

NATIONAL QUALITY FORUM
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SURGERY ENDORSEMENT MAINTENANCE
2010 STEERING COMMITTEE

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MONDAY
FEBRUARY 28, 2011

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The Steering Committee met at the Washington Hilton, Lincoln West room, 1919 Connecticut Avenue, N.W., Washington, D.C., at 9:00 a.m., Arden Morris, Chair, presiding.

PRESENT:

ARDEN MORRIS, Chair, University of Michigan Health System

NASIM AFSAR-MANESH, UCLA Medical Center

JAMES CARPENTER, University of Michigan

ROBERT CIMA, Mayo Clinic

CURTIS COLLINS, University of Michigan Health System

PETER DILLON, Penn State Hershey Medical Center

RICHARD DUTTON, Anesthesia Quality Institute

STEVEN FINDLAY, Consumers Union

PAULA GRALING, Inova Fairfax Hospital

VIVIENNE HALPERN, Carl T. Hayden VA Medical Center

EILEEN KENNEDY, Pepco Holdings

RUTH KLEINPELL, Rush University Medical Center

JOHN MORTON, Stanford University

DENNIS RIVENBURGH, St. Anthony's

TERRY ROGERS, The Foundation for Health Care

Quality

CHRISTOPHER SAIGAL, UCLA Medical Center

NICHOLAS SEARS, MedAssets

ALLAN SIPERSTEIN, Cleveland Clinic
RENAE STAFFORD, University of North Carolina
CONNIE STEED, Greenville Hospital System
CAROL WILHOIT, Blue Cross Blue Shield of
Illinois
CHRISTINE ZAMBRICKI, American Association of
Nurse Anesthetists

NQF STAFF:

HELEN BURSTIN
KRISTIN CHANDLER
ALEXIS FORMAN
ANN HAMMERSMITH
MELINDA MURPHY
JESSICA WEBER

ALSO PRESENT:

RICHARD PRAGER, The Society of Thoracic
Surgeons
HARRIET GAMMON, The Joint Commission
SHARON SPRENGER, The Joint Commission
DAVID SHAHIAN, The Society of Thoracic
Surgeons (via telephone)
JANE HAN, The Society of Thoracic Surgeons
(via telephone)

JOHN BOTT, Agency for Healthcare Research and
Quality (via telephone)
JEFFREY GEPPERT, Battelle Memorial Institute
(via telephone)
PATRICK ROMANO, UC-Davis (via telephone)
ANNE SNOWDEN, MPH, CPHQ, Minnesota Community
Measurement*

JOHN A. SPERTUS, MD, MPH, University of
Washington School of Public Health*
SAMANTHA TIERNEY, MPH, American Medical
Association
MANASI TIRODKAR, PhD, MS, National Committee
for Quality Assurance

*Present via telephone

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

2 9:02 a.m.

3 CHAIR MORRIS: Good morning.

4 We're going to go ahead and get started. I'd
5 like to thank everybody for coming to the
6 meeting today on surgical endorsement and
7 maintenance measures with the National Quality
8 Forum.

9 We're going to start by going
10 around the table and introducing ourselves,
11 and then just mentioning whether we have any
12 disclosures and what they are.

13 And I'll start. I'm Arden Morris.
14 I'm an associate professor of Surgery and the
15 University of Michigan.

16 MS. MURPHY: And let me just
17 remind everyone that everything from this
18 point forward will be recorded. So be sure
19 that you're using the microphone, that you
20 press the button and see the red light when
21 you're speaking. When you are no longer
22 speaking, be certain that you turn it off,

1 because we'll get a lot of noise if we have
2 multiple speakers on. But we are recording
3 from this point forward.

4 CHAIR MORRIS: And in addition to
5 that, the transcripts will be posted online,
6 so you'll be able to go back and review them
7 if you desire. So I'm Arden Morris. I'm an
8 associate professor of Surgery at the
9 University of Michigan.

10 Today, I'm the Chief of General
11 Surgery at the Ann Arbor VA and tomorrow I'll
12 be the Chief of Colorectal Surgery at the
13 University of Michigan. I have no disclosures
14 besides that. Beg pardon? Day after? We'll
15 see.

16 (Laughter.)

17 CHAIR MORRIS: Stay tuned. So
18 let's go ahead and go around.

19 MS. HAMMERSMITH: Hi. I'm Ann
20 Hammersmith and NQF's general counsel. Before
21 you finish up with disclosures, I just want to
22 remind you of a few things and make a few

1 statements. You all received the conflict of
2 interest form from NQF, which you all filled
3 out. We went through those. We eliminate
4 people who we believe had conflicts or had
5 apparent conflicts of interest.

6 What we ask you to do today in the
7 spirit of openness and transparency, which NQF
8 is known for, I'd just ask you to go around
9 the table, introduce yourselves, as your chair
10 did, and disclose anything that you think your
11 fellow committee members should know.

12 One thing I want to remind you of
13 is that you sit on the committee as an
14 individual. We often have people say I'm
15 representing the interests of or the views of
16 fill in the blank organization. That's
17 actually not the case.

18 Even if that organization
19 nominated you, you sit as an individual, as an
20 expert. So I'll ask you to go around the
21 table.

22 DR. GRALING: Good morning. I'm

1 Paula Graling. I'm the clinical nurse
2 specialist at Perioperative Services at Inova
3 Fairfax Hospital here in D.C., and I have no
4 known conflict of interest.

5 DR. STAFFORD: Good morning. I'm
6 Renae Stafford. I'm an assistant professor of
7 Surgery at the University of North Carolina in
8 Chapel Hill.

9 I have no known conflicts;
10 however, I am a member of a number of
11 different surgical and trauma organizations
12 that clearly would be benefit from this, and
13 I also have an indirect conflict in that I
14 have a family member who works for a biotech
15 firm.

16 DR. CARPENTER: Good morning. I'm
17 Jim Carpenter. I'm an orthopedic surgeon.
18 I'm the chair of Orthopedic Surgery at the
19 University of Michigan, and I have no
20 conflicts regarding these topics.

21 DR. COLLINS: Hi, good morning.
22 My name is Curtis Collins. I'm a clinical

1 pharmacist also at the University of Michigan,
2 and no conflicts.

3 MR. RIVENBURGH: Good morning. My
4 name is Dennis Rivenburgh. I'm a physician
5 assistant practicing Orthopedics and Sports
6 Medicine in St. Petersburg, Florida, and I
7 have no conflicts.

8 DR. MORTON: I'm John Morton. I'm
9 chief of Minimally Invasive and Bariatric
10 Surgery at Stanford. I'm a director for
11 Surgical Quality at Stanford. My one
12 disclosure is I have an educational grant from
13 Ethicon Endo-Surgery.

14 DR. KLEINPELL: Good morning. I'm
15 Ruth Kleinpell from Chicago, Illinois, Rush
16 University Medical Center. I serve as a
17 director for Clinical Research there and I'm
18 also a professor of Nursing and a nurse
19 practitioner.

20 DR. CIMA: Good morning. My name
21 is Robert Cima. I'm a colorectal surgeon and
22 vice chair of the Department of Surgery for

1 Quality and Safety at Mayo Clinic in
2 Rochester, and I have no disclosures.

3 DR. SIPERSTEIN: Hi. Allan
4 Siperstein, a professor of Surgery at the
5 Cleveland Clinic, chair of Endocrine Surgery
6 there. I have no conflicts.

7 DR. HALPERN: Vivianne Halpern.
8 I'm the chief of Vascular Surgery at the Carl
9 T. Hayden Phoenix VA Medical Center, and
10 associate professor of Surgery at the
11 University of Arizona. I have no conflicts.

12 DR. DILLON: Good morning. I'm
13 Peter Dillon. I'm chair of Surgery at Penn
14 State-Hershey, and I have no conflicts other
15 than contracts with Synthese.

16 MS. STEED: Hello, I'm Connie
17 Steed with the Greenville Hospital System
18 University Medical Center, and I have a
19 research grant with Deb Rovai (ph), which is
20 doing research on hand hygiene and surgical
21 sepsis.

22 DR. SAIGAL: I'm Chris Saigal.

1 I'm an associate professor of Urology at UCLA.
2 I did some consulting for American Medical
3 Systems last year.

4 DR. ROGERS: Hi. I'm Terry
5 Rogers. I'm a recovering pulmonologist who
6 currently is a CEO at the Foundation for
7 Health Care Quality in Seattle. We're a
8 state-wide organization that looks at various
9 surgical and medical procedures. I have no
10 conflicts.

11 DR. DUTTON: I'm Rick Dutton. I'm
12 a trauma anesthesiologist from Baltimore, and
13 currently the executive director of the
14 Anesthesia Quality Institute.

15 MS. ZAMBRICKI: Hello. I'm
16 Christine Zambricki. I am as of two weeks ago
17 the deputy executive director for the American
18 Association of Nurse Anesthetists. Prior to
19 that, I was chief operating officer and chief
20 nursing officer for a hospital, and the
21 conflict that I previously reported is that I
22 sit on the Executive Advisory Board of

1 Surgical Information Systems, SIS, which is an
2 information system technology company for the
3 perioperative interval care.

4 DR. SEARS: I'm Nick Sears. I
5 serve as the chief medical officer for
6 MedAssets, Incorporated, and I have no
7 conflicts.

8 DR. WILHOIT: I'm Carol Wilhoit.
9 I'm Quality Improvement medical director for
10 Blue Cross/Blue Shield of Illinois, and I have
11 no conflicts to report.

12 MS. KENNEDY: Good morning. I'm
13 Eileen Kennedy. I'm the manager of Benefits,
14 Reporting and Compliance for PEPCO Holdings,
15 and I have no known conflicts.

16 DR. AFSAR-MANESH: Hi. I'm Nasim
17 Afsar. I'm an associate professor in Internal
18 Medicine and Neurosurgery, and I'm the
19 associate director of Quality at Ronald Reagan
20 UCLA Medical Center, and I have no conflicts.

21 MS. HAMMERSMITH: Okay, thank you
22 everyone. Is anyone on the phone? Anyone

1 participating on the phone? No. Okay. Do
2 any of you have anything you want to discuss
3 about what was disclosed, any questions for
4 each other or for me?

5 (No response.)

6 MS. HAMMERSMITH: Okay, great.
7 Have a good meeting. Thank you.

8 CHAIR MORRIS: All right, thank
9 you. We're going to briefly run through some
10 of the expectations in the process for the
11 meeting next. I'm sorry. But first, Helen
12 Burstin is going to say a few words, and have
13 we been successful at all at reaching David
14 Torchiana on the telephone?

15 MS. FORMAN: I've sent him the
16 dial-in information, so he can call Donald to
17 let us know.

18 CHAIR MORRIS: Okay. For those of
19 you who came late, he's ill with the flu and
20 so has been unable to make it today.

21 DR. BURSTIN: At least we're
22 healthy and we're here, so we'll take it as a

1 benefit. Good morning, everybody. I'm Helen
2 Burstin. I'm the senior vice president for
3 Performance Measures at NQF. Thank you all
4 for coming together.

5 I just wanted to add my welcome
6 and also just to let you know a little bit
7 about this process. Some of you who may have
8 served before will recognize it's a bit
9 different.

10 This past spring, the NQF Board
11 approved a change, where we moved from doing
12 endorsement of new measures separate from
13 maintenance and instead brought them together
14 in this process we called endorsement
15 maintenance.

16 The idea is is that we are
17 actually going to be looking with equal
18 footing at measures that are newly-submitted,
19 and measures that are endorsed and up for
20 maintenance. The measures that are up for
21 maintenance will actually now be subject to
22 the full review of all the criteria of full

1 submission that you've already seen.

2 The idea here is it really allows
3 us to achieve two important things. The first
4 is we really want to allow the measure that we
5 think is really best in class to move forward.
6 It's very confusing, we feel, to have multiple
7 competing measures on the same topic. The
8 only way to do that is to allow you to see the
9 two measures head to head.

10 The way we'll accomplish that is
11 if there are measures that are related or
12 competing, and we'll go over that with you as
13 we get deeper into it, we will ask you to
14 review each measure on its merit individually.

15 Then we'll have a process, usually
16 at this meeting or to follow, we'll see how
17 your timing works, to actually put those
18 ratings head to head and actually assess the
19 best in class and try to help make that
20 determination.

21 The second thing it allows us to
22 do is actually harmonize measures. There's a

1 lot of differences in measures that are used
2 at the ambulatory level, the hospital level,
3 the post-op, just the cacophony we've all seen
4 of measures that change, depending on setting
5 of care.

6 The only way for us to at least
7 harmonize it on target, target condition,
8 target surgery, patient population, whatever
9 the case may be, is by bringing them head to
10 head. So that's why this change in process.

11 So this is somewhat new for our
12 developers as well. You're only the second
13 committee that's done this. Cardiovascular
14 met last week and my understanding is you
15 don't have nearly as many competing measures
16 as they did. It was kind of one big competing
17 measures, aspirin beta blockers, ACE/ARBs. I
18 mean it was just extraordinary.

19 So I think you're in a little bit
20 better shape here, and again, I'm here to help
21 if there's any questions about process or
22 where we're going or just general questions

1 about direction. But we now have over 670
2 endorsed measures across multiple sites,
3 settings, types of providers, specialties,
4 etcetera.

5 Some of that growth is great,
6 because it allows us to say yes, we have
7 measures for a particular area where they're
8 needed. Some of that growth is duplication,
9 which we don't want.

10 So this is really our attempt to
11 hone in on what's important, what's most
12 useful at the end of the day for public
13 reporting and accountability, and the things
14 that are really not being used by anybody or
15 not meeting the rigorous tests of reliability
16 and validity could probably fall to the
17 wayside.

18 So that's kind of our thinking,
19 and again, I'll be here with you if you have
20 any questions as we move forward. Arden's a
21 veteran. I think this is your third steering
22 committee.

1 CHAIR MORRIS: Yes, it is.

2 DR. BURSTIN: I'm sorry, we don't
3 have David with us, but hopefully he'll get to
4 call in. So thanks.

5 CHAIR MORRIS: And we can just go
6 through a couple of things, just to give you
7 an overview of the agenda. So as you heard,
8 our goals here are to review the maintenance
9 of measure issues and then also some new
10 measures, and they all are going to be
11 evaluated by the same criteria.

12 As I spoke before in our earlier
13 executive meeting, one of my roles is to make
14 sure that the discussion moves forward, but
15 another role is to make sure that everybody
16 really has an opportunity to talk about it if
17 they have any issues or questions,
18 particularly questions for the developers, who
19 will be on the line or are present in person.

20 We'll start with a brief
21 introduction of the measures by the
22 developers, and then as we discussed

1 previously, we will go through the measures
2 one by one and we'll evaluate them by each
3 criteria.

4 I think that -- so one thing that
5 I really want to underscore is that if you
6 have any concerns about any of the measures,
7 please do bring it up. You're here for that
8 reason. Okay.

9 MS. MURPHY: So I'm going to give
10 you a bit of introduction to the project, to
11 the way in which the criteria will be
12 approached before we get started, and we're
13 actually running nicely ahead of schedule at
14 this moment.

15 What you already know is much of
16 what you're going to hear, so hopefully this
17 will reinforce some of the things you've
18 already looked at, as you did your preliminary
19 evaluation of the measure. So we'll start
20 with just the purpose of the project.

21 As Helen had said, we're looking
22 at endorsing measures that address the care of

1 the surgical patient and surgical procedures,
2 and at the same time you're considering new
3 measures, you will also be conducting a
4 review, a maintenance review of surgical
5 measures that have been endorsed by NQF, and
6 specifically to look at those that were
7 endorsed prior to June of 2008. Measures from
8 that, endorsed from that point forward, will
9 be considered in a later project.

10 NQF endorses measures for public
11 reporting and quality improvement, and so it's
12 not "or." It's public reporting "and" quality
13 improvement. So as you consider these, think
14 about both those.

15 As you know, by this point, even
16 if this is your first activity with NQF, there
17 is a standardized consensus development
18 process that is used, and it is that process
19 that's both set out in terms of what the
20 components are in law, and it's also one
21 that's been used overtime with NQF to develop
22 consensus through multiple iterations of

1 consideration of measures or other potential
2 standards.

3 When NQF measures are endorsed,
4 they are known as voluntary consensus
5 standards, and as you should know by this
6 point, they are widely used across government
7 sector, the states, health plans and insurers
8 and accrediting organizations, which makes it
9 very important that any measures that you are
10 recommending and considering be carefully
11 considered in terms of the criteria.

12 This project, as I've already
13 mentioned, will be looking at newly-submitted
14 measures, and those measures that are being
15 considered for maintenance. No measure gets
16 a bye. Every measure that you're going to
17 consider today you will consider based on each
18 of the four major criteria.

19 So the measures that are here for
20 maintenance will also be evaluated against
21 each of those criteria additionally, and we'll
22 talk about that in a minute. Each measure

1 that's being considered for maintenance must
2 also be looked at in terms of information
3 gained over the period of time that the
4 measure's been in use.

5 We're doing this in two phases.
6 So you will be involved in both those phases,
7 and this first phase, looking at measures that
8 are cardiac surgery-related.

9 We've got also esophageal
10 resection, VTE prophylaxis and a set of newly-
11 submitted blood transfusion measures. Phase
12 II will pick up general surgery and a number
13 of the other surgical specialties.

14 As Helen mentioned, we're also
15 looking at what is the potential for
16 harmonization of measures, whenever there are
17 similar or related measures, in order for them
18 to be harmonized in terms of the
19 specifications in terms of the populations and
20 any, again as Helen mentioned.

21 If a measure has become no longer
22 relevant for whatever reason, including no

1 longer having a performance gap that is
2 significant, and one other thing I would say
3 about the gap is the fact that a measure is
4 performing at a very high rate doesn't in and
5 of itself suggest it should be retired.

6 There may be good and valid
7 reasons why it should be continued. But there
8 is the opportunity to look at measures. In
9 fact, you should be looking at measures in
10 terms of performance gaps, and then the
11 opportunity to expand any related measures.

12 The orientation in looking at the
13 measures is very much moved to a patient
14 focus. So we're looking at the care
15 coordination across settings; care
16 transitions; hand-offs; shared accountability
17 across individuals, teams, systems,
18 organizations; shared decision-making with the
19 patient sharing in the decision; and also
20 looking at value.

21 So if you're looking at a measure
22 that is an excellent measure in terms of what

1 it targets, what it gives you information
2 about, but it is exorbitant in terms of what
3 it costs to collect the information, to assess
4 it, then you want to look at whether the value
5 gained is significant enough to support the
6 cost. This also feeds to supporting the
7 payment reform approach.

8 So as measures have evolved, it is
9 no longer looking at let's get some measures
10 to look at various aspects of care; it's let's
11 be certain that as those measures are applied
12 and we're able to look back at them in terms
13 of the performance, that they are in fact
14 driving toward higher performance; that we are
15 having the essential measures, that we're not
16 having so many measures that it's impossible
17 to deal with everything that's out there.

18 So looking at shifting towards
19 composite measures, looking at harmonizing
20 measures across sites and across providers,
21 and measuring the largest possible group
22 that's supported by the evidence. So if

1 you've got two very similar measures or two
2 related measures, and they look at two
3 populations, and you can harmonize those into
4 a measure that looks at both populations with
5 a single measure, maybe stratifying results,
6 to look at what are the opportunities to do
7 those things, and to promote shared
8 accountability and measurement across the
9 patient-focused episode of care.

10 Not focused on individual
11 providers, not focused on hospitals or
12 professionals, but focused on the continuum of
13 care within which the patient receives care.
14 So outcome measures, appropriateness measures
15 and looking at the resource utilization
16 balanced against the quality information
17 that's gained.

18 Your role as a steering committee
19 is to act as a proxy for the NQF's multi-
20 stakeholder membership. You are the
21 individuals with the expertise in the subject
22 matter area. You can be expected to opine

1 upon the measures with full knowledge of what
2 it takes to establish the evidence, to
3 evaluate the evidence and to evaluate the
4 value of the measure as a proxy for the NQF
5 membership.

6 You'll work with the NQF staff and
7 primarily those of us who are here in the
8 room, to achieve the goals of the project.
9 Our job is to try to facilitate and make your
10 job as straightforward and easy and put things
11 for you, to have you not have to do all of the
12 searching and work.

13 You will make recommendations to
14 the NQF membership for endorsement through the
15 process you're engaged in today, which will go
16 into a report that will go to the NQF
17 membership and the public for review and
18 comment.

19 You'll be able to look at the
20 result of that review period and provide
21 information about whatever improvements need
22 to be made, and either going back and have

1 conversations with the measure developers, or
2 in the report itself.

3 Then post-vote, you will have
4 another opportunity to look at the report. So
5 throughout the process, you are acting on
6 behalf of the over 400 members of NQF.

7 The co-chairs of the Committee
8 will represent you whenever the Consensus
9 Standards Approval Committee meets to consider
10 your recommendations. This is just a
11 schematic of what I've just mentioned, in
12 terms of the process.

13 So at this meeting, the objectives
14 are that you will evaluate the measures that
15 you have before you according to the NQF
16 criteria, to determine if those measures are
17 suitable for endorsement initially or
18 continued endorsement if they're maintenance
19 measures, as voluntary consensus standards.

20 Then once you have done that, to
21 the extent that there are related measures or
22 competing measures, you will look at those in

1 terms of are there opportunities to harmonize
2 the measures. If there are measures that are
3 clearly competing in terms of having the same,
4 essentially the same numerator, the same
5 denominator, the same specifications, the same
6 population, is there one that is best of the
7 two?

8 And then to identify gaps in the
9 performance measures that are available for
10 the care of the surgical patient and surgical
11 procedures. That we really expect we will
12 have an introduction for you at this meeting,
13 and will consider more fully at during Phase
14 II.

15 Okay. So basic consideration for
16 any measure to be brought forward to you. If
17 it is a non-government organization, there
18 must be a measure steward agreement that,
19 among other things, provides the information
20 that everything that is available to utilize
21 the measure in terms of all of the
22 specifications and access to any tools that

1 are needed to apply the measure will be made
2 fully available for any measure that's
3 endorsed, and that includes any measure that
4 has proprietary components.

5 There also on the part of the
6 measure steward must be a commitment that they
7 have in place the tools and a process to
8 maintain and update the measure as needed, and
9 at least every three years to provide the
10 information that it is up to date, or to
11 provide updates.

12 They must commit that the measure
13 is available and is expected to be used for
14 both quality improvement and public reporting,
15 and the measure submission information must be
16 complete. The measures in general must be
17 fully developed and have been tested, so that
18 all of the evaluation criteria that you're
19 going to use have been addressed, and you can
20 assess that.

21 The endorsement criteria that
22 you're going to be looking at, and you've

1 looked at this already in your preliminary
2 review, are the four that you see on the
3 screen, and they are in an order for a reason.

4 First, Importance. Importance to
5 measure the topic area and report the
6 information. This would be measures that have
7 the greatest opportunity to really drive
8 improvement.

9 If the measure is not important,
10 based on evidence; you're looking for evidence
11 of the importance. If it's not important,
12 nothing much else matters. Once it passes the
13 threshold of Importance, and this is a yes/no
14 question, yes it is or no it isn't, if the
15 group determines that it is important to
16 measure and report based on the evidence, the
17 next consideration is Scientific Acceptability
18 of the measure properties.

19 So you're looking for validity;
20 you're looking for reliability. If the
21 measure is scientifically acceptable, you can
22 go on to consider Usability, and that is can

1 it be used to come to conclusions and make
2 decisions.

3 If again it doesn't pass that
4 threshold, then it probably doesn't matter if
5 it's easy to reasonable to collect. But if it
6 is usable as defined, then the next question
7 is -- the next criterion is Feasibility.

8 The objective with Feasibility is
9 the ability to collect it with as little
10 burden as possible, and there will be people
11 who say yes, right. But at this point, we
12 really have had a lot of experience, and there
13 are many efforts underway to improve the
14 ability to collect information electronically.

15 So you're looking for as little
16 burden as possible, and then if they're
17 competing measures, you're looking for best in
18 class.

19 For each of the criteria, there
20 are subcriteria. For each of the criteria and
21 subcriteria, there's rarely a time whenever
22 it's all or nothing, apart from importance,

1 yes or no. But for the others, it's generally
2 you've got to weigh a number of factors.

3 The rating scale that you will use
4 and you're going to use the electronic voting
5 mechanism, is what you see on the screen right
6 now.

7 You will be looking at each and
8 every one of the criteria and evaluating,
9 after Importance, which is yes or no, you'll
10 be evaluating them in terms of whether they
11 completely meet the criteria, partially,
12 minimally, not at all, or it doesn't apply,
13 and there are very few that don't apply.

14 The steering committee has already
15 had the opportunity to use the voting hand-
16 held device. You'll see the information from
17 the voting on the screen by title and number,
18 okay, and if it is necessary to re-vote for
19 whatever reason, that can be done.

20 So what you're going to be voting
21 on, Importance. The extent to which there is
22 the evidence that demonstrates importance, the

1 information that the use of the measure would
2 have a significant impact, that there is a gap
3 in performance to be addressed by the measure,
4 and the evidence supports the focus of the
5 measure.

6 In terms of Importance, there are
7 a few things in the subcriteria that are for
8 maintenance, and that's what you see with the
9 second smaller font size information on each
10 of these subcriteria.

11 So for the summary of data
12 demonstrating the performance gap, you're
13 going to be interested in knowing what has
14 occurred over the time that this measure has
15 been in use, in terms of the results of its
16 application.

17 You're going to be looking for
18 what is that performance gap. You're going to
19 be looking for whether or not they've
20 identified and what they have identified in
21 terms of disparities by population group, and
22 when looking at the information about

1 disparities, you're going to want to see
2 specific information about the disparities.

3 Any of those things that you do
4 not see, you're perfectly welcome, in fact,
5 encouraged to ask questions of the developers,
6 to collect that information, to provide you
7 that information. Sorry. You will vote on
8 importance. That will be one of those times
9 you'll have your keypad and you'll say yes,
10 it's important or no, it's not.

11 Scientific Acceptability, you're
12 looking for validity and reliability. You're
13 looking for is it precisely specified? Has
14 reliability and validity been tested? Are the
15 exclusions that have been identified
16 justified?

17 In the risk adjustment method, if
18 there is risk adjustment used, is it evidence-
19 based, and are any factors that are risk-
20 adjusted out certain that they are factors
21 that were present at the start of care.

22 You don't want to see factors that

1 could be changed as a result of care to be
2 risk-adjusted out. Statistically significant
3 differences in performance.

4 If there are multiple data
5 sources, do they provide comparable results?
6 If there are disparities, are they stratified?
7 Can you see what the performance is with the
8 measure across different groups for which
9 there are disparities.

10 Then at the end of the
11 consideration of Scientific Acceptability, you
12 will vote on each of those areas, about
13 whether it completely meets, etcetera. Then
14 you'll move on to Usability, looking for the
15 extent to which audiences can understand the
16 result of the measure, and can find them
17 useful in decision-making, including
18 consumers, including patients, and are they
19 harmonized, and you'll have an opportunity to
20 look at any that should be considered for
21 harmonization, and do they add value to the
22 current set of performance measures that are

1 available to look at that topic area.

2 Again, for maintenance measures,
3 any of the measures that are not being
4 publicly reported, the measure steward should
5 be able to tell you what is their plan for
6 public reporting.

7 If the measures are not being used
8 for quality improvement, again, you should be
9 able to hear from the developers about what is
10 their plan for using them for quality
11 improvement.

12 Because again, these are measures
13 that are -- the maintenance measures have been
14 in use. So there will be information related
15 to the extent to which they've been used for
16 quality improvement in public reporting. And
17 at the end of the Usability discussion, you
18 will vote on that criterion.

19 Feasibility, the extent to which
20 the data that you need for the measure is
21 readily available, without undue burden, and
22 what you see A through E are potential sources

1 of information.

2 If there are exclusions that are
3 there, you'll be looking for whether or not
4 they have to go to some other data source to
5 find the information for the exclusion, and
6 whether or not that activity adds significant
7 additional burden. So you're looking for can
8 the data collection strategy be implemented,
9 and you will vote.

10 So Step 1 that you see there is
11 what gets us through each of the measures that
12 you have to consider today. A full
13 evaluation, based on each of the criteria.

14 Step 2 will be for any measures
15 that are similar related, looking at those in
16 terms of the potential for harmonization. As
17 Helen said, in this particular project,
18 particularly in Phase I, there are very few,
19 but there are a few.

20 At the end of Day 2, there will be
21 some discussion about those. The question
22 right now that will resolve it before we get

1 there is whether or not we can take care of
2 being clear that we know what those are, in
3 order to ask developers to look at them for
4 harmonization, and then if there are competing
5 measures, and there may be a couple, the
6 opportunity responsibility to take a look at
7 those in terms of is there a best in class,
8 and then a final recommendation for
9 endorsement.

10 So each of you were assigned a
11 measure or more than one measure to do a
12 preliminary evaluation. At this meeting,
13 everybody should participate in the discussion
14 of each measure and vote on each measure.

15 Those of you who have the
16 responsibility or had the responsibility for
17 doing an indepth review of individual measures
18 will kick off the discussion. So you can
19 provide some summary information, but the
20 whole group should then engage in the
21 discussion, and the entire committee will
22 discuss each of the four criteria and will

1 vote.

2 So format always. NQF member and
3 public are invited to the meetings. Their
4 input, their comment, their insights are
5 always useful and are always provided for
6 within the agenda. The measure developer, and
7 today we will have measure developers in the
8 room. We have some here now, and we're very
9 happy to see them.

10 Each of the measure developers
11 will have an opportunity to introduce the
12 measures that they're bringing forward at the
13 beginning of each day. After they have
14 introduced the measure, then they will remain
15 in the meeting, so that if you have questions
16 or if there's additional information that you
17 would like from them during the course of the
18 day, they can provide that for you.

19 They will also be able to offer
20 additional comments during the public and
21 member comment period. We've already talked
22 about your voting. Any questions about any of

1 what I mentioned?

2 DR. ROGERS: Linda, just a quick
3 question about the life cycle of an approved
4 measure. So that if approval is granted for
5 a certain measure, it's likely to be in force,
6 if you will, or present in that form for two
7 years, three years?

8 MS. MURPHY: What we are asking is
9 that there be an opportunity to take a look at
10 them every three years. The expectation is
11 that if the evidence changes, that the
12 measure will be updated.

13 If the developer finds that, for
14 example, there is a really high level of
15 performance, they might come back and say
16 there's something that we want to do about
17 this because there's such a high level of
18 performance, which could mean that they might
19 want to make some adjustment in the measure,
20 in order to make it more sensitive.

21 They might want to repilot. But
22 the expectation is when there is new

1 information, new data, new evidence, that the
2 developer would update the measure and provide
3 the information, but that at least every three
4 years we would have the information that it's
5 either been updated or that there is no data
6 to support a change.

7 DR. ROGERS: So it's then
8 incumbent upon the developer, if you will, to
9 keep an eye on this longitudinally, to
10 guarantee that there's appropriateness as time
11 goes on?

12 MS. MURPHY: That's correct.

13 DR. ROGERS: Good, thank you.

14 MS. MURPHY: Right, and my
15 experience has been that they do, that they're
16 very good about that, and that organizations,
17 entities or stakeholders who have a particular
18 interest in particular sets of measures around
19 which they have knowledge and understanding
20 about the evidence will take that forward to
21 the developers, whom I have seen over time to
22 be very sensitive and open to that.

1 If not anything else, than we
2 could hear from developers.

3 CHAIR MORRIS: Okay. We're a
4 little bit ahead of schedule here. Any other
5 questions or any issues that anybody has?

6 (No response.)

7 CHAIR MORRIS: Do we have measure
8 developers on the telephone as well as here in
9 person? No, nobody yet? All right. Shall we
10 just -- sorry?

11 DR. PRAGER: Hi. I'm Richard
12 Prager, another person actually from Ann
13 Arbor. I'm a cardiac surgeon. I am here as
14 a chair of two task forces for the Society of
15 Thoracic Surgeons, which is one of the measure
16 maintenance groups that you will see today.

17 I believe Jane Han from the STS in
18 Chicago is to be on the phone actually to
19 present the history of these measures. Jane,
20 are you on?

21 DR. HAN: I am here, Dr. Prager.

22 DR. PRAGER: Arden, would you like

1 that to start this?

2 CHAIR MORRIS: That sounds good.

3 DR. PRAGER: Okay. Jane, it's all
4 yours.

5 DR. HAN: Sure. I just have a
6 couple of brief sentences for you regarding
7 the history of the measures. Currently, in
8 Phase I of the Surgery Endorsement Maintenance
9 project, we have 17 of 22 STS-built cardiac
10 surgery measures in front of you today.

11 These measures were all endorsed
12 in 2004 and received reendorsement in 2007,
13 and as scheduled, in 2010 they were up for
14 maintenance, and that's why they're being
15 reviewed by you.

16 They have been in use by the STS
17 database for years, and measures data are
18 reported to STS Adult Cardiac Surgery database
19 participants on a semi-annual basis. We'll be
20 on the phone all day today and tomorrow, so if
21 you have any questions, Dr. Prager will be
22 there and I will be here as well.

1 CHAIR MORRIS: Thank you. Do we
2 have anybody that wants to go next?

3 DR. GAMMON: Hello. I'm Harriet
4 Gammon from the Joint Commission, and we're
5 bringing forward the Patient Blood Management
6 measures. This is really a new area for
7 measurement. I think as a nation we've worked
8 a lot on blood safety, but this is the first
9 time we've really looked at patient
10 transfusion safety.

11 We have five measures that are
12 directly related to transfusion, and we have
13 two measures that are related to surgical
14 patients, the first one being pre-anemia
15 screening, in that we wanted to optimize our
16 patients before they go to surgery, because
17 there is an association. If they're optimized
18 before they go to surgery, they may not need
19 as much blood during surgery or after surgery.

20
21 The other measure looks at type
22 and cross and type and screen prior to the

1 procedure, and we want to make sure that it's
2 done before the anesthesia start time. A lot
3 of times with the patients coming in on the
4 same day for surgery, this isn't always done
5 in advance.

6 You know, we've heard of some
7 difficult cases that have had some issues with
8 this, and so we would like to bring this
9 forward as a measure for patient safety.

10 CHAIR MORRIS: Thank you very
11 much. I have a question for folks on the
12 phone. We're looking specifically for John
13 Bott from AHRQ, for Jeffrey Geppert from
14 Battelle Memorial Institute and for Patrick
15 Romana from UC-Davis. Are any of you on the
16 telephone?

17 (No response.)

18 CHAIR MORRIS: Just silence.
19 Okay. Anybody else want to go next, in terms
20 of the measure developers introducing their
21 measures?

22 (Off mic comment.)

1 CHAIR MORRIS: Okay. So that's
2 what we have. All right, great. We're moving
3 along at quite a rapid clip, which is not
4 always so bad. Yes, I'm sure. Okay. So
5 let's go ahead and get started then for Work
6 Group A, Measure 0113, and that was Dr.
7 Wilhoit.

8 DR. WILHOIT: Measure 0113 is
9 titled "Participation in a Systematic Database
10 for Cardiac Surgery." This measure assesses
11 whether an entity is participating in a multi-
12 center data collection and feedback program
13 that provides benchmarking relative to peers
14 and uses process and outcome measures.

15 Work Group A did review this
16 measure and had a number of comments in
17 response to it. First and foremost, the work
18 group felt that there is value for an entity
19 to participate in such a database, and that
20 there is evidence that participation in a
21 database leads to improved quality of care.

22 There were a lot of positive

1 comments related to the sense of the measure.
2 However, there was also discussion within the
3 work group about whether there was value for
4 NQF to have this as a stand-alone measure,
5 particularly given the other measures being
6 considered today that require basically
7 database participation. So you know, that was
8 certainly one of the considerations of the
9 work group.

10 Regarding the four NQF criteria,
11 first of all, Importance. While the work
12 group could see the value for public
13 reporting, it was less clear that there was
14 value for internal quality improvement
15 purposes. Additionally, since such a high
16 percentage of entities are already
17 participating, it was not clear whether there
18 was opportunity for a lot of improvement.

19 Second, in terms of Scientific
20 Acceptability, the work group had some
21 questions about the numerator specification,
22 which requires participation but does not

1 define what it means to participate. Is
2 submitting one case participation, or does
3 participation require submitting 100 percent
4 of cases.

5 Also of note, while the measure is
6 about systematic databases for cardiac
7 surgery, the numerator says absolutely nothing
8 about the database being related to cardiac
9 surgery.

10 Secondly, in terms of Scientific
11 Acceptability, the measure is not a rate, but
12 rather indicates that an entity either
13 participates or does not. So there's no
14 denominator. However, despite the lack of a
15 denominator, the form gives details in terms
16 of age and gender about the target population,
17 which seemed a bit confusing.

18 We did feel that it would be of
19 benefit to have a clear statement about what
20 types of entities are eligible to report the
21 measure, and that that might be an area where
22 there could be improved clarity.

1 In terms of Usability, the primary
2 issue identified here was the question as to
3 whether the indicator is redundant, and
4 whether it remains useful with the addition of
5 the other indicators that are dependent upon
6 participation, and in terms of Feasibility,
7 there were not any specific issues identified.

8 CHAIR MORRIS: I have a question
9 about that discussion around this. Suppose
10 that, I think this is unlikely, but suppose
11 that none of other related measures are
12 endorsed. Would it be worthwhile to endorse
13 this measure in that case?

14 DR. WILHOIT: Well, that's
15 obviously a matter for the group to discuss.
16 But that certainly, you know, could
17 potentially change that, yes.

18 DR. ROGERS: Well, it wasn't clear
19 to me that you are actually in favor of
20 endorsing this one or not. In the nature of
21 your comments, it was unclear.

22 DR. WILHOIT: Oh, me personally?

1 DR. ROGERS: Well, yes. I think
2 we are going to queue a lot off of the
3 presenter.

4 DR. WILHOIT: Right, and overall,
5 I had trouble with this one, as an individual.
6 Again, not anything negative in terms of -- I
7 mean participation in a database seems like a
8 really good idea.

9 The way this was written up seemed
10 really confusing, lacked clarity and whether
11 it, you know, and clearly this is dependent
12 upon other measures being approved. But
13 whether it -- its role in light of all the
14 other measures just seemed really ambiguous as
15 well.

16 DR. DUTTON: I was initially
17 concerned about the redundancy of this
18 measure, and we discussed this on the phone,
19 with the fact that all the other measures are
20 reported through a registry. So you would
21 seem like you would get this.

22 On the other hand, registry

1 participation is a good marker for quality in
2 a program, and even though it's already over
3 90 percent, as presented by the developers, I
4 think it needs to be as close to 100 percent
5 as you can possibly get.

6 Obviously, if only some practices
7 participate in the registry, you have an
8 inherent selection bias as to whose data
9 you're capturing and it's then going to affect
10 everything else you do. So I am in favor of
11 this measure. I do think, from what Carol
12 said and the technical points, they need to
13 define what constitutes a qualifying registry.

14 I mean this is all presented from
15 the STS point of view, but there are other
16 cardiac surgical registries, as Dr. Torchiana
17 mentioned on the phone, and Carol raises the
18 very valid question. What makes a registry
19 that would give you a yes on this measure?

20 CHAIR MORRIS: Any other comments
21 or questions?

22 DR. HALPERN: I think also Carol's

1 comment about having a denominator to judge
2 what, how, like she said, if you put one case
3 in, does that count as participation.

4 MR. FINDLAY: Yes. So let me get
5 this clear. There's no way who would say, who
6 would acknowledge to this one single measure
7 no position, no real practice, without also
8 essentially acknowledging to others or
9 fulfilling the others, right?

10 In other words, this is as a
11 stand-alone measure, it's sort of, you know,
12 not pointless to your point. But it's not
13 really essential. Is that what I'm hearing?

14 DR. WILHOIT: Well and I think,
15 you know, from looking at a group of measures,
16 that if there were no other measures being
17 reported, if you weren't looking at mortality,
18 if you weren't looking at outcomes, if you
19 weren't looking at complications, if you
20 weren't looking at the output of the database,
21 then the fact that somebody is participating
22 or not becomes more meaningful if that's all

1 you have.

2 MR. FINDLAY: Okay, that clarifies

3 --

4 DR. WILHOIT: But if you've got
5 the outcomes, the complications, the mortality
6 and so on, then the value of this as a yes or
7 no stand-alone measure seems less clear. The
8 yes or no would be presumably for a surgical
9 practice for a hospital, for a state.

10 But even there it's confusing,
11 because if you look at a hospital, a hospital
12 could either participates or doesn't. A
13 surgical practice either participates or
14 doesn't. The measure refers to units, I
15 think, such as states or counties.

16 But a state or county doesn't
17 participate or not. You might be able to say
18 that 80 percent of the facilities in a state
19 participated. But this isn't a rate measure.
20 It doesn't have a denominator defined. So it
21 doesn't really allow you to report a
22 percentage for a geographical area.

1 Again, that's why I had so much
2 trouble with this measure, was trying to
3 understand really what it was getting at. If
4 it's a practice or a hospital, I understand it
5 better. But it refers to larger entities as
6 well.

7 CHAIR MORRIS: Can STS respond to
8 that?

9 DR. PRAGER: Yes, I'm happy to
10 respond. I think some of this needs a little
11 bit of historical perspective. As we all
12 know, the clinicians around the table,
13 creating opportunities for our colleagues to
14 submit data to a registry has not been an
15 automatic or a given in anyone's practice, or
16 at least in our lifetimes to date.

17 I think one of the things that
18 helped the STS a great deal was NQF having
19 this as a measure, obviously supported by the
20 professional society, the STS. So I think I
21 would share the comment that was made, that
22 we're not at 100 percent.

1 We would like to be at 100
2 percent, and having -- while there is poor
3 wording, there is no question, and this can be
4 clarified, and neither Jane, who's on the
5 phone, nor I were part of the wording. But we
6 recognize it when we read it over that this is
7 not clear what it means to participate.

8 Having said that though, this has
9 helped the STS and frankly surgical practices
10 regions, and we haven't defined it by regions.
11 There are many states that mandate this
12 participation, and perhaps that would clarify
13 aspects for you, including Massachusetts and
14 other states.

15 So having said that, understanding
16 the wording needs clarification, I think from
17 the STS' perspective, if I may be that broad,
18 this is very important to us, to encourage
19 others to participate, so frankly eventually
20 we have a 100 percent capture of cardiac
21 surgical cases that are done in every practice
22 in the United States.

1 To clarify just three things. To
2 participate means you submit all cases you do
3 every year. You are audited. We are at about
4 a five percent audit. We will be at a 20
5 percent.

6 So every fifth year, every site
7 participating in the STS will be audited for
8 completeness. So that is running parallel to
9 the expansion of the database. I hope that
10 answers some of the thoughts.

11 DR. SAIGAL: I had a question. So
12 does this measure allow you to record whether
13 a practice or hospital participating, and the
14 question is the regional definition is not
15 clear?

16 DR. WILHOIT: The wording, I
17 believe, in the measure is generic, and --

18 DR. DUTTON: I think we eventually
19 heard from STS that this is on the practice
20 level, that it's the unit of -- your unit of
21 collection or capture is a group of cardiac
22 surgeons. Is that correct?

1 DR. SAIGAL: It actually can be
2 both. It can be both, and it can -- it can be
3 either/or or both.

4 DR. WILHOIT: Under the level of
5 measurement analysis, which 2.A-32 through 35,
6 it says "Check the levels for which the
7 measure is specified and tested. Clinicians,
8 group; facilities/agency; population,
9 national; population, regional/network;
10 population, states; population, counties or
11 cities."

12 So it lists all those different
13 entities, but there's no definition about how
14 you get there. The only definition is the
15 numerator; you participate or you don't.

16 DR. SAIGAL: Okay. Well, I hear
17 what you're saying about that. I do think,
18 though, that for the value of this in terms of
19 practices in hospitals, you get information
20 about people that aren't participating in a
21 database.

22 So although there are other

1 measures that help you understand what's
2 happening in the folks that are reporting,
3 this measure would help you get information on
4 people that are not reporting to a database in
5 that sense.

6 DR. SEARS: If we consider this,
7 do we need to take into account what this
8 means for other databases and the implication
9 of whether NQF supports those? Because I'm
10 sure, for instance, the American College of
11 Surgeons would probably love everyone to be in
12 -- to have the implementer here and be in the
13 NSQIP.

14 So what's the implication in terms
15 of focusing on one specific database?

16 CHAIR MORRIS: I think that's a
17 good question, what precedent does this set.
18 I guess, you know, my response to that is that
19 the STS cardiac surgeons have been recording
20 their data and working together to improve.
21 There are a limited number of operations for
22 a long time.

1 In general surgery, obviously we
2 have an enormous number of different kinds of
3 operations that we do on many different kinds
4 of people, and it's much more -- it's much
5 harder to get your arms around it than it is
6 around the operations in thoracic surgery and
7 cardiac surgery.

8 So we've been -- so in many ways,
9 the STS and cardiac surgeons have really led
10 the way for us, and I think that rather than
11 the implications really being negative, it's
12 very likely that general surgeons will be
13 learning from how thoracic surgeons organize
14 it, and everything won't be applicable to us
15 because we're in it and have to deal with it
16 a lot more.

17 DR. BURSTIN: And just to add to
18 that, and this has already come up. We've had
19 other structural measures like this submitted
20 by other surgical disciplines.

21 We also had a measure endorsed
22 last year, we'll send the details out, or two

1 years ago, to all of you, which was a generic
2 measure that came in through our Health IT
3 Structural Measures project, which is
4 participation by a hospital, physician or
5 other clinician in a systematic clinical
6 database registry that includes consensus-
7 endorsed quality measures.

8 So there is now a more generic
9 measure, and I guess one question for the
10 group would be is there a need to continue to
11 have the narrower measures, if in fact a more
12 generic measure would allow, for example, the
13 urologists to come forward, the various
14 groups.

15 As an internist myself, it would
16 be nice if some of my colleagues came forward
17 as well, not just you guys in surgery. You're
18 so far ahead. But just, it's just a thought
19 and a consideration, and we'd be happy to
20 share those detailed specs with the group.

21 You should still vote on this
22 measure on its own, but again, in the next

1 phase, we can continue to think about whether
2 there are opportunities to either improve this
3 one or that one.

4 DR. MORTON: I was just going to
5 mention that I think it's important to endorse
6 the specific measure, because it's something
7 that hospitals use to get support for the
8 database.

9 A lot of these databases are
10 supported by hospitals, and without
11 ratification of this, then that support may
12 not be there. So it's a theoretical
13 consideration.

14 DR. CIMA: I have a question about
15 that, to follow up, is attribution. If a
16 hospital, if a cardiac surgical group doesn't
17 want to participate, let's say in a hospital,
18 that they work in a hospital and another one
19 does, I mean how does this get attributed to
20 the hospital?

21 I mean we have to realize that
22 there are -- what we're doing here is people

1 are looking at it and making choices. But
2 sometimes, it's beyond the control of those
3 institutions or those individuals to do it.
4 If the group wants to do it but the hospital
5 won't pay for it, who's at fault, and who's
6 net quality are you tracking?

7 So you know, if you're going to
8 measure outcomes, measure outcomes. Is this
9 really an outcome? This has so many people
10 involved in it that have different stakes in
11 it and different participation, that whether
12 or not it really is going to help, that's my
13 concern, is who are you going to attribute
14 this to? Whose quality or whose measurement
15 are you supporting?

16 That's the only concern with what
17 Carol's saying. It seems very vague, you
18 know. Is it the state? Is it the government?
19 Who's being held responsible?

20 DR. DUTTON: My question about
21 this measure is if we endorse it, do we want
22 it to have a denominator or not, and if we --

1 because I think people are looking at it in
2 two different ways right now.

3 If we have -- if it has a
4 denominator, it's presumably something like
5 the number of cardiac surgeries done in the
6 United States. Who calculates that? I mean
7 who is responsible then for maintaining or
8 calculating the measure, and I'm not sure I
9 understand that.

10 CHAIR MORRIS: I agree. I think
11 that's an important structural issue, and I
12 think that -- I really agree. When the
13 denominator is unclear, it's hard to get to
14 the answer for my question for the STS, which
15 is after the initial endorsement of this
16 measure, how do you know what the
17 participation rate changed to, from and to,
18 with sort of an unclear denominator here?

19 DR. PRAGER: I'm not sure I can
20 answer the specifics from 2000 -- well, for
21 the last eight years. What the STS has used
22 is the calculation of the number of hospitals

1 in the United States that do cardiac surgery,
2 and then looking at who is submitting to the
3 STS, either groups or institutions.

4 Basically, as of January, it was
5 felt that there was a 95 percent penetrance of
6 all hospitals that do cardiac surgery were
7 currently submitting either their group as a
8 group submission or the institution as an
9 institutional submission to the STS,
10 understanding when they started this database
11 in 1989, there were 50 groups, 200 groups, and
12 it has continued to rise.

13 DR. STAFFORD: So does the STS
14 know how many groups participate that also
15 aren't associated with a hospital that
16 participates? I think that's some of what
17 we're trying to get at, and that's what
18 muddies the waters a bit with this.

19 DR. PRAGER: Jane may have to help
20 me on the phone, but this is -- it's an
21 important question because actually we have,
22 and I don't want to step into something to

1 confuse it, but we have public reporting now,
2 two vehicles. Consumers Union, and that is
3 out as institutional public reporting, but the
4 STS has public reporting now on its own
5 website, that is both by group and/or
6 institution.

7 So that doesn't answer -- that
8 doesn't really clarify it, but we have both of
9 those sources available in the database.

10 Jane, can you expand on that?

11 DR. HAN: I can certainly look
12 into -- I don't have the number of groups not
13 associated with hospitals that p- I don't have
14 that information right now off the top of my
15 head, but I can certainly investigate that and
16 get back to the steering committee.

17 DR. SHAHIAN: This is Dave
18 Shahian. We have done pretty extensive
19 mapping over the past year or so to look at
20 this issue. We contract and have always
21 contracted with participant groups. In most
22 cases, a group tracks to a hospital, and most

1 hospitals have one major group. So there is
2 typically a one to one mapping.

3 There are some instances where a
4 group will travel to multiple hospitals, or a
5 hospital will have multiple groups. But that
6 is a distinct minority. So in most cases,
7 it's a one to one mapping.

8 DR. STAFFORD: That's pretty much
9 what I would have expected. I guess the other
10 reason this is important to talk about is, as
11 all of us who are clinicians know, now with
12 maintenance of certification in various
13 fields, you actually, as part of your
14 maintenance of certification, have to
15 participate in quality improvement and
16 performance improvement projects, and
17 submitting your data to a database and having
18 that data evaluated is important. So in some
19 sense, it does make this an important thing
20 for clinicians who are out there.

21 DR. CARPENTER: I would just like
22 to get back to one point Carol made, which was

1 whether this was redundant if you're
2 participating in these other measures. I
3 think participation in a registry is really
4 fundamentally different than reporting outcome
5 measures from your own internal database.

6 So that this really should be a
7 stand-alone measure that we should keep. I
8 would argue for that and that reporting all
9 these other measures doesn't mean you're
10 participating in a registry. I means you have
11 a database, maybe an internal database, but it
12 doesn't mean you're reporting these as a group
13 with patient-specific level data at each
14 point, which a registry can do and can be much
15 more powerful potentially.

16 So I think this should be a stand-
17 alone. We shouldn't assume that this is
18 redundant if the other measures are being
19 reported on.

20 DR. SEARS: The question I have is
21 is this a measure that's for individual
22 practicing physicians or institutions. Maybe

1 what we should do is fracture this measure, so
2 it looks at either individual surgeons and
3 then as a group the facility itself.

4 DR. AFSAR-MANESH: I was just
5 going to add on to what Jane said as far as in
6 a data-starved profession, I think what the
7 STS has been able to do with getting the
8 various groups to submit data has really been
9 key. I think we've brought up a number of
10 different challenges and barriers that really
11 warrant us to not only discuss them but figure
12 them out as we move forward because we do need
13 other, not just surgical again, medical
14 specialties creating databases like this as we
15 move forward. So I also do think that this is
16 a stand-alone on its own.

17 MS. ZAMBRICKI: My question is one
18 of clarification. Looking at the numerator
19 statement, whether or not the facility
20 participates in a multi-center data collection
21 feedback program that provides benchmarking,
22 et cetera, then the numerator details

1 "participates in STS database."

2 Is this measure specific to STS
3 database, or is it like the title the measure
4 implies, that it is participating in a multi-
5 center data collection feedback system?

6 CHAIR MORRIS: Can you guys
7 clarify?

8 MS. ZAMBRICKI: The reason I ask
9 that is because as a health care executive at
10 a large hospital, I remember we were comparing
11 outcomes for certain cardiac surgery
12 procedures with other large medical
13 center/academic centers, and there was one in
14 particular that was reporting using different
15 definition and different criteria for
16 mortality. They were not using the STS
17 definition of mortality. So I'm just
18 wondering.

19 CHAIR MORRIS: Can you guys
20 clarify if you're specifically referring to
21 the STS registry?

22 DR. PRAGER: If it's not clear, it

1 will be. Yes, we are.

2 DR. WILHOIT: So just -- that is,
3 actually, I had not noticed that. But there
4 is a disconnect there between the numerator
5 statement and the numerator details, where one
6 refers to STS and the other one doesn't.

7 CHAIR MORRIS: Okay. So those are
8 some -- okay.

9 MR. FINDLAY: Helen, just a
10 clarification. The broader measure of
11 participation in a registry, could you repeat
12 that? How mature is that measure? When was
13 it implemented? When is it going to be? I
14 missed a little bit of that.

15 DR. BURSTIN: It was endorsed, I
16 believe, at the -- let me just pull it up real
17 quick -- it was endorsed at the end of August
18 2008.

19 MR. FINDLAY: So it's not in place
20 -- it's not in the field.

21 DR. BURSTIN: It actually is being
22 used. CMS adopted it as part of the hospital

1 program. They actually modified the measure
2 to add hospital to it. It's being used, for
3 example, as part of currently payment for
4 hospitals around nurse-sensitive measures and
5 stroke measures, as I recall. So it was
6 intended to be generic enough to capture --

7 MR. FINDLAY: So it's not a broad-
8 based --

9 DR. BURSTIN: Actually, it's
10 fairly broad. I mean literally it says, the
11 description is "Participation in a systematic
12 qualified clinical database registry that
13 involves hospital, physician or other
14 clinicians submitting standardized elements to
15 the registry. Data elements are applicable to
16 endorsed quality measures. The registry must
17 include at least two NQF-endorsed measures and
18 report on all patients eligible for the
19 selected measures.

20 "D. The registry provides
21 calculated measures results, benchmarking, QI
22 information on individual hospitals,

1 physicians and clinicians. The registry must
2 receive data from more than five separate
3 practices and may not be located at an
4 individual hospital or practice.

5 "Participation in a national or
6 state-wide registry is encouraged for this
7 measure." So it specifically tries to get at
8 that point. Then lastly, "The registry may
9 provide feedback directly to the hospital
10 provider's local registry if one exists."

11 So it's quite broad, and the
12 question would really be, you know, is there
13 still a need, if the STS measure would fit
14 under this, that an STS stand-alone measure
15 would need to persist. This has been an issue
16 that's come up before, particularly when the
17 NSQIP measure had come forward, which I
18 believe did not get through, saying do we
19 really want to go down this path of bringing,
20 you know, a measure in for every stripe, to
21 say yes, we have a registry, we're
22 participating, as opposed to a more generic

1 measure that could be more encompassing.

2 DR. CIMA: But that would then
3 brings the issue of, you know, what if you are
4 participating in the NSQIP multi-specialty and
5 has cardiac surgery in it? Then you're no
6 longer participating in STS.

7 Or if your hospital's
8 participating in UHC, which does collect
9 cardiac surgical outcome data, maybe not to
10 the specification, it uses administrative
11 databases. So we're basically then saying if
12 we endorse this, you have to pay STS to do it.

13 Which is, I think, is not what the
14 purpose of the NQF is supposed to do. It's
15 supposed to look at quality outcomes. You're
16 almost mandating participation in a private
17 entity's process.

18 DR. STAFFORD: Yes, and my
19 understanding is, and correct me if I'm wrong,
20 but the STS database is not the only
21 cardiothoracic database that's out there that
22 does this work.

1 DR. DUTTON: Dr. Torchiana
2 mentioned two others on the phone when we were
3 talking. One was the Northern New England
4 collaborative, that's been looking at cardiac
5 surgery outcomes for a very long time, and I
6 don't know if that rolls into STS, and the
7 other was the New York state mandated
8 registry.

9 DR. PRAGER: The Northern New
10 England does not automatically roll into STS,
11 number one. The eight sites do not. Some of
12 the eight sites currently are part of it, and
13 others are now considering joining it. It
14 certainly was the gold standard of early
15 databases. New York state, there are many
16 participants in New York state, although it's
17 not 100 percent yet that are in the STS as
18 well.

19 MS. ZAMBRICKI: I'd like to speak
20 in favor of a measure that requires
21 participation in a database. It does drive
22 behavior. It does change how people look at

1 their work, and as far as the issue of whether
2 it should be specific or not, I think that is
3 -- one, it is very helpful having this
4 discussion. The point that I want to make is
5 I believe enrollment in a database, where you
6 compare across institutions performance and
7 outcomes, does have an impact on quality.

8 CHAIR MORRIS: Okay. So we've all
9 made several points. Do you also have one
10 Ruth?

11 DR. KLEINPELL: I did. I think,
12 you know, Christine, you brought up an
13 important point. As the measure reads and as
14 the numerator statement reads, it's broad.
15 But then in the numerator details is where you
16 see it's specified for STS. So if we endorse
17 that as it's written, we are saying STS.

18 Now at this point in time, can we
19 ask for modification and clarification of that
20 language in the numerator, or is that a whole
21 separate process?

22 MS. MURPHY: May I comment on

1 that? What you need to do as a first step in
2 the process is to vote on the measure as
3 submitted, as specified. If the measure
4 fails, as specified, then you have an
5 opportunity to identify any conditions that
6 you would want to have considered in order to
7 find it as meeting the criteria.

8 CHAIR MORRIS: So specifically we
9 could ask for -- if the measure fails, we
10 could ask for a clearer definition of the
11 registry throughout the measure, and then also
12 a clearer definition of the denominator
13 throughout the measure. Any other -- if there
14 is anything else that we'd like a clearer
15 definition on, then this is a good time to
16 succinctly bring it up.

17 DR. ROGERS: Is there not a
18 necessity to sort of look forward to what we
19 have in front of us also because if in fact
20 the rollout of a number of measures that we
21 are yet to evaluate actually requires the kind
22 of information that can actually only be

1 obtained through being in this registry, to
2 the extent that will populate all of the other
3 measures that we're going to look at, I think
4 that needs to be considered also.

5 I'm not savvy enough to know the
6 details, but the other cardiac surgical
7 registries, I doubt, have the content and the
8 complexity that STS has, that would allow us
9 to actually move ahead with all the others
10 that we have in front of us. So that's just
11 something --

12 DR. SHAHIAN: This is Dave
13 Shahian. If I could just make a brief
14 response to that. The other clinical data
15 registries, like NNE and New York, are superb
16 databases. They suffer, however, from the
17 fact that they're not nationally
18 representative. I think that is the
19 distinctive feature of the STS, that it
20 permits national benchmark referencing.

21 CHAIR MORRIS: Okay. I think --
22 is there anything else anybody else wants to

1 say about this before we move on to a vote of
2 the individual criteria?

3 DR. KLEINPELL: Yes. I just have
4 one other question. This is not a new
5 measure, so it's been in effect, and so this
6 is not new language; correct? So it has been
7 endorsed previously as it's stated? Okay.

8 CHAIR MORRIS: All right. Let's
9 go ahead with the vote, then, on the
10 individual criteria.

11 [COMMITTEE VOTING.]

12 MS. MURPHY: So you see, you're
13 voting on the first criteria, importance of
14 the measure, based on the evidence.

15 CHAIR MORRIS: Okay. So we have
16 18 responses for yes and 4 responses for no on
17 the importance of the criteria. Do we move on
18 to the next criteria or is there -- do we want
19 to have more discussion now?

20 MS. MURPHY: We should move on to
21 the next criteria, and if there is any
22 additional discussion prior to vote on

1 Scientific Acceptability.

2 CHAIR MORRIS: Okay. So time to
3 vote on Scientific Acceptability.

4 [COMMITTEE VOTING.]

5 CHAIR MORRIS: Okay. So in the
6 summary of responses for Scientific
7 Acceptability, we have 4 say completely meets
8 the criteria, 15 say it partially meets the
9 criteria, 1 says that it minimally meets the
10 criteria, and 2 say not at all. Next, we're
11 voting on usability.

12 [COMMITTEE VOTING.]

13 CHAIR MORRIS: I think we're
14 waiting on one vote. If everybody puts their
15 vote in one more time, then it won't record
16 twice. But if for some reason it missed your
17 vote, then it will be recorded.

18 [COMMITTEE VOTING.]

19 So summary of responses, we have 9
20 that say it completely meets the criteria for
21 usability, 13 say partially, 3 say -- oh,
22 nobody says minimally and nobody says not at

1 all. Next, we are voting on criteria for
2 feasibility.

3 [COMMITTEE VOTING.]

4 CHAIR MORRIS: Okay, and in terms
5 of the vote on feasibility, 17 say that it
6 completely meets the feasibility criteria, 5
7 say it partially meets the feasibility
8 criteria.

9 So then the next vote is whether
10 this measure meets all of the NQF criteria for
11 endorsement. We had several different votes
12 on this. Now do we need to all say that
13 yes/no or do we need to have a majority? What
14 do we do? Do we have more discussion here to
15 try and reach better consensus?

16 MS. MURPHY: If there is any other
17 discussion points that need to be brought
18 forward, then yes. Otherwise, the group can
19 vote whether or not each individual sees the
20 measure as meeting the criteria.

21 DR. BURSTIN: And that's separate
22 from a "do you recommend the measure move

1 forward," which you'll do after you've had a
2 chance to look at competing measures. This is
3 basically just the test on its own. Does it
4 meet the criteria?

5 CHAIR MORRIS: This is whether it
6 meets the criteria. If for some reason we
7 decide that it does not meet the criteria for
8 endorsement, then we have the opportunity --
9 am I correct in saying that we have the
10 opportunity to ask the STS to make further
11 clarifications?

12 DR. BURSTIN: Yes, you're voting
13 as is.

14 CHAIR MORRIS: Okay.

15 DR. CIMA: So if we want them to
16 take out, strike STS and make it a generic, is
17 this the time to do it now?

18 CHAIR MORRIS: What we would do is
19 vote no, if that's what you want, vote no on
20 this, and if -- ultimately if this has a
21 majority of no votes, then we would say what
22 it is that we're looking for.

1 [COMMITTEE VOTING.]

2 CHAIR MORRIS: Still waiting for
3 one more vote, so please hit your markers
4 again and hit send. Okay.

5 [COMMITTEE VOTING.]

6 CHAIR MORRIS: So we have a dead
7 tie. Why do we have an even number of people
8 voting?

9 DR. BURSTIN: Because David's not
10 here. You're not supposed to.

11 CHAIR MORRIS: Oh, yes. So let's
12 clarify the conditions that we'd like from the
13 STS for this measure.

14 DR. DUTTON: I'll start. I'm
15 supportive of the measure. I think it's
16 important. I would be perfectly in favor of
17 a measure that required registry or submission
18 to a registry that looked exactly like the STS
19 registry, but didn't mention it by name.

20 CHAIR MORRIS: So one of the
21 clarifications is that exactly which, what the
22 registry is and what qualifies as a registry?

1 DR. DUTTON: Yes. I'm supportive
2 of the concept, no question. I just think
3 it's a mistake for NQF to endorse a particular
4 registry by brand name.

5 DR. DILLON: So then how does the
6 STS then become the steward of such a measure
7 because now you're appealing to multiple
8 databases that they may not have access to.
9 How do they then measure? Can we -- I don't
10 think we can ask them to measure, you know,
11 what's going on in other databases.

12 MR. FINDLAY: Yes. Doesn't that
13 fragment the world of this?

14 DR. DILLON: If -- it requires a
15 larger governing body to be able to collect
16 that data. STS isn't in the process of
17 collecting who's in or who's out in NNE or the
18 New York database. It's a higher level now.

19 CHAIR MORRIS: One thing that we
20 could request is that there's uniformity of
21 the descriptions throughout the measure. That
22 was one of the sources of confusion here. But

1 that doesn't really speak to the point of the
2 concern about branding.

3 MS. ZAMBRICKI: Could we request
4 that the measure require that the other
5 measures that are listed later be collected by
6 the body, that that's the criteria, that they
7 collect the other cardiac measures?

8 DR. HALPERN: How does the more
9 broad one that you mentioned, how are they
10 collecting the data from the various
11 databases?

12 DR. BURSTIN: It's self-report by
13 hospitals or groups to -- and again, it
14 describes what's considered a registry with
15 adequate numbers. You know, there are some
16 issues that STS does that are in a special
17 like auditing. So you know, it's not a one to
18 one match, but you should certainly take a
19 look at it.

20 But it would be self-report by
21 hospital, physician or group, that yes, we
22 participate in a registry that matches these

1 characteristics. I do think STS could not
2 realistically get information on other
3 people's -- in other people's registries.

4 It would still be very limited
5 just to cardiac surgery. So it's, I think,
6 more of a philosophical issue than a
7 feasibility issue, actually.

8 DR. AFSAR-MANESH: Well, and I
9 understand the concern with it being STS-
10 owned, but I think at the end of the day, I
11 don't really foresee another body that could
12 ever come in, rather than a professional
13 society, to collect this type of data.

14 So I think, again, looking at
15 other subspecialties, at the end of the day
16 it's likely going to be a professional society
17 stepping in to do this.

18 So I think instead of being
19 uncomfortable with how STS is doing, probably
20 it's better just to make sure that we're
21 defining it appropriately for the data that we
22 want collected. But we are going to need to

1 have one body so that we can compare data
2 nationally.

3 DR. HALPERN: I will just mention,
4 coming from the VA system, that the VA does
5 have a system that measures nationally that
6 isn't a specific society's.

7 DR. AFSAR-MANESH: But it's just
8 the VA, correct? Yes. So, I mean, that's
9 still very limited compared to all the other
10 hospitals.

11 DR. CIMA: So basically you're
12 saying that if a society comes up with their
13 own set of rules, that we're going to have to
14 follow those rules. You know, you're picking
15 a winner. I mean, I'm not arguing
16 participation. But I'm saying if you're
17 participating in the NSQIP multi-specialty,
18 which has cardiac in it, doesn't that qualify?

19 DR. AFSAR-MANESH: Sure, and I
20 understand that. I guess it's not that I
21 think we should pick a winner. I think we
22 should pick the criteria that we want for

1 quality and safety of patients.

2 But we do need to have one body
3 doing that, versus five different ones, where
4 we're not going to be able to compare all the
5 different groups that are out there. That's
6 what I --

7 DR. CIMA: But then you're saying
8 we have to pick a winner, because if you say
9 oh, I'll let you participate in NSQIP but you
10 still also have to participate in STS to do
11 this measure.

12 DR. AFSAR-MANESH: Well, how else
13 would you propose that we could compare data
14 nationally as we move forward in ensuring --

15 DR. CIMA: Well, you either have
16 to have one national database, or you're going
17 to have to figure out a better rule. But is
18 this the rule that does it?

19 DR. AFSAR-MANESH: And I guess I
20 don't know any other organization that at the
21 end of the day can come in and have a national
22 umbrella to cover that, and that's my concern.

1 DR. HALPERN: The American College
2 of Surgeons is what he's saying, the NSQIP
3 multi-specialties out of the American College
4 of Surgeons.

5 DR. AFSAR-MANESH: I understand,
6 but from my understanding of what STS does, is
7 that their database is actually more in-depth
8 than what NSQIP offers right now for cardiac
9 surgery, correct? Not for cardiac?

10 DR. CIMA: I'm not arguing for or
11 against it. I'm just saying this measure,
12 which we're looking at, this one specific
13 measure, says at the top "Participating in a
14 cardiac registry nationally," and then
15 throughout it says you have to participate in
16 STS.

17 That's the only thing I'm talking
18 about. I agree with everyone saying
19 participation in a registry that provides you
20 feedback is great, I think. But are we in the
21 place of picking the winners? Are you saying
22 you have to use STS?

1 Then the fundamental problem
2 becomes, as Peter pointed out, for all the
3 other cardiac ones that have been presented,
4 it uses the STS database. So then are we
5 saying that we have to endorse that everyone
6 participates in STS? I'm just pointing that
7 out there. As you go down this road, then you
8 are picking a winner.

9 CHAIR MORRIS: At some point we
10 will be picking a measure steward, and the
11 only measure steward here is the STS. Helen,
12 do you have a point?

13 DR. BURSTIN: I just want to make
14 one clarification. So NQF has endorsed
15 measures that certainly come from various
16 registries. That's not an issue. The
17 important thing to note that the
18 specifications that STS promulgates are fully
19 transparent and open to anyone.

20 You don't have to submit your data
21 to STS, but you can go ahead and use these
22 data, including the risk model. It's all

1 publicly available to do your patients. It's
2 not easy to do, but it is doable, and that's
3 the requirement from where NQF sits.

4 It's fully transparent, anybody
5 can do it. I don't want to confuse the issue
6 of this measure, which is a structural
7 measure, yes/no, do you participate in a
8 registry, which is, I think, getting more at
9 your issue. But I think the overall issue of
10 the quality of cardiac surgical care and the
11 STS being the data source for that. Exactly,
12 right.

13 DR. SAIGAL: And just to this
14 point, I think pragmatically, I mean other
15 entities could bring forward measures in a
16 similar vein, and they'd be harmonized with
17 this.

18 DR. BURSTIN: Or competing, or
19 competing.

20 DR. SAIGAL: Or competing. So to
21 the extent to which there are other measure
22 stewards who have equivalent data sources, we

1 could eventually, when the time is right,
2 harmonize them. Right now, STS is the one
3 that's in front of us. I mean, it's certainly
4 better than not having the measure, in my
5 view, at least.

6 DR. WILHOIT: The other things
7 that I think need clarification, one is the
8 definition of participation. Is it one case?
9 Is it 100 percent? Is it somewhere in
10 between? But some kind of a clean definition
11 of participation.

12 And also clarify with respect to
13 the denominator. Is it a yes/no for whatever
14 entity chooses to report? Is it by practice?
15 Is it by hospital, is it by state? But adding
16 some clarity so it's clean.

17 CHAIR MORRIS: Okay. So we have
18 three things that we're requesting from STS.
19 One is a clearer and more consistent
20 definition of registry. Another is the
21 definition of the denominator, and the third
22 is definition of participation. Can we move

1 on? Okay.

2 DR. SHAHIAN: Hi, this is Dave
3 Shahian. I could clarify that right now. I
4 think in terms of the definition, I think if
5 you are going to consider eliminating STS from
6 the definition, it would be important,
7 however, to put nationally representative or
8 nationally inclusive in that statement, which
9 I think we could certainly do.

10 In terms of what it means to be a
11 participant, it means inclusion of all your
12 cases, and in fact, that is one of the things
13 that we audit when we go to programs. We
14 actually compare the cases that have been
15 submitted to STS with the hospital operative
16 logs, to make sure that all cases have in fact
17 been included.

18 In fact, we've also done a
19 separate audit and have compared our results
20 for inclusiveness with data from MEDPAR, and
21 it's 98, 99 percent. So that's the answer to
22 the second question, and I'm sorry, the third

1 question?

2 CHAIR MORRIS: Definition of
3 participation, the denominator.

4 DR. SHAHIAN: It's a yes/no. I
5 mean, for a particular participant, you know,
6 you participated or not. I think the
7 denominator in this sense is only of interests
8 to get a sense of national variability in
9 participation. But in terms of the individual
10 institution, you did or you didn't.

11 CHAIR MORRIS: So it sounds like
12 you're saying that the denominator is
13 institution; is that correct?

14 DR. SHAHIAN: It's participant
15 group, which in the vast majority of cases is
16 an institution. But in some cases, no. You
17 may have Lakewood Surgical Group, for example,
18 that happens to be one of two groups that
19 practice in a given hospital. You have a few
20 situations like that nationally.

21 CHAIR MORRIS: Are you satisfied
22 with those responses?

1 DR. CIMA: So it's 100 percent
2 participation. So again, based on the NSQIP
3 methodology, only 20 percent of cases are
4 captured. So that would exclude them. UHC is
5 based on a sampling provided by CMS, so that
6 would exclude them.

7 So again, I'm getting -- I agree
8 with the registries. I think it's important.
9 I have concerns about this.

10 DR. WILHOIT: And I, at least,
11 would want to see the numerator and
12 denominator in writing, to be comfortable of
13 just, you know. I don't necessarily disagree
14 with the concepts, but would want to see
15 what's there.

16 MS. MURPHY: And in the case of
17 any of the measures in which there is a vote
18 for a measure with conditions, we would always
19 ask that they provide that information back to
20 us from the developer, precisely what they
21 would be able to do. So in all cases, we'd
22 ask for that to come back, written

1 information.

2 CHAIR MORRIS: Okay. So we have
3 questions that we'd like to have written
4 confirmation of the answers on or written
5 information on, and we have a dead tie here,
6 and I think that we need more information from
7 the developer before we proceed on this.

8 DR. ROGERS: I think that last
9 piece of information for me is very useful,
10 because if we are representing -- if this
11 group represents the community and advice to
12 the NQF, and we're looking at options that
13 would include two other programs that only do
14 sampling, there's no comfort in my mind about
15 recommending then.

16 And although yes, there's some
17 endorsement about picking a winner, if that's
18 the only program that does 100 percent, we
19 have no option in my mind. I mean, I am
20 completely uncomfortable recommending an
21 option that just does sampling. Makes no
22 sense.

1 CHAIR MORRIS: I think that's
2 important to keep in mind. For this measure
3 itself, this is just about the STS. So those
4 other things don't really apply here, but it
5 will come up.

6 DR. DILLON: And we have to be
7 careful with that statement, because we're not
8 in a position to compare scientific validity
9 of the other databases. You know, NSQIP, I'm
10 very comfortable with NSQIP. So again, this
11 is really stretching it in my mind what the
12 STS is asking of the NQF.

13 I don't see this as solvable,
14 because, as I said, I think if we want a
15 participation in a database, which obviously
16 I think that's what we all do agree on, STS
17 cannot answer that, because by definition, it
18 will be a forced or a limited report from
19 them, because they won't have everyone.
20 There's no way of them measuring the
21 overarching denominator, which is what we're
22 talking about.

1 CHAIR MORRIS: Okay. I think what
2 we need here is more information, and then
3 basically to hold another vote, all right.
4 Anything else before we move on, Melinda?

5 Let's move on to the next measure.
6 So that was a good discussion, and we'll
7 probably touch on it in our upcoming measures.

8 DR. BURSTIN: The first measure --
9 just to make you feel better, the first
10 measure, having now done this for four years,
11 usually takes 90 minutes, so you're ahead of
12 schedule. You're doing fine, and then it just
13 goes much, much faster, because you've kind of
14 gotten it out of your system.

15 CHAIR MORRIS: So we're all warmed
16 up. The next measure is 0114, Postoperative
17 Renal Failure, and Dr. Stafford is going to
18 talk about this.

19 DR. STAFFORD: Thank you. Good
20 morning, everybody. Well, at least on the
21 conference call, this was much easier than the
22 first one. So if that holds true today, I

1 think that will be a little bit better.

2 The title of this measure is Risk-
3 Adjusted Postoperative Renal Failure, and the
4 description of the measure is the percent of
5 patients undergoing isolated coronary artery
6 bypass grafts without pre-existing renal
7 failure, who develop postoperative renal
8 failure or require dialysis.

9 In general, on the conference
10 call, I think all of us agreed that this was
11 important to measure, and there really wasn't
12 any controversy about that.

13 When it came to Scientific
14 Acceptability, there were a number of concerns
15 that we had with the measure, one of those
16 being were there any exclusions for emergency
17 cases, because we know those cases are much
18 more susceptible to the development of renal
19 failure for a whole lot of issues, including
20 need for blood transfusions, as patients are
21 often sicker to begin with.

22 The anesthesia isn't going to be

1 as well-thought-out as an elective-type case.
2 Should there be a specified time window for
3 the development of renal failure, and that was
4 not found anywhere on the documentation that
5 we had. So was this the development of renal
6 failure at 30 days, at 60 days, at one week
7 during the hospitalization?

8 Because it is linked to the
9 process of actually having the bypass graft,
10 the outcome should be measured and should be
11 close in time. So we'd like some more
12 information on that.

13 Let's see. Then, secondly, we had
14 a question about how the definition of renal
15 failure was actually defined, and why wasn't
16 something like RIFLE criteria used in the
17 development of this measure? Then also, how
18 did you just arbitrarily pick a creatinine of
19 two for an exclusion. So we had trouble with
20 the exclusion criteria as well.

21 I'll stop there on the scientific
22 assessment, because I think that was one of

1 the biggest things, and then we can -- the
2 Feasibility was very straightforward.

3 There were some questions about
4 yes, the costs are low for the database, but
5 there was nothing in the documentation about
6 the cost of actually hiring people to do your
7 data abstraction. So that actually does cost
8 groups and/or hospitals, and everybody felt
9 that the Usability was not really an issue.

10 CHAIR MORRIS: Thank you. I have
11 a question about what you said, and that is,
12 I thought your first point was that the
13 exclusions were not clearly defined. Is that
14 correct?

15 DR. STAFFORD: The exclusions were
16 defined. What we couldn't tell was why they
17 chose a creatinine of two as an exclusion
18 criteria. So they were defined, but we didn't
19 know where that came from. There was no
20 documentation for that.

21 DR. DUTTON: Just had the science
22 point there, and this may be a suggestion more

1 for future measure development or expansion of
2 this, but wouldn't we also be interested in
3 renal failure worsening in patients who
4 already have it?

5 DR. CIMA: I had one question
6 about the denominator. When they say isolated
7 CABG, in the risk adjustment from the STS, or
8 whatever the listing, is there -- what about
9 patients who've had a prior CABG, and you're
10 doing a reop?

11 We know in almost all surgical
12 practices, orthopedics, cardiac, that patients
13 who have had prior surgery, you know, are at
14 higher risk for complications or a sicker
15 patient they're different.

16 I couldn't see anywhere in the
17 denominator that there's anything about
18 reoperative patients, because you know,
19 there's another measure about using an
20 inferior mammary artery.

21 Well, what if that's been used,
22 and now you're coming back and doing two new

1 vein grafts? I mean, is that anywhere in
2 there? I didn't see it anywhere in here.

3 DR. SHAHIAN: Rich, you want to
4 take that, or do you want me to respond?

5 DR. PRAGER: David, you can
6 respond. I was waiting for all the questions.

7 DR. SHAHIAN: First of all, we
8 have in general tried to avoid exclusions. We
9 feel it's much better to include significant
10 factors such as reoperation or emergencies,
11 the two that you've mentioned, to include them
12 in the risk model. In fact, those sorts of
13 things are included in the risk model. So
14 that's how we deal with those particular
15 things. We try to avoid exclusions.

16 Second, in terms of the specific
17 cutoffs that were used, greater than two and
18 two times preop, those really have historical
19 roots. In discussions with a nephrologist at
20 the time, I think there have been probably
21 more sophisticated subsequent definitions.

22 But I don't think these are that

1 far different, and for the sake of
2 consistency, so that we can actually look at
3 this particular complication over years and
4 decades literally, we basically decided to
5 leave it as it is.

6 We had a lengthy discussion about
7 this when we had our specification upgrade
8 earlier this year. We discussed RIFLE and
9 similar definitions.

10 But we decided for the sake of
11 continuity and consistency, that it was a
12 reasonable enough definition that we would
13 just retain it as it is. And the question was
14 also asked about the time frame.

15 DR. PRAGER: Right.

16 DR. SHAHIAN: We have limited the
17 measurement of post-operative renal failure,
18 and in fact all complications other than death
19 and sternal infection are limited to the in-
20 hospital, index hospitalization.

21 DR. STAFFORD: Great. That helps
22 a little bit. So I would have two questions

1 for you. So you talked about consistency in
2 terms of keeping your definition. I have a
3 little bit of a problem with that, because the
4 RIFLE criteria is now being used by everyone.
5 It helps you define where your patients are,
6 where they start, where they go.

7 We have to code our patients that
8 way in the ICU for our coding purposes. So
9 I'm a little concerned that you decided, after
10 all of that discussion, to leave something
11 like that out, just because it makes it easier
12 to measure.

13 The fact of the matter is
14 everybody measures creatinine. These patients
15 usually get daily creatinines at least in the
16 early part of the hospital stay. So I can't
17 see that it would be that much more difficult
18 for people to collect that data for you, and
19 I think on a national level it would make the
20 data, for those people who are going to look
21 at it, a lot more robust.

22 So that would be one point about

1 that. But I do appreciate that you're
2 measuring it within a 30-day hospitalization.
3 However, what do you do with a patient who's
4 been in the hospital for quite some time?

5 They sailed through their coronary
6 artery bypass graft and at the end of two
7 weeks, you know, they maybe stayed a little
8 longer than usual and they're about ready to
9 go home. Then they have a GI bleed or they
10 perforate a tic in their colon, end up having
11 emergency surgery and then developing renal
12 failure then.

13 So there could be a problem with
14 ascertainment bias, because that renal failure
15 may not be related to your coronary artery
16 bypass graft.

17 DR. SHAHIAN: Anything that
18 happens in the hospitalization after the
19 coronary bypass is something that we own. So
20 you know, if the patient had a GI bleed that
21 led to a cascade of complications including
22 renal failure, we own it. That's the way

1 we've always done it, and I think that's the
2 right way to do it.

3 DR. SEARS: David, one other
4 question. What about patients who have pre-
5 operative catheterizations? We all know that
6 dye can be renal nephrotoxic. So do we take
7 that into account?

8 DR. SHAHIAN: No. I think that's
9 part of the game. I think you should, unless
10 it's an emergency, you have some latitude in
11 when you schedule a surgery.

12 If the patient has any evidence of
13 pre-catheterization renal insufficiency,
14 hopefully they've gotten appropriate measures
15 during their cath to try to mitigate the
16 possibility of post-operative renal or post-
17 cath renal failure, and their renal function
18 should be checked, and I think you have the
19 responsibility to have the patient in the best
20 possible shape.

21 On the other hand, if it's an
22 emergency and they get a cath, yes, they are

1 going to be at higher risk. But I think
2 there, the emergency status that's included in
3 the risk model will help to account for that.

4 DR. HALPERN: I have a question.
5 Before you said it was only in-hospital
6 changes in creatinine. So let's say the
7 creatinine was sort of trending up but didn't
8 hit your threshold prior to them leaving the
9 hospital, and then two weeks later, after
10 discharge, come up with a creatinine that
11 meets your threshold. Do those get captured?

12 DR. SHAHIAN: No.

13 DR. PRAGER: No, no.

14 CHAIR MORRIS: Any other
15 questions? Did you feel that your question
16 about the source of exclusions was answered,
17 Dr. Stafford?

18 DR. STAFFORD: Not really. I mean
19 it clearly was listed, but I didn't really --
20 I mean, they talked about it, but I didn't get
21 where that actually came from. Where did that
22 data come from? How did you come up with that

1 definition?

2 DR. PRAGER: You know, I'm not
3 sure. Unless David or Jane can be more
4 specific, I'm not sure I can answer that
5 either, how the definition originally became
6 part of the measure.

7 DR. SHAHIAN: This goes back
8 probably a decade or more.

9 DR. CIMA: So this is a historical
10 definition used by just STS?

11 DR. PRAGER: I'm not sure we
12 invented it, frankly, so as David said, this
13 came from discussions. I'm not sure we're
14 privy to it at this point.

15 DR. CIMA: No, but what I'm saying
16 is that this is something that the STS has
17 built into their criteria --

18 DR. PRAGER: Yes.

19 DR. CIMA: And have been using it?

20 DR. PRAGER: Correct.

21 DR. CIMA: So for consistency
22 purposes, they're continuing to use it?

1 DR. PRAGER: Correct.

2 DR. CIMA: But if there's new data
3 or something out there, if you want to use
4 your risk model, you have to continue to use
5 this?

6 DR. PRAGER: At this point,
7 correct.

8 DR. STAFFORD: But the risk model
9 could be adjusted for RIFLE criteria?

10 DR. PRAGER: David, do you want to
11 take that?

12 DR. SHAHIAN: I'd have to go back
13 and look at the criteria. But don't the RIFLE
14 criteria require an assessment at a longer
15 period of time?

16 DR. STAFFORD: No, actually they
17 don't. You can assess it during the
18 hospitalization.

19 DR. DUTTON: I guess this is going
20 to be a common issue with a lot of different
21 measures that we talk about. I mean, this
22 measure was created 25 years ago. They took

1 their best guess at what the criteria is, and
2 they've stuck with it, which has made it very
3 consistent for repetitive use and reporting.

4 Now we have a better understanding
5 of the disease and we want different criteria.
6 One reason not to change would be to allow
7 continued comparisons with the past.
8 Obviously, there's a science reason to change,
9 because we think we defined the disease. I
10 think we're going to see that tension in a lot
11 of these measures.

12 Then there is the additional
13 burden of data collection, and the real
14 question about RIFLE is does that require data
15 that the STS is not capturing now?

16 CHAIR MORRIS: So I think that
17 that's, you know, that's really why we're
18 talking about maintenance here. Maintenance
19 is for upkeep, and if upkeep includes
20 upgrading the way that criteria are defined
21 and collected, then that's what we're here to
22 do. Just because it -- oh, I'm sorry.

1 DR. BURSTIN: And if there is a
2 national standard, and I just looked it up.
3 The RIFLE criteria certainly looks like that
4 is the national standard, I assume STS already
5 has creatinine and urine output, which is
6 really all that's required to compute it.

7 There's a long history of measures
8 that do change based on changes in evidence,
9 changes in process. So certainly, I think, if
10 the Committee thinks that's important, it
11 would be an important consideration for STS to
12 consider.

13 DR. STAFFORD: And actually the
14 RIFLE criteria requires either/or. So you can
15 make the definition based on creatinine, which
16 you're already capturing, or urine output
17 change. So either one, and if you're already
18 calculating creatinines, then it shouldn't be
19 that much more in terms of the database.

20 DR. WILHOIT: A couple of other
21 things, and this is, you know, throughout the
22 STS measures, but a couple of things that were

1 a little bit troubling to me. One is like in
2 2.A-8, the denominator details. The
3 denominator is defined in terms of the STS
4 database, but there's not a specification that
5 you need to be using the STS database.

6 And yet you can't get to the
7 details without using the STS database. So
8 that troubled me throughout the measures, that
9 it seemed like if it's contingent upon STS, I
10 can live with that. I don't have a problem.
11 But it would be better for me to be upfront
12 about that.

13 But the way the denominator
14 details are written, you can't read the
15 details and understand what it is without
16 going through all of the fields in the
17 database and trying to understand what they
18 mean. There's no clear specification as to
19 what it means to be in the denominator. It's
20 just all based on fields, which you need to
21 understand the database for.

22 The second thing that's troubling

1 to me, and again, this goes throughout, is in
2 2.C-3, the testing agreement rate, the -- you
3 know, there's a number here that for renal
4 failure there was a 98.5 percent agreement
5 rate.

6 Well, if you reviewed 200 cases
7 and only three people had renal failure, there
8 might have been disagreement, I think; I'm not
9 sure how that's defined, but I think you might
10 have disagreed on all three cases. But yet it
11 comes up to a high number because most people
12 didn't have renal failure and it wasn't
13 relevant.

14 So I'm not sure how that's
15 defined, but I never knew quite how to
16 interpret those numbers for the agreement
17 rate, because I'm not sure how many of the
18 cases reviewed had the outcome of interest.
19 And there's no numerator, there's no
20 denominator.

21 So again, it's left to me, the
22 reader, to assume that the data are good, but

1 I don't really have any basis for agreeing or
2 disagreeing.

3 CHAIR MORRIS: One of the other
4 issues that was raised, I think by Dr.
5 Stafford, was sort of the feasibility
6 question, and that was the cost of the data
7 abstraction. Is that something that we tend
8 to get into here, talking about that aspect of
9 feasibility? Does the STS have any response
10 to that?

11 DR. PRAGER: The cost of data
12 abstraction? We do in the abstract, in that
13 we have -- certain of us have calculated the
14 cost for data management, if you will, and
15 abstraction, and at least in certain areas of
16 the country done it on an FTE basis of to
17 enter 500 cases into the database, and the
18 database is getting, is more robust now. So
19 there are more variables to enter and will be
20 more in July.

21 Having said that, it is one FTE
22 ballpark for 500 cases. That FTE, though, can

1 range, frankly, from a data manager who's a
2 nurse practitioner with a great deal of
3 experience, to someone who is looking at the
4 chart and is a coder. So salary would range
5 then between those two. David, do you have
6 any other thoughts from Massachusetts?

7 DR. SHAHIAN: No. I think that's
8 right. I think there are many institutions
9 that do this with FTE. There are small
10 programs that do it with part of an FTE, and
11 it's the data abstraction costs that are the
12 major costs. Our actual costs to be a
13 participant are really quite small. So it's
14 data abstraction that is the cost.

15 DR. STAFFORD: And I think that's
16 important, and just you don't address that in
17 the application. So if you had -- the
18 application just says the cost is minimal and
19 it's really just related to the database.

20 But we all know that it isn't, and
21 so I think to be open and transparent about
22 the process, you should at least say it may be

1 one half to one FTE per 500 cases, and then
2 institutions can figure out how they would
3 want to spend that money and what kind of FTE
4 they would want to have.

5 But I think in the application,
6 that needs to be clear. It's not just the
7 cost of the database itself.

8 CHAIR MORRIS: Okay. Any other
9 questions about this measure? So just to very
10 briefly summarize, the source of the
11 exclusions is a historical decision-making
12 process by the STS. The time window is the
13 hospitalization itself and not after the
14 hospitalization has concluded.

15 The definition of renal failure is
16 based on a previous definition which the STS
17 decided to continue for comparison purposes
18 over time, and does not correspond to what
19 sounds to be the current standard, the RIFLE
20 criteria. The cost of data abstraction
21 includes one FTE for 500 cases, and that cost,
22 of course, would vary, depending on whose FTE

1 we're talking about.

2 And then the exclusions are
3 minimal in order to capture all cases, but
4 they are -- but some of the potential
5 confounders would be adjusted for in the
6 model, including things like previous
7 operation, previous use of the internal
8 mammary artery potentially, or other potential
9 influences on the outcome.

10 There is a desire for a clearer
11 specification of the numerator and
12 denominator, and ultimately for a clearer
13 definition of renal failure, which I guess is
14 that last one I already said. Anything else
15 that anybody's concerned about with this
16 measure before we vote?

17 DR. WILHOIT: One question I have
18 is with something like the time window, which
19 is during the hospitalization is what we were
20 told, but it's not in the write-up, it seems
21 like that's just really, really key to have in
22 the documentation, and it's not there at all

1 right now.

2 So what's the process? Do we have
3 to basically turn down this measure in order
4 to request that that be added, or what's the
5 process for that?

6 MS. MURPHY: The process is that
7 you vote on the measure as specified, and if
8 it is voted down, then you have the
9 opportunity to ask that certain conditions be
10 met, be reconsidered.

11 DR. WILHOIT: So then just to
12 clarify, the only way to get, to request that
13 the time frame be added to the measure is to
14 turn it down?

15 MS. MURPHY: If there's
16 information that can be provided to clarify
17 what is in fact the case, then that
18 information could be brought forward, yes,
19 without having to vote it down. So if it's
20 something that is known and just was omitted
21 from the documentation, then that could be
22 clarified here and now even, and be able to

1 vote on that, yes.

2 DR. HALPERN: I think what she's
3 asking, though, is -- I think what you're
4 saying is you feel uncomfortable voting on it
5 affirmatively if it's not in writing, or at
6 least going to be added?

7 DR. WILHOIT: And I think --
8 right. But maybe not, I mean, I trust it.
9 That's not the issue on that, and that's
10 pretty clear. But in terms of the measure
11 that goes forward, the way it's documented for
12 the public, the way it's documented for public
13 review, the way it's documented for the next
14 time it's reviewed, it just seems like it's
15 really, really key that it be there.

16 And the fact that we understand it
17 in this room today is one thing; whether we'll
18 remember it in six months when we look at it
19 or whether somebody else reading the measure
20 has the opportunity to have that information
21 is different. And it seems to me like that's
22 really important to have in the document

1 itself.

2 DR. BURSTIN: And that's certainly
3 something you can request as part of the
4 follow-up from the measure developers, to
5 clarify that whatever needs to be in the
6 documentation gets added to the documentation.

7 I think the issue that you raised
8 though, about whether they would shift to the
9 RIFLE criteria, I think, is something more
10 substantive that you would need to potentially
11 make a condition if you thought that was
12 appropriate.

13 DR. CIMA: Just one question to
14 clarify. This has penetrance of about 93
15 percent, they said, STS. So what about the
16 organizations -- this is a separate measure
17 from the one we discussed previously. What
18 about organizations that don't participate in
19 STS? How are they going to report? This is
20 a national quality initiative. They only have
21 five percent of the practices that don't
22 participate.

1 DR. WILHOIT: And the denominator
2 definition requires the STS fields. So the
3 denominator definition is not really flexible,
4 at least as I read it, to take data from some
5 other sources, or would require a ton of work
6 to map and create the STS fields in some other
7 database.

8 DR. CIMA: And to further that, my
9 concern about, you know, emergency case versus
10 a reop CABG was mentioned that that's in the
11 risk adjustment model. But that means then
12 you have to be using that model to adjust your
13 patients, which therefore mandates that you
14 participate in STS.

15 DR. BURSTIN: The model is fully
16 transparent. They give you the actual
17 intercepts, the whole thing, published
18 annually. So somebody could conceivably take
19 it and run it. They would unlikely be
20 submitting it then to STS. It would be
21 something they might do on their own, so they
22 could then -- to STS?

1 DR. CIMA: So that's an additional
2 burden that they would have to do, a reporting
3 burden? No, it's not potentially. It is,
4 right?

5 DR. BURSTIN: If they choose to do
6 it, yes.

7 DR. CIMA: Yes.

8 DR. DUTTON: I think the
9 fundamental question is about the difference
10 between a measure steward and somebody
11 reporting on a measure. So that the steward's
12 job is to put out a rational measure that
13 makes sense of quality, that if we were going
14 to define quality, this is how we would do it
15 in this area.

16 Presumably, in most cases, the
17 steward is also going to be reporting on the
18 measure, because they have some expertise in
19 it. But it doesn't, as long as it's
20 transparent, it doesn't preclude anybody else
21 from reporting on that also; correct?

22 CHAIR MORRIS: Anything else

1 before we vote?

2 DR. HAN: This is Jane Han from
3 STS. If I may add just regarding how the
4 specifications and the field names are
5 presented. As the measure developer and
6 steward, we are instructed to provide detailed
7 specifications that we can measure and report
8 upon and maintain.

9 So we use data field names that
10 are used in the STS database for that purpose.
11 But data specifications, definitions, code
12 names and what they stand for, they're all
13 provided in the supplemental documentation
14 that we provide, and it's also publicly
15 available on the STS website.

16 So it's not that we are mandating
17 that STS be used. As Dr. Burstin had stated
18 earlier, everything is transparent and
19 available online. So it can be used by,
20 theoretically by organizations that don't
21 participate in the database. It's a
22 preference that they do, but it's not

1 necessary.

2 CHAIR MORRIS: Okay. Did you have
3 one more thing to say before we vote?

4 MS. ZAMBRICKI: Just one more
5 thing. It seems that there are going to be a
6 number of measures where this issue is going
7 to come up. So I think it's really important
8 for us to talk about the content of the
9 measures, and to recognize that this same
10 fundamental discussion about the source and
11 the stewardship and the options is going to be
12 there.

13 I wonder if it would be possible
14 for our learning, for staff to do some type of
15 a summary of the different potential measure,
16 I don't know what they're called, like STS and
17 the others that have been named.

18 Not stewards, because the stewards
19 are the one that brings the measure forward,
20 but the VA, the different systems that are to
21 collect this information on a multi-clinical
22 site basis, and whether or not they do collect

1 the specific measures that we are asking for
2 down the line, like renal failure, like
3 mortality within 30 days, etcetera.

4 Because I personally don't have
5 any knowledge of the other ones on a basis,
6 and is it possible to know what the enrollment
7 is in those other systems, so we know what the
8 scope is?

9 DR. BURSTIN: Just to try to set
10 some benchmarks, just to be clear, you know,
11 we have endorsed measures from STS in the
12 past. We have in fact brought in a couple of
13 NSQIP measures last year. We have numerous
14 measures that emerge out of the American
15 College of Cardiology registry database.

16 CMS has adopted several of the
17 NSQIP/ACC measures, and has actually put it
18 forward that you can either submit to NSQIP or
19 ACC, or here, they're going to be developing
20 an alternative data platform for you to submit
21 the data individually.

22 So I don't think in and of itself

1 we view the registry as being something that
2 would hold you back from saying the measure is
3 well-defined, all -- it meets the criteria.
4 One of the issues is when you get to
5 Usability, and we've talked about this a
6 little bit in the past, is this issue of does
7 the data -- since they are both the steward as
8 well as the holder of the data, what's the
9 transparency of the data, which has been
10 certainly something that's come up in the
11 past.

12 But the bottom line is we have
13 felt very comfortable endorsing those measures
14 because the steward is fully transparent.
15 Everything is available. Again, I understand
16 it's clearly a burden, but it's a burden if
17 you're in or you're out, and you're collecting
18 your data some way.

19 So that those data are available
20 -- the measure specifications are fully
21 transparent is our requirement. We can't
22 force hospitals or use or not use it. We

1 don't make the ultimate decision. The end
2 users do, whether that's CMS or other payors
3 that says you must use X, you must use Y.

4 But the NQF endorsement is there
5 to indicate that the measure is important,
6 reliable, valid, precise specifications to
7 compare, usable and feasible. We can't make
8 the ultimate end decisions. That's for others
9 to make.

10 But how the measure gets used if
11 it's picked up for payment, if it's picked up
12 for public reporting, your job is to say do
13 you think the measures meet the standards that
14 we've set forth.

15 I do think the issues around
16 feasibility are fair play, the amount of
17 burden in terms of collecting these data are
18 things that are going to come up on all, on
19 many of these measures, because they are such
20 rich outcome measures.

21 It's hard to do them quickly off
22 of claims data, for example. But I don't

1 know, as was pointed out. You don't have the
2 information in front of you of the other
3 competing, more regional registries. I think
4 it would be difficult for you to really make
5 that assessment today.

6 DR. STAFFORD: Helen, I think your
7 point about trying to separate the two in
8 terms of we put the endorsements out there and
9 other groups, whether it's CMS or even JCAHO
10 may adopt them, or AHRQ or whoever wants to
11 look at them, it's up to them.

12 But I think what everybody, what
13 I'm hearing underneath all of this is that
14 everybody realizes that they aren't totally
15 separate, that if NQF puts something out
16 there, the likelihood of CMS adopting
17 something is actually probably going to be
18 pretty good.

19 So they are linked, and I think
20 that's the importance that you're hearing
21 everybody really struggling with thinking
22 about this, about you know, putting a winner

1 out there, because that's exactly what does
2 happen. We know that's what happens, and
3 while it may not be NQF's goal to have that
4 happen, it's the reality.

5 DR. BURSTIN: And that's true, and
6 I think you can only evaluate what's before
7 you today, I guess would be my last comment.
8 You've only got this one on the table. We
9 don't have something else for you to look at
10 that you think is superior or not superior.

11 So I think you have to weigh the
12 criteria and think about whether it's worth
13 having a measure like this out there, to drive
14 public reporting and quality improvement in
15 the field of cardiac surgery.

16 CHAIR MORRIS: Let's move on to
17 the vote. So the first criteria is Importance
18 to Measure and Report.

19 [COMMITTEE VOTING.]

20 CHAIR MORRIS: Our results are 100
21 percent of the people said yes. 22 responders
22 said it's important to report. Second item is

1 Scientific Acceptability of the Measure
2 Properties.

3 [COMMITTEE VOTING.]

4 CHAIR MORRIS: And we have 3 say
5 completely meets criteria, 18 say it partially
6 meets criteria and 1 says that it minimally
7 meets criteria. Next is Usability.

8 [COMMITTEE VOTING.]

9 CHAIR MORRIS: And we have 12
10 responders who say that it completely meets
11 criteria for Usability, 9 say it partially
12 meets criteria and 1 says not at all. Next is
13 Feasibility.

14 [COMMITTEE VOTING.]

15 CHAIR MORRIS: We have 14 said it
16 completely meets criteria for Feasibility, 8
17 say that it partially meets the criteria for
18 Feasibility. Then our last vote is does the
19 measure meet all of the NQF criteria for
20 endorsement, and we raised a couple of issues
21 here.

22 One was the definition of renal

1 failure. Another issue was clarification of
2 the time window in the language of the measure
3 itself not within the supporting documents.
4 Another issue that was raised was the cost of
5 data abstraction.

6 Clearly, if data is to be
7 abstracted, somebody bears the cost. Then
8 request for clearer specification of the
9 numerator and denominator in the language of
10 the measure itself, again not in supporting
11 documents. Let's go ahead, and if there's any
12 more discussion, please feel free to go ahead
13 and bring it up.

14 DR. ROGERS: It's still not clear
15 to me what it takes for the NQF to endorse it,
16 with respect to complete or partial. I
17 realize this is a yes/no, but after we're done
18 all our work today and tomorrow, what happens
19 next? I mean what does it take for the stamp
20 to actually be put on? Perhaps others
21 understand it; I don't.

22 DR. BURSTIN: This is still fairly

1 early in the process. You'll have a chance to
2 have the responses back from the developers.
3 You'll then ultimately compare to other
4 measures.

5 Potentially, if there are
6 competing measures in the portfolio, for
7 example, you will then make a recommendation
8 that will go forward for public comment,
9 public and member comment. We get lots of
10 those.

11 You'll have a chance to wade
12 through those, see if any of those public
13 comments sway your opinions, and it will then
14 ultimately go out for member vote and to our
15 Consensus Standards Approval Committee, which
16 is a board-level committee that reviews it and
17 the Board, and then an appeals process. So
18 you're still fairly early overall.

19 But your question is a really
20 important one, in terms of what's the
21 threshold of passing, and I think that, you
22 know, this is -- if it was a simple

1 mathematical formula, we wouldn't need all you
2 guys to sit here since we have your votes.
3 It's not.

4 Other than having a must pass
5 criteria of Importance to Measure and Report,
6 and a hierarchy for Scientific Acceptability
7 as being the next one, this really does get
8 into your expert opinion as to whether or not
9 at the end of the day, seeing how you voted,
10 do you think the measure is appropriate to
11 move forward.

12 DR. ROGERS: So potentially then a
13 no vote at this point in time can easily be
14 changed to a yes vote, if some of the
15 questions that are brought up in this
16 conversations are satisfactorily answered?

17 DR. BURSTIN: Yes.

18 DR. ROGERS: Okay.

19 DR. KLEINPELL: And then
20 conversely, Helen, if we do have a yes vote,
21 will all of the comments that Arden
22 identified, will they be addressed per our

1 request, or do we really have to have a no for
2 those to really go forward?

3 DR. BURSTIN: I think we would
4 still send them to the developers for their
5 response. It doesn't necessarily mean that
6 you would say, for example, going back to the
7 point that was raised earlier, what you
8 wouldn't necessarily say is that you're voting
9 it with conditions "I will only take this
10 measure if you make the following change."

11 Which I think it would be very
12 reasonable to pass the comments that Renae
13 made about, for example, the RIFLE criteria
14 aren't here and get their response, and then
15 you would weigh that in your final decision.

16 CHAIR MORRIS: Okay. So let's go
17 ahead and vote on this final one. On the
18 question of whether the measure meets all
19 criteria for endorsement, we're again very
20 close. 12 voted yes, 10 voted no.

21 [COMMITTEE VOTING.]

22 CHAIR MORRIS: So the majority

1 voted yes, but we have -- obviously we have
2 some issues that a substantial proportion of
3 the group need to have answers on. Okay. Can
4 we move on to the next measure? What time is
5 it? Oh, it's 11:15.

6 Do you want to take a short break?
7 Okay. Let's take a short break. I think
8 we're scheduled for 15 minutes from 10:00 to
9 10:15. So our break is over now. Just
10 kidding. Let's just take a ten minute break,
11 if you would, and come back to the room in ten
12 minutes.

13 (Whereupon, the above-entitled
14 matter went off the record at 10:20 a.m. and
15 resumed at 10:42 a.m.)

16 CHAIR MORRIS: Dr. John Martin was
17 going to go ahead and describe the next
18 measure, Surgical Reexploration. That's 0115.

19
20 DR. MORTON: Thank you. This is
21 Measure 0115, and it refers to risk-adjusted
22 surgical reexploration, and the steward of the

1 measure is STS.

2 The description is percent of
3 patients aged 18 years or old undergoing
4 isolated CABG who require a return to the OR
5 for bleeding, with or without tamponade, graft
6 occlusion, valve dysfunction or other cardiac
7 reason.

8 Numerator is, as mentioned before,
9 those number of patients who had the
10 descriptor event, and the denominator is all
11 patients undergoing isolated CABG.

12 So in terms of looking at the
13 criterion, this is clearly in the public
14 domain and interest. It's actually one of the
15 PQRI measures from CMS as of 2009. It's
16 Measure 168. I'm going to resist the
17 temptation of saying that this is an easy
18 measure to endorse, given our previous
19 discussion.

20 But this is actually an
21 interesting measure, in the sense that the
22 database doesn't have to be STS. Many, many

1 hospitals around the country maintain some
2 sort of reop data collection through their OR
3 systems like Midas and things like that. So
4 theoretically, that data can be obtained
5 through a variety of measures.

6 In terms of validity, it's got
7 very strong correlation to complications,
8 certainly with bleeding. If there is a
9 reexploration, there's an increased risk of
10 other downstream complications such as
11 mediastenitis, which is a hospital-acquired
12 condition.

13 There's a definite correlation to
14 cost. There are some implications around
15 transitions from the pump team to the ICU, and
16 in a way, this was presented as kind of a
17 mini-readmission, if you will, within the
18 episode of care.

19 With all that being said about its
20 validity, there were some questions that came
21 up in looking at the measure as written. The
22 first question is for a return to the OR, why

1 is it only for cardiac reasons? In looking at
2 the literature, about 80 percent of the
3 reasons for a return to the OR because of
4 bleeding or graft occlusion.

5 But there are circumstances for
6 things like infection or a retained foreign
7 body. The other issue that came up is why is
8 there risk adjustment at all. In some ways,
9 does this obscure opportunities for quality
10 improvement? If it's risk-adjusted, we don't
11 find out exactly which specific conditions or
12 procedures will lead to this return to the OR.

13 Just like the previous measure
14 about timing, this was left open-ended. Some
15 of the concern about the timing definition is
16 mitigated by the fact that it's strictly about
17 cardiac. If we do open it up for other
18 reasons, then perhaps that timing issue should
19 be better-defined.

20 One kind of procedural issue is
21 there appears to be a little bit of a conflict
22 between the denominator statement saying all

1 patients undergoing isolated CABG, which
2 interprets to mean strictly CABG, no valve.
3 But if you look at the descriptor, it says
4 "valve dysfunction."

5 So some way or another, that needs
6 to be resolved. Those were essentially the
7 main questions about the measure itself.

8 CHAIR MORRIS: Thank you. Was
9 there anything else from the group or anybody
10 else want to bring up any issues or concerns,
11 questions about the measure?

12 DR. HALPERN: I would say I
13 actually agree with just looking at cardiac
14 complications, since that's why you're doing
15 the surgery, and I think the valvia
16 dysfunction probably relates to possibly
17 clotting up one of your coronary vessels,
18 which can lead to acute valve dysfunction.

19 CHAIR MORRIS: Any other issues or
20 concerns? Dr. Martin.

21 DR. MORTON: I guess, you know,
22 the only thing about the risk adjustment,

1 again, the risk adjustment is made through the
2 case mix adjustment model that's in the
3 attachment from STS. Again, it's open, so
4 anybody can access it.

5 Just more of a philosophical point
6 about, you know, do we really need to continue
7 to do the risk adjustment. If you dig into
8 it, as to reasons why the risk factors for
9 reexploration, they tend to be about non-
10 modifiable risk factors, age and things like
11 that.

12 So risk adjustment looks like it's
13 appropriate to maintain, but just out of
14 philosophy it would be nice if we moved beyond
15 risk adjustment and just looked at the measure
16 itself.

17 CHAIR MORRIS: I have a question
18 for the STS. Did you all discuss this amongst
19 yourselves, and think about changing risk
20 adjustment, or having arguments for keeping
21 versus changing it?

22 DR. PRAGER: I don't know if

1 David's on the line. David, are you on?

2 DR. SHAHIAN: Yes I am, and I
3 would respectfully disagree with the issue on
4 risk adjustment. We know from national data
5 that there is very substantial variability
6 across institutions in the prevalence of high
7 risk characteristics.

8 For example, a small community
9 hospital that does 150 cases a year has a much
10 different patient population, or hopefully
11 has, than the Cleveland Clinic. That's cases
12 from all over the country that nobody else
13 wants to do.

14 To account for the differential
15 risk in the patients between those two
16 institutions, that really imposes an unfair
17 burden on the institutions that are taking
18 those sort of last resort sorts of cases. So
19 we believe strongly that risk adjustment is
20 essential.

21 In terms of the question on valve
22 dysfunction, you're right. Acute coronary

1 occlusion can lead to that, or you can have a
2 patient where you have a two plus
3 microregurgitation. You're not sure whether
4 you want to do something or not, and you end
5 up not doing the mitral valve repair.

6 Then the patient develops heart
7 failure secondary to what in fact has now
8 become three or four plus microregurgitation.
9 So that's the valve dysfunction.

10 And you know, we -- this was
11 intended to be a cardiac reoperation measure.
12 There are other reasons that patients come
13 back to the OR, but this is specifically
14 designed as a cardiac reop measure.

15 DR. MORTON: I guess the only
16 question I had about cardiac reop, right now
17 it's essentially for bleeding, graft
18 occlusion, valve dysfunction. There can be
19 kind of a cardiac-related reason in terms of,
20 you know, mediastenitis and things like that,
21 where you reopen.

22 Or a routine foreign body was the

1 other one. Even though it's rare, it looks
2 like the vast majority of returns to the OR
3 fulfill the criteria. But those were other
4 considerations.

5 DR. SHAHIAN: To capture the
6 reexploration for mediastenitis, we capture
7 that separately, and I think that's another
8 measure that will be coming up at some point,
9 captured separately.

10 CHAIR MORRIS: And I think the
11 other -- I'm sorry, go ahead.

12 DR. MORTON: No. I was just going
13 to add what David said, as we do for retained
14 foreign bodies and things like that, a
15 separate capture.

16 DR. DUTTON: I wanted to raise the
17 question about this measure, and it might
18 apply to a couple of the others. Are we
19 creating an unintended consequence here? We
20 would like to think that the decision to
21 reoperate on a patient would be cut and dried
22 and absolute, and applied the same way by

1 every surgeon every day.

2 But I've certainly stood around
3 the ICU looking at people bleed, and trying to
4 decide do we transfuse them or do we give them
5 Factor 7, do we go back into the OR? While we
6 have the subject matter experts here on and on
7 the phone, how do you do that in gathering the
8 data? How do you prevent gaming it by, for
9 something that's publicly reported like this?

10 So it has some --there's some
11 paranoia around it. Can the surgeon make his
12 rate lower by choosing not to reoperate on
13 people, and you know, how do audit for that?
14 How do you see, make sure that doesn't happen?

15 DR. SEARS: Can I ask one other
16 question as well, sort of a corollary to that.
17 We don't have any exclusions here, and have
18 you taken into account some of the newer
19 therapies that are being used by cardiology,
20 the anti-platelets in particular?

21 Are they part of the risk
22 adjustment, or do we need to be considering

1 those, because those certainly increase the
2 level of bleeding post-operatively?

3 CHAIR MORRIS: Dr. Prager.

4 DR. PRAGER: As far as the gaming,
5 obviously certainly in our field, there are
6 criteria to be considered when someone should
7 be reexplored, and at training institutions
8 they become a mantra for the residents as well
9 as the faculty. If you're asking me could
10 this be gamed by having a surgeon give
11 platelets, plasma, wait it out, and the answer
12 is if that's gaming, the answer's yes.

13 There are other surgeons, frankly
14 because we see this when we look at rates,
15 whose threshold for going back to the
16 operating room is a very different threshold.
17 They'll go back earlier, because they don't
18 want to give blood, they don't want to give
19 plasma.

20 So I think on balance, we actually
21 balance out. But can we measure the gaming?
22 The answer to that's no. Yes, we know if

1 patients are going to the operating room on
2 active anti-platelet therapy, and can you
3 tease that out eventually? Yes. If someone
4 did a study, we could tease it out eventually.

5 DR. SEARS: So for right now, we
6 don't list those as exclusionary?

7 DR. PRAGER: No, they are not
8 exclusionary.

9 CHAIR MORRIS: Are they included
10 in the model?

11 DR. PRAGER: I don't believe --
12 David, are they included in the risk model?
13 I don't believe so.

14 DR. SHAHIAN: There were -- that
15 did not fall out as a, actually as a
16 significant predictor. The question, though,
17 about the gaming, I think, would apply to
18 every single measure that I'm aware of, not
19 just in cardiac surgery but, you know, every
20 measure that's out there, I think, is
21 potentially gameable, potentially can have
22 adverse influence on physician behavior.

1 I think at some level, we have to
2 trust the ethics and the good medical practice
3 of our colleagues. We cannot police gaming,
4 nor can we eliminate any adverse consequences
5 that might result from attempts to make one's
6 score better.

7 This is true in mortality
8 reporting, where risk aversion is such a
9 concern. It's very hard to police that.

10 CHAIR MORRIS: Okay. I think it's
11 a good issue to bring up and air, just because
12 it always comes up in private conversations,
13 and better to address it explicitly. I agree
14 with what you said, Dr. Shahian. So in terms
15 of exclusions, sounds like really not, no
16 exclusions here.

17 But that you already examined for
18 what would fall out as predictors, in order to
19 adjust for those in the risk model. Then the
20 last question I think Dr. Morton brought up
21 was the timing of collecting this data.
22 Should we assume that this is during the index

1 hospitalization, or is the timing otherwise
2 specified?

3 DR. PRAGER: It's during the whole
4 hospitalization.

5 CHAIR MORRIS: Not a 30-day window
6 or --

7 DR. PRAGER: Not for this.

8 CHAIR MORRIS: Any other
9 discussion on that before we move to a vote on
10 the criteria?

11 (No response.)

12 CHAIR MORRIS: All right. Well,
13 let's go ahead. So the first criteria,
14 Importance to Measure and Report. I'd like
15 everybody to go ahead and cast your vote.

16 [COMMITTEE VOTING.]

17 CHAIR MORRIS: And the result is
18 that 22 out of 22 said yes, this is important.
19 The second criteria, Scientific Acceptability
20 of Measure Properties.

21 [COMMITTEE VOTING.]

22 CHAIR MORRIS: We have 19 that

1 said completely meets criteria for scientific
2 acceptability, and 3 said it partially meets
3 criteria. Next, Usability.

4 [COMMITTEE VOTING.]

5 CHAIR MORRIS: 20 of us said that
6 it completely meets Usability criteria, and 2
7 of us said that it partially meets Usability
8 criteria. Next is the Feasibility criteria.

9 [COMMITTEE VOTING.]

10 CHAIR MORRIS: 21 of us said that
11 it completely meets the Feasibility criteria,
12 and 1 of us said that it partially meets the
13 Feasibility criteria. Then the last vote is
14 does the measure all of the NQF criteria for
15 endorsement?

16 Is there any other comment or any
17 issues that anybody wants to bring up before
18 we go to this one? Dr. Morton, your light is
19 on, but I'm not sure if that means you want to
20 speak.

21 DR. MORTON: No. I'm sorry about
22 the light.

1 CHAIR MORRIS: All right. Let's
2 go ahead and vote then.

3 [COMMITTEE VOTING.]

4 CHAIR MORRIS: We have 22 out of
5 22 say that yes, it does meet the criteria for
6 endorsement. I think this is going to be our
7 fastest measure. The first one is our
8 slowest, and this is our fastest.

9 PARTICIPANT: You were right,
10 John. Maybe you were right.

11 DR. WILHOIT: And the one piece of
12 feedback that John had raised was the time
13 frame, and I think it's worth feedback that
14 that should be incorporated into the document.

15 CHAIR MORRIS: I agree. Okay. So
16 the next measure is 0116, Anti-Platelet
17 Medication at Discharge, and this will be
18 introduced by Dr. Stafford.

19 (Off mic comment.)

20 CHAIR MORRIS: Oh, I'm sorry.
21 You're right. I'm sorry about that. Yes.
22 We're at 0129, Prolonged Intubation. Dr.

1 Stafford.

2 DR. STAFFORD: So on page nine of
3 the handout they gave us today at the bottom.
4 So this is Measure 0129, Risk-Adjusted
5 Prolonged Intubation (Ventilation). The topic
6 is the percent of patients aged 18 years and
7 older undergoing isolated coronary artery
8 bypass grafting, who require intubation for
9 more than 24 hours.

10 Overall, the group felt that this
11 was important. There really weren't any large
12 issues when it came to Importance, and in fact
13 we all felt this was actually very important
14 to measure.

15 When it came to Scientific
16 Acceptability, there were several issues, one
17 of which has been addressed, and that has to
18 do with the time window for the numerator, and
19 we've heard that it's now within the
20 hospitalization. So that's really no issue.

21 Dr. Dutton actually brought up a
22 really good point about some potential

1 confounders, and the largest one being how do
2 you capture, what do you do with the patient
3 who is clinically ready to extubate by all the
4 criteria that we all use in the ICU every day,
5 but is kept intubated longer than that 24
6 hours for some logistic reason, needing some
7 other procedure, say needing to travel for a
8 CAT scan because they're not waking up post-
9 CABG and they need to go for a head CT?

10 So how do you deal with that?

11 It's probably a small effect, but it's
12 something that I think is worth discussing.
13 That was the major issue with that. When it
14 came to Usability, again, Dr. Wilhoit had some
15 issues with the denominator details, more
16 discussion about confounders, and then finally
17 in terms of Feasibility, there really weren't
18 any large issues with the measure.

19 I think one of the larger
20 questions, and it similarly related to the
21 renal failure question and why did STS choose
22 24 hours as a gold standard, as opposed to

1 maybe 48 hours. That's more just a
2 discussion. When we talk about ventilator-
3 associated pneumonias, if you use the CDC
4 criteria it would be a 48-hour window.

5 One of the problems with leaving
6 patients intubated longer is the development
7 of EAP. So that was a question that we had in
8 terms of the definition.

9 CHAIR MORRIS: Any other questions
10 or issues?

11 DR. ROGERS: With respect to the
12 duration of ventilation, I would actually
13 wonder about a shorter time period than a
14 longer time period.

15 I think the vast majority of
16 patients actually are off of ventilator
17 sooner, and I just wonder if this is sensitive
18 enough to be useful, to lead a discussion
19 about how do you actually get people off
20 ventilators, or extubated a lot quicker.

21 DR. STAFFORD: I think that's
22 actually a really good point, and I think --

1 but I think that's why this measure is
2 important, because you stated the vast
3 majority are, and at least in the number of
4 places I've seen, I think there's actually a
5 large gap here in that.

6 You're right. Something less than
7 24 hours might be appropriate. But I think at
8 least it gets to the importance of this
9 measure in picking some time frame.

10 DR. ROGERS: I think in the state
11 of Washington, I think we're at about six
12 hours average, and I -- so, from a
13 discriminatory standpoint, I understand your
14 point. But does it help us really guide the
15 fine-tuning of, I mean any minute with a tube
16 left in is an unhappy minute, as you know.

17 DR. STAFFORD: I would absolutely
18 agree with that, and I think you're coming
19 from a background where you're lucky to be in
20 some place where you have a robust database
21 and a group that catches all of their data.
22 Some states do, some states don't. I think

1 that's where participation in the database is
2 helpful.

3 Perhaps, perhaps somebody in the
4 group could come up with a proposal measure
5 that's actually shorter. I think that would
6 be a valuable discussion point to have.

7 CHAIR MORRIS: Let me ask the STS
8 a question about this, the sensitivity of that
9 measure. Can you speak to whether it is
10 adequately discriminative, or how
11 discriminative it is, how sensitive it is?

12 DR. PRAGER: Yes. I think I need
13 Jane on the phone, but it is reported out, and
14 you can ask that it be reported out in less
15 than 24 hour time frames, and I'm not sure it
16 is in everyone's report. so I think the
17 discussion is --

18 I think the discussion is a very
19 good discussion about this, and I would guess
20 that David will answer that 24 hours was
21 picked years ago, unrelated to -- before the
22 definition of VAP and things like that, and it

1 has been a great target, if you will, for
2 quality initiatives and improvement.

3 Although we can be more sensitive,
4 and certain states do pull their data in six-
5 hour time frames purposely to look at this,
6 and yes, I think it's fair to say the majority
7 of coronary bypass patients in most states
8 that have quality initiatives are extubated
9 within 12 hours.

10 CHAIR MORRIS: As a great target,
11 can you tell us what percentage of people are
12 extubated within 24 hours, if it's -- are we
13 topped out --

14 DR. PRAGER: Yes. I can't tell
15 you STS, unless Jane can look it up right now.
16 I don't have that number. Jane, do you?

17 DR. HAN: I'm scrolling through
18 looking for it right now, but not at this
19 moment.

20 CHAIR MORRIS: How about this?
21 Instead of giving me the exact number, can you
22 tell me is this measure actually topped out at

1 the 24 hour mark? Are we topped out?

2 DR. SHAHIAN: This is Dave. It's
3 not topped out, and there in fact is still a
4 fairly substantial distribution, and in fact,
5 I believe in the past, this measure was at 48
6 hours, and we actually have come down to 24.

7 It's a compromise. I think if we
8 were -- you know, ideally, I think six hours
9 to 12 hours would be ideal. But I think you
10 have to reach a compromise between what's
11 acceptable practice and what is the absolute
12 optimal practice, and that's why we settled on
13 24 hours.

14 We have the data on what
15 percentage of patients are extubated by 24
16 hours. If Jane doesn't have it right now, we
17 can get that for you very easily. But it is
18 a very substantial proportion.

19 DR. WILHOIT: What's in the
20 article that was attached to the submission
21 was 9.7 percent. I think, I assume it did
22 not comply with the 24 hours. But what's in

1 the table is 9.7.

2 DR. SHAHIAN: No, I think that's
3 correct.

4 DR. DUTTON: On the sensitivity
5 and specificity, if you look at the 2008
6 performance compared to the 2009 performance,
7 it's on page 17 in the measure submission.
8 It's very linear, with a very high row value.
9 So this is a system issue, in other words,
10 places that are bad one year tend to be bad
11 the next year as well or good. So I think
12 this is a very discriminatory measure.

13 DR. STAFFORD: The only other
14 comment I'd say, and I'm going to play the
15 devil's advocate. If we, and then we'll get
16 to Dr. Dutton's questions earlier about
17 unintended consequences. If we set a time
18 frame that's very short, then we ought to be
19 measuring reintubation, and other morbidity
20 associated with the measure.

21 So I think picking some reasonable
22 time frame is appropriate, and I think we have

1 to be careful not to go too far on either end
2 of the spectrum.

3 DR. SHAHIAN: And we do in fact
4 measure reintubation. That is one of our
5 measures.

6 CHAIR MORRIS: And would you
7 please also speak to Dr. Stafford's question
8 about adjustment, risk adjustment or potential
9 exclusions?

10 DR. SHAHIAN: Yes. Once again, I
11 think prolonged ventilation is the common
12 final pathway for a lot of different problems.
13 It could be preexisting lung disease; it could
14 be massive fluid overload, you know. It could
15 be a complication like a stroke that
16 develops. It could be, you know, some other
17 complication.

18 Rather than, you know, rather than
19 try to sort out all those various things,
20 we've simply accepted the fact that it is kind
21 of a good general metric for a patient that
22 has had a problem, that might not necessarily

1 be captured by other factors. Now the issue
2 of a systems problems, you keep the patient
3 intubated because you need to move them
4 somewhere to get a test.

5 I guess I would say that's a
6 systems problem within a hospital, and it's
7 one of the things they ought to be able to
8 deal with.

9 DR. CIMA: So if that's the case,
10 do we even really need the risk adjustment
11 model? I mean what role does it play in this?

12 DR. SHAHIAN: Well, I think the
13 role -- I think if a patient, for example, has
14 severe chronic lung disease preoperatively,
15 meaning by our definition they're on home mode
16 2, that's going to be a very significant
17 predictor for prolonged post-operative
18 ventilation. I think that sort of thing needs
19 to be adjusted for as it is in our model.

20 CHAIR MORRIS: Does that respond,
21 satisfy your question? Okay. Any other
22 issues or any other comments anyone wants to

1 raise?

2 (No response.)

3 CHAIR MORRIS: Let's go ahead and
4 move onto the vote then. That first vote is
5 on the Importance to Measure and Report this
6 item.

7 [COMMITTEE VOTING.]

8 CHAIR MORRIS: Let me ask for
9 everybody to put in their responses and hit
10 the send one more time.

11 [COMMITTEE VOTING.]

12 CHAIR MORRIS: And 22 out of 22
13 agree yes, this is important. Next,
14 Scientific Acceptability of the Measure
15 Properties.

16 [COMMITTEE VOTING.]

17 CHAIR MORRIS: 17 said that the
18 measurement properties are completely
19 acceptable, and then 5 said partially. Next
20 is Usability.

21 [COMMITTEE VOTING.]

22 CHAIR MORRIS: And 20 of us said

1 it completely meets the criteria for
2 Usability, 2 said it partially meets the
3 criteria for Usability. Next is Feasibility.

4 [COMMITTEE VOTING.]

5 CHAIR MORRIS: 20 of us said it
6 that it completely meets the criteria for
7 Feasibility. One of us said that it partially
8 meets the criteria and one said it minimally
9 meets the criteria for Feasibility. Then
10 we're back at the yes/no, and that is does the
11 measure meet all the NQF criteria for
12 endorsement.

13 So the issues that I heard raised
14 were questions about the duration of
15 ventilation. There was a reasonable
16 discussion of that, and some acknowledgment
17 that it's been a bit of a moving target over
18 time, but that it sounds like 24 hours is
19 pretty reasonable right now, and that close to
20 ten percent are not extubated within 24 hours,
21 9.7 percent or something, among those measured
22 while this measure has been place. Please

1 correct me if I'm wrong about that.

2 Then there was a question about
3 adjustment for potential confounders, and it
4 sounds like Dr. Stafford was satisfied with
5 that discussion. Dr. Cima raised the issue
6 of, you know, why are we adjusting at all.

7 DR. CIMA: I just wanted to
8 clarify that. It's like your point about
9 topped out on this. If there's risk
10 adjustment for seven or eight or nine percent
11 of patients, are they being kept intubated
12 because they meet all these other criteria.
13 So are we tapped out? I mean that's the
14 question.

15 If you're going to risk adjust it,
16 then do we know how many of these people are
17 chronic lung disease, how many people had a
18 stroke in that 24-hour period? If that's the
19 criteria, then do we really know if we have
20 much more room to move. That was what I'm
21 talking about.

22 CHAIR MORRIS: Okay. Thank you

1 for bringing that up. It sounds like the STS
2 has told us that there is a -- although it
3 could appear to be close to tapped out,
4 there's still a wide distribution. So
5 although more than 90 percent of people are
6 extubated at the 24 hour point --

7 (Off mic comment.)

8 CHAIR MORRIS: How can the
9 distribution -- that's just kind of where
10 places fall out on the, you know, on the
11 curve. So room for improvement among some
12 centers.

13 DR. SHAHIAN: That's the issue.
14 It is very hospital-specific, and there are
15 some hospitals that are doing much more poorly
16 than that, and then there are some superstar
17 hospitals that are getting everybody extubated
18 within a few hours.

19 CHAIR MORRIS: Is everybody
20 comfortable with going ahead and voting on the
21 last item, do we meet NQF criteria for
22 endorsement?

1 (No response.)

2 CHAIR MORRIS: Let's go ahead and
3 vote.

4 [COMMITTEE VOTING.]

5 CHAIR MORRIS: And 21 of 22 said
6 yes, we should go ahead and endorse this. One
7 said no. We're really picking up speed here.
8 So of our next measure, 0131, Strokes,
9 Cerebrovascular Accident is Dr. Dutton.

10 DR. DUTTON: Yes. Sorry. I'm
11 trying to get the static out of it. This
12 Measure 131, risk-adjusted stroke after
13 isolated CABG surgery. The numerator is
14 defined as a new neurologic deficit persisting
15 for at least 24 hours. The deficit has to be
16 associated with a structural abnormality in
17 the brain.

18 The denominator is all patients
19 greater than 18 having an isolated CABG
20 operation. There's an exclusion for prior
21 CVA. It's not specified how the exclusion is
22 calculated. I believe this measure is

1 important. It has a great deal of face
2 validity.

3 Obviously, if you're a consumer,
4 this is an outcome that matters to you very
5 greatly. So I think this is an important
6 measure. I think there are some harder issues
7 around how it is defined and how it is
8 measured.

9 I note, and I don't know if Alexis
10 was able to get my picture up, but if you look
11 at page 18 in the submission, you have that
12 same scattergram of 2008 to 2009 data. You
13 discover that the reproducibility of this from
14 reporting centers year on year is actually
15 fairly low. It's only, the row is .26 on
16 this.

17 In other words, a center can be
18 good one year and bad the next, which I think
19 is a consequence of this being a very low
20 number event. It doesn't happen very often.
21 These are anecdotes rather than something that
22 it's easy to make a rate out of. So using

1 this on an individual hospital basis for
2 performance improvement would be hard.

3 On the other hand, I think it has
4 a great deal of credibility as a national
5 measure and aggregated nationally, and I know
6 that the SDS has reported a decline in this
7 rate over time, and this is very useful. So
8 I think it's a very supportable measure.

9 The other thing I'll say about
10 definitions, again some potential for
11 gamesmanship in this, because there is an
12 exclusion for prior CVA. You need to
13 understand how that exclusion is made.

14 If it's by ICD-9 codes, for
15 example, from the hospital record, versus
16 specific testing, versus if you want to look
17 at the most expensive alternative, do a CT
18 scan every patient before surgery, to rule out
19 events and establish a baseline for subsequent
20 CTs.

21 Obviously, not feasible in that
22 respect, but that's the slippery slope that

1 you're on with this kind of measure. I think
2 you just have to pick what is the most
3 rational definition for cost and a reasonable
4 criteria and go with that, and I think STS has
5 done that.

6 Then the same question has come up
7 with renal patients, is if a patient does have
8 a prior deficit, shouldn't we be interested in
9 the ones that are getting worse, and why not
10 measure everybody, include everybody, have no
11 exclusion for a prior event. But instead,
12 have a measure based on worsening of a
13 neurologic state. That's all I have to say.

14 CHAIR MORRIS: Any other issues
15 anyone wants to raise? Questions?

16 (No response.)

17 CHAIR MORRIS: So it sounds -- let
18 me just recap that for you. Thank you for
19 that discussion. First of all, it sounds like
20 you had a question is how is this exclusion of
21 a prior CVA calculated.

22 Secondly, you're concerned about

1 the level of analysis, whether it's at
2 individual hospitals, which shows a lot of
3 variability from year to year, versus in the
4 aggregate, which may be more reflective of a
5 national trend.

6 And then thirdly, related back to
7 the first one, should we be including all
8 patients, so that we can look at folks who
9 have had a prior stroke and whether or not
10 their deficits are worsening with a CABG,
11 after a CABG. Does that capture it? Okay.
12 Does the STS want to respond to these?

13 DR. PRAGER: Yes I can start, and
14 then David and Jane, feel free to chime in.
15 I think on a national basis, it has proven to
16 be a very good target to look at, at the
17 individual hospital.

18 In other words, the individual
19 hospital that does 150 isolated coronaries and
20 has no strokes one year looks great, and the
21 next year they could have five, because they
22 were older, had a prior history of stroke or

1 whatever the issue was, had an atherosclerotic
2 aorta based on aging.

3 So I think that point is well-
4 taken, and we would agree with it. We have
5 found that it is very useful on the local
6 level, and prompted by both national levels
7 and comparing yourself to that.

8 The issue of prior stroke being
9 ruled out. I think historically, we have done
10 that. I think that also is a fair issue. Do
11 we want a bigger number to look at? I think
12 when this was initially selected, it may have
13 been based on the assumption that people with
14 prior stroke, which to my understanding is
15 simply by history, not by CT scans, not
16 because the relative said that grandma had the
17 stroke. It is someone took a history.
18 Frankly, that's how we do it.

19 Having said that, we haven't
20 broadened it, and I'm not sure we have really
21 entertained that discussion in any robust
22 fashion at this time. David, any other

1 thoughts or Jane?

2 DR. SHAHIAN: Yes. First of all,
3 in terms of the sample sizes, you're exactly
4 right. This is a fairly rare event. But if
5 you think about it, the incidence of stroke
6 after coronary bypass surgery is roughly in
7 the same ballpark as the incidence of
8 mortality, you know. It's a percent to a
9 percent and a half, in that ballpark, in most
10 recent studies.

11 So we're dealing with the same
12 issue that we deal with in assessing mortality
13 as a --, and there are ways to mitigate these
14 problems to some extent using the statistical
15 techniques that we do, and one can also look
16 at data year over year.

17 I think a program that's bouncing
18 around from zero to four to one to two says
19 one thing. I think a program that is
20 consistently 0.3 percent year after year tells
21 you something else, and a program that's
22 consistently four percent year after year

1 tells you still another story.

2 So I think there is information to
3 be gained from looking at trended data, and of
4 course we have that capability. In terms of
5 this issue of previous stroke, Rich is right,
6 and that we simply accept that a history has
7 been taken, that there was a previous stroke.
8 Now why is this important?

9 In cardiac surgery, most of us
10 have seen this syndrome where a patient has a
11 previous stroke, seemingly recovers from it or
12 does recover from it functionally, undergo
13 cardiopulmonary bypass and then perhaps
14 because of transient cerebral edema in the
15 area of the previous scar, or interruption of
16 some new collateral pathway that developed,
17 patients that have completely cleared their
18 previous neurologic event may develop some of
19 those same symptoms that they had with their
20 previous strokes, even without evidence of new
21 stroke.

22 So that becomes very difficult to

1 sort out. So that's why we've tried to
2 exclude that particular group of patients,
3 because it does get a little bit difficult to
4 sort out what's new, what's old. So just try
5 to make it a cleaner measure.

6 DR. HALPERN: I have a question
7 about how the model works, because I noticed
8 in your risk-adjusted model, part of that risk
9 adjustment was a previous history of stroke.
10 So is that somehow like double-counting it?
11 Does it get double-counted that way?

12 DR. SHAHIAN: Well, those patients
13 would not be included in the measure, in this
14 particular measure, right? I think they would
15 be excluded. It is, you know, let's see. I
16 have to go back and look at that in terms of
17 how that's calculated.

18 DR. DUTTON: Prior stroke is prior
19 stroke?

20 DR. SHAHIAN: That would not --
21 those patients, that actually would not end up
22 being -- although our general risk adjustment

1 model for stroke includes that, that
2 particular group of patients -- measure.

3 DR. DUTTON: Yes. It's not part
4 of this measure, but prior stroke is part of
5 the mortality risk adjustment, which is the
6 sort or generic risk adjustment they're
7 showing us for all of these measures.

8 DR. HALPERN: So is that a typo
9 then in this particular measure. Dr. Halpern.
10 It's down in their risk adjustment
11 methodology. It's included.

12 CHAIR MORRIS: Okay. So
13 potentially a typo on the part of the measure
14 developer. Dr. Afsar-Manesh, do you have
15 anything to add to this discussion in terms of
16 your clinical expertise?

17 DR. MORTON: I had a question
18 about at what point are some of the preop
19 characteristics obtained in data collection?
20 Is this all done after the episode of care is
21 done? Do you get some of these data before
22 the surgery or more contemporaneous with the

1 surgery?

2 For the issue about stroke, is it
3 correlated to the prior to admission ICD-9
4 codes that might be present?

5 DR. SHAHIAN: We recommend that
6 data are collected contemporaneously within
7 the usual processes of care. So these data
8 would be collected by admission or a PA
9 preoperatively, and then recorded in the
10 database by the data manager. That's our
11 preferred methodology.

12 The data are collected
13 preoperatively; it's just a question of
14 whether the data manager abstracts them down
15 the line, or whether they're doing it
16 contemporaneously.

17 We, you know, hospitals would have
18 the option of using, of going back to previous
19 ICD-9 codes for a history of stroke, or going
20 to a letter from a referring doctor. There
21 are many ways. We haven't been proscriptive
22 about how that stroke, previous stroke is

1 defined.

2 CHAIR MORRIS: Let me ask you
3 another question about that. We're getting
4 some static, I think also. Is that on his
5 line? Okay. It just stopped, which is nice.
6 We'll see if it comes back.

7 MS. MURPHY: But if you're not
8 speaking, please, if you're on the phone, mute
9 your line when you're not speaking. Don't put
10 it on hold, mute it. Thanks.

11 CHAIR MORRIS: Okay. So my
12 question is does this require that the data
13 abstractor then go through letters from
14 referring physicians or go through the
15 physician's written notes in the chart, in
16 order to identify a previous -- and I think
17 that's really what Dr. Morton was getting at,
18 a previous episode of stroke.

19 If it's not reliant on ICD-9
20 codes, does this require that the abstractor
21 spend what could be a lot of time and
22 potentially not available in the hospital

1 chart?

2 DR. SHAHIAN: Well -- go ahead,
3 Rich.

4 DR. PRAGER: Okay. The most
5 recent to the time frame of the operation
6 history and physical, certainly for coronary
7 artery bypass patients and cardiac patients
8 frankly should include whether there is a
9 history. So it does not require going back.
10 We don't use ICD-9 codes, and it should be
11 frankly the most recent history that was done.

12 CHAIR MORRIS: Does that answer
13 your question?

14 DR. MORTON: Yes, I guess so. Is
15 it part of the -- I heard there was going to
16 be validation of the centers collecting the
17 data. Is that going to be part of the
18 validation, to see how this data's collected
19 and how contemporaneous the data collection
20 is? Is that a plan for the STS?

21 DR. PRAGER: Yes. The STS is
22 actually doing that now, and this is one of

1 the variables of the 73 that are audited, and
2 as part of the Iowa Foundation for Medical
3 Care, which is our auditing agency, they
4 actually then tabulated were the data put
5 together prospectively by the site, which is
6 obviously what we recommend, or is it
7 retrospectively or how is it done?

8 Is it electronically,
9 contemporaneously? So we have some of those
10 data starting to emerge, but this is an
11 audited variable.

12 CHAIR MORRIS: Okay, and one
13 further question. Does this apply only to the
14 index hospitalization, or is it over a 30-day
15 period?

16 DR. PRAGER: Index, index.

17 DR. STAFFORD: Arden, I have one
18 more question, and this gets to the
19 development of stroke in particular, but may
20 affect some of the other end points. Has STS
21 considered looking at, or do they discriminate
22 between on pump cases and off pump cases?

1 DR. PRAGER: Yes, we do.

2 DR. STAFFORD: I didn't see that
3 in your risk model. Have you considered doing
4 that?

5 DR. PRAGER: Yes. David, help us
6 with that a little bit, because I'm not quite
7 sure that's in the risk model, but we now have
8 data points for it.

9 DR. SHAHIAN: No, you wouldn't
10 want to put that in the risk model, because
11 then you might be, it's kind of like
12 socioeconomic status in a way.

13 That's one -- the type of
14 procedure performed within isolated CABG is
15 something that you might want to do a
16 stratified analysis for, but you might
17 conceivably adjust away the salutary effect
18 of off-pump CABG, if you believe that off-pump
19 CABG is less likely to produce a stroke.

20 You might adjust that away if you
21 include it in the model. So I think
22 stratification would be the better approach.

1 CHAIR MORRIS: Any other issues
2 before we move on to the vote? Anybody want
3 to bring any other questions up?

4 (No response.)

5 CHAIR MORRIS: Let's go ahead and
6 move on to the vote. Does the measure meet
7 NQF criteria for Importance to Measure and
8 Report?

9 [COMMITTEE VOTING.]

10 CHAIR MORRIS: 22 out of 22 said
11 yes. Next, does the measure meet NQF criteria
12 for Scientific Acceptability of the Measure
13 Properties?

14 [COMMITTEE VOTING.]

15 CHAIR MORRIS: 12 said completely,
16 10 said partially. Next, does the measure
17 meet NQF criteria for Usability?

18 [COMMITTEE VOTING.]

19 CHAIR MORRIS: I'll just ask
20 everybody to hit their response one more time
21 and hit send.

22 [COMMITTEE VOTING.]

1 CHAIR MORRIS: Okay, and the vote
2 was that 17 out of 22 said yes, it completely
3 meets the criteria, and 5 said partially. And
4 then does the measure meet NQF criteria for
5 Feasibility?

6 [COMMITTEE VOTING.]

7 CHAIR MORRIS: 18 said completely,
8 4 said partially. Then lastly, does the
9 measure meet all the NQF criteria for
10 endorsement, and I just want to recap some of
11 the concerns that were voiced.

12 There was a question about how the
13 exclusion is calculated, whether this is from
14 -- well, it could be calculated in a number of
15 ways. But it sounds like Dr. Prager said that
16 primarily it's determined based on most
17 proximal history and physical done prior to
18 the operation. So not by prior ICD-9 codes.

19 Secondly, there was an issue about
20 whether or not prior strokes that had worsened
21 as a result of the CABG operation would be
22 captured, and the answer is really no, because

1 there's so much noise from prior strokes and
2 potentially cerebral scar tissue or residual
3 effects of the prior stroke.

4 Then there was a concern about the
5 level of analysis, whether this truly
6 represents the experience at individual
7 hospitals, or whether aggregate data are more
8 useful. For low yield events, for fortunately
9 low yield events like this, mortality and
10 other events, there probably will be a lot of
11 potential noise in there for some hospitals or
12 institutions.

13 I believe it was Dr. Shahian, but
14 it might have been Dr. Prager brought up that
15 this might be most useful, dealing with that
16 particular question, by measuring trends,
17 which is not part of this measure, as I
18 understand it, but could potentially be
19 explored in the future in individual
20 hospitals.

21 Then there are some issues in the
22 language of the measure that sounded almost as

1 though potentially editing of the language of
2 the measure would have been appropriate by the
3 STS. For example, including in the model that
4 it adjusts for prior stroke when those
5 patients would have been excluded.

6 Then lastly, there was a decision,
7 a purposeful decision by the STS, as I
8 understand it, not to adjust for on or off
9 pump, in order to be able to compare those
10 operations more appropriately. Does this --
11 anybody have any issues besides what I've
12 brought up to address? Any other questions?

13 DR. WILHOIT: Specification of
14 time frame.

15 CHAIR MORRIS: Yes, thank you.
16 The specification of time frame -- I'm sorry.
17 I don't recall the answer to this. It was
18 during the index hospitalization, you said?
19 Okay. So stroke during the index
20 hospitalization and not after. All right.

21 DR. SHAHIAN: Could I just clarify
22 one issue that was raised, the issue of the

1 inclusion in the risk model of patients who
2 had a previous stroke, whereas they're
3 excluded from the measure. They're really,
4 they're related but separate issues.

5 We devised risk models, generic
6 risk models, to be used for many different
7 purposes, not just for the purpose of this
8 measure. So that generic risk model includes
9 patients who have had a previous stroke. For
10 the purposes of this measure, of course, there
11 are no such patients.

12 So all the patients in the
13 particular cohort being evaluated for this
14 measure would have previous stroke, no. So
15 that would not have any impact on the risk
16 adjustment model. So it's not a typographical
17 error; it's just two slightly different
18 things.

19 DR. WILHOIT: Can I raise a
20 question? In the document, it does not list
21 prior stroke as being an exclusion, I don't
22 think. Am I looking at the wrong one? Oh,

1 I'm sorry. I am looking at the wrong one.

2 I'm sorry.

3 CHAIR MORRIS: Okay.

4 DR. MORTON: I did have one
5 question about the risk adjustment issue,
6 about off and on pump. I guess I'm still not
7 clear, because one advantage of the off pump
8 is to prevent stroke, is that right? So I'm
9 wondering why I understand the stratification,
10 but I don't know. I guess I'd like a little
11 more clarification around that.

12 DR. SHAHIAN: Sure. Risk models
13 used for profiling should include
14 characteristics of the patient that are
15 present when they first encounter the
16 provider. Discretionary decisions, such as on
17 pump, off pump, repair, replacement, whatever,
18 all those sorts of things are, I think, not
19 appropriate for use in risk models designed
20 for profiling purposes.

21 They might be useful if they were
22 being used specifically for patient

1 counseling, for example. If you wanted to
2 devise a model that, to enable you to discuss
3 with a patient what's your likelihood of
4 stroke after this procedure, and, oh by the
5 way, I've planned to do it using the off-pump
6 technique, that's fair game.

7 But in terms of profiling models,
8 data collection or patient characteristics are
9 collected up to the time you encounter the
10 provider, but not beyond that. At least
11 that's my understanding. That's the way we've
12 done it.

13 DR. CIMA: Just one question about
14 this. If this is not anything modifiable,
15 according to the data that we know of, and not
16 really a system issue that we know of, not
17 like whether or not you extubate patients
18 early, this is more like just a rate.

19 Can you drive quality improvement
20 if there's not a modifiable system or risk
21 factor issue here? I mean that's one point,
22 and the second one I'm just going to make

1 again the plea, to understand, you know, the
2 usability of this model.

3 The model as -- the more and more
4 complex, the modeling is going to be
5 important, and institutions that don't
6 participate are going to be excluded, and
7 we're going to have to come up with another
8 system.

9 So again, those are the two
10 points. But in this one in and of itself,
11 there's no quality improvement aspect that I
12 can actually see.

13 DR. DUTTON: I'll tackle that,
14 because I started this with a discussion about
15 the rate and the impact of a very low rate on
16 using this. It is certainly a system-
17 modifiable event. How you manage a fib, how
18 you, you know, where you put your holes in the
19 aorta, you know, are you using ultrasound?

20 I mean there's a lot of variables
21 that contribute to this that are well
22 understood, how you manage perfusion on pump.

1 There are a lot of variables. The problem is
2 that the end result, the stroke, occurs at
3 such a low rate that it's hard to measure in
4 an individual institution.

5 But certainly if you came up three
6 years in a row with a high odds ratio in this,
7 you would have a very good incentive to go
8 look at your practice and figure out what you
9 could do to make it better.

10 DR. STAFFORD: Yes. I think the
11 measure becomes a trigger tool. So you see a
12 change in practice over time or in outcomes
13 over time, and that should trigger the
14 institution to look for the reason that that
15 occurred. Sometimes in many places, these are
16 sentinel events.

17 So depending on how your
18 institution looks at outcomes, that's -- but
19 that's the reason to have that.

20 DR. SHAHIAN: I completely agree
21 with all those comments.

22 DR. PRAGER: And I would just add

1 that it is a modifiable event in the
2 institution that has a four or five percent.
3 If you look at maybe the use intimate and
4 cross-clamp, one of the techniques.

5 Maybe they run their perfusion
6 pressures at 40 or 45. So we have learned
7 that you can actually modify this. Now it's
8 not going to be zero, but you can modify it,
9 and it is a trigger for that.

10 CHAIR MORRIS: Okay. So we're
11 going to go ahead and vote on, does the
12 measure meet all the NQF criteria for
13 endorsement.

14 [COMMITTEE VOTING.]

15 CHAIR MORRIS: Twenty-two out of
16 22 of us said yes, it does meet the NQF
17 criteria for endorsement. We have two more
18 measures here in consideration of candidate
19 measures for the pre-lunch session. But we
20 also have a caterer who's brought lunch.

21 So I think what we'll do now is
22 we'll break for lunch. It's a half-hour lunch

1 break, so it's relatively rapid. Be sure you
2 chew your food, and then we'll come back and
3 go over the two measures that are left over,
4 and then proceed.

5 (Off mic comment.)

6 CHAIR MORRIS: Right now? Oh
7 sure. Yes, okay. I'm sorry everybody. We're
8 going to take a brief break, I'm sorry. We're
9 going to take a brief -- before we take our
10 lunch break, we're going to take a brief
11 moment for NQF member and public comment. I
12 think this is from folks in the room and then
13 folks on the phone.

14 NQF Member/Public Comment

15 (No response)

16 CHAIR MORRIS: Okay, wonderful.
17 It's lunch time.

18 (Whereupon, the above-entitled
19 matter went off the record at 12:26 p.m. and
20 resumed at 1:02 p.m.)

21

1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 1:02 p.m.

3 CHAIR MORRIS: Okay. We're going
4 to go ahead and get started, and we have a
5 couple more measures to finish up from the
6 morning. First, we're going to Ms. Graling
7 talk about Measure 0134, Coronary Artery
8 Bypass Graft using Internal Mammary Artery.

9 DR. GRALING: Right. This was
10 another one of the measures that Work Group A
11 took a look at. It is in process. It's been
12 reported since 2007. We felt that it was
13 important to measure. It certainly is well
14 tied to improved outcomes because of the high
15 patency rates of the IMA.

16 One question we had is that there
17 was no information that really addressed the
18 disparities, and there is some literature
19 there that discusses certainly women and
20 regional use of the IMA. In terms of
21 Scientific Acceptability, the numerator is the
22 number of patients undergoing CABG with IMA.

1 The denominator is all patients undergoing
2 isolated CABG, which really leads us to the
3 exclusions, which is those patients who have
4 had a previous CABG are not eligible for the
5 IMA.

6 We had some discussion related to
7 some of the other exclusions. Those you see
8 listed in terms of subclavian stenosis,
9 Mediastinal radiation, no LAD disease, and I
10 think it was to Dr. Dutton's point about is
11 this someplace where the surgeon can game the
12 system if he chooses not to use the IMA.

13 Usability is well established as
14 part of the CABG composite scores, and
15 certainly Feasibility has the same issues in
16 relation to acknowledging the fact that you do
17 need a data abstractor. But otherwise, we
18 felt it was quite feasible.

19 CHAIR MORRIS: Any questions or
20 comments from the group?

21 (No response.)

22 CHAIR MORRIS: I have a question

1 for the STS around disparities, and I'm glad
2 that you brought that up. That's something
3 that we are really trying to discuss with each
4 of these measures that have been present for
5 some time. What's the data on disparities,
6 and new measures as well? What's the
7 information about disparities? We need to
8 attend to that.

9 We have measures that have been
10 present that are up for maintenance. We need
11 to know a little bit more about what the
12 measure developers have learned since the
13 measures were first endorsed.

14 So we need to know how things have
15 changed, since this is really for maintenance
16 measures, they're being held to a different
17 standard than when they were initially
18 introduced. But also they've been present for
19 some time, and hopefully have made some
20 changes. We need to know if these quality
21 measures are actually having any impact.

22 Would the STS like to respond to

1 the comments?

2 DR. PRAGER: Yes. I'll start the
3 response. The answer for the IMA is we are
4 having an impact. There is significant
5 regional variation in utilization of the IMA,
6 between -- in various states that look at it
7 regionally, the variation ranges between 65
8 percent and 100 percent at different sites.

9 So utilizing these data allow us
10 to create opportunities for quality
11 improvement. I think that's the -- we well
12 know, as the Committee knows, that certainly
13 utilization of the IMA is a gold standard.

14 The other aspects of the learning
15 are now the exclusion issues that have come
16 after a great deal of debate as well, but a
17 recognition of certain realities that can be
18 encountered. So I think the STS has learned
19 a great deal. I think the clinicians,
20 frankly, have had an impetus to utilize it
21 more frequently when appropriate.

22 CHAIR MORRIS: Have you seen a

1 reduction in the variation in IMA use?

2 DR. PRAGER: Yes.

3 CHAIR MORRIS: Can you give us any
4 parameters around it?

5 DR. PRAGER: Parameters meaning I
6 can -- there is a recently published article
7 in the Annals of Thoracic Surgery about three
8 months ago from the state of Michigan, showing
9 increased usage via a quality collaborative
10 approach, to up over the STS average now, from
11 an average of in the 80s.

12 CHAIR MORRIS: Great. Any other
13 questions or issues that you have? Does
14 anybody else have any questions or issues that
15 they want to raise, to be discussed by the
16 measure developers, or questions for the
17 measure developers?

18 DR. ROGERS: I just want to be
19 certain I understand the disparity issue.
20 This is not social disparities in any way.
21 We're talking medical disparities with post-
22 radiation, that sort of thing?

1 DR. GRALING: Well, some of the
2 recent literature actually points at the
3 disparity in the use in women and non-white
4 race groups. So I think that's really
5 important in terms of the learning, in terms
6 of how that's looked at, and then the other
7 big piece was the region.

8 CHAIR MORRIS: So regional and
9 then socially vulnerable populations, and
10 we're talking about disparities. That means
11 disparities among socially vulnerable
12 populations?

13 DR. ROGERS: Dr. Prager, do you
14 have any comment about that?

15 DR. PRAGER: Yes. While regions
16 have perhaps looked at that, the STS has not
17 really asked DCRI or of itself to look at
18 that, but we are more than willing to address
19 it.

20 DR. DUTTON: I'd just expand for
21 one second on the gaming issue, because it
22 comes up because this is a publicly reported

1 measure, and the obvious gaming in this is
2 there's an exclusion for IMA not suitable, and
3 that determination is made by the person who's
4 being judged by the measure. So I mean
5 there's an obvious concern there.

6 I think this is a very important
7 measure for private reporting and for
8 improving quality, and there's no question the
9 STS has moved this indicator to better
10 outcomes, no question. But if it's going to
11 be publicly reported, it raises the concern
12 of, you know, who decides whether the vessel's
13 unsuitable or not?

14 DR. HALPERN: Are there specific
15 criteria for suitability?

16 DR. PRAGER: I was waiting for
17 that question. I was waiting for both of
18 those questions, and I think that question
19 really addresses a significant issue, and
20 perhaps this group ought to discuss this
21 briefly, as to whether that exclusion criteria
22 is a fair and reliable exclusion criteria,

1 because you're absolutely right. That is
2 specific to the person performing the
3 operation.

4 Now we would like to believe that
5 100 percent of people performing the operation
6 would make the same decision. Having said
7 that, we also know that that doesn't happen.

8 MS. WEBER: Are there any criteria
9 out there by which somebody can judge?

10 DR. PRAGER: There are historical
11 flow criteria for the mammary artery. If you
12 take this down off the chest wall and then
13 people in the 60s and 70s frankly would
14 measure flow into any kind of basin and see
15 how much flow was in a minute, and people
16 would say yes, you needed 50 cc of flow or 80
17 cc of flow would be wonderful. If you had 20,
18 you probably wouldn't use it.

19 But we also know in this era of
20 putting Papaverine or something like that
21 around an artery to reduce spasm may change
22 the flow. So even using historical notations,

1 if you will, not truly evidence-based, as we
2 say today, but historical notations about it,
3 those can, one, also be gamed and, two, we
4 can, with experience, if you will, improve the
5 flow in many of the mammaries that you wonder
6 whether they're questionable.

7 But the other side of gaming is
8 hypoperfusion with a mammary. I don't want to
9 get overly technical, but if you use the
10 mammary and you put it to a dominant vessel on
11 the heart, and it's not really flowing well,
12 you have set up a potential problem.

13 DR. DUTTON: Yes, and I assume you
14 capture the negative side of the indicator,
15 which is objective, which is how often does an
16 IMA fail.

17 DR. PRAGER: Well, you don't
18 capture that unless they're recatheterized.
19 Or they go back to the operating room, and
20 that's a small number. So we won't, we don't
21 know that number.

22 DR. HALPERN: Are women, somebody

1 had mentioned about women being
2 underrepresented. Is that because like with
3 many other vessels in women, that they're
4 smaller than in men?

5 DR. PRAGER: The answer to that is
6 that's not consistent, and it is still, if you
7 will, under disparities, can certainly be --
8 there have been many papers in the literature,
9 and frankly I think there's an increased
10 utilization in everyone: men and women.

11 We use it in children. I mean the
12 fact is children who have complex operations
13 not for anomalous coronaries, but other
14 complex operations where the LAD can be
15 injured, redo aortic roots, things like that,
16 Ross procedures, if you have a 12 year-old,
17 we'll take the mammary down on pump and use it
18 in a 12 year-old. So it's not just size-
19 related; it's experience-related.

20 CHAIR MORRIS: So I just want to
21 make sure that I understand this correctly.
22 So there are, let me just make sure that I get

1 this. If the IMA is deemed not a suitable
2 conduit, those cases are excluded. But there
3 are no explicit criteria for whether the IMA
4 is a suitable conduit.

5 There is a historical precedent
6 that was developed the way many historical
7 things are. But there isn't really any
8 explicit, and particularly no evidence-based
9 criteria for a suitability.

10 DR. PRAGER: Unless we either
11 added to that or said there was no flow in the
12 mammary or the flow was less than X. I don't
13 know if David's on the line. He may have
14 other thoughts.

15 DR. SHAHIAN: Yes. This is Dave.
16 This is one that we have struggled with. We
17 have not used this before as an exclusion. We
18 want it in our current -- in our new data
19 specs, we wanted to include granular detail on
20 why an IMA was not used.

21 But I would not be at all
22 disappointed and would be willing to stipulate

1 right now that we would remove that particular
2 exclusion, the suitability, because of its
3 subjectivity. I have no problem with that.

4 CHAIR MORRIS: Does anybody in the
5 group want to talk about that?

6 DR. HALPERN: I think that's a
7 great idea. Then are you going to have some
8 kind of analysis, because on the negative side
9 of things, is like you were mentioning. If
10 people are going to be judged by how many IMAs
11 they're using, will people start using IMAs
12 that may not be suitable?

13 DR. SHAHIAN: You know, we don't
14 expect that -- even with the remaining
15 exclusions on this list, we don't expect that
16 every patient is going to get an IMA.
17 Everybody is going to have a certain number of
18 cases where the IMA will not be of adequate
19 size or flow. That's why our median and mean
20 usage are, you know, in the 94 percent or so
21 range.

22 Is there the potential for

1 incentivizing surgeons to do the wrong thing?
2 Yes. Like everything else that we've
3 discussed, every process measure out there has
4 that potential. But I don't think there are
5 many surgeons that are going to use an IMA
6 that is clearly inadequate because it comes
7 back to bite you very quickly.

8 DR. HALPERN: Is there a target
9 number that you're looking for then? Is there
10 a target usage of IMAs that you're looking
11 for?

12 DR. SHAHIAN: I'd say the best
13 programs are up in the 95 percent range right
14 now. Rich, do you agree?

15 DR. PRAGER: No, I agree. I
16 agree.

17 CHAIR MORRIS: Any other questions
18 or issues with regard to this particular
19 measure?

20 DR. MORTON: I had a question
21 about, is obesity a contraindication to using
22 the IMA?

1 DR. PRAGER: Historically, yes.
2 Currently, absolutely not.

3 DR. HALPERN: How about diabetes?
4 I remember diabetes used to be an issue too.

5 DR. PRAGER: No, diabetes is not a
6 contraindication.

7 DR. CARPENTER: So we're having
8 this discussion about how, about the exclusion
9 criteria. Do we have any idea how common that
10 is used as an exclusion criteria? Is that
11 something you capture? How often -- is it
12 deemed unusable?

13 DR. PRAGER: We have not captured
14 it on a national level. Regional groups have,
15 and that's what has fostered including it in
16 the national database.

17 CHAIR MORRIS: And then can you
18 say a few words about the distribution of
19 this, of use of the IMA. If it's used in 95
20 percent of centers, is there actually -- are
21 there places that could do better, and how
22 much better could they do?

1 DR. PRAGER: Well, experience at
2 several of our states, Washington, Virginia,
3 the Northern New England all saw after
4 initiatives to increase utilization, regional
5 improvement.

6 DR. SHAHIAN: But there are still
7 programs, there are still isolated programs
8 that are down in the 80s, 80 percent range.
9 So there is definitely room for improvement.

10 CHAIR MORRIS: I have a question
11 for you, Melinda. If we would like, as a
12 group, we decided that we wanted to move
13 forward, that we wanted to vote in an
14 approving way for this measure, but we wanted
15 to put on the condition that this exclusion be
16 removed, how would we do that? How would we
17 add the condition to that?

18 MS. MURPHY: Well, I'm looking at
19 Helen. One of two ways. One would be that it
20 would be voted down, and you would say with
21 that condition of removal of it, that it would
22 be acceptable. The other one, which would be

1 the question, is if STS committed now, if
2 they're saying we can strike that, then it
3 would be a vote on it with that struck from
4 the exclusions at this point, contingent on
5 getting that back in the measure
6 documentation.

7 DR. PRAGER: I believe David and I
8 would both agree with that, that we could
9 strike that.

10 DR. SHAHIAN: Yes.

11 CHAIR MORRIS: Any thoughts or
12 comments among the group with regard to that?

13 MS. STEED: So when we vote, we
14 vote with striking that from the exclusions.

15 CHAIR MORRIS: Okay. Is there
16 anybody here that wishes to vote on the
17 exclusion as it stands without striking that?

18 (No response.)

19 CHAIR MORRIS: Okay, great. Let's
20 go ahead and proceed with the vote then. So
21 first, as you recall, does the measure meet
22 NQF criteria for Importance to Measure and

1 Report?

2 [COMMITTEE VOTING.]

3 CHAIR MORRIS: I'll ask everybody
4 to once more press their vote and then press
5 the send, aiming at Jessica.

6 [COMMITTEE VOTING.]

7 CHAIR MORRIS: We have 20
8 responses of yes and 2 of -- I'm sorry 1 of
9 no. How did that happen? Oh. Second vote,
10 does the measure meet NQF criteria for
11 Scientific Acceptability of Measure
12 Properties? This is with that exclusion
13 struck.

14 [COMMITTEE VOTING.]

15 CHAIR MORRIS: 14 said completely,
16 7 said partially. Thirdly, we're voting on
17 does the measure meet NQF criteria for
18 Usability?

19 [COMMITTEE VOTING.]

20 CHAIR MORRIS: 20 said completely
21 and 1 said partially. Next, does the measure
22 meet NQF criteria for Feasibility?

1 [COMMITTEE VOTING.]

2 CHAIR MORRIS: 20 said yes
3 completely, and 1 said partially. So with our
4 last vote, does the measure meet all the NQF
5 criteria for endorsement? Let's just recap
6 what some of the issues were.

7 First of all, in terms of
8 disparities and measuring disparities, the STS
9 says that they haven't looked at this at a
10 national level, but that they're willing to.
11 It sounds like there are disparities in use
12 among some regions that have been examined.

13 There was a question about the
14 exclusion, which the STS agreed to strike.
15 The exclusion specifically is that the IMA is
16 not a suitable conduit due to size or flow,
17 since at this point there aren't explicit
18 evidence-based criteria for determining that,
19 and it really is the judgment of the
20 individual provider, based on potentially
21 their experience, their training. But not
22 something that somebody external to them could

1 necessarily understand.

2 There was a question about whether
3 or not this particular measure would have an
4 impact, since it has -- since it's applied,
5 estimated, in about 95 percent of cases. But
6 the STS thought that there was still
7 substantial variation, in that since the
8 introduction of this measure in particular
9 regions, that there had been an improvement in
10 IMA use.

11 Then there was a mention of
12 concerns regarding gaming the system. This
13 speaks back to that particular exclusion that
14 was struck. Any other issues that anybody has
15 with regard to this measure, before we do our
16 last vote? Any comments?

17 (No response.)

18 CHAIR MORRIS: Okay. So the last
19 vote, does the measure meet all the NQF
20 criteria for endorsement?

21 [COMMITTEE VOTING.]

22 CHAIR MORRIS: And please once

1 more hit your vote and then hit the send
2 button.

3 [COMMITTEE VOTING.]

4 CHAIR MORRIS: We had 21 votes for
5 yes, no votes for no, which is pretty good.
6 So moving on, next we have Dr. Wilhoit talking
7 about 0119, Risk-Adjusted Operative Mortality
8 for CABG.

9 DR. WILHOIT: Okay. So this
10 measure our work group reviewed. I think many
11 of the things we've talked about with respect
12 to the other measures apply to this measure as
13 well. So there's not a lot of new discussion.

14 For Importance, the outcome speaks
15 for itself. I think it certainly has face
16 validity, and mortality is certainly what
17 patients and families care about a great deal.

18
19 In terms of Scientific
20 Acceptability, the measure does not require
21 participation in the STS database, but it is
22 defined in terms of the STS database fields.

1 So again, that's similar to what we saw with
2 some of the other measures.

3 Usability, we identified no
4 issues, and Feasibility, we identified no
5 issues.

6 CHAIR MORRIS: All right. Any
7 issues that anybody wants to bring up?
8 Questions or comments?

9 MS. STEED: I was wondering if
10 there had been any consideration to changing
11 the measure from 30 days to 100 days.

12 DR. SHAHIAN: I can speak to that.
13 The answer is no, although I think in the
14 future, perhaps the next time we're coming
15 back to you, that might be possible. Right
16 now, it is difficult, costly and time-
17 consuming even to obtain 30 day data. We
18 have, however, established now a linkage with
19 Social Security Death Master File, that will
20 permit us to obtain long-term mortality, and
21 we in fact have developed, and will be
22 publishing soon, a long-term risk prediction

1 model for CABG.

2 Because I agree, that as short-
3 term mortality has diminished, it is
4 increasingly relevant to all stakeholders, I
5 think, to know what the longer-term outcomes
6 are. In some sense, the early postoperative
7 period has also lengthened, because of our
8 ability to keep patients alive.

9 So I think it's a very relevant
10 question. Right now, the answer is no. We
11 don't have that capability, but I think the
12 next time we come back to you, we will have
13 that operationalized.

14 CHAIR MORRIS: Okay, and then --

15 DR. ROGERS: I have a question,
16 Arden, that will have pertinence, I think,
17 with the next section that we look into, which
18 is all mortality-related. As I understand
19 risk-adjusted mortality, it addresses the
20 global characteristics of patients for a given
21 institution, and that's kind of how that's
22 done.

1 I'm concerned that that may be a
2 relatively blunt instrument with respect to
3 mortality, and I wonder if there's a
4 possibility of discussing or at least raising
5 the issue of what was the specific patient
6 risk of each patient who died?

7 It's one thing to have an okay
8 mortality rate. It's quite another to have
9 the wrong people dying, if you look at their
10 individual risk. I know that's possible to
11 do, and I wonder if the sponsors of these
12 criteria might comment about that.

13 DR. SHAHIAN: Well, we calculate
14 -- obviously, in order to calculate the global
15 risk adjusted mortality or O to E ratio for a
16 particular hospital or participant, we have to
17 calculate the estimated risk of death for each
18 patient. We tally them up, and then we
19 compare that with the actual number of
20 patients that died.

21 Now you can also, and we have done
22 this, looked at deciles of risk, so that you

1 can low risk deciles and high risk deciles,
2 and you can do it across, you know, as broad
3 a distribution of risk as you want. We've
4 done this, and actually the model performs
5 very well across the spectrum of risk.

6 Performance of the model tends to
7 fall off a little bit at the extremes, and
8 this is true of any risk prediction model.
9 But over the broad range of typical expected
10 mortality rates, model performance is very
11 good.

12 CHAIR MORRIS: Are you satisfied
13 with that answer?

14 DR. ROGERS: I wish I knew. I'll
15 stop here for the moment. Thank you.

16 CHAIR MORRIS: I think that that's
17 actually a very insightful question, in that
18 it's -- I'm not aware of very many situations
19 where that has actually been looked at. What
20 is the actual risk for individual patients,
21 and are the patients expected to survive
22 surviving, versus those that are expected to

1 have a harder time?

2 DR. SHAHIAN: Well, if I can just
3 expand a little bit further, no prediction
4 model does a fantastic -- there's not a
5 prediction model in existence that does a
6 fantastic job for individual patients. It can
7 tell you for a patient, for a general patient
8 that has renal failure, severe chronic
9 pulmonary disease and an emergency operation,
10 if you take 100 of those patients, five will
11 die.

12 Unfortunately, most models won't
13 tell you which five patients will die. The
14 best metric that gets at this in terms of
15 model performance is discrimination.
16 Discrimination of our models has been pretty
17 good.

18 So you take all possible
19 discordant pairs of patients, where a patient
20 lives -- one patient lives and one patient
21 dies, take all the combinations of those, and
22 then ask in how many of those individual

1 experiments, if you will, did the patient that
2 died have a higher probability of death than
3 the patient who lived? That's discrimination
4 or C index.

5 That's about the closest we get to
6 answering the question that you just posed.
7 But we are not real great at, and no model in
8 existence is great at, predicting for an
9 individual patient, John Smith.

10 We can do a pretty good job of
11 describing what generally happens to patients
12 like John Smith that have John's particular
13 combination of risk factors. But actually
14 predicting for John is very difficult.

15 DR. ROGERS: Well, I think it's
16 less about predicting for John than it is
17 knowing about what the patient -- who actually
18 died. That can be done, and I happen to have
19 a slide.

20 But we can wait. I mean I think
21 it's an important point. It could be that the
22 patient -- usually, this comes in the context

1 of, well, you can measure our stuff in our
2 hospital, but you haven't the faintest idea
3 how tough it is to do what we do -- you know,
4 the old adage of my patients are sicker.

5 In fact, this addresses it very
6 well. It could be in a hospital that has a
7 very good mortality rate for very sick
8 patients, for some reason it doesn't do so
9 well with patients who aren't that sick, or
10 the opposite may occur.

11 I'm just, I'd just comment that I
12 think the measure that we're proposing for all
13 of our mortality, I think, doesn't take that
14 into account. If indeed that is -- if we're
15 capable of doing that, are we putting
16 ourselves in an advantageous spot by approving
17 something that's going to last for the next
18 three years, when in fact there's something
19 that could be done now that could be used in
20 a more advantageous way over that period of
21 time. I don't know the answer to that
22 question.

1 DR. SHAHIAN: Well, I think model
2 testing that should be performed and that we
3 perform, and I think all responsible model
4 developers do this, they assess calibration.

5 I think what you're talking about,
6 I think, is calibration. How does the model
7 do for patients with low risk? How does it do
8 for patients with medium risk? How does it do
9 for patients with high risk? Am I misreading
10 you?

11 DR. ROGERS: Again, I wish I was
12 smarter about this. What I do know is that
13 what I see is that what it does do is it looks
14 retrospectively, and immediately at the risk,
15 the preoperative risk of the patients who
16 died, and gives you some reflection of you may
17 have an absolutely acceptable OE ratio. You
18 may have a star or you may have a smiley face,
19 similar to other hospitals.

20 But the patients who died probably
21 shouldn't have died, as opposed to the
22 patients who died at another hospital whose

1 risk, individual risk, was really quite high
2 and they did the best they can. That would be
3 my response, whether that's useful or not.

4 DR. DUTTON: I think some of what
5 you're asking, Terry, has to do with the uses
6 you make of the data, rather than the data
7 itself. Risk adjustment and comparison to
8 national benchmarks for mortality are very
9 common in trauma. I know we've been doing it
10 for 20 years in trauma.

11 Part of looking at that report is
12 not just how do you do statistically O to E
13 overall, but who are your unexpected deaths
14 and who are your unexpected survivors, and
15 what lessons can you learn from them. So it's
16 more of an application than a requirement of
17 the data itself.

18 DR. SHAHIAN: All right. Now I
19 see what you're saying, and that's absolutely
20 right. I think the way to get at that -- it
21 really has to be at the institutional -- or
22 you have Dr. Prager there who really has led

1 nationally an effort to look at every single
2 death in his region and divides their
3 hospitalization up into various time periods,
4 and tries to identify was this a preventable
5 death? What could have been done better?

6 So I absolutely agree with that,
7 but I think that's not a risk adjustment issue
8 so much.

9 DR. SEARS: One other comment. We
10 don't take into account here any of the
11 volumes of the programs. So a small volume
12 program that has five percent mortality, but
13 within the confines of competence limits may
14 be normal for them, you know, for year-in over
15 year-out, versus a program that does 500,
16 where you might get a more accurate assessment
17 of the true mortality.

18 So it's just a comment, but it
19 makes using this as a measure somewhat
20 difficult to adjudicate.

21 DR. STAFFORD: I think volume,
22 though, comes up in some of the other

1 measures, and I suspect that's going to be a
2 very large discussion, because if you look at
3 the literature on volume, depending on what
4 procedures you're talking about, it runs the
5 gamut.

6 For a lot of procedures, we don't
7 know. The question becomes is it the volume?
8 Is it the volume per surgeon? Or is it the
9 system that you work within that's really the
10 matter, and not necessarily the numbers?

11 So I think what, at least in this
12 large database, you kind of take some of that
13 out of the picture and have to look at your
14 own institution. But I think it's probably
15 going to generate a lot of discussion as we
16 get into some of the other measures.

17 CHAIR MORRIS: I agree with that.
18 Will we have the opportunity to request
19 harmonization of this measure, of mortality
20 with volume measures, or is that already in
21 the works for later?

22 MS. MURPHY: There will be an

1 opportunity to look at areas for
2 harmonization.

3 CHAIR MORRIS: Okay. So let's
4 keep that in mind, and let's go ahead and
5 proceed to the vote. Does the measure meet
6 NQF criteria for Importance to Measure and
7 Report?

8 [COMMITTEE VOTING.]

9 CHAIR MORRIS: 21 said yes, 1 said
10 no. Next vote is does the measure meet NQF
11 criteria for Scientific Acceptability of
12 Measure Properties?

13 [COMMITTEE VOTING.]

14 CHAIR MORRIS: I'd like to ask you
15 all to just hit your vote one more time, and
16 then hit send, directing toward Jessica.

17 [COMMITTEE VOTING.]

18 CHAIR MORRIS: 17 said completely
19 meets the criteria; 5 said partially meets the
20 criteria. Next, does the measure meet NQF
21 criteria for Usability?

22 [COMMITTEE VOTING.]

1 CHAIR MORRIS: And one more time,
2 please press down firmly on your button, and
3 then hit send.

4 [COMMITTEE VOTING.]

5 CHAIR MORRIS: 21 said completely
6 meets the criteria, 1 said partially meets the
7 criteria. And then does the measure meet NQF
8 criteria for Feasibility?

9 [COMMITTEE VOTING.]

10 CHAIR MORRIS: Okay, and please
11 press down firmly on your button again and
12 then hit send?.

13 [COMMITTEE VOTING.]

14 CHAIR MORRIS: 20 said yes, it
15 completely meets the criteria; 2 said
16 partially. Then lastly, does the measure meet
17 all of the NQF criteria for endorsement?

18 So just to recap briefly, we
19 talked about risk-adjusted mortality rate, and
20 could it be better performed to better
21 identify whether the people who should do well
22 actually are doing well within institutions.

1 We had quite a bit of discussion
2 about that. Ultimately, Dr. Rogers, did you
3 feel satisfied with that discussion?

4 DR. ROGERS: Partially. I'm okay,
5 that's fine. I just wanted to raise the
6 point. I appreciate the opportunity.

7 CHAIR MORRIS: Yes. I do think
8 it's an important point to bring up. Then
9 there was the point that volume is not taken
10 into account with this measure, and perhaps
11 we'll find an opportunity to harmonize with a
12 volume measure in the future.

13 I think that the underlying
14 message there is that in some ways, in high
15 volume centers, in medium and high volume
16 centers, volume actually may predict mortality
17 with more regularity than mortality does from
18 year to year.

19 In low volume centers, that's
20 probably even more so the case. Any other
21 issues that anybody wants to bring up with
22 regard to this measure before we vote?

1 DR. SHAHIAN: This is Dave
2 Shahian. Could I just ask that your last
3 statement contain a qualifier from us. The
4 evidence for a strong volume relationship for
5 CABG, which is I think what we're discussing
6 right now, is really fairly problematic. For
7 other procedures that we'll talk about, I
8 would concede.

9 But for CABG, risk-adjusted
10 mortality is a much better predictor, and in
11 fact even John Birkmeyer, who's an advocate of
12 volume as a performance metric, has published
13 a paper with Justin Dimick showing that for
14 CABG surgery, risk-adjusted mortality is a
15 much, much stronger predictor than volume.

16 CHAIR MORRIS: I agree. I think
17 that's an important point, and I think that
18 volume is a better predictor for some specific
19 operations.

20 Then there are other operations
21 which will not necessarily come up in this
22 particular session, but that will definitely

1 come up in the future, within general surgery,
2 for which volume is really not a good
3 predicter at all. So that is something to
4 keep in mind. I agree.

5 So does the measure meet all of
6 the NQF criteria for endorsement?

7 [COMMITTEE VOTING.]

8 CHAIR MORRIS: We had 22 out of 22
9 saying yes, it does meet the criteria. Okay.
10 So now we're moving on to Work Group B, and
11 first we'll start with Dr. Dillon, 0120, Risk-
12 Adjusted Operative Mortality for Aortic Valve
13 Replacement.

14 I'd also like for you to try and
15 provide information regarding whether the
16 measure developer has anything to report since
17 -- for maintenance measures -- since the
18 measure was initially endorsed. So is there
19 anything new that we know since the measure
20 was initially endorsed, for those that are
21 being maintained.

22 Then we need to probably pay a

1 little more attention to disparities and what
2 is known or what is not known about
3 disparities in these measures.

4 DR. DILLON: Right. Team B will
5 take over or take the baton from Team A, but
6 we'll probably continue with a familiar theme
7 here.

8 So NQF 0120 involves risk-adjusted
9 operative mortality for aortic valve
10 replacement. It looks at the percent of
11 patients undergoing isolated aortic valve
12 replacement who die within 30 days or within
13 the hospitalization.

14 It is publicly reported. It is
15 certainly a measure that is of great
16 importance to the public. In terms of
17 scientific validity -- and I guess, Dr.
18 Morris, addressing your question -- in terms
19 of what is known about some of the
20 disparities, certainly the risk-adjustment
21 process is well-established.

22 They have multiple years of

1 analyzing and tracking trends across
2 institutions with this. The issue does come
3 up in terms of being able to determine some of
4 the disparities using this measure alone, in
5 terms of subgroup analysis, which was one of
6 the minor points that we discussed as a work
7 group, that perhaps with stratification or
8 further evaluation, STS database would allow
9 for that information.

10 But the report itself does not
11 allow, does not allow one to determine that at
12 face value. It certainly is quite -- the
13 Usability of it, we found as a group no
14 particular issues or problems, and certainly
15 the Feasibility was adequate.

16 So in general, our work group had
17 no particular issues with this measure, and
18 indeed I think there was rather a unanimous of
19 congruence in terms of evaluating it.

20 CHAIR MORRIS: Anybody have
21 anything else to say about this measure?
22 Issues or comments, questions?

1 DR. STAFFORD: I have just a quick
2 question. So for the overall mortality after
3 CABG, the time frame for the denominator was
4 12 months, and here, the time frame for the
5 denominator is 60 months. Is there something
6 that informs that difference in time frames?

7 DR. PRAGER: I'm not sure. It
8 should be on, sorry. I'm not -- the 12 months
9 is not in the specs that I read, unless I
10 missed something in the 60 months.

11 DR. STAFFORD: So in --

12 DR. PRAGER: I may be missing
13 something. I mean we report 30 day or in-
14 hospital.

15 DR. STAFFORD: So it's in the
16 application for mortality after CABG, in the
17 denominator statement. Denominator time
18 window is 12 months. In this measure, 0120,
19 same place, the denominator time window is 60
20 months.

21 DR. SHAHIAN: No, I think the
22 issue there is that we aggregate data for the

1 valve cases, because there are far fewer of
2 them historically than CABG cases.

3 I don't know if Jane is still on
4 the line. I don't -- I'm not absolutely sure
5 that 60 months is correct. But if she has
6 that down here, I'm sure it is. But because of
7 the smaller number of cases, we do aggregate
8 the valve cases.

9 DR. PRAGER: But for the
10 individual site, you'll get a report that will
11 give you what happened in three months or six
12 months.

13 DR. DUTTON: In other words, it's
14 always 30 day mortality, and it's just a
15 question of whether you're reporting a five
16 year window or a one year window?

17 DR. SHAHIAN: That's right, right.

18 DR. STAFFORD: Right, yes. The
19 numerator's the same. It's the denominator
20 that I was struggling with.

21 DR. SHAHIAN: Yes.

22 CHAIR MORRIS: Okay. Are we ready

1 to vote? Anybody else want to bring anything
2 up with that one?

3 (No response.)

4 CHAIR MORRIS: Let's move on then.
5 Does the measure meet NQF criteria for
6 Importance to Measure and Report?

7 [COMMITTEE VOTING.]

8 CHAIR MORRIS: And we said -- 20
9 out of 20 said yes. The next vote, does the
10 measure meet NQF criteria for Scientific
11 Acceptability of Measure Properties?

12 [COMMITTEE VOTING.]

13 CHAIR MORRIS: 20 said completely
14 and 1 said partially. Next vote, does the
15 measure meet NQF criteria for Usability?

16 [COMMITTEE VOTING.]

17 CHAIR MORRIS: 20 said completely
18 and 1 said partially. Then the last -- then
19 the second to last vote, Feasibility. Does
20 the measure meet NQF criteria for Feasibility?

21 [COMMITTEE VOTING.]

22 CHAIR MORRIS: 21 out of 21 said

1 completely. The last vote here, does the
2 measure meet all the NQF criteria for
3 endorsement. Then just to recap again, it
4 sounded like Team B actually approved of this
5 measure pretty uniformly. There was a
6 question or discussion of stratification by
7 race, ethnicity, gender or other socially
8 vulnerable markers.

9 And the report here does not
10 clarify the presence of disparities, but that
11 could potentially be clarified further by the
12 developer. In addition, something that we
13 haven't talked about quite so much was the
14 plan for public reporting. So this is, as I
15 understand it, not a publicly reported
16 measure. Is there a plan in place for
17 publicly reporting?

18 DR. PRAGER: David and I will echo
19 this. Yes, there's a plan for over the next
20 several years to roll out multiple measures
21 for public reporting, and aortic valve is the
22 next in queue, and we would hope within 12

1 months to have that be able to be publicly
2 reported.

3 CHAIR MORRIS: Can you describe
4 the plan?

5 DR. PRAGER: Can I describe the
6 plan? The plan is in its early stages of
7 creating a composite for public -- a composite
8 metric for publicly reporting the outcomes for
9 aortic valve replacement. David Shahian is
10 leading this with DCRI.

11 DR. SHAHIAN: Yes. I can just
12 speak briefly to that. We are developing --
13 as you know, for CABG, we have a combination
14 of outcomes and process measures that we
15 publicly report. There is not the analog of
16 internal mammary artery use in the case of
17 valve surgery, and we are going to confine
18 this particular composite to strictly to
19 outcomes measures.

20 So this aortic valve composite
21 measure that we'll be publicly reporting will
22 consist of risk-adjusted mortality and the

1 five major risk-adjusted morbidities, stroke,
2 renal failure, reoperation, prolonged
3 ventilation and I've left one out. Five
4 majors, yes.

5 So we're developing that right
6 now, and the goal is to develop it this year
7 and publicly report it next year. It's been
8 a big undertaking to publicly report the
9 isolated CABG. We're still working the kinks
10 out of that, and we wanted to be pretty far
11 along in that process before we roll out a
12 second measure.

13 But I think we can commit to 2011
14 for public reporting, or 2012, excuse me.

15 CHAIR MORRIS: Okay, thank you.
16 So we'll go ahead and vote. Does the measure
17 meet all of the NQF criteria for endorsement?

18 [COMMITTEE VOTING.]

19 CHAIR MORRIS: We had 21 out of 21
20 say yes. The next measure to discuss is 0121,
21 Dr. Sears, talking about Risk-Adjusted
22 Operative Mortality for Mitral Valve

1 Replacement.

2 DR. SEARS: Thanks. This is very
3 similar to the last discussion, where we're
4 looking at the percent of patients undergoing
5 strictly mitral valve replacement who die,
6 either within 30 days of operation or within
7 the time of the hospitalization.

8 Our team felt that this was an
9 important measure. There was really no
10 problems with the scientific validity,
11 usability or feasibility for the measure.

12 CHAIR MORRIS: Any issues anybody
13 wants to bring up with regard to this one,
14 issues or problems?

15 (No response.)

16 CHAIR MORRIS: That's a very short
17 discussion. Okay. Is there -- no? Okay.
18 Well, let's go ahead and vote. Does the
19 measure meet NQF criteria for Importance to
20 Measure and Report?

21 [COMMITTEE VOTING.]

22 CHAIR MORRIS: I'll ask everybody

1 to once again press firmly on your vote and
2 then press send.

3 [COMMITTEE VOTING.]

4 CHAIR MORRIS: We had 21 out of 21
5 say yes. The next vote, does the measure meet
6 NQF criteria for Scientific Acceptability of
7 Measure Properties?

8 [COMMITTEE VOTING.]

9 CHAIR MORRIS: I'll ask everybody
10 once more to press firmly on their vote and
11 hit send.

12 [COMMITTEE VOTING.]

13 CHAIR MORRIS: 20 said it
14 completely meets the criteria and 1 said it
15 partially meets the criteria. Does the
16 measure meet NQF criteria for Usability?
17 Please vote twice this time.

18 (Laughter.)

19 [COMMITTEE VOTING.]

20 CHAIR MORRIS: 21 out of 21 said
21 completely meets the criteria, and it seems
22 that voting twice works well. Next, does the

1 measure meet NQF criteria for Feasibility.

2 [COMMITTEE VOTING.]

3 CHAIR MORRIS: 21 out of 21 said
4 completely meets the criteria for Feasibility.
5 Next, does the measure meet all of the NQF
6 criteria for endorsement? We really had no
7 discussion about this to speak of. I have
8 nothing to recap. Is there anything anybody
9 wants to say about the measure before we vote
10 on it?

11 DR. SEARS: For public reporting
12 as well, what's the plan?

13 DR. PRAGER: The plan is yes,
14 we'll develop the aortic model. As David
15 said, there is no IMA for these, so it will be
16 based on the other publicly reported NQF-
17 endorsed aspects, and it would probably be
18 sequenced, and hopefully it will be less than
19 the next full year after, because we will have
20 experience in the model.

21 DR. WILHOIT: One small question
22 about that that I was thinking about with

1 respect to what you said about the aortic
2 valve replacement. We're looking here at a
3 stand-alone measure, but what you're talking
4 about publicly reporting are composites.
5 Those are very different. So I just wondered,
6 just thought that was an issue worth putting
7 out on the table.

8 DR. PRAGER: Yes. I'll let David
9 handle most of that, but our public -- what is
10 publicly reported currently now is a composite
11 metric for coronary bypass, based on a feeling
12 created over years that this allows the
13 opportunity to put in multiple measures and
14 have various discretionary factors in the
15 model that's reported. David, can you add to
16 that?

17 DR. SHAHIAN: Yes. Just like our
18 CABG model, the AVR composite model we develop
19 will have drill-down capability, so that
20 you'll be able to look specifically at the
21 risk-adjusted mortality component, which will
22 be the equivalent of this measure, and we will

1 come back to NQF at a future time, to get the
2 composite, to put the composite before you for
3 endorsement.

4 CHAIR MORRIS: Okay. Do you feel
5 that that answers your question?

6 DR. WILHOIT: Well, one of -- you
7 know, looking at the documents -- one of the
8 criteria for even considering a measure is
9 that it be brought forward for both quality
10 improvement and public accountability.

11 If the measure isn't being
12 considered for public accountability, as a
13 stand-alone measure, which is what we're
14 looking at, is it one, you know, does it meet
15 that criteria? That's my question, I guess.

16 DR. SHAHIAN: Well, if it -- the
17 composite then has X and Y in it, it's
18 publicly report. If X is endorsed and we have
19 the ability in that composite to separately
20 report the X component of it, it seems to me
21 that satisfies the requirement for public
22 reporting. I mean you'll have it. You'll

1 have this publicly reported.

2 You'll just have more. You'll
3 have this plus the ability to have this
4 incorporated into a larger composite measure.
5 But you'll have this. It will be publicly
6 reported. We'll also have the capability of
7 providing you with additional information on
8 other outcomes as well.

9 CHAIR MORRIS: So let me just try
10 and clarify that a little bit. With your
11 public reporting of a composite measure, then
12 you would also publicly report the components
13 that went into the composite?

14 DR. SHAHIAN: We do that now. If
15 you look at the public reporting that we have
16 of the STS CABG composite, it gives the -- you
17 have, it's four domains. One of those domains
18 is risk-adjusted mortality for CABG. You can
19 go to our website right now and get that
20 information, or go to Consumer Reports.

21 CHAIR MORRIS: So your plan for
22 the composite measure would include -- it

1 would be an individual composite measure for
2 each of these operations then?

3 DR. PRAGER: Yes.

4 CHAIR MORRIS: Okay. So Dr.
5 Prager is saying yes to that. Let's go ahead
6 and vote, unless there's anything else anybody
7 wants to add. Thanks for your comments, guys.
8 Does the measure meet all of the NQF criteria
9 for endorsement? And please vote twice.

10 [COMMITTEE VOTING.]

11 CHAIR MORRIS: 21 out of 21 said
12 yes, it does meet the criteria for
13 endorsement. Just to clarify for the
14 transcript, as we started this, we learned
15 when we started this meeting today that voting
16 twice is only recorded as once. Early and
17 often.

18 All right. The next measure is
19 0122, Risk-Adjusted Operative Mortality for
20 Mitral Valve Replacement and CABG Surgery, and
21 this Dr. Rogers.

22 DR. ROGERS: Yes, thank you. Just

1 a point of clarification. Is it okay press
2 once, twice and then send twice, or do you
3 have to do it in sequence?

4 CHAIR MORRIS: I recommend doing
5 it in sequence; otherwise, you'll be voting
6 11.

7 DR. ROGERS: Thank you. We are
8 dealing with risk-adjusted operative
9 mortality, mitral valve replacement plus CABG
10 surgery, and I think the same kind of issues
11 that have previously been reported on the two
12 similar measures apply here.

13 Except for my residual and
14 probably singular concern about the risk
15 adjustment, there was no issue with respect to
16 the importance to report. Similarly, the same
17 would apply to both Scientific, Usability and
18 Feasibility. So it's pretty straightforward
19 and I think similar to what we've already
20 heard.

21 DR. MORTON: Just one question.
22 Any exclusion criteria about this?

1 DR. ROGERS: I'm not aware of any.
2 Dr. Prager, do you know?

3 DR. PRAGER: No. As long as it's
4 a repair and a coronary -- I'm sorry. As long
5 as it's a replacement and a coronary bypass,
6 no.

7 DR. ROGERS: Did you have
8 something in mind?

9 DR. MORTON: Re-dos.

10 DR. ROGERS: I'm sorry.

11 DR. MORTON: Re-dos. If it's a --

12 DR. ROGERS: Oh, I see. Yes.

13 DR. PRAGER: I think it is what it
14 is. I'm not aware. David, do you know?

15 DR. SHAHIAN: I'm sorry, I didn't
16 hear the question.

17 DR. PRAGER: David, the question
18 is whether -- what exclusions? So the patient
19 had a coronary bypass and then they're having
20 a reop for a mitral and a coronary. Is that
21 case excluded?

22 DR. SHAHIAN: No. The reoperative

1 status is just included in the risk
2 adjustment. You have -- Ipd have to go to the
3 specific measure, but I'm sure there are some
4 --

5 DR. CIMA: There's a comment here
6 that in one spot, it says "replacement," and
7 other spots it says "replacement/repair."
8 It's supposed to be replacement, correct?

9 DR. PRAGER: This is supposed to
10 be replacement, yes.

11 DR. CIMA: There's a separate one
12 for repair?

13 DR. PRAGER: Correct.

14 DR. SHAHIAN: Are we talking about
15 the isolated MVR or the MVR CABG right now?

16 DR. PRAGER: MVR CABG.

17 DR. SHAHIAN: I'm having trouble
18 finding that in my document. Are exclusions
19 listed, Rich?

20 DR. PRAGER: I'm looking, too.

21 DR. HAN: There are no exclusions
22 listed, Dr. Shahian. This is Jane.

1 DR. PRAGER: So no exclusions
2 listed in the document.

3 DR. WILHOIT: One question I had
4 about this measure, looking at the data that
5 was provided, is that the volume of these
6 cases seems to be low. In the other measure
7 that had to do with volume, it reported a
8 median of 27 and a mean of 38 cases.

9 And this is a five-year measure,
10 which makes the denominator a little bigger,
11 but -- because you're aggregating over five
12 years. But even with five years of data, the
13 number of centers for which results are
14 reported is only 33.

15 That makes me wonder whether, how
16 useful of a measure this is. It may be that
17 it's useful for the higher volume places, and
18 that's good enough. But it just seemed like
19 it was -- that the results were different
20 enough, in terms of the number of centers for
21 which there's data. It seems like it was
22 worth putting that on the table.

1 DR. SHAHIAN: Yes. Dr. Prager
2 comes from one of those institutions
3 nationally that does a very high volume of
4 mitral valve surgery, and I think you're
5 right. This measure will be much more
6 relevant for certain centers where this
7 procedure is practiced more commonly.

8 Aortic valve replacement is done
9 at most hospitals. Mitral valve surgery,
10 because of the special techniques done in
11 repair, and the desire to try to get as many
12 valves repaired as possible, rather than
13 replaced -- these cases tend to gravitate to
14 major centers. Rich, do you want to comment
15 on that?

16 DR. PRAGER: No. I would just
17 echo that, and I think your observation is
18 absolutely correct. But I think the
19 importance of it remains.

20 CHAIR MORRIS: Okay. Are we ready
21 to vote? Any other comments, issues,
22 questions?

1 (No response.)

2 CHAIR MORRIS: Does the measure
3 NQF criteria for Importance to Measure and
4 Report, and I'll ask you to hit whatever your
5 vote is and then send, and then hit whatever
6 your vote is and send.

7 [COMMITTEE VOTING.]

8 CHAIR MORRIS: I'm sorry to say
9 this, but let's all vote one more time.

10 [COMMITTEE VOTING.]

11 CHAIR MORRIS: We had 19 out of 19
12 say yes, it does meet the criteria. The next
13 vote, does the measure meet NQF criteria for
14 Scientific Acceptability of Measure
15 Properties?

16 [COMMITTEE VOTING.]

17 CHAIR MORRIS: 16 said yes
18 completely; 3 said partially. Does the
19 measure meet NQF criteria for Usability?

20 [COMMITTEE VOTING.]

21 CHAIR MORRIS: 16 said yes
22 completely and 3 said partially. Does the

1 measure meet NQF criteria for Feasibility?

2 [COMMITTEE VOTING.]

3 CHAIR MORRIS: 18 said completely,
4 1 said partially. And then lastly, does the
5 measure meet all the NQF criteria for
6 endorsement, and we talked very briefly about
7 the public reporting plan. We talked about
8 the limited number of centers that does this
9 sort of operation. Any other issues that
10 anybody wants to bring up?

11 (No response.)

12 CHAIR MORRIS: Okay. Let's go
13 ahead and vote.

14 [COMMITTEE VOTING.]

15 CHAIR MORRIS: 19 out of 19 said
16 yes, this does meet the criteria. Okay.
17 Let's see now. Next is Dr. Saigal, 0123,
18 Risk-Adjusted Operative Mortality for Aortic
19 Valve Replacement and CABG.

20 DR. SAIGAL: Okay. So this is in
21 the same theme. They're looking at the
22 clinical patients who have a combined aortic

1 valve replacement and CABG who die either in
2 the hospital, after the surgery or within 30
3 days of their discharge.

4 In terms of the Importance of the
5 measure, I think it has got great face
6 validity, it's very important in patients and
7 it varies by center. In terms of the
8 scientific validity of it, as modeled and
9 tested and published, they didn't report
10 anything about disparities. I'm sure that's
11 actually available pretty easily.

12 I didn't see any information about
13 how this measure has changed practice or had
14 an impact, but I'm sure that's available as
15 well. And Feasibility and Usability, I think,
16 are also acceptable.

17 I didn't see a public reporting
18 plan either, but I think it's probably in the
19 same sort of plan that they've articulated
20 already.

21 CHAIR MORRIS: Thank you. Anybody
22 have any other issues, comments, questions

1 about this measure? Can the STS respond to
2 the issues around no information regarding
3 disparities on any data about the impact of
4 this measure and can you confirm or add to the
5 question of a public reporting plan?

6 DR. PRAGER: Disparities, again,
7 is something that we have data that can be,
8 that can be turned into information for all of
9 us, frankly. Two, public reporting plan will
10 be sequenced. I will be honest, that I am not
11 sure we can give you a time frame, 24 to 36
12 months perhaps.

13 The aortics and then the mitrals,
14 and then mitral coronaries, aortic coronaries,
15 hopefully tied closely to each other. The
16 third, other than intermittent publications of
17 research on these types of patients, I am not
18 sure we have, and using it in regional
19 collaboratives and starting to look at what we
20 may get into later about volume and outcomes
21 in these cohorts of patients, I'm not sure we
22 can tell you anything other than we expect

1 these numbers to continue to rise as
2 technology has influenced this group of
3 patients, having more hybrid operations, more
4 coronaries done in the cath lab, and then more
5 higher risk valves done in the operating room,
6 including now percutaneous valve approaches.

7 So I think we are at a cusp, if
8 you will, for this. David, do you have other
9 thoughts?

10 DR. SHAHIAN: No.

11 CHAIR MORRIS: Okay. Any other
12 issues before we go to a vote?

13 (No response.)

14 CHAIR MORRIS: All right. Does
15 the measure meet NQF criteria for Importance
16 to Measure and Report?

17 [COMMITTEE VOTING.]

18 CHAIR MORRIS: Twenty out of 20
19 say yes. Does the measure meet NQF criteria
20 for Scientific Acceptability of Measure
21 Properties?

22 [COMMITTEE VOTING.]

1 CHAIR MORRIS: Eighteen say
2 completely; 2 say partially. Does the measure
3 meet NQF criteria for Usability?

4 [COMMITTEE VOTING.]

5 CHAIR MORRIS: Nineteen say
6 completely; 2 say partially. Does the measure
7 meet NQF criteria for Feasibility?

8 [COMMITTEE VOTING.]

9 CHAIR MORRIS: Twenty-one out of
10 21 say completely. Does the measure meet all
11 the NQF criteria for endorsement?

12 DR. SAIGAL: Could I ask one
13 question before we vote?

14 CHAIR MORRIS: Yes.

15 DR. SAIGAL: The response about
16 the mortality rates rising over time because
17 the indications for the procedure in the OR
18 have changed, and a higher-risk population is
19 undergoing the procedure in the OR. Does that
20 mean the risk adjustment model is failing to
21 account for that, or should that be like
22 changed, because of the nature of the

1 population undergoing the procedure?

2 CHAIR MORRIS: Dr. Prager, do you
3 want --

4 DR. PRAGER: No, I apologize. I
5 may have been misinterpreted. I didn't say
6 that mortality rates are rising over time. We
7 are starting to see a higher-risk population,
8 because of percutaneous approaches and other
9 hybrid approaches, so that more people are
10 becoming, if you will, candidates for a
11 higher-risk operation.

12 Those data, those analyses of
13 those data -- we don't have all those data
14 yet. This is just over the last year or two
15 or three or four, and we expect to see more.

16 DR. SHAHIAN: So we're seeing more
17 patients with specific high risk predictors,
18 and the expected risk of the patient
19 population is increasing. But in fact
20 observed mortality has not been increasing as
21 rapidly or remains stable or in some cases
22 declining from any of these procedures. So,

1 and the data, these models are recalibrated
2 every year, as well.

3 But it's mostly the expected risk
4 that's been increasing.

5 DR. SEARS: One other thought
6 here. Do we need to alter this a little bit
7 with the advent of the percutaneous
8 techniques, as they go through their
9 evolution, and should this measure be more
10 geared to open repair or open replacement?

11 DR. HALPERN: Actually, you'll see
12 there's two coming up that are repairs, rather
13 than replacements.

14 DR. SEARS: Okay. Well no, but
15 I'm just talking about percutaneous versus
16 open aortic valve replacement. Not repair,
17 just replacement, either through a catheter
18 technique, which is not an open-chest
19 procedure.

20 DR. PRAGER: David, help us a
21 little bit, but catheter technique is not in
22 this model at this point; correct?

1 DR. SHAHIAN: Well, that's right.
2 I mean we are collecting data on those
3 patients, but those patients are all being
4 done under protocol right now.

5 CHAIR MORRIS: So it sounds like
6 that is -- in a way, it's sort of an
7 exclusion, because they're being done under
8 protocols, so they're not really captured
9 here; is that correct? Okay, and potentially
10 we'll be looking at this in the future. Okay.
11 Any other issues, comments?

12 (No response.)

13 CHAIR MORRIS: Does the measure
14 meet all of the NQF criteria for endorsement?

15 [COMMITTEE VOTING.]

16 CHAIR MORRIS: Twenty-one out of
17 21 say yes, it does meet all of the criteria.
18 The next measure is Dr. Sears's, 1501, Risk-
19 Adjusted Operative Mortality for Mitral Valve
20 Repair, and this is split from Measure 0121,
21 and I'm hoping that you will clarify the
22 reason for splitting from Measure 0121.

1 DR. SEARS: Yes. This is very
2 similar to 0121, in the fact that you're
3 dealing with a mitral valve. But this
4 specifically looks at repairing of the valve
5 and not replacing it.

6 So that there are various
7 techniques that are used to repair the mitral
8 valve today, and so it's incumbent upon us to
9 recognize that the repairs are different than
10 the mitral valve replacement.

11 When we talked about this within
12 our group, we felt this was an important value
13 for the society, for the Quality Forum to
14 endorse. The Scientific Acceptability was
15 pretty much uniformly accepted, as was the
16 Feasibility and Usability of the measure.

17 DR. HALPERN: This is actually
18 where I had more of a question of what repairs
19 are being included, because the other ones
20 were specifically replacement. These next two
21 are repairs.

22 DR. SEARS: You're talking about

1 1502 as well? Well, 1502 is mitral valve
2 repair plus CABG. This is strictly a mitral
3 valve repair, no CABG involved with it. So
4 they're different techniques.

5 DR. HALPERN: They're all open
6 chest.

7 DR. SEARS: Right, they're all
8 open. The mitral valve is visualized and then
9 whatever technique the surgeon opts to use.
10 That doesn't break down technique, obviously.

11 CHAIR MORRIS: Can you go a little
12 bit further in your question? I'm not sure
13 that I'm understanding specifically what
14 you're asking.

15 DR. HALPERN: As somebody was
16 indicating, there's percutaneous ways of
17 repairing valves now. But this is
18 specifically referring just to open-chest
19 cases.

20 DR. SEARS: Yes. Again, I think,
21 and David probably can clear this up more than
22 I can, I think most of the mitral valve

1 percutaneous techniques are still being done
2 under some kind of a protocol. Wouldn't you
3 say that's right, David?

4 DR. SHAHIAN: Absolutely. That is
5 -- I think, Rich, most of those are still
6 being done in Europe, aren't they?

7 DR. PRAGER: Yes. There are some
8 in this country. They're mostly protocol- or
9 company-driven at this point in time and they
10 are not in this grouping of patients. These
11 are all operative patients. Could be
12 robotically, it could be right thoracotomy,
13 could be mediastenotomy, could be a left
14 thoracotomy. They're operative patients, not
15 percutaneous.

16 CHAIR MORRIS: And then split from
17 the other measure because it's a repair and
18 not a replacement; is that correct?

19 DR. PRAGER: Yes, that's correct.

20 CHAIR MORRIS: Okay, and is there
21 more that you'd like to say about it? Okay.
22 Any other issues with regard to this?

1 (No response.)

2 CHAIR MORRIS: Are we ready to
3 vote? Great, okay. Does the measure meet NQF
4 criteria for Importance to Measure and Report?

5 [COMMITTEE VOTING.]

6 CHAIR MORRIS: Twenty-one out of
7 21 say yes. Does the measure meet NQF
8 criteria for Scientific Acceptability of
9 Measure Properties?

10 [COMMITTEE VOTING.]

11 CHAIR MORRIS: Nineteen said
12 completely, 2 said partially. Does the
13 measure meet NQF criteria for Usability?

14 [COMMITTEE VOTING.]

15 CHAIR MORRIS: Nineteen said
16 completely, 2 said partially. Does the
17 measure meet NQF criteria for Feasibility?

18 [COMMITTEE VOTING.]

19 CHAIR MORRIS: Twenty-one out of
20 21 said completely. I'm afraid that there's
21 not much for me to recap on this one, unless
22 anyone wants to bring anything up. I actually

1 don't have any further comments. Please feel
2 free to bring anything up that you think is
3 important to note before the final vote.

4 (No response.)

5 CHAIR MORRIS: Okay. Does the
6 measure meet all of the NQF criteria for
7 endorsement?

8 [COMMITTEE VOTING.]

9 CHAIR MORRIS: Twenty-one out of
10 21 said yes. The next measure is 1502, Dr.
11 Rogers, Risk-Adjusted Mortality for Mitral
12 Valve Repair and CABG Surgery, again split
13 from Measure 0122.

14 DR. ROGERS: Right. This is the
15 evil twin of the prior measure evaluation.
16 Risk-adjusted operative mortality for MV
17 repair and CABG surgery. I have really
18 nothing new to add that hasn't been said
19 already. Meets the criteria for Importance to
20 Report, Scientific Acceptability, Usability,
21 Feasibility, and there are no listed
22 exclusions. So we would recommend its

1 approval.

2 CHAIR MORRIS: And I assume the
3 same issues with lack of information about
4 disparities, lack of information about changes
5 in practice, and lack of -- and future plan
6 for public reporting of the composite measure.

7 DR. ROGERS: I have nothing to add
8 to that.

9 CHAIR MORRIS: I hope that the
10 lack of discussion is not because everybody's
11 been beaten into submission by the carbs at
12 lunch. But we'll probably pick up a little
13 bit as we move on. So let's go ahead and
14 vote. Does the measure meet NQF criteria for
15 Importance to Measure and Report?

16 [COMMITTEE VOTING.]

17 CHAIR MORRIS: Twenty-one out of
18 21 said yes. Does the measure meet NQF
19 criteria for Scientific Acceptability of
20 Measure Properties?

21 [COMMITTEE VOTING.]

22 CHAIR MORRIS: Sixteen said

1 completely, 4 said partially. Does the
2 measure meet NQF criteria for Usability?

3 [COMMITTEE VOTING.]

4 CHAIR MORRIS: Twenty said
5 completely, 1 said partially. Does the
6 measure NQF criteria for Feasibility?

7 [COMMITTEE VOTING.]

8 CHAIR MORRIS: Twenty-one out of
9 21 said completely. Does the measure meet all
10 the NQF criteria for endorsement? This is the
11 last chance to say something about this
12 measure before we take a vote on it.

13 (No response.)

14 CHAIR MORRIS: All right. Let's
15 go ahead and vote.

16 [COMMITTEE VOTING.]

17 CHAIR MORRIS: Twenty-one out of
18 21 said yes, it does meet all the criteria.
19 The next measure is Dr. Halpern, 0124,
20 Surgical Volume. A, Isolated Coronary Artery
21 Bypass Graft Surgery, B, Valve Surgery, C,
22 CABG and Valve Surgery.

1 DR. HALPERN: I think everybody
2 was saving up their discussion for this one.
3 So this only looks at volume. There is no
4 other quality measure here, and therefore it's
5 like only one number. It's not a numerator,
6 a denominator.

7 We had a very intense discussion
8 about this in our group, and all of us felt
9 that volume alone cannot be -- is not an
10 adequate quality marker, for reasons that have
11 already been brought up here today earlier,
12 including the fact that low-volume places may
13 still have good quality.

14 There was actually an editorial in
15 the Journal of Thoracic and Cardiothoracic
16 Surgery, because there was a paper published
17 out of Japan, where their high volume was
18 actually our low volume in this country, and
19 they had very excellent outcomes, pointing to
20 the fact that processes may be more important
21 than volume.

22 So with that, that meant to us

1 that it didn't even pass the first criterion.

2 CHAIR MORRIS: Any other things
3 that came upon your discussion that you'd like
4 to bring up now?

5 DR. HALPERN: No. Really, those
6 were the main ones, and the main question that
7 got discussed quite vigorously was whether
8 volume alone could be a quality marker.

9 CHAIR MORRIS: Okay. Anybody else
10 want to make a comment before we ask STS to
11 respond? Dr. Morton?

12 DR. MORTON: Was there mostly
13 concern about just volume in general, or was
14 it the number that was given?

15 DR. HALPERN: It was volume in
16 general as a sole marker for quality, because
17 this is for quality improvement. It's
18 important to know volume, but so it is
19 important to know -- measure and report, but
20 even the person who was on the phone who was
21 of the public, i.e., not a physician but the
22 consumer, felt that she was concerned also by

1 our discussion, that volume alone would be a
2 quality marker, having listened to our
3 discussion about it.

4 MS. KENNEDY: And I guess I can
5 comment, because I was that person. I think
6 just by itself, it could just be kind of
7 misconstrued, if there's not something to
8 accompany it, as far as the quality
9 performance.

10 DR. STAFFORD: I would add to
11 that. So not only, and you could have all of
12 these quality measures on somebody's publicly
13 available dashboard. So you could have volume
14 and you could have all the other measures we
15 talked about. But I can tell you, as probably
16 most lay people, the first thing they're going
17 to look at is going to be volume.

18 I mean that's a number. I mean
19 people conceptually get numbers, and they may
20 or may not look at all the other quality
21 measures that go with it. So you could have
22 a very high volume center, but then you go and

1 look at their mortality, you look at their
2 renal failure, you look at their incidence of
3 stroke, and it may actually be way worse than
4 some of the smaller volumes.

5 So you're right. In context, you
6 know, if somebody just looks at the number,
7 which I suspect is what a lot of people would
8 do, that could be a problem.

9 DR. HALPERN: Another thing that
10 was brought up is that if volume alone becomes
11 your quality marker, will people be doing more
12 procedures than they actually need to, in
13 order to make that volume criteria?

14 MR. FINDLAY: Well, I guess STS is
15 going to respond here, but was this intended
16 ever as a measure to stand alone, apart from -
17 -

18 DR. HALPERN: It actually was --
19 from my understanding from the discussion that
20 we had, is that CMS actually had this marker
21 and STS picked it up.

22 MR. FINDLAY: Okay. But it's

1 meant as a dashboard really. I mean in
2 reality you wouldn't use this alone. The
3 physician community wouldn't use it alone, and
4 the worry is that consumers might and would,
5 and that's misleading and we all know that.
6 So I concur.

7 DR. BURSTIN: I'll just point out
8 that NQF has at times paired measures,
9 indicating one should always be reported with
10 the other, next to each other, and I believe
11 the AHRQ quality indicators that have volume
12 attached to them, in fact, actually Melinda
13 was the lead on this, in fact are paired
14 measures.

15 So volume is only reported with
16 the mortality measures, not as a stand-alone.
17 Is that right?

18 CHAIR MORRIS: There's also a
19 question about whether the STS supports public
20 reporting of this particular measure. So
21 could the STS please respond to the concerns
22 about whether this is a valid marker of

1 quality standing alone, about whether this is
2 meant as a dashboard actually, about whether
3 they do or do not support public reporting of
4 this measure, and to the concerns about
5 manipulating the system potentially?

6 DR. SHAHIAN: I'm going to take
7 that one on. Actually, the editorial that you
8 referred to was my editorial, and I've dealt
9 a lot with this volume issue. I think the
10 discussion you just had has been a very high
11 level and appropriate discussion.

12 We in general have greatly favored
13 the reporting of risk-adjusted outcomes or
14 composite outcomes, as opposed to volume,
15 because some entities, including CMS,
16 Leapfrog, others, have expressed an interest
17 in volume, and because for some procedures
18 that are less frequently performed than CABG,
19 there is a volume outcome association that's
20 much stronger, we included this measure.

21 But it was not without some
22 trepidation, because we don't want to seem to

1 be endorsing this as a stand-alone quality
2 metric, for all the reasons that you've
3 discussed. You know, we have a measure here
4 that is well specified in terms of the
5 particular types of procedures that should be
6 included if you're going to talk about volume.

7 So if a volume measure were going
8 to be used, we're comfortable with the one
9 that we have proposed here. But in general,
10 you know, volume is simply a surrogate or
11 proxy for outcomes measurement, which is the
12 preferred measure. If in fact outcomes
13 measures are available, then that's always
14 preferred.

15 CHAIR MORRIS: Any other
16 discussion on that?

17 DR. DUTTON: I'm sorry. I
18 couldn't -- David, could you be a little more
19 specific? I'm not sure what you just said.
20 It sounds to me like we actually don't believe
21 in this one, but want to recommend it anyway.
22 Could you help us lay people figure that out?

1 DR. SHAHIAN: Well, there is a lot
2 of -- there's a lot of interest in volume out
3 there in the measurement world, and you know,
4 I think if volume is going to be used, we
5 would just as soon be a player and define it
6 correctly and have an appropriate source for
7 that volume.

8 However, we think that risk-
9 adjusted outcomes are preferred. I would not
10 lose any sleep if this measure, if you decided
11 not to endorse this measure. But I would hate
12 to have CMS or some other entity come back
13 with another volume measure that you did
14 endorse. I mean I think that -- so that's
15 basically where we stand.

16 I think there are some procedures
17 where volume is a pretty darn good metric or
18 proxy. One is esophagectomy. Another one is
19 pancreatotomy, where there is a very strong
20 volume-outcome association. For the major
21 operations in cardiac surgery, not so strong.
22 Certainly for CABG. Very weak for CABG.

1 Moderate for valve procedures, I would say.

2 DR. KLEINPELL: Well then really,
3 based on what you've just said, I would
4 question why is this being proposed then, you
5 know, in terms of there has been volume to
6 outcomes for others, but not necessarily for
7 this. But it seems that the impetus for
8 submitting this is because CMS may do that.
9 Is that -- that's sort of how I'm interpreting
10 this discussion. If you could help me out a
11 bit?

12 DR. SHAHIAN: Yes. I mean if
13 there is a desire from other stakeholders to
14 have a volume measure, we think it should be
15 one that's well specified, that gets the right
16 combination of, you know, procedures, and we
17 just as soon have it be an STS measure. But
18 we are not wildly enthusiastic about using
19 volume as a metric, when there are good risk-
20 adjusted results available.

21 CHAIR MORRIS: Melinda.

22 MS. MURPHY: There are two

1 approaches that NQF has taken in the past with
2 respect to measures, particularly of volume,
3 and Helen mentioned one, and that is to
4 recommend that it always be reported with
5 mortality. That's one thing.

6 Another, whenever measures have
7 been considered for use in a composite, is
8 that a measure be evaluated in terms of its
9 use within a composite only, not as a stand-
10 alone measure.

11 CHAIR MORRIS: So it seems to me
12 that the appropriate thing to do here would be
13 to proceed to a vote, to know that if we vote
14 this down, that we could make the
15 recommendation that it always be paired with
16 a more meaningful outcome measure in the
17 future.

18 DR. STAFFORD: Well not only that;
19 I'd actually rather see all of the other
20 measures presented stratified by volume. That
21 might give me a better idea of an effect of
22 volume. But I think even pairing it isn't

1 what I would want to see. I just want that
2 out there.

3 CHAIR MORRIS: Okay. So let me
4 just sort of reiterate, to make sure I've got
5 it here. So your preference would be to not
6 include it, but if it is included, to stratify
7 other measures by this. So not necessarily to
8 pair it with another outcome measure, but
9 instead to not consider it to be a measure at
10 all, but to stratify other measures.

11 DR. STAFFORD: Exactly, and report
12 it that way.

13 DR. SEARS: If we report -- if we
14 vote this down, can somebody else vote it back
15 in through another committee, if you're going
16 to use a CMS measure, for example?

17 DR. BURSTIN: There is no other
18 measure.

19 DR. SEARS: Well, this --

20 DR. BURSTIN: It's theoretical, I
21 think, a theoretical concern that if there's
22 going to be another measure, you prefer to use

1 the one built off the registry.

2 DR. SEARS: Right.

3 (Simultaneous speaking.)

4 DR. HALPERN: I think then what
5 we're more concerned about is outside agencies
6 putting that forth as a quality marker,
7 outside of the NQF. So like somebody
8 mentioned Leapfrog was very hot for a long
9 time on volumes as a marker of your ability to
10 do -- you know, the more you did, the better
11 you were, which is not necessarily the case.

12 DR. PRAGER: I would just add the
13 historical aspect of this is this is an
14 adopted measures by STS, one. Two, we really
15 do, as David eloquently stated, you know, this
16 is not how we believe you measure quality.
17 However, there are others that utilize this to
18 measure quality. If that's the case, then
19 either pairing it or having it available, we
20 believe, keeps the field level, if you will.

21 But we're not endorsing it as an
22 independent quality measure, and that is part

1 of one of your responsibilities.

2 MS. STEED: But that doesn't mean
3 that the NQF needs to endorse it.

4 DR. ROGERS: We actually could
5 make a statement by not endorsing it.

6 CHAIR MORRIS: All right. So then
7 in that case, let's go ahead and vote on this
8 first criteria. Does the measure meet NQF
9 criteria for Importance to Measure and Report?

10 [COMMITTEE VOTING.]

11 CHAIR MORRIS: I'm sorry. Let's
12 go ahead and start over with that. We're
13 going to vote on the Importance to Measure and
14 Report.

15 [COMMITTEE VOTING.]

16 CHAIR MORRIS: So 4 said yes, 17
17 said no. This does not meet Importance. Beg
18 your pardon?

19 Okay. So we don't have to go
20 through the rest of the votes for this
21 particular criteria.

22 I think based on the discussion

1 among the group, that we really want to add
2 that the concerns, both that Dr. Stafford
3 brought up and that others brought up, that
4 either this should be paired with another
5 measure or it should be used to stratify, but
6 should not be used as a stand-alone measure.

7 DR. SHAHIAN: That's perfectly
8 acceptable to STS.

9 CHAIR MORRIS: All right, next
10 measure. Oh, next is Work Group C, and we
11 have a break. We actually made up for lost
12 time here. Should we go ahead and take our
13 break right now and then come back for Work
14 Group C? Let's do that. So a 15-minute
15 break, and let's reconvene at five to 3:00.

16 (Whereupon, the above-entitled
17 matter went off the record at 2:40 p.m. and
18 resumed at 2:59 p.m.)

19 CHAIR MORRIS: All right. We're
20 going to go ahead and get started. We have
21 somebody from AHRQ on the phone. I'll ask all
22 of you guys to take your seats. Okay.

1 This is, I believe we have John
2 Botts on the line from AHRQ who we'd like to
3 give the opportunity to say a few words about
4 the measure, since you weren't be to be
5 present this morning earlier. Can you hear me
6 okay?

7 DR. BOTT: Well, we seem to be
8 rather minimalistic in our comments. We're
9 mainly here to be able to respond to
10 questions.

11 But really, really quickly in
12 regard to the two AHRQ QIs. One is of course
13 a volume measure, a count measure for counting
14 the number of the procedures. The other
15 measure is a mortality measure which uses risk
16 adjustment in the measure.

17 These are measures that use
18 electronic claims data set to complete the
19 measures, the electronic claims data defined
20 by, inserted by the user into the AHRQ QI
21 software. So that's as much as I have for an
22 introduction. I believe a couple of other

1 folks are on the call, if they want to add
2 anything.

3 DR. GEPPERT: And this is Jeffrey
4 Geppert from the QI support team, and I have
5 nothing particular to add, but I'd be happy to
6 answer any questions.

7 CHAIR MORRIS: Then, is Dr. Romano
8 on as well? Maybe not yet. We're ahead of
9 schedule a little bit here, which is an
10 unusual situation. My question for you is, we
11 were just talking about mortality in volume
12 measures, and talking about the importance of
13 pairing them.

14 Can you discuss any plans for
15 pairing these measures in the future, or is
16 there anything that we should know about what
17 you have in mind for these measures together?

18 DR. BOTT: I'll let Jeff comment
19 on it further, but at the time, we do not have
20 concrete plans to implement something
21 different. We're exploring some things, but
22 that's the phase we're in, that exploratory

1 phase.

2 So at this time, we do not have a
3 particular plan for it with a due date and
4 what version a change might go into. Jeff can
5 feel free to elaborate further in any
6 direction, if you'd like.

7 DR. GEPPERT: Yes. So the
8 indicators, you know, could potentially be
9 paired in two respects. So they were
10 developed as a pair. They were intended to be
11 analyzed together jointly, because the
12 rationale for the mortality measure was the
13 volume-outcome relationship, so they were not
14 ever intended to be analyzed jointly, and have
15 been since they were, you know, initially
16 released in 2002.

17 The more sort of recent
18 methodological pairing has to do with
19 incorporating both measures into a single
20 composite measure, sort of a volume-outcome
21 composite measure. The construction of the
22 composite measure uses basically the same

1 methodology that's incorporated in the QIs and
2 what we call the smooth rates.

3 Basically, it's the univariate
4 shrinkage estimator, and in some of the
5 Leapfrog work it's basically the same
6 methodology, but the key difference being that
7 sort of your prior, the thing that you shrink
8 to, is a volume-specific mortality measure.

9 So a couple of things in respect
10 to that. One, as John mentioned, there's an
11 indicator development process that AHRQ
12 employs, and so the earliest something like
13 that could be implemented after it went
14 through that AHRQ process would be at least a
15 release from now, at least. Our most, our
16 current release is scheduled for some time
17 this spring. So it would be some time after
18 that, after it went through a review process.

19 The second thing I'll just say
20 about that is that all of the pieces that you
21 would need to construct such a composite are
22 currently available as output from the current

1 QI software. So you know, you need the volume
2 measure to shrink back to. You need the
3 mortality measure, and then you need the
4 weight, the reliability weight that's used in
5 the shrinkage, and that's an output from the
6 software as a signal ratio, which is a
7 parameter to the software, and a noise, a
8 signal variance, which is a parameter, and a
9 noise variance, which is computed and
10 reported.

11 So all that sort of information is
12 currently sort of incorporated into the
13 software and available, you know, for
14 researchers.

15 CHAIR MORRIS: Okay, thank you.
16 The measure's going to be introduced by Dr.
17 Siperstein.

18 DR. SIPERSTEIN: Great, thank you.
19 I think some of the points have already been
20 made. This measure, 0360, Esophageal
21 Resection Morbidity Rate is described as being
22 paired with 0361 that does look at the

1 hospital volumes.

2 The measure has been around for a
3 number of years, and just in way of
4 background, why look at esophageal resection?
5 It's a relatively unusual procedure. However,
6 it's a particularly high-risk procedure for a
7 number of different reasons.

8 The patients themselves are fairly
9 high risk due to comorbidity, older age,
10 smoking, ethanol and also malnutrition
11 secondary to the obstruction from their
12 cancer. As they typically present, they've
13 often received preoperative chemo and
14 radiation therapy.

15 In addition, the operation itself
16 is particularly high risk, with entry into
17 multiple body cavities. This has really in
18 the literature been one of the prototype
19 procedures for correlating operative mortality
20 with hospital volume. So unlike the prior
21 measure, there's a long and established
22 literature track record making this

1 correlation.

2 The measure uses mortality rate,
3 where the numerator, simple number of deaths
4 in patients undergoing esophageal gastric
5 resection for cancer, and the denominator has
6 to do with the number of hospital discharges.
7 In our phone conversation, one of the issues,
8 not an issue, it's addressed. But just in
9 terms of there's a risk adjustment model
10 that's built in. One of the questions for the
11 folks on the phone has to do with a little bit
12 of the vetting or the detail of that risk
13 adjustment model. It also uses hospital
14 discharges, as opposed to 30-day mortality,
15 and one of the potential issues, although
16 practically probably not a big concern, is for
17 example hospital transfers are specifically
18 excluded. So that may skew the data slightly,
19 and there is a stratification of results that
20 can be presented.

21 In terms of usability, the only
22 potential issue is that because it's a low

1 volume procedure, those hospitals that are
2 doing this in relatively low volume may have
3 fairly wide confidence intervals in terms of
4 reporting their mortality data on a center-by-
5 center basis, but in terms of an aggregate,
6 would hold up to statistical scrutiny. In
7 terms of the feasibility, relatively
8 straightforward, because it uses
9 billing/administrative data.

10 CHAIR MORRIS: Thank you. Anybody
11 who was involved in that work group want to
12 comment on some of the things that we
13 discussed in this measure?

14 (No response.)

15 CHAIR MORRIS: Dr. Dutton, is your
16 mic on for a reason?

17 DR. DUTTON: Yes. I wasn't in
18 that work group. I was waiting. But you
19 mean, you did say that transfers were excluded
20 in this measure?

21 DR. SIPERSTEIN: Yes. It's based
22 on hospital discharges.

1 DR. DUTTON: It seems like a
2 pretty substantial flaw, in that I mean it's
3 death after esophagectomy is not a clean kill.
4 It's a go to the ICU and get multiple organ
5 failure and dwindle, and wouldn't a lot of
6 those patients tend to get transferred to
7 tertiary care centers, thus biasing this
8 result pretty substantially?

9 DR. SIPERSTEIN: I mean as
10 described as a potential flaw, I do not know
11 what the track record's been in that
12 department. It wasn't in the materials.

13 DR. GEPPERT: I've done some --
14 excuse me. This is Jeff Geppert again, some
15 analysis of -- there's two ways to sort of
16 think about that. So a lot of our QIs are
17 inpatient measures, and so, you know, some of
18 the steering committees that we've worked with
19 have viewed that as sort of an inherent
20 characteristic of the measure. Not that
21 inpatient is supposed to proxy for something
22 else, but it's reflective of the patient's

1 experience in that hospitalization.

2 The other perspective is the
3 relationship with an out of hospital measure,
4 and we did do some work with some linked
5 mortality measures, linked vital records data.
6 The general finding was that the vast majority
7 of the mortalities occurred in hospital.

8 There were very few patients that
9 were transferred post-procedure for this
10 particular measure. We were capturing, you
11 know, 90-some percent of the deaths. The
12 reason, let me just explain the reason for the
13 transfer is that over time, to avoid this
14 double-counting at discharge.

15 So we're using state hospital
16 discharge data, so we don't presume that one
17 can link it from one hospitalization to the
18 next. So if you don't link from one
19 hospitalization to the next, and you only want
20 to count a patient once in the denominator,
21 you count them in sort of a receiving, into
22 the -- you count them in the receiving

1 hospital.

2 So that's the rationale. But for
3 this particular measure, it doesn't have a big
4 impact, because there's not that many patients
5 that fall into that category.

6 DR. WILHOIT: One thing that
7 concerned me about this measure is that, as
8 best as I can see, there's not a minimum
9 number of cases required to report it. The
10 median mortality is about six percent, which
11 means that on average, I'd need to do 16 cases
12 to have one die.

13 If I haven't done 16 cases, then
14 my rate's going to be zero and I'm going to
15 look really good. But we know from the next
16 measure, 361, at least as best we can tell
17 from the data that's provided there, a lot of
18 places or a lot of surgeons wouldn't do 16
19 cases.

20 So you end up with a lot of zero
21 results, and folks look really good, but not
22 based on the fact that care is good

1 necessarily but that the numbers are small.

2 So I'm wondering if the small numbers, at
3 least at a facility basis, make this not
4 particularly useful, and whether it's, you
5 know, more useful on a larger scale.

6 But I'm not sure how helpful of a
7 quality measure it would be for assessing
8 hospitals or doctors.

9 DR. SIPERSTEIN: I think that's
10 exactly what I tried to point out in the
11 summary, and what came out on our conference
12 call, was exactly what you're, you know, what
13 you're saying, is that the purpose of this is
14 not for an individual hospital to market their
15 results, but for statistical purposes, you
16 really have to look at aggregated results.

17 Also being interested from the
18 sponsors, in terms of what the track record
19 has been in terms of reporting, because a
20 number of centers are using this and reporting
21 it.

22 DR. GEPPERT: Can I make one

1 statistical point about the volume, the low
2 volume? So the way that's addressed
3 methodologically is in two ways. One is that
4 the software actually does not report any
5 rates for a denominator less than three. So
6 there is a threshold in that respect.

7 Then the second way it addresses
8 volume is it uses this shrinkage approach. So
9 you're right. For a small volume hospital,
10 there's a probability that the rate would be
11 zero, even if the true rate were in fact not
12 zero. So the shrinkage addresses that by
13 pulling hospitals closer to the overall mean.

14 So a hospital that had a zero
15 observed rate, even a zero risk-adjusted rate,
16 would not have a zero smooth rate, which is
17 what we call it, or a shrunken rate. The
18 rationale for that is being that the shrinkage
19 rate, the shrunken rate is a better predictor of
20 future performance, a better predictor than
21 zero would be essentially. That's the
22 rationale.

1 But I'll let John just mention
2 what we know about how this indicator is being
3 publicly reported.

4 DR. BOTT: Yes, which I don't have
5 a lot of information on. AHRQ doesn't really
6 systematically go out and canvass the
7 community as to who's using which measures
8 how. But just informally because we're fairly
9 close to a number of states, we do compile
10 this largely for NQF's purposes.

11 But we're really not going back to
12 states to ask them what their experiences have
13 been with the measure. If people have
14 technical issues or questions or concerns or
15 suggestions about any given measure, they use
16 the AHRQ QI support line to deliver those
17 questions and to resolve any issues they're
18 having for consideration for future
19 enhancements to the measures, which happens
20 quite a bit because of the widespread use of
21 the software and the measures.

22 DR. GEPPERT: The biggest topic

1 that we've received comments on through user
2 support is not so much about low volume and
3 reliability, but just whether we're capturing
4 the right set of procedures. So we went
5 through our clinical panel review a few years
6 ago and made some refinements to the
7 denominator with that in mind. Those have
8 been the bulk of the comments.

9 DR. ROGERS: It's not clear to me,
10 is this administrative data or is it -- it all
11 is administrative data. So I have a question
12 relative to the conversation we've had all
13 day. Looking at what are relatively,
14 particularly CABG, relatively high-volume
15 procedures kind of globally, and the kind of
16 useful information that can be fed back to
17 those people who are doing it, no matter where
18 they happen to be, with esophagectomies, I
19 think we're talking about considerably lower
20 volumes.

21 So can I ask the question, is the
22 intent of this kind of study, to lead to a

1 kind of different conclusion that we've been
2 pondering earlier, and the conclusion here
3 would be, you know, if you're not going to --
4 if you can't anticipate you're going to do
5 more than eight or 10 or 12 or 15 procedures,
6 you shouldn't be doing them at all? Is that
7 the intent of this measurement?

8 CHAIR MORRIS: Terry, are you
9 asking the developers that question?

10 DR. ROGERS: Yes. Well, whoever
11 might have the answer. I mean because it's a
12 different animal, I think, than we've been
13 talking about and has been pointed out. I see
14 hidden in here this notion, and I'm not
15 opposed to it. I think if I were going to
16 have my esophagus out, I'd be sad to begin
17 with. But then I'd kind of look at some place
18 who actually did have some experience. So
19 help me, sponsors, with that.

20 DR. GEPPERT: That rationale has
21 certainly been put forth, that there's a
22 safety accountability component for this

1 particular measure, and there's kind of a
2 related measure for pancreatic resection,
3 which it is to be discussed at a later time,
4 but a similar low volume kind of procedure.

5 So certainly that's the
6 suggestion, that if you're performing one or
7 two of these a year, and we know on average
8 that hospitals that perform that few
9 procedures have significantly higher mortality
10 rates than hospitals that perform, you know,
11 15 or 20 of these procedures, and that's a
12 safety accountability issue.

13 DR. CIMA: Just to follow up on
14 that, can you sort of clarify in Section
15 1(b)(2), where one of the issues we're looking
16 at performance gap, and most people, you know,
17 actually the STS has been presenting it
18 differently.

19 They sort of give you a total
20 percentage. You gave this distribution of
21 medians and values. Can you just explain what
22 that means, because it's got the 5th, 25th,

1 median, 75th, 95th, and then there's a series
2 of numbers underneath.

3 Is that just for percentage or
4 what exactly is that telling us about
5 performance gap? Because that's going to be
6 a real issue if you have a very low volume
7 system. How is it going to impact this,
8 versus higher? If you look at the UHC data,
9 which is major, about 230 major academic
10 centers, there's only like five that do more
11 than 75 esophagectomies a year, you know.

12 So that's a real, you know,
13 depending on where you sit on this spectrum of
14 hospitals, that's a huge difference. So can
15 you clarify what that performance gap data
16 shows us?

17 DR. BOTT: Are you referring to
18 the volume measure or the mortality measure?

19 CHAIR MORRIS: We're talking about
20 the mortality measure, and Dr. Cima was
21 talking about 1(b)(2).

22 DR. BOTT: 1(b)(2) in the

1 mortality measure application.

2 CHAIR MORRIS: We're talking about
3 the mortality measure.

4 DR. GEPPERT: Yes. So that
5 distribution information comes from basically
6 the -- it's the distribution of the hospital
7 performance, estimated from this Bayesian kind
8 of approach. But it's basically the
9 distribution in the hospital rates after
10 you've done this shrinkage process.

11 So it takes a lot of our risk-
12 adjusted rates, which can be high, but there's
13 a lot of noise in that. It shrinks them down.
14 Sort of, the more noise in the measure, the
15 more it shrinks it down, and those
16 distributions reflect the hospital
17 distribution after that shrinkage has
18 occurred.

19 CHAIR MORRIS: I have a related
20 question. The signals-to-noise ratio that's
21 described in (2)(c), the validity testing
22 section, it looks like there's about three and

1 a half times more noise in there as signal in
2 this measure, which is troubling, and probably
3 related to everything else that's being said.

4 DR. GEPPERT: Well, not
5 necessarily. It's troubling in the sense that
6 I mean that's the reason you do the shrinkage.
7 If an indicator has a high signal-to-noise,
8 you know, .8 and above, then shrinkage isn't
9 really necessary. There's a lot of signal in
10 the risk-adjusted rate.

11 If the signal ratio is lower, as
12 it is to be used in a lot of low volume,
13 infrequent types of measures, then that means
14 you want to do the shrinkage. So once you've
15 done the shrinkage, then you've sort of
16 accounted for that, and to the extent that
17 there's variation that remains after the
18 shrinkage has been done, that's true signal.

19 DR. SIPERSTEIN: Well, maybe I can
20 partially answer that, because in looking
21 through some of the references that were
22 provided, when they aggregated data for lower

1 volume and higher volume centers, there was a
2 very large gap between -- in mortality between
3 the lower and the higher volume centers.

4 So you know, although it may
5 average a five or six percent mortality rate,
6 it ranged from like 2 to 12-plus percent in
7 the various groups.

8 DR. GEPPERT: Right.

9 DR. SIPERSTEIN: So there's a very
10 wide range, and I think the issue or the
11 strength of this measure is in its aggregated
12 view of the world, rather than trying to make
13 any statement about an individual, particular
14 low volume center.

15 DR. WILHOIT: And the thing, you
16 know, the whole thing, the more we talk, the
17 more uncomfortable I get, I guess. I know
18 that, you know, if it's out there as an AHRQ
19 indicator, you push the automated software
20 button from the AHRQ website, and it produces
21 and you do whatever you jolly well please with
22 it, you know, without the benefit of being

1 aware of what the small numbers mean.

2 AHRQ has done a great job of
3 automating things and making the data readily
4 available, but then it assumes you know what
5 you're dealing with. I don't have tremendous
6 statistical expertise, but the more I hear
7 about, you know, the noise being higher than
8 the signal and using statistics to smooth that
9 out, again, the less comfortable I feel with
10 it.

11 DR. BURSTIN: I just want to point
12 out that, and I know the folks from AHRQ know
13 about this, this is Helen, that we actually
14 had a discussion about the competing measure
15 which you'll come back to at the end of this,
16 that was recently endorsed from Leapfrog,
17 where the whole basis of that measure was
18 actually focusing almost predominantly more on
19 volume rather than risk adjustment, clinical
20 risk adjustment.

21 We commissioned an evidence report
22 for this, and in fact found volume explained

1 about a third of the variation mortality for
2 esophagectomies. We went ahead and put that
3 measure through, as we did for pancreatectomy,
4 a very similar RQI, a competing RQI.

5 I think one of the ideas was that
6 AHRQ was interested in, and as and I think
7 that Jeff was indicating this earlier, that as
8 they move to the next version of the RQIs,
9 they would potentially also add volume
10 smoothing, in addition to the clinical risk
11 factors smoothing, because we know these are
12 areas that are really very, very highly
13 volume-sensitive.

14 So I just want to at least put
15 that on the table. You'll have a chance to
16 revisit this after you evaluate it and have a
17 chance to look at the competing measures
18 issue. But you are absolutely right. The
19 volume issue, as Dr. Stafford raised this
20 morning, is huge, particularly in this
21 procedure.

22 DR. HALPERN: I think it goes back

1 also to Terry's point about so what does each
2 death mean. Like why do low volume hospitals
3 have poor outcomes? Is it because of their
4 process or just the numbers? Is it because
5 they're not used to taking care of these
6 patients and what might happen to them
7 postoperatively?

8 CHAIR MORRIS: On the other side,
9 if you have a low volume center that does one
10 esophagectomy and the patient lives, then they
11 have 100 percent survival. So it's not just
12 that low volume places look bad; it's just,
13 you just don't know what they look like.

14 DR. CIMA: I hate to just point
15 that out, but you know, I agree with Carol.
16 I mean I have less confidence for very low
17 volume things, all the statistical
18 manipulation that has to go into them to give
19 us a number, then to publicly report that
20 number.

21 It may be misleading. I know the
22 data that says there's a tight relationship to

1 it, but in order to really put it out as a
2 public reporting thing.

3 I mean so when we say Importance
4 to Measure and Report, I think people would
5 say yes, mortality rate for this procedure is
6 important to know. But when you have to do
7 all these manipulations to do it, does it
8 really meet the criteria we're looking at?

9 DR. BURSTIN: I think some folks
10 would say, particularly in an area where it is
11 low volume and volume is such an important
12 indicator, this is especially a place where
13 public reporting is extra important for people
14 to vote with their feet.

15 So that's why putting these data
16 out here, and again, they've got -- I mean if
17 you look at the statistical analyses AHRQ has
18 done, they're able to explain. I mean happen
19 to have the C statistic in front of me, John,
20 but it's, you know, it's .851. It's a very
21 good, robust model they're able to explain.

22 So I don't want us to, without

1 really diving into the statistics, just say
2 it's complicated and therefore don't play. We
3 should really take a deeper dive. And again,
4 you can only look at the measure in front of
5 you, knowing that they will potentially be
6 looking towards adding more volume adjustment
7 going forward.

8 But it has been used, I think
9 especially, you know, God forbid any of us had
10 to make a decision. It's kind of one of those
11 things you'd probably go to the website really
12 fast for, and try to find some information,
13 because volume and mortality are so linked.

14 CHAIR MORRIS: We went through
15 that, but I'm concerned that people in general
16 won't really be able to do that at all,
17 because I think even very sophisticated people
18 don't really understand shrinkage necessarily.

19 One of the other issues that came
20 up in our work group meeting was
21 accountability at the hospital level. So we
22 really don't know quite what this means for a

1 low volume hospital's accountability at that
2 hospital level, and a medium volume hospital
3 is too potentially, since this is such a
4 relatively rare operation.

5 So that came up during our
6 discussion as well. So, Bob, in answer to
7 your question, what are we really voting on,
8 I guess, you know, we have a few options here.
9 We can vote on the measure as it stands. If
10 we vote the measure down, we could make
11 recommendations that it be paired with volume,
12 or other recommendations. Okay. That it be
13 linked. So Helen's saying that this is linked
14 to volume. It's not really a stand-alone
15 measure; is that correct?

16 MS. MURPHY: It's endorsed as an
17 individual stand-alone measure with the
18 recommendation that it be reported only with
19 the pair, volume and mortality. That's the
20 way they've submitted it.

21 CHAIR MORRIS: So that's what
22 we're deciding on, whether that should be

1 continued, that this should be endorsed as a
2 stand-alone measure that always be -- that we
3 recommend always be reported with the volume
4 measure. Allan, do you have more to add to
5 that?

6 DR. SIPERSTEIN: No. I think
7 again, it has to do with kind of
8 philosophically what the purpose is, you know.
9 I don't think the purpose of this is for an
10 individual patient to go to the website to
11 figure out whether their corner hospital has
12 good results, because the statistics are too
13 difficult to apply to an individual site.

14 It really has much broader
15 applicability in terms of, you know, health
16 care policy and how insurers want to direct
17 their patients to given centers. So I think
18 it has a higher, kind of higher level quality
19 purpose than, as I said, looking at your
20 corner hospital.

21 CHAIR MORRIS: I would like to
22 bring up, in that context, a disparity issue.

1 Suppose you can't afford to go to the higher
2 volume hospital?

3 DR. WILHOIT: The other thing is
4 that while the intent may not be for you, the
5 consumer who needs an esophagectomy, to go
6 look on the website, I can tell you we have it
7 on our website. You know, so do lots of other
8 folks. So it is there, and marketed for people
9 to look at.

10 DR. MORTON: You know, if we're
11 looking at quality improvement, I guess in my
12 mind what else is out there? Do we have the
13 equivalent of an IMA process here for
14 esophagectomy? There's not a lot that I know
15 of short of volume, you know, that's been
16 published out there to demonstrate
17 differences, and I'm sensitive to the small
18 numbers. But this seems to be the best thing
19 out there at the moment.

20 CHAIR MORRIS: Does the STS have
21 any stake in the discussion?

22 DR. PRAGER: I am sitting here as

1 a visitor. However, the reality of the
2 discussion, the question is you've hit on all
3 the salient features, and maybe you can tell,
4 NQF can tell us, because I think the general
5 thoracic is coming with measures in a few
6 months.

7 But are they all pulmonary, or is
8 there an esophageal measure that has more than
9 volume in it? No here, to NQF.

10 DR. BURSTIN: I believe there's
11 already, and I was going to check online. I
12 believe there already is an endorsed general
13 thoracic surgery measure from STS, which is a
14 combination of, it scares me I remember these,
15 mortality and morbidity following
16 esophagectomy, specifically for cancer. I can
17 pull up the details and share them with you,
18 but it does not --

19 DR. PRAGER: So there is, yes. I
20 didn't know if that was endorsed or not.

21 DR. BURSTIN: It was endorsed a
22 couple of years back, two or three.

1 DR. PRAGER: Okay.

2 DR. BURSTIN: Again, this is a
3 different data source. These are
4 administrative-based measures. Public
5 reporting is out there already.

6 DR. ROMANO: This is Dr. Romano.
7 Could I address the linkage issue?

8 CHAIR MORRIS: Patrick, go ahead.

9 DR. ROMANO: Yes. This is Patrick
10 Romano. I'm a physician member of the AHRQ QI
11 support team based at UC Davis. I think this
12 concept of linkage of these two indicators is
13 an important concept, and it certainly is
14 AHRQ's intent.

15 The way that I would describe this
16 is basically that there's a certain volume
17 threshold that hospitals ought to have, as a
18 previous speaker said.

19 So for low volume hospitals, you
20 would focus on the volume, and say well, this
21 hospital is in such a low volume range that
22 it's very unlikely that they would be able to

1 achieve high quality outcomes. Not
2 impossible, but unlikely.

3 On other hand, when the volume
4 gets up to a certain level, then it makes
5 sense to look at the hospital's own
6 experience, to look at the risk-adjusted
7 mortality for its own patients.

8 So in that case, you want to know
9 well, this is a high volume hospital. They do
10 have the experience necessary, but are they
11 able to achieve good outcomes given that
12 experience?

13 So that, I think, describes why
14 it's so important to look at these two
15 indicators together, and certainly anybody who
16 sponsors a report card is encouraged to
17 present the indicators in that way. Many
18 sponsors of report cards impose additional
19 limits, such as a minimum number of cases to
20 report mortality indicator, although that's
21 not inherent to the design of the indicator.

22 CHAIR MORRIS: Okay. Is there

1 anybody who feels that their questions haven't
2 been addressed adequately, or who would like
3 to request more clarification?

4 DR. WILHOIT: I guess in light, in
5 the light of Patrick's comment, which made a
6 lot of sense, is it -- you know, is AHRQ open
7 to limiting reporting the result to a hospital
8 with a denominator of 15 or 20 or 25 or 30, or
9 some number that's bigger than five or seven
10 or ten?

11 I mean is that a way to address
12 this, because I think we all understand that
13 the mortality rate is important. It just
14 seems that with a very small denominator, it's
15 just hard to assume that it's meaningful.

16 DR. ROMANO: Well, that is the aim
17 of the shrinkage, so that effectively if the
18 volume is very low, then a hospital's
19 mortality rate shows up simply as the mean
20 mortality rate. So then the hospitals become
21 indistinguishable from each other.

22 That has been the preferred

1 approach for all of the AHRQ quality
2 indicators, and in our previous discussions
3 with other NQF panels. But I'll defer to John
4 about further details.

5 DR. ROMANO: I don't think, we
6 don't have any particular plan at the time to
7 come up with such minimum thresholds, as
8 suggested. I defer to what Jeff had noted
9 before, as that we need three to perform the
10 calculation.

11 DR. GEPPERT: You know, the
12 implications of what you're suggesting are
13 very broad. I mean you look at, like, you
14 know, the CMS mortality measures. They have
15 a threshold, but the reason for the threshold
16 is not because of statistics or the validity
17 of inferences, but has more to do with
18 concerns about confidentiality.

19 Statistically, you know, the whole
20 rationale for the shrinkage is because it
21 results in a better prediction than the non-
22 shrunk estimate.

1 So the whole rationale, that if
2 you're a consumer, and you're making a
3 decision, you're going to make a better
4 decision on average using these estimates than
5 you would based on, certainly based on no
6 information. That hardly seems like a formula
7 for a good decision, but a better decision
8 than you would make on just a simple risk-
9 adjusted mortality measure.

10 So there is a direct connection
11 between the methods and the usefulness for
12 decision-making by consumers that provides the
13 whole rationale for the -- you know, we're not
14 doing this just because it's good statistics.
15 It's because it results in a better decision
16 by a consumer at a particular hospital.

17 That's the whole purpose of this
18 method. That's the whole purpose, so that the
19 hierarchical models that CMS uses for AMI and
20 CHF mortality becomes standard practice.

21 DR. CIMA: Just as a
22 clarification, why does it have to be two

1 measures, two separate measures? Why can't a
2 measure be designed that has integrated the
3 two to give you a value?

4 I mean I'm just trying to
5 understand why does it have to be two
6 measures, that we have to get a faith and
7 recommendation that it gets linked, versus why
8 not there just be one measure?

9 DR. STAFFORD: Assume that with
10 the Leapfrog tomorrow, when we look at the
11 comparison of the three linked measures. The
12 Leapfrog one looks like it integrates the two.

13 DR. BURSTIN: They're not exactly
14 overlapping measures, though. The Leapfrog
15 measure doesn't have any clinical risk
16 adjustment. This one doesn't have any volume
17 smoothing, per se. Correct me if I'm wrong
18 here on the wording, Patrick. So in fact
19 they're probably elements of both that are
20 important here.

21 I guess one question might be, you
22 know, is this something for the next iteration

1 of the QIs that you would recommend, that this
2 just get, the volume get built into the
3 measure. But for right now, I think the
4 measure before us is what they have. They do
5 pretty rigorous testing of their measures.
6 Patrick, do you want to talk about future
7 plans at all?

8 DR. ROMANO: I'll defer to Jeff
9 and John.

10 DR. BOTT: Yes. Well, I thought
11 we touched on that at the top of the call.
12 Jeff noted the way in which volume is
13 currently integrated into the measure, and
14 there's some exploration of basically creating
15 a composite, as Jeff characterized it before.

16 But we're at the front end of that
17 conversation and that consideration, and it's
18 certainly a consideration for a forthcoming
19 version. I just don't want to right now
20 promise that we're going to make that.

21 It needs to go through other steps
22 in the evolution, and that some checks and

1 balances need to occur before making a
2 decision to inform that decision if we're
3 going to go there.

4 DR. GEPPERT: And just, you know,
5 I mean I'm not sure that's -- if the concern
6 is one of lack of transparency and statistical
7 complexity, I mean, to make the
8 recommendation, have it more statistically
9 complex and less transparent is a little at
10 odds. But you know, from a methodological
11 perspective, the composite has a lot of things
12 to its advantage, which is why it's under
13 consideration.

14 DR. SIPERSTEIN: So if I can just
15 kind of summarize what I think I'm hearing.
16 I mean, obviously these two measures are being
17 presented as a quote "paired measure."
18 However, the hospital volume is not used as a
19 risk adjustment factor. Am I understanding
20 that correctly?

21 DR. GEPPERT: Well, more
22 accurately, the hospital volume is not being

1 used to inform the prior distribution. That's
2 the distinction with the Leapfrog measures.
3 Hospital volume is used to inform the prior
4 distribution in a Bayesian analytic context.

5 CHAIR MORRIS: Are you satisfied
6 with that answer?

7 DR. SIPERSTEIN: Yes. I know what
8 they're saying, yes. But I mean, obviously if
9 you're not looking at both numbers together,
10 it's very difficult to interpret. I fully
11 understand the issue of the individual patient
12 not understanding the statistical details, and
13 potentially making, misinterpreting the
14 information in terms of the quality of a
15 particular center that they're looking for.

16 So the question is, and for a
17 lower volume center, should there simply be an
18 n/a next to it or saying that, you know, due
19 to low volumes, we cannot report a
20 statistically reliable number, as opposed to
21 reporting, you know, zero percent versus 100
22 percent if you've done one case.

1 DR. BOTT: That's not what we're
2 doing, so --

3 DR. SIPERSTEIN: No, I understand.
4 You're throwing in a fudge factor in there,
5 based on volume, to try to kind of regress it
6 towards the mean a little bit. But still with
7 a low volume center, your results are going to
8 be very skewed by a very limited number of
9 mortalities.

10 CHAIR MORRIS: I have a question
11 actually for Carol. You mentioned that you
12 are, in your organization and organizations
13 like yours, you are looking at these numbers.
14 Are you looking at them in the intended paired
15 way, or are you looking at them individually?

16 DR. WILHOIT: Well, we do a couple
17 of different things with the AHRQ indicators,
18 and what we do in terms of our quality
19 efforts, we actually don't report things that
20 are really low volume, because of all the
21 issues.

22 However, I know that on our

1 website, totally unrelated to quality
2 directly, our marketing people post all kinds
3 of things. If they can find numbers, they
4 post them.

5 I honestly don't know if this
6 specific indicator is there, but most of the
7 AHRQ indicators, you can go through the
8 marketing part of our website and pull things
9 up, and anything that there's a methodology to
10 run and there's data to run gets run, gets
11 posted, and does not have clinical input
12 necessarily to that. If that happens with us,
13 I assume it happens elsewhere as well.

14 CHAIR MORRIS: I would say this
15 sounds like it sort of speaks to your concern,
16 is that right?

17 DR. SIPERSTEIN: Yes. I mean, you
18 know, the question is you vet a measure. I
19 mean, this measure's been out there for almost
20 a decade, and you know, the question is there
21 is, you know, I think as we had on our phone
22 conversation, there is a lot of validity to

1 this measure, because I think as John pointed
2 out, there is no other way to statistically
3 deal with low volume. So you do the best you
4 can, even though it's not ideal.

5 CHAIR MORRIS: So maybe a major
6 question for the Committee is, do we want to
7 go ahead and move ahead on voting to endorse
8 this measure as a stand-alone, but knowing
9 that it's paired with the next measure, or do
10 -- and this is something that we all
11 individually have to make a decision on -- or
12 do we want to say that it really has to be a
13 composite measure? That's sort of what we're
14 wrestling with right now.

15 DR. SIPERSTEIN: And I guess the
16 semantic point is, you know, what's the
17 difference between these two measures being
18 quote, "paired" and being quote, "composite"?
19 I mean, is just it semantic or is it really a
20 major functional difference? Just asking.

21 MS. MURPHY: And AHRQ would need
22 to speak to that, but it very well could be a

1 significantly different result if you reported
2 each of the measures, but report them together
3 as a pair, versus them being integrated into
4 a composite measure, where the way in which
5 the data was handled might be different. So
6 Jeff or John?

7 DR. GEPPERT: Well, the composite
8 is basically a weighted average of the risk-
9 adjusted rate, the volume-specific weight. So
10 the difference between the weight is now where
11 they're reported separately, and the way it
12 would be reported as a composite is that, the
13 way you would be reporting, instead of having
14 a mortality rate, you would be reporting a
15 weighted average of the mortality rate and the
16 volume-specific mortality rate, where the
17 weight is this reliability ratio.

18 So as Patrick was saying, for
19 small hospitals, that ratio would be close to
20 zero. So the rate that you would be reporting
21 would be very close to the volume-specific
22 mortality. So you can say it's very similar

1 to just looking at the volume itself.

2 For larger hospitals, the weight
3 would be closer to one, although for these
4 measures, never that close to one because the
5 volumes never get that high. But they might
6 be .5 or .6 for the highest volume hospital.
7 Then the composite would be a weighted average
8 of the observed risk-adjusted mortality rate,
9 and the volume-specific mortality rate, with
10 a weight of .6 and .4. That's what you'd be
11 reporting.

12 CHAIR MORRIS: Okay. Does
13 anybody, would anybody like to ask for any
14 further clarification or additional questions
15 with regard to this measure?

16 DR. GEPPERT: Just one last
17 comment. So you can get that same result. As
18 I was mentioning at the very beginning, you
19 could get that exact same result by simply,
20 you know, reporting the existing data sort of
21 stratified by volume.

22 CHAIR MORRIS: Anybody else?

1 (No response.)

2 CHAIR MORRIS: All right, and I
3 have one more question, and that is, if this
4 came forward as a composite measure in the
5 future, then could it potentially be examined
6 as a competing measure to this, to both of
7 these paired measures?

8 MS. MURPHY: To 360 and 361? I
9 would suspect that it could, but I wouldn't
10 know why AHRQ would retain the two if they
11 built a composite.

12 CHAIR MORRIS: All right, thank
13 you. Unless there are any other comments
14 anybody wants to make, let's go ahead and take
15 a vote, all right. So first vote, does the
16 measure meet NQF criteria for Importance to
17 Measure and Report?

18 [COMMITTEE VOTING.]

19 CHAIR MORRIS: 18 said yes, 4 said
20 no. Next vote, does the measure meet NQF
21 criteria for Scientific Acceptability of
22 Measure Properties?

1 [COMMITTEE VOTING.]

2 CHAIR MORRIS: 3 said completely
3 meets the criteria, 16 said partially meets
4 the criteria, 2 said minimally and 1 said not
5 at all. Third, does the measure meet NQF
6 criteria for Usability?

7 [COMMITTEE VOTING.]

8 CHAIR MORRIS: 6 say it completely
9 meets the criteria for Usability, 13 said
10 partially, 1 minimally and 2 not at all.
11 Next, does the measure meet NQF criteria for
12 Feasibility?

13 [COMMITTEE VOTING.]

14 CHAIR MORRIS: 17 said that it
15 meets the criteria completely, 4 said
16 partially, 1 minimally. Then lastly, does the
17 measure meet all the NQF criteria for
18 endorsement? We had a little bit of a longer
19 discussion with this. It's challenging to
20 recap that.

21 I think bottom line, there was
22 concern about low volume hospitals in

1 particular, and what their mortality rates
2 mean in terms of whether they predict future
3 mortality. We heard a little bit about the
4 methods that AHRQ used to try to account for
5 that and to correct for it to an extent.

6 People continued to express
7 concerns about it, and particularly concerns
8 about misinterpretation if this measure is
9 maybe reported with the paired measure, but
10 maybe extracted by anyone separately from its
11 paired measure. So there were concerns about
12 that.

13 Any other issues that anybody else
14 wants to either underscore or bring up anew
15 before we take our vote, our last vote?

16 (No response.)

17 CHAIR MORRIS: Okay. So does the
18 measure meet all the NQF criteria for
19 endorsement?

20 [COMMITTEE VOTING.]

21 CHAIR MORRIS: 14 said yes, 7 said
22 no, 1 abstained. So it looks like the measure

1 -- looks like we as a group in general agree
2 to endorse the measure. So the next measure
3 is also Dr. Siperstein.

4 DR. SIPERSTEIN: Hopefully, this
5 discussion will be slightly shorter than the
6 last one. This really, as we've already
7 discussed, is an identical measure, identical
8 patient population in the metrics, but simply
9 looks at hospital volume. And that ends my
10 formal discussion.

11 (Laughter.)

12 CHAIR MORRIS: All right. So
13 previously what we were talking about were
14 concerns that mortality was not adequately
15 predictive, and several people raised the
16 point that volume is a little bit more
17 predictive when we're talking about
18 esophagectomy, particularly for anything
19 other than a high volume center. Anybody want
20 to bring up any particular points around
21 measuring volume here?

22 DR. WILHOIT: I had one question.

1 On 2.F-3, it lists thresholds, and there's
2 Threshold 1, which is six or more, Threshold
3 2 is seven or more per year, and then it
4 repeats Threshold 2 as seven or more. Is that
5 just a typo? Are there really only two
6 thresholds, or is there a third threshold
7 that's meant to be there but isn't there? I
8 couldn't tell.

9 DR. BOTT: Jeff, can you see where
10 the person's referring to?

11 DR. GEPPERT: Give me one minute
12 here.

13 CHAIR MORRIS: Carol, could you
14 repeat the location of that?

15 DR. WILHOIT: 2.F-3.

16 DR. BOTT: About two-thirds of the
17 way down the form.

18 DR. GEPPERT: Threshold 1 is
19 supposed to be six or more, and Threshold 2 is
20 seven or more. The distinction between
21 Threshold 1 and Threshold 2 is when we did our
22 literature review, often the studies used

1 slightly different thresholds if they were
2 using some sort of cutoff or reported results
3 based on different thresholds.

4 So we were, the intention was to
5 kind of report the range of thresholds that
6 have been observed in the literature, six or
7 seven.

8 CHAIR MORRIS: And can you confirm
9 there is no Threshold 3?

10 DR. GEPPERT: There's no Threshold
11 3, yes.

12 DR. BOTT: It looks like they just
13 accidentally copied and pasted Threshold 2
14 again. Sorry about that.

15 CHAIR MORRIS: Okay. Anything
16 else anybody wants to add to this, to be a
17 part of the discussion?

18 (No response.)

19 CHAIR MORRIS: I can say that in
20 our work group, in our telephone conference in
21 the work group, this didn't really provoke
22 much conversation at all, did it, Allan?

1 DR. SIPERSTEIN: Well, I think the
2 two measures were really discussed together as
3 a paired measure. So we really didn't have a
4 totally separate discussion about hospital
5 volumes, because it was really brought out in
6 the first discussion. That's, I think, what
7 happened in the room here today.

8 CHAIR MORRIS: Thank you.

9 DR. WILHOIT: But I think the one
10 thing that's just really interesting here is
11 on 1(b)(2), is it gives the volume by
12 quartile. The first quartile is one
13 procedure; the second quartile, 1.4; third
14 quartile, 2.4; and fourth quartile is 8.4. So
15 75 percent of hospitals, it looks like, do
16 less than two and a half a year. So it just,
17 it really emphasizes, I think, how important
18 this is.

19 DR. STAFFORD: I was going to say
20 the opposite. If we have the mortality and
21 the outcome measure, why have a structure
22 measure like this, especially because that

1 data's being gathered at the same time?

2 CHAIR MORRIS: Do the folks from
3 AHRQ want to respond to that?

4 DR. BOTT: I don't have a
5 particular comment. I don't know if Jeff
6 does. He was more involved at the inception
7 of the measure than I was or Patrick.

8 DR. GEPPERT: I guess I'm not
9 quite sure I understand. So why report the
10 volume separately?

11 DR. DUTTON: Yes, exactly. Why
12 report the volume separately?

13 DR. GEPPERT: For the reasons that
14 we were talking about before, where it's sort
15 of an accountability issue. We want to be
16 able to identify those hospitals that are
17 performing a very, very low annual volume.
18 There's a slight methodological or slight
19 definitional difference between the two
20 indicators, which was the further rationale.

21 The volume measure is focused on a
22 particular procedure. The mortality measure

1 is a slightly restricted subset of that, which
2 requires a diagnosis of esophageal cancer.
3 The volume outcome relationship has been
4 primarily documented on the basis of the
5 procedure. But for the mortality measure, we
6 wanted a more homogeneous definition of the
7 denominator.

8 CHAIR MORRIS: Are you satisfied
9 by that? You look quizzical. Let me see if
10 I can rephrase your question, and make sure
11 that it seems clear. It sounds like you're
12 saying if they're already correcting for
13 volume with shrinkage in the first measure,
14 then why are we measuring volume again?

15 DR. DUTTON: Yes. I think that
16 covers it.

17 DR. GEPPERT: Well, I think it
18 provides additional information, right? I
19 mean, if you have two hospitals that have the
20 same mortality rates that are both at the
21 mean, and one hospital has a minimum level
22 volume and another hospital has the higher

1 level of volume, then that could have -- with
2 the rationale, you have a higher degree of
3 confidence in the mortality rate of the higher
4 volume hospital.

5 DR. DUTTON: Okay. That's getting
6 to be a fairly subtle concept, especially if
7 you look at this from the point of view of
8 public reporting. If Hospital A has the same
9 outcome as Hospital B in terms of mortality,
10 but Hospital B does three times as many, you
11 think I should prefer Hospital B, that it's a
12 better quality hospital, simply because it
13 does more, even though they have identical
14 mortality outcomes?

15 DR. GEPPERT: No. It's a question
16 of which measure is a better predictor of
17 future performance. That's the rationale
18 behind all of these methodologies.

19 DR. DUTTON: So you're saying that
20 volume is a better predictor of risk-adjusted
21 mortality than risk-adjusted mortality. I
22 mean, that's essentially the argument you're

1 making. I could understand where
2 statistically that would be true, but I'm not
3 sure, for public reporting purposes, it's very
4 easy to say.

5 DR. GEPPERT: I don't think I'm
6 saying that. I'm just saying that if you
7 separately ran a correlation from one year to
8 the next, and you did it based on risk-
9 adjusted mortality in Year 1, statistical
10 mortality in Year 2, and you stratified that
11 analysis by volume, you're going to get a
12 higher correlation for the higher volume
13 hospital than you are for the lower volume
14 hospital.

15 That's the sort of independent
16 piece of information that the volume provides,
17 plus the fact that it's a slightly different
18 metric, for the reason that I said before.

19 DR. ROMANO: And the volume
20 information, I think, helps you put in context
21 the risk-adjusted mortality information, so
22 that if the volume is very low, then you know

1 that that risk-adjusted mortality rate is
2 really measured with a lot of random error,
3 and you shouldn't put a lot of weight on it.

4 Now if it's shrunken down toward
5 the mean, but it's still -- it's not worth
6 putting a lot of weight on that measure. On
7 that other hand, if the volume is high, then
8 you know that you'll really get additional
9 information value from looking at the
10 mortality measure as well.

11 From the contracting perspective,
12 certainly a payor might choose not to contract
13 with a low volume provider, simply based on an
14 evidence-based volume performance threshold.

15 DR. HALPERN: I think, though,
16 what he's trying to say is if you're a patient
17 looking at this data, that may not be so
18 readily evident to them.

19 CHAIR MORRIS: I think -- I really
20 think that we've said about all we have to say
21 about this. I do think that it's been a good
22 discussion.

1 I'm glad that you brought those --
2 I'm glad that everybody brought their points
3 up, because I think we needed to clarify this
4 and air a lot of those concerns, and to get as
5 full an explanation as possible regarding the
6 value of these measures.

7 There is one other issue that I
8 think came up in the work group conference
9 call, and that is -- and Allan, I'd like for
10 you to particularly remind me if I'm not
11 remembering this correctly or if you had a
12 different interpretation of this.

13 I think the group was talking
14 about the time span during which this would be
15 measured, and whether it would be a 30-day
16 measure versus an index hospitalization
17 measure. Didn't the group -- I believe it's
18 put forth as an index hospitalization measure,
19 isn't it, and we thought 30-day would be more
20 useful?

21 DR. SIPERSTEIN: Correct.

22 CHAIR MORRIS: Potentially. Are

1 we at least going to ask about it?

2 DR. SIPERSTEIN: Yes. Well, I
3 think I mentioned that briefly during the
4 former measure. But yes, it's index
5 hospitalization, because it's administrative
6 data. But clearly this measure is the number
7 of procedures done, and so it's not going to
8 be confounded by that.

9 CHAIR MORRIS: We could pick up
10 mortality in the administrative data. The CMS
11 data is very good on mortality.

12 So nobody under the age of 65
13 would be measured that way. Okay. Well, that
14 clarifies that. Is there anything else that
15 anybody wants to discuss with regard to this
16 measure before we go ahead and vote?

17 DR. SEARS: I just want to bring
18 up one other point. The problem here is the
19 technique used to do the esophagectomy, I
20 think, as well. Some people use thoracotomy
21 and abdominal exploration and some people use,
22 you know, abdominal and neck incision. So

1 that there are different ways, and I think it
2 all filters down to what the mortality could
3 be, depending on the techniques you use.

4 So I think these are hard to
5 measure, because they're not asking for the
6 technique, whether it's a thoracoabdominal
7 incision or an abdominal incision or a
8 thoracotomy or a neck incision.

9 CHAIR MORRIS: Okay. So perhaps
10 some technical issues as well in terms of
11 mortality. Let's go ahead and vote, unless
12 you would like for the measure developers to
13 make a comment about that, Nick.

14 DR. SEARS: They can if they'd
15 like. I think I threw it out there because I
16 think, I mean, I did a lot when I was a
17 resident and a few when I was an attending,
18 and I mean, it's just like it varied from case
19 to case. You know, it depends where their
20 tumor is and what you're going to be doing for
21 the patient.

22 DR. CIMA: Just to clarify, you

1 know, the first one we said was just cancer.
2 This one's volume, and now we're saying that
3 they're paired. That it's volume against
4 volume of all type of esophagectomies.

5 Although the vast majority are
6 done for cancer, at certain institutions,
7 certainly at my institution, we do a lot for
8 motility problems, patients that have had
9 caustic injuries, things like that.

10 So what would the AHRQ say about
11 the influence of that, you know, because there
12 are certain other reasons to do
13 esophagectomies, and then we're saying it's
14 paired.

15 DR. ROMANO: Well, the rationale
16 there, I think, is that in the course of
17 performing esophagectomies for other
18 indications, surgeons and surgical teams gain
19 experience, which is likely to improve their
20 outcomes for all esophagectomies, including
21 the largest upset for cancer.

22 So it's basically saying that the

1 experience that you get on other indications
2 is relevant to your treatment of patients with
3 esophageal cancer. It's giving the benefit of
4 the doubt, if you will, to hospitals and
5 surgeons that do a significant number of
6 esophagectomies for benign disease. So those
7 get counted.

8 CHAIR MORRIS: Thank you. Let's
9 go ahead and move ahead with the vote. Does
10 the measure meet NQF criteria for Importance
11 to Measure and Report?

12 [COMMITTEE VOTING.]

13 CHAIR MORRIS: 18 out of 22 said
14 yes, 4 said no. The second vote, does the
15 measure meet NQF criteria for Scientific
16 Acceptability of Measure Properties?

17 [COMMITTEE VOTING.]

18 CHAIR MORRIS: 8 said it
19 completely meets the criteria, 11 said
20 partially, 3 said minimally. Next, does the
21 measure meet NQF criteria for Usability?

22 [COMMITTEE VOTING.]

1 CHAIR MORRIS: Let's have
2 everybody hit their buttons one more time and
3 hit send again.

4 [COMMITTEE VOTING.]

5 CHAIR MORRIS: 7 said completely,
6 14 said partially, 1 said minimally. Does the
7 measure meet NQF criteria for Feasibility?

8 [COMMITTEE VOTING.]

9 CHAIR MORRIS: 17 said completely,
10 5 said partially. Then the next vote is does
11 the measure meet all the NQF criteria for
12 endorsement? And I'd like to remind everybody
13 that this is endorsement of just this measure,
14 the volume measure.

15 It's not -- as several of you have
16 pointed out, our conversation included both
17 this measure and the previous measure, when we
18 were talking about the previous measure, and
19 then again when we were talking about this
20 measure. But we're really just voting on this
21 measure right now.

22 And before we do our final vote,

1 would anybody else like to say anything else
2 about it?

3 (No response.)

4 CHAIR MORRIS: Okay.

5 DR. ROMANO: Hello?

6 CHAIR MORRIS: Yes.

7 DR. ROMANO: Oh, I just wanted to
8 point out also that I'm not sure if this was
9 within the scope of your review, but there are
10 separate reporting tools that AHRQ has
11 produced, to help users and report card
12 sponsors in the process of reporting
13 information on these measures to the public.

14 So there are templates for public
15 report cards. There's also a system called
16 Monarch, which provides an electronic
17 interface for generating web-based report
18 cards. So people may want to look at those to
19 see examples of how AHRQ suggests that these
20 indicators could be reported to the public.

21 CHAIR MORRIS: All right. Let's
22 go ahead and vote.

1 [COMMITTEE VOTING.]

2 CHAIR MORRIS: Let's hit our votes
3 one more time and then send again.

4 [COMMITTEE VOTING.]

5 CHAIR MORRIS: Okay, and then one
6 last time, press hard. I think the batteries
7 are wearing down.

8 [COMMITTEE VOTING.]

9 So 16 voted yes that it does meet
10 all of the criteria. 5 voted no, 1 abstained.
11 Okay. So with that in mind, it sounds like
12 the measure passed for endorsement. I think
13 that that was an important discussion, to pull
14 out the different issues within reporting on
15 mortality, for esophagectomy particularly.

16 Our next measure is going to be
17 introduced by Mr. Rivenburgh, and this is
18 1526, Transfusion Consent.

19 MR. RIVENBURGH: Measure 1526,
20 Transfusion Consent. The description is the
21 percentage of patients with a signed consent
22 for blood transfusion who received information

1 about the risks, benefits and alternatives of
2 transfusion prior to the initial transfusion,
3 or the initial transfusion was deemed as a
4 medical emergency, applicable to inpatients of
5 all ages.

6 The numerator was the patients who
7 signed the consent, or those patients who got
8 their initial transfusion which was deemed as
9 a medical emergency. The denominator was all
10 patients who received red blood cells,
11 platelets or plasma.

12 The exclusions were listed as
13 none, but there was a question in 2(f)(1)
14 about -- well, let me pull that up real quick.
15 Patients greater than four months of age that
16 had been selected for measures was used from
17 the eligible measure population of inpatient
18 discharges. So there was a little bit of
19 confusion in reference to that, that we had
20 discussed a little bit at the time.

21 CHAIR MORRIS: Thank you. This is
22 a JCAHO measure. Does anybody else want to

1 add issues, comments, questions, before we ask
2 for JCAHO to respond?

3 DR. STAFFORD: I have a question.
4 I wondered why in the numerator they just
5 chose blood, and in the denominator, they said
6 red cells, platelets or plasma?

7 So why not have blood or blood
8 products or have the numerator and denominator
9 be the same from a language standpoint,
10 because I think different people, people might
11 see blood and think of red cells, as opposed
12 to blood products. So I would make those
13 standard either way.

14 DR. WILHOIT: The other thing that
15 puzzled me a little bit was why emergency was
16 a numerator event rather than an exclusion.
17 It seemed more like that belonged in the
18 exclusion bucket rather than in the numerator.

19 MS. ZAMBRICKI: We're on 1526,
20 right? Okay. I had two comments. The first
21 has to do with a Feasibility issue, and that
22 is related to burden. I was wanting

1 clarification as to whether a preoperative
2 consent that lists blood products and
3 explanation given would be considered meeting
4 this measure.

5 Then a second broader issue is
6 looking at the literature supporting this
7 measure, I was unable to find a connection
8 between patients receiving an explanation and
9 signing a consent, and reduced use of blood
10 products.

11 There was one study from Australia
12 that asked the opinion of people as to whether
13 if they knew there were options would they
14 choose options, and they said yes. But
15 considering that we have experience with
16 patients signing consents and explanations
17 given for blood administration, there is no
18 evidence to show that doing that results in
19 less use of blood products.

20 I think we would all support
21 communicating with patients and families about
22 their care, and that really should be the rule

1 for everything, whether it's getting a CT scan
2 it should be explained that the radiation can
3 have a cumulative effect. So I just don't see
4 the science that this is going to improve
5 care.

6 DR. STAFFORD: Well, and I wonder
7 if part of the point was for decreased
8 utilization, and part of it I was seeing more
9 under the umbrella of patient-centered care,
10 making sure that patients are informed, sort
11 of the latter part of what you were talking
12 about.

13 Unfortunately, I would echo your
14 thoughts, which is that there wasn't
15 necessarily, or there isn't necessarily as
16 much literature out there on patient-centered
17 care, and I think that's just something that
18 needs to be developed, not that there's
19 evidence against it.

20 MS. ZAMBRICKI: The patient-
21 centered care is really a culture that is a
22 thread running through the entire hospital

1 stay.

2 DR. STAFFORD: And I'm going to
3 add onto that. In terms of the burden, so
4 blood is considered a pharmaceutical. It's
5 considered a drug by the FDA. You need a
6 prescription for it, which is why a physician
7 has to order it.

8 So why don't we just take this all
9 away? Every time I want to give somebody, you
10 know, a beta blocker, do I have to get consent
11 for that? I mean, when you really -- if you
12 really want to take this down that slippery
13 slope, I can see that happening.

14 While I understand there are some
15 specific things related to blood and blood
16 products, in terms of morbidity, the mortality
17 issues aren't as clear, actually, and so I
18 think the burden for this is really huge. I
19 absolutely agree that we need to have
20 discussions with patients about whatever we do
21 when we can.

22 But if I have to get a consent for

1 every single thing that I do in the hospital,
2 I'm never going to be able to take care of
3 patients.

4 DR. SIPERSTEIN: I just wanted to
5 comment that one of the additional
6 complexities is that, you know, the
7 indications for giving blood and the
8 circumstances are very different in different
9 parts of the hospital. What goes on on a
10 medical oncology ward is very different than
11 what happens on an orthopedic service and what
12 goes on on a cardiac service, or goes on on a
13 liver transplant service.

14 You know, in some of these
15 instances, it's very, very predictable in
16 terms of what's going to happen, and in other
17 situations it's very unpredictable with what's
18 going to happen. That just adds another layer
19 of complexity in terms of trying to have a
20 uniform model of patient discussion.

21 DR. SAIGAL: I had a comment about
22 -- I wasn't sure the way they described it.

1 The denominator is people who have a consent
2 signed for a blood transfusion, and the
3 numerator is the people that got more
4 information about blood products. Is that
5 what it is? Because the way it's written, it
6 seems to imply that, to me at least.

7 DR. CARPENTER: Well, as I
8 understand it, the denominator is everyone who
9 got a blood product, and the numerator is
10 everyone who has a documented consent for that
11 blood product, be it platelets or red blood
12 cells or anything else, and back to
13 Christine's comment.

14 I don't know, it wasn't clear to
15 me what qualifies as consent, because a
16 typical operative consent may have a box that
17 includes consent for blood transfusion.
18 That's not generally the main conversation
19 that goes around about that consent. You're
20 usually consenting for the operative
21 procedure, and not that it's an afterthought.

22 But does that qualify or is it a

1 separate consent document that was required
2 for those? I think that needs clarification.

3 DR. HALPERN: I think most
4 operation consents, having been to at least
5 seven different hospitals in my career, most
6 operation consents include blood consent. But
7 I agree. It's not the main focus of your
8 conversation. You do say to the patient now
9 we might need to give you blood. These are
10 the risks of transfusions, you know.

11 DR. SAIGAL: But it says percent
12 of the patients with a signed consent for
13 blood transfusion, who receive information
14 about the risk. So the denominator is people
15 with a signed consent for blood transfusion,
16 and then the percent of those that receive
17 information about the risks. That's the way
18 it's written.

19 CHAIR MORRIS: Well, the
20 denominator is people who received red blood
21 cells, platelets or plasma. That's the
22 denominator.

1 DR. SAIGAL: I mean the brief
2 description of the measure. So maybe it's a
3 different sense.

4 DR. STAFFORD: Yes, it's
5 different. I think the assumption is is that
6 a signed piece of paper is informed consent,
7 and we all know that's not the case.

8 DR. MORTON: Well, I was going to
9 make the point about, that was just made
10 earlier, that when you sign the consent for
11 the OR, that's generally part of it. Even
12 some general hospital admission consent forms
13 have it, too.

14 I would say that blood is a little
15 bit different. In a lot of ways, blood is,
16 you know, an organ transplantation. We know
17 there's a lot of downstream complications that
18 have been associated with blood transfusions.

19 There's some patient-centric
20 issues around this, if you're a Jehovah's
21 Witness. So I think this was one I'd
22 generally like to see discussed and consented.

1 DR. ROGERS: If the intent here is
2 to have -- to lead towards more appropriate
3 use of blood, it seems odd that we'd approach
4 it in this way, because this doesn't address
5 the issue of whether the blood, the desire or
6 the impetus to give blood was in any way
7 appropriate.

8 This just measures whether the
9 patient agreed with the doctor, who may be
10 completely wrong about the suggestion that
11 they actually get blood. I'm really
12 uncomfortable about this as a valuable
13 measure, because I think if we're talking
14 about appropriate use of blood, we're looking
15 at the wrong audience, or asking the wrong
16 question.

17 DR. AFSAR-MANESH: And to address
18 that, there are measures coming up that will
19 address that. But you're right. This doesn't
20 really do that.

21 MR. RIVENBURGH: And I think the
22 question falls to is are we looking at the

1 risk of giving blood, or are we looking at the
2 issue of making sure that the patient
3 understands all of the risks and benefits of
4 what they are going to be receiving in this
5 particular case, and that it's being fully
6 explained to them from a patient perspective,
7 not from, yes, it's on the surgical consent,
8 you know, it's on the medical, you know, the
9 hospital admission form.

10 But are we truly saying to them
11 these are all the things that could possibly
12 go wrong when we give you a unit of blood?

13 DR. DUTTON: I think the latter is
14 what we're aiming for, but I'm not sure this
15 says -- it's feasible to capture that, because
16 you're trying to capture a conversation with
17 a piece of paper retrospectively. I'm not
18 sure that works. Incidentally, it may be the
19 patents who refuse the blood transfusion that
20 we're more interested in.

21 CHAIR MORRIS: There was one other
22 issue that I had with this particular measure,

1 and that was that it was unclear to me --
2 Dennis, you may be able to answer this or you
3 may go and ask the developers to answer it --
4 but it was unclear to me whether this included
5 signed consent for every single unit that was
6 transfused or is it separated by a 24 hour
7 period? How is that determined?

8 (Off mic comments.)

9 CHAIR MORRIS: So just the first
10 unit in some period, some time period --
11 because you wouldn't want just the first unit
12 in their life. You wouldn't want -- just the
13 first unit a month.

14 DR. CIMA: But the question is a
15 surgical consent, okay. You sign it. But
16 then let's say you've had a long hospital
17 course or something, and then you're a week
18 away from surgery or something like that, and
19 all of the sudden an intern comes by and says
20 we're going to give you some blood.

21 I mean is that same consent from
22 the time of surgery applicable here? It's not

1 -- there's no time specificity. I think I
2 agree with everything that's been said. I'm
3 not sure it adds value at all. But that
4 becomes an issue then.

5 You know, what consent are we
6 looking at? You can go through a chart and
7 someone's been in a hospital. There are
8 probably 20, 30 consents for different things
9 if they've been in there long enough, and then
10 you're going to have to try and pull this out.
11 So it's going to become a burden for very
12 little added value, in my opinion.

13 DR. HALPERN: And I think a lot of
14 times, you know consents, like where I
15 practiced previously, the consent from
16 surgery, the blood consent was good for 30
17 days.

18 DR. BURSTIN: Just a question for
19 the developer. It specifically does say in
20 the notes for abstraction that for hospitals
21 that use a general consent for treatment that
22 includes transfusions, select yes. Do we know

1 how commonplace that was? You did do
2 reliability sampling of this. How much of an
3 issue is that, especially for surgery
4 consents, in addition to just general hospital
5 consents? It's pretty broad.

6 MR. FINDLAY: That was part of my
7 question, too, is how often is general
8 surgical consent with various other components
9 around that, how often is this included in
10 that? I would assume that most of the time?

11 DR. WILHOIT: I looked at the
12 document that was attached, which was really
13 long and cumbersome, and I thought it was hard
14 to find things. But on page 41 is a flow
15 chart, and that I figure out, because I don't
16 know the codes that are on here.

17 But it separates out transfusion
18 consent, and whether education addressed
19 risks, benefits and alternatives to
20 transfusion. But I can't follow the coding,
21 so I'm not sure what ends up in what bucket.
22 So I'm not sure -- you know, from the

1 abstraction instructions, I'm not sure what's
2 being measured either.

3 CHAIR MORRIS: Any other issues
4 before I recap?

5 (No response.)

6 CHAIR MORRIS: Okay. I was going
7 to recap before they respond, just to try and
8 be thorough, and make sure that we've covered
9 the things that concern everyone.

10 First of all, it sounded like
11 there were some issues with standardizing the
12 language throughout the measure. Is this red
13 blood cells, platelets, plasma, everything?
14 It sounds like the language changed a little
15 bit during the measure.

16 Secondly, and this is not
17 necessarily in order of priority. Secondly,
18 including emergency in the numerator versus
19 simply excluding it from the measure was an
20 issue that was brought up.

21 Next, Feasibility and the burden
22 on the hospital, and there were a lot of

1 different concerns around the burden on the
2 hospital abstractor or whatever the unit of --
3 whoever's responsible for doing the measuring,
4 particularly the burden around whether this
5 opens the door to requiring a consent for many
6 things that don't require consent right now,
7 including other things that are considered
8 drugs.

9 There was a concern about whether
10 this is sort of a one-size-fits-all medicine,
11 or one-size-fits-all measure, meaning that in
12 various locations in the hospital the need for
13 blood is very different. The opportunity to
14 have a discussion with patients is very
15 different.

16 For example, the trauma bay, which
17 would hopefully be excluded or at least
18 included in the numerator, is very different
19 from say the orthopedic ward, which is very
20 different from say the oncology ward.

21 Then there were questions, again
22 going back to the burden, in what qualifies as

1 a consent. Is a simple checkbox adequate?
2 Does there have to be documentation of a
3 conversation? How many consents do we need?
4 What's the time span that consent is good for?
5 That may vary in different hospitals,
6 particularly in the VA hospital versus the
7 rest of -- versus many other systems.

8 And then, perhaps most
9 importantly, is there any evidence of an
10 impact on practice using this measure? I
11 can't remember who brought that up, but I
12 think it's probably the most important issue
13 that came up.

14 So we'd like to give J-Co an
15 opportunity to respond. I know that this is
16 a lot of different issues to respond to, but
17 I'm hoping that you can cover them.

18 DR. GAMMON: Well, on the
19 numerator, we go with a standard with CMS and
20 Joint Commission measures. What we usually do
21 is the denominator is the larger general area.

22

1 Once we mention the red blood
2 cells, plasma and platelets, then we don't
3 usually mention it again in the numerator. So
4 that's why there's a little bit of difference,
5 perhaps, between the numerator and
6 denominator, that maybe you're not used to.

7 We had looked at excluding the
8 patients that had emergency transfusion, but
9 no one could come to consensus about what an
10 emergency transfusion was. So we were going
11 to look more for documentation that the
12 initial transfusion was deemed a medical
13 emergency, because we thought that would be
14 clear in the documentation. So those people
15 wouldn't have to have a signed consent.

16 As far as the feasibility and the
17 burden, we know each hospital does this a
18 little bit differently, and so we looked at
19 the initial transfusion. I know that you
20 could have a transfusion in one area and then
21 another.

22 But because of that burden, we

1 would just look to see if there was a consent
2 for the first initial transfusion, and we also
3 know that, you know, you're going to be
4 talking about different things, risks,
5 benefits and alternatives, depending on your
6 hospital and perhaps on the product that
7 you're going to be giving and given.

8 As far as the time span, again, we
9 kind of go with whatever the hospital expects,
10 but we're still going to look just for the
11 initial transfusion consent.

12 As far as the evidence, this
13 measure was not intended to show a difference
14 and a decrease in blood products, but more to
15 have a patient educated and maybe to have the
16 process to make sure that it's being
17 documented and the patient is really receiving
18 the information.

19 Because it's so important because
20 of the side effects and the morbidity and
21 mortality that can occur. We want them to
22 understand that. So it's more the process and

1 more patient-centered, getting the patient
2 involved in their care. That's what we feel
3 was the value of this measure.

4 DR. KLEINPELL: So just to
5 clarify, it's having a signed consent. It's
6 not having a signed consent plus documentation
7 of additional information that was given to
8 the patient about risks and benefits and such,
9 yes?

10 DR. GAMMON: Well, it is a signed
11 consent. But we were looking more for the
12 information that was there about the risks,
13 benefits and alternatives. It's more like the
14 process that they would have to go through.

15 DR. KLEINPELL: So how would a
16 hospital identify that that was done, aside
17 from the fact that the consent was signed?

18 DR. GAMMON: Sometimes at the
19 bottom of the consent, it says -- the doctor
20 will sign that they've had a discussion with
21 the patient, or in the consent itself it will
22 say the patient signs that I've been given

1 this information.

2 DR. CIMA: So it has to be a
3 specific blood consent? It can't be like a
4 general surgical consent.

5 DR. GAMMON: No, it can be
6 whatever, as long as they mention those three
7 things, that the patient is aware of the
8 risks, benefits and alternatives, and no
9 matter -- whatever way the hospital wants to
10 present that. We noticed that a lot of the
11 hospitals have their own separate transfusion
12 consent for that.

13 DR. WILHOIT: Are the abstraction
14 instructions, do they make that clear
15 anywhere, that it requires the, you know,
16 specific risks and benefits? I couldn't find
17 it in the abstraction tool.

18 DR. GAMMON: We had the data
19 dictionary and we had a data element that says
20 the information addressed the risks, benefits
21 and alternatives. The abstractors didn't feel
22 this was a burden.

1 CHAIR MORRIS: Okay. Any other
2 questions around this?

3 DR. STAFFORD: I have a couple of
4 comments. So again, you're assuming that a
5 piece of paper in the chart. What you're
6 really getting at is patient-centered care,
7 and what you're assuming is that a signed
8 piece of paper, which you're telling us can
9 look like any number of different things, has
10 actually provided the information to the
11 patient, and actually did true informed
12 consent.

13 So included in a true, informed
14 consent you want a teachback, you want to make
15 sure that the patient understands what you've
16 said to them, that they can repeat back to all
17 the appropriate information, and that they
18 truly understand the risks and benefits of
19 what you're talking about.

20 If you're really going to go -- I
21 mean, I know it's on the Joint Commission
22 site, and I know about informed consent, and

1 I think that's -- so I'm afraid that putting
2 this burden on practitioners is not going to
3 get what you're really looking for.

4 So it's not going to measure what
5 you really want to measure. So to have this
6 measure, and to have it not measure what
7 you're looking for, I don't think, is the
8 appropriate thing to do. And getting at the
9 first unit of blood or the first transfusion;
10 so I practice in a big academic center, I have
11 patents come in and out of my ICU all the
12 time, who have been transferred from the NICU,
13 who come from another service.

14 Now I'm going to have to go look
15 in the computer, try to find their transfusion
16 record, to figure out if they've been
17 transfused before, because then I don't have
18 to -- or I'm going to have to take the time
19 and consent everybody. So that just adds more
20 burden to the everyday practice of the
21 practitioners.

22 DR. GAMMON: Could I just say that

1 we didn't make it specific that the provider
2 had to do it. We know sometimes they have a
3 transfusion specialty officer or someone, an
4 APN, or a physician's assistant could also
5 give this information about the ordering.

6 Also, the Joint Commission allows
7 hospitals to determine which treatments should
8 have an informed consent. We don't say that
9 blood has to have an informed consent. But we
10 know that most hospitals do have to have
11 informed consent. So we call this transfusion
12 consent, and we looked at that, to make sure
13 that the patient has been instructed and has
14 the information about the consent.

15 DR. HALPERN: I have a question
16 though then about the emergency. So are you
17 having two separate numerators that you're
18 comparing, or you're adding in the emergency
19 products there?

20 DR. GAMMON: We either look at the
21 initial transfusion, or we looked to see that
22 the first one was deemed a medical emergency.

1 DR. HALPERN: As two separate
2 measurements within the same thing?

3 DR. GAMMON: Well, you open up the
4 chart and you find out whether it was one or
5 the other, and they're treated the same. I
6 mean you're still going to pass the measure if
7 it was deemed a medical emergency, or if they
8 have had this information.

9 DR. SIPERSTEIN: What's the
10 definition of medical emergency and what
11 documentation would be required to fulfill
12 that?

13 DR. GAMMON: We would look for
14 documentation, that the blood was given for a
15 medical emergency. I think there's some forms
16 that every hospital has that they have to
17 sign, because they have to --

18 DR. HALPERN: Not if you're in the
19 middle of a trauma that just came in.

20 DR. GAMMON: Well, we're not
21 asking to sign it at the beginning. I mean
22 just in the medical record. It could be just

1 a retrospective review.

2 DR. CIMA: Didn't you just say
3 that you're not asking for a specific consent?
4 But doesn't this say you have to have a
5 specific consent?

6 DR. GAMMON: We just have to have
7 documentation of a signed consent, and also
8 that they were given the information, or the
9 first transfusion was a medical emergency.

10 DR. WILHOIT: I found the
11 abstraction instructions finally. They're on
12 page 98 of the document that we got, and it
13 doesn't say anything about information about
14 risks and benefits.

15 It does say, as somebody pointed
16 out earlier, it says notes for abstraction for
17 hospitals that use a general consent for
18 treatment that includes transfusion select
19 yes. So a general consent for your admission
20 plus transfusion or your surgery plus
21 transfusion sounds like it counts. There's no
22 requirement that there be risks and benefits,

1 which means that it's not necessarily getting
2 at the patient-centeredness.

3 DR. SIPERSTEIN: Yes. After
4 hearing some of the discussion, it doesn't
5 sound like this adds anything. It really
6 doesn't.

7 CHAIR MORRIS: Okay. So we've
8 heard a lot of different things about this
9 measure. We've said a lot of things about the
10 measure. I think we -- I think we have a lot
11 out there.

12 We gave J-Co a chance to respond,
13 and then it's time for us to go ahead and
14 vote. So does the measure meet NQF criteria
15 for Importance to Measure and Report?

16 [COMMITTEE VOTING.]

17 CHAIR MORRIS: Okay. We had 22
18 out of 22 who said no, and so we're able to
19 move on. We're going to skip a little bit
20 here. One of our panelists has to leave a
21 little bit early, so we're going to 1532, Dr.
22 Afsar-Manesh is going to talk about Plasma

1 Transfusion Indication, and then 1539,
2 Platelet Transfusion Indication.

3 DR. AFSAR-MANESH: Thank you. So
4 the measure number again is 1532. The title
5 is "Plasma Transfusion Indication." This is
6 actually in a series of three transfusion
7 indications that we're going to be reviewing
8 this afternoon. This is the first in the
9 series.

10 The description of the measure is
11 the percentage of transfused plasma units,
12 with pre-transfusion PTI and all resulting
13 clinical indication documented applicable to
14 inpatients of all ages. Of note, this does
15 have an exclusion for trauma.

16 So in general, our work group
17 reviewed this and we do recognize that plasma
18 transfusions, the same as the other
19 transfusions, are performed frequently in the
20 inpatient setting, but there is considerable
21 variation in the utilization of this rare
22 resource, and that it is important to

1 acknowledge and improve our utilization of
2 this resource.

3 However, there are a number of
4 concerns that were brought up that I would
5 like to share with you. When it came to the
6 Importance to Measure and Report this, again,
7 there hasn't been clear indication that
8 putting the indication or doing the INR is I
9 fact going to improve your quality outcomes or
10 decrease your utilization.

11 So there was some concern about
12 what this would translate to as far as
13 improved quality outcomes.

14 We had some concerns about the
15 Scientific Acceptability. The exclusions, we
16 felt, needed to be broadened. So for example,
17 when you have active bleeding, or in some
18 cases again when you do ECMO in emergencies we
19 talked about. Again, there are a number of
20 different cases where you would need to do the
21 transfusion. Again, we would need to have
22 that be in the exclusion criteria.

1 The Usability, there weren't much
2 concerns in that area. But then for
3 Feasibility, again, we had a number of
4 different concerns that I'll share with you.
5 Again, one of the major weaknesses that we saw
6 was that there are currently not any clear
7 guidelines or indications for transfusion.

8 So therefore telling providers
9 that you need to put the indication for the
10 transfusion is going to again lead to even
11 greater variability, on top of which because
12 we don't know what we're looking for, we could
13 have people just put whatever indication.
14 It's not really going to change the outcome
15 and get us the quality improvement that we
16 want.

17 Another concern that we had was
18 there could be some concerns with cost of
19 implementing this if the institution doesn't
20 have electronic health records. Again, you'd
21 have to go in and abstract the PT INR and also
22 the consent form.

1 There is a tool that the store at
2 the Joint Commission has, which is similar to
3 the tool or is the tool that we just spoke of,
4 and there is definitely a web-based component
5 to that.

6 But from our understanding, you
7 still needed to have vendors and abstractors
8 obtain that information. So again, as we're
9 adding a couple of these measures, we had a
10 little bit of a concern about the feasibility
11 of getting that.

12 Another concern that was brought
13 up is that the PT and INR, if they have to be
14 drawn, there's not really a clear indication
15 of how long before the transfusion they have
16 to be drawn. So we wanted to have that
17 clarified.

18 There was a pilot that was done
19 for validity and their reliability testing.
20 That's on page eight of the PDF document, in
21 that it says that the measure-specific issues
22 were revised to strengthen and provide

1 additional clarity for the data elements, but
2 it doesn't speak to exactly what was
3 clarified.

4 Again, we'd like to know what were
5 some of the barriers and challenges in
6 abstracting this in the pilot phase that we
7 should be aware of. Even though that
8 apparently has been clarified, it can shed
9 some light into some of the obstacles that
10 could be presented for institutions as they
11 try and obtain this information.

12 Then lastly, from our
13 understanding, the measure addresses the first
14 three events, which I'm assuming is the first
15 three transfusions, the first three times that
16 you get transfusions, and each time it
17 addresses the first three transfusions. So we
18 were wondering kind of where the three and
19 three came -- where that number was derived
20 from, and what was kind of the reasoning
21 behind that. And that's it as far as our
22 concerns.

1 CHAIR MORRIS: Anything else
2 anybody wants to add to this one?

3 DR. DUTTON: Yes. As somebody who
4 does this a lot, transfuse people, the
5 indications for plasma transfusions are
6 changing very rapidly right now, and I would
7 argue that it's almost to the point where the
8 only clinical indication for transfusing
9 plasma platelets is bleeding, and that any
10 kind of prophylactic transfusion is almost off
11 the books now.

12 So this is going to be a hard to
13 define the indications part of the numerator
14 very clearly, because the science is moving.
15 The other thing I'll point out is this is
16 referenced to PT and INR, but it would be
17 perfectly reasonable to transfuse plasma on
18 the basis of the TEG, for example, or other
19 tests of coagulation.

20 DR. DILLON: In addition, is there
21 any consideration in terms of point of care
22 testing versus lab testing?

1 MS. ZAMBRICKI: I wanted to make a
2 comment again about feasibility and burden.
3 If I understand this measure correctly, it
4 calls for both. It calls for reporting of the
5 value, and then a statement about why you are
6 treating it. It's easy that is a burden, that
7 if the value is tremendously extended just
8 writing value transfused is sufficient.

9 You do not have to have the
10 provider then write some statement like to
11 improve or treat coagulopathy or improve
12 bleeding time or something like that. So if
13 it stays, I would say "or," "one or the other"
14 would be adequate.

15 DR. WILHOIT: One question that I
16 had was about the accuracy of abstraction, and
17 I wasn't quite sure what it meant. But under
18 the testing results, which are on page
19 8(2)(b)(3), for example it said the
20 originally, when the cases were abstracted,
21 there was a rate of 78 percent. The
22 reabstracted rate was 70 percent.

1 I'm not sure. I assume that was
2 sort of tests, you know, two different sets of
3 people doing the abstractions to measure
4 accuracy. But I noticed on all of these
5 measures, there was a big difference between
6 the two, which also then raises the question
7 of is it a measure that can be accurately
8 abstracted.

9 DR. HALPERN: I also agreed with
10 your statement that the exclusions have to be
11 broadened, because you're not going to take
12 time when you have somebody who's
13 exsanguinating in the OR necessarily to either
14 draw a lab or document why you're doing it.

15 DR. STAFFORD: I would agree with
16 that. I mean in our massive transfusion
17 protocol, it's almost one to one now, which is
18 what's come out of most of Iraq and
19 Afghanistan, in terms of for trauma or for
20 massive bleeding. You don't wait for an INR,
21 and by the time you get an INR, it potentially
22 could be normal.

1 So you could get dinged for having
2 given that, and so I think that's an issue.
3 Actually, I think it is important to measure
4 all of these. I would, I mean I sit on a P&T
5 Committee at our institution, and I know we
6 look very closely at blood usage and plasma
7 usage, and have done a number of interventions
8 with certain providers, because of how they
9 were using it.

10 I know that most of the forms that
11 when we sign the orders, we have to give an
12 indication already. So I'd be curious, at
13 least for those who are here, if they know at
14 their institutions, do you already have to do
15 this? Because my suspicion is is that in a
16 lot of large institutions, at least, you do.

17 Now it doesn't get to the smaller
18 ones who may not monitor it, but is this
19 something that's best left at the individual
20 institution level?

21 DR. DILLON: I think the other
22 area we have to be careful of is the age, this

1 sort of all-inclusive age range, because I'm
2 not sure that the indications for the
3 management of neonatal sepsis in a
4 coagulopathy will, you know, be the same as
5 what's now going on with the adult system. So
6 I think putting it to all ages is of serious
7 concern on my part.

8 DR. HALPERN: I would say that, in
9 addressing the prior comment, we do have a
10 transfusion committee that carefully monitors
11 what we do. But we do not have any statement
12 on the transfusion form saying exactly why
13 you're doing it.

14 CHAIR MORRIS: Okay. So just to
15 recap, again, numerous issues or questions
16 with this measure. Please let me know if you
17 feel like I haven't adequately covered the
18 particular issues that you're concerned about.

19 First of all, indications for
20 transfusion are changing. It's a moving
21 target, and so this makes it very hard to
22 determine precisely what the indications

1 should be.

2 In addition, tests besides PT or
3 INR may be equally appropriate for obtaining
4 before doing a transfusion, or it may be
5 appropriate not to do any tests at all,
6 because of the patient need.

7 Secondly, there were issues around
8 the feasibility and the lack of clear
9 guidelines, which really refers back to the
10 first one. So it's not clear that reporting
11 this indication is related to the desired
12 outcome.

13 There is a cost, concerns about
14 the costs of implementing this measure, and
15 unclear parameters, exactly how this should be
16 reviewed by hospitals or measured by
17 hospitals. Unclear where the data was derived
18 regarding the fact that this is supposed to be
19 the first of three transfusions.

20 A lot of concerns about the
21 indications, and concerns about the accuracy
22 of this measure. Also concerns that there

1 would be -- that we don't know what the
2 barriers were to abstracting these data in the
3 pilot phase, and it would be very helpful in
4 terms of understanding of how it impacts
5 hospitals, to understand what the barriers
6 that were in the hospital phase, in the -- I'm
7 sorry, pilot phase.

8 Then lastly, there were concerns
9 about the exclusions, and in some ways that
10 the exclusions should be broadened, but also
11 that the exclusions in other ways were too
12 broad. For example, the all-inclusive age
13 range was a concern.

14 So it was felt that this was both
15 not adequately sensitive and also not
16 adequately specific. Would JCAHO like to
17 respond to those, and does anybody have
18 anything else that they want to bring up for
19 JCAHO to respond to right now? Anything
20 succinct that they would like to bring up?
21 Okay.

22 DR. GAMMON: Okay. Well, the

1 blood bankers and the panel felt that as much
2 as possible, you should do an INR before each
3 time that you gave plasma. We do allow a TAG
4 as well as an INR. It was changed after the
5 pilot. The indications for this one was
6 actively bleeding, and we do realize that if
7 someone's having a massive transfusion, and
8 sometimes when you're actively bleeding,
9 you're not going to get a pre-transfusion lab
10 for that.

11 So those patients would pass
12 without that. We did the first three
13 transfusions because of the abstraction
14 burden. We know that patients receive more
15 plasma than just three, but until we can get
16 to the electronic phase, we just -- we're
17 going to look at three.

18 The concern of the panel was also
19 that a lot of patients are getting these for
20 procedures when the INR is not very high. So
21 you know, they weren't bleeding. So that was
22 their concern, that they would be looking at

1 this, and then sometimes when you're looking
2 at a surgical record, you can't even tell if
3 plasma's being given and for what reason.

4 CHAIR MORRIS: I think that there
5 was agreement among many of the group that
6 this is actually conceptually very important.
7 We're just not sure that this -- so I think as
8 a group we really agree with JCAHO, that this
9 is an important thing. Just not sure that
10 this measure really captures what it is that
11 we want to capture. Can you speak to that a
12 little bit more?

13 DR. AFSAR-MANESH: Absolutely. In
14 the small group discussion that looked at a
15 series of transfusions, I think there was
16 overall agreement that there are variations in
17 utilization, and there is some data for that
18 that we could, and some hospitals have
19 committees.

20 But in general nationally, we
21 could look at our utilization and decrease
22 that or make sure that we're appropriately

1 using this rare resource. I don't think it's
2 a matter of the importance of it. It's just
3 exactly as you mentioned, which is this is not
4 the best way at capturing that, because of
5 those mentioned areas.

6 But I think once those are
7 addressed, that this could potentially be
8 something that could be reevaluated.

9 DR. WILHOIT: Other things in the
10 abstraction details. It indicates that the
11 lab value being looked for is the most recent
12 one. But it could be a day before, a week
13 before, a month before, a year before.
14 There's no time constraints on what most
15 recent is. That seems like a significant
16 issue as well.

17 It also goes up to the third unit
18 given, and doesn't say that you have to have
19 rechecked after previous units, or that you
20 should or that you shouldn't. Again, there's
21 nothing about that.

22 DR. HALPERN: But along the lines

1 of a lab test, you could have had a completely
2 normal INR preop, and then you get into
3 unexpected bleeding, and you end up having to
4 give a transfusion. You don't have time,
5 anesthesia may not have time to write down why
6 you did it.

7 DR. SIPERSTEIN: To that point, it
8 looks like this measure was intended for the
9 patient who has a high PT on coumadin, for
10 example, who's scheduled to undergo a semi-
11 elective procedure, and just to make sure that
12 we're not willy-nilly giving excess units of
13 fresh frozen to reverse that.

14 But it really does not apply at
15 all to the intraoperative massive bleeding
16 patient. It really is a very different
17 clinical situation, where we use clinical
18 parameters, not laboratory parameters to make
19 that decision. So I think, you know, if this
20 measure were really restricted to that initial
21 group, then it makes some clinical sense in
22 terms of documentation.

1 But the latter group is thrown
2 into that really, in my opinion, kind of makes
3 it clinically irrelevant.

4 CHAIR MORRIS: I think that
5 summarizes it pretty nicely. So I would say
6 that in our first vote around the Importance
7 to Measure and Report, if this is voted down
8 as inadequately important, it doesn't
9 necessarily mean that we think that the
10 concept is unimportant.

11 But just potentially the impact of
12 this particular measure, or the outcome or
13 evidence around this particular measure.
14 Anybody else want to say anything before we
15 move on to a vote?

16 (No response.)

17 CHAIR MORRIS: Okay. So the first
18 vote, does the measure meet NQF criteria for
19 Importance to Measure and Report?

20 [COMMITTEE VOTING.]

21 CHAIR MORRIS: Summary of
22 responses, 2 for yes, 20 for no. We'll move

1 on to the next measure, which is also slightly
2 out of order. It's 1539, Platelet Transfusion
3 Indication.

4 DR. AFSAR-MANESH: Perfect. So
5 the description of this measure is the
6 percentage of transfused platelet doses with
7 pre-transfusion platelet count results, and
8 clinical indication document applicable to
9 inpatients of all ages.

10 Again, not to sound redundant,
11 I'll just summarize it very briefly. We
12 realize that this is a rare resource that the
13 utilization of it should be done thoughtfully.
14 But again, reporting it as far as looking at
15 your pre-transfusion platelet counts and
16 indication outlines all the same problems that
17 we highlighted in the previous measure, 1532.

18 I'd be happy to review all those
19 again, but if no one has any questions about
20 them, we can open it up to discussion, if
21 anyone feels particularly different about
22 platelets.

1 CHAIR MORRIS: Anything that
2 anybody wants to add with regard to platelets,
3 compared to plasma previously?

4 DR. CIMA: Just to clarify for the
5 Joint Commission what my view on this is, that
6 this is even more difficult than the other
7 one, because if they're on a medication that
8 inhibits platelet function, they may have a
9 congenital abnormality that inhibits platelet
10 function.

11 You can have too many platelets
12 and still have platelet dysfunction. I mean
13 azotemia, yes uremia, any of those things.
14 This is really even more difficult than the
15 plasma one. I think these are all very good,
16 but perhaps a different avenue would be to say
17 you have to have a blood utilization review
18 committee in your hospital, as opposed to
19 trying to do it piecemeal, you know, as
20 opposed to this.

21 CHAIR MORRIS: That's a good
22 suggestion. Would JCAHO like to respond to

1 this at all, or shall we move on to the vote?

2 DR. GAMMON: I think it's about
3 the same as the last one. I mean it's based
4 on the same.

5 CHAIR MORRIS: Okay. So does the
6 measure meet NQF criteria for Importance to
7 Measure and Report?

8 [COMMITTEE VOTING.]

9 CHAIR MORRIS: We had 22 out of 22
10 saying no, and again, I just want to stress
11 that this does not mean that we think that the
12 concept is not important, but just that the
13 measure needs a little retooling. Now we're
14 going to go back --

15 DR. ROGERS: Arden, can I just
16 make one comment? I want to follow up on what
17 Dr. Cima said, because I think it's really
18 important, and Dr. Morton mentioned it
19 earlier.

20 Receiving blood products is in
21 fact a transplant of some type. It is not
22 just a thing, like can you get this pill, I'm

1 going to get this, whatever. I think we in
2 general as a profession have been very
3 sluggish to recognize the seriousness and the
4 importance of this whole environment.

5 I think that the NQF could do
6 something pretty powerful actually, and make
7 not only a suggestion, but lead the
8 conversation to the recognition that a normal
9 process in a hospital would have a blood
10 utilization panel. They should be specialists
11 who are ordering this, not just anybody who
12 has hospital privileges.

13 So that's just a little bit of an
14 editorial, but I think it's something that we
15 -- that's a message I'd like to get to the NQF
16 and perhaps we can help that along.

17 CHAIR MORRIS: Potentially similar
18 to hospital restraints now. You need a lot of
19 levels of approval before a patient is
20 restrained for any particular period of time,
21 and maybe something along those lines would be
22 appropriate for blood transfusion as well. So

1 we will take note of that. Any other comments
2 before we move on to 1527?

3 (No response.)

4 CHAIR MORRIS: Okay. 1527, Red
5 Blood Cell Transfusion Indication, Dr.
6 Carpenter.

7 DR. CARPENTER: So this is the
8 third of the grouping. This should be more
9 straightforward, because red blood cell
10 transfusion is a little more straightforward,
11 but shares some of the same problems.

12 It is also a newly-proposed
13 measure. It has the two parts as the other
14 ones do, a measurement part, which is
15 hemoglobin hematocrit before the transfusion,
16 and a documentation of an indication in the
17 chart.

18 Both conditions need to be met to
19 satisfy this, this criteria. The discussion
20 that we had as a group and I think it's
21 similar to what we've had here is that this is
22 an opportunity for improvement. This is an

1 important area that we have. There is an
2 opportunity to decrease the risk and the
3 expense of unnecessary transfusions, so that
4 this is an important area.

5 However, the sort of on the
6 Scientific Acceptability part of it, shared
7 some of the similar problems with the other
8 measures. The timing of the laboratory
9 measurements relative to the various
10 transfusions, what a documented indication
11 was.

12 Was it a documented lab value? Is
13 it wording of documentation? Is that really
14 what is standardly charted now, or is that
15 going to be a burden. In addition, the same
16 criteria.

17 Exclusions were really not well
18 thought-through. Intraoperative use, use
19 around trauma, use around dialysis, use with
20 active bleeding. That all needs a lot of work
21 to figure out what the exclusions are there.

22 My reading of their reliability

1 and abstraction of this was really quite poor,
2 with a match rate of 60 percent, I think, when
3 they went back to re-extract. I think it's
4 around what's an indication and what's not an
5 indication in the chart. So the use of this
6 wasn't very reliable.

7 In addition, it does require quite
8 a bit of work in chart abstractions, since
9 many of these things are not captured
10 electronically. They're not routinely
11 charted. So the abstraction of this from the
12 charts seem to be quite difficult.

13 The rest of the conversation we've
14 had around these measures, to some degree.

15 CHAIR MORRIS: Anything else? Do
16 you have something?

17 DR. DUTTON: Sure. At the
18 University of Maryland, about half of all red
19 cell units are given in the operating room,
20 and about half of those are given in the
21 trauma center. My practice gives 600 units a
22 year of uncross-matched blood. Not having a

1 trauma exclusion here is insane. I mean we
2 teach, it's in the textbooks, that you should
3 not be waiting for hematocrit to give blood to
4 somebody who needs it, somebody who's truly
5 exsanguinating, and to not exclude emergency
6 situations here, I think, is a big mistake.

7 CHAIR MORRIS: Anything else
8 anybody has to add?

9 (No response.)

10 CHAIR MORRIS: Okay. Would JCAHO
11 like to respond to the issues that have been
12 brought up for this particular measure?

13 DR. GAMMON: Well, this is, you
14 know, the closest pre-transfusion value was
15 not a problem for any of the hospitals to
16 collect. We originally had for the test it
17 had to be within 24 hours.

18 And then for some chronic
19 patients, you know, chronic blood use
20 patients, they thought it could be expanded a
21 little bit to 48 hours. But there was usually
22 a pre-transfusion lab that the abstractors

1 didn't have a problem with.

2 The other thing on the match rate
3 about 60 percent, that was only one of the
4 data elements for red blood cells, and it was
5 a little bit different, because every hospital
6 does have a different way of if they do
7 document, of what they use for the
8 documentation criteria.

9 Even though the abstraction burden
10 has been mentioned for this one and for
11 others, we are moving toward electronic health
12 records. The values are readily available
13 there, as well as the trauma codes.

14 It was never the intent for
15 someone who's having a massive transfusion to
16 be getting a pre-transfusion lab value before
17 each one, and that would be excluded as well
18 as uncrossed blood units that were being
19 transfused.

20 Also, some of the units that we've
21 been finding that are used to prime pumps,
22 ECMO machines and also some of the bypass

1 machines that are getting that as well, so --

2 CHAIR MORRIS: Let me just ask a
3 question. As I read the numerator and
4 denominator and exclusions, it looks a little
5 bit different from the way that you're
6 presenting it right now. Can you explain
7 that?

8 DR. GAMMON: Yes. We had a panel
9 meeting just in November, and we're revising
10 the specifications, and we've been looking.
11 We had that new data element called "red blood
12 cell unit exclusions."

13 It was supposed to have been
14 brought over for number two, as well as number
15 five, because we've excluded patients from
16 five for the massive transfusion uncross-
17 matched blood, and those are the units that
18 prime flow on pumps. It just didn't get
19 brought over for that, red blood cells.

20 DR. CARPENTER: Can I say
21 something? I think, you know, a lot of people
22 spend a lot of time reviewing these, and then

1 we get here and then they've been changed
2 already, because they weren't maybe fully
3 vetted or really gone through before they were
4 proposed, it seems.

5 So what we spend time on, what we
6 evaluate, what we discussed is not what you
7 say the current measure is. I think that's
8 discouraging for the group here, to hear that
9 maybe it wasn't fully vetted before it was
10 proposed, and now we're going to vote on
11 something that you say isn't even the current
12 proposed measure.

13 So I don't know that that can be
14 fixed at this point, but I think it should be
15 understood by your group that a lot of work
16 goes into evaluating what's proposed, and if
17 it's proposed before it's really ready for
18 proposal, then it just slows that whole
19 process down.

20 DR. GAMMON: The data element is
21 in your packet, the red blood cell unit
22 exclusions. It's just that at the top it says

1 it's applicable for five and for two, and the
2 two didn't get put over to the exclusions for
3 the measure. That's all, which is
4 unfortunate.

5 DR. DUTTON: I'll throw a little
6 more data on the table about the burden of
7 abstraction here. I don't, you know, I spend
8 a lot of time for research purposes trying to
9 look at transfusion from anesthesia records.
10 So that's half the transfusions in the
11 hospital potentially.

12 It's not easy to get those off of
13 paper anesthesia records, which are right now
14 today 85 percent of the universe.

15 CHAIR MORRIS: Okay. Melinda, you
16 just clarified something for me that might be
17 good for the group to hear as well. But we're
18 voting on the measure as it's written;
19 correct?

20 MS. MURPHY: That's correct. The
21 only that we would consider something else is
22 again the same thing we've talked about all

1 day. You'd vote it down and then you would
2 suggest whatever changes, or we would hear
3 what we've just heard, that changes have been
4 made and we need to see all of those changes
5 for a revote.

6 CHAIR MORRIS: Okay. I think in
7 addition to that was it's not unusual for
8 measure developers to continue to try to make
9 their measures better over time. But I really
10 have to agree with Dr. Carpenter, that if you
11 think about the number of hours that we spend
12 and our time is pretty valuable, that it is a
13 little bit discouraging, even if that's
14 normal. We'll be voting on the measure as
15 it's written.

16 So let's go ahead and proceed to a
17 vote, unless anybody has anything else to say
18 about this measure. Does the measure meet NQF
19 criteria for Importance to Measure and Report,
20 as it's written?

21 [COMMITTEE VOTING.]

22 CHAIR MORRIS: Okay. 2 for yes,

1 19 for no. We'll move on to the next measure,
2 which is also Dr. Carpenter, 1541, Blood
3 Administration Documentation.

4 DR. CARPENTER: This is another
5 Joint Commission-proposed new measure that is
6 in the family of the blood management project.
7 This is looking at when a blood product is
8 administered, documenting three things that
9 happen during that process, and each one of
10 these needs to be met to pass this criteria.

11 First is an identification process
12 matching the unit that's been prepared to the
13 patient. The second is dating and timing of
14 the transfusion, and the third is measuring
15 vitals pre-transfusion, during transfusion and
16 post-transfusion. So all those items need to
17 be met to satisfy this criteria.

18 In discussion and reviewing this,
19 I think all the group thought all three of
20 those were really important things to do,
21 critical things to do. What wasn't clear is
22 how big a problem this is for the hospitals

1 right now. These are standard protocols that
2 hospitals follow with essentially all
3 transfusions, except in potentially life-
4 threatening situations.

5 So what is the gap? What's the
6 opportunity for improvement? It wasn't clear
7 from the documentation. Although there
8 certainly were references to this continuing
9 to be an occasional problem, it wasn't put in
10 perspective with how many transfusions are
11 given and the relative risk of this.

12 Most of the risk seems to occur in
13 the identification process. We felt, without
14 doing a complete review, that in most
15 hospitals this is standardly required process.
16 So that was a first question, is how big is
17 the gap? How big is the opportunity for this
18 measure, even though we all thought it was,
19 these were important things to do?

20 In terms of the acceptability,
21 it's a lot of information to get out of a
22 medical record. So the other part of concern

1 was even if this was all done, is this all
2 documented? Is this all something that Can be
3 achieved out of the medical record
4 consistently?

5 We had a similar concerns about
6 exclusions as we did in the previous blood
7 product use measures that we discussed. The
8 intraop measurements, I think, proved to be
9 quite difficult for this, as you might
10 imagine, especially if it's not electronic
11 system.

12 So abstraction, as far as I could
13 tell from their system, seemed to be
14 challenging and difficult, because of the
15 number of data elements required to satisfy
16 this one criteria.

17 So that was basically the summary,
18 is that is this really an opportunity for
19 improvement, and is -- there's a significant
20 burden to collect this data from the chart.

21 CHAIR MORRIS: So just to
22 reiterate, there was a strong sense among the

1 group that this measure is valuable that
2 topped out. Can you describe what happens at
3 your institution?

4 DR. DUTTON: Well, I'll point out
5 we also give uncross-matched plasma, universal
6 donor plasma as well. So that's a minor
7 change to this that would be needed.

8 It is very important, obviously,
9 to make sure you identify the right patient to
10 get the blood, and Dr. Carpenter is correct,
11 in that a handful of patients every year are
12 killed outright in the United States by ABO
13 mismatch, transfusion mismatch, and probably
14 the Joint Commission actually knows the
15 number, since they're all reported as sentinel
16 events.

17 All of the things that are asked
18 for here, these three sets of requirements,
19 are all sort of standard operating procedure
20 for any hospital I've ever been in, and/or
21 audited in those hospitals as well. I think
22 that's because they're ADD standards to begin

1 with, and Joint Commission standards for
2 practice anyway.

3 If this is something that the
4 hospital's doing anyway and reporting anyway,
5 and this is just a matter of rolling that up
6 and do a national indicator, I guess the
7 burden of doing so would be less, since you're
8 already gathering all the data necessary.

9 On the other hand, I'm not sure
10 what value it adds, putting this measure on
11 the table, if it's something that everybody's
12 already doing.

13 DR. HALPERN: I see that they have
14 a statement here that the frequency is 1 in
15 1,000 events. That's in 1(b), number one.
16 But my question would be how often -- of the
17 sentinel events that happen, what has been the
18 common root cause problem? Is it a
19 misidentification of the patient, or a
20 miscross-matched unit?

21 DR. WILHOIT: The data provided in
22 2(b)(3) says that the -- for the 274 units

1 that they reviewed, the rate was 89.4 percent.
2 That's a ten percent deficit from what we
3 would expect. So it sounds like it's a real
4 issue. It sounds like it's an important issue
5 to address if we're only scoring 90 percent,
6 you know, and the hospitals that usually do
7 testing are usually, you know, better --

8 DR. HALPERN: Are they including
9 emergencies?

10 DR. WILHOIT: But unless it's an
11 exclusion issue. However, the thing that's
12 really problematic for me is that they
13 reabstracted this and got a rate of 67
14 percent.

15 Well, if it's a 20 percentage-
16 point difference from the first abstraction to
17 the second, which I think is what this means,
18 then it sounds like the methodology for
19 abstracting hasn't been well enough defined to
20 have clean data. So I'm not sure what we're
21 left with.

22 DR. CARPENTER: You know, I

1 interpreted that rate of 80-some percent as
2 something was missing in the documentation.
3 Not necessarily that it wasn't done, but it
4 was something was missing, a post-vital or
5 something that wasn't specifically documented.

6 Because clearly this is being done
7 in our hospitals at a higher rate than listed
8 there. It's just not documented or
9 abstractable consistently.

10 CHAIR MORRIS: Any other issues?

11 Okay. Would JCAHO like to respond to the
12 question about whether there's actually
13 evidence of a gap, and questions regarding
14 whether or not the abstraction process is
15 adequately defined, given the large
16 discrepancy in the first and second data
17 retrievals?

18 DR. GAMMON: Well here in the
19 United States, we are just now beginning to
20 collect hemovigilance data on adverse events.
21 But if you look at data from UK hemovigilance
22 system, they've been looking at data for the

1 last 15 years, and they've had more deaths
2 from bacterial contamination of the wrong
3 blood and also from the administration of the
4 wrong blood more than they've had for HIV
5 infections.

6 So and patient identification is
7 just -- I know it's a standard of care, and we
8 hope it's being done. What we found out that
9 a lot of times the identification is there,
10 although our rate was, you know, not like 90
11 percent when we looked at everyone's. It was
12 different infill that was missing, as Dr.
13 Carpenter had mentioned.

14 You know, we have people that
15 collect core measures, and they're very used
16 to collecting data elements like these, and
17 the abstraction burden was not that much for
18 them. I think it was more for the people that
19 were doing it for testing alone, and that's
20 not usually their main job.

21 I think the difference, and like I
22 said, the difference in the rate between the

1 original abstracted and the reabstraction was
2 for the missing documentation. A lot of
3 times, if someone's in surgery, you can't
4 really tell when everything was given. I mean
5 it's just very illegible.

6 But the main thing about this data
7 element is that if our hospitals are going to
8 participate with the hemovigilance, you do
9 need this data. This is the exact data that's
10 needed to participate with them, so they can
11 figure out if there is going to be an adverse
12 event, they have to have this information. So
13 we've aligned with them, and they just hope
14 hospitals will begin reporting on those
15 things.

16 CHAIR MORRIS: Anybody have any
17 other questions or comments?

18 DR. STAFFORD: I just have two
19 comments. I would A, be somewhat reticent to
20 use data from other countries or cultures and
21 trying to extrapolate it to the U.S. health
22 care system.

1 So the UK is very different than
2 it is here. I guess the other point that
3 maybe I would like to make is, as we've all
4 said, I think we all think all of these
5 measures actually are probably important
6 somehow, and it's more how they come about.

7 My proposal would be that this
8 might be something to turn into a patient
9 safety goal, where you might say, you know,
10 with the goal being to reduce X, Y and Z
11 related to inappropriate or, you know,
12 transfusion of blood products, and that then
13 you require hospitals to put in place some
14 method of monitoring that.

15 Just like you've done for rapid
16 response teams. Because similarly, when there
17 is a lot of talk about National Patient Safety
18 goals and rapid response teams, the original
19 proposal, proposed goal was to actually say
20 you had to have a rapid response team.

21 When the measure finally came out,
22 it was worded differently and was more broad,

1 which allowed institutions to get to the same
2 end point, but using different methods that
3 actually fit their institution and their
4 culture and their resources, because not every
5 institution has the same resources to do this.

6 CHAIR MORRIS: Any other comments?
7 Do the developers want to say anything else
8 about the measure? Okay. Let's go ahead and
9 vote. Does the measure meet NQF criteria for
10 Importance to Measure and Report?

11 [COMMITTEE VOTING.]

12 CHAIR MORRIS: We have 8 who said
13 yes, 13 who said no. So the noes outweigh the
14 yeses, although this is a little bit closer
15 than some of our previous measures. So I
16 think that we're not going to go ahead and
17 continue with the vote on this particular
18 measure.

19 Next is 1542, Mr. Rivenburgh,
20 Preoperative Anemia Screening.

21 MR. RIVENBURGH: Measure 1542,
22 Preoperative Anemia Screening, the description

1 of which is a percentage of selected
2 orthopedic, cardiac and hysterectomy elective
3 surgical patients with documentation of
4 preoperative anemia screening 14 to 45 days
5 prior to the anesthesia start time.

6 The numerator for this were
7 patients with documentation of preoperative
8 anemia screening 14 to 30 days before the
9 anesthesia start time. The denominator were
10 selected elective surgery patients that fell
11 under these criteria.

12 The exclusions were patients not
13 admitted from home, and this is one of the
14 areas where we had some concerns as to what
15 were the differences and levels of anemia that
16 can be out there and the testing sources at
17 the time of the testing, as much as 45 days in
18 advance.

19 The time frame is particular, and
20 it's very -- is it clinically relative, in the
21 sense that if a patient has their anemia
22 tested 45 days in advance before a

1 hysterectomy-type procedure, and they happen
2 to be bleeding extensively and then that
3 bleeding stops and their hematocrit and
4 hemoglobin then normalized.

5 Some adjustments. There were no
6 risk adjustments necessary, and again we were
7 concerned about all of the exclusions that
8 were listed.

9 CHAIR MORRIS: Anybody else have
10 anything to add to that?

11 MS. ZAMBRICKI: Just a point of
12 clarification. The measure description says
13 "45 days before anesthesia start date," and
14 the numerator inclusion said 30 days before.
15 And then there was a difference in the age.
16 The description of measure says "Equals 18
17 years," and the numerator said greater than 18
18 years. So just some standardization of the
19 terms.

20 CHAIR MORRIS: So we're looking
21 for clarity on standardization of the terms,
22 14 to 45 days before the anesthesia start

1 date, or 14 to 30 days before, and then
2 particularly with regard to the age. That
3 probably is a simple typo, but we're looking
4 for clarification of it.

5 Then secondly, we're concerned
6 about the timing of the anemia testing. I Can
7 tell you my particular, one concern I have
8 about this is seeing somebody in clinic for
9 the first time say one week, having an opening
10 in my operative schedule and it's clear that
11 they need to have an operation.

12 So I get them into the operating
13 room within a week. Well, they're not inside
14 of that 14 to 45 day window. How does this
15 play out? Not an emergency, but somebody who
16 does need an operation.

17 That was one of the things that
18 stood out for me immediately. Does anybody
19 have any other issues with regard to this
20 measure?

21 DR. CIMA: Does it have to be -- I
22 mean is it specifically? So what if it's the

1 day before?

2 DR. STAFFORD: I understood that
3 to be an exclusion, that they look at the
4 record, and if the patient was scheduled for
5 surgery less than 14 days, then that is an
6 exclusion. That's what I read in here.

7 DR. HALPERN: They're trying to
8 get -- it sounds to me like they're trying to
9 get rid of the sort of more emergent cases,
10 and this was the easiest way to do it on a
11 global level, without increasing the burden of
12 data extraction.

13 DR. STAFFORD: The baseline rate
14 was in the 30's. How important is this to
15 those of you who are surgeons and doing these
16 kinds of cases? Is this something that's
17 clinically important or something that's not
18 clinically important? It sounds like it's not
19 being consistently done.

20 DR. MORTON: I think age matters a
21 lot. You know, that's why they have the
22 exclusions, I guess, in there. The thing that

1 pops into my mind, we recently took a look at
2 what we're doing preop with all of our
3 patients, and there's a lot of labs that are
4 being done that aren't always necessary.

5 So we looked at this because of
6 the cost that's involved with it, and there's
7 not a lot of data to support that the
8 screening actually makes a big difference.
9 I'd be happy to hear if there are some data
10 about it.

11 DR. HALPERN: Actually, the New
12 England Consortium for Vascular Surgery,
13 anemia is one of the predictors of mortality
14 for lower extremity bypass.

15 DR. MORTON: I know it's a
16 predictor, but you know, the ability to act on
17 and do something else.

18 DR. SIPERSTEIN: Different cases
19 have very different risk factors for needing
20 transfusion. So there are many types of
21 surgery where transfusion is almost never
22 done, and therefore you know, the preoperative

1 CDC, if it picks up something, you know, yes,
2 you act on it.

3 But doing any formal anemia
4 screening would be, you know, not that
5 clinically effective in that group. Whereas
6 you've got other groups of patients like
7 undergoing hip replacements, that you know,
8 the risk-benefit equation may change.

9 CHAIR MORRIS: The three types of
10 operations in which this would be done would
11 be orthopedic, cardiac and hysterectomy.

12 MS. ZAMBRICKI: So would that be
13 like a carpal tunnel would be included in
14 that?

15 DR. CARPENTER: I think they have,
16 I didn't look at it right this minute, but
17 they had an appropriate list, total knee,
18 total hip mostly. Maybe there was some spine
19 in that. But it was mostly appropriate,
20 although many of the -- most groups have
21 backed off on the number of cases that need
22 preoperative hematocrit evaluation.

1 Certainly older people getting
2 total hips and total knees need it done, but
3 you know, a healthy person with a tibia
4 fracture doesn't need it done. They're not
5 going to lose a significant amount of blood
6 and they're hematocrit's unlikely to be a
7 problem if they're otherwise healthy.

8 DR. STAFFORD: Yes. I mean I
9 think getting back to kind of what, I think,
10 and certainly you can correct me if I'm wrong.
11 You're really trying to get at those elective
12 cases, because we do know that being anemic
13 is a risk factor. It's a risk factor for
14 actually getting more blood, and it's a risk
15 factor for infections and also mortality and
16 morbidity.

17 So I think what you're actually
18 getting at is those truly elective cases where
19 you could do something. So somebody comes in,
20 they're anemic. You may have -- if you have
21 six weeks to work up their anemia, to put them
22 on erythropoietin, and perhaps even let them

1 then donate their own blood, so that they
2 could have it for the operation, that's
3 appropriate.

4 So I think there's probably a
5 small subset of patients where this could be
6 used, and along those lines, getting back to
7 the exclusion for not coming in from home,
8 well, the large number of those patients who
9 would fit in this population are going to be
10 in nursing homes or assisted living
11 facilities. So you may be excluding a patient
12 population that you actually want to benefit.

13 DR. DUTTON: There is a strong
14 association between anemia and bad outcomes,
15 no question.

16 But that may be because sicker
17 patients do or some of the same things that's
18 making the patient anemic, malnutrition, age,
19 cancer, whatever, is increasing their surgical
20 risk. Is there any evidence at all that
21 addressing it makes any difference in
22 outcomes?

1 DR. STAFFORD: And I think that's
2 what we don't always know, and I guess the
3 only way that I could see a definite outcome
4 would be if it keeps you, if you can build up
5 their blood stores, give them, you know, have
6 blood available so that if they need to be
7 transfused, they get their own blood.

8 That would for me seem to be the
9 one place where you could really make a
10 difference.

11 DR. CARPENTER: Not that this
12 directly addresses that, but that used to be
13 very common. We used to give a lot of auto-
14 blood or direct to donors.

15 But that's become increasingly
16 unpopular, and many people think it's less
17 safe than giving anonymous blood. So I don't
18 -- it used to be done commonly for elective
19 orthopedic procedures, and it's not done very
20 often anymore.

21 DR. DUTTON: Yes, autologous blood
22 is fine, your own. But directed donation

1 blood, yes, is more dangerous than random
2 donor blood.

3 CHAIR MORRIS: Okay. So the
4 issues that were brought up were timing of
5 anemia testing, concerns regarding the
6 exclusions, and help me out here. Other
7 issues? The value, the value of this measure.
8 The evidence. Would JCAHO like to respond to
9 these?

10 DR. GAMMON: Sure. The time line
11 is from 14 to 45 days. There's the -- NATA
12 has developed some guidelines, and that's --
13 they have said they should have it by 30 days,
14 and a lot of that is to do with the Medicare
15 refunding. It has to be within 30 days in
16 order to be able to qualify.

17 Also feel it takes that long to
18 actually treat these people with some of the
19 medications and to build them up to treat, to
20 manage them, to detect it. We looked at just
21 high blood use, like the elective surgeries
22 that have that much time.

1 There's been quite a few studies
2 that show that if you can bring up their
3 hemoglobins, that they won't need the blood
4 during the surgery. So this would be very
5 important.

6 We're having a lot of patients
7 that are older, that are going to be getting
8 hips and knees done, and this could really
9 decrease the blood use and decrease the
10 outcomes, you know, improve their outcomes if
11 they don't have to add blood.

12 A couple of hospitals that did
13 this in the pilot had nothing but -- they're
14 using less blood, they've had great results,
15 and it's actually going over to other patient
16 groups, because it's been so successful.

17 DR. SEARS: Have you documented --
18 I'm sorry, sorry.

19 DR. HALPERN: We might be asking
20 the same question, but is there actually
21 evidence that giving erythropoietin pre-op and
22 building up their crit reduces mortality

1 afterwards? Because erythropoietin itself has
2 risks.

3 DR. GAMMON: I know.

4 DR. SEARS: Giving hemoglobin and
5 giving iron is the same thing. It takes a
6 while to build it back up.

7 CHAIR MORRIS: Can you be a little
8 bit more specific about the data that was
9 collected in the pilot study?

10 DR. GAMMON: We looked at patients
11 that had elective surgeries, hysterectomies
12 and cardiac, and we looked at what the date
13 was for the pre-anemia screening. And then we
14 looked at what was their anesthesia start time
15 and the date.

16 Then we looked to see how many
17 days difference there was, and noticed a lot
18 of people fell out because they weren't having
19 it within that time frame. A lot of them were
20 having it a lot closer to surgery, when there
21 wasn't enough time to do much about it,.

22 We also needed to make sure that

1 we were collecting the data on people that
2 weren't scheduled in less than 14 days.

3 That's why we made these --

4 CHAIR MORRIS: My question is you
5 said that in your pilot study that hospitals
6 used this and wound up giving less blood. Can
7 you say how many hospitals used this measure
8 and how much less blood they gave, and how
9 that related to the amount of blood that they
10 might normally be expected to give?

11 DR. GAMMON: I'm not saying --

12 CHAIR MORRIS: Was there a
13 statistically significant difference?

14 DR. GAMMON: I'm not saying they
15 used our measure to do that. But when we went
16 to their hospital, they had already been doing
17 this, the pre-anemia screening, and they had
18 been using less blood as a result of it. So
19 they were very supportive of this measure, is
20 what I was saying.

21 DR. HALPERN: Did they give you
22 data to show that that happened and that it

1 actually affected the patient outcomes?

2 DR. GAMMON: I don't know if they
3 published it or not.

4 DR. CIMA: The data that was put
5 in here for demonstrating performance gaps,
6 this is one of the things that bothered me
7 about it, was high outliers for SSI tended to
8 be hospitals that had, you know, patients that
9 had more anemia.

10 But we don't talk about
11 intervention; we don't talk about
12 comorbidities, you know. If this is what the
13 data is that's supporting it, it doesn't, it's
14 not tied directly to what you're asking.
15 You're just -- there's an association between
16 people with anemia and bad outcomes, but
17 checking that beforehand or -- are those
18 modifiable risk factors that you necessarily
19 want to do?

20 If someone has a bleeding tumor, a
21 tumor, ovarian, an endometrial cancer that's
22 bleeding, the treatment is to get it out. So

1 waiting, I'm not sure the data here, at least
2 what you've used as performance gaps, don't
3 correlate with what you're talking about.

4 DR. GAMMON: Well, we're looking
5 at the elective surgery patients, though, that
6 have that opportunity. I mean if someone's
7 bleeding, you're not going to --

8 DR. CIMA: Well, those patients
9 have an opportunity. The question is, is it
10 right to wait, and will you have an improved
11 outcome?

12 CHAIR MORRIS: Let me just clarify
13 what I was asking about. I'm getting a sense
14 from you that even in a pilot study, you don't
15 have to have fabulous data and it doesn't have
16 to be statistically significant necessarily.
17 But I'm just trying to understand. I'm
18 getting the sense from you that the hospitals
19 that participated in the pilot study thought
20 that they had a better outcome.

21 But I guess that is very, very
22 qualitative, and I'm looking for something

1 that might be a little bit more quantitative.
2 It sounds like maybe perhaps you don't have
3 that data. That's okay. I just want to know
4 what it is if you have it.

5 DR. CIMA: But I guess one of my
6 questions too is I mean I think we've been
7 talking about two related outcomes. Number
8 one, trying to transfuse less units of blood,
9 and number two, trying to reduce morbidity and
10 mortality.

11 CHAIR MORRIS: And the first is
12 probably a more short-term thing that would
13 potentially be easier to measure. But if we
14 don't have the numbers, then we don't have
15 them.

16 DR. GAMMON: I don't have a
17 specific number of a hospital that
18 participated with us that I can have -- direct
19 you to. I just have the aggregate number of
20 all the hospitals that participated, and that
21 is anecdotal. I don't know if they have a
22 published study that they were doing this

1 process and they've been able to save on
2 blood.

3 CHAIR MORRIS: Any other issues
4 anybody wants to bring up?

5 (No response.)

6 CHAIR MORRIS: Okay. I think it's
7 time to vote. Does the measure meet NQF
8 criteria for Importance to Measure and Report,
9 specifically impacts, evidence of a
10 performance gap and outcome or evidence?

11 [COMMITTEE VOTING.]

12 CHAIR MORRIS: We have 3 that say
13 yes, the measure meets criteria, and 18 that
14 says no, the measure does not meet criteria.
15 You received kind of a long list of issues
16 regarding the measure.

17 I think once again that we all
18 agree this is actually important. This is
19 very important in concept, and that we're --
20 I believe that many of us are hopeful that a
21 more defined measure may come forth in the
22 future, that will help to address the concept.

1 So next is 1547, and this is our
2 last measure for today, Preoperative Blood
3 Type Testing and Antibody Screening. Again,
4 Dr. Carpenter.

5 DR. CARPENTER: So this is a
6 sister measure to the one we just discussed.
7 It's the same group of patients, so it's
8 patients who are at higher risk for getting
9 blood transfusions during their
10 hospitalization, who are admitted for elective
11 surgical procedures, certain cardiac
12 procedures, certain orthopedic procedures and
13 hysterectomy.

14 It's simply a measure about
15 whether their preoperative type and screen or
16 type and cross-match was completed prior to
17 the starting of surgery. So it's everybody
18 that was presented with those conditions, and
19 whether they had this completed at the time of
20 surgery.

21 The justification for this is
22 really that this is important to do, and that

1 doing this at the last minute might make it so
2 that appropriate blood was not available in a
3 timely fashion for someone that needed it.
4 The proposal sort of realized that there were
5 very few studies documented that this was a
6 problem. The studies about this really were
7 minimal.

8 There's one study that found seven
9 percent that it was not completed before
10 surgery. But overall, there's very few
11 studies saying what the magnitude of this
12 problem is, and then if it's not done, what
13 are the implications for complications or
14 mortality and morbidity following that?

15 So that was one thing that the
16 group discussed, that this is mostly standard
17 practice. It does not, it certainly does not
18 happen every single time. Sometimes the ball
19 gets dropped and it is not completed, and it's
20 sometimes done on the day of surgery, which is
21 a potential problem, especially for the first
22 case of the day. Not quite as big a problem

1 later, because it usually can be done by the
2 time surgery starts.

3 I thought that and we thought that
4 the cases were acceptable. That list was,
5 we've already discussed that as a reasonable
6 list. The rate, I believe that they measured,
7 was compliance rate with this measure was
8 quite high, about 98 percent or so was, it was
9 being completed. It was not 100 percent. So
10 maybe the gap is not huge, but it is there.

11 It's probably important to have
12 this done for cases that have a high risk for
13 needing transfusions. Most of these elective
14 cases don't need blood intraoperative. Maybe
15 some of the cardiac ones, but certainly not
16 the orthopedic ones.

17 So I think the biggest discussion
18 was around how big is the gap, and is this
19 really an opportunity for improving patient
20 care or not, because what is the consequence
21 of getting this done on the day of surgery
22 rather than before surgery. But otherwise, it

1 was pretty -- more straightforward, I think,
2 than the other ones.

3 CHAIR MORRIS: I'd like to make a
4 comment about this, in terms of how big the
5 gap is. Being done 98 percent of the time
6 sounds like a lot to me, and that sounds
7 actually commendable.

8 In my hospital, I don't think that
9 it happens that commonly, because we
10 frequently have first-case delays because
11 there is no type and screen or type and cross-
12 match in the computer system.

13 The way that I can see this being
14 an issue of consequence is of course when we
15 get into the situation in which we need blood
16 right away, and the hospital may actually be
17 low on blood. I don't know how many of your
18 hospitals that comes up in, but Detroit's
19 about an hour away from Ann Arbor, and it's
20 not uncommon actually that we have to call to
21 Detroit for blood.

22 So if we have somebody who needs

1 blood and we don't have appropriate blood in
2 the hospital for them, that can be a real
3 issue in our hospital. We do a lot of cases.
4 It's a VA, so it's smaller volume, of course,
5 than the university.

6 But I could definitely see this
7 coming up on a somewhat regular basis in our
8 hospital. I don't know if other people's
9 hospitals are similar.

10 DR. HALPERN: I know some
11 hospitals also require two types to complete
12 the type, and that's where I think the problem
13 comes in. Both in the hospital where I came
14 from and in the VA where I currently work,
15 they require two types if you've never
16 received blood before, to confirm your type.

17 So that's where I see it as an
18 issue, you know. What is completing the type?
19 Because a lot of times completing the type is
20 doing that second blood draw, which often does
21 not -- not often, but not infrequently doesn't
22 get done until the morning of surgery.

1 DR. WILHOIT: One of the things
2 that I thought was problematic here were the
3 exclusions. If a type and screen or type and
4 cross-match wasn't ordered, that was an
5 exclusion. But it seems like that might be
6 the situation in which it was most of a
7 problem.

8 Also, there was an exclusion for
9 patients not admitted from home, and that was
10 a proxy for a non-emergency admission. Again,
11 the exclusions just weren't working for me.

12 DR. HALPERN: I don't have a
13 problem so much for the patients not admitted
14 from home, because I think it's hard, you
15 know, when you try to do a large volume chart
16 abstraction, to figure that out.

17 I think, you know, the patients
18 who are not admitted from home tend to be the
19 ones who are going to be more urgent and not
20 so elective, and I think they really wanted to
21 focus on the elective patients.

22 DR. WILHOIT: And I don't have a

1 problem excluding patients not admitted from
2 home. But it seems like then there should
3 also be an exclusion for emergency cases, or
4 something -- you know, and that's the only --
5 I mean that's the whole proxy for non-
6 emergent, and it seems like it's a fine
7 exclusion, but not adequate.

8 DR. SAIGAL: I think the nursing
9 home point is important as well. A lot of
10 patients from nursing homes would need this
11 done, and it's not an emergency. It's just
12 they're in a different location than home.

13 MR. RIVENBURGH: But it clearly
14 says these are elective cases. So if the
15 patient's coming from a nursing home and it's
16 an elective case, you know. I mean I agree
17 with --

18 DR. SAIGAL: But they're excluded,
19 right? They're --

20 MR. RIVENBURGH: Right, and they
21 shouldn't be in that particular situation, if
22 it's elective and they're coming from a

1 nursing home. But the emergent case,
2 obviously, is a whole different ball game.

3 DR. DILLON: Are the groups
4 defined strongly enough or properly enough
5 that this isn't just going to just drive
6 everyone ordering a type and cross on every
7 single patient within these specialties?

8 CHAIR MORRIS: It was the same
9 group, wasn't it, orthopedic?

10 DR. CARPENTER: Yes. I thought
11 the groups were -- I thought they had a list
12 of diagnoses. I thought that was reasonably
13 straightforward.

14 DR. DILLON: And we know that from
15 the cardiac patients as well. I didn't look
16 at the cardiac list, and that's -- but again,
17 my concern is just from a pure cost point of
18 view, that all of the sudden now we're going
19 to have 85 type and cross every morning, and
20 it's just going to overload the blood bank, in
21 terms of being able to handle these.

22 DR. STAFFORD: Yes, and I think in

1 a particularly in teaching institutions, the
2 default would be I'm not really sure which
3 ones I'm supposed to get it on, so I'm just
4 going to get them on everybody, and that way
5 we're covered and we don't get dinged.

6 So those are some of the
7 unintended consequences of putting some of
8 these things out there. People find work-
9 arounds, and we know work-arounds cause their
10 own problems.

11 DR. CIMA: But I mean it says type
12 and screen or type and cross. So it's very
13 clear that you can do one or the other. So
14 you just have to have very strict protocols
15 about which ones would get it.

16 CHAIR MORRIS: Okay. So several
17 issues. One, a question about the gap and how
18 big of a problem this is. Another is, is this
19 an issue of consequence. Would this matter?
20 I think that it is an issue of consequence, to
21 an extent. But then there are some points
22 about the exclusions, patients without an

1 order to type and screen or type and cross are
2 excluded. That doesn't necessarily make sense
3 to me.

4 Patients not admitted from home.
5 A very valid point was brought up that those
6 maybe precisely the patients having elective
7 operations that need to have this measure.
8 And then the last issue, could you please
9 restate that, Dr. Stafford?

10 DR. STAFFORD: It got to what
11 happens in a lot of institutions, when you
12 have very specific cases that you apply a rule
13 to, or a measure to, particularly in large
14 teaching institutions.

15 People aren't going to remember
16 who's supposed to have what, so the default
17 will be to order a type and screen or a type
18 and cross on every patient who goes to the
19 operating room, which then causes more anemia,
20 because we're bleeding patients we don't need
21 to, overworks the blood bank, and uses
22 resources that could be used better elsewhere.

1 CHAIR MORRIS: Okay. So a concern
2 about overuse. Would JCAHO like to respond to
3 these issues?

4 DR. GAMMON: Yes. Our pilot rate
5 was 92 percent, and really we had a self-
6 selected group of hospitals that were
7 interested, I believe, in blood management.
8 So I think that that reflects it probably, it
9 can't be used for the universe of hospitals.

10 We also used the exclusion of you
11 had to have it ordered, because in order to be
12 in the numerator, you have to be in the
13 denominator. So we could have selected
14 elective surgical patients, and if they didn't
15 have a type and screen ordered, then they
16 couldn't get to the numerator.

17 So we wanted to exclude anybody
18 that didn't have an order for type and screen
19 or type and cross, and only concentrate -- if
20 you did have one ordered, then was it done.
21 We were really hoping and, you know, there's
22 a hospital-wide initiative for the safety

1 surgical sheets where you have it on there,
2 and you're checking before you go into the
3 surgery -- did you have your -- is your blood
4 available, because you know, and some of it is
5 anecdotal, because not everybody gets -- Can
6 be captured in some kind of a rate of how many
7 people didn't have the blood ready by the time
8 that they went to surgery?

9 Because nobody's really capturing
10 that right now, and then you know, sometimes
11 they have to end up getting uncross-matched
12 blood if they don't have their blood type
13 available.

14 CHAIR MORRIS: Does anybody have
15 any further questions about this measure?

16 (No response.)

17 CHAIR MORRIS: Okay. Let's go
18 ahead and vote. Does the measure meet NQF
19 criteria for Importance to Measure and Report?

20 [COMMITTEE VOTING.]

21 CHAIR MORRIS: Four say yes, 17
22 say no. So that concludes the discussion of

1 this particular measure.

2 We now have a few moments of
3 member and public comments before we adjourn
4 for today. So I'd like to invite the
5 developers and the public to speak, if they'd
6 like to, anybody on the phone or here in
7 person.

8 (No response.)

9 CHAIR MORRIS: It's very quiet out
10 there. So I guess what I'd like to do next is
11 to thank our developers. I know a tremendous
12 amount of work went into creating these
13 measures, and a lot of sweat equity there.
14 I'd also really like to thank our panel, our
15 steering committee, for devoting quite a bit
16 of time, precious time and for their presence
17 as well, and for their stamina today.

18 Hopefully tomorrow will be a
19 little bit less grueling. It will be shorter,
20 and we only have one set rather than three
21 sets of measures to go through. Anybody want
22 to add anything?

1 (No response.)

2 CHAIR MORRIS: The room will be
3 locked overnight. If you would like to leave
4 anything in the room, that's your call. If
5 there's anything you feel uncomfortable
6 leaving in the room although it's locked,
7 please do take it with you. We're starting at
8 8:30 tomorrow morning.

9 DR. ROGERS: Great. Just one
10 quickie. You mentioned, and I want to make
11 sure that JCH hears the message, that this is
12 a very, very important issue, and the fact
13 that we have not supported the measures as
14 they've been presented in no way reflects the
15 importance and the way we would -- we'd love
16 to see something positive out of this, rather
17 than the negative, and I think that's the
18 message I'd like to propose.

19 CHAIR MORRIS: Thank you. All
20 right, thanks, everybody. Good night.

21 (Whereupon, the above-entitled
22 matter went off the record at 5:42 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Surgery Endorsement Maintenance 2010
Steering Committee

Before: Arden Morris, Chair

Date: 02-28-11

Place: Washington, DC

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