

NATIONAL QUALITY FORUM

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SURGERY STANDING COMMITTEE

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THURSDAY

MARCH 19, 2015

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The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:30 a.m., Lee Fleisher and William Gunnar, Co-Chairs, presiding.

COMMITTEE MEMBERS:

LEE FLEISHER, MD, Committee Co-Chair; Professor and Chair of Anesthesiology, University of Pennsylvania; American Society of Anesthesiologists

WILLIAM GUNNAR, MD, MPH, Committee Co-Chair, Director, National Surgery Program Office, Veterans Health Administration

ANTHONY ASHER, MD, FAANS, FACS, Carolina Neurosurgery & Spine Associates*

ROBERT CIMA, MD, MA, Professor of Surgery, Mayo Clinic

RICHARD DUTTON, MD, MBA, Executive Director, Anesthesia Quality Institute

ELISABETH EREKSON, MD, MPH, Dartmouth Hitchcock Medical Center

JOHN HANDY, MD, Thoracic Surgeon, American College of Chest Physicians

FREDERICK GROVER, MD, Professor of Cardiothoracic Surgery, University of Colorado School of Medicine

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 Professor of Surgery, Department of
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 Health Policy, American College of
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LAWRENCE MOSS, MD, Surgeon-in-Chief, Nationwide
 Children's Hospital

AMY MOYER, Manager of Value Measurement,
 The Alliance

KEITH OLSEN, PharmD, FCCP, FCCM, Professor and
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 University of Nebraska Medical Center;
 American Society of Health-System
 Pharmacists

COLLETTE PITZEN, RN, BSN, CPHQ, Clinical
 Measure Developer, MN Community
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 Professional Practice, American
 Association of Nurse Anesthetists

GARY ROTH, DO, FACOS, FCCM, FACS, Medical
 Director, MHA Keystone Center

CHRISTOPHER SAIGAL, MD, MPH, Professor, UCLA

ALLAN SIPERSTEIN, MD, Chairman Endocrine
 Surgery, Cleveland Clinic

LARISSA TEMPLE, MD, Colorectal Service,
 Department of Surgery, Memorial
 Sloan-Kettering Cancer Center

MELISSA THOMASON, MS, PMP, Patient/Family
 Advisor, Vidant Health

A.J. YATES, MD, Associate Professor, University
 of Pittsburgh Medical Center

NQF STAFF:

MARCIA WILSON, Senior Vice President, Quality
Measurement

JULIET FELDMAN, Project Manager, Stakeholder
Collaboration

KAREN JOHNSON, Senior Director

ANDREW LYZENGA, Senior Project Manager

MELINDA MURPHY, Senior Director

YETUNDE ALEXANDRA OGUNGBEMI, Project Analyst

ALSO PRESENT:

RONY ADAM, MD, American Urogynecologic Society*

SVEN BERG, MD, MPH, CPE, Quality Insights of
Pennsylvania

SHERYL DAVIES, MA, Stanford University*

ELIZABETH E. DRYE, MD, SM, Yale Center for
Outcomes Research & Evaluation (CORE)

VIVIENNE HALPERN, MD, Society for Vascular
Surgery*

COLLEEN HUGHES, American Urogynecologic
Society*

BRAD JOHNSON, MD, Society for Vascular Surgery

JANE LUCAS, RN, Quality Insights of
Pennsylvania

TOM MILLER, PhD, American Society of
Anesthesiologists*

JAMES MOORE, MD, American Society of
Anesthesiologists*

DAN MORGAN, MD, American Urogynecologic
Society*

CRAIG PARZYNSKI, MD, Yale Center for
Outcomes Research & Evaluation (CORE)

MATTHEW POPOVICH, PhD, American Society of
Anesthesiologists

MARK PRESTON, MD, American Urogynecologic
Society*

SAMANTHA J. PULLIAM, MD, American
Urogynecologic Society*

PATRICK ROMANO, MD, MPH, UC Davis

CAROL STARKS, AHRQ

GARTH HARRISON UTTER, MD, MSc, UC Davis

* present by teleconference

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

(8:30 a.m.)

DR. FLEISHER: Good morning. Welcome to the second meeting of the Surgery Standing Committee. I'm Lee Fleisher. I'm an anesthesiologist from the University of Pennsylvania.

Just as a reminder, when we are speaking we need to hit the button. And when we're not speaking, we need to turn it off.

So the nice thing is this is -- these are now standing committees, so we have been together before. And for some of us we will be together for two to three years. We have a number of measures to go through, and the agenda, as you will see, is really structured as everything but the STS measures today, and the STS measures will be tomorrow.

But as a standing committee, we are actually -- hopefully, we will have some robust discussions about general concepts today, in addition to specific measures.

1 Hopefully, Bill will be here shortly.
2 But I think at this point I can turn it over to
3 -- Amanda, are you going to --

4 AMANDA: First, I just want to open
5 the line with the operator. So, Operator, can
6 you please open the line?

7 OPERATOR: You are live.

8 AMANDA: Great. Thank you.

9 Can you inform us if Dr. Asher or Dr.
10 Jarrett are on line?

11 OPERATOR: Certainly. We will put a
12 message in the chat, so that you will see it.

13 AMANDA: Thank you.

14 DR. FLEISHER: Welcome, everybody.
15 It's good to see you all again. I will hand it
16 over, actually, to Melinda to say a few words
17 before we get into our disclosures of interest.

18 MS. MURPHY: Thank you. And I told
19 Andrew I wanted to say hello to everyone. I have
20 not been with this -- the entirety of this group,
21 and was with Surgery Project some years ago. But
22 it is very enjoyable to me to be back with this

1 group and back inside the NQF office.

2 I work from the field most of the
3 time, so thank you very much for being here, for
4 taking the time, for investing and being very
5 interested in this topic on behalf of doing the
6 right thing for the patients in this country. So
7 welcome, and thank you for being here.

8 DR. FLEISHER: So with that, Marcia,
9 I think, we can just jump right into the
10 disclosures. As you did the last time you were
11 here, I think we will sort of redo that process
12 of asking you to disclose any interests, but I
13 will let Marcia speak about that.

14 MS. WILSON: Again, I am Marcia
15 Wilson. I am Senior Vice President of Quality
16 Measurement here at National Quality Forum, and
17 I'm going to walk us through the disclosure
18 process this morning. I have a few comments to
19 make.

20 You received a disclosure of interest
21 form from us before you were named to this
22 committee, and on that form we asked you a number

1 of questions about your professional activities.
2 And today we'll ask you to orally disclose any
3 information you provided that you believe is
4 relevant to the subject matter before the
5 committee.

6 When you do your oral disclosure, it
7 is not necessary to review your entire resume.
8 We are only interested in your disclosure of
9 information that is directly relevant to the work
10 that the committee will be doing. We are
11 especially interested in grants, research or
12 consulting, but again, only if it relates to the
13 subject matter before the committee for the next
14 two days.

15 A couple of reminders. You sit on
16 this committee as an individual. You do not
17 represent the interests of your employer or
18 anyone who may have nominated you to this
19 committee.

20 Secondly, we are not only interested
21 in disclosure of activities where you were paid.
22 For example, you may have been a volunteer on a

1 committee. We are looking for you to disclose
2 those types of activities as well, but, again,
3 only if it's relevant to the subject matter
4 before the committee.

5 Just because you disclose it does not
6 mean you have a conflict of interest. We do oral
7 disclosures in the interest of openness and
8 transparency.

9 So we will do this by going around the
10 room. Please state your name, who you are with,
11 and if you have anything to disclose. And then
12 when we're finished with everyone who is present
13 here in D.C., we will turn to the people on the
14 phone and I'll call your name. So, sir, if we
15 may start with you, by giving your name, who
16 you're with, and if you have anything to
17 disclose.

18 DR. GROVER: I'm Fred Grover from
19 Denver, Colorado. I'm a cardiothoracic surgeon,
20 and the major areas -- I have been very involved
21 with the STS database over the years, although I
22 am more distant from that now, so that is an area

1 you need to know about.

2 Also, I served on the American
3 College, although -- not only at this meeting,
4 but on the American College of Cardiology NCDR
5 Board, so I have that.

6 So I suppose anything related
7 particularly to the STS or competing measures
8 within STS I would have to -- at least if I make
9 a comment, say that. With the STS, I will just
10 recuse myself.

11 MS. WILSON: Okay. Thank you.

12 DR. HANDY: John Handy. I'm a
13 thoracic surgeon from Portland, Oregon with no
14 disclosures.

15 MS. WILSON: Thank you.

16 MR. MARKMAN: Barry Markman. I'm a
17 plastic surgeon. I'm also a Senior Corporate
18 Medical Director for Aetna. And I support the
19 SIU plans in Medicaid throughout their
20 enterprise. That's all I can disclose.

21 I also have a patent on biologics, and
22 that is pretty much what I need to disclose.

1 MS. WILSON: Thank you.

2 DR. EREKSON: Hi. Liz Erekson. I'm
3 a gynecologic surgeon. I'm at Dartmouth, and I
4 also am at the Dartmouth Institute, and I have no
5 disclosures.

6 MS. WILSON: Thank you.

7 MS. MOYER: Hi. Amy Moyer. I'm the
8 manager of value measurement at The Alliance. We
9 are a cooperative of employers who purchase
10 health care directly, and I have no disclosures.

11 MS. WILSON: Thank you.

12 DR. MOSS: Hi. I'm Larry Moss. I'm
13 a pediatric surgeon and surgeon and chief at
14 Nationwide Children's Hospital. I sit on the
15 Verification Review Committee for the American
16 College of Surgeons that verifies children's
17 surgery centers, and the Executive Steering
18 Committee for the National Surgical Quality
19 Improvement Program of the American College of
20 Surgeons.

21 MS. WILSON: Thank you. Go ahead. If
22 you have a red light on your mic and you're not

1 speaking, please turn it off.

2 MS. THOMASON: I am Melissa Thomason.
3 I am a real patient, and I'm happy to be here.
4 And I am a patient advisor from Eastern North
5 Carolina. I have no disclosures.

6 MS. WILSON: Thank you.

7 MS. PITZEN: Collette Pitzen,
8 Minnesota Community Measurement. I'm a measure
9 developer. However, we have no measures in the
10 general surgery portfolio. So I am happy to be
11 here. Thanks.

12 MS. WILSON: Thank you.

13 MS. REEDE: Good morning. Lynn Reede.
14 I'm a certified registered nurse anesthetist from
15 the American Association of Nurse Anesthetists.
16 Even hard for me to say. I'm Director of
17 Practice. I have no disclosures.

18 MS. WILSON: Thank you.

19 DR. DUTTON: Hi. Rick Dutton. I'm an
20 anesthesiologist and the Chief Quality Officer of
21 the American Society of Anesthesiologists. We
22 are a measures steward for one of the measures,

1 which I will be recusing myself from discussion.
2 I also served on the Technical Expert Panel for
3 the hospital readmission measure that is on here
4 today.

5 DR. LEVY: Good morning. I'm Barbara
6 Levy. I'm an OB/GYN. I'm Vice President for
7 Health Policy at the American College of
8 Obstetricians and Gynecologists. I serve on the
9 Executive Committee, the PCPI, which has no
10 competing measures for these today.

11 MS. WILSON: Thank you.

12 DR. SAIGAL: I'm Chris Saigal. I'm a
13 urologist at UCLA. I sit on our -- the AUA's
14 Quality Improvement and Patient Safety Committee,
15 Data Committee and the EMR Committee. I'm a PI
16 at RAND where we do work on quality using claims,
17 and I'm the co-founder of a company called
18 WiserCare that does shared decisionmaking
19 software.

20 DR. OLSEN: I'm Keith Olsen, a
21 pharmacist and professor at the University of
22 Nebraska Medical Center. Disclosure -- I am an

1 elected member to the Board of Regents of the
2 American College of Critical Care Medicine.

3 MS. McCARTY: I am Kelsey McCarty, and
4 I'm currently in transition. Recently resigned
5 Anesthesia Quality and Safety Manager from
6 Massachusetts General Hospital, and incoming
7 Director of Operations and Strategy for Boston
8 Medical Center. I have no disclosures.

9 DR. ROTH: I am Gary Roth.
10 Clinically, I'm a cardiothoracic surgeon. I'm
11 also the Medical Director for the Michigan Health
12 and Hospital Association. And I have no
13 disclosures.

14 DR. YATES: Adolph Yates. I'm from
15 Pittsburgh with the University of Pittsburgh
16 Medical Center. Because we are going to be
17 talking about gap analysis this afternoon, I have
18 been on -- and still serve on the Technical
19 Expert Panels for PhysicianCompare.gov with no
20 measures for review today.

21 I am also on the Technical Expert
22 Panel for the cost measure being developed for

1 CMS by Yale CORE for the total joint
2 replacements.

3 And, finally, because it is part of
4 the job and we look at policy issues, I am the
5 Chairman of the Evidence-Based Medicine Committee
6 for the American Association of Hip and Knee
7 Surgeons.

8 DR. TEMPLE: I am Larissa Temple. I'm
9 a colorectal surgeon from Memorial Sloan-
10 Kettering in New York. I am Vice Chair of
11 Quality, and I have no disclosures.

12 DR. SIPERSTEIN: Allan Siperstein. I
13 do endocrine surgery at the Cleveland Clinic. I
14 have no disclosures.

15 DR. CIMA: I'm Bob Cima, a colorectal
16 surgeon at the Mayo Clinic, and Vice Chair of the
17 Mayo surgical practice. No disclosures.

18 MS. WILSON: Okay. Thank you. And on
19 the phone is -- oh, I'm sorry, my co-chairs.
20 Sorry.

21 DR. GUNNAR: Bill Gunnar, National
22 Director of Surgery, Department of Veterans

1 Affairs. I have no disclosures.

2 DR. FLEISHER: Lee Fleisher, Chair of
3 Anesthesiology at the University of Pennsylvania.
4 I'm on the Evidence-Based -- the Practice
5 Parameter Guideline Oversight Committee for the
6 American College of Cardiology, American Heart
7 Association.

8 I'm the Technical -- the Medical
9 Advisory Panel of the Technical Evaluation Center
10 of Blue Cross/Blue Shield, and I was a member of
11 the Committee on Practice and Outcome Measures
12 for the American Society of Anesthesiologists.

13 That last one conflicts with the
14 temperature measure, and I will recuse myself.

15 MS. WILSON: Okay. Thank you, Lee.

16 DR. FLEISHER: And I have grants from
17 AHRQ with Jeff Silber on process measurement.

18 MS. WILSON: Thank you. And now I
19 think we are ready to go to the phone. Is
20 Anthony Asher on the phone with us? Is Mark
21 Jarrett on the phone with us? Okay. Not at this
22 time, so we may go back to them when they join

1 the meeting a little later on.

2 And just a few closing comments. I
3 would like to remind you that if you believe you
4 may have a conflict of interest at any time
5 during the meeting, please speak up. You can
6 speak in real time, or you can approach either of
7 the co-chairs or any of the NQF staff.

8 If you believe that a fellow committee
9 member may have a conflict of interest or is
10 behaving in a biased manner, you may point this
11 out during the meeting, again, by speaking up,
12 approaching the co-chairs, or going directly to
13 NQF staff. We don't want you to sit in silence
14 if you believe there are any irregularities due
15 to conflict or bias. So please do speak up.

16 And, at this time, are there any
17 questions or anything we need to discuss based on
18 the disclosures today?

19 AMANDA: Marcia, Dr. Sawin is on the
20 phone as well.

21 MS. WILSON: Thank you. Doctor?

22 DR. SAWIN: Good morning. I apologize

1 for not being there in person. I'm Bob Sawin.
2 I'm the Surgeon-in-Chief at Seattle Children's
3 Hospital, Chairman of the organization at
4 Children's Hospital Surgeon-in-Chiefs, and I have
5 no disclosures.

6 MS. WILSON: Thank you very much. And
7 I think we're done with the disclosures of
8 interest, Andrew.

9 DR. LYZENGA: I think so. And maybe
10 we should introduce ourselves as staff. I know
11 we've got a few new folks here, faces in the
12 room. I'm Andrew. I met you -- most of you
13 before. I'm a Senior Project Manager here at
14 NQF. I worked on a number of safety projects and
15 other projects as well, and have staffed this
16 Surgery Committee the last time around. So,
17 again, welcome. Good to see you all again.

18 MS. FELDMAN: Good morning, everyone.
19 My name is Juliet Feldman. I'm a Project Manager
20 here. This is my first CDP project, so I'm very
21 excited to experience today's in-person meeting.
22 And, yes, that's it.

1 MS. MURPHY: I am Melinda Murphy. I'm
2 a registered nurse. I have been with NQF for 10
3 years in various capacities and have worked
4 primarily with safety-related activities.

5 MS. JOHNSON: Good morning. I'm Karen
6 Johnson. I am a Senior Director here at NQF, and
7 I am really just here to observe today.

8 MS. WILSON: And, again, I'm Marcia
9 Wilson. I'm Senior Vice President of Quality
10 Measurement and delighted to be here. Thank you.

11 DR. LYZENGA: All right. So we have
12 got just a few sort of introductory items to
13 cover. We have already introduced the committee.
14 You've already heard Marcia say that you are
15 acting as a proxy for the multi-stakeholder
16 membership, but not as a representative of any
17 particular interest group. And as we told you
18 the last time, you'll be serving two- to three-
19 year terms. I think we drew some names the last
20 time here, but we won't be getting to the
21 turnover for another year or two, I believe.

22 I think just to sort of reiterate what

1 your sort of duties as a standing committee here
2 are, to work with NQF staff to achieve the goals
3 of the project, evaluate the candidate measures
4 against the measure evaluation criteria.

5 We will have a public comment period,
6 as you know, and we'll get you together on a
7 phone call after that and just go over the
8 comments, have some -- adjudicate those comments
9 and come up with some responses for them. And
10 then to respond to any directions from the CSAC
11 once we make our recommendations to them, and
12 we'll answer any questions or anything that they
13 have.

14 So, as you know, all of the members
15 will review all of the measures, but we have
16 assigned a few people to be discussants for each
17 measure. And we'll ask those discussants to sort
18 of introduce the measures after the developer
19 speaks, and just kind of walk us through the
20 evaluation process.

21 But certainly we would ask all of the
22 committee members to jump in and add their

1 thoughts. It shouldn't just be the discussants
2 discussing the measures.

3 We will be walking through each of the
4 measure evaluation criteria and voting on each
5 subcriterion. And we've got a new voting system,
6 which Alexandra is going to walk us through a
7 little later. We hope that that will be much
8 better than the last time around. We know that
9 there was some frustration with the voting
10 buttons and everything, and we hope that this
11 will be a little bit more efficient this time.

12 We will be making recommendations to
13 the NQF membership for endorsement or not --
14 endorsement of these measures.

15 And as Lee mentioned a moment ago, we
16 will be doing a bit of review of the sort of
17 surgery portfolio and thinking about gaps in that
18 portfolio, potential gaps in surgery measurement
19 overall, where we might like to see some
20 measurement development, if you have any ideas on
21 potential measure concepts that could be sort of
22 prospected for development, but we'll get more

1 into that conversation later today.

2 So, again, this -- do you want to talk
3 through the portfolio?

4 MS. FELDMAN: So, very briefly, this
5 project is to address the areas in general on
6 specialty surgery, focusing on pre- and post-
7 surgical care, adverse surgical outcomes, timing
8 of prophylactic antibiotic and other related
9 topics.

10 Currently, this is one of NQF's
11 biggest portfolios of measures related to
12 surgeries. It's one of the biggest areas of
13 measurement. There are over 100 NQF-endorsed
14 measures related to surgery, and 69 of those are
15 assigned to this committee.

16 I'm not going to go into detail into
17 this, because we have a -- as Andrew said, we
18 have a discussion later today that will focus on
19 reviewing the portfolio in further detail.

20 There are 24 measures that we will be
21 reviewing over today and tomorrow, so this slide
22 just lists those out for you in detail.

1 And just to speak to the activities
2 and time -- timeline after this meeting. On
3 March 27th, that's next Friday, we have a post-
4 meeting webinar scheduled from 2:00 to 4:00 p.m.
5 This will be where, if anything, that we don't
6 have the opportunity to address over the next two
7 days, this will be the opportunity for us to
8 shore things up. If we are able to be very
9 efficient over the next two days, we won't need
10 to have this meeting.

11 After this meeting, and after the
12 webinar, NQF staff will be writing the draft
13 report. This will be posted for NQF member and
14 public comment from April 17th to May 18th.
15 There will be a standing committee called to
16 review -- a call with the Steering Committee to
17 review and respond to the comments.

18 The draft report will be posted to the
19 NQF website for NQF member vote. Then, the CSAC
20 will review. It will go to the Board for
21 endorsement, and then the appeals process, if
22 necessary, so -- and then, to conclude the

1 project, it will be finished by the end of
2 September.

3 So I'll turn it back to Andrew.

4 DR. LYZENGA: So, yes, just a few
5 ground rules. We will ask that you have reviewed
6 the measures beforehand. We hope that you have.
7 And we do ask that you base your evaluation --
8 try to base the discussion as much as possible in
9 the measure evaluation criteria. We have --
10 those criteria are pretty carefully crafted and
11 designed to get to the important issues here, and
12 we try to keep the discussion focused around
13 those criteria and not go too much outside of
14 that, if possible.

15 We do ask that you attend the meetings
16 and try to remain engaged without distractions,
17 if possible. Keep your comments concise and
18 focused, to the extent you can. And, you know,
19 allow others to speak. You know, try to foster a
20 meaningful participation and discussion. And
21 indicate agreement if you need to, but, you know,
22 we'll try not to repeat ourselves too much, just

1 in the interest of time and efficiency.

2 So the process for discussing each
3 measure, we will start out by asking our measure
4 developers for their respective measures to come
5 up here to the table. We've got a couple of
6 places here at the front. And they will just
7 take a couple of minutes and introduce their
8 measure, say a few words about them, and then
9 we'll ask our lead discussants to get us started
10 with the committee discussion by just giving us a
11 quick summary of the pre-meeting evaluation
12 comments that were provided by your colleagues on
13 the committee, if there are any, emphasizing any
14 particular areas of concern or differences of
15 opinion, if those have emerged, and to just sort
16 of walk us through each of the criteria, at which
17 point we will vote on each.

18 The developers will be here and will
19 be able to respond to your questions, as needed.

20 Also, just to, again, go over the
21 criteria again very briefly. We do endorse --
22 NQF endorses measures for accountability

1 applications. That means public reporting,
2 payment and accreditation, as well as quality
3 improvement purposes. So when NQF endorses a
4 measure, that implies that it is suitable for
5 accountability purposes, including public
6 reporting and payment programs.

7 We do have a standard -- set of
8 standardized evaluation criteria. These -- you
9 know, the quality measurement enterprise is
10 evolving, and the criteria evolved over time in
11 response to that. One change I think since the
12 last time we had you here is that we have removed
13 the high priority subcriterion of importance. We
14 weren't finding that that was providing a lot of
15 value.

16 Pretty much every measure is a high
17 priority or can be construed that way in some
18 sense, and that was kind of how the votes were
19 turning out. So we decided to sort of skip over
20 that, and we won't be voting on that particular
21 subcriterion this time, although the developers
22 have provided some information along those lines,

1 just for your information.

2 Here is the endorsement criteria,
3 again, just to remind you the importance to
4 measure and report. The goal there is to measure
5 those aspects with greatest potential of driving
6 improvements. Scientific acceptability, we want
7 to make sure that these measures are making valid
8 conclusions about quality, that you can collect
9 the data reliably and consistently, and that
10 there is -- you know, the results of the measure
11 will lead to appropriate interpretations about
12 quality.

13 Usability and use -- the goal here is
14 to look at how the measure is used, how usable it
15 is for accountability and improvement purposes.
16 In terms of feasibility, the burden on providers
17 in terms of data collection, the goal is ideally
18 to cause as little burden as possible. If a
19 measure is not feasible, to consider alternative
20 approaches.

21 So we do have these voting tools here.
22 It's a new system, and I'll ask Alexandra to come

1 up here and talk us through it for a moment.

2 MS. OGUNGBEMI: Good morning,
3 everyone. My name is Alexandra Ogungbemi, and I
4 am the project analyst on this surgery project,
5 this phase.

6 For those committee members in the
7 room, you all have a remote control. When you
8 are voting, you will point towards me. And I'm
9 over here by the windows, on the east side of the
10 building. And that's when you will make your
11 selection to vote.

12 Once we get a solid number of votes
13 during each voting slide, upon the discretion of
14 our chairs, we will move on to the next criteria
15 or the next vote. I will actually also act as
16 the proxy member for those who are not in the
17 room. So Dr. Sawin, Dr. Asher, and Dr. Jarrett,
18 when they do join, I will act as the voting
19 member for them. And if you have any questions,
20 please let me know.

21 DR. LYZENGA: Thanks, Alexandra. So,
22 yes, just let us know if you have any questions.

1 We'll probably -- can we do a test run maybe on
2 the first one? I don't know. We'll see how it
3 goes. Hopefully, again, it will be a better
4 process than the last time around.

5 So, yes, we just wanted to note also
6 that we have a few measures that we identified as
7 related to measures that are being considered
8 today. And prior to the meeting, we notified the
9 developers if a related or competing measure had
10 been identified. We asked them to consider how
11 they could work together with the other developer
12 of the measure to harmonize or otherwise align
13 those measures in terms of definitions and other
14 elements.

15 The committee is invited to ask the
16 developers about those harmonization
17 opportunities when the measure is being
18 discussed. And we've got, I think, a bit of time
19 after the discussion of each measure to -- each
20 measure in which that harmonization discussion is
21 relevant to talk over those little -- issues a
22 little bit after we have discussed the measure.

1 For the gaps discussion -- and, again,
2 we'll go over this a little bit more later, we
3 are thinking that we would like to assign each of
4 you a topic area based on your expertise and area
5 of focus. We will certainly -- we would
6 appreciate your feedback on what you would like
7 to -- sort of what topic area you would like to
8 cover in terms of identifying gaps. But we've
9 sort of made some tentative assignments, and I
10 think we may distribute that to you today.

11 We will ask, moving forward, that you
12 -- we will have some exercises that we will go
13 through to try to identify potential measure
14 concepts that might identify any gaps in
15 measurement in your given topic area. Again, we
16 will walk through this a little bit later at 4:00
17 today. But we just wanted to kind of mention
18 that up front.

19 And now I think we can jump into the
20 evaluation process. We are going to start out
21 with a measure from AHRQ, so we would ask the
22 developers to come up to the table at this point.

1 DR. FLEISHER: Okay. I'd like --
2 before we start that discussion, I'd like two
3 things. I think Marcia needs to have Cliff
4 introduced and then, secondarily, I'd like to
5 have a brief discussion about types of evidence.

6 MS. WILSON: Okay. Thank you, Lee.

7 Dr. Cliff Ko has joined the meeting
8 here in D.C., and, Dr. Ko, we have been doing
9 oral disclosures of any professional activities
10 that may be relevant to the subject matter before
11 this committee. So I would ask that you give us
12 your name, your organization and if you have
13 anything to disclose, please.

14 DR. KO: Hi. Good morning. My name
15 is Clifford Ko. I work at -- I'm a professor of
16 surgery at UCLA, and I work at the American
17 College of Surgeons and run their Division of
18 Quality.

19 MS. WILSON: Thank you. And I will
20 also take a moment -- has Dr. Jarrett joined us
21 on the phone to do an oral disclosure? Or Dr.
22 Asher? Thank you.

1 DR. FLEISHER: One of the things we
2 thought would be useful this morning is we do
3 have measures that are administrative, we have
4 measures that are clinical, and we have registry
5 measures. And maybe Marcia can give us a brief
6 overview of how NQF looks at this. I can comment
7 -- no?

8 Just from the perspective of CSAC, the
9 question in the current space, things are in
10 flux. We are not at the point where we can have
11 e-measures. And although we acknowledge that
12 ideally robust clinical data to inform
13 measurement would be the ideal once we get to
14 e-measures, and some are becoming e-measures,
15 that they may provide complementary information.

16 So it is from a hierarchical
17 standpoint, and I don't mean that from an
18 analysis standpoint. But they are all useful,
19 and that -- if we feel they truly should be
20 harmonized, we can have that discussion. But if
21 we feel that an administrative measure, such as
22 something developed by AHRQ or Yale CORE,

1 complements a registry measure, for example, by
2 STS, then both can be endorsed.

3 So I would like to open that up for
4 any discussion, because we thought that should
5 actually be addressed at the beginning. If
6 anyone has any thoughts on these issues. And I
7 think as we go around, it is probably easiest --
8 tradition at NQF is just to put your name plaque
9 up, and, therefore, we can call --

10 MS. McCARTY: Can you just clarify
11 what an e-measure is?

12 DR. FLEISHER: An electronic measure,
13 just something that would come from an electronic
14 health record.

15 MS. McCARTY: Oh, I see. Okay.

16 DR. FLEISHER: There are separate
17 groups where --

18 DR. DUTTON: I can help with that. We
19 are grappling with this quite a bit in our
20 registry now, because we are -- we have a high
21 penetration of electronic records, and we are
22 right in the evolution. So, for instance,

1 Kelsey, we can measure post-operative nausea and
2 vomiting by asking the PACU nurse to check a box.
3 Did this patient have nausea and vomiting? Or we
4 can get the same or similar information by
5 looking at the pharmacy records to see if an
6 antiemetic was dispensed.

7 You get different answers from those
8 two. They are not perfectly aligned. But they
9 are the same spirit and the same concept.

10 And I agree. I actually was putting
11 my thing up to agree with Lee that both can
12 coexist for now.

13 DR. FLEISHER: Right. That may change
14 over the course of our time here.

15 Any other comments? Thoughts on this
16 topic? Okay. Bill, did you want to say
17 anything?

18 DR. GUNNAR: This is Bill Gunnar. I
19 have no additional comments to make before we get
20 started. Let's get into it.

21 DR. LYZENGA: If we could just have
22 our measure developers introduce themselves

1 briefly. Patrick?

2 MS. STARKS: Hi. My name is Carol
3 Starks, Agency for Healthcare Research and
4 Quality. And I'm the task lead for the quality
5 indicators that -- the inpatient quality
6 indicators and the prevention of quality
7 indicators.

8 We have a -- our current contract is
9 with Stanford University, and Patrick Romano is
10 an important part of that from UC Davis.

11 DR. ROMANO: So my name is Patrick
12 Romano. I think I've met many of you before. I
13 am a practicing general internist based at UC
14 Davis School of Medicine, Sacramento, California.
15 And we search as subcontractors to Stanford on
16 the enhancement of the AHRQ quality indicators.

17 DR. FLEISHER: So if you'd like to
18 just very briefly introduce the first measure
19 here, which I believe is -- we're talking about
20 hip fracture mortality first. So it's Measure
21 354.

22 DR. ROMANO: Thank you. So, yes, so

1 this measure is one of a family of measures that
2 most of you are probably at least somewhat
3 familiar with. So these are the AHRQ quality
4 indicators, which are based on administrative
5 data that are collected by state health data
6 organizations and compiled by the Agency for
7 Healthcare Research and Quality, made available
8 to researchers and others.

9 They are also used extensively by
10 state health departments, by regional coalitions,
11 researchers, and others for a variety of
12 purposes.

13 The particular measures that -- the
14 first measure that we're talking about is part of
15 the module called the inpatient quality
16 indicators. This module focuses on hospital
17 outcome measures and structural measures of
18 hospital care that are related to outcomes.

19 The IQI for hip fracture mortality,
20 specifically, is one of a subset of these IQIs
21 that focus on inpatient mortality for patients
22 who undergo certain common procedures in acute

1 care hospitals. So the focus of these measures
2 is on inpatient mortality. The reason for that
3 is that many of our users only have access to
4 inpatient data. Ideally, they might like to have
5 data on post-discharge follow-up of patients, but
6 a hospital's ability to collect that information
7 obviously is limited.

8 So these indicators were designed to
9 focus on inpatient mortality and to include some
10 fairly sophisticated risk adjustment to account
11 for variation in severity of illness across
12 hospitals. There are a number of these mortality
13 IQIs that I think are in the domain of this
14 committee. I think the only one that is under
15 review today is the one focusing on hip fracture
16 mortality. But I'll stop there.

17 DR. FLEISHER: Thanks, Dr. Romano.

18 And I think we have a couple of
19 discussants on this. Dr. Ko and Dr. Yates are
20 discussants for this measure. So can you kind of
21 get us started with the discussion?

22 DR. KO: Sure. Good morning, again.

1 Can I -- I'm trying to use your template for
2 doing this, so -- but keep -- it was a little
3 complex, so can you tell me -- I know we have to
4 go a certain way and then put it up for a vote.
5 So can you help me with the first area until we -
6 - to present until we vote?

7 DR. LYZENGA: Sure. So, I mean, we
8 will start out with -- evidence is the first
9 subcriterion for the importance to measure and
10 report criterion. And this is an outcome
11 measure, so I think we discussed the last time
12 around that for an outcome measure we do not
13 require the same sort of volume or type of
14 evidence as we do for a process measure.

15 For a process measure, we ask that the
16 evidence be based on a guideline, a systematic
17 review of the evidence. We ask for some
18 information on the quality, quantity and
19 consistency of that evidence supporting that
20 particular process of care.

21 For an outcome measure, really what we
22 are asking for is that there is a plausible

1 rationale connecting at least one health care
2 structure, process or intervention to the
3 outcome, that there is some sort of rationale for
4 a linkage there, that providers can influence the
5 outcome in question.

6 So, again, we are not looking for a
7 sort of systematic review of the evidence there.
8 Just a sort of justification of sorts, a
9 rationale for that connection between processes
10 and the outcome in question. So that is sort of
11 the question at hand here, at least first.

12 DR. KO: Perfect. So, again, this is
13 Measure 0354, and it's entitled the Hip Fracture
14 Mortality Rate, IQI 19. It's -- the steward is
15 AHRQ, and you just met them. The description of
16 the measure -- it's an in-hospital death per
17 1,000 hospital discharges with hip fractures, the
18 principal diagnosis for patients 65 and older.

19 The rationale is that providers can
20 adopt processes of care -- of best performers,
21 and consumers can select the best-performing
22 providers in order to reduce the overall

1 mortality rate.

2 Again, the data source is
3 administrative. The level of analysis is
4 facility.

5 In terms of evidence, this is an
6 outcomes measure. And in terms of processes of
7 care that can influence the outcome, the number
8 one process is probably time to surgery, when
9 somebody has a hip fracture, when they are
10 brought to the operating room. In working with
11 the orthopods, the AAOS, and other of the
12 orthopedic societies, they all agree that this is
13 an important issue, although some have -- there
14 is still a little variability as agreement in
15 terms of time of surgery, but most believe that
16 time to surgery is the process that can influence
17 that outcome.

18 There are a number of other issues in
19 terms of influencing the outcome in terms of
20 rescuing from a complication with PE and MI as
21 the big complications occurring post-op or
22 peri-op during a hip fracture case. And so there

1 are other processes as well.

2 DR. YATES: I am the co-discussant.
3 This is Adolph Yates speaking. If I'm not
4 mistaken, however, there is nothing in the
5 measure that captures time to OR. Am I correct
6 in that?

7 This is data that is extracted from an
8 administrative -- from administrative data sets
9 or codes. And my one comment is, is that it is a
10 fairly blunt measurement. Without a doubt, there
11 is a process of intervention, which is somebody
12 comes to the hospital with a hip fracture, and
13 ideally they leave with the ability to heal and
14 eventually walk. And death would be an outcome.

15 So I -- there is no question that
16 there is a process here. The problem is, is that
17 there is a black box in this process, and the
18 black box is, is that the numerator and
19 denominator are only defined by the level of the
20 fracture, i.e. whether or not it was attributed
21 to being or assigned to being, for instance, a
22 femoral neck fracture versus a subtrochanteric

1 fracture. And the other parameter is age.

2 And so you really only have a couple
3 different variables with which to both assess
4 risk and both to assess the nature of the
5 baseline population. So my concerns or my
6 questions with this is, yes, it is an outcomes
7 measure. But when you look at page 2, the
8 percentile of the distribution of outcomes of
9 deaths, in the fifth percentile, in the 25th
10 percentile are zero.

11 So it seems to me that there is -- it
12 is a strange distribution of the curve here.
13 This measure includes pediatric hospitals, it
14 includes orthopedic-specific or specialty
15 hospitals, which don't have emergency rooms
16 frequently. It includes a whole slew of
17 hospitals that may never see a hip fracture. So
18 that's the one question I have.

19 And the other question I have --

20 DR. FLEISHER: Can I --

21 DR. YATES: Yes.

22 DR. FLEISHER: -- just hold because

1 those -- Marcia, if I'm not mistaken, and
2 Melinda, that is not the evidence criteria,
3 correct? You are moving on to --

4 DR. YATES: Discussion.

5 DR. FLEISHER: -- how it's defined.

6 Do we want to go and --

7 DR. YATES: I'm sorry. I moved to
8 discussion.

9 DR. LYZENGA: Yes. Typically, we like
10 to try to kind of keep the discussion focused
11 around the criteria that we are, you know,
12 speaking about at the moment. It's okay to, you
13 know, give you --

14 DR. YATES: Well, what I'm getting at
15 is the numerator and denominator. And the
16 numerator and denominator are -- I have questions
17 about that.

18 DR. LYZENGA: I think that is probably
19 in scientific acceptability. I would say that
20 the specifications go under validity and
21 reliability.

22 DR. YATES: And so that's at the very

1 beginning, I believe.

2 DR. LYZENGA: Importance. So evidence
3 is at the very beginning.

4 DR. YATES: Right. And I agree it's
5 outcomes.

6 DR. LYZENGA: Okay. Great.

7 DR. FLEISHER: As we go through this
8 -- and this is great, because we will -- we have
9 to get back into that theme. I think we should
10 vote on evidence, and then we can quickly get to
11 those very important points.

12 DR. GUNNAR: Just to go back and,
13 Cliff and Adolph, can you just sort of sum up
14 your advice or your perspective on evidence?

15 DR. KO: As far as the opportunity for
16 mortality itself to be a metric for hip fracture,
17 the evidence shows that there are processes that
18 are linked, although, you know, with what Dr.
19 Yates said, that should be understood in that
20 context. But it's mortality itself that -- the
21 process of time to surgery is thought to be an
22 important process where the outcome may be

1 mutable.

2 DR. YATES: And I agree that there is
3 something to be measured here and that it has
4 evidence. I would just say that -- and this is
5 why I slipped into that slope of discussion.
6 There is no time of outcome measured in this
7 measure, just for clarification. That's why I
8 started talking.

9 DR. FLEISHER: No. This is great.
10 Just want to --

11 DR. GUNNAR: And just one other --
12 just to point out this is in-hospital mortality
13 as opposed to a defined period of time, which we
14 will discuss tomorrow in some depth?

15 DR. YATES: Correct. In-house
16 mortality is the discharge to diagnosis.

17 DR. EREKSON: So, and I don't know if
18 this falls into reliability or if it falls into
19 evidence. But one big glaring thing on this
20 measure is patient preference, and I don't know
21 if that's in this discussion, which is evidence,
22 or if that should be an exclusion of this

1 measure. That if a patient is 102 and falls, do
2 they choose not to have surgery? And does that
3 affect your mortality?

4 MS. JOHNSON: I think that would be
5 discussed in two different places, probably in
6 the specifications, and then also under validity
7 when you think about exclusions to the measure.
8 So you have two opportunities to talk about that.

9 DR. LYZENGA: So if there is -- go
10 ahead, Patrick.

11 DR. ROMANO: I just wanted to point
12 out that -- so the form asks developers to focus
13 on at least one process measure that demonstrates
14 this link. There are of course others. There is
15 25 years of literature on preventing thrombosis
16 after hip surgery using both mechanical and
17 pharmacologic measures. There is also literature
18 related to cardiac evaluation, cardiac risk
19 assessment, and prevention of post-operative
20 myocardial infarction.

21 So those weren't highlighted in the
22 literature review, but those are also part of our

1 literature.

2 DR. LYZENGA: All right. Well, if
3 there are -- oh, go ahead. Dr. Cima.

4 DR. CIMA: I think to follow up on Dr.
5 Romano's point is that about a time to OR, that -
6 - I mean, that may not be the best measure
7 because then you're going to have to get into,
8 well, is it reasonable to say it's 72 hours, but
9 what if a patient needs an extensive medical
10 evaluation before -- to make it safer to go to
11 the OR. I mean -- so, I mean, I think if you're
12 going to do a mortality measure, you sort of do
13 the risk adjustment, but you don't start putting
14 in process measures in the middle of it.

15 DR. YATES: We are getting into the
16 scientific discussion about the measure itself.
17 But, again, this measure does not capture whether
18 or not DVT prophylaxis was performed, whether or
19 not there was a time to OR issue. This is
20 strictly mortality, and the numerator and
21 denominator are the type of fractures and the
22 patient's age across a wide spread of hospitals.

1 So that is what the measure is
2 measuring, but those other things are the
3 processes that could justify the measure. And I
4 would agree with the last comment in that it's --
5 all of the papers that show 48 hours being some
6 sort of a magic time period for getting someone
7 to the operating room and repaired, all of those
8 exclude those patients that have significant,
9 reversible, other medical issues that could be
10 improved upon before they have surgery.

11 So that is an important point, but
12 that's going on into the scientific validity.

13 DR. SIPERSTEIN: So just a quick
14 comment that one of the values of this type of
15 measure obviously is for the institution itself
16 to know what their own rates are, so they can
17 then do an internal reflection in terms of, are
18 there processes in line in terms of improving it.
19 And time to OR, pre-op evaluation, all of these
20 factors, may play a role. But we -- I see the
21 value primarily as the institution knowing their
22 rate, being able to benchmark, and then figure

1 out whether they have an optimum process in
2 place.

3 DR. FLEISHER: So, John, do you have
4 a comment about the evidence? Because what I
5 would like to do -- this is a review of an
6 approved measure, correct? This is a currently
7 established measure. So --

8 DR. HANDY: Well, I would just -- as
9 I recall from my reading of this, it's a small
10 proportion of patients. But transferring it to
11 another hospital is an exclusion, and that's the
12 way you can take that patient and move him
13 downstream. And so that's going to be a
14 description of the measure versus the evidence.

15 DR. FLEISHER: So can we vote on
16 evidence, and then we can just --

17 DR. LYZENGA: These are really
18 important points. So maybe we can use this as a
19 little test case, go through this and see how it
20 works. Do you want to take us through it,
21 Alexandra? All right.

22 So I'll read it off. All right. So,

1 again, just to remind you, we are voting on
2 whether a rationale supports the relationship of
3 the health outcome, in this case hip fracture
4 after surgery, to at least one health care
5 structure, process, intervention or service.

6 One indicates yes, two indicates no,
7 and we'll start voting now. So tell us --
8 Alexandra, how many is that? How many have
9 voted?

10 MS. OGUNGBEMI: Yes.

11 DR. LYZENGA: And what's in the right
12 corner? Oh, it's the timer. You're not timing
13 this, so -- it looks like we've got 22 votes. I
14 think that's it.

15 All right. So clear result there, and
16 we can move on to -- scientific acceptability is
17 next, or actually -- sorry, we've got more in
18 importance to measure and report yet. Can you
19 skip to the next slide, Alexandra?

20 So performance gap here. That's the
21 next point of discussion, whether data
22 demonstrate a variation or overall less-than-

1 optimal performance across providers and/or
2 populations and groups. Basically, what we're
3 trying to get to here is whether there is a gap
4 in care, an opportunity for improvement, that the
5 measure is not so to speak topped out or
6 otherwise unable to achieve improvements in
7 performance.

8 Is there any discussion on this? Go
9 ahead.

10 DR. YATES: To make up for the last
11 section, I would say yes. That's easy.

12 (Laughter.)

13 DR. LYZENGA: Anything else from the
14 committee on this, or should we go ahead and
15 vote? Yes, let's go to the vote. Alexandra?
16 You can go ahead and start.

17 Can we see the vote? Okay. Yes. So
18 it passes.

19 And then we'll move on, and, again,
20 this is -- go ahead, Karen. Good point. Can you
21 back to the last slide, Alexandra? Just for the
22 purposes of the transcript I'll read off the

1 vote. Can we do that? Oh, we can't. All right.

2 Well, we'll go back and correct that later.

3 Seventy-nine percent high? All right.

4 So, again, we're not actually voting
5 on high priority, so we can go ahead and skip
6 over this one. And we're not looking at a
7 composite now, so we can skip that one as well.

8 So now we're at scientific
9 acceptability, and this does include the
10 specifications, whether the measure is specified
11 precisely, whether it has been tested
12 appropriately and with adequate results to
13 demonstrate reliability and validity.

14 So we'll -- I'll hand it over to the
15 lead discussants to talk over this issue.

16 DR. KO: So this measure is an
17 administrative data measure. The numerator and
18 denominators are specified. Numerator is the
19 number of deaths among cases meeting inclusion
20 and exclusion rules. The denominator is
21 discharges of patients 65 and older, principal
22 diagnosis with ICD codes with a diagnosis of hip

1 fracture from their evidence.

2 The hip fractures, there are 350,000
3 discharges, and 300,000 or so of them have an ICD
4 of -- primary diagnosis of hip fracture.

5 The exclusions are -- well, I won't go
6 through that, but the -- you can see what those
7 are. The fact that it's an inpatient mortality
8 measure means that -- obviously, that this is
9 just the inpatient aspects of mortality and
10 cannot get any longer or post-discharge mortality
11 rates. And so that may be a concern. I know
12 that clinically a number of people have brought
13 that up.

14 Do I get into -- is reliability
15 testing in this section as well?

16 DR. LYZENG: Yes.

17 DR. KO: So with this data and with
18 the -- with the data and the analysis that was
19 performed, the reliability testing, the
20 reliability of distinction testing that was
21 performed with this measure has been very good
22 and very scientifically sound. And you can see

1 that -- from Table 2 that the cut point of .4 as
2 a reliability is marked there. I mean, they
3 looked at it very scientifically and
4 methodologically well.

5 It looks like the deciles that meet
6 the .4, however, is the eighth, ninth, and tenth
7 deciles, and the first seven deciles do not. So
8 that is an issue with this measure. That is
9 probably an issue with a lot of measures in terms
10 of looking at reliability to that degree. I
11 think that there are a number of measures, just
12 as a comment, in -- that are evaluated by the NQF
13 that do not look at reliability at all.

14 So the fact that they did is a plus.
15 And I think that their numbers are -- their
16 findings are probably in line with a lot of the
17 measures that we have in the endorsed category.

18 So I will stop here, unless there is
19 another section in this that I'm missing.

20 The validity, is that in this area?

21 DR. LYZENGA: We will go to validity
22 next. They are two separate votes, actually.

1 DR. YATES: The issue of reliability
2 is I think open to question, in that it is -- it
3 may be that they are able to demonstrate
4 mathematically that there is reliability. But
5 the -- not to belabor the point, it is very
6 difficult for even orthopedic surgeons to decide
7 what level of fracture they are dealing with. So
8 there may be several different things on the
9 margin here that wouldn't be called "a hip
10 fracture." Proximal femoral fractures, and the
11 like, sometimes are lumped into that category.

12 But aside from that, there are some
13 reliability issues in that I'm not sure that the
14 lower percentiles showing -- or the higher
15 performing percentiles showing zero hip fractures
16 indicates that they are capturing the right
17 hospitals in that percentage. There may be -- I
18 mean, I don't understand for a measure that's
19 looking at patients 65 and older why they would
20 include pediatric hospitals. I don't -- I mean,
21 they are obviously going to have zero.

22 So I worry -- it would be nice to see

1 a graphical distribution of that occurrence
2 across those hospitals. I assume that it's going
3 to be skewed. Likewise, in the reliability
4 portion, they include as part of the measure open
5 fractures. It takes an incredible amount of
6 energy for someone to have an open -- femoral
7 neck, open intertroch, or open subtroch fracture,
8 and those would represent patients that might be,
9 at 65 and over, in a trauma hospital.

10 And I don't believe that's the
11 intention of this measure, to look at high energy
12 trauma patients as opposed to, say, grandma and
13 grandpa with osteoporosis falling and having a
14 hip fracture in the community.

15 So, yes, you can -- the reliability is
16 mathematically correct, but the reliability of
17 what we are looking at I'd just call into
18 question from just what the numerators and
19 denominators are capturing.

20 DR. LYZENGA: Amy?

21 MS. MOYER: I believe the inclusion of
22 the pediatric hospitals is somewhat related to

1 the feasibility. You don't have to then take the
2 data set and look at, is this a pediatric
3 hospital, is this an adult hospital. But then
4 the removal of all patients under age 65
5 effectively takes those out -- those hospitals
6 out of the measure. So it does remove them,
7 because they don't qualify for the measure in the
8 denominator.

9 DR. LYZENGA: Collette?

10 MS. PITZEN: Great. I have two
11 comments. One is in general about mortality
12 measures, and a consideration for having a 30-day
13 mortality rate. And I think we will be getting
14 into that more as time goes on.

15 But just, for example, if you have
16 someone that is discharged after 120 days, that
17 has a different kind of a case than perhaps a 30-
18 day mortality rate.

19 And the second comment I'd like to
20 make is about the reliability score. I applaud
21 the measure developers for providing that
22 performance score. I think that's an important

1 value, and many of the measures that we are
2 looking at over the next couple of days do not
3 have that performance score.

4 I am a little bit concerned about at
5 .4. We publicly report all the clinics in the
6 State of Minnesota, and our reliability scores
7 for doing those comparisons clinic to clinic are
8 in the .8 and .9 range. We like to see something
9 at .7 or above, and we start to get concerned
10 when a reliability score starts dipping down
11 below that .7.

12 Thanks.

13 DR. FLEISHER: Rick, and then we'll
14 get responses.

15 DR. DUTTON: Yes. A couple of
16 questions for the developers. As Dr. Yates
17 mentioned, there may be a hard time
18 distinguishing signal from noise in this measure.
19 The distinction between high energy and low
20 energy fractures is one. Another one brought up
21 was patients who have a fracture but choose not
22 to have treatment, for instance, end-stage

1 Alzheimer's patients who might become DNR, or the
2 final -- be transferred to hospice or a skilled
3 nursing facility before dying.

4 Do you have any comment about how we
5 might improve the measure to better discriminate
6 the population we are trying to get at?

7 DR. FLEISHER: Comments from the
8 developer?

9 DR. ROMANO: Sure. Okay. Let me --
10 I will try to hit them all, but we'll see. So,
11 first, with reference to pediatric hospitals,
12 yes, they're in the source data set. They're in
13 the original data set, but they are effectively
14 excluded. So the 2,72
15 1 hospitals are basically the hospitals that had
16 at least three patients who were eligible,
17 patients who had hip fractures who were over 65.

18 So the original number of hospitals in
19 the data asset is close to 4,000, right? Do you
20 know, Carol? Over 4,000, right? So 2,721 is a
21 subset of those.

22 Second is in terms of the definition,

1 yes, this measure was deliberately specified in
2 consultation with an expert panel that included
3 specialists from a variety of relevant
4 disciplines. It was specified to include both
5 patients who are managed surgically and patients
6 who are managed medically. And that was
7 deliberate because of the fact that some patients
8 may opt for non-surgical management.

9 There may be some particular
10 contraindications to surgical management, and the
11 type of management in this case is actually
12 included in the risk adjustment. So that there
13 are -- the risk adjustment model is actually
14 quite fully specified with the C statistic of
15 0.893.

16 For those of you who are familiar with
17 risk adjustment models, that's a very high
18 discrimination, and it reflects the fact that the
19 model incorporates the type of procedure that was
20 necessary, whether the fracture was open or
21 closed, and whether the patient was treated
22 medically or surgically. So that's incorporated

1 into the risk adjustment. We can talk about the
2 pros and cons of doing that, but that was the
3 decision that was made in consultation with the
4 expert panel.

5 In terms of reliability scores, yes,
6 this is a problem across I think a wide panoply
7 of measures that are in the NQF portfolio. And
8 we do want to be honest about this, and sort of
9 recognize that this measure is not going to be
10 reliable. Most procedural mortality measures are
11 not reliable for hospitals that are in the lower
12 part of the volume distribution.

13 So the way that we account for this
14 methodologically is to do what is called
15 smoothing, and this is basically the same
16 approach that Yale CORE uses for CMS measures, so
17 that the risk-adjusted rates for these lower
18 volume hospitals are shrunken or smoothed back to
19 the overall mean.

20 Again, this method has certain
21 strengths and limitations that we can discuss,
22 but what it basically means is that for low

1 volume hospitals the publicly reported metric --
2 for those who choose to publicly report, the
3 publicly reported metric will basically look very
4 similar to the average.

5 As hospitals move into higher volume
6 categories, then the hospitals' own experience
7 becomes the primary driver of the reported
8 metric, the smooth metric. So we in fact adjust
9 for the difference in reliability that you see
10 across the volume deciles in the smoothing
11 process.

12 So basically we recommend that when
13 hospitals are using the data themselves, or
14 within their organizations, that they should
15 focus on the unsmoothed rates to reflect their
16 own experience. For public reporting
17 applications, we generally recommend use of the
18 smoothed rate to account for the variable
19 reliability across volume thresholds.

20 Another approach to this problem, of
21 course, would be to set a volume threshold, a
22 single arbitrary number, and to say that this

1 measure should not be recorded if your volume is
2 less than X. That's an approach that we have not
3 taken in the AHRQ quality indicators program,
4 sort of leaving it up to users, presenting the
5 data, and allowing them to make their own
6 decisions in their own context about what the
7 right threshold is. But that would be an
8 alternative approach would be to dictate or to
9 suggest a single threshold for volume.

10 So, and then, finally, so in terms of
11 patient preference, yes, we certainly recognize
12 that this is an important issue. I will point
13 out that age is a powerful factor in the risk
14 adjustment model. So, for example, patients who
15 are over age 85 have 2.4 times higher odds of
16 mortality, as you would expect. We also find
17 that hospitals that receive patients transferred
18 in from other hospitals, there is a factor in the
19 risk adjustment model to account for that. And
20 so those patients also have somewhat higher
21 mortality.

22 So as far as -- we don't have any way

1 of knowing specifically what the patient's values
2 were, one thing I will say that we are also
3 exploring analytically, but it's not reflected in
4 the current specifications, is using information
5 about hospice enrollment as a proxy for patients
6 who have chosen palliative care as their
7 approach. It is consistent with their values.

8 We still have some uncertainties about
9 our ability to capture that information
10 accurately across all payers. These are intended
11 as all payer measures. So it's not reflected in
12 the current specification, but it is a topic of
13 ongoing analysis.

14 DR. FLEISHER: Thank you. I don't
15 think you addressed the -- well, Larissa, a
16 comment?

17 DR. TEMPLE: I just have a point of
18 clarification, and this speaks to sort of not
19 being a hard-core methodologist. But when you
20 talk about your smooth rates, that includes the
21 risk adjustment or does that not?

22 DR. ROMANO: Yes. It starts with the

1 risk adjustment, correct.

2 DR. TEMPLE: Okay.

3 DR. FLEISHER: Any comments back?

4 Cliff?

5 DR. KO: I have maybe a clarification
6 from you or from Bill, that when -- data source
7 is clearly an important issue, and this is a
8 billing data source. And there is pros and cons,
9 and we all know what those are.

10 But how should we look at this? In
11 what perspective? So as a methodologist, you
12 know, if I take a data source and I'm like, well,
13 there are good things about it, and there is not
14 such good things about it, and I just like, okay,
15 we just acknowledge that, and then we go forth
16 with that data source, and, you know, AHRQ and
17 Pat has done a great job in doing the methods
18 with that piece.

19 But if there are issues like what Dr.
20 Yates brought up that there are clinical issues
21 that are just not there, or there are risk
22 adjustment issues that you cannot address because

1 you can't tell the level of fracture or patient
2 preference, and things like that, how should we
3 look at this in totality?

4 Because as a methodologist doing the
5 best you can with what you have, but if you were
6 working in the real world it misses a lot of
7 things that are important to this topic of, in
8 this case, hip fracture mortality. So the
9 perspective of the way we look at this is very
10 important as to whether we think this is going to
11 cut it or not.

12 DR. FLEISHER: I think you actually
13 outlined the question that you -- this committee
14 has to decide from a reliability standpoint. I
15 mean, this is -- we can't change the measure
16 unless we turn it down. I mean, we have an up or
17 down. They can respond to questions, and I go
18 back to either Andrew or Karen for further
19 comments. If you feel that the reliability is
20 not high enough with this data set, at this point
21 in time that's a decision you make as a member of
22 this committee and pass it over to CSAC.

1 Other thoughts? So I -- you know, it
2 would be great to have the ideal patient
3 preferences. We have actually published on the
4 fact that there are racial differences that I'm
5 not sure are patient preference differences based
6 upon work by Neumann's paper. So, I mean, this
7 may not be preferences, and this would be
8 important data that can be found in this measure.

9 So I think the answer to your question
10 is you have to decide if you think it's good
11 enough, as currently stated. And if there's a
12 better measure -- this gets back to the
13 harmonization. If there's a better measure,
14 could be unintended consequences of using this
15 data are too great and there's something better
16 out there, then you should I think vote for the
17 better measure. If there's nothing else to
18 compete, then the question is, is it good enough?

19 DR. YATES: We're going to move on to
20 validity separately.

21 DR. KO: Yes. That will be the next
22 one.

1 DR. YATES: Or are we going to vote on
2 reliability first?

3 DR. KO: We'll vote on reliability
4 first.

5 DR. YATES: Okay.

6 DR. GUNNAR: But I think specific to
7 what -- and Cliff's question is a good one -- is,
8 how do we evaluate this from a perspective of, is
9 it as designed have an underpinning of reliable
10 information that allows it to then have the
11 observed outcome?

12 And the answer, that it's easier I
13 think in a measure that has been around since
14 2008, which this has, if the data has been
15 treated essentially the same from its creation,
16 and we don't believe the world has developed an
17 enormous workaround, that there is improvement.
18 That's what they're showing, that the observed
19 rate per hundred has improved over the last --
20 when you look at the totality of hospitals that
21 they're acquiring information from.

22 I think the questions -- or the

1 granular questions, then, raised are, what are
2 people doing in response to this? Are they
3 reacting to this measure and modifying their
4 behavior to the good of the outcome, or are they
5 modifying it to the good of "I can find a way of
6 not being seen or that mortality being counted."
7 So I think that gets to the reliability and the
8 validity. I hope I hit that on the head.

9 DR. YATES: Well, and along those
10 lines, one big wraparound gets back to Collette's
11 point, which is you'd have to know what the
12 length of stay was in that -- in terms of knowing
13 whether or not there was really a reduction in
14 mortality or was the mortality outsourced, if you
15 will, to the skilled nursing facility, which that
16 would be a trend that is also very much
17 concurrent with length of stays all dropping.

18 DR. FLEISHER: John, and then Barb.

19 DR. HANDY: I mean, while Cliff's
20 point is incredibly dead on, almost nobody else
21 has a resource that doesn't involve or that
22 involves a very detailed clinical database,

1 because almost -- most measure sponsors are using
2 administrative data. So it's a really important
3 point, but you would say that we, therefore, will
4 only go with somebody that has a very extensive
5 clinical database to be able to overcome those
6 points, but --

7 DR. LEVY: And, more importantly, we
8 don't know that mortality isn't the outcome that
9 the patients wanted. I mean, to -- to the
10 earlier point, this may not be improvement, that
11 we are discharging these folks alive. So, you
12 know, this is a philosophical point that we are
13 going to need to talk about. But the fact that
14 mortality is a measure of quality may or may not
15 be an accurate assumption on our part, and we
16 don't have an opportunity to know what the
17 outcome was that these patients really wanted to
18 have.

19 So I'm not sure that the assumption
20 that we've had improvement in mortality is a
21 workaround or is an improvement in process, but
22 it may actually be detrimental to the true

1 outcomes that we're looking for.

2 DR. LYZENGA: I just want to note that
3 a lot of these issues I think are -- kind of
4 relate more to validity. So just for voting
5 purposes, again, the first vote we're going to
6 take is on reliability really, while the
7 information can be collected in a sort of
8 reliable way to sort of form a reliable
9 foundation for the measure results, again. And
10 then validity will really be talking about the --
11 whether it is a true reflection of quality. So
12 maybe we should vote on reliability at this
13 point, so we can kind of get into some of these
14 validity issues?

15 DR. ROMANO: One final response, which
16 I just got by email from another member of our
17 team. So just to clarify that -- so when we are
18 looking at these measures of reliability, there
19 are several different measures out there. And so
20 it's a little bit caveat emptor to some extent.

21 So just to be clear, the measure that
22 we use is a measure of signal to noise, which

1 basically compares the between hospital variance
2 to the total variance, including both between and
3 within hospital variance. So this is a measure
4 that focuses on whether there is a signal that
5 hospitals can be identified as having a higher or
6 lower than expected mortality.

7 Now, this is a little bit different.
8 Some other measure developers use a test/retest
9 measure, which is simply looking at whether there
10 is consistency and performance over time. And we
11 are actually doing some comparative analyses
12 right now to understand the relative performance
13 of these two different approaches.

14 But in these types of outcome measure
15 applications, signal to noise metrics generally
16 give you lower reliability numbers than
17 test/retest measures. In other words, it's
18 easier to show that the performance of a hospital
19 is consistent over time than it is to show that
20 it's statistically distinguishable from the
21 performance of other hospitals. So that's just -
22 -

1 DR. FLEISHER: Thank you.

2 So, Alexandra, you ready?

3 DR. LYZENGA: All right. So now we're
4 voting on reliability. Is the measure precisely
5 specified and tested with an appropriate method
6 and scope with adequate results?

7 We have 21. Last second to try voting
8 again. We have 22. Alexandra, can you --
9 Andrew, are you reading or -- who is leading up
10 the -- lead it off. Go ahead. Do we have the
11 results? So we have 39 percent high, 59 percent
12 moderate -- sorry, 57 percent moderate, four
13 percent low, zero insufficient.

14 And now we can go ahead and jump into
15 the validity questions, again, sort of really
16 more focused around whether this -- the measure
17 results reflect quality of care and whether valid
18 conclusions about quality can be drawn from the
19 measure results.

20 DR. FLEISHER: So Barbara's comment
21 really feeds into a lot of questions that will
22 come up tomorrow again with STS, and we wanted

1 STS also to be here, so we'll have a brief
2 discussion about that, which we will get to STS
3 to be prepared to have a more full discussion,
4 but it is something that has obviously been
5 commented on, including in The New York Times
6 recently.

7 Cliff?

8 DR. KO: Well, I will just go through
9 it. A lot of the testing they had done was on
10 face validity. They performed a panel, like a
11 RAND panel, of 14 clinicians, and basically they
12 had acceptable indeterminate agreement of overall
13 usefulness rating as a quality improvement
14 metric, overall usefulness rating as a
15 comparative reporting metric.

16 The issue that was brought up
17 previously about the caveats of indicator use
18 suggested by the panel is exactly the length,
19 which is use of 30-day mortality measure would
20 offer additional information and reduce the bias.
21 But overall they thought that -- from this panel
22 that there was high face validity.

1 DR. LYZENGA: A.J.?

2 DR. YATES: Thanks. The issue of
3 validity is probably more than anything else what
4 drives the discussion we will have on usability
5 and feasibility and reportability, because the
6 reliability is something that most of the
7 developers can provide mathematically through
8 statistics and the like. I think that's a given.

9 And the issue on validity is that
10 unfortunately we can't vote three different ways.
11 I think this is a very valid study in terms -- or
12 valid measure for national trends. I think this
13 is a very valid measure for individual hospitals
14 to look inside at themselves and see what they
15 can do for improvement.

16 But in terms of the validity of this
17 measure to measure the quality of one hospital
18 versus another, I don't think that the risk
19 adjustments, which I see as being offered as
20 being -- as being level of fracture, type of
21 fracture, and also age, and transfer in or out,
22 is enough to truly decide that one hospital is

1 more highly -- has higher quality than another.

2 There are -- what I don't see here is
3 within the black box out of the administrative
4 data set codes that could have been captured is
5 any indication of comorbidities or other things
6 that are important. There will be community --
7 there will be specialty orthopedic hospitals that
8 might take a transfer of a hip fracture that
9 wants to have a total hip replacement that is in
10 perfect health, an ASA-1 at age 66. That's a
11 different population than, say, a hospital that
12 has a large oncology and cardiac population, such
13 as ours, where I may operate on four ASA-4s in a
14 row, and trying to get them better and get them
15 out of the hospital.

16 And I don't see where there is any
17 risk adjustment for those type of issues. The
18 validity can be adjudged in terms of, yes, it --
19 death is a -- death is a great dichotomous 01
20 thing, and I see that as being very valid.

21 But I would say that in terms of the
22 risk adjustment, for the purposes of comparing

1 hospitals' quality, I would be hard-pressed to
2 say that I can say it's valid.

3 DR. FLEISHER: Thank you. Before we
4 go forward to others, just from the perspective -
5 - and I'd like Andrew's perspective -- if we
6 approve this, we should also be providing the
7 developers with our concerns for the next time
8 this comes back. If we don't approve it, we
9 should also be providing the developers with the
10 key things that we need fixed if they come back,
11 to bring it back.

12 So it will be important that I assume,
13 Patrick, you are also taking notes of what are
14 our greatest concerns going forward.

15 DR. YATES: And, Lee, just to add to
16 that, you are making public comment on those that
17 might use such a measure as to whether or not the
18 NQF has concerns that can be expressed in this
19 forum for the use of this, which can be something
20 that can be used for payment penalties to
21 hospitals and also public reporting. And so, on
22 that note, I want to make sure that when we say

1 something is valid, it may not be valid for
2 certain uses. We don't have the ability to
3 distinguish that in this process in terms of
4 voting.

5 DR. FLEISHER: So let me let Marcia
6 quickly comment, because CSAC and the board are
7 wrestling with this made for -- measure fit for
8 purpose. So do you want to comment?

9 MS. WILSON: Just very briefly. This
10 obviously is of great concern to many
11 stakeholders. And what NQF is doing is going to
12 be looking at intended use, because right now
13 it's the global language that we use as the
14 measure can be used for accountability and
15 quality improvement, and that has been our
16 language for a very long time.

17 So, yes, we are aware of this problem.
18 We are going to be looking at this. I don't
19 think this is an issue we will solve quickly or
20 in the near term, but it's very much on our radar
21 and we'll be bringing together a group to talk
22 about intended use.

1 Unfortunately, for today we are
2 operating under the existing language, which is
3 the point that you raise. So that's how we're
4 operating today, but it is on our radar and we
5 will be looking at the issue.

6 DR. FLEISHER: And just, Andrew, in
7 the report, will there be comments about whether
8 or not a hospital internally, whether the
9 committee felt strongly one way or the other
10 about internal quality improvement versus
11 external? That will be in the report?

12 DR. LYZENGA: We can certainly reflect
13 that in the discussion in the report, yes.

14 DR. FLEISHER: But thank you for
15 bringing that up. That will be important.

16 Collette and --

17 MS. PITZEN: Just a couple of
18 comments. With an administrative claims-based
19 type measure, one could construct a measure that
20 is a 30-day mortality rate, as I talked about
21 before. And perhaps setting your location would
22 not matter as much if you're using that claims

1 data. So that would be one recommendation to
2 make the measure stronger.

3 And I just want to share some thoughts
4 about how I feel about mortality, perioperative
5 mortality measures in general. I think they do
6 have their place in terms of kind of a monitoring
7 function. Are things going okay? Are things
8 perhaps getting out of hand? And when I'm
9 looking at the various measures coming through
10 here, I want to understand, is this a fairly high
11 volume procedure that makes a difference to a lot
12 of people, or are we looking at something that is
13 really rare and hard to measure anyway?

14 And then, is there any potential for
15 a small improvement on that rate? Has it been
16 demonstrated over time? Or are we looking at
17 something that now has an incidence of
18 .28 percent in the population?

19 DR. GUNNAR: So that is a really great
20 question. If you look at the numbers, if you say
21 -- if you assume that we have now improved by
22 half a patient per hundred, and 200,000 cases a

1 year, or episodes, you've got 1,000 people per
2 year who have benefited from this measurement
3 just if it's the same measure and the same data
4 and no one has done a workaround in the last,
5 what, five years that they have measured it.

6 So in and of itself, to your point
7 exactly, I think they -- when looking back, you
8 actually can say that it has -- mortality as a
9 broad indicator of quality has resulted in 1,000
10 patients this year that are alive that wouldn't
11 have been alive before. If I've got the numbers
12 right.

13 Dr. Romano, do I have the numbers
14 correct? About?

15 DR. ROMANO: We wouldn't take any
16 credit for that, but --

17 (Laughter.)

18 DR. GUNNAR: But if I'm reading your
19 evidence correctly, that's --

20 DR. FLEISHER: We can get back as --
21 Rick?

22 DR. DUTTON: Yes. A quick comment on

1 the mortality thing. This is not a surgical
2 measure. This is a disease measure of a patient
3 with a hip fracture that may be managed with
4 surgery or not. And to Barbara's point, I am
5 much fonder of mortality measures where the
6 patient has chosen to have an operation. So if
7 they are presenting for a CABG, they have made a
8 decision already, as opposed to you don't decide
9 to have a hip fracture; it just happens. And you
10 may have patients who don't want surgery, who
11 want to be DNR at that point.

12 DR. SAIGAL: Two points. I was
13 definitely struck by Barbara's comments as well.
14 I actually looked into this while we were sitting
15 here, and there is a survey of older men and
16 women, and 80 percent of them preferred to die
17 rather than be discharged from a hospital with a
18 hip fracture to a nursing home and lose
19 independence.

20 So that may not be, you know,
21 representative of everyone in this country, of
22 course, but it may be a significant thing to

1 think about.

2 And the other question I had was about
3 Dr. Yates' comment about the open fractures.
4 Maybe the way to handle that would be to risk
5 adjust for that and include open fracture as a
6 mediating fracture in a model, in terms of
7 mortality.

8 DR. FLEISHER: Clifford, did you --

9 DR. KO: I wanted to ask Pat, and
10 maybe the rest, that if -- if we know if the
11 reason for the improvement. I know you don't
12 take credit for it, but do we know? Because I
13 know a lot of institutions that I know I visited,
14 they decreased their mortality rate by
15 transferring everyone to hospice. We definitely
16 did that, if we needed to.

17 So, I mean, is this something going on
18 here? Because I'm sure some of our patients that
19 were on that track were transferred to hospice.
20 That's the first thing.

21 The second thing is, the issue that
22 Dr. Yates brought up about the accountability and

1 quality improvement measure, and whether this is
2 for, you know, reporting or for tiering for
3 payment, because then, you know, if we're -- if
4 we're grading on a pass/fail and a C minus is a
5 pass, you know, you have a medical student who
6 gets a C minus, they pass, they graduate.

7 But, you know, sometimes we have that
8 cut point as an A. We want that cut point to be
9 between an A minus and a B plus, and we just want
10 A level care. And so how -- when we think about
11 accountability, how should we think about that as
12 we vote, not just for this measure but for all
13 measures? Because it's a little different how we
14 look at that.

15 DR. FLEISHER: That is part of what
16 we're wrestling a lot at CSAC, and I assume the
17 same questions are at the boards. And we have
18 talked about, are there different levels of
19 passing? So I think that needs to be reflected.

20 If we decide to go forward, since
21 we're not the graders, the graders are CMS and
22 the -- and other end users, I think we should

1 think about the measure itself -- but reflect in
2 the report, and we should all read it, but it
3 accurately reflects those concerns, if that's the
4 concern.

5 Would you agree, Marcia and Karen?

6 Okay. Kelsey?

7 MS. McCARTY: Perhaps we will bring
8 this up later in the gap discussion. But I was
9 looking in the NQF database and there isn't a
10 comparable measure for patients under the age of
11 65, which I know Dr. Yates brought up earlier. I
12 know that AHRQ has that older population at the
13 core of who they care about, but we're talking --
14 earlier someone mentioned, you know, grandma and
15 grandpa, they have falls, whatever. That's the
16 population we cared about.

17 But another big at-risk population are
18 the younger patients that have obesity and are at
19 risk for a pulmonary embolism. And so that's not
20 getting -- if that's the kind of thing we care
21 about, improving those processes about medical
22 optimization or choosing the surgery correctly

1 for those types of patients, then they are not
2 captured at all under what NQF has as its
3 measures.

4 So I don't know if that's relevant to
5 this or to later, but I thought I would mention
6 that.

7 DR. FLEISHER: Unless there is another
8 measure, which there is not, correct? But that
9 sounds like that should be in the gap, and I
10 would ask you to help us write that section
11 related to that measure. So when you do -- okay.
12 Fred?

13 DR. GROVER: I guess this is getting to
14 be redundant at this point, but I have concerns,
15 too, in a population that -- part of which may be
16 doing -- turning down an operation really leading
17 to the consequences, are we really going to
18 improve quality with this measure? And
19 particularly without the risk adjustment with the
20 comorbidities, because this is a population that
21 so frequently has a lot of comorbidities that
22 really can impact the hospital, and does there

1 need to be avoidance of risk, and that type of
2 thing.

3 DR. FLEISHER: Melissa?

4 MS. THOMASON: I just wanted to weigh
5 in. As a patient with lots of -- I've spent tons
6 of time in a hospital bed, open heart surgery,
7 three in a year, aortic dissection, I mean, over
8 and over and over. And most of the work I do is
9 inpatient-centered care.

10 I would never want a measure to imply
11 that a hospital delivers lower quality care
12 because they honor my wishes as a patient. You
13 know because if I really am DNR, and I do have
14 that hip fracture, as we were talking -- and I
15 know that's a philosophical question that we will
16 probably get into later, but I certainly wouldn't
17 want to imply that a hospital is not doing its
18 job by honoring my wishes and by listening to me.

19 DR. FLEISHER: Thank you. I think we
20 have had a lot of comments about that within all
21 of these measures. So as we vote on the
22 validity, I think that's something that cuts

1 across almost any hospital mortality measure.

2 But it will be good to identify that here.

3 Two quick more comments, because we --
4 I want to move on.

5 MR. MARKMAN: So with this specific
6 measure, what -- I mean, is there public
7 reporting? This is going back to Clifford's --
8 what is this used for?

9 DR. LYZENGA: So we -- that is, again,
10 something that we are currently wrestling with,
11 how to kind of address these questions. As a
12 standing committee, dealing with the question of
13 endorsement, we really are -- our guidance so far
14 has been to try to kind of stay agnostic in some
15 sense to that question of use.

16 Not exactly agnostic because, again,
17 endorsement does imply that it is suitable for a
18 range of purposes, including public reporting,
19 payment, and quality improvement. But we -- you
20 know, this committee is supposed to be looking at
21 the measures, sort of scientific properties, the
22 -- you know, is it a good measure? And sort of

1 staying, again, to some degree agnostic about
2 what we would want it to be used for. But it's -
3 - you can't avoid, you know, having that question
4 in your head.

5 MR. MARKMAN: This is in the public --
6 I mean, you know, it's in that -- it's in the
7 body of the statement of, you know, is there
8 public reporting of -- I know we're jumping ahead
9 towards, you know, a more --

10 DR. LYZENGA: Yes. The usability
11 section, we should get some information about how
12 it is being used and how it is -- how AHRQ and
13 others intend to use it, so we'll address that to
14 some degree.

15 DR. FLEISHER: I would like to focus
16 on new points related to this section, so that we
17 can move forward. If you do -- Amy?

18 MS. MOYER: Well, I certainly don't
19 want to put measures out there that, you know,
20 might drive patient's wishes be overridden. I
21 think when measures get used is when they really
22 get looked at, and when data really gets improved

1 and things really happen. I know we've certainly
2 seen that when we've asked for measures or
3 reporting from providers we work with.

4 Suddenly, it's, "Oh, we were putting
5 that into the registry wrong." Or, "Oh, you
6 know, we looked at our data and we found this."
7 And so I guess my concern is if we just say,
8 "Well, we're not going to measure things like
9 this because there is this issue," the impetus
10 for resolving that issue goes away somewhat, if,
11 you know, we kind of back away and take things
12 off the table.

13 I don't want to put things out there
14 that are misleading, but I also don't want to
15 let, you know, perfect be -- or I don't want to
16 strive for perfection and not get something good
17 out there as well I guess.

18 DR. FLEISHER: Thank you. You're
19 paraphrasing it clearly.

20 DR. MOSS: I just wanted to expand on
21 Melissa's point, which I think is very well
22 stated. The issue is wrapped into all mortality

1 measures. Where does patient choice figure into
2 that? You can make a conclusion that while that
3 applies to all mortality measures, it is just
4 built into the system, and we just have to accept
5 it.

6 But I think it really is of very
7 differential relevance depending on the patient
8 population and the measure. I mean, patient
9 choice to die in an elderly patient with a hip
10 fracture is a much more significant issue, for
11 example, than mortality in something like
12 congenital heart surgery.

13 So I would just suggest that for this
14 measure in particular that's a highly relevant
15 point, and probably plays very strongly into how
16 we might rate validity.

17 DR. FLEISHER: Thank you. I think we
18 have outlined a lot of the issues.

19 New points. Patrick, do you want to
20 make one quick comment before we vote? Go ahead,
21 please.

22 DR. ROMANO: So, first of all, there

1 are some fundamental misconceptions about the
2 risk adjustment that I need to address. So, in
3 fact, all of the things that were mentioned here
4 are included in the risk adjustment. So the risk
5 adjustment approach that is used here is --
6 includes not just age and transfer status and
7 gender, and the type of procedure that was done,
8 but it includes a method that was developed by 3M
9 that is called APR DRGs, risk of mortality score.

10 So some of you who work in hospitals
11 are familiar with this. So the risk of mortality
12 score incorporates comorbidities. So if you look
13 in Table 5 that is shown in the materials, you
14 can see that there are different levels of risk
15 of mortality -- minor, moderate, major, and
16 extreme. And those levels of mortality risk are
17 essentially based on comorbid conditions.

18 So the -- as a result, the overall
19 performance of this model is a C statistic of
20 .893. And so those of you who are familiar with
21 mortality models, that's actually an
22 exceptionally high C statistic. That is a

1 measure of the discrimination of the model.

2 What it means in lay terms is that if
3 you take a randomly selected survivor, and a
4 randomly selected person who died, that 89
5 percent of the time a person who died would have
6 the higher risk of mortality than the person who
7 survived.

8 So the model actually does quite well
9 in terms of discriminating different levels of
10 mortality risk, precisely because it takes into
11 consideration all of the things that were
12 discussed today, including open fractures, which
13 have 50 times higher odds of mortality in the
14 risk adjustment model.

15 With reference to the patient's
16 choice, so in consultation with the expert panel,
17 the decision was made specifically to include
18 patients -- there are about five percent of
19 patients who opt not to have surgery. And to be
20 honest, there was some concern that that may
21 differ across hospitals, and that there may in
22 fact be some tendency, if you ignore those

1 hospitals, for surgeons to discourage very high-
2 risk patients from having surgery.

3 So, in fact, it was a deliberate
4 decision to include the patients who don't have
5 surgery to avoid this opportunity for gaining,
6 and to sort of level the playing field across
7 hospitals so that hospitals where the surgeons
8 are more enthusiastic versus hospitals where the
9 surgeons are less enthusiastic essentially get
10 treated the same way.

11 And then the choice of whether to
12 perform surgery or not, and what type of surgery
13 to do, is then incorporated into the risk
14 adjustment rather than as an exclusion.

15 Finally, with reference to the
16 availability of 30-day mortality, I would just
17 point out that this is only possible if you have
18 data from a single payer. So Medicare can do
19 this with their own data. Medicaid plans can do
20 this. But the essence of the AHRQ quality
21 indicators is that they are built on multi-payer
22 data to capture all of the patients who cared for

1 in hospitals.

2 And then, unless the state has set up
3 some specific data system to allow linkage to
4 death certificates, which a few states have but
5 most haven't, then there is no way to capture
6 those post-discharge deaths.

7 Finally, the age cutoff of 65, this
8 again was a deliberate decision/recommendation
9 from the expert panel, because in the younger age
10 group the hip fractures are boosted with people
11 who have a pathologic condition, so have
12 particular reasons to have early osteoporosis or
13 degeneration of the hip joint. Many of these
14 patients have cancer or other disease, myeloma,
15 that is invading the bone. And so it creates a
16 more heterogeneous and atypical population.

17 So for mortality measures, we would
18 like to have in general less heterogeneous
19 populations. And so that was the rationale for
20 the age restriction. So I think hopefully that
21 should clarify.

22 And then, finally, DNR, if we -- we

1 have the issue with DNR that some patients choose
2 to become DNR after they have experienced
3 complications in the hospital. So this is a
4 problem, because we would like to know just
5 whether the patient came in knowing that they
6 didn't want to have any intervention and knowing
7 that they wanted to go directly to hospice. That
8 would be the ideal approach to perhaps separate
9 those patients.

10 Unfortunately, again, we don't have
11 consistent, accurate data collection with respect
12 to the post forms or DNR status at admission to
13 the hospital, which is what we'd like to know.

14 DR. YATES: The APR DRG that you're
15 signing, is that on admission, or is that after
16 the hospitalization?

17 DR. ROMANO: Correct. That is based
18 on the conditions that were identified by the
19 hospital as being present on admission.

20 DR. YATES: On admission.

21 DR. ROMANO: Yes.

22 DR. YATES: And so there is -- and

1 critical to the APR DRG that you're using is what
2 they qualify the diagnosis as, whether someone
3 has been predetermined to get a hip -- how do
4 they know they're going to get a hip replacement
5 for their hip fracture?

6 DR. ROMANO: Well, the focus of this
7 measure is on patients who are admitted for hip
8 fracture. So patients who have hip fracture in
9 the hospital are excluded. So this is patients
10 who are coming into the hospital --

11 DR. YATES: Right. The patient comes
12 into the hospital with a hip fracture. How do
13 they know they're going to have a total hip
14 replacement on admission? How do they get
15 qualified for total -- for hip replacement, minor
16 or moderate?

17 DR. ROMANO: They don't know that.
18 We're talking about the -- we're talking about
19 the diagnoses that are used for adjustment. So
20 those diagnoses -- for example, if a patient
21 experienced a pulmonary embolus after
22 hospitalization, we would not be adjusting for

1 that because that's a complication of the care.

2 DR. FLEISHER: I think that A.J.'s
3 question is, do you then use the CPT code to also
4 adjust, correct? What they actually had, the
5 procedure?

6 DR. ROMANO: Yes. We use the
7 procedure codes as part of the adjustment as
8 well.

9 DR. FLEISHER: Okay. That's to move
10 forward.

11 DR. YATES: But that's after the fact.
12 You're now applying a pulmonary embolism as part
13 of your APR DRG.

14 DR. ROMANO: No. The diagnoses have
15 to be diagnosed at admission.

16 DR. YATES: Right.

17 DR. ROMANO: They have to be labeled
18 as present on admission. The procedures are
19 counted whenever they're done. That's --
20 whatever the procedure is done, it's --

21 DR. YATES: Right.

22 DR. ROMANO: -- that's the patient was

1 treated.

2 DR. YATES: And then there is a
3 pulmonary embolism after the procedures, does
4 that count toward the APR DRG, or is that assumed
5 to have been there at present? Or it wasn't
6 there at present?

7 DR. ROMANO: Okay. If the hospital
8 reports that the patient came in with a PE, then
9 it gets counted. If the hospital reports that
10 the PE arose in the hospital, then it doesn't get
11 counted in risk adjustment.

12 DR. YATES: Okay.

13 DR. ROMANO: But the procedure gets
14 counted no matter when the procedure was done.
15 Okay?

16 DR. YATES: I'm going to hold to my
17 original statements.

18 DR. FLEISHER: Okay. That's fine.

19 The one question I have, Patrick, for
20 myself is, do you have -- there are some states
21 who have linked data, and there is Medicare who
22 has linked data. Do you have any linked data to

1 say, if we look at 60 or 90 or 120 days, does
2 this measure hold in that subset of patients, to
3 see if there is any difference in how they are
4 ranked from a quality standpoint?

5 DR. ROMANO: We have not ourselves
6 done that analysis. There has been some
7 empirical work in the area. And in general, as
8 you might imagine, as you get longer time
9 intervals following the event, the correlations
10 weaken. And so the correlations are fairly
11 strong at 30 days, but when you get out to 120
12 days, frankly, they weaken substantially,
13 presumably because of outpatient care factors.

14 DR. FLEISHER: But you're not seeing
15 -- my question was, you're not seeing people are
16 getting 30 days and then putting them into
17 hospice, so they avoid the 30-day measure,
18 because at 35 days they die at a higher rate.

19 DR. ROMANO: Well, clearly, 30-day
20 mortality is significantly higher than inpatient
21 mortality. So, and clearly many of those deaths
22 are occurring in skilled nursing or hospice

1 settings. So I can't deny the fact that some
2 patients are being transferred out of the
3 hospital with the expectation that they will die
4 after discharge, either at home or in another
5 setting of care. This is true.

6 But the question is, we haven't seen
7 -- over this time period, we haven't seen a
8 systematic change in length of stay or discharge
9 distributions. Now, we did see that -- so back -
10 - if you go back to the literature 20 years ago
11 when the DRG system was introduced, there was a
12 dramatic change in length of stay and in
13 discharge patterns.

14 But over this period of observation,
15 the last five years, we have not seen a
16 significant trend towards shorter length of stay
17 or a change in discharge distribution.

18 DR. FLEISHER: Thank you. I think --
19 that's one of the things I think Cliff and I were
20 concerned about monitoring.

21 We should go forward and vote on
22 validity.

1 DR. GUNNAR: Just one final -- so it
2 would be possible for you to go back historically
3 to 2008 through '12 and determine whether the 30-
4 day or 60-day or 120-day mortality actually
5 changed through any one of those years for that
6 cohort.

7 MS. STARKS: I am not sure how many
8 states achieved the data from that. We'll take
9 that into consideration, I'm sure.

10 DR. FLEISHER: Thank you for our
11 report. That will be important information.

12 Can we vote?

13 DR. LYZENGA: Yes. Let's go ahead and
14 vote on validity. So your options here are high,
15 moderate, low, and insufficient. Go ahead and
16 vote.

17 DR. FLEISHER: Chicago rules, vote
18 often, so that we can -- because it only counts
19 once, correct?

20 DR. LYZENGA: Okay. All right. So
21 we've got nine percent for high, 68 percent
22 moderate, 23 percent low, zero percent

1 insufficient. So this passes on validity.

2 Now we can go ahead to usability.

3 Sorry, we can skip past this. Or do we vote on
4 each of these separately? Karen? I didn't think
5 so either. We can skip over this, yes. We can
6 go to -- oh, yes, skip this as a composite.

7 Okay. Feasibility. All right. So
8 whether the data is generated during care or
9 through electronic sources, data collection can
10 be implemented without undue burden. That's kind
11 of what we are addressing here.

12 MS. JOHNSON: Just real quickly, all
13 of the other threats to validity, exclusions,
14 that sort of thing, you did talk about risk
15 adjustment. That's probably the biggest one.

16 But you -- we may want to just make
17 sure from the committee that no one had any
18 concerns about exclusions, just in case they
19 didn't realize that that was part of the validity
20 discussion.

21 DR. FLEISHER: Okay. So if you --
22 anybody have any specific concerns about

1 exclusions?

2 MS. THOMASON: I just have a quick
3 questions for clarification purposes, Andrew. So
4 when we say it passed on validity, does it pass
5 on validity in the high, moderate, and low
6 categories, and insufficient would mean it would
7 not pass? Or low also means --

8 DR. LYZENGA: Low also means, I
9 believe, it would not pass. So we're going with
10 the two top and then the two bottom.

11 MS. THOMASON: Okay. Thank you.

12 DR. FLEISHER: Cliff, or A.J., any
13 comments on feasibility?

14 DR. YATES: No comment.

15 DR. KO: Their Table 1 shows the
16 number of hospitals. The one question I had is,
17 why did the number of -- why is the number of
18 hospitals going down in that table? It's just
19 the data set. You have 3,500 in 2008, and down
20 to 26-, 2,700 more recently.

21 DR. GUNNAR: They are all transferring
22 to my hospital.

1 (Laughter.)

2 DR. FLEISHER: I think there is some
3 regionalization. Do you have an answer or --

4 DR. ROMANO: Yes. So the rationale or
5 the reason for that particular drop is in
6 footnote -- the third footnote here, which is
7 that basically between 2010 and 2011 we made a
8 change in the hospitals that were considered
9 eligible for the measure.

10 And so there were certain, for
11 example, specialty hospitals and rehabilitation
12 hospitals that previously were in the reference
13 population for the measure, and so we cleaned
14 that up and focused only on the acute care, the
15 general acute care hospitals. And so that is the
16 drop of the 800 hospitals from 3,500 to roughly
17 2,700.

18 DR. FLEISHER: Okay. Why don't we
19 vote.

20 DR. LYZENGA: Yes. Let's go ahead and
21 vote on feasibility. Again, you've got high,
22 moderate, low, and insufficient as your options.

1 DR. FLEISHER: You had a comment
2 before we voted?

3 MS. McCARTY: Yes. Based on what he
4 just said. So if you've changed the methodology
5 in terms of which hospitals are included, then in
6 terms of the drop that we've been talking about,
7 how there has been noticeable improvement over
8 the past five years, was that analysis redone
9 going back to 2008 to look at just the population
10 you care about? Are we comparing apples and
11 oranges with those two different cohorts?

12 DR. ROMANO: Well, effectively, all of
13 the -- these are patients with acute hip
14 fractures who are being brought in by ambulances.
15 So, in effect, they are all going to general
16 acute care hospitals anyway. So these 700 or 800
17 excluded hospitals essentially had no cases
18 anyway, so it makes the data set more logical.

19 DR. LYZENGA: All right. So go ahead
20 and cast your vote on feasibility. Okay.
21 Sufficient votes. We have 74 percent high, 26
22 percent moderate, and zero for low and

1 insufficient. The measures passes --
2 feasibility. And we'll move on to usability now,
3 use and usability.

4 So this is sort of a question of how
5 the measure has been used, how it is planned to
6 be used, if it has shown improvement during the
7 course of its use, and whether it is usable for
8 consumers and other viewers of the health care
9 information.

10 DR. FLEISHER: Any comments from our
11 developers first? No? Cliff or A.J.?

12 DR. YATES: My comment earlier is that
13 we are not allowed to tier these. There is
14 definite usability for the process. It's just a
15 question of whether or not it's usable at a level
16 that would imply public reporting across all
17 hospitals and across possible payment and
18 adjustments. So I --

19 DR. FLEISHER: Can you separate those
20 two different just real quickly? I mean, public
21 reporting --

22 DR. YATES: Well, public reporting is

1 -- there is 500 different public report cards out
2 there on the internet that are commercial, and of
3 course there's hospitalcompare.gov, which is a
4 centralized Medicare reporting system.

5 And then that would be one set of
6 consequences is that something is used to adjudge
7 that public reporting by hospital and regions or
8 across the country. And the second thing would
9 be value-based payments or payments would be
10 based on either CMS or on HMOs.

11 DR. FLEISHER: So I am just saying, do
12 you have a different opinion or the same opinion
13 for both?

14 DR. YATES: I'm sorry. I beg your
15 pardon. I have the same opinion for both of
16 those, but my -- I still think it's a very usable
17 and important measure for general trends and for
18 individual hospitals to assess themselves.

19 DR. FLEISHER: Quality improvement.
20 Great.

21 Any other comments? Great. Let's
22 vote.

1 Sure. Go ahead. Melissa?

2 MS. THOMASON: Have you guys looked at
3 the -- do we know if real-world patients are
4 using this data as they look for providers? Do
5 we have any idea yet?

6 DR. ROMANO: There is limited evidence
7 on that. So this measure is not a measure that
8 is used in the CMS HQR, hospital quality
9 reporting program. So, therefore, it is only
10 available when the state health data agency has
11 chosen to report it or when hospitals themselves
12 have chosen, in the interest of transparency, to
13 report it publicly.

14 So I would suspect based on that that
15 there has been very little actual use by
16 consumers. I think we see more consumer use of
17 the measures that are incorporated into the CMS
18 programs.

19 One that -- I just also have to say in
20 terms of -- there is a general sort of question
21 about process measures to outcome measures. It
22 is the philosophy of the QI program to focus on

1 outcomes and to let the hospitals and doctors
2 kind of figure out the processes. So a natural
3 response to an outcome measure like this would be
4 if patients are dying, well, let's look at why
5 they're dying.

6 And if they're dying from PEs, what do
7 we need to do in terms of pharma prophylaxis? If
8 they're dying from infection, what do we need to
9 do in terms of infection prevention? If they're
10 dying from MIs or arrhythmias, what do we need to
11 do in terms of cardiac risk assessment and risk
12 reduction?

13 So it's understood that outcome
14 measures really pose questions, and that it's our
15 work -- and, again, putting on my doctor hat now,
16 it's our work within healthcare organizations to
17 kind of figure out what is going on, what is
18 contributing to the issue, and to address those
19 process factors.

20 DR. FLEISHER: Thank you. And just to
21 reiterate -- to follow up on that CSAC, really
22 the process measures -- really, if we have

1 outcomes measures, that's what we should focus
2 on. And we should only approve process measures
3 if they are -- as a substantial absence of
4 outcome measure or the process measure would so
5 move the field forward.

6 And I think this committee has seen
7 that, where we retired or put in -- excuse me, we
8 put on reserve status process measures that are
9 still evidence-based but are topped out or in and
10 of itself would not make performance improvement.

11 Cliff?

12 DR. KO: Yes. I just wanted to ask
13 Pat, have you -- since this measure has been out,
14 available for such a long time, and, you know,
15 when you -- in your application you said it's
16 being used, and you mentioned two I guess systems
17 that is using it for public reporting, but why
18 hasn't the uptake been much greater? Because it
19 has been out there a long time. It's a
20 relatively easy measure to get, to do, to
21 perform. Have you received any feedback why it
22 hasn't been taken up?

1 MS. STARKS: Well, I think, first of
2 all, it's a very difficult thing to capture, what
3 the take-up is. But there are a number of states
4 that are reporting this particular measure. I
5 don't know the exact number, but we have a
6 program called Monarch. And software is used,
7 and this measure is included in that software.
8 So I wish that we did have better information
9 about the uptake.

10 DR. FLEISHER: Amy, did you have a
11 definitive comment?

12 DR. ROMANO: Sorry. I was just going
13 to say I think that we are missing -- in this
14 submission, we are missing some information about
15 from an inventory of state reporting programs.
16 And I can get you that information, but there are
17 several states that are recording it. I just --
18 we don't know those states off the top of our
19 head.

20 DR. FLEISHER: Okay. It would be
21 great to get that for the -- any follow-up call
22 or get out to the committee, if there is any

1 question.

2 MS. MOYER: I was just going to say
3 as, you know, our population is commercial and we
4 do public reporting. And I think what I would
5 struggle with including this measure in our
6 public report is, what is our population going to
7 do with that information? I mean, they are not
8 really the ones targeted by the measure.

9 It is not really shoppable, as we may
10 call it. So I think it can be really helpful,
11 you know, if you're a state and you're kind of
12 trying to look at overall quality or, you know,
13 how hospitals in the state are doing. But I
14 think would really struggle from a commercial
15 application.

16 DR. FLEISHER: Thank you. Shall we
17 vote on usability? One more comment from --

18 MS. THOMASON: So I thought of it
19 entirely different. I thought it would be very
20 "shoppable" when we talked about mortality, and
21 if I was looking at a hospital and where I wanted
22 to have these things done, if I had broken my hip

1 or if my mother had, and all those things. I
2 would want to know that.

3 DR. FLEISHER: It's an emergency
4 operation and people go to the closest hospital.
5 So I think that's the point that was made
6 previously.

7 MS. THOMASON: So none of it is like
8 a procedure at all. It's all an urgent --

9 DR. FLEISHER: No. This is an
10 emergency.

11 MS. THOMASON: Okay.

12 DR. FLEISHER: And we can take that
13 offline for further details.

14 DR. LYZENGA: Let's go ahead and vote.
15 It looks like some folks have started already.
16 Go ahead and enter your votes.

17 DR. FLEISHER: Missing two. Go ahead.
18 Alexandra?

19 DR. LYZENGA: All right. We have 23
20 percent high, 73 percent moderate, five percent
21 low, and zero percent insufficient. So the
22 measure passes on usability and use.

1 So I think the next step is to go
2 ahead and vote on the measure's overall
3 suitability for endorsement, unless there are any
4 other points of discussion that we haven't
5 covered yet. We could probably just vote.

6 All right. Let's go ahead. Are you
7 ready, Alexandra? Okay.

8 DR. FLEISHER: Andrew?

9 DR. LYZENGA: Ninety-one percent yes,
10 nine percent no. The measure passes.

11 DR. FLEISHER: I want to thank
12 everyone. I think it was an incredibly robust
13 discussion.

14 (Laughter.)

15 I mean that in all sincerity, despite
16 the laughter, because I think it really will help
17 inform the next couple of days -- today and
18 tomorrow -- it will inform the report, it will
19 inform CSAC, since I will be able to bring it
20 back as the Vice Chair. And as we go forward, I
21 think it will be important to bring new comments,
22 so that we can continue to stay on time.

1 We are done this --

2 DR. LYZENGA: Yes.

3 DR. FLEISHER: Why don't we take a
4 break, and then Bill will take over for the next
5 measure. We will take until 10:45, if you can
6 come back here then.

7 (Whereupon, the above-entitled matter
8 went off the record at 10:27 a.m. and resumed at
9 10:41 a.m.)

10 DR. GUNNAR: So, Andrew, do you want
11 to take a dinner vote or --

12 DR. LYZENGA: I think we were going to
13 try to sort of get a sense of that at lunch, how
14 many people wanted to -- I guess we could
15 actually just -- yes, might as well just do a
16 hand count now. How many of you are interested
17 in going to dinner? We can make a reservation at
18 a restaurant around here, and just want to kind
19 of get a headcount. Let's call it 15.

20 Thanks, everybody.

21 DR. GUNNAR: So the next measure to be
22 discussed is 0360, esophageal resection mortality

1 rate. And just to be clear, this is -- this has
2 been an endorsed measure since 2008 and
3 reendorsed in 2011. So who are the discussants?
4 Oh, I'm sorry, the -- I also want to know who the
5 discussants are. Okay. Great. That would be
6 wonderful.

7 All right. Developers? Dr. Romano?

8 DR. ROMANO: So this is an unusual
9 measure in that we are going to say right up
10 front that this measure is unreliable for the
11 great majority of hospitals. And so best to get
12 that out of the way.

13 (Laughter.)

14 This measure is intended for use in
15 combination with the measure of esophageal
16 resection volume, which is IQI 1, which is the
17 next measure that will be under consideration.

18 And the notion here is that there is
19 a very strong repeatedly demonstrated volume
20 outcome association in a total of 29 studies,
21 according to our latest literature that exists.
22 So we know that from the patient's perspective,

1 absent any information about specific hospital
2 quality, that volume is very important, that the
3 hospitals that have more experience with this
4 type of surgery show better outcomes.

5 Among the hospitals that have higher
6 volume, there is a real difference in mortality.
7 And so it makes sense, thus, to have both a
8 volume measure and a risk-adjusted mortality
9 measure, because for hospitals in the lower part
10 of the volume distribution you focus on their
11 volume and their low volume. For hospitals at
12 the higher end of the volume distribution, you
13 can actually learn something from their actual
14 experience with risk-adjusted mortality.

15 And that mortality experience may
16 drive the hospital's own self-examination as well
17 as decisions by, for example, payers in
18 contracting with centers of excellence. So that
19 is just a quick background to really viewing
20 these measures together.

21 DR. LYZENGA: Thanks, Patrick. And I
22 think we have Melissa and Larissa as our

1 discussants.

2 DR. TEMPLE: Well, I will start. True
3 disclosure, I found this measure very difficult
4 to evaluate. And I do think that maybe as we go
5 through it we can also have some input from the
6 people who looked at the volume measure as well.

7 This is a simple measure in the sense
8 that it is looking at the number of inpatient
9 deaths per 100,000 discharges for patients
10 undergoing esophageal resection for predominantly
11 GI -- for esophageal and upper gastric cancers.

12 It is, as reported, high volume
13 relationships, and the developers argued that in
14 addition to a volume mortality relationship there
15 is also variability within each of the volumes,
16 to suggest that mortality, in and of itself, is
17 worth measuring.

18 If we go to -- so as an outcome
19 measure, there is plenty of evidence to suggest
20 that there is a volume relationship. And they
21 define, actually, that more than eight procedures
22 per year seems to be the acceptable high volume

1 center.

2 So I guess we're looking first at the
3 evidence. I was just looking for the slide to
4 vote. Melissa?

5 MS. THOMASON: So do you want me to
6 jump in, Larissa, for evidence? Okay. So, for
7 evidence, again, there is that rationale behind
8 it, just like we talked about with the last
9 outcome measure. And it's an established fact
10 that hospitals that perform more of these also
11 have fewer mortalities of them. Thus, there is a
12 relationship that exists. Therefore, we can say,
13 yes, there are processes that have been
14 identified that affect the outcomes, and so it
15 has an evidential basis. Is that correct?

16 DR. LYZENGA: Any other comments or
17 thoughts or questions?

18 MS. THOMASON: That was a stretch for
19 me, I'll be honest. Sort of following the logic
20 of that, coming into this as a non-
21 clinician/third party, you know, to say this,
22 then this, then this, and then there's this other

1 conclusion way over here. And until I heard I
2 think it's Patrick speak earlier, it didn't make
3 a lot of sense, but now it does.

4 DR. LYZENGA: So any other comments on
5 evidence, or should we go ahead and vote? Sounds
6 like we can vote. So we're voting, again, on
7 evidence, whether there's a rationale supporting
8 the relationship with the health outcome to at
9 least one health care structure, process
10 intervention, or service. One for yes and two
11 for no. Just go ahead and vote. And one more.
12 There we go.

13 We have 95 percent yes, two -- or,
14 sorry, five percent no. The measures passes on
15 evidence.

16 So now we can move to performance gap.

17 DR. TEMPLE: So under the script,
18 using the opportunities for improvement -- right,
19 Andrew? So the authors report that there has
20 been -- that there is room for improvement with
21 rates ranging from 59 per 1,000 to now 41 per
22 1,000 deaths per year. There is -- if you look

1 at the table they provide from 2008 to 2012, they
2 do show the rates of esophageal mortality being
3 relatively flat.

4 There is a drop from 2011 to 2012 from
5 59 to 41 per 1,000, which I don't think that they
6 can -- they didn't -- we really don't know why
7 there was that drop. I'm curious if the
8 measurers have any comments on that. But there
9 is certainly room for improvement.

10 They do demonstrate that there are --
11 there is variability in the outcome based on age,
12 gender, insurance, region, and income, to suggest
13 that, again, there are opportunities for
14 improvement.

15 DR. LYZENGA: Thanks, Larissa. Any
16 other comments or questions about opportunity for
17 improvement? Go ahead.

18 MS. PITZEN: Great. Thanks. I just
19 wanted to make a comment. This is a relatively
20 low, low volume procedure. If I'm looking at the
21 numbers correctly, less than 5,000 cases
22 nationally on an annual basis. So it's really

1 hard to measure and discriminate changes between
2 practices, hospitals, et cetera.

3 DR. DUTTON: This may be the opposite
4 of the situation Dr. Yates was referring to
5 earlier where this is a very important measure
6 for public accountability. We need to tell the
7 public we are not killing people in esophageal
8 surgery, but where there is very little
9 opportunity for quality improvement out of it,
10 because the discrimination is so low, because the
11 numbers are so low. I mean, the improvement from
12 51 to 49 is a tenth of a patient per facility
13 doing this or something like that.

14 So there is no -- there is not going
15 to be a quality signal at the facility level.
16 What Patrick was saying, it's not reliable to
17 discriminate hospital performance. But at the
18 same time, I think it is an important measure for
19 public accountability.

20 DR. GUNNAR: Yes. Dr. Romano?

21 DR. ROMANO: Yes. I can address one
22 of the comments, which is that this is actually -

1 - these indicators have gotten a fair amount of
2 attention, because the Leapfrog Group actually
3 publicly reports similar information for
4 esophageal and pancreatic surgery. And I think
5 some payers in fact have focused on contracting
6 with centers with excellence for this type of
7 cancer surgery.

8 So what we have seen between 2011 and
9 2012 is a decrease from 198 hospitals performing
10 this surgery to 155. So basically 43 hospitals
11 dropped out of this market, and those turned out
12 to be higher mortality hospitals.

13 So that basically is what explains the
14 drop from 51.9 to 40 -- or 5.2 percent to 4.0
15 percent in terms of in-hospital mortality.

16 DR. TEMPLE: So I'm going to actually
17 ask the developers to put that in the comments in
18 that section, because it is not clear there,
19 because that is actually very, very important
20 data.

21 DR. LYZENGA: Any other comments on
22 performance gap, or should we vote?

1 DR. GUNNAR: Yes. I just want to --
2 this comes up in the -- may be Fred wants to
3 comment on this -- the STS's comment about low
4 volume facilities for CABG surgery. And it's not
5 that low volume facilities can't perform
6 excellent surgery, but if there is a -- but there
7 is a higher tendency in the lower volume
8 facilities to actually accumulate mortality.
9 Let's put it that way.

10 So we just don't -- but that doesn't
11 mean that there aren't a substantial number of
12 low volume facilities that are actually doing
13 great work. That is -- this gets to the issue
14 of, is it -- is the measure prohibiting, you
15 know, essentially the free practice in those
16 facilities to be able to do good work? I guess
17 is the fundamental question. Or do we care?

18 DR. GROVER: I would strongly -- I
19 think for sure -- in cardiac surgery, that is
20 very true, and particularly in things like
21 coronary bypass and straightforward valve
22 surgery. There are people -- there are surgeons

1 in low volume hospitals that do very good work,
2 and so we have always gone by the real outcomes.

3 And I think esophagectomy and Whipple
4 procedures are an area that is different. And
5 Cliff obviously knows a lot about that, too, from
6 the NSQIP database.

7 But so I think the logic here
8 actually, Bill, probably is reasonable, because
9 you can still be -- you can still stay open. And
10 I'd ask this to you, Patrick. You can still
11 continue to practice at a low volume hospital if
12 your results are good, right? I mean, that's --
13 this is just kind of alerting people to the fact
14 that -- well, you could have a surgeon who came
15 out of a training program, say, in Michigan where
16 they have always done a lot of esophageal work,
17 and maybe in a smaller volume hospital might do
18 quite good work. So --

19 DR. GUNNAR: So let's -- and then the
20 last piece to this is, before I turn it back to
21 Melissa, that -- it's about access. So when you
22 have now decreased the number of -- when you --

1 we don't know that a decrease in the number of
2 hospitals from 244 to 155 is -- was actually
3 higher, lower volume. Your assumption is that
4 those were low volume hospitals, now moving
5 volume to what now is higher volume hospitals,
6 and that -- those other hospitals benefited from
7 the acute additional volume.

8 But we don't know what that did in
9 relationship to access or distance to travel.
10 These aren't simple procedures. And they -- it
11 is really nice, given the potential for post-
12 operative complications and having to manage
13 those complications, to be closer to your
14 physician. So I guess the question is, how have
15 we have impacted access in relationship to this
16 driving to a centers of excellence model?

17 DR. FLEISHER: Just one comment, which
18 gets back to the public reporting. And I'd be
19 curious, as we think about this -- public
20 reporting may not be patients. It may be
21 hospitals making decisions. So as we look at
22 usability, it would -- a robustness of that data

1 could help frame some of the questions going
2 forward.

3 Thank you for that information.

4 DR. GUNNAR: So hearing any additional
5 -- yes, Dr. Cima.

6 DR. CIMA: You know, the one issue
7 with this is, you know, we've talked about the
8 volume and stuff, but the one issue that we --
9 and this is mortality measure, but the people who
10 have taken care of esophagectomy patients know
11 that mortality measure is one thing. The
12 morbidity measure is a bigger thing. These
13 patients can linger and go months and months
14 after complications of the surgery and die. So
15 that is not going to be picked up here.

16 And so that is one of the issues here
17 is, you know, yes, you can do excellent -- I
18 mean, an excellent operation, do it six times in
19 a year, and, you know, you're going to have 100
20 percent survivability. It's going to look great.
21 But you're not capturing the process of care
22 which these centers of excellence do very well to

1 manage and mitigate complications. And that is
2 really quality improvement.

3 I hate to say it, you know, because it
4 is such a low volume thing. Mortality is not the
5 best marker of quality here. You know, it is one
6 thing to do 150,000 colectomies a year across the
7 country and use that as a marker. But when
8 you're doing less than 5,000 esophagectomies,
9 that is probably even a high number, because a
10 lot of patients now are getting neoadjuvant
11 therapy, they are getting things, and they are
12 not coming to surgery, other things.

13 That is the big issue with this is
14 that -- is it really a reflection for a low
15 volume hospital as mortality -- even if it's
16 stellar or poor, is that really a marker of
17 quality of surgical care that we can't risk
18 adjust or at least monitor complications? I
19 mean, is there a way of doing that for you?

20 DR. ROMANO: Yes. No, this is a very
21 good point. Certainly, the complications after
22 major esophageal surgery can be quite serious and

1 quite difficult to deal with and can lead to a
2 protracted hospitalization. Obviously, this is
3 an inpatient mortality measure. So if the
4 patient dies after a series of complications,
5 that is captured. But if they go home, and die
6 at home, that would not be captured.

7 DR. CIMA: Or what if they -- more
8 likely they go home and come back.

9 DR. ROMANO: Exactly. Yes.

10 DR. CIMA: They go to the nursing --
11 the rehab and come back.

12 DR. ROMANO: Right.

13 DR. CIMA: Six or seven times.

14 DR. ROMANO: Yes. This -- we have
15 seen this, yes. So, I mean, all I can say is
16 that here we have the advantage that this is an
17 elective surgery, where the surgeon and the
18 patient together make the decision to go for this
19 kind of aggressive surgical resection. And so
20 they presumably do that knowing the risks of the
21 surgery, which are quite considerable. And they
22 do that, you know, with a curative intent,

1 basically.

2 So this is clearly a minority of
3 patients who have esophageal cancer. Most
4 patients with esophageal cancer don't get this
5 type of resection surgery. So, but these are the
6 patients who are willing to travel. These are
7 the patients who are seeking out the Mayo and
8 Cleveland Clinic and the centers where they can
9 go to experienced surgeons and experienced
10 hospitals in the treatment of these conditions.

11 The other thing I would say is that
12 there is -- there has been repeatedly
13 demonstrated a correlation between -- so we have
14 volume, higher volume is better consistently for
15 esophageal surgery. Higher volume has been
16 correlated with both morbidity and mortality
17 outcomes, and length of stay. So, and those
18 correlations are strong.

19 So we know that, in general, these
20 things are tracking together. Morbidity
21 measures, mortality measures, and length of stay
22 are all tracking together with volume. But,

1 obviously, there may be some exceptions in
2 individual hospitals that may differ.

3 DR. GUNNAR: That is a gap. So --

4 DR. LYZENGA: Every time you make
5 these suggestions, we are writing your name down.

6 (Laughter.)

7 DR. SIPERSTEIN: So I kind of look at
8 this as different measures for different focuses.
9 I mean, this data is very easy to collect. It is
10 all inclusive. But gives you -- I mean, the
11 price you pay is that you have a more limited
12 dimension of what you're looking at. On the
13 other hand, the flip side, if you're
14 participating, for example, in a -- you know, a
15 procedure-specific risk-adjusted database, where
16 you may have more limited participation, but you
17 get more granular data in terms of your
18 morbidities and mortalities, that may serve a
19 different purpose.

20 So I would see this as kind of two
21 ends of the spectrum where I think there is a
22 value to this just because of the ease and

1 completeness of data collection, and that all
2 hospitals can be easily represented.

3 DR. GUNNAR: Shall we vote on
4 performance?

5 DR. LYZENGA: Yes. We have gotten a
6 little off track here on discussion. So just to
7 remind you, we are voting on performance gap
8 here. So your options are high, moderate, low,
9 and insufficient. And I think you can go ahead
10 and vote now.

11 DR. EREKSON: Andrew, can you phrase
12 the question, please?

13 DR. LYZENGA: Sure, yes.

14 DR. EREKSON: Before we answer the --

15 DR. LYZENGA: Yes. That's a good
16 point, and I think actually we need to start up
17 the vote again. But so we're asking here whether
18 data demonstrate considerable variation in
19 performance or overall less than optimal
20 performance across providers. Again, sort of
21 getting here to whether there is a demonstrable
22 performance gap that this measure is addressing,

1 whether there is an opportunity in improvement --
2 opportunity for improvement in care that this
3 measure is addressing.

4 Have we started up yet, Alexandra? I
5 suppose while we're waiting maybe we could get
6 started on our discussion of reliability. Never
7 mind. We'll complete the vote. Scratch that.

8 DR. GUNNAR: We don't have -- it's
9 technical difficulties.

10 DR. LYZENGA: Yes. It's just waiting,
11 computer --

12 DR. GUNNAR: It's getting close to
13 reboot.

14 DR. LYZENGA: Yes, go ahead, Melissa.

15 MS. THOMASON: So when we were
16 speaking earlier and you said that so there are
17 places -- facilities with low volume that you may
18 actually get really good care at --

19 DR. GUNNAR: Exactly. Yes.

20 MS. THOMASON: -- but then you said,
21 but mortality accumulates here. And so is that -
22 -

1 DR. GUNNAR: No, no. What I'm trying
2 to say is if you take the -- if you just look at
3 populations of hospitals by, in this case,
4 esophageal -- we are really trying to -- we are
5 combining mortality and volume relationships by
6 virtue of the way that these are written by the
7 developer.

8 So this is mortality rate, and the
9 evidence is that there is an association between
10 volume and mortality. This discussion really
11 should be left for the volume measure, which is
12 0361. This is -- we really need to refocus
13 ourselves, and this is a good -- maybe this is
14 good that we've had the white screen, the fact
15 that this is really just mortality rate.

16 So that if you are accumulating
17 mortality in your center, regardless of the
18 volume, that is a measurable outcome. It's an
19 outcome measure that is related back to quality,
20 and that has been endorsed since 2008.

21 MS. THOMASON: So, as a patient, I
22 guess -- and it's really in all of these

1 mortality measures, it almost seems limiting that
2 we look at it as a facility and not as a
3 provider. So I'm not even sure that -- but when
4 you say you have -- you know, you have this
5 doctor that comes from this place where they do
6 all of these procedures and he's so great at
7 them, and then he comes to this place, this
8 facility, with this -- with low volume. So it
9 looks like, you know, he is in a place with
10 numbers that don't really represent what he is
11 capable of doing.

12 As a patient, I would love to know
13 that he is so really great at it. But it seems
14 that by making mortality these facility-
15 designated measures, we limit that.

16 DR. FLEISHER: Lynn, did you have a
17 comment related to that?

18 MS. REEDE: I do. And I appreciate
19 the concern, Melissa, that it being provider-
20 specific, but this really is, as we talk about, a
21 team sport. And particularly this procedure is
22 very complex in how the team cares for this

1 patient. So it does look more across the
2 facility than just the person who provided the
3 surgical intervention. At least that's my
4 perspective.

5 DR. FLEISHER: Dr. Moss, did you --

6 DR. MOSS: Another way to answer that
7 is, in aggregate, all low volume centers taken
8 together will have a higher mortality rate. But
9 if you look at them individually, there are going
10 to be isolated low volume centers that do very,
11 very well. But these kind of analyses can't
12 prove that statistically because the volume is
13 low.

14 So they might do well, but you're not
15 going to be able to confirm that with this kind
16 of information.

17 DR. FLEISHER: Amy?

18 MS. MOYER: One other thing I would
19 add, I agree it would be nice if we could look at
20 both surgeon and facility. I think in some ways
21 it could a shortage -- a shortcoming of the data
22 set we are using. At least I know the one we get

1 for the State of Wisconsin, we can't identify the
2 surgeon. We can only tell where the facility was
3 where this happened.

4 MS. THOMASON: And I guess I'd ask,
5 because one of the things I'm concerned about --
6 like I co-chaired NQF's Committee on Consumer
7 Affordability last year, and we talked about
8 access to data, access to cost data, access to
9 quality data, and all of these things, and a lot
10 of this quality data we're talking about today.

11 So having access to the data and it
12 being usable by someone who needs these
13 procedures, it just seems that -- like if it's a
14 team sport, and it really is, so we know in these
15 -- especially in like these procedures. So maybe
16 it's not advantageous for me to go to a low
17 volume facility, even if there is a provider
18 there who may provide excellent care. You know?
19 So maybe it is an accurate representation from
20 that perspective. Yes?

21 DR. GUNNAR: Again, that could be just
22 to refocus ourselves on this -- this is the

1 mortality measure. So this is really about -- I
2 would refrain that not about volume but about
3 mortality rates.

4 MS. THOMASON: So I guess the question
5 comes in -- my question with that is, so is
6 mortality a good representation of quality in
7 this instance? I guess that's where my question
8 would --

9 DR. GUNNAR: And I think the -- and
10 we're going to have to speak to Dr. Romano, but
11 it -- I think they have -- that has been asked
12 and I believe it has been answered in the
13 evidence.

14 DR. LYZENGA: And we will vote on that
15 again in validity, actually. So that -- and
16 we'll have a question and you can weigh in on
17 that question specifically.

18 DR. GUNNAR: Okay. So the -- yes, Dr.
19 Romano?

20 DR. ROMANO: Yes. Just two things I
21 can address quickly from some good literature
22 that has been published from John Birkmeyer's

1 group from Michigan and Dartmouth.

2 So in The New England Journal of
3 Medicine, in 2011, they described that 32 percent
4 of the decrease in adjusted mortality for
5 esophageal cancer surgery between 1999 and 2008
6 appeared to be attributable to higher hospital
7 volumes, so directly to your point.

8 So one-third of the decrease -- one-
9 third of the observed decrease in mortality
10 appears to be due towards -- due to a
11 concentration of patients in higher volume
12 hospitals; two-thirds presumably to other
13 factors.

14 And partitioning out the physician
15 versus the hospital effect, it appears that
16 physician and hospital volume are correlated with
17 each other. So physicians who go to higher
18 volume hospitals tend to get more volume, as you
19 would expect. But statistically 46 percent of
20 the hospital volume effect is explained by
21 surgeon volume; 54 percent is not.

22 So there is a correlation to some

1 extent. Hospital volume is proxying for or
2 picking up the effect of surgeon volume. To some
3 extent it is an independent effect, reflecting
4 the team concept of care that Lynn has described.

5 DR. LYZENGA: So I think actually as
6 we are trying to resolve this technical
7 difficulty, we may just do a hand vote on this
8 one, so we can go ahead and move forward. We do
9 have four options here, so I guess I'll just go
10 one by one and ask people to raise their hands
11 for each. So, again, we're voting here on
12 opportunity for improvement and the options are
13 high, moderate, low, and insufficient.

14 So first I'll ask who wants to rate
15 this measure high? I've got nine for high. And
16 who would like to vote moderate?

17 PARTICIPANT: One vote from the phone.

18 MR. LYZENGA: I've got 14 including the vote
19 on the phone. Thank you.

20 And low and insufficient. Okay. So
21 the measure passes on importance to performance
22 gap and we can go ahead and move to reliability.

1 Next vote we should be able to use the
2 system.

3 DR. TEMPLE: Can I see the next voting
4 slide? Is that okay?

5 MR. LYZENGA: Yes. Alexandra, can you
6 skip to the reliability vote slide?

7 I'll record it just by hand here and
8 then we'll add it into the report. It's in the
9 transcript as well.

10 DR. TEMPLE: So the reliability, I
11 know we want to stay away from the volume piece
12 of it. I'll do my very best to do that. But it
13 will come into play a little bit.

14 They did the reliability testing. They
15 had data from 36 states. It included 82 percent
16 of hospital who do esophageal resection. It was
17 655 hospitals with 4,331 patients. So they did
18 the reliability testing. They state that the
19 data is very reliable when there's more than
20 eight patients discharged with esophageal
21 resection per year.

22 But when they start to look at their

1 signal to noise ratio, it's really 0.14. So it's
2 very poor. They have done the risk adjustment
3 with the smooth curve statistical modeling. And
4 that does report out that there's some
5 reliability.

6 But I think we're going to struggle
7 with this because it's reliable in higher volume
8 centers and not as reliable in lower volume
9 centers. But yet there's no exclusion of low
10 volume centers in this measure. So I put it out
11 to the Committee to discuss.

12 DR. GUNNAR: Any argument? Dr.
13 Romano.

14 DR. ROMANO: Yes, I mean we have to
15 accept the fact that it's not reliable. And the
16 question is is it then despite the lack of
17 reliability useful together with the volume
18 measure. And we argue that it is because it
19 allows you to identify on either end among the
20 higher volume hospitals the difference in
21 performance between those that are both high
22 volume and provide the highest level of care and

1 those maybe that provide a lower level of care.

2 But there are a variety of -- I should
3 say there's been some very interesting work
4 that's been done again by Birkmeyer's group to
5 try to combine these two measures into a single
6 measure. And some of you may be familiar with
7 that.

8 It's been picked up by the Leapfrog
9 Group as what's called a mortality predictor.
10 The idea is to use a Bayesian approach to
11 actually combine these two measures together into
12 a single measure that might be more -- that would
13 have the reliability advantages of the volume
14 measure but would still incorporate information
15 about mortality.

16 So that's something that is currently
17 under evaluation as part of our current work with
18 AHRQ. And it may be a direction that we go in
19 the future.

20 DR. TEMPLE: Can I just ask a point of
21 clarification? And I'm sorry to go into the low
22 volume piece, but I think we have to with this

1 measure. If your volume is low, is the metric of
2 mortality reliable? And it's not. Right. So
3 it's only helpful for --

4 DR. GUNNAR: You framed it in
5 relationship to the mortality measurement. So
6 it's correct. There is the reliability of this
7 data at a low volume center is poor by admission.

8 Dr. Moss. Oh, did you -- No. Anyone?
9 Dr. Yates.

10 DR. YATES: That is true for any small
11 sample size. You're going to have as part of how
12 physician profiling that we have to throw out the
13 small volume physicians because the sampling is
14 so wide in terms of center of deviation. I think
15 it's just a mathematical necessity of that being
16 the case.

17 DR. GUNNAR: Any other discussion?

18 DR. CIMA: But then that gets to the
19 usability. I mean down the road it's for
20 patients and even for payers or health business
21 in general.

22 DR. GUNNAR: But to be clear that's

1 why if any one of these fails to meet. My
2 understanding, Andrew, is that if we failed any
3 one of these measures or any one of the
4 components then the measure fails. Correct?

5 MR. LYZENGA: Only the first two
6 criteria, importance to measure and report and
7 scientific acceptability. Those two are must
8 pass. Usability and feasibility actually are not
9 must pass.

10 DR. GUNNAR: Amy, did you have
11 something?

12 MS. MOYER: I guess I had a question
13 in looking at the volumes that are in the measure
14 and the reliabilities that relate to volume for
15 this. I would almost want to probably run this
16 as a multi-year if I were using this using more
17 than one year of data. And I was curious if
18 you'd done that and looked at that and how that
19 might not impact the performance of the measure.

20 DR. GUNNAR: So question for the
21 developers. Have you considered or would you
22 consider multi-year analysis for the mortality

1 relationships when you're dealing with low volume
2 reliability issues?

3 DR. ROMANO: Yes and I believe -- I'm
4 going to check. Is Sheryl Stanford on the line?
5 Do we have the lines open?

6 MS. FELDMAN: Can you let us know --

7 MS. DAVIES: Yes, I'm here.

8 DR. ROMANO: Thank you. Sheryl, can
9 you address whether this particular analysis was
10 done with two years of data or one year?

11 MS. DAVIES: This is done on our
12 typical measure set, which is done on one year.

13 DR. ROMANO: Yes. In answer to your
14 question, yes. For some analyses we use two
15 years of data. In this case, clearly I think
16 reliability would be higher with two years of
17 data or three years of data. We could estimate
18 those numbers and bring them back to the
19 Committee.

20 DR. GUNNAR: Melissa.

21 MS. THOMASON: I know when we talked
22 about the last measure and we talked about low

1 volume and less reliable and you went through the
2 reliability adjusted rate and smoothing and all
3 that. How much does that help with this measure?

4 DR. ROMANO: The same approach is used
5 here with smoothing so that hospitals are
6 smoothed back to the overall average. And in
7 fact the practical result of that is that most
8 hospitals' performance appears to be average.
9 And that's a limitation of a measure that
10 admittedly has low reliability. The smoothed
11 measures come back to the average. So it looks
12 like the hospitals are indistinguishable from the
13 consumer's perspective except again for the high
14 volume hospitals where the smooth measure is
15 primarily reflecting the hospital's own
16 experience.

17 DR. GUNNAR: Any other discussion? I
18 think we're ready to vote on reliability.

19 MR. LYZENGA: Are we ready to vote?

20 DR. GUNNAR: Yes. Go ahead and start.

21 MR. LYZENGA: This is a test for
22 anyone who votes moderate or high.

1 All right. I think that's everybody.
2 Can we get the results? All right. So we have
3 zero percent high, 17 percent moderate and 70
4 percent low and 13 percent insufficient.

5 That means that the measure does not
6 pass on reliability which means we stop the
7 discussion I believe. And that means the measure
8 will be recommended -- The Committee will
9 recommend that this measure loses endorsement.
10 And that saves us some time at least. We'll go
11 on to the next one.

12 DR. ROMANO: So I guess I'll just ask
13 a question. Is there -- So we'll go on to
14 discuss the volume measure now. My question
15 would be whether there -- Well, maybe we'll
16 discuss in the context of volume measure whether
17 they may be an opportunity to come back to the
18 Committee with a combined measure or some other
19 approach.

20 MR. LYZENGA: We can certainly discuss
21 that.

22 DR. FLEISHER: So that would actually

1 be coming back after the next Surgery Standing
2 Committee as opposed to within this project.

3 MR. LYZENGA: We would have to talk to
4 AHRQ about the time line and feasibility of doing
5 that, but likely within the next project I would
6 expect. It kind of depends on funding and other
7 factors. So we can't really say with too much
8 certainty when the next surgery cycle will be.
9 But we would expect it to be within the next year
10 or two I think.

11 DR. FLEISHER: So we --

12 MS. JOHNSON: I'm sorry, Lee. We
13 should probably talk about that a little bit
14 later offline with Patrick. If you guys could do
15 it quickly, there is a small possibility it might
16 get looked at after comments. But we can -- It
17 doesn't -- yes.

18 DR. FLEISHER: Right. My question to
19 Carol and Patrick is do you want to go forward
20 with the volume measure alone if we're not going
21 to consider the outcome measure. That's just a
22 question. Because if you think you could come

1 back within this cycle, then we should probably
2 discuss it. And I don't know if you could come
3 back by the conference call that we're going to
4 have.

5 Is there an interest from the original
6 discussants that if they came back with a paired
7 measure we should look at it?

8 DR. TEMPLE: Yes.

9 DR. FLEISHER: Yes, that's a pretty
10 resounding yes. So my question to AHRQ. And if
11 that's okay, NQF Staff?

12 MS. MURPHY: I was just going to say
13 that as endorsed currently they are endorsed to
14 be reported as a pair.

15 DR. FLEISHER: So what's the
16 implication?

17 MS. JOHNSON: Patrick, you are talking
18 about bringing back a measure that in one measure
19 incorporates the volume, not having a separate
20 measure that's volume versus -- Am I correct?

21 DR. ROMANO: Correct. So the current
22 endorsement does stipulate that the measures are

1 always paired. And NQF staff can better explain
2 what that means in practice.

3 But what we could do is to come back
4 with a single measure. It would combine both
5 volume and that preparatory work has actually
6 been already by Birkmeyer's group. And we've had
7 multiple discussions about how that would be
8 operationalized. So it could be done. It's just
9 that we haven't yet -- We wanted to see how the
10 discussion flowed in this process before
11 implementing that.

12 DR. GUNNAR: Could I ask a fundamental
13 question? So is the reliability issue going to
14 plague the volumetric measurement as well?

15 DR. ROMANO: We'll find out, but I
16 don't think so.

17 DR. GUNNAR: Under your own data
18 understanding now. The mortality at low volumes
19 suffers a reliability issue. Does the volume
20 measurement of a low -- is that impacted as well?
21 Okay. So you can identify reliably low volume
22 centers, just not the mortality within that low.

1 So how that will help a composite or a combined
2 measurement?

3 DR. ROMANO: The approach is that as
4 I mentioned in a smoothed measure the hospital's
5 actual risk-adjusted mortality is smoothed or
6 shrunk back to the overall need based on the
7 distribution that's observed in the reference
8 population.

9 Now in the approach that John
10 Birkmeyer's group has developed, the risk-
11 adjusted measure is smoothed back not to the
12 overall mean, but to the mean of hospitals with
13 the same volume. So what this means is that it's
14 really incorporating volume and mortality
15 together into a single measure.

16 The assumption is that if you don't
17 know anything else about the hospital you go with
18 the volume. And you go with the fact that on
19 average low volume hospitals have higher
20 mortality. If you know a lot about the hospital
21 from the hospital's own experience and their
22 risk-adjusted mortality, then you put more weight

1 on the observed experience.

2 This is a Bayesian design of the
3 measure where the prior is driven by volume
4 stratified mortality. And then that prior is
5 adjusted according to the hospital's own
6 experience. And Birkmeyer's group has shown that
7 this approach has very high reliability actually
8 and repeatability over time.

9 DR. CIMA: Let me make a comment. I
10 mean in some ways we have a conundrum of any low
11 volume event being able to statistically measure
12 it. And I think in the zeal to be able to
13 measure the mortality rate of a hospital who does
14 four cases a year in some ways it's throwing out
15 the baby with the bath water here.

16 And the question is statistically if
17 you have a low volume hospital should they simply
18 have an asterisk that says within competency
19 intervals we can't give you a result for this
20 particular institution. I mean there are other
21 ways to deal with this because there is a
22 reliability for higher volume institutions. It's

1 simply I think the difficulty that we're having
2 is do we have reliability for every institution
3 included in the metric.

4 DR. FLEISHER: It sounds like both
5 Birkmeyer's group and actually Jeff Silber and
6 Paul Rosenbaum are submitting a manuscript on the
7 part of my group that has also done a new
8 Bayesian model. I think there will be new
9 statistics coming out.

10 DR. SAIGAL: But I would agree with
11 that point. I mean basically you're putting like
12 lipstick on a pig in some ways. You've got very
13 little data on small volume hospitals and you can
14 sort of say that they're all the same. But you
15 don't really know that.

16 So from a consumer point of view I
17 think it's not helpful to say that you think
18 these are all the same. Higher reliability it's
19 confused by that we just don't know. So I'm not
20 sure that even with a Bayesian approach you're
21 really getting to the consumer's point of view.

22 DR. FLEISHER: John was next.

1 DR HANDY: If we are going put on a
2 reserve status esophageal outcomes and an
3 operation that's infrequent but does have the
4 potential for high mortality and lots of
5 morbidity, this is an area that cries out for a
6 composite measure. Getting to Dr. Cima's point
7 is that most patients don't die. Most patients
8 have morbidity.

9 I don't know that fast-tracking this
10 into lesser surrogates is really the best way to
11 go. Maybe a rethinking with a more comprehensive
12 composite is a way to monitor this important
13 clinical activity.

14 DR. FLEISHER: So this would not be
15 eligible in my mind for reserve status. This is
16 an up or down. Reserve status means the evidence
17 is high. Everything else passes except gap.

18 DR HANDY: Gap, okay. Got it.

19 DR. FLEISHER: So this would
20 essentially lose endorsement as the decision.

21 DR HANDY: Right. So what I say still
22 stands though.

1 DR. FLEISHER: Amy.

2 MR. LYZENGA: We're on 361, right?

3 We've moved past 360.

4 MR. LYZENGA: We're having a general
5 discussion right now. We haven't jumped into the
6 measure quite yet.

7 DR. FLEISHER: Amy and then we want to
8 come back to Patrick and Carol about how they
9 want to approach, whether they want to move
10 forward with this measure after these comments or
11 how they want to approach it. Amy.

12 MS. MOYER: I have one comment on
13 process. I'm wondering if -- You know last year
14 we had those series of calls that felt like it
15 gave the developers a little more lead time on
16 potential issues we might have.

17 And I'm not saying like the measure
18 could be respecified. But if we said, "Hey, we
19 want to see this for two years of data" there was
20 a time frame that might have allowed for that.
21 I'm not saying I don't like the new process and
22 do not miss all the calls. But it's something

1 that potentially was lost.

2 And if both measures are coming back,
3 I just wanted to touch on one thing that confused
4 me which was it appeared they had different
5 denominators. So for the mortality rate, the
6 inclusions all required not just the procedure
7 but also the cancer diagnosis.

8 And then for the volume it was any
9 resection regardless of diagnosis. And then
10 gastrectomy for a cancer diagnosis. That to me
11 was a little confusing and I don't want you to
12 bring it back and then blindside you with that
13 concern.

14 DR. FLEISHER: Collette.

15 MS. PITZEN: Thanks. I just wanted to
16 share that I understand the relationship between
17 volume of procedures and technical proficiency.
18 But I think the measure science has evolved
19 beyond reporting structural measure of volume
20 when you could have good outcome measures in
21 place. And given our prior discussion about the
22 unreliability of a low volume procedure and

1 mortality rates, I'm just kind of throwing it out
2 there.

3 I know for some of the measures that
4 we do we're actually reporting functional status
5 outcomes post on knee and hip -- I am sorry, on
6 knee and spine surgery. And we're actually
7 reporting the volume along with the outcome
8 rates, not as a separate measure but together.

9 DR. FLEISHER: I would like NQF staff
10 to just comment because Fred checked that there
11 is a risk-adjusted mortality and morbidity, NQF
12 approved measure from STS which we have said that
13 if there are two competing measures and they're
14 both valid we should approve them both.

15 But it also gets to in this space of
16 what the right thing to do is because we are a
17 standing committee now, not a measure-specific.
18 So thoughts if I'm making myself clear.

19 MS. JOHNSON: It's a little bit
20 difficult because we ask you to do something
21 that's a little hard to do which is consider
22 measures with blinders on, not thinking about

1 whether there is a competing measure or not. And
2 then if you like both measures, then to have the
3 discussion about competing or related and that
4 sort of thing.

5 I'm not as familiar with the STS
6 measure. I haven't to look at it. When measures
7 are competing, you as a committee can decide if
8 you think that there's justification for having
9 both or if there's a reason to pick a superior
10 one. I think if you're going to look at that
11 measure tomorrow, we'll just have to remember --
12 You're not going to, okay. So this is outside of
13 -- Okay.

14 DR. FLEISHER: The reason I'm just
15 bringing it up and I wouldn't bring it up if we
16 didn't have the problem with the first half of
17 this measure. Essentially, Patrick and Carol,
18 any thoughts on it? I'm happy to continue
19 proceeding. The question is given the comments
20 how would you like to proceed? Is that
21 appropriate?

22 DR. ROMANO: I think we can't commit

1 AHRQ here and now. Part of it is that our lead
2 program officer is not here and we'd need to have
3 a broader discussion. What I would say is that
4 if the staff and this Committee are open in the
5 current cycle to potentially considering a
6 composite measure that would be a composite of
7 volume and mortality, then we should go ahead and
8 discuss the volume measure. We would want to
9 incorporate any questions or concerns that the
10 Committee might have regarding the volume measure
11 into what we bring back. If that is not an
12 option, then we'll take both measures off the
13 table.

14 MR. LYZENGA: Again, it depends on
15 AHRQ's capacity to do the work within this cycle.
16 We'll maybe have to loop back with you on that.

17 I should also ask. The measure is
18 officially paired with the volume and mortality
19 measures. So that would actually under NQF
20 policy, if they are paired, that means if one
21 goes down the other goes down is my
22 understanding.

1 MS. JOHNSON: I think I want to confer
2 with somebody else and see if that's the case or
3 not.

4 MR. LYZENGA: Yes, we'll have to check
5 on that.

6 MS. JOHNSON: That one throws me every
7 time. I have to apologize.

8 MR. LYZENGA: But potentially a
9 question for you is whether you're open to
10 dropping that pairing so that this one could
11 maintain endorsement, if that is the case,
12 without the other.

13 DR. GUNNAR: I think, to the
14 developer's benefit, why don't we have the
15 discussion on the next measure, the volume
16 measure, and then make a determination if the
17 fact that they're paired should have influence on
18 our decision. And then we can move on.

19 DR. FLEISHER: I agree. Although I
20 don't think we can actually make a final
21 determination of an endorsement. But we can
22 actually give you insight to what it would take

1 to get over the hurdle this time. Because if we
2 don't have that, we'll fail at the next call if
3 you decide to make it. If that's okay, the
4 discussants are? Okay. And who wants to start?

5 DR. SAIGAL: I am happy to start if
6 you want. This is a measure about resection
7 volume. The outcome is a structural measure of
8 quality in terms of the evidence. They present
9 direct evidence of a relationship between
10 hospital volume and outcome. There's also
11 evidence that the surgeon volume is an
12 explanatory variable here.

13 There are a few studies that show a
14 lack of relationship. But the preponderance of
15 data indicates that there is a relationship. I
16 did find one site I didn't cite from the NIS that
17 showed the C statistic from this dataset was
18 about three percent. So very little of the
19 variation in mortality was explained by just the
20 hospital volume in that study versus the national
21 study. Probably the surgeon volume is also very
22 important and other factors are being measures in

1 terms of its relationship to mortality.

2 That's the evidence. I don't know if
3 there's anything else to say about that.

4 PARTICIPANT: Three percent?

5 DR. SAIGAL: That's a C statistic, yes.
6 The best model was like more than 15 procedures
7 in the C statistic which was three percent. So
8 it wasn't very high. That's from NIS.

9 PARTICIPANT: The difference?

10 DR. SAIGAL: No, that absolute C
11 statistic was three percent. This was something
12 that came out in 2009. And the C was 3.87
13 percent and varied between different models by
14 0.64 percent. So the overall volume which was a
15 less than one percent variance was due to the
16 volume of the hospital patient mortality.

17 I didn't see that study in this. So
18 this wasn't a comprehensive review that was
19 submitted. It was basically a scan of what they
20 found in more of an ad hoc way it seems like.

21 DR. FLEISHER: What I might suggest
22 given one measure has failed of a paired measure

1 is that we just have a discussion without a vote
2 on any individual aspect of evidence,
3 reliability, validity if the Committee is
4 acceptable. We essentially inform AHRQ so that
5 they can respond. Does that work for staff? If
6 you want to continue, Chris.

7 DR. SAIGAL: Okay.

8 DR. FLEISHER: And any other comments.
9 And then we have a robust discussion and then
10 call it.

11 DR. SAIGAL: Sure. There is a gap.
12 There's a very large variation that hospitals
13 reported from 2 to 25 surgeries annually. It's
14 claims-based. In terms of validity testing, I
15 don't really see any besides face validity
16 basically showing people the measure to say "Does
17 this look meaningful to you?"

18 And it is a claims-based or
19 administrative approach looking at IC-9 codes as
20 someone said which are procedure codes that are
21 less specific than CPT codes. I didn't see any
22 evidence that there was a chart abstraction at

1 any point to say whether they were capturing the
2 surgeries. I thought they were capturing the
3 surgeries from a chart review. There is just no
4 data about that that I saw in their application.

5 In terms of its -- One thing about
6 usability and use, it's being used in three
7 states by one AMC and one health system for a
8 couple of years. They did not report that I saw
9 in this application that there was a shift in the
10 distribution of volumes of hospitals.

11 Someone else said earlier that there
12 was a drop of low volume hospitals that Leapfrog
13 was measuring. But I didn't see it in this
14 application. At least in what is here, there
15 wasn't data to say that the impact of the measure
16 had changed the distribution of procedures in
17 different hospitals. But maybe that wasn't
18 presented in this application.

19 DR. FLEISHER: That was Patrick. Do
20 you have data to answer that, Chris'?

21 DR. ROMANO: This particular analysis
22 as reported here is only with the 2011-2012 data.

1 In the other data that we just reviewed for IQI
2 8, that analysis goes back to further years and
3 shows that change in volume.

4 DR. SAIGAL: I would suggest if you
5 have better data to say it's impactful you should
6 include it. And if that's the case, then I would
7 say that's great. According to this application,
8 there's been no impact. I guess I'll defer until
9 it's been revised. Those were my overall
10 comments.

11 DR. FLEISHER: Amy, comments?

12 MS. MOYER: My biggest question had
13 been the discrepancy between the denominator
14 definition on the two measures. If we're saying
15 -- If we're somehow pairing them, it feels like
16 we should be looking at the same patients for
17 both instead of including additional people.

18 I was wondering if a way to increase
19 the volume covered by the mortality rate would be
20 to drop the cancer diagnosis. But then my guess
21 was we're potentially trying to weed out
22 traumatic or emergent patients potentially by

1 limiting it.

2 DR. FLEISHER: Allan.

3 DR. SIPERSTEIN: If we're unhappy
4 knowing the mortality rate of each hospital,
5 we're even less happy just knowing the volume. I
6 mean it's even a looser surrogate of quality
7 outcomes. And it kind of begs the question
8 because we know if you go under the hood you're
9 going to know what the morbidities and the
10 mortalities are. Obviously, a structural measure
11 like this gives us even less information or
12 guides the patient with even less information in
13 terms of how to seek care.

14 DR. FLEISHER: Thank you. Other
15 comments? Are individuals comfortable with not
16 voting and asking AHRQ to come back to us quickly
17 with whether or not you want to develop a
18 composite in this cycle which it sounds like we
19 are open to? Robert.

20 DR. CIMA: Just one question for
21 Patrick. Is there a specific reason to pinpoint?
22 I know you're looking at esophageal resection

1 volume of all causes. And then you separate out
2 mortalities.

3 What was the rationale behind doing
4 that? That seems to me to that point is if
5 you're saying there's a direct volume
6 relationship, then the denominator should be the
7 same across both. Even the title of that doesn't
8 say esophageal resection for cancer patients. It
9 seems like -- I'm just trying to figure out why.

10 Now I'm starting to get concerned that
11 Allan's point is we're taking something away that
12 may be useful for patients out there even though
13 it's not a good marker. If you pair them
14 together, it might be. But why was it done
15 differently and probably in the future it
16 shouldn't be.

17 DR. ROMANO: That's an interesting
18 question. The answer to that question reflects
19 the unreliability of the NQF review process.

20 (Laughter.)

21 No criticism. I edit a journal and I
22 know unreliability of review processes. When

1 this measure was originally developed, the
2 denominators were paired to be identical and to
3 be limited to cancer patients. But in the
4 previous endorsement review, the Committee felt
5 that surgeons should get credit for procedures
6 that they do for benign disease.

7 They felt essentially the volume, the
8 total volume, for both benign and malignant
9 disease was the relevant metric of volume. It's
10 essentially the same surgical technique for
11 benign disease versus malignant disease.

12 Whereas, for the mortality measure,
13 there was a feeling that the cancer patients have
14 particular challenges in terms of mortality. And
15 that cancer in particular is a focus of public
16 attention and referral.

17 And, of course, most of those
18 procedures are done in affiliation with
19 designated cancer centers. So there was an
20 interest in keeping the focus on cancer for the
21 mortality measure.

22 But I think that this is obviously an

1 issue where reasonable people could disagree.
2 And I would say that from the methodologic
3 perspective I'm always in favor of a broader
4 denominator if it makes sense because we can deal
5 with cancer through risk adjustment. And it
6 strengthens the reliability of the measure as a
7 whole.

8 DR. HANDY: I was just going to make
9 the point that when you look at esophageal
10 surgery risk assessment with cancer patients
11 that's a risk for doing worse.

12 DR. ROMANO: That's easy to handle
13 through risk adjustment because it's well known
14 the patient has cancer.

15 DR. EREKSON: I just have a
16 theoretical or ethical question for the group to
17 consider. And as a surgeon who does mostly
18 elective surgery I think it's a really big point.
19 It's not as necessary for cancer surgery.

20 But when surgery is very patient
21 preference sensitive, we have to be very, very
22 careful of structural measures that just measure

1 volume. That will really influence how the
2 surgeon and the center counsel those patients on
3 what their options are for treatment.

4 I really like the fact that these
5 measures are tied to also outcomes so that this
6 was a volume measure tied to an outcome. And
7 maybe we could get into that the outcome
8 shouldn't be mortality and maybe it should be
9 morbidity and functional status which is a great
10 direction to head in.

11 But I really, really think it's
12 important on these volume measures that we
13 consider having it linked to something else.

14 DR. FLEISHER: Thank you. I think
15 that should be included in our report. And when
16 the report gets written, hopefully you can ensure
17 that that's accurately reflected in the report.

18 Other comments?

19 (No response.)

20 What I'd like to do is take a simple
21 hand vote on who thinks it's important for AHRQ
22 to bring back a composite or paired measure at

1 this time.

2 (Hand vote.)

3 It looks unanimous to me. I think
4 from the standpoint -- and Carol and Patrick --
5 we would like to see it. And if it can come back
6 within this cycle, I think there would be great
7 interest in the Committee looking at this. I
8 think that was a great discussion. Thank you.

9 MR. LYZENGA: Thanks everyone. Next
10 we'll be moving to --

11 Also an AHRQ measure. So we'll ask
12 our developers to -- We'll give them a moment
13 here.

14 DR. FLEISHER: Background. I just
15 wanted to say one thing, Patrick. Your
16 observation about NQF we were just discussing was
17 very helpful which is the reason of a standing
18 committee for those of you who were not aware.
19 They used to be ad hoc.

20 Hopefully, the people here can have
21 memory as to the approach we take. For those if
22 we do change our approach, people should call us

1 out on that so that we stay consistent.

2 That's actually -- Just to be aware,
3 that was a Kaizen to actually -- This is one of
4 the outcomes because of that reliability. So
5 thank you for pointing that out.

6 DR. GUNNAR: Just to tee this one up,
7 it is an endorsed measure as of August 2009. Dr.
8 Romano.

9 DR. ROMANO: Okay. Now we're
10 switching gears to a measure of morbidity. This
11 is part of the patient safety indicator or PSI
12 module. These measures key off of complications
13 that arise during the care of patients in the
14 hospital. This is a measure of post-operative
15 respiratory failure. It's one of several
16 measures of different types of post-operative
17 complications.

18 This particular measure uses both
19 diagnosis and procedure codes in a manner that
20 I'm sure we'll discuss to identify patients who
21 had evidence of respiratory failure after what's
22 called a major operating room procedure. And it

1 is based on evidence of course that there are a
2 variety of interventions that can reduce post-
3 operative respiratory complications.

4 DR. GUNNAR: Any other comments?
5 Discussants?

6 MS. THOMASON: Is Dr. Asher on the
7 phone?

8 MR. LYZENGA: Is Dr. Asher on the
9 line? I just want to check to see if he's
10 available.

11 (No response.)

12 DR. DUTTON: Go ahead, Melissa.

13 MS. THOMASON: I just wanted to make
14 sure if he was on the phone to give him an
15 opportunity to weigh in. This is Measure 0533,
16 Post-Operative Respiratory Failure. It's a
17 measure of respiratory failure, mechanical
18 ventilation, reintubation cases per 1,000
19 elective surgical discharges. It's a facility
20 measure and it's intended to identify adult
21 patients with particularly significant adverse
22 events that are at least partially preventable.

1 I do have one -- I'm going to ask the
2 developers really quickly for clarification.

3 Does it only pertain to elective surgical
4 discharges because you can clarify there was no
5 respiratory distress going into that? Or why do
6 we cut out the emergent procedures?

7 DR. ROMANO: Currently, the measure
8 has a variety of exclusions that are intended to
9 exclude patients who have respiratory failure
10 before surgery or where respiratory failure is
11 the indication for surgery.

12 There are also a wide variety of
13 exclusions for patients who have underlying
14 severe lung disease and heart disease. But there
15 is no exclusion based on the urgency of the
16 surgery.

17 DR. DUTTON: This is both an outcome
18 measure and a marker for further bad outcomes.
19 Post-op respiratory failure itself is painful and
20 dangerous and highly costly. It's also
21 associated with significantly higher subsequent
22 morbidity and mortality.

1 This is an important thing to measure.
2 The rate is high enough. There is a significant
3 gap in care here and significant variability
4 among centers.

5 DR. GUNNAR: Any other discussion?

6 MS. PITZEN: I don't know if this was
7 brought up. I'm just going to continue the
8 discussion about the exclusions. And this
9 measure actually came up through our last phase.

10 MR. LYZENGA: Actually, can I cut you
11 off?

12 MS. PITZEN: Yes.

13 MR. LYZENGA: Just because that's part
14 of the validity discussion.

15 MS. PITZEN: Okay.

16 MR. LYZENGA: Take a vote on evidence
17 first.

18 DR. GUNNAR: We need one more.

19 MR. LYZENGA: Again at the discretion
20 of the Chair. I think we can probably call it.

21 DR. GUNNAR: There we go. We got them
22 all.

1 MR. LYZENGA: All right. Ninety-six
2 percent yes and four percent no. The measure
3 passes on evidence. We can move on to
4 opportunity for improvement or a gap in care.

5 DR. DUTTON: I thought gap was on the
6 last vote. It was on the last slide.

7 MR. LYZENGA: Was it on the last
8 slide?

9 DR. DUTTON: Yes, I thought we were
10 doing those altogether.

11 DR. GUNNAR: Do you want to go back
12 and vote again or? Anybody want to change?

13 DR. DUTTON: No, that's fine. I don't
14 want to discuss it again.

15 DR. GUNNAR: Any other discussion
16 regarding having this already been addressed on
17 this? All right. Vote?

18 Always seems to take that little less.
19 Let's see what it says if there's a -- One
20 additional vote wouldn't have made a difference.

21 MR. LYZENGA: Seventy-three percent
22 high, 27 percent moderate and zero for low and

1 insufficient. The measure passes on performance.

2 Now we'll move to reliability.

3 DR. GUNNAR: Any comments from the
4 discussants on reliability?

5 MS. THOMASON: For reliability we run
6 into the same conversation that we've been
7 having. The reliability testing score was 0.744
8 of one. But it's significantly less reliable for
9 lower volume hospitals.

10 DR. DUTTON: I am a little less
11 concerned about the reliability based on the size
12 of the hospital. Since this is a common enough
13 problem, there will be plenty of data and very
14 low volume hospitals are going to be ones that
15 aren't dealing with that kind of patient. I
16 don't think that's as big a deal.

17 If you read the measure
18 specifications, there are multiple denominator
19 exclusions in this. And I understand why they're
20 there, particularly if the measure is going to be
21 used for public accountability.

22 Some of them I think are very

1 reasonable and very objective. Others though,
2 exclusion for specific co-morbidity codes of
3 chronic heart or lung disease, that's going to be
4 very hard to nail down. And I think it offers a
5 large potential for gamesmanship in the measure.
6 As I do my hospital coding, I may have a lot more
7 patients with chronic lung disease as a result of
8 having to report this measure.

9 MS. THOMASON: And just to echo Dr.
10 Dutton, I think, from a reliability standpoint
11 even with the low volume issue that the
12 developers pointed out, it certainly isn't a
13 concern in that area. But the exclusions were
14 another thing that I wanted to hear from the
15 developers.

16 MR. LYZENGA: And exclusions are
17 actually I think in the validity again. For
18 purposes of voting, we'll focus on reliability
19 here.

20 DR. GUNNAR: So I guess to frame that
21 correctly, could a hospital or is there any
22 evidence that low volume hospitals use the

1 exclusion list to mask outcomes?

2 MR. LYZENGA: First, let's vote on
3 reliability.

4 DR. GUNNAR: Yes absolutely. Did I
5 capture that correctly for the record? Hearing
6 no argument, I'll assume that that was correct.
7 Yes sir.

8 DR. SAIGAL: Thank you. A question
9 for our patient representative as well and
10 basically this issue with low volume hospitals,
11 is it for a consumer looking at hospitals and for
12 us looking at how to identify problems, is it not
13 more honest to not report data where hospitals
14 have low reliability and just say the volume is
15 too low to say? That in itself is information
16 for everyone to use versus other approaches which
17 I think might be providing information that isn't
18 there. I was just wondering if that's a way to
19 address the reliability issue with the low volume
20 hospitals that people find interesting.

21 MS. THOMASON: I can't speak for
22 everyone, but I will say that certainly from my

1 perspective I would definitely prefer for the low
2 volume hospitals for it to say not reportable or
3 not numerically significant or these facilities.
4 Then I can say okay instead of adjusting the
5 numbers or smoothing it over or bringing them to
6 average so that I have the sense of they're all
7 operating at the same level.

8 DR. GROVER: To follow up on that, I
9 agree. I think an asterisk or something. You
10 could report it, but you could say that the
11 numbers were, however you want to phrase it, too
12 small to know if this is a significant difference
13 or something or not significantly higher.

14 MS. MOYER: We actually publicly
15 report this. We're listed in the application as
16 a user of the measure and that's what we do. We
17 just have an asterisk and indicate there's not
18 enough volume to really reliably calculate
19 performance for this.

20 DR. GUNNAR: What do you use for your
21 reference point for not enough reliable? What
22 are you using? An own internal?

1 MS. MOYER: I believe the software
2 does that for us is my understanding. I can
3 check on that with my programmer.

4 DR. GUNNAR: Because the measure is
5 capturing it. It's not making that distinction.
6 It's incorporating all data regardless of whether
7 that data came from low volume or not. It's not
8 excluding low volume data. Is that correct?

9 But we are voting on reliability. And
10 I think the discussants' impression is, at least
11 as I hear it, is that their recommendation is
12 that the number of low volume facilities does not
13 impact the overall reliability of this measure
14 due to the fact that it's a relatively high
15 volume event. Any other --

16 DR. ROMANO: Maybe I'll just clarify
17 a couple of things. One is that this of course
18 is a strikingly different situation from the
19 measure that we just reviewed in that the overall
20 reliability here is 0.74. And it's not until you
21 get down to the bottom 30 percent of hospitals
22 that you get into this low reliability range.

1 For the great majority of hospitals this is a
2 reliable measure.

3 Now how to handle that low volume
4 situation, obviously different entities in the
5 public reporting space make different choices.
6 And AHRQ software tried to support a variety of
7 choices that users may make.

8 Some users choose to implement a
9 threshold. I think CMS for example in its
10 measures has generally used a threshold of 30 in
11 the denominator if I remember correctly. Some
12 users, other users, have adopted that. But that
13 is a matter of user discretion.

14 I do want to explain that there is a
15 conceptual and statistical advantage to this
16 approach of using all the data and doing this
17 shrinkage. And that is it gets back to a nice
18 example that a famous statistician described,
19 Ephron, related to batting averages.

20 If you imagine early in the season
21 somebody has just come up to the major leagues
22 and their batting average is based on a limited

1 number of times at bat. And maybe their batting
2 average is 0.500. And you say, "Wow, this is an
3 incredible baseball player." And you pay that
4 person a lot of money. But then as the season
5 goes on, the batting average drifts back to the
6 average, so-called regression to the mean.

7 We often see this phenomenon in
8 practice where there's a period of time when a
9 hospital looks really good and it drifts back.
10 So we know that we're always using data that are
11 a year or two old to provide information to the
12 market about current performance. That's the
13 nature of the beast here. What we want to do is
14 to maximize the correlation with current
15 performance which of course we won't measure
16 until a year or two from now.

17 It's been conclusively shown that to
18 get the best prediction of current performance we
19 would use both the information about the
20 hospital's own performance in the prior period as
21 well as the information from other hospitals,
22 because on average, hospitals will tend to

1 regress towards the mean.

2 In fact, this statistical approach,
3 it's not just mumbo jumbo. It's based on the
4 practical issue that we're trying to give the
5 field the best information that we can about
6 what's really going on right now. But we don't
7 know that yet.

8 The best way we know that is by
9 looking at how that same hospital did a year or
10 two ago and how other hospitals did, knowing that
11 there will be a tendency for hospitals to regress
12 towards the mean of all the hospitals that are in
13 the population of interest. That's the conceptual
14 approach.

15 DR. GUNNAR: And I appreciate that.
16 Just to get back on to reliability and this vote
17 though is that the discussions about volume and
18 the reliability and the ability to predict
19 current events, it's easier in higher volume
20 events. And this is a relatively high volume
21 event. Can we have a vote?

22 MR. LYZENGA: Let's go ahead and vote

1 on reliability.

2 There we go. So we have 30 percent
3 for high, 65 moderate, four percent low and zero
4 insufficient. The measure passes reliability. So
5 we'll go onto validity. And this would certainly
6 include concerns about the exclusions. Maybe we
7 can start with Collette.

8 MS. PITZEN: Great. Thanks. Now the
9 right time for discussions of exclusions. This
10 came up during our last cycle. Our small group
11 actually had the opportunity to review. I have
12 the same feedback that I had back then.

13 I'm concerned that some of the
14 exclusions for this measure are a bit broad, in
15 particular, MDC 5 diseases/disorders including
16 procedures of the cardiovascular system. This
17 would exclude every coronary bypass patient,
18 every pacemaker. I think that there needs to be
19 some careful thought in terms of having that as
20 an exclusion.

21 I feel the same way about the MDC 4,
22 although perhaps not as strongly. Just for

1 background, an MDC is a major diagnostic category
2 that's a grouping, a very large roll up of the
3 DRGs at the hospital base. So I would hope that
4 there would be some careful consideration of
5 exactly what types of patients you're pulling out
6 of the measure.

7 DR. DUTTON: I already expressed a
8 concern about the exclusions. And I wanted to
9 say something about the risk adjustment model
10 because I think that's an exception as well. I
11 guess I favor -- I think that we do have to risk
12 adjust measures when they're going to be used for
13 public accountability. So payment is on the
14 line. It's important to level the playing field.

15 But at the same time risk adjustment
16 has the risk of throwing away the very data that
17 we need to take meaningful action and just the
18 very simple observation of patient age. All of
19 these measures are adjusted for age.

20 But I would actually like to know that
21 my older patients have a higher risk of post-op
22 pulmonary dysfunction because I may concentrate

1 more of my hospital's resources on that in order
2 to improve that. I may have more physical therapy
3 with my old patients, etc.

4 I just want to raise the concern.
5 This applies to all of our risk-adjusted
6 measures. As the CSAC starts to look at tiering
7 of measures or uses of measures, we may have a
8 different model for measures used for public
9 accountability versus measures used for quality
10 improvement. And one of the big differences
11 would be how much or how hard you risk adjust.

12 DR. GUNNAR: Amy.

13 MS. MOYER: I had a question on the
14 exclusion of the MDC related to obstetrical care.
15 And I was curious if that would exclude caesarian
16 section patients from this measure. If so, why?

17 DR. ROMANO: I can address some of
18 these exclusion questions and I just want to say
19 joining me here at the table now is Dr. Garth
20 Utter who's a trauma surgeon and critical care
21 surgeon on our team. And he's written some of
22 the papers related to this indicator. He'll

1 participate as well.

2 We actually share the concern that
3 some of these exclusions are a bit broad. They
4 were to some extent inherited from a progenitor
5 version of this indicator which was developed by
6 Lisa Iezzoni and her group under the rubric of
7 the complication screening program.

8 We went through two rounds of expert
9 panel review with AHRQ with multidisciplinary
10 panels including surgeons, critical care
11 physicians, nurse anesthetists,
12 anesthesiologists, so forth. And there is a
13 tendency frankly in these panels reviews for
14 people to throw out exclusions and say "Oh, you
15 ought to exclude these people. You ought to
16 exclude these people." And then the exclusions
17 start to add up. So this is a legitimate
18 concern.

19 But I do want to point out that the
20 MDC exclusion is based only on the principal
21 diagnosis. We're not excluding people who had a
22 co-morbidity of severe lung disease or a co-

1 morbidity of severe heart disease. We're
2 excluding people who were admitted specifically
3 for treatment of lung disease or heart disease.

4 The idea is that if the patient is
5 being admitted for example for a lung cancer
6 resection, then presumably the surgeon has had
7 some discussion with them about the risk. And
8 they're undertaking this procedure aware that by
9 losing some of their lung they may go into
10 respiratory failure. And similarly patients who
11 are undergoing a procedure, for example a
12 transplant procedure or a procedure for severe
13 heart disease, they're doing so obviously
14 recognizing that we're operating on the chest.
15 And that confers a very high risk of respiratory
16 failure.

17 These MDC exclusions are based only on
18 the principal diagnosis, why the patient was
19 admitted to the hospital. You're right that
20 obstetric patients are excluded across the board
21 from these measures.

22 Part of that is because obstetric

1 patients are subjected to different coding rules.
2 And of course post-operative respiratory failure
3 is a very rare event in the obstetric setting.
4 It would require modeling in a completely
5 different way. It's such a different patient
6 population that it just made more sense to
7 exclude it.

8 Garth, do you want to add anything on
9 the exclusions?

10 DR. UTTER: Only the point that some
11 of the exclusions concern airway protection
12 issues. And this is a particularly challenging
13 issue. It creates a conundrum of trying to avoid
14 penalizing people for doing something that is
15 really intended to prevent the problem in the
16 first place. That's the only point I'd add.

17 DR. YATES: I just have a technical
18 question for the developers. In one of your
19 previous measures, you used the composite risk
20 adjustment variable of an APR DRG. In this
21 measure, you use specific co-morbidities. Is
22 that because there would be so many APR DRGs? Or

1 is this an older measure? Or why the difference
2 in methodology?

3 DR. ROMANO: Yes, two reasons for
4 that. One is that the APR DRG system that we use
5 is the risk of mortality or ROM classification.
6 And that is designed specifically for predicting
7 mortality. That would not be exactly appropriate
8 for a morbidity complication of this type.

9 Now there is a different tool in APR
10 DRG. It's called the severity of illness
11 subclass. But that's really designed more to
12 predict length of stay. And again this is not
13 exactly length of stay.

14 The first reason is a tailoring. The
15 APR DRG approach is tailored to the outcome for
16 the mortality IQIs. It's not tailored to this
17 outcome. We felt that developing a tailored
18 model approach was better.

19 The second reason is that for the
20 patient safety indicators we want to be
21 particularly careful about not adjusting for
22 things that arise during the patient stay in the

1 hospital. We actually discussed earlier for hip
2 fracture how using the APR DRG framework we are
3 adjusting for the procedures that the patient had
4 regardless of when those procedures were
5 performed. And we accepted that for hip fracture
6 because we know that certain types of hip
7 fracture require certain types of procedures.

8 In this case, we have a very, very
9 broad range of procedures that are being done and
10 it would as you point out lead to a large number
11 of APR DRG parameters to adjust for all those.
12 And some of those procedures are being done to
13 treat complications that actually arose during
14 the hospital stay.

15 Now it would be really difficult to
16 sort out was the procedure being done to treat
17 the hip fracture. Well, we know the hip fracture
18 was there on admission. But was the procedure
19 being done to treat something else that was
20 happening during the hospital stay?

21 So APR DRGs implicitly adjust for
22 procedures. To avoid adjusting for procedures,

1 we only want in this case to adjust for the main
2 reason the main procedure why the patient came to
3 the hospital and not for all those secondary
4 procedures. That's the other reason we're not
5 using those.

6 DR. YATES: Then to follow up on that,
7 those co-morbidities that you are capturing
8 ideally those would be captured as present on
9 admission. Now how do you separate present on
10 admission and this administrative dataset
11 collection? Some of those co-morbidities may
12 develop during the admission and be collected
13 retroactively or after the event.

14 DR. ROMANO: Correct. Right. The
15 hospitals are required to report in the case of
16 Medicare on CMS claims. And most state health
17 data agencies also require hospitals to report
18 for each diagnosis whether that diagnosis was
19 present on admission or not.

20 Those of you who are in the clinical
21 documentation improvement side know that
22 sometimes there is disagreement and sometimes the

1 coders are unclear about whether the condition
2 was actually present on admission or not. And
3 we've been doing some sensitivity analyses to
4 explore that further.

5 Fortunately, it doesn't really seem to
6 make a difference in the modeling. So there are
7 some patients where it appears that the diabetes
8 developed after admission. We know it didn't.
9 But it turns out that that kind of miscoding is
10 so uncommon that it doesn't make a difference in
11 the modeling.

12 MS. McCARTY: The explanation around
13 the reason for the exclusions makes me wonder
14 with everything that is risk-adjusted for -- I
15 guess two questions: One is if we can risk-
16 adjust for all these things, why can't we also
17 risk-adjust for the MDC 4 and MDC 5 indications?

18 And if that isn't a possibility then
19 it sort of indicates that maybe there needs to be
20 subsequent measures that just focus on those
21 groups. Because to say that it's a high risk and
22 known outcome, I think we care just as much about

1 knowing to what extent that that does occur and
2 if we can improve the frequency of those known
3 risks happening. So potentially coming back with
4 a measure structured like this but with just that
5 group as the focus.

6 DR. GUNNAR: But marked as a gap.
7 Right, Andrew?

8 MR. LYZENGA: Yes.

9 MS. THOMASON: As is, the exclusions,
10 post-op respiratory failure for any coronary
11 bypass patient, it's excluded. Right?

12 I would love to hear other clinicians
13 in the room weigh in. I know that certainly
14 having tons of surgery doesn't qualify me to
15 weigh in from a clinical perspective especially
16 you, Dr. Dutton. You know, from a clinical
17 standpoint, is that valid?

18 DR. DUTTON: My take is Kelsey's
19 thing. I think I would favor a lot fewer
20 exclusions and then risk adjustment around things
21 like cardiac bypass surgery or pre-existing COPD
22 or what have you.

1 DR. GUNNAR: I think that may be for
2 future to refocus on this measure and the
3 validity associated with the data. Any other
4 discussion on the validity?

5 DR. GROVER: Bill, it was brought up
6 earlier about the importance obviously of the co-
7 morbidities being captured at admission.

8 One problem that was revealed back to
9 us in the 80s was that, at least in our
10 specialty, there are a fair number of things that
11 can happen after admission but before the
12 operation. People can go into shock, whatever.

13 They can be taken to the operating
14 room where if you just capture these risks on
15 admission people can really deteriorate, and it
16 doesn't capture their risk as they go into the
17 operating room.

18 I'm just curious how you handle that.
19 You could just say when that appears in the chart
20 as long as it's before the operative day rather
21 than admission.

22 DR. ROMANO: Garth reminds me that one

1 of the limitations in the denominator for this
2 measure is that it is limited to surgical
3 discharges that are identified as elective. So I
4 may have misspoken earlier on that question, so
5 that addresses Dr. Grover's comment.

6 DR. GUNNAR: Just to reframe it for
7 myself in relationship to -- this is a measure
8 where the denominator is a group of patients who
9 the expectation of respiratory failure is low.

10 I appreciate the other comments about
11 the exclusions, but from a quality improvement
12 sort of environment of care perspective, I
13 personally don't have an argument with the way
14 this was created.

15 Other measures should look at that
16 excluded population but potentially for a
17 different purpose.

18 DR. ROMANO: I think AHRQ would agree
19 with that, that it would make sense to look at
20 cardiopulmonary operations separately, but
21 obviously those patients are much more like to
22 come in with some degree of respiratory

1 compromise and that would have to be carefully
2 considered in the adjustment approach.

3 DR. GUNNAR: Lee and then Dr. Cima.

4 DR. FLEISHER: One of the things,
5 getting back to Rick's comment, this is part of
6 PSI 90 but unweighted, which is interesting how
7 that happened which I think gets to reliability
8 because that is used in the current payment model
9 but not used. I haven't figured that one out
10 yet.

11 Can you comment as to what happened to
12 this measure as it became part of the composite?
13 Do you have any clue?

14 DR. ROMANO: I'm just conferring with
15 staff. I'm not trying to be evasive. It's just
16 that the issue is that the composite measure is a
17 different measure. It's being reviewed by a
18 different committee, and so we are trying to keep
19 the processes separate.

20 I would say that PSI 90 was endorsed
21 before PSI 11 was endorsed. This is why PSI 11
22 is currently unweighted in PSI 90. It's the

1 original endorsement by NQF of PSI 90 predated
2 the original endorsement of PSI 11.

3 DR. FLEISHER: Thank you. That's
4 sufficient.

5 DR. CIMA: I just want to bring up
6 probably the dirty little secret about PSI 11.
7 And it's not about how you wrote it or how you
8 did it, but as you know the reality is that I
9 have visited a number of institutions, sent down
10 by my institution to go say, boy, they did great.
11 Their PSI 11 dropped like this.

12 And the reality is when you go there
13 it was all because of how they changed their
14 documentation. It had nothing to do with the
15 number of patients that were on ventilators, and
16 I think everyone including the developers know
17 that that's a significant portion of this problem
18 here.

19 When we talk about validity, that's
20 not captured in the measure, and I'd like the
21 developers to discuss the reality of what this
22 whole process had done now. It's that people are

1 able to significantly alter this PSI by just how
2 they describe the post-op patient on the
3 ventilator.

4 DR. UTTER: I think it's safe to say
5 this is a topic we've given considerable thought
6 to, our team.

7 And in summary, approximately 20
8 percent of records flagged by this indicator are
9 flagged on the basis of the diagnosis codes only.
10 They do not have one of the procedure codes for
11 either the length of intubation or reintubation.

12 I don't know that there's any clear
13 cut right direction to go on this. We have
14 considered just eliminating the diagnosis code
15 component. However, we realize that that will
16 probably leave uncaptured some cases that truly
17 represent quality deficiencies.

18 DR. CIMA: To follow up, how can you
19 address the validity then? On face validity,
20 there's a problem.

21 DR. UTTER: Yes, I think we have to
22 admit that there is an issue with the validity

1 because of the diagnosis code options basically.

2 This is not the only code that might
3 be used. There are other codes that might be
4 applied to the same clinical phenomenon that will
5 not trigger this indicator. We acknowledge that.

6 DR. CIMA: My point is that when we
7 talk about reliability that's one thing, but to
8 go to the public and say we have a measure that
9 has a validity issue you can't put an asterisk by
10 that. It's either valid or not.

11 And that's been my big -- I mean I was
12 shocked. You know, 50, 60 percent improvement in
13 people's PSIs literally within a quarter or a
14 year based upon just what they told people to
15 document. The nurse practitioners in the ICU
16 never write this down for this patient.

17 I mean I'm not saying it's ethical.
18 We're not talking ethics. We're talking validity
19 of a measure that's going to be used for public
20 reporting, and I have very real concerns about
21 the validity here.

22 And that's the only concern that I

1 have about it. The exclusion I agree with,
2 William and everything, but I think that's a real
3 issue we need to put up front.

4 DR. GUNNAR: I saw Melissa, then
5 Kelsey, then Dr. Yates and Dr. Grover.

6 MS. THOMASON: Patrick, did we go back
7 to ---- it said the denominator does specify
8 elective procedures? Correct?

9 So what was the train of thought
10 behind that? Is it because if it's not elective
11 we don't have a standing respiratory point to
12 compare it to or?

13 DR. ROMANO: It was Dr. Gunnar's point
14 that these are patients who should be very low
15 risk, where there's no expectation of respiratory
16 failure after surgery. So it may provide a
17 quality improvement opportunity.

18 DR. GUNNAR: Kelsey.

19 MS. McCARTY: Just to the point about
20 the workarounds, I think it's related to a
21 comment that Amy made earlier.

22 By making things a measure, no one is

1 surprised that those behaviors start to happen
2 and I think it's a known thing across a lot of
3 measures. Maybe in the first quarter or in the
4 first year or maybe in the second year, they're
5 able to get those huge improvements, but then
6 after year two they can't -- that kind of
7 exhausts itself.

8 It maybe reestablishes the baseline,
9 and there are some behaviors in there that we
10 don't want, but I think those workarounds will
11 happen. I think it just maybe reestablishes the
12 baseline, but then there's still potential for
13 improvement from there forward.

14 DR. GUNNAR: Microphone, please.

15 DR. CIMA: To allow that to go on,
16 that's a problem. You're facilitating them to do
17 that.

18 Let's say if they go from a high
19 outlier to as expected, everyone's happy then,
20 but you're still having a whole bunch of people
21 that aren't treated, but they now have the
22 justification of saying, well, we're doing fine

1 on this PSI.

2 That's my only point. I mean I'm not
3 trying to -- but I'm just saying this PSI is
4 inherently one of the ones that can be gamed
5 masterfully. And you're not helping people.
6 That's the point. It all becomes then just a
7 display. It becomes window dressing.

8 DR. GUNNAR: Dr. Grover.

9 DR. GROVER: With this question having
10 been raised, I guess I'm wondering what your
11 audit process is. Do you audit? How do you know
12 the data is accurate? What are the consequences
13 of gaming the codes?

14 DR. ROMANO: I can address this in
15 several ways. There have been a number of audit
16 studies that have been done. They're cited in
17 the validity review. Dr. Utter has authored a
18 couple of them as well as the VA, Dr. Borzecki
19 and colleagues from the VA.

20 One thing that we learned -- again
21 just to sort of address Dr. Cima's question. So,
22 right now there are two potential ways of

1 identifying patients with respiratory failure.
2 You can identify them based on procedures that
3 they had, a reintubation after they were
4 extubated from surgery or they had a prolonged
5 course on ventilation. So you could use
6 procedure codes or you can use a diagnosis of
7 acute respiratory failure or now an acute post-
8 operative respiratory failure.

9 Now in the design of this indicator we
10 chose to use both, and we did so based on an
11 earlier validation study in which we used NSQIP
12 data from the VA, VASQIP data, that were linked
13 to the VA's patient treatment file, and we showed
14 that if we used the procedure codes alone, the
15 sensitivity of the indicator was suboptimal.

16 So to get this balance between false-
17 positive/false-negative error we had to use or
18 logic to capture either the diagnosis or the
19 procedure. Fundamentally, the postoperative
20 respiratory failure sometimes is treated without
21 mechanical ventilation. Sometimes it's treated
22 with very high FiO2, with CPAP or other kinds of

1 interventions.

2 This is the problem. So when we tried
3 to apply a clinical definition from the VASQIP
4 program, we found that the best balance between
5 sensitivity and positive predictive value was to
6 use this or logic, using either the diagnosis
7 code or the procedure code.

8 Now we have about 20 percent of the
9 numerator cases that are identified based only on
10 the diagnosis code. I find it hard to believe --
11 I mean it's not impossible, but I find it hard to
12 believe, given that 80 percent also meet the
13 procedure criteria, that there are more than a
14 handful of hospitals that could reduce their rate
15 by 60 percent just by addressing the coding of
16 the diagnosis.

17 Maybe there are a couple out there at
18 the extreme, but overall we have only 20 percent
19 of the numerators being captured by the diagnosis
20 codes. The great majority are being captured
21 using procedure codes.

22 And as part of the audit study, we did

1 look at a stratified indicator of positive
2 predictive value -- what we're going to call the
3 marginal positive predictive value, which is what
4 is the PPV among the patients who have only one
5 criteria.

6 The patients who had only the
7 diagnosis criteria, their PPV was 79 percent
8 versus the patients who had the procedure
9 criteria, their PPV was 83 percent. Again, we
10 concluded that the difference between 79 percent
11 and 83 percent was not high enough at this time
12 to exclude the diagnosis code from the definition
13 of the indicator.

14 It was the results of the audit -- of
15 a series of audits, that have led to this kind of
16 incremental process of trying to refine the
17 indicator definition, but this is an ongoing
18 process and of course we welcome input from the
19 field.

20 DR. CIMA: The only thing I would say
21 is if you had asked the U.S. Army what an IED was
22 ten years ago, they had no plan for it.

1 So basically all these audits were
2 done, when this was developed -- which was almost
3 10 years ago, if not more. These insurgents have
4 developed a way around it and you have no data to
5 suggest that's not the case now, and that's what
6 I'm saying.

7 That's the problem with it, is when
8 these were developed in all good honesty and
9 integrity and everything and you guys were
10 looking at it to develop it through an already
11 existing database, that's great to develop it,
12 but I'm just telling you what the reality is in
13 the field. And you have no data to suggest
14 otherwise now, that it's not being gamed, and we
15 know it's being gamed.

16 I'm just saying that's the problem.
17 This has been recycled and recycled multiple
18 times. Circumstances on the ground and in the
19 field are different, and now we have to
20 understand whether it's valid. And I don't think
21 there is any data to suggest that it is.

22 DR. GUNNAR: The question I had raised

1 for the force of the Committee and the way
2 forward is in evaluating the validity, do we
3 evaluate the validity in perspective to its raw,
4 granular data or do we evaluate the validity in
5 relationship to the intent of the measure?

6 That there is enough data, it may not
7 be perfect, but does it drive improvement? Or
8 are we in an isolated way just looking at is this
9 valid information? I'd like a little on that,
10 and then Dr. Yates.

11 DR. YATES: To address that question,
12 I think you look at the validity in terms of the
13 intent and whether or not it has some -- it
14 captures what it's supposed to.

15 I think the granularity is critically
16 important, but I think that's part of the --
17 these measures are all going to evolve, and how
18 they're responded to is going to evolve. And
19 that evolution over time is something that has to
20 be captured and looked at.

21 When you see dramatic evolution, you
22 bring up the things that Robert has brought up,

1 and you address that and perhaps by better
2 capture.

3 This is a public forum. I just wanted
4 to say that not every change in reporting is
5 because of people being devious or trying to hurt
6 people or trying to hide things, which could be
7 implied, but I know you're not implying it.

8 But the fact is that regionally some
9 hospitals and locally some hospitals will have
10 the wrong language, and their coders pick up on
11 the language the wrong way. If they adjust the
12 language or they adjust how they're dictating or
13 how they're recording things, it doesn't mean
14 that they've changed their practice. They're
15 just better at coding.

16 There's a certain regression to the
17 mean that occurs with people learning that coding
18 counts. That may be part of this as well and
19 that's -- you're going to see that with the
20 puncture and laceration one that we're not
21 talking about, but if you add the words that this
22 was inherent to the procedure in entering

1 something it eliminates a lot of punctures and
2 lacerations.

3 DR. FLEISHER: Yes, I actually would
4 be curious. We want to be consistent. I don't
5 know if the staff has any comments, but the
6 second part is I think you've sent a clear signal
7 that we should make sure in the report that when
8 this comes back if this is approved they have to
9 do that testing is maybe a comment that I'm
10 hearing to ensure for threats to its validity in
11 the future.

12 And we should be clear in the report
13 if that's the comment. I just want to be
14 consistent across how we look at validity beyond
15 us.

16 MS. WILSON: I think you're making an
17 important point, Lee, which is if there are
18 threats to validity, if there is something that
19 you want the measure developers to consider, we
20 capture that in the comments of the report, and
21 it's a way of informing.

22 And just as AJ said, the measures are

1 evolving, and this is a way of informing them and
2 help drive that evolution and to keep these
3 issues in front of us as we continue to look at
4 these measures.

5 DR. GUNNAR: Dr. Yates, one last
6 comment.

7 DR. YATES: No, that's all.

8 DR. GUNNAR: Okay. Can we go ahead
9 and vote on validity then? Amy looks like she
10 can't.

11 MS. MOYER: I was just asking ----
12 related to what we're asking to be captured, are
13 we asking for anything that's measured with a
14 nonmedical record source to be validated back to
15 the medical record? Is that the level of
16 validity question we're asking? I just want to
17 make sure we're clearly stating.

18 DR. GUNNAR: I think all of that is
19 fair game, but you as a committee member voting
20 on this, you vote on it with the knowledge that
21 there may be issues with regard to validity that
22 make it your rating of high, moderate, low or

1 insufficiency, but also don't forget the impact
2 that it's that intent of the measure in
3 relationship to that data. Does that make sense?

4 Can we vote now?

5 MR. LYZENGA: All right. So we're
6 voting on validity. Your options are high,
7 moderate, low or insufficient.

8 I think that looks like all we're
9 getting. We can close it out.

10 We've got five percent high, 59
11 percent moderate, 36 percent low, zero percent
12 insufficient. So that passes.

13 And you can skip that. Skip that,
14 too. I think we're on over -- here we go.
15 Feasibility. So feasibility of implementation is
16 what we're considering here.

17 DR. DUTTON: It's drawn from
18 administrative data. So it's certainly feasible
19 to get that out of records. The fact that you
20 need a lot of different codes to know whether the
21 case is in or out makes it harder. So the burden
22 is relatively high, but I would say it is

1 feasible.

2 DR. GUNNAR: Hearing that, any other
3 discussion? Seeing none, go ahead and vote.

4 I think Cliff was out. So do you want
5 to vote on this, on the feasibility?

6 I think we go ahead and record it and
7 see.

8 MR. LYZENGA: Fifty-nine percent high,
9 41 percent moderate, and it passes on feasibility
10 and we move to usability.

11 The extent to which audiences use or
12 could use performance results for both
13 accountability and performance improvement
14 activities.

15 Any comments before we vote? It
16 doesn't look like it. Let's go ahead and vote?

17 MS. THOMASON: Is this -- I have a
18 question. The questionable validity and all the
19 conversation we had surrounding that, does that
20 come into play here at all, to say, at the end,
21 is this a usable measure? Or do we negate all of
22 that validity conversation and say --

1 DR. GUNNAR: I might frame it the
2 other way. What I hear is that yes, they're
3 using it. They're reacting to it and potential
4 reaction to it may actually diminish its validity
5 if you exclude your patients.

6 And then the last comment which came
7 from Kelsey was you can only do that so long. At
8 some point, you're going to have to react to the
9 actual people that are being included and who are
10 being measured.

11 Can we restart usability please unless
12 there are any other comment? Yes, Dr. Romano.

13 DR. ROMANO: Just again we heard two
14 things loud and clear that I think we'll take
15 back to the whole team.

16 One is that there is a desire and
17 interest to have a broader denominator that would
18 include a larger set of patients, including
19 patients with underlying lung disease or heart
20 disease. That may require a different measure or
21 different stratification of the measure.

22 The other thing that I think we heard

1 loud and clear is that there's a need for updated
2 evidence regarding validity. We can't rest on
3 the evidence from five, six, seven years ago.
4 And that before this measure comes back again
5 that NQF will expect a revalidation of the
6 measure to reflect current practice.

7 DR. GUNNAR: We'll go ahead and vote
8 on usability.

9 MR. LYZENGA: Do we get numbers here?
10 All right. We're going to have to go back and
11 examine that one, but it looks like it's a pass.
12 So now we're at overall suitability for
13 endorsement.

14 DR. GUNNAR: Any final comments?
15 Hearing none, please vote.

16 MR. LYZENGA: All right. Does the
17 measure meet NQF criteria for endorsement? Yes
18 or no?

19 We have 91 percent yes, nine percent
20 no. The measure passes, and before we break for
21 lunch, we wanted to make sure to take a moment to
22 get public comments.

1 Operator, can you let us know if we
2 have anybody on the line to make public comment?

3 OPERATOR: Yes, sir. If you would
4 like to make a comment please press star, then
5 the number 1 on your telephone key pad.

6 There are no public comments at this
7 time.

8 MR. LYZENGA: Okay. Is there anyone
9 in the room who'd like to make a public comment?
10 It does not appear that way.

11 So I think we are going to at this
12 point set aside Measure 236 for the moment and
13 allow you to grab a bite to eat for lunch, but
14 we're going to do a shortened lunch. Just about
15 15 minutes and then come back.

16 You can eat while we're continuing our
17 work, but we'll jump back into things around 1:00
18 p.m. So go ahead and grab some food and come
19 back to your places around 1:00 p.m. And we'll
20 get back going. Thank you. Off the record.

21 (Whereupon, at 12:43 p.m., the meeting
22 went off the record, and resumed at 1:08 p.m.)

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

2 (1:08 p.m.)

3 DR. FLEISHER: Our next measure --
4 we've done public comment. I think we're doing
5 great. The next measure is actually -- I think
6 0236. Correct?

7 DR. GUNNAR: Yes.

8 DR. FLEISHER: I'm going to recuse
9 myself because I worked on this I think
10 originally. I was on the TEP. Is this -- which
11 measure is this? Was this developed by
12 Pennsylvania?

13 PARTICIPANT: Yes.

14 DR. FLEISHER: I was on the -- I
15 chaired the original TEP. So perhaps you should
16 -- and I should recuse myself from this measure.

17 DR. GUNNAR: Do we have it? The
18 measure is 0236, CABG: Preoperative beta-blocker
19 in patients with isolated coronary bypass graft
20 surgery. And CMS is the developers. If you
21 would like to begin.

22 DR. BERG: Sure. I guess as you did

1 this morning you want us to introduce ourselves
2 and we have some people on the phone as well.

3 I'm Sven Berg, I'm the Chief Medical
4 Officer at the West Virginia Medical Institute.
5 We are the parent company for Quality Insights of
6 Pennsylvania, who is the original measure
7 developer for this measure, and with me is Jane
8 Lucas.

9 MS. LUCAS: Hi, Jane Lucas. I'm a
10 project manager at Quality Insights of
11 Pennsylvania.

12 DR. BERG: And we have some folks on
13 the phone as well. So I'll ask them to chime in
14 and introduce themselves.

15 MR. CRAWFORD: This is Al Crawford
16 from Thomas Jefferson University.

17 DR. BERG: Thank you, Al.

18 MS. DETLANA: This is Hiro Detlana
19 with Quality Insights of Pennsylvania.

20 DR. BERG: And, Gary, are you on the
21 phone?

22 MR. REZEK: Gary Rezek, yes. Thank

1 you, Dr. Berg. My name is Gary Rezek. I work
2 for Quality Insights of Pennsylvania.

3 DR. BERG: And our person from CMS
4 actually had to drop off because she had another
5 call at 1:00 p.m. Quality Insights of
6 Pennsylvania will represent CMS today.

7 I was going to open with something,
8 since we were originally scheduled to be doing
9 this this morning. I was going to say something
10 about being the only thing between you and lunch,
11 but I don't have that at this time.

12 Now I can just say that I remember
13 back to medical school days and eating on the run
14 when I was doing surgery rotations, and I see
15 that nothing has really changed from that either.
16 You were only given ten to 15 minutes to have
17 lunch before reconvening, but we appreciate being
18 here this afternoon and having the opportunity to
19 present this measure.

20 On behalf of CMS and the measure
21 developers, Quality Insights of Pennsylvania, I'm
22 pleased to reintroduce NQF 0236: Preoperative

1 Beta-Blocker in Patients with Isolated Surgery
2 for consideration for NQF reendorsement.

3 The measure was first implemented in
4 the Physician Quality Reporting System, PQRS, in
5 2007 in an effort for specialist to report
6 measures that address the relevant clinical
7 strategy. Since then the measure has been
8 expanded to include use by anesthesiologists.

9 The intent of this process measure is
10 that a beta blocker would be received within 24
11 hours prior to an isolated coronary artery bypass
12 graft surgery. The denominator of this measure
13 is isolated CABG surgeries for patients 18 years
14 and older.

15 The reporting requirement is each time
16 an isolated CABG procedure is performed during
17 the 12 months reporting period. And this is done
18 by way of administrative claims or a registry.

19 The American College of Cardiology
20 Foundation and the American Heart Association
21 2011 Clinical Guidelines on Myocardial
22 Revascularization support the use of beta

1 blockers and the use of them administered at
2 least 24 hours before CABG to all patients
3 without contraindications to reduce the incidence
4 or clinical sequela of postoperative atrial
5 fibrillation.

6 Postoperative atrial fibrillation is
7 a common complication following cardiac surgery
8 occurring in 25 to 40 percent of patients and has
9 been associated with increased rates of
10 postoperative morbidity and mortality and
11 consequently increased costs.

12 The prophylactic administration of
13 beta blockers has been shown to reduce the risk
14 of postoperative atrial fib and mortality
15 following isolated coronary bypass graft surgery,
16 and a review of the literature revealed that
17 there was an 19.5 increase in preoperative use of
18 beta blockers from 2000 to 2009.

19 We appreciate the opportunity to
20 review the measure with you today and we look
21 forward to your comments and questions.

22 DR. GUNNAR: We have Dr. Olsen and Dr.

1 Roth.

2 DR. OLSEN: If we just start with the
3 evidence, the risks of postoperative atrial fib,
4 about 25 to 40 percent. And as we've already
5 heard, there are clinical practice guidelines
6 that recommend that beta blockers be administered
7 anywhere from 1B to 2B to 1A recommendations.

8 I would say that there's also a 2012
9 meta-analysis that says although there's a
10 substantial risk reduction that it was not
11 statistically significant. Another paper
12 published in 2014 said although the burden of
13 supraventricular arrhythmias can be reduced there
14 is really unclear evidence on mortality, AMI,
15 stroke, heart failure, hypertension, bradycardia,
16 and a couple of other new papers with atrial fib
17 were not statistically significant as well.

18 DR. GUNNAR: Dr. Roth.

19 DR. ROTH: Not much to add to it.
20 Again, the concern is that actually disparity of
21 the literature, although the literature that was
22 provided supported mostly Class B evidence.

1 That's not surprising considering that the meta-
2 analysis not being statistically significant
3 certainly caught my attention.

4 DR. SIPERSTEIN: I'd just like to
5 comment in general about beta blocker payment.
6 Obviously, some of the initial studies on beta
7 block paid for noncardiac surgery were
8 exceptionally optimistic, and then a whole host
9 of subsequent studies have basically come to an
10 opposite conclusion that it really plays minimal
11 if any risk on perioperative morbidity and
12 mortality, and obviously a lot of those measures
13 have retrenched as well.

14 I guess the question I really have is
15 for those have studied the literature in detail
16 what is the evolving state of the art in terms of
17 the literature, in terms of whether this practice
18 really improves morbidity and mortality despite
19 the fact that at its inception various societies
20 endorsed it.

21 Yes, it's become more of a routine
22 part of practice, but I'm really interesting in

1 whether the follow-up studies have really
2 continued to support its use.

3 DR. GUNNAR: That is an interesting
4 question, and Fred should address this as well
5 and Dr. Handy. The overall mortality risk now in
6 elective coronary bypass grafting is remarkably
7 low. It's one percent or less. And from the STS
8 for VA's data from whatever you want to look at,
9 that's come down substantially in the last 10
10 years.

11 The question is where does any single
12 component of that play in, and does beta blocker
13 use 24 hours beforehand, what part does that
14 play? And I think you're never going to be able
15 to distinguish that at this point forward. And
16 I'm not sure there would be -- would anyone ever
17 put a randomized control study of -- nowadays no
18 beta blocker versus beta blocker?

19 DR HANDY: The literature is best vis-
20 a-vis strictly A-Fib for amiodarone. Most
21 programs are focused on amiodarone, not beta
22 blockade.

1 DR. GROVER: You're right. I think
2 there was more initial enthusiasm for this than
3 now. Having said that, however, I'm not quite
4 sure that the administration preoperatively --
5 the way it's being done is the way envisioned by
6 the ACC/AHA guidelines.

7 And the measures -- and we struggle
8 with this in our STS measure a little bit too.
9 It's hard to show a difference in mortality and
10 yet if somebody goes into atrial fibrillation
11 postoperatively, they have a lower ventricular
12 rate and they're -- I think, more easy to
13 control. You usually do can most of that by just
14 increasing or modulating up the beta blockers.

15 But it is right now still a guideline,
16 ACC/AHA guideline, and I think it's useful from
17 that standpoint, but probably we need to
18 determine how many of these patients that are
19 say they have pre-op for either you or us get it
20 in a very short period of time and how many are
21 loaded over a day or two beforehand. In other
22 words, the dosing, it's not just being done

1 acutely right preoperatively is an issue.

2 I mean you're an anesthesiologist, I
3 might throw this back to you, too. What are your
4 thoughts with the anesthesia?

5 DR. FLEISHER: Actually, Chair, for
6 the last two versions, the noncardiac guidelines.
7 We've written extensively on this and I don't
8 think you should extrapolate from the noncardiac
9 to the cardiac. So that's my only comment.

10 DR. SIPERSTEIN: That wasn't my
11 intention at all, but simply the fact that there
12 is some initial reports that are very
13 enthusiastic guidelines get set and then
14 subsequent studies may not support them.

15 We saw a little bit of that here in
16 that we've seen some subsequent studies that did
17 not seem to show a statistically significant
18 difference.

19 DR. FLEISHER: There is actually a
20 paper out of Mark Neumann from Penn showing how
21 frequently ACC/AHA guidelines get modified. And
22 it's only in a level of evidence B class 1 it's

1 about seven percent in subsequent guidelines.

2 But you're right. As of now, I know
3 the guidelines exist.

4 DR. GROVER: I wouldn't change things
5 right now. I think it's still a personally
6 useful measure. I just think we ought to define
7 it a little better and be sure that it's being
8 given as recommended in the guidelines.

9 DR. OLSEN: I can stand corrected, but
10 I believe this is an extension of the 0127. And
11 now the proposal here is to expand it into the
12 outpatient area as well.

13 DR. FLEISHER: I think you're talking
14 about the SCIP measure because this I don't think
15 is the outpatient. There is an outpatient
16 measure, but that's for noncardiac surgery.

17 Can we look up 0127?

18 DR. ROTH: Actually, is it 0117, the
19 beta blocker at discharge that we're referring
20 to? And you have to help me with this. On the
21 agenda, there's also a harmonization discussion.
22 Is that what it's referring to is 0117.

1 MS. FELDMAN: You have a document that
2 was provided in your copies that is a measure
3 comparison table, and the first page is 0127 and
4 0236.

5 MR. LYZENGA: Remember, we're
6 discussing this measure first and then should we
7 recommend endorsement of it, then we'll move onto
8 the discussion of harmonization with 0127.

9 DR. GUNNAR: And just remind me. 0127
10 comes up this time or is it a endorsed measure
11 that's currently endorsed?

12 MR. LYZENGA: Currently endorsed.

13 DR. GUNNAR: Okay. So the
14 harmonization is not another measure that we will
15 consider. It's to a measure that's currently
16 endorsed. Okay. We should bookmark that,
17 address this separately.

18 Any further discussion on evidence?
19 Amy.

20 MS. MOYER: My question was more on
21 the outpatient item. I believe what this is is
22 it's not a measure of things happening

1 outpatient, but the claim source is outpatient
2 from the physician practice group. Is that
3 correct?

4 DR. BERG: This was originally
5 developed as an outpatient measure and is an
6 outpatient measure.

7 DR. GUNNAR: Any further discussion?
8 Let's vote. Technical difficulty.

9 MR. LYZENGA: Just wanted to make sure
10 we had the right slide. In fact, we've come to a
11 decision that we're going to leave that fifth
12 option off for now.

13 If it comes up that we have
14 insufficient evidence in the voting on the first
15 four options, then we'll consider an exception,
16 but right now, we'd ask you just vote on those
17 first four: high, moderate, low or insufficient
18 evidence.

19 DR. GUNNAR: For this process. We'll
20 miss one. So 22 is a complete vote.

21 No one else is recused, right? I
22 think that's right. All right. Here we go.

1 MR. LYZENGA: Did we get results?

2 Okay. I think we're going to need to revote on
3 that one. If you could cast your vote again on
4 evidence.

5 I think that was it. It will be a 21
6 if you can stop it there. Oh, 22. All right.
7 We have 27 percent for high, 55 percent for
8 moderate, 14 percent low and five percent for
9 insufficient. So the measure does pass on
10 evidence, and we can move on to opportunity for
11 improvement.

12 Again, this is whether a performance
13 gap demonstrates quality problems and opportunity
14 for improvement or overall low performance.

15 DR. GUNNAR: Dr. Olsen.

16 DR. OLSEN: In 2012 we were at an
17 average of 95.5 percent compliance rate. Rural
18 with 98.2 versus urban 91.8, and 31 percent of
19 the providers were reporting.

20 It certainly appears the high
21 compliance rate with what's currently being done.

22 DR. GUNNAR: Dr. Roth, any other

1 comments?

2 DR. ROTH: Nothing to add.

3 DR. GUNNAR: I'll be proactive. Is
4 this measure topped out?

5 DR. SAIGAL: I would say that it's not
6 because you've only got one-third of the people
7 reporting.

8 DR. DUTTON: Yes, exactly my point.
9 It's topped out among people who reported.

10 DR. YATES: Yes, words out of my
11 mouth.

12 DR. GUNNAR: Let's go to the vote. Is
13 there any other discussion?

14 Okay. This is performance gap on this
15 process measure. There we go, 22.

16 MR. LYZENGA: I think we can close it
17 at this point. So we have 23 percent high, 45
18 percent moderate, 32 percent low, zero
19 insufficient.

20 So the measure passes on performance
21 cap, and we can go ahead and move on to
22 reliability. It's the first part of scientific

1 acceptability.

2 DR. OLSEN: In reliability testing,
3 the averages were about -- the reliability score
4 was 0.85 with a 1.0 max from the registry
5 reporting and 0.99 from claims-based reporting.
6 Of course, this is based on the cohort that was
7 reporting to the registry.

8 DR. GUNNAR: Any other discussion?
9 We'll go ahead and vote.

10 DR. ROTH: It's the same situation as
11 the reliability of those that are reporting.

12 DR. GUNNAR: We will go ahead and
13 vote. Yes. I think we collected the data and
14 it's reliable.

15 MR. LYZENGA: Did we get a result on
16 that? All right. I think we have to retry
17 again. Sorry, one more vote on reliability.

18 Is that it? Can we close it up? I
19 think we're having technical difficulties again.
20 Sorry, we thought we had a smoother system this
21 time. It's not turning out so great. Maybe we
22 can take a hand vote on this one again.

1 So let's see a count of hands for
2 reliability -- those who think it has high
3 reliability.

4 I've got five for high. Okay, and
5 moderate.

6 PARTICIPANT: One vote from the phone.

7 MR. LYZENGA: Okay, 15 for moderate,
8 and low.

9 One for low, and insufficient. Zero.
10 So that passes on reliability. We'll move onto
11 validity.

12 Are there any comments on validity?
13 This is whether the specifications are consistent
14 with the evidence and the measure yields
15 credible, valid results about the quality of
16 care. This also includes exclusions, risk
17 adjustment and other threats to validity.

18 DR. OLSEN: I think as a process
19 measure it does what it's set out to do and
20 capture the number of patients that receive beta
21 blockers, and exclusion was left up to the
22 prescribers. About 4.4 percent of patients were

1 excluded from the denominator.

2 DR. GUNNAR: Any discussion?

3 MS. PITZEN: Just a question and a
4 comment. Let's see.

5 The validity testing was from several
6 years ago in 2010 and the inter-rater agreement
7 rate between what was submitted and what was
8 abstracted was at 64.2 percent. That's a little
9 bit on the low end and would tend to lead one to
10 maybe question the ability or feasibility to
11 collect that data, and then an additional
12 comment.

13 This is just in general. I know many
14 of the PQRS measures have a wide, open physician-
15 can-document-any-reason for contraindication.
16 It's been our experience that when those
17 contraindications are better defined and
18 specified you have a stronger measure.

19 DR. GUNNAR: Any other comments? Dr.
20 Yates.

21 DR. YATES: Given the fact that only
22 about 30 percent of the surgeons are reporting,

1 we have to wonder if those that aren't reporting
2 are doing so because they don't use beta blockers
3 or they're reusing amiodarone or because the
4 literature has evolved to where they don't feel
5 the need to give it.

6 And it's not going to change the
7 validity for those 30 percent that ---- in the
8 statistics that support that 30 percent that
9 respond, but again this would be one of those
10 tiered answers in validity.

11 You wouldn't want to make this
12 something that becomes a required PQRS or applied
13 for hospital quality in comparing hospitals, if
14 there's only 30 percent of surgeons replying.

15 Now I'm correct in that 30 percent,
16 right? And if that's the case, then this should
17 be one of those tiered questions. So I would
18 answer it's valid for those people that answer.

19 It means something to them and they
20 have answered correctly or incorrectly, but for
21 those that don't report we don't know, and it
22 needs further study. Someone should do a poll of

1 STS members as to how many people use beta
2 blockers anymore.

3 DR. CIMA: Can I turn that around to
4 say that due to the fact that 60 some percent
5 don't report impacts of validity of the measure
6 in its entirety in relationship to its outcome
7 and driving quality.

8 DR. YATES: The surgeons have voted
9 with their feet in terms of how valid they think
10 it is. So I have -- I'm always loathed to be one
11 of the ones that throws a measure out of the bus,
12 but I'm trying to say that I think that's a big
13 deal that so many people aren't replying.

14 It means they've decided it's not a
15 valid thing to be worried about and reporting.

16 MR. LYZENGA: This can also be
17 considered a question of use again, in the use
18 and usability of the measure, but I mean if
19 you're construing it as a question of validity I
20 think we can --

21 DR. YATES: Yes, it probably goes to
22 usability more than validity because the validity

1 is inherent to what you have statistically, but
2 I'm going to face validity. Does it pass the
3 sniff test? And so that's just raises an issue.

4 DR. GUNNAR: I would say that the
5 validity is impacted by the data that you receive
6 in relationship to its overall -- I don't know
7 how valid 95 percent is in relationship to the
8 fact that only 30 percent of the -- we only get
9 reporting of 30 percent.

10 DR. SAIGAL: Are we testing the
11 validity measure as reported and how that
12 measures, you know, what we think that measures.
13 And it's not reported we can only count on it
14 that it's not used.

15 MR. LYZENGA: Right. I would say
16 that's accurate, and that's a decision made by
17 clinicians they have ---- as I understand the
18 PQRS program, they can select from a slate of
19 measures that they choose to report on.

20 DR. SAIGAL: If they chose to report
21 it, the data we have now is what we have now.
22 You had a question about the validity of that

1 data. You said that you had some concerns about
2 that. Is that right?

3 And would you say that on the data
4 that we have now is it strongly valid or weakly
5 valid? Or would you vote for it or not?

6 MR. LYZENGA: Is that question for
7 everyone?

8 DR. SAIGAL: For the presenter.

9 MR. LYZENGA: Sorry. Could you repeat
10 the question?

11 DR. SAIGAL: I think it was Collette,
12 am I right, that mentioned that? Did you say
13 that you had a problem with the validity of the
14 measure?

15 You had some data that you were
16 concerned about? So would you vote for it or
17 not?

18 MS. PITZEN: I would tend not.

19 DR. BERG: Let me provide just a
20 little additional information because there was
21 additional ---- and I believe this is part of the
22 package as well that when the medication

1 administration record was looked at as well the
2 documentation was found therein.

3 So the inter-rater reliability with
4 the addition of the MAR to the data it improved
5 from the 64 percent that you're talking about to
6 an 87.8 percent.

7 MS. PITZEN: Thank you for the
8 additional point, but of what of the whole does
9 that represent?

10 Because when you're saying your inter-
11 rater reliability agreement is 64 percent, then
12 to me that would mean that not many people were
13 using the medication administration record. Is
14 that a correct assumption?

15 DR. BERG: With the medication
16 administration record, originally when our
17 reviewers ---- so when we look at inter-rater
18 reliability we're comparing between different
19 reviewers and we're comparing our reviewers to
20 the other reviewers as well, the people who were
21 reporting.

22 With the addition of the MAR, our

1 reviewers were not originally looking at that.
2 When we made it a requirement to look at the MAR
3 as well, then the inter-rater reliability
4 increased.

5 This measure comes from registry data
6 and et cetera, and so what we are doing when
7 we're looking at that and assessing the
8 reliability and validity of the measure then is
9 we're trying to determine whether the information
10 in the record supports the decision that was
11 entered into the registry by the hospital or the
12 claims data. We needed that additional piece of
13 information to show that the measure was valid.

14 Obviously, we can't tell you what was
15 in the minds of the people who were actually
16 reporting it to the registry, but what we can
17 report is that when our reviewers were looking at
18 the MAR, then the IRR improved.

19 MS. PITZEN: Okay. This is Collette.
20 Then I amend my previous comment because the MAR
21 would be the source of the data.

22 And just kind of comment or feedback

1 is we do a lot of validation in Minnesota as well
2 and we're validating against data received versus
3 what's actually in the medical record. Anything
4 you can do in the future to outline that would be
5 great. Thanks.

6 DR. REZEK: This is Gary Rezek. If I
7 could just say a quick word about that. I think
8 that 64 percent speaks more to our methodology
9 than it did the actual validity of the measure
10 because our measures are typically outpatient
11 measures.

12 This of course is ---- our sample of
13 providers who we requested documentation from
14 were from part B record. We requested medical
15 documentation to support the numerator code or
16 the code they reported, and we think what was
17 going on is the medical records were often in the
18 inpatient setting, and I think it was just
19 difficulty in obtaining those records and
20 submitting them to us.

21 We didn't often get the parts of the
22 medical record that we were requesting and it

1 took several rounds of requests for further
2 information before we began to really get the
3 documentation that we needed to validate the
4 measure.

5 DR. GUNNAR: Any other comments?
6 Seeing none, let's go ahead and vote on validity.

7 MR. LYZENGA: All right. Fingers
8 crossed here. Yay, all right.

9 We've got nine percent high, 64
10 percent moderate, 27 percent low and zero
11 insufficient. The measure passes on validity, so
12 now we'll move to feasibility.

13 DR. GUNNAR: Any comments, Dr. Olsen?

14 DR. OLSEN: The only thing I would say
15 is that if we think that the records can be
16 accessed readily then the feasibility should go
17 right in line with that.

18 DR. GUNNAR: Gary.

19 DR. ROTH: The same comment other than
20 of course what we're hearing with the disparity
21 of the data that we're receiving. I might
22 suggest that feasibility has been limited for

1 now.

2 DR. GUNNAR: Any additional comments?

3 Go ahead and vote. Yes, Dr. Yates.

4 DR. YATES: I was just going to make
5 the comment that that's part and parcel part of
6 the problem with PQRS for specialists which
7 hasn't been a smooth transition for this process.
8 It hasn't been real easy to involve specialists
9 with the PQRS process. It hasn't been smooth.

10 DR. GUNNAR: Go ahead and vote.

11 MR. LYZENGA: We are voting on
12 feasibility.

13 We have nine percent high, 73 percent
14 moderate, 18 percent low and zero insufficient.
15 So the measure passes on feasibility, and we'll
16 move onto use and usability.

17 DR. GUNNAR: And usability.

18 DR. OLSEN: Since it's a process
19 measure, all it is is measuring whether people
20 were compliant with beta blockers or not. So
21 there's no strict outcomes associated with
22 the process measure.

1 DR. GUNNAR: And I believe there was
2 other discussion you can apply to this. Amy.

3 MS. MOYER: Circling back to earlier,
4 I decided my comment belonged better here, and I
5 think it builds on what Dr. Yates was saying.

6 I don't think we're necessarily seeing
7 surgeons voting with their feet away from this
8 measure. I think we're kind of seeing them
9 voting with their feet away from PQRS. As I
10 understand it, participation has been low in
11 general in the program.

12 So it's not like they're saying, oh,
13 I don't want to use this measure. It's not good.

14 DR. ROTH: Not only are they voting away
15 from PQRS, but also just that the management ----
16 I can use the state of Michigan as an example.

17 We have a very extensive statewide
18 cardiothoracic collaborative where every hospital
19 participates in it that performs cardiac surgery,
20 and it's all about amiodarone. They don't even
21 discuss beta blockade, as was mentioned earlier.

22 I think if you looked at our state

1 we'd see that we probably are part of those that
2 are not participating in this measure.

3 DR. YATES: And just to follow up what
4 I said, it's not something that they can walk
5 away from. They're going to have to participate
6 in PQRS as time goes by, and there hasn't been a
7 lot of different specialty-specific PCQMs or
8 other vehicles to report PQRS through.

9 If you have one and it's gone through
10 all these steps up to this point, I would beg
11 that everyone allow it to stay in place for the
12 cardiac surgeons to have at least another PQRS
13 that they can use when they report that's at
14 least applicable to what they do.

15 DR. GUNNAR: I think it would hard to
16 say it's not a measure when it's still a process
17 measure still in the guidelines. Fred.

18 DR. GROVER: I am conflicted here, but
19 it is part of the STS composite score for a
20 process of care.

21 When my colleagues are here tomorrow,
22 it might be interesting to ask them what

1 percentage of people ---- I'm pretty sure
2 virtually 100 percent report it because it's one
3 of our metrics in the composite.

4 The question would be what is the
5 level of compliance. It can be a tough one if
6 you're getting patients transferred in and out of
7 other hospitals.

8 DR. GUNNAR: I think that's
9 interesting because my impression was it was
10 topped out. I mean I was ---- a little from the
11 STS perspective, but that was my bias. So I
12 shouldn't bring that in.

13 DR. GROVER: As I said, I think the
14 enthusiasm for it isn't as high as it was a few
15 years ago as has been state, but I don't know
16 that anybody's come up with the evidence to
17 eliminate it by any means.

18 DR. GUNNAR: Right.

19 DR. GROVER: And it's in the
20 guidelines.

21 DR. GUNNAR: What's interesting is
22 that the data in the noncardiac patient

1 population hasn't influenced, at least in the
2 thirty ---- in the people who report this, it
3 hasn't influenced their actions. Right? The
4 compliance is still going on.

5 DR. GROVER: And this doesn't mean
6 that you can't still just amiodarone in the
7 postoperative period for the purposes of atrial
8 fib.

9 DR. GUNNAR: All right. Any other --
10 Amy, yes.

11 MS. MOYER: I went to the STS's site
12 because I was curious and this is ---- you know,
13 perioperative medicines is supposed to be
14 reported. And there's at least enough radiation
15 to have all of the star groups represented in the
16 publicly reported results. There's ones and twos
17 and threes.

18 DR. GUNNAR: Any other comments?
19 Chris, you had your -- okay.

20 Let's go ahead and vote.

21 MR. LYZENGA: We have nine percent for
22 high, 73 percent moderate, 18 percent low and

1 zero insufficient information. The measure
2 passes on usability and use.

3 We can go ahead and discuss the
4 question of overall suitability for endorsement
5 or just vote on it if there are no further
6 comments.

7 DR. GUNNAR: I think we can go ahead
8 and vote.

9 MR. LYZENGA: 77 percent yes, 23
10 percent no. The measure passes. Thanks to our
11 stewards.

12 DR. FLEISHER: I think you heard the
13 concerns of the Committee with regard to what
14 would be required the next time it comes back.

15 DR. BERG: I agree, and it certainly
16 will be comments that will go to our technical
17 expert panels the next time as well.

18 Just thinking about it, there may be
19 increase in exclusion criteria utilizing other
20 alternative -- appropriate alternative
21 medications, et cetera.

22 So perhaps the use of amiodarone as an

1 exclusion criteria might be something that would
2 increase the validity of this, but we'll go back
3 to the TEP and see what they say.

4 MR. LYZENGA: Now we had placed an
5 item on the agenda to discuss harmonization. I
6 don't know if everybody has had a chance to take
7 a look at this comparison table, but we have sort
8 of a side-by-side look at the two measures that
9 we've identified as being related or potentially
10 competing, 0127 and 0236.

11 The 0127 is preoperative beta
12 blockade. That's an STS measure. I understand
13 that's in the composite, and then the measure
14 that we just discussed.

15 Really we're just actually looking for
16 some feedback from the developers on whether this
17 has been -- the specifications here, harmonized
18 with the STS measure. To the extent that they
19 have not, is there a plan to do so? Or is there
20 a justification or rationale for not doing so?
21 Share your thoughts on the need for harmonization
22 in general.

1 MS. LUCAS: Yes, we've reviewed the
2 other measures that we submitted on the form and
3 several of them, 0017, is beta blockade at
4 discharge. So that has the patient coming from
5 the inpatient setting, and the target population
6 is the same.

7 However, as I said, it's a beta
8 blocker at discharge and our measure focuses beta
9 blocker within 24 hours prior to surgical
10 incision.

11 As far as 0117, that is a registry
12 reporting only option, and our 0236 is a claims
13 and registry reporting option. 0119 is risk
14 adjusted operative mortality for CABG. So the
15 measure focus is different.

16 I think after reviewing even the
17 composites we felt that the closest one to 0236
18 is 0127.

19 MR. LYZENGA: I believe so, that's the
20 one we had identified as well, 0127.

21 MS. LUCAS: Right. However, that one
22 is -- I believe that is inpatient and registry

1 only and ours is outpatient.

2 MR. LYZENGA: Just for our sake, to
3 clarify, this is an outpatient only measure.

4 MS. LUCAS: Yes.

5 MR. LYZENGA: I think the submission
6 form does indicate that it is applicable to the
7 hospital, acute care facility. So maybe we'll
8 just ask you to correct that.

9 DR. YATES: We are discussing
10 harmonization. My one comment ties into what I
11 have said earlier in that to date, at least last
12 year, we heard STS say time and again on each of
13 their measures that they didn't feel comfortable
14 breaking that out into surgeon-specific data.
15 They felt only comfortable going by program or
16 hospital.

17 As such, if this is a measure that
18 addressed the ability of the surgeon to report to
19 PQRS, they're meeting this measure then I think
20 there is room to keep both measures and there's a
21 need to because there's again a dearth of
22 surgical specialty measures within which to

1 report in the vehicle of PQRS. So I think it
2 should be protected.

3 DR. DUTTON: I will go even a little
4 further. One big difference between these two
5 measures is that anesthesiologists are able to
6 report this one because CPT codes anesthesia for
7 cardiac surgery have been included here, whereas
8 they're not included in the STS measure.

9 It makes a difference from our
10 perspective and anesthesiologists are very often
11 the ones giving the beta blockers or writing pre-
12 op medication orders.

13 DR. GUNNAR: Any others?

14 DR. CIMA: If they were to have them
15 rechange it from the acute setting and take that
16 out, then the anesthesia providers would be
17 excluded because they're giving them the beta
18 blocker in the acute setting and not in the
19 outpatient.

20 I'm still trying to figure out how a
21 CABG is an outpatient. In my level of training I
22 have yet to see an outpatient CABG done. I'm not

1 sure about why we are even discussing this as an
2 outpatient.

3 DR. YATES: I think that means that
4 they're outpatient up to the moment of day of
5 admission.

6 DR. CIMA: That's on the
7 anesthesiologist side.

8 DR. YATES: Right, but it depends on
9 your definition as to when inpatient starts.

10 DR. DUTTON: Bob, this may explain the
11 difference between 64 percent in the outpatient
12 pharmacy record and then we add the MAR, which is
13 where it would appear when the anesthesiologist
14 administers it.

15 DR. CIMA: Because if you use the SCIP
16 data on administration of beta blockers before
17 CABG that was basically almost topped out. So
18 I'm trying to figure out how those things are
19 different.

20 This is not saying the patient came to
21 the cardiac surgeon on a beta blocker. This is
22 just saying did they get a beta blocker within 24

1 hours. It just depends on how you define that 24
2 hours. Usually it's within incision, but a lot
3 of institutions it was the morning of. If they
4 didn't take the beta blocker within the last 12
5 hours, they're getting a beta blocker in the pre-
6 op hold.

7 I'm just trying to figure out why does
8 it make a difference if this is an outpatient or
9 whatever. Why not just use the same definition?
10 Twenty-four hours before incision. Some
11 hospitals don't count incision as an inpatient
12 activity. It's only when they hit the recovery
13 room or the ICU.

14 How you decide whether outpatient or
15 inpatient it's dealer's choice, and so it's
16 basically 24 hours before incision. That's sort
17 of what it comes down to.

18 If you take it from an outpatient
19 setting, then the anesthesia providers are going
20 to get -- I'm not trying to see -- I'm trying to
21 figure out what the difference are here.

22 MR. LYZENGA: I guess I would turn to

1 the developers.

2 DR. BERG: It's a good question.

3 MR. LYZENGA: It sounds like there is
4 some consensus that we're comfortable having both
5 measures. The 0236 is important and it provides
6 an avenue for specialists and individual
7 clinicians to report to PQRS outside of the
8 inpatient setting

9 DR. GUNNAR: Do you want to vote on
10 that?

11 MR. LYZENGA: I don't think we need to
12 take a vote on it. This was really just for
13 purpose of discussion, clarification, and sort of
14 to inform our report.

15 That can be a recommendation of the
16 Committee if you would like to recommend
17 harmonization between the STS measure and the CMS
18 measure. This was a good question about the care
19 setting. I'm not sure how harmonization works in
20 that instance.

21 Usually we would say if it's two
22 different care settings then they're not

1 competing measures, but I guess there would still
2 be an opportunity for harmonization there I would
3 imagine.

4 So I guess that's something we can
5 pose to the developers and to STS tomorrow what
6 kind of opportunity there is for harmonization of
7 those two measures. I don't know.

8 I turn to Melinda and Marcia, too, if
9 you have any thoughts.

10 MS. MURPHY: I would say to Dr. Cima,
11 can you articulate what harmonization of the two
12 measures would be that you might recommend for
13 the Committee to consider.

14 DR. CIMA: I don't know. Maybe just
15 to have more measures to have more measures is
16 probably not a good idea. Why not just have one
17 measure that does the same thing and that's what
18 these basically do. So why have two on the
19 records, just have one?

20 I'm sure we will hear it from the STS
21 tomorrow, because they always say it, 98 percent
22 of all cardiac surgeons are members of the STS.

1 So the data is there. The last time we were here
2 the reason we had to have separate ones from CMS
3 was because we only care about 65 years old, but
4 STS has age in it.

5 We can figure out ---- with an Excel
6 sheet, I can sort from age and then I can draw a
7 line. I'm just saying we should simplify as well
8 as do the right thing, and they're the same
9 measures. They're basically the exact same
10 measures.

11 It just has subtle differences in
12 wording which to lawyers makes sense, but to
13 people on the street makes no sense.

14 MS. MURPHY: Are you then saying --

15 DR. CIMA: There should be one
16 measure.

17 MS. MURPHY: Yes, one measure which is
18 different than harmonization which would be
19 having them look very similar. We're talking
20 about having a single measure.

21 DR. FLEISHER: If I could just comment
22 because CMS is not here and this is a CMS -- no,

1 CMS is not at the table.

2 MS. MURPHY: Right.

3 DR. FLEISHER: Besides STS.

4 MS. MURPHY: Right.

5 DR. FLEISHER: And what you're really
6 asking is can CMS use the STS dataset, which I
7 think is a question that is beyond the scope of
8 this committee, but is something that we can
9 communicate.

10 And if you can also communicate to
11 CMS, I think that would be a ---- is that your
12 question? Okay. No, if that's a great question,
13 we should move on but forward that to CMS.

14 MS. MURPHY: And we can do that and
15 have a conversation with the STS and then the
16 Committee when it next convenes, a conference
17 call, whatever, to consider. Okay.

18 DR. FLEISHER: Thank you. Did you
19 have a -- you always look --

20 MS. MOYER: I'm thinking. I guess in
21 additional question I might have is this is a
22 PQRS measure, and I believe that would then allow

1 an individual surgeon or anesthesiologist or
2 whoever to say, yes, this can be posted on
3 physician compare -- when we get to that, and
4 this could be publicly reported. How useful a
5 general person might find that, I'm not sure.

6 I'm wondering what the similar
7 requirement might be to individually report, if
8 the surgeon wanted to, their results out of STS.
9 If they need to get like facility signoff or
10 signoff from their group, that potentially could
11 be a barrier that could exist for that source
12 that might not exist for this. I don't know that
13 it is, but it's something I'd be interested in
14 hearing about.

15 DR. FLEISHER: I think that's actually
16 beyond the scope of what our focus is, but we can
17 forward that on.

18 Fred, did you want to comment?

19 DR. GROVER: I was just going to say
20 in terms of PQRS we for a number of years have
21 had a way where the STS database can -- when our
22 members request that, that data is transferred

1 without them having to do anything. Other than
2 that, it's straight into PQRS.

3 We don't count that as part of our
4 regular public reporting business because it's an
5 individual surgeon's preference, and what we
6 count as public reporting is what we do through
7 Consumers Union and through our own website.

8 DR. FLEISHER: Thank you. We have two
9 hours to get through five measures. We seemed a
10 little postprandial, but hopefully we can get
11 some energy back. Thank you very much.

12 We next have perioperative anti-
13 platelet therapy, SVS. Is SVS here? Great.

14 I think the next four measures are
15 process measures. Correct?

16 MR. LYZENG: Yes.

17 DR. FLEISHER: And then we have an
18 outcome measure. Marcia, did you have a comment?
19 Dr. Jarrett?

20 DR. JARRETT: Yes, I'm on the phone.

21 MS. WILSON: Hi, Dr. Jarrett. This is
22 Marcia Wilson with the National Quality Forum.

1 Earlier this morning, all the Committee members
2 had a chance to do an oral disclosure of any
3 professional activities that might be relevant to
4 the subject matter before the Committee.

5 If you would be so kind as to state
6 your name, who you're with and disclose any
7 activities that we need to know about, please.

8 DR. JARRETT: Sure. I'm Dr. Mark
9 Jarrett with the North Shore LIJ Health System,
10 and I have no conflicts to disclose regarding any
11 of these measures.

12 MS. WILSON: Thank you so much.

13 DR. FLEISHER: Great. And our
14 discussants are Alan and Dr. Jarrett. Okay.

15 DR. JARRETT: Yes.

16 DR. FLEISHER: Okay. Dr. Johnson, do
17 you want to quickly introduce yourself and tell
18 us what you're presenting?

19 DR. JOHNSON: I'm Brad Johnson, a
20 vascular surgeon from the University of South
21 Florida, a professor of surgery. And I'm on
22 behalf of the Society of Vascular Surgery. I'm

1 here and there should be two of my colleagues or
2 at least one. Vivienne Halpern should be on the
3 phone today with us.

4 DR. FLEISHER: Is she on the phone?

5 MS. HALPERN: Vivienne Halpern. I'm
6 also here.

7 DR. CIOCCA: Rocco Ciocca, I'm also
8 online.

9 DR. JOHNSON: All right. I'm here to
10 present the NQF Measure No. 0465, Perioperative
11 Anti-Platelet Therapy for Patients Undergoing
12 Carotid Endarterectomy.

13 It was originally endorsed by NQF in
14 July of 2008. It is a reporting of a percentage
15 of patients undergoing a carotid endarterectomy
16 who are taking antiplatelet agents within 48
17 hours prior to surgery and/or prescribed this
18 medication hospital discharge following surgery.

19 This measure is reported by the
20 Society of Vascular Surgery/Vascular Quality
21 Initiative registries. VQI participates,
22 receiving benchmark reports on this measure to

1 see how they are performing relative to their
2 peers and to the quality goals set for the
3 measure of 90 percent antiplatelet uses for
4 carotid endarterectomy procedures.

5 While progress has been made towards
6 this quality goal for this measure, there still
7 is a gap based upon our VQI reporting data. Our
8 VQI data goes through an annual validation
9 process to assure validity and reliability of the
10 data.

11 I'm happy to answer any questions that
12 the Surgery Standing Committee has.

13 DR. SIPERSTEIN: In the interest of
14 time, I won't repeat that very nice summary, and
15 ---- you know, some of the key aspects.

16 Simply a process measure, looking at
17 medication use and discharge prescribing in many
18 ways similar in format to the measure we just
19 discussed. One of the key issues in the original
20 submission and then in some of the supplemental
21 material is the impact of compliance with
22 reducing morbidity and mortality.

1 There are a number of different papers
2 that have addressed this. They come to somewhat
3 different conclusions both on the morbidity as
4 well as the mortality aspect of things, but in
5 aggregate, there is a tendency to reduce
6 complications by the use of these agents.

7 DR. FLEISHER: Mark, any comments?

8 DR. JARRETT: Yes, I do. I agree with
9 everything that's been said. I think the evidence is
10 not super-strong. What bothers me the most is looking
11 at the data and looking at the history since this has
12 been around for a good number of years. There's two
13 groups. There's two groups: there's -- almost
14 everybody is getting on with giving these drugs at the
15 time of discharge, but there seems to be a group of,
16 you know, practices or --

17 DR. FLEISHER: Mark, we're focusing just
18 on the evidence. You were not here this morning.

19 DR. JARRETT: But I think the evidence is
20 there. It's weak but it's there.

21 DR. FLEISHER: Okay. And we'll get back
22 to your other comments. Thank you.

1 DR. JARRETT: Okay.

2 DR. FLEISHER: Any other comments?

3 (No response.)

4 DR. FLEISHER: Can we vote? We'll call
5 it?

6 Yes, go ahead.

7 MR. LYZENGA: So we have 5 percent high,
8 81 percent moderate, 14 percent low.

9 So the measure passes evidence. And we
10 can move to opportunity for improvement.

11 DR. SIPERSTEIN: So I would say yes. As
12 stated, half the centers did not achieve the 90
13 percent benchmark, and 20 percent of the centers were
14 like under 80 percent. And there was a distribution
15 among centers. So, yes, there is an opportunity for
16 improvement.

17 DR. FLEISHER: Mark, I think your comments
18 now.

19 DR. JARRETT: Yes. I agree there has been
20 opportunity for improvement but the question is why
21 are the centers not doing it --- is that they are
22 looking at the literature, reading it one way, while

1 other people are looking at it another way, looking at
2 it, you know, that maybe the evidence is there since
3 it's not super-strong. And I don't know, since
4 looking at the data it looks like there has not been
5 a budge on the pre-op usage really significantly
6 since, you know, all the years. And I don't know if
7 continuing to measure that and making that endorsement
8 is going to really change behavior, which is really
9 the goal.

10 DR. SIPERSTEIN: I had a question about
11 that also, and actually looked up a more recent
12 abstract. And that indicated that as the number of
13 centers participating in this program increased, the
14 newer centers tended to be lower users as they came on
15 board.

16 DR. JARRETT: Right.

17 DR. SIPERSTEIN: And over time they built
18 up their compliance. So if you'll simply look at the
19 aggregate compliance over time, that's why it actually
20 went up initially and then ticked down a little bit.

21 DR. JOHNSON: Yes, can I reply? I would
22 reply that VQI has evolved then from, you know, maybe

1 30 to 40 centers to over 335 centers now. We've gone
2 from -- so far this year we reported 40,000 carotid
3 endarterectomies. As far as the benefit and the
4 evidence to show that it does reduce stroke and death,
5 pre-op and discharge, I've got some other papers of
6 course, but we have shown that it does do that.

7 As far as usage, and the importance of
8 this is the fact that it does reduce stroke, it does
9 reduce death. And now that we have increased the
10 number of centers participating in the registry I
11 think you will see a move forward toward increase in
12 compliance and more use of antiplatelet agents prior
13 to carotid endarterectomy.

14 DR. SAIGAL: Can I make a comment? To
15 clarify, we are just saying the vascular surgeons
16 believe that it works.

17 DR. JOHNSON: Correct.

18 DR. SAIGAL: Is it non-vascular surgeons
19 in the survey don't believe it works? Or what's the
20 distinction?

21 DR. JOHNSON: I'm not sure. But if you go
22 to board certified vascular surgeons who are now doing

1 the majority of carotid endarterectomy across the
2 nation, yes, they believe it works. So, yes, you do
3 have some people that aren't board certified, aren't
4 fellowship trained that are still a little leery of
5 using -- they are worried about bleeding
6 complications. And that was one of the questions,
7 comments here.

8 I've got a paper here from Stone in 2008,
9 with use of antiplatelet agents across the board in
10 vascular procedures, the bleeding complication is
11 negligible and certainly does not warrant not using
12 antiplatelet agents for carotid endarterectomy or
13 bypass operations.

14 DR. SAIGAL: And I would add that if these
15 guys think it works then the rest of the committee
16 should be convinced that mechanism is measuring this
17 to see what's going on with their performance, in my
18 view.

19 DR. HALPERN: I would also add that I can
20 -- most of the neurologists, they're not surgeons but
21 the neurologists who do strokes are on board with
22 peri-operative use of antiplatelets.

1 DR. FLEISHER: Thank you. Very helpful.

2 Oh, Tom?

3 DR. HANDY: Do non-specialist non-board
4 certified surgeons use this registry? I would imagine
5 that it's primarily the specialists that use this
6 registry.

7 DR. JOHNSON: It's primarily vascular
8 surgeons but there are also cardiologists. It's not
9 an exclusive registry of vascular surgeons. So, yes,
10 if you look at the type of centers participating in
11 it, of the 330 or 40 we have now, one-third are
12 academic, one-third are teaching-affiliated hospitals,
13 and one-third are private. So it's pretty
14 representative of a community of people performing
15 vascular surgery.

16 And as this progresses along I think we
17 will see more non-board certified vascular surgeons
18 that are still performing carotid endarterectomies,
19 they will be using more platelet, antiplatelet agents.

20 DR. FLEISHER: To follow up on that, do
21 you know the percentage of vascular surgeons, the
22 percentage of vascular operations that are being

1 performed in the United States that are part of this
2 database? This gets to the STS comment that we
3 usually hear.

4 DR. JOHNSON: I know we are increasing but
5 I can't give you that number, no.

6 DR. FLEISHER: That might be useful going
7 forward.

8 DR. JOHNSON: Yeah, that would be going
9 forward. Yes, sir. I agree.

10 DR. FLEISHER: To find out that piece of
11 information.

12 DR. JOHNSON: I agree.

13 DR. FLEISHER: Right. Correct; the
14 neurosurgeons' performance.

15 DR. HALPERN: I think it also varies by
16 area of the country. So in the big cities it tends to
17 be more board certified vascular surgeons. In the
18 rural areas there are probably -- because I saw data
19 on this not too long ago, but there are not a huge
20 percentage, but maybe 20 percent general surgeons who
21 are also doing vascular procedures or other
22 specialties.

1 DR. FLEISHER: Thank you.

2 My comment refers to the ability to drive
3 performance since the group who would probably need
4 the biggest incentive may be the group outside, so.

5 DR. HALPERN: Yes.

6 DR. JOHNSON: I totally agree.

7 DR. FLEISHER: Shall we vote? We will
8 call it.

9 MR. LYZENGA: Thirty-five percent high, 61
10 percent moderate, 4 percent low, zero insufficient.
11 So the measure passes on performance cap.

12 Move on to reliability.

13 DR. SIPERSTEIN: So just a couple quick
14 comments. Obviously the inclusion/exclusion were
15 clear cut. This is for elective carotid only, for
16 example not combined with CABG. This obviously
17 excludes emergency cases, those with drug intolerance.
18 And so all of that seems perfectly reasonable.

19 They presented evidence on reliability
20 testing by doing chart abstractions and corresponding
21 -- correlating with what was in the database, and it
22 was a very high, approximately .9 level. It's not a

1 very hard thing to measure actually.

2 DR. FLEISHER: Mark, any comments?

3 DR. JARRETT: No comments. Agree 100
4 percent.

5 DR. FLEISHER: Okay. Can we vote? We can
6 see the results.

7 MR. LYZENGA: Eighty-three percent high,
8 17 percent moderate, zero low, zero insufficient. The
9 measure passes reliability. And we will go on to
10 validity next.

11 DR. SIPERSTEIN: So again I would say that
12 there is a high degree of validity with this measure.
13 I mean obviously we've had a little bit of discussion
14 in terms of whether the, you know, literature has
15 shown a huge benefit, but in terms of the actual
16 measurement, the exclusion, there isn't, the risk
17 adjustment's not applicable, all make sense.

18 DR. FLEISHER: Mark?

19 DR. JARRETT: I agree. Nothing to add
20 really.

21 DR. FLEISHER: Any other comments?

22 (No response.)

1 DR. FLEISHER: Please vote.

2 Okay. If we can get the vote, please?

3 MR. LYZENGA: Fifty-seven percent high, 43
4 percent moderate, zero low, zero insufficient. The
5 measure passes validity. And so we will move on to
6 feasibility.

7 DR. FLEISHER: We will let Mark go first.

8 DR. JARRETT: Feasibility is, you know, I
9 mean it's just basically the same as the other STS
10 databases, I mean as the STS databases, the same type
11 of thing. I don't see a problem with it. I think
12 it's very feasible to do this. It's not a -- it's an
13 easy measure to measure.

14 DR. FLEISHER: Allan?

15 DR. SIPERSTEIN: Yes. If you're part of
16 the database, obviously very, very easy. If you're an
17 institution that wants to do this independently,
18 obviously getting the data together would be more of
19 a challenge. But for the growing number of
20 participants, very straightforward.

21 DR. FLEISHER: Larissa?

22 DR. TEMPLE: What's the cost to belong to

1 the registry?

2 DR. JOHNSON: Our cost for Tampa General,
3 at my institution, is \$14,760 this past year. It
4 comes in modules. Each module is \$2,100. Most
5 institutions will have like a carotid endarterectomy
6 module, endovascular aneurism module, so you're paying
7 \$2,100 per module. So our cost was \$14,000.

8 Data entry again is the big problem. And
9 that cost right now is -- originally at our
10 institution we have medical students. Most people
11 have a nurse entering it. And currently Tampa General
12 has now hired, I've got two people that work in their
13 IT who are doing my data entry for me. So data entry,
14 of course, but all things is a cost.

15 DR. TEMPLE: So in looking at who is
16 participating in the registry and who is not, it would
17 be very helpful to see both the solo providers or the
18 smaller hospitals and what the uptake in the registry
19 -- because it doesn't sound like it's a measure you
20 can really collect outside of the registry very well,
21 right?

22 DR. JOHNSON: Yes, you are correct, it's

1 difficult outside the registry.

2 DR. FLEISHER: So if we can make sure,
3 Larissa, that in the report we reflect what we would
4 like to see back --

5 DR. JOHNSON: Okay.

6 DR. FLEISHER: -- when this measure comes
7 back, should it pass.

8 DR. JOHNSON: Okay, thank you.

9 DR. FLEISHER: Amy?

10 MS. MOYER: I was just curious if it's
11 billed on kind of a per facility basis or if it
12 matters, you know, how many individuals are in the
13 registry. So, for instance, if a facility purchases
14 access to the carotid endarterectomy module can they
15 enter all their people who perform that or is there
16 kind of a incremental fee for that?

17 DR. JOHNSON: No. It's per module, so
18 number of physicians does not increase costs for
19 anybody at Tampa General. Cardiologists,
20 interventional cardiologists, vascular surgeons,
21 general surgeons, they all participate and they only
22 pay that one fee.

1 DR. FLEISHER: Yes, A.J.?

2 DR. YATES: Given the fact that it's a
3 yes/no dichotomy, I mean you do it or you don't do it,
4 wouldn't it be simple to extend the measure in such a
5 way that it can be reported in other venues other than
6 just the registry?

7 DR. HALPERN: We are actually working, we
8 were actually working on G-codes for PQRS. And I
9 can't, I don't remember what stage we are in that,
10 frankly. But we did have, we were working on G-codes
11 for that.

12 DR. YATES: Okay.

13 DR. FLEISHER: Great. It sounds like that
14 will be an important answer -- important to answer at
15 the next phase.

16 Collette?

17 MS. PITZEN: I'm just curious how many
18 data elements are coming through in the registry?

19 DR. JOHNSON: You mean data -- why don't
20 you define for me better what do you mean by data
21 elements?

22 MS. PITZEN: Well, a little bit for this

1 module, for cardiac endarterectomy.

2 DR. JOHNSON: For how many entries, how
3 many things are we entering?

4 MS. PITZER: Correct.

5 DR. JOHNSON: Yes, for carotid
6 endarterectomy, yes, a huge -- not huge, but it's a
7 number of elements involved, anywhere from their
8 history of smoking, significant, four or five pages
9 just for carotid endarterectomy. So it's a 15- to 20-
10 minute per patient entry.

11 MS. PITZER: Can I make an additional
12 comment? Just something for the committee to consider
13 as more registries are being used, and I know STS has
14 a big uptake in the country, also has lots of data
15 elements, this is a process measure that could be
16 collected using other sources of data in perhaps a
17 more efficient way. So I just wanted us to keep that
18 in mind in terms of feasibility.

19 DR. FLEISHER: Sure.

20 Marcia, from an NQF perspective where
21 would that discussion occur or where could that occur?

22 MS. WILSON: I'm sorry. It would come

1 under a recommendation or comment from the committee
2 and be highlighted in the report as such, raised under
3 the feasibility section.

4 DR. FLEISHER: And perhaps again under the
5 gaps, it could be highlighted as a general comment --

6 MS. WILSON: Absolutely. Yes.

7 DR. FLEISHER: -- throughout the document
8 of surgical registries and the initiative.

9 Barry? I'm sorry, I'll get you next.

10 MR. MARKMAN: You're the first registry --
11 what could be done for the October ICD-10 coming in
12 versus the nine codes that we --

13 DR. FLEISHER: What can be done?

14 MR. MARKMAN: Yes. I mean have you
15 prepared? A lot of these registries work on codes;
16 right? So ICD-10 is coming in in October. So how,
17 have you done anything in preparation for that?

18 DR. FLEISHER: Vivienne, can you answer?

19 DR. HALPERN: In terms of how the registry
20 gathers this data?

21 MR. MARKMAN: Yes, yes.

22 DR. HALPERN: Yes, the company that helps

1 run the registry they've already started changing over
2 to ICD-10 coding. So they will be ready.

3 MR. MARKMAN: Okay.

4 DR. HALPERN: They are well aware of that.

5 DR. FLEISHER: Great. Liz?

6 DR. EREKSON: I just wanted to play off of
7 Collette's comment just slightly, aspirin is over-the-
8 counter, and so this isn't something that we are going
9 to be able to get in all things because doctors aren't
10 prescribing it in terms of e-measures and things like
11 that. So for this particular measure, the way it's
12 collected right now seems very valid to me. But I
13 would have concerns if we started morphing into an
14 easier data set to grab things off of.

15 So for this particular measure I think the
16 way it's written is the right way. And when we are
17 thinking about future measures or making things
18 easier, when patients have access to things that may
19 not be in the medical chart or may not be prescribed
20 by physicians in the EMR, we just have to consider
21 that.

22 DR. FLEISHER: Thank you. We will add

1 that to the comments.

2 Cliff?

3 DR. KO: I just have a question of
4 clarification. Is the measure has to be put into the
5 VQI, or it's just the specs and just put it in however
6 you can?

7 DR. JOHNSON: It has to be put in through
8 the database through VQI.

9 DR. KO: And we don't know what percent of
10 carotids are in the VQI now?

11 DR. FLEISHER: That is what we are asking
12 for them to provide that data. It perhaps could be
13 useful, given you can go into the mix as it goes
14 through --

15 DR. JOHNSON: Correct.

16 DR. FLEISHER: -- the process to have that
17 for the CSAC.

18 DR. JOHNSON: I will, yes, I will get that
19 number.

20 DR. HALPERN: Yes, it should be fairly
21 easy for us to do because we can take it -- because we
22 did -- the VQI had 48,000 carotids captured, so we

1 could get -- at least from CMS, we could get an idea
2 of how many more are being done.

3 DR. FLEISHER: Okay. We can vote.

4 MR. LYZENGA: So voting on feasibility:
5 high, moderate, low or insufficient.

6 DR. FLEISHER: Do we have the numbers?

7 MR. LYZENGA: Thirty-three percent high,
8 54 percent moderate, 8 percent low and 4 percent
9 insufficient. So the measure passes on feasibility.
10 And we go to usability.

11 DR. FLEISHER: Comments on usability?

12 DR. SIPERSTEIN: Yes, very briefly. The
13 document indicated that probably the primary users for
14 institutions themselves get their own report cards and
15 work internally on improving compliance, not publicly
16 reported. There was a statement that it was PQRS
17 approved but not currently used.

18 DR. FLEISHER: Mark?

19 DR. JARRETT: This is Mark. Yes, if I'm
20 not mistaken I think it may be part of a composite of
21 PQRS. But I may be wrong on that. But otherwise,
22 again, there is no issues with the usability that I

1 see. It really should be used locally for
2 improvement.

3 DR. FLEISHER: Amy?

4 MS. MOYER: I'm not sure if this goes in
5 this section, but I am looking at measures that are
6 out there for carotid stenting and seeing there's not
7 a similar measure I'm not sure what percentage of
8 patients choose an endarterectomy versus stenting, but
9 it would be nice to have something similar that looks
10 like there's similar medication requirements around
11 that.

12 DR. HALPERN: In fact there's additional
13 because most, most carotid stents need aspirin and
14 Plavix post-procedure. So, yes, I believe that they,
15 the VQI also collects data on carotid stenting, and I
16 know we are actually actively working on several more
17 measures for various vascular procedures. So I think
18 that's one of them in the future. And I think we are
19 also trying to work with the American Heart
20 Association so that it can be a composite, so there
21 are many other interventional groups. And can also be
22 SCIVR, the Society for Interventional Radiology,

1 because many other groups are also doing carotid
2 stenting.

3 DR. JOHNSON: But Amy, just to give you it
4 number-wise, so far as total procedures captured so
5 far this year through March, carotid endarterectomy
6 48,000, carotid stents just 7,000.

7 DR. FLEISHER: Thank you. I think we will
8 also take it back as a potential area of gap to ask a
9 question of stents versus carotid.

10 DR. JOHNSON: Right.

11 DR. FLEISHER: And whether that's
12 harmonization, or whatever the appropriate term is,
13 thank you for bringing that up.

14 Are we prepared to vote?

15 MR. LYZENGA: Voting on overall
16 suitability for endorsement now. I believe --- oh,
17 are we still on usability? I thought we'd gotten
18 through that already.

19 Usability and use. I'm sorry.

20 We have 29 percent high, 63 percent
21 moderate, 8 percent low, zero insufficient
22 information. So it passes on usability and use.

1 And now we can go to overall suitability.
2 Any other comments before we vote?

3 (No response.)

4 MR. LYZENGA: All right, go for it.

5 DR. FLEISHER: And the verdict is?

6 MR. LYZENGA: Ninety-six percent yes, 4
7 percent no. The measure passes.

8 DR. FLEISHER: Thank you very much.

9 DR. HALPERN: Thank you.

10 DR. FLEISHER: Dr. Johnson, thank you.

11 DR. JOHNSON: Thank you.

12 MR. LYZENGA: Oh, I'm sorry, we actually
13 -- they've already hung up now, I think -- yes,
14 harmonization. And I don't know that we have much to
15 talk about here. This one we do have another STS
16 measure, I believe, of antiplatelet medication at
17 discharge. Although this one, it appears, applies to
18 patients undergoing isolated CABG, whereas the STS
19 measure is carotid endarterectomies.

20 DR. SIPERSTEIN: Yes, I don't think those
21 two overlap. There actually is an outcome measure
22 that does overlap, 1540, it's post-op stroke and death

1 in asymptomatic patients undergoing carotid
2 endarterectomies that was approved in 2012. And so
3 it's an actual outcome measure that kind of overlaps
4 in some ways with what this was looking at.

5 MR. LYZENGA: We wouldn't consider that
6 competing though or --- but yes.

7 DR. FLEISHER: As we said in the
8 beginning, the question will be, as it gets more
9 robust, whether this process measure will survive in
10 the face of the robust outcome measure. But it sounds
11 like we just endorsed it to go to the next level for
12 approval.

13 MR. LYZENGA: And it sounds like we're
14 comfortable with these two measures existing together.

15 So next measure. Thank you. Appreciate
16 it. Now we will go to the AUGS measures. The first
17 one is 2038. I don't know if our developers are on
18 the phone.

19 DR. GUNNAR: So this is measure 2038,
20 performing vaginal apical suspension at the time of
21 hysterectomy to address pelvic organ prolapse. And
22 just to remind us, when this was considered in the

1 past I'm reminded. It's a new measure, this
2 application, but it had been considered and turned
3 down in the past.

4 MR. LYZENGA: Yes.

5 DR. GUNNAR: Do we know what the
6 recommendations were at that time that we brought it
7 up?

8 MR. LYZENGA: So this was actually
9 discussed in our previous -- by this committee the
10 last time around. And I believe we actually may have
11 deferred it rather than -- or maybe, no, it went down.
12 I'm sorry. It did, it was voted down. And they have
13 resubmitted it now after -- sorry, I'm remembering
14 now.

15 This was one where we have the issue of
16 testing where there was one site in particular out of
17 I believe four sites that had had a weird issue with
18 their coding. And it's sort of a systematic problem
19 that had given -- really skewed the results. So we
20 asked them to come back with some -- to give us some
21 further explanation and data review testing results I
22 believe. So, yes, that was, that was the issue in the

1 last round of evaluation.

2 DR. GUNNAR: So I'm seeing Barbara giving
3 me a head -- So before we --

4 MR. LYZENGA: Maybe we could have our
5 developers.

6 DR. GUNNAR: --- have the developers
7 address. So who is on the phone?

8 DR. PULLIAM: Yes, I am representing the
9 developers. My name is Samantha Pulliam and I am
10 representing the American Urogynecology Society.

11 MR. LYZENGA: Thank you. And if you could
12 give just a quick overview of the measure, an
13 introduction?

14 DR. PULLIAM: Okay. So this measure, as
15 you've mentioned, is performing vaginal apical
16 suspension at the time of hysterectomy to address
17 pelvic organ prolapse. A brief description of the
18 measure just is that the percentage of patients
19 undergoing hysterectomy for the indication of pelvic
20 organ prolapse, in which a concomitant vaginal apical
21 suspension is performed. We believe this is an
22 important measure and have persisted with it after our

1 last experience, mostly because so many women undergo
2 surgery, over 200,000 surgeries a year, for pelvic
3 organ prolapse. And yet up to 34 percent of them
4 don't undergo a current, a concurrent colpopexy or
5 apical suspension procedure.

6 The statistics essentially show that the
7 risk of re-operation within ten years is significantly
8 elevated if one doesn't have an apical suspension at
9 the time of the hysterectomy.

10 With regard to the changes that have been
11 made in this submission from last year, I think
12 specifically we addressed the concerns regarding the
13 testing. Our testing had been reporting based only on
14 billing codes. And we have reevaluated the testing
15 based on electronic and paper chart review. So that's
16 the main difference in terms of the submission from
17 last year.

18 MR. LYZENGA: Great. Thank you.

19 And I think we have whoever --

20 DR. LEVY: So we had a fairly robust
21 discussion about this the last time. It is a process
22 measure but if you look at what the outcome measure

1 would be, it's something you would measure three years
2 later, four years later, and it's not really feasible
3 to look at an outcome measure that you could assess
4 reasonably.

5 So from the standpoint of a process
6 measure that's directly related to an outcome, I think
7 they've demonstrated that it is. And given the robust
8 discussion we had last time, I'm not sure how much
9 more discussion you want to have. We, I believe,
10 passed this last time, based on the evidence.

11 DR. FLEISHER: So the evidence last time?

12 MR. LYZENGA: It did pass on the evidence
13 last time I believe.

14 DR. LEVY: Yes.

15 MR. LYZENGA: It failed on reliability
16 testing is my understanding, so --

17 DR. LEVY: Correct.

18 MR. LYZENGA: I don't know if we want to
19 go through the votes again or if we, do we have a
20 motion to --

21 DR. TEMPLE: If I'm not mistaken, wasn't
22 this one of the ones that was the pilot in surgery

1 where the evidence had been approved even before we
2 reviewed it last time?

3 MR. LYZENGA: That is correct. Although
4 I think maybe the time frame now has sort of, the
5 window has been exceeded from the point where we would
6 want to review evidence again.

7 DR. LEVY: Yes, I think the evidence is as
8 robust as they can give us given the retrospective
9 nature of the data that they can provide. But clearly
10 there are, you know, of the 200,000 procedures being
11 done annually for pelvic organ prolapse, about 78,000
12 of those are hysterectomies. And their evidence is
13 pretty clear that only 35 percent of them are having
14 apical suspensions performed at the same time.

15 There is reasonably good evidence,
16 certainly at ten years, that doing an apical
17 suspension at the time will reduce the number of re-
18 operations for apical prolapse. And that's really
19 what we want that married to that outcome. And I
20 think the evidence is reasonable that that's the case.

21 DR. FLEISHER: Dr. Erekson.

22 DR. EREKSON: So I just wanted to comment

1 on the NQF worksheet beforehand. The NQF pulled out
2 a Cochrane Review that showed that there is likely to
3 maybe change some recommendations. And I think it's
4 really important to realize that this Cochrane Review
5 is looking at the different types of apical
6 suspensions, not apical suspension versus vaginal
7 hysterectomy.

8 And so the measure developers are not
9 choosing that you have to do one type of apical
10 suspension over the other, they are just saying please
11 do an apical suspension because that's actually
12 addressing the problem which is the prolapse that's
13 being done. So I just wanted to make sure that the
14 committee was aware of that distinction.

15 DR. GUNNAR: Is this risen to essentially
16 the standard of care -- I'm just naive -- is this a
17 standard of care issue and those who don't really
18 aren't meeting the standard of care? Or is this just
19 -- because it doesn't make any sense to my why you
20 would --

21 DR. LEVY: The evidence in the ACOG
22 committee opinion is, you know, level B to C evidence.

1 And in that regard I think we would like to see it
2 rise to a standard of care. And one way to do that is
3 to create a measure that's holding people's feet to
4 the fire.

5 MR. LYZENGA: Dr. Moss?

6 DR. MOSS: Just a question. Not having
7 content knowledge in this area, if the evidence is so
8 compelling that this is advantageous, why do 34
9 percent of board certified surgeons not do it?

10 DR. LEVY: Actually it's only 35 percent
11 are doing it. Yes, so go ahead, Liz.

12 DR. EREKSON: So I think the other thing
13 to realize about this specialty is that it's been an
14 evolving specialty over a long period of time. And
15 the actual subspecialty of female public medicine --
16 and reconstructive surgery just was approved and had
17 its first board certified surgeons in 2013. So the
18 field has been evolving. But then you have all of
19 this other, all of these other surgeons out there.
20 And I'm not saying that those surgeons can't perform
21 these procedures, but I think the evidence, it's a new
22 field, and the evidence is pointing towards this

1 direction.

2 DR. MOSS: What does it add to the
3 operation time-wise?

4 DR. LEVY: It doubles or triples the time
5 of the operation if you do it right.

6 DR. KO: Wow, really?

7 DR. LEVY: Yes. It can. I mean it
8 depends on, you know, if the uterus is falling out and
9 it's small then it takes 20 minutes maybe to get the
10 uterus out. And it might take you an hour-plus to
11 find the uterosacrals, high up, protect the ureter, do
12 the suspension, do the cystoscopy to make sure you
13 haven't kinked the ureters, and then close.

14 DR. EREKSON: In addition, it's more
15 technically difficult, which also speaks towards this
16 evolving specialty and more training, because it's
17 certainly a more difficult procedure than just doing
18 a hysterectomy.

19 MR. LYZENGA: Dr. Moss.

20 DR. MOSS: So again just a question, is
21 there a potential unintended consequence of driving
22 folks who aren't, either aren't adequately trained or

1 experienced to be pushed into doing something they
2 might not do well?

3 DR. EREKSON: Well --

4 DR. PULLIAM: I guess I could answer that
5 if I should.

6 DR. FLEISHER: Go right ahead, absolutely.

7 DR. PULLIAM: I suppose in theory there is
8 that consequence. But I think a more likely
9 consequence would be that patients would be cared for
10 by physicians who are proficient in these types of
11 procedures. I think this is a change that's afoot as
12 new trainees become gynecologists. And I think it
13 will continue to be true that people who are able to
14 do these procedures will become a source for referring
15 to these procedures.

16 MR. LYZENGA: Larissa?

17 DR. TEMPLE: Just in terms of
18 consequences, when you do the suspension can you do it
19 vaginally or do you have to do it transabdominally?
20 And the second, when you do the suspensions is there
21 a higher risk of ureteric injury?

22 DR. PULLIAM: So it can be done vaginally,

1 abdominally, retroperitoneally. There are a bunch of
2 different suspensions, some with mesh, some without.
3 And as Liz said, we are not, this measure doesn't,
4 doesn't capture that.

5 Yes, there is a higher incidence of
6 ureteric kinking or injury. Cystoscopy is basically
7 required when you are doing this procedure to ensure
8 that the ureters are intact.

9 DR. GUNNAR: I guess the next question
10 specifically is in the literature that's provided to
11 support this, when you perform this procedure do you
12 tack on complications? Even though you are protecting
13 a long-term outcome benefit, do you add complications?

14 DR. LEVY: So short term when performed by
15 those who are doing this properly, which includes
16 cystoscopy, the answer is no, because you identify the
17 kinked ureter, you change your sutures and you re-do
18 it. So it's an intraoperative recognition of kinking
19 of the ureter when you do a high suspension.

20 DR. EREKSON: So the cystoscopy at the
21 time of apical suspension is actually an approved
22 measure that we approved last standing committee to

1 make sure that we don't have unrecognized ureteral
2 injury. When you look at the data of what is the
3 actual morbidity of prolapse procedures, and
4 especially perioperative morbidity and 30-day
5 outcomes, I have published on some of this data and
6 it's incredibly low.

7 Older woman, woman over the age of 80,
8 undergo these procedures and do very, very well. And
9 so it's in the wrong hands, yes, you could have more
10 ureteral injury but we've already protected against
11 that because we have a measure that says you should do
12 a cystoscopy. And a lot of older women undergo these
13 procedures and do very well with them.

14 DR. GUNNAR: I guess not to beat this up,
15 but then shouldn't those two be combined? We've had
16 this discussion earlier. That is, if you do the
17 suspension you should, you must do the cystoscopy, or
18 are they separate or are they connected? I know just
19 from the NQF point of view I would bet these are tied.

20 DR. EREKSON: I think they are two process
21 measures. And I would love to hear from the measure
22 developers. But I kind of see this as when you have

1 process measures then you can have composite process
2 measures too. And they are measuring two separate
3 things. And, yes, we want our surgeons doing both.
4 But --- and I think it can move towards that.

5 DR. PULLIAM: Right. So as a measure
6 offer I think we had sort of two concerns: one is
7 that neither of these have been a measure yet, so I
8 think to combine them we would need to really address
9 a couple of issues. One is that the exclusion
10 criteria for the measure we are talking about now are
11 different than those for the cystoscopy measure.

12 And then the second thing just is that the
13 goals of the two are separate. This is as closely
14 tied to an outcome measure as we have. And the other
15 is primarily a safety procedure. So whether both
16 measures that involve an apical suspension, I think
17 the intent is different than the applicability
18 specifically of a cystoscopy is more broad.

19 DR. KO: I just have a quick question. I
20 didn't realize the board came in 2013. And so I
21 assumed that the people who are boarded in this are
22 able to do the primary procedures, the suspension and

1 then do the cystoscopy. Is cystoscopy part of the
2 training of everyone in gynecology and so that's not
3 a --

4 DR. LEVY: Yes, it is.

5 DR. KO: -- resource issue?

6 DR. LEVY: Yes, it is. It's within our
7 CREOG guidelines. And we have modules and measurement
8 on that.

9 DR. CIMA: So just --- I am not sure that
10 this fits right in with this segment or it's just this
11 is evidence, but the problem is does the evidence
12 apply to all people doing this procedure? I mean, I
13 was also looking at this and the next one about where
14 you are going to get this is from a registry that's as
15 yet to be defined, and is it only a urogynecologist
16 that's going to be applying that or will all these
17 gynecologists have to participate in this registry in
18 order to get this data processed? And so, you know --

19 DR. LEVY: So this is easy data to get
20 from claims or from records. But there are different
21 codes for the suspension and for the hysterectomy
22 itself. So you don't have to participate in the

1 registry in order to be able to report this. And it
2 would apply to all gynecologists who perform
3 hysterectomies for prolapse.

4 MR. LYZENGA: Collette?

5 MS. PITZEN: Yes, just a comment, I'm not
6 a content expert, but I want to talk a little bit
7 about process measures and the expectation that if you
8 have a process that you are actually requiring
9 everyone who is in the denominator to have that
10 process performed, I'm wondering if the evidence is
11 strong enough in that area, and I'm going to use to
12 strengthen the body and the quantity and the overall?
13 What I am hearing is the evidence is grade B and C.

14 So just kind of throwing that out there.

15 MR. LYZENGA: Lee?

16 DR. FLEISHER: So one of my questions --
17 I apologize but it was the time to get my match list
18 -- one of the things I'm wondering about is does
19 everyone perform the suspensions because is this a
20 full employment act for the urogynecologists?

21 DR. LEVY: So it should not be. I mean
22 these are, these are bread and butter procedures when

1 they're performed for prolapse. There are certainly
2 different degrees of prolapse. Mild to moderate
3 prolapse is something easily managed by a general
4 gynecologic surgeon. If honestly it's down to her
5 knees and she's got huge prolapse, those cases are
6 generally being sent to the subspecialists, because
7 they need much more robust and multi-compartment
8 management.

9 DR. FLEISHER: So not that you could speak
10 on behalf of the College, but would general
11 gynecologists support a measure developed by the
12 urogynecologists?

13 DR. LEVY: Yes, I think we would.

14 DR. SAIGAL: I'd like to make a comment
15 too about I think Collette's point's great about the
16 evidence level. I think the thing we're to think
17 about is whether every process measure like this is
18 going to have a randomized trial to support it?
19 Probably the answer is no.

20 So I think if a society really does feel
21 we're making surgery better, I think for cystoscopy it
22 makes perfect sense to me that you want to make sure

1 you're not hurting the patient --- it's a quick thing
2 to do. And even if it wasn't compensated people would
3 do it because they don't want to have -- they're not
4 as bundled perhaps. So it might be, you know, you
5 just don't want the woman to have a blocked ureter.
6 So I think it makes good sense and we should probably
7 support it even without randomized data.

8 DR. LEVY: I would just say that the
9 outcomes we are looking at are so far down the road
10 that to generate controlled trials and level one
11 evidence is going to be nigh on to impossible.

12 MR. LYZENGA: Barry?

13 MR. MARKMAN: Yes, that was my question:
14 how long has this procedure been performed?

15 And the second part of that is, is it --
16 I mean, you know, there's a systemic review but is
17 there any level one or level two studies within that
18 systemic, you know, review to support this?

19 DR. EREKSON: So these operations have
20 been around for quite some time. Sacral colpopexy has
21 been around since 1962, the uterosacral ligament
22 suspension, in some form or another, from before

1 that. So these are operations that have been around
2 quite a long time.

3 I think one of the things that you have to
4 remember is that uterine prolapse does not happen
5 because the uterus is diseased, uterine prolapse
6 happens because it's a hernia. And unless you address
7 that hernia in your repair your procedure is going to
8 fail.

9 And so if you look at the large, multi-
10 centered research networks for pelvic floor disorders
11 they are not going to look at a randomized controlled
12 trial of vaginal hysterectomies for prolapse and not
13 do anything for apical support. What they are looking
14 at is randomized controlled trials between the
15 different surgical procedures to try to figure out
16 which is the right procedure to do. And so that's
17 where the data of the field is at.

18 And in terms of does this have to be a
19 urogynecologist versus a gynecologist, if you read the
20 residency requirements for graduation as well as board
21 certification for general gynecology, these are
22 procedures that board certified general gynecologists

1 can be trained in and perform. But what we want, I
2 think the measure is looking at please do something.
3 Please do right by these women and please do
4 something.

5 DR. GUNNAR: So we are going to go back
6 and vote on the evidence; is that right, Andrew?

7 MR. LYZENGA: Yes.

8 DR. GUNNAR: Okay. So can we ---I don't
9 know what we're saying here. We're saying --

10 MR. LYZENGA: No, no, we need our process.
11 There we go.

12 DR. GUNNAR: Are you ready? Go ahead.

13 MR. LYZENGA: I think we can tally them
14 up. Twenty-one percent high, 71 percent moderate, 8
15 percent low, zero insufficient. So that measure
16 passes importance to measure -- I'm sorry, evidence.

17 Now we will go to opportunity for
18 improvement, performance gap.

19 DR. LEVY: So again we've already
20 addressed that, but 35 percent of the time it's being
21 done, which means 65 percent of the time it's not
22 being done. And I think that's evidence in and of

1 itself that there is quite a large gap.

2 MR. LYZENGA: Any additional comments or
3 can we vote? Let's vote. You ready, Alexandra? Go
4 ahead and vote.

5 Seventy-nine percent high, 21 percent
6 moderate. The measure passes performance gap.

7 So we can go to reliability. And again
8 this I think is where we had the issue last time, so
9 --

10 DR. LEVY: I don't know if the developer
11 wants to --

12 DR. PULLIAM: Sure.

13 MR. LYZENGA: Yes, maybe let's hear from
14 the developer and hear what they've done to address
15 the committee's concerns from the last time.

16 DR. PULLIAM: All right. So in the last
17 round we used billing codes both for the
18 identification of the hysterectomy procedure and the
19 identification of the apical suspension procedure.
20 And I think our difficulty there was that we found an
21 institution that didn't do what other institutions do
22 in terms of those codes.

1 So instead of that we reevaluated based on
2 chart review. So the reliability evaluation or
3 calculations in this submission are based on the
4 identification of a hysterectomy based on ICD-9, ICD-
5 10 or CPT codes for hysterectomy supported by
6 diagnosis of prolapse, and then chart review to
7 confirm the presence or absence of an apical
8 suspension procedure.

9 So that's been the new way to identify
10 this which basically eliminates the problem that we
11 had with the prior submission.

12 DR. LEVY: And so with that chart review,
13 it certainly appears to meet reliability criteria.

14 DR. GUNNAR: Any other discussion?
15 Collette?

16 MS. PITZEN: Just a comment. For a
17 relatively high-volume procedure this is still a small
18 number of cases that are being used to talk about the
19 performance of the measure and the reliability.

20 DR. CIMA: Yes. And to go to the point
21 earlier, Barbara says, you know, these are all
22 procedural codes that are there that we can use so now

1 it becomes a feasibility issue if you actually had to.
2 So how reliable are we going to be going forward if in
3 order to do this, half of the time, or half of the
4 procedure needs to be chart extracted?

5 DR. LEVY: Well that, it's actually a
6 bigger discussion than that. So maybe why don't we
7 talk about that during feasibility.

8 DR. GUNNAR: So with regard to this, the
9 reliability evidence as they present or the data as
10 you're collecting it -- is it reliable? That's what
11 we are voting on right now. So is it measuring what
12 it says it measures?

13 DR. CIMA: Well, it does when you go back
14 and look at the charts. So that means --

15 DR. GUNNAR: And let's -- and that -- yes,
16 correct. Any other discussion?

17 (No response.)

18 DR. GUNNAR: All right, let's vote.

19 MR. LYZENGA: Calculating. We have 32
20 percent high, 52 moderate, 16 percent low. So the
21 measure passes on reliability. We can go to validity.

22 DR. GUNNAR: So any further discussion on

1 validity?

2 DR. LEVY: I just had a question for the
3 measure developers about the risk adjustment here and
4 why there is a risk adjustment for degree of prolapse?
5 It would seem to add a lot of complexity that seemed
6 unnecessary because any hysterectomy for prolapse, it
7 seems like, ought to have a suspension. And I didn't
8 understand the reason for a risk adjustment.

9 DR. PULLIAM: Right. So I think you're
10 correct, largely. I think the concern we had was just
11 that there might be some confounding between the
12 surgeon volume and the degree of prolapse as in were
13 all of the high-volume surgeons doing the more
14 advanced prolapse cases and so they ended up having
15 more apical suspensions. And so I think what we
16 wanted to prove with our evaluation there was just
17 that there was a gap, regardless of whether you were
18 looking at high-volume surgeons or low-volume
19 surgeons, and regardless of whether you were looking
20 at degree of prolapse.

21 I think our intent wasn't so much to
22 provide any more complexity to the evaluation except

1 to bolster our evidence that the gap was there and
2 that this was not just an anomaly of surgeon volume.

3 DR. LEVY: But so when you are specifying
4 the measure are you risk adjusting for Baden Walker?
5 Because that's going to require chart review.

6 DR. PULLIAM: Right.

7 DR. LEVY: You're not going to get that
8 from --

9 DR. PULLIAM: No, we are not. We are not.

10 DR. SAIGAL: Can I ask a question? So
11 what you are saying is that you are using
12 administrative codes for this. And the last time the
13 problem was is that one of these facilities used those
14 codes differently?

15 DR. PULLIAM: That's correct.

16 DR. SAIGAL: So how does this address
17 that? How do these data address that?

18 DR. PULLIAM: Right. So the
19 administrative codes that were used differently were
20 the apical suspension codes. So instead of using
21 those codes to calculate the numerator, we instead
22 used the chart review to calculate the numerator.

1 DR. SAIGAL: Okay, I get that. But so if
2 people will be reporting on the measure using codes
3 you'll still have a problem capturing what you want to
4 capture; right?

5 DR. PULLIAM: So the codes will be used to
6 identify the hysterectomies for apical suspensions.
7 And of 638 patients who underwent chart review, 600 of
8 them were accurate with hysterectomy and codes from
9 all institutions.

10 DR. SAIGAL: So that one institution just
11 codes differently and it will not be --

12 DR. PULLIAM: That one institution --

13 DR. SAIGAL: -- so it wouldn't be valid in
14 that hospital still? We still think that's true?

15 DR. PULLIAM: No, no. The one institution
16 codes apical suspensions differently. The
17 hysterectomy codes and the billing codes for
18 hysterectomy were accurate.

19 DR. SAIGAL: I get that. But if the
20 measure is looking at apical suspension and that
21 hospital does it differently, then this measure won't
22 function at that hospital and presumably other

1 hospitals that use the same billing pattern?

2 DR. PULLIAM: No. The hospital would use
3 the identification of hysterectomy with a diagnosis of
4 prolapse for the identification of cases. So the
5 denominator -- the numerator would be calculated from
6 that cohort based on chart review. So that the
7 billing codes for apical suspension which were
8 erroneous at that institution would not come into
9 play.

10 DR. SAIGAL: Okay. So the measure is
11 specified by chart review now.

12 DR. PULLIAM: That's correct.

13 DR. SAIGAL: Okay. Thank you.

14 DR. EREKSON: So just when I was going
15 through the validity testing, I read through it, I
16 think that there was a little bit of confusion that
17 has slightly been cleared up with the NQF worksheets.
18 Can you clarify specifically, this measure is not risk
19 adjusted by either prolapse grade or by surgeon
20 volume; correct?

21 DR. PULLIAM: That's correct.

22 DR. EREKSON: And why you looked at

1 prolapse grade and surgeon volume was to add to the
2 face validity of this measure that women with larger
3 prolapses and surgeons doing more cases are actually
4 performing apical suspension more often; correct?

5 DR. PULLIAM: That's correct.

6 DR. EREKSON: Okay.

7 DR. GUNNAR: Yes, Fred, did you have a --

8 DR. GROVER: It is good to see you bring
9 this back and that you have done all this work to try
10 to bring a answer to our questions from a year ago.

11 DR. PULLIAM: Thank you.

12 DR. GUNNAR: All right. I think -- okay,
13 Collette?

14 MS. PITZEN: Okay. Maybe I am stating the
15 obvious but a measure that is using procedure codes to
16 identify the numerator and denominator was not
17 successful, and frequently identifying the numerator
18 I have really strong concerns about the threat to the
19 measure.

20 DR. CIMA: When you either have four
21 hospitals and one of them, so that's a quarter, and
22 you look at 200,000 hysterectomies being performed,

1 90,000 being performed for prolapse, or greater
2 numbers than that, this measure would then force a lot
3 of people, a quarter of those people to have to set up
4 a system to do chart abstraction for this procedure.
5 So that, in other words, this is one of the issues.

6 DR. GUNNAR: So I think that goes to
7 feasibility.

8 DR. CIMA: That goes to feasibility. But,
9 you know, if you pass this then you pass and we have
10 to go through everything. But taking into the picture
11 the whole big thing, it's valid to do it but is it
12 really valid that we are going to be able to do it?
13 Because a quarter of them are not going to have
14 accurate data until they do the chart review.

15 DR. PULLIAM: That's -- I'm sorry to
16 interrupt -- but that's correct. I think we are
17 specifying this as a chart review data, but everyone
18 will be required to do the chart review data. This is
19 not, this is not something that allows both to be
20 done. We've only submitted it for a chart review.

21 So if you were talking about -- I mean I
22 think there are many things that will require a chart

1 review but the full evaluation will require a chart
2 review of everyone.

3 DR. EREKSON: And, Collette, just to --
4 and maybe this is the measure developer, the way I
5 read the measure, the denominator is billing codes and
6 the numerator is chart review; correct?

7 DR. PULLIAM: That's correct.

8 DR. EREKSON: Okay.

9 DR. PULLIAM: That's correct.

10 MR. LYZENGA: So we may need a
11 clarification in the submission form for that as well.
12 I think it appears right now that it -- to be
13 specified for use with administrative data only. I
14 don't think it lists chart review. So we'll just
15 coordinate with you on that.

16 DR. PULLIAM: Okay.

17 DR. KO: Just a quick question of
18 clarification. The one out of the four hospitals that
19 coded it differently, was it different and wrong or
20 just different and that's just the way they code it?
21 And will it be kind of like the pulmonary measure
22 where they'll learn how to code it?

1 DR. PULLIAM: Right. So we did some work
2 on that and what essentially we learned was that the
3 place from which we obtained data was not within the
4 system, the place where the ultimate billing codes are
5 dispersed. And so there was some error locally. It
6 sort of defies my understanding. But in the end
7 apparently if we had obtained our information from a
8 different department we would have had the correct
9 codes.

10 So they are essentially insisting that the
11 codes that they eventually bill for are correct. And
12 we didn't have that information.

13 DR. KO: Because making it, if it's
14 something that's correctable, making it a chart
15 abstraction measure increases the burden multi-fold.

16 DR. PULLIAM: Absolutely.

17 DR. GUNNAR: All right, so any other
18 discussion on validity?

19 (No response.)

20 DR. GUNNAR: All right, let's vote.

21 So we have 8 percent high, 67 percent
22 moderate and 25 percent low. It passes.

1 Keep going. Feasibility. Dr. Levy.

2 DR. LEVY: I think we all have a problem
3 with feasibility around the table. First of all,
4 chart abstraction is a problem.

5 The second issue with this measure is that
6 if we were to look at a way to do this with
7 administrative data, the correct coding initiative
8 has, in their wisdom, decided that all apical -- all
9 suspension procedures will be bundled into
10 hysterectomy. We've been able to actually bypass that
11 but it's going to require a modifier. And so we don't
12 have any testing to say whether using administrative
13 claims we would be able to capture things
14 appropriately.

15 Given that they have specified this as a
16 chart review, that means that particular problem is
17 gone for the moment but certainly the feasibility of
18 collecting this using chart review is going to be
19 terrifically burdensome, as Cliff said.

20 DR. GUNNAR: Amy?

21 MS. MOYER: I am curious what the
22 difference in burden is -- and maybe it's that the

1 data are conveniently captured somewhere -- between
2 taking something from a chart and putting it in the
3 registry versus taking something from a chart for a
4 measure. Are they similar? Are they different? I
5 mean, should I think about them similarly?

6 DR. LEVY: I think that people who
7 participate in the registry commit themselves to a
8 great deal of abstraction. This is much less burden
9 than participating in a registry. You know, my hope
10 was that these could be specified using claims, and
11 that would have been much better for all. You know,
12 I don't have a lot of confidence that there will be a
13 lot of people participating in the registry. And that
14 leaves people with the only opportunity to do things
15 to do chart review.

16 You know, could you do ongoing chart
17 review when you come back from the OR and keep an
18 ongoing record? You could do that. And there are
19 ways to do it that are not horribly burdensome, that
20 don't require you to pull every chart you did last
21 year, but just do it on an ongoing basis.

22 But there is a big difference.

1 DR. GUNNAR: Yes, I mean the surgical, you
2 know, improvement projects get measures where those
3 are pulled by chart review. I mean this isn't, this
4 isn't a unique point of view from NQF's perspective.

5 DR. LEVY: I think the only difference
6 there is that the SCIP measures might be facility
7 measures or individual practitioner measures. These
8 are individual practitioner or group practice
9 measures, they're not hospital measures. So we're not
10 going to have hospital abstractors spending time in
11 doing this work, it will be done by the individual
12 provider.

13 DR. CIMA: And the SCIP chart polls
14 were almost universally electronic, for almost
15 all institutions, after a fashion.

16 DR. GROVER: Can I ask, how many data
17 elements are there -- will be required to be
18 pulled by chart review?

19 DR. MORGAN: My name is Dan Morgan,
20 and I'm one of the developers. Dr. Pulliam had
21 to step off the call.

22 The number of elements is actually

1 fairly small. It's really a matter of looking at
2 the operative note and looking for the
3 description that the colpopexy was done.

4 DR. GROVER: So it's at one spot in
5 the chart, and it's -- is it five data elements,
6 ten, or three, or -- ?

7 DR. MORGAN: I would -- I would
8 imagine that we -- when we did the chart
9 abstraction for this, we did a more extensive
10 look. I really think that it could be down to
11 one or two -- excuse me, one or two elements
12 identifying which colpopexy was done, that it
13 satisfies it, and that -- that would be it.

14 DR. GROVER: Okay, thank you.

15 DR. LEVY: Fred, I think we'd need to
16 know that the hysterectomy was done for prolapse,
17 so we would need to know the primary ICD-10 code
18 for -- for the reason for the hysterectomy, and
19 then just the other data element would be was a
20 suspension performed?

21 DR. GROVER: But that -- that would be
22 -- what you -- the coding could be identified

1 administratively, so you've honed it down to just
2 looking then at those patients, and you're
3 picking up two or three data points --

4 DR. LEVY: Yes.

5 DR. GROVER: -- in the op note?

6 DR. LEVY: Yes.

7 DR. GROVER: I mean, that sounds
8 pretty doable to me, but I'm not -- I'm not
9 paying for it.

10 (Laughter.)

11 DR. GROVER: But on the other hand, to
12 put this in perspective, we got a lot of pushback
13 on -- I mean, the best data is clinical data, and
14 how much of the health care expenditure in this
15 country is spent toward quality and safety?

16 I don't know the exact answer to that.
17 Is it two percent at that, or one percent? It's
18 very little, and I think we tend to overemphasize
19 the cost of collecting good data sometimes at the
20 expense of our quality of our care.

21 DR. GUNNAR: Dr. Yates.

22 DR. YATES: Yeah, just a question I

1 got from our GYN colleagues that are here and for
2 the developers.

3 I am not familiar with that part of
4 the CPT book, but, you know, they defined some of
5 our CPTs by the diagnosis going into it depending
6 on what type of hip fracture it is, whether or
7 not you get paid one way or the other. They
8 don't distinguish prolapsed versus non-prolapsed
9 for a hysterectomy in the CPT.

10 DR. LEVY: That's correct.

11 DR. YATES: And they have no intention
12 of expanding the CPT so that it would --

13 DR. LEVY: No.

14 DR. YATES: -- include, with or
15 without apical --

16 DR. LEVY: Well --

17 DR. YATES: -- with --

18 DR. LEVY: -- so I'll put on my ACOG
19 hat for a minute and tell you that because of the
20 CCI edits and our inability then to collect data
21 appropriately, we probably will be putting in
22 code change proposals to put in bundled codes

1 that have vaginal hysterectomy with the different
2 suspensions and the different repair codes.

3 You know, we're looking at at least
4 two years to two and a half or three years down
5 the road before that can get through the system,
6 but clearly, in order to be able to use
7 administrative data, we've got to be able to
8 capture it in a way that's not going to require
9 three modifiers.

10 DR. GUNNER: Any further -- oh, Dr.
11 Moss.

12 DR. MOSS: Just a quick question for
13 the NQF staff: is there experience with other
14 measures that requires abstraction of a small
15 number of elements from an op note, and what has
16 been the feasibility experience with those?

17 MR. LYZENGA: I don't know that we've
18 collected any data or anything like that, or
19 really gotten much feedback. I mean, in general,
20 measures that require chart review are sort of
21 considered to be lower feasibility than those
22 that use administrative data, but you know,

1 that's kind of up to your judgment as experts
2 here.

3 DR. EREKSON: So our Surgical Standing
4 Committee, last time that we were in session,
5 approved 2052 and 2063. Both were measures that
6 were identified by denominators, and then the
7 cystoscopy, which is that one data element of the
8 procedure, was identified by chart review.

9 So our committee last time did approve
10 those.

11 DR. DUTTON: I am sensitive to burden
12 of reporting, but one of the things I think we've
13 learned over 20 years of doing this is if we have
14 a good measure and put it on the table, people
15 will figure out how to measure it and how to get
16 the data.

17 DR. GUNNAR: All right. Let's vote on
18 feasibility.

19 MR. LYZENGA: So voting on whether
20 this measure has high, moderate, low, or
21 insufficient feasibility.

22 (Pause.)

1 MR. LYZENGA: So we have zero for
2 high, 67 percent moderate, 33 percent low, zero
3 insufficient. It passes on feasibility.

4 And we move on to usability and use.

5 Any comments from the Committee on
6 usability or use of the measure?

7 (No response.)

8 I believe we have, just looking at the
9 form here, it hasn't been used yet. Is that
10 correct, I'd ask the developer?

11 DR. LEVY: Yes, it hasn't been
12 developed -- it hasn't been used.

13 DR. MORGAN: Yes, it has not been used
14 yet.

15 MS. REEDE: So pelvic floor registry
16 is a goal, not --

17 DR. LEVY: Correct. It -- it just
18 came to fruition this year, and just enrolling
19 practices right now.

20 DR. GUNNAR: Amy?

21 MS. MOYER: Listening -- I mean, in
22 listening to you all talk about this, this

1 certainly sounds like something that I'd want to
2 know if I were having this kind of surgery, and
3 as a purchaser, although we don't purchase a lot
4 of hysterectomies, they are very expensive when
5 they happen, and avoiding that re-operation and
6 complications down the line would -- would be of
7 interest to us, and getting it done right the
8 first time, so -- .

9 MR. LYZENGA: All right. Shall we
10 vote?

11 Go ahead and cast your vote for
12 usability and use. Your options are high,
13 moderate, low, or insufficient information.

14 (Pause.)

15 MR. LYZENGA: We have 13 percent high,
16 71 percent moderate, 17 percent low, zero
17 insufficient. It passes usability and use.

18 So now we will move to overall
19 suitability for endorsement.

20 Any additional comments?

21 (No response.)

22 MR. LYZENGA: Seeing none, let's go

1 ahead and vote on overall suitability for
2 endorsement.

3 Your options are yes or no.

4 (Pause.)

5 Oh, we lost it again.

6 All right. I think we're going to
7 have to do another re-vote -- redo on this one.
8 Let us know when you're ready.

9 (Pause.)

10 All right, here we go. Let's re-vote
11 on overall suitability for endorsement.

12 (Pause.)

13 Okay, we have 92 percent yes, eight
14 percent no. The measure passes.

15 I believe the next measure is an AUGS
16 measure as well. This is 2677. If the developer
17 wants to give a just very brief introduction of
18 this one as well?

19 DR. GUNNAR: So before we go there --

20 MR. LYZENGA: Sorry, one moment.

21 DR. GUNNAR: -- I think that question
22 that still remains is now that we have two

1 measures that really are connected, how should
2 they -- are they tied together? Should they be
3 tied together?

4 They didn't propose them together, but
5 really, they are intricately entwined.

6 MR. LYZENGA: And so this again is the
7 measure that we discussed a little bit earlier
8 that was passed in the previous cycle,
9 cystoscopy. So I guess the question is whether
10 we think that should be combined or in any other
11 way -- harmonized in any other way, as I think we
12 had a bit of discussion about this earlier, and
13 there were some -- the developer noted that there
14 were some differences in the exclusions for the
15 two measures, and maybe they could give us --
16 just reiterate what the differences are between
17 these two measures, or where there may be
18 opportunities for harmonization, or where
19 harmonization is not feasible.

20 DR. GUNNAR: Does the -- yeah, does
21 the developer fully understand what we're asking?

22 DR. MORGAN: I think that ostensibly,

1 down the line, we could look at that. I think
2 for right now, these both being new measures that
3 have not yet been collected, that we would like
4 to gain some experience with these to start, and
5 that they do entail populations that are similar,
6 so we'd like to keep that open for the future,
7 but for right now, get some experience --

8 DR. SAIGAL: I think that the -- the
9 idea that these are two different -- they have
10 two different outcomes they affect, and the
11 quality improvement initiative may be directed in
12 two different directions: we'd indicate that for
13 the start at least, let them start out with these
14 measures, and then see what needs to be done to
15 improve the compliance, and then, if the
16 processes are in place, then merge them.

17 DR. LEVY: Yeah. The other point is
18 that the denominator for these two measures is
19 quite different. So I was just looking at the
20 definition again for what we passed last time,
21 and it's "performing cystoscopy at the time of
22 pelvic organ prolapse to determine lower urinary

1 tract injury," so we may or may not be capturing
2 the same -- I -- we just need some experience
3 with this.

4 DR. GUNNAR: So I think for the
5 record, a future evaluation should address
6 whether or not they are connected, should be
7 harmonized or combined.

8 MR. LYZENGA: And I think the
9 recommendation of this Committee is that they
10 should go forward as individual measures at this
11 time and that we need to explore, as we gain more
12 experience with the measure, whether combination
13 with another measure or harmonization would be
14 appropriate. Is that -- is that fair?

15 DR. GUNNAR: Does anybody disagree
16 with that position?

17 (No response.)

18 DR. GUNNAR: Seeing none, we will
19 carry on with the next measure.

20 DR. PRESTON: This is Mark Preston
21 here. Can you hear me?

22 MR. LYZENGA: Yes.

1 DR. GUNNAR: Yes.

2 DR. PRESTON: Okay. My name is Mark
3 Preston, I'm a urogynecologist and member of
4 AUGS, and on behalf of AUGS, I want to thank you
5 for giving us the opportunity to present our
6 measure 2677, entitled Pre-Operative Evaluation
7 for Stress: Urinary Incontinence Prior to
8 Hysterectomy for Pelvic Organ Prolapse.

9 This is a process measure, as
10 mentioned before, which is briefly described as
11 the percentage of women undergoing hysterectomy
12 for pelvic organ prolapse who have pre-operative
13 evaluation for stress urinary incontinence.

14 And what is our rationale for this
15 measure and why do we feel it's important? You
16 know, as was mentioned with the last measure,
17 pelvic organ prolapse is a very common problem
18 affecting women, and it is the primary indication
19 for approximately 200,000 surgeries annually in
20 the U.S.

21 Many women in the above group
22 undergoing hysterectomy for pelvic organ prolapse

1 also have stress urinary incontinence. However,
2 the presence of the stress incontinence is not
3 always volunteered by the patient, and what is
4 more, in cases of severe prolapse, underlying
5 stress incontinence may be masked by kinking of
6 the urethra due to the prolapse, which is often
7 referred to as occult stress urinary
8 incontinence.

9 When stress incontinence is not
10 treated at the time of prolapse repair, the
11 patient will often suffer from stress urinary
12 incontinence following the prolapse repair,
13 necessitating either an additional surgery with
14 its associated risks and costs, or the patient
15 having to live with her incontinence.

16 Implementation of this measure will
17 improve quality by increasing the pre-operative
18 diagnosis of stress incontinence in women
19 undergoing hysterectomy for pelvic organ
20 prolapse, allowing for both better pre-operative
21 patient counseling as well as greater likelihood
22 of appropriate treatment of the stress

1 incontinence at the time of surgery, thus
2 decreasing the incidence of post-operative stress
3 urinary incontinence.

4 So thanks again for considering the
5 measure.

6 DR. FLEISHER: Liz, comment or
7 evidence?

8 DR. EREKSON: So when you're looking
9 at the evidence the authors present, I think the
10 most compelling is the up-to-date flow diagram,
11 where you look at -- it's just assess for stress
12 urinary incontinence and have a conversation
13 about these symptoms before surgery, and not all
14 patients are going to choose to actually undergo
15 a concomitant anti-incontinence procedure, but
16 this will significantly -- doing this assessment,
17 having this conversation with the patients, can
18 reduce your re-operation rates by quite a
19 substantial amount.

20 DR. FLEISHER: And --

21 PARTICIPANT: The numbers are small,
22 but I have no reason to doubt them in the way

1 they're presented. It's just hard to divorce
2 myself from how this is going to be
3 operationalized, but I will try. So the evidence
4 is successful.

5 DR. FLEISHER: So I have a comment.
6 I was a little confused because it actually
7 talked about preferences, and it actually talked
8 about evidence saying you should go forward, but
9 it also talked about that the evidence of a
10 negative test is not necessarily good enough, if
11 I remember correctly, to say you shouldn't go
12 forward with doing something together.

13 So one of my questions is how tightly
14 linked is a pre-operative evaluation with the
15 correct decision in surgery?

16 DR. EREKSON: So I think the best
17 data, when you look at this evidence, is some
18 randomized control trials, and they can give you
19 a number needed to treat, so if you have a
20 negative cost stress test prior to prolapse
21 surgery and you don't undergo a sling, and the
22 measure developers can correct me, there -- one

1 out of five women will need a sling in the next
2 year.

3 And so there's pretty substantial
4 numbers needed to treat, but it looks to me like
5 the measure, and what this measure is trying to
6 get at, is do something, do an assessment, have a
7 conversation with the patient. I don't -- maybe
8 I am mistaking?

9 Yeah, yeah. But in the patients who
10 have this assessment and then undergo concomitant
11 sling procedure, they're much less likely to need
12 surgery then in the future.

13 DR. FLEISHER: But my question for the
14 developer or for you Liz is but if it's negative,
15 there are still a number of women who undergo
16 this procedure, so the question is, is this the
17 right process measure? Is the evidence linked
18 closely enough? Or is this really should be a
19 PROM, and it should be was there a good
20 discussion, as opposed to was there a pre-
21 operative test?

22 DR. PRESTON: Well, so I mean you do

1 raise a good point. You know, the predictive
2 value of doing this is not 100 percent, and it's
3 not -- the negative predictive value is
4 definitely not anywhere near 100 percent, and if
5 you look at the flow chart that Liz was referring
6 to, you know, in women who have no -- in women
7 with a negative occult stress test, or even in
8 women who have -- in women who have a negative
9 occult stress test, 26 percent still end up
10 having some urinary incontinence afterwards.

11 But if they have a positive occult
12 stress test, there's an over 50 percent chance,
13 you know, about a 50 percent chance. So there's
14 a -- you know, there's -- even though the
15 predictive value is not perfect and there's a
16 substantial difference in doing that evaluation
17 and letting it guide not only the -- well, mostly
18 the conversation because obviously you have to
19 have the conversation, and the patient gets to
20 participate, in discussion, the decision-making
21 process, but doing the evaluation allows you to
22 have a much more informed discussion with the

1 patient as to what the likelihood is of having
2 this problem following surgery than if you don't
3 have, you know, if you don't -- if you don't do
4 the evaluation.

5 DR. FLEISHER: So --

6 DR. PRESTON: If you have a -- but,
7 you know, the positive stress test picks up about
8 two-thirds of those people, so -- that are going
9 to have post-operative stress incontinence.

10 DR. FLEISHER: Thank you. I would
11 argue that a negative predictive value as low as
12 you talk about, that my question is do you have
13 sufficient evidence that doing this test leads to
14 a discussion which leads to better outcomes, as
15 opposed to all your -- you have done is your
16 process is doing a test, that's all your process
17 is? So -- .

18 DR. CIMA: That's all -- the real --
19 the issue is the measure is basically saying did
20 you do a test? And not did you act appropriately
21 upon that test, did you have the discussion and
22 make a decision?

1 And that was the -- I mean, the data
2 basically on about 800 patients, two different
3 trials looked at it, and basically, they said
4 yes, you don't -- if you do the test, you're
5 going to identify patients, but the real question
6 -- and you know, so we said earlier that the
7 reason to do the suspension is to avoid surgeries
8 down the road, but this test, this is different.
9 This is saying did you have the discussion, and
10 that a certain number are going to need to have
11 it anyway, and how are you going to define who
12 that group is and who is accountable for it? You
13 really just are saying who is -- who has the
14 test?

15 So the evidence suggests that asking
16 the question does have an -- provides
17 information, but it doesn't impact an outcome.

18 DR. FLEISHER: So recognize that's the
19 question, does the relationship with the health
20 -- no, this is not the right --

21 DR. PRESTON: And, you know, it really
22 depends on if you were to -- you can never answer

1 that question the way you're phrasing it because
2 what you're saying then is that you would 100
3 percent of the time -- I mean, if you 100 percent
4 of the time said if you have a positive stress
5 test you should do the incontinence procedure,
6 okay, but that takes then -- then you're
7 eliminating any patient interaction and patient
8 participation in that discussion.

9 So, you know, if you were -- if we
10 were to phrase it and say if you have a positive
11 cough stress test, you should do a sling, and
12 you're going to -- you know, if you look at it
13 that way, yes, then you -- then we reduce -- you
14 change the outcome significantly. If you have a
15 positive cough stress test and you do the
16 surgery, you have a 16 percent chance at having
17 incontinence afterwards, versus not doing the
18 surgery, where you have a 50 percent chance of
19 having incontinence after the surgery. So there
20 is a big difference in the outcomes.

21 But -- what -- the step that is
22 missing there is the conversation, but you can --

1 no test would pass that criterion because you're
2 -- you can't eliminate that step, right?

3 I mean, it's just like saying if
4 you're in the 90s percent blockage of your
5 coronary artery --

6 DR. FLEISHER: No, I understand. I
7 think --

8 DR. PRESTON: -- you understand what
9 I am saying, right?

10 DR. FLEISHER: Yeah, no, I understand
11 what you're saying. Do I have other comments from
12 any Committee members? Because I understand what
13 your argument is.

14 DR. SIPERSTEIN: Yeah, I guess, you
15 know, the evaluation -- I mean, requiring the
16 evaluation, I think it's -- it moves towards
17 impacting the outcome. It's just like we just
18 approved a measure saying it's okay to write a
19 prescription for antiplatelets at discharge.
20 We're not proving that they filled it or they
21 took their pills, but we feel that that action is
22 moving towards a positive outcome. So it's a

1 surrogate of moving in the right direction.

2 DR. FLEISHER: And people get to vote
3 on that.

4 DR. SIPERSTEIN: We're not -- we're
5 not demanding perfection.

6 DR. FLEISHER: Right, people get to
7 vote.

8 Fred, did you have a comment? No?
9 Okay.

10 A.J.?

11 DR. YATES: I hear where you're coming
12 from. The issue is what is the healthcare state
13 that is affected by doing the screening? And in
14 this particular case, you would have to say that
15 the healthcare state is the -- this is going to
16 sound ephemeral, but it's the ability to do an
17 effective shared decision-making with the patient
18 in terms of how to go ahead, and that would be --
19 without the stress test, you're not giving the
20 patient a fair, full assessment that impacts
21 their shared decision-making as to whether they
22 want to agree to go ahead to have a sling versus

1 not.

2 It's not -- it's -- it may not be
3 necessary for them to have that sling, but it
4 does enter into the shared decision-making that
5 the patient deserves to have with the surgeon.

6 I would argue that this is -- this is
7 moving ahead to usability and everything, but in
8 terms of this evidence, this comes down to an
9 office visit discussion that I don't know why
10 this is a hospital measure as opposed to a PQRS-
11 type measure that would be aimed at the surgeon's
12 processes as opposed to surgical outcome.

13 DR. FLEISHER: Liz?

14 DR. EREKSON: I also think if you're
15 really going to the nuts-and-bolts, that I am
16 going to check a box and say I did a cough stress
17 test versus I am going to check a box and say I
18 talked to the patient about her options, I think
19 I'd want that cough stress test there. You know,
20 I would want that testing there to back up the
21 fact that I had that conversation, yes.

22 DR. FLEISHER: So recognize that CSAC,

1 we would like to not have the physician do the
2 checkmark, it would actually be the patient who
3 does the checkmark that they have an adequate --
4 now, that's not there yet, but that's really a
5 PROM as opposed to a physician instructional
6 member.

7 Other comments? And I don't want to
8 -- Collette.

9 MS. PITZEN: I am going to try my --
10 maybe I won't make sense.

11 But again, to me, this feels like a
12 standard of care, an assessment that should be
13 happening that perhaps maybe is not happening,
14 versus a process measure that is going to be used
15 for whatever use, quality improvement or
16 accountability.

17 Again, you want it to have that direct
18 relationship with the outcome, and again, I think
19 that brings it into question a little bit.

20 DR. FLEISHER: Other comments before
21 we vote solely on evidence that this process is
22 linked to -- that performing this process is

1 linked -- and actually, I would like NQF staff to
2 say it correctly because I don't want to bias it.

3 MS. JOHNSON: I am going to hand it
4 over to Andrew just because my mind was still a
5 little bit in the next frame, sorry about that.

6 MR. LYZENGA: Well, we're -- what
7 we're voting on is the -- the level -- the degree
8 to which you feel sufficient evidence has been
9 provided to support this process as a performance
10 measure, again, suitable for public reporting or
11 accountability or quality improvement.

12 We have some sort of guidance, and
13 there's an algorithm which we -- it should be in
14 your -- oh, it's not in here. It should be in
15 your packet of information. It's these little
16 colored things here, which walks through
17 evidence, or your decision tree with respect to
18 evidence, and there are some sort of standards
19 that we like to see, including a systematic
20 review of the evidence; a statement on the
21 quality, quantity, and consistency of the
22 evidence; we would like it to be based on a

1 guideline. So there are, again, some sort of,
2 you know, sub-criteria here that we would like
3 you to look at when you're making this decision.

4 But ultimately, the question is how
5 strong is the evidence supporting this measure,
6 this process measure?

7 DR. CIMA: So the one thing about
8 practice variation -- now that's unpublished data
9 from a survey from a specialty society, so I'm
10 just -- I mean, it's not really published data,
11 and all this refers to published data.

12 MR. LYZENGA: I think -- I mean, I
13 think we allow, Karen correct me if I am wrong,
14 for the developer to sort of do their own review
15 of the evidence, and that will -- we can allow
16 that to speak to the evidence, but I will turn it
17 over to Karen, maybe, for some additional
18 remarks.

19 MS. JOHNSON: Yeah, so the best thing
20 to have would be a systematic review that
21 somebody else has already done all that work and
22 graded the evidence, but in -- if that didn't

1 happen, then it would be up to the developer to
2 summarize all the evidence for you and tell you
3 about its quantity, quality, and consistency. So
4 is that what you're referring to? I see --

5 DR. CIMA: No --

6 MS. JOHNSON: -- a different page up

7 --

8 DR. CIMA: -- because this is them
9 providing their own evidence, that we don't know
10 where it came from.

11 MS. JOHNSON: Is this under 1(b) or
12 1(a), I am sorry?

13 DR. CIMA: 1(b).

14 MS. JOHNSON: Okay. So this is the
15 gap information.

16 MR. LYZENGA: Yeah, we are 1(a).

17 MS. JOHNSON: So --

18 DR. CIMA: I thought 1 was all done
19 together.

20 MS. JOHNSON: No.

21 MR. LYZENGA: No, we do those
22 separately.

1 MS. JOHNSON: No, they suggest
2 evidence, and then we'll come back to gap, but
3 I'll go ahead and answer your question. It is
4 okay for the developer to give you kind of
5 proprietary information if that's what they're
6 giving you for gap.

7 DR. FLEISHER: Collette, and then we
8 --

9 MS. PITZEN: Hi again.

10 We had a measure for our diabetes
11 patients, we went from an intermediate clinical
12 outcome of LDL less than 100 to appropriate use
13 of statin, so moving from an outcome measure to a
14 process measure, and that process measure needed
15 really strong evidence that I expect every
16 diabetic patient according to the ACC/AHA
17 guidelines to be on a statin.

18 I think where this perhaps maybe is a
19 little bit lacking is -- or how it could be
20 stronger is if the patient did demonstrate
21 urinary incontinence, then you would expect that
22 kind of procedure to be happening.

1 DR. MORGAN: Can -- this is Dan
2 Morgan, I am one of the developers.

3 And this may speak to some of these
4 concerns. The -- when a stress test is done, and
5 that is through our own proprietary data, and
6 this -- we have evidence that the -- an anti-
7 incontinence procedure is much more likely to be
8 performed, so I think that that -- that while
9 this is a process measure and it may be something
10 that the physician is saying yes, I have done or
11 documented, it does -- we do have evidence that
12 it leads to a change in their care that we know
13 is a highly effective treatment, so that I hope
14 that you can see that it's -- that yes, that it
15 is a test that's performed, but it also leads to
16 definitely a change in treatment plan that leads
17 to a change in outcome.

18 DR. FLEISHER: Okay. Why don't we
19 vote?

20 MR. LYZENGA: So voting on evidence.
21 Your options are high, moderate, low, and
22 insufficient.

1 DR. FLEISHER: Okay.

2 MR. LYZENGA: We have 67 percent --
3 zero percent for high, 67 percent for moderate,
4 24 percent for low, and ten percent insufficient,
5 so the measure passes on evidence.

6 And we can go ahead to performance
7 gap.

8 DR. FLEISHER: Comments? Liz?

9 DR. EREKSON: So the information that
10 the measure developers present on performance gap
11 is proprietary information that they did from a
12 chart review. They essentially went back and
13 looked at -- from a sample across four sites,
14 they then selected high-, medium-, and low-volume
15 surgeons, and then looked back in the chart to
16 see if this cough stress was performed.

17 And low-volume surgeons were much less
18 likely to do the cough stress, or at least
19 document it in their records, than high-volume
20 surgeons.

21 And so that does show a variation in
22 care.

1 DR. FLEISHER: Any other comments?

2 (No response.)

3 MR. LYZENGA: All right, let's go
4 ahead and vote on performance gap. High,
5 moderate, low, or insufficient.

6 (Pause.)

7 MR. LYZENGA: So we have 23 percent
8 high, 68 percent moderate, nine percent low, zero
9 insufficient. The measure passes performance
10 gap, and we'll go ahead to reliability.

11 DR. EREKSON: So this is a measure
12 that's collected from chart review. The
13 denominator is identified, and please correct me
14 if I'm wrong, by ICD-9 and CPT codes, the
15 numerator is identified by chart review.

16 And the measure developers went back
17 and looked at if they could find if it was
18 documented in the chart, and they had a separate
19 person then review the charts, and their kappa
20 was 0.83.

21 DR. FLEISHER: Other comments?

22 (No response.)

1 DR. FLEISHER: Okay, vote? Do you
2 have a comment?

3 DR. TEMPLE: I guess I am just trying
4 to understand if the reliability of the reporting
5 reflects the reliability that they'll get when
6 they use this measure in real life.

7 So is it the intention of the
8 developer that there will be constant chart
9 review, or is it the plans of the developer that
10 the physician will tick off stress tests done,
11 and that will be how the measure is done?

12 And I am just -- it's the same -- I
13 mean, I am just curious if the plan is always
14 chart abstraction versus physician self-report
15 with some subsequent audit.

16 DR. PRESTON: You know, I think for
17 now, chart review -- we're kind of looking at
18 chart review as sort of really kind of having to
19 be essential, and from my point of view, the
20 problem with, you know -- we all love tick boxes,
21 I would love to have a tick box, but I think we
22 all know that the reliability -- it's a lot

1 easier to check a box whether you did something
2 or not than it is, you know, making sure you've
3 documented it in the chart, somebody went back to
4 the patient and asked.

5 We can't say it would verify it at
6 least most of the time --

7 DR. FLEISHER: In the specs, what does
8 it say? Because we are voting on the measure as
9 is, and I --

10 DR. PRESTON: Yeah, it's -- well, as
11 is is chart review.

12 DR. FLEISHER: It is chart review in
13 the specs, and therefore that is what we're
14 approving or not approving.

15 DR. TEMPLE: Right. I just wanted to
16 make sure from a reliability perspective that
17 that's what it was.

18 DR. FLEISHER: Thank you.

19 Any other comments?

20 DR. YATES: Yes.

21 DR. FLEISHER: A.J.?

22 DR. YATES: I just -- my comment is

1 that there's a lot of things in a busy clinic
2 that you comment on because they're pertinent
3 positives, but it doesn't mean that you comment
4 on every pertinent negative.

5 Now, this would make that pertinent
6 negative more important to comment on, if they're
7 going to adjudge your quality by whether or not
8 you're doing this part of the exam, but I would
9 -- I would say that this may be under-reporting
10 what is actually done because it may be done by
11 more surgeons than the chart review shows, but
12 they just chose not to comment on it in the body
13 of their dictation.

14 DR. FLEISHER: Thank you.

15 Other comments?

16 (No response.)

17 DR. FLEISHER: Vote?

18 MR. LYZENGA: Voting on reliability.

19 Your options are high, moderate, low, or
20 insufficient.

21 (Pause.)

22 MR. LYZENGA: All right. We have nine

1 percent high, 83 percent moderate, nine percent
2 low, zero insufficient, so the measure passes on
3 reliability.

4 We can go ahead to validity.

5 DR. EREKSON: So again, in the
6 validity, this is the proprietary information
7 that the measure developer is presenting, and
8 they divide surgeons into high-volume, low-
9 volume, and medium-volume.

10 Oh, I am sorry. So one of the face
11 validity testing is that the high-volume, low-
12 volume, and medium-volume surgeons perform the
13 cough stress test more often. The other is that
14 when a cough stress test is performed, that the
15 anti-incontinence procedure is more likely to be
16 performed at the same time.

17 DR. FLEISHER: Amy?

18 MS. MOYER: So a concern I have if I
19 am reading this correctly is there is no
20 exceptions to the measure, so if a patient comes
21 in and says yeah, this is an issue, they still
22 have to have the tests to confirm, is what I am

1 reading, which seems like it could lead to over-
2 testing or over-utilization.

3 DR. EREKSON: So the --

4 DR. FLEISHER: Comments from the
5 developer -- oh, Liz?

6 DR. EREKSON: So the measure is
7 described -- and I really read through this very,
8 very critically because there's very invasive,
9 very expensive testing called urodynamic testing,
10 and then there is a reduction cough stress test
11 that does not even necessarily require
12 catheterization.

13 And so as it is written, they are not
14 talking about the very invasive, you have to get
15 catheterized, you have to come in for an hour to
16 an hour-and-a-half-long procedure, it is during
17 your pelvic exam when we're assessing for
18 surgery, was the cough stress test performed, so
19 the pelvic exam is performed with a full bladder.

20 So I don't think it necessarily
21 produces a huge burden or increased risks to
22 patients the way it is written.

1 DR. PRESTON: I would agree with what
2 Liz has said, I think that was you, Liz.

3 This -- you know, for those of us who
4 are -- who do this as our primary clinical work,
5 this is a part of pretty much every evaluation.
6 It takes ten seconds, and there is no -- there is
7 no resource used other than, you know, my breath
8 that says cough.

9 DR. CIMA: Is this something that is
10 done by all members of the specialty?

11 DR. LEVY: Yes.

12 DR. PRESTON: Yeah, I would say so.

13 DR. FLEISHER: Other comments?

14 (No response.)

15 DR. FLEISHER: Voting? Yeah, let's
16 vote.

17 MR. LYZENGA: Voting on validity:
18 high, moderate, low, or insufficient.

19 (Pause.)

20 MR. LYZENGA: We have four percent
21 high, 87 percent moderate, nine percent low, zero
22 insufficient.

1 The measure passes validity, so we can
2 move on to feasibility.

3 DR. EREKSON: So again, for
4 feasibility, this measure identifies the
5 denominator by CPT codes, and -- CPT and ICD-9
6 billing codes, but the numerator is a chart
7 review.

8 DR. CIMA: I have a question for the
9 developer on that because I didn't quite -- so
10 since the procedure is done in a hospital, that's
11 where the ICD-9 codes are going to reside. This
12 is an office-based procedure, so you're going to
13 have to go back to your record. How are you
14 going to merge those? How are you going to
15 operationalize that?

16 DR. PRESTON: That's a really good
17 question.

18 DR. LEVY: From a practical
19 standpoint, you also code in the office, when you
20 get back to the office, you code for your
21 procedure using ICD-9 or -10 and a procedure
22 code, so your clinic note will identify an ICD-9

1 or -10 code that you're evaluating the patient
2 for prolapse.

3 DR. CIMA: Well, I'm just trying to
4 figure out if it's linked -- you're going to
5 identify groups that actually had the surgery --

6 DR. LEVY: Correct.

7 DR. CIMA: -- but then you may
8 identify in your clinic patients whom you're
9 evaluating for pelvic organ prolapse who then you
10 have to -- you don't -- so how -- you know, some
11 are going to go to surgery, some are not, so I am
12 just wondering how you --

13 DR. LEVY: So you'll pull --

14 DR. CIMA: -- because you may have two
15 different populations.

16 DR. LEVY: You'll use your
17 administrative data in your office to pull those
18 charts of patients who have had a hysterectomy
19 for prolapse, and then you'll do the chart review
20 to see was the cough stress test done.

21 DR. CIMA: Glad you'll be the one
22 selling this to your group.

1 (Laughter.)

2 DR. PRESTON: No, but it -- from a
3 practical standpoint too, this is something that
4 should -- you know, most of us -- I will speak
5 for myself, I would put in my admission note when
6 the patient is coming for surgery as part of the
7 evaluation under my physical exam.

8 And I don't think -- you know, it's
9 not a big burden to include that in your note,
10 and I think if people know they're being measured
11 on it, they'll make sure they put it in.

12 DR. MOSS: So since the criteria can
13 be satisfied by a ten-second interaction in the
14 physical exam, will that mean that the
15 abstracters will read the whole physical exam,
16 and what level of sophistication will be required
17 to figure out whether they did it or not, and how
18 much variability is there in the way people might
19 document that in their physical exam?

20 DR. FLEISHER: Any comments?

21 DR. PRESTON: I would think that it
22 would actually be -- what we looked for when we

1 did this in our institution was for a description
2 either of Valsalva cough -- Valsalva stress test
3 or a cough stress test, and usually, there is
4 really standard language around it that stress
5 incontinence was or was not the module.

6 DR. FLEISHER: A.J. and then Amy?

7 DR. YATES: Yeah, I mean, if you are
8 going to try to harmonize the outpatient record
9 with the inpatient data, it just sort of strikes
10 me that this is headed towards a reporting
11 requirement for SCIP sort of thing where we all
12 had -- as surgeons, we all had to make our
13 attestation that there was antibiotics given and
14 antibiotics expected to be given within four
15 hours after surgery and completed within 24 hours
16 after surgery and DVT prophylaxis was to start
17 tomorrow.

18 And it may be that when someone is
19 doing a hysterectomy, that they're going to now
20 have to have their attestation as part of their
21 operative note that a urinary stress test was
22 done in the office before this hysterectomy and

1 the results were, and did it influence the
2 outcome of this procedure.

3 That might be where you collect your
4 data, but that's --

5 DR. FLEISHER: Thank you.

6 DR. YATES: -- but I -- but that may
7 -- but that may be what evolves to make this
8 happen, because we don't know where the data is
9 going to be put.

10 DR. FLEISHER: Correct, but that is
11 actually not our -- that is not what we're voting
12 on now. It's how they will implement it.

13 DR. YATES: Well, it's not --

14 DR. ADAM: Hello there, this is Rony
15 Adam. I am another one of the measure
16 developers, and I got on a little late, I
17 apologize.

18 I also wanted to mention to everybody
19 that this is also intended to be a registry
20 measure, which would take care of a lot of the
21 difficulty in an outpatient versus an inpatient
22 because it's already going to be loaded onto the

1 registry.

2 DR. CIMA: So where is the registry
3 right now?

4 DR. ADAM: AUGS.

5 DR. CIMA: And you're -- it's in AUGS?

6 DR. ADAM: Well, it's in -- it is
7 fairly advanced implementation. We have already
8 started the registry now, we're getting --

9 DR. CIMA: So the registry is for
10 every gynecologist, or is it a specific group
11 that's going to use it? Because this becomes the
12 issue. We're going to be --

13 DR. ADAM: It's for anybody, anybody
14 who does pelvic floor disorder surgery, whether a
15 gynecologist, urologist, or a urogynecologist.

16 DR. CIMA: So that's the other issue,
17 though, that I was going to bring up on the
18 feasibility, is there are other people that do
19 this other than gynecologists, correct?
20 Urologists will also be doing this, so -- and
21 they're not on the development team here, so if
22 they're going to be asked to be measured, has

1 there been a consultation with them?

2 DR. PRESTON: Well, they're not going
3 to be doing hysterectomies for prolapse.

4 DR. SAIGAL: Well, I -- I mean, as a
5 urologist, at our center at UCLA, we do do them.
6 I mean, I don't do them personally, but we have a
7 pretty active program, but maybe it's not
8 nationally common, I don't know.

9 MS. PITZEN: I just wanted to share,
10 technically, it is possible, when you're
11 collecting data retrospectively, to use the CPT
12 procedure codes that a surgeon is billing
13 actually from his office for the procedure as a
14 way to pull in your denominator, and then you're
15 collecting your numerator information based on
16 that denominator.

17 DR. FLEISHER: Thank you. Liz, did
18 you have a -- ?

19 DR. EREKSON: I just wanted to comment
20 on my understanding of the registry, and I know
21 there's measure developers on line as well.

22 The registry was created as a multi-

1 stakeholder panel between the FDA mesh companies
2 and AUGS, and what it is, it's a very feasible
3 registry that's an online interface, so it's
4 very, very easy to enter data into, and could you
5 talk to the cost of participation in the
6 registry? And there is no requirements of
7 membership in any society to participate,
8 correct?

9 DR. ADAM: Correct. It is not
10 designed for one specific subspecialty.

11 I don't know the cost offhand, but it
12 is -- if anybody is on line that recalls the cost
13 particularly, please chime in, but it is not
14 onerous.

15 DR. FLEISHER: Hello?

16 MS. HUGHES: Hi, this is Colleen
17 Hughes. It is going to be \$195 for each
18 participant, and that's a yearly fee, so it's
19 very affordable.

20 DR. FLEISHER: Thank you, John?

21 DR. ADAM: That's what I was going to
22 say.

1 DR. FLEISHER: John?

2 DR. HANDY: Yeah, I just wanted to
3 mention the pre-meeting comments, the American
4 Urological Association endorsed this measure.

5 DR. FLEISHER: Thank you.

6 So our focus should be on how the
7 measure specified is what we vote on. It is
8 great that we can give them suggestions of how to
9 implement it, but that's separate and outside of
10 this.

11 So if we can vote on feasibility.

12 MR. LYZENGA: Feasibility now: high,
13 moderate, low, or insufficient.

14 (Pause.)

15 MR. LYZENGA: We have five percent
16 high, 68 percent moderate, 23 percent low, and
17 five percent insufficient, so it does pass
18 feasibility.

19 So we'll go to usability and use.

20 DR. FLEISHER: Any comments?

21 (No response.)

22 DR. FLEISHER: Why don't we vote?

1 MR. LYZENGA: All right, voting on
2 usability and use: high, moderate, low, or
3 insufficient information.

4 (Pause.)

5 MR. LYZENGA: Five percent high, 64
6 percent moderate, 32 percent low, zero
7 insufficient, so the measure passes on usability
8 and use, and we'll move to overall suitability
9 for endorsement.

10 We can go ahead and vote unless
11 anybody has any comments.

12 (No response.)

13 MR. LYZENGA: All right, voting.

14 (Pause.)

15 MR. LYZENGA: Seventy-three percent
16 yes, 27 percent no. The measure passes.

17 So that means we will move to the ASA
18 measure.

19 Ah, break, you're right. We should do
20 a break.

21 DR. FLEISHER: We have a 15 minute
22 break, and then we'll try to start up quick. I

1 think we've gone through a lot of the gaps, and I
2 think it will only take about five minutes to
3 assign people gaps to do it afterwards, so the
4 goal is still to get home -- by 5:15 at the
5 latest, go to public comment.

6 (Whereupon, the hearing went off the
7 record at 3:59 p.m. and resumed at 4:13 p.m.)

8 DR. GUNNAR: So, this is Measure 2681,
9 Perioperative Temperature Management. It is a
10 new measure and the developers are the American
11 Society of Anesthesiologists who we have here in
12 the room.

13 And so, if you will present, sort of
14 tee it up for us, we'll go from there.

15 MR. POPOVICH: Sure, thank you, Dr.
16 Gunnar.

17 Can I just ask if Dr. Jim Moore is on
18 the line? Okay, he was on the line before, can I
19 just check to make sure that he's on?

20 DR. MOORE: Hello, this is Jim Moore
21 on the open line phoning in on behalf of the ASA.

22 MR. POPOVICH: Great, thank you, Dr.

1 Moore.

2 Okay. Good afternoon, my name is Matt
3 Popovich. I'm the Director of Quality and
4 Regulatory Affairs at the American Society of
5 Anesthesiologists. I'm joined here with Tom
6 Miller, Director of Health Policy Research at ASA
7 and joining us on the phone is Dr. James Moore
8 who chairs one of our ASA committees that
9 develops, reviews and provides expertise on
10 measures aimed at improving the care of
11 anesthesiologists provided to patients -- that
12 anesthesiologist provided to patients to each
13 day.

14 Dr. Moore is a Clinical Professor and
15 Administrative Director of the Preoperative
16 Evaluation Planning Center in the Department of
17 Anesthesiology and Perioperative Medicine at
18 UCLA.

19 The measure before you is a
20 Perioperative Temperature Management Outcome
21 measure. The measure was developed in 2010 as a
22 revision to a measure this committee is very well

1 aware, NQF 0454.

2 That measure in particular allowed
3 either a process of care, the active warming of a
4 patient or a patient meeting a temperature
5 threshold at the end of anesthesia time as
6 counting towards successful performance.

7 That was changed by the -- or the ASA
8 felt that more emphasis should be placed on the
9 outcome, that a temperature of 35.5 degrees
10 rather than a process of care would prove better
11 quality given to the patient.

12 ASA maintains that this is an
13 improvement over the previous measure, as
14 mentioned in our submission as it focuses on a
15 pure outcome of a vital sign rather than a
16 process of care.

17 We are introducing this measure, as
18 Dr. Gunnar noted, as a new NQF measure.

19 As part of this initial presentation,
20 I ask that Dr. Moore provide a few introductory
21 remarks on how this measure can drive quality
22 improvement at the local level and the patients

1 under care that this measure provides to patients
2 and patient outcomes.

3 Dr. Moore.

4 DR. MOORE: Thanks, Matt. Thanks,
5 everyone, I appreciate the opportunity to address
6 your committee.

7 This revised measure evaluates the
8 percentage of procedural patients who undergo
9 general or neuraxial anesthesia of at least one
10 hour duration and for whom the temperature of at
11 least 35.5 degrees Celsius was recorded within 30
12 minutes before or 15 minutes after anesthesia end
13 time.

14 As Dr. Popovich mentioned, it is
15 intended to replace Measure 0454 which is
16 potentially a set of a process of the applying
17 active warming for the patient.

18 Anesthesiologists have struggled to
19 design rigorous outcome measures that reflect
20 meaningfully the quality of the care we provide.

21 One reason for this is that many of
22 the important clinical outcomes for our patients

1 don't depend only on what we do.

2 In preventing hypothermia, we
3 potentially prevent a variety of clinically
4 important complications, include morbid
5 myocardial outcomes, surgical wound infections,
6 coagulopathy, increased transfusion, delayed
7 wound healing and delayed recovery from
8 anesthesia.

9 And beyond these sequelae, hypothermic
10 patients also experience increased shivering, and
11 discomfort. Temperature management is something
12 anesthesia providers do have direct control over
13 once the patient arrives in the operating room.

14 We believe holding anesthesia
15 providers accountable for preventing hypothermia
16 will improve patient care and reduce
17 complications through preservation of
18 normothermy.

19 Allowing a process which is active
20 warming to fulfill the current measure the
21 current measure without demonstrating that the
22 warming effort would be effective is less

1 desirable.

2 So, while adverse outcomes associated
3 with hypothermia occur on a continuum of
4 temperature, and there's no one temperature that
5 can be used to draw clear lines for all patients
6 for all operations. The selection of 35.5
7 degrees as the target was the best opinion of the
8 experts at the time and remains the selection
9 best supported by the current clinical evidence.

10 And the ASA appreciates your
11 consideration of this measure.

12 DR. GUNNAR: Dr. Grover?

13 DR. GROVER: Yes, let me start out.
14 That was very well stated and I won't repeat all
15 of that.

16 Before we go down the various avenues
17 here that we go down, though, I would like
18 clarification on one area and that is the way
19 that this is stated, it's either a pre-op
20 temperature or an early post-anesthesia
21 temperature.

22 And it seem to me like you have to

1 have the post-anesthesia temperature or an
2 intraoperative pressure. And just with the way -
3 - I mean if it said pre-op and post-anesthesia,
4 that would be fine, but or, you could just do a
5 pre-op and you aren't going to know whether the
6 patient developed hypothermia.

7 DR. MOORE: That would be correct,
8 sir. And the intention and as it's currently
9 worded that the temperature would be within 30
10 minutes before the anesthesia end time or 15
11 minutes after the anesthesia end times.

12 And as a practical consideration,
13 although the time periods may really be somewhat
14 arbitrary, they're at least based in part on the
15 notion that near the end of the operation, and
16 this is an intention to capture a temperature
17 near the end of anesthesia care, it's a logical
18 accommodation to differing systems of care and
19 systems of data recording and capture.

20 Clearly, it's at the end of care,
21 within 30 minutes of the end of anesthesia time
22 but also potentially within 15 minutes after.

1 The temperature does not change
2 quickly near the end of anesthesia care, but we
3 do want it to be reflecting that general period
4 of time. And near the end care, a variety of
5 things can happen that can dislodge the probe
6 unintentionally or as there's preparation to
7 leave the operating room, it's intentionally
8 withdrawn.

9 Also, the timely measuring of
10 temperature in the recovery room is not always
11 consistent. So, if we capture a temperature
12 within 15 minutes of the end time in the PACU,
13 that does suffice. We do expect to need to have
14 the times recorded during anesthesia care which
15 is the 30 minutes before as well.

16 And as an aside, the current measure
17 0454 specifies 30 minutes before or 30 minutes
18 after the anesthesia end time.

19 Does that address your concern, sir?

20 DR. GROVER: Well, as long as it -- I
21 don't like the or part. I mean you've got to
22 have -- you can do it before, but there's got to

1 be during and after.

2 And I think you said you've changed
3 that and that was my main criticism of that. But
4 otherwise, I think excellent measure that we can
5 go into.

6 DR. MOORE: Thank you.

7 DR. SAIGAL: Can I ask a question?

8 DR. GUNNAR: Yes.

9 DR. SAIGAL: So, the way you're
10 measuring this here with the one measurement,
11 that is consistent with how the evidence was
12 developed that hypothermia leads to arrhythmias
13 so forth.

14 Like, in those studies they looked at
15 one temperature measurement or how do they -- if
16 you measure this, we'd be capturing the relevant,
17 you know, predictive factor? That's my question.

18 DR. MOORE: Well, the intent is to
19 reflect the quality of anesthesia care provided
20 in warming the patient or maintaining
21 normothermia by virtue of the temperature as it
22 exists towards the end of case.

1 There is quite a lot of variability in
2 patients with respect to the start of the case
3 and how they often come in hypothermic.

4 It's also a practical consideration as
5 to how to design a measure that's reportable and
6 consistently so. Which is not to say that the
7 temperature should not be measured throughout
8 anesthesia care and anytime we apply active
9 warming, it is the intention that, for
10 appropriate practices, that those things will
11 apply.

12 As far as the time point with respect
13 to the measurements, there have been studies that
14 looked at a variety of time points and some that
15 don't suggest a threshold in the comparative
16 groups but rather find that patients who are
17 actively warmed versus those that aren't have
18 quite different temperatures.

19 So, there wouldn't be one way of
20 describing all of the various papers that we
21 cited with respect to that particular
22 consideration.

1 DR. GROVER: The premise here as I
2 understand it, and is that the -- I mean the
3 evidence is really Class 1A in terms of
4 hypothermia and the adverse periprocedural
5 hypothermia and the adverse outcomes.

6 So, switching over to outcomes only
7 are showing that you're preventing hypothermia,
8 you would assume then that this would be
9 correlated with less adverse events.

10 And I don't want more questions on
11 this or move into the evidence, Bill, or you all?

12 DR. GUNNAR: I think we have one more
13 colleague.

14 MR. LYZENGA: Yes, I was going to ask
15 Kelsey if she wanted to comment here, backup
16 discussion.

17 MS. MCCARTY: Sure, just I mean I do
18 think that the wording of the measure is
19 confusing. I had the same thought that Dr.
20 Grover did when I first read it that it was
21 before the start of the anesthesia and the last
22 15 minutes as opposed to a contiguous 45 minute

1 period.

2 So, I do think that that part could be
3 improved. But, generally, I think, you know,
4 there's a lot of literature to support that
5 looking at that postoperative hypothermia does --
6 is a bad outcome and has associated downstream
7 bad outcomes and that it is a good thing to
8 measure it and try and reduce it. I think
9 there's strong evidence for that.

10 DR. GUNNAR: Thank you.

11 Collette?

12 MS. PITZEN: Just a technical question
13 for staff.

14 I guess I view this as an intermediate
15 outcome measure and not a pure outcome measure.

16 MR. LYZENGA: That was our assessment
17 as well, I think, in our preliminary assessment
18 here. We did identify it as an intermediate
19 clinical outcome and really the difference there
20 is the level of evidence required and they have
21 provided the level of evidence required for an
22 intermediate clinical outcome.

1 So, we can -- I don't know if the
2 developer is also okay with classifying it as a
3 intermediate clinical outcome, but --

4 MR. POPOVICH: We're okay with that.

5 MR. LYZENGA: You're okay with that?
6 So, maybe we just change it in the follow-up to
7 this meeting.

8 MR. MILLER: Yes, my one question is,
9 you have to show the -- or the preface of the
10 question is, you have to show 35 degrees
11 sonogram. Sometime within that 45 minute period,
12 how do you handle other measurements if someone
13 was 34 degrees on three measurements up to the 35
14 degree five minutes before the end of the case
15 and then hit the recovery room at 33?

16 Do they still get credit for the 35
17 one time if they were able to warm them up when
18 they saw they weren't quite warm enough? Is it
19 enough to have the one time 35 degree?

20 DR. MOORE: Well, generally, we do
21 believe that it is if you have a temperature of
22 at least 35.5 degrees. The temperature does not

1 change quickly if the measurement is accurate.

2 We do have problems, at times, where
3 when there can be significant variability in the
4 probe reading, in which case, it may not be
5 reliable. Normally, that's in the direction of
6 artifactually lower temperatures and not
7 artifactually higher.

8 However, when patients do start
9 hypothermic, it is more difficult to warm them.
10 Even so, if they have a low temperature at any
11 point or at the start of a case and can be warmed
12 to 35.5 or higher, we do believe that that
13 reflects good care with respect to warming
14 measures and should help to prevent significant
15 sequelae as well.

16 DR. GUNNAR: So, I was just getting my
17 grounding evidence here.

18 I mean, for me, from a surgeons
19 perspective, it's easy for me to think, okay, end
20 of, you know, incision, drapes removed, patient
21 extubated, patient out of the room, patient
22 entering PACU.

1 Is it just me that it might lead to
2 some -- that it's too subjective to say end of
3 anesthesia end time? Because I don't know what
4 anesthesia end time is.

5 DR. MOORE: And, sir, as a surgeon,
6 you probably wouldn't see it routinely. It
7 typically happens when the care of the patient is
8 transferred from the anesthesia provider to the
9 PACU nurse.

10 So, typically, it's happening in the
11 PACU. And that commonly may occur 10 to 15
12 minutes after leaving the operating room once the
13 report is given and vital signs are taken.

14 So, the idea of being 30 minutes prior
15 to that anesthesia end time or 15 minutes after
16 is to represent the end of the end of the case,
17 generally speaking.

18 It's also the same wording as in
19 Measure 0454 which also may be a little confusing
20 in that except that the time has changed from 30
21 minutes immediately after in the current 0454 to
22 15 minutes immediately after.

1 I do appreciate the potential
2 confusion generated by saying immediately before
3 or 30 minutes immediately after instead of being
4 more clear about what that is supposed to mean.

5 DR. GUNNAR: But, let's be practical.
6 Say you have an esophageal temperature probe in.
7 You take that out at the time the patient's
8 extubated. That temperature, that last recorded
9 temperature actually would be your most useful
10 temperature if the rest proceeded as planned,
11 which was patient was, you know, placed on the
12 cart, moved to PACU.

13 You wouldn't have to rely on the PACU
14 temperature as the first temperature, it would be
15 the one that you used in the operating room at
16 the time of the esophageal temp was removed. Is
17 that -- did my ear catch that correctly from a
18 process point of view?

19 DR. MOORE: That's correct, sir.
20 Prior to the extubation and the last temperature
21 according to the esophageal temperature probe in
22 someone who was intubated would likely be the one

1 that would pertain to the reporting of this
2 measure.

3 MS. MCCARTY: I would just add that
4 not all cases have intraoperative temperature
5 management. And so there are some cases, I know
6 we do some at our institution, where that's one
7 vital sign for certain cases we don't document.

8 And, so the first temperature reading
9 you get you one pre-op and you get one post-op
10 and those are your temp readings and you really
11 do rely on the nursing teams to capture those
12 measurements. And you don't have the anesthesia
13 team capture it.

14 So, not all work flows as you
15 described.

16 DR. GUNNAR: And, for that reason, I'm
17 trying to ground it to a point in time. Maybe
18 it's just me, I think end of anesthesia is -- or
19 anesthesia end time is --

20 MS. MCCARTY: Well, so for billing
21 purposes, on the anesthesia side, that's actually
22 a requirement for billing.

1 DR. GUNNAR: Sure.

2 MS. MCCARTY: And so --

3 DR. GUNNAR: No, understood.

4 MS. MCCARTY: Oh, okay.

5 DR. GUNNAR: Understood, understood.

6 I understand that it's a point in time
7 that's measured in the chart, I guess.

8 In relationship to this temperature,
9 the intent of, you know, identifying the
10 temperature upon which you're going to measure
11 quality is anesthesia end time. That can go
12 quite far into the PACU experience, right?

13 DR. MOORE: It is possible, sir. I
14 would say that typically it may go about 10
15 minutes at the most in a routine case after the
16 entry into PACU.

17 And just as a practical matter, if we
18 were wanting to describe a measure by one
19 consistent event, it's just it seems like the
20 most likely to fulfill all intended
21 circumstances, although you could go by, say the
22 end of surgery, there is conflict in determining,

1 is that when the last suture is done? Is it when
2 the dressing is done? Is it when the
3 anesthesiologist now has control again of the
4 patient?

5 Whereas, the anesthesia end time is
6 recorded for every case for which we bill.

7 DR. GUNNAR: No, I'm just saying what
8 -- I was trying to figure why it wouldn't be
9 within 30 minutes immediately before or 15
10 minutes immediately after the patient leaves the
11 operating room.

12 DR. MOORE: That would be a pretty
13 close approximation as well. There are cases
14 where when we transfer to an ICU it can take
15 longer than that and we are still caring for the
16 patient.

17 And I do agree that leaving the
18 anesthetizing location which is usually the
19 operating room, sometimes other places, is
20 another thing that is often reported. Although,
21 at the same time, it is not necessarily commonly
22 recorded in the anesthesia record in all places.

1 Whereas, the anesthesia end time is. So, maybe
2 in part a practical consideration.

3 DR. GUNNAR: And again, I'm not trying
4 to be argumentative, but if I take the patient to
5 the ICU with anesthesia, the first thing they do
6 if the patient's still anesthetized under really
7 the effects of anesthesia, the first thing they
8 do is transfer, you know, they end their
9 relationship, transfer to the ICU nursing care
10 and head back to the operating room.

11 So, actually, the likelihood that, in
12 most cases, that the anesthesiologist is going to
13 be connected to the patient in the ICU is less
14 than if they were in the PACU.

15 DR. MOORE: Well, I still would argue
16 with a potentially long transfer, it's still
17 incumbent upon us to try to maintain appropriate
18 temperature or warming measures if it's feasible.

19 And it may be more likely that that
20 temperature after the end time would be the one
21 we would have to look at if we end up with a
22 prolonged situation which isn't likely, I agree,

1 to go beyond 30 minutes before, but it can
2 happen.

3 But I appreciate you point. It's some
4 of these choices -- they seem arbitrary, they are
5 also designed to be consistently reportable by
6 mechanisms that are already in place for 0454 as
7 well.

8 DR. GROVER: I guess I had one other
9 comment and I think I know what the answer is
10 going to be to this.

11 But, ideally, it'd be nice to know
12 what the lowest temperature was during the
13 operation, but I assume then that somebody could
14 be looking away or that might not be picked up.

15 So, this would be a more reliable --
16 what you're describing here is a more reliable
17 way to do it to measure at certain times. Am I
18 correct on that?

19 DR. MOORE: Yes, sir. I think it's
20 more consistently reportable across practices.
21 Places that have an electronic record system and
22 the abilities from that to determine the lowest

1 temperature could make that feasible.

2 Although even with doing things like
3 looking at a lowest heart rate as a
4 contraindication for a beta blocker
5 intraoperatively, often those data are manually
6 abstracted. So, I think you're right.

7 MS. MCCARTY: I don't know if there's
8 a good place to talk about unintended
9 consequences and this might be a dumb question,
10 so I apologize.

11 But, is hyperthermia at all a risk and
12 is there any danger of once this is a metric and
13 people are pushed towards doing more warming of
14 going too far in the other direction? Is that a
15 concern at all?

16 DR. MOORE: I think hyperthermia is a
17 concern any time that we actively warm patients
18 and, even in some cases, without substantial loss
19 of heat during surgery and with patients covered
20 by a lot of draping and blankets, it can occur.

21 It's incumbent on us to always measure
22 the temperature anytime we're applying active

1 warming and it is a concern. I would say yes.

2 It doesn't happen very often to such
3 an extent that it is considered a clinically
4 important sequelae, but I think that there's
5 evidence that the benefits of preventing
6 hypothermia are real that in balance, we, in
7 providing appropriate care for monitoring closely
8 the temperature when it starts to rise, we can
9 take measures to prevent it from rising too high.

10 MS. MCCARTY: Thank you.

11 DR. GUNNAR: Any other discussion?
12 Are we ready to vote on evidence? I think so.

13 MR. LYZENGA: Alexandra, I think we're
14 actually going to call this an intermediate
15 clinical outcome, so we'll go with the next
16 slide.

17 So, you're options are here, high,
18 moderate, low or insufficient evidence.

19 DR. GUNNAR: You should have 22, right?

20 MR. LYZENGA: We have 62 percent high,
21 33 percent moderate, zero low, zero for
22 insufficient evidence, one with insufficient

1 evidence with exception.

2 The measure passes on evidence. So,
3 we can move to performance gap.

4 DR. GUNNAR: Dr. Grover?

5 DR. GROVER: You want me to take that?

6 Well, the measure developers supplied
7 considerable data beginning in 2010 going back
8 from when they had the 0454 measure showing
9 increase in compliance with the measure of the
10 course of years, but still less than a 100
11 percent when looking at the 10, 20 and 30
12 percentiles, leaving room for improvement, as
13 they noted, with approval of the processes of
14 care to encourage attention to keeping patients
15 at normothermia.

16 In 2013, the mean performance score
17 was 95.3 percent. But, again, they didn't -- I'm
18 not sure about the post-anesthesia temperature
19 management in that situation and the author
20 published that 5.8 percent of patient who
21 actually appeared to pass that measure actually
22 did develop hypothermia.

1 So, I guess my point is, it looks like
2 there is a gap and there's still room for
3 improvement in the lower 30 percentile quartile
4 of practitioners.

5 DR. MOORE: We would agree with your
6 reasoning.

7 MS. MCCARTY: Maybe I was wrong, I
8 thought that I read in the measure submission
9 that the 5.8 percent of patients that still had
10 postoperative hypothermia were under the previous
11 definition where it was also possible just to use
12 warming technique.

13 So, I don't know if it was split out
14 between of the 5.8 percent which only had intra-
15 op warming but not a postoperative measurement or
16 if it was all combined?

17 DR. GROVER: I wasn't sure, either.
18 But it was related to the previous measure.

19 DR. MOORE: So, yes, the paper I
20 believe you're referring to from 2014 showed that
21 about six percent overall of patients who met
22 that current measure arrived in PACU with a

1 temperature of less than 36 degrees. And some of
2 the surgical subpopulations had an even higher
3 incidence than that.

4 DR. GUNNAR: Any other discussion?
5 So, let's vote on gap.

6 MR. LYZENGA: Voting on performance
7 gap. Your options are high, moderate, low or
8 insufficient.

9 I think we can call it. Yes, ten
10 percent high, 90 percent moderate, zero low, zero
11 insufficient.

12 So, the measure passes on performance
13 gap. And we can move to reliability.

14 DR. GUNNAR: Dr. Grover?

15 DR. GROVER: Well, again, from what I
16 read, the reliability appears to be high. With
17 the measure itself, I have it progressing from
18 .733 to .975 from 2010 to 2013, the previous one.

19 And the reliability for providers
20 improved from .523 to .644 from 2010 to 2013.

21 So, taking that previous measure and
22 assuming this measure's actually tighter, I think

1 the reliability looks very promising, realizing
2 this is a new measure, so we don't know for sure.

3 MS. MCCARTY: We had a slightly
4 different interpretation on the reliability.

5 I think earlier we had talked about
6 the threshold being .7 and it looks like all of
7 the reliability data is below that.

8 In addition, I think the metric
9 measure developers, I thought it was in here that
10 they said it's admittedly low reliability based
11 on those and especially gets even worse when you
12 start to take out some of the exclusion criteria.

13 And that the thought was that as more
14 data comes into the NACORE database that that
15 might be improved over time.

16 DR. GUNNAR: Developers want to
17 address that?

18 MR. MILLER: Sure, thank you. I'll
19 start with that.

20 So, yes, the latter measures that you
21 were talking about were from the NACORE data set
22 versus the claims data which were the previous

1 measure for NQF. And we were looking at about
2 two percent of the cases and two to three percent
3 of the physicians and providers. So, a much
4 smaller data set, as you can tell, very small,
5 very new.

6 I took the old measure and I randomly
7 sampled, this is not scientific, but I randomly
8 sampled small sample sizes like we have now and
9 that really kicked down the reliability measures
10 quite a bit.

11 So, we're pretty confident that most
12 of the low reliabilities could have meant that we
13 have only a couple hundred physicians and only
14 three facilities is due to the low sample size.

15 So, we have seen increases here but we
16 think that as the data gets more and more
17 populated, we'll see those reliability measures
18 go up to what we saw before, hopefully, in the
19 prior measures since the change is pretty small.

20 MS. MCCARTY: And this metric proposes
21 to only take the data from the NACORE database or
22 will it be going through the claims data as well?

1 MR. POPOVICH: Sure, we have a CPT
2 code that is applied to this, so using the
3 previous measure which also had a CPT code, we
4 would expect that more data would be available
5 more than NACORE.

6 MS. MCCARTY: Thank you.

7 DR. GUNNAR: Collette?

8 MS. PITZEN: A question for the
9 developer.

10 Did you undo some data element
11 reliability testing? So, in terms of the
12 numerator, was the temperature that was provided
13 through the database, was that actually the right
14 temperature within that time frame?

15 MR. MILLER: Right, no, we did not.
16 To my knowledge, we did not do any, though, I
17 believe in that sense.

18 MS. MCCARTY: I'm sometimes not sure
19 which -- if this comment is good for reliability
20 or validity, but since Collette mentioned it,
21 along those lines, I'm wondering to what extent
22 equipment kind of plays into this?

1 So, temperature probes are known to be
2 much more reliable methods of capturing these
3 versus the forehead stickers or sometimes even
4 the wands can give really inaccurate readings.

5 And we've had cases where, you know,
6 those types of equipment that are used in more
7 out of main OR areas have been used in, you know,
8 due to clinical judgment, things didn't look
9 right so someone pulled the temperature probe and
10 got much different readings and it turned
11 patients were having issues.

12 So, to what extent can we really trust
13 that people aren't having hypothermic issues if
14 we don't know what their processes for obtaining
15 those measurements are?

16 MR. POPOVICH: Sure, Dr. Moore, can
17 you speak to that, please?

18 DR. MOORE: Yes. Well, yes, certainly
19 the site of temperature monitoring is important
20 and ideally, we give most credence to true
21 measurement of core temperature monitoring which
22 can be done with an esophageal temperature probe

1 and some other means especially when someone is
2 under general anesthesia and intubated, that's
3 quite feasible.

4 When you mentioned the skin
5 temperature monitoring, that actually does
6 correlate fairly closely with core temperature.
7 Although it's not a true reflection of core
8 temperature, it is pretty close, although,
9 generally, it tends to run about two degrees less
10 than the corresponding core temperature.

11 So, when the forehead skin monitoring
12 is used, you will get a lower measurement even
13 though that may reflect, say, a temperature of 34
14 degrees on a skin temperature on the forehead may
15 reflect a core temperature of 36 degrees.

16 The measure does not specify the site
17 of measurement and it's certainly a valid point.

18 And I apologize if I didn't quite hear
19 the whole question, I have been on the road and
20 left a conference room to get into a cab and I
21 just left the cab. So, if I didn't address
22 everything you asked, please let me know.

1 MS. MCCARTY: I think mostly addresses
2 it, but based on that, I do have a follow-up
3 question.

4 I'm just curious where that data comes
5 from on the stickers being consistently two
6 degrees low. Is that sort of -- is that
7 consensus or is there any kind of data showing
8 that that's the case?

9 DR. MOORE: I do have papers and
10 citations consistent with that which I can pull
11 up and try to give you as we're speaking. I need
12 to pull over from where I am a bit.

13 But, it's pretty well established that
14 specifically a forehead skin temperature reflects
15 fairly well a core temperature.

16 However, generally, skin temperature
17 does not and there can be limitations, especially
18 when this measure applies to both neuraxial
19 anesthesia as well as general anesthesia without
20 intubation.

21 There can be limitations as to whether
22 we can reliably get a core body temperature which

1 can also be obtained by femoral artery catheter
2 probe, nasopharyngeal probe which isn't always
3 that easy to place correctly to get a true core
4 and some tympanic probes, although those can also
5 be not necessarily widely available in the
6 operating room and also difficult to place that.

7 DR. GUNNAR: So, I think that to frame
8 this, I think the question is, is it true that
9 esophageal temp, rectal temp and a blood temp are
10 reliable or are equally reliable and that skin
11 temperature is less reliable than the first
12 three, is that a reasonable statement? Or would
13 you say they are all equally reliable?

14 DR. MOORE: I would revise it to say
15 that, in the interest of reflecting a true core
16 body temperature, that esophageal, pulmonary
17 artery and when placed correctly, nasopharyngeal
18 can well reflect core temperature.

19 Rectal probes, not as much. Rectal
20 probes do not as reliably reflect the core
21 temperature and neither do generally skin surface
22 temperature monitoring.

1 There are other technologies that can
2 be used, but even when we do the esophageal
3 temperature probe, you must place them distally
4 enough to get an accurate reading or it may
5 itself not reflect the core appropriately.

6 And the skin surface temperatures are
7 generally considered lower than core and I can
8 provide some references specifically on that
9 correlation.

10 But there are special cases of skin
11 temperature monitoring such as temporal artery
12 thermometers which are a different kind of
13 measuring a region of the temporal artery near
14 core temperature and that the supervening skin
15 temperature should approximate core temperature
16 in those. That is also not widely used in the
17 operating room.

18 MS. MCCARTY: One of the themes we've
19 been talking about today is sort of the
20 workarounds that might come from making some of
21 these measures.

22 And just to follow on Dr. Yates'

1 earlier question about how you might have an
2 anomaly of a reading that might be high whereas
3 the pattern has been that the patient is
4 consistently hypothermic and you kind of
5 addressed that part of it.

6 But, in general, I'm just curious from
7 the developers if you have any concerns about
8 behavior changes that might be unwanted as a
9 result of making this a metric and workarounds
10 that people might develop that would get away
11 from the spirit of what you're trying to
12 accomplish?

13 DR. MOORE: Well, one thing I'd expect
14 is that people may go more away from that type of
15 forehead skin temperature measure that you
16 mentioned and that we commonly used for a wide
17 variety of cases because the number won't suffice
18 even though we think it reflects by virtue of the
19 relationship of the core temperature what may be
20 adequate normothermia, though it may lead to more
21 expense for probes that would replace such a use.

22 And I think practically speaking, it's

1 still going to be difficult in cases of neuraxial
2 anesthesia to get a valid core temperature
3 because none of the modalities we commonly use
4 are very easy to apply in someone who's not
5 intubated and especially with neuraxial
6 anesthesia.

7 DR. GUNNAR: All right, we're going to
8 move along. If there are -- thank you for those
9 comments. Unless there's any other new position,
10 we'll vote on reliability.

11 MR. LYZENGA: Go ahead and vote.

12 We have 20 percent high, 65 percent
13 moderate, 15 percent low, zero insufficient.

14 So, the measure passes on reliability
15 and we'll go to validity.

16 DR. GUNNAR: Dr. Grover?

17 DR. GROVER: Well, on validity, they
18 use face validity for one with 23 physicians with
19 a five level rating scale, five being the highest
20 and with maximal agreement, and the mean rating
21 there was 3.78 out of five with four disagreeing,
22 three being neutral and 16 agreeing or strongly

1 agreeing.

2 They also investigated the effect of
3 adding the exclusions, as I think you mentioned
4 earlier, which was cardiopulmonary bypass and
5 what regional blocks, I think. And they found if
6 they added those in, that actually decreased the
7 validity which went along -- which confirmed the
8 fact that it was ideal to exclude those people.

9 So, I think, by and large, the measure
10 met the validity testing.

11 MS. MCCARTY: I'm just curious if
12 you're able to share, if you know, what were the
13 reasons of the four people on your committee that
14 weren't in favor of it?

15 MR. POPOVICH: Well, the process, we
16 didn't solicit them for actual, you know, why did
17 you vote this way. We have a diverse amount of
18 opinions on the measure expert panel and I think
19 it was four that you mentioned, but we didn't go
20 into any detail about why they may be not fully
21 agree or strongly agree.

22 DR. GUNNAR: Any other comments?

1 Dr. Yates?

2 DR. YATES: My one comment is
3 basically circling back to my original question
4 but it's more relevant to validity at this point.
5 And that is, is the validity of this as good as
6 it could be if it's just one measurement out of
7 several in that same 45 minute period?

8 And would it not be a more valid
9 measure if you at least had two contiguous points
10 in time that were 35.5 or higher? And then you
11 might be able to at two points make a line and a
12 line makes a trend, it's at least graphical for
13 me in terms of optics and I can see that being
14 more valid.

15 But, and I can't change how they have
16 written the measure, and I can see that, but it
17 would be interesting to see whether or not the
18 reliability and validity improved if they were
19 forced to use two contiguous points in time as
20 opposed to one.

21 But, that's my only comment and it's
22 not meant to be a suggestion, it's an

1 observation.

2 MS. MCCARTY: If I could comment on
3 that just to play devil's --

4 So, I agree with you and I kind of
5 made the same comment earlier and that does
6 concern me. But, I also, in thinking about the
7 work flows, I know that there's many situations
8 where you might only have one reading and that
9 might be with the sticker, other types of
10 measurement tools where I can see a major
11 increased burden or increased cost to having
12 people repeat it.

13 And I'm a little bit more concerned
14 about that impact of having multiple measurements
15 than the ideal of only having one measurement as
16 a starting place.

17 So, just to throw that counter
18 argument out there for the record.

19 DR. YATES: And to make it a
20 conversation, I would argue that the -- I find it
21 hard to believe that within 30 minutes of the end
22 of the surgery or the anesthesia time there

1 wouldn't be at least one last temperature in the
2 operating room and certainly the PACU nurse gets
3 one when the patient hits the door.

4 So, I'd be surprised if those two
5 aren't out there somewhere. And that would --

6 DR. MOORE: I mean so, that can
7 pertain to how the values are reported. When
8 traditional paper records are used, it's probably
9 most common that the temperature values are
10 recorded more frequently than every 15 minutes.

11 With electronic records, documentation
12 you may have it every single minute.

13 DR. CIMA: But you do get into issues
14 of technique. We noticed that when we were doing
15 SCIP. You go from esophageal probe under general
16 anesthetic in the OR and then you go to a
17 tympanic probe in the PACU.

18 And what I didn't know then is that
19 tympanic probes, there's, you know, there's an
20 art to doing it right. And if you actually throw
21 it in -- if you just throw it in at the wrong
22 angle, you can get a three, four degree

1 temperature difference, you know.

2 And so, if you want to -- if you start
3 with probes and trends, that's going to be a very
4 hard case and I think that even counts in the OR
5 as we do more and more local regional blocks, I
6 mean our orthopedic practice hardly ever gets a
7 general anesthetic now. So, you're going to be
8 using different technologies and comparing
9 technologies is a big hassle.

10 So, I don't know how the developers
11 would handle that.

12 DR. YATES: I don't mean to be all
13 sentimental and go back in time, but, boy, I can
14 remember when you always asked, when you had that
15 low temperature, you always asked for the mercury
16 thermometer.

17 DR. MOORE: I agree, tympanic
18 measurements is tricky to do correctly. When
19 it's done well, it does reflect the core
20 temperature. It's often not done perfectly.

21 DR. GUNNAR: All right, I think we can
22 -- any other discussion on validity?

1 Collette?

2 MS. PITZEN: I appreciate the face
3 validity that was submitted. However, with this
4 piece of clinical information that's coming from
5 hospital systems, I really would have liked to
6 see some data element validity testing.

7 You're asking for a range of a time
8 period of when that temperature can be provided
9 and that you're providing the right temperature
10 during that time frame.

11 So, I do have concerns about the
12 validity testing.

13 DR. GUNNAR: Any other comments?

14 Shall we vote?

15 MR. LYZENGA: Let's vote. Voting on
16 validity, high, moderate, low or insufficient.

17 We have 15 percent high, 65 percent
18 moderate, 20 percent low and zero insufficient.

19 So, the measure passes on validity.
20 And we'll go on to feasibility.

21 DR. GUNNAR: Fred?

22 DR. GROVER: Well, this is, I mean you

1 guys in anesthesia can correct me, but this is
2 pretty much routine practice. I mean
3 measurements, you're on the soup in terms of
4 practicing evidence-based medicine.

5 So, I think this is quite feasible.
6 You're trying to keep it relatively simple by
7 collecting a few. You know, those of us that
8 are, you know, in the OR might say, well, why
9 don't you pick on in 30, too? But again, you
10 begin to start decreasing maybe the reliability
11 of your data and we understand that.

12 So, I think overall this is quite
13 feasible.

14 DR. GUNNAR: Kelsey?

15 MS. MCCARTY: I agree.

16 DR. GUNNAR: Any other discussion?
17 Collette?

18 All right, no problem. Let's vote.

19 MS. MURPHY: May I speak

20 DR. GUNNAR: Yes, yes.

21 MS. MURPHY: It speaks to abstraction
22 of paper records and it's not specified for that,

1 so could you speak to that question?

2 MR. POPOVICH: Sure. Collecting this
3 information, it's part of a process of care that
4 would typically take place within 24 hours after,
5 you know, for coding, for CPT coding.

6 So, in that regard, some abstraction
7 would have to take place, but it would immediate
8 as a process of care. The data is readily
9 available as a vital sign.

10 Dr. Moore, did you want to add
11 anything to that?

12 DR. MOORE: You're correct and the
13 data should be readily available, although there
14 may be cases where abstraction need to occur.
15 The mechanisms are in place.

16 MR. LYZENGA: All right, if no other
17 comments, let's vote on feasibility.

18 Your options are high, moderate, low
19 and insufficient.

20 We've got 58 percent high, 37 percent
21 moderate, 5 percent low, zero insufficient.

22 The measure passes feasibility. And

1 we'll move to usability.

2 Any comments from the committee on
3 usability or use?

4 DR. GUNNAR: Fred?

5 DR. GROVER: Well, I think, I mean I
6 assumed reading this that this would be
7 communicated to each provider and institutions so
8 they know what their results are.

9 And then I see that you're also
10 planning to allow professionals to report this
11 measure to PQRS and the QCDR reporting mechanisms
12 beginning in 2015.

13 So, I would think there are no
14 unintended consequences, I would think, that
15 amount to anything, so I would think this is very
16 usable.

17 MR. LYZENGA: Any additional comments?
18 Seeing none, let's vote on usability and use.

19 And 53 percent high, 42 percent
20 moderate, 5 percent low, zero insufficient.

21 The measure passes on usability and
22 use and we'll go to overall suitability for

1 endorsement.

2 Any discussion before we vote?

3 Appears not, let's go ahead and vote on overall
4 suitability for endorsement.

5 Unanimous yes, 100 percent.

6 Thanks to our developers, we
7 appreciate your coming here.

8 MR. POPOVICH: Thank you.

9 MR. LYZENGA: So, we owe our
10 representative from Yale, Elizabeth can join us.

11 To continue, we will actually do the
12 gap analysis probably by email or on the phone
13 call. And perhaps you can send some stuff out.

14 So, this is a measure of Admission
15 After Outpatient Surgery and our discussants are
16 Dr. Cima and Dr. Grover.

17 So, Dr. Drye, you want to introduce
18 yourself and give us a brief overview?

19 DR. DRYE: Hi, my name's Elizabeth
20 Drye. I'm a Director at the Center for Outcomes
21 Research and Evaluation at Yale and I directed
22 the development of this measure along with some

1 very talented staff, including our lead who is in
2 Australia and couldn't be here today.

3 I'm trained as a pediatrician, not as
4 a surgeon, so you are really the experts on this
5 topic and it involves all of you because it's a
6 broadly defined measure.

7 I was just going to quickly walk
8 through the process for development, the
9 rationale, a couple key challenges and our
10 learning to date and I'll try to do that in three
11 minutes.

12 So, we developed the measure under
13 contract to CMS. It's their measure and we used
14 their typical transparent process that included
15 literature review, a national expert panel Dr.
16 Dutton served on, so I think he's recusing
17 himself and we held a public comment period as
18 well, a national public comment period.

19 In our view, the measure fills an
20 important gap and can help advance quality
21 improvement. As you all know, about 70 percent
22 of surgeries are done in the outpatient setting.

1 The outcome for the measure is
2 hospital visits within seven days of outpatient
3 surgery, their direct admission or after
4 discharge, an unplanned admission, an observation
5 stay or an ED visit.

6 And we're focused on that outcome for
7 several reasons. First, in the cohort of
8 patients we're looking at which is Medicare 65
9 and older, the rate is relatively high at 10.5
10 percent within seven days.

11 Second, the causes are often not
12 always often preventable and they include things,
13 as you know, like nausea, vomiting, uncontrolled
14 pain, urinary retention, wound infection,
15 bleeding or more serious complications.

16 And third, and this is a key point,
17 often the surgical team is really not aware of
18 these outcomes because the patient circles back
19 to the hospital or an ED and the loop is not
20 closed to inform the providers of the patient's
21 outcome.

22 And fourth, we see variation across

1 hospitals in the rate of hospital visits after
2 adjusting for the differences in their patient
3 mix and the wide differences in the types of
4 surgeries that they do.

5 So, the intent of the measure is to
6 really make those visits transparent to providers
7 and patients and support quality improvement.

8 There are many challenges to this
9 measure, I'm sure you'll flag some of them for
10 me. But, two that I wanted to just highlight was
11 that we wanted to really identify a cohort of
12 same-day surgeries so the patients expected to go
13 home.

14 And to do that, this is a claims-based
15 measure. We took a conservative approach and we
16 used a list of surgeries that Medicare has
17 approved for ambulatory surgery centers.

18 So, this measure is designed to
19 profile hospital outpatient departments only, not
20 ASCs. But we used the ASC list because it helps
21 us stay focused on same-day surgeries and we
22 further narrowed it in a couple of ways we can

1 talk about.

2 And then, second, we had to risk
3 adjust as I alluded to before, not just for
4 patient comorbidities but for the differences in
5 the types of surgeries across hospitals because
6 the outcome rate really follows from the type of
7 surgery done.

8 And so we adjust not just for 24, I
9 think it is, patient comorbidities but also for
10 the relative value unit that reflects the
11 complexity of the specific surgery and for the
12 body system operated on, the anatomical body
13 system using a body system classification that
14 AHRQ developed.

15 And that approach served us well, but
16 that's a little more complex than our typical
17 risk adjusted measure.

18 And then, finally, I just wanted to
19 note, we've already had some learning to date,
20 even though this measure is not in use. It has a
21 related measure which is on the agenda with a
22 little bullet on harmonization below this

1 measure.

2 We developed for CMS also a measure of
3 hospital visits within seven days following
4 outpatient colonoscopy. And that measure right
5 now is we're running, not we but another
6 contractor, is running a national dry run for the
7 measure and they're going to report to both ASCs
8 and HOPDs their measure scores.

9 And there's a lot of learning taking
10 place during that dry run and some of it applies
11 to the surgery measure because the data
12 processing and the outcome are very similar.

13 So, we've already learned then a need
14 to handle a particular merged statement in our
15 input files a little differently than we did for
16 the analysis that went into this application.

17 We rerun all our analyses and things
18 look pretty much the same, so we didn't resubmit
19 the application. But I did want to note that the
20 outcome rate for the population is 10.5 percent,
21 not 10 percent as stated in the application we
22 submitted. It just -- we had missed a few

1 surgeries and outcomes.

2 And as that dry run continues over the
3 spring, the scores will be sent to facilities in
4 July for the colonoscopy measure. We may do some
5 additional learning and we may need to jiggle our
6 results here a little. We don't anticipate
7 anything major, but I just want to let you know
8 that we will come back to the committee if we had
9 to change the measure in any way or any of the
10 results change.

11 So, I look forward to your questions
12 and your comments.

13 DR. SAIGAL: Quick question. Is just
14 for hospital outpatient or also ASCs?

15 DR. DRYE: So, this measure is just
16 for hospital outpatient departments in contrast
17 to the colonoscopy measure.

18 And the quick reason for that is that
19 ACSs, as you know, are really, really highly
20 varied in the kinds of surgeries they do and we
21 just, we would have loved to include them but we
22 couldn't find a way to include them. Some are

1 also very small, so we stuck with hospital
2 outpatient departments.

3 DR. FLEISHER: Can we go -- first get
4 the comments from Robert and Fred and then we'll
5 go the floor?

6 DR. CIMA: As the developer went
7 through, this is to look specifically at hospital
8 outpatient practices, not ASCs, which is a big
9 distinction. And it's looking at returns,
10 unplanned returns, to emergency rooms, admission
11 to the observation status, admission to hospital
12 or other interventions that require
13 hospitalization in Medicare patients.

14 The rationale behind this really is to
15 see what -- and just sort of putting words from
16 other documents here, to see if providers who are
17 doing the outpatient procedures can improve
18 processes to avoid these events.

19 It's unclear from the data provided if
20 there's anything they can do about, but I don't
21 think we have enough data to actually say one way
22 or the other.

1 But that's the rationale behind the
2 measure.

3 The numerator and the denominator is
4 pretty clear. The denominator is basically,
5 there's a large list of procedures in the
6 Appendix that goes through what I would consider,
7 you know, sort of routine hospital-based
8 outpatient procedures.

9 There are some exclusions for
10 cataract, eye things are excluded.

11 And then the numerator is basically
12 anyone that falls into that category showing up
13 within seven days.

14 And so, it's pretty as to what they're
15 trying to do with the groups. They're well
16 defined and it's based on administrative
17 outcomes.

18 So, I mean the outset says ten percent
19 who are doing this will show up for some type of
20 need and that's when we sort of get into the
21 details of, well, are you really going to be able
22 to alter that? And that's a different question.

1 DR. GROVER: Yes, I think Elizabeth
2 did a great job of describing this. It's a
3 pretty complex metric, really.

4 And I think the importance of risk
5 adjustment like you're doing for the procedure as
6 well as the comorbidities is helpful.

7 But, one area I think that you really
8 get into in detail that's very, very important in
9 the protocol is how you make the distinction
10 between an unplanned visit versus a planned
11 visit. And you might want to get into a little
12 more detail on that for the group because that's
13 key.

14 DR. DRYE: Sure, yes, sure.

15 So, we do, if post-discharge of the
16 patient comes back and is admitted, it could be
17 for a planned procedure for treatment of a
18 condition whether it's something was identified
19 during the first surgery and it's follow-up more
20 definitive care.

21 And we used an algorithm that we
22 developed for the readmission measures that Yale

1 developed for CMS that classifies admissions. It
2 was actually focusing when we developed it on
3 admissions, not readmissions as planned.

4 If they are not for an acute diagnosis
5 like sepsis and they're for something you would
6 typically schedule as an inpatient procedure.

7 So, there aren't a lot of those in
8 this outcome but we don't count planned
9 admissions. And we've actually pretty much, all
10 our outcome measures now that are looking at
11 readmissions or admissions follow that approach.

12 DR. FLEISHER: A.J.?

13 DR. YATES: Yes, a point of
14 clarification, the number ten percent came up.
15 If I'm looking under the worksheet, the range,
16 the risk adjusted range is 0.5 to 2.5, correct?

17 DR. DRYE: Yes, so I couldn't squeeze
18 everything into my three minutes, but I'm really
19 glad you asked that question.

20 So, this measure score, we would
21 recommend reporting as a ratio rather than a
22 rate. It's calculated like our readmission

1 measures. On the denominator, is the -- and like
2 a lot of the STS and other risk adjusted measures
3 -- the denominator is the expected number of
4 hospital visits.

5 The expected rate is not going to be
6 zero for anyone. It's always going to be some
7 expected admissions. We don't really know what
8 the -- or visits -- we don't know what the really
9 best number we could get to is at this point.

10 And then the numerator it's like an
11 observed count, it's not an observed because we
12 use hierarchical modeling to account for the
13 sample size variation and clusterings. But it
14 takes into account the observed amount of
15 hospital visits.

16 So, it's like a smoothed estimate and
17 I think a lot of you on this committee have seen
18 similar models before.

19 So, the score we recommend reporting
20 as the ratio of -- you can call the numerator
21 different things, but we call it a predicted over
22 expected. And the typical hospital, that would

1 be one.

2 And so, if the ratio is less than one,
3 it would be, you know, 0.9, 0.8. They would be
4 having fewer hospital visits than expected. And
5 if it was greater than one, they would be doing,
6 in this case, having more visits than expected,
7 it would be doing worse.

8 In our other measures and some other
9 measures like all our readmission measures, we
10 multiply that ratio by the national accrued rate
11 of the outcome.

12 So, in this case, we could have said,
13 well, let's just -- we'll multiply it by ten, so
14 instead of reporting one, we'll say, you know,
15 the average hospital is 10.5. And if you're at,
16 you know, 0.8, you know, it'll be eight.

17 And we would report that rate instead
18 of ratio because consumers have an easier time
19 with that than thinking about a ratio of observed
20 over expected or predicted over expected.

21 But, we don't recommend doing it here
22 because hospitals vary so much in what they do.

1 So, if they're mainly doing orthopedics, you know
2 they're going to have a really low rate than if
3 they're urology or some of the other -- focused
4 on some of the other specialties.

5 And so, that number then, it just
6 isn't as good of an indicator as it is when we're
7 taking, for example, like a cohort of heart
8 failure patients and we're reporting a
9 readmission rate only for the heart failure
10 patients across hospitals.

11 DR. YATES: Well, let me rephrase my
12 question because you've corrected me, that's not
13 a percentage, that's the ratio.

14 But, if I look at the raw numbers of
15 hospital visits out of 212,000 surgeries, there
16 was 4,000. So, you're really talking about a two
17 percent incidence, correct? I mean if I read
18 those numbers right, it would be about two
19 percent.

20 DR. DRYE: Yes.

21 DR. YATES: And that two percent
22 incidence, in terms of determining performance

1 gap, can you, in that small percentage of
2 patients that are coming back, I have two
3 questions.

4 In that small percentage, can you
5 assure the committee that you're model for the
6 planned readmissions, your protocol for planned
7 readmission capture doesn't have enough noise
8 that it doesn't rattle around inside that two
9 percent which is such a small number?

10 And then the second question I have
11 is, does that two percent represent a higher
12 number than those patients that were done as
13 outpatients under Medicare in other environments
14 such as an ASC since this is hospital based?

15 My concern being that the patients
16 that might be higher risk are done in a hospital
17 based ambulatory surgery center or outpatient
18 center out of concern that they might have a
19 complication and might need to be kept.

20 So, those two questions, are you sure
21 that with that small rate, you're really going to
22 eliminate the planned admissions?

1 And the second question is, how does
2 this compare in terms of the numbers of people
3 being seen in hospitals after they've been to a
4 surgery center, for instance, that maybe only
5 deals with less ill patients?

6 DR. FLEISHER: Before you do that
7 excellent questions, let's vote on evidence
8 because this is --

9 DR. YATES: It's about performance
10 gap. I'm asking is this the performance.

11 UNKNOWN PARTICIPANT: I would say it's
12 a lot about performance gap.

13 DR. FLEISHER: Right, so, but we're
14 only --

15 DR. YATES: I thought that was a gap
16 question because I don't know that I'm seeing two
17 percent of people coming back.

18 DR. FLEISHER: But this is a health
19 outcome. The simple question we have, is there
20 evidence to say this is --

21 DR. YATES: Oh, I'm sorry, yes.

22 DR. SAIGAL: Can I ask a question on

1 evidence?

2 DR. YATES: I thought we got to gap.

3 DR. FLEISHER: Yes.

4 DR. SAIGAL: About the evidence before
5 we vote on it?

6 DR. FLEISHER: Yes, the evidence. But
7 this is a valid outcome.

8 DR. SAIGAL: The question we have here
9 is where there's evidence at the process that
10 they suggest, like patient education and pain
11 medication management, will impact this outcome.
12 Is there evidence that that's true?

13 DR. FLEISHER: It's actually not even
14 evidence, it's just a rationale really.

15 DR. SAIGAL: So, can we --

16 DR. FLEISHER: It's just sort of
17 plausible rationale.

18 DR. SAIGAL: That's what it seemed
19 like, thank you.

20 So, can we use that as justification
21 for the measure if there's no evidence and it's
22 just a thought process?

1 DR. FLEISHER: Yes.

2 DR. SAIGAL: We can?

3 DR. FLEISHER: If you find it, you
4 know, adequate.

5 DR. SAIGAL: Should we?

6 DR. FLEISHER: Right.

7 DR. CIMA: That's a different
8 statement, a very important question and I think
9 it'll get answered when we go to the performance
10 gap.

11 DR. FLEISHER: The question, do you
12 think there's sufficient evidence that this could
13 be an outcome that could be modified?

14 DR. SAIGAL: Well, there is no
15 evidence. So, basically, the question is really,
16 do you agree with the thought process and does
17 anyone know about any studies that have -- like
18 where they've looked at how do you better educate
19 a patient or jump on their pain management and
20 the discharge planning, if that reduces
21 readmissions?

22 DR. FLEISHER: There are studies

1 related to pain management as well as nausea and
2 vomiting measures.

3 DR. SAIGAL: That reduce readmissions?

4 DR. CIMA: This is more of a holistic
5 approach because if you look at the top reasons
6 that a provider in the Appendices for why people
7 are coming back, it's not those.

8 It's urinary retention, urinary
9 symptoms, renal papilla, I mean, these are all
10 measured in percents of things.

11 DR. FLEISHER: Yes, actually, one of
12 the pieces of evidence is actually a paper I
13 wrote on 750,000 cases for Medicare data and it's
14 --

15 DR. CIMA: Yes, but nausea and
16 vomiting is in there, but what I'm just saying,
17 when you look at total numbers, it's small.

18 DR. YATES: And for those on the phone
19 call, for the record, performance gap is on the
20 big screen. So, I'm sorry if I jumped ahead.

21 DR. FLEISHER: Thank you for putting
22 it out.

1 Fred?

2 DR. GROVER: Maybe I'm missing
3 something here, but I had down on the evidence
4 here that you reviewed a number of manuscripts
5 and the rates vary from 0.5 to nine percent,
6 depending on the type of surgery with ones
7 varying from 1.3 percent to 13.6 percent of
8 outpatient surgeries in HOPDs.

9 DR. DRYE: Wait, the outcome rate --

10 DR. GROVER: Did I misinterpret that?

11 DR. DRYE: That's correct. And the
12 outcome rate here is 10.5 percent, but that's the
13 percent of patients that nationally across all
14 hospitals that have a follow-up visit within
15 seven days.

16 The score is different, it's a ratio.
17 And so, it's low number, one is the average and
18 less than one is better. But you can think about
19 it in your head, you're going to multiply that by
20 ten. The average outcome rate for hospitals here
21 is ten percent and some will be 2.5 times that,
22 that's our max. So, you know, 25 per hundred and

1 some would be, you know, lower than that.

2 So, we leave it as a ratio so as not
3 to suggest that any particular hospital's rate is
4 around ten because the surgeries vary so much
5 that the hospital rates vary a lot.

6 You know, we're estimating the
7 expected and then how well the hospital is doing
8 compared to its peers with similar peer hospitals
9 doing similar surgeries.

10 Does that answer your question? So,
11 on average it is ten percent and there are
12 studies which we talk about in here about
13 addressing, you know, nausea, vomiting, pain,
14 some of these are straight complications.

15 And so, again, this measure, like our
16 other risk standardized measures is a peer
17 comparison. So, the fact that you see variation
18 shows that some hospitals are doing a lot better
19 in avoiding hospital visits with these patients
20 than others.

21 DR. FLEISHER: Other comments on
22 evidence? Okay.

1 DR. PARZYNSKI: Can you hear me?

2 DR. FLEISHER: Yes, go ahead.

3 DR. PARZYNSKI: Hi, this is Craig
4 Parzynski at Yale.

5 DR. FLEISHER: Yes?

6 DR. PARZYNSKI: I'm the statistician
7 on this project. So, I just wanted to add that
8 on Table 2 in the Appendix that there are
9 actually 21,000 outcomes and so the rate is ten
10 percent. So, I just wanted to point to the
11 correct table in the Appendix. But, I'm not sure
12 what you all have, I'm just looking at what we
13 submitted.

14 DR. FLEISHER: Please vote.

15 MR. LYZENGA: We have lost a couple,
16 so think we'll have a lower number. I think we
17 can go ahead and call it.

18 DR. FLEISHER: Yes, call it.

19 MR. LYZENGA: Eighty-three percent
20 yes, 17 percent no.

21 And the measure passes on evidence.

22 And now, we'll move to performance gap,

1 opportunity for improvement.

2 DR. FLEISHER: So, if you can address
3 Dr. Yates' comments.

4 DR. DRYE: Sure, and I know Dr.
5 Fleisher's done research on this exact issue of
6 this outcome, or almost this exact outcome
7 between hospital outpatient apartments and ASCs
8 and other settings.

9 Yes, there is a difference, and in our
10 data, there was a difference looking at HOPDs
11 versus ambulatory surgery centers. And the
12 expected rates and the actual rates are higher in
13 HOPDs, as you would expect because presumably,
14 the more in the more complex high risk patients
15 are there.

16 And that's one of the reasons we
17 didn't want to report this measure simultaneously
18 in the same data set for HOPDs and ASCs. So, we
19 stuck with HOPDs and we tried to just narrow the
20 cohort of surgeries, the group of surgeries in
21 the measure to those that are explicitly
22 identified as same-day surgeries and that they

1 could be conducted at ASCs.

2 We don't look at a lot of surgeries
3 that are done in hospital outpatient departments.
4 If they're not the ASC list, they're not in here
5 and if they're more complex or inpatient
6 surgeries, they're not in here.

7 DR. CIMA: It's on the gap issue and
8 excuse me if I don't understand how this
9 variation was generated. But the hospital
10 variation, that's the big issue we're getting to.

11 So, we're saying it's ten percent and
12 it's different depending on the surgery, so we
13 can't really use that. We don't have that data.

14 But then when they go through in the
15 Appendices, it basically says that they found in
16 this part here, it's 211 hospitals that were at
17 24 percent had fewer than expected and 95 percent
18 -- there were 34 percent that were better.

19 But then when it goes through when you
20 did an interval estimate, so almost like putting
21 the confidence interval around it, it said that
22 out of those, what was it, 4,200-plus hospitals,

1 80 hospitals were worse than expected, 4,119,
2 there was no variation and 35 were better. So
3 that works to like one percent was bad and a
4 little bit more than one percent was bad and a
5 little bit less than one percent was bad.

6 So, I'm wondering about the
7 performance gap here. I mean it's like 98 point
8 something percent are doing as expected. So,
9 we're going to go through all of this and I'm
10 just wondering, that, to me, was the biggest
11 striking thing.

12 And I don't understand the statistics
13 behind it. So, maybe you can say, but when we're
14 talking about one percent performance gap --

15 DR. FLEISHER: That was the model.

16 DR. DRYE: Yes, so I apologize that
17 this measure's coming at the end of the day.
18 It's complex, so please ask your questions.

19 So, there's two things that apply
20 here. The first is that we only had a 20 percent
21 sample of these surgeries. So, we have one-fifth
22 of the volume at each hospital.

1 So, when we run this nationally, CMS
2 reports is nationally, they'll have five times as
3 many cases. So, instead of about 50 cases per
4 hospital, they'll have 250 cases. So, we have
5 small sample size.

6 And the second thing which Dr.
7 Fleisher was alluding to is we use a modeling
8 approach which takes into account sample size and
9 if there are very few cases, it assumes the
10 hospital is a typical performer.

11 So, it kind of pulls -- it makes those
12 outliers hard to find. It pulls estimates toward
13 the middle because it weighs that we have very
14 few observations and so we're less certain.

15 So, what we expect to see with this,
16 you have one percent and two percent outliers on
17 each side, like you said, is we'll have five
18 times the cases. We expect to a lot of outliers.
19 We'll have a million cases nationally which is
20 great.

21 So, as outcome measure developers,
22 we're just plagued when we don't have enough

1 cases. But for this measure, we expect to see a
2 lot more outliers. We don't have the ability to
3 run that now because we don't have enough data.

4 DR. CIMA: But our problem here is
5 we've approved a lot and disapproved a lot on a
6 lot less data and we have to go with what's being
7 submitted. And you have 200,000 surgeries and
8 so, I'm just wondering with what we have, as
9 we've said before, in the submission, there is no
10 performance gap.

11 We're making an estimation that there
12 will be when we get the data. But I'm saying,
13 right now, in front of us -- and that's what was
14 I confused by because we always say we go with
15 what were submitted. I mean, is that not right,
16 Andrew?

17 DR. FLEISHER: Yes. One of my questions
18 to staff, because we've had this debate at CSAC a
19 lot, of what's considered in and outside the
20 measure as far as quality rating precludes.

21 DR. DRYE: Yes, I just want to
22 differentiate, there is a big range of

1 performance when you look at the point estimate.

2 And then we use a very strict 95 percent
3 confidence interval to identify outliers.

4 I mean it's because what CMS does when
5 they publically report, they use 95 percent
6 intervals.

7 But you could decide that we could
8 identify, you know, that's just what we ran for
9 this. If you thought, well, if there are 80
10 percent confident that they're truly different,
11 you're going to see a ton more outliers.

12 But the key point, no, it's important
13 because as policy people, we're not -- we're
14 trying to see is there really variation there.

15 When we have five times as many cases,
16 you will see that variation even with the 95
17 percent interval estimate. We know that. I
18 mean we're going to move from 50 cases per
19 hospital to 250 on average. So, you'll see many
20 more outliers.

21 I think others who are familiar with
22 this modeling approach, you know, can chime in

1 on.

2 DR. FLEISHER: So, let me ask, because
3 the issue is cut points Yale set in the document.
4 Because if CMS says a different cut point for
5 confidence intervals that will change, correct?

6 DR. DRYE: Yes, but CMS would never --
7 I mean I can't -- CMS is on the phone, they would
8 never report this with a 20 percent sample.

9 So, there's two ways to see more
10 outliers, use 100 percent sample which they would
11 do if they use it or if you just wanted to see it
12 for the committee's understanding, we could use a
13 less strict confidence interval and show you how
14 many outliers we get.

15 DR. FLEISHER: So, my question for NQF
16 staff is, as we rate the measure, they've chosen
17 what's an outlier which is, Robert, your
18 question.

19 DR. CIMA: Yes, but, so reliability
20 testing, this is part of this also, is they
21 scored it as a 0.5. So, I'm just wondering if
22 this is being treated specially here because

1 we've said reliability testing has to be 0.7 and
2 what's written is what's written.

3 And so, I just don't want to get the
4 sense that we're treating this differently than
5 what we normally say.

6 MR. LYZENGA: And this is something,
7 again, that we've been wrestling with a bit, the
8 question of how the measure score is, you know,
9 is reported.

10 So, Karen, I don't know if you were
11 listening to this earlier, but we're discussing
12 that if we report these, we've got the observed
13 to expected ratio and we see variation in that
14 score, I think. But when we sort of apply a 95
15 percent confidence interval, we get -- and, you
16 know, say if you fall -- if you're going above,
17 you know, outside of that 95 percent interval or
18 below, then you're getting a very small number
19 where above average or below average, something
20 like one percent above and one percent below.

21 But this is sort of the question of
22 how you're, you know, applying the measure to

1 some degree.

2 Now, you could configure it in
3 different ways and report it in different ways
4 and get different results.

5 I don't know if you have any thoughts
6 on that and whether sort of to what extent this
7 committee should be addressing that? Or what is
8 in the purview of our discussion here?

9 MS. JOHNSON: Well, when I think about
10 gap, I think about variability and I don't think
11 as much about the confidence interval, part of
12 it. To me, that's a little bit more reliability.

13 So, I think those are the questions
14 that you'd ask for reliability. Can you really
15 distinguish one provider from another?

16 So, I think the question here is, are
17 you getting variability between the scores? I
18 don't think I'm helping you guys much on this
19 one.

20 DR. FLEISHER: I guess the way to ask
21 this question is, if they didn't do the modeling
22 the way they're doing it, there'd probably be

1 more variability. The modeling is creating the
2 lack of variability which is a reliability.

3 DR. YATES: I have a question on that.

4 DR. FLEISHER: Yes, A.J.?

5 DR. YATES: I apologize about the two
6 percent, I'm going by what I interpreted as
7 events out of surgeries and that's the centers.

8 But out of the ten -- in your
9 Appendix, 65 percent of the visits ended up in
10 readmission. Did you run the proportion
11 difference, the proportional difference of -- I
12 mean that's five percent of the patients of 6.5
13 percent -- or what and I saying -- 6.5 percent of
14 all the patients ended up admitted.

15 Did you run that separately and look
16 at admissions? And the reason I ask is because
17 the readmission for total joint replacement, for
18 instance, the readmission model only looks at
19 admissions not at hospital visits or ER visits or
20 ob status.

21 And since we're dealing with a
22 population of patients that are 65 and older, is

1 it necessarily a performance gap that out of an
2 abundance of caution, someone calls up and they
3 come to the ER and they end up not having
4 anything or they are put in obs for overnight
5 because they complained of some dizziness and
6 they're okay. Is that as important as the fact
7 that they literally had to be admitted?

8 And it would be interesting -- I mean
9 do you have that data?

10 DR. DRYE: I think you might be asking
11 for -- were you asking about the reasons for
12 admission for the admission?

13 DR. YATES: No, just solely admission.

14 DR. DRYE: Yes.

15 DR. YATES: Just in terms of
16 harmonization, the readmission model for the
17 readmission measure that's out there --

18 DR. DRYE: Yes, yes, I know that one
19 well.

20 DR. YATES: -- only counts hospital
21 readmissions?

22 DR. DRYE: Yes, yes.

1 DR. YATES: It doesn't count ER visits,
2 it doesn't count obs visits. And so, I'm asking
3 you, I guess, one, why did you add those on
4 there?

5 DR. DRYE: Yes, sure.

6 DR. YATES: And was there a
7 significant performance gap for just hospital
8 admissions, which still represent 6.5 percent of
9 all the patients that have the outpatient
10 surgery?

11 That, to me, seems like the bigger
12 question.

13 DR. DRYE: Yes, yes. So, that's a
14 good question. I don't think that we looked at
15 the performance gap by admissions only during
16 development, but I can check and, Craig, you're
17 there, do you remember doing that? I don't think
18 we did.

19 But, the reason, while you're thinking
20 about I'm going to go ahead and answer the second
21 part.

22 Why did we include emergency

1 department visits and observation stays?

2 It really goes to the measure concept.
3 These are patients who expect to go home and not
4 have to go back to the emergency department or to
5 go and be observed in the hospital or get
6 admitted because we've limited the surgeries in
7 this measure to surgeries where that's what's
8 expected.

9 And yet, a lot of these patients go
10 back and I think you -- this is really just think
11 about it from the patient's perspective, this is
12 a patient centered measure design that's saying,
13 hey, we should make these outcomes visible
14 because a lot of people are going back with
15 urinary retention, as you note, with nausea, with
16 vomiting, with pain.

17 Those are things that happen post-op,
18 but, you know, can they be better managed? Can
19 they be addressed with a phone call or a visit in
20 the outpatient setting or prevented with better
21 planning.

22 And they're just not visible now,

1 either the patients or providers. So, we wanted
2 to include those EDFs stays even though they're
3 less severe than the admissions, most likely, and
4 we didn't have a way to sort of -- we could have
5 tried to score them, you know, like as less or
6 more, I mean as less than admissions but we
7 didn't have a good way to do that.

8 DR. YATES: Yes. Just as a
9 countervailing argument, I mean as for in terms
10 of patient centered expectations, when a
11 patient's discharged from the hospital, they
12 don't expect to come back to the hospital and be
13 readmitted or be seen in obs or in the ER within
14 a few days either.

15 So, I'm not sure that that follows
16 that it's something special about being in
17 outpatient surgery. I mean the patients
18 discharged from the hospital hope to stay home
19 for the next 30 days. Yet, we don't use these
20 other parameters.

21 And so, I'm just wondering whether or
22 not those parameters were added to make the

1 performance gap bigger or you just didn't look
2 for the different.

3 DR. DRYE: No, they were totally added
4 because we felt that from the patient
5 perspective, those were important outcomes.

6 DR. YATES: Okay.

7 DR. FLEISHER: So, Liz, is this about
8 performance gap? Because -- great.

9 DR. EREKSON: So, when I look at the
10 Appendix that was provided, there's Table 2 and
11 Table 2 shows a wide variation, depending on
12 organ system on whether or not these patients
13 fall into these categories.

14 And so, male genitalia and female
15 genitalia surgeries in that body are somewhere
16 over 20 percent.

17 And then when I look at Table 5 and 6
18 where you're using the model, you're having that
19 2.3 percent in the low-liers and the 26.7 percent
20 in the high-liers. So, and those are deciles, I
21 believe is what the table says.

22 So, it does seem like there's a wide

1 variation in practice and I think that speaks to
2 a performance gap.

3 DR. CIMA: Yes, but they risk adjust
4 that. I mean that's the whole point and so,
5 you're going to expect higher -- for certain
6 procedures you expect higher but that doesn't --
7 when you mean the whole body of those procedures,
8 it's still not a huge difference. I mean, I
9 don't know if I'm getting that.

10 DR. FLEISHER: John?

11 SR. HANDY: Well, if you do the
12 numbers in the Section 2(b)(5.2), so of the 4,000
13 providers that you had, 80 were under performers.
14 They were doing worse.

15 And so, if you extrapolate that to the
16 200,000 patients, it's 4,000 patients. So, it's
17 a lot of people that are being affected by that
18 even though the confidence intervals drive them
19 out to be small numbers with regard to the
20 providers.

21 DR. FLEISHER: Thank you.

22 Why don't we vote? Or, Liz, do you

1 have -- no, you've already commented.

2 Why don't we vote on performance gap?

3 I think we're done.

4 MR. LYZENGA: We have 25 percent high,
5 65 percent moderate, 10 percent low, zero
6 insufficient.

7 The measure passes on performance gap.
8 So, we'll move to reliability.

9 DR. CIMA: Well, the developers
10 provide that with the model, if we want to use
11 the model as a thing, the reliability score is
12 0.5. Now, I'm not sure if that's -- I mean
13 that's just because of the modeling.

14 DR. DRYE: So, the way we're doing
15 reliability here is we're looking at two samples
16 from each hospital of patients to -- we split the
17 sample in half and then we look and see whether
18 the score is the same using one group of patients
19 and the other group of patients so that we're
20 getting at an underlying quality signal. It
21 should be similar.

22 And we use the interclass correlation

1 coefficient to look at the comparability of the
2 score.

3 And 0.5 in the world of risk
4 standardized outcome measures is pretty strong.
5 And here, we're also still not using a full
6 sample, we combined three years to get more
7 cases, but we had to split the sample, so we're
8 using about 30 percent of what each hospital
9 would have. And as you get bigger sample sizes,
10 reliability goes way up.

11 So, we're happy with 0.5 as it is even
12 with 30 percent compared to other risk
13 standardized measures. We know it will be better
14 when we have a full sample.

15 It's a different scale, I think, than
16 what you guys are talking about for process
17 measures and the reliability in that context.

18 DR. FLEISHER: Comments? No? Please
19 vote.

20 MR. LYZENGA: Voting on reliability.

21 Is that it?

22 Twelve percent high, 88 percent

1 moderate, zero low, zero insufficient.

2 So, the measure passes reliability.

3 We'll go to validity.

4 DR. FLEISHER: Okay, Robert, comments
5 on validity?

6 DR. CIMA: It just depends on if you
7 look at how in the Appendices whether or not you
8 think this really represent things that can be
9 modified. We have our opinions those who
10 actually who do surgery versus those who may not.

11 But, you know, face validity was on a
12 panel of 13 or 14 people and most people seem to
13 agree that there was some valid, four people were
14 high, most were somewhat agreed.

15 And so, I mean it's a measure, I
16 think, could it be better? Should it be
17 inpatient versus ED visits? Those are
18 discussions, but I think, you know, people don't
19 expect to go back to need care.

20 The only question, you know,
21 sometimes, are we making an assumption that all
22 these visits are related to the surgery? We

1 don't know that, so it could be other reasons.

2 People go to the emergency room for a lot of

3 different reasons.

4 But those are the three issues that I
5 would think we need to be -- someone would have
6 to process in their mind.

7 DR. FLEISHER: Fred, any comments?

8 DR. GROVER: Face validity is pretty
9 much as described. I thought the validity
10 overall was probably pretty good.

11 I mean, do you have further comments,
12 Elizabeth, to refine that?

13 DR. DRYE: No, I mean within our TEP
14 which is mostly surgeons and also providers and
15 patients, payers, there was a lot of discussion.

16 There was some discussion around, you
17 know, combining ED, obs and admissions. But, in
18 the end, I think it was broad agreement that
19 there was valid and we received public comments
20 to that effect as well.

21 DR. FLEISHER: My one question is,
22 what starts an, quote, outpatient procedure?

1 Because that can vary greatly in a hospital base
2 because a lot of times, they'll start in the
3 outpatient setting and be admitted.

4 DR. DRYE: Yes, so that's a great
5 question.

6 So, you have to bill, and Craig,
7 you're on the phone, I know, and you can --

8 We only include, again, procedures
9 that are billed as outpatient and that are
10 expected to be same-day procedures. But even
11 that might vary across hospitals.

12 We wish there was a perfect like code
13 that said, this starts as an outpatient procedure
14 but there isn't that code yet. And so, we tried
15 use very careful claims processing algorithms to
16 make sure we're focused only on outpatient
17 claims.

18 We, like other measures that you have
19 looked at, we used physician, you know, claims,
20 we look at those settings, we take into account
21 issues like the three-day payment window and make
22 sure we're capturing those. There's no 100

1 percent clean way to do it.

2 Some of the learning that we'll do
3 with the colonoscopy measure will help us here as
4 well. And when, you know, when providers -- the
5 way that CMS reports this type of measure, they
6 provide patient level data to facilities and
7 facilities can look at it and, you know, dispute
8 it.

9 So, I think there's still some
10 learning to do to make sure 100 percent we are
11 identifying outpatient. But even if you use the
12 claims perfectly, as you know, transitions can
13 take place mid-course.

14 Patients that stay overnight are not
15 counted in the outcome. So, they're not counted
16 as admit patients. We don't look at look at what
17 happens until they're discharged home. So, there
18 is that flexibility in the outcome that if you're
19 just kept overnight, we're still calling you an
20 outpatient and we're not saying that there was
21 something that happened that wasn't supposed to
22 happen.

1 DR. FLEISHER: So, 23 hour stays of
2 outpatient?

3 DR. DRYE: It's, I mean one night
4 because CMS uses -- most hospitals, if it's a
5 second night, they'll have to bill as an
6 inpatient.

7 DR. FLEISHER: That's billed on whose
8 code on the surgeons, anesthesiologists or
9 hospitals?

10 DR. DRYE: It's the -- Craig, you're
11 on the phone, right? It's the surgeon, it's the
12 operating surgeon that we looked at. Craig, I
13 want you to confirm, please.

14 DR. PARZYNSKI: I'll jump in if you
15 say anything incorrect.

16 DR. DRYE: Okay.

17 DR. FLEISHER: Other questions?
18 Sorry, I -- excuse me.

19 DR. GUNNAR: Yes, I wanted to just --
20 so the observation bed rules have changed to just
21 under a minute less than 48 hours.

22 So, and then there's also this intent

1 or unintended consequence potentially of, you
2 know, laparoscopic cholecystectomy is an
3 outpatient procedure now with the good feeling
4 that you've got this two days of observation bed
5 if you need it for that particular patient.

6 If this measure goes into endorsement,
7 does that conflict with that otherwise usable
8 mechanism for a safety net?

9 DR. DRYE: I think they're aligned
10 and, honestly, we talked with the CMS payment
11 people to make sure we weren't going to, you
12 know, we weren't creating some strange
13 misalignment with that.

14 Because, here, we really want
15 unanticipated returns to the hospital or
16 unanticipated, you know, admissions which the
17 threshold, as you were saying, if you're really
18 admitted for two days post one of these
19 surgeries, that's really -- or more -- that's
20 really unexpected.

21 So, here, you have your obs stay and
22 you're not going to be counted in the outcome of

1 this measure. So, both things give you
2 flexibility to -- I'm not sure that's what you're
3 saying to keep the patient.

4 DR. GUNNAR: Well, there are actually
5 interqual criteria around, you know, what is an
6 acceptable use of an observation bed. And if the
7 mere use of the observation bed is nonperformance
8 or less than excellent performance, then I'm sure
9 -- I envision there's a potential conflict in
10 that.

11 DR. YATES: Well, one of the
12 unintended consequences of the readmission
13 penalty is that the use of observation status has
14 gone through the roof. I mean it's gone up
15 dramatically over the last, you know, few years
16 enough that it, you know, the 48-hour -- 47-hour
17 rule is being debated again.

18 DR. FLEISHER: Other comments?

19 DR. DRYE: I'm just not sure I'm
20 understanding -- I'm communicating well because,
21 in this measure, you would not be counted as in
22 the outcome. It would not be an adverse outcome

1 if you stayed in observation status, for example,
2 overnight.

3 So, we're only counting the obs if
4 they go home and come back.

5 DR. GUNNAR: Correct. All I'm trying
6 to say is that if you have excellent backup to
7 your same-day surgery environment, there are
8 cases that you would use that environment for and
9 the patient would benefit from going home.

10 So, I guess what I'm asking is, is
11 that could you subselect or think about
12 subselecting outpatient procedures that really
13 there's no expectation of an inpatient or an
14 observation stay associated with that?

15 That's a different subselection than
16 what's happening in the community or across the
17 country which is, let's push our outpatient
18 environment. If we've got good backup and we
19 have an observation bed readily available and
20 comprehensive inpatient care.

21 So, this is where I'm struggling.

22 DR. YATES: And I know where you're

1 coming from because there's people trying to do
2 same-day 23 hour total hip replacements.

3 But along those -- the contrary -- the
4 flip side of that is, is that those patients that
5 you fully expect to go home that day in
6 arthroscopy of the knee, for instance, if they
7 have now -- I mean you may drive behavior to
8 keeping those patients under obs if they're
9 having a little bit of trouble peeing or they're
10 having a little trouble with the food they're
11 trying to put down. And you just have this low
12 threshold of using obs beds which, you know, does
13 have --

14 DR. GUNNAR: Which is good quality
15 care.

16 DR. YATES: Right. Well, it just
17 changes the behavior. But that's neither here nor
18 there with validity. I'm following on your
19 conversation.

20 But, you know, I think they showed --
21 in defense of the measure, the validity, I think,
22 is really good when you look at their numbers.

1 DR. FLEISHER: So, let me ask
2 something of Elizabeth because the colonoscopy
3 measure, just to be aware, was actually
4 identified as sort of pilot measure, but there
5 was going to be further testing and that was
6 actually just debated again in CSAC.

7 How come you've chosen to put this out
8 as a fully formed measure or is there?

9 DR. DRYE: Yes, I mean these
10 outpatient measures, this is where the big
11 measure gaps are and they are new and they do
12 need testing.

13 The colonoscopy measure, the reason
14 that it makes sense to lead with that national
15 testing that's going on right now in all
16 facilities, ASCs and HOPDs will see their scores
17 in July, is that actually it is going to help us
18 learn about a lot of the things that you're
19 talking about now, how observations define, you
20 know, like how much variation there is, whether
21 what we're seeing differs at all than what
22 hospitals are seeing in their own data because

1 they'll all get their data.

2 So, we're sequencing a little, this is
3 like lean management, right, we're sequencing so
4 that we learn from the first one. But this one,
5 I mean we tested it with 20 percent sample. We
6 think it's really strong. We know policy around,
7 you know, observation stay is going to be a
8 little bit dynamic.

9 And you all are raising something
10 that, you know, CMS is always saying and I think
11 we need to see as much of this as possible that
12 they will track for unintended consequences and
13 follow it.

14 All these issues you're raising are
15 really important to be looking at further. But
16 we don't think it's not a reason to move forward
17 at this point.

18 DR. FLEISHER: Okay, any other
19 comments?

20 DR. GROVER: Well, just that the -- I
21 think for the validation, too, the risk
22 adjustment's critical, you know, that you've done

1 that.

2 DR. DRYE: We copied some other good
3 people on that one.

4 DR. FLEISHER: Okay, let's vote
5 validity.

6 MR. LYZENGA: We're voting on
7 validity, just in case if anybody's on the phone
8 still who didn't hear it.

9 Sixteen percent high, 84 percent
10 moderate, zero low, zero insufficient.

11 So, the measure passes on validity.
12 We'll go to feasibility.

13 DR. FLEISHER: Comments?

14 DR. CIMA: It's all coded in
15 administrative data. It's hard to hide somebody
16 showing backup in their emergency room.

17 But, how about -- what about -- it'll
18 track someone going having hospital A and showing
19 up in emergency room C somewhere else down the
20 road, right?

21 DR. FLEISHER: Fred?

22 DR. GROVER: I think it's very

1 feasible for the reasons just mentioned.

2 DR. FLEISHER: Great. No other
3 comments, please vote.

4 MR. LYZENGA: We have 84 percent high,
5 16 percent moderate, zero low, zero insufficient.

6 So, the measure passes feasibility.
7 We'll go to usability and use.

8 DR. FLEISHER: Comments?

9 DR. GROVER: This is what we had --
10 the conversation we had previously.

11 DR. FLEISHER: Right. I would hope a
12 lot of these comments and A.J. and Robert and
13 others, particularly since I suspect by the time
14 this is actually rolled out, they'll be up for
15 reendorsement. So, these are going to be really
16 critical to get into it.

17 DR. GROVER: I know it's late.

18 DR. FLEISHER: No, I meant -- I didn't
19 mean it that way.

20 DR. GROVER: Okay.

21 DR. FLEISHER: I meant the fact that
22 it's going to -- they have to come back in three

1 years. Well, you have to come back every year
2 for endorsement so let's make sure a lot of those
3 comments are in the final report because they're
4 really critical for Yale to address.

5 So, I keep saying that, but I --

6 DR. GUNNAR: Then I won't say anything
7 else.

8 DR. FLEISHER: No, it's really
9 important work.

10 Okay, let's vote.

11 MR. LYZENGA: Voting on usability and
12 use, high, moderate, low or insufficient
13 information.

14 We have 33 percent high, 61 percent
15 moderate, six percent low, zero insufficient.

16 So, the measure passes on usability
17 and use. And we will take overall suitability
18 for endorsement next.

19 Are there any comments before we vote?
20 Does not appear so, let's go ahead and vote.

21 Ninety-five percent yes, five percent
22 no.

1 The measure passes.

2 Thanks everybody, it's been a marathon
3 session.

4 DR. FLEISHER: We need to open for
5 public --

6 MR. LYZENGA: Oh, yes, public comment.
7 Operator, can you open the lines for
8 public comment?

9 OPERATOR: Yes, sir. At this time, if
10 you'd like to make a comment, please press star
11 then the number one.

12 At this time, there are no public
13 comments.

14 MR. LYZENGA: All right, thank you.

15 DR. FLEISHER: Thank you all. We will
16 see you in 30 minutes for those joining us for
17 dinner. And outstanding, in my perspective,
18 comments today.

19 MR. LYZENGA: Thanks everybody, good
20 work.

21 (Whereupon, the above-entitled matter
22 went off the record at 5:55 p.m.)

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This is to certify that the foregoing transcript

In the matter of: Surgery Standing Committee

Before: NQF

Date: 03-19-15

Place: Washington, DC

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