

NATIONAL QUALITY FORUM

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SURGERY PHASE 3  
STANDING COMMITTEE

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TUESDAY  
AUGUST 16, 2016

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The Standing 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.

PRESENT:

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

WILLIAM GUNNAR, MD, JD, Co-Chair; Director, National Surgery Program Office, Veterans Health Administration

KARL BILIMORIA, MD, MS, Director, Surgical Outcomes & QI Center; Vice Chair for Quality, Northwestern University and Northwestern Medicine

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

RICHARD DUTTON, MD, MBA, Chief Quality Officer, United States Anesthesia Partners

ELISABETH EREKSON, MD, MPH, Dartmouth Hitchcock Medical Center

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

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

CLIFFORD KO, MD, MS, MSHS, FACS, Director,  
 Division of Research and Optimal Patient  
 Care, American College of  
 Surgeons/Professor of Surgery, Department  
 of Surgery, UCLA School of Medicine,  
 American College of Surgeons/UCLA School  
 of Medicine

BARBARA LEVY, MD, FACOG, FACS, Vice President,  
 Health Policy, American College of  
 Obstetricians and Gynecologists

BARRY MARKMAN, MD, Senior Medical Director  
 Medicaid, Aetna

KELSEY MCCARTY, MS, MBA, Senior Manager, Quality  
 and Safety Program, Department of  
 Anesthesia, Massachusetts General Hospital

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  
 Dean, College of Pharmacy, University of  
 Arkansas for Medical Sciences

COLLETTE PITZEN, RN, BSN, CPHQ, Clinical Measure  
 Development, Minnesota Community  
 Measurement

LYNN REEDE, DNP, MBA, CRNA, Senior Director,  
 Professional Practice, American  
 Association of Nurse Anesthesiologists

CHRISTOPHER SAIGAL, MD, MPH, Professor, UCLA

SALVATORE T. SCALI, MD, Assistant Professor of  
 Vascular Surgery, University of Florida-  
 Gainesville

ALLAN SIPERSTEIN, MD, Chairman Endocrine  
 Surgery, Cleveland Clinic

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

BARBEE WHITAKER, PhD, Director, American  
 Association of Blood Banks\*

A.J. YATES, MD, Associate Professor and Vice  
 Chairman for Quality Management,  
 Department of Orthopedic Surgery,  
 University of Pittsburgh Medical Center

**NQF STAFF:**

HELEN BURSTIN, MD, MPH, Chief Scientific Officer  
 ANN HAMMERSMITH, JD, General Counsel  
 ELISA MUNTHALI, MPH, Vice President, Quality  
 Measurement  
 MARCIA WILSON, PhD, MBA, Senior Vice President,  
 Quality Measurement  
 KAREN JOHNSON, MS, Senior Director  
 MELINDA MURPHY, RN, MS, Senior Director  
 CHRISTY SKIPPER, MS, Project Manager  
 KATHRYN STREETER, Senior Project Manager

**ALSO PRESENT:**

SOPHIA CHEN, MD, Centers for Medicare & Medicaid  
 Services\*  
 TRACI CONNOLLY, American College of Cardiology  
 SHERYL M. DAVIES, MS, Stanford University\*  
 KAREN DORSEY, MD, PhD, Yale-CORE  
 YAZAN DUWAYRI, MD, Society for Vascular Surgery  
 LILIANA GOUMNEROVA, MD, FRCSC, Boston Children's  
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 BRUCE GRAY, DO, FSVM, FSCAI, Greenville Health  
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 LEANNE HAHN, MD, Centers for Medicare & Medicaid  
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 JEPH HERRIN, PhD, Yale-CORE\*  
 SARAH JERNIGAN, MD, MPH, University of Miami  
 Health System\*  
 BRAD JOHNSON, MD, FACS, Society for Vascular  
 Surgery  
 PAMELA L. OWENS, PhD, Agency for Healthcare  
 Research and Quality\*  
 LISA G. SUTER, MD, Yale-CORE  
 GARTH H. UTTER, MD, MSc, UC Davis Health System\*  
 PAT ZRELAK, PhD, CNRN, CNAA, BC, UC Davis Health  
 System\*

\* present by teleconference

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Adjourn

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

2 8:38 a.m.

3 CO-CHAIR FLEISHER: Are we recording?

4 I guess we'll get started. Welcome to the third  
5 iteration of the Surgery Standing Committee. As  
6 you may remember, I'm Lee Fleisher from the  
7 University of Pennsylvania.

8 As you may remember, one of the  
9 advantages of standing committees is our ability  
10 to actually monitor and create a model over time  
11 in a particular domain expertise. So it's great  
12 to have you all back. And that's where I'll end  
13 the brief welcome.

14 CO-CHAIR GUNNAR: So I'm Bill Gunnar.  
15 I'm National Director of Surgery for the  
16 Department of Veterans Affairs. Most of us are  
17 familiar faces. Do you want to do introductions  
18 around?

19 (Off the record comment.)

20 CO-CHAIR GUNNAR: Okay. That will be  
21 fine. Welcome. We like to be efficient and  
22 competent, right. That's our plan.

1 MS. SKIPPER: Good morning, everyone.  
2 My name is Christy Skipper. I'm the Project  
3 Manager for Surgery. And it's nice to see you  
4 all in person and not just read your words back  
5 over email.

6 MS. STREETER: Hi. Good morning. I'm  
7 Katie Streeter. I'm a Senior Project Manager  
8 here at NQF on the Surgery Team.

9 MS. MURPHY: And I'm Melinda Murphy.  
10 I'm a Senior Director at NQF. I've been here for  
11 about ten years. Many of you, I have seen in  
12 multiple different meetings and activities and so  
13 very much appreciate the fact that you continue  
14 with the high interest and high energy in working  
15 with this.

16 Today we've got three new members, Dr.  
17 Scali. Did I say it properly? Okay. Dr.  
18 Bilimoria, there, all the way at the very end.  
19 And Dr. Whitaker may or may not be on line today,  
20 but she will be here tomorrow.

21 MEMBER WHITAKER: I am online. Thank  
22 you.

1 MS. MURPHY: Oh great. Nice to have  
2 you, Barbee.

3 MEMBER WHITAKER: Thank you.

4 MS. MURPHY: So welcome all of you and  
5 thank you so much for continuing with the  
6 interest and the energy.

7 Did you want to say something?

8 DR. BURSTIN: I just want to say good  
9 morning to everybody and thank you for joining.  
10 Helen Burstin. I'm the Chief Scientific Officer.  
11 Nice to see so many of you again. I was just  
12 talking that I think this is your third rodeo for  
13 many of you and we appreciate you coming back.

14 It really does help when we have these  
15 committees give a sense of trust across the  
16 table. But also our process doesn't seem quite  
17 as opaque as it might to some newbees. I know  
18 the new folks will jump right in.

19 I'll be popping in and out. But again  
20 you're in great hands. Thank you so much again.

21 MS. JOHNSON: Good morning. I'm Karen  
22 Johnson. I'm one of the Senior Directors here at



1 NQF and I get to serve as our measure  
2 methodologist most of the time.

3 MS. MURPHY: So with that, I think  
4 we're ready to have introductions, disclosure of  
5 interest. We have Ann Hammersmith who is the  
6 counsel for NQF and always a pleasure to have  
7 Ann.

8 MS. HAMMERSMITH: Thank you, Melinda.  
9 That is rarely said about a lawyer. So I  
10 appreciate that.

11 I see some familiar faces, too. So I  
12 think many of you have done this before. For  
13 disclosures of interest, I'll give you a few  
14 reminders and then we'll go around the table and  
15 you can introduce yourselves and disclose.

16 This is a CDP committee. So we look  
17 at your professional activities in detail before  
18 we seat you on the Committee. We do the oral  
19 disclosures in the spirit of transparency so that  
20 you have the opportunity to let the public, let  
21 the staff, let your fellow Committee members know  
22 about your background.

1 I want to emphasize that just because  
2 you disclose does not mean that you have a  
3 conflict. You may have engaged in some activity  
4 that you believe is relevant, but it is not a  
5 conflict. And we do ask you to disclose that.

6 We're especially interested in  
7 research activities, grants and consulting. We  
8 want to remind you that you sit on the Committee  
9 as an individual. You don't represent your  
10 organization. You don't represent anyone who may  
11 have nominated you for service on this Committee.

12 And with that, we'll go around the  
13 table. Tell us who you are, who you are with and  
14 if you have anything you wish to disclose. And I  
15 would start with the Co-Chairs. It's the only  
16 perk they get as Co-Chairs. They get to start  
17 the disclosure.

18 CO-CHAIR GUNNAR: This is Bill Gunnar.  
19 I have no disclosures.

20 CO-CHAIR FLEISHER: Lee Fleisher. I  
21 work for the University of Pennsylvania. I am a  
22 member officially of the American Society of

1 Anesthesiologists' Committee on Performance and  
2 Outcome Measures, although I have not  
3 participated for approximately one year.

4 I am a consultant to Yale CORE in the  
5 development of the hospital-wide mortality  
6 measure. And I am a co-investigator on two  
7 grants from the NIH looking at performance  
8 measurement with Jeff Silber from Children's  
9 Hospital of Philadelphia.

10 MEMBER HANDY: My name is John Handy.  
11 I'm a thoracic surgeon from Portland, Oregon.  
12 And I'm the Director of Thoracic Surgery and  
13 Thoracic Oncology at the American College of  
14 Chest Physicians.

15 MEMBER GROVER: I'm Fred Grover. I'm  
16 a cardiothoracic surgeon from the University of  
17 Colorado, a past president of the STS.  
18 Currently, I'm not working on any of the database  
19 committees there. I serve as Vice Chair of the  
20 transcatheter valve registry. We work with the  
21 STS and the American College of Cardiology.

22 MEMBER KO: Hi. I'm Clifford Ko. I

1 work at UCLA in the Department of Surgery. I'm a  
2 colorectal surgeon. I also am the Director of  
3 the Division of Research and Optimal Patient Care  
4 at the American College of Surgeons which houses  
5 all the quality programs including NSQIP, the  
6 Bariatric Program, Cancer, Trauma and Peds. So  
7 the disclosure for this meeting is that there are  
8 a number of measures that are either developed  
9 with some of these registries or programs and  
10 another one that uses the Peds NSQIP Program.

11 MEMBER SIPERSTEIN: Allan Siperstein.  
12 I'm with the Cleveland Clinic. I do endocrine  
13 surgery. I serve on the American College of  
14 Surgeons Performance Measure Committee.

15 MEMBER YATES: Adolph Yates. I'm in  
16 the Department of Orthopedic Surgery at the  
17 University of Pittsburgh where I'm the Vice  
18 Chairman for Quality Management and I'm also  
19 serving as the chief of our hospital in  
20 orthopedics.

21 I'm also the Evidence-Based Medicine  
22 Chairman for the American Association of Hip and

1 Knee Surgeons. And I have served unpaid on  
2 technical expert panels with both Acumen and  
3 Yale. But none of the measures today are of  
4 note. And I will also say that those are  
5 unrelated. Thank you.

6 MEMBER MOSS: Morning. My name is  
7 Larry Moss. I'm a Pediatric Surgeon at  
8 Nationwide Children's Hospital in the Ohio State  
9 University. I am on the steering committee for  
10 Pediatric NSQIP as well as the Children's Surgery  
11 Verification Program in the American College of  
12 Surgeons.

13 I serve for the Children's Hospital  
14 Association on the Quality Measure and Standards  
15 Committee that's developing measures, but none  
16 are under submission at this time. And also I'm  
17 President-Elect and Chair of a group in the  
18 organization, the Children's Hospital Surgeons in  
19 Chief that's developing quality measures for  
20 submission but none currently submitted.

21 MEMBER TEMPLE: I'm Larissa Temple.  
22 I'm a colorectal surgeon in Memorial Sloan-

1       Kettering Cancer Center in New York. I'm the  
2       Vice Deputy Physician and Chief for Quality  
3       there.

4               My research is in patient-reported  
5       outcomes and I'm doing some work with the college  
6       on working towards building that out. But I  
7       don't have any conflicts.

8               MEMBER MCCARTY: My name is Kelsey  
9       McCarty. I'm the Director of Operations and  
10      Strategy for Cardiology and Endocrinology at  
11      Boston Medical Center. And I have nothing to  
12      disclose.

13              MEMBER OLSEN: I'm Keith Olsen, Dean  
14      and Professor at the University of Arkansas for  
15      Medical Sciences, College of Pharmacy  
16      representing the American Society of Health  
17      System Pharmacists.

18              I do sit on the Board of Regents for  
19      the Society of Critical Care Medicine, American  
20      College of Critical Care Medicine. And we do  
21      review all the guidelines for the Society.

22              MEMBER SAIGAL: I'm Chris Saigal. I'm

1 a urologist at UCLA. To disclose, I worked with  
2 AUA in a variety of ways in the past. I've been  
3 on the Quality Improvement Patient Safety  
4 Committee. I'm on the Data Committee right now  
5 which looks at how to use data to improve care.  
6 I'm also, in our department, one of our QA  
7 participants.

8 MEMBER BILIMORIA: Hi. Karl  
9 Bilimoria. I'm a Surgical Oncologist in  
10 Northwestern. I run a research center that's  
11 funding in quality measurement and quality  
12 improvement programs. And I do a variety of  
13 projects with the American College of Surgeons.

14 MEMBER DUTTON: Rick Dutton. I'm a  
15 former Chief Quality Officer for the American  
16 Society of Anesthesiologists. Now Chief Quality  
17 Officer for USAP, a large group practice. I do  
18 work with Yale and CMS on a number of technical  
19 expert panels, but I have no measures here today.

20 MEMBER MOYER: I'm Amy Moyer. I'm the  
21 Manager of Value Measurement for the Alliance.  
22 We are a healthcare purchasing cooperative, a

1 not-for-profit, largely in Wisconsin, Illinois  
2 and Iowa.

3 We use several of the measures that  
4 are under consideration today in our programs,  
5 but I have no other conflicts to declare.

6 MEMBER PITZEN: Collette Pitzen,  
7 Minnesota Community Measurement. I'm a measure  
8 developer. We have no measures in the surgery  
9 portfolio. I also serve as the consultant to ANA  
10 Yale CORE TEP group and the PCORI grant with the  
11 American Society of Clinical Oncology.

12 MEMBER MARKMAN: Barry Markman. I'm  
13 a Senior Corporate Medical Director for Medicaid  
14 for Aetna. I do have some research projects with  
15 MTF, the Musculoskeletal Transplant Foundation.  
16 Otherwise I don't see any conflicts with any of  
17 the measures today.

18 MEMBER EREKSON: Hi, Liz Erikson. I'm  
19 a gynecologist. I work at the Geisel School of  
20 Medicine at Dartmouth and also with the Dartmouth  
21 Institute for Health Care Delivery Science.

22 I have done a lot of work with the



1 American Urogyn Society and currently serve as  
2 the National Advisor to their Outcomes Research  
3 Network. But I have no conflicts of interest for  
4 today.

5 MEMBER LEVY: Good morning. I'm  
6 Barbara Levy. I'm the Vice President for Health  
7 Policy at the American College of Obstetricians  
8 and Gynecologists. I do serve on the PCPI  
9 Executive Board, but have no conflicts in that I  
10 don't participate in any of the measures or  
11 measure development.

12 MEMBER SCALI: Good morning. My name  
13 is Sal Scali. I'm a vascular surgeon at the  
14 University of Florida. I also serve as the Chair  
15 of the Endovascular Aortic Aneurysm Committee for  
16 the Vascular Quality Initiative.

17 And I also serve on several other  
18 standing committees through the VQI and SVS on  
19 quality. But I have no other disclosures or have  
20 not been a participant in any of the measures  
21 that are being discussed today.

22 MS. HAMMERSMITH: Okay. Thank you.

1 Now I'll call on the people on the phone. Robert  
2 Cima?

3 MEMBER CIMA: Yes, this is Bob Cima.  
4 I'm at the Mayo Clinic in Rochester. I serve as  
5 the Surgical Quality Officer and I serve on the  
6 ACS measurement committee, much like Allan. I'm  
7 the American Society of Colorectal Surgeons  
8 Quality group, but we have no measures on this.  
9 I'm not a very big fan of Delta right now.

10 (Laughter.)

11 MS. HAMMERSMITH: Sorry to hear that.  
12 Mark Jarrett. Is Mark Jarrett on the line?

13 (No response.)

14 Melissa Thomason.

15 (No response.)

16 Barbee Whitaker.

17 MEMBER WHITAKER: Hi. I'm Barbee  
18 Whitaker. I'm Senior Director of Research and  
19 the AABB Center for Patient Safety at the  
20 American Association for Blood Banks. And I have  
21 no conflicts of interest.

22 MS. HAMMERSMITH: Okay. Thank you,

1 everyone, for those disclosures. Before I leave,  
2 I want to remind you of a few things, and then  
3 I'll ask you if you have any comments or  
4 questions.

5 The big reminder is that in order to  
6 make a conflict of interest process work, we rely  
7 on the Committee members. Everybody has a part  
8 in this. NQF does. The public does. And so do  
9 the Committee members.

10 So if you're sitting in a meeting and  
11 you think that you may have a conflict or that  
12 one of your fellow Committee members may have a  
13 conflict, please speak up in real-time. What we  
14 don't want is to get six months down the road and  
15 have someone say well, you know. Actually, I  
16 think I may have had a conflict. We want you to  
17 tell us now.

18 If you'd like to bring it up in the  
19 meeting, you're welcome to do that. If you'd  
20 like to approach your Co-Chairs, you can do that,  
21 or you can connect with NQF staff and they will  
22 talk to the Co-Chairs.

1 Any questions or comments regarding  
2 anything that's been disclosed today?

3 (No response.)

4 Okay. Thank you.

5 MS. MURPHY: Unless anyone has  
6 anything they would like to comment about right  
7 now, we'll get started with a little bit of an  
8 overview of the process and an introduction to  
9 the project which won't be new to any of you. So  
10 we'll move through it pretty rapidly.

11 As you know and as many of you have  
12 participated in multiple rounds of the surgery  
13 project, there are over 100 measures of which  
14 about 64 of them are assigned to this Committee.  
15 At this point, you have seen, or will in these  
16 two days, be seeing the last of all of them. So  
17 you can see there you're going to be looking  
18 obviously at all kinds of surgery care,  
19 perioperative, adverse outcomes, other related  
20 surgical topics.

21 And what you have there is just a list  
22 of the maintenance measures that are under

1 review. You have those. We'll move on.

2 And then there are in addition to  
3 those 14 maintenance measures, there are ten new  
4 measures that you'll be considering. One is an  
5 orthopedic trauma measure, the first one you see  
6 there. There are five blood-related measures  
7 from The Joint Commission that you'll be looking  
8 at.

9 There's a new one that actually the  
10 group has seen an earlier iteration of it on  
11 carotid endarterectomy. And there are three new  
12 composite measures from STS that you will be  
13 looking at today.

14 At the last phase, you reviewed the  
15 portfolio of measures and made recommendations  
16 about where you felt gaps were still occurring.  
17 And what you see on this slide are some areas in  
18 which you felt there were gaps.

19 The next slide has information about  
20 the kinds of measures that you indicated that you  
21 were interested in seeing being brought forward.  
22 So what you will be doing, the next slide just

1 has a little bit of very difficult to read  
2 information. But what this does is to show you  
3 that in that last report, you had identified  
4 gaps. We provided the list of measures that were  
5 in place. You took that and you identified gaps  
6 where you felt that measures were needed.

7 What we will ask you to do after this  
8 meeting -- you'll get it at your home site -- is  
9 that list of the measures that are currently  
10 endorsed plus those areas where you felt there  
11 were gaps and ask you to provide us update on  
12 where you see gaps now occurring. But we'll send  
13 that to you after this meeting after you're back  
14 at home.

15 What you have in starting off with  
16 your measure evaluation is that you have among  
17 your souvenirs a measure worksheet that has a  
18 preliminary analysis that NQF staff has put  
19 together. I want you to know that in the course  
20 of that preliminary analysis, there were multiple  
21 NQF staff who reviewed those documents and who  
22 provided input directly or to staff who were

1 working at those.

2 In no case is what you see the work of  
3 an individual. We do this as a collaboration to  
4 try to do the best we can do to give you  
5 information in advance.

6 What you also will have -- Christy, I  
7 think this is right in PDF. Is that right?

8 CO-CHAIR FLEISHER: Can I just  
9 comment?

10 MS. MURPHY: Absolutely.

11 CO-CHAIR FLEISHER: I mean we really  
12 need to give kudos to the staff. This is  
13 something that the CSAC really felt was a great  
14 advance in that there's consistency across all  
15 the measures. We can take exception to what the  
16 staff did and that's part of our role, but I  
17 really need to give kudos because they did a  
18 phenomenal job as they always do. It really  
19 provides a uniform foundation across the entire  
20 NQF portfolio. So kudos to the team, to Helen  
21 and her team. But she's gone.

22 MS. MURPHY: A large team. And you

1       should know that the team members don't always  
2       agree. But we do come to a point that we are  
3       reasonably comfortable with going forward.

4               And I would want to say, certainly  
5       repeat what Lee has said. Please do challenge  
6       where you feel it should be. What we've tried to  
7       do is give you preliminary information. Yours is  
8       the opinion and the consideration that counts.

9               In those measure worksheets, where we  
10      have received them, you will have pre-evaluation  
11      comments that those of you who reviewed the  
12      measures have provided. There is only one set of  
13      pre-meeting public and member comments and that's  
14      on Measure 2998. Typically we would receive more  
15      than that, but this time one set of comments.

16              And then among the items that you  
17      would have seen in the materials available to you  
18      on the SharePoint site, in addition to the  
19      measure worksheet, the measure information form  
20      submitted by the developer, there are attachments  
21      speaking to the evidence related to each  
22      individual measure. There are attachments that



1 speak to the testing that's been done by the  
2 developer in putting together and bringing the  
3 measure forward.

4 And then there are other attachments.  
5 You will see attachments with codes. You will  
6 see attachments with definitions. So those  
7 things that the developer provided in order to be  
8 helpful to you as you were evaluating their  
9 measures you will already have seen.

10 And probably enough said on  
11 challenging, challenging what NQF has brought to  
12 you and in your discussions.

13 CO-CHAIR FLEISHER: Just a couple of  
14 things and then Barbara and Marcia will keep me  
15 honest in this space. The CSAC, one of the  
16 things we're supposed to do is bring back some of  
17 the general consensus of reserve status. If you  
18 remember, this Committee was one of the first to  
19 really utilize reserve status.

20 There have been some areas in which we  
21 feel that the measure may have little gaps for  
22 improvement. But it's still important to keep on

1 the books because it's still a valid and reliable  
2 measure. It can be used as part of a composite.  
3 However, if the gaps are small -- for example,  
4 it's a never measure and there are rare events --  
5 but it remains important to keep it in active  
6 status, then we have the right to keep it in  
7 active status even though the gap may be small.  
8 Correct? That's the most recent determination.

9 MEMBER DUTTON: On that point, we've  
10 discussed this many times here before, the  
11 concept of topped out measures and particularly  
12 the very important ones like mortality after  
13 surgery that seem to have a lot of face validity  
14 or public value, I noticed in several of the  
15 measures there was a comment from the NQF analyst  
16 this time and I'll quote it. Generally rare-  
17 event outcomes do not provide adequate  
18 information for improvement or discrimination.  
19 However, serious reportable events that are  
20 compared to zero are appropriate outcomes for  
21 public reporting and quality improvement.

22 Is that our policy, and are we the

1       ones who decide whether a measure fits that bill?

2                   CO-CHAIR FLEISHER:   Marcia, if you  
3       have comments you can please add them.   But I  
4       think that's essentially where the CSAC, we feel  
5       it's important to keep that measure active rather  
6       than reserve status.   The answer is yes.   But,  
7       Marcia, if you could.

8                   DR. WILSON:   Yes, it was very much  
9       CSAC wanted the standing committee to have the  
10      leeway to make that decision.   What they  
11      recognized is a single, across-the-board policy  
12      would not be appropriate in these instances.   And  
13      they felt that the standing committee would have  
14      the expertise to understand on a measure-by-  
15      measure basis because obviously this is a  
16      complicated topic.   They wanted the standing  
17      committee to have the ability to make the  
18      decisions themselves.

19                   And the guidance from the CSAC was  
20      that the Committee was allowed to decide when it  
21      was appropriate to leave a measure active,  
22      meaning not move it to reserve status especially

1 in the case of patient safety, mortality, a  
2 number of different issues. So the authority  
3 rests with you. But CSAC would want to hear the  
4 explanation like in the report when a measure  
5 goes back to CSAC. They would want to hear your  
6 rationale for making the decision.

7 Does that help, Lee?

8 CO-CHAIR FLEISHER: One of the  
9 important things is that the Board -- I don't  
10 know if it's implemented yet -- CSAC is the final  
11 arbitrator now.

12 DR. WILSON: Right.

13 CO-CHAIR FLEISHER: And the Board is  
14 getting out of the business of readjudicating.  
15 And CSAC is trying to get out of the business of  
16 readjudicating what the standing committee did  
17 unless the CDP process was not appropriately  
18 followed or it's not consistent with the overall  
19 theme of the direction.

20 So being clearer about why we have  
21 chosen a particular route will actually help not  
22 readjudicate and leaving a lot of the decisions

1 in this Committee and therefore the place where  
2 it's readjudicated if it's not consistent with  
3 the theme of the entire body of measures.

4 Bill, I'm sorry.

5 MEMBER DUTTON: I thought that was a  
6 huge step forward.

7 CO-CHAIR GUNNAR: So help me  
8 understand a little bit. I think the umbrella of  
9 focus for us is quality improvement. But there  
10 are certain situations or measures where the  
11 incidence has declined or the measure is topped  
12 out. And public reporting of that or the ability  
13 of that facility to publicly report is the right  
14 thing to do. Is that the perspective?

15 MEMBER DUTTON: Yes. So if we take  
16 the classic death after CABG that is 30 years old  
17 and the best measure out there -- that's  
18 obviously very important to the public -- it has  
19 huge face validity. But look at 800 hospitals  
20 and there are three low outliers and three high  
21 outliers. It's not incredibly useful for quality  
22 improvement as written. But it is a very

1 important measure to collect and report. And I  
2 guess you could phrase it that you want to keep  
3 reporting that because you wouldn't want to see  
4 backsliding or regression on something that  
5 important.

6 I'm glad that we have language that we  
7 can use to say, this measure is important  
8 essentially regardless of the variability in it,  
9 regardless of the fact that performance is very  
10 good. There are other process measures that are  
11 exactly the opposite.

12 From my own specialty, did we give the  
13 antibiotics on time? We sent that one to the  
14 Measure Hall of Fame a couple of years ago  
15 because it was clearly topped out. And as a  
16 process measure, it's not in itself critical. So  
17 I thought that was a very good decision.

18 But something like the mortality  
19 measures that we have in here -- and there's a  
20 bunch of them -- I think regardless of how they  
21 perform as quality indicators, they're going to  
22 be very important public measures.

1 CO-CHAIR FLEISHER: I think that's  
2 well said. Just a refresher because I forgot for  
3 a second, we should raise our placards when we  
4 want to speak. I think Barbara's hand is on it  
5 signifying.

6 MEMBER LEVY: Yes, I just want to give  
7 an analogy that maternal mortality for example is  
8 exquisitely rare, and it's very difficult to use  
9 as a measure for an individual institution  
10 because they may not see one for two or three  
11 years we hope.

12 But it's really useful for quality  
13 improvement. Maternal mortality reviews are  
14 things we're trying to get passed throughout the  
15 country.

16 Let's remember that even rare events  
17 can be very useful for quality improvement, and  
18 those kinds of events have a great deal of  
19 learning for us.

20 CO-CHAIR FLEISHER: Great. Others?  
21 Yes.

22 MEMBER MOSS: Yes, I just wanted to

1 put on the record that across-the-board event  
2 rates in children's surgery tend to be in the  
3 order of magnitude below adult surgery. So this  
4 concept is relevant across the board in  
5 children's surgery. And I support the decision  
6 of the group.

7 CO-CHAIR FLEISHER: Great. I mean I  
8 think what we were hearing is outcomes could be  
9 kept and not put into reserve status. The  
10 question will really be around process measures  
11 rather than outcomes. So that's invested back in  
12 this Committee.

13 Ready to start?

14 MS. MURPHY: All right. So I want to  
15 just tell you as you're thinking about the  
16 measures is that you're going to be thinking  
17 about new measures a bit differently than you're  
18 thinking about measures that are undergoing  
19 maintenance, in terms of the criteria.

20 So in looking at new measures, and  
21 you're evaluating evidence, you're evaluating gap  
22 as you always have. When you're looking at the



1 maintenance measures, you can place less emphasis  
2 on the evidence and gap -- well, not with gap,  
3 that's in fact increased emphasis -- but on the  
4 evidence piece. Because if they will have been  
5 through the process, they will have been  
6 endorsed. If there are changes in the evidence,  
7 then you will want to look at that carefully.

8 In many, if not most cases for the  
9 ones you'll look at in these two days where there  
10 is new evidence, it is directionally the same as  
11 evidence has been in the past, so maybe additive  
12 as opposed to in conflict with. If there is new  
13 evidence, you will consider that.

14 One of the other things that you will  
15 be looking at is with the maintenance measures if  
16 whatever was done before and was endorsed before  
17 raises a question in your mind in terms of the  
18 evolution of measurement through the NQF process.  
19 You may want to revisit that. But in general  
20 there will be decreased emphasis on the evidence  
21 piece.

22 There's actually greater evidence on

1 the gap because remember the maintenance measures  
2 will have been in use for a while. You would  
3 expect to see some improvement. If there hasn't  
4 been improvement you're going to be interested in  
5 wanting to know why there has not been any  
6 improvement. What are the issues? What's the  
7 variation? And what's contributed to those?

8 With respect to the criteria for  
9 scientific acceptability, you will be considering  
10 for -- again, for the new measures, you're  
11 looking at them in the same way you have looked  
12 at the measures in the past: complete. In terms  
13 of maintenance measures with scientific  
14 acceptability, there will be no difference in the  
15 way in which you look at the specifications of  
16 the measure other than you're looking for them to  
17 be updated where appropriate.

18 In terms of reliability and validity,  
19 if prior testing was adequate -- and that's a key  
20 question for you -- then there's not any need for  
21 additional testing for the maintenance process.  
22 For those measures to which it applies, the

1 effective sociodemographic factors should be  
2 addressed. You will be looking for that to have  
3 been addressed with the outcome measures.

4           Going ahead then to feasibility, there  
5 will be no difference in the way you're looking  
6 at feasibility whether it's new or a maintenance  
7 measure. And in terms of use and usability, you  
8 actually will be having an increased emphasis on  
9 the way in which you're looking at that. Much as  
10 you do with gap, you're going to be looking at is  
11 the measure in use? Is it useful? In terms of  
12 its impact, are there any unintended  
13 consequences? And if there are unintended  
14 consequences, what's being done to address those  
15 or what should be done to address those?

16           That's the CliffsNotes version of what  
17 you're going to be looking at differently in  
18 terms of maintenance measures as opposed to new  
19 measures.

20           We've talked about endorsement with  
21 reserve status. I think we've covered that  
22 adequately, Lee.

1 CO-CHAIR FLEISHER: Yes.

2 MS. MURPHY: And, Bill, are you okay  
3 with that? Okay.

4 MS. SKIPPER: Thank you, Melinda.

5 Good morning, everyone. Just a couple of  
6 housekeeping items I meant to mention. Our  
7 restrooms are past the elevators and to the  
8 right.

9 And microphones, please be sure to  
10 speak into your microphone. You may have to lean  
11 a little bit closer. The meeting is being  
12 transcribed. And only three microphones can be  
13 on at one time. So once you're finished speaking  
14 just be sure to click off.

15 And we'll continue with the role of  
16 the Standing Committee. Some of you have been  
17 through process before and to our new members,  
18 welcome. So your role on the Standing Committee  
19 is to act as a proxy for the NQF membership.  
20 Each of you will serve a two to three year term.

21 Overall, you all are tasked with  
22 overseeing the surgery portfolio of measures and

1 working with the project team to achieve the  
2 goals of the project. Additionally your role is  
3 to complete the measure evaluations as you all  
4 have done -- thank you so much -- and to make  
5 recommendations to NQF regarding endorsement of  
6 measures.

7 Here are a couple of ground rules for  
8 today's meeting. I will not read them, but if  
9 there are any questions, please let us know. But  
10 I'm sure that you all will agree to adhere to the  
11 ground rules. We'll be sure to keep you on task.  
12 But I don't believe we'll have an issue with  
13 that.

14 Okay. When it comes to discussing our  
15 measures today, we will be asking the measure  
16 developer to introduce the measure. They have  
17 about two to three minutes to do so. Some of our  
18 developers are on the phone. Those that are in  
19 person, we'll ask them to come to the table and  
20 they'll sit right next to Karen Johnson. And  
21 once we begin the discussion of the measures,  
22 should the developer have a question, they'll be

1 asked to raise their placard to respond.

2 And then also the lead discussants  
3 will begin the discussion of the measure  
4 providing a summary of their pre-meeting  
5 evaluation comments or emphasizing any areas of  
6 concern or differences of opinion. Within your  
7 packet, you should have a measure discussant  
8 script that can help you start off as we discuss  
9 each of the measures.

10 Then again developers will be able to  
11 respond to any questions or clarify anything that  
12 perchance is misspoken. Then also the Committee  
13 will vote on each criteria and subcriteria.

14 When we move to vote, there are four  
15 criteria that we will be voting on. The first  
16 one is importance to measure and report. And  
17 there are two subcriteria: evidence and  
18 performance gap.

19 For some of our composite measures, we  
20 do have three composite measures within the  
21 portfolio. There is an additional criteria that  
22 we'll be voting on. That's quality, construct

1 and rationale.

2 We'll then move to vote on scientific  
3 acceptability, so whether or not the measure is  
4 reliable and valid, credible and consistent. And  
5 then in addition for our composite measures we'll  
6 be taking an additional vote there as well. Then  
7 we'll also move to vote on feasibility and  
8 usability and use.

9 And I want to note that the first two  
10 criteria -- importance to measure and report and  
11 scientific acceptability -- are must passass  
12 criteria. If the Committee does not pass a  
13 measure on either of those two criteria then the  
14 discussion of the measure ends there and we will  
15 move to discussion on the next measure.

16 Achieving consensus. In order for a  
17 measure to be passed or recommended, greater than  
18 60 percent. So 60.1 percent of you must vote  
19 yes, high or moderate, on any criteria in order  
20 for the measure to pass. If at any time the vote  
21 falls between 40 and 60 percent inclusive of both  
22 of those ends, it's considered consensus not

1 reached.

2 If we vote consensus not reached on  
3 any of the two must pass criteria, then we will  
4 continue to vote on the remaining criteria, but  
5 we will not take an overall vote for suitability  
6 for endorsement. A measure is not passed if less  
7 than 40 percent of the Committee votes low or  
8 insufficient.

9 And just in general, quorum is 66  
10 percent of the Committee. And I believe we  
11 definitely have that today. And are there any  
12 questions at this point?

13 (No response.)

14 All right. So we will begin the  
15 consideration of candidate measures. I'll turn  
16 it over to Lee.

17 CO-CHAIR FLEISHER: Great. And if you  
18 remember and for those who are new, if there are  
19 measures that have the same validity and  
20 reliability, we may ask if anyone has any  
21 objection to using the previous vote and carry  
22 that forward. There are certain criteria that



1       it's essentially the same dataset and the same  
2       construct.

3               So we are starting with PSI 4. And I  
4       believe we have AHRQ. Pam and Garth are on the  
5       phone.

6               DR. OWENS: That's correct.

7               CO-CHAIR FLEISHER: That's correct.

8               DR. OWENS: Thank you. Should I go  
9       ahead and start?

10              CO-CHAIR FLEISHER: Great. So  
11       Christopher and Amy are lead discussants. We  
12       don't need to repeat the same thing for whoever  
13       is going first. And then whatever you add, Amy  
14       can add.

15              Christopher, do you want to start with  
16       this?

17              MEMBER SAIGAL: Sure.

18              CO-CHAIR FLEISHER: Or do you want to  
19       let the developer? Okay. Great. Why don't we  
20       have Pam or Garth? Do you want to give us an  
21       overview?

22              DR. OWENS: Sure. Thank you very

1 much. My name is Pam Owens. I'm the Scientific  
2 Lead of the AHRQ Quality Indicators. And first I  
3 want to apologize for not being able to be there  
4 in person or have any AHRQ staff member there in  
5 person. I also want to apologize that our  
6 clinical representatives aren't able to be there  
7 in person.

8 But as was mentioned, Dr. Garth Utter  
9 and Pat Zrelak are on the phone from UC Davis.  
10 They can answer any additional questions as I can  
11 as well.

12 AHRQ very much appreciates the  
13 opportunity to have PSI 4 or the death rate among  
14 surgical inpatients with serious treatable  
15 complications reviewed today. Before Garth gives  
16 a broad overview of the measure, I want to take a  
17 few seconds to tell you about some of the core  
18 principles of the AHRQ QI program as I think  
19 these are critical aspects to keep in mind during  
20 the review.

21 The hallmark of the AHRQ Quality  
22 Indicator development process is the continuous

1 enhancement and refinement of all indicators  
2 based on user feedback, review of clinical  
3 practice changes, validation studies, empirical  
4 testing for validity and reliability and input  
5 from expert panels such as yourselves like the  
6 NQF Surgery Committee or experts from the AHRQ  
7 Standing Work Group.

8 In addition, I want to highlight  
9 another key component of the AHRQ QI program and  
10 that is the transparency and usability of the  
11 indicators. Not only does the AHRQ QI program  
12 publicly post all of the technical  
13 specifications, but AHRQ also provides users with  
14 SAS and Windows-based software to be able to  
15 calculate thorough numerators, denominators,  
16 observed and risk-adjusted rates using their own  
17 administrative data.

18 Users are in fact a critical component  
19 of the QI program at AHRQ. For example, this  
20 month we released an updated AHRQ QI Toolkit that  
21 can be used by hospitals as a general guide to  
22 applying improvement methods in a hospital

1 setting as well as guidance to improving  
2 performance specifically to the PSI such as PSI  
3 4.

4 Garth, would you like to continue with  
5 an overview of the indicator?

6 DR. UTTER: Yes. Again, my name is  
7 Garth Utter. I'm a general surgeon, a trauma and  
8 acute care surgeon at UC Davis and a clinical  
9 lead on the QI project.

10 PSI 4 is fundamentally a measure of  
11 risk-adjusted, post-operative inpatient mortality  
12 across the --

13 MS. MURPHY: Sorry I'm interrupting.  
14 We can hardly hear the speaker. So you may need  
15 to get a little closer to the microphone.

16 DR. UTTER: Sure. I'll try again.  
17 Can you hear me better now?

18 MS. MURPHY: Yes, we can.

19 MEMBER SAIGAL: Yes.

20 DR. UTTER: Okay, great. So again I'm  
21 Garth Utter at UC Davis and a clinical lead on  
22 the QI project. I just wanted to emphasize that

1 PSI 4 is fundamentally a measure of risk-  
2 adjusted, post-operative inpatient mortality. It  
3 involves really the full spectrum of major  
4 operations.

5 Its denominator is limited to the  
6 subset of patients who experience one of a few  
7 common life-threatening complications. And the  
8 rationale for this is that it has been shown to  
9 support fairer comparisons across different types  
10 of procedures as well as it appears to be  
11 especially sensitive to the role of nursing care,  
12 such factors as staffing, skill mix, retention  
13 and turnover and the ability of hospitals to  
14 respond rapidly through effective teamwork as a  
15 patient's condition deteriorates.

16 It is, I should note, similar to  
17 another NQF-endorsed measure that was reviewed  
18 last year by the Patient Safety Standing  
19 Committee. That measure which is called Failure  
20 to Rescue differs slightly in that it captures  
21 all post-operative inpatient deaths, not just  
22 those that occur after one of these common life-

1 threatening complications. That measure was  
2 stewarded by the Children's Hospital of  
3 Philadelphia or rather Pennsylvania rather than  
4 AHRQ.

5 PSI 4 is built as a stratified measure  
6 combining deaths that occur after five different  
7 types of complications -- sepsis, pneumonia,  
8 shock, DVT/TE, or GI hemorrhage -- using  
9 different risk adjustment models tailored to  
10 predict the mortality related to each of these  
11 types of complications.

12 It's important to recognize that some  
13 of the deaths captured by PSI 4 are preventable  
14 while others most certainly are not. But these  
15 deaths appear to be worthy of investigation. The  
16 stratified risk adjustment models are designed to  
17 reduce bias in comparison across the hospitals.  
18 Thanks for the chance to summarize the measure.

19 CO-CHAIR FLEISHER: Great. Thank you.  
20 Any other comments from the developer?

21 (No response.)

22 Perfect. Chris.

1                   MEMBER SAIGAL: Okay. First we go  
2 over the importance to measure and report  
3 criteria.

4                   CO-CHAIR FLEISHER: Yes. And then if  
5 they need, any additional comments.

6                   MEMBER SAIGAL: Okay. As we have just  
7 heard, this is a measure looking at the number of  
8 deaths in surgical patients with serious,  
9 treatable conditions post-operatively. And the  
10 developer submitted evidence that it's into the  
11 quality of nursing care. So there's a process  
12 that supports that.

13                   In terms of performance gap, the  
14 performance has improved nationally by about six  
15 percent per year. But there is still a pretty  
16 significant gap in terms of there being 43,000  
17 deaths per year in 34 states measured in all-  
18 payer datasets. That's a pretty significant  
19 number of perhaps actionable deaths.

20                   There are variations in those deaths  
21 by age, insurance status and other subgroups. In  
22 terms of -- anything else that my co-discussant

1 wants to add on that?

2 (No response.)

3 So then in terms of how it's  
4 specified, do we move on to that? Or should we  
5 vote?

6 MS. SKIPPER: Yes. So if there are no  
7 other comments or discussion on evidence and  
8 performance gap, then we would stop here and vote  
9 on this criteria.

10 CO-CHAIR FLEISHER: Questions or  
11 comments? Yes, A.J.

12 MEMBER YATES: Yes, I just have a  
13 question for the developers. Of the five  
14 complications that you list, at least four of  
15 them could be indications for emergency surgery  
16 at a hospital to where they've been transferred.  
17 An example would be sepsis from a surgically  
18 correctable source of sepsis.

19 And I don't see an exclusion criteria  
20 for present on admission. And I don't see any  
21 sort of mechanism for deciding how those patients  
22 arrived and are they excluded when the actual so-



1 called complication is the indication for  
2 surgery.

3 DR. UTTER: Sure. I can help address  
4 that concern. So you're correct. The indicator  
5 is specified such that present-on-admission  
6 conditions are not excluded, however principal  
7 diagnoses are.

8 So the rationale here is that there  
9 were some prior analyses done by Needleman's  
10 group that pretty clearly established that  
11 excluding these cases that involve one of these  
12 complications having had an origin prior to  
13 arrival of the patient at the hospital didn't  
14 really improve the validity of the measure. It  
15 did detract pretty substantially from the number  
16 of events that could be ascertained with the  
17 measure.

18 MEMBER CIMA: I have a comment. But  
19 the assumption was initially that this was a  
20 measure of nursing care and quality of care in an  
21 institution. But as an institution like ours  
22 where we're surrounded by very small community

1 hospitals for a region about 400-500 miles, we  
2 get a lot of these issues. And it has nothing to  
3 do with our system of care.

4 For centers that are regional centers  
5 that receive this, it may make a very big  
6 difference because their volumes are so high of  
7 doing that.

8 MEMBER SAIGAL: So this is a fact of  
9 validity we're talking about I think. This is  
10 the next session. We should probably get into  
11 that there. It sounds like we're talking about  
12 validity questions.

13 CO-CHAIR FLEISHER: Okay. Why don't  
14 we get back to that? Rick, do you have a comment  
15 on importance?

16 MEMBER DUTTON: I think failure to  
17 rescue is an important thing to measure. I worry  
18 or maybe in the next discussion there's an  
19 exclusion for patients transferred out of the  
20 hospitals. So if my patient develops sepsis and  
21 I quickly transfer them out, I'm good. But isn't  
22 that creating a loophole in this measure?

1                   MEMBER SAIGAL: This is another  
2                   validity question. So why don't we vote on the  
3                   first one, importance to measure and report?

4                   CO-CHAIR FLEISHER: Thanks. Any other  
5                   comment? I appreciate you sticking with the  
6                   criteria. Did we lose Christy? Do you agree  
7                   with that?

8                   MS. SKIPPER: What we're going to do  
9                   actually, this is a maintenance measure. And due  
10                  to our new process, there's a decreased emphasis  
11                  on evidence if there is no new evidence. So you  
12                  all may elect to use the vote, carry over the  
13                  vote from the previous endorsement of this  
14                  measure. Then we will not technically take a  
15                  vote on evidence.

16                  CO-CHAIR FLEISHER: So does anyone  
17                  object to carry over the previous endorsed vote?

18                  MEMBER SAIGAL: For what?

19                  CO-CHAIR FLEISHER: For this criteria  
20                  for evidence. In other words, from the previous  
21                  endorsement, the new process -- and thanks for  
22                  reminding me -- is if there's no change from the

1 previous process, we can just endorse by  
2 acclamation, so to speak, the previous vote.

3 CO-CHAIR GUNNAR: But technically I've  
4 heard that the gap has diminished, but it's still  
5 substantive. So I think it's easier to vote  
6 since this is the first time. Why don't you run  
7 us through voting and we'll vote on it?

8 CO-CHAIR FLEISHER: Okay. And Karen,  
9 our expert on evidence, can comment.

10 MS. JOHNSON: Well, maybe not  
11 evidence. But I know the criteria pretty well  
12 and it has changed I think since the last time  
13 you guys have met and voted. So let me just  
14 restate again so that it's clear in what we're  
15 doing.

16 We're with our new maintenance process  
17 we're having less of an emphasis on evidence.  
18 Okay. So what happened with this measure is it  
19 is a maintenance measure. The developer did  
20 provide additional evidence, but it seems to be  
21 pretty much in the same vein as the other  
22 evidence.

1           So the question for you in terms of  
2 evidence, not gap but evidence, is do you feel  
3 that there's a need to vote again, or are you  
4 happy with just saying that the measure would  
5 still pass on evidence? So that will be your  
6 first question. Do you want to vote on evidence  
7 or not?

8           Now you haven't talked very much yet  
9 about gap. That's the next subcriterion under  
10 importance to measure and report. So you will  
11 have to definitely talk about and vote on gap.  
12 Okay. Does that make sense?

13           CO-CHAIR FLEISHER: So do we have a  
14 yes/no vote that we all do or are you taking just  
15 a raise of hands?

16           MS. JOHNSON: You can be informal on  
17 this. I think the question would be, does  
18 anybody feel the need to vote this morning on  
19 evidence for this measure.

20           CO-CHAIR FLEISHER: Do you want to  
21 just -- okay. We're all okay with that. Larry.  
22 Great. Larry, do you have other comments or?

1                   MEMBER MOSS: I just had a question  
2                   for the developer. Could you please explain the  
3                   rationale for excluding patients under 18 years  
4                   of age in the measure?

5                   CO-CHAIR FLEISHER: That's actually I  
6                   think the next one. Christopher, do you want to  
7                   go to the next criteria? This always starts like  
8                   this as we get back into the swing of things.

9                   MEMBER SAIGAL: Go on to number two,  
10                  is your idea? Okay. So then validity and  
11                  reliability.

12                  MS. JOHNSON: No, I'm sorry. Let's go  
13                  back to performance gap and maybe you guys did  
14                  talk about this and I just missed it.

15                  MEMBER SAIGAL: Yes, we did.

16                  MS. JOHNSON: Okay. So now what you  
17                  need to do is find out if anybody has any other  
18                  things you want to talk about about gap. If not,  
19                  then we'll go to vote on gap. Remember with our  
20                  new maintenance process we are actually  
21                  increasing our emphasis in our look at  
22                  performance gap.

1 CO-CHAIR FLEISHER: Okay. Questions  
2 on gap? No questions. So, Christy, do you want  
3 to help us vote?

4 MS. SKIPPER: Yes. Just a moment.  
5 I'm just preparing this slide. Okay. So we'll be  
6 voting on performance gap for Measure 0351.  
7 Everyone should have received a clicker. When I  
8 tell you that polling is open, you will point  
9 toward me and press number one, two, three or  
10 four, one for high, two moderate, three for low,  
11 four insufficient.

12 We do have two members participating  
13 over the phone and they will be chatting in their  
14 votes. And Katie and I will be voting on their  
15 behalf. So you all, polling is now open for  
16 Measure 0351 performance gap: one high, two  
17 moderate, three low and four insufficient.

18 (Voting.)

19 CO-CHAIR FLEISHER: Okay. Should we  
20 just keep pushing and we can't vote more than  
21 once.

22 MS. SKIPPER: We want that number in

1 the circle in the bottom left-hand corner to hit  
2 22.

3 (Voting.)

4 MEMBER SAIGAL: Still waiting on three  
5 more votes.

6 MS. MURPHY: Can you tell which ones  
7 you need?

8 MS. SKIPPER: No. If everyone could  
9 just --

10 CO-CHAIR GUNNAR: Mine is not lighting  
11 up. So does that mean it's not --

12 MS. SKIPPER: I would try again and  
13 aim it at me. The remote will record your last  
14 vote.

15 CO-CHAIR GUNNAR: My battery is dead.

16 MS. SKIPPER: Okay.

17 CO-CHAIR GUNNAR: Can we get new  
18 batteries?

19 CO-CHAIR FLEISHER: Is everybody  
20 seeing a red light?

21 MS. SKIPPER: Maybe someone stepped  
22 out of the room, but we're at 21.



1                   And thank you for your patience on  
2                   this first round. All right. Now we're at 22.  
3                   So 22 is at the very --

4                   Yes, so voting has closed. Twenty-  
5                   seven percent of votes were high. Seventy-three  
6                   percent of votes moderate. Zero percent low.  
7                   Zero percent insufficient. 0351 does pass on  
8                   performance gap.

9                   CO-CHAIR FLEISHER: Before we go on,  
10                  Lynn, are you prepared to just briefly introduce  
11                  yourself and any conflict of interest?

12                  MEMBER REEDE: Good morning. Lynn  
13                  Reede. No conflict of interest.

14                  CO-CHAIR FLEISHER: Thank you.

15                  MEMBER SAIGAL: Should I proceed?

16                  CO-CHAIR FLEISHER: Okay.

17                  MEMBER SAIGAL: So this is scientific  
18                  acceptability, the next phase. In terms of  
19                  specifications, it's very clear documentation on  
20                  how to define the numerator and denominator and  
21                  the comorbidities required. There are good  
22                  specifications.

1                   In terms of reliability, the developer  
2                   used what's called a signal-to-noise ratio which  
3                   is a measure of the variability between hospital  
4                   performance and within hospital stability. The  
5                   measure was acceptable with a ratio of 0.7 or  
6                   greater for only the largest hospitals, more than  
7                   436 discharges. But the developer feels that  
8                   lower signal-to-noise ratio standards are  
9                   actually acceptable which would include all the  
10                  hospitals in the datasets. So there's a bit of a  
11                  discrepancy there in terms of what's an  
12                  acceptable signal-to-noise ratio.

13                  In terms of validity testing, it did  
14                  face validity testing using the RAND Delphi  
15                  process. It passed on that. They also tried to  
16                  test how these measures performed in a Medicare  
17                  analysis looking at five other elements of the  
18                  hospital structure essentially with better  
19                  outcomes.

20                  MS. MURPHY: I'm sorry to interrupt.  
21                  Let's complete reliability and do the vote on  
22                  that.

1 MEMBER SAIGAL: Okay.

2 MS. MURPHY: And then do validities.

3 MEMBER SAIGAL: Okay. So for  
4 reliability.

5 CO-CHAIR FLEISHER: Amy, any  
6 additional comments and then we'll go to  
7 Collette.

8 MEMBER MOYER: The only thing I would  
9 add is this is a measure that we actually use and  
10 have calculated. AHRQ making the software and  
11 the code available takes a lot of the judgment  
12 calls that might go into play on calculating  
13 other measures. So we find that it's really very  
14 straightforward to feel like you're consistently  
15 calculating this measure.

16 CO-CHAIR FLEISHER: Collette.

17 MEMBER PITZEN: Just a question. Is  
18 this the part of reliability voting where we talk  
19 about specifications, because I heard some  
20 questions about exclusion?

21 MEMBER SAIGAL: That's coming up  
22 though actually. That's validity. That's

1 subsequent.

2 CO-CHAIR FLEISHER: Let's get a --  
3 Karen.

4 MS. JOHNSON: You talked mostly about  
5 specifications under reliability. So you want  
6 them to be very precise and unambiguous and you  
7 want to agree with how they're specified.

8 They do come into play a little bit  
9 with validity as well if you feel like the way  
10 something has been specified invalidates the  
11 measure. For the most part you will be talking  
12 about it under reliability.

13 CO-CHAIR FLEISHER: So the present on  
14 admission questions would be under?

15 MS. JOHNSON: They start under  
16 reliability.

17 DR. OWENS: This is Pam Owens. And I  
18 just want to speak to the question regarding  
19 transfer patients. Transfer patients are  
20 actually part of the risk model. So we account  
21 for that potentially increased risk in each of  
22 the risk models for each of the strata.

1 CO-CHAIR FLEISHER: Rick.

2 MEMBER DUTTON: I'm sorry. Is that in  
3 the risk model for the receiving hospital which  
4 was A.J.'s question or for the transferring  
5 hospital which is my question?

6 DR. OWENS: So each hospital would  
7 have their own rate and the patients in the risk  
8 model is if they are transferred in. That is the  
9 criterion in the risk model. Does that make  
10 sense?

11 MEMBER DUTTON: Yes. So that's A.J.'s  
12 question. So if the hospital like Penn, for  
13 example, received a patient in transfer who is  
14 desperately ill with one of these surgical  
15 conditions and goes to the OR, the risk-  
16 adjustment model accounts for the higher risk of  
17 that patient dying. That makes perfect sense.

18 My question was about the hospital  
19 transferring out. So the small community  
20 hospital we do a colectomy electively. We put a  
21 hole in the bowel. The patient develops sepsis.  
22 We fail to identify that in a timely fashion.

1 When we do identify it, we transfer the patient  
2 to Penn. So according to the specifications as  
3 I'm reading them, that case now doesn't count for  
4 us because it was an acute care transfer out. Is  
5 that correct?

6 DR. OWENS: That is correct.

7 MEMBER DUTTON: And does that create  
8 the potential for gamesmanship?

9 DR. OWENS: I see what you're saying.

10 DR. UTTER: I was just going to  
11 comment. This is Garth. It does create possibly  
12 a small window for gaming. However, there is  
13 just simply no way to assess the outcome of  
14 interest here in those cases of course.

15 MEMBER CIMA: But this goes to the  
16 point of validity as opposed to reliability  
17 because on face validity that makes no sense.  
18 And that's the concern. If you're looking at  
19 processes of care to identify patients in your  
20 hospital this is how we started this conversation  
21 was we're looking at processes of care to  
22 identify people early and things.

1                   And then if the receiving hospital  
2 gets a desperately ill patient, they had nothing  
3 to do with the process of care. And if the  
4 patient dies, how can they be held responsible  
5 for that? And if you're excluding those  
6 hospitals as you just said you are, there's no  
7 validity here.

8                   DR. UTTER: No, we're simply excluding  
9 the cases in which we can't assess whether a  
10 death occurred or not because the episode of care  
11 really hasn't completed. And as Pam emphasized,  
12 the issue of receiving a patient from another  
13 hospital, we don't want to exclude those cases  
14 because they contribute really to the signal that  
15 can be detected. Therefore, we handle them with  
16 the risk adjustment.

17                   MEMBER CIMA: But you can't risk-  
18 adjust all that away. That's the problem with  
19 risk adjustment. There is some risk adjustment  
20 that you can't handle. And the validity of this  
21 is receiving hospitals are going to be faced with  
22 this issue of, how can we be responsible for

1 this. And now you're talking about the  
2 practicality of this.

3 DR. UTTER: Sure. And we certainly  
4 understand that. We've received numerous queries  
5 from users over the years on this issue. And I  
6 guess one piece of information that may  
7 contribute to our understanding of this is that  
8 actually these transferred patients end up having  
9 lower rates of death than ones that occur  
10 inpatient. So it's not perhaps quite the issue  
11 that it's perceived to be.

12 CO-CHAIR FLEISHER: Larry and I think  
13 -- okay. A number of questions. Larry, why  
14 don't you start?

15 MEMBER MOSS: I have a new topic. I  
16 think Karl had something on this topic. So why  
17 don't you go first?

18 CO-CHAIR FLEISHER: Okay. Karl.

19 MEMBER BILIMORIA: I think leaving  
20 transfer patients in just because that improves  
21 your signal doesn't really make a lot of sense.  
22 I think that we all would rather see those



1 excluded. I mean just including a complex  
2 population because that improves your event rate  
3 doesn't seem to make sense. I think that's what  
4 was said.

5 MEMBER YATES: My clarification was is  
6 that transferred in with the diagnosis that's  
7 being evaluated as the principal -- not as the  
8 principal, but as the present-at-admission  
9 diagnosis. My concern being that if the patient  
10 dies from something else during the  
11 hospitalization, that then becomes the principal  
12 diagnosis. Whatever was found to be causing the  
13 sepsis, might be gangrenous gallbladder, that  
14 becomes the principal diagnosis. But the word  
15 sepsis is then a secondary diagnosis just because  
16 of the way they coded it.

17 MEMBER BILIMORIA: No, I was taking  
18 exception with what one of the developers was  
19 talking about in terms of why they leave  
20 transfers in. Yes, I understand what you are  
21 saying.

22 MEMBER YATES: And I'm just saying

1       it's not the transfers. It's the transfer with  
2       that diagnosis that I would be worried about.

3               DR. OWENS: This is Pam. And I will  
4       say as Garth mentioned, we have grappled with  
5       this over the years. And part of our concern  
6       here with the failure to rescue originally, by  
7       Jeff Silber, my understanding is that included  
8       all patients.

9               And the transfer patients are sort of,  
10      if you exclude them, then that's a missed  
11      opportunity to see what is going on. And  
12      absolutely we've had both sides of the argument  
13      conceptually to include them or don't include  
14      them.

15              Our approach right now is risk  
16      adjustment. We certainly can show you some  
17      additional analyses that shows what happens, not  
18      today, what happens if we were to exclude them.  
19      But conceptually, we were harmonizing originally  
20      with Jeff Silber's measure, and that's where this  
21      originated a long time ago if that helps in terms  
22      of historic information.

1 CO-CHAIR FLEISHER: Okay, and I have  
2 just for disclosure: as I mentioned, I worked  
3 with Jeff. So I have an email into Jeff to find  
4 out. Karl, did you have anything else?

5 DR. OWENS: Excellent.

6 CO-CHAIR FLEISHER: And then Fred.

7 MEMBER BILIMORIA: No, I think the  
8 notion that this doesn't matter, I think most  
9 people when they look at their own data will tell  
10 you that it does matter. Most of our hits on  
11 this are transfers in. And so the idea that this  
12 is a small problem I don't think is valid. And I  
13 think it would be worth seeing the data on what  
14 happens when you exclude these patients.

15 CO-CHAIR FLEISHER: So I think since  
16 we always see back, Christy, is it okay if we ask  
17 if they have data-specific --

18 MEMBER SAIGAL: Can I tell you? There  
19 is data. If you look on page 575 of that big  
20 document that was sent around this morning, they  
21 do list -- and we're jumping around here. We're  
22 in another part of the review, right? We're in

1 validity.

2 If you look at this page, they show  
3 you how many people have been excluded based on  
4 various criteria. So 3 percent are excluded  
5 based on they were transferred out to acute care  
6 facilities. Then there is the number of people  
7 who are excluded because their primary diagnosis  
8 is a complication; that ranges from 3 percent to  
9 actually 13 percent of patients who had a  
10 principal diagnosis of septicemia who were  
11 excluded. That's the principal diagnosis.

12 So they do provide some data to  
13 address some of these concerns. But I would  
14 suggest that we vote on reliability before we get  
15 into this part of it because we're really jumping  
16 around, and it's going to be a big mess.

17 CO-CHAIR FLEISHER: Thank you. Fred,  
18 do you want to -- you'll pass. Okay. Larry.

19 MEMBER MOSS: Sorry for my misplaced  
20 question before. But if I understand correctly,  
21 exclusions belong under reliability. So I'd like  
22 to ask my question about the rationale for

1       excluding patients under 18.

2               DR. UTTER: Yes, this is Garth. So I  
3       think some of this goes back to the origin of  
4       this measure and the work of Needleman's group to  
5       base it on these five conditions, not all of  
6       which would necessarily apply to the pediatric  
7       setting, and most prominently DVT/TE and PE. And  
8       so I think it's just the construct of the time  
9       that this was developed. It was really more  
10      applicable to the adult population is the main  
11      reason.

12             MEMBER MOSS: I appreciate that, and  
13      I share and accept your rationale, although I  
14      would like to see these measures include in the  
15      text a specified reason for excluding patients  
16      under 18 rather than just the assumption that  
17      that's okay.

18             CO-CHAIR FLEISHER: Okay. Karen, I  
19      mean that's pretty standard, the exclusion for  
20      18. But it could be that we include that in  
21      gaps, that this might be an important measure to  
22      measure in the pediatric population. Can we,

1 Melinda? I think that's a -- we should look --  
2 one of the gaps could be that this should be  
3 extended into the pediatric population. A lot of  
4 the time, they don't have the data. Would that  
5 be okay?

6 MEMBER MOSS: Yes, and I think that's  
7 reasonable. And I'm not trying to advance  
8 personal agenda. I just wanted to raise the  
9 issue that if we excluded black people or poor  
10 people, we'd be all over it.

11 And we routinely exclude children and  
12 say it's standard. And I'd like that not to be  
13 considered standard.

14 CO-CHAIR FLEISHER: So let's not make  
15 that a personal agenda. Let's include that in  
16 gaps that whenever you see a measure that should  
17 be extended to the pediatric population, we  
18 identify that and put it in our document.

19 MEMBER MOSS: Thank you.

20 CO-CHAIR FLEISHER: Cliff.

21 MEMBER KO: So I hate to bring up  
22 issues without a solution, but this is just a

1 blanket statement for measures that use claims  
2 data. I know a lot of people around the table  
3 have registry-based data. And it's our  
4 environment.

5 But our environment is changing in  
6 that most reliability and validity studies that  
7 compare claims data to the gold standard of what  
8 happened in the medical record showed the  
9 lessened reliability and lessened validity of  
10 using claims data, especially -- we're a surgery  
11 group -- for surgical complications.

12 Usually when the patient dies, we know  
13 it in claims data. But it's the accuracy of the  
14 complications. And I know that Fred and STS and  
15 in NSQIP and the VQI have shown the problems with  
16 claims data. I'm not sure what the solution is,  
17 but it is something that we should have on the  
18 record.

19 CO-CHAIR FLEISHER: So another  
20 potential gap or area for improvement if it could  
21 be created in registry data is what I'm hearing.  
22 We could mark that. Fred.

1                   MEMBER GROVER: Yes, we feel strongly  
2                   in our specialty that fail to rescue really needs  
3                   to be examined. As I listen through this, this  
4                   is really a tough problem because we've got  
5                   patients at these outlying hospitals that  
6                   probably the best thing for the patient is to  
7                   refer them out to a center that has more complex  
8                   facilities to take care of complex issues. So  
9                   that's the right thing to do.

10                  And yet then you're potentially -- and  
11                  I see this every day, you're penalizing a  
12                  tertiary care center that receives these patients  
13                  unless you can totally risk adjust. As Cliff  
14                  says, I don't think in this complex patient set  
15                  you can totally and accurately risk adjust unless  
16                  you have clinical data. I mean, it's really  
17                  tough.

18                  I don't know what the solution is. But  
19                  those are my concerns.

20                  CO-CHAIR FLEISHER: So we will have to  
21                  vote on whether or not we feel that invalidates  
22                  the measure. Barry, Karl and then Amy.



1                   MEMBER MARKMAN: In terms of the  
2                   reliability, how many codes deep do you go in the  
3                   discharge diagnosis? I mean how do you pick up  
4                   the shock and the sepsis, and how do you  
5                   differentiate between the two?

6                   CO-CHAIR FLEISHER: That's a question  
7                   for the developer.

8                   DR. OWENS: So the measures are  
9                   developed on data from the Healthcare Cost and  
10                  Utilization Project and the State Inpatient  
11                  Databases. Some of those databases have up to 50  
12                  diagnoses. So it could be up to 50.

13                  Because in itself, the SAS program,  
14                  you can set it to whatever number your  
15                  administrative data has. I believe that 25 is  
16                  the number for the CMS Medicare data. That's  
17                  just what happens to be on Medicare.

18                  So it could be any number that you  
19                  want it to. We develop it on up to 50. The  
20                  majority of the states have between 25 and 30.

21                  MEMBER MARKMAN: Okay, and these codes  
22                  are generated by the billing departments of the

1       respective hospitals? It's ability to get those  
2       things.

3               DR. OWENS: Right. The Healthcare  
4       Cost and Utilization Project is based on billing  
5       data or discharge abstract data. The coder that  
6       enter it are all certified coders. And they take  
7       tests, and they look at the coding clinic for  
8       additional guidance or guidance that's put out by  
9       the federal government. So there's a standard  
10      for how to code what's in the medical record.

11             MEMBER MARKMAN: Right.

12             MEMBER CIMA: This is Bob. But that  
13      being said, there's a number of studies that look  
14      at -- well, I don't think the word standard is  
15      actually appropriate for coders. There are very  
16      significant variations in how coding is applied  
17      by institutions. That's been shown multiple  
18      times.

19             Just because one coding institution  
20      has their own internal way of reviewing their  
21      records, another institution may not. So that  
22      introduces variability between institutions and

1       how they code.

2                   And given the complexity of this, as  
3       has been said, when you're looking at sepsis,  
4       sepsis is multifactorial. There's a lot of  
5       issues. That may not be as good a choice to  
6       discriminate between institutions if you're going  
7       to use coding as your main thing. And that's  
8       been shown multiple, multiple times.

9                   MEMBER MARKMAN: One last question.  
10       Now have you performed an audit just to do your  
11       own validity test? Have you audited some charts  
12       to make sure that diagnosis codes were  
13       appropriate?

14                  DR. OWENS: Internal to the project,  
15       yes, we have done some validation studies. Some  
16       of them have been published, not all of them,  
17       where we do individual hospitals or we partner  
18       with various consortiums across the country to do  
19       mini hospitals. In terms of Medicare, yes, they  
20       do their own auditing. So there are various  
21       places that audits are done.

22                  CO-CHAIR FLEISHER: Thank you. We

1 need to keep moving. So I want to get a vote on  
2 this. But Karl, Amy and then Cliff. Excuse me.  
3 Liz and then Cliff.

4 MEMBER BILIMORIA: Yes. So I think  
5 the variability in coding between hospitals is a  
6 definite threat to reliability. That really  
7 relates to the validity then of the definitions.

8 And there have been studies that have  
9 compared, as Cliff said, the clinical data to the  
10 administrative data and found out only a false  
11 negative rate, but a high false positive rate.  
12 So it's all over the place. I think the threat  
13 of validity here, really we should question the  
14 validity of this measure entirely.

15 CO-CHAIR FLEISHER: Amy.

16 MEMBER MOYER: So I guess I have a  
17 couple of things. One, I don't think we can just  
18 generally say claims data are bad, and you can't  
19 measure things from them. There's been some  
20 measures we find a high correlation between the  
21 record and the measure, and some we don't.  
22 Frankly, we have yet to incorporate any measure

1 in our program including registry measures where  
2 we haven't had at least one hospital then come  
3 back to us and say, oh, we were sending the wrong  
4 data in. So there are issues with any data.  
5 There are no perfect datasets when it comes to  
6 healthcare that I've seen.

7 The comment I had actually originally  
8 wanted to make is, I think, new this year in the  
9 measure worksheet that NQF actually chose how you  
10 walk through the algorithm. And I personally  
11 really appreciated that, being able to see the  
12 thought process and see how you applied the  
13 algorithm in evaluating the reliability and the  
14 validity of the measures. That really was  
15 helpful to me to see where we are on the same  
16 page and where we aren't. Thank you for doing  
17 that.

18 CO-CHAIR FLEISHER: Great. That was  
19 -- Karen. No. Okay, Liz.

20 MEMBER EREKSON: And I apologize for  
21 not knowing everything about this measure. But  
22 my question is the discharges to hospice. Does

1       that count as transfer out of the facility? And  
2       where do those patients get counted? And can the  
3       measure developers provide any information about  
4       how many hospice patients actually get included  
5       in the outcome?

6               DR. UTTER: This is Garth. So if I  
7       can recall correctly, I believe the hospice  
8       discharges, they're included in the way the  
9       indicator is designed. But they really represent  
10      a very small proportion of the denominator.

11             CO-CHAIR FLEISHER: Thank you. Cliff.

12             MEMBER KO: This is again about the  
13      claims, and it's not to attack Garth or AHRQ, but  
14      just of claims. So at the college, we did a  
15      validation study of claims versus registry with  
16      NSQIP and with CMS data. This was over 100,000  
17      patients and like 300 hospitals just where we had  
18      data. And of the same patient, we had claims  
19      data and we had the registry data. So we could  
20      do that study where we look at claims versus  
21      registry.

22             Karl mentioned that the big problem is

1 the false positive. If we took an SSI, surgical  
2 site infection, the most common complication for  
3 surgery, the sensitivity was around 30-35  
4 percent. So it detected. It was a low  
5 detection rate, which it's okay.

6 Fine. We look better because we don't  
7 find them all. But the false positive rate was  
8 around 70 percent. So we're inappropriately  
9 ding people for an SSI when they don't really  
10 have an SSI. And when we first found that, I was  
11 like, why? Why would that happen? And it's the  
12 definitions.

13 And the biggest thing, the best  
14 example is that if I write in the chart after I  
15 do a colon operation, on the fifth day, the  
16 patient is spiking fevers. I write, "Please get  
17 a CT scan to rule out infection." The coder will  
18 write that that's an infection because I wrote  
19 the infection, even though consider infection,  
20 rule out infection, or whatnot.

21 It's not by the CDC definition of a  
22 culture or gram stain or anything like that.

1       It's those words, and that's how the code is  
2       working. That's how ICD is. We're not going to  
3       change the International Classification of  
4       Disease. But that's what it is.

5               So that discrepancy between clinical  
6       and claims is there, and it's just a matter of  
7       definition. What we should probably decide is  
8       how do we reconcile that, or do we not reconcile  
9       that.

10              I can tell you that when we brought  
11       this work with CMS, and if you see the payment  
12       programs, of how they're starting to go away from  
13       claims and go to registry and go to electronic  
14       measures, that is the direction we're all  
15       heading. I don't know if this is the time to  
16       stop all these claim measures or have a limited  
17       time that we have a shorter window to start to  
18       reevaluate them again. But that's the direction  
19       that seems to be heading for the environment.

20              CO-CHAIR GUNNAR: Can I ask a  
21       question? And maybe to Chris and Amy as well.  
22       Is the perspective that the improvement in



1 performance associated with this measure, is it  
2 due to real quality improvement? Or is it due to  
3 an enhanced ability to code or to manage the data  
4 if you will? I guess that's the philosophical  
5 question to the group regarding this particular  
6 measure. A.J.

7 MEMBER YATES: I would second that  
8 question, and I would offer my answer, which is I  
9 think in the time frame we're talking about, a  
10 significant improvement is as likely a paradigm  
11 shift in coding as it is an improvement in  
12 surgical care. And I think that the coding, now  
13 that hospitals are graded by stars and face  
14 millions of dollars in penalties in both HAC, VBP  
15 and readmission rates, they're a lot more careful  
16 about their coding. And I can give several  
17 examples, but won't.

18 CO-CHAIR FLEISHER: What I would  
19 suggest, and we're having a lot of discussions up  
20 here is Helen Burstin is the best person right  
21 now to have a discussion about, is this time to  
22 abandon? I mean this is a much bigger question

1       than this measure, this committee. This is a  
2       question for CMS, Luanne being on the phone.

3               MS. MUNTHALI: And just one more  
4       reminder.

5               CO-CHAIR FLEISHER: Yes.

6               MS. MUNTHALI: As you're looking at  
7       this measure, remember you're looking at it as  
8       it's currently specified.

9               CO-CHAIR FLEISHER: Right.

10              MS. MUNTHALI: We understand that  
11      there are a lot of aspirational hopes for  
12      measurement in general in this measure. But  
13      you're evaluating it against NQS criteria as it's  
14      currently specified.

15              CO-CHAIR FLEISHER: I actually had one  
16      quick question because Jeff Silber did answer me.  
17      And the original failure to rescue -- this is for  
18      the developer -- transfers were kept in and  
19      adjusted for, it sounds like as a covariate, they  
20      just transfer in. But transfer out, they  
21      assigned death and failure to rescue to where the  
22      original surgery occurred. Do you not do that in

1 your failure to rescue, which, I guess -- the  
2 Needleman failure to rescue as opposed to the  
3 Silber?

4 DR. UTTER: This is Garth. If I  
5 understood you correctly, the question is, do we  
6 assign death where it occurred? Was that the  
7 question?

8 CO-CHAIR FLEISHER: Actually assign  
9 death to the original hospital that did the  
10 original surgery in which the complication  
11 occurred. It sounds like what you said is you  
12 don't do that even though the original failure to  
13 rescue measure did do that.

14 DR. UTTER: No, at least on a broad  
15 basis it's not possible to do that without some  
16 ability to link hospitalizations. So, no, we  
17 don't do that.

18 CO-CHAIR FLEISHER: So you don't. We  
19 need to take a vote. We will come back to this  
20 really critical issue. Does anybody have critical  
21 comments to the vote on reliability? Karl, did  
22 you have one?

1                   MEMBER SAIGAL: I think we should  
2 specify what we're voting on now because we had a  
3 pretty broad discussion.

4                   CO-CHAIR FLEISHER: We're going to ask  
5 -- I say staff, but really the other experts in  
6 the room. Do you have a comment?

7                   MEMBER PITZEN: Thanks. I do have a  
8 comment. I'll put my measure developer hat on  
9 for a second. And I might be traipsing into  
10 validity. But I think we have to be careful in  
11 disclaiming all ICD-9, ICD-10 diagnosis codes  
12 because there are very reliable ways of  
13 identifying a population of interest in using  
14 those codes.

15                   I think part of this speaks to  
16 validity. If there are concerns about the sepsis  
17 portion of this measure, what can the developer  
18 perhaps tell us about the validity when comparing  
19 that administrative code against again the  
20 medical record? You're validating.

21                   So the difference in this measure is  
22 we're using ICD-9, ICD-10 for the numerator. So

1 one needs to understand if I'm pulling these  
2 particular ICD-9 codes, ICD-10 codes to identify  
3 sepsis, what is my reliability in having that  
4 true measure?

5 DR. UTTER: This is Garth. Just one  
6 very important issue. I don't know if it was  
7 just a matter of misspeaking. But these codes,  
8 the diagnosis codes, establish the denominator  
9 and not the numerator, which determined by death.

10 And maybe just to address more broadly  
11 the concerns about use of administrative data,  
12 it's not quite as clear what biases may be  
13 introduced by over and undercoding of these  
14 diagnoses since they function just in the  
15 denominator specifications. That said, we do  
16 have some concerns that over time, hospitals are  
17 in effect potentially trying to whittle down  
18 their denominator by more selective use of the  
19 codes. And that's a valid concern.

20 Maybe in the long term, the ultimate  
21 consideration is, do we go back to the Jeff  
22 Silber approach of really including all

1 hospitalizations with the procedure?

2 MEMBER PITZEN: Thank you.

3 CO-CHAIR FLEISHER: Thank you. What  
4 I've heard -- Do you have critical comments to  
5 reliability?

6 What I've heard is that we clearly  
7 have significant concerns about the use of claims  
8 data, which when Helen comes in, she'll talk  
9 about the transition and how much longer we  
10 continue to accept claims data for measures. And  
11 we will clearly put that in the surgical arena,  
12 which was at the forefront -- thank you, Fred, of  
13 doing these registries. That that was really  
14 critical.

15 So that will be in the report no  
16 matter what. That's a general consensus of this  
17 Committee, those two questions. Surgery has gone  
18 to registries. And how long should we do claims?  
19 We'll ask Helen.

20 Christy, do you want to tell us what  
21 we're voting on?

22 MS. SKIPPER: You're now voting on

1 reliability for Measure 0351.

2 CO-CHAIR FLEISHER: Define exactly  
3 what we're voting on so that people know what  
4 that means or Karen.

5 MS. JOHNSON: Let me take a shot at  
6 it, Christy. You are voting on the precision of  
7 the specifications and the testing that you saw  
8 under reliability. So all of the discussion that  
9 you had, you guys did go into a lot of validity  
10 discussions. Please put those to the side. Vote  
11 now on, are the specifications understandable to  
12 you? Are they precise? And is the testing that  
13 you saw in the results of the signal-to-noise  
14 testing adequate in your opinion?

15 CO-CHAIR FLEISHER: Thank you. That's  
16 very helpful.

17 MS. SKIPPER: So voting is now open.  
18 One, high; two, moderate; three, low; four,  
19 insufficient.

20 MEMBER KO: This would include the  
21 discussion we had about exclusion and the  
22 transfers? That's this part?

1 MS. JOHNSON: Yes. So do you  
2 understand what they're doing is the question.

3 MEMBER SAIGAL: Really. There's a  
4 different section under validity for all that. I  
5 think it's more --

6 MS. JOHNSON: Right. Whether you  
7 agree with it or not, you will talk about under  
8 validity. But the question for you now is, is it  
9 precise enough? Do you know what's going on with  
10 the transfers out? Do you know what's going on  
11 with the transfers in?

12 (Voting.)

13 MS. SKIPPER: And we're waiting for  
14 just one more vote.

15 (Voting.)

16 If everyone could just re-vote and aim  
17 your remote in this direction.

18 (Voting.)

19 Polling has closed. Results are 4  
20 percent high; 65 percent moderate; 22 percent  
21 low; 9 percent insufficient. Measure 0351 passes  
22 on reliability.



1 CO-CHAIR FLEISHER: Okay. Validity is  
2 now open.

3 MEMBER SAIGAL: Okay. So we talked a  
4 lot about this already. I'll just say that from  
5 the point of view of what was submitted, validity  
6 testing was done by looking at teaching status  
7 and seeing how the measure performed with and  
8 without adjustment. And as teaching status and a  
9 few other areas became -- were risk factors for  
10 risk performance before adjustment and then  
11 became effective after adjustment. So I was  
12 testing the use of the risk model here.

13 But the other issues around validity  
14 testing we think about in terms of, does this  
15 measure measure what you think it's measuring?  
16 There was no data specifically presented about  
17 that.

18 I looked at, in the literature, there  
19 was a couple of articles from many years ago that  
20 said that this, as Cliff mentioned, was not a  
21 very sensitive approach to finding problems  
22 compared to chart reviews from single

1 institutions.

2 I didn't find the data around the  
3 specificity issues Cliff mentioned, but I believe  
4 they exist. I guess their application was silent  
5 on those issues.

6 And the rest of this validity, we  
7 talked about a little bit in terms of whether the  
8 transfer issues are big enough, or whether it's  
9 addressed adequately to understand whether it's a  
10 significance threat to the validity of the  
11 measure.

12 CO-CHAIR FLEISHER: Other comments?

13 Okay. Fred.

14 MEMBER GROVER: I think failure to  
15 rescue is an important topic. But I don't see  
16 how it can happen unless it's within one  
17 institution where you can resolve meaningful data  
18 in terms of the face validity. The idea being  
19 that if you have a complication of an operation  
20 you've done, what do you do save that patient  
21 from a very, very serious complication?

22 When patients are being out or

1 transferred to other centers, it just seems to me  
2 like it makes it impossible to validate that that  
3 indeed is taking place.

4 CO-CHAIR FLEISHER: Can you explain?  
5 Do you feel it's not valid to not include the  
6 transfers out? Is it an appropriate way to look  
7 at it?

8 MEMBER GROVER: I think if we want to  
9 learn about is how to improve survival following  
10 a complication, there probably needs to be how  
11 they're treated within a single institution. If  
12 you take somebody who a lot of times isn't  
13 transferred in a timely fashion, they're hung  
14 onto, and then you get an absolute disaster, what  
15 do you learn from that? It's hard to analyze.

16 CO-CHAIR FLEISHER: Allan.

17 MEMBER SIPERSTEIN: Kind of a  
18 different dimension of complexity. Within a  
19 single institution, if you want to track your  
20 improvement over time, I see some validity to the  
21 measure. If I want to benchmark my institution  
22 against yours, that's where I start to have more

1 questions.

2 CO-CHAIR FLEISHER: So that, it's  
3 measure for intended use, Marcia, is that I'm  
4 hearing? Are you questioning whether or not PSI  
5 -- are you concerned about how it's being used?  
6 Or how the measure is specified? Those are  
7 different things that we still have yet to fully  
8 address.

9 MEMBER SIPERSTEIN: I'm just  
10 addressing the validity part of it. Whereas, if  
11 I'm looking only at my own institution over time  
12 to drive process improvement, I feel more  
13 comfortable with that. If I'm looking at the  
14 validity of the -- I know this crosses a little  
15 bit into usability. But if I'm looking at, is  
16 the measure valid as a comparison tool, that's a  
17 different question.

18 CO-CHAIR FLEISHER: Thoughts from  
19 staff in this area?

20 MS. JOHNSON: I will just say that  
21 measures that are endorsed by NQF are expected to  
22 be useful for both quality improvement and

1 internal efforts as well as different kinds of  
2 accountability applications. So you would think  
3 about whether you feel like this measure is not  
4 valid for those kind of applications.

5 I would say that -- let me stop there.

6 MEMBER HANDY: Not to throw the baby  
7 out with the bathwater, when we look at their  
8 data, there is over 300,000 patients that we're  
9 talking about. 3 percent of them were  
10 transferred and therefore excluded.

11 I think that the discussion here is  
12 colored by the bias that most of the physicians  
13 practice at tertiary care centers, and they  
14 receive these patients. So they feel kind of  
15 snake-bit by it, so I wonder if we're getting  
16 distracted.

17 CO-CHAIR FLEISHER: Remember we sit  
18 here to judge the measure, not how it will affect  
19 us, but whether or not the measure is valid.  
20 A.J., and then is that Rick?

21 MEMBER YATES: My comment is just  
22 following up on what Allan said, which is that

1 the validity is in fact tied to the end use  
2 because there are -- and again, this is the  
3 concept of tiered validity and the fact that you  
4 may need only a 10 times microscopic view to see  
5 something is either black or white. But to see  
6 very fine shades of gray, you might need a 100  
7 times microscope.

8 And the question is, does it have the  
9 degree of focus and clarity in terms of risk  
10 adjustment, in terms of the dataset, in terms of  
11 the signal-to-noise variables and all of those  
12 things? All of those things tie into what the  
13 end use. And if you're determining whether a  
14 hospital is about where you expect them, about  
15 slightly worse than you expect, or just slightly  
16 better than you expect, you're talking about  
17 gross categories of classification.

18 When you start to define hospitals by  
19 very fine percentage points or tenths of a  
20 percentage point in percentile rankings in terms  
21 of how they're affected by value-based purchasing  
22 or HAC, it does make a difference how fine the

1 instrument is attuned.

2 CO-CHAIR FLEISHER: So let me be --  
3 I'd like, Barbara, if you could comment, because  
4 you were there. We had a major discussion that  
5 got all the way to the Board of whether or not  
6 there should be another level of endorsement if  
7 it's used in accountability in which pay for  
8 performance -- in fact, we didn't say  
9 accountability versus pay for performance should  
10 be different. Quality improvement potentially  
11 should be different. But there is this,  
12 developing this idea of further testing and what  
13 that means.

14 But right now we're not -- how CMS  
15 implements it in pay for performance is a  
16 separate question. Am I getting -- Barbara, for  
17 you and Marcia. But Barbara was sitting in the  
18 room.

19 MEMBER LEVY: Yes, I think that's  
20 exactly right. As we did a deep dive into this,  
21 it became clear that the specifications of the  
22 measures and the criteria that we use in the

1 science of quality measurement shouldn't be  
2 different depending on the use of the measure.  
3 The science that we apply as we look through  
4 things is the same.

5           However, as we sit around here and  
6 think about the practical implications of what  
7 we're doing, that's where I think we get into  
8 really muddy waters. It's impossible to do a  
9 perfect measure. And the question is how far  
10 along that spectrum of imperfection we're willing  
11 to tolerate.

12           Clearly, if we're using it internally  
13 for our own purposes, it matters not. We use the  
14 data. We determine whether the data is good  
15 data, bad data.

16           When it's being used to judge or to  
17 pay, that's fundamentally a different problem.  
18 And Lee and I were talking about this this  
19 morning. The payment world and the quality world  
20 are separate. And we're in trouble because we're  
21 confounding them in our minds.

22           We have a job to do with respect to



1 the science of these measures. And that's  
2 different than extrapolating that to what happens  
3 in an accountability world. It's really hard for  
4 us to do that because we know what the  
5 consequences are.

6 And yet measurement science is telling  
7 us something different really than our practical  
8 side is telling us. And we're surgeons. So  
9 we're practical.

10 CO-CHAIR FLEISHER: Yes, and I think  
11 Barbara said something really important. If we  
12 feel how it's employed in value-based purchasing,  
13 that's what our societies can do. We're sitting  
14 here as individuals saying, is this measure  
15 valid?

16 I think it was Rick, Christopher and  
17 then Fred and then Cliff.

18 MEMBER DUTTON: On the transfers out,  
19 as Fred said, the transfers out can be good if  
20 you're saving the patient's life by sending them  
21 greater resources and can be very appropriate.  
22 It can be bad if you're doing it for gamesmanship

1 to avoid getting dinged by a publicly reported  
2 measure.

3 The perfect measure specification, you  
4 would follow that patient. You know whether they  
5 lived or died. So it should count. But we  
6 should have the outcome counted in both the  
7 numerator and the denominator. Obviously, we can  
8 do that in some registries. It's harder to do  
9 that in administrative data.

10 So practically maybe that's not a  
11 valid answer. And I think that's what the  
12 developers said. They're excluded because we  
13 can't track them in the data. We don't know  
14 whether they lived or died.

15 What I might suggest -- I'm reassured  
16 to hear it's only 3 percent that are excluded on  
17 that basis. Perhaps the developers could provide  
18 some sensitivity around that. Is there  
19 variability across facilities? Are there some  
20 facilities that exclude a lot of patients because  
21 of that? Does it vary by rural/urban, high tech/  
22 low tech, big/small?

1           If we could look at that and say, no,  
2       these exclusions are happening at random, we  
3       would probably be okay with letting this measure  
4       go forward as specified. If it's clear that some  
5       hospitals really are doing this badly, that would  
6       send the opposite message.

7           CO-CHAIR FLEISHER: Answer from the  
8       developer.

9           DR. OWENS: Certainly, we could do  
10      some additional analyses and bring that back  
11      regarding transfer status. I will tell you,  
12      within the Healthcare Cost and Utilization  
13      Project, we actually can follow some patients for  
14      some states. And the patients aren't lost. The  
15      question is you don't want a patient counted in  
16      two different hospitals, right, both the transfer  
17      out and the transfer in. But certainly we could  
18      come back with some additional analyses.

19          CO-CHAIR FLEISHER: Recognize that we  
20      can vote, but then we will see additional  
21      information back. We have post-calls before we  
22      make a decision. So it sounds like that is

1 request from the Committee.

2 DR. OWENS: This is Sheryl Davies, has  
3 another, she is from Stanford and she is the lead  
4 contractor for AHRQ. Sheryl, would you like to  
5 speak?

6 MS. DAVIES: Yes, I just wanted to  
7 mention a couple of things about the transfers.  
8 Again, those analyses are important analyses, and  
9 some of them, as Garth has mentioned, we have  
10 explored. And some of them as Pam just  
11 mentioned, we will be able to explore using the  
12 data.

13 I do want to make sure that it's very  
14 clear that the only issue here isn't just the  
15 ability to follow-up. There's also, so when we  
16 look at transfers out and patients that are  
17 transferred, for those patients, they have an  
18 attribution issue in that the patients, it could  
19 be the care that the hospital previously provided  
20 or it could be the care in the receiving hospital  
21 that ends up resulting in that complication.

22 Now recall that we do exclude patients

1 with a principal diagnosis of the complication.  
2 So if a hospital receives the patient for  
3 specifically that complication, they would be  
4 then excluded from the measure at that receiving  
5 hospital. So really, there is a little bit of an  
6 attribution for those that aren't excluded in the  
7 receiving hospital. Certainly for those that are  
8 transferred without a complication, there is an  
9 attribution issue.

10 MEMBER MOYER: Really quick. Is that  
11 admitting diagnosis or discharge diagnosis?

12 DR. OWENS: These are discharge  
13 diagnoses.

14 CO-CHAIR FLEISHER: Christopher, Fred,  
15 Cliff.

16 MEMBER SAIGAL: The audience or the  
17 Committee has some questions about comparability.  
18 I should make a note that this measure could only  
19 distinguish about 25 percent of the hospitals at  
20 being above or below the threshold. So it's not  
21 so great. It's moderate to be able to  
22 distinguish between hospitals.

1                   Another question I had was for the  
2                   developer. The gentleman made a comment that  
3                   they had information on the transfers in, in  
4                   terms of how they did. I would like to hear if  
5                   that was the case if they have done specific  
6                   subanalyses on the impact of those transfer  
7                   patients and if they've ever looked at a hospital  
8                   without that data included.

9                   CO-CHAIR FLEISHER: Comments from the  
10                  developer?

11                  DR. OWENS: Garth, I think this is a  
12                  question for you.

13                  DR. UTTER: Yes. I don't have that  
14                  information right at my fingertips at the moment.

15                  CO-CHAIR FLEISHER: Then why don't you  
16                  get it to the Committee before the next phone  
17                  call. Cliff.

18                  MEMBER KO: I wanted to follow up on  
19                  what Barbara said and what we were talking about  
20                  in terms of how do we think in the context of  
21                  this wide spectrum of how these measures might be  
22                  used. On the one hand, like you said, there's

1 quality improvement internal in one hospital,  
2 like okay, whatever. To pay it, where we're  
3 going to get penalized up to whatever, this huge  
4 10 percent of what we're bringing in. Because if  
5 we vote towards the mean, then we're going to  
6 have really atrocious measures when it comes to  
7 accountability and public reporting and all that.

8 But if we're told to vote for the  
9 mean, then we should all vote the same way. But  
10 then it's just recognizing that that's an issue  
11 of when it comes to these measures where they are  
12 out there. And these are the things that we get  
13 hammered on. Whether it's a professional  
14 organization or the NQF or CMS, that we start  
15 using these measures that have some level of  
16 scientific acceptability. But it's here at the  
17 mean rather than an acceptability for what you  
18 would want it to be and a payment where you  
19 absolutely do not want to inappropriately ding  
20 people.

21 CO-CHAIR FLEISHER: Comments? I mean  
22 I would vote personally on whether or not I think

1       it's a valid measure. I mean it's that simple.  
2       I think that within a 5 percent -- the fact that  
3       they implement where they take the top and the  
4       bottom and that there are people at the edges who  
5       make it, heard or not heard. If I think  
6       independent of how it's implemented, there is too  
7       much -- the risk model makes me uncomfortable  
8       about the validity to show it to the public, not  
9       whether or not I'd win or lose at the margin,  
10      then I would vote on low validity.

11               MEMBER KO: So is that what you're  
12      saying? So we should think about this in terms  
13      of like you said showing it to the public, this  
14      data?

15               CO-CHAIR FLEISHER: Right.

16               MEMBER KO: Is that the mindset we  
17      should have? Is this measure good enough to show  
18      on a website for 10?

19               CO-CHAIR FLEISHER: About the  
20      validity. I mean that's how I personally vote.  
21      Elisa, do you want to?

22               MEMBER KO: Because that's a different



1 level than just saying, all right. We're going  
2 to use it in our hospital in our department.

3 CO-CHAIR FLEISHER: Yes, I think  
4 whether or not I'd feel comfortable that it's  
5 valid. Whether or not I was at the 24th  
6 percentile versus the 26th percentile, whether  
7 I'd get a penalty or not, I don't think that's  
8 how we should vote. That's my gestalt, but --

9 MS. MUNTHALI: That is true. You  
10 should be looking at the scientific merits of the  
11 measure. We always say that our criteria should  
12 be use-agnostic. But we do recognize that it's  
13 very difficult to have these conversations about  
14 the scientific merits without thinking about the  
15 implications and the application of these  
16 measures. With that said, every measure that  
17 comes to NQF must be suitable not just for  
18 quality improvement but also for accountability  
19 purposes.

20 What you're looking at here is the  
21 questions around validity. There is another  
22 criterion on use and usability. And that's where

1       this discussion should take place.

2                   CO-CHAIR GUNNAR:   Yes, if I could only  
3       jump in.  I think this is an issue, to give the  
4       24 and 26 percent comment, which is if I get  
5       dinged on this measure, is it valid data?  That  
6       connects the dots, right?

7                   So we're voting on the validity of the  
8       measure itself.  Its application is downstream  
9       but tightly connected to that.  I don't think  
10      that's lost, your bias, Lee.  But I think if we  
11      can put ourselves back in the bubble here and  
12      just vote on the validity of the measure  
13      independently, then the rest will happen.

14                  CO-CHAIR FLEISHER:  I'm trying to say  
15      I shouldn't be biased of whether or not I'm at  
16      the margin.  I should be biased about whether or  
17      not my data looks valid and forget the fact that  
18      they happen to use these arbitrary cut points at  
19      CMS.

20                  CO-CHAIR GUNNAR:  Independent of that,  
21      you want to know that if I was at a cut point,  
22      somebody made an independent cut point, that what

1       you're being measured on is actually valid  
2       information.

3                   CO-CHAIR FLEISHER:   Correct.

4                   CO-CHAIR GUNNAR:   That's what we're  
5       trying to --

6                   CO-CHAIR FLEISHER:   That is correct.  
7       Barbara, do you have a comment, and then we'll go  
8       --

9                   MEMBER LEVY:   I do.   So I just want to  
10       bring us back again.   I'm a very practical  
11       person.   For this particular measure, we have to  
12       vote whether we are confident that both the risk  
13       adjustment and the exclusion of a death that  
14       occurs related to the admitting diagnosis, or the  
15       reason the patient came in, are sufficient to  
16       make this a valid measure.   And that's really  
17       where the rubber meets the road.

18                   Is the risk adjustment and the  
19       exclusion of people who die -- if it's a saddle  
20       embolism and they're sent to a tertiary center,  
21       quaternary center, to do management of that very,  
22       very dangerous complication and the patient dies,

1 is that exclusion sufficient for us to have  
2 confidence in the validity?

3 CO-CHAIR FLEISHER: So Christopher,  
4 Karl, Amy, Larry, and then we're getting to the  
5 end of the one hour we had dedicated. And we're  
6 still only on 2b.

7 MEMBER SAIGAL: Yes, I would just say  
8 given the comments we have, you have to judge  
9 validity against all uses. I think you have to  
10 go to the highest criteria you would use for  
11 validity. And I have not seen validity data  
12 presented regarding the false positive rates for  
13 this measure that would be used for payment. The  
14 evidence isn't present.

15 CO-CHAIR FLEISHER: Remember, vote  
16 your conscience and what you believe, and the way  
17 Barbara nicely framed it, how valid you think it  
18 is, and if there are questions, the developer is  
19 clearly hearing some of the concerns here as far  
20 as whether they need to come back. There's  
21 always an opportunity to readjudicate should that  
22 change.

1 Karl, Amy and Larry.

2 MEMBER BILIMORIA: For this particular  
3 measure, I want to be clear there are concerns  
4 about administrative data, and we can have that  
5 higher discussion. But this particular measure,  
6 I think we're hearing about a number of validity  
7 threats. There's the POA transfer status, the  
8 risk adjustment. And some of it is amplified  
9 because the denominator requires these  
10 complications to be included.

11 And all of the complications have  
12 research around them that shows that there may be  
13 issues, and not just in one hospital's chart  
14 reviews. I mean Cliff said it's in hundreds of  
15 hospitals. I think that really is a threat to  
16 validity.

17 I think one of the other things -- and  
18 I'm biased on this because our team does the bulk  
19 of the research on this -- is we've shown that  
20 VTE is not a valid measure, and it's all about  
21 how much you look. And hospitals will end up  
22 with more cases in the denominator here because

1 they are doing a good job looking for VTE.

2 Those are the hospitals that perform  
3 better on other objective measures of quality.  
4 So you've seen VTE dropped as an outcome measure  
5 from a number of programs, most recently, U.S.  
6 News, UHC. I think that trend is continuing with  
7 a number of other groups. States are dropping  
8 it. I think having VTE here is a validity  
9 threat.

10 CO-CHAIR FLEISHER: Thank you. I love  
11 this Committee. It's the most academic  
12 committee.

13 MS. DAVIES: This is the measure  
14 developer. Can I just mention something about  
15 VTE, because I think it's important? This  
16 measure just recently went through the Patient  
17 Safety Committee, which recommended for  
18 endorsement the VTE measure. The denominator for  
19 this one does closely align with that PSI 12.

20 It is important to note that in that  
21 submission, and we're happy to provide additional  
22 information. I don't want to spend the time to

1 go through all of it right now. It does  
2 specifically address the issue of surveillance.

3 And there's also, just remember,  
4 there's also competing I guess polls on hospitals  
5 to reduce their PSI rate in order to perform  
6 better on complications measures, whether they be  
7 the PSI specific measures or other measures, as  
8 well as those that would work to increase their  
9 denominators with less severe cases in order to  
10 improve their PSI 4 rate. That does provide a  
11 little bit of a cross-check I guess on hospitals  
12 when you're reporting both of them.

13 CO-CHAIR FLEISHER: Great. What I  
14 would ask is rather than continuing to question  
15 individual threats to validity that if there are  
16 comments to help us vote, because those  
17 individual threats will give you your personal  
18 determination of its validity. That's how you  
19 should vote.

20 Amy and then Larry.

21 MEMBER MOYER: I was actually going to  
22 focus us back in, that we're not being asked to

1 evaluate validity in a vacuum. There are NQF  
2 criteria standards around this. They're  
3 hopefully summarized in algorithm number 3, which  
4 walks you through the questions that go against  
5 the NQF criteria and then how they judged the  
6 validity according to those set criteria. And  
7 it's outlined in the measure worksheets.

8 We're not being asked to just, I don't  
9 know what's validity, and how does this fit?  
10 It's really pretty straightforward.

11 Now if we don't agree with those  
12 criteria, then I'm sure there's some method to  
13 address those or revise those in some future  
14 state. But they are out there, and that is my  
15 understanding of how we're supposed to be guiding  
16 our voting informed by our expertise.

17 CO-CHAIR FLEISHER: Thank you for  
18 saying that. I'm watching Karen smile. Probably  
19 about every two years if not yearly, annually, we  
20 actually reevaluate those criteria which is why  
21 they're so complex.

22 Larry, last comment. And then we're



1 going to call for a vote.

2 MEMBER MOSS: My question is for NQF  
3 staff to help give me guidance for voting. I  
4 thought Barbara articulated very clearly the  
5 distinction between scientific acceptability and  
6 use. And I understand the importance of  
7 distinguishing those two.

8 However, scientific acceptability is  
9 not binary. It's not yes or no. There is a  
10 spectrum and we all have to determine  
11 individually our own threshold for acceptability  
12 on that spectrum.

13 I have difficulty coming up with that  
14 point in the spectrum for me without taking into  
15 account how that measure might be used. Can you  
16 give me guidance on how to vote?

17 CO-CHAIR FLEISHER: I think we use the  
18 -- I think Amy said it really nicely. We go  
19 through the criteria for validity, and then you  
20 determine. But do not determine -- do not look  
21 at the question of the cut points that CMS is  
22 utilizing for payment just from the criteria.

1                   So that gets back to -- can we put up  
2                   the algorithm please?

3                   MS. SKIPPER: And you also have a copy  
4                   in your packet. But we'll also display it on the  
5                   screen.

6                   MS. JOHNSON: And while you're pulling  
7                   that up, I will -- Amy, you did a great job.  
8                   Some of you guys know this criteria almost as  
9                   well we do which is great.

10                  Just remember that you guys talked a  
11                  lot about what we would call here at NQF data  
12                  element validity, going back and validating those  
13                  data elements against the records.

14                  That is something that we would love  
15                  to see here at NQF. It is not something that is  
16                  required. So we require either testing at the  
17                  data element level or at the score level. So we  
18                  would again love to see both, but we don't have  
19                  to have both.

20                  And I think that will be clear on the  
21                  algorithm. Do you want me to walk through this,  
22                  or --

1 CO-CHAIR FLEISHER: Yes, please.

2 MS. JOHNSON: Okay. So let's pull up  
3 the algorithm. The first question is, are  
4 measure specifications consistent with the  
5 evidence? If not, then you rate it as low, and  
6 you're done.

7 If they are, then were all potential  
8 threats to validity addressed? In other words,  
9 did the developers tell you things about  
10 exclusions, about risk adjustments, about missing  
11 data, and how they handled it.

12 If the answer to that was yes, then  
13 you go down and ask, box three, was empirical  
14 validity testing conducted using the measure as  
15 specified with an appropriate statistical test?  
16 And the answer to this I believe was yes because  
17 they did empirical data testing.

18 So we would go down to box six for  
19 that. Then the next question is, it relates to  
20 the level of testing that was done. So was  
21 testing at the score level done? And in this  
22 case again, the answer was yes.

1           That takes you over to box seven. Was  
2 the method described then appropriate? I believe  
3 they did a construct validation kind of testing.  
4 And tell me if I'm wrong on that, team. I didn't  
5 look as closely at the testing. So it was  
6 construct validation.

7           So that takes you over to box eight.  
8 And there you look at the results of that  
9 testing. And that testing hopefully would tell  
10 you if you have a high certainty that you have a  
11 valid indicator, a moderate certainty or a low  
12 certainty.

13           I will say that -- and I don't know  
14 your name over here, but you're exactly right.  
15 It's not a yes or no. It definitely is on a  
16 continuum. So you have to vote in a way that you  
17 feel is most appropriate. But I believe if there  
18 is nobody from the project team or anybody else  
19 disagreeing with me, you need to look at box  
20 eight. Your choices will be high, moderate or  
21 low.

22           MEMBER SAIGAL: Karen, didn't we also

1 say that we didn't see validity testing for the  
2 very basic, the false positive/false negative  
3 data?

4 MS. JOHNSON: Right.

5 MEMBER SAIGAL: So I don't think we  
6 can go that far. I think we may have to stop  
7 much earlier than that.

8 MS. JOHNSON: Well, the false  
9 positive/false negative is what we would call  
10 data element testing. That's where you check  
11 your claims against the medical record. Right.  
12 That if you go down box -- I believe it's box 10.  
13 So we don't even get to box 10.

14 If they have done the score level  
15 testing, that is enough to potentially meet our  
16 requirements. In other words, we don't have to  
17 see that to be able to say that it meets NQF  
18 requirements for --

19 MEMBER SAIGAL: Score level testing  
20 wasn't done like that. They didn't do -- They  
21 tested the scores, at least in what they  
22 presented, they looked at the ability of the

1 score to discriminate in risk adjustment and  
2 looked at an omega-statistic. That wasn't really  
3 -- the score testing wasn't done at the level of  
4 specificity and sensitivity of chart review.

5 MS. JOHNSON: Okay. Can we pull --

6 MEMBER BILIMORIA: This is only  
7 talking about what they did. I mean there's  
8 other evidence available, and that's not in the  
9 measure packet. So how we reconcile that part?

10 MS. JOHNSON: Right. So you have to  
11 look at what they have submitted to see if it  
12 conforms to our criteria. I definitely hear you.  
13 You would like to see this yes or no data element  
14 testing. And hopefully the developers have heard  
15 you.

16 MEMBER SAIGAL: Score testing. Score  
17 testing is what I'm talking about.

18 MS. JOHNSON: Okay. And let's pull  
19 open the -- Bear with me a little bit -- validity  
20 testing section. And let's just go to the PA  
21 section if you will. Let's look at --thank you.  
22 Let's see. I apologize for not having done my

1 homework on this one.

2 Okay. So what they did was they --  
3 I'm looking at that very first -- sorry. I'm  
4 looking at the PA. In 2007, there was some  
5 construct validity. There was some face  
6 validity, which we still allow.

7 And then updates to testing. So the  
8 most recent thing, the testing has been updated  
9 since the last review by using the HCUP data.

10 Teaching hospitals --

11 MEMBER SAIGAL: We discussed this  
12 already. We have reviewed all of this, and  
13 basically they didn't do any kind of false  
14 positive/false negative testing on the score.

15 MS. JOHNSON: Right. It doesn't have  
16 to be the score. The false positive/false  
17 negative we would consider at the data element  
18 level. So what they did is what we would  
19 consider score level testing. And we would  
20 generally call it construct validity testing.

21 MEMBER SAIGAL: That's not what  
22 everyone else thinks about validity though.

1 Basically, the concern that people in the room  
2 have had is, is this going to pick up things that  
3 didn't happen primarily and unseen evidence about  
4 that and the score?

5 MS. JOHNSON: I understand. Right.  
6 They would not have it on the score. They would  
7 need to be doing that at each individual level  
8 test, right, at each individual data level  
9 element. You're saying, did they actually have  
10 the complication of sepsis? Is that what you're  
11 talking about?

12 MEMBER SAIGAL: The score is  
13 determined by that.

14 MS. JOHNSON: Right.

15 MEMBER SAIGAL: So score level testing  
16 would include understanding whether the score was  
17 right or wrong. I just don't see that. Maybe I  
18 missed it, but I don't know if co-developer  
19 looked at that and saw that. But I didn't see  
20 it.

21 MS. JOHNSON: The typical way that you  
22 would test at the score level for validity is to



1 do things like correlational analysis or  
2 construct validation. Basically, the idea is to  
3 see if the scores are tracking in the way that  
4 you expect. It's not always easy to do because  
5 there's not always great variables for other  
6 measures to correlate against.

7 You have score level testing. You do  
8 not have data element level testing. So you do  
9 not have the thing that tells you that if the  
10 claim said sepsis, it was actually sepsis. Or if  
11 the claim said sepsis, the claim -- let me flip  
12 it. If the medical record said sepsis, does the  
13 claim say it?

14 They did not provide you that  
15 information. You can certainly ask for that  
16 information. I'm just pointing out that on the  
17 algorithm, we accept either type of testing,  
18 score level or data element testing.

19 CO-CHAIR FLEISHER: Are we ready to  
20 take -- well, we are ready to take a vote. Yes,  
21 A.J. Microphone please. Thank you.

22 MEMBER YATES: This is maintenance

1 and I don't want to open up a can of worms. But  
2 the SDS question wasn't addressed, disparities,  
3 SDS. Is that because it's sort of a separate  
4 argument within the hospital, that it doesn't  
5 have any application in this case?

6 CO-CHAIR FLEISHER: There has to be a  
7 theoretical construct. For most in-hospital  
8 measures, the answer is that -- I think the  
9 Disparities Standing Committee, right, Marcia,  
10 has pretty much said the in-hospital there is  
11 much less of one?

12 Perfect. There will be lots of  
13 questions for you. Some after the break. But  
14 the question is, this is an in-hospital measure,  
15 and A.J. asked they simply state that there is no  
16 theoretical construct to apply SDS. Do you want  
17 to give any comment?

18 DR. BURSTIN: Yes. So what the SDS  
19 Committee proposed and said, and what we've moved  
20 forward with, is the idea that to move forward  
21 with SES or SDS adjustment, you should have both  
22 a conceptual basis for it as well as an empiric

1 basis. That conceptual basis could be based in  
2 literature, for example, a clear relationship  
3 between an SDS factor and the outcome. Or it  
4 could just be logically there is a relationship  
5 between them.

6 At least what we've seen to date is  
7 most purely inpatient measures, where all the  
8 control happens inside the context of the  
9 hospital, unless there is something unusual  
10 clinically that would explain a logical  
11 relationship to an outcome, has not usually been  
12 deemed appropriate to have a conceptual basis for  
13 adjustment.

14 MEMBER YATES: That's why it was only  
15 a point of order. I didn't want it to go without  
16 mention.

17 CO-CHAIR FLEISHER: Thank you. And  
18 we'll see that later on some of the measures  
19 you'll be discussing. So we'll get back to the  
20 real fun that you're going to have after the  
21 break. Can we call for a vote?

22 MS. SKIPPER: Yes. We're now voting

1 on validity for Measure 0351. One, high; two,  
2 moderate; three, low; four, insufficient.

3 (Voting.)

4 CO-CHAIR FLEISHER: We need one more.

5 MS. SKIPPER: Voting has closed.

6 Measure 0351, 0 percent votes high; 39 percent  
7 votes moderate; 43 percent, low; 17 percent,  
8 insufficient. This measure does not pass on  
9 validity, and we will stop at this point. The  
10 measure does not go forward.

11 CO-CHAIR FLEISHER: Okay. What I  
12 would suggest is we take a break. I will confer  
13 with staff whether or not, because the developer  
14 will likely come back. I can probably assure you  
15 they will come back with some answers. So we may  
16 discuss a little bit of other issues that the  
17 developer should be aware of. But why don't we  
18 take a 10 minute break.

19 (Whereupon, the above-entitled matter  
20 went off the record at 10:45 a.m. and resumed at  
21 10:59 a.m.)

22 CO-CHAIR GUNNAR: All right. We'll

1 begin gathering back again to try to get back on  
2 track here.

3 CO-CHAIR FLEISHER: Okay. We all set?  
4 I don't know if I'm going to make my comment,  
5 starting on time but procedure --

6 (Simultaneous speaking.)

7 (Off the record comments.)

8 CO-CHAIR FLEISHER: Okay. As an  
9 anesthesiologist I do have to say that we tried  
10 to start on time, but the procedure was longer  
11 than booked. And I think this has happened every  
12 time with this group is that we should try to  
13 make the comments succinct and what data we need  
14 from the developer.

15 We were discussing this. This measure  
16 has not passed one of the must pass criteria, but  
17 I think what would be very helpful because I'd  
18 say there's a 99 percent chance that they will  
19 come back with a lot of answers to our questions  
20 is if, Christopher if you could and Amy, just go  
21 through other questions that you may have for the  
22 rest of the criteria.

1                   And unless somebody has any specific  
2                   comment about something they may want the  
3                   developer to come back with, then we'll move on  
4                   to the next, and I'll turn it over to Bill.

5                   And then at some point, Helen can  
6                   comment about the question that was raised about  
7                   registry versus electronic. But Christopher, any  
8                   other critical issues that the developer must  
9                   address going through the other criteria?

10                  MEMBER SAIGAL: These are on  
11                  feasibility and usability, comments about that.  
12                  A lot of it's feasible, obviously. It's been  
13                  used and it requires AHRQ software to use it, but  
14                  that's free.

15                  The unintended consequences are  
16                  relevant to what we discussed earlier. But  
17                  that's no new data. Just the data we discussed  
18                  needs to be presented.

19                  MEMBER MOYER: No, as I said, we've  
20                  run these measures. It's very easy to do. I  
21                  know it's widely in use. The only unintended  
22                  consequences I have personally seen is, and I

1 think this is more on the people reporting the  
2 measure, I have sometimes seen patients  
3 misinterpret what it is this measure is  
4 reporting.

5 But I think that's more about clearly  
6 explaining from a reporting perspective and not  
7 on the measure developer.

8 CO-CHAIR FLEISHER: Any other comments  
9 on any other? So I think we are done then.  
10 Helen, do you want to say anything now about  
11 registry versus claims data?

12 DR. BURSTIN: I mean, I missed the  
13 conversation so I don't want to repeat a lot of  
14 what was said, but I think again just you need to  
15 evaluate what's in front of you. It's hard to  
16 evaluate something to a theoretical comparison  
17 that's not before you.

18 So we would just ask you to look at  
19 what's presented, look at the data presented,  
20 look at the reliability and validity of the  
21 measures in their own right.

22 Whenever we can get to better data

1 sources, that's always our goal, but I think  
2 we've seen that in the interim at least we are  
3 still relying fairly heavily, at least in the  
4 safety arena, on claims based measures as others  
5 come into being. But again, we just encourage  
6 you to look at them on their face value for what  
7 they are, not in comparison to something which we  
8 don't yet have before us.

9 MEMBER MCCARTY: Earlier in the  
10 discussion we were talking about separating the  
11 quality from the accountability, but my  
12 understanding is that what happens once we  
13 endorse measures and put them out there in the  
14 library for anyone to see is that anyone then  
15 says oh, this was endorsed by NQF. This is a  
16 great measure. Why don't we use it for these  
17 purposes?

18 And I understand that we're supposed  
19 to look at them separately, but doesn't that  
20 create some risk and accountability on our part  
21 knowing that when people see our stamp of  
22 approval, they feel like they have the green



1 light to go forth and use them kind of at will?

2 And so how do we reconcile that?

3 DR. BURSTIN: We did bring together an  
4 expert panel to specifically look at this  
5 question of whether measures should be endorsed  
6 for their specific applications and uses.

7 And ultimately, they didn't feel like  
8 there was enough there to do that yet. We don't  
9 have logical cut points, for example, for when a  
10 measure would be useful in one application versus  
11 another.

12 But we do have a whole other process,  
13 which is our Measures Application Partnership.  
14 So as measures come forward and they're being  
15 considered for different federal programs,  
16 endorsement is one thing they will consider as a  
17 factor, but then they will also look at the  
18 characteristics of the program, the  
19 characteristics of the measure and see if it's a  
20 good fit.

21 So I don't want you to feel like what  
22 you're doing is sort of the last step in the

1 process. You're really looking at the measure in  
2 terms of the measurement properties. Is this  
3 overall a good measure?

4 And I think, keep in mind there are  
5 other groups and some folks around the table sit  
6 on both groups, will have that discussion as an  
7 application comes forward for should we be using  
8 this, for example, in value based purchasing for  
9 hospitals.

10 Should this be part of the MIP  
11 program? There will be groups like you,  
12 clinician workers, hospital workgroups and the  
13 overall coordinating committee of the MAP who  
14 will then make that recommendation based on what  
15 you have said in addition to having the  
16 information in front of them of how the actual  
17 payment program works because without having that  
18 information, it's hard to make that assessment at  
19 this table.

20 CO-CHAIR GUNNAR: I guess one thing  
21 back to NQF would be recognizing the NQF measures  
22 are used in performance, with specific to

1 validity, is it -- and back to what was said a  
2 second ago, don't we have a personal reflection  
3 regarding or evaluation of whether if this is  
4 used as performance is it valid and fair, which  
5 is -- I mean is the validity of this measure such  
6 that if used in performance there is fairness to  
7 that?

8 DR. BURSTIN: You would look at it  
9 across the all the criteria, and I think at the  
10 end of the day if there's a sense that you would  
11 want to ensure that this measure, if used for one  
12 of the accountability applications, works. But  
13 that would be based on your criteria for  
14 reliability, validity and evidence.

15 CO-CHAIR GUNNAR: Perfect, so to go  
16 back to that initial comment, I don't think  
17 they're dissociated. I think what we've gotten  
18 from guidance here is they actually, in  
19 relationship to validity, they actually are  
20 connected.

21 DR. BURSTIN: Yes. There's  
22 distinction between a measure that's currently

1       used for -- we don't always know, for example,  
2       when a measure comes forward to us what the  
3       actual use will be.

4               Sometimes it could be measures in use  
5       for years and quality improvement only, could be  
6       measures like come to us and within a year  
7       they're in a pay-for-performance program.

8               We won't necessarily know that, which  
9       is why at these tables you want you to stick to  
10      the criteria that are before you and not -- we  
11      can't sequester you like a jury and say don't  
12      think about all these other things, but this  
13      table is really constituted to specifically look  
14      at the measures against the criteria.

15              CO-CHAIR GUNNAR: Thank you. A.J.?

16              MEMBER YATES: Yes, and just a follow  
17      up question generically. Some of the measures  
18      used, technical expert panels and committees for  
19      face validity or consensus validity statements  
20      and the precursor to this process, which is the  
21      standing committee but the committee that was  
22      brought up ad hoc before would have to vote on

1       usability.

2                   And in those situations when the face  
3       validity was given by a consensus vote or by --  
4       and usability was given a pass by the ad hoc  
5       committee and the end use was public reporting  
6       only, is it fair to ask if that's a valid --  
7       remains a valid face validity point to bring up  
8       six years later if the end use has changed?

9                   DR. BURSTIN:  You bring up a really  
10      important point.  We've had lots of discussions  
11      about whether face validity is the appropriate  
12      floor.  It's certainly not the ceiling for  
13      validity, but is it a reasonable floor?

14                   And we've worked a lot with  
15      developers.  We've worked a lot with end users,  
16      and it's very difficult, particularly in the  
17      outcomes space to do validity comparisons to  
18      another outcome to -- really coming up with other  
19      empiric methods of assessing validity of  
20      outcomes.

21                   So many of us aren't terribly  
22      satisfied, to be perfectly honest, with face

1 validity. It is, at least in our current process  
2 for our current criteria, an acceptable floor.

3 It is not something that would get you high  
4 validity, but it will at least get you moderate.

5 And one of the recommendations that  
6 did come out of the committee that we did convene  
7 around intended use is we need greater  
8 transparency so people can, in fact, see this is  
9 a measure that was face validity only but passed  
10 based on the strength of other criteria. And we  
11 will work make sure that's available.

12 CO-CHAIR FLEISHER: Thank you.

13 Colleen?

14 MEMBER PITZEN: I just wanted to add  
15 on Helen's comment. We spent a lot of time on  
16 the validity criteria today, and I'm just  
17 wondering if there's any future thought about  
18 requiring data element level validity testing,  
19 especially when many outcome measures don't have  
20 great statistical score testing that can be done.

21 CO-CHAIR FLEISHER: Thank you for that  
22 question. It's obviously stimulated some

1 discussion up here. And again, I participated.  
2 Helen ran a phenomenal committee that had  
3 multiple stakeholders. We discussed this issue,  
4 measures for intended use including CMS at the  
5 table. So it was quite robust. It's your turn.

6 CO-CHAIR GUNNAR: So the next measure  
7 for discussion is 1550, hospital level risks,  
8 standardized complication rate following elective  
9 primary total hip anthroplasty and total knee  
10 anthroplasty, Centers for Medicare and Medicaid  
11 Services.

12 Developers are on the phone, or  
13 they're here. Very good. My apologies. They  
14 are coming to the table. Please introduce  
15 yourselves, and you have three, four minutes to  
16 introduce.

17 DR. SUTER: Thank you. I'm Lisa  
18 Suter. I'm a rheumatologist and associate  
19 director at the Center for Outcomes Research and  
20 Evaluation, and I really appreciate the  
21 opportunity to present our measures today.

22 I'm here with Karen Dorsey. On the

1 phone we have Dr. Leanne Hahn from the Centers  
2 for Medicare and Medicaid Services as well as  
3 Sophia Chen at CMS and Jeph Herrin who's an  
4 analyst who's worked with us on these and other  
5 measures.

6 So as you introduced, we're talking  
7 today about the 30-day unplanned readmission  
8 after elective primary hip and knee replacement  
9 procedures as well as the complications measure  
10 that is paired with it.

11 The complications measures, the events  
12 of AMI, pneumonia, sepsis that occur within seven  
13 days of an elective primary hip or knee  
14 replacement. It also captures death, pulmonary  
15 embolism, surgical site bleeding within 30 days  
16 of an elective procedure, hip and knee  
17 replacement procedure, as well as mechanical  
18 complications, prosthetic infections within 90  
19 days.

20 Those 30 and 90-day events are  
21 associated with hospitalization, not death but  
22 certainly surgical site infection. Mechanical



1 complications and periprosthetic joint infections  
2 are only considered complications if they are  
3 associated both with an admission as well as with  
4 the diagnostic as well with procedural code for  
5 either revision or debridement.

6           These measures were put in front of  
7 NQF in 2012 and were endorsed and we're back for  
8 endorsement next. They've been in public  
9 reporting since December 2013 for the  
10 complication measure and July 2013 for the  
11 readmission measure.

12           The complication measure received  
13 medical record validation of its complications  
14 outcome, and both measures were overseen through  
15 intense involvement from a clinical expert panel  
16 as well as a formally engaged, diverse technical  
17 expert panel of stakeholders.

18           There are many topics that we could  
19 choose to spend our remaining two minutes to talk  
20 about, and we're happy to talk through some of  
21 the issues that were brought up earlier today.

22           But I think based on some advice,

1 we're going to focus a little bit on the  
2 sociodemographic status analyses that we  
3 presented as part of the endorsement maintenance  
4 application. But we're happy to address any and  
5 all concerns from the committee.

6 So we know that these measures are  
7 somewhat different from the other CMS sorted  
8 measures that have gone in front of NQF in that  
9 they address elective procedures where surgeons  
10 have an opportunity to filter access to the  
11 procedures, which is somewhat different than the  
12 acute medical conditions that are measured with  
13 other CMS measures, so we understand that SDS may  
14 play a more distinct or unique role in these  
15 measures than they do in other measures.

16 In order to look at SDS in these two  
17 measures we followed the same analytic pathway  
18 that we did for our other measures. We  
19 investigated a number of aspects of the  
20 relationship between SDS and these outcomes.

21 We aim to answer the extent to which  
22 providers with more low sociodemographic status

1 patients perform worse on the measures. The  
2 extent to which there's a relationship between  
3 SDS and the outcomes for patients, particularly  
4 within the measure's multivariable models.

5 We investigated the influence of risk  
6 adjustment for SDS on hospital level scores and  
7 whether the influence of SDS was primarily a  
8 patient or a hospital level effect. And those  
9 analyses are presented in the testing forum.

10 To just summarize them, we do see that  
11 hospitals serving high proportions of dual  
12 eligible African American or low AHRQ SES Index  
13 score patients, those are the three measures we  
14 were able to find national data for, have largely  
15 overlapping performance distributions although  
16 the median outcome rates are -- there's a slight  
17 increase in outcome rates of 0.2 percentage  
18 points for hospitals with high proportions of  
19 underserved or low SES patients.

20 When we include any of these variables  
21 in a multivariable model for the readmission or  
22 complication measures we see model level effects,

1 odds ratios that range from 1.07 to 1.22.

2 Those effects are attenuated in the  
3 multivariable model from univariate analyses, so  
4 there is some effect that's being captured by the  
5 clinical variables that are in the multivariable  
6 model but they remain statistically significant  
7 with up to a moderate level of effect in  
8 multivariable models.

9 When you include SDS, any of these  
10 variables, dual eligibility, race, African  
11 American race or low AHRQ SES in the risk model  
12 the median change in a hospital's outcome rate  
13 with adjustment is around two one-hundredths of a  
14 percentage point change for both of those  
15 measures, regardless of the variable used.

16 In decomposition analyses, clinical  
17 risk variables for these measures are more  
18 influenced by patient level components as we  
19 would expect, and the SDS variables are more  
20 influenced by hospital level factors.

21 This does not explain the discordance  
22 and the disparities, but we do think that it

1 raises the possibility that there are both  
2 patient and hospital level effects playing in  
3 this situation, and it's hard to tease those out  
4 even with our extensive analyses.

5 We've also looked at the disparities  
6 over time. These measures have been in public  
7 reporting since 2013, and we're happy to share  
8 these results with you. They are actually  
9 publicly available in the annual chart book --  
10 medical chart book publication that CMS posts.

11 But since 2013, there has been no  
12 change in this median difference between  
13 hospitals serving high proportions of low SES  
14 patients versus those serving high proportions.

15 It's about a 2.2 percentage point  
16 difference, which as I stated originally, is the  
17 difference we see in the current measure. So  
18 we're not seeing a worsening of disparities with  
19 the public reporting of these measures.

20 We're happy to add any discussion, and  
21 we're also happy to do additional analyses. We  
22 look for guidance from the committee if there are

1 specific analyses that you're interested in  
2 seeing. I think there was a concern about the  
3 variation of some of the different variables that  
4 we investigated for the SDS analyses.

5 The reason we chose dual eligibility,  
6 so Medicaid and Medicare status, African American  
7 race and also the AHRQ SES Index is that those  
8 are available indices and validated indices in  
9 terms of the AHRQ SES Index.

10 They're available on all Medicare  
11 beneficiaries. The AHRQ SES Index utilizes a  
12 nine-digit zip code, which takes us down to the  
13 census tract level, and there are about six to 12  
14 census tracts in any given five digit zip code.  
15 So it's a more granular division of geographic  
16 location than a five-digit zip code.

17 I think the other thing to acknowledge  
18 is that while we're not recommending SDS risk  
19 adjustment, we understand that this will be a  
20 robust discussion today.

21 We also want to flag that in this  
22 year's IPPS rule, CMS signaled that they will be

1 exploring stratification of measures in the  
2 future, and so we do think that there has been  
3 formal signaling from CMS that stratification is  
4 something that they will investigate for its  
5 appropriateness for use in these measures. So  
6 I'll stop there. Thanks very much.

7 CO-CHAIR GUNNAR: Thank you. Our  
8 discussants are Dr. Yates, and Dr. Cima is on the  
9 phone I believe.

10 MEMBER YATES: My wingmate is  
11 practically in the air I would hope by now.

12 CO-CHAIR GUNNAR: So you're flying  
13 solo.

14 MEMBER YATES: Well --

15 MEMBER CIMA: Oh, I'm here.

16 MEMBER YATES: Good to hear from you.  
17 I should have taken Delta being in the hot seat,  
18 but I'm going to take the lead if you don't mind  
19 on this Robert because I was led first. Or do  
20 you want to go?

21 MEMBER CIMA: Oh, sure.

22 MEMBER YATES: The description has

1 already been given. I'm following this script.

2 This is a maintenance measure. The critical

3 thing is that the evidence has not changed.

4 Again, this is in regard to our last

5 conversation. The use has advanced, however.

6 And just to put it in perspective but

7 not to make it a part of the voting, the

8 utilization of this measure is in

9 hospitalcompare.gov.

10 It's also used in the value-based

11 purchasing with estimated effect in terms of

12 payments in 2019 currently being selected for a

13 look back at that time and in the Health Care

14 Planning and Action Network they have as a

15 consortium decision decided to use this measure

16 and promote it for utilization in the private

17 sector as well as probably for Medicare Advantage

18 when they go to value-based purchasing as well.

19 But that's in the future and that's conjectural.

20 It should be noted that the

21 distribution of the rate of complications is

22 relatively rare at the median. This is something



1 that's happened at 4 percent, and as an  
2 arthroplastic surgeon I'm happy to say that it  
3 does happen rarely and that the distribution is  
4 tight, that the bell curve is high and steep  
5 between two and six for the most part.

6 CO-CHAIR GUNNAR: Can I stop for a  
7 second?

8 MEMBER YATES: Yes.

9 CO-CHAIR GUNNAR: So your comment  
10 regarding evidence, since it's a maintenance and  
11 our new process is to take a hand vote on whether  
12 anybody believes we should have a vote regarding  
13 evidence.

14 MEMBER YATES: I think it's reasonable  
15 that the evidence is unchanged and still  
16 reasonable to vote for rather than it's being  
17 acceptable.

18 CO-CHAIR GUNNAR: Anyone want to  
19 oppose that? Hearing no objection, we will move  
20 past evidence to the gap, which is --

21 (Simultaneous speaking.)

22 MEMBER YATES: There's a subset of the

1 evidence section which has to do with SDS  
2 disparities, but in conversation with Dr.  
3 Fleisher beforehand, we decided that we would put  
4 that discussion into the reliability section in  
5 terms of risk adjustment.

6 CO-CHAIR GUNNAR: Very well. So we'll  
7 stick to gap. Now we have to vote next on gaps,  
8 so if you'll discuss the --

9 MEMBER YATES: I would say that the  
10 gap is reasonably sufficient. We would like to  
11 see these complications be zero, and we would  
12 like to see every plane that takes off land and  
13 have that kind of effect in our arthoplastic.

14 CO-CHAIR GUNNAR: From a quality  
15 improvement point of view and taking sort of the  
16 simple approach, do you think this measure has  
17 enough influence on the quality improvement of an  
18 organization.

19 MEMBER YATES: Yes.

20 CO-CHAIR GUNNAR: -- that the current  
21 gap in performance is such that it's still not  
22 topped out.

1 MEMBER YATES: Yes, sir.

2 CO-CHAIR GUNNAR: Very good. Do we  
3 need to then vote on gap? We do. Set us up.

4 MEMBER YATES: And then under evidence  
5 I would just add one sub note, and this just to  
6 advise the developers and stewards. It's just  
7 fascinating to me that the complications don't  
8 have some sort of weighting.

9 I think that there are incidental  
10 pneumonias that get better in a few days and were  
11 only picked up on a fever work up that shouldn't  
12 be weighted as much as perhaps a deprived  
13 periprosthetic infection.

14 And so the lack of some sort of Delphi  
15 process by patients looking at the weighting of  
16 these complications would be a valuable insight  
17 in the future. And the other thing I would point  
18 out is that along the lines of weighting it's  
19 curious to me that neither neurologic nor  
20 vascular injury, including amputation, are  
21 captured by the codes.

22 CO-CHAIR GUNNAR: Dr. Suter, any

1        comments?

2                    DR. SUTER: First of all, thanks very  
3 much for the feedback about weighting of  
4 complications. In terms of the vascular injury,  
5 those were raised during development. There was  
6 a discussion of whether or not to capture  
7 neurologic or vascular injuries.

8                    Part of the challenge in developing  
9 this measure was ensuring measure complications  
10 that could be attributed back to the original  
11 surgery. So for example, we don't have DVT or  
12 UTI or some other very common due to the  
13 ascertainment challenges with those.

14                   And the feeling was we couldn't drill  
15 down to those complications appropriately at this  
16 point, but certainly with the increase in  
17 clinical data and maybe moving toward EHR data,  
18 that could be an expansion of the measure in the  
19 future.

20                   MEMBER YATES: Yes, and Lisa, that's  
21 said in the context of being weighted. If it  
22 were weighted, those would be weighted very

1 heavily by the patient.

2 CO-CHAIR GUNNAR: Very good. We ready  
3 to -- any other discussion? Carry on. Vote for  
4 gap is open.

5 MEMBER SAIGAL: Yes, voting for gap on  
6 1550 is now open. One high, two moderate, three  
7 low, four insufficient.

8 (Voting.)

9 CO-CHAIR GUNNAR: Looking for one  
10 more.

11 MS. SKIPPER: And Barbee, if you can  
12 hear me, we're now voting on performance gap for  
13 measure 1550, one high, two moderate, three low,  
14 four insufficient.

15 CO-CHAIR GUNNAR: Be under validity in  
16 terms of risk adjustment. Fair enough.

17 MS. SKIPPER: Voting has closed for  
18 1550 on performance gap. Thirty-five percent  
19 votes high, 65 percent moderate, zero percent  
20 low, zero percent insufficient. This measure  
21 passes on performance gap.

22 CO-CHAIR GUNNAR: Okay. Off to

1 reliability. Dr. Yates?

2 MEMBER YATES: I would just like to  
3 stop and make sure Robert doesn't have anything  
4 to add.

5 CO-CHAIR GUNNAR: Good point.

6 MEMBER CIMA: No, I mean one thing  
7 that's notable is that the performance has  
8 improved over the two measurement period that  
9 they've been using, so this is obviously having  
10 some type of impact.

11 CO-CHAIR GUNNAR: Very well. Ready to  
12 move on to reliability.

13 MEMBER YATES: It should be noted that  
14 the calculation of the numerator, denominator  
15 it's predicted to the number of expected  
16 admissions with a complication multiplied by the  
17 national observed complication rate.

18 That smooths things out a little bit,  
19 but bottom line is that the numerator is the  
20 number of the listed complications which are  
21 time-dependent in terms of their occurrence. The  
22 reliability testing, there is some noise and the

1       measure an ICC score of 45 percent. It would be  
2       ideal to have a higher score than that.

3               The c-statistic for risk adjustment is  
4       only 0.65, and that has been a constant over the  
5       last three or four years of different  
6       measurements of this over time. And that seems  
7       to be a fixed statistic.

8               It has been noted that if certain  
9       orthopedic-specific risk factors are added to the  
10      risk adjustment that the measure can, and this  
11      has been published, can be raised to a c-  
12      statistic that is 0.7 or above which would make  
13      it more acceptable.

14              And that's something that the  
15      developers are well aware of and are working with  
16      them on that from other professional societies.  
17      The next paragraph that I had written, and this  
18      is not Robert's, but I was worried about the  
19      question of tiered validity.

20              And tiered validity has been taken off  
21      of the table. I still would argue that the c-  
22      statistic and the relatively low ability to risk

1       adjust does have something to do with the  
2       potential for unintended consequences, which  
3       we'll come to later.

4               But for the most part I would say that  
5       the reliability has been proven, and I would  
6       advise the panel to vote for reliability.

7               CO-CHAIR GUNNAR: Dr. Cima?

8               MEMBER CIMA: Yes, that was my major  
9       concern. This was a hospital-based measure.  
10      You're looking for patients to try and decide  
11      where to go from there, and this is a very --  
12      0.45 the developers say is moderate, but that's  
13      basically flipping a coin.

14              So I have real problems using  
15      hospital-based comparisons. One of our goals is  
16      to allow these measures for people to make  
17      choices, and they really, really can't with this  
18      measure with that data.

19              Although Dr. Yates has recommended  
20      that we pass on the reliability, I really have a  
21      hard time saying that we're endorsing a measure  
22      where it's like flipping a coin. And that was



1        what I was hoping in my comments to get people to  
2        discuss that. Is that really a reliable measure  
3        for a hospital-level measure?

4                MEMBER YATES:     Dr. Cima, I would  
5        agree with you that it's disappointing that it's  
6        not a better risk adjustment. And I'm just happy  
7        that it's risk adjusted at all given --

8                MEMBER CIMA:     But our goal is to get  
9        a measure out there to the population where  
10       people can make informed decisions. And this is  
11       a hospital measure. So it's saying this hospital  
12       compared to this hospital as far as hips and  
13       knees go, for primary hips and knees, this is the  
14       difference.

15               But there's a great amount of  
16       inaccuracy in the measurement, so is this a  
17       patient-centered view? Is this really giving the  
18       patient adequate information to make an informed  
19       decision? Or am I just going to send them a  
20       quarter so they can flip between two hospitals?

21               MEMBER YATES:     And I agree again with  
22       you. You're using the example of the end use,

1 and if I was allowed within the rules of  
2 engagement to use end use as an important  
3 criteria, I would agree with you even more. And  
4 I would say it's a very debatable point, but I  
5 will be quiet now and let people speak.

6 CO-CHAIR GUNNAR: Can I ask a naive  
7 question? These total knees have move to  
8 ambulatory environments, so if you're an  
9 ambulatory center and then you get admitted with  
10 a complication to another hospital, does it  
11 track?

12 MEMBER YATES: I can answer that  
13 because currently Medicare does not recognize a  
14 total knee replacement as an outpatient  
15 procedures. There is a proposed rule that came  
16 out about a month ago commenting on their  
17 possibly allowing for it to be an outpatient  
18 procedure, but currently --

19 CO-CHAIR GUNNAR: So it won't be --

20 (Simultaneous speaking.)

21 CO-CHAIR GUNNAR: Got it.

22 MEMBER YATES: At this point in time,

1       it's a moot point until they come out with a  
2       final rule that would say that they're going to  
3       accept total knees as an outpatient procedure.

4       Not to interrupt --

5                   CO-CHAIR GUNNAR:   No, it's perfect.  
6       That's the answer I wanted.   Thanks.

7                   MEMBER CIMA:   Well, I just wanted to  
8       go back to one point that Dr. Yates raised.   It's  
9       about the usability, but if I look at the  
10      measurement sheet, the questions for the  
11      committee, there's three questions.

12                   So the test could be an adequate  
13      sample, yes, but then it goes, do the results  
14      demonstrate sufficient reliability so that  
15      differences in performance can be identified.  
16      And then in the next one, do the results  
17      demonstrate meaningful differences in performance  
18      that could be identified.

19                   It's unclear if an ICC of 0.5 is  
20      adequate to meet those two questions.   That's  
21      what I was going at, not the end result.   I'm  
22      just saying what the end result would be, but it

1 does address in reliability these very two  
2 questions.

3 CO-CHAIR GUNNAR: Dr. Suter? One  
4 minute, please.

5 DR. SUTER: Okay. This is Lisa Suter.  
6 So I think I heard two specific concerns, one  
7 about the reliability testing, specifically about  
8 the test, retest. So the value of ICC of 0.5 is  
9 an established moderate value for this kind of  
10 use.

11 I think we can all assume that if we  
12 were looking at a blood pressure value and we  
13 knew that the blood pressure was being  
14 repeatedly assessed and it varied a certain  
15 amount but over a mean of values you got a  
16 reliable sample, we would accept that.

17 If a measure was being based on a  
18 blood pressure result and that measure had a hard  
19 line where you assign a quality value to that  
20 blood pressure, that may be more of a problem.

21 What we're looking at here are  
22 aggregated results at the hospital level. And

1 when you split those results at the hospital  
2 level and do two random samples and test the  
3 hospital's measure result using half of its  
4 sample and then compare it to the measure result  
5 with the other half sample, you get an ICC that's  
6 dictated in the moderate range by established  
7 criteria.

8 So it's not a coin flip that you're  
9 getting an association. That 0.5 is not an ROC  
10 curve. It's not a c-statistic. It's a  
11 correlation coefficient that indicates a moderate  
12 level of correlation between the hospital  
13 performance values when half of the sample is  
14 compared to the other half of the sample at the  
15 hospital level. Karen?

16 DR. DORSEY: Let me just add that we  
17 do a very conservative test of reliability of the  
18 measures where we're actually correlating the  
19 score itself, and when these measures are  
20 publicly reported, they are publicly reported in  
21 categories that include a confidence interval.

22 So we hold ourselves to a very high

1 standard when we're calculating reliability at  
2 the measure score level. But there is cushion in  
3 the public reporting such that if we were only  
4 comparing which buckets hospitals fell into,  
5 right, we would -- as Lisa was saying, the  
6 correlations would be much high. So just want to  
7 point that out to the committee, thank you.

8 CO-CHAIR GUNNAR: So on this side we  
9 have -- I think I saw Rick, Collette, Barry and  
10 then Karl and Chris. I'm sorry.

11 MEMBER DUTTON: Very quickly for the  
12 developer, why just patients over 65? Why  
13 shouldn't this measure be specified for  
14 everybody?

15 DR. SUTER: So that's a great  
16 question. Specifically this has been implemented  
17 with Medicare beneficiaries, and for Medicare  
18 beneficiaries under the age of 65 your  
19 qualifications for Medicare are usually  
20 disability and dialysis.

21 And we -- this measure was originally  
22 specified testing just above 65. We have

1 validated it in all-payer data and shown that you  
2 do not see substantive differences, nor do you  
3 need to make substantive changes to the risk  
4 model other than changing your age variable in  
5 the risk model to have it applicable in all-payer  
6 data under the age of 65.

7 MEMBER DUTTON: So why not specify it  
8 for everybody?

9 DR. SUTER: We're specifying it for  
10 the use that we have systematically tested. We  
11 have not followed up with all-payer testing on a  
12 systematic basis, on an annual basis.

13 CO-CHAIR GUNNAR: Collette?

14 MEMBER PITZEN: Just a question. So  
15 in terms about reliability score testing, the  
16 staff had questioned the split-sample methodology  
17 and I'm a statistician.

18 We use a beta-binomial statistic to  
19 compare our medical groups when we're doing this  
20 kind of comparison in Minnesota, so I'm wonder  
21 what the staff concerns were with the model and  
22 maybe there isn't any concern.

1 DR. SUTER: Does the staff want to  
2 address that?

3 MS. JOHNSON: I can give it a shot.  
4 So they did do the split-sample methodology, and  
5 that's something that we have to date accepted as  
6 an appropriate methodology. And they have a  
7 moderate range correlation.

8 We put out the 0.7 threshold as just  
9 a rule of thumb that's out there but do not  
10 consider that as if you have to see something  
11 greater than 0.7 because that is not the case.  
12 It's just something out there that some people  
13 use.

14 The other piece that they did was look  
15 at their model variable frequencies and odd  
16 ratios over time, and we don't -- while it's  
17 interesting, we don't really accept that as score  
18 level reliability.

19 Frankly, we expect numbers to change  
20 over time, or at least scores, maybe not so much  
21 model frequencies and that sort of thing. So  
22 they did two different things. One of them right



1 now we're saying is an acceptable method. The  
2 other we're saying we don't interpret it as an  
3 acceptable method.

4 DR. SUTER: And to just clarify, so  
5 from NQF staff's perspective since we've met the  
6 measure result reliability criterion where it's  
7 an appropriate measure for moderate reliability  
8 by NQF staff.

9 MS. JOHNSON: You have done score  
10 level testing, so according to our algorithm you  
11 are eligible for high. But the results aren't  
12 necessarily stellar, so you don't have to rate it  
13 as high, but you could. So that's where it is.

14 I will say that we are as staff  
15 learning all the time, so we're learning about  
16 new methods and that sort of thing. And I've  
17 actually been in discussions with another  
18 statistician, another developer, who is very  
19 interested in this idea of stability over time  
20 and is trying to talk to us about maybe adding  
21 that in or in some way looking at that.

22 So be prepared. We might at some

1 point say yes, we see the utility in that and  
2 we'd like to see, that sort of thing.

3 CO-CHAIR GUNNAR: Yes?

4 MEMBER YATES: For the developers, a  
5 clarification question. You mentioned confidence  
6 intervals for public reporting. Do those  
7 confidence intervals have fine enough detail for  
8 the percentile rankings when it's used for the  
9 quality metrics in the CJR and when it's applied  
10 to the percentile rankings that are applied to  
11 the value-based purchasing?

12 DR. SUTER: So my understanding of the  
13 calculations for the CMMI, CJR bundled peanut  
14 program are that they do stratify the percentile  
15 rankings. They are using the point estimate.  
16 They are not using the performance categories  
17 that are on Hospital Compare.

18 I believe that they adjusted their  
19 methodology in response to public comment  
20 precisely about that concern, but that there is  
21 some wiggle room on the point estimates and  
22 therefore using point estimates as a sole

1 measure.

2 And so that I think that's why they  
3 moved to a stratified scoring system as opposed  
4 to an all or nothing black line cut off. You  
5 either meet a criterion for payment or you don't,  
6 in the original proposed rule.

7 CO-CHAIR GUNNAR: Barry?

8 MEMBER MARKMAN: Is your data patient-  
9 specific? I mean, do you capture those patients  
10 that are operated on by one provider in one  
11 hospital but then have the complication within  
12 the 90-day period but go to let's say a different  
13 provider at a different hospital? And what's  
14 your confidence in that?

15 DR. SUTER: Yes, so the measure  
16 captures every event for a patient no matter what  
17 hospital it occurs at, and every hospital that  
18 has a reported result receives a hospital-  
19 specific report from CMS every reporting period,  
20 every year. And that report gives each hospital  
21 every single patient that was in measure, every  
22 patient that was excluded from the measure, so

1 the fracture patients that didn't get measured,  
2 and tells them what happened to them, whether or  
3 not they had an outcome event.

4 For the readmission measure, it tells  
5 them what hospital they were readmitted to, so  
6 they have all of that information. So even if  
7 it's not transparent to them at their own  
8 hospital that they're having complications in  
9 outlying hospitals and they're not coming back to  
10 their own hospital, they do see that information.

11 MEMBER MARKMAN: Very good.

12 CO-CHAIR GUNNAR: Chris?

13 MEMBER SAIGAL: Yes, clarification Dr.  
14 Yates. You mentioned that there is a c-statistic  
15 that was reported, used for the risk adjustment  
16 model I assume, that was insufficient, that  
17 basically you couldn't discriminate.

18 MEMBER YATES: It's not fair to say  
19 insufficient. It would be considered low. It  
20 depends on your definition of what's a good c-  
21 statistic, and that's sometimes in the eyes of  
22 the beholder. But the literature that at least

1 I've reviewed would usually like to see a c-  
2 statistic of at least 0.7.

3 The c-statistic in this case is 0.65,  
4 which is low, but given the nature of the  
5 database is probably where it is right now. And  
6 I can leave that to the developers to answer  
7 better than myself.

8 MEMBER SAIGAL: Okay.

9 CO-CHAIR GUNNAR: Any other comments?

10 DR. SUTER: We were thinking maybe we  
11 would address that with the larger question about  
12 validity and the risk adjustment model. Would  
13 that make sense to pause for that?

14 CO-CHAIR GUNNAR: Amy?

15 MEMBER MOYER: So one thing I wonder  
16 about with the reliability, and I know the  
17 feedback had come from the MAP Clinician  
18 Workgroup that this is a measure we'd love to see  
19 at the individual surgeon level because there are  
20 probably some factors that are hospitals and  
21 factors that are surgeons.

22 Having seen admittedly non-risk

1 adjusted surgeon level data from your measure, it  
2 appears there is in some cases some wide  
3 variation among surgeons, so I don't know if that  
4 could kind of muddy the waters in terms of  
5 attributing things to hospitals. But that's  
6 something that we feel could make this more  
7 useful and would like to see in the future.

8 CO-CHAIR GUNNAR: Dr. Yates, any other  
9 comments? Dr. Cima?

10 MEMBER CIMA: No.

11 CO-CHAIR GUNNAR: Very well. Ready to  
12 vote on reliability.

13 MEMBER SAIGAL: Voting is now open for  
14 reliability on Measure 1550, one high, two  
15 moderate, three low, four insufficient.

16 (Voting.)

17 CO-CHAIR GUNNAR: Everyone in the room  
18 has voted. We're just waiting. Oh, we're good?  
19 All right.

20 MS. SKIPPER: Measure 1550 on  
21 reliability, 13 percent votes high, 83 percent  
22 moderate, 4 percent low, zero percent

1 insufficient. The measure passes on reliability.

2 CO-CHAIR GUNNAR: Moving on to  
3 validity.

4 MEMBER YATES: Several different  
5 analyses are offered for validity. The majority  
6 are very satisfying. Two that I would just raise  
7 questions about, the original technical expert  
8 panel was convened, I believe, with the  
9 impression that it was going to be public  
10 reporting as a process.

11 And again, they're not going through  
12 the NQF process in terms of going all the way to  
13 the end as to usability, but that was the  
14 original focus of that convened group was public  
15 reporting and not the utilization and value-based  
16 purchasing. Is that impression correct?

17 DR. SUTER: So when we originally  
18 developed this measure and asked the technical  
19 expert panel to weigh in on the NQF criteria of  
20 reliability, validity and usability, we presented  
21 it with the question of does this measure assess  
22 quality in a meaningful way, not necessarily does

1       it assess quality appropriate for public  
2       reporting versus pay-for-performance.

3               The use was not indicated in any way,  
4       so committee members may have made assumptions in  
5       their mind in that validity vote just as we have  
6       heard in prior discussions here the challenge of  
7       teasing out those issues.

8               But the question was stated explicitly  
9       as do you this TEP based validity for a measure  
10      of quality, does it measure what you think it  
11      should measure, and do you think it's a  
12      meaningful thing to measure and unanimously  
13      endorse that?

14              MEMBER YATES:   Then the one question  
15      that has already come up in other discussions  
16      earlier today was the question of the database or  
17      the data source, and the data source in this case  
18      is administrative data from coding for CMS.

19              And I will leave it to the committee  
20      to decide on the validity of that data, but the  
21      one thing I want to point out is the only  
22      validity study that was done was just done with



1 six hospitals, and it was done and reported in  
2 Version 2 of the measure.

3 In Version 2, they took something.  
4 There were 319 reported complications out of the  
5 six hospitals, and when they went and looked at  
6 the charts there were, I believe, 97  
7 discrepancies amongst 86 patients.

8 Now that's the -- that's a measure of  
9 the specificity of what's found. Now when you  
10 add in the fact that very few actually know,  
11 charts were found that missed a complication.

12 That would be the sensitivity being  
13 added in, and it's reassuring that hospitals  
14 weren't hiding complications in their coding. I  
15 think that's great.

16 But when hospitals are being compared  
17 for public reporting and for advancement of  
18 quality, they really only care about the  
19 numerator, which is what complications are  
20 captured and are they accurate.

21 So I would argue that although the  
22 agreement may have been calculated to go to 99

1 percent, which is your accuracy of your test if  
2 you will if this was a lab test, it's the true  
3 positives versus the false positives, i.e. the  
4 specificity of the test that's important.

5 And when first looked at, there was a  
6 30 percent discrepancy when some of the outcomes  
7 were changed and some of the complications were  
8 redefined.

9 That was brought down to 10 percent  
10 difference, 30 true complications, but yet there  
11 was still a 10 percent specificity discrepancy.  
12 And it's the 10 percent that I'm asking the  
13 developers to address.

14 And in addition to that, having  
15 changed the complications and given the fact that  
16 out of those six hospitals I didn't see a  
17 subgroup analysis but there have been some huge,  
18 unique intrinsic variability in terms of how they  
19 were coding some of those codes or some of those  
20 complications that were dropped, doesn't this  
21 measure which affects a whole lot of hospitals  
22 deserve another test of the validity of the

1 database?

2 So the two questions are, isn't it  
3 true that the specificity of the test is the more  
4 important question here and that it actually is  
5 about a 10 percent discrepancy according to the  
6 only valid validity study done.

7 DR. SUTER: Thank you, A.J. So this  
8 is Lisa again. So I think it has been -- which  
9 has been stated earlier by Barbara is that it's  
10 really hard to make a perfect measure. And we,  
11 as developers, are humbled by the challenge in  
12 front of us.

13 So what I will say is this has been a  
14 learning process. This is a live measure that we  
15 evaluate every year. The validation test with  
16 medical record data was a process that we learned  
17 from, and we adjusted the measure.

18 It coming in and out for dry run with  
19 hospitals, we learned from that process. We made  
20 adjustments to the measure based on how we  
21 identified fractures in order to exclude those  
22 from the measures.

1           Those were measure adjustments that  
2       were made in response to feedback from hospitals  
3       in use prior to public reporting. We made  
4       changes to the measure in response to NQF's  
5       initial committee review where our planned  
6       readmission algorithm which has been vetted by  
7       dozens of surgeons and other clinical experts.

8           We included, I think it was  
9       angioplasty procedures as an elective readmission  
10      and therefore as a planned readmission it was  
11      excluded from the readmission measures and the  
12      NQF committee said that's not acceptable.

13          If I take a patient to an elective  
14      joint replacement and they have angioplasty  
15      within 30 days after that, that's -- I shouldn't  
16      have been taking them to surgery, right. That's  
17      a complication of care for this elective surgery.

18          So this measure has been modified over  
19      every opportunity to do so. I think our  
20      experience is when it comes down it and the NQF  
21      committee that voted in response to all of this  
22      information last time felt that this was a valid

1 measure.

2 It continues to be in use. It  
3 continues to, we think, contribute meaningfully  
4 to the quality information available for  
5 hospitals caring for these common -- patients  
6 undergoing these common procedures.

7 We can debate whether those numbers  
8 justify an invalid measure versus a valid  
9 measure. I think there are many, as you said,  
10 pieces of information to pull together for this  
11 validity.

12 And we're eager to hear what that  
13 information is where you get to learn and evolve  
14 the measure appropriately so that it stays a  
15 meaningful measure as we go forward.

16 MEMBER YATES: I guess my point is  
17 that it has been reported I think in presentation  
18 to this committee and also in the Federal  
19 Register and on CMS' web page the different times  
20 that it's been put into print that it's got a 99  
21 percent agreement rate, which is absolutely true  
22 the way it's been statistically used or

1 presented.

2 But I would just point out that it's  
3 really the false positives that we're worried  
4 about, and there's a 10 percent error rate in  
5 terms of that defining the numerator based on  
6 administrative data sets and which is, quite  
7 frankly, better than what studies have shown for  
8 other administrative data sets.

9 So I'm not debating the validity based  
10 on that. I would just argue that it ought to be  
11 presented as such that it's not -- there's an  
12 error rate. It's not 99 percent agreement.

13 DR. SUTER: Fair enough.

14 MEMBER YATES: I think point of  
15 contention is to sort have been begging the  
16 question.

17 DR. SUTER: Great. Good input. Thank  
18 you. I appreciate it.

19 CO-CHAIR GUNNAR: Dr. Erekson?

20 MEMBER EREKSON: So it's actually very  
21 reassuring to me to see that the 90-day follow up  
22 for patients staying in the fee-for-service

1 Medicare is only at 0.15 percent.

2 In doing a lot of claims analysis and  
3 trying to track patients through Medicare, it's  
4 very surprising to me to see how many patients  
5 drift in and out of fee-for-service and into the  
6 HMO Medicare plans.

7 And that's just something for the  
8 committee to consider and especially it goes to  
9 what you've already said which is this can be  
10 used in other paired data sets. But even in this  
11 Medicare population we tend to think that the  
12 patients are staying in Medicare, and they're  
13 drifting in and out all the time.

14 CO-CHAIR GUNNAR: Any other comments  
15 regarding validity?

16 MEMBER YATES: Well, we're now in the  
17 question of c-statistic and also disparity or SDS  
18 risk adjustment because that's part of the  
19 validity. So we've already talked about the fact  
20 that the c-statistic is 0.65, and that's been  
21 fairly steady over time.

22 The discussion about the variability

1 due to SDS or social risk factors, I think that  
2 the group from Yale should be congratulated for  
3 doing an extensive work on that.

4 My -- several comments that I would  
5 make though is that it's reassuring to see that  
6 at the median in the stratification that there's  
7 no difference in outcome for all practical  
8 purposes because of race.

9 And I would agree with that because I  
10 don't think complications happen because of the  
11 color of someone's skin, and I don't think  
12 complications happen because of someone being  
13 poor per se.

14 I would argue that the -- those two  
15 though do not define the rest of the population  
16 that the hospital takes care, and they go to  
17 great lengths to show that it's a hospital effect  
18 and not that patient.

19 And I think that's a reasonable  
20 assumption from what they showed. However,  
21 without getting into the weeds, the problem is  
22 that just because you don't -- the problem is



1 that you do show that there is an increased risk  
2 of complications that is measurable between the  
3 lowest percentile or the lowest quintile of  
4 hospitals that are populated more -- less heavily  
5 with African Americans, people with dual  
6 eligibility and hospitals that have a lower EH or  
7 AHRQ SES score versus those that have a high  
8 proportion of African Americans or the highest  
9 quintile proportion of African Americans dual  
10 eligibility and the AHRQ cut off of 42.7.

11 My argument is that the rest of the  
12 people that are taken care of in that community  
13 or in that hospital don't automatically become  
14 rich. And unfortunately in our society an  
15 African American status in an urban environment  
16 is a surrogate for poverty in a lot of cases.

17 Certainly dual eligibility is a  
18 surrogate for poverty, but just because there are  
19 other people in that community that aren't dual  
20 eligible, they don't automatically become more  
21 rich.

22 And finally, the cut off of 42.7

1 doesn't describe the entire population. So I  
2 would argue that the hospital effect may in fact  
3 be a community effect, and my question is, did  
4 you test for the spectrum of the AHRQ SES scores  
5 to see whether or not it played an effect in  
6 terms of -- as a single variable, that being  
7 poverty.

8 Did the poorer hospitals or the  
9 hospitals that take care of the larger proportion  
10 of the poor, even those are just over 42.7, are  
11 those communities not affecting the hospital  
12 score? And shouldn't that be something that's  
13 risk adjusted?

14 CO-CHAIR FLEISHER: Just one point.  
15 The CSAC has made it very clear that to even  
16 address the issue of race with SDS risk  
17 adjustment is inappropriate.

18 It may be disparities is something we  
19 want to look at it, so I think I would ask that  
20 we actually not go into that issue because it's  
21 not something that we should appropriately be  
22 addressing with the issue.

1                   MEMBER YATES: Right, and just to  
2 clarify, I made that point that I don't think  
3 it's an issue.

4                   CO-CHAIR FLEISHER: Right, so --

5                   MEMBER YATES: And I think that  
6 actually the data shows that. I think it has to  
7 do with it being a possible surrogate for --

8                   CO-CHAIR FLEISHER: Right, so that's  
9 what we should be discussing.

10                  MEMBER YATES: Right, and so I'm  
11 making that point right now.

12                  CO-CHAIR FLEISHER: Great. Thank you.

13                  DR. DORSEY: Can I just clarify that  
14 we did not use race in our analyses as a proxy  
15 for SES? Those are two completely separate  
16 issues. We use race really as a comparator  
17 variable because we believe that many of the  
18 mechanisms by which race is associated with  
19 outcomes are parallel, not all but some, with  
20 mechanisms by which SES is associated with  
21 outcomes.

22                               And it helped us to understand and

1 interpret our analyses to have those types of  
2 variables in the model, but we were not using  
3 race as a proxy for SES which is the explicit  
4 direction of the disparities committee and the  
5 SDS trial guidelines.

6 CO-CHAIR GUNNAR: Any other comments?  
7 Barry?

8 MEMBER MARKMAN: Was the -- well I  
9 noticed in one of your bullet points that's  
10 removed other post-operative infection which is a  
11 pretty common code that's with this complication.  
12 Was that -- and now it's just wound infection or  
13 just specific periprosthetic joint infection?

14 Can you comment on that because if you  
15 go through the codes, that's much more specific?  
16 And was that a result of your audit, or was that  
17 --

18 DR. SUTER: So that decision  
19 originally to define the complications in that  
20 specific way was based on feedback from  
21 orthopedic surgeons and the clinical experts to  
22 try and -- that was reinforced by empiric

1 analyses to try and avoid including complications  
2 that were -- that would contribute to the false  
3 positive concern -- false positivity concern that  
4 A.J. brought up.

5 And so really we just look at  
6 periprosthetic infections or joint infection  
7 codes. In addition, you have to have a  
8 readmission for that. So it can't just be in the  
9 outpatient setting, and you have to have a  
10 concomitant surgical either debridement or  
11 revision code.

12 So there is -- it's a very high bar to  
13 achieve that, which is one of the reasons this  
14 complication rate is very low. I mean I think if  
15 you included UTIs in this complication rate, it  
16 would be a very different outcome rate.

17 But UTIs are messy, so those decisions  
18 were made with the influence of the clinical  
19 experts that helped us develop this measure. I'm  
20 happy to address the c-statistic, but do we want  
21 to collect other comments first or --

22 MEMBER CIMA: Can I just ask a

1 question of the developer about the 90 days for  
2 the hip infection? Just as a point of  
3 harmonization, CDC is now requiring reporting for  
4 one year for prosthetics.

5 Is there a reason for being different?  
6 Is it harder to collector or is there too much  
7 noise, or does it not add much? Just because  
8 again requirements for institutions for reporting  
9 and looking were using different definitions, and  
10 I just was wondering why the CDC wants to use one  
11 year for this, but you are choosing 90 days?

12 MEMBER YATES: Robert, this is Yates.  
13 I think you may have it backwards because my  
14 understanding, and I live in these waters, the  
15 CDC actually went from one year down to 90 days  
16 as their cut off for the periprosthetic being  
17 accounted for by the surgery.

18 That's the current ruling that I'm  
19 aware of. It used to be one year, and now it's  
20 90 days.

21 MEMBER CIMA: I thought it was the  
22 opposite.

1           MEMBER YATES: Yes, no I mean I look  
2 at our surgical infection rates every month, and  
3 I know that it's currently -- and we go strictly  
4 by CDC standards and CDC standards are 90 days.

5           MEMBER CIMA: Oh, okay.

6           MEMBER YATES: So they're actually  
7 harmonized with that at this point.

8           CO-CHAIR GUNNAR: Lee?

9           CO-CHAIR FLEISHER: So the dual  
10 eligible status has an odds ratio of 1.21, and  
11 then you make the comment that you decided not to  
12 include it in the measure. That's actually I  
13 believe a decision of NQF. So can you tell us  
14 how you decided not to include the measure since  
15 it was, I believe, statistically significant?  
16 Correct?

17           DR. SUTER: So every single variable  
18 that we looked at for the SDS analysis, dual  
19 eligibility, the AHRQ SES and race, which we were  
20 not looking at as a proxy but as an additional  
21 variable, are all statistically significant in  
22 the multivariable model.

1           They all have reduced odds ratios from  
2       univariate analyses, so they are attenuated by  
3       combining them in a robust clinical model. We  
4       did not make the decision to recommend exclusion  
5       or inclusion of these variables based solely on  
6       their odds ratios in the multivariable analysis.

7           We think it's a much broader  
8       discussion. When you include all of those  
9       variables in, you don't change the c-statistic  
10      from 0.65. I think acknowledging that there are  
11      models out there that have achieved higher c-  
12      statistics, those models have incorporated  
13      patient reported outcomes, such as functional  
14      status and position reported concomitant lower  
15      extremity disability or pain.

16           We think those are really meaningful  
17      risk variables. We don't have access to them on  
18      a national level. They are not adequately coded  
19      in claims data, so we can't include them in our  
20      model.

21           We're working with the societies, as  
22      he mentioned, to encourage the collection of that



1 information so that maybe someday we could  
2 include them. Maybe we'll get to EHR data well  
3 before that that may be more meaningful.

4 In terms of the decision whether or  
5 not to include SDS, I think there are lots of  
6 things that influence that. One is it's not --  
7 it does not make a difference. It does not  
8 change the c-statistic.

9 It does not change the median point  
10 estimate for a hospital's complication or  
11 readmission rate. The median change is two one-  
12 hundredths of a percentage point. So for some  
13 hospitals, it may change.

14 The thing to recognize about our  
15 measures is they are measures of relative  
16 performance compared to the national average. So  
17 when one -- when you add SDS into the model, one  
18 group of hospitals' rates will go down and  
19 another group of hospitals' relative rates will  
20 increase.

21 And so we don't think that risk  
22 adjustment for these variables necessarily

1 addresses the issue that physicians legitimately  
2 have concerns about, which is are there things  
3 that are not captured that influence but even if  
4 you included in the model, we're not seeing a  
5 marked change.

6 And I'm not sure. It doesn't address  
7 that, and it certainly takes the ability to see  
8 the disparities away, and we do know that there  
9 are disparities. There's an article in JBJS that  
10 came out last week or the week before that  
11 indicated that minority patients have less access  
12 to these procedures, and they have higher  
13 complication rates.

14 So I think it is a reality in this  
15 situation, and we just think that there may be  
16 other options available to us, like  
17 stratification that may be --

18 (Simultaneous speaking.)

19 DR. DORSEY: Can I just add something?  
20 I just want to add specifically to your point  
21 that the guidance that we've received and other  
22 measure developers received about the SDS trial

1 was that in making a decision about whether to  
2 include SES risk factors or not we had to include  
3 -- consider two things.

4 One was the conceptual relationship,  
5 and the other was the empirical relationship. So  
6 the empirical relationship alone was not  
7 sufficient to recommend that we include the  
8 variable.

9 And the conceptual relationship was  
10 that potentially socially disadvantaged patients  
11 had a higher disease burden. If that were the  
12 case, then our current model would adjust away  
13 the independent association between SDS risk  
14 factors and the outcome.

15 We saw some attenuation but not a  
16 complete disappearance of the effect. The second  
17 was that socially disadvantaged patients get  
18 worse care or get disparate care, sometimes don't  
19 get adequate care, right. That will be measured  
20 at the patient level.

21 And the third is that there's some  
22 source unrelated to hospital quality of care,

1 things like competing economic priorities which  
2 hinder adherence to post-discharge instructions,  
3 et cetera.

4 What we did to look at that was the  
5 decomposition analysis where we tried to see how  
6 much could be measured at the patient level and  
7 how much could be measured at the hospital level.

8 When we looked at that we saw that the  
9 hospital effect tends to dominate with SDS  
10 variables, which is in contrast to the clinical  
11 data elements where the patient effect tends to  
12 dominate.

13 Because that is true, because we see  
14 a dominant hospital effect what we conclude from  
15 that is by including the variables we risk adjust  
16 away a component of hospital quality uniquely the  
17 SDS variables as compared to clinical variables.

18 So because of that issue with a  
19 conceptual relationship, the empirical  
20 association alone was not enough. And I agree  
21 that we also see that it just makes no difference  
22 which adds further weight to the decision not to

1 recommend.

2 CO-CHAIR FLEISHER: I actually ask are  
3 any of the other clinical variables on the same  
4 level. I mean we know about severity of clinical  
5 variables, and we've discussed that this morning  
6 that you've included in your model because  
7 building a model is something that is well used,  
8 but I would argue that it is driven by the data.  
9 It's not fully driven purely by the data, and we  
10 make assumptions.

11 The other question is in your Bayesian  
12 model because of the way you create your Bayesian  
13 hierarchical model, do you have -- do you know  
14 how that may influence how your potential risk  
15 adjustment might change because of the shrinkage,  
16 because of where the SDS factors may or may not  
17 play the most influence?

18 DR. DORSEY: So again, we were just  
19 talking about the effect size, the odds ratio.  
20 We do include risk factors with higher and lower  
21 odds ratios in the current risk model.

22 But again, I'll circle back to the

1 fact that it's not just an empirical association  
2 that we are charged to consider, but it's also  
3 the conceptual relationship, which is the point I  
4 just made earlier, right.

5 So the SDS variables are distinct as  
6 we could see in the decomposition analysis from  
7 clinical variables. And so we're applying a  
8 different conceptual relationship than we are  
9 with comorbidities there.

10 With respect to the hierarchical  
11 model, as is true with all the covariates in our  
12 model or the model if we consider it overall as a  
13 whole, we acknowledge the limitations that you're  
14 bringing up with a hierarchical model.

15 This is something that's been  
16 considered and brought up by many statistical  
17 experts and stakeholders and an active area of  
18 reevaluation for us where we're constantly  
19 looking at new techniques and tested some of the  
20 fixes that have been recommended by statistical  
21 experts.

22 We have not yet found something that

1 is better than our current model, which I think  
2 many experts have acknowledged that there's not  
3 evidence that something is better than our  
4 current model.

5 But this, I would say that in terms of  
6 the empirical relationship and the shrinkage  
7 issue that you talk about, it's equivalent to the  
8 other risk factors that we include. Correct.

9 CO-CHAIR FLEISHER: If you analyze  
10 that within the shrinkage model itself, SDS or  
11 the AHRQ.

12 DR. DORSEY: Jeph, do you want to jump  
13 in?

14 LT. MOORE: Yes, this is Jeph Herrin.  
15 I'm not sure I follow the question. These  
16 results that we're presenting are from a  
17 shrinkage model, from a Bayesian model, so if  
18 you're asking whether these results are the same  
19 in this model. I guess that answers your  
20 question.

21 If you're asking whether SES is  
22 somehow influenced by shrinkage in a way

1 different from other clinical risk factors, I'm  
2 not quite sure how to answer that question.

3 I think that they -- the numbers of  
4 low SES patients are not necessarily concentrated  
5 in larger or smaller hospitals. So I wouldn't  
6 expect to see any kind of differential impact to  
7 clinical factors, but we haven't dug into that.

8 MEMBER YATES: Can I add something?

9 CO-CHAIR GUNNAR: Please.

10 MEMBER YATES: We -- you can't -- just  
11 leaving it at the dual eligibility and the AHRQ  
12 SES score, it's a dichotomy whether or not you're  
13 dual eligible or not. You can't look at the rest  
14 of the population the hospital cares for and say  
15 well, they were really close to being dual  
16 eligible so ignore that.

17 So you're really left with the zip  
18 code analysis and the AHRQ SES score, and you  
19 chose to look at the population of 42.7 and  
20 below. What about the rest of the population?

21 And if you were to look at it as a  
22 variable from the entire scale of AHRQ across the



1 entire population of the hospital and use that as  
2 a variable, wouldn't that not maybe perhaps  
3 explain the hospital effect that you're seeing.  
4 In other words, some really great hospitals live  
5 in some really poor neighborhoods.

6 DR. SUTER: And so we have looked at  
7 this. We have looked at the AHRQ SES index as a  
8 continuous variable. We've looked at it --

9 MEMBER YATES: You have or have not?  
10 I'm sorry.

11 DR. SUTER: We have for the  
12 readmission measures. I don't believe we've done  
13 this analysis for the complication measure, so  
14 we'd be happy to run those analyses for this  
15 committee.

16 We did not see any difference in the  
17 results when we ran it as a continuous variable,  
18 so wherever you were on your AHRQ Index, that was  
19 your -- influence of the AHRQ SES Index did not  
20 change the results for the readmission measure.

21 MEMBER YATES: As a hospital?

22 DR. SUTER: At the hospital level.

1           MEMBER YATES: And that's presented in  
2 1551? I don't believe that's in --

3           DR. SUTER: No, it's presented with --  
4 we presented that to the readmissions committee  
5 with -- several readmission measures went forward  
6 to the readmission committee.

7           There was a more formal presentation  
8 of SDS in front of that committee. And those  
9 results were shared with that committee. But we  
10 can certainly rerun those analyses for these  
11 measures.

12           MEMBER YATES: Well, let me step  
13 outside of the statistical world and just ask you  
14 as a statistician and you as a statistician.  
15 There's this debate over the hospital being the  
16 cause of the -- or that the patients with SDS  
17 compromise tend to go to less good hospitals.

18           Yet, you're still talking about some  
19 of the world's greatest hospitals being in some  
20 very poor neighborhoods. I mean as point of  
21 contention, I'm not there anymore, so I will use  
22 it as an example.

1           But ten years at Hopkins, I'm well  
2   aware of the neighborhood around Hopkins being  
3   very poor and being -- I mean the gunfire and  
4   everything else at night, it's a poor  
5   neighborhood.

6           Yet no one would say that Hopkins is  
7   giving horrible care to those patients, or at  
8   least I would hope you wouldn't. So if in your  
9   heart of hearts do you feel like we're really  
10   saying it's the hospital's fault for some of  
11   these great centers that are taking care of some  
12   of the poorest patients in the country?

13           Are we missing something, or is there  
14   some way of just still discerning the two that  
15   would still maybe make you want to put SES in  
16   there just to make sure it's followed on a  
17   parallel basis so that we don't miss anything?

18           DR. SUTER: So I don't actually know  
19   what Hopkin's results are, but we could  
20   investigate. I think the other point of  
21   information that's helpful to think about is that  
22   there is a distribution curve.

1                   So when you look at hospitals by any  
2                   measure of socio-demographic, be the AHRQ SES  
3                   Index, dual eligibility, you can look at  
4                   unemployment rates. You can look at a whole host  
5                   of other SES variables that may or may not be  
6                   available for all Medicare beneficiaries.

7                   But when you look at those  
8                   distribution curves, you see distribution. So  
9                   you see people who are lumped -- hospitals that  
10                  are lumped in the middle and then you see  
11                  hospitals at either end of the curve.

12                  And what's fascinating is that there  
13                  are hospitals, and maybe Hopkins is one of them,  
14                  where they are caring for patients in a highly  
15                  underserved area with lots of underserved  
16                  patients. And yet they are achieving remarkably  
17                  good outcomes.

18                  And we know those hospital exist. We  
19                  also know the other hospital that's dealing with  
20                  mostly non-minority, non-vulnerable patients that  
21                  are doing very poorly, so the hospitals at either  
22                  end of the spectrum exist no matter what group of

1 patients they're caring for, which at least  
2 suggests to us that it's possible to do well on  
3 these measures, regardless of your patient  
4 population.

5 I think the question is do you want --  
6 how do you want to incentivize hospitals. Do you  
7 want to incentivize them to take care of patients  
8 and to acknowledge okay if you have dual  
9 eligibility or AHRQ SES or whatever the measure  
10 of SDS is, if you have that group of patients  
11 you're going to get an extra bye for that  
12 proportion of patients because we're going to  
13 risk adjust for those patients?

14 Or do you want to want to say no,  
15 we're going to publish a transparent non-adjusted  
16 measure results and then maybe acknowledge that  
17 payment for those hospitals may -- I guess we're  
18 talking about the measure right now.

19 We're not talking about payment  
20 policy, but there are lots of downstream ways to  
21 acknowledge that you do not want to limit  
22 resources to hospitals serving for under-

1       resourced populations based on their quality.

2               You want to acknowledge the societal  
3       implications of those measure results, but I'm  
4       not sure that you want to hide those measure  
5       results.

6               DR. DORSEY: And let me just add that  
7       the results of our analyses indicate that putting  
8       one of these indicators into the risk model would  
9       actually not resolve a problem of making -- based  
10      on how under-resourced hospitals look.

11              MEMBER YATES: And it would be nice to  
12      have -- adjust the -- what you did with the AHRQ  
13      scores for readmission. It would be nice to do  
14      it for the 1550.

15              CO-CHAIR GUNNAR: We're going to need  
16      to move on, but Rick and Barbara?

17              MEMBER DUTTON: Sorry. I just wanted  
18      to agree with Lisa's comment earlier that --

19              CO-CHAIR GUNNAR: It was nicely  
20      stated. Wasn't it?

21              MEMBER DUTTON: We don't -- I would  
22      not recommend risk adjusting for SDS because

1       that's one of the things we want to find when we  
2       report this measure.

3                   CO-CHAIR GUNNAR:   Barbara?

4                   MEMBER LEVY:   I just want to point out  
5       that finding it doesn't imply that the payment  
6       should be different or that people should be  
7       penalized.   And I think we need to be advocates  
8       to very strongly state that finding those  
9       disparities should not and perhaps as a committee  
10      we can say that, translate into a reduction in  
11      payment for these facilities.

12                   And looking at the Hopkins example,  
13      some of the facilities have resources.   They have  
14      other resources that they can apply to this  
15      population and some catchment hospitals have  
16      nothing.

17                   The only thing they have is the  
18      payment for the services that they deliver.   And  
19      I think that we need to make a very clear  
20      statement from this committee that says we want  
21      to see what those disparities are, but we do not  
22      think that it is inherently a measure of the

1       quality of the institution that is remediable.

2               For example, if we look at staffing,  
3       if you don't have the money to mind the nursing  
4       ratio that is what you have to do to take care of  
5       this population, if you're in an area where you  
6       don't get enough payment from CMS to drive that  
7       nursing ratio, you can't correct for these  
8       things.

9               So I think again we need to separate  
10       out the payment piece of this from the scientific  
11       assessment of the measure so that we do what's  
12       right. We discover disparities when they're  
13       there and then we can address them in a multitude  
14       of different ways.

15              MEMBER YATES: And I would just add  
16       that it would be very -- I don't want to give the  
17       developers another 100 hours of work, but it  
18       would be great to stratify the top performers and  
19       the low performers and then look at whether or  
20       not some top performers are weighted down by the  
21       challenges that they face, which with limited  
22       budgets and cut budgets do make a difference.



1           And I think that the -- I would argue  
2    though that over time because the rubber is  
3    hitting the road now for those reasons, I think  
4    that over time this has to be continuously  
5    monitored because what you've shown in your data  
6    is that there are -- in the upper quintile  
7    proportional hospitals, that there is an effect  
8    of some sort.

9           And that effect could change, and it's  
10   an effect that's demonstrated I think more  
11   dramatically than what's been presented in the  
12   quality papers and the quality reports. The bell  
13   curves --

14           MEMBER YATES: So I think that you  
15   have to -- you've picked up something here that  
16   there is something in the noise, and then if you  
17   can get to follow it over time because it's going  
18   to be a big distinction in terms of possibility  
19   of unintended consequences --

20           MEMBER YATES: -- more of one  
21   population versus another that does --

22           CO-CHAIR GUNNAR: Can we move to vote

1 on validity?

2 MEMBER SAIGAL: Voting is open for  
3 validity, one high, two moderate, three low, four  
4 insufficient.

5 (Voting.)

6 MEMBER YATES: If I could make a  
7 public comment, Dr. Fleisher.

8 CO-CHAIR FLEISHER: Yes.

9 MEMBER YATES: Or Dr. Gunnar.

10 CO-CHAIR GUNNAR: Yes.

11 MEMBER YATES: I just want to reassure  
12 the committee that almost everything that we've  
13 been talking about on this measure will be very  
14 similar to the next one.

15 CO-CHAIR GUNNAR: My assignment was to  
16 get done with 50 and 51 by 12 o'clock.

17 MS. SKIPPER: Voting has closed on  
18 validity, 13 percent votes high, 83 percent  
19 moderate, 4 percent low, zero percent  
20 insufficient. The measure passes on validity.

21 CO-CHAIR GUNNAR: We have to open up  
22 at 12:30. We'll stick to the schedule, 12:30 for

1 comment. All right. We can move on now to  
2 feasibility.

3 MEMBER YATES: Feasibility, it's been  
4 demonstrated to be feasible because it's been  
5 happening. And that's -- I know that's a  
6 tautological argument, but it's actually very  
7 true. So having seen it in action for going on  
8 four, five years, I think it's reasonable to say  
9 it's feasible.

10 CO-CHAIR GUNNAR: Rather than take a  
11 -- well, I guess -- do we have to -- it's a  
12 maintenance measure.

13 MEMBER YATES: Yes. We have to with  
14 maintenance.

15 CO-CHAIR GUNNAR: We have to vote, so  
16 carry on.

17 MS. SKIPPER: Voting is open for  
18 feasibility on Measure 1550, one high, two  
19 moderate, three low, four insufficient.

20 (Voting.)

21 CO-CHAIR GUNNAR: You've got two  
22 missing, so that's all right. Close it.

1 MS. SKIPPER: Voting on feasibility  
2 has closed, 90 percent votes high, 10 percent  
3 moderate, zero percent low, zero percent  
4 insufficient. And the measure passes on  
5 feasibility.

6 CO-CHAIR GUNNAR: Next is usability  
7 and use.

8 MEMBER YATES: I can promise you it's  
9 usable, and it has been used in public reporting  
10 now through hospitalcompare.gov. It's also being  
11 used, as I said, as one of the -- it actually  
12 modifies as a quality metric for the CJR bundle.

13 Twenty-three percent of the hospitals  
14 have their price point set in part by some of the  
15 percentile rankings from this measure as well as  
16 others. And it's going to be used in -- it's  
17 already in the IPPS for 2019 for usability as  
18 part of the value-based purchasing.

19 So it's got usable endpoints that have  
20 been -- that we're not going to debate the  
21 accuracy of or the like. But under usability  
22 there is the question of unintended consequences,

1 and I would argue that given the fact that this  
2 is an elective surgery and being very elective,  
3 it is the sine qua non of the surgical procedures  
4 that might face unintended consequences of  
5 patients with slightly higher or marginal risk  
6 finding their access to care blocked by a sense  
7 of -- a lack of risk adjustment and by a sense of  
8 lack of accuracy of the database.

9 And I say that in conjunction with its  
10 use because its use is in a competitive zero sum  
11 environment. And in game theory, everybody's  
12 going to be assuming that the other person is  
13 lowering their risk and their risk population.

14 And it is now a commonly enough used  
15 word that it's in literature, so I'll use the  
16 word cherry pick as being something that this is  
17 at high risk for inducing as time goes by.

18 And with a 2 to 6 percent range, and  
19 a median that's a very, very -- has a very sharp  
20 bell curve, the differences between one hospital  
21 and other or heaven help if it goes to the level  
22 of provider.

1           The differences are very small that  
2           make a difference in terms of hospital penalties  
3           and other public disclaimers. So I continue to  
4           be worried about the unintended consequence of  
5           risk shedding. I will leave it at that. That's  
6           the usability portion.

7           CO-CHAIR GUNNAR: Oh, we have Amy,  
8           then Collette.

9           MEMBER MOYER: So a couple of comments  
10          on this. So our population is entirely  
11          commercial, so while it's useful to have this  
12          measure there, the fact that it's Medicare  
13          limited use and we're seeing just a massive ramp  
14          up in ambulatory surgery hopping up and saying,  
15          well, we're do joint replacements.

16          Well, that's great, but what's your  
17          quality. And so the ability to really feel like  
18          we're making as robust a possible comparison and  
19          holding them to the same standards is very  
20          important to us, especially as the joint  
21          replacement age has kind of dropped, we're seeing  
22          more patients have their first replacement on us

1 and then Medicare is left to kind of deal with  
2 the fall out and revisions if things didn't get  
3 right first time.

4 And the other thing I would add is  
5 that we hear from a lot of patients okay, it's  
6 great that you can tell me something about the  
7 hospital, but I'm going to pick a surgeon. And  
8 so not knowing that additional level of  
9 granularity for them is a challenge.

10 MEMBER PITZEN: Just a question. In  
11 the data that's provided back to the hospitals,  
12 are they able to see the detail of which  
13 complication occurred? Thank you.

14 DR. SUTER: Yes. Sorry for the  
15 recording and those on the phone, the answer is  
16 yes to Collette's question.

17 CO-CHAIR GUNNAR: Barbara, do you have  
18 a comment? No. Are we ready to vote on  
19 usability and use? Does Robert have anything to  
20 say? There you go. Proceed.

21 MS. SKIPPER: Voting is open for  
22 usability and use, Measure 1550, one high, two

1 moderate, three --

2 MEMBER CIMA: I was muted. I have no  
3 problems with this. I don't think these are all  
4 the right discussions, but I think it's going to  
5 be used as it is and the risk of cherry picking  
6 is there. But it's always going to be there.

7 (Voting.)

8 MS. SKIPPER: Just waiting on two more  
9 votes.

10 (Voting.)

11 MS. SKIPPER: Voting has closed on  
12 usability and use, 39 percent votes high, 57  
13 percent moderate, 4 percent low, zero percent  
14 insufficient. The measure passes on usability  
15 and use. We will now need to move on and take a  
16 vote on overall suitability for endorsement.

17 CO-CHAIR GUNNAR: Any other comments  
18 before we take a vote on the measure? Proceed.

19 MS. SKIPPER: Okay. One yes, two no  
20 for overall suitability for endorsement of  
21 Measure 1550.

22 (Voting.)



1 MS. SKIPPER: One hundred percent of  
2 votes are yes for overall suitability for  
3 endorsement for Measure 1550.

4 CO-CHAIR GUNNAR: So I'm going to take  
5 a -- yes, Helen?

6 DR. BURSTIN: Just a quick comment.  
7 This isn't about directly this measure, but since  
8 so many of you have raised this issue of cherry  
9 picking, this would be a great group to maybe  
10 have a small workgroup off cycle just to talk  
11 through are there companion measures.

12 How do you actually kind of keep track  
13 of that issue because I do think -- it's  
14 something you guys are working on already?

15 DR. SUTER: No, but actually as a  
16 developer thinking that we'll need to bring these  
17 measures back, understanding exactly what  
18 analyses you guys would like to see from us would  
19 be really helpful in terms of guiding the  
20 surveillance on this.

21 DR. BURSTIN: So we will pull a  
22 workgroup together for those of you who are

1 interested just to have a conversation. Again,  
2 it's going to keep coming up.

3 And I think if we have a handle both  
4 on what the analyses are or some people have even  
5 called for -- sometimes for some of these kinds  
6 of measures, particularly if they involve costs,  
7 the concerns if you actually have companion  
8 measures that look at concerns around stenting in  
9 addition to cherry picking.

10 So I think it might just be a good  
11 discussion. This seems like a good group to  
12 start that with. Thanks.

13 MEMBER YATES: Could you spearhead  
14 that --

15 DR. BURSTIN: Yes, absolutely.

16 MEMBER YATES: -- because this is a  
17 temporal thing, and we have to capture it as it  
18 occurs.

19 DR. BURSTIN: Yes, I agree. And we  
20 are also trying to very much as part of our new  
21 strategic plan think about how we increasingly  
22 get feedback in real time as things happen on the

1 ground. But to the earlier point, we need to  
2 know what we're looking for and how you would  
3 even measure it. So, thank you.

4 CO-CHAIR GUNNAR: I'm going to take  
5 the chair's prerogative and push through the next  
6 measure we have. The measure developer's here,  
7 and I think we can move through it fairly  
8 quickly.

9 So this is the companion measure,  
10 1551. It's the hospital-level 30-day, all-cause  
11 risk standardized readmission rate following  
12 total knee and hip replacement, CMS.

13 DR. SUTER: This is Lisa Suter. We  
14 have no additional comments and happy to answer  
15 any questions.

16 CO-CHAIR GUNNAR: Discussants are Dr.  
17 Erekson and Dr. Yates.

18 MEMBER EREKSON: So I would say from  
19 my reading of this measure, the only tangible  
20 difference in this measure is the outcome which  
21 is a 30-day readmission rate where they used a  
22 very standardized readmission look for all-cause

1 readmissions.

2           There are very strict exclusion  
3 criteria for planned readmissions for maintenance  
4 chemotherapy and some of those things, but  
5 otherwise the measure is almost identical to the  
6 last.

7           MEMBER YATES: I have no more comments  
8 on evidence, and I think the evidence can be  
9 accepted as presented. And I would also argue  
10 that the discrepancy and future validity  
11 arguments versus the SDS question have been  
12 discussed ad nauseam already and that we can  
13 accept those as being discussed. So I think you  
14 can vote on the evidence.

15           CO-CHAIR GUNNAR: So we don't need to  
16 vote on the evidence. We accept the evidence.  
17 It's a maintenance measure.

18           MEMBER YATES: I accept that  
19 distinction.

20           CO-CHAIR GUNNAR: Anyone want to vote  
21 for the evidence? Seeing none, we can move on to  
22 the cap.

1                   MEMBER EREKSON: So what is presented  
2 in the gap is that when this measure was first  
3 reported the hospital performance score was 4.9  
4 in the first year. It dropped -- actually, maybe  
5 my numbers are slightly different.

6                   It dropped slightly and right after  
7 the measure was first instituted, and it's  
8 remained at a four point -- well, this is 5.3,  
9 4.9, 4.4 for an overall mean of 4.9. So it is  
10 continuing to drop.

11                  CO-CHAIR GUNNAR: Dr. Yates?

12                  MEMBER YATES: Nothing to add.

13                  CO-CHAIR GUNNAR: We'll go to vote.

14                  Yes? Christy?

15                  MS. SKIPPER: We're now voting on gap  
16 for Measure 1551, one high, two moderate, three  
17 low, four insufficient.

18                  (Voting.)

19                  MS. SKIPPER: Just waiting on one more  
20 vote from the phone.

21                  CO-CHAIR GUNNAR: All right. You  
22 good?

1 MS. SKIPPER: Voting has closed for  
2 gap, Measure 1551, 38 percent votes high, 62  
3 percent votes moderate, zero percent low, zero  
4 percent insufficient. The measure passes on gap.

5 CO-CHAIR GUNNAR: Moving on to  
6 reliability. Any further discussion based on --  
7 beyond what was --

8 MEMBER YATES: The c-statistic is  
9 amazingly the same.

10 CO-CHAIR GUNNAR: Yes.

11 MEMBER YATES: And the ICC jumps to  
12 0.49, so it's the same level of moderate in the  
13 correlation and you have the same moderately low  
14 lucky to model.

15 CO-CHAIR GUNNAR: Dr. Dutton?

16 MEMBER DUTTON: Just a quick question  
17 for the developers. Transfers out are excluded  
18 again. How big an effect does that have? Does  
19 it transfer out include sending a patient to  
20 rehab?

21 DR. SUTER: It does not. A transfer  
22 out is a patient who is transferred from --

1 transfers in are excluded. Transfer out they're  
2 -- you're -- the outcome of readmission is  
3 assigned to the hospital that discharges the  
4 patient. So it's shifting the attribution but  
5 not direct.

6 CO-CHAIR GUNNAR: Any further  
7 discussion? Carry on. Christy?

8 MS. SKIPPER: Voting is open for  
9 reliability, one high, two moderate, three low,  
10 four insufficient.

11 (Voting.)

12 MS. SKIPPER: Twenty-three percent  
13 votes high, 77 percent votes moderate for  
14 reliability of Measure 1551. This measure passes  
15 on reliability.

16 CO-CHAIR GUNNAR: So Lee?

17 CO-CHAIR FLEISHER: Validity.

18 CO-CHAIR GUNNAR: Yes, validity,  
19 calling it. Dr. Fleisher?

20 CO-CHAIR FLEISHER: Yes, I just want  
21 a point of clarification. Helen can correct me  
22 if I'm wrong. Lisa or Karen, you made a comment

1       that we would only see the risk adjust rate. It  
2       is a requirement that SDS is incorporated, that  
3       both the risk adjusted with and without SDS.

4               So your statement is inaccurate just  
5       for the committee's purpose that we will always  
6       be able to see whether or not, at least under the  
7       trial period whether or not --

8               DR. BURSTIN: Right, so when this al  
9       went through a couple years ago, the idea would  
10      be that if a measure was endorsed with adjustment  
11      for SDS factors it was required that there would  
12      also be stressifications for the stratified  
13      results.

14              So you would always, in fact, see what  
15      was underlying and driving those differences  
16      while allowing potentially for a level playing  
17      field. Again, we'll see how that plays out.

18              What's not clear is exactly how that  
19      gets played out, for example, on Hospital Compare  
20      although that may be our recommendation. So  
21      again, I think there's still a lot of play in  
22      this space. I think we're all learning



1 collectively over the last year.

2 MEMBER YATES: I've got to ask a  
3 question. We didn't vote on whether SDS should  
4 be required or not be required. We just voted on  
5 the validity of the measure as is, so I don't  
6 understand your last comment because you said  
7 that if it's endorsed with the --

8 DR. BURSTIN: If you had made the --  
9 let's play this out just for the sake of  
10 argument.

11 MEMBER YATES: Right.

12 DR. BURSTIN: If you had said, back to  
13 Yale, we disagree with you. We believe that  
14 given your odds ratio of 1.21 for dual eligibles  
15 we want that to actually be in the model and that  
16 happened to be what got voted on, then if the  
17 measure was endorsed with adjustment in the  
18 model, we would require, we being NQF, that there  
19 would also be specifications to see whatever  
20 variable was actually adjusted for for STS  
21 stratified to get at this issue of masking.

22 You've basically agreed with the

1 developers to leave the model as is, so there's  
2 nothing with which to stratify.

3 MEMBER YATES: Actually, we were told  
4 to vote on it as for validity and we didn't get  
5 asked a question as to whether or not it should  
6 be modified.

7 DR. BURSTIN: Yes.

8 MEMBER YATES: In other words, you're  
9 saying that if it had flunked validity because it  
10 didn't --

11 DR. BURSTIN: Correct.

12 MEMBER YATES: -- included SDS. And  
13 see this was part of the technical questions I  
14 was asking on the phone --

15 DR. BURSTIN: Okay.

16 MEMBER YATES: -- a month ago was how  
17 do we handle that. Is it supposed to be a  
18 parallel process or a process that's embedded  
19 into the question?

20 DR. BURSTIN: At this point, we have  
21 embedded SDS adjustment into validity, at least  
22 for the two year trial period, which we're

1       halfway through. And so you could have rejected  
2       that measure theoretically on the basis of the  
3       fact that you do not think the information  
4       presented suggested the measure should remain  
5       unadjusted for SDS.

6               The conversation you had around this  
7       table didn't suggest that was the direction you  
8       were going.

9               MEMBER YATES: I would argue that as  
10      a point of clarification it wasn't really made  
11      clear --

12              DR. BURSTIN: Okay.

13              MEMBER YATES: -- that we were doing  
14      it that way.

15              DR. BURSTIN: We will do a better job  
16      of that. Thank you.

17              CO-CHAIR GUNNAR: Would you handle a  
18      new versus a maintenance measure differently in  
19      that space?

20              MS. MUNTHALI: No, we would handle  
21      them the same way, so yes.

22              CO-CHAIR GUNNAR: Any other comments

1 regarding validity?

2 MEMBER YATES: On validity? I would  
3 just point out the same question about the  
4 original TEP and face validity.

5 The second comment is that I'm really  
6 not sure how -- since this is a dichotomous  
7 result, either readmitted or not readmitted, I'm  
8 not sure that it can borrow the validity of 1550  
9 in its original validation study and then again  
10 the Federal Register and in multiple things it's  
11 given a 99 percent agreement rate based on a  
12 study that was really looking at readmissions, I  
13 mean excuse me, complications.

14 So I think that's a little bit of a  
15 slide on that. The -- to look at the validity of  
16 this versus the charts, you'd have to look at all  
17 of the risk factors and you'd have to go back  
18 through the charts of 12 months.

19 So I don't think that study can be  
20 done. So I'm giving it a pass on validity since  
21 it's a dichotomous endpoint. And then since we  
22 now have this other question then, I would still

1 say it should considered by the committee whether  
2 or not the inclusion or non-exclusion of SDS is  
3 an important factor in terms of voting for the  
4 validity of the measure because I don't think it  
5 was phrased that way in the last process.

6 DR. SUTER: This is Lisa. So in  
7 response to A.J.'s input, so a couple things.  
8 The validity of the planned readmission algorithm  
9 was performed through a chart, a medical record  
10 review.

11 It's distinct from the complications  
12 validation. That information is not included in  
13 every single readmission measures application to  
14 NQF.

15 We're happy to share that with the  
16 committee, but it is -- the planned readmission  
17 algorithm has been vetted by a number of  
18 different committees, mostly the admission and  
19 readmission committee that's investigated those  
20 other readmission measures.

21 This measure is paired with its  
22 complications partner and is in the surgery mouth

1 of admissions/readmissions committee. In regards  
2 to the SDS, we see similar results in the  
3 readmission measure as with the complication  
4 measure.

5 MEMBER YATES: And correct me if I'm  
6 wrong, but when you say it's been validated for  
7 the risk factors, that validation is based on the  
8 previous validation for the HCC model. Correct?

9 DR. SUTER: The key measures have not  
10 had their risk adjustment models validated in a  
11 clinical record review. They have had their  
12 outcome assessments validated in medical record  
13 review.

14 MEMBER YATES: Okay.

15 CO-CHAIR GUNNAR: Any other comments,  
16 concerns regarding validity? Seeing none.

17 MS. SKIPPER: We're now voting on  
18 validity for Measure 1551, one high, two  
19 moderate, three low, four insufficient.

20 (Voting.)

21 MS. SKIPPER: Voting has closed, 9  
22 percent votes high, 78 percent votes moderate, 9

1 percent low, 4 percent insufficient. This  
2 measure passes on validity.

3 CO-CHAIR GUNNAR: Moving to  
4 feasibility.

5 MEMBER YATES: Yes, it's feasible.

6 CO-CHAIR GUNNAR: Any other  
7 discussion? Christy on feasibility?

8 MS. SKIPPER: Voting is open for  
9 feasibility, one high, two moderate, three low,  
10 four insufficient.

11 (Voting.)

12 MS. SKIPPER: We have 20 votes and we  
13 need three more, so if you can aim your clicker  
14 in this direction. Eighty-seven percent votes  
15 high, 13 percent moderate, zero percent low, zero  
16 percent insufficient. The measure passes on  
17 feasibility criteria.

18 CO-CHAIR GUNNAR: Use and usability.

19 MEMBER YATES: It's used as part of  
20 hospitalcompare.gov, and it's also used in the  
21 Readmission Reduction Program from CMS. It has -  
22 - if it's payment quality implication having

1 started this year, it's part of the basket of  
2 conditions and procedures that make up that  
3 basket of procedures and conditions at risk for  
4 that.

5 That's a weighted basket, so for some  
6 hospitals it becomes a very large part of the  
7 weight. And the penalty is 3 percent across all  
8 CMS reimbursement as a potential worst case  
9 scenario.

10 And in terms of gaming and unintended  
11 consequences, I would argue the same things that  
12 I argued before. And I would also argue that the  
13 research that's been done before, not seeing an  
14 increase in observations days preceded probably  
15 the attention level of hospital administrators in  
16 that the OBS base have possibly gone up at least  
17 in my perception and that more recent data than  
18 2013 would be more indicative of that as an  
19 unintended consequence.

20 CO-CHAIR GUNNAR: Any other comments?

21 MS. SKIPPER: Voting is open for  
22 usability and use, one high, two moderate, three



1 low, four insufficient.

2 (Voting.)

3 MS. SKIPPER: Fifty-seven percent  
4 votes high, 39 percent moderate, 4 percent low,  
5 zero percent insufficient. This measure passes  
6 on usability, and we can move on to -- the  
7 committee can move on to a vote for overall  
8 recommendation for endorsement.

9 CO-CHAIR GUNNAR: It's open.

10 MS. SKIPPER: Your options are one  
11 yes, two no.

12 (Voting.)

13 MS. SKIPPER: Thank you, 95 percent  
14 votes yes, 5 percent votes no. This measure is  
15 recommended for overall suitability for  
16 endorsement.

17 CO-CHAIR GUNNAR: We'll open up the  
18 line now to public comment.

19 OPERATOR: If you have a comment at  
20 this time, please press star 1. There are no  
21 public comments at this time.

22 CO-CHAIR GUNNAR: So we will break for

1 -- what do we need, ten, fifteen minutes for bio  
2 break and gather lunch, bring it back and we'll  
3 carry forward. Thanks for your efforts this  
4 morning.

5 (Whereupon, the above-entitled matter  
6 went off the record at 12:48 p.m. and resumed at  
7 1:05 p.m.)

8 CO-CHAIR FLEISHER: We actually  
9 promised the developer, for those in the room, we  
10 promised that at 1:05 we would be back on. I  
11 don't like to have my surgical colleagues be  
12 concerned about starting on time.

13 So we're going to start with 0713, VP  
14 Shunt Malfunction Rate in Children. Is the  
15 developer on the line?

16 DR. GOUMNEROVA: Yes, we're both here.  
17 My name is Lili Goumnerova, and I have Sarah  
18 Henderson with me, as well.

19 CO-CHAIR FLEISHER: Okay, great. We  
20 can hear you, but it would be great if you could  
21 speak a little louder.

22 DR. GOUMNEROVA: Okay, can you hear me

1 now?

2 CO-CHAIR FLEISHER: Yes. If you could  
3 just -- three to four minutes about the measure,  
4 itself, from your perspective.

5 DR. GOUMNEROVA: So, the reason we  
6 decided to come up with this measure, it is a  
7 relevant measure, since hydrocephalus is treated  
8 primarily with ventriculoperitoneal shunts, and  
9 they have a very high failure rate.

10 And this is probably one of the most  
11 common neurosurgical procedures that is performed  
12 across pediatric hospitals. It is a good way to  
13 evaluate how we, as hospitals, do amongst each  
14 other, and also to get a good sense of what the  
15 malfunction rate of these very commonly inserted  
16 devices is amongst hospitals, not necessarily  
17 just looking at individual experiences in  
18 academic hospitals, but across all hospitals.

19 The measure was submitted a number of  
20 years ago, and we have been using it here for at  
21 least five years. And it is very reliable in our  
22 institution, and it provides us good data on how

1 we're doing. We have made changes in our  
2 practice based on the measure, so we find it  
3 useful.

4 Additionally, I have submitted this  
5 measure to the pediatric neurosurgical group.  
6 There is the pediatric section of the AANS, which  
7 is the American Association of Neurological  
8 Surgeons, and Congress of Neurological Surgeons.  
9 There has been interest from other institutions  
10 in the hospital to use it. So it is being also  
11 used in other institutions.

12 I'm not quite sure what more you would  
13 like to hear from me. Anything specific or not?

14 CO-CHAIR FLEISHER: No, that would  
15 great. Our discussants are Larry, correct, and  
16 Cliff? And this is of concern or not of concern,  
17 the potential conflict --

18 MEMBER MOSS: As you suggested, I'll  
19 just state it briefly. Does that make sense?

20 CO-CHAIR FLEISHER: Yeah, and Cliff  
21 can --

22 MEMBER MOSS: As the developers

1 mentioned, this is a measure that was recently  
2 adopted for use by the Pediatric NSQIP program.  
3 My secondary reviewer, Dr. Ko, has recused  
4 himself completely because of his leadership of  
5 that program. I want to make the Committee aware  
6 that I'm a founding member of the steering  
7 committee of Pediatric NSQIP. I was not involved  
8 in the selection of the use of this measure and  
9 don't believe it prohibits me from providing an  
10 objective review, but I did discuss with Dr.  
11 Fleisher in advance, and I'll recuse myself from  
12 voting, even though I'll discuss the measure.

13 CO-CHAIR FLEISHER: Before we start,  
14 is everybody comfortable with Larry -- and I  
15 honestly think, Cliff, if you have any comments,  
16 to comment, they will just recuse themselves from  
17 voting and giving us a formal recommendation.  
18 But discussing would be fantastic.

19 DR. GOUMNEROVA: And Larry who? I'm  
20 sorry; I didn't catch the last name.

21 MEMBER MOSS: Moss.

22 DR. GOUMNEROVA: Larry Moss, okay. I

1 used to be on the executive committee of Pedi  
2 NSQIP until a year or so ago. So I'm familiar  
3 with it. Okay.

4 MEMBER MOSS: Okay, I'll move forward.  
5 I'll just begin with a couple of brief content  
6 comments because I know most of the audience are  
7 not pediatric providers. Hydrocephalus is  
8 accumulation of cerebrospinal fluid around the  
9 brain in excess, which can cause permanent  
10 neurologic injury.

11 It is treated with a diversion  
12 procedure where there's a mechanical device that  
13 takes CSF out of the cerebral ventricles and puts  
14 it into the peritoneal cavity for absorption. As  
15 Dr. Goumnerova stated, these fail commonly, and  
16 thus the initial rationale for the measure.

17 I want to begin with a discussion of  
18 evidence. There is some new evidence provided by  
19 the developers for this outcome measure, which is  
20 submitted for maintenance. It's submitted under  
21 1b.5, but I think it's more relevant to 1a, as  
22 we're discussing here. And that's a paper by

1 Rossi et al., who looked at a single institution  
2 retrospective review trying to identify risk  
3 factors for shunt malfunction or failure.

4 Of note, this paper concluded strongly  
5 that -- in fact, I'll just read from the  
6 conclusions. That would be the best way to do  
7 this.

8 In this study, none of the risk  
9 factors that were examined were statistically  
10 significant in determining shunt failure within  
11 90 or 180 days. Given the negative findings and  
12 the fact that all other risk factors for shunt  
13 failure that have been proposed in the literature  
14 are far beyond the control of the surgeon, i.e.,  
15 non-modifiable, the use of an institution's or  
16 individual's global shunt revision rate remains  
17 questionable and needs further evaluation before  
18 being accepted as a quality measure.

19 So I think it calls into question the  
20 initial evidence that was presented in 2011.  
21 I'll add to that, before I'll stop for the  
22 developer's comments, that I would ask the group

1 to consider that the intent of the measure is to  
2 identify shunt malfunction rate, but what is  
3 actually measured is redo operation for a failed  
4 shunt. There are not uniformly accepted,  
5 evidence-based criteria for the indications for a  
6 redo, so the redo rate is potentially heavily  
7 influenced by local practice, or the local  
8 approach and definition of shunt failure, as much  
9 as it might be by the actual outcome.

10 So I'll pause there for the developer.

11 DR. GOUMNEROVA: Yeah, so I am  
12 familiar with the paper by Rossi. It is very  
13 interesting. When we looked at risk adjustments  
14 and risk factors -- I should say risk factors --  
15 we do agree that there are some historically  
16 thought to be risk factors which did not prove to  
17 be valid. So I'm not going to disagree with  
18 their comment. However, I think that,  
19 nevertheless, when we looked at our data, there  
20 do appear to be trends.

21 And I think that's one of the things  
22 that Pedi NSQIP shunt measure is going to be



1 looking at that in some granularity, also, is  
2 going to try and address this issue of risk  
3 stratifications, risk factors. I'm not going to  
4 be able to answer that completely, but I'm  
5 familiar with that, and we're working on  
6 addressing that.

7 I do want to comment: we're not  
8 looking at re-operation patients here. The way  
9 we actually look at these patients, patients who  
10 have had an immediate prior operation, are not  
11 the ones that are looked at in this dataset. So  
12 I don't understand why you think that is the  
13 case.

14 MEMBER MOSS: So, correct me if I'm  
15 wrong, but my understanding from the coding  
16 definitions provided is that a patient becomes  
17 part of the denominator if a shunt is a de novo  
18 procedure, and then becomes part of the numerator  
19 if a second operation is done within the  
20 specified period. Is that correct?

21 DR. GOUMNEROVA: Where do you have  
22 that? Where was that in the --

1                   MEMBER MOSS: I've got that from the  
2 development worksheet. I'll try to find the  
3 specific place, but I'm not sure I can do that  
4 off the top of my head.

5                   DR. GOUMNEROVA: Right. We  
6 specifically tried to actually get around that.  
7 Because you are correct, you do not want to be  
8 looking at re-operation rate for the same patient  
9 over and over again. So, in actual fact, that is  
10 not the way it is. And I specifically look at  
11 these data periodically, at a quarterly basis.  
12 And I know that is not what is being captured.  
13 That is not the way the measure was defined --

14                   (Simultaneous speaking.)

15                   MEMBER MOSS: I'm sorry, go ahead.

16                   DR. GOUMNEROVA: I'm just trying to  
17 find where that is in the --

18                   MEMBER MOSS: Yeah, I've got the  
19 numerator statement here, so I'll just read it so  
20 we're all on the same page. The numerator  
21 statement is the number of initial  
22 ventriculoperitoneal shunt placement procedures

1 performed on children between the ages of zero  
2 and 18 years of age that malfunction and result  
3 in shunt revision within 30 days of the initial  
4 placement.

5 DR. GOUMNEROVA: Correct, yes. So  
6 what we say is initial placement. So a patient  
7 who, for example, has had an operation within --  
8 say, for example, a patient comes in, has a shunt  
9 placed, and then it's revised within 30 days,  
10 that is exactly what we're capturing. However,  
11 if that patient then goes back to the operating  
12 room in another 15 days, we're not counting that.  
13 We're avoiding the patient who has the multiple  
14 repetitive procedures.

15 MEMBER MOSS: I want to make sure that  
16 I understand you clearly. As I understand the  
17 measure, what becomes a positive, or what enters  
18 you into the numerator, is a shunt revision,  
19 correct?

20 DR. GOUMNEROVA: Correct, yes.

21 MEMBER MOSS: Okay, thank you.

22 CO-CHAIR FLEISHER: So, right now,

1 we're on evidence, because this is a new measure,  
2 but you're discussing a little bit of validity.

3 MEMBER MOSS: Yeah, I understand this  
4 goes a little bit into validity, but I think it  
5 does speak to some changes in the core evidence.  
6 My understanding is that evidence for an outcome  
7 measure needs to relate to whether there are  
8 processes of care that can influence the outcome,  
9 and that's what I'm getting at with this  
10 discussion.

11 CO-CHAIR FLEISHER: Okay, Barry?

12 MEMBER MARKMAN: I think it's a  
13 maintenance measure, isn't it? It's a  
14 maintenance measure. But then the question I was  
15 just going to ask the developer is --

16 CO-CHAIR FLEISHER: Your mic's not on,  
17 is it?

18 MEMBER MARKMAN: I think so.

19 DR. GOUMNEROVA: Hello? Yeah, I can  
20 hear it.

21 MEMBER MARKMAN: Okay, so why did you  
22 pick 30 days, when the retrospective cohort

1 study, the large study, shows almost a five times  
2 complication rate after 90 days?

3 DR. GOUMNEROVA: That is a very good  
4 point, and we have talked about extending that to  
5 90 days. It is true, when we first started out  
6 with this measure, we wanted to look at 30 days,  
7 only, but we are in the process of extending it  
8 to 90 days. We have not done all of the work on  
9 that, but exactly to address those concerns.

10 MEMBER MARKMAN: Okay, good. And what  
11 actually is the malfunction? Is it a device  
12 malfunction? Is it a clogging of the shunt?  
13 What actually is the malfunction?

14 DR. GOUMNEROVA: There are a number of  
15 things that can go under the category of  
16 malfunction. By and large, it is a clogging of a  
17 device.

18 The device is essentially a tube, a  
19 piece of plastic tube with holes on one end,  
20 through which the fluid enters. There is then a  
21 component called a valve, which is then attached  
22 to another piece of tubing that goes into the

1 distal cavity, whether it's the peritoneum or  
2 atrium or some other space. Anywhere along that  
3 valve/tubing area, there can be a clogging. In  
4 the majority of cases, it is a clogging of the  
5 tubing that is in the brain, in the ventricles..

6 MEMBER MARKMAN: It's not the actual  
7 pump? It's not the actual pump, it's the tubing  
8 that's clogged, right?

9 DR. GOUMNEROVA: It's the tubing, that  
10 is correct. The valve -- so, 80 percent, about  
11 70 to 80 percent of the malfunction occurs  
12 because clogging of the tube in the brain. The  
13 rest are related to malfunction of the valve that  
14 regulates the flow.

15 Now, when people talk about  
16 malfunction, they also frequently will code it as  
17 malfunction, where in actual fact the tubing was  
18 placed in the wrong location. With this current  
19 measure, we do not have a way of separating the  
20 clogging of the tube which happens normally, or  
21 because there was an error where the tube was not  
22 placed in the correct location.

1 CO-CHAIR FLEISHER: Thank you. Are  
2 there other questions about evidence? Because he  
3 major question you had asked, from my  
4 understanding, is for a process, or this outcome,  
5 could it be influenced?

6 MEMBER MOSS: Correct. So, my  
7 understanding is that for evidence to be  
8 revisited in a maintenance measure, it needs to  
9 be because there is new evidence. And the  
10 submitted paper that I referenced was submitted  
11 by the developers as new evidence, And I think  
12 that and some other factors at least call into  
13 question whether this measure is a valid  
14 indicator of processes of care at an institution.

15 DR. GOUMNEROVA: I still think it is  
16 a valid measure, despite the paper. I think if  
17 we -- there needs to be a rethinking of how we  
18 evaluate hydrocephalus treatment. And that's a  
19 big question. I understand your concern.  
20 However, this is not necessarily accepted amongst  
21 the neurosurgical community as a way of looking  
22 at treatment of hydrocephalus. But I'm willing

1 to -- open to discussion on that.

2 CO-CHAIR FLEISHER: Well, I think what  
3 I'm hearing is -- and I actually think, based  
4 upon those comments, we should actually vote if  
5 people would agree on this one. Does anybody  
6 want to vote, or does everybody agree that the  
7 evidence is sufficient from the -- okay, we've  
8 gotten calls for votes. Christy?

9 MS. SKIPPER: Voting is now open for  
10 Measure 0713, whether the rationale supports the  
11 relationship of the health outcome to at least  
12 one healthcare structure, process, intervention,  
13 or service. 1 yes, 2 no.

14 (Voting.)

15 MS. SKIPPER: We have 20 votes. And  
16 we're just waiting on one more, so if you can aim  
17 in my direction. Oh, two that aren't voting.  
18 We'll move on.

19 We do have 20 votes, 55 percent votes  
20 yes, 45 percent votes no. This measure is  
21 consensus not reached, but we will continue the  
22 evaluation of the other criteria.



1 CO-CHAIR FLEISHER: With consensus not  
2 reached?

3 MS. SKIPPER: No? So this measure  
4 would be moved to our post-comment call where you  
5 all would then make a decision.

6 MS. MUNTHALI: Yes, you will vote on  
7 the rest of the major criterion, except the  
8 overall vote. You'll vote on the overall during  
9 the post-comment call.

10 CO-CHAIR FLEISHER: Okay, everybody  
11 got -- good. Next?

12 MEMBER MOSS: Okay, we're moving on to  
13 performance gap now. The evidence provided is a  
14 study comparing the rate of shunt malfunction at  
15 the developer's institution, Boston Children's  
16 Hospital, with what they define as a benchmark,  
17 which is derived from ten hospitals in the PHIS  
18 database, which is an administrative database of  
19 the Children's Hospital Association. That's  
20 provided, but my question for the developers are  
21 a few.

22 First of all, since this measure's

1       been endorsed since 2011 and there's been five  
2       years of duration, why isn't there more  
3       information available comparing institutions  
4       against each other?

5               Second question is why have the  
6       developers not taken the PHIS database and used  
7       the administrative data to compare institutions  
8       against each other?

9               DR. GOUNNEROVA: I think that there  
10      are other institutions that have used it. I  
11      guess it is our failure in not wanting to compare  
12      ourselves to other institutions. It has been,  
13      essentially, trying not to want to compare each  
14      other. That's basically the reason.

15              MEMBER MOSS: My other comment here is  
16      regarding sociodemographic disparities. The  
17      developers state that these data are not required  
18      to be collected at the institutions utilizing  
19      this measure. But I wanted to point out that a  
20      significant portion of this patient population is  
21      premature infants, which have been shown in many  
22      other domains of care to have marked differences

1 that are related to socioeconomic status. So I  
2 just question the developers on that decision and  
3 if they could take us through the thought process  
4 a little bit.

5 DR. GOUMNEROVA: I think that you are  
6 correct, and we're aware of those. However, when  
7 we looked at some of the data, it did not appear  
8 to be a valid -- in our data, it did not appear  
9 to be valid, looking at that and outcomes. I  
10 think that, although in other data that is  
11 supported, it did not appear to be relevant in  
12 our VP shunt malfunction data. We're happy to  
13 look at that again, but it's not been a  
14 significant factor.

15 CO-CHAIR FLEISHER: Thank you.  
16 Comments? I have a question for Karen or staff.  
17 Your internal rating, can you give the rationale  
18 between your preliminary assessment, so we can  
19 actually understand how the staff think about  
20 this?

21 MS. JOHNSON: I think it mainly has to  
22 do with the fact that it was one hospital, 46

1 eligible cases, and only two repairs or  
2 revisions. So that's not to say that there's not  
3 a problem with quality, it's just we weren't  
4 quite sure that there was enough information for  
5 you to make that rating.

6 So you can decide if you need more  
7 information. You can decide if you think that is  
8 good enough to indicate a gap in care. And we  
9 will point out again our new guidance from the  
10 CSAC, dated July, so hot off the presses.

11 You are kind of given permission, if  
12 you will, to think about some of these outcome  
13 measures, particularly mortality measures or  
14 patient safety measures. And I don't know if you  
15 consider this to be a patient safety measure or  
16 not. I think we had that conversation earlier.  
17 You know, you might not have to feel that there  
18 is as huge a gap as you might for a process  
19 measure.

20 CO-CHAIR FLEISHER: Are we ready to  
21 vote? Other comments? And what I've heard is  
22 this has been endorsed for six years, and there's

1 data from one center. Am I repeating that  
2 correctly?

3 DR. GOUNNEROVA: That's correct, yes.

4 MS. SKIPPER: We're now voting on the  
5 performance gap for Measure 0713, 1 high, 2  
6 moderate, 3 low, 4 insufficient.

7 (Voting.)

8 MS. SKIPPER: Voting has closed for  
9 performance gap. Five percent votes high, 15  
10 percent moderate, 40 percent low, 40 percent  
11 insufficient. This measure does not pass on  
12 performance gap.

13 CO-CHAIR FLEISHER: So we do not go  
14 further, correct, at this point?

15 MS. MURPHY: So, what you can do, if  
16 you feel that the measure is important and the  
17 information that is provided thus far provides  
18 you that information, is that you can go ahead  
19 and look at the other criteria. Karen's shaking  
20 her head no.

21 MS. JOHNSON: Maybe not that  
22 emphatically. I think since it completely

1 failed, you're not in that gray zone. We  
2 generally would not go forward. It's your call.  
3 If you want to, we could. I think the other  
4 question that you may want to answer is, is there  
5 something that perhaps the developer could come  
6 back with on post-comment that would potentially  
7 make you change your mind about this?

8 CO-CHAIR FLEISHER: I think that's the  
9 key thing. I will actually defer to the  
10 committee first. Barry, did you --

11 MEMBER MARKMAN: Yeah. I mean, I  
12 would like to commend the developer for at least  
13 attempting to address a significant surgical  
14 problem. A 30 percent complication rate within  
15 180 days? I mean, that's unacceptable. So I  
16 commend the developer for trying it. Maybe she  
17 can restructure it or something else, but that's  
18 my feeling. That's my personal feeling.

19 CO-CHAIR FLEISHER: Okay, Rick and  
20 Larry and Fred? What I'd like is specific  
21 instructions to potentially get past the  
22 performance gap as the first comment.

1                   MEMBER DUTTON: Having been in this  
2 position myself, I know that the developer will  
3 appreciate whatever feedback we can give about  
4 how to make it better.

5                   DR. GOUMNEROVA: Absolutely.

6                   MEMBER DUTTON: I guess it's good,  
7 generally, that a measure that's passed before is  
8 now not up to our standards. That suggests  
9 evolution of our process.

10                  I would say this needs to come back  
11 with more data attached to it, more performance  
12 data from more than one hospital, larger sets of  
13 data, whether through NSQIP or other mechanisms,  
14 to show, to tell us more about what that  
15 performance gap is.

16                  DR. GOUMNEROVA: Okay.

17                  CO-CHAIR FLEISHER: I think that's  
18 very helpful. And I don't know how quickly you  
19 can get that. When's our post?

20                  MS. SKIPPER: Our post call is August  
21 25th, so about a week from now. That's our  
22 post-meeting call, is August 25th.

1                   MEMBER MOSS: I wanted to just echo  
2                   Barry's comment that this is a critical area of  
3                   need with respect to patient care. And I also  
4                   commend the developers for the effort. And a far  
5                   more favorable outcome than seeing this go away  
6                   would be for NQF staff to work with the  
7                   developers and ultimately come back with  
8                   something that could be endorsed.

9                   I wanted to make one specific  
10                  suggestion to the developers. There is way more  
11                  compelling evidence about the relationship  
12                  between VP shunt infection and processes of care  
13                  than there is about malfunction. That may be  
14                  something to consider that would meet the NQF bar  
15                  and keep VP shunt care on the radar.

16                 CO-CHAIR FLEISHER: Fred.

17                 DR. GOUMNEROVA: I agree. We can --  
18                 yes.

19                 MEMBER GROVER: I think, generally,  
20                 the measures that we have approved, at least  
21                 historically, tend to be more than one. And to  
22                 test reliability and usability, it needs to be



1       beyond one center, to see how easy and reliable  
2       the data is as it's collected across centers.

3       And I guess my advice would be to find a number  
4       of other children's hospitals that would be  
5       willing to be involved with this and maybe put  
6       that together and come forward.

7               And I would ask the NQF staff, though,  
8       would they need -- I would think they would need  
9       to have data showing performance over a period of  
10      a few years, across several hospitals, with  
11      consistent data and reliability to validate the  
12      process.

13              I think it's an important project. I  
14      think we all agree on that.

15              CO-CHAIR FLEISHER: I think that's --  
16      hopefully the developer's hearing that. Do you  
17      have data? Cliff, do you know, data in the  
18      Pediatric NSQIP for more than Boston Children's?

19              (Off the record comment.)

20              DR. GOUMNEROVA: I'm sorry, I can't  
21      hear.

22              CO-CHAIR FLEISHER: Dr. Ko is saying

1       that you're talking about putting it in. It  
2       sounds like the Committee would like to see, if  
3       not data across years, at least data across more  
4       than one hospital. Is that the consensus of the  
5       Committee? What I also think you would probably  
6       hear is the Committee agrees this is an important  
7       measure, just it's insufficient is actually what  
8       a lot of people, 40 percent, said.

9               Why don't we go Amy, then Liz, then  
10       Barbara. And you'll also have the expertise of  
11       having Cliff being at NSQIP.

12               MEMBER MOYER: This is Amy. I'm  
13       sensitive to the fact that sometimes our  
14       limitations on our measures are placed there by  
15       the data sources. But barring that, I'd like to  
16       see some sort of rational time period for the  
17       measure. Because looking at the failure rates  
18       that are in some of the studies cited, it feels  
19       like longer than 30 days might be an appropriate  
20       period to capture more of the rates, if feasible.

21               DR. GOUMNEROVA: Okay, I appreciate  
22       those comments.

1 CO-CHAIR FLEISHER: Liz?

2 MEMBER EREKSON: Yeah, thank you for  
3 bringing this measure. And I would just -- when  
4 you go back and reset, when you're looking at a  
5 measure where a device has malfunctioned, the  
6 point is very well taken that the device can be  
7 misplaced, and so that is a reason for a failure,  
8 but there are so many times where our medical  
9 devices fall down on us and our data about  
10 changes in medical devices fall down us. So  
11 while you're resetting this measure, I would  
12 really advocate that you collect data on the  
13 device itself, and the manufacturer.

14 DR. GOUMNEROVA: Yeah, that is fairly  
15 easy, since it's a relatively low incidence, so  
16 we can get those data.

17 MS. SKIPPER: This is Christy Skipper.  
18 I'd just like to correct myself for the record.  
19 Our post-comment call is November 3rd. I don't  
20 know if that will give you enough time, but I  
21 just wanted to correct and notify that our  
22 post-comment call, where a developer could

1 present additional information to the Committee,  
2 is November 3rd. Thank you.

3 CO-CHAIR FLEISHER: Melinda, can you  
4 help us if -- what I'm hearing around the room,  
5 or feeling around the room, is that there's a  
6 desire to see this back. If they don't meet the  
7 post-comment call, what happens in this context?

8 MS. MURPHY: If they don't -- I guess  
9 I'd like to back up one step from there and ask  
10 whether or not, at the time the Committee has its  
11 post-meeting discussion, if there's anything that  
12 the group would want to hear back from the  
13 developer, in terms of, having heard what they've  
14 heard today, that they have some plan or some  
15 concept of how they would move forward to address  
16 the concerns you've raised.

17 And then if it goes for a post-comment  
18 call, post-member comment, so it would go out to  
19 the membership in a draft report saying where it  
20 sits at that time of the call of this Committee.  
21 Given where it is today, it wouldn't be a  
22 positive set of comments, in terms of moving

1 forward without some plan.

2           You would expect that without the  
3 support of the Committee, there wouldn't be a  
4 high likelihood of a positive vote, a positive  
5 comment, I should say, around moving the measure  
6 forward. That time window gives more time to get  
7 information, but it will appear in a draft  
8 report, given where it is right now, that it's  
9 not supported, with a different set of words, but  
10 essentially, it would say that.

11           CO-CHAIR FLEISHER: Other comments?  
12 Barbara?

13           MEMBER LEVY: I wanted to go back to  
14 the evidence, because I really think that we've  
15 got a couple of issues here. One is, as a  
16 quality measure, is there anything that the  
17 provider can do differently, or the institution  
18 can do differently, to impact this outcome?  
19 That's Question No. 1, and a major for this.  
20 It's not that the condition isn't really  
21 important.

22           And secondly, to reiterate what Liz

1       said, having a registry of these things to look  
2       at device malfunction is different than having a  
3       quality measure that looks at performance and  
4       gaps in performance.

5               Whereas I think it's very important to  
6       track this and to try to figure out what the  
7       issues are, a device registry might be a better  
8       way to get at some of the malfunction. I,  
9       personally, given the newest evidence, as  
10      presented to us, would have a problem with this  
11      measure, even with additional data from  
12      additional institutions, rather than just one  
13      institution, because, getting back to the  
14      fundamental issue, is this really a measure of  
15      quality, or is this a measure of how seriously  
16      ill these kids are, or some other -- that the  
17      devices are just inadequate to resolve the  
18      problem for them?

19             CO-CHAIR FLEISHER: Collette?

20             MEMBER PITZEN: I just wanted to add  
21      on to Barbara's comments. I was thinking about  
22      that as I was voting for evidence, trying to

1 think of one process that would perhaps change  
2 that outcome. And came up with good monitoring  
3 of that child over time might prevent a  
4 malfunction. No?

5 CO-CHAIR FLEISHER: Larissa, did you  
6 -- no?

7 MEMBER TEMPLE: It's been a long time  
8 since I've put VP shunts in, but I do remember  
9 that they do malfunction. To my recollection,  
10 it's usually not the device. And I think what  
11 we're hearing, though, is that when you come back  
12 with that measure, you really need to demonstrate  
13 that it's not a device issue, or that you have  
14 mechanisms to track that. Because I don't want  
15 the developers to get discouraged by the fact  
16 that they need to focus on the device, as opposed  
17 to other pieces. But I think you're hearing we  
18 need to hear the evidence that it's not device,  
19 or that it's a very small component of it.

20 CO-CHAIR FLEISHER: Larry?

21 MEMBER MOSS: Just in reference to  
22 Barbara's point, well stated, that there are not

1 existing evidence that processes of care  
2 influence the rate of shunt malfunction. That's  
3 not the same as saying the processes of care  
4 doesn't influence it. It's just that there isn't  
5 evidence currently that links those two, which  
6 goes to my suggestion that if we focused on  
7 something such as infection and put attention on  
8 shunt care, there are often parallel improvements  
9 outside of the specific factor being measured,  
10 and overall shunt failures may go down. We may  
11 be able to have an overall positive influence on  
12 the problem by focusing on a different outcome.

13 CO-CHAIR FLEISHER: Fred, final  
14 comment?

15 MEMBER GROVER: Just briefly, going  
16 back, I really do think you need to enlist other  
17 hospitals to take on your database. I agree, you  
18 need to at least list the device, so you can, if  
19 you see a discrepancy in results, you can at  
20 least identify that. But it's like anything  
21 else. If you have a high -- hospitals are high  
22 outliers, whatever you want to call it, are



1       having more difficulty than others, then that  
2       leads you to examine the processes of care at the  
3       high end and the low end and to see what  
4       differences there are. But I think you have to  
5       start there, but you really have to make sure  
6       this database works across more than one center.

7               DR. GOUMNEROVA: I appreciate that,  
8       yes, thank you.

9               CO-CHAIR FLEISHER: Thank you. I  
10       would suggest you get back to Melinda and the  
11       rest of the staff to determine how to move  
12       forward.

13              DR. GOUMNEROVA: Absolutely.

14              CO-CHAIR FLEISHER: Staff will contact  
15       you on the best approach to moving forward.

16              DR. GOUMNEROVA: Okay, thank you.

17              CO-CHAIR FLEISHER: Cardiology  
18       colleagues, we're up to 3024: Carotid  
19       Endarterectomy, Evaluation of Vital Status and  
20       NIH Stroke Scale at Follow-up. Collette and Liz  
21       are the two discussants.

22              If we could get from the measure

1 developer, if they could introduce themselves and  
2 give us a three-minute overview of the measure,  
3 that would be fantastic.

4 DR. GRAY: Dr. Bruce Gray, from  
5 Greenville, South Carolina.

6 MS. CONNOLLY: I'm Traci Connolly. I  
7 work with measure development at the American  
8 College for Cardiology, within the registries of  
9 the NCDR.

10 CO-CHAIR FLEISHER: Do you want to  
11 give us --

12 DR. GRAY: Sure, try to give a brief  
13 background in regards to carotid  
14 revascularization. Two standard treatment  
15 alternatives for patients with significant  
16 atherosclerotic disease include carotid artery  
17 stenting and carotid endarterectomy, two  
18 different type of procedures.

19 Carotid endarterectomy is an open  
20 procedure, requiring an incision, performed by  
21 surgeons, in which the main goal is stroke  
22 prevention and correction of an underlying

1 atherosclerotic lesion that was felt to be  
2 causative or perhaps a risk for subsequent  
3 stroke.

4           Traditionally, the procedure is  
5 performed with a median stay of one to two  
6 hospital days. And it's important that we not  
7 only follow patients out beyond their hospital  
8 course, but out to 30 days, because approximately  
9 one third of neurovascular events after the index  
10 hospitalization, symptoms can occur in about a  
11 third of patients who do develop stroke after the  
12 procedure, after discharge.

13           And so the proposal is to use a  
14 certified stroke trainee, it does not have to be  
15 a physician. The NIH Stroke Scale certification  
16 is easily attainable, can be performed within  
17 about ten minutes of time, and with great  
18 inter-rater reliability. This NIH Stroke Scale  
19 would be performed pre-procedure, during the  
20 hospitalization, and at 30 days follow-up.

21           This is important because for  
22 hospitals to be able to show potential outcomes

1 and safety of the procedure, measurement needs to  
2 be continued out. We want to focus on stroke and  
3 death as simple measures.

4 The current, recent randomized trials  
5 use 30-day end point as a reference. And this  
6 process measure is in direct parallel to the  
7 previously approved process measure for carotid  
8 artery stenting. So this is a direct parallel  
9 type of measure proposal.

10 CO-CHAIR FLEISHER: Thank you.

11 Collette, you want to --

12 MEMBER PITZEN: Sure, thank you. I  
13 commend the developers for bringing this measure  
14 to us again. It was presented in 2010, as I  
15 understand. I do have some concerns about the  
16 overall measure construct as it's currently  
17 specified and tested. I'm going to share those,  
18 and then we'll go into evidence.

19 Good outcome measures based on either  
20 patient-reported outcome tools or  
21 clinician-reported assessment tools can be built  
22 and implemented into clinical practice. Along

1 with these measures, it's a good idea to have an  
2 accompanying paired process measure to understand  
3 the rate at which the assessments are being  
4 performed. The process of simply administering a  
5 tool really can't stand by itself and should be  
6 considered with an outcome measure.

7 The follow up of vital status of  
8 assessment of alive or deceased, I'll also note  
9 that the time frame for follow up could be stated  
10 more clearly. The registry algorithm credits 21  
11 to 60 days; the recommendation is a 30-day follow  
12 up. So in terms of assessing patients, it's just  
13 important to clearly state what your window of  
14 time is that you're allowing for numerator  
15 credit.

16 And then I have, also, some concerns  
17 about the fields that were listed in the  
18 specification in terms of the actual calculation  
19 of the measure. I think that there could be some  
20 enhancements or improvements there.

21 So, going into evidence. The  
22 evidence, as stated, is insufficient for a

1 process measure. As a reminder, process measures  
2 need strong evidence that they should be done for  
3 each and every patient going forward. The first  
4 citation relates to an upgraded guideline, with  
5 recommendation to monitor neurological outcomes.  
6 And the second relates to non-invasive imaging,  
7 which is not a part of this measure.

8 If it was an outcome measure, then  
9 some of the steps in the process flow submitted  
10 make sense, but it is simply a process of  
11 administering a tool and assessing for mortality,  
12 which are not linked strongly to the desired  
13 outcome. The desired outcome is improved quality  
14 of care, so how do we know when we've hit that  
15 outcome? I'll open that for discussion of  
16 evidence.

17 CO-CHAIR FLEISHER: Liz, and then  
18 Fred.

19 MEMBER EREKSON: I would just echo,  
20 slightly, what Collette's saying, that this  
21 measure, the way that I'm reading it and the way  
22 that it's written, is that what we are measuring

1 is if the stroke scale was performed at 30 days  
2 and we have that, not what the stroke scale was.  
3 So it is a process outcome.

4 And so when I'm reading through all of  
5 the information and evidence presented, multiple  
6 societies agree that it's a good idea to do this  
7 exam, but I did not find evidence that said that  
8 patients who had this exam done did better at a  
9 year, two years, five years than patients who did  
10 not have this exam done.

11 CO-CHAIR FLEISHER: Fred, did you have  
12 a comment? And then Cliff.

13 MEMBER GROVER: Yeah, I'm just kind of  
14 curious how this came about. What surgical  
15 involvement do you have, as in people that are  
16 actually doing the procedure?

17 DR. GRAY: Restate that, please?

18 MEMBER GROVER: This is out of the  
19 American College of Cardiology. I thought it  
20 might be out of the Society of Vascular Surgeons.  
21 You have cardiologists doing endarterectomies?

22 DR. GRAY: No, sir, surgical, but over

1 180 hospitals are involved with the registry.  
2 The registry is inclusive, with over 12½ thousand  
3 stenting procedures involved in the registry, as  
4 well. So I think the value to overall healthcare  
5 is the complete collection of datasets from  
6 hospitals, not just divided according to turf and  
7 specialty.

8 MEMBER GROVER: I just was, I suppose,  
9 wondering if you incorporated them in the  
10 process. I knew about your following the  
11 endovascular ones and their college.

12 DR. GRAY: Sure. Certainly, the  
13 multispecialty CREST trial utilizes similar data  
14 points, and acceptable end points, if you will.  
15 Having an adjudicated neurologic assessment is  
16 terribly important. It just hasn't been done.  
17 In order to get to outcomes, we've got to measure  
18 something. And to say, well, we don't have any  
19 consistent use of this stroke scale yet, how are  
20 we going to get it if we don't start measuring  
21 something? And as you know, there's tremendous  
22 contention in regards to who's performing what



1 and let's make it clear.

2 They're surgeon-performed  
3 endarterectomies, but that doesn't mean that the  
4 collection of that information, done in a  
5 systematic, comprehensive, quality way, wouldn't  
6 provide a meaningful tool that potentially could  
7 be used for outcome assessment in the future.  
8 And I think that's what we're driving for in the  
9 process part, is we need to measure it, and not  
10 just say, well, it's not been done yet, or  
11 somebody else needs to do it.

12 MEMBER GROVER: Okay, I get that.  
13 Yes, thank you.

14 CO-CHAIR FLEISHER: Cliff?

15 MEMBER KO: I have a couple questions.  
16 Number 1 is that this for carotid endarterectomy;  
17 does this also include stenting, or is that going  
18 to be a separate measure?

19 DR. GRAY: That's already been an  
20 approved measure, No. 2396.

21 MEMBER KO: So it's basically this  
22 same measure, except this is for carotid

1       endarterectomy?

2                   DR. GRAY:   Correct.

3                   MEMBER KO:   Isn't there a post-carotid  
4       endarterectomy stroke measure, an outcome  
5       measure?   Because we keep on hearing from CMS  
6       that they would rather have outcomes than  
7       process, and so this is a process measure to  
8       evaluate it, but it's getting to the stroke issue  
9       of post-operative stroke. Is that a measure?

10                  DR. GRAY:   It's getting there.

11                  MEMBER KO:   But is there not measure  
12       already, or is that on the list?

13                  DR. GRAY:   No.   There's no comparable  
14       measure.

15                       (Off the record comment.)

16                  MEMBER KO:   So there is a measure  
17       already for post-op?   So this is basically, if we  
18       fulfill that measure that's maintained, then this  
19       is kind of a duplicate, because it's the process  
20       to the outcome?

21                  CO-CHAIR FLEISHER:   Karen, do you want  
22       to make some comment?   No?   You're staying quiet?

1       Okay.   Sal?

2                   MEMBER SCALI:   If I may, I'm a  
3       vascular surgeon.   I think you're probably  
4       looking at trying to standardize the way that the  
5       strokes are adjudicated, because there's always a  
6       lot of variability in the literature about who's  
7       measuring what, just like wound infection, etc.  
8       Is that sort of the spirit of this, is you're  
9       trying to institute some type of more strict  
10      criteria of who says or who's qualified to make  
11      the diagnosis of stroke?

12                   Because one of the issues, whenever  
13      you look in the literature, is just like wound  
14      infection, just like any other complication after  
15      procedures, who's measuring it, and how's it  
16      being measured?   And what is the definition of a  
17      stroke?   Is it neurologist says it?   Is it  
18      radiologic?   Or is it just some clinician,  
19      whether it's a physician extender, resident,  
20      whatever, who sees the patient at those time  
21      points and says, bing, they hit some NIH Stroke  
22      Scale assessment, so we're going to call it a

1 stroke?

2 DR. GRAY: Extremely germane comment.  
3 And that's why the use of a certified NIH Stroke  
4 Scale person is required, so that you have a  
5 standard. And that standard is universally  
6 accepted, I would believe, in the clinical arena,  
7 certainly is the standard for randomized control  
8 trials. And I think the extrapolation into real  
9 world makes sense as a routine.

10 CO-CHAIR FLEISHER: I think that's  
11 probably validity, when we get back to -- but  
12 other comments on evidence? A.J.?

13 MEMBER YATES: Is there any literature  
14 at all stating that there's a relationship  
15 between this outcome with a better patient  
16 result?

17 DR. GRAY: Certainly, the NIH Stroke  
18 Scale relates directly to long- and short-term  
19 outcomes.

20 MEMBER YATES: But the process  
21 occurring, is there anything to say that changes  
22 the outcome?

1 DR. GRAY: No, sir, that's not been  
2 measured to-date.

3 CO-CHAIR FLEISHER: Okay, we will  
4 vote, but Karen's going to talk to us first. Now  
5 she's ready.

6 MS. JOHNSON: Let me explain a little  
7 bit about our process for these kind of measures.  
8 If it's sounding like you may be thinking that  
9 this measure doesn't have the evidence required,  
10 and that an exception may be warranted, we do  
11 have an option for what we call an exception to  
12 evidence that you can invoke.

13 If you are thinking that's how you  
14 want to go, we need you to vote insufficient on  
15 this vote, and then we would have a separate vote  
16 that you would say up or down, yes or no, we want  
17 to invoke the exception. If you are not  
18 interested in invoking the exception, then, of  
19 course, you would not say insufficient there. It  
20 would be more low. Actually, that's not exactly  
21 right. You could still say insufficient, but we  
22 need more than 60 percent of the voting members

1 to land on insufficient before we could even talk  
2 about going to exception. So, I hope I didn't  
3 confuse you. Do you need me to repeat it again?

4 CO-CHAIR FLEISHER: Collette?

5 MEMBER PITZEN: This is Collette. I  
6 don't want to be too negative, but there has been  
7 a space of six years between when this measure  
8 first came, and now it's coming to us again,  
9 pretty much with the same feedback. So I'm not  
10 sure that the measure itself is strong enough to  
11 warrant insufficient with an evidence exception,  
12 unless there's a strong feeling that this would  
13 get the NIH stroke tool out there. I have some  
14 concerns around that to a hospital-based measure.  
15 Their follow-up rate, I forget the rate list, but  
16 the actual administering of the stroke tool is  
17 less than 2 percent.

18 CO-CHAIR FLEISHER: Okay, Christy?

19 MS. SKIPPER: We're now voting on  
20 evidence for Measure 3024: 1 high, 2 moderate, 3  
21 low, 4 insufficient.

22 Did someone leave the room? If we

1 could just all aim once more.

2 (Voting.)

3 MS. SKIPPER: Okay, with 22 votes, we  
4 have zero percent high, zero percent moderate, 59  
5 percent low, 41 percent insufficient. The  
6 measure does not pass on evidence, and we will  
7 stop discussion of it here.

8 CO-CHAIR FLEISHER: So, John?

9 MEMBER HANDY: I just want a point of  
10 clarification. In the evolution of measure  
11 development, process is where we started.  
12 Historically, I think many of the processes had  
13 very good evidence behind them, internal mammary  
14 artery and coronary artery bypass, but is there a  
15 precedent for this sort of process measure being  
16 approved? Because I'm sympathetic to the  
17 developer's statement that we've got to start  
18 measuring something. And this is a meaningful  
19 outcome, if you can demonstrate stroke.

20 CO-CHAIR FLEISHER: The staff can  
21 comment, but we have said if there's no outcome  
22 in this space, process is certainly sufficient.

1 Cliff?

2 MEMBER KO: If the process is to  
3 evaluate for stroke, and there is a stroke  
4 outcome measure, but it's done, as someone was  
5 saying, all kinds of different ways, is this  
6 potential harmonization, that if it's going to be  
7 a stroke, it is done this way, if that is the  
8 issue? Or is that not the issue?

9 If we're measuring stroke in the  
10 outcome stroke measure, and everyone does it --  
11 someone was like, I'm a colon surgeon, that looks  
12 like a stroke, it's a stroke -- if that's wrong,  
13 and we have to all do it using this process  
14 method, is that worthy of a harmonization of the  
15 process leading to that outcome measure -- within  
16 the outcome measure? Just throwing it out there.

17 CO-CHAIR FLEISHER: It's up to the  
18 developer to decide.

19 MEMBER KO: When the college was asked  
20 to harmonize something with the CDC, it came from  
21 the NQF.

22 CO-CHAIR FLEISHER: Right, but that



1 was -- I assume that's an approved measure.

2 MEMBER KO: No.

3 CO-CHAIR FLEISHER: No?

4 MEMBER KO: While it was going through  
5 this.

6 DR. BURSTIN: Cliff's referring to  
7 efforts we did early on to harmonize and actually  
8 come together on the CDC and the college's  
9 measures around surgical site infection. My  
10 understanding, at least from the neurology side  
11 -- and we've had a lot of these discussions about  
12 potential inclusion of the NIH Stroke Scale in  
13 risk adjustment, for example, for stroke  
14 patients. The NIH Stroke Scale, I think, is  
15 clearly the one that had been most identified as  
16 the leading candidate. The question that has  
17 come up, I believe, when we've talked about this  
18 in other committees, as well, is the idea that it  
19 requires a certified person who knows how to  
20 administer the process, administer the test.

21 But you need to speak to what happened  
22 in -- did this come up in cardiology, as well?

1 Do you want to speak to the discussion there,  
2 just for consistency?

3 MS. MUNTHALI: The cardiology  
4 committee landed in much of the same places as  
5 this committee. We missed much of the  
6 discussion, but it sounds like, from the recap  
7 that Karen gave me, they struggled with many of  
8 these same issues.

9 CO-CHAIR FLEISHER: So we don't move  
10 forward. Any other recommendations from the  
11 committee or staff? Barbara?

12 MEMBER LEVY: I just want to point out  
13 that this process is something that's validated  
14 and used in clinical trials. That doesn't  
15 necessarily mean that it should be extrapolated  
16 and used clinically for all patients, at all  
17 times. It's a costly -- Fred was just doing  
18 this, but this would be an added cost that may or  
19 may not be clinically relevant.

20 To Cliff's point, if we have a measure  
21 already in existence that looks at clinical  
22 stroke, we may tweak that measure to make it a

1 little bit better, but to say that we need to use  
2 a research tool that's excellent and perfect for  
3 research, and use that clinically, I think that's  
4 a stretch that probably we're not ready to go  
5 that far.

6 CO-CHAIR FLEISHER: Thank you.

7 DR. GRAY: Could I just comment to  
8 that?

9 CO-CHAIR FLEISHER: Please.

10 DR. GRAY: I'm a little bit concerned  
11 that I didn't clarify the ease and ability to  
12 perform an NIH Stroke Scale. It's not just the  
13 purview of research people, but it needs to reach  
14 the bedside on a regular, consistent basis. And  
15 it just, quite frankly, is not. For me to say  
16 that I performed a procedure and the patient had  
17 no stroke, but to have a third-party independent  
18 observer say the same thing using objective,  
19 simple criteria that takes than less ten minutes,  
20 does not involve an MRI scan, does not involve  
21 the cost of an ultrasound, even, and could be  
22 part of the routine follow-up in the office, of

1       which most practitioners will see their patient  
2       within that time frame in the office, we're not  
3       talking about much additional cost.

4               Now, in regards to the acquisition of  
5       that skill, it's readily available online, and it  
6       would promote providers to obtain that skill  
7       level. And so my plea isn't to say that this is  
8       adding a lot of extra burden. It's going to put  
9       some objectivity to the bedside and extend it out  
10      beyond the hospital window.

11              CO-CHAIR FLEISHER: Okay, so just for  
12      staff's purposes, I want to just ask, the vote --  
13      because the majority felt it was low evidence,  
14      there is no exception to the evidence rule. If  
15      the majority had voted insufficient evidence, we  
16      could revote on whether there's an exception.  
17      Does anyone want -- people understand that? So  
18      essentially, we've said it's not going forward.  
19      Does anyone want a revote?

20              MEMBER BILIMORIA: Can I ask to  
21      clarify?

22              CO-CHAIR FLEISHER: Okay, Karl.

1                   MEMBER BILIMORIA: I think process  
2 measures are great. We don't have an outcome,  
3 that's fine. It's also great in the setting of a  
4 well-documented processes or a consensus panel  
5 that stated that a particular process is good for  
6 an improving an outcome, even if we don't have  
7 evidence to back it up.

8                   There are certain things in the wound  
9 infection bundle that don't have a tremendous  
10 amount of evidence behind them, but they're good  
11 processes to adhere to. I think one of the  
12 things that I was looking for was to hear whether  
13 there is, for this specific tool to be applied in  
14 every circumstance, whether there's broad ranging  
15 society approval for that, and maybe that, for  
16 me, might change the way I would think about  
17 this.

18                  DR. GRAY: Once again, we're trying to  
19 take a developing tool and make it more -- to  
20 create the value by recognizing that following  
21 patients objectively with some type of measure  
22 out beyond their hospital window is of value.

1                   MEMBER BILIMORIA: But have multiple  
2 societies said this is --

3                   DR. GRAY: Yes.

4                   MEMBER BILIMORIA: -- the thing to do?

5                   DR. GRAY: Without a doubt.

6                   MEMBER BILIMORIA: Can we go over --  
7 this specific instrument should be used all the  
8 time to evaluate stroke patients -

9                   (Simultaneous speaking.)

10                  DR. GRAY: It's a part of every  
11 randomized clinical trial assessing stroke. Now,  
12 you say is it used consistently in the real  
13 world? I would answer that no. I think that's  
14 no. Can it be? To the question in regards to  
15 cost, I think it was a very important question,  
16 but I thought the leading into the usability and  
17 the cost makes sense.

18                  CO-CHAIR FLEISHER: Okay, Liz, and  
19 then --

20                  MEMBER EREKSON: When I look at the  
21 entire measure, not just the evidence, we have  
22 12,000 patients who participate in the registry,

1 and the 30-day follow up is 58 percent. Of the  
2 12,000 patients who participated in the registry  
3 -- which is a wonderful undertaking to get that  
4 many patients in a registry and be collecting  
5 data on those patients -- only 2 percent of them  
6 had the stroke scale. What that tells me, while  
7 I'm reading the measure, is that the people who  
8 are invested in the registry, which are people  
9 who are already invested in the quality  
10 improvement efforts, are not invested yet in the  
11 stroke scale. So why is the actual process so  
12 low in the patients that were presented to us?  
13 Right now, it's at 2 percent. Can we get it  
14 higher without this being a quality measure?

15 DR. GRAY: I would say that the  
16 chances are less likely without some motivation.  
17 Now, why are people in the registry to begin  
18 with? Because it was mandated by CMS for you to  
19 be involved in stenting trials, and to be  
20 reimbursed on Medicare population, you had to be  
21 involved in the trial. So it wasn't without that  
22 carrot. Is it the chicken or the egg? We're

1 back to the same story.

2 If we don't start measuring something,  
3 we're not going to get any outcomes, and that's  
4 my plea. We've got to start measuring something  
5 that's objective without significant additional  
6 cost. You can't just run an MRI on everybody at  
7 30 days, and you're certainly not going to use  
8 duplex ultrasounds as a surrogate endpoint, and  
9 you're not going to take the surgeon's or the  
10 interventionist's word, per se, without some  
11 independent objective confirmation with a very  
12 simple scale. So that's my plea.

13 CO-CHAIR FLEISHER: So --

14 DR. BURSTIN: I was going to say that  
15 in some ways, this is -- I was just looking at  
16 Fred -- this is somewhat analogous to the very  
17 early days when STS came forward with measures  
18 that said, did you participate in a registry with  
19 benchmarking? Part of the logic presented back  
20 to us by STS at that time was it's what will help  
21 drive participation. I think this is a similar  
22 argument. The tendency is we think about



1 measures being fairly distal or proximal to the  
2 outcome.

3           This one's pretty distal, which is not  
4 our preference, but I do think the logical chain  
5 they're presenting is that if this is the  
6 dominant tool -- and I will say, from lots of  
7 discussions with the NIH Brain Attack Coalition  
8 around the stroke measures in the past, the lack  
9 of risk adjustment for the NIH Stroke Scale,  
10 there's a great deal of interest in trying to  
11 move towards this as the standardized tool. But  
12 you need to decide whether you think it's too  
13 distal for the outcome, or is it sufficiently  
14 close? That's the reason why I think Karen  
15 raised the specter of would you potentially be  
16 interested in reviewing the full measure and  
17 using the evidence exception, that you believe  
18 that the benefits to patients would significantly  
19 exceed the risks, even if you don't, in fact,  
20 have evidence right now that says use of this  
21 dramatically effects outcomes?

22           CO-CHAIR FLEISHER: Let me just call

1 one question first again. Do people want to  
2 revote based upon everything we hear? Is anybody  
3 asking for -- Barry would like a revote. Okay.  
4 Let's revote, and then we can continue the  
5 discussion.

6 MEMBER YATES: Can I ask a question?

7 CO-CHAIR FLEISHER: The question is --

8 MEMBER YATES: No, I had a question --

9 CO-CHAIR FLEISHER: Oh, you have a  
10 question. Go ahead, sorry.

11 MEMBER YATES: This is the act of  
12 doing it, but is there, as part of the measure, a  
13 repository where the end result goes? Because  
14 that would be more consistent with the STS  
15 argument because they had a registry that  
16 collected it. Does this require it being  
17 captured by the registry?

18 DR. GRAY: It doesn't require it to be  
19 captured by the registry. It is available to be  
20 captured by the registry.

21 MEMBER YATES: See, I would make an  
22 argument that it's different than the STS because

1 they would have required their registry to  
2 capture the things that they were asking to be  
3 captured. It just needs that extra step.

4 DR. GRAY: Maybe I didn't understand  
5 your question. Without it, yes, it's captured  
6 three times. In CS, it's captured three times in  
7 pre-procedure, within the hospital stay, and at  
8 30 days.

9 MEMBER YATES: So the act of doing it  
10 actually gets it put into the register, so it  
11 could be utilized?

12 DR. GRAY: Yes.

13 MEMBER YATES: That's a big  
14 distinction.

15 DR. GRAY: Yes.

16 MEMBER YATES: That's why I'm asking  
17 the question. I think people are focused on the  
18 process happening, but there's an end result in  
19 which place there's a repository. Okay.

20 CO-CHAIR FLEISHER: So the vote -- and  
21 correct me if I'm wrong -- if you believe that  
22 there's low or insufficient evidence, but there

1 might be a rationale for an exception, then vote  
2 insufficient. If you believe there's low  
3 evidence, but there is not a rationale for an  
4 exception, then vote low. Correct, Karen?

5 MS. JOHNSON: Or -- and this is my  
6 fault for not being clear enough earlier -- if  
7 you feel like you do not want to go with an  
8 exception, but you still feel that the evidence  
9 is insufficient, that's fine to vote insufficient  
10 here. If more than 60 percent say insufficient,  
11 we will go to the vote yes or no for exception,  
12 and you can decide then if you want to do the  
13 exception. In other words, you don't have to  
14 vote low to make sure that it doesn't go through  
15 on an exception.

16 CO-CHAIR FLEISHER: Thank you.

17 MS. SKIPPER: We're now voting on  
18 evidence for Measure 3024, 1 high, 2 moderate, 3  
19 low, 4 insufficient.

20 (Voting.)

21 MS. SKIPPER: There was an error.  
22 We're going to revote for Measure 3024, 1 high, 2

1 moderate, 3 low, 4 insufficient.

2 (Voting.)

3 MS. SKIPPER: Just a second. I'm  
4 having a technical difficulty. Let's try this  
5 again. Voting is open for Measure 3024, high  
6 moderate 1, 2 moderate, 3 low, 4 insufficient --  
7 1 high, 2 moderate, 3 low, 4 insufficient.

8 (Off the record comments.)

9 CO-CHAIR FLEISHER: Yes. Okay, all  
10 those who believe high, raise your hand.

11 (Show of hands.)

12 CO-CHAIR FLEISHER: Moderate?

13 (Show of hands.)

14 CO-CHAIR FLEISHER: Low?

15 (Show of hands.)

16 CO-CHAIR FLEISHER: Nobody voted until  
17 now. One, two, three, four, five, six, seven,  
18 eight, nine, ten, eleven. Is that correct?

19 (No response.)

20 CO-CHAIR FLEISHER: All those who vote  
21 insufficient? One, two, three, four, five, six,  
22 seven, eight.

1 MS. SKIPPER: Dr. Cima voted as well.

2 CO-CHAIR FLEISHER: What did he vote?

3 MS. SKIPPER: Low.

4 CO-CHAIR FLEISHER: Low. So it's 12 to  
5 eight. So, 12 for low.

6 MS. SKIPPER: That's 20 votes.

7 CO-CHAIR FLEISHER: I think we've done  
8 this twice and I've gotten the same result.

9 MS. SKIPPER: I'm just going to, for  
10 the record, state it. So sixty percent votes were  
11 for low, 40 percent for insufficient, so the  
12 measure does not pass on evidence, and we will  
13 stop the discussion.

14 DR. GRAY: Thanks for having us.

15 CO-CHAIR GUNNAR: So moving on to the  
16 next measure, 1519, statin therapy at discharge  
17 after lower extremity bypass, Society of Vascular  
18 Surgery, who are coming to the table.

19 DR. JOHNSON: Hello, I'm Brad -- go  
20 ahead.

21 CO-CHAIR GUNNAR: Welcome, and you  
22 have your three minutes.

1 DR. JOHNSON: I'm Brad Johnson. I'm  
2 a vascular surgeon. I'm chairman of the Quality  
3 Performance and Measures Committee for the  
4 Society of Vascular Surgery. We're here to talk  
5 about five different maintenance issues. I'm  
6 going to talk about the first two. 1519, I'm  
7 going to limit my discussion on this since the  
8 other four have many more questions to be  
9 addressed.

10 So for the second time, I'll limit my  
11 discussion on 1519 to the fact that statins have  
12 already been shown to decrease the perioperative  
13 mortality and morbidity of our lower extremity  
14 bypass operations. We do have a compliance  
15 problem with range from maybe 1 percent up to --  
16 down to 76 and back 79 percent in 2015, so there  
17 is room for improvement with this measure. I'll  
18 limit my comments to that.

19 CO-CHAIR GUNNAR: Discussants are Drs.  
20 Olsen and Saigal. Dr. Olsen?

21 MEMBER OLSEN: As you can see, this is  
22 up for a process measure up for approval again,

1 originally in 2012. The data's really relatively  
2 constant over the last four years, with about 75  
3 to 80 percent reporting, ranging from 69 to 84  
4 percent.

5 CO-CHAIR GUNNAR: As this is a  
6 maintenance measure, any other need to revote on  
7 the evidence? Seeing none, we will carry forward  
8 to gap.

9 MEMBER OLSEN: The gap original goal  
10 was a 90 percent. There's still a range, as  
11 indicated, of around 69 percent to 84 percent in  
12 compliance with the measure.

13 CO-CHAIR GUNNAR: Chris, anything else  
14 you want to say?

15 MEMBER SAIGAL: I agree. There's  
16 still a gap.

17 CO-CHAIR GUNNAR: Very good. We can  
18 vote. Christy?

19 MS. SKIPPER: Voting is open for  
20 Measure 1519 on performance gap, 1 high, 2  
21 moderate, 3 low, 4 insufficient.

22 (Voting.)



1 MS. SKIPPER: On performance gap, 76  
2 percent votes were high, 24 percent moderate, 0  
3 percent low, 0 percent insufficient. The measure  
4 passes on performance gap.

5 CO-CHAIR GUNNAR: Moving to  
6 reliability. Dr. Olsen?

7 MEMBER OLSEN: Let me find my place  
8 here real quick. Reliability has been tested in  
9 100 patients from five institutions or over a  
10 two-year period, with 100 percent compliance  
11 rate, although it's probably low, considering  
12 there's 23,000 patients that have been evaluated  
13 over that -- over a five-year period.

14 MEMBER SAIGAL: I have one comment and  
15 question for the developer. They include in here  
16 the kappa statistic for the numerator, which I  
17 think is more of a validity measure, but it's 80  
18 percent agreement with the -- whether statin was  
19 actually prescribed or not. Is that acceptable  
20 to the registered participants if they're being  
21 used to -- say be measured in terms of  
22 value-based purchasing, is that acceptable, in

1 terms of the validity of the measure?

2 DR. JOHNSON: Yes, you're correct. It  
3 is more validity. I'd like for it to be better  
4 than that. That's not acceptable. So hopefully,  
5 we can improve upon that aspect.

6 CO-CHAIR GUNNAR: So we'll address  
7 audits and that sort of thing in the next  
8 section. John?

9 MEMBER HANDY: That's exactly my  
10 question. Actually, this kind of goes to some of  
11 the other SVS measures being proposed. I'm a  
12 little confused as to what you're using. You've  
13 got a New England database. You've got a Society  
14 of Vascular Surgery database. You don't really  
15 distinguish between them. You kind of use the  
16 New England one as the primary data source, and I  
17 don't really know what the penetrance of these  
18 databases is and the adherence to them.

19 DR. JOHNSON: Yes, that's a good  
20 question, and hopefully I can answer for the next  
21 couple measures because there was a lot more  
22 questions. Yazan, go ahead and introduce

1       yourself.

2                   DR. DUWAYRI:   Yazan Duwayri.   I'm a  
3       vascular surgeon at Emory.

4                   DR. JOHNSON:   This was a maintenance  
5       -- of course, it's a maintenance measure.   All of  
6       the development was done based upon most of the  
7       data from the New England registry, which  
8       eventually evolved into the Vascular Quality  
9       Initiative database.   We have updated data based  
10      upon the Vascular Quality Initiative with  
11      validity results and so forth that we didn't send  
12      in to you.   We can get that data to you.   Maybe  
13      it's our fault that we were thinking maintenance,  
14      and we didn't do the amount of work needed for  
15      validity and reliability.   But yes, the New  
16      England database is now the Vascular Quality  
17      Initiative database, which covers the country,  
18      which has 400 and some centers in it and, across  
19      the board, includes 30 percent academic  
20      practices, 30 percent private practices, has  
21      cardiologists in it, has interventional  
22      radiologists in it.   So it's become a very

1 powerful database. If you need more validity and  
2 reliability data from that, we're glad to provide  
3 that. Any other comment?

4 DR. DUWAYRI: Yes, I think that covers  
5 most -- VSGNE, which is the Vascular Study Group  
6 of New England, is the parent study group of VQI.  
7 It basically -- it reflects the same thing. It's  
8 currently a regional group of VQI among many  
9 other regional groups covering the entire  
10 country.

11 MEMBER HANDY: But it's a  
12 self-reported registry, you sign on as a  
13 participant, and you submit data?

14 DR. JOHNSON: Yes, it is  
15 self-reporting yet. For instance, in 2015, they  
16 went back in and audited. We do audit and  
17 validation studies in each hospital and each  
18 provider that participates in it. We have  
19 quality measures and auditing measures into the  
20 system.

21 DR. DUWAYRI: Yes, the claims data are  
22 -- you have to enter 100 percent of your

1 procedures, it's not selective, and the claims  
2 data are tested against data entered in VQI.  
3 That's a way of maintaining the integrity of the  
4 data.

5 CO-CHAIR GUNNAR: But in regards to  
6 reliability, it's a question -- this is a  
7 particular question in the registry that they  
8 submit, are you -- is your statin therapy -- is  
9 it there, present at discharge, yes or no, and  
10 you report that in the registry?

11 DR. DUWAYRI: Correct. It's a  
12 registry entered by data managers and  
13 abstractors, yes, correct.

14 CO-CHAIR GUNNAR: Fred?

15 MEMBER GROVER: What's your  
16 penetration? What percentage of your vascular  
17 surgeons in the U.S. participate in this  
18 database?

19 DR. DUWAYRI: I don't have an actual  
20 percentage, but the number is growing. We are  
21 growing annually, and now we've reached close to  
22 500 medical centers. I think the growth rate is

1 very fast. Sal may want to --

2 MEMBER SCALI: I'm Sal. I'm a  
3 vascular surgeon from the UF. There are 3,100  
4 vascular surgeons that are board certified in the  
5 United States. Currently, there are over 2,000  
6 providers in the VSG or VQI, 48 percent of them  
7 are vascular surgeons. If you do the rough math,  
8 it's about a third of the vascular surgeons in  
9 the United States currently participate in the  
10 VQI.

11 It doesn't mean that they all  
12 participate in those modules. Because when you  
13 participate, you may just participate in venous  
14 disease and not report your carotid outcomes. To  
15 your question, how many vascular surgeons in the  
16 VQI represent what's going on nationally with  
17 carotid-based care, I don't have the specific  
18 numbers, but about a third of the vascular  
19 surgeons in the U.S. participate in some manner  
20 in the registry.

21 DR. DUWAYRI: Just to answer that  
22 question. The data currently has 914 providers

1 participating in the infrainguinal bypass module,  
2 which we are covering in this measure, so 914 out  
3 of the total number of vascular surgeons, so  
4 around 30 percent -- 25 to 30 percent.

5 CO-CHAIR GUNNAR: Any other comments?  
6 Chris, anything you want to add to reliability?

7 MEMBER SAIGAL: On this topic, no. My  
8 only question was about that validity question,  
9 but I guess it's acceptable to the members that  
10 are using it.

11 CO-CHAIR GUNNAR: Any other discussion  
12 regarding reliability? Hearing none, voting.

13 MS. SKIPPER: I would like to note  
14 that testing was completed -- reliability testing  
15 was completed with patient-level data elements,  
16 and according to our algorithm, the highest  
17 rating this measure could get on this criteria is  
18 moderate. Now, you'll be voting 1 for moderate,  
19 2 for low, 3 insufficient.

20 (Voting.)

21 MS. SKIPPER: Voting has closed for  
22 reliability on Measure 1519, 82 percent votes

1 moderate, 18 percent low, 0 percent insufficient,  
2 and the measure passes the reliability.

3 CO-CHAIR GUNNAR: So we'll move on to  
4 validity. I'll turn to the developers  
5 anticipating the audit questions. Maybe you can  
6 fill us in on how you validate the data that's in  
7 the registry.

8 DR. DUWAYRI: So again, we did not do  
9 new validity testing. The testing that was  
10 performed was performed at the time of the  
11 initial submission of the measure, and it was  
12 performed by a random sampling of around 100  
13 procedures representative of the procedures  
14 enrolled in VQI and abstracting the data  
15 separately by separate data abstractors and  
16 comparing that to the data already existing in  
17 VQI. I don't have the -- the results are present  
18 in our submission.

19 CO-CHAIR GUNNAR: Dr. Olsen?

20 MEMBER OLSEN: I don't have any  
21 additional comments to that.

22 CO-CHAIR GUNNAR: Chris?



1                   MEMBER SAIGAL: Don't remember what I  
2                   said.

3                   CO-CHAIR GUNNAR: Any other discussion  
4                   regarding validity? I think we're open to  
5                   voting. Oh, I'm sorry.

6                   MEMBER TEMPLE: When we have  
7                   self-report data that goes into registries and  
8                   there's an audit process and that's how the  
9                   registry presented the data before, do you think  
10                  as this committee, sort of it behooves us every  
11                  three years that another check of validity's  
12                  done? In that if a measure becomes reportable,  
13                  you could see how, potentially, people start  
14                  changing how they do self-report.

15                  I wonder if, when we ask for  
16                  maintenance, whether we need to say we need to  
17                  see the same kind of -- we need to do an audit.  
18                  You need an audit for the three years between the  
19                  endorsements? It's a question. I don't know the  
20                  answer.

21                  CO-CHAIR GUNNAR: Certainly, that  
22                  audit process is in other registry -- ingrained

1 in their SOPs. Helen, do you want to comment?

2 DR. BURSTIN: Karen and I were just  
3 having an offline conversation about the need to  
4 pull together our stats consultants to kind of  
5 have a relook, broadly, at what's required for  
6 validity. I think we will add that to the list  
7 because I think that's a fair question is if a  
8 measure's in use, how does it change, and how  
9 does audit fit into that? That's not something  
10 we have as a requirement right now.

11 MEMBER TEMPLE: The other question I  
12 had is how much missing data is there with that  
13 statin reporting?

14 DR. DUWAYRI: I don't have that data  
15 available right now.

16 DR. JOHNSON: M2S, or it's called  
17 streamlining, is now running our database now. I  
18 didn't send this to the committee, but they, in  
19 2015, put out a PQRS Validation Execution Report.  
20 They're going in and looking at our data. That  
21 one they submitted on behalf of 65 vascular  
22 physicians participating in the 2014 PQRS

1 program. They looked at 12 measures and went  
2 through and did an audit on that, looking at ten  
3 numbers in NPI combinations and stuff. So there  
4 is ongoing auditing and validation going on  
5 within our registry.

6 CO-CHAIR GUNNAR: Is there any feeling  
7 that we should delay a vote until we have this  
8 information?

9 MEMBER SAIGAL: There's 2 percent  
10 missing data, they report, so it wasn't a very  
11 large amount.

12 CO-CHAIR GUNNAR: We have the answer.  
13 Any further -- Collette, yes, and Rick.

14 MEMBER PITZEN: I have a question. In  
15 the reliability section, the kappa statistic for  
16 statin at discharge was .8. I don't know if that  
17 means agreement, but in the validity, in your  
18 random sample of 100, I would expect that you  
19 would have a fairly high capture of statin at  
20 discharge, so I'm just trying to understand the  
21 difference between the two.

22 CO-CHAIR GUNNAR: Can you answer?

1 DR. DUWAYRI: Again, this testing was  
2 performed a while ago, at the time of initial  
3 submission. I'm sorry?

4 MEMBER PITZEN: The validity? Okay.

5 DR. DUWAYRI: Yes, the testing we  
6 submitted was the previous testing submitted at  
7 the time of initial submission.

8 MEMBER SAIGAL: I think the validity  
9 testing, to your question, that they report is  
10 really between the discharge summary and the  
11 discharge orders, not between the registry and  
12 the discharge orders. I think measuring the  
13 validity is something else they couldn't quite  
14 follow. The key part of validity here was in  
15 reliability, the kappa statistics. Looking at  
16 what they actually captured, it was 80 percent.  
17 That is just a question for vascular surgeons, I  
18 think, if that's okay with them, which I think I  
19 would have to answer that it is.

20 MEMBER DUTTON: I'm just going to note  
21 quickly looking at the kappa statistics, the  
22 reviewers agreed highly on what procedure was

1 done, 80 percent on whether a statin was given,  
2 100 percent agreement on the patient's age, but  
3 only 90 percent agreement on whether the patient  
4 died or not. I found that curious..

5 CO-CHAIR GUNNAR: I believe that's a  
6 point of fact and needs to be evaluated in your  
7 decision regarding validity.

8 CO-CHAIR FLEISHER: I urge people to  
9 read Tom Lee's editorial in the New England  
10 Journal last week about the death of one of his  
11 patients.

12 CO-CHAIR GUNNAR: Any other  
13 discussion? Anyone feel that we should not move  
14 to vote on validity because we need additional  
15 information? Seeing none, I will carry forward.

16 MS. SKIPPER: All right. We're now  
17 voting on validity for Measure 1519, the highest  
18 possible rating is moderate, so you will be  
19 voting 1 for moderate, 2 for low, 3 insufficient.

20 (Voting.)

21 MS. SKIPPER: Voting has closed for  
22 validity on Measure 1519, 68 percent votes

1 moderate, 23 percent low, 9 percent insufficient.  
2 This measure moves forward on validity.

3 CO-CHAIR GUNNAR: Dr. Cima, do you  
4 have a question? I see your -- don't hesitate to  
5 speak up. He's not locked out, is he, from  
6 commenting over the line? You have an open line,  
7 so feel free. Chime in whenever he'd like.  
8 Next, we move on to feasibility. It's a  
9 maintenance measure, but evaluated independently  
10 every time it comes up. Dr. Olsen?

11 MEMBER OLSEN: I was wondering we  
12 should use the reporting, it's high, so usability  
13 from that standpoint is very easy. If you're  
14 not, you're not involved. It's less than 2  
15 percent missing data, as we've already indicated.

16 CO-CHAIR GUNNAR: Chris, anything  
17 else?

18 MEMBER SAIGAL: We discussed this  
19 before. This is a registry measure, so it's only  
20 feasible if you're part of the registry, and  
21 usable. To the degree to which that's a barrier,  
22 that's a barrier, but I think it's feasible and

1       usable if you're in the registry.

2                   CO-CHAIR GUNNAR: Do you report this  
3 data anywhere else, other than to participants?

4                   DR. DUWAYRI: No.

5                   CO-CHAIR GUNNAR: All right, I think  
6 we're ready to vote.

7                   MS. SKIPPER: We're voting on  
8 feasibility for Measure 1519, 1 high, 2 moderate,  
9 3 low, 4 insufficient.

10                   (Voting.)

11                   MS. SKIPPER: Voting is closed for  
12 feasibility, 9 percent votes high, 86 percent  
13 moderate, 5 percent low, 0 percent insufficient.  
14 This measure passes feasibility.

15                   CO-CHAIR GUNNAR: Moving on to  
16 usability. Dr. Olsen?

17                   MEMBER OLSEN: Yes, usability is  
18 reported through the PQRS web payment website.  
19 There's no other, really, data available.  
20 Developer doesn't report whether it has any  
21 potential harms in this area. Really pretty  
22 straightforward.

1 CO-CHAIR GUNNAR: Chris, anything  
2 else?

3 MEMBER SAIGAL: Yes, I agree.

4 CO-CHAIR GUNNAR: All right. Any  
5 other discussion? Yes, Larry?

6 MEMBER MOSS: I understand the measure  
7 is being used. I have a question about the  
8 impact it's having. When the measure was  
9 initially submitted, the rate of statin use was  
10 in the 40 percent range, went up very quickly to  
11 79 percent, and then over the last five years has  
12 essentially been unchanged.

13 That still means that 20 percent of  
14 patients aren't getting this clearly valuable  
15 therapy. Any comments on how we could do better?  
16 And a corollary question is this is in registry  
17 participants, I've got to assume, across the  
18 globe, outside of the registry, the rate's even  
19 worse than this.

20 DR. JOHNSON: Yes, especially since  
21 reimbursement is going to be changing. We think  
22 that we can get this measure up higher than we



1 currently are at 80 percent. The good thing  
2 about VQI is we are doing clinical improvement  
3 activities across the registry, and we do it in  
4 regions.

5 For instance, we realize that our  
6 surgical wound infection was higher in people  
7 that use the old-fashion betadine prep for  
8 prepping, so we sent that message back to our  
9 participants and told everybody they needed to  
10 change that.

11 Subsequently, our surgical wound  
12 infection went down. The same thing, I think,  
13 will occur here, now that people will be a little  
14 more incentivized to follow recommendations of  
15 the group, as a whole, that we know statins  
16 decrease mortality and morbidity with our lower  
17 extremity operations. We're at 80 percent.

18 This is a measure we need to address  
19 and get up into the 90s, 90 percent. I think  
20 that we certainly have room for improvement, and  
21 I think our society in VQI has the ability to  
22 communicate back to not only the participants in

1 this, but taking data from this database, when we  
2 go to our society meetings, we're able to  
3 communicate that same message back to all the  
4 members of our society, all the vascular  
5 surgeons.

6 MEMBER SCALI: I'll just add to that.  
7 Part of the issue with the number not changing  
8 all that much is that the VQI has seen a rapid  
9 proliferation of centers coming online in the  
10 last three to four years, the most rapid growth.  
11 If you look at the more mature centers, over  
12 time, they're actual statin utilization rates  
13 approach 90 percent.

14 It's just that with newer centers,  
15 that's not -- you're sort of bringing them into  
16 the fold, telling them about the initiatives that  
17 are already -- and then they have to sort of put  
18 that into their process of care. There's been a  
19 bit of a lag that you'll see on things like wound  
20 infection, statin utilization, etc.

21 MEMBER SAIGAL: One comment about  
22 that. If you consider that the reliability is 80

1       percent, or the validity's 80 percent of the  
2       measure, and you're peaking at 80 percent, in  
3       terms of use, I wonder how much of that is  
4       measurement error? Maybe you're getting better  
5       performance than you know.

6               DR. DUWAYRI: That's one of the things  
7       that has to be improved. I think it gets  
8       improved when we keep this measure going.

9               MEMBER KO: Can you clarify one of  
10      your statements? Because the information we got  
11      from your packet was that you're reporting this  
12      publicly through PQRS. Is that --

13              DR. DUWAYRI: Yes, I wanted to correct  
14      myself to say that. I thought there -- other  
15      than this public reporting, if you were asking  
16      about other entities that we report to.

17              MEMBER KO: Sorry, can you say that  
18      again? That was my question. This is a PQRS  
19      measure?

20              DR. DUWAYRI: Yes, all five measures  
21      we are submitting today are PQRS measures.

22              MEMBER KO: Okay.

1 CO-CHAIR GUNNAR: Yes, A.J.

2 MEMBER YATES: Since it applies to all  
3 the measures, is that PQRS through QCDR?

4 (Simultaneous speaking.)

5 DR. JOHNSON: Through the measures  
6 group, yes.

7 MEMBER YATES: The distinction being  
8 is that an eMeasure or something that's reported  
9 by the self, it's being reported twice, then. If  
10 it's being reported to the registry and reported  
11 by the surgeon, himself, then it doesn't make  
12 sense, but if it's QCDR, then it's going through  
13 your registry, and then to CMS.

14 DR. JOHNSON: Correct, it's going  
15 through our registry, then through that, yes.

16 MEMBER KO: So this is QCDR, not  
17 qualified registry?

18 DR. JOHNSON: Right.

19 CO-CHAIR GUNNAR: Usability for this  
20 maintenance measure.

21 MS. SKIPPER: We're now voting on  
22 usability for Measure 1519, 1 high, 2 moderate, 3

1 low, 4 insufficient.

2 (Voting.)

3 MS. SKIPPER: Thirty-two percent votes  
4 high, 68 percent moderate, 0 percent low, 0  
5 percent insufficient, Measure 1519 passes on  
6 usability and use. We will now vote on overall  
7 recommendation for endorsement.

8 CO-CHAIR GUNNAR: Any further  
9 discussion before that? Okay.

10 MS. SKIPPER: 1 yes, 2 no, for overall  
11 suitability for endorsement.

12 (Voting.)

13 MS. SKIPPER: One hundred percent  
14 votes recommend this measure for overall  
15 suitability for endorsement.

16 CO-CHAIR GUNNAR: Very well. Next  
17 measure -- so that's 1519. Next measure is rate  
18 of open repair of a AAA, where patients are  
19 discharged alive, Society of Vascular Surgeons.

20 DR. JOHNSON: You all asked that  
21 question. The reason we changed that -- because  
22 we did have mortality -- was the Quality

1 Performance Measures Committee, in a discussion,  
2 felt like we needed to project a more positive  
3 outcome versus having death from open procedures,  
4 so that's the reason that is worded -- that  
5 measure. Tim Kronowitz, you all thank him for  
6 that.

7 CO-CHAIR FLEISHER: There is data in  
8 the business literature that that's actually a  
9 good thing to do. That actually stimulates  
10 people in a positive way when you create value  
11 statements.

12 PARTICIPANT: CMS generally encourages  
13 positively-phrased messages just because there's  
14 less confusion about the specifications.

15 DR. JOHNSON: Yes, Tim Kronowitz is  
16 one of our more experienced members, who  
17 participates a lot, came back to us and told us  
18 that was the case, and we need to project a  
19 little more positivity within our group.  
20 Vascular surgeons can be a little cynical, at  
21 times.

22 Regarding the rest of the measure, a

1 lot of questions have been answered on the first  
2 measure concerning our risk adjustment and our  
3 validity. Concerning risk adjustment with AAA  
4 repairs, we don't do risk adjustments because it  
5 gets all about certain selection. That's the  
6 reason we don't. Again mentioned was concern  
7 concerning reliability and validity.

8 As mentioned earlier, our kappa scores  
9 are all 1, indicating a strong agreement for  
10 identification of the correct procedure AA  
11 perform, the diameter of our aneurysms, our  
12 elective repair, and our hospital mortality.  
13 Concerning performance gap, many mortality still  
14 has a large range across our centers. It ranges  
15 anywhere from 0 to 14.3 percent. The other thing  
16 we found is also -- and we don't understand why  
17 we do have a higher rate of mortality in  
18 Hispanics. We have, also, being Hispanic as an  
19 independent risk factor for increased, not only  
20 mortality, but also higher hospital charges,  
21 which we can't explain. We're hoping to continue  
22 this measure as a maintenance and hope to

1 determine why these things are occurring.

2 CO-CHAIR GUNNAR: Discussants are Drs.  
3 Grover and Levy. Fred?

4 MEMBER GROVER: First of all, I'd like  
5 to congratulate the Society of Vascular Surgeons  
6 for really stepping up to the table and coming  
7 forward with a lot of measures and respectable  
8 penetration in your vascular colleagues. I think  
9 this is still the best way to get doctors to buy  
10 in and their teams to buy in to improving care  
11 when they develop their own measures.

12 This is relatively straightforward,  
13 about as straightforward as something can be.  
14 It's basically looking at a gray area, in terms  
15 of the size of the aortic aneurysms in males and  
16 females and the ones that are enlarged like for  
17 females from five to five and a half centimeters  
18 for males to five and a half to six. Whereas it'  
19 not as indicated as much move ahead just on the  
20 size of the aneurysm. These are asymptomatic  
21 patients. Obviously, the caveat is that if  
22 you're going to operate on one of these



1 asymptomatic, smaller aneurysms, you really need  
2 to have excellent results. That's what they're  
3 measuring.

4 It's not risk adjusted, and I might  
5 make some suggestions later about a broader way  
6 to look at your aneurysms, where it is risk  
7 adjusted. But for this particular measure, I  
8 don't believe that's necessary. You're  
9 monitoring whether or not your surgeons are  
10 making the correct assessment of these  
11 asymptomatic patients in achieving a low  
12 mortality.

13 By and large, that's being done on the  
14 average. But as you point out, there are  
15 variations geographically and from center to  
16 center. I don't know whether you want to just  
17 move straight on. I think the evidence is  
18 supported for what they do. The performance gap,  
19 as I mentioned, and as mentioned by the measure  
20 developers, is a geographic one. It's low, but  
21 it should be. The specifications or, I think,  
22 the reliability in regard to specifications, this

1 is clinical data. It's verified against some  
2 administrative data, as well, in the New England  
3 group. You audited, I believe, as well. The  
4 kappa score is one or approaches one, so it's  
5 high. All of these things, I felt, were positive  
6 and passable. In terms of --

7 CO-CHAIR GUNNAR: If we get back to  
8 just evidence, itself, because that's what we'll  
9 vote on. First, your recommendation is --

10 MEMBER GROVER: Yes --

11 CO-CHAIR GUNNAR: -- there is --

12 MEMBER GROVER: -- it passes.

13 CO-CHAIR GUNNAR: -- sufficient  
14 evidence to support this measurement? Dr. Ko --  
15 or actually, Dr. Levy, and then Dr. Ko.

16 MEMBER LEVY: I agree.

17 CO-CHAIR GUNNAR: Okay, Dr. Ko?

18 MEMBER KO: Is there another AAA  
19 measure that's out there for mortality that --

20 (Off the record comment.)

21 MEMBER KO: No, not from the SVS. I  
22 thought there was another mortality AAA measure,

1 CMS or AHRQ.

2 (Off the record comments.)

3 MEMBER KO: Because the problem with  
4 that other measure was that it incorporated both  
5 elective and urgent -- emergent AAAs. This is  
6 probably a better one, but then just knowing that  
7 there's something --

8 CO-CHAIR GUNNAR: We looked at it.  
9 There were no other competing measures. We'll  
10 look for that while we continue.

11 (Off the record comments.)

12 MEMBER KO: It was something that Pat  
13 Romano put out many, many years ago. There was a  
14 lot of heat to it because it put all these things  
15 together.

16 DR. JOHNSON: I'll have to look. I'm  
17 not sure.

18 MEMBER KO: It was statistically done  
19 well, but clinically, it didn't make sense.

20 (Off the record comments.)

21 (Simultaneous speaking.)

22 DR. DUWAYRI: I can give you the

1 number here. In five years, for open, we had  
2 4,266 in the registry. In the vascular, we had  
3 13,487, so three times, four times as much, so 75  
4 percent, 25 percent.

5 CO-CHAIR GUNNAR: All right. Larry, go  
6 ahead?

7 MEMBER MOSS: I've got a question  
8 about the exclusions. Is this the appropriate  
9 section to raise that?

10 CO-CHAIR GUNNAR: No. We'll stick to  
11 evidence. Is there sufficient evidence to  
12 support this measure? Can we move to vote on  
13 that?

14 (Off the record comments.)

15 CO-CHAIR GUNNAR: Oh, yes, it's a  
16 maintenance, that's right. Thank you. Does  
17 anyone want to vote on evidence? No. Can we go  
18 to the gap?

19 MEMBER GROVER: We can go to the gap.  
20 As he mentioned and I mentioned, the average  
21 mortality is very low, but there is a range of  
22 difference from hospital to hospital in

1 geographic areas, so there's still a gap there.  
2 There's room for improvement.

3 MEMBER LEVY: I also think it's  
4 critically important, as we're shifting more and  
5 more to EVAR, that the ones that are being done  
6 open, we definitely need to track outcomes in  
7 asymptomatic patients that are being done open.

8 CO-CHAIR GUNNAR: Helen, is there a  
9 competing measure?

10 DR. BURSTIN: There is a competing  
11 measure. Cliff's right. The AHRQ measure is  
12 still endorsed, which is the claims-based measure  
13 of AAA repair mortality rate. It's IQI 11,  
14 number of deaths amongst cases, and it's got four  
15 stratum, open repair of a AAA, open repair of an  
16 unruptured AAA, endovascular repair of a ruptured  
17 AAA, and endovascular repair of an unruptured  
18 AAA.

19 MS. MURPHY: They withheld submitting  
20 that one at this time because they're looking at  
21 doing some work with Leapfrog to combine the  
22 Leapfrog measure with the AHRQ measures.

1 CO-CHAIR GUNNAR: So remind me the NQF  
2 process for --

3 DR. BURSTIN: You still evaluate this  
4 one on its own, on its own merits. When that  
5 other measure -- we will have an opportunity to  
6 do a competing measures discussion afterwards,  
7 but this measure should be reviewed on its own.  
8 I think the other distinction is I think the  
9 Leapfrog measure was claims-based, as well, so I  
10 think both of those are working towards a single  
11 claims-based measure. This measure's obviously  
12 registry based.

13 CO-CHAIR GUNNAR: So the fact that the  
14 two screens went blank in the front of the room,  
15 is that a predictor of the way the afternoon's  
16 going to roll out? Those screens all went blank.  
17 We're going to vote on gap. Gap is next.

18 MS. SKIPPER: Voting is now open for  
19 performance gap on Measure 1523, 1 high, 2  
20 moderate, 3 low, 4 insufficient.

21 (Voting.)

22 MS. SKIPPER: We're waiting for one

1 more vote in the room, unless someone stepped  
2 out, which I didn't see. Measure 1523 passes on  
3 performance gap, 32 percent high, 68 percent  
4 moderate, 0 percent low, 0 percent insufficient.

5 CO-CHAIR GUNNAR: Very well, we move  
6 on to reliability. Dr. Grover?

7 MEMBER GROVER: Again, I got a little  
8 ahead of myself earlier. This is clinical data,  
9 so it's chart reviews, which in my humble opinion  
10 leads to likely a higher level of accuracy. The  
11 discharged alive is a very clear outcome and  
12 easily defined, so from that standpoint, the end  
13 point is very simple to collect and collect  
14 across centers.

15 I personally believe -- and let me  
16 just digress here. I'll only take one minute --  
17 that the direction here really should go -- would  
18 be to risk stratify. You've said in your  
19 proposal, several times, you haven't had --  
20 you've got the population to do that, or there  
21 aren't risk models out there. My suggestion  
22 would be you do your own, based on the number of

1 patients you have.

2 Now, you can have a model that would  
3 cover a broad spectrum of aortic aneurysms, where  
4 you consider size, comorbidities, the whole nine  
5 yards, the location and symptomatology, but  
6 that's just aside. For this particular study, I  
7 think what you're trying to do is to monitor the  
8 mortality in a very low-risk group and be sure it  
9 is indeed low and stays low, and you don't need  
10 risk adjustment for that particular thing. I  
11 gave the reliability a moderate score.

12 DR. JOHNSON: Can I make one comment?

13 CO-CHAIR GUNNAR: Yes.

14 DR. JOHNSON: Your point was very to  
15 the point because nowadays, when you're training  
16 -- I'm in a vascular track residency training  
17 program. As we increase the number of  
18 endovascular aneurysm repair, we are concerned  
19 that our trainees won't have as much experience  
20 in open aneurysm repair and what is going to  
21 happen to the mortality in an elective procedure,  
22 whose only benefit is based upon the natural



1 progression of that disease to rupture and lead  
2 to the death of the patient. That's the reason  
3 we think this is a very important maintenance  
4 measure to continue.

5 MEMBER YATES: Yes, question. All  
6 surgical specialties have seen a reduction in  
7 length of stay with ERS processes and  
8 interventions. The discharge of the length of  
9 stay has dropped by a day, say, over half a  
10 decade, average. It's taking away one less day  
11 for an opportunity to not be alive, to be  
12 positive. Why stop -- since this is a registry,  
13 and I'm assuming that the registry would pick up  
14 someone that dies five days after they leave the  
15 hospital, why does it stop at the door, as  
16 opposed to some sort of time course, like the  
17 first 30 days, that would be more in harmony with  
18 other measures? This is sort of begging the  
19 question, if you get them out day half you really  
20 reduce -- or increase your leaving alive.

21 DR. DUWAYRI: The registry, itself,  
22 currently requires that we have long-term

1 follow-up data that exceeds nine months  
2 post-operatively. However, still in compliance  
3 with this long-term follow-up data entry, there's  
4 not as much as we want. We are in the process of  
5 improving that. For accuracy of this measure, we  
6 chose the in-hospital death, but yes, we  
7 understand the importance of long-term follow up,  
8 particularly in those prophylactic measures.  
9 Hopefully, we will have, sometime in the future,  
10 long-term data.

11 MEMBER YATES: As part of the data  
12 collection for this measure, do you collect which  
13 day they're discharged, so that you can monitor  
14 whether or not there may be the possibility that  
15 people leaving on day two versus day four makes a  
16 difference, in terms of the numbers, as opposed  
17 to being an improvement?

18 DR. DUWAYRI: You're asking if we're  
19 collecting length of stay as an --

20 (Simultaneous speaking.)

21 MEMBER YATES: -- as part of this  
22 measure, just as one of the covariables?

1 DR. DUWAYRI: No, we are not  
2 collecting it as part of this measure, but we are  
3 collecting it in the registry.

4 MEMBER YATES: Okay, I'm just pointing  
5 out it's a temporal variable that's important  
6 right now.

7 CO-CHAIR GUNNAR: Any other comments  
8 regarding reliability?

9 MEMBER KO: I just have a quick  
10 question. If this is a raw rate of the survivors  
11 over all the open AAAs, this can be done with a  
12 lot of different datasets. You can do this with  
13 claims. Can people participate in this measure  
14 without belonging to VQI?

15 DR. DUWAYRI: Claims does not have  
16 diameter. We chose aneurysms of moderate size  
17 here.

18 MEMBER KO: Okay, got it.

19 CO-CHAIR GUNNAR: Dr. Temple?

20 MEMBER TEMPLE: This is just a point  
21 of clarification. Most of the mortality measures  
22 that we've been looking at are 30-day

1 mortalities, am I right? How many of them are a  
2 discharge?

3 CO-CHAIR GUNNAR: The three sessions  
4 I've had, I can't independently think of another  
5 one.

6 MEMBER TEMPLE: Again, I guess it's  
7 just a question for the group. Do we want to  
8 harmonize that everything's 30 day versus  
9 discharge? My impression with AAAs is that there  
10 is a real mortality between discharge and 30  
11 days, as well. I wonder if you could comment?

12 DR. JOHNSON: Usually with open AAAs,  
13 if they leave the hospital, they usually are  
14 going to be alive in 30 days. The ones -- this  
15 is an operation where if you don't recover very  
16 well right after the operation, you're going to  
17 be in the hospital for a month or two with some  
18 of these open aneurysms repair. I just don't  
19 think there's that high of a -- people that leave  
20 the hospital -- and I don't have the data, but  
21 people that leave the hospital, the percentage  
22 that survive 30 days is pretty high, or should be

1 high. Do you want to comment?

2 DR. DUWAYRI: As we know from other  
3 registries, 30-day follow up after discharge is  
4 very -- we think it's easy. You can do it with a  
5 phone call or any other way, but it is not. We  
6 have a lot of missing data in all registries at  
7 30 days. I think this will -- as we look at that  
8 for surgical patients, we have, first, to make  
9 sure that we are able to obtain accurate data at  
10 30 days.

11 CO-CHAIR GUNNAR: Amy?

12 MEMBER MOYER: In looking at the links  
13 you've provided to your specifications, it's  
14 actually not very clear to me what you're  
15 measuring, but it seems even beyond the 30 days,  
16 you could get around this mortality measure by  
17 discharging someplace other than home, based on  
18 the description of it. If I send someone to a  
19 SNF, or send someone to some other unit, that  
20 would potentially escape the measure?

21 DR. JOHNSON: Yes, in this measure,  
22 you could get around that. Hopefully, in the

1 registry, in our follow up, we would pick that  
2 up, but in regard to this measure, yes, if you  
3 send them to a nursing home facility and they  
4 died, we would have no idea.

5 CO-CHAIR GUNNAR: Fred?

6 MEMBER GROVER: I just reiterate the  
7 30-day importance, realizing that it's a little  
8 more difficult. We just ran an analysis of our  
9 open aortic valve replacements for if you just do  
10 it within hospital versus 30 days, if they're  
11 discharged prior to 30 days.

12 We did it for TAVR, as well, the  
13 transcatheter aortic valves. Collecting what we  
14 call the operative mortality, which includes the  
15 30 days, there's about a 1½ percent to 2 percent  
16 increase in mortality if you get the 30 days.

17 CO-CHAIR GUNNAR: I guess my concern  
18 is when you have a dwindling number of cases  
19 being electively sent for open repair, if you  
20 have an event, it then lingers forever. It also  
21 has a huge impact on your overall rate.

22 You never collect enough cases to

1 actually overwhelm the fact that you may have had  
2 one unanticipated outcome that was just  
3 unfortunate. So I guess the question for this  
4 particular measure actually comes down to the  
5 numbers and the impact of having small numbers,  
6 and an event that then overwhelms -- there's this  
7 huge noise in the system, then, if you will, per  
8 institution.

9 MEMBER KO: Sorry, so this is at a  
10 facility and individual surgeon level?

11 DR. JOHNSON: Correct, we were able to  
12 take the data back to the individual surgeon, and  
13 we can take it back to the facility.

14 MEMBER KO: So if this is a PQRS  
15 measure, it's exactly what Dr. Gunnar said. It's  
16 going to be you have one case every three years.  
17 I think that issue, the technical statistic  
18 piece, should be almost separated between  
19 facility and individual provider.

20 CO-CHAIR GUNNAR: I guess the question  
21 goes back to when it gets -- this needs to be  
22 considered independently, but when it gets

1 potentially harmonized with the AHRQ measure,  
2 which measures far more than just a single  
3 elective, open AAA, there may be some value in  
4 trying to get these -- it really would -- from my  
5 perspective -- and from a quality improvement  
6 perspective, don't you really just want to know  
7 what the overall rate of discharging patients who  
8 have been treated for AAAs is, or elective AAAs?  
9 What's the need to necessarily separate open and  
10 EVAR, given the fact that now the numbers in open  
11 are so low? Go ahead, Fred.

12 MEMBER GROVER: I could give you some  
13 and probably a lot of my vascular colleagues here  
14 in the room, I would think probably a lot of the  
15 opens, maybe not in this size group, of aneurysm,  
16 but they may relate to higher risk patients. I  
17 think at this point in time, we need to collect  
18 both. I think if you're looking at individual  
19 surgeons, you have to lump several years together  
20 to come up with a reasonable number of cases.  
21 You can't do it on an annual basis, unless maybe  
22 you're at the Cleveland Clinic or something.



1                   MEMBER HANDY: I was just going to say  
2                   that with a longer post-operative follow up, you  
3                   uncover camouflaged patients that you didn't  
4                   identify. As a matter of fact, most specialties  
5                   are moving -- or many specialties, I should say,  
6                   not most -- are moving to 90-day follow up  
7                   because there's a body of literature looking at  
8                   that increased time frame that has plausible  
9                   morbidity and mortality associated with the  
10                  operation, as opposed to shortening it.

11                 CO-CHAIR GUNNAR: In your registry,  
12                 what's the number of AAAs performed by any one,  
13                 single provider in a year?

14                 DR. DUWAYRI: We don't have the data,  
15                 but there is -- it's probably not per provider,  
16                 per medical center is a better way of looking at  
17                 it, and there is a huge variability. There are  
18                 medical centers who perform none. So it's hard  
19                 to provide -- I don't think an average will  
20                 represent that.

21                 CO-CHAIR GUNNAR: The back of the  
22                 envelope calculation here is that 25 percent of

1 the cases in this dataset now are open, and 75  
2 percent are EVAR. If the average facility does  
3 30 cases a year, a single mortality is going to  
4 make them an outlier immediately. Barry?

5 MEMBER MARKMAN: The next measure I'm  
6 presenting is pretty similar to -- in fact, it's  
7 the same language, actually, throughout the whole  
8 thing. Dr. Grover, you said 1 percent or 2  
9 percent? Because the mortality rates we're  
10 talking about here are .3 or .4 percent.

11 (Off the record comment.)

12 MEMBER MARKMAN: I know. He's talking  
13 about 1 percent carrying out for 30 days, but --

14 MEMBER GROVER: I was using the aortic  
15 valve --

16 (Simultaneous speaking.)

17 MEMBER MARKMAN: Yes, that's an  
18 important point because --

19 (Simultaneous speaking.)

20 MEMBER MARKMAN: -- if you do  
21 extrapolate out, you would want to look at that  
22 data. Do you do any re-admission in your

1 registry, re-admission rates?

2 DR. DUWAYRI: Not for now, but this is  
3 coming in our registry. Currently, no, there is  
4 no re-admission data in our --

5 MEMBER MARKMAN: Yes, because you can  
6 capture a lot of this stuff, this 30-day stuff,  
7 with re-admission data. Are there any other  
8 measures, other than mortality? Do you look at  
9 other datasets, other than mortality?

10 DR. DUWAYRI: In open aneurysms?

11 MEMBER MARKMAN: Yes.

12 DR. DUWAYRI: We also have length of  
13 stay is one measure that we -- but it's not  
14 submitted here.

15 MEMBER MARKMAN: Right, no, I'm just  
16 saying, you said you have a registry, you have  
17 some data points --

18 DR. DUWAYRI: Yes, length of stay  
19 usually reflects other -- the number of  
20 complications and the severity of complications  
21 that occur after open aneurysm repair. This is  
22 one other way of tracking those. Of course,

1 everything is tracked, including pneumonias, MIs,  
2 and other things. The main feedback that we give  
3 to centers and providers is death and length of  
4 stay.

5 MEMBER MARKMAN: Going back to what  
6 Dr. Gunnar said is that when you begin to  
7 harmonize, I don't know what the variables are in  
8 the other measures, but you may want to be  
9 forward looking and try and see if you can  
10 capture --

11 (Simultaneous speaking.)

12 MEMBER MARKMAN: Yes.

13 CO-CHAIR FLEISHER: Getting back to  
14 reliability, you mentioned that if they're  
15 discharged to SNFs -- I'm not really concerned,  
16 but LTACs is where you would send some patient  
17 who could linger. One of the nice things -- and  
18 we spent a lot of time, and I think it was with  
19 the STS group, because if I'm not mistaken, your  
20 measure is always 30 days or in hospital, so  
21 LTACs could be an exclusion, too? Maybe that's  
22 validity, and I have a lot of questions about

1 validity.

2 CO-CHAIR GUNNAR: Yes, I think that's  
3 validity.

4 CO-CHAIR FLEISHER: Okay, then I'll --  
5 (Simultaneous speaking.)

6 CO-CHAIR GUNNAR: We've crossed the  
7 chasm between reliability and validity a few  
8 times here. Why don't we -- is everybody ready  
9 to vote on reliability? This is a maintenance  
10 measure currently being collected. Reliability.

11 MS. SKIPPER: Yes, and again, the  
12 highest rating here is moderate, so you'll be  
13 voting 1 moderate, 2 low, 3 insufficient.

14 (Voting.)

15 MS. SKIPPER: Measure 1523 passes on  
16 reliability, 74 percent moderate, 26 percent low,  
17 0 percent insufficient.

18 CO-CHAIR GUNNAR: So now we'll proceed  
19 to validity, which I think has been, really, the  
20 focus of the discussion for the last five  
21 minutes. Lee, you had comments you wanted to --

22 CO-CHAIR FLEISHER: I gave one. The

1 other thing is the risk assessment. You actually  
2 have data to say that at the extremes of age is  
3 just one example where there's wide disparity,  
4 but you don't risk adjust. The validity of the  
5 measure to measure what you're talking about  
6 without risk adjustment has me concerned because  
7 with that change, could there be -- if you risk  
8 adjust it, then that would at least stratify.  
9 That would be more comfortable. But you even are  
10 able to show one variable that does have an  
11 extreme, you're saying, influence. Then the  
12 other validity is I just wanted to know, do you  
13 have a plan for -- do you have any data on the  
14 clinician level assessment?

15 Because as you heard, the statistical  
16 validity of -- maybe the facility, I think you  
17 have, maybe, some data to say it's valid at the  
18 clinician level. I didn't see any data to show  
19 validity, so that would just be -- three  
20 questions, sorry.

21 DR. DUWAYRI: I'll answer on the age.  
22 Again, we're starting just moderate to small

1       aneurysms. Regardless of what the age is, the  
2       risk of rupture in those aneurysms is the same.  
3       So if we are, again, looking at patient  
4       selection, if you're doing an open aneurysm and  
5       you're an 80 year old or 90 year old, then your  
6       rate of death is higher than 10 percent for an  
7       aneurysm that has a risk of rupture less than 5  
8       percent. I think that is what this measure is  
9       looking at. Although you can risk adjust for  
10      age, yes, I think still, what we are trying to  
11      look at is if the surgeons are performing repairs  
12      in patients who are high risk because of their  
13      age or other risk factor, other comorbidities  
14      and, therefore, have a higher, although  
15      acceptable for age, mortality rate. In our  
16      opinion, this probably is not justified in a  
17      small aneurysm. That's why we are limiting this  
18      measure to a small aneurysm. That's the answer.

19               MEMBER GROVER: I hear what you're  
20      saying. I do think, though, that you might get  
21      some risk aversion because you aren't taking the  
22      age into account. Whereas, if you had a model

1       that showed -- indeed reflected that even in  
2       these small aneurysms, the risk goes up somewhat  
3       by various comorbidities, age is one of them,  
4       that would be useful. I'm not saying that  
5       negates the value of this, but in the future, I  
6       think that would be a way I would move.

7               CO-CHAIR GUNNAR:  Alternatively, if I  
8       just verify, if I somehow identify a symptom,  
9       then it takes you out of this evaluation?

10              DR. JOHNSON:  Yes, because once an  
11       aneurysm becomes symptomatic, the risk of rupture  
12       substantially goes up, and along with it, the  
13       mortality.

14              CO-CHAIR GUNNAR:  Thank you.

15              MEMBER MARKMAN:  I'm just going to hit  
16       another point because I assume you submitted the  
17       same five articles as new evidence.  One of the  
18       articles that you submitted was -- had a total of  
19       128,000 patients, 14-year period.

20              We're talking about risk assessment,  
21       but when we submitted that article, the comment  
22       or the conclusion on that article goes beyond



1 patient risk, but it said that hospitals that  
2 complete fewer than five OARs and eight EVRs  
3 annually have a significantly greater mortality  
4 compared to their counterparts, which I think is  
5 part of what you're doing in this measure.

6           You're saying if you don't do enough,  
7 your mortality increases. That's why it varies  
8 from 0 to 14 percent. What you're doing is  
9 you're kind of isolating out the hospitals that  
10 don't do enough or the providers that don't do  
11 enough. Explain a bit more about the validity of  
12 that statement. Because what you're doing is  
13 really kind of -- and this is public. This is a  
14 public reporting. When it comes to validity, I'm  
15 just, to your measure, can you explain a little  
16 bit more about it?

17           DR. DUWAYRI: It's a real point. High  
18 volume center, high full volume surgeons do  
19 better. That's one of the things that surgeons,  
20 before embarking on those procedures, should  
21 consider. It will first affect their outcome  
22 because it's going to show faster than it is

1 going to show in a higher volume center, but it's  
2 also possibly likely better for the patient to  
3 consider a referral to undergo treatment in a  
4 higher volume center.

5 MEMBER MARKMAN: Does your data show  
6 that, too? Because I'm looking through your  
7 data. Is it statistically significant in your  
8 data, in your registry?

9 DR. DUWAYRI: As far as I recall, I'm  
10 not sure that analysis has been done, but it's  
11 doable.

12 MEMBER MARKMAN: Okay. Because that  
13 goes to validity because it's all over this  
14 measure about low volume. I didn't see it  
15 addressed specifically in your measure.

16 DR. JOHNSON: I agree with you the  
17 importance of that. If you look across the  
18 nation, more and more open aneurysms are  
19 difficult aneurysms to repair and, therefore,  
20 more and more open aneurysms are getting referred  
21 to tertiary centers. I'm in a tertiary center,  
22 so I get more open aneurysms sent in from people

1 who don't do a lot of open aneurysms anymore. As  
2 we progress on, you're going to see that -- we  
3 hope that will happen.

4 To continue to report this data, we  
5 have the ability to identify those centers that  
6 don't do a lot of aneurysms, and we have an  
7 ability to report back to them that you're not  
8 doing a lot, and your results aren't that good,  
9 and maybe you need to transfer, or you need to  
10 refer these patients to other centers. That's  
11 the direction that I hope this is going to take  
12 is VQI has grown from 160.

13 We're up to 400 or 500 centers, and  
14 it's going to get bigger. Our goal is to let  
15 people know what the results are, because we can  
16 provide them to the providers and to the  
17 facility, and then hopefully encourage people to  
18 refer patients to the appropriate center to do  
19 the operation.

20 MEMBER MARKMAN: I don't want to  
21 backtrack, but that's basically how you want to  
22 close this performance gap because you want to

1 focus on doing that. Okay, I got it.

2 CO-CHAIR GUNNAR: I'm going to go to  
3 Rick, and then Larry.

4 MEMBER DUTTON: Just quickly, I wanted  
5 to speak in support of the SVS concept of an  
6 un-risk-adjusted measure. What we're trying to  
7 measure is surgical and facility judgment.  
8 Should we do this case? These are elective and  
9 discretionary cases. I think that's really  
10 getting at the key question. So measuring it in  
11 unadjusted fashion does that. If it's a  
12 high-risk case, you shouldn't do it, and you  
13 wouldn't be in here.

14 CO-CHAIR GUNNAR: Actually, Larry  
15 first, and then Sal.

16 MEMBER SCALI: I just wanted to sort  
17 of follow up and say, again, I think that  
18 philosophically, if you think the quality measure  
19 is there for patient selection, then I think for  
20 something that has a low annualized rupture risk  
21 to begin with, then I think you should probably  
22 vote to say yes, it should be non-risk adjusted.

1 If you think the spirit of the measure is to say  
2 once you've decided the operation and you're now  
3 doing this operation, did your operation do what  
4 was intended, which was make sure the patient's  
5 alive and they got home and all those other  
6 things and didn't die, then it has to be risk  
7 adjusted. But it's about patient selection, and  
8 it's because the annualized rupture risk of a  
9 small aneurysm is so low that the risk/benefit  
10 window, therapeutic window for surgery is also  
11 very low.

12 So you're trying to drive or change  
13 surgeon behavior to not select the octogenarian  
14 with renal insufficiency with a 5.3-centimeter  
15 aneurysm, and to do the EVAR, who has a life  
16 expectancy that's not going to be long enough to  
17 derive benefit of the prophylactic repair.  
18 That's sort of the spirit of the measure, I  
19 believe.

20 CO-CHAIR GUNNAR: Larry?

21 MEMBER MOSS: Now, I'm going to ask a  
22 question about exclusion. I'm slow, but I'm

1 teachable. Related to the point that Barry made,  
2 I'm interested in your decision to suppress all  
3 data on surgeons who do less than ten cases for  
4 an elective procedure with a demonstrated volume  
5 outcome relationship, where patients have a lot  
6 of time to choose their surgeon.

7 DR. DUWAYRI: Why we're excluding  
8 low-volume surgeons?

9 MEMBER MOSS: Less than ten, why did  
10 you make that decision?

11 DR. DUWAYRI: Just basically to avoid  
12 the problem that we were just talking about, in  
13 terms of how a low number will affect the  
14 mortality rate.

15 MEMBER MOSS: Yes, I understand that,  
16 but if the underlying concern is that --

17 DR. DUWAYRI: It's to pick up the --

18 MEMBER MOSS: -- experienced people  
19 should do these cases, are we missing that?

20 DR. DUWAYRI: It is possible.

21 CO-CHAIR GUNNAR: Larry, it speaks  
22 directly to validity, thank you very much.

1 Collette?

2 MEMBER PITZEN: Thanks, this is  
3 Collette. I guess I would just recommend, for  
4 future, I would like to see a measure that has a  
5 larger time frame than discharge.

6 CO-CHAIR GUNNAR: Cliff?

7 MEMBER KO: I don't want to belabor  
8 the point of risk adjustment for an outcome  
9 measure, but I'd like to ask any of the NQF  
10 staff, are there a lot of outcome measures that  
11 are unadjusted, they're raw rates? Is this  
12 something that I'm missing?

13 DR. BURSTIN: It's not usual.

14 Actually, our criteria specifically say outcome  
15 measures should be risk adjusted, unless there is  
16 justification why you're not. I think part of  
17 what we've heard -- and correct me if I'm wrong  
18 -- is that essentially, you're saying the patient  
19 selection, by selecting this lower-risk group,  
20 inherently, they're doing a bit of poor man's  
21 risk adjustment.

22 We've seen that, for example, with

1 cataract surgeries. We've seen measures come  
2 forward looking at complications after cataract  
3 where they limit it only to the lowest risk  
4 patients. I think it's almost a way of  
5 stratifying as a way of getting at risk  
6 adjustment. But it's not common, and it's  
7 certainly not -- I think it's an issue that gets  
8 raised pretty commonly --

9 (Simultaneous speaking.)

10 MEMBER KO: To the measure developers,  
11 is that what volume is -- you have a high--volume  
12 surgeon, they pick their patients better?

13 DR. JOHNSON: No, I don't think  
14 high-volume surgeons pick their patients better.

15 MEMBER KO: So there's something  
16 beyond selection?

17 DR. JOHNSON: Right.

18 MEMBER KO: Which means that the risk  
19 adjustment is probably important.

20 CO-CHAIR GUNNAR: Lee?

21 CO-CHAIR FLEISHER: As I'm thinking  
22 through this -- because there's both selection --



1 and the crazy thing about selection, when I hear  
2 stories, is actually the low-volume surgeons get  
3 the worst patients because the high-volume  
4 surgeons have the volume to continue to do it.  
5 I'm worried about unintended consequences. I  
6 don't know where that fits within the criteria --  
7 in usability? Okay, so we'll go back to that  
8 because -- thank you. We haven't addressed that.  
9 The holy grail in this area, besides patient  
10 selection, is actually appropriateness. I'm  
11 wondering how your measure gets to  
12 appropriateness, as opposed to patient selection  
13 by the surgeon of what they'll do. Will there be  
14 -- we can get to this in usability. Will  
15 patients who should be operated on not get  
16 operated on because of the way you've constructed  
17 the measure? All you're saying is the patients  
18 they chose, not the patients they refused.

19 MEMBER LEVY: So in an elective case,  
20 in a patient who's unlikely to rupture, you're  
21 not denying care to someone where there's an  
22 algorithm that says these people should have

1 surgery. I think that's the whole point of the  
2 risk adjustment, or lack of risk adjustment for  
3 this. These are highly elective procedures,  
4 where you really need to be able to do shared  
5 decision making with a patient and say, in my  
6 hands, these elective procedures for small  
7 aneurysms that are unlikely to rupture gives you  
8 a better outcome than not doing anything.

9 I think that's really the issue. I  
10 don't think there's an unintended consequence  
11 here of denying surgery to people -- the more  
12 likely scenario that you're talking about, Lee,  
13 is the patient who comes in with symptoms, or the  
14 patient who's ruptured in a rural setting.  
15 You've got a low-volume surgeon who has to deal  
16 with an emergency right then. That's a totally  
17 different scenario.

18 MEMBER MARKMAN: Just one brief  
19 comment. It may not just be the surgeon because  
20 you're looking at the facility. It may be the  
21 fact that the facility that's not doing enough of  
22 these cases has the capacity, the nursing, the

1 ICU and everything else in a community hospital  
2 that can't -- it's not appropriate for the  
3 facility. They're focusing on the provider.  
4 Some facilities have an elective procedure but  
5 still a major procedure. That's just a question.

6 CO-CHAIR GUNNAR: But they exclude  
7 low-volume centers.

8 MEMBER MARKMAN: But the conclusion --  
9 but you just said that's kind of what they're  
10 aiming at. They're not studying it, but it's  
11 still mentioned throughout the entire measure.

12 MEMBER CIMA: Isn't that the problem,  
13 then, with validity here? You'd have to be doing  
14 40 or 50 aneurysms a year to get ten open.  
15 That's a lot of aneurysms for a single site,  
16 other than a big academic center.

17 CO-CHAIR GUNNAR: Do you have any --  
18 back to the developers, do you have any  
19 information regarding what percentage of your  
20 centers actually meet the threshold for  
21 submission or evaluation of this measure?

22 DR. DUWAYRI: No, not now, but this

1 can be obtained.

2 CO-CHAIR GUNNAR: Does anybody feel  
3 that information would help us in making a  
4 decision, that we should delay the decision on  
5 validity or vote on it until we actually have  
6 that information?

7 MEMBER TEMPLE: I have one more  
8 question, I think, that fits -- may require  
9 coming back to -- again, I'm confused about the  
10 registry, in terms of how death is recorded. Is  
11 it self-report, and is every physician -- it's a  
12 procedure specific for provider and for  
13 institution.

14 Do we know that each provider within  
15 an institution reports, or is it just 60 percent  
16 of providers that work at that institution? I'm  
17 having a little bit of a problem understanding  
18 how the mortality rate is actually reported in  
19 the registry. That may be more information that  
20 we need coming back to before making a final  
21 decision.

22 DR. DUWAYRI: Your question is about

1 if a provider -- as I understand your question,  
2 I'm going to answer it. Basically, yes, if a  
3 provider is participating in VQI, he or she will  
4 either participate individually or under the  
5 hospital umbrella. But regardless, if I start  
6 participating in this open aneurysm module, I  
7 will have to continue to participate, and I will  
8 not choose to enroll this patient who died or  
9 avoid to enroll him.

10 MEMBER TEMPLE: So do I put in the  
11 patient died, or does Cobra put in that a patient  
12 died?

13 DR. DUWAYRI: You do, or your data  
14 manager. It's basically removed from the medical  
15 record.

16 MEMBER TEMPLE: So, then, if I, as a  
17 surgeon, am going to do the open AAA module, is  
18 every surgeon in that institution also committed  
19 to that module?

20 DR. DUWAYRI: Most of the participants  
21 are participating under institutional umbrellas  
22 and, therefore, yes. But that does not -- I

1 cannot say that 100 percent of the surgeons in  
2 all of the institutions are participating. So it  
3 is possible that one institution will have some  
4 surgeons that are not participating.

5 MEMBER TEMPLE: Thank you.

6 DR. JOHNSON: But in general, yes.  
7 For instance, I'm with the University of South  
8 Florida. Tampa General is the main hospital.  
9 They pay for the registry fee, and all the  
10 surgeons in Tampa General are underneath that  
11 institutional thing, so we all get reported  
12 through that. Then when --

13 MEMBER TEMPLE: You all use the same  
14 module?

15 DR. JOHNSON: All use the same module,  
16 yes. We all use the same module, and when it  
17 gets audited, we all get audited. When VQI sends  
18 in somebody to look at our patients to make sure  
19 that each physician has recorded each of his  
20 cases, and then recorded and make sure it is  
21 reliable and valid data.

22 MEMBER TEMPLE: I guess I'm cynical,

1 and I'm kind of wanting to see more -- a little  
2 bit more information about how the coding works  
3 for the groups and for the providers and the  
4 auditing. I think that is affecting my sort of  
5 sense of validity. Yet, I really, really  
6 recognize how hard these registries are to get  
7 off the ground, and I think it's the right thing,  
8 to be using registry data, but I think it would  
9 be helpful to get a little more information.

10 MEMBER SCALI: I can clarify. All of  
11 the mortality events in the VQI are linked to the  
12 SSDI. Every six months, those mortality events  
13 are updated. It's like 99 percent accurate for  
14 mortality. That's why there's --

15 (Simultaneous speaking.).

16 MEMBER TEMPLE: At discharge or a  
17 30-day --

18 (Simultaneous speaking.)

19 MEMBER SCALI: -- so that's the issue.  
20 There's a six-month lag. So at discharge, they  
21 capture, you would have to read that data  
22 abstractor for the surgeon who didn't enter the

1 mortality for that event on that admission.

2 That being said, mortality, in general  
3 in terms of capture within the registry is  
4 literally 99 percent, but there is a six-month  
5 lag when the SSDI gets updated to that. That's  
6 why some of the capped statistics that people  
7 have talked about are reviewed. So it is  
8 possible that you can get 30-day mortality events  
9 from the registry, if that's specifically what  
10 the committee recommended for you guys. That's  
11 the clarification on mortality.

12 CO-CHAIR GUNNAR: So validity speaks  
13 to the participants for not participating?

14 MEMBER SCALI: For open AAA, and  
15 specifically, obviously, the vast majority of  
16 open AAA repair at least in the registry is done  
17 by the vascular providers who are doing that.  
18 There are about 10 percent -- I'm the chair of  
19 the EVAR committee, but I also do a lot of work  
20 with the open aneurysm repair committee for the  
21 VQI, so I know that at any one institution that  
22 participates in these modules for data capture,



1 it is theoretically possible, if you're a single  
2 surgeon in a five-surgeon group and you wanted to  
3 participate and you open AAA repair module, you  
4 could be a single person that does that.

5 Then the VQI doesn't force -- because  
6 it has to be voluntary. It's less than 10  
7 percent of all of the people putting data in the  
8 registry for open and endovascular AAA repair  
9 that have that specific scenario. The  
10 overwhelming majority of participants who are in  
11 the module, it's at a center level, so they  
12 capture all of the cases at the level.

13 MEMBER TEMPLE: So should we be  
14 looking at center rather than provider level?

15 CO-CHAIR GUNNAR: Again, I think we're  
16 voting on validity recommendations back to the  
17 developer on how -- this is a changing landscape  
18 because of the relationship between -- an  
19 asymptomatic patient's relationship between  
20 referrals to open versus EVAR. We're going to  
21 get to that in the next measure. The validity of  
22 this particular measure, as far as the data

1       that's in the registry, the information that's in  
2       the registry, I think that's been addressed.

3       Does everybody agree? Okay, which means we can  
4       then carry on and vote? Okay.

5               MEMBER KO: When we vote for validity,  
6       we're voting for both the -- to what Larissa was  
7       asking, both facility and individual?

8               CO-CHAIR GUNNAR: That's how it's  
9       specified.

10              MEMBER KO: Exactly, unadjusted  
11      facility/individual --

12              (Simultaneous speaking.)

13              CO-CHAIR GUNNAR: Correct.

14              MEMBER KO: Okay.

15              CO-CHAIR GUNNAR: And does it actually  
16      measure what it's measuring?

17              MS. SKIPPER: Voting is open for  
18      validity on Measure 1523, 1 is the highest  
19      rating, moderate, 2 low, 3 insufficient.

20              (Voting.)

21              MS. SKIPPER: Measure 1523 passes on  
22      validity, 61 percent votes moderate, 30 percent

1 low, 9 percent insufficient.

2 CO-CHAIR GUNNAR: We'll move on to --

3 CO-CHAIR FLEISHER: If I may add --

4 CO-CHAIR GUNNAR: Yes.

5 CO-CHAIR FLEISHER: Just a point of  
6 letter. I would strongly urge the measure  
7 developers to consider the clinician issue  
8 because you may want to consider whether or not  
9 -- I think there were many of us who felt  
10 uncomfortable with that aspect of the validity.

11 MEMBER YATES: You mean in terms of the  
12 volume?

13 CO-CHAIR FLEISHER: In terms of  
14 validity and whether this can be measured, I ask  
15 them to consider, during the post-comment period,  
16 getting us data on that validity because it just  
17 squeaked by. I agree with Larissa, and I've  
18 heard it from others.

19 MEMBER YATES: I just want to make  
20 sure I understand; it's the volume question being  
21 suppressed that you're worried about?

22 CO-CHAIR FLEISHER: Whether it was

1 tested, and whether there was sufficient volume  
2 to say anything at the clinician level.

3 MEMBER YATES: Thank you. Just making  
4 sure I understood.

5 CO-CHAIR FLEISHER: That's what I'm  
6 asking. I don't know if others are asking that.

7 CO-CHAIR GUNNAR: Looking at it sort  
8 of globally, I would recommend that it be brought  
9 together with this other -- this is a measure  
10 that actually is claims based, right? You don't  
11 have to necessarily -- it's not currently risk  
12 adjusted. It's really just dead or alive at  
13 discharge. It's CPT code. I had an open  
14 aneurysm. The only thing, the caveat to this is  
15 asymptomatic and some moderate size issues that  
16 clarify the cohort.

17 I don't know how -- I think it's worth  
18 a discussion later downstream whether or not  
19 these two measures are so disparately separate,  
20 or they can be brought together. That's the way  
21 I would look at it. It's an important thing to  
22 measure. I don't think anybody disagrees in the

1 room. The question is does it need so many of  
2 these excluders that it actually gets us down to  
3 a group of patients that now, I'm not even sure  
4 exists that often, quite frankly.

5 (Off the record comment.)

6 CO-CHAIR GUNNAR: All right, next is  
7 feasibility. It's currently measured. It's been  
8 so long that -- who's our commenters again? It's  
9 Fred and Barbara, right? Yes. Any issues on --

10 MEMBER LEVY: No --

11 CO-CHAIR GUNNAR: -- feasibility from  
12 either one of you?

13 MEMBER LEVY: -- other than you have  
14 to participate and register.

15 CO-CHAIR GUNNAR: Shall we vote?

16 MS. SKIPPER: Voting is open for  
17 feasibility, 1 high, 2 moderate, 3 low, 4  
18 insufficient.

19 (Voting.)

20 MS. SKIPPER: We're just waiting on  
21 one more vote for feasibility. We'll move  
22 forward with 22. Results are 45 percent high, 55

1 percent moderate, 0 percent low, 0 percent  
2 insufficient. The measure passes on feasibility.

3 CO-CHAIR GUNNAR: All right, we'll  
4 move on to usability. Comments, Dr. Grover? Dr.  
5 Levy?

6 MEMBER GROVER: It's very easy, it's  
7 very straightforward, it's very simple.

8 CO-CHAIR GUNNAR: Right. Any other  
9 discussion? Yes, Dr. Moss?

10 MEMBER MOSS: I wanted to raise a  
11 comment about unintended consequences. I'm glad  
12 Barbara brought up patient choice. I can't think  
13 of a better, more exemplary example of a  
14 situation where patient choice is highly  
15 relevant.

16 I could imagine patients that are  
17 moderate risk that don't want to walk around  
18 every day with the risk of sudden death, and they  
19 might choose to take that risk up front and have  
20 the operation. The question is does this take  
21 patient choice off the table and make that value  
22 judgment for them?

1                   MEMBER LEVY: I think not. I think  
2 what it does is it gives patients valid, we hope,  
3 data to say in the hands of a certain  
4 institution, certain surgeon, given their  
5 circumstances, that the risk of mortality from  
6 the procedure is greater than or less than the  
7 risk of walking around with the aneurysm.  
8 Definitely, you're right, we live in a world  
9 where our patients think more intervention is  
10 better. To the extent that we can provide data  
11 for patients to show what the down side to  
12 intervention is or can be or you could project  
13 that it would be for those patients, I think  
14 that's really important.

15                   MEMBER MOSS: I guess I'm also asking  
16 are we disincentivizing centers and surgeons from  
17 taking on moderate risk patients who want an  
18 operation and make that choice for themselves?

19                   MEMBER LEVY: Shouldn't we be, if the  
20 risk of death for them is higher than the risk of  
21 rupture and mortality? The question is shouldn't  
22 we be? Shouldn't we be collecting enough data to

1 be able to answer that question?

2 DR. JOHNSON: The discussion that  
3 occurs at a patient level -- in fact, we train  
4 our vascular surgeons this way -- is what is the  
5 natural progression of the disease if we do  
6 nothing at all versus intervening? In that  
7 discussion, I need as much data as I can tell  
8 them about what happens when I intervene, as far  
9 as mortality and morbidity.

10 Because I know what happens with the  
11 natural progression of rupture without  
12 intervening. I don't think we're going to  
13 de-incentivize -- surgeons like to operate. I  
14 don't think we're going to de-incentivize them  
15 from that. Hopefully, we're just going to  
16 de-incentivize them from operating on people that  
17 the outcome is going to be worse if we do nothing  
18 at all.

19 MEMBER CIMA: The one thing is given  
20 the volume threshold requirement, a lot of  
21 surgeons and institutions are not going to be  
22 captured by this, so we're not providing patients



1 with any reasonable information -- the vast  
2 majority of patients.

3 DR. JOHNSON: I would say that the  
4 vascular surgeon community is so small -- there's  
5 only 5,000 of us -- that the majority of open  
6 aneurysms nowadays, since the communication  
7 levels -- already open aneurysms are getting  
8 moved into tertiary centers. I think most of the  
9 information is getting out to patients and other  
10 surgeons to say that if you're not a high volume  
11 -- if you're not doing this operation ten times,  
12 fifteen times a year, you don't need to be doing  
13 this operation.

14 CO-CHAIR GUNNAR: Just remind me  
15 again, this is reported every six months in a  
16 rolling -- it's a rolling 12 month, with 6-month  
17 submissions, right?

18 DR. JOHNSON: Right, correct.

19 CO-CHAIR GUNNAR: So the unintended  
20 consequence is if I have -- if I was going to do  
21 ten or eleven open AAA repairs, and I had one  
22 death in number four, the one thing I'm not going

1 to do is -- seven more. I might do six or five,  
2 but I'm not going to do -- I'm going to refer two  
3 of those out. Okay, Amy?

4 MEMBER MOYER: I had a slightly  
5 different scenario for the usability to a patient  
6 and where can we really effective decision making  
7 in a patient. I'm wondering if by splitting out  
8 open repair and endovascular repair, if we're not  
9 making it more challenging to give that patient  
10 usable information? Because I'm guessing they're  
11 not like, I think I need this kind of a specific  
12 repair. I'm going to look and I'm going to make  
13 my surgeon choice.

14 They're probably going to have a  
15 conversation with the surgeon first, and once  
16 that conversation, unless it goes very poorly,  
17 will happen, it's hard to redirect care at that  
18 point. It really does kind of come down to the  
19 surgeon then saying, you need this type of  
20 intervention. You should go to this area. I  
21 don't think that --

22 (Simultaneous speaking.)

1 CO-CHAIR GUNNAR: I think there's an  
2 intersection, which is what we're getting at, is  
3 the intersection between informed consent on a  
4 case-by-case basis. Your obligation or your  
5 participation and reporting your outcomes in  
6 these cases. That's separate and distinct, but  
7 not really germane, I think, to this discussion,  
8 although it is from an ethical and quality  
9 improvement point of view, if you will.

10 I don't see -- I guess I don't see how  
11 we evaluate a measure based on, as we've come to  
12 a number of places here, the unintended  
13 consequences or how it might be manipulated or  
14 this idea about gaming. That's for a separate  
15 discussion that NQF is committed to have. I  
16 think we have to evaluate them for what they are  
17 on face value. Yes?

18 MEMBER MCCARTY: Just another comment  
19 about the way that the volume can play out at the  
20 individual level. It's not clear to me if this  
21 particular measure gets reported by facility, and  
22 then by surgeon. Some of the metrics I'm

1 familiar with are that way. I've encountered the  
2 scenario where a surgeon who wants to participate  
3 and do a procedure at an off-site facility runs  
4 into this issue of that satellite facility  
5 doesn't have the volume, so then they get dinged  
6 if something happens at that satellite facility,  
7 or there's more restrictions about there has to  
8 be two surgeons, and then it depletes resources  
9 because you have to have two people.

10 I don't know if there's a way for the  
11 developer, when looking at getting that data, to  
12 look at the surgeon level, if it can be across  
13 facilities, and not just by each individual  
14 facility where someone might practice.

15 CO-CHAIR GUNNAR: Again, this goes  
16 back -- informed consent and what you're bringing  
17 up is actually an ongoing professional practice  
18 evaluation and the constant need to update your  
19 credentialing and privileging of an individual.  
20 Personally, I see that the data exists, but the  
21 processes are separate and distinct, if you will.  
22 But I appreciate the perspective. Lee?

1 CO-CHAIR FLEISHER: Perhaps the one  
2 thing I can suggest is one of the advantages of  
3 the steering committee is continuity, as well as  
4 being able to ask for certain things when this  
5 comes back either for maintenance in a year or  
6 maintenance in three years. If I can ask that we  
7 collect some of these concerns that people have,  
8 assuming this measure passes, that we would like  
9 to see. There's actually, now -- Helen and the  
10 group created this wonderful database, so that  
11 it's a living document about some of the concerns  
12 we have, so the next time it comes up, that will  
13 exist.

14 This is something relatively new, the  
15 full extent. Does that sound reasonable to  
16 people, that we would get some of these concerns  
17 of what we'd like to see if this measure comes  
18 back, either in one year or three years?

19 MEMBER YATES: I think that's a great  
20 idea. I think it should be captured -- you could  
21 technically call it the captured concern database  
22 and non-technically call it the worry list or

1 anxiety closet, but somehow or another, having a  
2 collection of those, so that the -- there's  
3 better ways of making an acronym for it, but I  
4 think that you have to come up with something  
5 that collects those.

6 (Off the record comment.)

7 MS. MUNTHALI: You mean the annual  
8 update process or --

9 MEMBER YATES: No, the data --

10 (Simultaneous speaking.)

11 MS. MUNTHALI: We don't have a clever  
12 name. I would suggest that you give a specific  
13 time frame to the developer. It would be for us  
14 to say during your annual update period, in a  
15 year, if you can come back with the changes,  
16 we'll make sure we capture all of that.

17 CO-CHAIR FLEISHER: Great --

18 (Simultaneous speaking.)

19 MEMBER YATES: Yes, but Elisa, don't  
20 you intend that to be something that's attached  
21 to the Phase 3, then Phase 4 --

22 CHAIR SHORT: Yes --

1 (Simultaneous speaking.)

2 MEMBER YATES: It should be in that  
3 dataset, as opposed to being outside of the  
4 dataset.

5 CHAIR SHORT: Correct, that is what  
6 they created. Yes, that has been a major  
7 project, if I remember correctly.

8 MEMBER LEVY: Just to follow up on  
9 that, as I look through these measures and look  
10 at things that are coming back for  
11 re-endorsement, it would be helpful to have an  
12 intro to the measure, when we first click on it,  
13 that gives us the worry list, because it frames  
14 for us how to look at that measure as we're  
15 looking forward, rather than embedding it in the  
16 discussion of the different elements that we're  
17 looking at. I think having a frame as we're  
18 beginning to look at that measure would be really  
19 helpful.

20 (Simultaneous speaking.)

21 MEMBER YATES: Then along those lines,  
22 when I was asked to prepare a preliminary data

1 sheet, no one asked me to list a set of concerns  
2 separately that would be good to add to that. It  
3 would be good that this script allows for a list  
4 of concerns to be created, so that there's an  
5 easily retrievable list for the staff to put  
6 together into that list.

7 Maybe the group, as a whole, could  
8 knock some of them off and say, don't worry about  
9 this; don't worry about that, from the  
10 conversation, but leave these. That would add  
11 something to the script and the preparation by  
12 the prep ahead of time. I think that'll go to  
13 what you're talking about.

14 CO-CHAIR FLEISHER: That's great and  
15 maybe the lead discussants can even take a role  
16 in working with staff to solicit input to create  
17 those data elements.

18 MEMBER YATES: Given the fact that we  
19 didn't do it this time -- because I have lots of  
20 things I'd like to put in my list

21 (Simultaneous speaking.)

22 MEMBER YATES: Can we be given the



1 opportunity, or have it sent to us, to submit  
2 those questions or worries, so that they can be  
3 collected from this meeting, because we didn't do  
4 that prospectively?

5 CO-CHAIR FLEISHER: We can do whatever  
6 we want. Sounds great.

7 MS. MURPHY: Can I just say one thing  
8 real quickly? We can do that. What I think will  
9 be really important for the group to do is be  
10 certain that whatever you submit as concerns are  
11 really important concerns to you that you  
12 positively want information back on in some  
13 period of time. Otherwise, you will drown  
14 yourself in this kind of information.

15 CO-CHAIR FLEISHER: Perhaps if we do  
16 that, then we will collect it, send it back to  
17 everybody, and check that it has the consensus of  
18 the committee, sort of the editorial work. Go  
19 ahead, sorry.

20 CO-CHAIR GUNNAR: Experience drives  
21 wisdom. Anything else, Dr. Yates?

22 MEMBER YATES: No. I mean, when in

1 doubt, don't. Benjamin Franklin.

2 CO-CHAIR GUNNAR: Yogi Bear?

3 Usability and use, can we vote?

4 MS. SKIPPER: Voting is open for  
5 usability and use, Measure 1523, 1 high, 2  
6 moderate, 3 low, 4 insufficient.

7 (Voting.)

8 MS. SKIPPER: Measure 1523 passes on  
9 usability and use, 22 percent high, 65 percent  
10 moderate, 13 percent low, 0 percent insufficient.  
11 We will now vote on overall suitability for  
12 endorsement.

13 (Voting.)

14 CO-CHAIR GUNNAR: We'll wait for this,  
15 but I would not, I would just keep pushing. We  
16 have now moved into the woefully behind schedule  
17 phase.

18 MS. SKIPPER: Just for the record,  
19 Measure 1523 passes on overall suitability for  
20 endorsement, 78 percent yes, 22 percent no.

21 CO-CHAIR FLEISHER: Just a point  
22 because we have STS waiting, which is why we're

1 pushing through. Tomorrow, we'll start at 8:00.  
2 I don't know when the food will get here, but the  
3 STS, our colleagues, need to be out of here by  
4 10:00, so we're going to start very promptly.

5 CO-CHAIR GUNNAR: Very well. We'll  
6 move on now to in-hospital mortality following  
7 elective EVAR of AAAs, Society of Vascular  
8 Surgeons.

9 DR. DUWAYRI: This measure parallels  
10 the one that we were just talking about. It  
11 discusses EVAR, endovascular repair of abdominal  
12 aortic aneurysm. It is not worded as positively  
13 as the open aneurysm repair measure. We're  
14 looking at mortality rate after EVAR. EVAR, over  
15 the last 15 to 20 years, has become an  
16 alternative to open aneurysm repair.

17 Multiple randomized control trials  
18 have shown its effectiveness in preventing death  
19 from aneurysm rupture. Perioperative mortality  
20 has been found to be lower than open aneurysm  
21 repair and, therefore, it has become the most  
22 common method of repairing aneurysms. This

1 measure looks, again, at repairing aneurysms that  
2 are at relatively low risk for rupture. Again,  
3 the key concept in this measure is that patients  
4 who are at low risk of aneurysm rupture should  
5 only be offered elective EVAR if their procedural  
6 mortality rate is low. Therefore, again, here,  
7 no risk adjustment is performed. I will leave  
8 the rest for your discussion.

9 CO-CHAIR GUNNAR: Our discussants are  
10 Drs. Dutton and Scali.

11 MEMBER MARKMAN: I think you're jumping  
12 forward.

13 CO-CHAIR GUNNAR: Did I -- oh, I did.  
14 My apologies. Thank you for the correction, Dr.  
15 Markman --

16 (Simultaneous speaking.)

17 MEMBER MARKMAN: In fact, in this  
18 1,000-page document, I don't think 1534 was in  
19 there -- 1,000 pages, it's unclear, we're trying  
20 to find it. You can bring it up, but it's  
21 exactly right. It mirrors the preceding measure.  
22 It's outcome maintenance, data collected by PQRS,

1 publicly reported. The evidence is the same.  
2 They gathered five new studies which were similar  
3 to the ones in the other, so I think we could  
4 bypass the evidence.

5 CO-CHAIR GUNNAR: As this is a  
6 maintenance measure, we can -- any other  
7 discussion regarding evidence? Any further need  
8 to vote on evidence? Dr. Yates, you're good?

9 MEMBER YATES: Yes.

10 CO-CHAIR GUNNAR: You have your -- we  
11 will carry on to gap?

12 MEMBER MARKMAN: Right, I asked my  
13 questions on the gap before, in the preceding,  
14 very similar --

15 CO-CHAIR GUNNAR: Other than the  
16 denominator being significantly larger?

17 MEMBER MARKMAN: Yes.

18 CO-CHAIR GUNNAR: Any other discussion  
19 on gap? All right, shall we vote? Is Christy  
20 around?

21 MS. SKIPPER: She just ran out.

22 CO-CHAIR GUNNAR: We can do it by hand

1 for this one if you want, unless you --

2 MS. SKIPPER: We might want to do  
3 that. Let's do it by hand.

4 CO-CHAIR GUNNAR: You want to do it  
5 like this? We're ready for gap.

6 MS. SKIPPER: Voting is now open for  
7 performance gap on Measure 1534: 1 high, 2  
8 moderate, 3 low, 4 insufficient.

9 (Voting.)

10 MS. SKIPPER: This measure passes on  
11 performance gap, 38 percent high, 62 percent  
12 moderate, 0 percent low, 0 percent insufficient.

13 MEMBER MARKMAN: In terms of  
14 reliability, you answered our questions about the  
15 percent of the members that are in it. I don't  
16 think we have to go over that again, and we felt  
17 like it was okay in the last measure, so.

18 CO-CHAIR GUNNAR: Any other questions  
19 about or comments about reliability? Hearing  
20 none, I think we can vote.

21 MS. SKIPPER: We're voting on  
22 reliability for Measure 1534. Again, the highest

1 rating is moderate at 1, 2 low, 3 insufficient.

2 (Voting.)

3 MS. SKIPPER: Measure 1534 passes on  
4 reliability, 82 percent moderate, 18 percent low,  
5 0 percent insufficient.

6 MEMBER MARKMAN: In terms of  
7 feasibility, we discussed that, too.

8 CO-CHAIR GUNNAR: Reliability --  
9 validity.

10 MEMBER MARKMAN: Validity, yes.

11 (Simultaneous speaking.)

12 CO-CHAIR GUNNAR: Validity is next.

13 MEMBER MARKMAN: Too many -ilities  
14 there. We've discussed the validity question,  
15 which was the major question that we had raised  
16 before. We've addressed a lot of these issues.

17 CO-CHAIR GUNNAR: Any other comments?  
18 Go ahead and vote.

19 MS. SKIPPER: Voting is open for  
20 Measure 1534, validity, 1 moderate, 2 low, 3  
21 insufficient.

22 (Voting.)

1 MS. SKIPPER: I've got 21 votes,  
2 looking for one more. Moving forward with 21  
3 votes. This measure passes on validity, 76  
4 percent moderate, 24 percent low, 0 percent  
5 insufficient.

6 CO-CHAIR GUNNAR: Usability?

7 MEMBER MARKMAN: No, it's feasibility.

8 CO-CHAIR GUNNAR: Feasibility.

9 MEMBER MARKMAN: Feasibility. I was  
10 just commenting that you're only missing 1  
11 percent of your -- that's in the high category.  
12 That's pretty good. That wasn't mentioned  
13 before, that 1 percent of the data, so I think  
14 there's a high feasibility to it.

15 CO-CHAIR GUNNAR: All right, any other  
16 discussion? Move forward.

17 MS. SKIPPER: Voting is open for  
18 feasibility: 1 high, 2 moderate, 3 low, 4  
19 insufficient.

20 (Voting.)

21 MS. SKIPPER: Moving forward with 20  
22 votes on feasibility, 40 percent high, 55 percent



1 moderate, 5 percent low, 0 percent insufficient.  
2 The measure passes feasibility.

3 MEMBER MARKMAN: Last time you came  
4 before the Committee, you were thinking about  
5 putting these two together. You decided to go  
6 separate ways, but now we're a couple years  
7 later. Do you want to put it together in the  
8 same measure, or consider that at some point when  
9 you come back? That's my only comment. I read  
10 the notes from last time comparing -- yes, EVAR  
11 and open in the same measure.

12 DR. DUWAYRI: I think they are  
13 different. They're offered for different  
14 reasons. Therefore, we prefer to keep them  
15 separate.

16 MEMBER MARKMAN: Okay. You said that  
17 last time, too, but I'm just bringing it up  
18 because you did make the comment last time, or  
19 the committee made the comment, I mean, you're  
20 doing this so why not compare it in one measure.  
21 I don't know if there's any comments on that.

22 CO-CHAIR GUNNAR: Any other

1 discussion? Go ahead and vote on usability.

2 MS. SKIPPER: Usability and use, 1  
3 high, 2 moderate, 3 low, 4 insufficient.

4 (Voting.)

5 MS. SKIPPER: This measure passes the  
6 usability and use criterion, 38 percent high, 52  
7 percent moderate, 10 percent low. We'll now vote  
8 on overall recommendation for endorsement with 1  
9 yes, 2 no.

10 (Voting.)

11 MS. SKIPPER: Measure 1534 is  
12 recommended for endorsement, 91 percent yes, 9  
13 percent no.

14 CO-CHAIR GUNNAR: All right, moving on  
15 to 1540, post-operative stroke or death in  
16 asymptomatic patients undergoing carotid  
17 endarterectomy, SVS.

18 DR. DUWAYRI: The definition of this  
19 measure is looking at the mortality and stroke  
20 rate after elective carotid endarterectomy  
21 performed for stroke prevention in asymptomatic  
22 patients. Carotid endarterectomy has been proven

1 by randomized trials, in the past, to have  
2 benefit in stroke prevention in the presence of  
3 carotid stenosis.

4 The key concept, again, here is to  
5 offer this surgery to patients who would benefit  
6 from this stroke risk reduction and who are not  
7 high risk to -- who are not at high risk of death  
8 or a stroke in the perioperative period. The  
9 usual perioperative mortality and stroke rate in  
10 the literature, from randomized control trials,  
11 is somewhere between 1 to 2 percent. However,  
12 many surgeons and centers who perform this  
13 procedure do not meet the high standards that are  
14 followed in randomized control trials.

15 There is a variation in the  
16 literature, when looking at the real-world data  
17 in the perioperative stroke and death rates, that  
18 goes from 1.4 percent in the hospitals that  
19 participated in these trials, up to 2.5 percent  
20 in low-volume hospitals. We also have VQI data  
21 from around 1250 providers, including 27,000  
22 carotid endarterectomies. The median

1 perioperative stroke and death rate is .4  
2 percent, but it ranges from 0 percent to 100  
3 percent, again, reflecting low-volume centers.  
4 It's also found that the rates are higher in  
5 females and older patients. Therefore, there is  
6 a gap -- there is variability in the literature,  
7 and we feel that this measure is a good quality  
8 measure in patients who would undergo an elective  
9 prophylactic procedure.

10 CO-CHAIR GUNNAR: Discussants now are  
11 Dr. Dutton and Dr. Scali.

12 MEMBER DUTTON: I think this measure  
13 has high face validity. It's obviously what the  
14 patient wants to know if they are going to  
15 undergo this procedure. My only real question on  
16 the evidence, is it the highest level? Compared  
17 to maximal medical management -- Dr. Dutton, you  
18 have an asymptomatic carotid stenosis. Take  
19 statins, take aspirin, versus have a carotid  
20 endarterectomy or a stent. When is the  
21 endarterectomy or the stent indicated, and what  
22 is the most current evidence about that?

1 DR. DUWAYRI: Well, the evidence that  
2 we have from high-quality randomized control  
3 trials is relatively old, from the ACAS study  
4 that told us 60 percent is a good threshold for  
5 treatment. Most surgeons these days do not  
6 follow this and go higher, up to 80 percent,  
7 again, based on the knowledge that best medical  
8 therapy is much better than it was 20 years ago.

9 There is an ongoing randomized control  
10 trial now, CREST-2, which randomizes to carotid  
11 endarterectomy versus current maximal medical  
12 therapy or carotid stenting versus current  
13 medical therapy. I think the data is still to  
14 come. We do not have current randomized control  
15 trial data to tell us the answer. But most  
16 surgeons, in general, follow the 70 to 80 percent  
17 rule, but the data that we have available now is  
18 old and would support surgeons performing this  
19 for more than 60 percent.

20 The recommendations from the American  
21 Heart Association is to not offer this procedure  
22 or carotid revascularizations unless you can

1 predict that your perioperative stroke or death  
2 will be less than 3 percent.

3 CO-CHAIR GUNNAR: As this is a  
4 maintenance measure, the question to the two of  
5 you is that the evidence really hasn't changed  
6 since the last time, and nothing new has come  
7 forward. Is your recommendation that we vote on  
8 that, or that we proceed?

9 MEMBER DUTTON: I don't think we need  
10 to vote. Dr. Scali?

11 MEMBER SCALI: Yes, there's an  
12 evolution in the data in the post-statin era, but  
13 no Level 1A evidence, like Yazan alludes to.  
14 There's certainly some literature, and there's  
15 naysayers that say that the role of surgery, or  
16 stent, for that matter, for asymptomatic patients  
17 is no longer, because the annualized stroke rate  
18 for a patient on a high-intensity statin, and  
19 some of the natural history data trials which are  
20 out there, published in Stroke 2010/2012, can  
21 have annualized stroke risks of 1 to 1.4 percent.  
22 In the old data, we were quoting patients 2

1 percent annualized stroke risk.

2           We've reduced that risk to 1 percent,  
3 so it's a 1 percent annualized stroke risk  
4 reduction benefit for surgery over best medical  
5 therapy in the pre-statin era. That was what we  
6 hung our hats on, and that's what we still do  
7 today because we don't have the Level 1A  
8 evidence. Because there may be certain  
9 subgroups, those who have carotid disease  
10 progression, those who have contralateral  
11 occlusion, et cetera, they're younger patients,  
12 et cetera, what may still benefit from  
13 prophylactic endarterectomy. So most societal  
14 guidelines, certainly the SVS, still holds that  
15 ACAS sort of governs our decisionmaking, but it  
16 does have to be surrounded -- you have to be very  
17 circumspect about who you offer this operation  
18 to.

19           I don't think we need a vote on the  
20 literature. I just would say that there are a  
21 lot of caveats when this discussion rolls out  
22 with the subsequent sections about how to measure

1 and validity and so forth because where a lot of  
2 the decisions are being made are based on trials  
3 from the 1990s.

4 CO-CHAIR GUNNAR: Dr. Yates?

5 MEMBER YATES: Unlike AAAs, which may  
6 be picked up by ultrasound or MRI of the spine  
7 incidentally, CT scans, finding a carotid that's  
8 in trouble means that somebody's looking.  
9 Somebody has to do an elective ultrasound.  
10 Likewise, the lower risk from the statins has to  
11 be aggressively treated. There's a lot of things  
12 going on. I only see a question about  
13 disparities that has to do with gender and age.  
14 Is there any evidence, or was there any effort to  
15 look at disparity in terms of treatment of what  
16 is probably the sine qua non of elective vascular  
17 surgery, that being the endarterectomy of the  
18 asymptomatic carotid? Is there any evidence for  
19 disparity?

20 (Simultaneous speaking.)

21 MEMBER YATES: -- that's part of the  
22 evidence that has -- the maintenance component



1 has to go through this time?

2 DR. DUWAYRI: You mean by physician,  
3 medical center, region, those kind of things?

4 MEMBER YATES: No, by STS versus  
5 doctors.

6 DR. JOHNSON: But are you saying in  
7 regard to risk of stroke with no treatment at  
8 all, or risk of stroke after treatment?

9 MEMBER YATES: Access to the care, and  
10 also the outcomes, perhaps because they come  
11 later, or their symptoms haven't been as  
12 carefully observed? We're supposed to, in this  
13 maintenance period, look at that question, and  
14 that question I don't see being addressed in  
15 this.

16 MEMBER SCALI: Great points. I would  
17 just say that there are currently no screening  
18 guidelines for carotid disease, for asymptomatic  
19 carotid disease, so we don't really know the  
20 antecedent history, in terms of -- we just know  
21 the patients with PAD, by and large, and/or CAD,  
22 also have a high preponderance of carrying

1 carotid occlusive disease. But there's no  
2 welcome to Medicare physical, get your ultrasound  
3 to screen for aneurysms, so you wouldn't really  
4 know about certain disadvantaged groups that may  
5 or may not get found to have that disease.

6 We do know the prevalence of risk  
7 factors that predict likelihood of having carotid  
8 occlusive disease, but we really don't have any  
9 screening guidelines to say these patients may  
10 have been vulnerable or didn't get screened  
11 appropriately, or there was delays in care or  
12 access to care that led to a higher subsequent  
13 stroke risk. I'm unaware of any literature or  
14 guidelines that would help us clarify those  
15 points in the maintenance phase.

16 MEMBER YATES: I only say it because  
17 these things are found either because of somebody  
18 with a high degree of medical expertise that  
19 wants to be screened, or they are the end result  
20 of a high-utilization patient that, because of  
21 other procedures, gets screened. As such, it's  
22 sort of like a -- it's a composite measure,

1 really, for disparity.

2 MEMBER SCALI: Yes, the more vocal  
3 majority, as a director of a busy vascular lab,  
4 this is one of the most common things that we  
5 see, in terms of carotid ultrasounds are pre-op  
6 evaluations for cardiac surgeon, pre-op  
7 evaluation for some other operation, a bruit,  
8 those types of things, or there's symptoms that  
9 aren't consistent with lateralizing hemispheric  
10 stroke, and there's some dizziness workup, et  
11 cetera, syncope events. That's the vast majority  
12 of the indications where people come to  
13 ultrasound for screening.

14 CO-CHAIR GUNNAR: Liz?

15 MEMBER EREKSON: I just want to make  
16 one point about healthcare utilization and  
17 disparity. There's a lot of work that's been  
18 done with healthcare utilization and the  
19 geographic variation that happens with it. If  
20 you take disparity out, you still have huge  
21 variations in the utilization that are not  
22 explained by disparity. I think we just have to

1 be careful with that.

2 If you look at it, if you take out  
3 disparity, the utilizations are more likely  
4 defined by the hospital region you're in than it  
5 is by your disparity.

6 MEMBER YATES: It's just a point of  
7 reference, though, that we're -- it's a point of  
8 continuity here that we're supposed to ask that  
9 question in this process, at this meeting. This  
10 is the one that's more elective than the  
11 procedures because if it's coming out of varied  
12 screening processes.

13 CO-CHAIR GUNNAR: To get back to  
14 sequence --

15 MEMBER YATES: That's part of the  
16 sequence in this.

17 CO-CHAIR GUNNAR: Eventually, when we  
18 get to validity, right?

19 MEMBER YATES: No, it's supposed to be  
20 disparities are in the gap, in the first part, in  
21 the evidence.

22 CO-CHAIR GUNNAR: Just for

1 confirmation, we've all agreed that we don't need  
2 to vote on the evidence?

3 MEMBER YATES: That's fine.

4 CO-CHAIR GUNNAR: Anyone believe that  
5 we do? Okay, now we go to the gap.

6 MEMBER YATES: And I've made my point.

7 CO-CHAIR GUNNAR: Any other comments?

8 MEMBER DUTTON: The gap in measured  
9 performance presented is small.

10 I think we heard about a 1 percent  
11 difference between good centers and bad centers.  
12 But again, referring to the discussion this  
13 morning, this is an outcome measure with strong  
14 importance to patients, so I think as a public  
15 accountability measure, I think this is very  
16 appropriate.

17 MEMBER SCALI: That, and I also think  
18 that there's enough center and region variation  
19 that we sometimes pick up in-patient sample  
20 papers, Medicare papers, or even our own analysis  
21 through the VQI, there's still enough center and  
22 region variation that's of import, even though

1 the surgeon-specific outcomes are -- they're  
2 driven incredibly low. The perioperative stroke  
3 risk contemporary outcomes, asymptomatic carotid  
4 disease, in those patients, it's a 1 percent  
5 number, even lower in many circumstances  
6 nowadays.

7 CO-CHAIR GUNNAR: Any other discussion  
8 on gap? All right, I think we're ready to vote.

9 MS. SKIPPER: We're now voting on gap  
10 for Measure 1540, 1 high, 2 moderate, 3 low, 4  
11 insufficient.

12 (Voting.)

13 MS. SKIPPER: Measure 1540 passes on  
14 performance gap, 5 percent high, 82 percent  
15 moderate, 14 percent low, and 0 percent  
16 insufficient.

17 CO-CHAIR GUNNAR: Moving on to  
18 reliability.

19 MEMBER DUTTON: Again, this measure's  
20 been discussed before. I had no particular  
21 questions around it. Dr. Scali?

22 MEMBER SCALI: I agree. I think your

1 points were well taken in your critique. I would  
2 echo the sentiment that it's technically a  
3 construct of two different outcomes that seem  
4 very reasonable because obviously individually  
5 significant and serious and important for the  
6 patient, provider, and institution, so yes.

7 CO-CHAIR GUNNAR: Any other  
8 discussion? Hearing none, proceed with the vote.  
9 Oh, I'm sorry, Liz.

10 MEMBER EREKSON: I'm sorry. I just  
11 have one question for the developer, and this  
12 just echoes the previous measure that we reviewed  
13 from a different society. How do you define  
14 stroke, and do we need a validated way of  
15 measuring stroke in this population? Obviously,  
16 this is a very different measure, and you're  
17 looking at 120-day outcomes, but I think it might  
18 help the developer of the other measure.

19 DR. DUWAYRI: Stroke is defined as any  
20 post-operative neurologic deficit, whether it's  
21 from a hemorrhagic or an ischemic event, whether  
22 it's ipsilateral or contralateral to the

1 treatment site, any neurologic deficit that lasts  
2 more than 24 hours in those previously completely  
3 asymptomatic patients.

4 MEMBER EREKSON: Does the surgeon  
5 decide that? Does a neurologist decide that?  
6 Does the coder decide it?

7 DR. DUWAYRI: It's a coder slash  
8 surgeon. We enter Rankin's score, but this  
9 outcome is based on, really, what the medical  
10 record states, which is basically what the  
11 surgeon says.

12 CO-CHAIR GUNNAR: Any other questions?  
13 Voting on reliability.

14 MS. SKIPPER: You'll be voting  
15 reliability for 1540, 1 moderate, 2 low, 3  
16 insufficient.

17 (Voting.)

18 MS. SKIPPER: Measure 1540 passes the  
19 reliability criteria, 86 percent moderate, 14  
20 percent low, 0 percent insufficient.

21 CO-CHAIR GUNNAR: Okay, next is  
22 validity.



1                   MEMBER DUTTON: Again, I had no  
2 issues.

3                   CO-CHAIR GUNNAR: Any other  
4 discussion? Hearing none -- oh, Collette?

5                   MEMBER PITZEN: This is Collette. I  
6 have the same concerns with the mortality  
7 measures that we looked at previously, in terms  
8 of having a longer window instant to discharge.

9                   MEMBER SCALI: I can answer that.  
10 This has actually been studied pretty  
11 extensively, at least in carotid patient  
12 population. It sort of speaks to the prior  
13 discussion about the 30-day versus in-hospital  
14 outcomes now. It may be very relevant to  
15 harmonize with what's been reported in the  
16 literature. Maybe we can ask the developers to  
17 speak more about using the in-hospital versus 30  
18 day, but we've actually studied this in several  
19 different methods, whether it be through  
20 Medicare, in-patient sample, as well as through  
21 the VQI.

22                   Patients who suffered in-hospital

1 stroke or death is about one third of the events,  
2 as it was discussed earlier, that occur out of  
3 the hospital, but within 30 days. The identical  
4 predictors have been shown and reported in  
5 several papers. The patients who get those  
6 events in hospital have the identical predictors  
7 for the ones who get it out of hospital.

8 While it is true it dominates the  
9 overall denominator of the events, as long as  
10 you're comparing across centers and surgeons  
11 within the same time points, whether it's the  
12 in-hospital event or the 30-day event, you should  
13 get the same relative differences as shown.

14 About one third of the events that occur occur  
15 out of the hospital, but it's an identical set of  
16 predictors that shows patients who get those  
17 events in hospital are the same as the type of  
18 patients who get them out of hospital.

19 CO-CHAIR GUNNAR: Collette?

20 MEMBER PITZEN: I'd just like to reply  
21 from a patient-centric standpoint of the measure  
22 that could have the potential to have fairly low

1 rates of mortality, which is a good thing, I  
2 think it's important to appropriately handle.

3 CO-CHAIR GUNNAR: Appropriately what?

4 MEMBER PITZEN: To include an extended  
5 window. You can say theoretically and  
6 epidemically everything is all the same, but when  
7 you have something that's reported at a very low  
8 rate. If, perhaps, the concern for mortality or  
9 whatever within a window is more important to  
10 them making that decision, I just think that  
11 there's some value in considering that.

12 CO-CHAIR GUNNAR: Dr. Handy?

13 MEMBER HANDY: That was my point,  
14 exactly, earlier. Every specialty that looks at  
15 this, the longer you look, the more you find.

16 MEMBER DUTTON: The problem with --  
17 I'll speak to the opposite point of Collette, and  
18 I don't mean to be facetious, obviously. Extend  
19 the window long enough, it's 100 percent, and  
20 it's easy to count. One reason to make an  
21 argument for keeping it shorter, if it's the same  
22 -- as Dr. Scali said, if it's getting the same

1 result, in other words, the same reading of  
2 hospitals and doctors, even at a lower level of  
3 mortality. The burden of collection is lower  
4 earlier.

5 It's easier to get more accurate data  
6 earlier. You heard the discussion earlier about  
7 follow-up at 30 days, and that starts to decline,  
8 and you can have, then, strokes or neurologic  
9 events for other reasons. You can be hit by a  
10 car and be dead for a different reason. You get  
11 greater specificity in the lower data collection  
12 burden earlier. That's one reason why  
13 in-hospital measurement might be appropriate in  
14 some cases.

15 MEMBER SCALI: I think the issue of  
16 the stroke adjudication outside the hospital, if  
17 those events were to occur, are very difficult  
18 for providers within that 30-day window. If you  
19 say that you did your carotid endarterectomy,  
20 they left and pos-operative Day 1, two weeks  
21 later they had some bizarre event at Hospital X  
22 that's not a VQI hospital, and then they see you

1 at 30 days and they say, I had a stroke, but they  
2 look okay to you, then how do you code that?  
3 That was, I think, probably one of the  
4 difficulties, I would imagine, perhaps the  
5 developers could probably speak to those  
6 challenges. Because mortality, yes, but I think  
7 the stroke adjudication out of the hospital makes  
8 this very challenging.

9 DR. DUWAYRI: There is no question  
10 that 30 days is better than the one day or two  
11 days after a surgery, but it is -- I think it  
12 will be inaccurate data. It will not be uniform  
13 across centers. Some centers will have the  
14 opportunity to follow their own patients, and  
15 other centers, due to their locations, will have  
16 to rely on follow-up outside.

17 It will increase the cost of  
18 participation in such registries and, therefore,  
19 will decrease our access to such data. So yes,  
20 it's much better to have 30 days, but I think it  
21 is -- it is not as practical as to have the  
22 short-term period.

1 CO-CHAIR GUNNAR: Larissa.

2 MEMBER TEMPLE: I completely  
3 appreciate the concerns with the accuracy and the  
4 costs of the data, the registry, but I think that  
5 in time, the patients are going to demand it. I  
6 think that when they see that all of the other  
7 outcome measures are 30-day, and you're  
8 presenting at discharge -- carotid  
9 endarterectomies go home very soon.

10 As a patient, you may wonder what are  
11 you hiding, and why aren't you giving 30-day?  
12 Clearly, you're not ready to capture 30-day in an  
13 objective way for all patients, but I do think  
14 that probably the next time this measure comes  
15 up, this will be a longer discussion item. I'm  
16 curious; we had a patient advocate on this  
17 committee in the past. Are we going to continue  
18 to do that? It would be interesting to hear that  
19 perspective, as well.

20 MS. MURPHY: The answer to the  
21 advocate is that, yes, we still have someone who,  
22 as it turned out, was an excellent

1 representative. She had a personal circumstance  
2 that was quite serious that prevented her from  
3 being able to be here.

4 CO-CHAIR GUNNAR: Focusing on  
5 validity. Fred, sorry.

6 MEMBER GROVER: It seems to me like if  
7 you're doing procedures or surgeries or whatever,  
8 we darn well ought to know how our patients are  
9 doing in 30 days. I mean, give me a break, but I  
10 think there's a certain ethical obligation. If I  
11 were the public, I'd probably demand it.

12 CO-CHAIR FLEISHER: One of my  
13 questions to the committee is at CSAC, there is  
14 patient representatives in a more diverse group.  
15 Do we want to put into our report that there's  
16 some -- that this is one of the concerns, that  
17 it's clear to the CSAC that this needs to be  
18 taken into consideration when they look across  
19 measures? Does that make sense as a solution?  
20 Am I overstepping?

21 MS. MUNTHALI: No, you're not  
22 overstepping, but I would like to have

1 clarification from Melinda. Will that patient  
2 advocate be able to weigh in, perhaps, before the  
3 CSAC?

4 MS. MURPHY: I'm not sure.

5 MS. MUNTALI: That might be an  
6 option, as well, in addition to --

7 (Simultaneous speaking.).

8 CO-CHAIR FLEISHER: That would be --  
9 okay, in the report, what I hear from many  
10 members of the Committee is, should this pass, we  
11 still want to reflect concerns of the Committee,  
12 so when we go out to voting, our membership  
13 groups, particularly trying to get the patient  
14 groups to comment, that that might be put in  
15 place.

16 DR. DUWAYRI: If I may add, again,  
17 this is a registry measure, and participation in  
18 the registry requires that you have -- although  
19 we are not including this in the measure, itself,  
20 but participation in the registry requires that  
21 you have long-term follow-up data, again,  
22 exceeding nine months, not only 30 days.



1           If you do not have that follow-up,  
2           more than 80 percent of the time, that is more  
3           than 80 percent of the patients need to be seen  
4           or documented, whether they're dead or alive, at  
5           more than nine months. If you do not follow  
6           that, you will be put on probation in the  
7           registry itself.

8           The registry takes care of this  
9           concern. I know the measure does not, really,  
10          because to keep it as accurate as possible, to  
11          keep it in this short period of time, but to  
12          address the concern of patient safety, the  
13          registry requires that we have long-term follow  
14          up.

15                 CO-CHAIR FLEISHER: Should that be in  
16          some part of the specifications of the ability to  
17          be part of the registry? Is that in the  
18          document?

19                 DR. DUWAYRI: I don't think we  
20          included it, but we can include this.

21                 (Simultaneous speaking.)

22                 DR. JOHNSON: This document here?

1 DR. DUWAYRI: This document, yes.

2 DR. JOHNSON: We could include it.

3 (Simultaneous speaking.)

4 MS. MUNTHALI: We will open up the  
5 measure submission form. So by the post-comment  
6 call, which I think is -- I don't know the date  
7 -- November 3rd, if you can update the submission  
8 form by then.

9 CO-CHAIR GUNNAR: Sorry, Karl?

10 MEMBER BILIMORIA: I just wanted to  
11 echo that a little further. We've done a few  
12 things. We've looked at what proportion of cases  
13 have a post-discharge event within the first 30  
14 days, and it's a huge proportion. You know, it's  
15 something like complex surgeries, 40 percent of  
16 people, their only complication happens in the  
17 outpatient setting. A quarter of deaths happen  
18 in that setting. Not only that, it does actually  
19 change hospital rankings on quality. I think it  
20 takes away a lot of the noise about whether you  
21 discharge people early or late or whatnot. So  
22 you have the data, it sounds like. I think there

1 are ways to standardize at 30 days, and you will  
2 just improve the measure.

3 CO-CHAIR GUNNAR: Any other comments?  
4 I think we're ready to vote.

5 MS. SKIPPER: We're now voting on  
6 validity for Measure 1540, 1 moderate, 2 low, 3  
7 insufficient.

8 (Voting.)

9 CO-CHAIR GUNNAR: Are we re-voting?  
10 Oh, there we go. That was reliability.

11 CO-CHAIR FLEISHER: I just asked the  
12 developer if they would add -- if they have  
13 beyond-three-month data, to add it to the measure  
14 submission form, in addition to the fact of you  
15 have to have 80 percent compliance. We will see  
16 that on our post-call.

17 MS. SKIPPER: I need everyone to  
18 please re-vote on the validity for Measure 1540,  
19 1 high, 2 moderate, 3 low, 4 insufficient.

20 (Voting.)

21 MS. SKIPPER: Measure 1540 passes on  
22 validity, 9 percent high, 57 percent moderate, 26

1 percent low, 9 percent insufficient.

2 CO-CHAIR GUNNAR: So up to  
3 use/usability -- or feasibility, yes,  
4 feasibility. Any comments before we vote? All  
5 right, carry on.

6 MS. SKIPPER: Voting is open for  
7 feasibility, Measure 1540, 1 high, 2 moderate, 3  
8 low, 4 insufficient.

9 (Voting.)

10 MS. SKIPPER: With 22 votes, this  
11 measure passes on feasibility, 27 percent high,  
12 68 percent moderate, 5 percent low.

13 CO-CHAIR GUNNAR: Now, use and  
14 usability. Any comments?

15 MEMBER SCALI: I think the use and  
16 usability, there's some questions for the  
17 Committee that were posed, specifically about the  
18 unintended consequences. I think it surrounds  
19 similar arguments about the moderate-sized  
20 asymptomatic AAA. Again, we're back to the same  
21 sort of construct, which is asymptomatic carotid  
22 patients have an annualized stroke risk of less

1       than 2 percent, so the role of operating on  
2       patients who would be deemed unfit for open  
3       surgery versus high risk for subsequent surgical  
4       complications, et cetera. Again, I think the  
5       spirit of this was -- and the developers can tell  
6       me if I'm wrong. I think the spirit was to look  
7       again at patient selection because of the same  
8       type of construct that you guys designed for your  
9       AAA indicators.

10               I think the unintended consequence, in  
11       terms from a patient-centric view, could be that  
12       you would be denying more patients surgery, but  
13       that's actually what's occurring in the United  
14       States currently. We're actually seeing that,  
15       and that's been occurring over the last five or  
16       ten years. If you look at claims data, there's  
17       sort of been plateaus, in terms of carotid  
18       revascularization -- open, that is.

19               Granted, the carotid stenting has  
20       muddied the waters. CMS has put a governor on  
21       how often are those procedures are being done  
22       because of the requirements for enrollment in

1 registries to get reimbursed. We have seen  
2 plateaus in the rates of carotid  
3 revascularization in the field that the risk  
4 profiles of patients, at least in claims data and  
5 when they do walk-overs between VQI and Medicare  
6 -- because we have a current initiative to look  
7 at matching between the VQI patients and the  
8 Medicare identifier for those patients. So you  
9 can get to re-admission and long-term outcomes  
10 because a lot of patients don't come back to  
11 their VQI hospital. We are looking to do that.

12           It's not an easy thing to do for a  
13 patient safety organization with de-identified  
14 data, in terms of how you do those coding  
15 algorithms. But we have figured out that, at  
16 least if you look at the risk profiles over the  
17 last five years for carotid revascularization, by  
18 and large, they tend to be younger patients.  
19 They tend to have less of the CHF, a lot less  
20 renal insufficiency, et cetera.

21           It all comes from societal guidelines  
22 in the literature that came out after ACAS

1 showing that patients with values greater than  
2 two, patients greater than age 75, female gender,  
3 et cetera, all things that were in the trial that  
4 were either a) under-represented, or 2) were  
5 excluded from the original ACAS data, didn't  
6 derive any benefit from prophylactic  
7 endarterectomy. While there is a potential for  
8 the unintended consequence of so-called denying  
9 patient surgery, I think I would put it in  
10 Barbara's construct. It's about telling the  
11 patients that the cure is potentially worse than  
12 the disease by doing nothing. I would just only  
13 raise those points about the usability.

14 CO-CHAIR GUNNAR: Any other comments  
15 about usability and use? Amy?

16 MEMBER MOYER: I apologize because  
17 this isn't specific to this. I'm looking around  
18 on your website. Do you publicly report this  
19 anywhere like the STS does, or do you have plans  
20 to do that?

21 DR. DUWAYRI: PQRS, that's it. Let me  
22 see how we submitted this, but the registry

1 provides us the ability to do both, but I think  
2 this is both here.

3 DR. BURSTIN: Will it go on Physician  
4 Compare then?

5 DR. DUWAYRI: Yes.

6 MEMBER SCALI: And Hospital, is that  
7 what he said? Is that what you asked?

8 MEMBER SCALI: Are the benchmarked  
9 facility data in public?

10 DR. DUWAYRI: Currently, other than  
11 PQRS, no.

12 MEMBER SCALI: Okay, so just in that.

13 CO-CHAIR GUNNAR: Karl, do you have  
14 something else? Fred, anything else? All right,  
15 ready to vote on use and usability? Christy?

16 MS. SKIPPER: Voting on usability and  
17 use for Measure 1540, 1 high, 2 moderate, 3 low,  
18 4 insufficient.

19 (Voting.)

20 MS. SKIPPER: Measure 1540 passes on  
21 usability and use, 13 percent high, 65 percent  
22 moderate, 22 percent low. We'll now be voting on



1 overall recommendation for endorsement, 1 yes, 2  
2 no.

3 (Voting.)

4 MS. SKIPPER: This measure is  
5 recommended for endorsement, 83 percent yes, 17  
6 percent no.

7 CO-CHAIR GUNNAR: Moving on to the  
8 last of the series from SVS is 1543,  
9 post-operative stroke or death in asymptomatic  
10 patients undergoing carotid artery stenting.  
11 Developers want to make any comments?

12 DR. DUWAYRI: Very similar to the  
13 carotid endarterectomy measure, looks at  
14 perioperative stroke and death. Carotid stenting  
15 is an alternative to carotid endarterectomy as a  
16 method of carotid revascularization for stroke  
17 risk for stroke prevention. Again, this measure  
18 looks at patients who are asymptomatic and,  
19 therefore, this is a prophylactic intervention.

20 The literature suggests that the  
21 stroke rate for carotid stenting is slightly  
22 higher than carotid endarterectomy, usually at

1 around 3 percent. Our data analysis from the VQI  
2 registry, from 3,342 carotid stent procedures,  
3 reveal that the perioperative stroke and  
4 mortality rate ranges between 0 to 1.7 percent.

5 The risk of these events is higher in  
6 patients older than 70 and in females. Again,  
7 this is a measure looking at the prophylactic  
8 intervention and, therefore, the key concept is  
9 to offer this procedure only in patients who will  
10 have a relatively low risk of events around the  
11 time of intervention. Carotid stenting is  
12 currently only reimbursed by Medicare in  
13 symptomatic patients. However, asymptomatic  
14 carotid stenting is being performed. Usually,  
15 the indications are for anatomic indications,  
16 either for high cervical lesion with previous  
17 operation or previous radiation.

18 CO-CHAIR GUNNAR: Discussants are Drs.  
19 Scali and Dutton.

20 MEMBER SCALI: The developers present,  
21 in terms of summary of the evidence, there's  
22 actually been a tremendous amount of activity in

1 this area looking at the role of carotid stents,  
2 specifically, in the asymptomatic patient  
3 population. On the heels of CREST-1, there were  
4 a series of additional trials and large registry  
5 analyses that were done. There was a lot of  
6 inter-group analyses, and the developers have  
7 offered more updated literature to support that  
8 this is something that needs to be measured.

9 One question I had with the developers  
10 that I always sort of have difficulty with, and  
11 it's in the spirit of measuring this, as you guys  
12 alluded to, it says that there's no published  
13 guidelines for carotid artery stenting for  
14 asymptomatic patients in three out of the four  
15 societies, with the exception of one society: the  
16 American College of Cardiology. So how do we  
17 reconcile that if we're going to make a quality  
18 measure about measuring an outcome for a  
19 procedure that's not even recommended by three  
20 out of four of the major societies that describe  
21 care and outline guidelines for asymptomatic  
22 carotid disease?

1                   Because what has been shown,  
2                   unequivocally, is that if you remove the MI  
3                   composite endpoint in the literature that's  
4                   there, if you just look at stroke and death,  
5                   stenting has a two-fold higher risk of stroke and  
6                   death, compared to surgery. That is Level 1  
7                   evidence.

8                   Then you sort of have to reconcile to  
9                   make a guideline or a comment about a procedure  
10                  that's been shown to have a higher risk than the  
11                  operation, which we just vetted for -- said it  
12                  had a very narrow therapeutic window to begin  
13                  with. If you can add some comment about that  
14                  because the literature and the evolution of this  
15                  literature has been very brisk in the last few  
16                  years, and it's really muddied the waters about  
17                  what we do with these interventions.

18                  DR. DUWAYRI: Yes, I can't agree any  
19                  more. I think it's another reason we need to  
20                  keep this track. We don't know the value of  
21                  carotid stenting in asymptomatic patients over --  
22                  again, comparing it to not only carotid

1       endarterectomy, but also to maximal medical  
2       therapy. This is, again, a procedure that  
3       carries a higher risk of perioperative events in  
4       asymptomatic patients than endarterectomy. So  
5       again, the answer to this is yes, that's why we  
6       need to continue to measure it.

7               MEMBER DUTTON: Let me ask a slightly  
8       different question. Unlike carotid  
9       endarterectomy, which we can imagine are being  
10      done by a fairly homogenous group of vascular  
11      surgeons, are there lots of specialties in the  
12      waters here, and how do you intend to get data  
13      across the landscape?

14             DR. DUWAYRI: I don't have the numbers  
15      now, but VQI is open for participation, and we  
16      have participants who are neuro interventional  
17      radiologists and interventional cardiologists. I  
18      do not know the exact number of how many of these  
19      are participating in this carotid stenting module  
20      and in other endovascular intervention modules.

21             DR. JOHNSON: Yet, looking into the  
22      future, our quality committee is already

1 interacting with interventional radiology, and  
2 hopefully in cardiology, in combining our --  
3 putting everybody into one database. The other  
4 thing we've discussed with interventional  
5 radiology is alternative payment models, is  
6 looking with them and doing one with them.  
7 You're right. Every specialty or society that  
8 participates in this intervention ought to be  
9 within one database, and that's what we hope to  
10 achieve, but getting there is another point.

11 CO-CHAIR GUNNAR: Dr. Ko?

12 MEMBER KO: I just want to pick up on  
13 Sal's comment. Am I understanding you correctly  
14 that we shouldn't be doing these? If that's the  
15 case, the performance measure should be an  
16 appropriateness measure that we shouldn't be  
17 doing these? Because the reason we have this  
18 measure should not be to collect data. It's not  
19 participation in a registry to collect data so  
20 that we have more knowledge. It should be a  
21 performance measure, and so --

22 (Simultaneous speaking.)

1 DR. DUWAYRI: There is literature to  
2 suggest that the surgeon -- that  
3 interventionalist experience and volume  
4 significantly influences the perioperative  
5 outcomes in these procedures. I think there is  
6 value in treatment of asymptomatic patients, and  
7 there are anatomic indications for carotid  
8 stenting in patients who are not candidates  
9 otherwise for carotid endarterectomy. The  
10 indication for carotid stenting is not usually  
11 the same indication as carotid endarterectomy,  
12 and it carries a higher perioperative risk, but  
13 if you can perform this procedure with a lower  
14 risk than what the natural history of the  
15 patient's carotid stenosis will carry, then I  
16 think it is okay to proceed with it.

17 MEMBER SCALI: I think, to Dr. Ko's  
18 point, that's what I was struggling with  
19 philosophically. I think you have to sort of  
20 evaluate it on each of the merits to make sure  
21 the NQF criteria for how the measure's been  
22 developed is appropriate.

1                   But I think stepping back, if you  
2                   endorse a quality measure for something that  
3                   three out of four societies say you shouldn't  
4                   really be doing to begin with, what is that  
5                   saying to providers who want to do this or don't  
6                   want to do this? What's the patient -- the guy,  
7                   gee, three out of four societies tell us we  
8                   shouldn't be getting this for this indication,  
9                   yet NQF says that we should measure it, meaning  
10                  you should do the procedure, I guess. That's  
11                  where I struggle a bit philosophically, but at  
12                  least on point to talking about the data, I think  
13                  the developers provided enough data to meet the  
14                  evidence-based algorithm that's needed for  
15                  vetting this as a measure. But I think the  
16                  bigger question, philosophically, is one that I  
17                  struggle with.

18                 CO-CHAIR GUNNAR: To get back to our  
19                  charge here, what you've stated and claimed is  
20                  that the evidence supporting this measure has  
21                  changed since this was vetted the initial time?  
22                  So we actually, in this case, should re-vote on



1 the evidence.

2 If it is insufficient or low to  
3 support this measure, then it will no longer  
4 carry, unless we then decide to make an  
5 exception.

6 DR. DUWAYRI: I will point out that  
7 this procedure --

8 CO-CHAIR GUNNAR: Just one second. Am  
9 I correct?

10 MS. MURPHY: Yes, except there  
11 wouldn't be an exception to that because it's not  
12 process.

13 CO-CHAIR GUNNAR: There we go. We've  
14 now gotten down the algorithm. It takes a  
15 village. We learn together.

16 MEMBER SCALI: I would say that for  
17 the evidence to support it, with the caveats  
18 mentioned with the newer evidence that is given  
19 for this, it's not the Level 1A evidence that,  
20 historically, things have been based on. The  
21 CREST trial looks at -- the primary end point was  
22 a composite end point when it compared carotid

1       endarterectomy and carotid stent.

2               It was stroke, death, MI, which  
3       unfairly -- or fairly, depending on how you look  
4       at it -- dings the surgical arm. That being  
5       said, when you remove the MI component and you  
6       look strictly at stroke/death, based on the only  
7       real Level 1A evidence that we have currently, it  
8       would tell you that there's a two-fold higher  
9       risk for doing prophylactic stenting versus  
10      surgical therapy for asymptomatic carotid  
11      disease. Now, subsequent sub-analyses in other  
12      registry data have clearly shown, as Yazan has  
13      mentioned, that in really experienced hands --  
14      like you've done 25, up to 50 carotid stents, in  
15      so-called high-volume centers, high-volume  
16      providers, looking at plaque morphology, calcium,  
17      arch, there's so many anatomic variants that also  
18      impact the outcome of this procedure, which have  
19      been published and are here represented in the  
20      literature, that would say that yes, in those  
21      specific providers' hands, you can get an  
22      equivalent, or even equivalent stroke/risk

1 outcome for the procedure compared to  
2 endarterectomy.

3 So the literature that's there does  
4 sort of represent the evolution of the data as we  
5 understand it, but there's still a -- I guess  
6 we'll get to the gaps and things like that.  
7 There's still some real issues about which  
8 patients would be eligible, which providers  
9 should be included and so forth.

10 The only Level 1A evidence that we  
11 have -- currently, CREST-2 is underway. CREST-2  
12 will look at medical, surgical and stenting, but  
13 it also has mixed groups. On CREST-1, only about  
14 -- it was half or just over -- there's less than  
15 half were actually asymptomatic disease.

16 So the natural history -- yes, so  
17 that's the other thing is again, we're making all  
18 these assumptions about stenting, but when --  
19 everybody came out after CREST-1, and if you were  
20 pro stent, you said, look, stents are as good as  
21 surgery. As long as you do a lot of stents, you  
22 can get as good outcomes as surgeons.

1           The devil was in the details to do the  
2       sub-analyses. Wait a minute, we pull out the MI  
3       from the composite end point and you look at  
4       stroke death specifically, the stroke end point,  
5       two-fold higher risk across the board, no matter  
6       how you looked at it.

7           This has been looked at in subsequent  
8       registries, when you look at stenting for  
9       prophylactic endarterectomy. That being said,  
10      there's been subsequent analyses and subsequent  
11      large registries that have also been produced in  
12      the last several years, and the authors present  
13      that data, again, showing that you can have  
14      equivalent outcomes for the measure with all of  
15      those caveats, being you have to have supremely  
16      good skillset, meaning you've done 25 to 50 of  
17      these things, and you have to be supremely good  
18      about patient selection, not just comorbidities,  
19      but anatomic specifications of the lesion.

20           Lesion morphology has a lot to do with  
21      outcome, as much as age, gender, et cetera. So  
22      therein lies the conundrum about the literature

1 and where the role of current carotid stenting is  
2 for asymptomatic -- that's why CMS doesn't pay  
3 for it. You can't do it right now, unless you  
4 are in a registry. You don't get reimbursed for  
5 this.

6 CO-CHAIR GUNNAR: Any comments from  
7 the developers?

8 DR. DUWAYRI: The procedure, whether  
9 it's endorsed by the Society for Vascular Surgery  
10 or not, is still being performed out there. It's  
11 endorsed by American College of Cardiology, which  
12 is a large society. I think for these reasons,  
13 we need to continue to monitor them. I don't  
14 think we are approving this procedure or  
15 rejecting it. We are just suggesting that we  
16 need to monitor its outcomes.

17 MEMBER YATES: For the sake of  
18 clarity, since you have your registry, has the  
19 incidence of its utilization gone down over the  
20 last year or two?

21 DR. DUWAYRI: I actually can find  
22 that.

1                   MEMBER YATES: While he's looking that  
2 up, Dr. Moss?

3                   DR. DUWAYRI: The answer is no. In  
4 2010, there were 100 cases in the -- no, I'm  
5 sorry. There were 198 cases in the registry, of  
6 carotid stenting, and it has gone down -- gone up  
7 every year.

8                   In 2015 -- yes, but this is by adding  
9 centers. In 2015, there are close to 2,000  
10 carotid stents entered. Accruing more, but  
11 that's one possibility, again.

12                  MEMBER YATES: Your rate per surgeon  
13 or rate per center hasn't gone up, or would you  
14 say -- you may not have that off the tip of your  
15 tongue, but it sounds like it's equivocal right  
16 now. Whether the literature says to do it or  
17 not, it's happening.

18                  DR. DUWAYRI: Yes, but we did not grow  
19 by ten times. The rate of growth on the  
20 procedure volume is ten times.

21                  MEMBER DUTTON: You could argue that  
22 if the procedure is -- if the indication for the

1 procedure is controversial, then measuring the  
2 outcome is even more important.

3 CO-CHAIR GUNNAR: Yes. Larry?

4 MEMBER MOSS: Sal, I just want to ask  
5 your opinion. This is not a scientific question,  
6 but you articulate your conflict well. In your  
7 opinion, are patients with carotid disease better  
8 off with this measure in existence, endorsed, or  
9 not?

10 MEMBER SCALI: In my humble opinion,  
11 I think the answer is yes because the activity is  
12 going to happen. And hopefully we'll have the  
13 answer soon enough with Level 1(a) evidence from  
14 CREST 2, but I think the answer is yes because we  
15 do want to know what those rates are nonetheless,  
16 despite all of the misgivings in the literature.

17 MS. MURPHY: So may I ask a question  
18 of Dr. Scali? Are you saying the measure should  
19 be endorsed by NQF versus information collected  
20 in the registry for analysis?

21 MEMBER SCALI: I thought the question  
22 was more do we think that there should be a

1       measure of stroke and death after carotid  
2       stenting for asymptomatic disease, and I think  
3       despite all of the concerns about the literature  
4       and where that really sits in the current  
5       treatment armamentarium for carotid revasc, I  
6       think the answer is yes, we -- the activity is  
7       occurring, there are people who do participate in  
8       registries and do do a modest amount of volume,  
9       and so you do want to sort of have an  
10      understanding of what their outcomes are and make  
11      sure the people are held accountable,  
12      particularly when the risk/benefit window is so  
13      narrow.

14                So, I'm not going to make the  
15      statement that NQF should endorse this without  
16      going through the formal process, but I would say  
17      that there should be a stroke/death endpoint that  
18      we're following for carotid stenting. Whether or  
19      not we do carotid stenting for the indication is  
20      a different issue. I think that is what I was  
21      struggling at, that Dr. Ko was mentioning, is do  
22      we endorse something that several societies say



1       that we probably should not do?

2                   CO-CHAIR GUNNAR:   And CMS does not pay  
3       for?

4                   MEMBER SCALI:   Unless you're in a  
5       registry or a trial, yes.

6                   DR. DUWAYRI:   Not this registry, but  
7       --

8                   MEMBER SCALI:   Not this registry, it's  
9       a carotid-specific stenting registry.

10                  CO-CHAIR FLEISHER:   We're getting back  
11       to evidence from an NQF endorsement perspective,  
12       separate than should this be in a registry, and  
13       that --

14                  DR. BURSTIN:   Evidence for the measure  
15       focus, there is a rationale that, again, this is  
16       an outcome.   Is there a rationale that there are  
17       logically processes et cetera that would  
18       influence the outcome?   Sounds like there's  
19       probably lots you can do to prevent stroke and  
20       death among patients getting an endarterectomy.  
21       I think the bigger question is, and I think this  
22       is what Melinda was trying to get at, does it

1 send a strange message to have an endorsed  
2 measure for a procedure for which the indications  
3 are in play, just kind of play it like that?

4 But the flip side of that is, if in  
5 fact it is still being done, is it important to  
6 measure the outcomes, even if perhaps it is at  
7 times being done inappropriately? And it  
8 probably sounds like the better measure we'd love  
9 to see you have come back with is a measure of  
10 appropriateness as this settles out, because  
11 certainly it sounds like we're seeing a lot of it  
12 being done based on your database, and it's not  
13 clear what guidance they're using to make that  
14 selection.

15 CO-CHAIR GUNNAR: So again, to get  
16 back to the evidence question, which I think  
17 needs to be re-voted on, is "Is there sufficient  
18 evidence, albeit that it has changed, to support  
19 a measure of this outcome in relationship to  
20 quality and quality improvement?" Dr. Yates?

21 MEMBER YATES: I would argue  
22 absolutely. The new evidence argues all the more

1 for making sure the measure goes on, especially  
2 since there is a whole different spectrum of  
3 specialties that seem to feel that the procedure  
4 is the correct one to do. And the evidence  
5 argues more strongly for continuing.

6 CO-CHAIR GUNNAR: Collette, and then  
7 Fred.

8 MEMBER PITZEN: I am just struggling  
9 a little bit, not being a vascular surgeon, but  
10 when I try to take it in the different thing, the  
11 criteria for evidence for an outcome measure says  
12 that there has to be at least one process or  
13 processes in place that support and lead you to  
14 getting to that outcome. The denominator of this  
15 measure is defining something that is  
16 controversial, so the first step in that process,  
17 or second step, patients evaluate a decision to  
18 proceed towards stent. So I am having a hard  
19 time wrapping my head around that.

20 Let me take another example: with  
21 cholesterol management for a vascular measure in  
22 our diabetes measure, the guidelines changes

1       drastically, and even though some wanted to stay  
2       with an LDL target, the evidence no longer  
3       supported treating to an LDL target of less than  
4       100, so we had to change it. It wasn't  
5       supported.

6               So again, I don't know where things  
7       are at in terms of controversy and studies yet to  
8       come, but I just have concerns.

9               CO-CHAIR GUNNAR: So based on that, I  
10       think we should vote on evidence because I  
11       believe that there's -- there's a -- a change of  
12       opinion amongst many of you regarding -- from the  
13       moment we started this discussion. Dr. Grover?

14              MEMBER GROVER: Well, I think we're  
15       interested in quality and patient safety, and you  
16       have raised some really serious red flags here in  
17       this discussion, and I think that to me makes it  
18       even more imperative you continue collecting this  
19       data just to see what it shows. And perhaps -- I  
20       mean, here you've got a database, and you've got  
21       a chance to measure that, and you document higher  
22       -- worse outcomes with that measure, that needs

1 to weigh into the guidelines in the future.

2 CO-CHAIR GUNNAR: So we're going to  
3 proceed with the vote on evidence. Christy?

4 MS. SKIPPER: We're now voting on  
5 evidence for Measure 1543. 1 yes, 2 no, that the  
6 evidence supports the relationship of the health  
7 outcome in at least one action.

8 (Pause.)

9 MS. SKIPPER: Measure 1543, we've  
10 landed in a gray zone on evidence: 55 percent  
11 yes, 45 percent no. So our options here are to  
12 -- well, we can move forward to vote on the  
13 remaining criteria, but we will not take an  
14 overall vote on suitability for endorsement.

15 CO-CHAIR GUNNAR: We have touched all  
16 the different variations today, I think.

17 MS. MUNTALI: So you will continue  
18 voting, and we hope that the public and member  
19 comments that come in will help to inform this  
20 criterion where you were not able to reach  
21 consensus.

22 CO-CHAIR GUNNAR: Okay. So we --

1 we've moved to gap.

2 DR. DUWAYRI: I had a comment on  
3 evidence, just to --

4 CO-CHAIR GUNNAR: Yes.

5 DR. DUWAYRI: -- clarify.

6 CO-CHAIR GUNNAR: Go ahead.

7 DR. DUWAYRI: So again, there is a  
8 recommendation from the American College of --  
9 American Heart Association to revascularize  
10 carotid if your perioperative risk is less than 3  
11 percent. There are randomized -- there is one  
12 major randomized trial that compared carotid  
13 endarterectomy to carotid stenting that has been  
14 interpreted in two different ways.

15 One is that yes, they have equal  
16 outcomes and another way is that carotid  
17 endarterectomy is better. Now, depending on how  
18 you interpret this data, you will recommend  
19 carotid stenting or carotid endarterectomy. So I  
20 think the data in the literature now does not say  
21 that -- I mean, in my opinion, it says that  
22 carotid endarterectomy is better than carotid

1       stenting, but there is a large medical society in  
2       this country that recommends carotid stenting as  
3       a major revascularization for carotid disease, so  
4       I don't think there is any condemnation currently  
5       in the literature for carotid stenting that is  
6       agreed upon by the majority that we shouldn't do  
7       carotid stenting. I just wanted to clarify this  
8       point.

9               MEMBER HANDY: Do we have a procedural  
10       way forward, because the spirit of monitoring it,  
11       because we don't know if the outcome is  
12       pertinent. So how do we get beyond this lack of  
13       evidence to say that we do want to follow it, we  
14       just don't have the evidence to say we recommend  
15       stenting?

16              MS. MURPHY: What we're going to do is  
17       continue the process through the remaining  
18       criteria. We will include in the draft report  
19       the information about the occurrence. We will  
20       hope, expect, that we will get public comment  
21       that can then help inform what should be done  
22       going forward.

1 DR. BURSTIN: Clarifying that, I'm  
2 really glad you raised that, and I don't want  
3 that to be misinterpreted as part of the report  
4 that goes out. I would also make it very clear,  
5 this vote on evidence has nothing to do with  
6 whether or not stenting is appropriate. It is  
7 the evidence focus for this particular outcome  
8 measure, should you look at these two outcomes  
9 for patients who are stented.

10 But I think it's an important  
11 distinction, because my fear is, and I think a  
12 lot of the fear in the room, is that people will  
13 look upon this measure as it goes forward as NQF  
14 coming forward and saying we endorse that this is  
15 an appropriate procedure, and that's not what the  
16 measure is. The measure is "Is it appropriate to  
17 continue to look at the outcomes of this  
18 procedure, regardless of where the literature is  
19 sorting out?"

20 MEMBER HANDY: So it's really an  
21 opportunity for the pertinent societies to weigh  
22 in in a very informed fashion to sway the



1 discussion.

2 CO-CHAIR GUNNAR: Barry?

3 MEMBER MARKMAN: Yes, I mean, I have  
4 been here for three years. I have never  
5 encountered this situation where we're trying to  
6 measure outcomes in something that is sometimes  
7 detrimental. I mean, have we had this -- Okay.  
8 Okay.

9 (Laughter.)

10 CO-CHAIR GUNNAR: I think Collette  
11 provided a good example, quite frankly. The  
12 evidence changes. Practice changes based on  
13 evidence, right?

14 All right. So gap.

15 MEMBER DUTTON: Well, there is clearly  
16 a gap in understanding about whether this  
17 procedure is indicated or not, so yes, it is  
18 controversial. That is the very reason we should  
19 measure it.

20 Otherwise, I think a discussion would  
21 have the same points as the last measure: one-day  
22 stay versus 30-day mortality, that question will

1       come up again. And again, in the measure data  
2       presented, variability is very low, but again,  
3       this is a significant outcome measure that the  
4       public will want to know the answer to.

5                   CO-CHAIR GUNNAR: Dr. Yates?

6                   MEMBER YATES: Yes, I mean, do the  
7       patients even stay in the hospital for this? Is  
8       this an outpatient procedure?

9                   DR. DUWAYRI: Most of the time, no,  
10      the patients stay as long as they do for carotid  
11      endarterectomy, which is one day. And largely,  
12      it is for perioperative blood pressure  
13      management, so yes, usually, it is an inpatient  
14      procedure. I don't know if CMS approves it as an  
15      outpatient procedure.

16                   CO-CHAIR GUNNAR: Any other comments?  
17      Dr. Grover?

18                   MEMBER GROVER: I guess I think of  
19      things somewhat differently, and I feel like  
20      we're a little bit restricted, and maybe it is  
21      because I am undisciplined. But I think this is  
22      a controversial issue, and that demands

1 collecting more data than some that are not. I  
2 mean, this is patient safety, and it is good to  
3 have more than one group collecting that data, I  
4 think.

5 CO-CHAIR GUNNAR: Collette?

6 MEMBER PITZEN: I just have a  
7 technical point, being the one that I was talking  
8 about, the 30-day window the entire time. All  
9 the data that I can see in the application is  
10 actually within 30 days of the carotid stenting  
11 procedure, so I am not exactly seeing data of at  
12 discharge, like how the measure is. So just  
13 technically, they should align.

14 CO-CHAIR GUNNAR: Barry, any other  
15 comments?

16 (No audible response.)

17 CO-CHAIR GUNNAR: You have none?  
18 Okay. Want to vote on gap, Christy?

19 MS. SKIPPER: We're now voting on gap  
20 for Measure 1543. 1 high, 2 moderate, 3 low, 4  
21 insufficient.

22 (Pause.)

1 MS. SKIPPER: Measure 1543 passes on  
2 performance gap: 32 percent high, 55 percent  
3 moderate, 14 percent low, 0 percent insufficient.

4 CO-CHAIR GUNNAR: Move on to  
5 reliability?

6 MEMBER SCALI: With regard to the  
7 reliability testing, I think the original  
8 development was done with a trial review analysis  
9 through the VSGNE patients, so that is the New  
10 England cohort of the VQI, and they did chart  
11 review analysis and showed excellent reliability  
12 testing, as indicated by their kappa statistic,  
13 which was a strong agreement for identifying the  
14 correct procedure as well as in-hospital  
15 mortality and stroke. That was seemingly done  
16 sort of above board.

17 MEMBER DUTTON: I'd like the  
18 developers to answer that question. I put in the  
19 discussion here I was confused in reading the  
20 specifications. Patients are excluded from the  
21 measure if they have criteria symptoms within the  
22 one-year proceeding stenting or symptomatic

1 carotid stenosis less than 120 days prior to  
2 procedure or other carotid stenosis 120 days or  
3 greater. I couldn't figure out what that meant.  
4 Are we asymptomatic for a year, or asymptomatic  
5 for 120 days, or what?

6 DR. DUWAYRI: For some reason, I don't  
7 really know the answer for sure for that, but  
8 they separated the one year into two exclusion  
9 criteria, and one less than 120 days. But the --  
10 this means that any symptoms within one year is  
11 an exclusion. I don't know why they put it in  
12 two exclusion points. I will have to check back  
13 with that.

14 August 22, 2016 I think the code is  
15 different for 120 days. For less than 120 days,  
16 the code is 9006F, and for more than 120 days,  
17 the code is 9007F, so I think this is the reason  
18 why we separated it, but I am not sure about the  
19 technicality of this.

20 MEMBER SCALI: So are you considered  
21 by the measure, are you asymptomatic if you've  
22 been without stroke-like symptoms for 120 days,

1 or it has to be a full one year? Because that is  
2 different than all of the trial data, right?.

3 CO-CHAIR GUNNAR: Any other  
4 discussion? Fred, you've got your -- you've got  
5 your card up.

6 (No audible response.)

7 CO-CHAIR GUNNAR: Okay. All right.  
8 I think we're ready to vote.

9 MS. SKIPPER: We're now voting on  
10 reliability for Measure 1543. 1 moderate, 2 low,  
11 3 insufficient.

12 (Pause.)

13 MS. SKIPPER: Measure 1543 passes on  
14 reliability, 64 percent moderate, 36 percent low,  
15 0 percent insufficient.

16 CO-CHAIR GUNNAR: Validity?

17 (Pause.)

18 MEMBER SCALI: So again, I think this  
19 is one of the things in terms of the risk  
20 adjustment question now, for carotid  
21 endarterectomy and small AAA, we don't tend to  
22 risk adjust, whereas for, you know, the patient

1 selection piece, again, it is critical here for  
2 providers offering CAS, so you know, the  
3 literature clearly shows that if you risk adjust  
4 for provider, hospital, anatomical variance, and  
5 patient covariance, then you can get those  
6 outcomes. But if the spirit of the measure is  
7 specifically to measure the appropriate patient  
8 selection of who you offer, then I do agree that  
9 probably no risk adjustment would be indicated.  
10 So I just wanted to bring up that point because  
11 of all of the other concerns already raised about  
12 the evidence evolution.

13 CO-CHAIR GUNNAR: Rick, any comments?

14 MEMBER DUTTON: No, I agree with that.

15 I think this is all about patient selection, so  
16 no -- no risk adjustment is appropriate.

17 CO-CHAIR GUNNAR: Any other comments?

18 (No audible response.)

19 CO-CHAIR GUNNAR: Ready to vote.

20 MS. SKIPPER: We're now voting on  
21 validity for Measure 1543. 1 moderate, 2 low, 3  
22 insufficient.

1 (Pause.)

2 MS. SKIPPER: Measure 1543 passes on  
3 validity -- or, I am sorry, it does not. It  
4 looks like we have landed in a gray zone for the  
5 validity of Measure 1543, and again, we will  
6 continue discussion of the remaining criteria.

7 CO-CHAIR GUNNAR: So next is  
8 feasibility, feasibility next?

9 MS. SKIPPER: Yes.

10 CO-CHAIR GUNNAR: Any other  
11 discussion?

12 MEMBER DUTTON: I think we have shown  
13 that it is feasible to collect in a registry, but  
14 this is not going to be easily transported to an  
15 eMeasure or to abstraction from claims data  
16 because the diagnosis of stroke is so specific  
17 and requires sort of hands-on testing, not  
18 abstract.

19 CO-CHAIR GUNNAR: Any other comments?

20 (No audible response.)

21 CO-CHAIR GUNNAR: Okay. Vote?

22 MS. SKIPPER: Voting on feasibility



1 for Measure 1543. 1 high, 2 low, 3 moderate, 4  
2 insufficient.

3 (Pause.)

4 MS. SKIPPER: Measure 1543 passes on  
5 feasibility, 5 percent high, 71 percent moderate,  
6 24 percent low, 0 percent insufficient.

7 CO-CHAIR GUNNAR: And now for the  
8 interesting one, use and usability, or usability  
9 and use.

10 MEMBER MCCARTY: This is more of a  
11 general comment for NQF and CSAC, but I want to  
12 go back again to the conversation earlier about  
13 quality versus accountability, and I wonder if in  
14 some ways we could tie into use and usability,  
15 instead of high, moderate, low, different  
16 purposes.

17 So tracking the outcome for self-  
18 improvement locally so you know what your  
19 outcomes are and you can improve if you need to,  
20 or potentially a level up from that is publicly  
21 reporting, but nothing is tied to it. And a  
22 level up from that is now we're publicly

1 reporting, and there is pay-for-performance,  
2 because in our conversations, that is becoming a  
3 theme, but I think there is some nervousness in  
4 endorsing. We only have one way to endorse a  
5 measure, it is endorsed or it is not.

6 And then from there, I know Helen  
7 described other ways that other groups then  
8 decide what to do with that, but I feel like I  
9 would be more comfortable if we had a way of  
10 being more explicit about these conversations and  
11 the intent of some of the reasons why or how  
12 we're saying these metrics should be used that  
13 are more explicit when the metrics are posted  
14 other than kind of buried in the meeting minutes  
15 and in the moderate rating or low rating of  
16 usability. So just a suggestion for NQF.

17 CO-CHAIR GUNNAR: Anyone from NQF want  
18 to comment?

19 MS. MUNTHALI: No, we have noted your  
20 recommendation, and what we would suggest is that  
21 the committee makes a statement, strong  
22 statement, about your preference for how these

1 measures should be used. We cannot dictate how  
2 these measures are picked up and used, but I  
3 think it would go a long way for the committee,  
4 the Surgery Committee, to say that in the report.

5 CO-CHAIR GUNNAR: Any other -- oh, Dr.  
6 Yates?

7 MEMBER YATES: Yes, I think we said  
8 that last time, and that went up to the central  
9 committee, and they came back and said, no, we're  
10 not going to do tiered usability, tiered  
11 validity, so we can say it again, but what I  
12 heard this morning from the people that are on  
13 the central committee was that they are not going  
14 -- that just look at the quality, whether it's a  
15 quality measure or not, but don't worry about the  
16 end use in terms of how you vote on things. So I  
17 think we did say that once, just as a point of  
18 clarity there.

19 MEMBER LEVY: So there is a difference  
20 between saying that as a general rule for how NQF  
21 endorses measures versus this committee making a  
22 recommendation about a particular measure so that

1 when the MAP looks at the measure, they will have  
2 our comments that we do not think it should be  
3 used for accountability, for example. So our  
4 comments on individual measures about our review  
5 of the literature may be useful for the MAP.  
6 That is different than saying that NQF in general  
7 will have different tiers of endorsement.

8 MEMBER YATES: I would argue that  
9 we're now halfway through the measures between  
10 the two days, and saying that now doesn't allow  
11 for us to -- as a committee, to say that for some  
12 of the measures we have already gone over that  
13 there was some questions, so I am not sure that  
14 those comments are in a logical enough place for  
15 the MAP to pick them out.

16 MEMBER LEVY: Well, we will still have  
17 an opportunity I think when we do the final call  
18 so that we could do that with the other measures.

19 MEMBER YATES: So just so that the  
20 staff know, make sure that's on the agenda.

21 (Simultaneous speaking.)

22 CO-CHAIR GUNNAR: Yes, I just want to

1 reiterate, maybe I am missing something, but  
2 there are NQF measurements measure process and  
3 outcomes that are important to the patient in  
4 informed consent. They are important to the  
5 evaluation of the physicians' ongoing  
6 professional practice. They are important to  
7 quality improvement. They are separate  
8 processes, yet the information is important to  
9 those separate evaluations. In my opinion, we  
10 can't confuse them. We can't mix them together.

11 MEMBER YATES: My comment would be is  
12 that when they are used by CMS, they are used  
13 with a nomenclature of NQF-endorsed, and it's in  
14 their Blue Book in terms of what performance  
15 measures to use that it has to go through the NQF  
16 process, so the two are intertwined and embedded.

17 And I understand that there are some  
18 measures that are too big to fail, but we can at  
19 least put some pressure on at least making them  
20 better and making them more focused for some of  
21 the more fine details that they are actually  
22 delineating us by in terms of performance by

1 hospital, and eventually, by physician.

2 CO-CHAIR GUNNAR: And I should say  
3 that the bucket -- the second, third, fourth  
4 bucket, then, is -- or third bucket, of use of  
5 NQF, is pay-for-performance, so I think that we  
6 have to figure out, are those unintended  
7 consequences of NQF, or are they natural uses of  
8 them? If they're natural anticipated uses of NQF  
9 measurements, then I think we have to be  
10 cognizant of that.

11 In this case, this is where it  
12 actually goes back to what Dr. Scali says, would  
13 an OPP want to know the percentage of -- you  
14 know, are you actually doing procedures that are  
15 not recommending by guidelines by three  
16 societies? Is that your management of  
17 asymptomatic patients?

18 MEMBER YATES: In this particular  
19 case, and CMS doesn't pay for this --

20 CO-CHAIR GUNNAR: And that is the --

21 MEMBER YATES: They're not going to  
22 get penalized for it.

1 (Laughter.)

2 CO-CHAIR GUNNAR: But I think it has  
3 been a great discussion for me. I think clarity  
4 going forward is on how, as a standing committee,  
5 we evaluate this, we have been told, go back,  
6 evaluate it as a single stand-alone measure for  
7 the use of quality improvement. We can't help  
8 collectively saying, yes, but it is used for -- .  
9 And that may not be an appropriate use.

10 Okay. All right. So I think --  
11 thanks for the side rant. We have to vote on  
12 usability and use, or are we  
13 -- yes.

14 MS. SKIPPER: Yes, and this is the  
15 last criteria that we have to vote on. And we  
16 will be done with the SVS set.

17 So we're now voting on usability and  
18 use for Measure 1543. 1 high, 2 moderate, 3 low,  
19 4 insufficient.

20 (Pause.)

21 MS. SKIPPER: Okay. With 20 votes, 10  
22 percent high, 45 percent moderate, 45 percent

1 low. We have also landed in a gray zone for  
2 usability and use. And since this measure did  
3 not reach consensus on validity, we will not take  
4 an overall vote for recommendation for  
5 endorsement.

6 CO-CHAIR GUNNAR: All right.

7 MS. SKIPPER: And -- and we've run  
8 over the agenda about half an hour, but we did  
9 have time for -- if we can ask the operator to  
10 open the line for member and public comment, and  
11 if there is anyone in the room who would like to  
12 make a comment on any of the measures discussed  
13 to this point.

14 THE OPERATOR: If you would like to  
15 make a public comment, please press star 1.

16 (Pause.)

17 THE OPERATOR: There are no comments  
18 at this time.

19 MS. SKIPPER: Are there any comments  
20 in the room?

21 (No audible response.)

22 MS. SKIPPER: Okay. Hearing none, I



1 just want to note that we did run over a few  
2 minutes. We have the STS measures that will be  
3 discussed in the morning. We will be beginning  
4 at 8 o'clock, so about a half hour earlier, to  
5 finish the review of the remaining measures.

6 And I also want to note that there is  
7 a reservation for dinner at P.J. Clarke's at  
8 6:30, and it is located at 1600 K Street. You  
9 can come see me if you need walking directions,  
10 but there is a reservation if you all would like  
11 to have dinner at P.J. Clarke's. And is there  
12 anything else I missed?

13 (No audible response.)

14 MS. SKIPPER: Yes, you can leave your  
15 remotes and your placards and get ready for the  
16 morning, 8 o'clock. And thank you all for a good  
17 first day.

18 (Whereupon, the above-entitled matter  
19 went off the record at 5:31 p.m.)  
20  
21  
22

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