no, or abstain?

20 (Vote.)

21 Nineteen, yes; two, no.

22 Okay. The next one, beta block at

1 discharge. Dr. Stafford?

2 MEMBER STAFFORD: Yes, that's
3 mine.

4 This is beta blockade at discharge
5 and isolated CABG, just so everybody
6 understands that that's what the measure was
7 about.

8 In terms of importance to measure,
9 everybody in the group really felt that it was
10 important to measure, that there is clearly a
11 performance gap. But even though the mean was
12 high, the median showed that a fair number
13 were off the scale and still needed to be
14 measured. So, we all felt it was important to
15 measure.

16 In the discussion about scientific
17 acceptability, there were some questions about
18 patients with contraindications who were
19 removed from both the numerator and
20 denominator, and, also, the time windows. And
21 those were pretty much cleared up in the phone
22 call with the developer. I don't think there

1 were any big issues that I can recall.

2 Everybody felt that for the most
3 part usability was not much of an issue.

4 And feasibility, there were
5 questions about cost for data abstraction that
6 were answered.

7 Lots of questions, it got around,
8 again, to gaming the system and whatnot, but
9 pretty much these are things that are going to
10 occur with a lot of the measures that we have.
11 Everybody felt that this was at least a
12 measure that the outcome measure was
13 relatively related to the process measure.
14 And so, from that standpoint, we felt it was
15 a good measure to have.

16 CO-CHAIR TORCHIANA: Comments or
17 further discussion?

18 MS. MURPHY: There was a question
19 in the Work Group discussion that the group I
20 thought felt Dr. Shahian could answer about
21 why no risk adjustment.

22 MR. SHAHIAN: Well, I think for

1 process measures, typically, exclusions and
2 eligibility requirements generally take the
3 place of risk adjustment. I think it would be
4 difficult to construct a risk-adjustment model
5 for this, although some people have advocated
6 using risk adjustment for process measures,
7 but I think, in general, eligibility and
8 exclusion criteria have been used instead.

9 CO-CHAIR TORCHIANA: Okay. Let's
10 vote on this.

11 Importance to measure, yes, no, or
12 abstain.

13 (Vote.)

14 Twenty-one in favor.

15 Scientific acceptability, on the
16 1-to-4 scale?

17 (Vote.)

18 Eighteen, completely; three,
19 partially.

20 If I could ask, again, a technical
21 question, do you have hit Send every time you
22 hit the number if you are voting repeatedly?

1 MS. WEBER: You have to hit Send.

2 CO-CHAIR TORCHIANA: Okay. So, it
3 takes two fingers to do this to keep it going.
4 Hit 1, 2, 3, or 4 and Send until you see 21 up
5 there, and maybe we will get under 10 seconds
6 consistently then.

7 Usability, a scale of 1 to 4.

8 (Vote.)

9 Seventeen, completely; four,
10 partially.

11 Feasibility, scale of 1 to 4.

12 (Vote.)

13 Eighteen, completely; three,
14 partially.

15 Does the measure meet the NQF
16 criteria for endorsement, yes, no, or abstain?

17 (Vote.)

18 Okay. Twenty-one, yes.

19 Where is the antenna actually
20 located that is receiving these? It is on
21 your computer? Okay. We can't ask to put you
22 in the middle of the room. I think that would

1 be unfair.

2 (Laughter.)

3 Okay. The next measure is 1480,
4 the Ingenix measure that we heard about,
5 patients 18 years of older.

6 Dr. Stafford again.

7 MEMBER STAFFORD: Yes, this
8 measure led to a lot more discussion. Again,
9 I think everybody said, well, isn't this
10 really related to the previous measure, and
11 should this somehow be harmonized, was one of
12 the questions that did come up for the group.

13 Everybody felt, again, that it was
14 important to measure beta blocker use in this
15 patient population. So, from an importance
16 standpoint, everybody felt that it was
17 reasonable.

18 As to the scientific
19 acceptability, there were lots of questions.
20 Some of those were addressed today about the
21 population, and particularly, the numbers of
22 CABGs that were actually included in the

1 group. Clearly, that was something that we
2 picked up on, and they found that, actually,
3 there was a bug in their computer system.

4 It still isn't clear to me, at
5 least hearing what we got from the developer
6 today, whether those numbers are still high
7 enough for us, at least for me thinking about
8 it.

9 There were, similarly, other
10 discussions about this being a proprietary
11 database and, therefore, it only applies to
12 people that actually have insurance benefits.
13 And so, there may be a large number of
14 patients in the population, particularly in
15 the Medicare and Medicaid population, where
16 this may not apply. And so, it may be not be
17 generalizable to the large population that we
18 would like to see the measure looked at.

19 The flip side of that discussion
20 was that, for health plans, it would be usable
21 because it was another way for them to get
22 that information.

1 Those were really the two biggest
2 things about the database.

3 As to the feasibility, it varied
4 from minimally to completely. And again, it
5 depended on what patient population people
6 wanted to look at.

7 CO-CHAIR TORCHIANA: Other
8 comments?

9 MEMBER CIMA: How is it going to
10 be attributed?

11 MEMBER STAFFORD: What was the
12 question?

13 MEMBER CIMA: Well, whose
14 scorecard is this going to go on, the
15 hospital's, the physician's? I mean the
16 cardiac surgeon can give a prescription for a
17 beta blocker. The hospital can give a
18 prescription for a beta blocker. The health
19 system can give a prescription for a beta
20 blocker. But if the patient doesn't fill the
21 prescription for the beta blocker, where is
22 this data, who is going to make the

1 performance measure? Who is going to improve
2 it? Who is the audience to change to get
3 quality?

4 MEMBER STAFFORD: Exactly, and
5 there was a lot of discussion about that,
6 whether this would be used for internal
7 benchmarking in health plans versus external
8 benchmarking; how would people use that?

9 And it was interesting because,
10 originally, we all thought that it meant
11 people would actually have filled the
12 prescription. But, after further discussion,
13 it was actually just that there was a
14 prescription written. They didn't actually
15 have to have gotten it filled. So, it doesn't
16 even really get to what we would all like to
17 measure: did they actually get the drug and
18 did they actually take it?

19 MEMBER CIMA: So, in that case,
20 isn't it the same as prescription at
21 discharge?

22 MEMBER STAFFORD: Yes, it is just

1 they are looking at a different population.

2 MS. JOHNSON: This is the
3 developer. Could I just make a comment?

4 Yes, when we spoke last time, we
5 did talk about codes that for prescriptions
6 written. However, there is no problem with us
7 taking out those codes and have it only
8 strictly represent pharmacy claims that have
9 been filled.

10 We just initially put them in
11 there because we were trying to make it as
12 consistent with STS as possible.

13 CO-CHAIR TORCHIANA: I think what
14 I would say, the other issue that came up on
15 the call in response to this line of question
16 was the fact that this comes off a different
17 dataset and publicly-accessible dataset was
18 seen as one of the selling points and for
19 complementary values of this measure above and
20 beyond the STS measure.

21 So, the way that I sort of walked
22 away in thinking about this was that it

1 represented a different look from a different
2 perspective in a different population, that it
3 potentially had the value that it could go to
4 claims or prescriptions that were actually
5 filled, but that it had the disadvantage that
6 it was a very narrow subset of the total CABG
7 population, which is more than half Medicare,
8 and that it at least originally was probably
9 not terribly accurate in identifying those
10 patients. It sounds like that accuracy has
11 been tightened up, although I agree with Dr.
12 Stafford; I am not exactly sure that we know
13 to what degree it has been tightened up.

14 MEMBER HALPERN: I would also say,
15 if you just look at prescriptions filled,
16 since a lot of these patients come in on beta
17 blockers, they may go back to taking their own
18 beta blockers and not fill a prescription
19 afterwards. So, that doesn't mean that they
20 are not taking it.

21 MEMBER WILHOIT: Have we seen the
22 revised data? I think seeing the numbers is

1 important to understanding what this measure
2 is getting at.

3 MS. JOHNSON: You are referring to
4 the new denominator that I talked about
5 earlier?

6 MEMBER WILHOIT: Yes. Well, the
7 new denominator and, then, the rate.

8 MS. JOHNSON: Yes.

9 MEMBER WILHOIT: All of the
10 results that we had seen originally apparently
11 aren't valid. So, what does the data show?

12 MS. JOHNSON: Okay. No, I haven't
13 submitted that. I definitely can.

14 What we did find was that there
15 was about 2300 patients in the denominator and
16 2100 patients in the numerator, giving us a
17 compliance rate of 91.5 percent.

18 MEMBER HALPERN: I also have a
19 question that I didn't see specifically. It
20 is, how are you defining that a prescription
21 was given? Is it just that it is on the
22 going-out medication reconciliation, or how is

1 it being defined?

2 MS. JOHNSON: It was getting
3 defined through CPT codes, beta blocker
4 therapy prescribed, which I believe is where
5 there is success. That is what it was going
6 out after. But that is the code that I
7 suggested that we can remove from it and just
8 have it strictly be pharmacy claims data,
9 outpatient pharmacy claims data.

10 MEMBER CIMA: So, if it is based
11 on outpatient pharmacy claims data, then that
12 means that they had to fill it?

13 MS. JOHNSON: Right.

14 MEMBER CIMA: Okay.

15 MEMBER HALPERN: So, I go back to
16 my original point. It is that patients may
17 already be on beta blockers and, then, they
18 will not be filling a new prescription because
19 they already have medications, certainly not
20 within seven days. They may fill it later on,
21 but, then, you are going to ding people for
22 things that may not be an issue.

1 MS. JOHNSON: Yes, you are right,
2 though our compliance rate went up. I guess
3 the bottom line is that you are right; that is
4 something to consider.

5 DR. BURSTIN: Just one
6 clarification. Actually, in the measure
7 submission form -- this is Helen Burstin -- it
8 specifically says that you have to fulfill at
9 least one of the three criteria, one of which
10 is you filled the prescription. So, it is
11 prescription filled --

12 MS. JOHNSON: Right.

13 DR. BURSTIN: -- within seven days
14 after hospitalization.

15 Charge two, that you had a claim
16 for that, and a beta blocker prescribed in the
17 35 days prior. So, that might answer a part
18 of your concerns.

19 And, three, that the patient had a
20 claim with a procedure code of beta blocker at
21 discharge. So, that is the only one she is
22 mentioning, but, in fact, there are two others

1 that she is not talking about that I think
2 address what you are saying.

3 MEMBER WILHOIT: It sounds like a
4 number of things have changed from what -- I
5 think we were just told that the HCPCS codes
6 were no longer, but at this point I am
7 confused about what is in the measure, what
8 has changed, what the results are. I am not
9 quite sure what we have got.

10 MEMBER STAFFORD: I would have to
11 agree with that. And if I were to vote right
12 now on this measure as it stands without all
13 of the other qualifications that we have
14 heard, I would say it is not important to
15 measure.

16 So, yes, I would request that we
17 either table this and come back and rediscuss
18 it or we vote on the measure as it stands.

19 MS. MURPHY: So, if you are
20 looking at tabling it for discussion at a
21 later time, what you need to do is say, in
22 addition to what you have just said in terms

1 of information that you need, in order to
2 consider, to properly consider, the measure,
3 and so, you could table it to do that.

4 There were a couple of other
5 things that during the Work Group were
6 discussed that I don't think you have
7 mentioned. One was some question about the
8 adequacy of the validity testing and whether
9 or not you were comfortable with that at this
10 point.

11 And another one I think with
12 respect to the plan for public reporting,
13 there was a question about that in terms of
14 the extent to which public reporting would
15 occur.

16 So, I just saying that, so if
17 there are conditions that you want to apply
18 for later consideration, it is probably time
19 to articulate all of them.

20 MEMBER WILHOIT: I think I am the
21 one that raised the issues about validity
22 testing. And for those of you that didn't go

1 through all the fine print, the validity
2 testing related to public reporting consisted
3 of surveying two customers. Well, customers
4 aren't the public, and two isn't a very big
5 number. So, I certainly was not comfortable
6 that that criterion was met.

7 MEMBER STAFFORD: Dr. Dutton
8 commented on the validity issues as well.

9 MEMBER CIMA: If we table it, we
10 are somehow saying that it seems to be a
11 useful measure and we want to bring it back to
12 make it robust and better. My fundamental
13 thought is I don't think this is a useful
14 measure. So, why don't we just put it out of
15 its misery?

16 (Laughter.)

17 MEMBER FINDLAY: For
18 clarification, this is not a publicly-reported
19 measure. Or is it? Yes, that's what I
20 thought. I was just confused by that
21 discussion there.

22 CO-CHAIR TORCHIANA: So, let's

1 have a little further discussion on the table
2 versus vote it up or down.

3 I guess the vote up or down would
4 be just to say we will keep it alive for
5 further consideration versus we don't think is
6 under any circumstance going to lead a
7 valuable new measure. That vote, obviously,
8 isn't up on the slides, but we could do that
9 perhaps by a show of hands, if that is an
10 acceptable process step to take.

11 MEMBER COLLINS: And from what I
12 remember, this is very similar to the lipid-
13 lowering agent proposal at the last meeting by
14 the same company, which I think we did, quote,
15 "kind of put out of its misery", if I am
16 right. We could clarify that, though.

17 MS. MURPHY: So, the critical
18 question is, from what you have heard and from
19 the additional information that you have
20 gotten in terms of changes and updates, would
21 it be useful for you to see that additional
22 and/or corrected information prior to going to

1 the vote about the importance of the measure?
2 Or do you feel confident that you understand
3 what that is and comfortable with proceeding
4 to a vote without that?

5 And I would say that you would
6 really only be able to go beyond importance if
7 you got the additional and corrected
8 information. Otherwise, you would not be
9 voting on current specifications.

10 MEMBER ROGERS: I think this issue
11 highlights a problem we have with some other
12 measures that we will look at, which really
13 has to do with followup and where patients go
14 after they leave the hospital environment
15 where the records are easily available.

16 And although this may not be a
17 perfect measure, it does help us address that
18 period of time after the acute event has
19 occurred, which is a challenge on all long-
20 term followups.

21 I mean Ingenix is a large
22 database. It is not comprehensive. It

1 doesn't have everybody, but it is a very good
2 start to answer questions that I think are
3 important.

4 And in the context of what they
5 do, it probably works reasonably well. So, I
6 just think we have to keep that in mind
7 because long-term followup is a challenge that
8 we are going to face on all of our measures.
9 It is one thing to do something in a hospital;
10 it is quite another to know what happens to
11 those patients a week, a month, or six months
12 later. And this is a step in that direction.

13 So, I think that we shouldn't
14 dismiss it out of hand. It may not be
15 perfect, but it is I think valuable.

16 MEMBER SAIGAL: While I would
17 agree with you on some of those points, one of
18 the sidebar discussions we had earlier out in
19 the hallway was I think understanding the
20 impact of what putting the NQF stamp on these
21 measures has long-term for people.

22 So, by putting this stamp on a

1 measure, that gives it some street cred
2 elsewhere with groups like CMS or JCAHO to
3 pick up that measure and, then, require that
4 people use it.

5 So, I think you have to be
6 careful, and we really need to think about
7 what we are doing when we put an endorsement
8 on a measure. NQF endorses the measures.
9 They don't monitor them. In terms of
10 implementation, they don't force
11 implementation. But the fact of the matter is
12 that is the effect that the NQF endorsement
13 has.

14 I think we need to be really
15 careful about endorsing measures that really
16 don't broadly cover a large population. I
17 understand your point about the long-term
18 followup. I am not sure this is the best way
19 to do it.

20 MEMBER ROGERS: It may not be, but
21 it also cuts both ways. And this relates to
22 a discussion that I had prompted at the last

1 meeting, having NQF approve measures which
2 actually, if not toothless, have less value in
3 the context of our ability to get more
4 information.

5 So, we have just approved, for
6 instance, mortality measures in cardiac
7 surgery, when, in fact, that may not be a
8 particularly useful measure and there is more
9 information available which would be valuable.

10 So, NQF has just put its or will
11 put its stamp on something for the next three
12 years which will be, I think, woefully behind
13 the times. So, it cuts both ways.

14 MEMBER WILHOIT: Coming from the
15 perspective of a health plan, having
16 administrative measures, being able to measure
17 the care provided for the health plan members
18 by health plan providers is really useful.

19 What makes me so uncomfortable
20 about this measure is there are 15 million
21 members in the database. I believe that
22 Ingenix said that there were 2200 members

1 identified with bypass surgery. Now this
2 measure is limited, I believe, to members of
3 the pharmacy benefit. I am going to make a
4 rough guess that 5 million of the people have
5 a pharmacy benefit.

6 So, that is around 400 people per
7 million, which, compared to our data -- and I
8 polled our data to see -- is probably about,
9 for our commercial population under age 65,
10 which matches up with this measure, looks to
11 me like maybe they are finding half the people
12 that I would expect to have had a bypass. So,
13 again, the numbers make a difference.

14 Also, if you are finding 500
15 patients per million, what is the use of the
16 measure? Are we looking at the health plan
17 level? At the health plan level, 500 members
18 is okay if I have a million members.

19 If I am breaking that down by
20 hospital or by doctor, you end up with numbers
21 that are so small that you somehow add
22 credibility to I am reporting on your 13

1 members who were in my health plan and had a
2 pharmacy benefit, and I am reporting for
3 another doctor on his 23 members. And that
4 isn't useful.

5 That is the thing that bothers me,
6 is that if you break it down by provider, the
7 numbers won't be big enough to be useful.

8 CO-CHAIR TORCHIANA: So, I am
9 going to take the prerogative of calling the
10 question here, since we are over time. So, I
11 think we can address this, actually, with the
12 vote on importance. So, if we vote importance
13 up, then we will proceed to the other criteria
14 and ask that the measure be optimized. If we
15 vote importance down, I think the topic is
16 closed for today at least.

17 So, let's do that vote. It is a
18 yes or a no.

19 (Vote.)

20 So, I think that is a fairly
21 definitive no on that question. So, we will
22 wrap up the voting on that item.

1 Now, before we break for lunch, we
2 have a required public comment. Should we
3 hold that for later, Melinda, or should we do
4 that prior to lunch?

5 MS. MURPHY: We should do it now.

6 CO-CHAIR TORCHIANA: Okay. NQF
7 member/public comment, those on the phone or
8 in the room?

9 (No response.)

10 Hearing none, we will go to lunch.
11 Lunch break is one-half an hour. Lunch is
12 outside.

13 (Whereupon, the foregoing matter
14 went off the record at 12:41 p.m. and resumed
15 at 1:11 p.m.)

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1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 1:11 p.m.

3 MEMBER DUTTON: All right.

4 Pancreatic resection mortality and volume.

5 The group generally thought these measures

6 were important, usable, feasible, and met

7 scientific applicability.

8 The particular issues identified

9 were, first, discussion about whether there

10 should be two different measures or one

11 harmonized measure or one measure that

12 combined both. I think we have had some of

13 that discussion about esophageal resection

14 already, and I think probably the same would

15 apply.

16 It is two measures, but a

17 companion or paired, so they would always be

18 reported together, probably makes the most

19 sense. It is both simple and gets both pieces

20 of data on the table.

21 There were a couple of questions

22 about harmonizing just these two together.

1 They actually measure slightly different
2 things, in that, the mortality measure, is
3 specifically for cancer surgery; whereas, the
4 other measure is not. It is for any
5 pancreatic resection.

6 The volume measure, looking at the
7 ICD-9 codes, it is only complete pancreatic
8 resection. So, we sort of wondered what
9 happened on the partial resections and partial
10 operations. One of them listed a lot more
11 codes than the other. That should probably
12 all be harmonized.

13 There was a problem. I identified
14 that the mortality measure, actually, both
15 measures exclude transfers. So, if you
16 transfer the patient to another acute care
17 hospital, they disappear from both the
18 numerator and the denominator, which, if you
19 are a small volume pancreatic hospital and you
20 are getting bad results, if you can ship the
21 patient downtown, this seems like a great
22 racket. And I know that happens. So, that

1 would seem a bad exclusion there.

2 And, then, finally, there is one
3 section with the volume one where it was
4 actually, it said esophageal; it is just a
5 typo or a missed cut and paste from the other
6 measure that they need to clean up.

7 I think that was everything that
8 we identified as the important issues.

9 CO-CHAIR TORCHIANA: Could we have
10 a comment from AHRQ on why transfers are
11 excluded?

12 MR. ROMANO: Yes. This is Patrick
13 Romano. I am happy to join you. I am a
14 general internist supporting the AHRQ quality
15 indicators program from UC Davis.

16 So, just to address a couple of
17 those questions, transfers out are excluded
18 because, of course, the outcome of those
19 patients is unknown if you only have data from
20 your own center or if you are using a dataset,
21 as most users do, that is not linked across
22 sites.

1 So, ideally, of course, we would
2 like to have a 30-day measure, and some payers
3 would be able to specify a 30-day measure.

4 But the AHRQ measures are designed for
5 applicability to a broader range of datasets
6 which do not generally permit that kind of
7 linkage across hospitals.

8 We have looked at this empirically
9 in the California dataset that does allow
10 linkage. And you might be surprised to find
11 that, in fact the post-transfer mortality is
12 quite low because of those are sort of back-
13 transfers to a community hospital setting or
14 a rural hospital after the patient has had the
15 aggressive procedure at a teaching center.
16 And, then, they go back to a site that is
17 closer to their home for some further
18 recovery. So, in fact, what we see
19 empirically is that post-transfer mortality is
20 quite low in the linked dataset in California,
21 anyway.

22 The other issue as far as the

1 difference in the denominators, this is an
2 issue that we have discussed in the first
3 round of endorsement. It has also been
4 discussed with Leapfrog.

5 The rationale, basically, is that,
6 of course, the mortality is much higher for
7 the cancer surgery, but the benign surgery,
8 experience with benign surgery appears to
9 translate into better outcomes for both
10 patients with benign disease as well as
11 patients with malignant disease.

12 So, including benign disease in
13 the volume measure kind of gives providers the
14 benefit of the doubt for doing procedures on
15 patients who have benign disease. So, that is
16 the rationale.

17 But it is subject to change. It
18 has just evolved through discussions with
19 expert panels previously.

20 CO-CHAIR TORCHIANA: Any further
21 discussion?

22 MEMBER STAFFORD: Yes. Hi. I am

1 Renae Stafford, and I am actually the one
2 brought up why the benign patients were
3 excluded. Can you give me a little more
4 background on that? I still don't quite
5 understand the rationale.

6 MR. ROMANO: Well, these
7 indicators are based on an empirical
8 literature that is overwhelmingly based on
9 cancer surgery. So, there have been a couple
10 of large meta-analyses, mostly based on
11 observational studies, and they were limited
12 to pancreatic cancer surgery.

13 There is, of course, a difference
14 in mortality between patients with pancreatic
15 cancer surgery and patients with surgery for
16 benign disease. That difference in mortality
17 could theoretically be adjusted for through
18 risk adjustment. So, that is an option. It
19 is just that we kind of tailored the original
20 definition to what other investigators have
21 reported on in the literature.

22 MEMBER HALPERN: So, should it be

1 titled, instead, pancreatic resection for
2 cancer? Because it seems to me, actually, it
3 would be more important to know what the
4 mortality is for benign disease since the
5 patients wouldn't otherwise necessarily die
6 from their disease process.

7 MR. ROMANO: It is a valid point.
8 At this point, you know, the indicator
9 specification is what it is, but we can
10 certainly perform some additional analyses to
11 explore what the impact would be of including
12 or stratifying separately for benign disease.

13 MEMBER DUTTON: My recommendation
14 there would be just to count it, you know, all
15 pancreatic disease in both the numerator and
16 the denominator, both of these measures. It
17 would keep them harmonized. It is a low-
18 enough-volume condition that I think trying to
19 subset it further isn't really helping you.

20 MEMBER HALPERN: I actually was
21 more implying the measure would be more for
22 benign disease, a separate measure. Because

1 I think measuring mortality for benign
2 disease, as I said, is almost more important
3 because you wouldn't otherwise die of your
4 disease process, and you would otherwise die
5 of pancreatic cancer, if you don't have your
6 resection.

7 MEMBER DILLON: Right. I agree.
8 I think you have to split these two out.

9 MEMBER CIMA: Other than sort of
10 emergency sort of pancreatic debreedment, what
11 other benign conditions lead people to have
12 major pancreatic surgery? I mean other than
13 IPMNs, but that is now almost becoming
14 classified as a malignancy.

15 So, the question is -- I think the
16 point is that it's such a low-frequency thing.
17 If anything, I would say exclusion should be
18 a diagnosis of pancreatitis. I mean those
19 patients have a 40 percent mortality or 30
20 percent mortality as is.

21 But, you know, what benign
22 condition do we operate on in such high

1 volumes of the pancreas?

2 MEMBER HALPERN: The volume is a
3 paired measure, is that right? Yes, so they
4 are always reported together.

5 MS. MURPHY: That is the way they
6 were endorsed, to be reported as paired
7 measures.

8 MEMBER DILLON: I am just looking
9 through the exclusion criteria, again, just to
10 make sure that, you know, in cases of
11 splenectomies and the tail of the pancreas
12 gets removed, I am just worried about the
13 possibility of coding variability here that
14 could cause a problem with the data.

15 A resection for a renal, you know,
16 a major surgical oncology procedure in which
17 you do a partial pancreatectomy but it is for
18 a primary renal or splenic tumor.

19 So, they would have to be able to
20 exclude those as well.

21 CO-CHAIR TORCHIANA: Could I ask
22 Melinda for some guidance? We have some

1 suggestions of some fairly-significant
2 modifications in the way that this measure is
3 constituted. Do we just proceed and vote on
4 it as is, or how would you suggest we go
5 ahead?

6 MS. MURPHY: In much the same way
7 you have done, which would be, if there are
8 recommendations, suggestions, conditions that
9 you would apply to the measure, that those be
10 stated and that we get the response from the
11 developer, and, then, vote the measure based
12 on that.

13 CO-CHAIR TORCHIANA: Well, I would
14 suggest that we have heard enough concerns
15 around the table over inclusions, exclusions,
16 how to address this, that we are not prepared
17 to vote.

18 So, should we put off the vote and
19 lay out what those concerns are? I think
20 pancreatitis is clearly one. Resection for
21 pancreatitis probably shouldn't count as a
22 pancreatic resection for this purpose.

1 And, then, the question as to
2 whether or not we should include and lump
3 benign and cancer or whether we should split
4 and/or exclude benign from one or both of the
5 measures.

6 Any further comments on those?

7 MEMBER DILLON: Let me just sort
8 of muddy the waters just a little bit, though.
9 And I will aim this at sort of Vivienne and
10 Robert and the other surgeons in the group
11 here.

12 In terms of the impact of disease,
13 which is what you are concerned about, within
14 a 30-day window, whether we are dealing with
15 pancreatic CA in nodes or a small cyst or an
16 IPMN in the tail of pancreas probably doesn't
17 matter, which, as I talk about it and think
18 about it, brings us back to a more unified
19 approach, you know, as this proposes.

20 Because I like this measure,
21 but --

22 MEMBER HALPERN: But to include

1 all pancreatectomies?

2 MEMBER DILLON: Yes.

3 CO-CHAIR TORCHIANA: So, that
4 would include all pancreatectomies for
5 malignant or benign disease for both mortality
6 and volume with the sole exclusion of
7 pancreatitis?

8 MEMBER DILLON: Yes, I think so.

9 MEMBER WILHOIT: One of the things
10 that would be helpful there would be to look
11 at the numbers. In one of the measures, in
12 0366, at the beginning under disparities, it
13 gives some volumes for a sample. But in 0365,
14 it doesn't give the volume. It just gives the
15 rates.

16 So, the numbers are probably
17 available to look at. It would be interesting
18 to see how the volumes compare for benign and
19 malignant disease and, also, how the mortality
20 rates compare.

21 MEMBER ROGERS: I think it makes
22 sense to kind of keep them together for any

1 reason that these are relatively rare
2 operations. There's not a lot of them going
3 on. I think there were maybe 3,000 Whipples
4 done last year. So, there's not a lot of
5 them. So, that is one argument to kind of
6 keep them together.

7 The other thing is it is mainly
8 the organ that helps determine a lot of these
9 complications. So, regardless if there is
10 cancer or if there is any other reason for the
11 operation, it is the fact that the pancreas is
12 so hard to work with that it can lead to
13 problems.

14 MEMBER SIPERSTEIN: We actually
15 had a very similar discussion about the
16 esophageal measure last time, where the
17 mortality figure dealt with cancer cases, and
18 the volume credited the hospital with a few
19 extra percent for overall esophageal volume,
20 but I don't think it really is changing the
21 way the wind is blowing on this because the
22 number of pancreas procedures for benign

1 disease is relatively small. If a hospital,
2 say, upgrades their numbers by 10 or 20
3 percent, by including all pancreatic
4 procedures, it is not going to really change
5 the impact of the measure one way or the
6 other.

7 So, it may be a lot of discussion
8 about something that really isn't affecting
9 the bottom line on this.

10 MR. ROMANO: Yes. This is Patrick
11 Romano again.

12 I just wanted to emphasize that
13 these measures were created through a process
14 of reviewing the published evidence. So,
15 again, the published evidence is limited to,
16 largely limited to resection for pancreatic
17 cancer because that is the overwhelming
18 majority of the pancreatic resections.

19 So, I appreciate the point about
20 benign disease, but it is kind of going beyond
21 the evidence on which the indicator was based.
22 So, that is why we have an Expert Panel, we

1 have an AHRQ Expert Panel process that led to
2 this specification. The decision was made to
3 give the hospitals credit, essentially, for
4 the additional volume, that they might get 10
5 percent, 20 percent additional volume with
6 benign cases. But the core of the concept is
7 based on the literature on pancreatic surgery
8 and mortality.

9 With respect to exclusions, that
10 is easier to address. I think we could easily
11 accept exclusions that this group wants to
12 propose as just part of the next revision
13 process.

14 CO-CHAIR TORCHIANA: And so, I
15 would say we table the vote for the time
16 being, that we ask for data on these topics
17 that you just explained, and to contemplate an
18 exclusion for pancreatitis, and that on
19 further review a decision ought to be made
20 whether to try to harmonize the volume and
21 resection mortality all into the same boat.

22 So, are we okay to move on to the

1 next measure?

2 MS. MURPHY: And we would need to
3 bring that back by the time of the call that
4 we will have in follow up to this meeting.

5 CO-CHAIR TORCHIANA: Okay. All
6 right. So, it is now 1:27. I don't think we
7 will get through perforated appendix in three
8 minutes.

9 Do we have our vascular surgery
10 developers on the phone?

11 MEMBER SEARS: Nick Sears is here.

12 CO-CHAIR TORCHIANA: I'm sorry,
13 could you say that again? I wasn't able to
14 understand.

15 MEMBER SEARS: Sure. No problem.
16 This is Nick Sears.

17 CO-CHAIR TORCHIANA: Great. Very
18 well.

19 So, there are a series of vascular
20 surgery measures before us for consideration.
21 Could you give us a brief summary, as the
22 developer?

1 MEMBER SEARS: I wasn't the
2 developer.

3 CO-CHAIR TORCHIANA: Oh, I'm
4 sorry.

5 MEMBER SEARS: I was the reviewer.

6 CO-CHAIR TORCHIANA: I thought you
7 were the SVS person. I apologize.

8 We need to wait for the Society of
9 Vascular Surgery person to come on the phone.

10 So, is there any way that we can
11 be notified of that, other than just asking?

12 MS. MURPHY: Yes. If you want to
13 go ahead to the next measure, and, then, we
14 can check --

15 CO-CHAIR TORCHIANA: At the end of
16 that?

17 MS. MURPHY: -- when that is
18 completed.

19 CO-CHAIR TORCHIANA: Okay. All
20 right. Very good.

21 So, we are at perforated appendix.
22 Dr. Morton?

1 MEMBER MORTON: Yes. This is
2 another AHRQ measure. It is perforated
3 appendix admission rate.

4 This has been something that has
5 been measured quite frequently in surgery from
6 time immemorial to know if it there is a
7 quality problem.

8 The particular measure is
9 important for a few reasons. It has got
10 scientific validity. It has been very easy to
11 implement. Unlike a lot of the administrative
12 measures that are out there, this has actually
13 had a referendum clinically where it went into
14 patients' charts to confirm the actual
15 diagnoses. Dr. Romano was involved with all
16 of that. So, from that end, it is pretty
17 useful.

18 In terms of meeting some of the
19 measures, it is useful in looking at different
20 things such as clinical management, waiting
21 until an appendix perforates can have some
22 untoward consequences.

1 There is also a big performance
2 gap. I was surprised to see it is on the
3 order of about 20 to 30 percent of apples are
4 perforated. So, there is still a lot of
5 potential opportunity there.

6 A lot of data in the literature
7 around the topic, particularly when it comes
8 to access to care. It seems like there is a
9 higher rate based on your socioeconomic
10 status, based on your rural status. So, there
11 is some evidence for disparities that haven't
12 been addressed.

13 It has some pretty important
14 consequences when there is perforation in
15 terms of longer length of stay and other
16 resource utilization.

17 As I mentioned before, there is
18 quite a bit of, quite a few perforated
19 appendectomies that are out there.

20 So, those were the main points.
21 It seems to be a feasible and important
22 measure with scientific validity.

1 CO-CHAIR TORCHIANA: Any other
2 comments?

3 (No response.)

4 Okay. Oh, I'm sorry.

5 MR. ROMANO: I just wanted to
6 clarify for the group that this is a
7 population-based measure. So, it is not a
8 measure that is intended for attribution to
9 individual surgeons or hospitals.

10 CO-CHAIR TORCHIANA: Right. We
11 discussed on a call it is reported by region.

12 MR. ROMANO: Right.

13 CO-CHAIR TORCHIANA: Okay. So,
14 let's go to the vote.

15 Importance to measure, yes or no.

16 (Vote.)

17 Nineteen, yes; two, no.

18 MR. KRESOWIK: Hello. I don't
19 know if you can hear me or not. This is Tim
20 Kresowik from the Society for Vascular
21 Surgery. I was on before, but, apparently,
22 somehow my line was muted, so I had to go

1 through the operator to get in. So, I am
2 here; I was here, and still am.

3 CO-CHAIR TORCHIANA: Okay. We
4 will be with you in about 30 seconds. We have
5 gotten really quick at voting these in.

6 (Laughter.)

7 So, we have just three more votes.
8 It should take us about 30 seconds.

9 Scientific acceptability, on a
10 scale of 1 to 4.

11 (Vote.)

12 Keep pushing those buttons.

13 Sixteen, completely; five,
14 partially.

15 Usability.

16 (Vote.)

17 Eighteen, completely; two,
18 partially; one, not at all.

19 Feasibility.

20 (Vote.)

21 Eighteen, completely; three,
22 partially.

1 Finally, yes, no, or abstain, does
2 the measure meet all the NQF criteria for
3 endorsement?

4 (Vote.)

5 Twenty, yes; one, no.

6 Thank you.

7 So, if we could hear, then, on the
8 SVS measures, please, from the developer?

9 MR. KRESOWIK: Thank you.

10 Again, this is Tim Kresowik. I am
11 a vascular surgeon at the University of Iowa,
12 representing the Society for Vascular Surgery.

13 I have been involved in measure
14 development going back a long ways, back to
15 the original Cooperative Cardiovascular
16 Project, and have spent a long time acting as
17 a consultant, a facilitator for all kinds of
18 measure development.

19 So, I would, if I could, try to
20 introduce a group of measures, just sort of as
21 an overview, because I think these are kind of
22 a unique approach. So, I would like, if I

1 could, just to start out and talk about
2 Measures 1523, 1534, 1540, and 1543.

3 CO-CHAIR TORCHIANA: That is
4 exactly how we would like to do it, too, if
5 you could cover them all together.

6 MR. KRESOWIK: Okay. Perfect.

7 So that, the basic concept here is
8 to try to get away from some of the problems
9 and perverse incentives that are associated
10 with current approaches to measurement of, if
11 you will, surgical mortality or other
12 complications.

13 What we are trying to do with this
14 group of measures is to try to focus on a
15 procedure and an outcome that requires minimal
16 risk adjustment. And in this cases, what we
17 are talking about, I will start first with
18 probably the carotid procedures would be
19 easier to introduce.

20 But the basic principle here is
21 that the majority of carotid revascularization
22 procedures performed in this country are done

1 on asymptomatic individuals. And in that
2 setting, the risk versus benefit is quite
3 narrow. So, it is essential for those groups
4 of patients that the procedures are performed
5 with an extremely-low mortality/morbidity.
6 And an important component of that is the
7 selection of patients who are at low risk.

8 And that becomes part of the
9 surgical decisionmaking and, therefore,
10 requires no further risk adjustment. In fact,
11 you would not want to, if you will, give
12 credit for someone performing interventions on
13 someone who is at high risk because of
14 comorbidities or people who have shortened
15 life expectancy because of their
16 comorbidities. Because in order to achieve
17 benefit in that patient population, the
18 asymptomatic population, the risk needs to be
19 quite low.

20 And it is always hard; I have
21 participated in many of these on a phone
22 versus an in-person meeting. So, I am just

1 going to stop there for a second and just see
2 if everybody is still with me or if there are
3 any questions about that overall principle.

4 CO-CHAIR TORCHIANA: Any
5 questions?

6 (No response.)

7 That sounds like a very succinct
8 approach.

9 MEMBER SEARS: I have one
10 question. When you say asymptomatic, so would
11 you qualify somebody who has a transient
12 ischemic attack but, otherwise, then resolves
13 and doesn't have another one, is that an
14 asymptomatic patient or is that a symptomatic
15 patient at that point?

16 MR. KRESOWIK: A very important
17 question. And the issue in this case is we
18 actually talk about three levels of
19 symptomatic status. And again, I don't know
20 the composition of the group in the room. So,
21 I am going to try to keep it at a fairly,
22 even, if you will, a layperson level.

1 But the issue as far as the data,
2 the randomized trials that have been done
3 support a strong benefit for patients who have
4 hemispheric or clear strokes or transient
5 ischemic attacks within a relatively short
6 period of time. The studies, let's say, for
7 the major trials are approximately 120 days or
8 four months.

9 So, for the purpose of the way we
10 have defined this measure, those measures
11 would be classified as symptomatic. So, these
12 are patients who have clear hemispheric that
13 is on the same side of the carotid that is
14 being operated on within four months of the
15 procedure.

16 We would have a second group which
17 we would call other symptomatic, which would
18 include the patients that would have had an
19 event sometime in the remote past, okay, that
20 is beyond the 120-day window, and would also
21 cover patients who have neurologic events in
22 the vertebrobasilar circulation or perhaps

1 have had events in the contralateral
2 hemisphere to the carotid being operated on.

3 And so, those two groups would be
4 separately classified. But this measure is
5 focusing on everybody else, which is the
6 patients who are truly asymptomatic in the
7 sense that they have never had a stroke or
8 transient ischemic attack in any distribution
9 at any time. So, these are purely
10 asymptomatic.

11 And again, from good data in the
12 Medicare population, that is still
13 approximately 60 to 70 percent of the patients
14 who are receiving at least for carotid
15 endarterectomy in this country. So, it is the
16 vast majority, but these are patients who are
17 completely asymptomatic.

18 Does that answer the question?

19 MEMBER SEARS: Yes, it does. This
20 is Nick Sears. I am a retired vascular
21 surgeon.

22 So, it is just logic there, yes.

1 MR. KRESOWIK: Okay. So, I note
2 there are some other measures. I will just
3 talk about I have been one who has strongly
4 advocated against volume-based measures
5 because they, in fact, encourage overuse and
6 potentially, as I said, create a perverse
7 incentive for people to operate on more and
8 more patients for whom the benefit is small.

9 So, I think the other advantage of
10 this approach is it does not have the perverse
11 incentive of encouraging overuse, and,
12 hopefully, in that way, also, will lead to
13 cost reduction, if you will, in the country.

14 So, the advantage of this
15 approach, as I said, is the simplicity of,
16 once you define this population as the
17 asymptomatic, you need to do no further risk
18 adjustment. And, then, you can focus just on
19 the event, which in this case would be stroke
20 or mortality.

21 I can stop there, and, then, I can
22 go on to the aneurysm measures, but --

1 CO-CHAIR TORCHIANA: No, please go
2 on.

3 MR. KRESOWIK: Okay. So, do you
4 want me to talk about the aneurysm measures
5 then?

6 CO-CHAIR TORCHIANA: Yes.

7 MR. KRESOWIK: So, the aneurysm
8 measures are designed to be the same basic
9 principle. Again, the data that would support
10 aneurysm repair in the case of non-ruptured
11 aneurysms, this is purely a preventive
12 operation. So, the risk versus the benefit
13 has to be balanced on an individual patient
14 level.

15 We have pretty good data about the
16 likelihood-of-rupture risk based on size. And
17 there is a slight size difference between men
18 and women, but the basic principle here is, if
19 you focus on the non-ruptured aortic aneurysms
20 that are, if you will, of small to what we
21 would call moderate size, you don't need to do
22 further risk adjustment, just as I discussed

1 with the carotids.

2 The basic principle here is that
3 that should be part of the decisionmaking.
4 And you don't, again, want to give credit to
5 someone who is taking a very sick individual
6 or someone with a shortened life expectancy
7 and fixing a small or moderate-size aortic
8 aneurysm. The likelihood of harm versus
9 benefit in that case would weigh against the
10 procedure.

11 So, it is exactly the same as what
12 we were talking about before. It minimizes
13 the need for any further risk adjustment as it
14 is part of the surgical decisionmaking.

15 So, I will just stop there. That
16 is really the principle before these four
17 measures. It is just separating into separate
18 categories the endovascular approach to aortic
19 aneurysms versus the open approach, the two
20 separate measures focusing on those
21 populations, and the same for carotid
22 endarterectomy and carotid stenting.

1 CO-CHAIR TORCHIANA: Do you want
2 to say anything about the surveillance
3 measure?

4 MR. KRESOWIK: Sure. The
5 surveillance measure is, again, based on the
6 principle that, if the patients are undergoing
7 endovascular aortic aneurysm repair, they do
8 require some post-procedure surveillance to
9 make sure that there are no potential
10 complications that could increase the risk of
11 future rupture.

12 There is, you know, I think a fair
13 amount of controversy as to exactly what the
14 time interval needs to be, exactly what the
15 imaging modalities need to be. This measure
16 is designed to be, it is sort of, I guess, a
17 very minimalistic approach of saying at least
18 one surveillance study between 3 and 15
19 months, which is really sort of the floor, if
20 you will, for what might be ideal and does not
21 necessarily specify the type of imaging study,
22 just that that imaging study needs to be one

1 for which you can comment on size and any
2 evidence of endo leak.

3 So, again, I don't think anyone
4 would argue that this would be the absolute
5 minimum that should be done for these
6 patients.

7 CO-CHAIR TORCHIANA: Okay. Thank
8 you.

9 MEMBER MORTON: I had a question,
10 if I could? The question is, given that the
11 endo leak rate is so high -- it has been
12 estimated 30 to 60 percent in some studies --
13 should you be more prescriptive about the
14 frequency of imaging as well as the type of
15 imaging, since this appears to be a very
16 common occurrence?

17 CO-CHAIR TORCHIANA: Why don't we
18 get to that when we discuss?

19 Tim, are you going to be able to
20 stay on the call or are you --

21 MR. KRESOWIK: No, I certainly
22 can. I am available.

1 CO-CHAIR TORCHIANA: Okay. So,
2 why don't we get to that when we get to
3 specifically discussing the measures?

4 So, thank you very much for that
5 introduction. We are now going to go back to
6 our agenda and follow along in the order that
7 we were set to go.

8 So, we have incidental
9 appendectomy in the elderly as the next item
10 up for vote.

11 John?

12 MEMBER MORTON: Yes. So, this is
13 another AHRQ measure, and it is looking at
14 incidental appendectomy in the elderly.

15 This one generated a little bit
16 more comment and questions than the previous
17 one about perforated appie. It appears to be
18 a relatively-rare event. The data that was
19 submitted looked anywhere from about 20 to
20 maybe mid-30s per 1,000 appendectomies. So,
21 we are relatively rare. There was some
22 supplemental data that was provided from the

1 State of Texas that was even lower, about 2
2 out of 1,000.

3 I think there is good science
4 behind the reasoning for the measure. A lot
5 of data has come out, particularly out of
6 Mayo, looking at performing an appendectomy
7 when it is not indicated leads to more
8 problems than it is worth.

9 The one other question that came
10 up in looking at the measure was there was an
11 exclusion for colon cancer. I am wondering if
12 there should be an exclusion for ovarian
13 cancer since a lot GYN oncologists do try to
14 remove the appendix at the same time.

15 What the measure has going in its
16 favor is there are not that many elderly
17 markers of quality out there. So, that is one
18 thing.

19 I think the only question mark
20 really from my end was whether or not this was
21 something that was useful to measure, given
22 that the numbers are fairly small.

1 CO-CHAIR TORCHIANA: Other
2 comments?

3 MEMBER CIMA: I just had one
4 followup. I know the exclusion for colon
5 cancer, but there is a fair number of
6 operations in colorectal surgery that you do
7 that involve the right colon for polyps,
8 benign neoplasms, colitis, that involve
9 removal of the appendix as part of the
10 procedure, not because it is abnormal. It is
11 just stuck to the colon there and it needs to
12 come out. And the pathologists often report
13 it as a separate specimen. They will say
14 appendix, you know, without diagnostic
15 abnormality.

16 How would that be handled because
17 colectomies are in the group that gets
18 included? I mean I just was wondering about
19 that.

20 MEMBER MORTON: Yes, I can address
21 that. So, the exclusion list includes,
22 basically, all colectomies that involve either

1 the entire colon or the right side of the
2 colon. They also exclude pelvic
3 exenterations. And there is separate
4 exclusion for patients who have either a
5 malignant neoplasm of the colon or malignant
6 neoplasm of the retroperitoneal or peritoneal
7 tissues or peritoneal carcinomatosis,
8 basically, as well as secondary malignant
9 neoplasms that involve those structures. So,
10 I think those cases would be excluded.

11 The ovarian cancer might still get
12 in here if the patient did not have a pelvic
13 exenteration and if the patient did not have
14 visible peritoneal carcinomatosis.

15 MEMBER CIMA: The only other
16 comment I would make is there is a lot of data
17 and interest in the perforated appie measure.
18 Not a whole lot has been kind of done with the
19 measure, at least in the literature regarding
20 it.

21 So, the question is we are
22 collecting them, but what we are going to do

1 with it?

2 MEMBER DILLON: So, in the sea of
3 metrics that we are all forced to collect, is
4 this one that we really need to do? I mean,
5 is this really going to make a difference in
6 terms of geriatric surgery or whatever?

7 MEMBER MORTON: Well, to Peter's
8 point, I think this is one that might fall
9 into that category about being a legacy
10 measure, if you will. It is kind of, again,
11 not a large volume. I am not sure if it
12 really is impactful on the quality of care of
13 the elderly.

14 MEMBER STAFFORD: The other
15 question I had got back to the exclusions, and
16 they are up there on the board. We talked
17 about this is the conference call.

18 I am not sure why you would
19 exclude a transverse colon resection, a left
20 hemicolectomy, a signoidectomy, because those
21 are operations where you wouldn't normally
22 take out the appendix. It is not associated

1 with those types of resections. So, I was
2 wondering why that was excluded.

3 CO-CHAIR TORCHIANA: Well, I am
4 going to make a guess, and I am on thin ice
5 here. But that the notion was that the
6 downside of an incidental appendectomy is
7 exposing the lumen of the large bowel, and
8 that deed has already been done, I would
9 guess, in what you cited.

10 MEMBER MORTON: That was the
11 rationale, plus the possibility there might be
12 some confusion in the coding as far as what
13 particular segment of the colon had been
14 removed.

15 CO-CHAIR TORCHIANA: So, Melinda,
16 if I could ask, the importance question or the
17 question of whether this remains relevant or
18 whether this should become inactive or moved
19 to the hall of fame? Do we address that when
20 we do this first vote on importance to
21 measure?

22 MS. MURPHY: Right. So, if the

1 group determines that it is not important to
2 measure by virtue of the level of performance
3 essentially being topped-out, so, then, it
4 could be intended it from moving to an
5 inactive status, assuming that the group also
6 agrees that all of the other criteria,
7 scientific acceptability, usability,
8 feasibility, are met.

9 CO-CHAIR TORCHIANA: Okay. So,
10 importance to measure: one, yes; two, no?

11 (Vote.)

12 Six, yes; fifteen, no.

13 So, let's pause at this moment,
14 then. I guess the question is, does this
15 imply that we are topped-out and it is no
16 longer important to measure? Or does it imply
17 that the measure itself is not of value and
18 should be dropped?

19 MS. MURPHY: And that is the
20 question that the group has to answer: have
21 you voted that it is not important because it
22 is topped-out? And if that is not the reason,

1 then we don't proceed.

2 MR. ROMANO: I could address the
3 issue of topped-out. So, looking at the
4 national data over a period from 1994 through
5 2007, the rate was 28.6 per 1,000 in 1994. In
6 2000, it was 26.7; in 2005, it was 20.5, and
7 in 2007, it was 19.6. So, it has dropped from
8 28.6 to 19.6 per 1,000 over a 14-year period
9 from 1994 to 2007, still about 2 percent
10 overall.

11 CO-CHAIR TORCHIANA: So, I guess
12 my impression, based on the discussion, was
13 really not a sense that this had been sort of
14 successfully put to bed, the topped-out
15 hypothesis, but more that it was of dubious
16 relevance and value, which would mean that we
17 would not inactivate it, but, rather, we would
18 eliminate it.

19 Is there a way that we can revise
20 the vote to reflect those two alternatives?

21 MS. MURPHY: Well, we will capture
22 the reason for the vote.

1 CO-CHAIR TORCHIANA: Okay.

2 MS. MURPHY: So, you do not need
3 to revote. We just need to be crystal-clear
4 that the reason for the no vote is other than
5 being topped-out.

6 CO-CHAIR TORCHIANA: Okay. I was
7 a no vote; it certainly was for me.

8 Does anyone feel otherwise that
9 voted no?

10 (No response.)

11 Okay.

12 MS. MURPHY: So, we stop there.

13 CO-CHAIR TORCHIANA: Okay.

14 Thanks.

15 So, now we have the first measure
16 from the -- oh, I'm sorry -- from the ASC
17 Quality Collaboration, hospital
18 transfer/admission, 0265.

19 MEMBER WILHOIT: This measure
20 assesses whether patients admitted to an
21 ambulatory surgery center were transferred to
22 a hospital or admitted to a hospital upon

1 discharge from the ASC.

2 The rationale for the measure is
3 that about 80 percent surgeries are performed
4 on an outpatient basis, and patients selected
5 for ambulatory surgery are not anticipated to
6 require hospital care upon discharge.
7 Therefore, high rates may be an indicator that
8 patient selection guidelines are in need of
9 review.

10 Work Group A reviewed this
11 measure, and it did have a number of concerns.
12 We felt that the measure as written could
13 potentially have unintended consequences:
14 encouraging a discharge to home with
15 instructions to go to the ER if there's
16 problems, because if the patient is discharged
17 home and, then, goes to an ER, that is a
18 success from the standpoint of the measure;
19 whereas, if the patient is directly admitted,
20 that is a failure.

21 And so, we felt that a better
22 numerator timeframe would be if the patient is

1 admitted to the hospital, instead of being at
2 the time of discharge, if it were within some
3 number of hours, maybe 24, maybe something
4 shorter than that, but that the measure needed
5 to include discharges within some timeframe or
6 admissions to the hospital within some
7 timeframe after discharge from the ASC.

8 Also, given the low admission rate
9 in the data that were presented, the Work
10 Group wondered if there is enough of a
11 performance gap for the measure to be
12 meaningful.

13 We also noted a number of apparent
14 discrepancies in this submission, and these
15 are all kind of fine-print, but play in.

16 The data were presented for a
17 convenience sample of 526 surgery centers, but
18 there is also comment that results are
19 publicly-reported for 1,185. We weren't sure
20 why we were only getting half the information,
21 if it is being publicly-reported for twice as
22 many as we got data on.

1 In the statistical analysis
2 section, it didn't seem like the statistical
3 analysis was valid. There was a comment of
4 how much deviation it took from the norm to be
5 an outlier, but it seems like that would vary
6 depending on the population for a given ASC.

7 And, also, in some of the measures
8 or in some of the data, the decimal point
9 seemed to be misplaced and rates per thousand
10 and percentages seemed to be confused.

11 So, there were a couple of fine
12 points where the submission wasn't clear.

13 CO-CHAIR TORCHIANA: Now, then,
14 David?

15 MR. SHAPIRO: Yes, we also have
16 Susan White on the phone.

17 Susan, if you are on the phone --
18 I know you are on a short schedule -- did you
19 want to speak especially to statistical issues
20 that were raised?

21 MS. WHITE: Yes, I can.

22 Can you hear me okay?

1 MR. SHAPIRO: Yes. Please go
2 ahead.

3 MS. WHITE: Okay. So, in a
4 statistical issue, really the analysis that we
5 were using was percentages that were rates by
6 ASC. So, these are analyses of ASC and not
7 the patient. So, that might be part of the
8 confusion in the error rates.

9 I am sorry. The other timeframe
10 questions -- I am sorry, I am boarding a
11 plane; I apologize. The delay kind of threw
12 me off.

13 All of the rates should be
14 reported by percentages. I hope Donna can
15 answer about the 500 versus the 1,000 for the
16 public reporting.

17 MR. SHAPIRO: Thank you, Susan.
18 Donna, do you want to answer?

19 MS. SLOSBURG: I am not sure why
20 there is that discrepancy. The only thing I
21 can think of is that the 500 came from the ASC
22 Association. And again, this is all self-

1 reported data. I could get that for you, but
2 it is self-reported, and those 500 are
3 reported in more detail than the 1100. Again,
4 it is facility data that is aggregated, so we
5 don't have specific demographics and
6 specifics. So, that is where I think the 500
7 came from, is from the ASC Association's
8 report.

9 MR. SHAPIRO: Yes, I want to
10 apologize. That is a great point, and it is
11 something that, unfortunately, we are not able
12 to investigate here on the fly, but we
13 certainly need to clear that up. And I
14 apologize to you all for not having had that
15 addressed prior to coming in here.

16 Let me just address one of the
17 main excellent points that you brought up.
18 That was the issue of the timing. And
19 actually, this was alluded to with some of
20 your other measures, and I was interested to
21 hear that it still pertains to other sites of
22 service.

1 And that is that, when we were
2 constructing these measures, we were very
3 concerned to only try to elicit data that was
4 observable directly under control and
5 reportable, therefore, during the continuum of
6 care at the surgery center. So, as soon as
7 that patient leaves the center, we have no
8 idea whether that patient got into a car wreck
9 or went home and, then, ingested whatever, got
10 a fishbone stuck in their throat even though
11 they had had a hangnail removal at the surgery
12 center, in other words, something completely
13 unrelated.

14 So, we felt that there were many,
15 many, many factors beyond our control
16 regarding the health and the eventual outcome
17 of that patient's surgical procedure after
18 they left the facility.

19 So, while I appreciate the notion
20 of the unintended consequences, I also want to
21 speak to the fact that this really has no
22 pejorative implications in terms of why to

1 track this. This is really a global
2 consideration for an ambulatory surgery center
3 which, by CMS's definition, is meant to treat
4 patients for a timespan of less than 24 hours.

5 So, it is very important that we
6 have this data for our own centers. I think
7 it is important to consumers, so that they
8 know that the centers are doing what they are
9 supposed to be doing. It is very important to
10 the regulators, but much more importantly, it
11 is to the facilities so that they can really
12 keep a good eye on their patient practices.
13 That covers pre-op, intra-op, and post-op.

14 And for pre-op, it is really
15 patient selection. We want to make sure that
16 we are taking the right patients into our
17 facilities.

18 Intra-op, we want to make sure
19 that we are not giving them too much
20 medication so that they are unable to go home.

21 And post-op, we want to make sure
22 that not only have we chosen the right

1 patients, but that we have arranged for
2 appropriate postoperative care, treated
3 postoperative nausea and vomiting and perhaps
4 pain in a timely and appropriate fashion.

5 So, the issue of direct transfer
6 is a lot because of the logistics of the
7 surgery center, but we feel there was very,
8 very much consideration, and we felt that the
9 way that we did it, doing it only direct,
10 rather than attaching a timeframe, was
11 something that was worth tracking.

12 I will tell you, however, that
13 Medicare does track both 24-hours and one-week
14 return to surgery for these patients in the
15 Medicare population. And we agree that those
16 other kinds of indices, although they are
17 specific for other issues, are also important
18 to track, but they fall outside of the purview
19 of this measure.

20 MEMBER SIPERSTEIN: We follow this
21 at our own institution, and it is not one of
22 these less-is-better metrics. I mean you

1 don't want a zero rate. It is like having a
2 zero negative appendectomy rate.

3 But the way we use it is to track
4 it longitudinally over time, where if there is
5 a marked increase or decrease, then that
6 really warrants a deep dive into individual
7 patients to find out why there is a change in
8 the pattern.

9 So, there may be a
10 misunderstanding that less is better. I don't
11 think that is the point of this metric.

12 MEMBER HALPERN: Is there a known
13 acceptable rate of transfer?

14 MEMBER SIPERSTEIN: Again, it
15 depends on the patient population, the type of
16 surgery done in your particular ASC. I mean
17 we have one ASC that does unilateral knee
18 replacements. So, it all depends on the
19 patient population that you are dealing with,
20 but within your ASC, given a relatively-stable
21 patient population, fluctuations in rate
22 should trigger some alarms.

1 MEMBER CARPENTER: I would follow
2 up with that and say, is this really a quality
3 measure? The options are, do these patients
4 at your surgery center with a slightly higher
5 risk of admission or do them as an in-patient.
6 And I am sure that their transfer from your
7 surgery center to your hospital is an
8 indicator that that is a poor quality or at
9 least a poor outcome.

10 And, in addition, the rate is so
11 low, it is .1 percent. Is that really
12 something that is going to be valuable to
13 measure differences between the surgery
14 centers, if they are that low, or even
15 differences over time?

16 It really has to do with the
17 extent of things you do at your surgery
18 center, how you are set up for these
19 transfers, whether you do people with sleep
20 apnea and things like that that have some
21 trouble with postoperative blocks and things
22 like that. Really, the options are doing

1 these patients at the in-patient facility,
2 which may not be a higher-quality experience
3 for them.

4 MR. SHAPIRO: Yes, I think that
5 you all are raising very good points. And,
6 actually, we talked about this last time we
7 were here, when we initially presented this
8 measure.

9 I still think that it is a very
10 important measure for a facility to track.
11 And that is what I was saying about it is not
12 pejorative. It is really something that you
13 want to trend and, then, do analysis on, and
14 you certainly cannot do that deep-dive
15 analysis or something along the lines of root
16 cause to see what is it that is causing an
17 increase or a decrease in your transfer rate.

18 We admit that they should be low,
19 but within a facility, given a patient
20 population and given the procedures that are
21 performed in facilities -- remember, there is
22 a wide range across ASCs -- this is something

1 that is very important, again, not only for
2 patients and consumers, but something that the
3 regulators are looking very closely at. And
4 we have always been encouraged, especially by
5 folks like CMS and at Medpac, to continue to
6 track, and they use these statistics and look
7 at those very closely.

8 So, I would encourage you to
9 encourage us to continue to have this as an
10 endorsed measure that we keep track of, again,
11 knowing that a lot of times a transfer
12 reflects actually good, and sometimes
13 preventative, medicine, and it is always done
14 in the best interest of the patient, But it
15 is something that we want to keep a very close
16 eye on, especially within a facility, for all
17 the reasons that myself and others at the
18 table have stated.

19 MEMBER HALPERN: So, how does it
20 get publicly reported, then, to say that a
21 given rate is not a bad thing? So, like let's
22 say you are doing, I don't know, the

1 unilateral knees or people who are more sick.
2 How do you report it in such a way, since this
3 is for public reporting, that it doesn't
4 become a punitive thing to that institution if
5 they are doing the appropriate care?

6 MR. SHAPIRO: I think that what we
7 have done in the past is we have the data
8 reported on our site, and it includes an
9 explanation such as some of the issues that we
10 have raised at this table, to make it very
11 clear to all that would go to the site,
12 including our patients as consumers, what the
13 implications are and, more precisely, what
14 they aren't regarding any one of the indices
15 that we track.

16 CO-CHAIR MORRIS: So, it sounds
17 like we don't know what the appropriate target
18 is for a transfer rate. And it also sounds
19 like this isn't necessarily ready for
20 primetime as a quality measure.

21 I understand that we are talking
22 about it in terms of maintenance of a measure.

1 But if we don't know what the number should
2 actually be, then, how can we say here's a
3 target?

4 MEMBER MORTON: Can I get one
5 point of clarification? Is this just for
6 transfer from an ASC to the same hospital? To
7 any hospital, right?

8 MR. SHAPIRO: ASCs are required by
9 Medicare conditions for coverage to have a
10 transfer agreement with a local hospital. So,
11 that can be any one in the community.

12 MEMBER MORTON: They are not
13 necessarily the same healthcare system?

14 MR. SHAPIRO: No, they do not have
15 to be at all. Sometimes that is impossible.
16 Of course, often that is the case, but that is
17 not a requirement for regulation or for
18 accreditation.

19 MEMBER MORTON: Thank you.

20 CO-CHAIR MORRIS: I absolutely
21 agree with you when you talk about the
22 importance of this measure. It sounds like it

1 is important to measure and track for your
2 organization and for individual ASCS, but it
3 is unclear to me how it is important to track
4 as a quality measure. Can you explain that?

5 MR. SHAPIRO: Well, I am going to
6 try.

7 I think it has a lot to do with
8 the quality of care that we provide. And
9 again, that starts with the preoperative
10 selection and preparation of our patients.
11 So, that includes making sure that they are
12 someone that has someplace to go to for
13 postoperative care. It also means that we
14 have evaluated them correctly for
15 comorbidities and that these are patients that
16 can, indeed, be appropriately done for that
17 procedure on that day in that facility.

18 And, then, it also goes to how we
19 treat them intraoperatively, again,
20 specifically, the anesthetic, but, also, make
21 sure that there are no intraoperative
22 complications as a result of the surgical

1 procedure itself.

2 And, then, finally, it really
3 relates very closely back to the postoperative
4 care in terms of how we are able to treat the
5 postoperative pain, either with IV medication
6 or pump, or both, and post-op nausea and
7 vomiting, and any other thing that would have
8 a patient be transferred to a hospital for
9 treatment and/or evaluation.

10 CO-CHAIR MORRIS: So, it is a
11 black box? It is a big black box that
12 encompasses a ton of stuff, and we know zero
13 is bad and 100 percent is bad. But it seems
14 very fuzzy to me still.

15 Again, I completely agree with you
16 that this is very important to understand and
17 to dig into, but right now we are not creating
18 a system for digging deeper. We are trying to
19 identify clear, concise quality measures.

20 MEMBER HALPERN: I think what we
21 are saying is, what parameters do you use? If
22 this is a quality measure to be measured,

1 because that is what measure implies, how do
2 you do it if you don't have a rate that is a
3 target?

4 MEMBER CIMA: Just to follow up on
5 that and what Richard said earlier, I mean you
6 have a rate here that goes from zero to 2.3.
7 The mean rate, as Jane pointed out, was .2
8 with a standard deviation of -- or .1 with a
9 standard deviation of .2 percent.

10 You're doing a great job. And we
11 would like to see it as zero, but we said
12 earlier the STS was fine and it was topped-out
13 at 95 percent. You guys are 99 percent doing
14 the right job.

15 Why go through this exercise? I
16 mean, for your institutions, you should track
17 it, yes, and make sure, but I am not sure,
18 because Arden's point is that you guys are
19 doing a great job. And should we continue to
20 make this something -- we could say it is
21 something ASC should do every year, to check
22 their rate. Are you going to put it on the

1 back shelf, or whatever we have been calling
2 it, as something to follow? But what we did
3 earlier, just sort of not retire it, but
4 inactivate it.

5 But I think I am not sure what all
6 the --

7 MEMBER MORTON: I would like to
8 speak. I would like to speak up for the
9 measure.

10 I think it is a good measure to
11 take a closer look at because the consequences
12 can be pretty severe. And it also looks at
13 the patient selection. A lot of things go
14 into play here.

15 It is not exactly germane to this
16 discussion, but we have looked at ambulatory
17 bariatric surgery. Yes, such a thing exists.
18 And we have seen some very untoward results
19 where a much, much higher mortality rate is
20 associated with an ambulatory bariatric
21 procedure.

22 So, I think this is something that

1 needs to get measured. There is not a lot of
2 good data out there about ambulatory cases
3 being done.

4 And I think the fact that we don't
5 have a set rate for it, I don't think that is
6 all that unusual sometimes in quality.
7 Sometimes we are looking for those rates, and
8 what is good now may not be good in the
9 future. So, I would be careful about pegging
10 it.

11 You know, I hate to keep bringing
12 up bariatric surgery, but 10 years ago 1
13 percent mortality was acceptable. It is now
14 .2.

15 So, it is something I think that
16 bears merit to continue to look at because
17 those cases are almost sentinel cases that
18 give you some insight as to what is going on
19 around patient selection or even the case
20 itself.

21 MEMBER HALPERN: So, how about a
22 delta for change? So, if you don't have a

1 specific rate, why don't you look for a
2 specific rate of change?

3 MEMBER AFSAR-MANESH: I am
4 wondering if, instead of even looking at rate,
5 which we seem to have a little bit of a
6 problem with, could we perhaps open up that
7 black box by looking at best practices or
8 guidelines that exist for various parts of
9 this pathway? So, patient selection, what
10 needs to happen intra-op, what needs to happen
11 post-op.

12 Are there some evidence-based
13 guidelines -- and I don't know; I'm asking --
14 is there something that we could use as
15 processes to make sure that this is happening
16 better as opposed to the rate?

17 MS. SLOSBURG: I think one of the
18 troubles -- and I apologize; this is Donna
19 talking -- is that there is not a lot of
20 evidence out there for ambulatory surgery, No.
21 1.

22 No. 2, we just don't have a lot of

1 data.

2 And, No. 3, again, these are 1200
3 facilities out of 5200. Again, this is
4 voluntary. When you talk about topped-out,
5 these are centers that have been doing this
6 for multiple quarters.

7 I think that if you looked at the
8 rest of the population, maybe their rates are
9 much higher, but we don't know that. And
10 again, I think from a quality standpoint, if
11 a center has a high transfer rate -- and I
12 know you all asked the question, what's high?
13 Personally, I think anything over 2 percent.
14 You definitely have to do some digging in and
15 finding out what is going on in that center
16 because maybe you are doing a lot of higher-
17 level cases, bariatrics or total knees or
18 total joints, but, also, maybe you are just
19 not doing a really good job on your
20 pre-assessment. That says a lot to the care
21 that is going on in those facilities.

22 I don't know how to get the point

1 across, but I am telling you all for our
2 industry this is a huge measure, and it is
3 really needed out there.

4 MEMBER HALPERN: I think we all
5 agree that it is important.

6 MS. SLOSBURG: It is just the
7 number.

8 MEMBER HALPERN: Yes. So, how
9 about something including, since it seems like
10 the people who are involved in doing it now
11 have done a good job, so maybe the target
12 should be to get more involved, more centers
13 involved.

14 MS. SLOSBURG: And that is
15 actually our goal. We are working on a
16 registry this year -- we do have some funds --
17 to allow anybody to come in and put their data
18 in, so we can get more centers, because we
19 just don't know what is going to happen with
20 CMS. We don't know if it will be January
21 2012, 2013. We don't know.

22 CO-CHAIR TORCHIANA: Could I butt

1 in for a second? I would like to recognize
2 speakers because there's a few people who are
3 trying to talk who aren't as quick on the
4 button.

5 (Laughter.)

6 DR. BURSTIN: Just two overarching
7 issues, I think in some instances this is very
8 analogous to some of the safety indicators.
9 A low rate doesn't necessarily mean it is the
10 thing you shouldn't track.

11 We also do have some good examples
12 of things like episiotomy, not a good thing,
13 but we don't actually know what the right rate
14 is. It is kind of dependent, but it is still
15 an important indicator that you might want to
16 track over time.

17 My third issue that I wanted to
18 raise, again, a cross-cutting issue, is I
19 think the idea of having a measure stop at the
20 time they leave your door has sort of changed
21 and evolved. There is a definitely shift
22 towards shared accountability. I suspect the

1 number is significantly higher, and I would be
2 curious to hear what the research would
3 suggest, if you actually looked beyond that
4 discharge time.

5 Certainly, many of us are held to
6 30-day accountability and things like that.
7 So, the idea that as soon as they leave your
8 door, you are kind of done I think is kind of
9 old thinking.

10 I think it is really important to
11 think about, whether it is a seven-day window,
12 or whatever the case may be, if you
13 overmedicate somebody and they are still woozy
14 and they fall in your parking lot, sorry, but
15 I do think that is the responsibility of the
16 ASC.

17 MEMBER SIPERSTEIN: But I think,
18 in aggregate, the measure makes sense, you
19 know, in that it is forcing the ASCs to pay
20 attention to this. And if the whole goal of
21 the metric is to try to improve quality, it is
22 at least focusing efforts because a rate,

1 again, that is too high or too low may prompt
2 you to do a root-cause analysis.

3 I think some of the scientific
4 issues are that we are trying to dissect it
5 apart a little too much and go be their
6 quality committee and do their root-cause
7 analysis for them.

8 I do see that if you have got a
9 group that has got a 5 percent rate, yes, that
10 is going to raise a red flag on a comparative
11 basis. But I think, in aggregate, it is not
12 a perfect metric, but at least it is
13 encouraging the ASCs to focus their attention
14 on the area that does have some important
15 potential quality impact.

16 MEMBER FINDLAY: If you were to
17 publicly report this by institution, would
18 consumers and prospective patients be able to
19 make sense of and discriminate between
20 centers, based on the data at this point?

21 MR. SHAPIRO: I think that is an
22 excellent question. That is why, as I said,

1 it is publicly reported now. It is on the ASC
2 Quality Collaboration website as an aggregate
3 number, not by facility.

4 MEMBER FINDLAY: But not by --

5 MR. SHAPIRO: Right.

6 MEMBER FINDLAY: If it were to be
7 reported by facility, as maybe you guys hope
8 in the future, would it be meaningful?

9 MR. SHAPIRO: I think it would be
10 very meaningful, but I think an informed
11 consumer would very, very legitimately ask the
12 exact same questions you are. And they are
13 great questions to ask, but I just maintain
14 that that does not invalidate --

15 MEMBER FINDLAY: No.

16 MR. SHAPIRO: -- the reason that
17 we should keep track of this.

18 MEMBER FINDLAY: I am not
19 suggesting it does. I just wanted that piece
20 of information.

21 MR. SHAPIRO: Yes. No, it is a
22 great question.

1 CO-CHAIR TORCHIANA: I think
2 Robert was next.

3 MEMBER CIMA: I mean I spoke
4 earlier about my feelings about this, but to
5 follow up on Allan's point, it is that, you
6 know, if you put someone out the door and they
7 end up in the emergency room that night
8 because they are having pain, you haven't done
9 an adequate job of preparing them for their
10 pain control.

11 In our practice, as a colorectal
12 surgeon, 15 percent of my male patients who
13 have anal surgery end up coming back within 24
14 hours because of urinary retention.

15 I mean, you know, you are doing a
16 procedure. I am held responsible at the main
17 hospital for readmission rates; everyone else
18 who does hospital-based work is held
19 responsible for readmission rates.

20 All right. So, let's say there is
21 a need to everyone to report it. Then, it
22 just can't be walking out the door is the end

1 of the road. If they show up in a hospital --
2 I mean I get in trouble for 30-day
3 readmission. I get 30-day deaths. I have had
4 two patients in the last five years that have
5 been killed within 30 days in car accidents.
6 It still comes back to me.

7 So, I mean, like Allan has been
8 saying, you know, responsibility does not end
9 at the end of the procedure or when they walk
10 out the door.

11 MEMBER CARPENTER: I was just
12 going to get back to I just think this is
13 being reported as a quality metric, and I
14 really don't think it is a measure of quality
15 for the individual patient.

16 We know that most surgical
17 outcomes have high quality in surgery centers.
18 So, in general, the quality of surgery is very
19 strong there.

20 If you have an option of in-
21 hospital or at a surgery center, I can lower
22 this rate by doing everybody that is a

1 slightly higher risk in the hospital. It will
2 drive up costs. It will lower this number for
3 me. But it won't provide better quality for
4 my patients. And my patients, if they are
5 comparing two centers, won't be able to tell
6 really what that means for them.

7 So, I do think it is important,
8 and I do think it needs to be tracked. I just
9 don't think it is a quality metric. I don't
10 think you have presented any evidence that
11 those patients that are transferred back have
12 worse outcomes than if they had been done in
13 a hospital, which is really the question.

14 MEMBER DUTTON: I think this is a
15 very important quality measure. I'm sorry,
16 Jim, but from the anesthesiologist's
17 perspective, you have to collect and examine
18 these people. You have to know what your rate
19 is over time. Seventy-five percent of the
20 anesthesia we do now is in the outpatients,
21 and knowing that they stay outpatients is
22 absolutely critical. It is pain management.

1 It is management of nausea and vomiting. It
2 is management of some surgical complications.

3 I do absolutely agree with Helen,
4 though, you have to push it out to 24-hour,
5 all-cause admission. You are calling all
6 those people back the next day to get your
7 satisfaction data. You can find out whether
8 they got admitted or not.

9 CO-CHAIR TORCHIANA: So, I am
10 going to take the prerogative of trying to
11 summarize where we stand, and, then, trying to
12 figure out if there is a way to resolve.

13 I guess a couple of things that I
14 would observe is that this is one of those
15 things that calls the question of what does
16 NQF certification actually mean. Because
17 there is no reason why the ASCs could not
18 continue to measure this measure ad infinitum
19 without NQF endorsement. So, what does the
20 NQF endorsement actually do?

21 I would guess that maybe the NQF
22 endorsement in this case helps to get the 1200

1 up closer to the 5,000, which would probably
2 be a good thing.

3 I can't think of a downside of it,
4 unless we feel like we are endorsing a truly
5 inferior quality measure. And it seems like
6 there are strong opinions on both sides of
7 that topic.

8 And so, I think my opinion of this
9 would be we ought to go ahead and vote, see
10 what the vote turns up, but I hope that the
11 folks in the ambulatory quality world in these
12 centers take this advice.

13 And particularly, I would say the
14 early argument, David, that you made that, you
15 know, if somebody goes home and they cut
16 themselves in the kitchen, or some other
17 completely unrelated event, I think that one
18 is a little bit specious because that exists
19 really for every quality measure that we have
20 once somebody is discharged. There is always
21 a baseline rate of mayhem in the population
22 once they get out of our doors. And so, that

1 is a problem with every quality measure that
2 you try to follow up, once a patient is
3 discharged.

4 So, I would urge -- and it may be
5 through the satisfaction survey method -- that
6 you take to heart the advice that this would
7 be a much more substantive measure if you
8 actually had a 24-hour window at least around
9 the admission piece. And, hopefully, if we
10 vote this in, next time you come back you will
11 have done some work on trying to accomplish
12 that.

13 MEMBER WILHOIT: You raised the
14 point of, what does NQF endorsement add?
15 Well, the NQF endorsement, according to the
16 criteria we are using, has to do with internal
17 quality improvement and, also, with public
18 reporting.

19 I think it sounds from the
20 discussion like, you know, there is real
21 agreement, I think, that this or some
22 variation is very relevant for internal

1 quality improvement. I think where the issue
2 is is the public reporting, and that is what
3 the NQF endorsement adds, is a blessing on
4 public reporting. And it just doesn't seem
5 like it is ready for that.

6 MEMBER ROGERS: I would like to
7 echo, David, what you said about the imprint
8 of NQF. What you do have is very nice data
9 and very acceptable data on the centers who,
10 in fact, have reported, but you have no
11 knowledge of what goes on in the other ones.

12 I think that one of the things
13 that this Committee might want to consider in
14 its charge is exactly that issue: could the
15 approval of a measure which may not be
16 perfect, but it is a good measure, because I
17 heard that, give them the kind of a little bit
18 of extra muscle to get more people in? I
19 think that that is a very important
20 responsibility for this Committee and NQF in
21 general. So, I would support it on that
22 basis.

1 CO-CHAIR TORCHIANA: A final
2 comment from our developers. Then, I think we
3 are going to vote.

4 MR. SHAPIRO: Yes, I would just
5 remind this group that we take very much all
6 the issues that you have raised. I think they
7 are excellent, and they are actually ones that
8 we have discussed during measure development.

9 But I can tell you from being, I
10 guess, a pioneer in the industry of ASC
11 quality reporting, and we are at the very,
12 very embryonic stages, that the last three
13 years of having the endorsement of this body
14 has really allowed us to get great mileage.
15 We started at zero three years ago, and we are
16 now up to 1600 centers and very close to
17 getting even more than that, as we are working
18 on incorporation in a registry and an AHRQ and
19 other things.

20 So, I can't tell you how much it
21 has meant to us. Even though this may be an
22 imperfect measure, as maybe our others are,

1 but to have had the approval and the
2 endorsement of this body has been an
3 exceptional boost for us and for our patients.
4 So, I appreciate that.

5 CO-CHAIR TORCHIANA: Thanks.

6 Let's vote on importance. One is
7 yes; two is no.

8 (Vote.)

9 We have at least one person out of
10 the room. I think 20 is the number.

11 So, fifteen, yes; five, no.

12 Scientific acceptability, a scale
13 of 1 to 4.

14 (Vote.)

15 So, this one is a bit more trying.

16 Two, completely; ten, partially; six,

17 minimally; two, not at all.

18 So, usability.

19 (Vote.)

20 Six, completely; nine, partly;

21 three, minimally; two, not at all.

22 Feasibility.

1 (Vote.)

2 Thirteen, completely; seven,
3 partially.

4 Does the measure meet all the NQF
5 criteria for endorsement? Here is a yes, no,
6 or abstain.

7 (Vote.)

8 Thirteen, yes; seven, no.

9 MS. MURPHY: May I ask a question?
10 At this point, as you did with measures in
11 Phase I, do you want to ask that the developer
12 come back to you with information about the
13 24-hour period?

14 (Chorus of yeses.)

15 MEMBER WILHOIT: And could we also
16 ask that the measure take a look at the
17 statistical analysis and the decimal points?
18 There's rates per thousand and percentages
19 that are mixed up, and the statistical
20 analysis I think is lacking in a major way.

21 MS. SLOSBURG: For clarification,
22 can I just ask, are you asking us, then, to

1 leave the measure as is and move it out to 24
2 hours? Is that what I am hearing?

3 CO-CHAIR TORCHIANA: I think we
4 would like to hear a plan as to how it could
5 be moved out to 24 hours, but for the time
6 being the measure is endorsed.

7 MS. SLOSBURG: Okay. We will do
8 that.

9 MS. MURPHY: Let me clarify. What
10 you voted on is whether or not the measure
11 meets criteria for endorsement. The feedback
12 that you bring back to the group will occur,
13 and they will consider that prior to making a
14 recommendation for endorsement.

15 CO-CHAIR TORCHIANA: For our next
16 measure, 1517, statin therapy at discharge.

17 MEMBER WILHOIT: This measure
18 assesses the percentage of patients undergoing
19 infrainguinal lower extremity bypass who are
20 prescribed a statin at discharge.

21 It should be noted that the
22 measure is defined in terms of medical record

1 data. There is no clear indication in the
2 documentation of how frequently a registry is
3 used. Without a registry, the data would not
4 be available electronically. So, the Work
5 Group that reviewed this had some questions
6 about the feasibility of implementation.
7 There was no mention of the number of
8 participants currently in the two registries
9 that exist.

10 One other question, a couple of
11 other questions that came up in our
12 discussion. One is that the measure is based
13 upon a guideline. However, the guideline that
14 is cited recommends statin use based upon the
15 level of LDL control, and the measure is
16 measuring statin use regardless of the LDL
17 level.

18 Also, the numerator and
19 denominator timeframes lack precision.

20 CO-CHAIR TORCHIANA: Comments from
21 the developers?

22 MR. KRESOWIK: This is Tim. I am

1 still on.

2 I don't know if Lindsey can
3 comment further.

4 This measure, it is coming out of
5 the Northern New England registry, and they
6 have a number of sites. I don't know the
7 exact number of participants.

8 I guess the only other thing I
9 could comment on with reference to the
10 guideline is, I mean, that is the existing
11 guideline, but certainly emerging evidence is
12 suggesting that LDL level is not as important
13 in terms of determining the benefits of
14 statin. As you all know, a lot of times the
15 guidelines lag a little bit behind the current
16 state of the evidence. But that is certainly,
17 I think the use of statin without reference to
18 LDL is certainly the current trend and I think
19 will be supported in the future guidelines.

20 CO-CHAIR TORCHIANA: Other
21 comments?

22 (No response.)

1 Should we be prepared to vote,
2 then?

3 Carol, do you have any other?

4 MEMBER WILHOIT: No.

5 CO-CHAIR TORCHIANA: Okay. So, if
6 we could vote on importance to measure and
7 report?

8 (Vote.)

9 It looks like we are not going to
10 get past 19 here. Nineteen, yes; one, no.

11 Scientific acceptability, a scale
12 of 1 to 4.

13 (Vote.)

14 Eight, completely; eleven,
15 partially; one, minimally.

16 Usability.

17 (Vote.)

18 Fourteen, completely; five,
19 partially; one, minimally.

20 Feasibility.

21 (Vote.)

22 Thirteen, completely; seven,

1 partially.

2 And does the measure meet the NQF
3 criteria?

4 (Vote.)

5 Nineteen, yes; one, abstain.

6 I am going to hand the rest of the
7 measures to Arden. I am not going to hand the
8 rest of the measures to Arden.

9 (Laughter.)

10 All right. So, the next one is
11 AHRQ, abdominal aortic aneurysm volume, 0357.

12 MEMBER SAIGAL: Okay. So, that is
13 me.

14 So, these are a composite pair
15 with the one that is following. Should I do
16 them together?

17 CO-CHAIR TORCHIANA: Please.

18 MEMBER SAIGAL: Okay. So, the
19 first measure is a volume measure of AAA
20 repair based on hospital discharge at the
21 provider level. And the companion measure is
22 discharge in which a AAA repair was done,

1 endovascular and open repairs, in which an in-
2 hospital death occurred.

3 I think that, in terms of the
4 first measure, in terms of importance, this
5 document, there is a lot of cutting and
6 pasting going on, and it was a little hard to
7 interpret it in certain places.

8 In terms of looking at the
9 performance gap, they report the numbers of
10 procedures done by age and race, but not by
11 provider. So, I am not sure if the person
12 doing this format, what they were trying to
13 get at with that data.

14 But we know this is a very
15 important measure. One of the earliest
16 measures for quality is AAA repair volume.

17 They didn't have much in terms of
18 disparities, either. They lump in
19 endovascular and open repairs in this. I am
20 not sure. There are some comments from our
21 group that those could be reported separately
22 because of the trend towards open repairs

1 happening in more complex cases now. But
2 there may be some dipstick value to the
3 overall discharge number that they don't
4 really talk about that much.

5 They have, in terms of usability,
6 in this measure they talk about a report that
7 was generated. There is a lot of cutting and
8 pasting of methods of the report, but there is
9 no data as to what the report said. So, I
10 would like to hear more about that.

11 And, then, in terms of the
12 mortality measure, there were two risk
13 stratification methods I read about. One was
14 in 2A.14, which was what they used in the NIS
15 analysis that looked at gender and age, I
16 believe, as the only stratifying variables for
17 mortality, probably because that is all that
18 is available in HCCUP.

19 And, then, the other one was a CMS
20 model that they referred to that was more
21 detailed in terms of a model. So, I wasn't
22 clear as to what they were proposing be done

1 for risk stratification for mortality.

2 And, then, the last thing that was
3 kind of troubling to me in the mortality
4 measure was that in Section 2B.3 they go
5 through a long thing about how they defined
6 signal-to-noise ratio in their measures. And
7 they mentioned that the mortality measure at
8 the provider level had a low signal-to-noise
9 ratio. So, I wasn't clear if they were -- it
10 is a kind of sentence fragment as well. Maybe
11 it was some typos in there. So, it was really
12 hard to interpret that, but it raised some
13 alarms in my mind as well.

14 MEMBER HALPERN: I also just
15 wanted to add about the endovascular versus
16 open repair, and lumping them together,
17 because open repairs are not what they were 10
18 years ago. And a lot of the literature that
19 is quoted is from 10 years ago.

20 Open repairs have become more
21 complicated because the vast majority are
22 being done endovascular, and when they are not

1 being done endovascular, it is generally
2 because it is a short neck. It may mean a
3 superrenal clamp. Or it is a bilateral iliac
4 artery aneurysms that are not well amenable to
5 endovascular repair. So, they are much more
6 complicated cases than they were in the past.

7 And, also, in terms of volume,
8 there is actually a paper that just came out
9 last year in Circulation that looked at volume
10 in relation to outcomes. And actually, in
11 endovasculars, the volume threshold is 10, 10
12 cases per year where they started to see a
13 difference, more or less than 10.

14 So, the volume, and it is much
15 more dramatic in open repairs, again, I think
16 because open repairs have become so much more
17 complex. So, I think lumping them together is
18 not a good thing.

19 MEMBER MORTON: Do we know what
20 the breakdown is in the vascular versus open?

21 MEMBER HALPERN: I would say
22 probably now at least 80 percent are done

1 endovascular, at least. I am not sure if the
2 SVS tracks that. They could probably answer
3 that better. But I would say I know in my
4 practice it is probably 80 percent, and those
5 that aren't, you know, again, the more
6 complicated patients anatomically.

7 MEMBER MORTON: Renae mentioned
8 about emergencies. Almost all of those are
9 being done open or?

10 MEMBER HALPERN: It depends on the
11 center. And it may be a reason why to take
12 out the ruptures. Those centers that have a
13 process in place to do them endovascularly do
14 them, tend to do them endovascularly.

15 And when I say a process, you have
16 to have grafts onsite. You can't be waiting
17 for a ref to come and bring you grafts. So,
18 if you don't have stock in grafts, you may not
19 be able to do them endovascularly unless it is
20 a stable ruptured aneurysm, you know, somebody
21 who presents with abdominal pain and has a
22 rupture on TT, but is not unstable. But for

1 unstable patients, unless you are set up to do
2 them, you are not going to be doing them.

3 And, then, of course, the open
4 ruptures are much more disastrous than the
5 endovascular ruptures. So, again, another
6 reason to separate them out.

7 MR. KRESOWIK: This is Tim
8 Kresowik. I am not here to comment on these
9 measures, but I will.

10 As I discussed in the introduction
11 to the other measures, the SVS and the people
12 involved with quality from the SVS would not
13 support either of these measures based on the
14 scientific validity.

15 Certainly, the risk-adjustment
16 methodology based on either NIS or
17 administrative claims data is far from valid.
18 I have already alluded to the previous
19 problems with volume, and there has been
20 multiple studies that have shown that,
21 certainly, when you try to come up with a
22 clear threshold, it is very problematic. And,

1 then, the trend is there.

2 But once you start risk adjusting,
3 you lose a lot of the validity, if you will,
4 and it always adds a perverse incentive, as I
5 said, because people tend to try to meet these
6 volume thresholds. And the only way you meet
7 these volume thresholds is by operating on
8 more and more patients who would be better off
9 not having a procedure altogether.

10 So, I just would register that,
11 from the Society for Vascular Surgery point of
12 view, we would not support these measures.

13 CO-CHAIR TORCHIANA: Could we hear
14 from AHRQ?

15 MR. ROMANO: Yes. So, we have
16 actually done extensive analyses here. There
17 was discussion of these points as well during
18 the original endorsement process several years
19 ago.

20 And there are actually strong
21 methodologic reasons for the choices that were
22 made here. So, in terms of, for example, the

1 increased use of endovascular procedures, the
2 national data, of course, lag several years
3 behind leaders' practice. The last national
4 data that we looked at showed about 60 percent
5 endovascular, but the trend was still upward.
6 So, it wouldn't surprise me if that was up to
7 75 percent now.

8 But what we have seen is that, as
9 people have converted to the endovascular
10 approach, the short-term mortality has
11 decreased. Now there is some argument in
12 literature about whether endo leaks and other
13 long-term complications may erode some of that
14 early benefit.

15 But the fact is that, from the
16 patient-centered perspective, that it is
17 important to combine the two types of
18 procedures because, otherwise, you miss the
19 fact that there has been a temporal trend
20 towards decreasing short-term mortality, which
21 is largely attributable to the switchover from
22 the open approach to the endovascular

1 approach.

2 So, this is a specific process
3 that has been implemented within most
4 hospitals that has improved short-term
5 outcomes. So, when we see that, we want to
6 give hospitals credit for that improvement.
7 And the way to do that is by constructing the
8 indicator in a patient-centered way, so that
9 it reflects the patients who are coming into
10 the hospital for their AAA repair.

11 In terms of the issue of the
12 ruptured and unruptured, so this is also, of
13 course, a very important issue. I would say
14 that the risk-adjustment model, and if you are
15 interested, I can show a copy of it, but it
16 certainly does include as one of the most
17 important factors the rupture of the aneurysm.
18 So, that is taken into consideration in the
19 risk model.

20 Again, putting these two types of
21 procedures together is based on three
22 premises. One is empirical literature showing

1 that surgeons' and hospitals' experience with
2 ruptured cases improves outcomes for all
3 cases, and vice versa.

4 So, generally, it is the same
5 surgeons who are operating on ruptured and
6 unruptured cases. And the experience that
7 they accumulate, basically, carries over to
8 improved outcomes for both ruptured and
9 unruptured cases.

10 So, by combining the two together,
11 the performance of the indicator substantially
12 improves in terms of the reliability and the
13 ability to discriminate amongst providers.
14 Roughly 50 percent of the variation that is
15 linked to the volume outcome association,
16 roughly 50 percent of that is attributable to
17 ruptured aneurysms; roughly 50 percent is
18 attributable to unruptured aneurysms.

19 So, we see this tracking together,
20 that the centers that have better outcomes
21 with ruptured aneurysms also tend to have
22 better outcomes with unruptured aneurysms.

1 So, again, this is sort of a methodologic
2 rationale for combining the two and dealing
3 with the obvious difference in risk through
4 adjustment in the statistical model.

5 MEMBER HALPERN: How much is
6 ruptured weighted in your model?

7 MR. ROMANO: So, the ruptured
8 cases constitute roughly 10 percent of the
9 cases and roughly half the deaths.

10 MEMBER SAIGAL: Could I ask, could
11 you comment on the notations you guys have in
12 there about the signal quality of the
13 mortality measure? And also, if the model
14 that you published in the application is not
15 the correct one, it would be nice to see the
16 one that you actually are going to use.

17 MR. ROMANO: Sorry. The model is
18 the one that is currently in use, and I am
19 pulling that up momentarily, but my internet
20 is a little slow here.

21 And I am sorry, I didn't prepare
22 this myself, so I will look over it and have

1 to respond in a minute.

2 MEMBER CIMA: If the purpose of
3 these measures is to inform the public as well
4 as the practices, most people don't choose
5 their hospital for a ruptured aneurysm.

6 (Laughter.)

7 So, although I understand the
8 methodology. You know, it is somewhat like a
9 trauma center. You know, you do a lot of
10 ruptured aneurysms; you get good at doing
11 that.

12 But to inform the public about
13 where to get your aneurysm repair, is it
14 necessary to have that in there? I mean we
15 have tried to segregate in other measures
16 acute CABG. You know, salvage CABGs and thing
17 like that have been separated out. Can't that
18 be done here, too? I mean I don't understand
19 why it would -- I understand your methodology
20 about tracking centers, but I don't understand
21 why it has to be done in this measure.

22 MEMBER HALPERN: And again, I

1 point out there is in terms of just using
2 volume, also, there is literature now showing
3 -- and this is from Circulation 2010 by
4 Landon, et al -- and they showed not really a
5 significant difference over 10 cases for
6 endovascular elective repairs versus open.
7 And again, because open repairs, open elective
8 repairs are becoming more complex, and like
9 Dr. Cima said, you know, you don't choose the
10 hospital where you wind up with a rupture.

11 MEMBER MORTON: Just out of
12 clarification, for CABG, do we segregate it
13 this way between emergency and elective?

14 CO-CHAIR TORCHIANA: It is in the
15 model. There is also a lot of controversy
16 around whether or not patients who are
17 receiving CPR, either on their way into the OR
18 or immediately prior to going to the OR,
19 should be included. But, as of right now,
20 they are included in the model.

21 MEMBER CIMA: There are some
22 exceptions in the sense a salvage operation

1 doesn't need a mammary. So, they have taken
2 those patients out, you know, those high-risk,
3 emergent-type patients, those are out of the
4 pool. I can't think of anything more emergent
5 than a person with a pre-ruptured AAA.

6 MEMBER SAIGAL: Can I add, so this
7 is a provider-level measure, according to the
8 AHRQ application? And they state that the
9 hospital-level measurement is unreliable,
10 although the usability report they reference
11 talks about informing policymakers about
12 hospital quality. So, that is also a little
13 confusing.

14 MR. ROMANO: I am sorry, I am
15 having a little trouble finding the specific
16 section of the document that you are referring
17 to, if you could clarify that? And I don't
18 know if --

19 MEMBER SAIGAL: 2B3.

20 MR. ROMANO: 2B3?

21 I don't know if the statistician
22 on our team is on the call. Jeff Geppert?

1 (No response.)

2 I guess not. Okay.

3 In the meantime, I am going to
4 pull up the risk-adjustment model for AAA
5 mortality. So, that model includes gender,
6 age categories starting at 65 up to 85 and
7 over. It includes ruptured versus unruptured
8 aneurysms. It includes major diagnostic
9 categories that reflect comorbidities, major
10 comorbidities.

11 And it is based on the APR-DRG
12 risk-adjustment scheme. So, it includes three
13 APR-DRGs that basically correspond to features
14 of the aneurysm and associated cardiovascular
15 conditions.

16 We are looking at 2B.3 here. So,
17 the signal ratio is the proportion of the
18 total variation across providers. It is truly
19 related to systematic differences in provider
20 performance, and it is 31 percent, which is
21 lower than some, but higher than others. So,
22 it was high enough to meet our threshold for

1 inclusion, but some other indicators are in
2 the range of 50 percent or over. So, this is
3 a policy debate as far as whether 30 percent
4 signal is high enough.

5 MEMBER CIMA: What was the value
6 for the weight of the rupture in your model?
7 I mean you put in, you cited off about a dozen
8 different things. But the main issue here is
9 ruptured should be included or not.

10 MR. ROMANO: Right. The point
11 estimate in a logistic model with a C
12 statistic of 0.909 is 1.8. So, that would
13 translate into an odds ratio of e to 1.8 or,
14 roughly, 5, I am thinking. So, I think that
15 corresponds, roughly, to the absolute
16 difference of about 5 percent versus 30
17 percent or so. So, yes.

18 And the overall C statistic of
19 .909 reflects the discrimination of the model,
20 and that is generally considered very good for
21 risk-adjustment models based on these type of
22 data.

1 MEMBER MORTON: Actually, I like
2 the argument about, if you are good at doing
3 some open cases or if you are good at doing
4 endovascular cases, you might be good at doing
5 emergency cases. So, I think Dr. Romano's
6 point there, actually, for me, had some
7 traction, that it is good to include them.

8 I understand that they are all
9 kind of different, but the fact that we don't
10 know where these cases are coming from and
11 what those providers do, I think it sounds
12 like it might be useful to keep them in there,
13 the emergency cases and the open cases.

14 MEMBER HALPERN: I am not saying
15 we shouldn't look at open, but I think there
16 is a vast difference now between endovascular
17 and open cases. And, remember, this is
18 publicly reported. So, if I were a patient,
19 I would actually rather know, if I had a
20 complex aneurysm, I would rather know about
21 the volume of open than the total volume
22 because maybe somebody dose 100 endovasculars

1 and two opens.

2 MEMBER MORTON: Because what I am
3 hearing is part of this --

4 MEMBER SEARS: This is Nick Sears.
5 What about the conversion to open
6 from an endovascular? Are we considering that
7 at all as well?

8 MEMBER HALPERN: No, I don't think
9 that is considered in actually any of the
10 measures.

11 MEMBER SEARS: Yes.

12 MEMBER HALPERN: I think the rate
13 is very low now. I remember seeing a paper
14 about it not too long ago, that the rate of
15 conversion is under 1 percent. I think our
16 selection criteria has gotten better.

17 MEMBER SIPERSTEIN: But I think
18 what I am hearing in this discussion is that
19 there is an overall mortality rate for these
20 vascular procedures, and you almost have a 2x2
21 matrix of open versus endovascular and
22 elective versus ruptured.

1 And looking at the overall and
2 looking at the subsets, I think both have
3 different values. I mean, if you are looking
4 within a hospital system in terms of are you
5 appropriately giving the right therapy to the
6 right group of patients, you want to look at
7 your overall numbers. Again, if you are a
8 given patient who is faced with having an open
9 versus an endovascular, yes, you may be
10 interested in looking at the details.

11 So, I think maybe what we are
12 doing is we are interested in the overall
13 number, but realize some of the inherent
14 weaknesses, and, then, maybe the
15 stratification into those subcategories would
16 be helpful to dissect this apart.

17 MR. GEPPERT: Patrick, this is
18 Jeff Geppert. Can you hear me okay?

19 MR. ROMANO: Yes, now we do.
20 Thank you.

21 MR. GEPPERT: Yes.

22 MR. ROMANO: Sorry.

1 MR. GEPPERT: Just on that last
2 point, so part of this process, starting from
3 when the indicator was originally endorsed,
4 there was a series of communications with
5 folks at SVS. And one of the things that AHRQ
6 said they would do in response to the points
7 that are being discussed is allow for the
8 stratification of the measure in the software
9 based on the open and the endovascular and the
10 ruptured and the unruptured. So, this kind of
11 2x2 stratification that you just mentioned is
12 a component of the current software.

13 CO-CHAIR TORCHIANA: So, of
14 course, the problem with trying to stratify
15 and have more homogeneous populations for
16 comparison is that the number in your cells
17 goes down and the ability to discriminate also
18 goes down.

19 This is not a measure generally,
20 nor are the pancreatic, nor are the esophageal
21 measures, that have an enormous power to
22 discriminate providers in the first place.

1 And so, this is one of the challenges around
2 the desire to have good outcomes measures for
3 these high-risk or relatively high-risk
4 interventions on the behalf of the public, is
5 that the aspiration for what the public wants
6 versus what is actually realistically
7 deliverable, there is kind of a big gulf
8 there.

9 So, on this one, I think I am
10 going to look to Melinda again. I think we
11 should take this as a vote on importance or
12 measure or we should send it back for more
13 refinement. And I think that is an important
14 discussion.

15 MEMBER HALPERN: I think we were,
16 also, at some point talking about harmonizing
17 the volume and the mortality into one.

18 MS. MURPHY: And discussion of
19 harmonization with related measures comes
20 after the vote related to meeting the
21 criteria, but before a vote on recommendation
22 for endorsement.

1 MR. ROMANO: And in this case, I
2 would say that this volume measure and
3 mortality measure do have the same
4 definitions. So, at least these two measures
5 are harmonized with each other.

6 And in this case, we have done
7 extensive analyses of these questions, of
8 looking at open versus endovascular, and so
9 forth. And I think the Chair has summarized
10 the issue very well, that we feel that the
11 loss of reliability, the loss of
12 discrimination in separating out half the
13 deaths is not justified empirically. So, that
14 is our view.

15 MR. KRESOWIK: This is Tim
16 Kresowik.

17 I was going to comment on this
18 endovascular versus open. I think it has to
19 be viewed in terms of where we are today
20 versus where we were when these things were
21 first being looked at, in that there was, if
22 you will, perhaps an option that people could

1 go one way or the other.

2 Then, I would have to say that in
3 2011 virtually nobody, if you will, is getting
4 an open repair if they are a reasonable
5 endovascular candidate. And so, I mean I
6 think these procedures really have become
7 quite distinct. They are not the same
8 population. The patients that are getting
9 open repair in 2011 are ones that have
10 anatomic configuration that does not allow an
11 endovascular repair.

12 So, I mean I think the environment
13 has completely changed. And so, I think that
14 has got to be taken into consideration as this
15 is viewed.

16 MEMBER SAIGAL: A technical
17 question. These things are composite
18 measures. So, do you have to vote the same
19 way for both of them?

20 MS. MURPHY: No. They are
21 recommended for use as a pair. They are
22 endorsed individually.

1 MEMBER SAIGAL: Okay. It is
2 concerning that 70 percent of the variance in
3 the provider level is noise in the measure.
4 So, if you are going to use this for reporting
5 about providers, that is a lot of noise, I
6 think.

7 MR. KRESOWIK: Although that is
8 similar to a lot of measures that are publicly
9 reported, including some of the ones that we
10 have talked about today for pancreatic and
11 esophageal.

12 The other thing that may be a
13 comment that is more appropriate for the
14 public commentary, but in order for
15 endorsement to be a meaningful process, it has
16 to be something on which people can rely for
17 planning and for decisionmaking. And this has
18 been a long, three-year process from when the
19 measures were originally endorsed to the point
20 now where they are scheduled to be included in
21 Hospital Compare.

22 And there have been publications

1 and notices in The Federal Register, you know,
2 public comments to The Federal Register
3 notices, several rounds of hospital reports
4 that have gone out for hospital comments.
5 This has been a several-year process.

6 And so, to change a decision based
7 on a lot of -- you know, I understood the last
8 point about there have been trends in the last
9 couple of years that maybe merit
10 reconsideration, but to make a decision based
11 on a lot of factors that have been previously
12 considered, were discussed with people like
13 SVS, you know, in some sense, it really pulls
14 the rug out of a process that the federal
15 government has spent a lot of money and time
16 and effort on. And so, it is just something
17 that should weigh very heavily, in my opinion.

18 MEMBER CIMA: So, what exactly are
19 we doing here, then?

20 CO-CHAIR TORCHIANA: The body
21 language around the table did not receive that
22 one well, since you are on the phone and can't

1 see it. I think justifying the continuance of
2 a bad measure because a lot has been invested
3 in it is not a very compelling argument.

4 MR. KRESOWIK: That is why I said
5 it was probably more appropriate for the
6 general comment period.

7 MEMBER MORTON: I kind of liked
8 Allan's idea about looking at this on overall,
9 all the individual ones. Because really what
10 you are talking about here is the care of the
11 patient with an abdominal aortic aneurysm,
12 whether it be open, where you have some
13 anatomy that drives that decision, or it is
14 EVAR, or if it is emergent. I think all of
15 them should be included.

16 You know, you have the overall
17 because these generally don't occur in
18 isolation. You just don't do opens and you
19 don't just do EVARs and you just don't do
20 emergents, right?

21 MEMBER HALPERN: I understand
22 that, but to report them as one lump I think

1 does disservice to the differences between
2 them. And if you are going to make judgments
3 based on lumping them all together, you are
4 not going to get a correct judgment.

5 CO-CHAIR TORCHIANA: So, I think
6 we have covered the pros and cons here pretty
7 well. And I guess I think the logical place
8 to go is to a vote unless somebody asserts
9 otherwise.

10 (No response.)

11 Okay. So, let's first answer,
12 does the measure meet NQF criteria for
13 importance to measure and report?

14 (Vote.)

15 MEMBER SEARS: Are you voting on
16 0357?

17 CO-CHAIR TORCHIANA: Yes, 0357, as
18 we talked about it.

19 It is a dead heat, 10 to 10.

20 MEMBER SEARS: Do you want me to
21 break it? Nick Sears.

22 CO-CHAIR TORCHIANA: Okay. Well,

1 let's continue through the remaining portions
2 of the vote.

3 Ah, Dr. Sears, can you break the
4 tie?

5 MEMBER SEARS: Yes. I would say
6 no.

7 CO-CHAIR TORCHIANA: Okay. Eileen
8 is also on the call?

9 MEMBER KENNEDY: I am.

10 CO-CHAIR TORCHIANA: Would you
11 care to vote yes or no?

12 MEMBER KENNEDY: I am actually ask
13 to abstain.

14 CO-CHAIR TORCHIANA: You're going
15 to abstain? Okay.

16 So, do we proceed with the
17 remainder of the vote, Melinda? Too tight?

18 DR. BURSTIN: It is so clearly a
19 split, though, and it is hard to argue there
20 is a consensus on that first vote. So, I
21 think either have more discussion or see if
22 there is additional information you want to

1 get from AHRQ and discuss on a subsequent
2 call. But to just table it at this point
3 seems a little, it doesn't sit right.

4 MS. MURPHY: So, some of the
5 discussion was around the question of having
6 it split and having open versus endovascular.

7 So, are there some conditions or
8 requests that the group has of AHRQ to bring
9 information back to reconsider it?

10 MR. ROMANO: And if I might say
11 it, in the context that the current measure
12 and software does support stratification, so
13 that is an option that is available to users.

14 What could be done that is not
15 currently done is separate risk-adjustment
16 models could be developed for the different
17 cells in that 2x2 table.

18 MEMBER CIMA: Well, I mean that is
19 one option, but I mean I think the general
20 consensus is people are viewing these as two
21 very distinct procedures now. And if you are
22 doing EVAR, you should have a mortality rate

1 of "X", and if you are doing opens, you should
2 have a mortality rate of "Y".

3 MEMBER SEARS: And if you want to
4 tie volume to them, you could tie volume to
5 them. But I am not big fan of volume these
6 days.

7 MEMBER CIMA: No, I am just
8 saying, could that be, rather than
9 stratifying, just have them separate? Because
10 I know in our health system all the open ones
11 come to our institution. All the surrounding
12 hospitals no longer do them. So, it is sort
13 of strange, you know. And all the ruptures
14 come to us. So, we get the worst of both
15 worlds because no one touches them. And so,
16 that is the reality.

17 And I think we are comparing
18 apples and oranges. As a surgeon in the room,
19 I view them as totally different patient
20 populations and totally different procedures.

21 MEMBER HALPERN: And as a vascular
22 surgeon, I concur with that.

1 MEMBER WILHOIT: This measure is
2 the volume measure, and if 75 percent or so of
3 the cases are endovascular, the numbers are so
4 small on volume anyway, if you separate out,
5 it seems like for the open procedures there's
6 not even enough left to report on volume.

7 So, in terms of this measure,
8 0357, which is volume, does it make sense to
9 make it just endovascular?

10 MEMBER HALPERN: No. Again, if
11 you look at the last paper that came out from
12 Circulation, the volume effect on mortality
13 for endovascular is very small. The threshold
14 where they saw the biggest difference was more
15 or less than 10, 10 surgeries a year. So, the
16 volume effect is very small.

17 The volume effect is much higher
18 for open. So, I think it would actually, even
19 though opens happen less frequently, they have
20 become so much more complex that I think it is
21 still reasonable to look at that volume. That
22 is where you really see the differences in

1 volume. At each quartile, the mortality goes
2 down with the number of volume that you do.

3 MEMBER WILHOIT: But looking at
4 the data in the volume measure, those 10 cases
5 -- and this is combining open and endovascular
6 -- 10 cases comes between the second and third
7 quartile. So, you have an awful lot of
8 facilities doing less than 10, no matter how
9 you count it.

10 The second quartile is 5.6. The
11 third quartile is 13.8. It is in 2F3.

12 CO-CHAIR TORCHIANA: So, I think
13 it is worth pointing out that this is, in
14 fact, just a volume vote, and we also need to
15 look at the mortality rate vote.

16 But I guess I would absorb from
17 the discussion that a reasonable charge for
18 the developers would be to come back with a
19 model that separates endovascular from open
20 for both volume and for repair, in the absence
21 of another suggestion.

22 MEMBER HALPERN: I will also

1 mention that there are papers out there --
2 actually, one written recently by my colleague
3 down in Tucson, Joe Mills -- where their
4 mortality rates, although they didn't hit
5 thresholds, were equal to the ones at higher-
6 volume hospitals.

7 So, at one point -- we have
8 discussed this with some of the other cases --
9 it is the process rather than just the volume.

10 MR. ROMANO: So, we are certainly
11 able to report back on the implications of
12 separating the volume according to open versus
13 endovascular and reporting those separately.

14 CO-CHAIR TORCHIANA: And I would
15 suggest, also, the mortality, we could go
16 through the exercise of voting on mortality as
17 well.

18 So, should we do that, Melinda?
19 Do you suggest we do? It is the same issue.

20 MS. MURPHY: Right. So, I would
21 say no, and we would get the information based
22 on what you just requested and, then,

1 reconsider the two of them at that time.

2 MR. ROMANO: For mortality, there
3 is a more explicit tradeoff with loss of
4 reliability and loss of discrimination
5 associated with reporting those outcomes
6 separately. So, we can try to estimate that.

7 There is already some concern
8 about the signaled noise ratio being a bit on
9 the low side at 30 percent. So, I would
10 expect that that would further decrease when
11 we split the measures.

12 Again, the other things is, from
13 the consumer's perspective, of course, the
14 consumer is not making the choice about what
15 type of procedure to have. So, I am not sure.
16 That argument is often made, that when there
17 is a choice that is made by the surgeon as far
18 as the particular technique, that that is not
19 appropriate for public reporting because it is
20 not the consumer's choice.

21 MR. KRESOWIK: This is Tim
22 Kresowik.

1 I just am going to have to
2 disagree with the idea that the consumers
3 aren't making this choice in reality. As I
4 said before, consumers want an endovascular
5 repair, if it is feasible. So, in a sense,
6 the decision is really, yes, it is a surgeon
7 decision, but to be based on the technical
8 characteristics of the aneurysm and whether it
9 is feasible or not.

10 I would just like to add one more
11 thing. In this discussion, and I would urge
12 AHRQ to do this, too, I think there is an
13 awful lot of focus on statistically-
14 significant differences in thresholds and not
15 enough on clinically-significant differences.

16 In other words, from having
17 reviewed a number of these volume outcome
18 studies, when you look at -- you know, a
19 threshold is picked because it meets some
20 statistical difference when, in fact, the
21 difference between two, if you will, volume
22 groups are the difference between 2 percent

1 mortality and 3 percent mortality or even 2.5
2 and 3 percent. I think that has to be taken
3 into consideration before too much stock is
4 put on a study that suggests that there is a
5 statistically-significant difference, when, in
6 fact, the clinical differences in terms of
7 mortality are minimal.

8 So, I would urge the group just to
9 consider all those factor when they look at
10 the data supporting these.

11 Thank you.

12 CO-CHAIR TORCHIANA: Thank you.

13 So, let's I think move on from
14 these two measures and go to 1523, in-hospital
15 mortality following elective open repair.

16 MEMBER HALPERN: I am going to do
17 these together because the EVAR one and the
18 open one are very similar.

19 So, as presented by the sponsors
20 previously, the reason they chose to look at
21 small asymptomatic aneurysms is because from
22 many studies the threshold for operating on

1 aneurysms is 5.5, and that is based on the
2 rupture risk versus risk of surgery.

3 For women, it is slightly smaller
4 than men. And that is why they chose the
5 thresholds that they did.

6 When you are operating on a
7 smaller aneurysm, there are reasons to
8 operate, growth rate and, quote, "symptoms",
9 although they are not ruptured. And there are
10 some studies that suggest that smaller
11 aneurysms in a certain subset of patients,
12 such as patients with poorly-controlled
13 hypertension and COPD rupture at smaller
14 rates. So, those are the reasons to operate
15 on smaller aneurysms.

16 But, if you are going to do that,
17 you have to make sure that your mortality is
18 also low. And as suggested by the sponsors,
19 that means that you have to have done some
20 kind of risk stratification before you even
21 perform the surgery. And, thus, it should be
22 implicit that you have already done that, and

1 the patients are pre-risk-stratified. And
2 that is why they felt they should just look at
3 those patient populations.

4 The comments that came up during
5 the discussion of this procedure is the in-
6 hospital mortality versus a 30-day mortality
7 for both measures. Particularly, it came up
8 with the endovascular because a lot of
9 endovascular patients are home within 48
10 hours.

11 And as with the discussion earlier
12 with the ambulatory surgery centers, your
13 responsibility doesn't end when the patient
14 leaves the door. And so, there was a lot of
15 discussion about asking the sponsors if they
16 can make it a 30-day mortality instead of just
17 an in-hospital mortality.

18 CO-CHAIR TORCHIANA: Other
19 comments?

20 (No response.)

21 Could the developers respond to
22 that request?

1 MR. KRESOWIK: Certainly. And
2 again, the intent, I should say the long-range
3 intent, with these measures is to make them
4 universally applicable in terms of being able
5 to capture this data with administrative, or
6 capture the outcomes anyway with
7 administrative data alone.

8 And that is the real problem with
9 30 days, is that, obviously, that is the
10 standard. That is ideal. But it requires
11 clear participation in some sort of, if you
12 will, prospective followup with calls, with
13 all those things that, obviously, are the
14 ideal, but are likely never to be universally
15 applicable. So, that is the reason for
16 focusing on the in-hospital mortality.

17 It certainly would say that in
18 both cases, regardless of the discharge within
19 48 hours for endovascular, you still are
20 picking up the vast majority of adverse
21 outcomes. And it is just based on numerous
22 studies, that ratio between what happens

1 within the hospital versus the 30 days is
2 pretty consistent. So, they do track very
3 well together.

4 And it is certainly our belief
5 that the tradeoff in terms of applicability of
6 the hospital mortality versus the 30-day is
7 well worth it in terms of the burden of data
8 collection and the applicability.

9 Thank you.

10 MEMBER HALPERN: Some of the
11 comments were that, since many folks are using
12 NSQIP, that the data could be picked up that
13 way or some other registry, especially with
14 our earlier -- I don't think you were on the
15 phone call earlier, but there is a measure out
16 there to look at the percentage of people
17 participating in some kind of multi-center
18 database.

19 MR. KRESOWIK: Absolutely. I mean
20 that is where it has got to start. I am
21 actually the clinical lead for NSQIP in our
22 institution. It does not currently capture

1 aneurysm size.

2 And I would say, you know, yes,
3 there is NSQIP out there, but it is certainly
4 not widespread in terms of the entire country.
5 And so, again, in order to move eventually to
6 something that could truly be publicly
7 reported at every single institution, that is
8 the reason to kind of design it the way it has
9 been at this point.

10 Part of the intent is to try to
11 create CPT-II codes that would allow the
12 aneurysm size to be reported administratively,
13 that would be the long-term goal for this set
14 of measures, again, to allow universal
15 applicability.

16 MEMBER HALPERN: The comments that
17 are coming up here are, then, why not a 30-day
18 mortality code?

19 MR. KRESOWIK: Again, it depends
20 on what your ultimate goal is. See, the
21 beauty is if you can -- I will try. You are
22 still requiring some sort of voluntary

1 participation and reporting. Even though that
2 is a laudable goal, we are, clearly, if you
3 look nationally, very far from that.

4 The opportunity is, again, to be
5 able to use existing administrative data that
6 would not require any participation on the
7 part of the provider, once you have this
8 aneurysm size as a criteria.

9 So, I will share sort of the
10 possibilities for the future. It is that you
11 could, in fact, if you don't get the kind of
12 reporting that you want, eventually say that
13 the assumption is that, if you are not
14 reporting this as a larger aneurysm, greater
15 than the threshold, the assumption will be
16 that it is within that threshold.

17 So, again, the idea is to finally
18 get to the point where we can have valid
19 comparison data. We just went through a
20 discussion about all the problems with the
21 AHRQ measures that are existing out there, and
22 this would be something that I think could

1 actually get us to something that would be
2 scientifically and clinically accepted by the
3 surgical community and get to what we really
4 want, which is real outcome data that patients
5 and others could use.

6 I would also say that the beauty
7 of these measures, too, is you can eliminate
8 the volume threshold issue. If you are only
9 doing a few aneurysms a year, you had best
10 have a zero percent mortality or else you are
11 going to look pretty bad.

12 So, with that kind of approach, if
13 you will, you still have a volume incentive,
14 but it becomes one where, if you are really a
15 low-volume provider, you almost have to have
16 a zero percent mortality or you are at least
17 going to be identified, if you will.

18 So, that is, I think, some of the
19 advantage to this approach. But, again, there
20 is no problem with the 30-day other than it
21 really limits the universal applicability down
22 the road.

1 MEMBER WILHOIT: A piece of fine
2 print is that the timeframes, again, are
3 written very confusingly. We are talking
4 about that it is in-hospital, but that is not
5 what the document says.

6 But my real question is the
7 denominator description for these includes
8 people with small aneurysms, but the data that
9 is reported includes people with larger
10 aneurysms. And I am just trying to understand
11 where the data comes from, if the measure only
12 includes people with small aneurysms.

13 MR. KRESOWIK: Yes, and probably
14 the term small is not, I mean it is a
15 difficult area to try to characterize. The
16 intent with the thresholds here were to, if
17 you will, exclude from the denominator
18 patients with large aneurysms. And that is
19 probably a better way to look at it.

20 The idea being that, you know,
21 again, where you draw that exact line, the
22 data certainly support that observation is

1 reasonable, the reasonable alternative for men
2 with 5.5-centimeter or less aneurysms and
3 women with 5.00centimer and less aneurysms.
4 Again, because of less limited data, the
5 validity of that 5 for women is a little bit
6 less robust.

7 But, anyway, so it is clearly safe
8 to observe those patients. And on the other
9 hand, we clearly know that someone that comes
10 in with a 10-centimeter aneurysm, which we all
11 see, even if they do have significant
12 comorbidity, the high rupture rate of that in
13 the short-term may justify an intervention.

14 So, the intent really was to
15 exclude from the denominator aneurysms for
16 which this concept of risk adjustment on the
17 part of the surgeon weighing the risks and
18 benefits becomes less important by excluding
19 those. So, that is the intent, not to really
20 identify the use of this term small, if you
21 will.

22 MEMBER WILHOIT: Okay. No, I

1 understand that. And that is how your
2 denominator is defined. But in 2D5, in the
3 testing results, there are results provided
4 for men with aneurysms larger than 6
5 centimeters and women with aneurysms larger
6 than 5.5 centimeters. And I wasn't sure where
7 that data would come from in this measure
8 because those people should have been
9 excluded, according to the denominator
10 definition.

11 MR. KRESOWIK: And I am sorry, but
12 that was supposed to be the denominator
13 definition. And if there is an error in the
14 submission -- the denominator definition was
15 supposed to be 6 centimeters or less for men
16 and 5.5 or less for women. That would be the
17 denominator inclusion criteria.

18 MEMBER WILHOIT: And, then, that
19 is what is in the description, but, then, the
20 data that is presented is different than that.
21 And so, I am not sure when the sample sizes
22 are given, do the sample sizes include people

1 with aneurysms that are larger than those
2 criteria? You know, I am not sure how to
3 interpret the data because the data that are
4 presented, both in terms of sample size and
5 results, include larger aneurysms than are
6 included in the denominator.

7 MEMBER HALPERN: That data that
8 you are looking at is the volume data. And I
9 think what he was trying to say is that they
10 want to use the volume data. They want to
11 make it an easy reliability.

12 The data that is evidence for
13 smaller aneurysms having less rupturing is a
14 couple of a very large studies, one out of the
15 UK, that looked at following aneurysms. They
16 basically followed aneurysms and saw what the
17 rupture rates were.

18 But that is not the data that you
19 are looking at right now. That was just
20 mortality by volume. That is actually the
21 AHRQ data.

22 MEMBER WILHOIT: But are these the

1 results -- I guess I am really confused now.
2 I thought the results in 2D5 were the results
3 of the indicator that is being described. Are
4 the results in 2D5 the results of something
5 else? That is what I am trying to understand.

6 MR. KRESOWIK: I am trying to
7 catch up with you here. I am sorry. So,
8 which measure are we talking about?

9 MEMBER WILHOIT: I think --

10 MEMBER HALPERN: It is both of
11 them.

12 MEMBER WILHOIT: -- it is both of
13 them.

14 MEMBER HALPERN: Because they have
15 the same background data implied in both. If
16 you look at 2 -- let's see if I can get to it
17 -- 2D5 --

18 MEMBER SEARS: And you are talking
19 about 1523?

20 MEMBER HALPERN: 2D5 says
21 refinement of HCUP quality indicators. They
22 are essentially using the AHRQ data, but I

1 think that is not really the background for
2 this study, this indicator, rather.

3 MEMBER WILHOIT: So, then, if we
4 don't know the sample size and we don't know
5 the results, are we even in a position to make
6 a decision?

7 MR. KRESOWIK: I am looking, and I
8 think I am caught up with you now.

9 So, the testing result was done by
10 the Northern New England group, okay? And so,
11 they are quoting just what the actual
12 mortality was in the thresholds that we
13 described. So, those should be the same
14 thresholds that are in the measure. If there
15 is not, there is an error. So, we are talking
16 about -- so, this is not AHRQ data -- this is
17 actual data from the Northern New England,
18 their registry.

19 MEMBER WILHOIT: Okay. So, if we
20 are looking at 1523 then, in 2D3, it describes
21 1201 patients. Is it 1201 patients with
22 aneurysms of all sizes or is it 1201 with

1 aneurysms below the size we are describing?

2 And it makes a difference.

3 Because are the data on the smaller aneurysms,
4 is it based on 100 patients or 1,000 patients.
5 We don't know if it includes both.

6 MR. KRESOWIK: I see what you are
7 saying.

8 The whole sample is all patients
9 undergoing open elective repair. I am sorry,
10 I don't the breakdown of that test. I was not
11 part of that testing group. And I can't
12 answer the question because I don't have the
13 testing data.

14 I would assume, okay, just based
15 on other studies, that the vast majority of
16 the patients are going to fall into what we
17 call -- and I don't like this term, either --
18 the small volume, so the less than 6
19 centimeters with men and less than 5.5
20 centimeters with women. Those are the vast
21 majority of patients being done. I assume
22 that is the same for Northern New England, but

1 I just don't have the exact numbers. I am
2 sure that could be provided for you, though.

3 MEMBER WILHOIT: And partly, it
4 makes a difference I think even in terms of
5 the relevance of the measure because this is
6 seven years of data for about 10 centers. And
7 if there's only 1200 patients over seven
8 years, and if some of those 1200 patients
9 don't even belong in the nature because they
10 have larger aneurysms, again, that affects the
11 relevance for me.

12 MR. KRESOWIK: But aren't we
13 confusing two things? The relevance and the
14 scientific evidence for the design threshold
15 is based on large trials. This section we are
16 talking about here is only a testing of the
17 measure more focused on feasibility. I think
18 we are talking about two separate issues.

19 This has nothing to do with the
20 scientific evidence behind the measure or the
21 choice of volume threshold. This was just,
22 again, to meet the NQF criteria that measures

1 for endorsement have to be tested in some way,
2 and just to show that you can collect the
3 measure, it is feasible, but that is quite a
4 different question from the scientific
5 validity.

6 MEMBER HALPERN: Also, you are
7 talking about importance. Okay, the
8 importance is that, as the sponsor just
9 indicated, there's a lot of people getting
10 done at smaller aneurysm size. There is
11 evidence that says you don't have to operate
12 on everybody with a smaller aneurysm. Many of
13 them stay the same and can be watched and may
14 never need an operation.

15 So, it is important because you
16 want to make sure that people who are getting
17 operations are really the correct people, and
18 that people are making the right choices in
19 operating on those patients. So, if you have
20 a 5 percent mortality in a small aneurysm
21 patient, well, that is actually higher than or
22 equal to their rupture risk.

1 MEMBER WILHOIT: No, and I
2 understand that, but if a center is doing 10
3 cases in 10 years, the meaningfulness of the
4 measure I think is limited. And again, I
5 don't know because I don't know what the
6 numbers are here.

7 MR. KRESOWIK: Can I just take you
8 through that a little bit because I am
9 confused by that?

10 But if a center is doing, let's
11 say they are doing 10 cases a year. And if
12 three of those patients have mortality, and
13 in this measure you pick that up, that is a 30
14 percent mortality, which would certainly be
15 something that I would think that people would
16 want to know.

17 And the point of this is, if you
18 are talking about this population, this should
19 be one that should have an extremely low
20 mortality in order to be, if you will, a
21 justified operation in the first place.

22 So, I think this is important and

1 it is very relevant regardless of the numbers
2 that are being performed.

3 MEMBER WILHOIT: Right, except for
4 when you get very small numbers, there is just
5 such year-to-year variation; it is really hard
6 to draw conclusions or take action.

7 You know, if you have one
8 complication this year and then none for five
9 years, if the numbers are small, it can just
10 cause such variation from year to year; it is
11 hard to interpret.

12 MEMBER HALPERN: I think it is
13 similar to what we were talking about the
14 ambulatory surgery centers, though. If you
15 have had a .2 percent mortality and, then, all
16 of a sudden, the next year you have a 30
17 percent mortality, it may make you go back and
18 look at your process. Or did you get somebody
19 who is -- you can't blame everything on the
20 patient. So, you have to go back and look at
21 your process if you suddenly have a spike in
22 your mortality.

1 CO-CHAIR TORCHIANA: I guess the
2 point here, it gets back to the study that
3 shows that zero mortality is predictive only
4 of low volume, and that it, in fact, predicts
5 average to high mortality in subsequent years
6 in surgical patients. And so, the whole
7 notion of when is low volume too low is tough.

8 This seems like a very innovative
9 measure in the sense that it, I think very
10 concisely, pares down this complex issue of
11 risk adjustment using administrative data.
12 So, it is a very intriguing measure. It has
13 potentially got applicability in a lot of
14 other surgical areas, I would guess.

15 And, you know, these concerns
16 about numbers notwithstanding, I guess the
17 question that seemed obvious to me at first,
18 and now seems less obvious, is, right now, do
19 you actually have -- and I am asking the
20 developer -- do you actually have a way of
21 identifying the small aneurysms in
22 administrative data? And if not, how are you

1 going to do it?

2 MR. KRESOWIK: No, and that is the
3 reason why this is being limited at the
4 current time to registry that would include
5 that variable. The Northern New England
6 registry does include aneurysm size as one of
7 their data points.

8 CO-CHAIR TORCHIANA: But could I
9 ask, then, does the Northern New England
10 registry include 30-day mortality?

11 MR. KRESOWIK: They do. And
12 again, maybe it is better to just discuss the
13 whole history of this. This measure or this
14 group of measures was originally proposed to
15 go forward as a non-registry measure. You are
16 up against -- and this is a problem with NQF
17 right now -- is you have got this whole
18 concept of testing. Well, you run into the
19 feasibility of how do you test something
20 without creating a way for testing.

21 So, we have got the CPT-II codes
22 to allow this, are working their way through

1 the CPT-II, it is called PMAG, so that group.
2 We have also had discussions with CMS about,
3 because you need to partner, if you are going
4 to do this with administrative data, you need
5 somebody that has that administrative data.

6 So, that is all part of the long-
7 term strategy, but in order to get these
8 considered, so that at least this whole
9 discussion -- and I think you just made a very
10 important point, is this could have
11 applicability in so many other surgical areas.
12 It is sort of what we have all been looking
13 for, is a way to get real outcome data without
14 a tremendous burden of data collection.

15 So, all those processes are in
16 place. The reason they are here before this
17 panel today is to start getting this concept
18 out there. And it is currently feasible to do
19 within a registry that would collect this
20 data. But this is only the stepping stone, if
21 you will, to hopefully a bigger picture.

22 CO-CHAIR TORCHIANA: Could I

1 suggest, though, that when you do this in the
2 registry, assuming we vote it up, that you do
3 the 30-day mortality, in addition to the in-
4 hospital mortality, just to establish the
5 credibility of your assertion that all the
6 deaths occur, by and large, in the hospital?

7 MR. KRESOWIK: Absolutely. Yes,
8 and that data, that is, the Northern New
9 England does collect the 30-day mortality.
10 And this was just sort of -- that is why I
11 went through the history a little bit.

12 This was originally designed, and
13 we had hoped to go forward with the bigger
14 picture in mind, but, then, they got pared
15 down, if you will, to just the registry. But
16 Northern New England does collect that data
17 and end point.

18 CO-CHAIR TORCHIANA: Great.

19 MEMBER CIMA: I am a little
20 confused now. What are we voting on in the
21 sense of, do you have to be a member of the
22 SVS? I mean this is like the discussion we

1 had with the STS at the last meeting and this
2 morning.

3 You know, I was going through
4 here, and it is talking about the New England
5 and the SVS. You have to be a member of a
6 registry, it says. So, is this a pilot or is
7 this for the whole country to do it?

8 Because the STS covers 95 percent
9 of cardiac surgeons, they said, in the
10 country. What does the SVS cover in the
11 registry?

12 CO-CHAIR TORCHIANA: I think the
13 registry in this case is in NNE, which is 10
14 hospitals.

15 MEMBER HALPERN: There is actually
16 an SVS registry that has started in the last,
17 I think, year and a half that people are
18 starting to participate in. So, there is a
19 growing SVS registry, but it is kind of in its
20 infancy.

21 However, if the CPT-II codes go
22 through, and notwithstanding the sponsor's

1 concern about 30 days, I can't believe that it
2 is that hard to collect 30-day mortality
3 because I think most hospitals and places are
4 tracking that now.

5 But it is the only additional
6 information you need is size of the aneurysm,
7 and it is a threshold. So, once you have
8 above or below that threshold in the CPT
9 codes, and, then, you have your 30-day
10 mortality, it is a yes/no question, alive or
11 dead. So, it should be fairly easy for
12 anybody to do, once those CPT codes are
13 through.

14 MR. KRESOWIK: Yes, and I think
15 that there is no question that -- I will try
16 to answer the question about whether it is a
17 pilot or not. And again, the intent, the
18 original intent, was to have this go forward
19 more to get this concept endorsed, so that
20 further, if you will, implementation strategy
21 could go on. But we do have the ability to do
22 this right now within the registry.

1 The SVS registry right now is
2 primary the carotid registry. So, it is
3 applicable to those two measures which are
4 related, but that is not what we are talking
5 about right now.

6 The Northern New England registry
7 -- and, again, I don't have the -- it is 1213
8 institutions. They basically cover most of
9 northern New England. So, that is ongoing.

10 The only reason that you are
11 talking about this as a registry-only measure
12 is because that is the only way we could get
13 this to this level at this point in time.
14 That was an NQF decision. There were multiple
15 phone calls and discussions that suggested
16 that it go this route.

17 Because, right now, there are a
18 number of groups out there like this one with,
19 I think, a creative approach, but you are
20 blocked by you can't the measure tested until
21 you get it endorsed. You can't endorse it
22 until it is tested. So, it is kind of a

1 Catch-22 that many groups are in.

2 So, this is an attempt to try to
3 get the concept which it is feasible to do
4 within the registry setting, but, again, this
5 is just the short-term.

6 I hope it didn't add more
7 confusion, but --

8 MEMBER MORTON: I just want to
9 clarify one point. We are talking about a
10 measure that we can only obtain through a
11 registry because you need the anatomic data
12 about the size of aneurysm. And we currently
13 don't have a registry other than the 10-
14 hospital group?

15 MEMBER HALPERN: You could get
16 that data because every operation somewhere
17 you have a CT scan that has the size of the
18 aneurysm. So, you could get that data, but it
19 would be more laborious to do that if you
20 don't have an easy way to do it, which it
21 sounds like why they were trying to create the
22 CPT-II codes.

1 So, the question that would come
2 up is, how far along are those CPT-II codes to
3 make this a universally-applicable measure?

4 MEMBER WILHOIT: And the other
5 thing is the measure is written very
6 specifically in terms of being based on
7 registry data. Switching to CPT-II codes is
8 dandy, but it is not what this measure is.

9 MEMBER CIMA: Can the staff tell
10 us what is going on here? I mean we have
11 never had one that was just for 10 hospitals.
12 So, why are we voting on this? We are
13 supposed to be here to do an overall thing,
14 right, for the country?

15 MS. BOSSLEY: Right. So, let's
16 step back for a second and just talk in
17 general because this applies to both the
18 measures that come from STS as well as these.

19 They are specified using registry
20 data. As they are written, they are not
21 specifically calling out any specific registry
22 and tying it to that. They just happen to be

1 using data to support for testing and to show
2 use with STS and, also, with New England and
3 the SVS registry.

4 So, any measure you have before
5 you that uses registry data can be used by
6 anyone who has a registry, assuming they are
7 in that field.

8 Helen, do you have anything to
9 add?

10 DR. BURSTIN: Yes. The only other
11 thing I would add is that they could, I mean
12 even the registry measures we have already
13 endorsed have sufficient specifications in
14 them that anyone could take them and apply
15 them doing a chart in your hospital, or
16 whatever the case may be, and, then, look
17 toward the benchmark and see where you are,
18 because we are trying to get to national
19 metrics.

20 So, I guess the question would be,
21 as this is written, can you take this, with
22 the specifications in this form, tested on a

1 registry, which is fine -- that is not an
2 issue for us -- and actually use it in a
3 widespread national scale?

4 MEMBER HALPERN: Again, in my
5 mind, you wouldn't even need a registry
6 because there are only two data points that
7 you need. You need above and below a certain
8 size, and you need alive or dead at whatever
9 time point you say. So, if you say a 30-day
10 time point, I mean you can get that from a
11 chart review. So, in my mind, you don't need
12 a registry to have this be a measure.

13 MEMBER WILHOIT: You may not need
14 it, but, then, the measure needs to be
15 rewritten, because the measure is defined in
16 terms of a registry.

17 MEMBER HALPERN: But, then, the
18 same thing applies to all the STS ones we
19 looked at.

20 DR. BURSTIN: Actually, those are
21 generally written as a real numerator and a
22 denominator, not specifically tied to the

1 registry. I mean they are elements within the
2 STS registry, but --

3 MEMBER CIMA: It says "a registry
4 that includes...", and, then, it goes on to
5 specify the Society of Vascular Surgeons
6 quality registry and the vascular surgeons
7 group have such information.

8 So, either you change the
9 wording --

10 MEMBER HALPERN: They say any
11 registry, though.

12 MEMBER CIMA: Yes, but, I mean --

13 MEMBER HALPERN: It doesn't say
14 the SVS registry.

15 MEMBER CIMA: -- but it does
16 specify two registries. I am just saying I am
17 not disagreeing with the two points that you
18 are getting at. I am just saying Melinda has
19 said multiple times we vote on what is written
20 in front of us. And what is written in front
21 of us, the way it is worded says using these
22 registries.

1 MS. MURPHY: Actually, I don't
2 think it says that.

3 MEMBER HALPERN: I don't think it
4 says that, either. It says --

5 DR. BURSTIN: He is absolutely
6 right. Under 2A3, it specifically says that
7 the numerator details is a registry that
8 includes hospitalization details. So, that
9 probably needs to be addressed.

10 MS. MURPHY: But it says what the
11 registry includes. It doesn't say this
12 registry. It has got to be a registry that
13 includes those elements.

14 MS. BOSSLEY: I think it could be
15 easily reworded --

16 MEMBER CIMA: Yes, it just a
17 wording thing.

18 MS. BOSSLEY: -- and taken care
19 of, yes.

20 CO-CHAIR TORCHIANA: Okay. So, my
21 head is spinning, to put it mildly.

22 (Laughter.)

1 MR. KRESOWIK: Mine, too. Mine,
2 too.

3 CO-CHAIR TORCHIANA: Let me see if
4 I can put together where we stand on these two
5 measures, which are obviously, more or less,
6 one and the same except for the method of
7 repair.

8 We need to allow activity to occur
9 to move this forward. On the other hand, the
10 way that this is exactly specified doesn't
11 seem to move it forward very much in terms of
12 having a significant impact on a lot of
13 patients at a lot of institutions.

14 But this is definitely a baby that
15 I think we want to nurture. So, the question
16 is, how do we nurture this measure in a
17 constructive way, staying within our pretty
18 constrained rule set?

19 MS. MURPHY: And this could be
20 heresy, but one of the ways that it could be
21 nurtured is by continued implementation and
22 bringing it to be considered for endorsement

1 at a point after some of the questions that
2 have been raised have been answered in the
3 application of the measure.

4 CO-CHAIR TORCHIANA: So, does that
5 mean we just don't vote at all?

6 MS. MURPHY: No, I don't think so.

7 CO-CHAIR TORCHIANA: Okay.

8 MS. MURPHY: I think the group has
9 to vote in terms of whether or not they
10 believe that at this point in time the measure
11 is matured, tested, and can be appropriately
12 applied on a national basis.

13 And I am looking in the direction
14 of my partners in crime here.

15 CO-CHAIR TORCHIANA: And, then,
16 just hold off on the final vote, on the last
17 vote?

18 MS. MURPHY: Well, in terms of the
19 vote on endorsement, we are going to hold off
20 on it anyway. We will not at this point vote
21 on endorsement.

22 CO-CHAIR TORCHIANA: Okay.

1 MS. MURPHY: We vote on the extent
2 to which it meets each of the criteria.

3 CO-CHAIR TORCHIANA: All right.
4 It sounds good to me.

5 Does everybody have that? We are
6 going to vote on the criteria, but not on
7 endorsement.

8 So, 1523, yes/no, important to
9 measure?

10 (Vote.)

11 Eighteen, yes; three, no.

12 Scientific acceptability of
13 measure properties, 1 through 4.

14 (Vote.)

15 Two, completely; sixteen,
16 partially; two, minimally; one, not at all.

17 Does it meet NQF criteria for
18 usability, 1 through 4?

19 (Vote.)

20 Four, completely; eleven,
21 partially; four, minimally; two, not at all.

22 NQF criteria for feasibility.

1 (Vote.)

2 Four, completely; ten, partially;
3 three, minimally; four, not at all.

4 Then, we will abstain on voting on
5 endorsement.

6 MS. MURPHY: The next vote is
7 whether we agree that it meets all the
8 criteria. That was what the next vote would
9 be, is whether it meets the criteria for
10 endorsement, not --

11 CO-CHAIR TORCHIANA: Okay. So, we
12 should have that vote then?

13 MS. MURPHY: Yes.

14 CO-CHAIR TORCHIANA: Okay. Does
15 it meet all the NQF criteria for endorsement?

16 (Vote.)

17 Nine, yes; eleven, no; one,
18 abstain.

19 Okay. Should we go on to the
20 endovascular?

21 MR. KRESOWIK: This is Tim.

22 Can I just ask -- I wasn't certain

1 what we were expected to get back with. Is
2 that going to be clarified at some point? I
3 thought, prior to the last discussion, there
4 was something the developer needed to provide.
5 Can somebody clarify that at a later point?

6 MEMBER HALPERN: I think it
7 sounded like, and I can be corrected, but it
8 sounded like one was rewording what your
9 denominator is, to not make it sound like it
10 is so specific to the surgery, those vascular
11 surgery registries.

12 Two is the 30-day mortality issue.
13 And I don't know. What was the
14 other thing?

15 MEMBER WILHOIT: Providing data
16 that gives results for the measure, including
17 the denominator and what the numbers are. You
18 know, what the sample size is or the
19 population for the facilities being measured,
20 but real data that exactly measures what is in
21 the measure.

22 MS. MURPHY: And for all of the

1 measures, we will send information back to the
2 developers about the additional information
3 that the group is requesting. So, we will get
4 it back to you, also, written.

5 MR. KRESOWIK: Thank you.

6 CO-CHAIR TORCHIANA: I think some
7 notion as to what the time course might be on
8 the CPT-II codes as well was raised.

9 So, let's follow through now and
10 vote on EVAR. It will be interesting to see
11 how these correlate, if anyone can remember
12 how they voted on the first one.

13 Importance to measure.

14 (Vote.)

15 Twenty-one, yes.

16 Scientific acceptability.

17 (Vote.)

18 Five, completely; thirteen,
19 partially; three, minimally.

20 Usability.

21 (Vote.)

22 Three, completely; fifteen,

1 partially; two, minimally; one, not at all.

2 Feasibility.

3 (Vote.)

4 We can't seem to get that 21st one
5 in.

6 Five, completely; ten, partially;
7 five, minimally; one, not at all.

8 Does the measure meet all the NQF
9 criteria for endorsement?

10 (Vote.)

11 Nine, yes; twelve, no.

12 So, I would suggest we are at the
13 time for our break. So, should we break now
14 and pick up these right where we are?

15 MEMBER SEARS: This is Nick Sears.
16 I have a time constraint. I have to leave for
17 the airport in about 35 minutes.

18 MR. KRESOWIK: This is Tim, too.

19 We just have the carotid ones. Do
20 you think we could deal with those? Because
21 the discussion should not be substantially
22 different than the one we just had.

1 CO-CHAIR TORCHIANA: Okay. I
2 thought you were going to say should be short.

3 (Laughter.)

4 MR. KRESOWIK: Well, I meant that.
5 I meant that. There shouldn't be any new
6 discussion, but I --

7 CO-CHAIR TORCHIANA: Okay. So,
8 well, let's see. So, we have these three
9 remaining vascular surgery measures. Can
10 people take trying to knock those off before
11 the break?

12 Okay. So, let's do 1548 -- this
13 is the surveillance one -- first.

14 And who is commenting on this?

15 MEMBER KENNEDY: This is Eileen
16 Kennedy.

17 CO-CHAIR TORCHIANA: Hi.

18 MEMBER KENNEDY: I am going to do
19 this one.

20 Hi.

21 Okay. So, yes, Measure 1548,
22 surveillance after EVAR. And as stated

1 previously by the sponsor, this measure calls
2 for one followup imaging study after three
3 months and within 15 months of the repair.

4 It is important to note that there
5 is a risk of potential failure of the
6 endograft therapy with problems leading to
7 potential rupture and increased mortality.
8 These complications may be identified during
9 optimal surveillance with the use of imaging
10 scans.

11 And there were opportunities for
12 improvement identified within the measure
13 material.

14 The measure does not require risk
15 adjustment.

16 The Work Group was divided on the
17 degree to which this measure meets the
18 scientific acceptability criteria. It was
19 noted that there are currently the two
20 registries that are used to record the
21 surgical details the EVR procedures. However,
22 the team raised a similar question to that of

1 the previous measures, to the requirement of
2 membership in these registries in order to
3 collect the surveillance data.

4 There was also an additional
5 observation made on the potential
6 socioeconomic impact of patients not complying
7 with the required followup due to the cost of
8 the scans or necessary travel.

9 And, then, the final issue that
10 was raised was just around the use of this
11 measure for public reporting.

12 CO-CHAIR TORCHIANA: Other
13 discussion?

14 MEMBER HALPERN: Yes. I think the
15 issue of public reporting was one of the major
16 issues we discussed. Because what does this
17 mean? There are so many reasons why a patient
18 may not have a CT scan.

19 The idea thing is that you have to
20 have some kind of followup for your
21 endovascular repairs because there are various
22 types of endo leaks that occur, and some of

1 them may lead to rupture.

2 As stated by the sponsor, the
3 exact timing is kind of still being a little
4 bit debated in the literature and, also, what
5 kind of imaging modality you need to do as
6 ultrasound becomes better. The sort of
7 original standard was x-rays and CTs, which is
8 an awful lot of radiation over time.

9 And so, it wasn't quite clear how
10 this would be used and in what manner it would
11 be used, and what its importance would be.

12 MR. KRESOWIK: So, let me just
13 clarify a couple of things.

14 The numerator for this is not CT
15 scans. It is any imaging modality, which
16 would include duplex.

17 And I can say that, as I tried to
18 say before, even though there is some
19 controversy or question about what is the
20 ideal post-procedure imaging strategy,
21 anything that is out there right now would
22 suggest that this is a floor. Okay? So,

1 anything less than this would not be possibly
2 acceptable.

3 And, you know, the problem is you
4 have got to start somewhere. I think you
5 would get into more controversy if you tried
6 to have a more aggressive imaging strategy
7 than this. But I don't think there is anybody
8 or any evidence that would support anything
9 less than this measure.

10 So, this should be looked on as an
11 absolute floor, and it does not specify any
12 particular imaging modality. So, duplex,
13 ultrasound, which avoids the radiation risk,
14 would meet this measure.

15 MEMBER HALPERN: And what is the
16 public reporting of this going to be? How do
17 you see that being utilized?

18 MR. KRESOWIK: I guess I don't see
19 it any different than any other process
20 measure. It is a process measure, just like
21 lots of process measures that are out there.
22 It has the same purpose.

1 I mean the ultimate purpose is to
2 get people to do the right thing. But I guess
3 I would view it as any other process measure.

4 CO-CHAIR TORCHIANA: And how is
5 this data acquired outside of a registry?

6 MR. KRESOWIK: Well, I mean,
7 again, I don't want to reopen the whole box we
8 just went through. But, again, it was because
9 of the limitations of getting it to this
10 point, it had to be constrained within a
11 registry format. It does not, as was said
12 before, does not require the specific
13 registries that were cited to support the
14 measure. But, clearly, this data could be
15 done simply with administrative claims, but we
16 couldn't test it except with what we had in
17 the registry format.

18 So, I hope I haven't added to the
19 confusion again, but this is just the advice
20 and the limitations of the current process
21 getting it to this point.

22 CO-CHAIR TORCHIANA: I think we

1 get that.

2 Any other discussion?

3 MEMBER SAIGAL: Most of these
4 ruptures happen after six months? They don't
5 happen early, is that right?

6 MEMBER HALPERN: Yes, for the most
7 part, and rupture is actually relatively rare,
8 but endo leaks are not.

9 MEMBER SAIGAL: So, the evidence
10 on imaging happens after six months?

11 MEMBER HALPERN: Different people
12 have different criteria. Some people image at
13 three months. Some people image at six
14 months. It also may depend on how comfortable
15 you were with your repair at the time of the
16 procedure. Like was it an angulated neck
17 where the risk of endo leak is higher? You
18 know, did you see an endo leak, type II endo
19 leak, at the end of the case?

20 So, there might be other things
21 that would promote you to have an earlier,
22 rather than a later, imaging. But he is

1 correct that anything longer than this would
2 really be unacceptable in any endovascular
3 repair.

4 MEMBER SIPERSTEIN: Can you
5 clarify for me the process of a patient has
6 their procedure at one institution and has
7 their long-term followup in a remote state or
8 country, how that is dealt with?

9 MR. KRESOWIK: Well, again, the
10 idea is that whoever -- if you are looking at
11 this in a registry, you would be required to
12 know that. You are still the responsible
13 person.

14 How it would act in reality, this
15 is not uncommon. Let's say a patient had it
16 done in another state, but it would still be
17 -- and this happens even within a state, where
18 you might have the study done elsewhere, but
19 you would be, the surgeon would be responsible
20 to find out what the results of that
21 information were. So, you would have that
22 available to you, regardless of where the

1 followup occurred. So, this would be the onus
2 on the surgeon, if you will, to know that that
3 study has been done and had the information as
4 to the results of that study.

5 CO-CHAIR TORCHIANA: Okay. Let's
6 vote on this and, then, try to get the last
7 two in on carotid.

8 CO-CHAIR MORRIS: Before we vote,
9 actually, could I add one more thing? So, our
10 issue with the registry inclusion exists with
11 this measure as well in the numerator. I just
12 want to make sure that everybody is aware of
13 that.

14 CO-CHAIR TORCHIANA: Agreed.

15 Importance of measure, yes or no?

16 (Vote.)

17 Twenty-one, yes; one, no.

18 Scientific acceptability, a scale
19 of 1 to 4.

20 (Vote.)

21 Three, completely; fifteen,
22 partially; three, minimally.

1 Usability.

2 (Vote.)

3 Three, completely; fifteen,
4 partially; three, minimally.

5 Feasibility.

6 (Vote.)

7 One is not in. Keep pushing.

8 Three, completely; eleven,
9 partially; five, minimally; two, not at all.

10 Does the measure meet all the NQF
11 criteria?

12 (Vote.)

13 Keep pushing.

14 Five, yes; fifteen, no; one,
15 abstain.

16 Thanks.

17 So, I think the message on that
18 measure is very similar, as was pointed out,
19 to the prior two, in that this confusion
20 around registry versus something that is aimed
21 for a broad use is, I think, one issue.

22 And, then, the second issue is,

1 how, short of a registry, will the followup
2 information ever be obtainable? It seems, by
3 definition almost, that it will only be via
4 registry.

5 So, let's handle 1540 and 1543
6 together.

7 Nick?

8 MEMBER SEARS: Yes, that sounds
9 like a plan.

10 I think we are going to have the
11 same discussion. 1540 is postoperative stroke
12 or death in asymptomatic patients undergoing
13 a carotid endarterectomy, and 15432 is
14 postoperative stroke or death in asymptomatic
15 patients undergoing carotid artery stenting.

16 Our group felt, everyone felt that
17 it was a reasonable measure from a measuring
18 standpoint. Some of the issues coming up, as
19 I think we heard from the Society of Vascular
20 Surgery, was the definition of what
21 asymptomatic was. I think a couple of
22 questions were raised around, how do you

1 document somebody is asymptomatic? Is it CPT
2 references or how can that be documented? And
3 I think that is a fair question, given the
4 fact that patients don't necessarily see the
5 same doctor over and over again.

6 But both measures, other than
7 that, met scientific reliability.

8 For the No. 3, efficiency, we
9 didn't have a whole lot of discussion there.
10 Again, public reporting and the registry issue
11 came up.

12 So, overall, I think most people
13 felt that these were reasonable measures.

14 MEMBER HALPERN: I would say that
15 the asymptomatic is actually easy with ICD-9
16 codes because you have to report them together
17 with your surgical code, as to why you are
18 doing the procedure. And it is either a
19 symptomatic or an asymptomatic carotid.

20 MEMBER SEARS: Okay. Well, that
21 should take care of that problem, then.

22 MEMBER WILHOIT: Although I think

1 you would want to test that to see. You know,
2 ICD-9 codes aren't always, don't always
3 correlate with the medical record. So, I
4 think don't know without looking.

5 MEMBER SEARS: Yes, and I would
6 love to just say, yes, that fixes the problem.
7 Unfortunately, the current administrative data
8 doesn't really capture this.

9 So, it is like the discussion
10 before. The intent is to actually get this
11 definition in the form of CPT-II codes. That
12 process is underway.

13 But, for the purpose of what you
14 are dealing with today, that definition is
15 part of the existing registries, not only the
16 Northern New England, but also the SVS carotid
17 registry. There's multiple other registries
18 dealing with carotid disease out there.

19 And I wish I could say all the
20 definitions are identical; they are not. But,
21 unless you go forward with this kind of
22 process of trying to get there -- we do need

1 to get a common definition. But it is
2 possible to do, and we still need to
3 ultimately get to standardization or
4 harmonization of the definition. And that was
5 the intent, ultimately, the CPT Category II
6 codes.

7 CO-CHAIR TORCHIANA: Okay. Other
8 comments?

9 MEMBER WILHOIT: Even though
10 CPT-II codes are a good goal for the long-
11 term, we see in our claims almost no CPT-II
12 codes being used currently. So, it is a good
13 goal. It is a direction to work. But, until
14 they are used consistently, they are not
15 necessarily useful for measurement.

16 MEMBER HALPERN: I would say,
17 also, that by using codes, I mean you can say
18 that for any of the measures we are looking
19 at. Codes can always be inaccurate.

20 But when you are charging for your
21 surgery, you have to put a diagnosis code.
22 So, I guess what I am saying is you will have

1 to trust that the surgeons are accurate or
2 whoever is doing the procedure is accurate in
3 terms of, are they doing it for a symptomatic
4 or an asymptomatic patient?

5 CO-CHAIR MORRIS: It seems to me
6 that this is part of where testing the measure
7 comes in and looking at the adequacy of
8 testing, and whether or not you are measuring
9 what you are think you are measuring, which if
10 this vote goes like the previous votes, and
11 SVS comes back to us, maybe that is something
12 that they could also include in what they
13 bring back.

14 MEMBER HALPERN: How accurate the
15 codes are, you mean?

16 CO-CHAIR MORRIS: Right, if they
17 have registry data available that can compare.

18 CO-CHAIR TORCHIANA: Any other
19 comments?

20 MEMBER HALPERN: Like with the
21 smaller aneurysms, I think these measures are
22 important in that, if you are to get benefit

1 from an asymptomatic carotid, you have to live
2 for five years. And your risk of your
3 procedure has to be about 1 to 3 percent or
4 less, probably closer to 1.

5 So, if you are doing the
6 procedure, you had better have good results
7 for asymptomatic patients because it is
8 essentially a prophylactic surgery.

9 CO-CHAIR TORCHIANA: Could I ask
10 the developer, what percentage of the carotid
11 stents are done by vascular surgeons versus
12 interventional radiologists versus
13 cardiologists? And what the sort of registry
14 and coding practices of those other
15 specialties? Are they similar or are they
16 very disparate?

17 MR. KRESOWIK: Yes, I can't answer
18 that question. It is a continued evolution.
19 Just it is an unanswerable question, I think,
20 at this point.

21 MR. ANDERSON: Excuse me. There
22 are some data on that.

1 MR. KRESOWIK: It depends on the
2 hospital, you know.

3 MR. ANDERSON: Yes, I am Skip
4 Anderson. I am a cardiologist with the ACC.

5 And we reviewed that material last
6 fall, and for the performance of procedures,
7 carotid standing procedures, it is about a
8 third done by vascular surgeons, about a third
9 by radiologists, and about a third by
10 cardiologists.

11 CO-CHAIR TORCHIANA: I guess I
12 would suggest to our colleague from the
13 Society of Vascular Surgery that it is really
14 important that the measure for carotid artery
15 stenting be developed in conjunction with
16 those other specialties. I would think that
17 is pretty critical from the standpoint of the
18 NQF endorsing them.

19 MR. KRESOWIK: Yes, and we have
20 had those discussions previously. I mean
21 those discussions about this measure have
22 occurred.

1 MEMBER STAFFORD: It is Renae
2 Stafford.

3 I would agree with that. Because
4 looking at the two measures, the level of
5 analysis is different. So, for the carotid
6 endarterectomy, the level of analysis is at
7 the clinician and group level. And for the
8 stenting, it is at the facility and agency
9 level. And that doesn't make any sense to me.

10 MEMBER SEARS: I thought it was at
11 both levels. I thought it was lifetime for
12 the surgeon and annual for the hospital,
13 reporting both.

14 MEMBER STAFFORD: It is hard to
15 tell. Looking at least at what the summary
16 that we received from the NQF, the level of
17 analysis is different for the two of them. I
18 haven't gone to the specific document.

19 MR. KRESOWIK: They shouldn't be,
20 but if that is, it is an error.

21 MEMBER SEARS: The only other
22 question I had, because I don't do stenting,

1 but is there any risk for the people who do
2 stent in following patients longer than 30
3 days? Because can the stent dislodge or do
4 what the abdominal stents do? The 30-day
5 numerator number may be off for the stent. I
6 don't know the answer to that.

7 MR. KRESOWIK: In both cases, I
8 mean, yes, there can be late complications.
9 They are not substantially different. In the
10 studies that have been done in comparison, the
11 kind of long-term outcomes are pretty similar.
12 Obviously, there are differences in the
13 procedural time, but, yes, there can be
14 late -- it is not stent dislodgment in this
15 case. You know, you can always have a late
16 embolism or thrombosis, but they are not
17 really actually different between the two
18 procedures.

19 MEMBER SEARS: Okay.

20 MR. KRESOWIK: And they don't
21 require -- I mean the surveillance approach
22 would be similar.

1 CO-CHAIR TORCHIANA: Okay. Let's,
2 then, vote on 1540, a stroke or death after
3 carotid endarterectomy.

4 Does it mean NQF criteria for
5 importance?

6 (Vote.)

7 Twenty, yes; one, no.

8 Scientific acceptability.

9 (Vote.)

10 Six, completely; fourteen,
11 partially; one, minimally.

12 Usability.

13 (Vote.)

14 Five, completely; fourteen,
15 partially; one, minimally; one, not at all.

16 Feasibility.

17 (Vote.)

18 Four, completely; thirteen,
19 partially; three, minimally; one, not at all.

20 Does the measure meet all the NQF
21 criteria for endorsement?

22 (Vote.)

1 Thirteen, yes; eight, no.

2 Now the same questions on carotid

3 stenting.

4 Importance to measure and report.

5 (Vote.)

6 Keep pushing those buttons,

7 please.

8 Twenty-one, yes.

9 Scientific acceptability.

10 (Vote.)

11 Six, completely; fourteen,

12 partially; one, minimally.

13 Usability.

14 (Vote.)

15 Six, completely; thirteen,

16 partially; one, minimally; one, not at all.

17 Feasibility.

18 (Vote.)

19 Six, completely; eleven,

20 partially; three, minimally; one, not at all.

21 Does the measure meet all the NQF

22 criteria?

1 (Vote.)

2 Can't seem to get that last one
3 over the finish line. It may be pushing the
4 buttons all these times is wearing the
5 batteries out.

6 Fifteen, yes; six, no.

7 Okay. Even though the last one is
8 on carotid, I think we should take our 15-
9 minute break and reconvene at, let's try to
10 shoot for 4:30.

11 MR. KRESOWIK: Could I just say
12 thank you to all of you for putting up with
13 having this as a phone-in. We really
14 appreciate the opportunity, and it is always
15 difficult, having done this many times.

16 My only other request, I would be
17 curious if someone there could try to
18 ascertain why the difference in meeting the
19 criteria between the carotid and the aortic
20 aneurysm measures. I think that would be
21 helpful to us to understand some of the
22 feeling in the future.

1 So, anyway, thank you very much.

2 CO-CHAIR TORCHIANA: Fatigue, yes.

3 (Whereupon, the foregoing matter
4 went off the record at 4:19 p.m. and resumed
5 at 4:39 p.m.)

6 CO-CHAIR TORCHIANA: We should
7 reconvene. I am sorry. We have gone a little
8 over our time.

9 So, our next measure is 1531,
10 followup assessment of stroke or death after
11 carotid revascularization.

12 MEMBER ROGERS: `Tis I. `Tis I.

13 (Laughter.)

14 Okay. So, this is an interesting
15 initiative that is actually a process measure.
16 It is not an outcomes measure. Really, it is
17 a measurement of how frequently an examination
18 was done within 21 to 60 days following a
19 procedure.

20 The interesting part is so there
21 is a challenge there that we have talked
22 around and about earlier today on other

1 procedures where a measurement is requested
2 following discharge.

3 The added feature to this one is
4 that the exam, then, is requested or required
5 to be done by someone who is certified, NIH
6 Stroke Scale certified. And it is also
7 specified that it not be done by the operator,
8 so that the surgeon involved is not the
9 person.

10 So, when we discussed this on the
11 phone, a couple of issues came up. One, of
12 course, was the feasibility and the likelihood
13 of being able to retrieve this information
14 subsequent to a procedure being done,
15 particularly because the hospitalization is so
16 short that it just isn't going to happen,
17 then, obviously, in 21 or 60 days. So, it is
18 the issue there, and, also, the issue of
19 certification.

20 And if there are changes noted in
21 the exam, if it was done by someone certified
22 at 21 days, and the initial baseline exam was

1 done by someone not certified, then, does it
2 count or does it not count?

3 So, I think the consensus is that
4 it makes sense. I think it really is a
5 feasibility issue more than anything else.

6 MEMBER DUTTON: To me, this
7 measure seems like an effort to gather
8 research data rather than quality data. We
9 have had a couple today that have kind of had
10 that flavor, like the reason to have this
11 measure is to generate data for somebody's
12 paper about strokes after carotid.

13 Is there any evidence here that
14 this will improve patient outcomes?

15 CO-CHAIR TORCHIANA: Do we have a
16 comment from the developer?

17 MR. ANDERSON: Yes. I am sorry.
18 Could you repeat the question? What was
19 the --

20 MEMBER DUTTON: This is a process
21 measure, as mentioned. I think to have a
22 process measure for quality purposes, it has

1 to be strongly linked to an outcome. So, how
2 does doing this additional assessment improve
3 patient outcomes?

4 MR. ANDERSON: Well, it is part of
5 obtaining outcomes, outcomes assessment. It
6 is an independent neurological exam based on
7 the NIH SS, Stroke Scale, which is a
8 relatively-simple clinical tool which many
9 people can use to try to find out if a
10 neurological event has occurred.

11 And the idea is to be able, for
12 internal quality purposes at institutions or
13 for reporting, public reporting, to try to
14 track clinical outcomes, particularly
15 neurological outcomes. But if you don't have
16 a uniform, standardized tool for assessing
17 that, then it becomes a little bit
18 problematic, and you have institutions that
19 don't do it at all or that aren't obtaining
20 quality data.

21 So, the idea around the tool, the
22 simple clinical tool, is to provide a little

1 bit of a standardization of assessments.

2 MEMBER HALPERN: Another question
3 that came up along those lines -- and Dr.
4 Rogers sort of referred to it before -- was
5 that, why not do this during the
6 hospitalization since the majority of
7 incidents happen soon after the procedure?

8 And from a feasibility standpoint,
9 that would also be easier to make sure you
10 have somebody who is not the provider who
11 performed the procedure doing it, because you
12 could have, say, a nurse on the floor. The
13 tool is very simple, because I actually looked
14 at it online after our phone discussion.

15 MR. ANDERSON: Well, the
16 background behind that was that, of course,
17 patients should have exams before and after
18 the procedure, and the expectation is that
19 they will.

20 Some clinical events happen after
21 discharge. Although it is oftentimes not
22 reported as such when the trials are

1 published, most of the clinical trials used a
2 30-day endpoint. However, a few of them
3 delved into the occurrence of events in-
4 hospital and those after discharge and up to
5 30 days.

6 And there were very little bit,
7 but about 10 to 25 percent of the neurological
8 events occurred after discharge, between
9 discharge and 30 days. So, you do miss a
10 substantial number of them if you only obtain
11 hospitalization data.

12 And since most of the evidence
13 base is centered around 30 days, the proposal
14 was that 30 days with a window, 30 days become
15 an acceptable reporting point.

16 MS. FITZGERALD: And this is Susan
17 Fitzgerald from the ACC.

18 I just want to say the
19 specifications are that the examiner should be
20 independent; it doesn't have to be, but we
21 recommend that they should be. It is
22 apparently a more valid test if somebody other

1 than the operator performs it.

2 And I think about 90, between 96
3 and 98 percent of the NIH Stroke Scales that
4 come through our registry, the examiner is
5 certified. They are a certified examiner and
6 have gotten their NIH certification.

7 MEMBER ROGERS: I guess I should
8 know this. Tell me again or remind me where
9 this data is collected.

10 MR. ANDERSON: Well, it begins at
11 the hospital. It begins at the institution.

12 MEMBER ROGERS: I know, but where
13 does it end up?

14 MR. ANDERSON: Yes. Well, for the
15 ones that participate in our registry --

16 MEMBER ROGERS: Right.

17 MR. ANDERSON: -- they accumulate
18 the data and transmit it to the ACC.

19 MEMBER ROGERS: So, it raises the
20 issue of belonging to a registry once again.
21 And can you tell us what options there might
22 be in addition?

1 MR. ANDERSON: Well, of course, we
2 would like for all institutions to collect
3 their own data and engage in quality
4 improvement initiatives and do public
5 reporting on their own without participating
6 in registries. But, you know, the trend has
7 been to do at least regional-based or
8 sometimes nationally-based registries for
9 doing comparisons between institutions, to try
10 to look at variability and quality improvement
11 initiatives on a larger scale. And we support
12 that, too.

13 But the level of collection is at
14 the institution. We currently have about 178
15 sites that participate and have about 15,000
16 records on carotid revascularization. And the
17 data is transmitted to a central warehouse,
18 where it undergoes analysis, and there are
19 reports generated back to the participating on
20 a quarterly and, then, an annual basis for
21 them to review their data.

22 Of course, we would hope that we

1 would review their own data anyway, since they
2 are the ones that sent it to us, for internal
3 purposes. But we were able to provide some
4 comparative analysis of the various
5 institutions.

6 MEMBER WILHOIT: One of the
7 assumptions that was stated in the measure at
8 the beginning is that everyone, obviously, has
9 an office visit following surgery. I think
10 that that isn't always an accurate assumption,
11 No. 1.

12 And, No. 2, since this requires a
13 visit to someone other than the surgeon, I
14 think that is a really big assumption, that
15 everyone already will have a visit.

16 Also, the numerator time window,
17 as we have seen on a lot of other measures,
18 doesn't match what is described in the
19 numerator.

20 It also seemed like there should
21 be exclusions for people who died because
22 people who died wouldn't be available for

1 followup.

2 And, also, people with a prior
3 neurologic event or a prior stroke, it seems
4 like there should be some way addressing those
5 people perhaps in the measure as well.

6 MEMBER HALPERN: Although I think
7 that what they are saying -- correct me if I
8 am wrong -- but my sense of the measure is
9 just that the exam was done, not that there
10 was a change, but just that the exam was done.
11 So, I understand why they don't have
12 necessarily prior exams because they are not
13 making a comparison. They just want to make
14 sure somebody is actually examining the
15 patient sometimes.

16 But I do wonder, I still wonder
17 about making it 21 to 30 days instead of some
18 time period after the surgery because, you
19 know, most of the practices I have seen, they
20 see their post-op patients a week or two
21 later. It might not be at 21 days and they
22 would fall outside that window.

1 MEMBER DUTTON: Wouldn't there
2 tend to be a bias in the data? That is, if
3 you had a stroke, you are more likely to go
4 back and see your doctor?

5 MEMBER HALPERN: Well, you might
6 go back to see a doctor, but it might not be
7 the person who is involved in the procedure or
8 necessarily related to the institution where
9 they came from.

10 CO-CHAIR TORCHIANA: Could I ask
11 what is a fairly obvious question here? This
12 is the American College of Cardiology measure.
13 And so, I assume we are talking about carotid
14 stenting predominantly and cardiology practice
15 predominantly?

16 MR. ANDERSON: Yes. No, the
17 registry that we operate is actually a
18 partnership between eight societies, including
19 the American College of Cardiology, the
20 American Academy of Neurological Surgeons, the
21 College of Neurological Surgeons.

22 So, it is a partnership. All

1 societies have input, and they all help
2 develop the various measures and reporting
3 standards. So, it is joint effort that is
4 involved in this.

5 CO-CHAIR TORCHIANA: Is it
6 endarterectomies as well as stenting?

7 MR. ANDERSON: Yes. We try to
8 capture and encourage reporting on all types
9 of revascularization, both endarterectomies as
10 well as stenting.

11 And the data that we have
12 accumulated so far is roughly equal between
13 the two types of procedures. Last year, for
14 2010, there were 2500 endarterectomies and
15 2500 carotid stents that were submitted to the
16 registry.

17 MEMBER HALPERN: Is SVS involved
18 in your registry?

19 MR. ANDERSON: SVS has been
20 involved in several levels. In fact, there
21 are discussions going on with them right now
22 about partnering up, as was discussed earlier,

1 for this.

2 In terms of organizational, no,
3 they are not part of, they are not one of the
4 other eight groups that are involved right
5 now. But that continues to be discussed.

6 CO-CHAIR MORRIS: Can you speak to
7 the 21-to-60-day window that was raised?

8 MS. FITZGERALD: Well, what we
9 find is that people submit records on
10 followup, and they submit the data followup.

11 And we understand that some
12 patients have followup at seven days, but if
13 you have a patient who has a followup at seven
14 days and other people are submitting followup
15 at much greater than 30 days, we find we can't
16 compare the two groups. So, we created that
17 followup window to be consistent.

18 Let me look at a couple of your
19 questions. That was one question.

20 The other one was that, if you
21 died, you would be counted because you are
22 assessing. You would not expect to have a

1 stroke scale if you died. If you died in the
2 hospital or you knew that the patient died
3 within 30 days, submitted a followup record,
4 you did the assessment accurately.

5 And, then, the third thing is
6 prior strokes are not excluded. Evolving
7 strokes and dissection are excluded because
8 carotid endarterectomies and stenting are
9 typically done on an elective basis to prevent
10 strokes. So, if you have a patient who is
11 very sick who is coming in, who they are
12 really not supposed to have procedures like
13 that, but do, we excluded them in the followup
14 because their stroke rates are higher, and
15 their assessment and followup is a little
16 different.

17 MR. ANDERSON: One other comment
18 is that, for the last decade, the clinical
19 trials that have been published on carotid
20 revascularization have pretty much all
21 centered around a 30-day assessment. And the
22 window is varied between 15 to 40, 25 to 60,

1 but those numbers were chosen as a sort of
2 average value from the clinical evidence base
3 from the trials that have been published over
4 the last 10 years. The 21 to 60 works out to
5 be roughly a window, an average window, around
6 30.

7 MEMBER ROGERS: Can you give us
8 some idea about the relationship of the
9 numbers of reported cases you had last year
10 versus the number, an estimate of the number
11 of cases that are done in the country for the
12 year? So, we are talking 10 percent or 25
13 percent? Do you have any idea?

14 MR. ANDERSON: Yes, I don't think
15 we have those. For 2010, I don't think we
16 have an estimate on that.

17 MEMBER ROGERS: So, the question
18 has been asked by Vivienne, and it has to do
19 with, do you see yourself as a competing
20 entity with SVS, or others, for that matter?
21 And I wonder whether there is a possibility of
22 harmonizing with some of the stuff they do,

1 perish the thought.

2 MEMBER HALPERN: I mean that would
3 be the idea, is to have, you know, a registry
4 where we all agree on what the data points are
5 going to be.

6 MS. FITZGERALD: Right, and there
7 is a physician that is I think the President
8 of SVS that is very close to a physician at
9 the College, and they both work at the same
10 center, who have kind of forged some recent
11 conversations about partnering and moving
12 forward with carotid as well as peripheral
13 vascular initiatives.

14 So, we did not, when we first
15 launched the registry, we actually had
16 conversations about it, but our registry
17 launched, and so did theirs, and it was kind
18 of too late. So, we reintroduced those
19 conversations.

20 MEMBER CIMA: I had a question
21 about feasibility. I mean, if you say that it
22 doesn't have to be the same person that does

1 the procedure, what if they have a procedure
2 and they go see their general practitioner?
3 First of all, you have got to get them to be
4 certified on this scale, the NIH scale. So,
5 you have already made it very difficult to
6 some extent, even though it is an easy thing
7 to do and they can get it offline.

8 But, then, how are we going to
9 capture the data that they had a carotid here
10 at this major center that they got referred,
11 and, then, the follow up with their
12 neurologist in Boise, Montana, or Boise,
13 Idaho? Sorry.

14 (Laughter.)

15 What is the feasibility of doing
16 it? Are you saying they have to be in a
17 registry then? Because you don't want to go
18 down that road because we have been down that
19 road a couple of times.

20 (Laughter.)

21 But what are we saying here? How
22 are you going to do the followup? I am just

1 looking at the usability and feasibility
2 aspects.

3 MR. ANDERSON: Well, I think, as
4 was mentioned earlier, the responsibility
5 doesn't stop when the patient leaves the
6 hospital. People that are engaged in carotid
7 revascularization have a responsibility to
8 have some sort of followup over what happened
9 to the patient. And that includes a
10 neurological examination.

11 It is easy enough to transmit
12 reports. And we hope that the responsible
13 operator would have enough of a relationship
14 with referring physicians, should they be
15 located far away, to get some report back, and
16 that at least at the institutional level, that
17 ought to be a relatively-common, quality-type
18 initiative that institutions, hospitals,
19 should be engaged in.

20 And there probably are cases, some
21 cases, where there may be a distance between
22 the patient, where they get their followup,

1 and the operator center, but, hopefully, that
2 will be harmonized, especially in this
3 increasing age of electronic transmission of
4 medical record data. So that, getting back a
5 report ought not to be all that difficult.
6 They ought to become expected.

7 CO-CHAIR MORRIS: I agree with you
8 that people who do these procedures should
9 follow up their patients afterward. I don't
10 think you have really answered the question
11 of, what do the vascular surgeons do who
12 follow up their patients in, say, seven to
13 fourteen days, so they are not inside of this
14 window, but are perfectly responsible and
15 perfectly interested in providing high-quality
16 care.

17 And, then, I have a second point
18 which I would like you to also address. That
19 is in the 2B and 2C area of this, reliability
20 and validity testing. I am wondering if Group
21 B discussed this in your conference call
22 previously. And if you could clarify a little

1 bit about those blank places in the
2 reliability and validity testing areas?

3 So, two questions. One is, can
4 you talk a little bit more about the window?
5 Because if a vascular surgeon follows up
6 between seven and fourteen days, they are not
7 within this window.

8 And, then, the second part is the
9 testing.

10 MR. ANDERSON: Yes. Well, again,
11 the window was chosen as a kind of averaging
12 phenomenon. The discussion around that was
13 that seven days was too soon, that a later
14 time point because events do happen was a more
15 preferable time point, and that that ought to
16 become more ingrained and embedded.

17 You know, we can't force people to
18 do these exams or do this reporting, but the
19 desire was that it should be between 21 and 60
20 days, based upon the evidence that is out
21 there in terms of clinical trial data for both
22 forms of revascularization and the occurrence

1 of events after discharge up to 30 days, that
2 the window of, roughly, 21 to 60 days was
3 acceptable.

4 There are trial data out there
5 that as short as 15 days. I don't know of any
6 that are as short as seven, but certainly 15
7 days and extending out to around 60, 65 days.
8 But seven was considered to be a little too
9 soon.

10 MEMBER DUTTON: Well, again, why
11 isn't this an outcome measure? I mean, if you
12 are putting this much precision into measuring
13 every patient in a very precise way, why not
14 report the outcome?

15 MR. ANDERSON: Perfect. That is
16 an excellent question. And obviously,
17 everybody would like to move that way, toward
18 an outcome assessment, and reporting of
19 outcomes.

20 In order to be fair, it would have
21 to be a risk-adjusted outcome or risk-
22 standardized outcomes. And we are moving in

1 that direction.

2 Risk models do not exist yet. But
3 in order to get to those outcomes and risk-
4 adjusted outcomes, you have to have a process
5 for ascertaining the outcome, and the process
6 is doing a standardized neurological
7 examination. Without the neurological
8 examination being done, you really don't have
9 a fair assessment of the outcome.

10 CO-CHAIR TORCHIANA: Just a
11 suggestion on the best-of-breed theory, the
12 idea of maybe doing this kind of followup only
13 on asymptomatic patients, where a risk
14 adjustment, as we have learned today, is of
15 minor significance, might be a way to thread
16 that needle.

17 MEMBER WILHOIT: Yes, and I think
18 that the followup timeframe of the zero to 14
19 days, it is interesting --

20 MS. FITZGERALD: I think, as ACC,
21 we think more of the stenting and not as much
22 the endarterectomy in the followup. The

1 operators performing the stentings, you know,
2 we have talked to them about this, and that
3 seemed to be an appropriate timeframe.

4 We could drop the front end of it,
5 but we didn't want to compare patients that
6 went into a doctor at seven days with a
7 patient who was going in 45 days with
8 different outcomes.

9 MEMBER HALPERN: Yes, we tend to
10 see the patients early because we want to see
11 what their neck incision is --

12 MS. FITZGERALD: Yes.

13 MEMBER HALPERN: -- especially if
14 they had any liminal swelling or, you know.

15 MS. FITZGERALD: Right, and that
16 is a really good point. We could drop that
17 end of it.

18 And, then, the other thing I
19 wanted to mention is, in working with
20 interventionalists and some cardiac surgeons,
21 we always have struggled to report myocardial
22 infarction and some other outcomes after a PCI

1 or a surgery. And it is because some
2 hospitals report, assess it differently than
3 others.

4 And we work with a lot of payer
5 programs, and we identify which of our metrics
6 and measures are appropriate to use in a pay-
7 for-performance program or not. And MI is
8 never it because some hospitals have an MI
9 rate of 7 percent because they check
10 biomarkers on every single patients, and
11 others don't. So, we have always stressed the
12 importance of a proper assessment in a patient
13 post-op.

14 We actually did a really
15 interesting paper on PCIs. Hospitals that
16 checked biomarkers routinely had a much
17 higher-quality hospital. They had a lower
18 mortality rate. They had much higher
19 adherence to process outcomes, medications
20 prescribed at discharge, and stuff like that.
21 It was interesting.

22 CO-CHAIR TORCHIANA: There is no

1 doubt that you find problems proportionate to
2 how carefully you look for them.

3 And could I ask, I think the
4 answer may be fairly straightforward, but the
5 reliability and validity testing, this is
6 obviously, a binary question. Either the exam
7 was done or not. But do you have any testing
8 of this that you could fill us in on?

9 MS. McGUINN: What we have is
10 performance rates in our registry. So, we
11 haven't audited the data to compare it to
12 medical record, or something like that, to get
13 reliability of the data.

14 CO-CHAIR TORCHIANA: I'm sorry, I
15 couldn't hear you.

16 MS. McGUINN: We haven't
17 established reliability by comparing to a
18 medical record or something like that, but we
19 have distribution of performance within the
20 registry.

21 CO-CHAIR TORCHIANA: Okay.

22 MEMBER WILHOIT: I just keep

1 thinking, if I were the patient who had had
2 this procedure done, and it is three weeks
3 later, I have been and I have had my followup
4 visit with Vivienne, and she checked my neck
5 and I was fine, I am a alert, I am oriented,
6 I am back at work, I am functioning normally,
7 I know I am alive, I know I didn't have a
8 stroke, why in the world would I, the patient,
9 want to take time off work to go see some
10 doctor I had never seen to have an exam to see
11 whether I had a stroke? And, then, I have to
12 pay out of pocket because I have a co-payment
13 or co-insurance, or whatever.

14 I mean that is where I am stuck.
15 It is, why would I ever bother to do that?

16 MEMBER DUTTON: Yes, is there any
17 evidence that you find more events this way
18 than what the previous two measures find?

19 MR. ANDERSON: Are you asking
20 about between hospital discharge and 30 days?

21 MEMBER DUTTON: Sure.

22 MR. ANDERSON: Yes. Again, based

1 upon the report the reporting from trial data,
2 it is roughly 10 to 25 percent of the
3 neurological events occur after discharge, up
4 to 30 days.

5 MEMBER HALPERN: But how long
6 after discharge? So, like, would you catch
7 most of them at seven days or fourteen days,
8 or something that is more reasonable for us
9 who would want to follow up on other aspects
10 of their post-op care?

11 MEMBER DUTTON: Or would you catch
12 them because the patient says, "I'm not right.
13 I need to go see my doctor."?

14 MR. ANDERSON: Yes, well, in the
15 trials everybody had the neurological exam.
16 So, for the trial data there's better
17 homogeneity of assessment. Sure, after seven
18 days, it is a declining function. Where you
19 draw that boundary is based on a lot of
20 things, including the ease, and seven days
21 would be okay. I mean the threshold could be
22 set at seven days. That would not be

1 difficult to do.

2 MEMBER CIMA: Just to follow up on
3 Carol's point, though, I am looking at it, the
4 value you add to the patient. So, if we have
5 set it at seven days, twenty days or whatever,
6 but how many patients sit at home with facial
7 droop and don't go see anyone? I mean, why
8 are we going to say every single person that
9 has surgery has been seen, has their followup
10 visit, they're global, it is all paid for?
11 Now they have to go make another doctor's
12 appointment. What is the value-add to that?
13 For the patient and for the payer and for
14 Medicare, what is the value-add?

15 MR. ANDERSON: Well, actually, the
16 discussions that we participated in were
17 actually the other direction. It was, if you
18 were comparing institutions A to B to C to D,
19 and you were looking at their reported
20 complication rates or reported event rates,
21 and you knew that Hospital A was collecting
22 excellent-quality data and had lots of exams

1 being done, neurological exams, and Hospital
2 B wasn't, how reliable would you feel or how
3 comfortable would you feel as a patient, say,
4 if you or your relative had to go to A or B or
5 C.

6 So, actually, when the discussions
7 were occurring, it was actually the reverse
8 side of that, looking at it, and how can you
9 compare institutions, knowing that one might
10 be doing a really good job of collecting data
11 and another one might not?

12 MEMBER HALPERN: I think what he
13 may be asking is, the later exam, how much
14 value? Going to a different provider to get
15 an exam, because your suggestion is that it is
16 somebody other than the person providing the
17 procedure, how much does that improve quality?

18 MR. ANDERSON: Probably a lot.
19 Most of the neurologists I work with, the
20 examiner is a nurse in the office. So, the
21 followup exam generally occurs, and one of the
22 nurses who are stroke-certified does the exam,

1 fills out the form, and actually faxes it
2 over.

3 CO-CHAIR MORRIS: I would like to
4 say something about that. You say that it
5 probably improves the quality a lot, but we
6 don't really know because all you have is a
7 distribution. You haven't really tested it.
8 So, we don't actually know that.

9 I think that this is very
10 interesting, and your comments about,
11 essentially, the culture of safety and high
12 quality that is reflected by performing this
13 exam, that is a very compelling argument. But
14 it just seems to me that there are parts of
15 this measure that are inadequately developed.

16 CO-CHAIR TORCHIANA: Okay. Let's
17 go on to vote on 1531, followup assessment of
18 stroke or death after revascularization.

19 Importance to measure and report.

20 MS. MURPHY: Before the vote, can
21 I just point out that a part of the scientific
22 acceptability that you have to look at is

1 testing, and there is no, I mean, there is no
2 information? And we do have the information
3 that reliability has not been tested.

4 CO-CHAIR TORCHIANA: So,
5 importance to measure.

6 (Vote.)

7 One, yes; thirteen, no. Oops,
8 excuse me. Seven, yes; thirteen, no. I am
9 reading the wrong numbers. Okay.

10 CO-CHAIR MORRIS: As a group, do
11 we want to request that the ACC consider
12 revamping this and bringing it back?

13 (Chorus of yeses.)

14 MEMBER ROGERS: If I may make one
15 suggestion, we play in this vascular field in
16 the State of Washington. One of the things
17 that has become very obvious is the tension,
18 not necessarily the tension, but the
19 relationship between and amongst the three
20 specialities who do this work.

21 I think this is an important
22 measurement, but I think it would be a problem

1 if we were to bless one professional entity
2 with a measurement that affects three
3 different specialities.

4 So, my invitation -- it is not
5 coming from the rest of the group -- is that
6 you have more, hopefully, productive
7 discussions with the other disciplines.
8 Because if it were brought as a combined
9 effort and identified as such, I think it
10 might have a little more weight.

11 MEMBER HALPERN: I would concur
12 with that, speaking as a vascular surgeon. I
13 think we all do need to get on the same page
14 because it is better for our patients.

15 CO-CHAIR MORRIS: Okay. Let's
16 move on to the next set, which is general,
17 ophthalmology, orthopedics, and pediatrics.
18 And we are going to go slightly out of order
19 here. We will start with 0352, Dr.
20 Siperstein, failure to rescue in-hospital
21 mortality, risk-adjusted.

22 CO-CHAIR TORCHIANA: If I could

1 just interject, we haven't heard from the
2 developer on this one as yet.

3 CO-CHAIR MORRIS: Hi, Jeff. Do
4 you want to speak to the group?

5 MR. SILBER: I am sorry, was I
6 supposed to give a brief overview, failure to
7 rescue? Is that --

8 CO-CHAIR MORRIS: Only if you want
9 to.

10 (Laughter.)

11 We are inviting you to give a
12 brief overview of the CHOP measures.

13 MR. SILBER: Okay. If there are
14 no specific questions, this is a measure that
15 has been previously endorsed, and this is in
16 the renewal process. We have updated codes
17 for both the 30-day measure and the in-
18 hospital measure.

19 Failure to rescue is an outcome
20 measure that is risk-adjusted. It is
21 something that complements mortality and
22 complications statistics and has been used for

1 a number of years to examine how hospitals
2 handle patients who develop complications.

3 Let me leave it at that then.

4 CO-CHAIR MORRIS: Okay.

5 MEMBER SIPERSTEIN: Okay. So,
6 this measure is actually paired with the
7 following measure, and I will explain why.
8 The concept of failure to measure, as was
9 explained, is the probability of death
10 following a complication. And so, the ratio
11 really looks at the number of deaths divided
12 by the number of patients who have had
13 complications.

14 And this concept is somewhat
15 interesting in the quality arena in that the
16 concept is that just looking at crude
17 mortality, even if risk-adjusted, may not sort
18 everything out for you.

19 It also is paired with the concept
20 that various safety measures that we do act to
21 reduce, but really do not completely eliminate
22 complications.

1 And the other concept is that a
2 good number of complications may be due to
3 underlying patient conditions, things that we
4 may not have control over.

5 And so, the concept is that once a
6 patient has had a complication in the
7 hospital, are the systems in place to prevent
8 that from progressing to death? That is the
9 bottom-line concept.

10 So, it is somewhat of a different
11 dimension of quality than we classically look
12 at. This measure proposes to look at general
13 surgery, orthopedic, and vascular surgery
14 cases, a large bundle of CPT codes for each of
15 those.

16 Obviously, the feeling is that it
17 is an important measure. There have been lots
18 of papers written on it.

19 It garners administrative data.
20 So, it is going to be fairly easy to gather
21 the information.

22 The measure is a maintenance

1 measure, but this particular measure has not
2 been used yet in public reporting.

3 The difference between this
4 Measure 0352 and the next one, 0353, differs
5 only in that this measure looks at in-hospital
6 mortality and the following measure looks at
7 30-day mortality.

8 And in our conference call, we
9 could clearly understand through
10 administrative data how you can get the in-
11 hospital and had some questions in terms of
12 the method of collection of the 30-day.

13 Also, I would parenthetically add
14 that there is another measure that we are
15 going to be reporting that is very similar to
16 this that has been in use and is used by a
17 number of states already.

18 MR. SILBER: Yes, I was going to
19 mention that we envisioned that the 30-day
20 measure could be used by datasets where 30
21 days is available, like Medicare data;
22 whereas, HCUP data would only have in-hospital

1 data. So, that was one of the reasons to have
2 both a 30-day measure and an in-hospital
3 measure.

4 Also, the other measure, the AHRQ
5 measure, is very, very different. That is a
6 spin on failure to rescue, but it only
7 includes patients who had a subset of the
8 complications. So, that they basically use
9 about half the deaths that would be available
10 in my original measures. So, they are very,
11 very different measures, and I have written a
12 paper to show that, which is referenced in the
13 packet.

14 CO-CHAIR MORRIS: So, Jeff, does
15 that mean that the 30-day mortality measure
16 should exclude patients who aren't in Medicare
17 or some other system that catches 30-day
18 mortality?

19 MR. SILBER: If you are using the
20 30-day measure, then you need a dataset that
21 has 30-day mortality, such that, for example,
22 Medicare has the ability, the beauty of

1 Medicare data is that it has the ability to
2 look at death at 30 days because you have the
3 denominator falling; you know when patients
4 die.

5 The problem with HCUP data is that
6 it is in-hospital data, not linked over time.
7 So, there are many situations where you can't
8 do 30-day mortality, and so, you are left with
9 in-hospital mortality.

10 There are also situations where,
11 for whatever reason, one wants to use in-
12 hospital mortality. Most of the time, we will
13 report our results using 30-day, if we have
14 the ability to report 30-day data.

15 So, that is why I think it is
16 important to have both measures, because there
17 are many studies that are done or many
18 analyses that are done with data that isn't
19 linkable, and therefore, they should have a
20 uniform way and a reasonable way to compute
21 failure to rescue for in-hospital. And if it
22 is linkable, then they have the 30-day

1 measure.

2 CO-CHAIR MORRIS: For the patients
3 in whom you are measuring 30-day mortality,
4 should there be an exclusion to not include
5 patients that are not in Medicare?

6 MR. SILBER: No. It depends on
7 the dataset that you have. If you have data
8 that is linkable, it is not just Medicare
9 data; there are other datasets. I gave that
10 as an example. Maybe I am not understanding
11 your question, but --

12 CO-CHAIR MORRIS: Okay. So, what
13 we are talking about here is in reporting that
14 hospitals or facilities could choose whichever
15 dataset they have and report one measure or
16 the other?

17 MR. SILBER: Well, just like
18 someone would report 30-day mortality or they
19 would report in-hospital mortality, this is
20 comparable, 30-day failure to rescue or in-
21 hospital failure to rescue.

22 So, when I think about, when I

1 look at different reporting sets, for example,
2 I mean there are state reporting systems where
3 they are not linked to death certificates,
4 and, therefore, they often use in-hospital
5 mortality. There are other reporting systems
6 where they do have linkable data, and they can
7 look at 30-day mortality.

8 The original reason to use 30-day
9 mortality was that you didn't want to miss,
10 you didn't want to have the problem of being
11 discharged sicker and quicker and dying
12 outside the hospital. That was always the
13 worry, the bias that might occur if there were
14 differences in length of stay that could lead
15 to different biases, lead to biases in the
16 reporting of hospitals that discharged
17 patients very quickly. Maybe their death
18 rates would look better.

19 If you have a linkable dataset and
20 you can use 30-day mortality, you don't have
21 to worry about that particular bias. That has
22 always been the drawback with in-hospital

1 mortality, is that people have been worried
2 that hospitals with different styles of
3 practice might show up differently in terms of
4 in-hospital.

5 So, we think it is important to
6 have both measures. There are problems when
7 people are more concerned; there are
8 situations where people are more concerned
9 about that, and they should be able to do 30-
10 day, or if they don't have 30-day data, use
11 in-hospital.

12 Just like people will report both
13 rates, 30-day and in-hospital, for mortality,
14 we would think it would be important to be
15 able to report both rates for failure to
16 rescue.

17 CO-CHAIR MORRIS: Okay. Thank
18 you.

19 MEMBER DUTTON: Given that you are
20 risk-adjusting the results, why are you
21 cutting it off at 90?

22 MR. SILBER: Oh, well, there was a

1 situation where we were worried that one might
2 have a greater chance of not wanting to rescue
3 after some age. So, we decided that 90 was a
4 reasonable cutoff. In other words, that the
5 intent to rescue might be different when one
6 gets exceedingly old.

7 MEMBER DUTTON: I think that is
8 ageist.

9 (Laughter.)

10 But, aside from that, if it is in
11 your risk-adjustment model, it shouldn't
12 matter. And why not get all the data and
13 report all the data?

14 MR. SILBER: Yes, we have gone
15 back and forth on this over the years and came
16 out with 90 being what we thought was a
17 reasonable way to look at the numbers. I
18 can't imagine there would be huge differences
19 between the two.

20 And our sense is that, you know,
21 whenever you are using a mortality measure,
22 there are always issues with mortality that

1 relate to questions of DNR, et cetera, which
2 generally in these kinds of databases you
3 don't have uniform DNR reported. You don't
4 have it collected or reported uniformly. So,
5 that is why we decided to use that 90 cutoff.

6 I would think that if one was
7 using public reporting and it included
8 patients up through 90, that that would still
9 do a very good job at getting at whether the
10 hospital has the ability to handle patients
11 who develop complications.

12 And in terms of being an agist,
13 which I am not, you know, we looked at this
14 mainly from a measurement perspective and
15 worrying about unobservables. So, you know,
16 I think that if there was a concern that some
17 hospitals were specifically undercaring for
18 the very, very old, a change in that
19 definition could be made. But I would say
20 that in most of the work that we have done, it
21 made sense to have some upper bound. That is
22 what we have developed up until now, and that

1 is the way we have developed the measure, not
2 thinking that it would have a huge change, but
3 we thought it would be slightly less -- put it
4 this way: the data would be a little bit more
5 comparable if we kept it at that upper bound
6 of 90. But I would have to consider going
7 back and seeing if there was some great need
8 to change that.

9 MEMBER WILHOIT: One question I
10 have is the measure is looking at the
11 percentage of patients with a complication who
12 died. But in the numerator and the
13 denominator, it looks like people who didn't
14 have a complication who died are also
15 included. And I am sort of trying to
16 understand how you describe the measure, then,
17 if you are including people who didn't have a
18 complication, but it is about people who had
19 complications. That is what I am having
20 trouble with.

21 MR. SILBER: Right. And this is
22 the way that I have developed this since the

1 very beginning.

2 I think it is important to look at
3 this in terms of why people die. And, in
4 general, the general way that I have looked at
5 this is that, in order to die or the
6 probability of death is equal to the
7 probability of dying, given a complication,
8 times the probability of a complication, plus
9 the probability of dying, given no
10 complication, times the probability of no
11 complication.

12 What we have thought was that,
13 since the probability of death, given no
14 complication, is generally pretty low in the
15 surgical arena, that what we are really
16 looking at is that death equals the
17 probability of a complication times the
18 probability of death, given a complication.

19 There are instances where people
20 die without complications. We call that, we
21 call the opposite of that the precedence rate.
22 We want to develop a measure that covers the

1 death. So, the way we construct the
2 complication list is that we try to get most
3 of the patients, the great majority of
4 patients who died, we try to have a list of
5 complications that includes the patients who
6 died.

7 So, for in-hospital, that means
8 about 95 percent of the patients who died had
9 a preceding complication. In the cases where
10 patients die without a preceding complication,
11 the assumption is, if they went through
12 surgery, they probably had something go wrong
13 with them before that.

14 So, we make sure that we cover all
15 the deaths. And so, the failure rate is, it
16 is always an adjusted measure, but the
17 numerator are the number of deaths; the
18 denominator are the number of complications
19 plus this very small, little piece, which is
20 the number of patients who died without a
21 complication but still underwent surgery.

22 So, the number, doing it that way

1 allows us to count all the deaths. And what
2 we basically say is that this is an
3 undocumented complication, that the patient
4 had an undocumented complication. They had
5 surgery. They died after surgery. Something
6 went wrong. In some way, we can document
7 that. In some way, we know that something
8 didn't go right and the patient died.

9 So, if we are talking about these
10 conditions that we have been studying, you
11 know, the situation is that these patients had
12 something that went wrong. Otherwise, they
13 wouldn't have died. They weren't dead when
14 they went into surgery. So, that is why it is
15 kind of filling in that gap.

16 The very, very different thing is
17 used with the AHRQ measure, where they use a
18 subset of complications, but they never worry
19 about covering all the deaths. And therefore,
20 they lose about 50 percent of the deaths with
21 a very, very limited set of complications.

22 The way I set up my list of

1 complications is I start by saying, what are
2 the complications that are associated with
3 death, and try to get all those complications.
4 When you do that, you end up with in the
5 elderly population, roughly speaking, between
6 40 and 50 percent of patients have some
7 complication.

8 If I would not be concerned with
9 covering the complications, but only use
10 deaths following the complication, as they do
11 in the AHRQ definition, then I would end up
12 with greatly disturbing the reliability of the
13 measure because the number of deaths gets cut
14 in half.

15 CO-CHAIR MORRIS: Okay.

16 MR. SILBER: So, there is that
17 small, little piece of patients who die
18 without a complication. It is very rare, and
19 it has to do --

20 CO-CHAIR MORRIS: Yes, you said
21 that.

22 MR. SILBER: -- with these

1 differences in the way the claims data pick up
2 some of the complications. But that is a
3 small piece that we try to minimize by setting
4 up a broad-enough list of complications, which
5 is what we have presented, that cover almost
6 all the deaths.

7 CO-CHAIR MORRIS: All right.
8 Thank you.

9 I think that that has actually
10 very good face validity. Whenever there is a
11 death within 30 days after an operation, we
12 have to assume that the operation is what led
13 to the death. Even if that is not actually
14 true, that is the assumption, so that we can
15 take the best possible care of our patients
16 and scrutinize our practices to try to make
17 them better. So, I think that seems very
18 valid to me surgically.

19 Anybody else in the room want to
20 speak to that?

21 MEMBER DUTTON: Well, one
22 exception might be trauma, where the patient

1 comes in and gets a desperate procedure in a
2 bid to save their life and then dies. That is
3 not included in here.

4 CO-CHAIR MORRIS: And it still
5 gets presented in the morbidity/mortality
6 conference.

7 MEMBER SIPERSTEIN: Yes, but this
8 covers general surgery, orthopedics, and
9 vascular.

10 MEMBER CARPENTER: I think these
11 are innovative, interesting, and seem to be
12 valid measures. The trouble is in the public
13 understanding of these and the public
14 reporting because they are complicated, and
15 they are a little harder to understand.

16 Now that doesn't mean we don't
17 endorse them or think about that, but I think
18 that creates some degree of difficulty using
19 these measures as publicly-reported measures.
20 If everybody uses them and we can compare
21 institution-to-institution, then that maybe
22 makes it easier, but they are a little hard to

1 wrap your brain around, unless you have been
2 doing it for a while.

3 MEMBER SIPERSTEIN: Actually, if
4 you don't understand anything about it, it is
5 simple understand because a lower death rate
6 is better.

7 (Laughter.)

8 If you understand a little, it
9 becomes complicated. And if you understand
10 everything, it becomes simple again.

11 (Laughter.)

12 MEMBER DILLON: One of the
13 problems in interpretation of the 30-day
14 result, the mortality, is going to be there is
15 now increasing data that shows that the
16 ultimate disposition of the patient in care
17 outside of the initial hospitalization or
18 institution has a significant impact on
19 readmission rates, subsequent postoperative
20 complications. This is some information that
21 has come out recently in the surgical
22 literature.

1 So, how does your measure take
2 into account those variables that are outside
3 the control of the initial hospitalization, if
4 you will, and those involved?

5 MR. SILBER: Right. Well, I mean,
6 looking at mortality, it would have the same
7 issue. You know, if you looked at 30-day
8 mortality, you would say, well, it is possible
9 that it wasn't our fault, that something went
10 wrong outside the hospital, and therefore, the
11 patient died.

12 It is always going to be the case
13 when you have a measure that doesn't include
14 just the in-hospital, but at the same time we
15 all recognize that, in part, the hospital is
16 in part responsible for this in terms of where
17 they discharge the patient to.

18 So, you know, I would say that we
19 wouldn't, as a group, say no one can look at
20 30-day mortality. It is often the gold
21 standard. But it does suffer from that
22 problem that you mentioned, and it has to be

1 thought about in the same way failure to
2 rescue would be suffering from that same
3 issue.

4 Anytime you talk about a mortality
5 rate that is occurring outside the hospital,
6 our sense is that, you know, to get a good
7 picture of the hospital, you are still going
8 to need 30-day, that most of the time most of
9 the deaths are occurring fairly early.

10 Secondly, the alternative of only
11 looking at in-hospital has its problems and
12 its bias, too.

13 So, what you are saying isn't
14 unique to failure to rescue. It is true for
15 any measure that has a set point in time that
16 can occur outside the hospitalization, but
17 those are often considered to be the gold
18 standard measures.

19 And if there are caveats about who
20 is to blame for this, I mean I think that has
21 to be addressed with future research, and
22 there might be certain situations where people

1 are very, very worried about this. But if you
2 are evaluating a hospital, they, in part,
3 should be responsible for, when they discharge
4 the patient, what happens to them.

5 The same is true for readmission,
6 right? And maybe are we going to be more --

7 CO-CHAIR MORRIS: We are not going
8 to talk about readmission right now.

9 MR. SILBER: Right. Okay.

10 CO-CHAIR MORRIS: Anybody else on
11 the Committee want to make any comments or ask
12 any questions?

13 MEMBER STAFFORD: I just have one
14 more question, and maybe it is philosophical.
15 But I would like to know why a group from CHOP
16 would propose an adult measure, and why you
17 wouldn't propose a pediatric measure. I
18 understand the complications in that
19 population are different, but why? It would
20 seem to me that your vested interest would be
21 in your pediatric population.

22 MR. SILBER: Well, I received my

1 Ph.D. in health services research in 1990
2 using Medicare data, and I have been doing
3 research in both adult and pediatric diseases
4 since that time. So, I have a long experience
5 with using claims data in adults and thinking
6 about surgical problems in adults and
7 pediatrics. So, I have never let the
8 particular age influence my research, age of
9 the patient influence my research areas.

10 And the nice thing about being a
11 CHOP is, you know, I am a professor at
12 University of Pennsylvania, I am a professor
13 at Wharton, I am a professor at the Medical
14 School. They have been wonderful about
15 letting me do my work in all different areas.

16 The fact that my primary
17 appointment is in pediatrics is why this is a
18 CHOP measure, why the word Children's Hospital
19 of Philadelphia is there, but, you know, I
20 have been doing work in adult surgery for over
21 20 years.

22 So, that is why it happens to be

1 just the fact that I originally am Board-
2 certified in pediatrics and I happen to be at
3 Penn in the Department of Pediatrics. I am
4 also in the Department of Anesthesiology and
5 Critical Care, both adults and pediatrics.

6 CO-CHAIR MORRIS: Okay. Thank you
7 very much.

8 Anybody else on the Committee have
9 any questions specifically for Dr. Silber
10 about this measure?

11 MEMBER ROGERS: I have a quick
12 question for Carol. Do you have any concern
13 that the basis for this is administrative
14 data, recognizing the little dissonance
15 between what actually happened and what gets
16 coded?

17 MEMBER WILHOIT: I think I don't
18 have a problem with this. And I think that we
19 have used the AHRQ measure for a number of
20 years, which, again, has some differences.
21 But, I mean, administrative data is useful.
22 There is just some things correlate better

1 than others.

2 MEMBER DILLON: Is it going to be
3 good enough to pick up conditions present on
4 admission?

5 MEMBER WILHOIT: It doesn't look
6 like this has present on admission as a
7 consideration. So, that obviously would be a
8 question, you know, as to whether it should.

9 MEMBER DUTTON: This looks like it
10 is based on the presence of an ICD-9
11 complication code. And I was wondering if
12 there was an increasing incentive to not
13 report those, if you don't get paid for that
14 admission.

15 MEMBER WILHOIT: And actually, we
16 are seeing more and more codes being submitted
17 rather than less and less, for a variety of
18 reasons, probably because of present on
19 admission, and so on.

20 CO-CHAIR MORRIS: Okay. Are we
21 ready to vote on Measure 0352, failure to
22 rescue in-hospital mortality, risk-adjusted?

1 First of all, does the measure
2 meet NQF criteria for importance to measure
3 and report?

4 (Vote.)

5 And the results are 18, yes;
6 three, no.

7 Does the measure meet NQF criteria
8 for scientific acceptability of measure
9 properties?

10 (Vote.)

11 Nine say completely; eleven,
12 partially; one, minimally.

13 Does the measure meet NQF criteria
14 for usability?

15 (Vote.)

16 Seven say completely; twelve,
17 partially; two, minimally.

18 Does the measure meet NQF criteria
19 for feasibility?

20 (Vote.)

21 Will that 21st person hit your
22 button again and, then, hit Send?

1 Eight say completely; twelve,
2 partially; one, minimally.

3 And, then, lastly, does the
4 measure meet all of the NQF criteria for
5 endorsement?

6 (Vote.)

7 Eighteen say yes; three say no.

8 The next measure is --

9 MEMBER DILLON: Can I just one
10 quick question?

11 CO-CHAIR MORRIS: Sure.

12 MEMBER DILLON: So, one of the
13 statements made at the beginning of this was
14 that this was not publicly reported, if I am
15 not mistaken. Did I hear that correctly, that
16 this is not in the public domain in terms of
17 reporting?

18 MEMBER SIPERSTEIN: No, it is just
19 not currently in use.

20 MEMBER DILLON: Okay. Does the
21 fact that we have endorsed it, will that
22 automatically move it into public reporting or

1 is there a whole other series of steps --

2 MEMBER SIPERSTEIN: No, my
3 understanding is that it is a maintenance
4 measure. It just has not yet been picked up
5 and adopted by any organizations.

6 MS. MURPHY: So, what you would
7 want to hear is the plan for public reporting
8 within this endorsement period, within this
9 next three years.

10 MEMBER STAFFORD: So, before we go
11 into the next one, can I just make a comment
12 and make sure that we somehow at some point,
13 when we are talking about harmonization,
14 harmonize these with the already two endorsed
15 NQF measures that are AHRQ measures? So, that
16 is 0220 and 0351. They were both, it looks
17 like, last endorsed September 2010, according
18 to the NQF website.

19 MS. MURPHY: So, the consideration
20 of harmonization or competing measures will be
21 taken up around these three measures.

22 MEMBER STAFFORD: Okay. Great.

1 CO-CHAIR MORRIS: Okay. The next
2 one is 0353, failure to rescue 30-day
3 mortality.

4 We had a little bit of a
5 discussion about, well, we really discussed
6 this already. And we can move on to the vote.

7 The one thing that still isn't
8 truly clear to me is whether hospitals are
9 supposed to go after 30-day mortality among
10 non-Medicare patients.

11 It is nice to have alternative
12 means of measuring these things, but the way
13 that it stands right now, it looks like this
14 is not really an alternative measure to the
15 first one, that it is an additional measure to
16 the first one.

17 So, for non-Medicare patients, how
18 feasible is identifying 30-day mortality among
19 postoperative patients? Anybody want to say
20 anything else about that before we go ahead
21 and vote?

22 (No response.)

1 Okay. Does the measure meet NQF
2 criteria for importance to measure and report?

3 (Vote.)

4 And please hit your button again
5 and hit Send again.

6 MS. MURPHY: He is out of the
7 room.

8 CO-CHAIR MORRIS: We are missing
9 somebody?

10 MS. MURPHY: We only have 20.

11 CO-CHAIR MORRIS: Okay. Seventeen
12 say yes; three say no.

13 Does the measure meet NQF criteria
14 for scientific acceptability of measure
15 properties?

16 (Vote.)

17 Six say completely; twelve,
18 partially; two say minimally.

19 Does the measure meet NQF criteria
20 for usability?

21 (Vote.)

22 Three say completely; ten say

1 partially; eight say minimally.

2 Does the measure meet NQF criteria
3 for feasibility?

4 (Vote.)

5 Three say completely; ten say
6 partially; seven say minimally, and one says
7 not at all.

8 And lastly, does the measure meet
9 all of the NQF criteria for endorsement?

10 (Vote.)

11 Thirteen say yes; eight say no.

12 So, among our considerations for
13 this, one is that we would like to know the
14 plan for public reporting, and the other is
15 that we would like to look at harmonization
16 among the other measures and the AHRQ
17 measures.

18 MR. SILBER: Thank you.

19 CO-CHAIR MORRIS: Okay. Great.

20 So, we are going to actually jump
21 around a little bit here and go to 1550.

22 MR. SILBER: I just want to say

1 thank you very much. And I guess we are
2 talking with you again tomorrow? Tomorrow?

3 CO-CHAIR MORRIS: That's right.
4 Yes.

5 All right. Thanks a lot, Dr.
6 Silber.

7 MR. SILBER: Bye-bye.

8 CO-CHAIR MORRIS: So, 1550,
9 hospital-level risk-standardized complication
10 rate following elective primary total hip
11 arthroplasty and total knee arthroplasty. And
12 this is being presented by Dr. Carpenter.

13 MEMBER CARPENTER: Yes, I will
14 present this. This is a newly-proposed
15 measure.

16 CO-CHAIR MORRIS: I'm sorry, let
17 me interrupt you for just a second.

18 So, another developer is going to
19 speak?

20 DR. BURSTIN: The developer
21 haven't had a chance to do their brief update,
22 if that is okay.

1 CO-CHAIR MORRIS: Okay.

2 DR. BURSTIN: She was on the train
3 earlier, if you recall.

4 CO-CHAIR MORRIS: Got you. Okay.
5 Would you like to give a brief
6 update?

7 MS. GROSSO: Yes.

8 CO-CHAIR MORRIS: Into the
9 microphone.

10 MS. GROSSO: So, we developed two
11 complementary administrative claims-based
12 measures for patients undergoing primary
13 elective total hip arthroplasty and total knee
14 arthroplasty.

15 We developed a risk-standardized
16 complications measure and a 30-day all-cause
17 readmission rate.

18 We developed the measures for
19 these procedures because they are high-volume,
20 high-cost procedures. In a cohort of Medicare
21 fee-for-service patients in 2008, there were
22 over 100,000 hip arthroplasties performed

1 across 3,000 hospitals and 241,000 knee
2 arthroplasties performed across 3300
3 hospitals. And that was after we excluded
4 patients with hip fractures and patients
5 undergoing partial hip arthroplasties,
6 revision procedures, and resurfacing
7 procedures.

8 And the trend in performance of
9 these procedures is projected to increase.
10 The cost is high, and that is projected to
11 increase also.

12 We developed these measures over
13 12 months with extensive input from
14 nationally-recognized leaders in the
15 orthopedic and surgery community, including
16 the past and current Presidents of the
17 American Academy of Orthopedic Surgeons, the
18 past President of the American Association of
19 Hip and Knee Surgeons.

20 And again, we developed two
21 measures that assess separate domains of
22 quality, a complications measure that captures

1 overall care and reflects the technical
2 aspects of the procedure. And that is
3 targeted toward, you know, geared toward more
4 targeted QI improvement efforts. And a
5 readmission measure which globally measures
6 care, including transitional care.

7 It is a risk-adjusted measure. It
8 is risk-adjusted for patient case mix, age,
9 gender, number and type of procedure.

10 Thank you.

11 CO-CHAIR MORRIS: Thank you.

12 Dr. Carpenter?

13 MEMBER CARPENTER: Yes. Thanks.

14 So you get a flavor for what these
15 are, these are useful to think about together.

16 The complications data in terms of
17 importance, the impact, again, they are high-
18 volume, costly procedures and they are
19 growing. The overall rate of these
20 complications is about 7 percent. So, it is
21 not super-high, but it is significant. The
22 range is around 2 to 9 percent that they

1 report. So, there is quite a variable range
2 from different institutions.

3 They did limit the complications
4 to what I think are appropriate ones,
5 including death, mechanical complications,
6 infection, bleeding, PE, MI, pneumonia, and
7 sepsis. So, it is not every little, tiny
8 complication. There can be some debate about
9 how severe a wound infection is, but other
10 than that, I think it is a good option.

11 The followup timing is interesting
12 because it is 90 days for some of these
13 complications; it is 30 days for others, and
14 seven days for others. So, that makes it a
15 little bit more complicated.

16 But it is a claims data measure.
17 So, hopefully, that is all available.

18 It is limited to patients 65 and
19 older, I think because that is where the data
20 is good. A lot of patients, I don't know the
21 percentage, but I would say 25 or so percent,
22 maybe 30 percent of these procedures are done

1 in patients under 65. So, there is a segment
2 of people that are not included in these
3 measures.

4 And exclusions I think are
5 appropriate, transfers, hip fractures, and
6 revision surgery.

7 The risk-adjustment method is
8 complicated, sophisticated. I don't think I
9 understood it all, but it is a hierarchical
10 linear regression that ends up reporting a
11 predicted complication rate versus an expected
12 complication rate, predicted based on your
13 past performance of your institution and how
14 you would do, and expected based on the mix of
15 patients that you have. So, it is sort of
16 like an observed to expected. That is how I
17 understood that.

18 So, I think it seemed valid.
19 There is a lot of math in there. So, it is a
20 little hard to understand, but I think it is
21 valid.

22 And it is similar to other

1 measures that I think are already approved for
2 MI and heart failure. So, some of those same
3 techniques have been used, I assume
4 successfully, although I don't know.

5 So, that is basically the
6 complications one, and maybe we should just
7 stop there. Then, we can discuss the other
8 one, but once we get through this, the other
9 one won't take very long.

10 And just in terms of the -- I was
11 not on the conference call. So, I don't know
12 all the discussion. There was some concern
13 about the 65-year-olds, why it was limited to
14 that, and some discussion about the risk-
15 adjustment technique.

16 CO-CHAIR MORRIS: Can somebody
17 that was on the call speak to that, the
18 concern about the risk-adjustment technique?

19 MEMBER AFSAR-MANESH: I don't
20 remember what type of discussion we had
21 exactly. I know we spoke about the different
22 number of days for each of the complications.

1 And part of the thought was that likely there
2 is something in the literature that correlates
3 seven days for sepsis. Thirty days or 90 days
4 is not going to be able to be tracked back to
5 that particular surgery. But that is the only
6 discussion I remember having.

7 MEMBER DILLON: And I would agree.
8 I think it was predominantly on the
9 variability in the length of followup for the
10 complications.

11 And, then, just two questions or
12 one question about two outcomes. Readmissions
13 and re-ops, were they factors that were looked
14 into and that dropped out of the analysis? Or
15 have they not been included?

16 MEMBER CARPENTER: So, this
17 measure, the first measure is just those
18 complications I listed. So, they had
19 readmissions that we will talk about next as
20 a separate reportable measure, but, generally,
21 they are going to fall into one of these
22 categories: mechanical failure, such as a

1 fracture or dislocation, or an infection or
2 bleeding. So, generally, the reasons for
3 reoperation and readmission would be captured
4 with these complications, if they happened in
5 that timeframe.

6 CO-CHAIR MORRIS: Can you clarify
7 why acute MI, pneumonia, and sepsis were not
8 included in the 30-day window, but rather in
9 a seven-day window?

10 MS. GROSSO: Yes. It was
11 clinically-driven, and we wanted to capture
12 the important medical complications. And we
13 felt that in order to be attributable to the
14 procedure, we set the cutoff at seven days
15 because anything beyond that, it would be hard
16 to attribute in this population to the
17 procedure.

18 CO-CHAIR MORRIS: Jim, what is
19 your perspective on that?

20 MEMBER CARPENTER: Well, I think
21 they had a lot of discussion. I think I would
22 applaud them for including a good group of

1 people experienced with these procedures in
2 their Technical Panel. So, I think that was
3 probably well-vetted and gone over pretty
4 thoroughly. It seems reasonable to me.

5 MEMBER DILLON: It is a
6 philosophical problem, though, because, again,
7 if the public perceives that most surgical
8 outcomes are going to be framed within a 30-
9 day followup period, and now they have to --
10 well, wait a minute. It says seven days; it
11 says 14 days.

12 To me, one of the things that we
13 should be discussing is somewhat of a
14 standardization of reporting these outcomes.
15 And to have different ones for different
16 procedures in different areas concerns me.

17 DR. BURSTIN: I just had a
18 question of whether the Yale team had actually
19 done any analyses to see if you maintained all
20 of them at 30 days, which would be certainly
21 more standard, how much higher did the
22 complication rate go, and was there

1 significant attribution? I mean, in general,
2 we are kind of going away from the idea that
3 it has to be directly related to the
4 procedure, as you do for all of the all-cause
5 readmission measures. So, I am just curious.

6 MS. GROSSO: We didn't look at
7 that specifically. But what we did do, we
8 looked at the trend in the rates over 90 days.
9 And for the AMI, pneumonia, and sepsis, they
10 peaked within seven days and then dropped and
11 went down to baseline.

12 And we looked at the trend over 90
13 days for all the complications. So, that was
14 clinical input, and based on an analysis of
15 the data, that informed the followup, the
16 decision to set the followup period for each
17 complication.

18 DR. BURSTIN: If a patient goes to
19 a SNIF, are they included still? Just a
20 question.

21 MS. GROSSO: If they are
22 discharged to a SNIF? Yes. Yes.

1 MS. BERNHEIM: And just remember
2 that part of the response to your question
3 about the rehospitalization is that this is
4 paired with a readmission measure. So, those
5 sort of readmissions that are less related to
6 the procedure, but more about the sort of
7 overall quality of care and transition are
8 going to be captured in the complementary
9 measure. So, that was part of the thinking
10 there as well.

11 CO-CHAIR MORRIS: Any other
12 discussion, comments?

13 MEMBER STAFFORD: Yes, I just have
14 a quick question. And you talked about it in
15 your exclusions, but it still isn't clear to
16 me why you would exclude DVT and UTI, just
17 because screening practices are different.

18 MS. GROSSO: Yes, we did have a
19 lot of discussion about that. The codes that
20 are used vary, and particularly the DVT.
21 Screening varies considerably across sites,
22 and readmission for screening varies.

1 The complications we chose are
2 associated with readmission. You had to get
3 readmitted for the complication.

4 And the surgeons felt that, with
5 the other two, it would just be some of the
6 codes aren't very specific, particularly those
7 for UTI, and with the DVT there was just so
8 much variability in screening and readmission
9 rates that it wouldn't be helpful to include.

10 MEMBER STAFFORD: But DVT is one
11 of the more common complications, and people
12 don't always screen for it, you're correct.
13 It is actually often picked up when somebody
14 complains about it. So, routine screening for
15 DVT in most surgical populations isn't done.
16 But it would seem to me that you are going to
17 miss a significant number of patients.

18 I am not an orthopedist, but that
19 is one of the things that the orthopedists all
20 worried about, and this is what we all argue
21 about when it comes to what kind of DVT
22 prophylaxis you use.

1 So, certainly, at least DVT I
2 think is something that you really need to
3 think about, and UTIs in the elderly
4 population are something that are common
5 enough as well.

6 And if you don't throw those out
7 -- if you throw those out, then maybe your
8 teams aren't getting those Foley catheters out
9 within 24 hours, which is one of the SCIP
10 measures. So, just a couple of thoughts.

11 MEMBER CARPENTER: Well, I will
12 make a comment about the DVT, I think.
13 Obviously, they discussed this thoroughly, but
14 the problem, this is a claims database. So,
15 if you could identify symptomatic DVTs versus
16 ones picked up that are asymptomatic from
17 screening, that might be helpful. But because
18 this database couldn't separate those out, it
19 is really going to be dependent on how much
20 screening is done in those patients because
21 the risk for a below-knee asymptomatic DVT in
22 these procedures is very high.

1 So, if you are going to screen
2 everyone, you are going to find a lot of
3 those. If you are going to screen no one, you
4 are not going to find very many of them, and
5 especially in this window.

6 So, I think it is not that it is
7 not important. It just probably wasn't
8 reliably in the measure enough to include.
9 And probably a measure isolated just on DVT
10 prophylaxis and measurement should be
11 developed, but right now I don't think the
12 technology and the use is there.

13 MEMBER WILHOIT: It was mentioned
14 that one of the concerns the Work Group had
15 raised was the age 65. Can you explain why it
16 isn't including younger people?

17 MS. BERNHEIM: Sure. This is
18 really at this point a matter of data
19 availability. As with our other measures, we
20 have developed this in the Medicare claims
21 data, and within the Medicare claims data the
22 younger-than-65 group is a very narrow group.

1 To get into Medicare before 65, it is, yes,
2 end-stage renal disease patients and patients
3 with disabilities.

4 We have been doing a lot of work
5 to look at our measures and see how well they
6 work in broader populations. And like this,
7 as with this measure, we actually expect that
8 the measure would work pretty well in those
9 are the populations and would hope to have its
10 use in those populations eventually. But, at
11 this point, it was just matter of data
12 availability.

13 DR. BURSTIN: And we have had some
14 discussions with CMS about bringing to us all
15 population-level measures. So, I guess since
16 it has already been brought up here as well,
17 again, one recommendation from the Committee
18 could be to specifically request that those
19 specifications, when available, come to NQF
20 because, again, this comes up again and again,
21 and then we wind up getting measures for the
22 below-65 population and we spend inordinate

1 months harmonizing them. So, we try to avoid
2 that.

3 MS. BERNHEIM: That work is
4 underway.

5 CO-CHAIR MORRIS: Any other
6 questions or comments?

7 (No response.)

8 Okay. Let's go ahead and vote.

9 On Measure 1550, does the measure
10 meet NQF criteria for importance to measure
11 and report?

12 (Vote.)

13 Nineteen say yes; one says no.

14 Does the measure meet NQF criteria
15 for scientific acceptability of measure
16 properties?

17 (Vote.)

18 And eleven say completely; eight
19 say partially, and one says minimally.

20 Does the measure meet NQF criteria
21 for usability?

22 (Vote.)

1 Ten say completely; ten say
2 partially.

3 Does the measure meet NQF criteria
4 for feasibility?

5 (Vote.)

6 Fourteen say completely; ten say
7 partially. Sorry, six. I don't know where
8 that came from. Oh-oh.

9 (Laughter.)

10 Does the measure meet all the NQF
11 criteria for endorsement?

12 (Vote.)

13 Twenty say yes; zero say no or
14 abstain.

15 All right. And, then, the next
16 measure, 1551, hospital-level 30-day all-cause
17 risk-standardized readmission rate following
18 elective primary total hip arthroplasty and
19 total knee arthroplasty.

20 We have really pretty much had the
21 discussion here, but, Jim, did you have more
22 to add?

1 MEMBER CARPENTER: Not really. It
2 is actually a simpler measure than the
3 previous one. And I think it is because they
4 use all causes for readmission other than
5 readmission for elective procedures, such as
6 the other hip or the other knee.

7 I think it is simpler. They use
8 the same risk-adjustment strategy, and it is
9 all 30 days. So, again, that makes it
10 simpler. So, I think this is a little more
11 straightforward than the other.

12 CO-CHAIR MORRIS: Any other
13 comments from the group or questions?

14 (No response.)

15 Let's go ahead and vote.

16 Does the measure meet NQF criteria
17 for importance to measure and report?

18 (Vote.)

19 Twenty say yes.

20 Does the measure meet NQF criteria
21 for scientific acceptability of measure
22 properties?

1 (Vote.)

2 And fifteen say completely; five
3 say partially.

4 Does the measure meet NQF criteria
5 for usability?

6 (Vote.)

7 Sixteen say completely; four say
8 partially.

9 Does the measure meet NQF criteria
10 for feasibility?

11 (Vote.)

12 Fourteen say completely; six say
13 partially.

14 And lastly, does the measure meet
15 all the NQF criteria for endorsement?

16 (Vote.)

17 Nineteen say yes; one says no.

18 DR. BURSTIN: Just one
19 clarification. Does the developer intend
20 these to be truly paired measures, meaning
21 they should always be reported together? You
22 used the word "paired" earlier. I just want

1 to check if that is what you intend.

2 MS. BERNHEIM: They were developed
3 to be complementary, but we did not intend
4 that they couldn't be separated. Yes. Right.

5 DR. BURSTIN: That means something
6 very different; that's all, I guess.

7 MS. BERNHEIM: Okay.

8 CO-CHAIR MORRIS: Okay. Since we
9 had our discussion not that long ago around
10 the topics of 0351, we will go back to that,
11 0351, death among surgical inpatients with
12 serious, treatable complications. This is the
13 AHRQ measure.

14 MR. ROMANO: Could I provide a
15 little background on that from the developer's
16 perspective?

17 CO-CHAIR MORRIS: Yes. Thank you.

18 MR. ROMANO: Right. So, I
19 appreciate hearing the discussion of the
20 earlier indicators. So, let me provide a
21 little bit of historical perspective that may
22 not have been clear from the documents.

1 So, this measure was definitely
2 inspired by the work that Jeff Silber and his
3 colleagues have done over the last 20 years.
4 So, it reflects the same underlying concept of
5 what he calls failure to rescue or what we
6 call death following serious, potentially-
7 treatable complications.

8 At the time that this measure was
9 developed by AHRQ as part of the Quality
10 Indicators Program, we surveyed the field to
11 find different specifications of this concept
12 for administrative data, because the original
13 specification was actually based on a more
14 complex dataset that was a proprietary
15 dataset.

16 Jack Needleman and Peter Buerhaus
17 did a large study that was funded by HRSA
18 looking at the impact of nurse staffing. And
19 they convened an expert panel to help them
20 identify measures that would be sensitive to
21 nurse staffing and nursing skill mix.

22 So, they identified this as such a

1 measure, but they specified it based on
2 patients having one of six complications to
3 get into the denominator. So, their expert
4 panel felt that these six complications were
5 complications that were particularly serious
6 and where a rapid response effort could
7 identify the complication early and
8 potentially slow or prevent the progression.

9 So, Needleman and Buerhaus
10 operationalized this specification based on
11 these six complications for the denominator,
12 showed that it was valid based on their work
13 on their staffing.

14 We were familiar with that work
15 and consulted with Needleman and Buerhaus. We
16 convened our own expert panel under AHRQ's
17 auspices, and they basically agreed that they
18 liked the concept of failure to rescue, but
19 they preferred a specification in which the
20 denominator was linked to specific types of
21 complications that they could get their arms
22 around clinically, where they felt that there

1 was a particular opportunity for early
2 intervention and, thus, actionability for
3 improvement.

4 So, that was the concept, and that
5 is how this measure came to be the original
6 NQF-endorsed measure of failure to rescue.

7 Jeff Silber and I are friends. I
8 was actually a co-author on the paper that he
9 described comparing these different
10 specifications. So, I have nothing bad to say
11 about his measure or his work.

12 But he decided to seek NQF
13 endorsement for his measures separately. And
14 at that time, the AHRQ measure was already
15 endorsed, and there was no mechanism at that
16 time for harmonization. So, this is an
17 opportunity for kind of revisiting the
18 underlying question and potentially
19 harmonizing.

20 We did, Jeff and I did together a
21 comparative analysis of these specifications.
22 And as you might expect, his specification

1 offers somewhat higher reliability because of
2 the fact that it includes all the deaths as
3 opposed to only including half the deaths.

4 The construct validity is actually
5 similar in terms of the correlation with
6 measures of nurse staffing, skill mix,
7 teaching status, Board certification of
8 physicians, and so forth. So, measures of
9 construct validity are similar.

10 The AHRQ measure is a little
11 somewhat less sensitive to patient
12 characteristics. The Silber measure is
13 somewhat more sensitive to patient
14 characteristics, and, thus, potentially to
15 confounding due to those characteristics.

16 Those numbers are all on the
17 paper. I am happy to share that with the
18 group, if you are interested.

19 So, in terms of going forward,
20 obviously, the AHRQ measure is available in
21 public-use software, and therefore, it has
22 been picked up more broadly in public

1 reporting applications by a variety of states
2 and other reporting organizations. That
3 doesn't necessarily mean that it is superior.
4 It is just the product of a different expert
5 panel process with Needleman and Buerhaus'
6 panel on nurse staff and, then, our panel on
7 the inpatient quality indicators.

8 So, we are open to your
9 suggestions and comments related to
10 opportunities for harmonization.

11 CO-CHAIR MORRIS: Thank you.

12 Dennis?

13 MEMBER RIVENBURGH: After that,
14 there's not tons to say. Again, this is a
15 maintenance measure that looks at outcomes
16 data based on all discharges with a
17 disposition of deceased.

18 And again, unlike 0353, which
19 talks about 30-day mortality, this is only in-
20 hospital mortality that they are going after
21 the data on. So, the dataset is a little bit
22 smaller.

1 We discussed this in the group,
2 and the consensus really was that these two
3 measures really needed to be brought together.
4 Actually, the three of them needed to be
5 completely paired and kind of brought together
6 into maybe one, definitely two measures that
7 could be harmonized and utilized.

8 And probably the biggest advantage
9 so far with 0351 is that it is being reported
10 to the public, unlike the other two which are
11 collecting data that is just collecting. So,
12 that is clearly the thing the Committee felt
13 that was the most efficacious of this, is that
14 it is currently being reported.

15 CO-CHAIR MORRIS: It sounds like
16 there is another potential advantage, which is
17 the goal of this is to improve rescue.

18 MEMBER RIVENBURGH: Right.

19 CO-CHAIR MORRIS: And if these are
20 conditions for which there is potentially a
21 more easy-to-identify rescue process, then
22 that also could be advantageous. And maybe

1 that could be considered during what I hope
2 would be a harmonization process.

3 Anybody else have questions?

4 MEMBER WILHOIT: Another advantage
5 is the age, which goes down to 18, I think.
6 But that is really important for state
7 reporting, for health plan reporting, for all
8 kinds of things, to include that broader
9 population.

10 MEMBER RIVENBURGH: And it
11 actually even goes lower than that with
12 certain conditions.

13 MEMBER DUTTON: Feel free to
14 include the 90-year-olds.

15 MEMBER RIVENBURGH: I'm sorry.
16 No, it is 18 is the lower limit.

17 MEMBER DUTTON: Yes, my
18 grandmother is going to kick you in the shins.

19 (Laughter.)

20 CO-CHAIR MORRIS: Anybody else?

21 (No response.)

22 Let's go ahead and vote then.

1 Does the measure meet NQF criteria
2 for importance to measure and report?

3 (Vote.)

4 Nineteen say yes; one says no.

5 Does the measure meet NQF criteria
6 for scientific acceptability of measure
7 properties?

8 (Vote.)

9 Thirteen say completely; seven say
10 partially.

11 Does the measure meet NQF criteria
12 for usability?

13 (Vote.)

14 Thirteen say completely; seven say
15 partially.

16 Does the measure meet NQF criteria
17 for feasibility?

18 (Vote.)

19 Fourteen say completely; five say
20 partially.

21 Does the measure meet all the NQF
22 criteria for endorsement?

1 (Vote.)

2 Eighteen say yes; one says no.

3 So, what we are looking at here is
4 harmonization; also, I think based on the
5 stuff that Richard was bringing up,
6 consideration of changing the upper age limit.
7 And, then, the plan for public reporting among
8 the CHOP measures.

9 DR. BURSTIN: It is actually more
10 than just harmonization because they are all
11 claims-based measures. I mean it would be
12 difficult, I think, to think about -- we would
13 need to think about how they could coexist or
14 can they come together in a better way?

15 MEMBER RIVENBURGH: Will there be
16 further discussion of the harmonization
17 question tomorrow?

18 CO-CHAIR MORRIS: All right. So,
19 moving on to Measure 0339, pediatric heart
20 surgery mortality.

21 MEMBER DILLON: Do I dare say that
22 we can go through this quickly because we are

1 dealing with small patients and small numbers?

2 (Laughter.)

3 All right, let me just bring this
4 up here.

5 So, these two measures, certainly
6 one is I think from a no-brainer point of view
7 to discuss and vote on. The 0339 looks at
8 pediatric heart surgery and mortality in a
9 risk-adjusted fashion dealing with congenital
10 heart surgery in an age population 18 and
11 under.

12 To cut to the evaluation of our
13 group, I think in terms of I think just about
14 all of the categories, our group felt that,
15 though there was some variability in terms of
16 meeting partial to complete concordance with
17 the requirements, that our Work Group felt
18 that this was a valid metric and thought that
19 it met all of the criteria to be proposed and
20 put forward.

21 There are some concerns in that,
22 in terms of its presentation, it does seem to

1 lack -- it would be nice if they had included
2 some current data. It is a maintenance
3 measure, and so they have gotten some years of
4 data, and it would be nice to see some of the
5 results.

6 The problem is, of course, as many
7 of you know, it is limited to a certain number
8 of institutions in the country, and the
9 numbers actually are not increasing. They
10 have been flat to decreasing in terms of
11 overall congenital heart surgery. But our
12 group thought that this was a valid metric for
13 proposal and support.

14 The volume, if you want me to just
15 continue, 0340 is right on its heels in terms
16 of looking at volume, and clearly meant as a
17 paired process.

18 Again, in terms of the writeup,
19 the citations are quite old. There is no lack
20 of current data.

21 Our group, I must admit, felt that
22 for the most part the criteria were met. Many

1 of us felt that some of it was partially.
2 Certainly, from a scientific and feasibility
3 point of view, the problem I have, again, it
4 gets into a personal bias of dealing with just
5 a pure volume report, particularly in this
6 situation where the numbers are just so small,
7 and whether it is sensitive enough to pick up
8 any differences in terms of institutional
9 performance.

10 The cut number I think in the
11 literature that was quoted was 200 cases or
12 so, and there are very few programs that are
13 doing those numbers. And as they have cited
14 in the literature, many programs are well
15 below that, 100 cases or less.

16 And so, again, I am not sure
17 -- this will be, obviously, a personal bias
18 injected here -- that the reporting of volume
19 in pediatric congenital heart surgery is a
20 suitable or a valid measure. Certainly, the
21 mortality is.

22 CO-CHAIR MORRIS: Anybody have any

1 questions or comments about that?

2 (No response.)

3 Do we want to request from the
4 developer that the references be updated?

5 MR. ROMANO: Yes, we actually do
6 have updated references. I am sorry if they
7 didn't get to you.

8 Dr. Welke's group, affiliated with
9 STS, has done some work more recently on this
10 issue. I am not sure if anyone is familiar
11 with that work, basically, showing a
12 consistent volume outcome relationship.

13 There was one study from
14 California that showed a weakening of the
15 relationship, but the problem there is that
16 the system is already highly regionalized, and
17 one hospital actually had much higher volume
18 than any other hospital in the State. And so,
19 it was a highly-skewed distribution. It
20 wasn't typical of the nation as a whole.

21 So, more recent literature is
22 consistent, and we will get to harmonization

1 issues later.

2 But this measure is really based
3 on the so-called RACs(1) scheme that has been
4 published on fairly extensively in the
5 literature.

6 MEMBER DILLON: In terms of a
7 volume, the real problem does come in the fact
8 that it is becoming so regionalized. I mean
9 it is getting driven into just certain
10 institutions. And so, for that reason, does
11 volume no longer become a valid measure of
12 quality here?

13 CO-CHAIR MORRIS: Okay. Let's go
14 ahead and move on to the vote.

15 I think that is an important
16 point. It probably will become more important
17 over time with other rare operations.

18 Does the measure meet NQF criteria
19 for importance to measure and report?

20 (Vote.)

21 Eighteen say yes; one says no.

22 Scientific acceptable of measure

1 properties.

2 (Vote.)

3 Thirteen say completely; six say
4 partially.

5 Usability.

6 (Vote.)

7 Fifteen say completely; four say
8 partially.

9 Feasibility.

10 (Vote.)

11 Fifteen say completely; three say
12 partially; one says minimally.

13 Does the measure meet all the NQF
14 criteria for endorsement?

15 (Vote.)

16 Eighteen say yes; one says no.

17 The next measure, 0340, is up for
18 vote next.

19 And Dr. Dillon brought up the
20 important point that these are being driven
21 into a few sort of high-volume centers.

22 Do we want to discuss that now or

1 is that just something to note?

2 DR. BURSTIN: Just one point of
3 clarification, that my understanding is the
4 volume measure is paired with the mortality
5 measure. So, the idea would be, if somebody
6 is looking to see which center they want to go
7 to as a parent or someone, that is potentially
8 information you would want to see paired with
9 mortality, though probably not as a
10 standalone, which is why it is paired.

11 CO-CHAIR TORCHIANA: If I could
12 just say the other obvious thing, the practice
13 of pediatric heart surgery has changed
14 drastically in the last 20 years, probably as
15 much as aortic aneurysm surgery in that sort
16 of the so-called bread-and-butter of pediatric
17 heart surgery, ASDs, BSDs, PEAs, CORs, are
18 virtually never operated on or only
19 occasionally operated on, and almost
20 everything is at a higher level of complexity.

21 And that influences a whole lot of
22 things, but one of the principal things that

1 it does is invalidate a big body of literature
2 from the more distant past.

3 CO-CHAIR MORRIS: Another good
4 reason to update the literature on that.

5 Let's go ahead and vote.

6 Does the measure meet NQF criteria
7 for importance to measure and report?

8 (Vote.)

9 Fourteen say yes; five say no.

10 Scientific acceptability of
11 measure properties.

12 (Vote.)

13 And ten say completely; eight say
14 partially; one says minimally.

15 Usability.

16 (Vote.)

17 Ten say completely; eight say
18 partially; one says minimally.

19 Feasibility.

20 (Vote.)

21 Thirteen say completely; six say
22 partially.

1 Does the measure meet all the NQF
2 criteria for endorsement?

3 (Vote.)

4 Now everybody please hit your
5 button one more time and hit Send aiming at
6 Jessica.

7 (Vote.)

8 Fifteen say yes; four say no.

9 All right. I would like to kind
10 of take the group's pulse here on Measures
11 0515 and 0301.

12 (Laughter.)

13 Do we want to table these until
14 tomorrow morning?

15 CO-CHAIR TORCHIANA: Well, do we
16 have people who can't attend?

17 CO-CHAIR MORRIS: Oh, are you
18 unable to attend tomorrow?

19 MS. SLOSBURG: We can attend
20 tomorrow, but I was just going to request that
21 it could be in the morning with the other
22 measure because Dr. Shapiro has a commitment.

1 CO-CHAIR MORRIS: Yes, we will do
2 it first.

3 MS. MURPHY: Can I just say that
4 updated information about references was sent
5 out to everybody, but it has just been AHRQ
6 updates, within the last day or two. Some of
7 you may also have been traveling. So, among
8 your souvenirs through email there is an
9 attachment with updated references.

10 CO-CHAIR MORRIS: We are scheduled
11 to start tomorrow at nine o'clock.

12 In terms of leaving your things in
13 the room, is that not a good idea? We are
14 going to go to another room tomorrow next
15 door, I think, hopefully, a little bit larger.
16 And I think there are more cookies in there.

17 MS. MURPHY: So, before everyone
18 departs, we do need to open the line for
19 public and member comment.

20 CO-CHAIR MORRIS: Okay. All
21 right. Any comments?

22 (No response.)

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I don't hear anything. I think we
are all set.
Goodnight, everybody.
(Whereupon, at 6:25 p.m., the
foregoing matter went off the record.)

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This is to certify that the foregoing transcript

In the matter of: Surgery Endorsement
Steering Committee

Before: NQF

Date: 05-04-11

Place: Washington, DC

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