

NATIONAL QUALITY FORUM

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SURGERY STANDING COMMITTEE

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WEDNESDAY

FEBRUARY 13, 2019

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

PRESENT:

LEE FLEISHER, MD, Co-Chair

WILLIAM GUNNAR, MD, JD, Co-Chair

ROBERT CIMA, MD, MA, Mayo Clinic\*

RICHARD DUTTON, MD, MBA, United States

Anesthesia Partners

TEMAYA EATMON, Patient Advocate

ELISABETH EREKSON, MD, MPH, FACOG, FACS,

Dartmouth-Hitchcock

FREDERICK GROVER, MD, University of Colorado

School of Medicine

JOHN HANDY, MD, American College of Chest

Physicians\*

MARK JARRETT, MD, MBA, North Shore-LIJ Health

System\*

AMY MOYER, The Alliance

CHRISTOPHER SAIGAL, MD, MPH, University of

California Los Angeles

SALVATORE SCALI, MD, FACS, RPVI, University of

Florida-Gainesville

ALLAN SIPERSTEIN, MD, Cleveland Clinic\*

JOSHUA D. STEIN, MD, MS, University of Michigan

LARISSA TEMPLE, MD, Memorial Sloan-Kettering

Cancer Center\*

ADOLPH YATES, MD, University of Pittsburgh

Medical Center

NQF STAFF:

ELISA MUNTHALI, Senior Vice President  
MELISSA MARINELARENA, Senior Director  
KATHRYN GOODWIN, Senior Project Manager  
CHRISTY SKIPPER, Senior Project Manager  
VAISHNAVI KOSURI, MPH, Project Analyst

ALSO PRESENT:

MARK ANTMAN, Society of Thoracic Surgeons  
VINAY BADHWAR, MD, FACS, FACC, West Virginia  
University

GAETANO PAONE, MD, Society of Thoracic Surgeons

SEAN O'BRIEN, Duke University\*

DAVID SHAHIAN, MD, Observer

\* present by teleconference

## CONTENTS

Opening Remarks and Housekeeping . . . . .	4
Introductions and Disclosures of Interest. . . . .	8
Portfolio Overview and Overview of Evaluation Process . . . . .	14
Consideration of Candidate Measures	
NQF 2561 STS Aortic Valve Replacement (AVR) Composite Score (STS). . . . .	45
NQF 2563 STS Aortic Valve Replacement (AVR) + Coronary Artery Bypass Graft (CABG) Composite Score (STS) . . . . .	45
NQF 0122 Risk-Adjusted Operative Mortality for Mitral Valve (MV) Replacement + CABG Surgery (STS) . . . . .	173
NQF 0118 Anti-Lipid Treatment Discharge (STS). . . . .	305
Member Comments and Public Comments. . . . .	342
Adjourn. . . . .	343

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

(8:30 a.m.)

MS. SKIPPER: All right. Good morning, everyone, and welcome to the Surgery Standing Committee's in-person meeting. Good morning to all of you in the room, those of you participating by the phone and, also, to our measure developers here.

Hi, my name is Christy Skipper, Senior Project Manager at CSAC. It's been a couple of years, since we had our last meeting.

So we're not going to keep you too long this morning. We do have 15 measures to -- I'm not going to talk too long, because we do have 15 measures to try to get through today.

So we'll do our standard introductions and disclosures of interest, briefly, briefly, review the portfolio, because you all know it, go through the overview of the evaluation process, jump into reviewing those measures.

And I want to note that, in addition to being logged in into the slide deck platform,

1       you also need to be logged into the Poll  
2       Everywhere link to vote later on today and then,  
3       we'll open the call for member and public comment  
4       and then, hear next steps.

5                   And so again, my name is Christy  
6       Skipper and I'll just turn it to, I'll start with  
7       Elisa, to give, to say, introduce yourself and  
8       then, we'll go through the rest of the project  
9       team.

10                   MS. MUNTHALI: Thank you, Christy.  
11       Good morning and welcome, everyone. My name is  
12       Elisa Munthali, I'm the Senior Vice President for  
13       Quality Measurements, and I wanted to thank you  
14       for being here, in person and on the phone.

15                   MS. MARINELARENA: Good morning. My  
16       name is Melissa Marinelarena, I'm the Senior  
17       Director. Welcome, all of you. I know a couple  
18       of you in from other projects, but it's a  
19       pleasure meeting all of you, for the first time  
20       face-to-face those of you that are here. Thank  
21       you.

22                   (Telephonic interference.)

1 MS. GOODWIN: Good morning and  
2 welcome. This is Katy Goodwin, Senior Project  
3 Manager.

4 MS. SKIPPER: Thanks, all. And so  
5 just a brief note, for those of you on the phone,  
6 please don't put the call on hold and I hear a  
7 little bit of feedback, so please try to mute  
8 your microphone.

9 And we do have a transcriber, court  
10 reporter here today, so as you speak, please say  
11 your name before you speak. And then, we'll also,  
12 for those of you on the phone, be monitoring the  
13 chat room, but you're encouraged to speak out.  
14 And, again, say your name before you speak, so  
15 that we can know who's speaking, when we go back  
16 and look at the transcript for this meeting.

17 Okay, so now I'll turn it over to  
18 Elisa to go through introductions and disclosures  
19 of interest.

20 MS. MUNTHALI: Thank you. And, before  
21 I do, I just, I think we missed one of our  
22 teammates, I wanted her to introduce herself, as

1 well.

2 MS. KOSURI: Hi, everyone, I'm  
3 Vaishnavi Kosuri, and I'll be helping out with  
4 voting today.

5 MS. MUNTHALI: Thank you, Vaish. So  
6 we're going to combine disclosures of interest  
7 with introductions and you, probably, remember,  
8 when you were named to the Committee, we asked  
9 you to fill out a pretty lengthy form that asked  
10 you a number of questions about your professional  
11 activities, as they're related to the Surgery  
12 Standing Committee.

13 And so what we're asking you today is  
14 to orally disclose anything that you provided us  
15 on that form. Before we go through the process,  
16 I just wanted to give you a couple of reminders.

17 You sit on this committee, as an  
18 individual, you do not represent your employer,  
19 or anyone, who may have nominated you for the  
20 Committee.

21 We're interested, not just in paid  
22 activities, as they're relevant to the work in

1 front of you, but also those that are unpaid.  
2 And this is, probably, the most important  
3 reminder, just because you disclose does not mean  
4 you have a conflict of interest. We go through  
5 this --

6 (Telephonic interference.)

7 MS. MUNTHALI: Sorry about that. We  
8 go through this process in the spirit of openness  
9 and transparency, and so we do have a number of  
10 people on the phone. We'll start with the  
11 disclosures of, disclosures of interest --

12 (Telephonic interference.)

13 MS. MUNTHALI: -- in the room, first.  
14 We'll start with your co-chairs. We'll ask them  
15 to introduce themselves. Right now, you only  
16 have one. I understand, Lee's on his way.

17 Introduce yourself. Let us know who  
18 you're with and let us know, if you have anything  
19 to disclose. We'll go through everyone here in  
20 the room and then, on the phone, I'll call out  
21 your name and let us know. So, Bill.

22 CO-CHAIR GUNNAR: William Gunnar,



1 Veterans Health Administration, and I have no  
2 conflict of interest. I'd also like to just say,  
3 take a moment, because -- to welcome everyone,  
4 those who are here, who, who had the intestinal  
5 and constitutional fortitude to actually travel  
6 to D.C., thank you.

7 And, two things. One, the Josh Stein,  
8 this is your first in-person meeting. You've  
9 been on the Committee for a while, so welcome, in  
10 person, it's nice to put a face to a name.

11 And I'd also like to welcome TeMaya  
12 Eatmon, who's our new patient representative for  
13 the Committee, so thank you for your commitment.  
14 So.

15 MS. MUNTHALI: Thank you for that.  
16 TeMaya, welcome, and your turn.

17 MEMBER EATMON: TeMaya Eatmon and I'm  
18 a Patient Advocate for several cancer  
19 organizations and I don't have any conflicts of  
20 interest.

21 MEMBER MOYER: Amy Moyer, I'm the  
22 Manager of Value Measurement for the Alliance,

1 we're a healthcare purchasing cooperative, a  
2 non-profit, and I have no disclosures of  
3 interest.

4 MEMBER YATES: Adolph Yates,  
5 Orthopedic Surgeon, from the University of  
6 Pittsburgh Medical Center, and I have no conflict  
7 of interest relevant to any of the measures that  
8 we'll be looking at today.

9 Although, I am involved in orthopedic  
10 measures and a whole bunch of committees and I,  
11 unfortunately, I have no commercial conflicts of  
12 interest, which is good news and bad news. And I  
13 will pass it on to Richard.

14 MEMBER DUTTON: Rick Dutton. I'm an  
15 anesthesiologist. I practice in Dallas. I'm a  
16 Chief Quality Officer for U.S. Anesthesia  
17 Partners, which is a large national private  
18 practice.

19 I have no conflicts of interest with  
20 any of the measures, today, although, like  
21 Adolph, I, I participate on lots of committees  
22 and technical expert for measure development.

1                   MEMBER SAIGAL: Chris Saigal, a  
2 urologist from UCLA, I have no disclosures.

3                   CO-CHAIR GUNNAR: I just wanted to  
4 point out that Chris came from L.A.

5                   (Laughter.)

6                   (Off the record comments.)

7                   MEMBER SCALI: Good morning, my name  
8 is Sal Scali, I'm a vascular surgeon at the  
9 University of Florida, in Gainesville, as well as  
10 the Veterans Health Administration.

11                   I have no financial conflicts and I do  
12 act as the Chair of the ER Quality Committee for  
13 the Society for Vascular Surgery's Vascular  
14 Quality Initiative.

15                   MEMBER EREKSON: Hi. Elisabeth  
16 Erekson. I work at Dartmouth-Hitchcock. I'm a  
17 urogynecologist and the interim chair for the  
18 Department of OB/GYN there. As discussed, I have  
19 no conflicts of interest with any of the measures  
20 today. I do sit on a number of committees and  
21 I'm the National Advisor for the OG's Quality  
22 Improvement Network.

1 CO-CHAIR GUNNAR: I just want to point  
2 out that Elisabeth drove an hour-and-a-half to  
3 Manchester, through the snowy Massachusetts  
4 countryside, and then took a plane here to D.C.,  
5 just pointing that out.

6 MEMBER STEIN: Hi, everyone, I'm  
7 Joshua Stein. I'm an ophthalmologist and health  
8 services researcher at the University of  
9 Michigan. I have no relevant conflicts of  
10 interest.

11 MS. MUNTHALI: Thank you very much to  
12 everyone in the room. On the phone, I'll start  
13 with Robert.

14 MEMBER CIMA: This is Bob Cima, in  
15 Rochester, Minnesota, and our highways were  
16 closed yesterday, so I couldn't get out. I have  
17 no conflicts.

18 MS. MUNTHALI: Thank you, Bob. John  
19 Handy.

20 MEMBER HANDY: John Handy, Thoracic  
21 Surgeon, Portland, Oregon. No conflicts of  
22 interest.

1 MS. MUNTHALI: Thank you. Mark  
2 Jarrett.

3 MEMBER JARRETT: Hi, Mark Jarrett.  
4 I'm Chief Quality Officer at Northwell Health. I  
5 apologize not being there in person, but I have  
6 grandchildren and infectious diseases and I have  
7 no conflicts.

8 MS. MUNTHALI: Thank you, very much.  
9 Barb, I'm not sure if you're on the line?

10 (No audible response.)

11 MS. MUNTHALI: Barbara Levy?

12 (No audible response.)

13 MS. MUNTHALI: Okay. Keith Olsen?

14 (No audible response.)

15 MS. MUNTHALI: Okay. And, Allan?

16 MEMBER SIPERSTEIN: Hi, Allan  
17 Siperstein, at the Cleveland Clinic. It's always  
18 warm and sunny here, and I have no conflicts.

19 MS. MUNTHALI: Thank you very much.  
20 We do, also, have Fred Grover, who just joined us  
21 in the, in the room. Can you introduce yourself?  
22 Let us know, who you're with and, if you have any

1 conflicts.

2 MEMBER GROVER: Yes, I'm Fred Grover,  
3 STS, so that's, obviously, a conflict today.

4 CO-CHAIR GUNNAR: I just want to point  
5 out that, Fred flew from Denver to get here and  
6 he's not voting on any of the measures today.

7 (Telephonic interference.)

8 MEMBER GROVER: I can always weigh in,  
9 occasionally.

10 (Off the record comments.)

11 (Laughter.)

12 CO-CHAIR GUNNAR: But I was pointing  
13 out to those, who actually -- we, we have quite a  
14 few empty chairs, here, in the room. I was just  
15 pointing that out.

16 (Off the record comments.)

17 MS. MUNTHALI: Yes.

18 (Laughter.)

19 MS. MUNTHALI: Thank you to everyone,  
20 who made the effort to participate, in person and  
21 on --

22 (Telephonic interference.)

1 MS. MUNTHALI: -- the phone. I just  
2 wanted to --

3 (Telephonic interference.)

4 MS. MUNTHALI: -- let you know, what  
5 William was saying, Fred will be recused from  
6 voting and discussing, unless there is some  
7 specific questions that the Committee has for him  
8 to address. And, I think, somebody on the phone  
9 may be trying to chime in.

10 MEMBER TEMPLE: Yes, so this is  
11 Larissa Temple, I'm on the Committee, as well,  
12 and I, unfortunately, I'm still in Rochester, New  
13 York, and all of our airports are snowed in.

14 MS. MUNTHALI: Okay. Thank you, so  
15 much. Sorry, for missing you. Okay, so before I  
16 turn the meeting over to Christy and colleagues,  
17 just wanted to remind you that, at any time, if  
18 you remember that you have a conflict, we want  
19 you to speak up.

20 You can do so in real-time, or you can  
21 get in touch with any one of us on the NQF staff,  
22 or your co-chairs. Likewise, if you believe that

1 one of your colleagues is acting in a biased  
2 manner, we want you to speak up. Thank you.

3 (Off the record comments.)

4 MS. SKIPPER: Okay, thank you, Elisa.  
5 So now, we'll just jump into a brief review of  
6 the Surgery Portfolio. As you all know, most of  
7 these measures are inpatient and the level of  
8 analysis is, mainly, at the group practice, or  
9 individual, level.

10 And the majority of the measures are  
11 within, fall within cardiac surgery, vascular  
12 surgery, and we have a great number of outcome  
13 measures, within a portfolio, and a handful of  
14 process structure and composite.

15 Two of our measures that you all will  
16 be reviewing today, were sent to the Scientific  
17 Methods Panel, they were deemed complex. And  
18 this panel consists of individuals with  
19 methodologic expertise, to help ensure a higher  
20 level of evaluation of the scientific  
21 acceptability of complex measures.

22 Okay, now, I'm just turning to Katy,



1 for roles of the Standing Committee and so on.

2 MS. GOODWIN: Thanks, Christy. And,  
3 most of you have been through this, quite a few  
4 times, now, but we wanted to remind you of the  
5 process and procedure for today's meeting.

6 As a reminder, as Standing Committee  
7 Members, you are acting, as a proxy, for the NQF  
8 Multi-Stakeholder Membership and, the main charge  
9 for today is to evaluate each measure against  
10 each measure evaluation criterion.

11 During the discussion, we ask that you  
12 indicate your rationale for the rating and the  
13 extent to which each criterion is met. This is  
14 to ensure that we adequately capture your  
15 discussion in our report.

16 You will be making endorsement  
17 recommendations to the NQF Membership and, as a  
18 reminder, NQF Members have an opportunity to  
19 submit comments on your recommendations and,  
20 also, express their support, or non-support, of  
21 the measures.

22 Some ground rules for today's meeting.

1 Please attend the meeting, at all times. If you  
2 do need to step away, please, let us know, for  
3 those of you on the phone, you can let us know  
4 using the chat function. It's just really  
5 important that we know who is present and ready  
6 to vote, because we do need quorum to vote. If  
7 we lose quorum, we will not be able to vote.

8 Please announce your name, prior to  
9 speaking. We ask that you remain engaged, during  
10 the discussion, and keep your comments concise  
11 and focused and, of course, base your evaluation  
12 and recommendations on the measuring evaluation  
13 criteria and guidance.

14 So the, the process for today's  
15 measure discussion, the measure developers, we  
16 are fortunate to have them here with us, in  
17 person, today. They will be invited to provide a  
18 brief introduction of the measures set for three  
19 to five minutes.

20 After the measure developer introduce  
21 their measures, Committee Members, who are the  
22 lead discussants on the measures, will then begin

1 the discussion of the measures, in relation to  
2 the measure evaluation criteria.

3 The lead discussants will be providing  
4 a summary of the pre-meeting evaluation comments  
5 that Standing Committee Members have submitted to  
6 us. They will, also, highlight, or note, if  
7 needed, the preliminary rating by NQF Staff.

8 As a reminder, the NQF Staff rating is  
9 intended to be used, as a guide, to facilitate  
10 your discussion. You are still free to discuss  
11 openly and, and vote, as you wish.

12 So we are using a new voting platform  
13 today. We no longer have those fun remote  
14 clickers that you've used in the past, so we're  
15 using a new platform called -- oh, can you go  
16 back one?

17 (Off-microphone comments.)

18 MS. GOODWIN: That's fine. It's  
19 called Poll Everywhere, and we did send a link on  
20 how you can access Poll Everywhere and you will  
21 need to be on that link, open that in a separate  
22 tab, on your computer, in order to vote.

1                   We'll walk through that again when we  
2                   get closer to our first vote, so if you don't  
3                   have that Email open, or if you don't have that  
4                   Email, just let us know and we'll be sure to  
5                   forward you the link.

6                   As for the discussion, we will be  
7                   starting with the first criteria, which is  
8                   important to measure and report. As a reminder,  
9                   this is a must-pass-criteria, which means, if  
10                  the, the measure does not pass, either, evidence,  
11                  or gap, the discussion will stop there.

12                  We'll then move on to Scientific  
13                  Acceptability. Under that criteria are two  
14                  sub-criteria reliability and validity, both, of  
15                  which, are, must pass, as well. We also have a  
16                  couple of composite measures, and so we'll be  
17                  voting on the quality construct under Scientific  
18                  Acceptability.

19                  We'll then move on to feasibility,  
20                  followed by use, which is, now, a  
21                  must-pass-criteria for maintenance measures, and  
22                  we do have several maintenance measures that are

1 under review today.

2 We'll then talk, discuss, and vote on  
3 usability and, finally, the overall  
4 recommendation for endorsement. Also, as a  
5 reminder, you will be voting on the measures, as  
6 they are before you, today.

7 If you have recommendations for the  
8 developers, they are present, they are here. We  
9 will also note that in the report, but your  
10 recommendations and, and voting is to be on the  
11 measures, as they are before you.

12 A reminder on achieving consensus,  
13 quorum is 66 percent of the Committee, so for  
14 this committee that is 15 voting members. We do  
15 have quorum present, on the phone and in the  
16 room, so we will be able to vote on the measures.

17 In order for a measure to pass, or be  
18 recommended, that requires greater than 60  
19 percent of the yes votes of the quorum. If the  
20 vote falls in between 40 and 60 percent that is  
21 consensus not reached, or the gray zone, as we  
22 call it.

1                   This means that this type of measure,  
2                   or recommendation, would move forward to the  
3                   public and NQF Member comment and the Committee  
4                   will re-vote and re-discuss the measure, during  
5                   the post-comment call, which is scheduled in May.

6                   (Off-microphone comments.)

7                   MS. GOODWIN: The measure does not  
8                   pass, or is not recommended, if it is less than  
9                   40 percent yes votes of the quorum. Any  
10                  questions on the process, or voting, for today's  
11                  meeting?

12                  CO-CHAIR GUNNAR: Rick.

13                  MEMBER DUTTON: Yes, hi. Richard  
14                  Dutton. Dumb question. We filled out surveys on  
15                  a lot of these and put a lot of comments in, in  
16                  advance, is there any way to access those?  
17                  Because, I don't necessarily remember what I  
18                  wrote, but I might be smarter than I am now.

19                  MS. SKIPPER: Yes, and I can send the  
20                  workbook to you all. I thought I had, but all  
21                  your comments have been incorporated and they're  
22                  going to be in the light pink boxes on the --

1 MEMBER DUTTON: In the measures?

2 (Simultaneous speaking.)

3 MS. SKIPPER: Yes.

4 MEMBER DUTTON: Oh, okay, good.

5 MS. SKIPPER: Yes.

6 MEMBER DUTTON: That's fine, I can  
7 find them then.

8 MS. SKIPPER: Okay. And so, Lee  
9 joined us. I just wanted to welcome our other  
10 co-chair, here, Lee, to our meeting this morning.

11 CO-CHAIR FLEISHER: Sure, Lee  
12 Fleisher. Thank you. Train just got in. No  
13 disclosures. Other than I'm on the Board, I  
14 guess. Thank you.

15 CO-CHAIR GUNNAR: So and, and the  
16 other, just as an overview, thanks for these --  
17 many of us are very familiar with the process,  
18 but it's changed a little bit.

19 I think, expanding some understanding  
20 of the scientific methodology would be helpful.  
21 The second is, all of these measures, most of  
22 them, were, except for the composite, which we

1       endorsed in 2014, all of these have been, this is  
2       the second round, we, we endorsed these in 2007.

3               And so can you explain how the use of  
4       criteria, now, because many of these measures are  
5       part of a composite measure, but they're not  
6       independently publically reported, so can we get  
7       some explanation, or help, on clarifying how we  
8       should interpret the use portion?

9               MS. MARINELARENA:   Sure.   So use --  
10       the criteria, itself, has not changed.   For use  
11       we require that a measure be in an accountability  
12       program, within three years of endorsement and  
13       publically reported, within six years.

14              The difference is that, now, use is a  
15       must-pass-criterion for maintenance measures.   So  
16       technically, the measure, if it doesn't meet that  
17       criteria, a maintenance measure, then it should  
18       fail and then it would not move forward to  
19       recommendation for overall endorsement.

20              So we have, we have seen, in the past,  
21       some measures that are beyond six years and not  
22       publically reported.   There have been reasons for



1 it and the Committee can decide, if that's an  
2 acceptable reason, some of them have changed  
3 measure developers and they're in the process of  
4 getting it, it publically reported. So the, the  
5 Standing Committee has said that the measure  
6 developer is making good faith effort to get it  
7 publically reported and in an accountability  
8 program. So that's something to consider.

9 CO-CHAIR GUNNAR: Yes.

10 MS. MARINELARENA: But, we did get,  
11 include, you know, initial endorsement,  
12 re-endorsement, and they are accepted to be,  
13 again, an accountability program and publically  
14 reported are loosely defined, but when we get to  
15 that part, we can, we can have that discussion.

16 CO-CHAIR GUNNAR: So, so help me just  
17 a follow-on question, help me understand. So if  
18 a, if an individual measure is part of a  
19 composite, but not independently has been  
20 publically reported, or, or fails in, in and of  
21 itself, to meet the use, how do we, that, does  
22 it, how do they maintain it, within the

1 composite?

2 MS. MARINELARENA: A measure does not  
3 -- part of a composite does not need to be  
4 NQF-endorsed.

5 (Off-microphone comments.)

6 MS. MARINELARENA: A part of a  
7 composite, a measure that is part of a composite  
8 does not have to be NQF-endorsed.

9 (Off-microphone comments.)

10 MS. MARINELARENA: Yes.

11 CO-CHAIR GUNNAR: So we'll go with  
12 A.J., then, then, Reg.

13 MEMBER YATES: Well just, just, just  
14 as a point of order, the vast majority of the  
15 measures we're talking about today are part of  
16 composites, but they're not publically reported.

17 MS. MARINELARENA: Correct.

18 MEMBER YATES: We could make a vote,  
19 right now, as to whether that we're going to  
20 accept that definition of being reported and go  
21 home five minutes from now, for about -- because  
22 that should be the first question, if it hasn't

1       been publically reported.

2                   And we're going through this exercise  
3       to endorse something that we're going to turn  
4       around at the very end and say, well we can't  
5       endorse it, because it hasn't been used in that,  
6       with that definition.

7                   I would argue that it is used for  
8       internal quality metrics and, and it is reported  
9       back to the surgeons and they find out, where  
10      they are in life, in terms of, their abilities  
11      and their skill sets and how they're taking care  
12      of patients.

13                  But, I, I read this and, and this is  
14      troublesome, because I don't understand why these  
15      measures are up for re-endorsement, at all, if  
16      they haven't been publically reported?

17                  MS. SKIPPER:   Elisa.

18                  MS. MUNTHALI:   So that that's a  
19      conversation we want the Committee to have and,  
20      to Melissa's point, it is up to the Committee's  
21      discretion to talk about, you know, the degrees  
22      to which, it meets accountability and public

1 reporting.

2 So we are not -- we don't define what  
3 that is, but because you're experts in surgical  
4 care and you bring different perspectives, I  
5 believe, you'll be able to land in a place -- now  
6 we, we don't only ask that the measures be  
7 publically reported, we also ask for a plan, if  
8 they're not.

9 So that could be a way forward, if the  
10 developer can articulate a plan to get these  
11 measures in an accountability program that's  
12 acceptable to us and would meet the criteria, as  
13 well.

14 MEMBER JARRETT: This is Mark Jarrett,  
15 on the phone. I, I, kind of, concur with the  
16 last speaker, you know, I'm all for public  
17 reporting and transparency and accountability,  
18 don't get me wrong.

19 However, I think having valid and  
20 reliable and scientifically-proven measures that  
21 are used internally, across the country, at local  
22 sites, is also critical, because the reality is,

1 we measure things, not so we can publically  
2 report them, we measure them so we can, actually,  
3 get better at what we do.

4 So I think that, although,  
5 accountability is critical, I, personally, kind  
6 of, tend, in my world, to believe that, you know,  
7 not everything has to be publically reported,  
8 again it can be very valuable.

9 (Telephonic interference.)

10 CO-CHAIR FLEISHER: So Elisa, I'm  
11 going to push in that, these rules are defined by  
12 the CSAC, correct?

13 MS. MUNTHALI: They're defined by NQF  
14 and upheld and, by the CSAC, so we've require  
15 accountability and public reporting --

16 CO-CHAIR FLEISHER: Right.

17 MS. MUNTHALI: -- not defined --

18 CO-CHAIR FLEISHER: Not defined. So  
19 being that I'm now taking a constitutional law  
20 class --

21 MS. MUNTHALI: Oh gosh, okay.

22 CO-CHAIR FLEISHER: -- with the Dean

1 at our law school, it's not in the Constitution  
2 that, how it's defined, as public reporting, so  
3 we could push back and say, based upon the fact  
4 that they're part of composites, that we feel  
5 it's important and CSAC can, either, uphold, or,  
6 or vote against us, in that way, is that an  
7 acceptable --

8 MS. MUNTHALI: That is an acceptable  
9 --

10 CO-CHAIR FLEISHER: -- decisionable  
11 from this group? So we, we could, actually,  
12 inform the higher courts, so to speak, that we  
13 feel that it meets a criteria, which I'm not  
14 saying we should, or shouldn't, but that is an  
15 acceptable, from your standpoint, approach to  
16 that?

17 MS. MUNTHALI: Yes, because what  
18 Melissa said, I just want to underscore that. In  
19 the past, components were required to be  
20 NQF-endorsed.

21 CO-CHAIR FLEISHER: Right.

22 MS. MUNTHALI: A few years ago, we

1 changed that, so the components have a composite  
2 do not need to be NQF-endorsed, so that could --

3 CO-CHAIR FLEISHER: And, in  
4 particularly, since the sites gets the individual  
5 scores back, the surgeons, we could help inform  
6 that STS has maybe has approached us from a  
7 higher perspective and, and therefore, we don't  
8 want to de-endorse something that's of such  
9 quality and such importance. So I'll -- I think  
10 that's --

11 CO-CHAIR GUNNAR: But, but as a point  
12 of order, normally, is the way this would work,  
13 based on NQF rules, if we get to use, I mean, we  
14 will say, it does not pass, because it doesn't  
15 meet the criteria, NQF criteria for use, but then  
16 you're supposed to stop. So what happens here?

17 MS. MARINELARENA: So you would have  
18 the conversation and then you would vote, if you,  
19 you know, if it passes, we need to capture a  
20 rationale, or justification, from the Committee,  
21 as to why you think, no it does meet.

22 And again, public reporting for us

1 doesn't mean that it has to be on, you know,  
2 hospitalgov.com that, that's not publically  
3 reporting.

4 It's, again, a loose definition. It  
5 means that you were -- the public can access it,  
6 in some way, we just need to be able to capture a  
7 justification for you passing it.

8 But it does, they have to meet all the  
9 other criteria. They have, there has to be  
10 evidence. There has to be a gap and they have to  
11 be reliable and valid, and then we can talk about  
12 use. Yes.

13 MEMBER STEIN: I have a separate, or  
14 a different question. I'm relatively new to the  
15 Committee. If, if we have suggestions of ways a  
16 developer can enhance their measures, if we pass,  
17 if we vote to pass a measure, as it is, is there  
18 any incentive for them to listen to our  
19 suggestions, or do we have to not pass the  
20 measure, so they can listen to our suggestions?

21 MS. MUNTHALI: So I think any  
22 suggestions and recommendations we will be taking



1 down, as part of the commentary, in the reports,  
2 and, you know, we, the developer will have that  
3 input and, hopefully, they will use it to, in  
4 their improvement, as they conduct maintenance.  
5 So don't feel -- don't withhold from giving  
6 recommendations that's part of the process.

7 MEMBER STEIN: But, but they're --

8 MS. MUNTHALI: But it doesn't go --

9 MEMBER STEIN: -- but their incentive  
10 to act on our recommendations is less, if we've  
11 been, if we've already endorsed the measure,  
12 correct?

13 (Simultaneous speaking.)

14 MS. MUNTHALI: So we wouldn't have  
15 like a condition recommendation, so we don't do  
16 that, but it could be part of the commentary, as  
17 you're discussing, you know, perhaps, look at  
18 this, or look at that, but not as a condition of  
19 endorsement.

20 CO-CHAIR GUNNAR: Rick.

21 MEMBER DUTTON: Yes I, I appreciate  
22 Lee's effort to find language that will make

1 everybody happy, but I really think we should  
2 tackle this one more head on.

3 The vast majority of cardiac surgery  
4 hospitals and cardiac surgeons in the country  
5 participate in SDS and we know that these  
6 measures are used, internally, by all of those  
7 people, to improve the quality of care.

8 Now, it seems to me, the, the spirit  
9 of what we're trying to achieve here, and I would  
10 consider that acceptable use for all of these,  
11 but if that's not going to be case, then I  
12 certainly agree with A.J., we should go home.

13 CO-CHAIR GUNNAR: A.J.

14 MEMBER YATES: Yes, I was just going  
15 to -- A.J. Yates. I was just going to follow up  
16 on the fact that, if NQF has made it no longer  
17 necessary for composite measure to have its  
18 components endorsed, it runs the risk of outside  
19 groups taking their composite measures and  
20 breaking them down, but then saying that those  
21 individual parts carry the weight of endorsement,  
22 because they were part of something that was

1       endorsed.

2                   And so as blowback to the committee  
3       that decided on all this, I think, is reasonable  
4       that we, again, give a circuit court opinion to  
5       satisfy --

6                   (Off-microphone comments.)

7                   MEMBER YATES: -- so to satisfy  
8       Counselor Fleisher's recommendation, or Judge  
9       Fleisher. And -- but I would argue that -- I  
10      would agree 100 percent with Rick.

11                  And I think that the, the value of the  
12      composites is made stronger by making sure that  
13      those parts that could be broken out, someday,  
14      are endorsed and ready to be broken out, but it  
15      doesn't do, it, it doesn't lower its value, in  
16      terms of, its use.

17                  And I would, I would suggest that we  
18      make, if possible, there would be extra  
19      schedulary (sic), but maybe we should vote on  
20      that concept, so that we don't discuss this and  
21      argue it on every single measure, but we can,  
22      certainly, open it up for consensus, but maybe,

1 we refer to this, as Fleisher Rule A, or, or  
2 Ruling A, and that might make things go smoother.

3 CO-CHAIR GUNNAR: So I did pass my  
4 constitutional law class and --

5 MEMBER YATES: Good.

6 CO-CHAIR GUNNAR: And so -- and, you  
7 know, the rules are established and are, and are  
8 well-recognized up-front, when you present your  
9 measure for endorsement on the, an initial  
10 approval.

11 And the rules are now that, if it's  
12 not -- that particular measure is not publically  
13 reported within a period of time, then it fails  
14 the use. It no longer passes the -- that's the  
15 rule.

16 It doesn't require that that  
17 individual measure be, which is part of a  
18 composite measure, be endorsed individually to be  
19 a member, or a part of the composite.

20 The composite's passed, I mean,  
21 fundamentally, it -- the issue is, in this --  
22 what we're, what we're faced with, for the first

1 time, as a group, is this, the, the fact that an  
2 individual measure was not publically reported in  
3 the period of time that was clear at, at  
4 initiation.

5 CO-CHAIR FLEISHER: But I do want to  
6 say and, and, sorry, is that, my recollection of  
7 the discussion was, this was not a case that,  
8 really, was thought about that, from the CSAC  
9 perspective, or from when this was developed and,  
10 like Elisa said, in that it's used, but only as  
11 part of a composite.

12 I mean, it really was trying to move  
13 the field forward to say, let's not endorse  
14 measures that never go into public reporting.  
15 Nobody thought that this very narrow use case of  
16 a measure that's part of a composite that's  
17 public reporting that's why I'm parsing it to say  
18 pushing back --

19 CO-CHAIR GUNNAR: Arguing the  
20 Fourteenth Amendment --

21 CO-CHAIR FLEISHER: Right, but --

22 CO-CHAIR GUNNAR: -- all right.

1 CO-CHAIR FLEISHER: -- but, pushing  
2 back --

3 CO-CHAIR GUNNAR: Also --

4 CO-CHAIR FLEISHER: -- on --

5 CO-CHAIR GUNNAR: -- he's also being  
6 a regionalist and then, he's saying that the  
7 initial intent of the founders was --

8 CO-CHAIR FLEISHER: Absolutely.

9 CO-CHAIR GUNNAR: -- this was not  
10 their original intent.

11 (Simultaneous speaking.)

12 CO-CHAIR FLEISHER: This was not the  
13 original intent that I remember, but Elisa --

14 MS. MUNTHALI: That is correct. I  
15 think it was a broader assessment of the entire  
16 portfolio and I don't think, you know, they were  
17 looking at the components of composites and,  
18 whether or not the, the actual composite was in,  
19 you know, publically reported in an  
20 accountability program and then, whether or not  
21 those components were. That did not come up in  
22 discussion.

1                   But, this is the first time that we're  
2                   having this discussion and this is why this  
3                   dialog is important and how you look at public  
4                   reporting will be reflected and should be  
5                   reflected in your vote and go along with your  
6                   recommendation.

7                   CO-CHAIR GUNNAR:   So to be clear,  
8                   there's two paths here.   The first path is we  
9                   kick the can upstairs.   We endorse -- we just go  
10                  ahead and override the NQF rules on use, pass it  
11                  on that basis, conceptually, send it upstairs and  
12                  let the powers that be manage this individually.  
13                  Alternatively, we follow the rules, we don't pass  
14                  those individual measures that, that aren't  
15                  publically reported, allow that the, the  
16                  developers to respond to that.

17                  It will then be, come back to this  
18                  committee, at which point, a decision would be  
19                  made, collectively, about those and a  
20                  recommendation from the Committee for decision.

21                  So one way, Path 1, is to send it  
22                  forward and eliminate the opinion of the

1 Committee in front of CSAC. The second path,  
2 actually, fundamentally, it brings it back to us,  
3 in my opinion, and it allows us to weigh in, as a  
4 committee. Does that make sense?

5 (No audible response.)

6 CO-CHAIR GUNNAR: Am I -- am I  
7 tracking and are you tracking?

8 MEMBER YATES: There's also a third  
9 path, which is to go through the process on each,  
10 endorse them to the point of usability and then,  
11 put them in limbo, to go back to Path 1.

12 CO-CHAIR GUNNAR: That's -- yes.  
13 That's Option 2. That, that just is, you know,  
14 we can call it 2A and 2B, but it's, it's  
15 fundamentally the same, we get to weigh in, as a  
16 Committee, on that.

17 MEMBER YATES: But, if we are sending  
18 up endorsed, other than the fact they're not  
19 used, if we send it up as endorsed, except for  
20 that fact, we do the higher committee service by  
21 saying that the measure looks pretty good and  
22 would be endorsed otherwise if it weren't for



1 use.

2 CO-CHAIR GUNNAR: I hate being  
3 overruled and we sent it up endorsed, with the  
4 potential for being overruled.

5 MEMBER YATES: No, I'm not saying it  
6 would be endorsed, it would be endorsed, but --  
7 well, on hold, for their opinion.

8 MS. MARINELARENA: No, it would be  
9 endorsed.

10 MEMBER YATES: You can't do that?

11 MS. MARINELARENA: So just to confuse  
12 you a little bit more, assuming the measure meets  
13 all of the criteria, you passed it on use. You  
14 say, you know, we think that it does meet the use  
15 criteria. You give it an overall recommendation  
16 for endorsement, then you have to look at the  
17 measures for related and competing.

18 We did pull them together. They're  
19 not competing, but they're related, because now  
20 you have these components, the individual  
21 measures that are part of the composites.

22 So we will ask you, to go to, through

1 the exercise and the questions are, do you need  
2 these additional measures, in addition to the  
3 composites?

4 Set of questions, you can say yes, or  
5 no, but we don't ever have the discussion about  
6 related and competing measures, until the  
7 measures have been endorsed, because that's a  
8 separate conversation.

9 If you say yes, we capture that, we  
10 need, we just need to have your discussion in the  
11 rationale, for having multiple measures and the  
12 measure goes forward.

13 CO-CHAIR FLEISHER: So just to be  
14 clear that, for the use case, and, Amy, I don't  
15 know, if you would, intermittently -- if we say  
16 that we believe that, being publically reported  
17 part of a composite measure is good enough to  
18 meet that use case, we can do that in this  
19 committee?

20 That's our definition of use, so we're  
21 -- and CSAC, in our report, we can say, this is  
22 our definition of use, why we passed it, they can

1       overrule us for our definition of use.

2               But it's our definition, and we make  
3       it very clear that if it's not part of a  
4       composite and it's just out there, we would have  
5       turned it down, our use, we've changed the use  
6       criteria slightly, or we interpreted the use  
7       criteria within our committee's purview?

8               MS. MUNTHALI: Right, and just to be  
9       clear, to the extent that the CSAC is overseeing  
10      our entire portfolio, we don't want them -- we  
11      want these cases -- there is oversight, so we  
12      don't want them to frequently overturn the expert  
13      committees, this is you, on surgical care.

14              And so if you were the experts, you  
15      understand the implementation of these measures,  
16      you have more knowledge of that, and you have  
17      justification, it would be challenging for the  
18      CSAC even to do that.

19              So we want to make sure the process  
20      goes forward. In case it doesn't, they are  
21      there, as an oversight body, to ensure that, you  
22      know, everything was considered and the process

1 and the criteria were applied appropriately.

2 MS. GOODWIN: This is Katy. We also  
3 have Robert Cima, on the phone, who'd like to  
4 make a comment.

5 MEMBER CIMA: Yes, I agree with what  
6 has been said, about the composite, but I still  
7 go back to Dr. Dutton's point is that, what, how  
8 do we define public reporting? I don't think we  
9 have the leeway of saying what public reporting  
10 is.

11 I mean, A, AHRQ has a very good  
12 statement about it and it says, it needs to be  
13 public reporting to be effective, reports need to  
14 provide consumers with transparent, timely  
15 information they can trust to help them inform  
16 conversations with their providers and payers, to  
17 help guide their healthcare decisions.

18 So if this information isn't available  
19 -- I mean, I understand internal quality control,  
20 but if it's not available to the public, in a way  
21 they understand and can access, in a timely and a  
22 transparent manner, then I'm not sure we're doing

1       our job.

2                   MS. MARINELARENA: This is Melissa  
3       from NQF. So Christy is pulling up our  
4       definition of transparency, or public reporting.  
5       So here we say, transparency is the extent to  
6       which performance results about identifiable,  
7       accountable entities are disclosed and available  
8       outside of the organizations, or practices, whose  
9       performance is measured the capability to verify  
10      the performance results adds, adds,  
11      substantially, to transparency.

12                  CO-CHAIR GUNNAR: I'd say that's  
13      pretty clear. So with that preamble, should we  
14      jump in with the first evaluation, then we'll  
15      just see how it goes?

16                  MS. MARINELARENA: Let's do it.

17                  CO-CHAIR GUNNAR: The first one is  
18      0114. I don't have my sheet with me, or do you  
19      have it -- it's --

20                  MS. MARINELARENA: I'm sorry, it's  
21      2561.

22                  CO-CHAIR GUNNAR: Oh.

1 MS. MARINELARENA: Here.

2 CO-CHAIR GUNNAR: Sorry, I didn't have  
3 it. So 2561, STS Aortic Valve Replacement  
4 Composite Score. And do we have -- Cliff is not,  
5 it's Cliff Cove (phonetic), Barbara Levy, and  
6 Robert Cima, but I don't think Cliff and Barbara  
7 are participating.

8 But Robert is, right? Robert, or Dr.  
9 Cima, are you prepared to present this all solo?

10 MEMBER CIMA: Yes, I can do this.  
11 This is an STS measure. We've gone through many,  
12 many of these --

13 CO-CHAIR GUNNAR: And my -- call to  
14 order -- we need to bring up STS Representatives  
15 and --

16 MEMBER CIMA: Okay.

17 CO-CHAIR GUNNAR: And they'll  
18 introduce the measure. My bad. Yes, this one  
19 is -- it won't address the issue until we get --

20 (Off-microphone comments.)

21 CO-CHAIR GUNNAR: So welcome. Whose  
22 -- oh, we have everyone coming up. I don't know

1       -- I can't move down.

2               MR. ANTMAN: Okay.

3               CO-CHAIR GUNNAR: So, welcome. If  
4 you'll introduce yourselves, for the record? Is  
5 there anything else we need from -- as far as,  
6 the introduction is concerned?

7               MS. MARINELARENA: They can, probably  
8 -- if you, you can, probably, introduce, both,  
9 2561 and 2563, since they're similar.

10              MR. ANTMAN: Okay.

11              MS. MARINELARENA: Okay?

12              MR. ANTMAN: May I speak to the  
13 measures, in general, to begin with?

14              MS. MARINELARENA: Sure.

15              MR. ANTMAN: Okay. So good morning,  
16 everyone. I'm Mark Antman. I'm Senior Manager  
17 for Quality Metrics and Initiatives, at the STS.  
18 I'm joined by Dr. Gae Paone and Dr. Vinay  
19 Badhwar, also, representing the STS.

20              Dr. Dave Shahian is, also, attending  
21 today. He's acting, as an observer. I think, we  
22 also have individuals, on the phone, Dr. Sean

1 O'Brien, Dr. Maria Grau-Sepulveda, may be on the  
2 phone, to speak to some technical aspects of the  
3 measures.

4 I want to thank the Committee and, and  
5 NQF Staff, for allowing us to have 15 measures  
6 reviewed today. I know that's beyond your usual  
7 limit of measures, per meeting, so we appreciate  
8 that.

9 These measures are calculated reported  
10 back to participating surgical groups and  
11 publically reported, in our perspective, based on  
12 clinical data submitted to the STS Adult Cardiac  
13 Surgery Database.

14 The database was launched in 1989 and  
15 contains more than 6.5 million cardiac surgery  
16 procedure records and represents the  
17 participation of over 90 percent -- probably  
18 well-over 90 percent -- of the surgical groups  
19 performing cardiac surgeon in the U.S., and the  
20 proportion of those surgical groups that  
21 participate in voluntary public reporting is now  
22 up to just about 70 percent.



1           The 15 measures under discussion today  
2       include seven that are component measures of the  
3       STS CABG composite. That CABG composite in 2010  
4       became the first, the STS's first voluntarily  
5       publically reported composite measure, and the  
6       CABG composite will actually be, be, be submitted  
7       to NQF for your review in the fall of this year.

8           Six, of these seven CABG composite  
9       measures, excuse me, component measures, are  
10      outcome measures. One, the anti-lipid treatment  
11      measure is a process measure. It's the only  
12      process measure of all 15, under review today.

13          Of the eight measures that are not for  
14      isolated CABG, six are operative mortality  
15      measures for valve, or valve plus CABG  
16      operations. And each of these, as has already  
17      been discussed by the Committee, is part of one  
18      of the STS valve, or valve plus CABG composite  
19      measures, all of which are voluntarily publically  
20      reported.

21          And two of those valve, or valve plus  
22      CABG composites, specifically the AVR and the AVR

1 plus CABG composite, are the remaining two of our  
2 15 and those are the first measures that are  
3 scheduled for review today.

4 So that's my overview. I think given  
5 the preceding discussion related to public  
6 reporting, Dr. Badhwar and Dr. Paone and I will  
7 be happy to speak to what we see, as the, how  
8 each individual component measure is public,  
9 publically reported, as each of them come up for  
10 discussion.

11 So with respect to the first two  
12 measures under review, 2561 and 2563, these are  
13 the AVR composite score and the AVR plus CABG  
14 composite score.

15 Each of these have a morbidity and a  
16 mortality domain. Each of those domains, as well  
17 as the composite score, are the data for each of  
18 those measures, for each of those, each of those  
19 domains and the composite score as a whole, is  
20 reported back to all participating surgical  
21 groups for their review and for quality  
22 improvement purposes.

1           Each of these composites as a whole  
2   is, as I have said, publically reported, and  
3   there is a publically reported domain score for,  
4   both, the mortality domain and the morbidity  
5   domain.

6           So in fact, those, those mortality  
7   component measures that are under review today  
8   for these two composites, they are, in fact,  
9   publically reported separately, on the STS Public  
10   Reporting site.

11          There is a separate mortality score  
12   and a separate mortality star rating, as well as  
13   a separate morbidity score and a morbidity star  
14   rating, for each of those domains. I hope that  
15   helps. We'll be happy to answer any questions.

16          CO-CHAIR FLEISHER: Just basically if  
17   I could ask, as you discuss your own vision of  
18   how it's publically reported, if we have  
19   questions, are you open to developing any plan  
20   for additional public reporting?

21          If that's an option, that would be  
22   useful for discussion today, because that is part

1 of the conditions for approval, correct? That,  
2 if there's a plan that would satisfy the intent,  
3 that that would also be helpful and that would  
4 allow us to go forward?

5 MR. ANTMAN: A plan for the individual  
6 components be public, publically reported  
7 separately?

8 (Simultaneous speaking.)

9 CO-CHAIR FLEISHER: Yes.

10 MR. ANTMAN: I'll defer to my surgeon  
11 leaders.

12 DR. PAONE: I'm not sure that I can  
13 state that there's a plan specifically to  
14 publically report each of these measures. The  
15 composite was developed specifically because we  
16 felt it was a better measure of what a patient  
17 needed to know and would want to know, about what  
18 their risks for the surgery were going to be.

19 I think it's pretty complicated for a  
20 patient to look at this variety of outcomes and  
21 try to determine whether that's an important  
22 piece of information for them to have.

1                   You know, our concept is what the  
2                   patient wants to know is, am I going to have this  
3                   operation and go home, without any major  
4                   complications, and to their mind, I don't know  
5                   that they can understand or recognize the  
6                   difference between whether I've had a stroke, or  
7                   renal failure, requiring a dialysis, or a  
8                   sternal, a deep sternal wound infection.

9                   So conceptually, this is why the  
10                  composite was developed, in addition to the fact  
11                  that, relatively speaking, the lower incident  
12                  outcomes would have less validity over a longer  
13                  term and the composite score is obviously a  
14                  better way to present that data.

15                 I can't say that we would not  
16                 consider, and I would defer to others higher up  
17                 in the society quite frankly, as to whether or  
18                 not we would consider publically reporting these  
19                 in the future, but again, I think the composite  
20                 score was developed specifically to address the  
21                 issues that I've mentioned.

22                 CO-CHAIR GUNNAR: And for me, it just

1 is a, and, and, maybe, take this back -- I mean,  
2 is it important to you that in the individual  
3 morbidity measures of the composite are  
4 NQF-endorsed independent of the composite, when  
5 they actually form the basis of the composite?

6 And as you say, Gae, it would be --  
7 does it really make, from a driving quality  
8 sense, having it in both places, so to speak,  
9 does that -- does it serve a mission, beyond what  
10 the composite does? I guess that's my fundamental  
11 question.

12 DR. PAONE: Yes, I would suggest,  
13 frankly, that having to have these individual  
14 outcome measures separately reported, for  
15 instance on our website, would, would do nothing  
16 more than just make it more busy and, and  
17 difficult to interpret.

18 Again, from the patient's standpoint,  
19 they don't really care if they get one of them,  
20 what's important to them is that they get none of  
21 them.

22 On a more practical level, though, I

1 think, first of all, and I can't tell you how  
2 many, but there are actually centers that will  
3 individually report this information on their own  
4 personal websites.

5 And I don't know how many that is, I  
6 know when I was at Henry Ford, we did. You could  
7 go to certain quality pages on our website and  
8 you would find many of these outcomes  
9 individually reported as the percent of stroke,  
10 percent of infection, those sorts of things.

11 And so I think you're correct. I  
12 think this would be, sort of, data, you know,  
13 overload, if we needed to do all this and put it  
14 all on the website.

15 The other part of it though is we do  
16 report them, individually, to the centers. And  
17 the centers do look at them individually and act  
18 on them when they get them.

19 And I think having these measures  
20 being continuing to be NQF-endorsed, furthers the  
21 significance of these measures and makes people  
22 take notice of them and pay more attention to

1       them, I suppose, than they might otherwise.

2               Although frankly I'd like to think  
3       that people pay attention to these, whether or  
4       not they're endorsed, but I do think it adds a  
5       validity to them that is beneficial.

6               DR. BADHWAR:   Hi, I'm Vinay Badhwar,  
7       from West Virginia University. To just add,  
8       minimally I think one of the most important  
9       aspects of these NQF-endorsed measures, the  
10      subcomponents of the composite measure is to  
11      follow along with the Fleisher, Gunnar, Yates  
12      doctrine that we just listened to, which was very  
13      erudite and you're right on the money in terms of  
14      how you've interpreted it, I think it is an  
15      excellent conversation, before this began, is  
16      that the, any, or none, aspect of that, I think,  
17      is the most important, as, as Gae just -- Dr.  
18      Paone just outlined that, it's even more  
19      stringent if they have anything.

20              And so to go to the core mission of  
21      what we're all here for, in terms of that  
22      transparency of any type of morbidity is that,



1        what the family member or their, the patient,  
2        would be able to walk out of the hospital free of  
3        any bad outcome.

4                    So having those subcomponents  
5        NQF-endorsed are, of course, of great value and,  
6        as Dr. Paone outlined, they are individually  
7        shared in the harvestry court by line item of  
8        those measures, with participant sites  
9        separately. So the question -- the short answer  
10       to that question is yes.

11                   MEMBER CIMA: So just to -- a question  
12       to the developer. This is Bob Cima. This is one  
13       of my questions I had is, if you're reporting, if  
14       you're pulling out the -- I mean, the composite,  
15       as is, is one score.

16                   But then I just heard that you're  
17       pulling out the separate components and reporting  
18       them separately, as two groups, mortality and  
19       morbidity, but really we endorse just the  
20       composite.

21                   So I was wondering about the -- is it  
22       appropriate to report them separately? Shouldn't

1       they then be separate measures that have been  
2       endorsed separately, because you're basically  
3       picking and -- you're pulling stuff out of them  
4       and saying them separately.

5               I understand the rationale behind it,  
6       it makes sense, but it wasn't necessarily what we  
7       endorsed. We endorsed a single measure, but  
8       you're pulling it all apart and making it two  
9       measures and saying they're both NQF-endorsed.

10              I understand it's a nit-picky thing,  
11       but, really, the composite measure is the only  
12       thing that's endorsed, and it should be presented  
13       unadulterated.

14              DR. PAONE: I think I understand the  
15       question that you're asking and it's, again, it's  
16       an -- the purpose of adding the composite to the  
17       mortality was to sort of broaden its reliability  
18       and give it more weight.

19              And because there's a difference  
20       between a patient who survives with a major  
21       complication, and the patient who survives  
22       without one, we thought that that certainly

1 strengthens the benefit and value of the measure.

2 I'm not sure what the advantage I --  
3 if I understood correctly, just to have an AVR, a  
4 separate AVR composite on morbidity and one for  
5 mortality, again, I think would be separating two  
6 things that don't need to be separated and should  
7 --

8 MEMBER CIMA: No, I appreciate that  
9 and I understand that, but what's -- but then  
10 you're doing it by reporting it separately. But  
11 what I'm saying is, we didn't endorse it to be  
12 reportedly separate, reported separately, but you  
13 just said, you are reporting it separately.

14 So then, if you are reporting it  
15 separately, then they should be evaluated and  
16 endorsed separately. You don't have the --  
17 because of the methodology is designed, a single  
18 composite score was developed.

19 You should report the composite score,  
20 but from what I heard, you separate them out and  
21 report them as mortality with a star rating, and  
22 then morbidity as a star rating.

1 (Off-microphone comments.)

2 DR. PAONE: Go ahead.

3 DR. BADHWAR: So first of all, this is  
4 Vinay Badhwar. I think your question's very  
5 important and the process through which you are  
6 given this introspection of the importance and  
7 the scrutinizability and the use of each of those  
8 measures, we totally respect.

9 I think the source of your question  
10 is, how best to report them? For clarity, we are  
11 reporting these back to, or the STS is reporting  
12 these back to the participant site, not  
13 publically, each of these NQF measures there, by  
14 allowing the participant sites to create quality  
15 improvement, based on these endorsed measures.

16 The value, however, if we went into  
17 publically reporting each individual measure, it  
18 would most definitely get unruly, in terms of the  
19 public being able to actually interpret, for  
20 example, isolated AVR and renal failure, as  
21 opposed to isolated AVR and deep internal wound  
22 infection, hence the reason for the composite.

1                   But to Dr. Fleisher's earlier  
2 question, if there's suggestions, of course, we  
3 are here to listen.

4                   CO-CHAIR FLEISHER: So I actually  
5 would ask, and I'm on your site now, you've said  
6 two things that I find interesting.

7                   One is you're saying the public  
8 doesn't understand it, but your sites have it.  
9 But if I were to go into your site and know, as a  
10 patient, that I can ask, I care about stroke and  
11 I can ask my physician, who has the data  
12 available that an individual with a stroke, you  
13 can find out how well they do in relation to the  
14 rest of the country, and that's available.

15                   That to me gives me the next piece of  
16 information. I wouldn't know that from your site  
17 currently, am I correct?

18                   In other words, you could be more  
19 transparent with the public with what's available  
20 to the individual sites.

21                   But currently you've made a decision  
22 that the public --

1 CO-CHAIR GUNNAR: Yes, let me ask it  
2 in a different way, if I wouldn't mind, I'm just  
3 going to turn the question. In your star rating  
4 on the composite, would it be possible, to have,  
5 to be within confidence limits for mortality and  
6 four out of the five morbidity components, and  
7 yet have an increase in stroke that is buried in  
8 the computation to the star system, do you see  
9 where I'm going with this?

10 So, you know, it's one thing to say,  
11 you know, fundamentally, it's you have to be in  
12 line in all measures, all components of this  
13 composite to have a two-star rating, right? Or  
14 better?

15 One variance would get me into the  
16 one-star, right? If that's the case, then  
17 fundamentally you are reporting those  
18 substantively to the public, right? You're  
19 giving them the information they need. If not,  
20 then that's helpful to the Committee, as we look  
21 to evaluate use.

22 DR. SHAHIAN: Yes, I just -- well,

1 first of all, I wanted to clarify something that  
2 came up on the phone comment. We do, in fact,  
3 present an overall single composite score that  
4 encompasses both morbidity and mortality. That's  
5 there, so we're doing that, but we also go one  
6 step further and provide you with scores and star  
7 ratings for the individual components.

8 And I think Dr. Fleisher brings up a  
9 very important point. And we've actually been  
10 doing this, but we should make it more explicit.

11 If you look at things that I've  
12 written, you will see that I always say, ask your  
13 surgeon and ask your hospital about their results  
14 and they should have the report available, and if  
15 they won't discuss those things with you, then  
16 I'd think about another program.

17 I've said that publically. I've put  
18 it in publications, and I think what we need to  
19 do is just put that more explicitly on our  
20 Website and say for additional information ask  
21 your program for the drill-down information.  
22 Thank you.

1                   MEMBER CIMA: Just to the comment you  
2                   made, that goes to my question. Yes, you have  
3                   reported the individual composite measure,  
4                   element.

5                   But, in doing so you, sort of, give  
6                   the impression that those are all NQF-endorsed,  
7                   because you pulled them out of the composite  
8                   measure. That's my concern. Is it sort of, you  
9                   know, not guilt by association, but, you know,  
10                  endorsement by association?

11                  I mean, we've improved the composite  
12                  measure; that's what should be displayed. You're  
13                  taking it a step further, but is it implying that  
14                  those are -- that's not how the methodology was  
15                  evaluated, it wasn't how we approved it in the  
16                  past, and now you're reporting it separately, as  
17                  giving the impression that it could be  
18                  NQF-endorsed. That's the only thing I was  
19                  asking, only --

20                  DR. SHAHIAN: It certainly was not our  
21                  intention to do that. We present the ADR, or ADR  
22                  CABG, whatever composite score is, we present it



1 and we just happened to take it one step further.  
2 There's no implication that the individual  
3 components of the composite are NQF-endorsed;  
4 it's the overall score that's endorsed.

5 CO-CHAIR GUNNAR: But once again, the  
6 answer is, now that you have, it may actually be  
7 helpful to the Committee, if you're giving a star  
8 rating to the component, to the morbidity  
9 component.

10 The question I have, specifically, is,  
11 can I have, can I be above the confidence limits  
12 in any one particular morbidity, you know, in  
13 renal failure, in stroke, the component of that  
14 morbidity score, can can I be, can I have a high  
15 rate of morbidity of a single part of that and  
16 still be a two-star?

17 Or, if I'm elevated beyond expected in  
18 any one of those that I would actually be taken  
19 to a one-star rating in morbidity? Does that  
20 make sense? Am I making myself clear?

21 DR. SHAHIAN: Yes. The morbidity  
22 domain of the composite is treated in the

1 composite as a dichotomous measure. You either  
2 have -- you either are a winner or a loser in  
3 that particular domain, and it doesn't matter  
4 what the rate is, if you have renal failure, you  
5 fail; it's any or none for an individual patient.

6 So for an individual patient, it's  
7 just like death, an individual patient either,  
8 lives, or dies, and an individual patient,  
9 either, has one of those complications, or  
10 doesn't have that complication and it is treated  
11 in the calculation as a dichotomous event.

12 Now, is it possible that somebody  
13 could have, somebody could have a poor score on  
14 the overall morbidity domain and still have a  
15 two-star rating, it is and it's a very complex  
16 algorithm?

17 And Sean O'Brien, our Statistician,  
18 may want to speak to that, but the mortality  
19 domain is rated about four times the importance  
20 of the morbidity domain, just so you know that.  
21 So the mortality is graded much more importantly.

22 CO-CHAIR GUNNAR: But you publically

1 report on morbidity as an isolated -- you give a  
2 star rating that you split them apart, as Dr.  
3 Cima states, and that's what's on the website,  
4 and I appreciate that.

5 That's actually -- and it's helpful to  
6 the Committee to have the understanding that it's  
7 the entirety of those five morbidity domains that  
8 make up the score.

9 And if I'm reading back what you just  
10 said, it is possible to be really good in renal  
11 failure, but have a higher stroke rate than  
12 expected, and still be a two-star because the  
13 statistical treatment of that entire morbidity  
14 domain, all five, allows that to occur?

15 DR. SHAHIAN: That's exactly right,  
16 yes.

17 (Simultaneous speaking.)

18 CO-CHAIR GUNNAR: Okay. I mean,  
19 that's, that's just the way that it is --

20 DR. SHAHIAN: I believe that's  
21 theoretically possible.

22 (Simultaneous speaking.)

1 CO-CHAIR GUNNAR: Yes that, that's  
2 just the way it is, and it's helpful, very  
3 helpful background for the Committee. Who do we  
4 have -- oh, Amy, yes.

5 DR. PAONE: If I could just add that,  
6 on the website, the components of the composite  
7 score, the individual scores for those are not  
8 noted, but the components themselves are noted.

9 And to a point that was made earlier,  
10 that does potentially or at least theoretically  
11 provide an opportunity for the patient to then go  
12 to the surgeon and ask how their results are  
13 specific to each of those components, and the STS  
14 report to that institution provides that  
15 information for them to be able to provide to the  
16 patient.

17 MEMBER MOYER: So I've actually used  
18 this measure to help a friend get care for a  
19 family member in the past couple of months. It  
20 was great that the information was available. I  
21 hate not being able to answer people's questions  
22 about things like that.

1                   The way it's reported on the STS site  
2                   didn't actually provide meaningful  
3                   differentiation for us in terms of the star  
4                   score. We actually went to the kind of data  
5                   that's on U.S. News and World Report. That was a  
6                   little more helpful for them in terms of being  
7                   able to evaluate.

8                   And, I think it's, you know, it's  
9                   great to say talk to your surgeon about this. My  
10                  understanding of the reports that surgeons and  
11                  facilities are allowed to share at least with us  
12                  as a purchaser was not the star ratings, it's  
13                  kind of a raw data and, for us, at least, it  
14                  required a little bit of, you know, statistical  
15                  analysis, to really understand and interpret  
16                  that, that I think would be hard for the  
17                  individual patient.

18                  And, also, would question, okay, so I  
19                  asked my surgeon, hey, look, they're like, I have  
20                  89 percent, well what the heck does that mean?  
21                  Is that good? Is that bad? Is there someone  
22                  else in your system who is better? Do you know

1       that?

2                   In this case, they ended up going to  
3       a different hospital, in the same system and were  
4       really happy with it. But if you have to go to  
5       each individual surgeon to get that information  
6       or each individual facility, that's not really --  
7       I don't think that's a reasonable expectation for  
8       a patient in terms of -- instead of just having  
9       it easily available in one spot.

10                  CO-CHAIR GUNNAR: Yes, just before it,  
11       and this is a sort of clarifying point, just so  
12       people -- it's a question I have, which, which  
13       is, is that, the star ratings is the publically  
14       reported data is available for 67 percent of  
15       participants, and that can either be a group  
16       practice or a facility.

17                  And Amy's point, an individual could  
18       actually be practicing at multiple sites, or  
19       could be listed once with a group practice. It's  
20       a little -- but 67 percent are publically  
21       reporting or are signed up for publically  
22       reporting.

1                   Just to be clear, the data that  
2                   underpins that star system is not just for those  
3                   67; it's for the 100 percent, correct? That,  
4                   just a point of clarification.

5                   DR. PAONE: So there's a few questions  
6                   there to just address.

7                   CO-CHAIR GUNNAR: Yes.

8                   DR. PAONE: So, to address your  
9                   comments, Dr. Gunnar, you're absolutely right in  
10                  terms of how it's interpreted.

11                  So the data's generated for all  
12                  surgeons. However, this is a voluntary public  
13                  reporting enterprise. So it's now 69.9 percent  
14                  of all surgeons actually publically report for  
15                  the adult cardiac component, more so for  
16                  congenital and otherwise.

17                  But so you're right that that star  
18                  rating is available on the Website and through  
19                  other side measures, but essentially on the STS  
20                  Website for those that volunteer report, and they  
21                  sign consent forms to participate.

22                  Now, as it pertains to Amy Moyer's

1 question, about -- I think you're asking about  
2 the availability of subcomponents, were you  
3 asking -- just for point of clarity, were you  
4 asking for a star rating of that individual  
5 participant hospital overall, or were you asking  
6 for a more specific piece of information such as  
7 a morbidity domain?

8 MEMBER MOYER: I was asking or  
9 clarifying that if a patient were to ask either a  
10 facility or a surgeon group, or surgeon, for  
11 information, as we've been saying, that group  
12 isn't going to then give to that patient or that  
13 purchaser.

14 So purchaser, here's our star report  
15 and we can share that with you, is my  
16 understanding that's, kind of, proprietary  
17 information, but they can share the raw or the  
18 risk adjusted registry data, which is a little  
19 harder to interpret.

20 DR. PAONE: Oh. So I clarify to say  
21 that any participant site, again, a participant  
22 site is a hospital, which quite frankly now in



1 the current era is the vast, vast, vast majority  
2 of participants.

3 But as Dr. Gunnar had mentioned that,  
4 in the past, when there are large surgical groups  
5 that signed up, as a participant, that was  
6 actually defined as a participant.

7 So that, as you know, very well, with  
8 the employee models that exists now, the vast  
9 majority are hospitals, and so if that hospital  
10 is signed up for publically reporting, then that  
11 data is completely available, both on the website  
12 of the STS, it's searchable, both on the  
13 morbidity and mortality domains, so that answer  
14 is totally publically reported.

15 However, if they're not signed up for  
16 public reporting, then that data is not readily  
17 publically accessible, and yes you do have to ask  
18 them for their numbers. Does that answer your  
19 question?

20 DR. SHAHIAN: But -- could I make one  
21 point of clarification? We do not restrict what  
22 a hospital may share. They can share,

1 voluntarily, can share with a peer or a patient  
2 anything that they get and it's about a 200-page  
3 report.

4 It's all available. There's a few  
5 quirky little things about STS overall results  
6 that for technical reasons we ask them not to  
7 share, but in terms of their own results and  
8 benchmark results, they can share anything they  
9 want. It's not proprietary.

10 (Off-microphone comments.)

11 CO-CHAIR GUNNAR: Oh, sorry. A.J.

12 MEMBER YATES: But just point of  
13 clarification, it's site-specific information to  
14 this point in terms of public reporting, but not  
15 surgeon-specific.

16 And the second thing is, is the data  
17 that the hospital has access to that can be  
18 shared, if they choose to share it, does it have  
19 the breakdown by surgeon at this point that they  
20 can share?

21 DR. PAONE: So, as Dr. Badhwar  
22 mentioned a moment ago, the overwhelming majority

1 of the over 1,000 programs now, would represent  
2 institutions, or surgical programs, or hospitals,  
3 and not any individuals, or not even anymore any  
4 individual surgical practices, which was more  
5 common in the past.

6 And, as far as what a hospital can  
7 share, it can share anything it wants, it's their  
8 data. It's once they receive it, they can put  
9 anything they want on their websites, they can  
10 share it publically in any form they want.

11 The only restriction would be that  
12 they're not allowed to say, we're better. They  
13 can say, we're two stars or three stars, but they  
14 can't say we're better than so and so because of  
15 our data.

16 (Simultaneous speaking.)

17 MEMBER YATES: At the level of a  
18 consumer, though, asking the hospital for data,  
19 can they ask for, is it available through the  
20 database, by surgeon?

21 DR. PAONE: The surgeon-specific data  
22 is not reported by STS to the institution. Within

1       their database they would certainly have an  
2       ability to breakdown that data in any form they  
3       wanted, and certainly included in that would be  
4       surgeon-specific outcomes for any number of  
5       reports that they wish to present, but that is  
6       not provided by STS.

7               MEMBER YATES: Right, it would be out  
8       of their own individual --

9               DR. PAONE: That would be out of their  
10      own individual database.

11              (Simultaneous speaking.)

12              MEMBER YATES: Right, but it would not  
13      have gone through the parsing and the risk  
14      adjustment that the STS does before they report  
15      it back to the institution?

16              DR. PAONE: Not in a composite  
17      fashion, no.

18              MEMBER YATES: Or as an individual  
19      measure, does it come back surgeon-specific to  
20      the institution, having gone through the risk  
21      adjustment and parsing of the STS?

22              DR. PAONE: Not to the same extent,

1 no. But they can get O/E ratios for individual  
2 surgeons on the individual outcomes, if they  
3 choose to.

4 MEMBER YATES: Within their own  
5 database.

6 DR. PAONE: Within their own database.

7 MEMBER YATES: Right. So in that  
8 regard, it's an institution-specific result and,  
9 you know -- I'm just making sure, I'm not sure  
10 that I'm doing, I'm, I'm making this point,  
11 because I'm well-aware that it's site and not  
12 surgeon, but I'm saying this for the public  
13 record for a new member that's a consumer  
14 representative.

15 DR. BADHWAR: I think you ask a very  
16 important question, A.J., but to echo Dr. Paone's  
17 answer, the O/E ratios do provide in lieu of that  
18 a risk-adjusted aspect per surgeon. These sites  
19 can have that information, but it's  
20 operation-specific.

21 So as you know, a surgeon does an  
22 aortic valve or CABG, a mitral valve, a double

1 valve, so the overall, you know, holistic  
2 experience of that surgeon is not currently they  
3 don't -- they can't just generate that; they can  
4 break it by operation though.

5 So you're right. They do have  
6 risk-adjusted data by surgeon, but it has to be  
7 pulled by each of those sites.

8 CO-CHAIR FLEISHER: So we, we do have  
9 -- TeMaya, do you want to -- TeMaya and Melissa  
10 and Elisabeth.

11 MEMBER EATMON: Okay. I was just,  
12 once I've seen the website as a patient advocate  
13 and a patient actually, I'm on the website and  
14 I'm seeing that it has the composite score and  
15 then it had the mortality and the morbidity  
16 score.

17 I know that you spoke that from a  
18 patient perspective, we may not want all of that  
19 information, but as a young patient, I want to  
20 find all of the information out there that's  
21 possible.

22 And so I'm not really comprehending

1 the mortality versus the morbidity when I scroll  
2 down to the bottom and it says that the overall  
3 composite score represents the two domain scores  
4 in a single number.

5 So across the board, just looking at  
6 it from a patient, I see that the composite  
7 score's a two, the mortality score's a two, the  
8 morbidity score's a two, per se.

9 So, for me, I want to understand what  
10 would be my risk for the mortality, what would be  
11 the risk for the morbidity, what are certain  
12 things that I would actually see that would  
13 distinguish between morbidity and mortality?

14 And, granted, you don't want to be  
15 there in the first place as a patient. I don't  
16 want to be -- I literally don't want to be there  
17 with you in the first place, so saying that I can  
18 walk out with one or the other is irrelevant to  
19 me because I'm there in the first place.

20 So at that particular point, I want to  
21 be armed with as much as I possibly can, and I  
22 want to go to a place to find the information

1       versus WebMD or blogs, or going into other type  
2       of places.

3               So granted, yes, it may seem like it's  
4       a lot of information or overload, or we wouldn't  
5       understand, I promise you that when you get a  
6       diagnosis, you are researching, you are looking  
7       up stuff, you are learning stuff and asking your  
8       doctors -- your specialists questions that they  
9       never thought they had seen since med school  
10      probably, but you are really sitting there  
11      researching.

12             And so I, as a patient, I just am  
13      trying to understand how that cannot be part of  
14      the overall composite, because I'm looking at it  
15      that, this mortality, this morbidity, it equals  
16      to that composite score, and so I want to  
17      understand more of what each of those actually  
18      are.

19             DR. BADHWAR: Well, thank you for that  
20      impassioned and very important question. So for  
21      clarity, two stars is as expected in terms of  
22      definitions, in terms of how we -- this is, I'm



1       talking at the 30,000-foot level first.

2               Three stars is better than expected.

3       One star is lower than expected. So two stars is  
4       actually a very good rating in terms of the  
5       Bayesian analysis of how we do this  
6       statistically. That's point one.

7               Point two is the subcomponents of the  
8       overall rating are available. And for example,  
9       in coronary bypass, it's the overall composite  
10      score, it's the absence of operative mortality,  
11      absence of major morbidity, and then some process  
12      measure uses.

13              And then that, together,  
14      statistically, gets combined with other measures  
15      to form the composite. So you do have  
16      availability. So say, for example, one program  
17      has three stars in mortality and two stars in  
18      morbidity, then you can, by interpretation, note  
19      that the absence of any or none, so absence of  
20      any morbidity is lower than the overall  
21      mortality.

22              I know that it can be confusing to a

1 patient to do that definitions, but that  
2 information or the inference of that information  
3 is available on the website.

4 Now, to Dr. Gunnar's earlier point, is  
5 the availability, on the website of, what's my  
6 stroke risk, what is my renal failure risk?  
7 That's not there because of the composite, so  
8 these are composites of composites, if that makes  
9 sense, at a high level.

10 DR. PAONE: Yes, you know, as someone  
11 who has spent many, many years being interested  
12 in database and quality outcomes and the like, I  
13 feel for your, you know, desire to have more  
14 information and yet difficulty for us in trying  
15 to provide that to you in a way that makes sense  
16 to you.

17 One of the things in the composite, in  
18 the database results, for instance, is when you  
19 look at the two-star rating for operative  
20 mortality, there's a score below it.

21 And so I'm looking at one now, and it  
22 says 97.7 is an absence of operative mortality,

1       so that means that the mortality adjusted was 2.3  
2       percent for that, and so you could theoretically  
3       scroll through those hospitals that you're  
4       looking at or considering, and compare those  
5       numbers, and similarly for an absence of major  
6       morbidity.

7               But an additional point that I make  
8       with the patients is that reality and the reason  
9       the composites, particularly the morbidity  
10      composite, is an all or none phenomena.

11              What we often don't talk about is that  
12      mortality for an individual patient is an all or  
13      none phenomena, and so whether you -- and  
14      patients will often ask for a number.

15              And then any of the surgeons that are  
16      at, around this table and on the phone will know  
17      this, they'll ask, you know, what is my risk for  
18      this?

19              And if you tell them 2 percent, or 4  
20      percent, or 10 percent -- sort of the  
21      conversation that I have learned to have over the  
22      years, is I add after that number is quoted, to

1 the best of my ability, but that for you is  
2 meaningless, because that's a number derived from  
3 looking at many, many patients statistically.  
4 You will have either a zero percent mortality or  
5 a 100 percent mortality.

6 And so these are things that are  
7 intended to, in a somewhat simplistic way, help  
8 you. The other thing that I would say, and it's  
9 not really intended to throw the onus back on the  
10 patient, because we are responsible for trying to  
11 provide as much information, as we can.

12 But to the point Dr. Shahian made  
13 earlier, this enables you to go with some  
14 information to talk to your surgeon, or to go  
15 through your program and see who you want to have  
16 do your surgery, with the ability to ask them  
17 some questions.

18 And I would say to you if a surgeon  
19 will not give you that information, or seems  
20 annoyed by your questions or by the fact that you  
21 have spent a great deal of time trying to find  
22 this information, then I would suggest that you

1 go find another surgeon.

2 And in a way that's where this can  
3 also provide assistance to the patient, is it's a  
4 beginning, it's not the end of the process. I  
5 don't, I don't know if that makes sense, but I  
6 hope that it makes a little bit -- I mean --

7 CO-CHAIR FLEISHER: So Melissa and  
8 then Elisabeth.

9 MS. MARINELARENA: So I think we can  
10 pretty soon probably just start going through  
11 the, these are great issues, start going through  
12 the criteria for the measures, but the  
13 conversation that you were having right before  
14 TeMaya is actually very important, because we do  
15 pose questions for all the measures, about the  
16 level of analysis for the measures.

17 They are checked off as specified at  
18 the facility and clinician. And we do talk to  
19 STS about this, and if these were the two  
20 composite measures were evaluated by the Methods  
21 Panel, so they are, there's some language in the  
22 preliminary analysis, because the specifications

1       need to match the testing, and the testing is not  
2       at the facility level. They are  
3       clinician-level-testing, so we do ask the --  
4       we're asking the Committee to discuss that and to  
5       give us some insight on if you think that the  
6       testing actually does include facility levels --  
7       normally we see testing that you can compare  
8       facility-to-facility, we have  
9       clinician-level-testing on there. And they did  
10      provide an explanation to us, but we'll have that  
11      discussion when we get to testing. I'll hand it  
12      over to Elisabeth, and then I think we should get  
13      started if we're okay with that?

14               CO-CHAIR FLEISHER: Yes.

15               MS. MARINELARENA: Okay.

16               CO-CHAIR GUNNAR: Okay, we'll move  
17      forward. Back to any other comments from STS,  
18      before we proceed?

19               (No response.)

20               CO-CHAIR GUNNAR: Very good. Dr.  
21      Cima, 2561.

22               MEMBER CIMA: This is Bob, yes, I was

1 on mute. So this is the composite measure for  
2 Aortic Valve Replacement 2561, STS's measure  
3 steward as we know, and it is composite. I mean,  
4 do you want to go through this like we normally  
5 would? We just went through most of this.

6 It's a composite of mortality, absence  
7 of mortality, risk adjusted, and major morbidity.  
8 The major morbidities are the ones associated and  
9 reported on multiple other STS measures, CBA,  
10 surgical re-exploration, sternal, deep wound,  
11 sternal wound infection, and excuse me,  
12 post-operative renal failure. The numerators  
13 they enter were very straightforward. It is the  
14 more -- the one we always talk about, for  
15 mortality, is that it's, within 30 days, or  
16 within that index hospitalization, even if it  
17 goes beyond 30 days. That is always, has been,  
18 in the past, a question of concern, so I, I think  
19 they all, they do a very good job of giving us  
20 the broadest picture, possible, and trying to  
21 capture the most patients that might be  
22 appropriate for that reportable component.

1           The major morbidities are basically  
2 anyone that has an isolated AVR that doesn't  
3 experience the five specified major morbidity  
4 endpoints, and as was pointed out by the  
5 developers, it's dichotomous. It's not a little  
6 renal failure. They have a strict definition, and  
7 you either have it or you don't.

8           So that is the measure they have done,  
9 as we know, a very detailed statistical analysis  
10 and have a number -- a little army of  
11 statisticians that help them, and so we have  
12 never had any questions about the validity of  
13 those statements.

14           The star rating is the composite.  
15 We've discussed that. I did make a comment on my  
16 worksheet because we had always talked about it  
17 being voluntary. We always know that there's  
18 90-plus percent of cardiac programs that are in  
19 STS, but originally it was you had to be  
20 voluntary.

21           I was wondering and, I guess, they  
22 confirmed already the statement that it is still



1 voluntary, it's not required reporting, which  
2 gets to one of the other discussions we had  
3 earlier and will probably come back to.

4 One question I did have for the  
5 developers about that, was the -- they didn't --  
6 they used to, in previous ones I reviewed, they  
7 gave the distribution, what percentage of  
8 patients, of institutions fall in the one star  
9 versus three-star.

10 And I just, I would just appreciate,  
11 if the developers, at the end of this, or before  
12 we get to the voting, could describe that? I  
13 remember --

14 CO-CHAIR FLEISHER: Just for  
15 clarification, NQF, we don't review the star  
16 ratings themselves, so that's not a relevant  
17 point for endorsement. That is post-endorsement,  
18 how it's displayed, correct?

19 So while it's of note, it's not part  
20 of the endorsement --

21 CO-CHAIR GUNNAR: It's not a  
22 determining factor.

1                   MEMBER CIMA: Okay. I just was  
2 wondering about the, the, the usability of it, in  
3 the sense of if you only have one percent of  
4 institutions, or one star and one percent of  
5 three star, does that -- is that really a  
6 usability?

7                   So, you know, we look at disparities  
8 and gaps and we look at that, but I would think  
9 how we're reporting it also because we're talking  
10 about publically reporting, is it useful, but if  
11 it's not within the purview, but that was my  
12 thought.

13                  So preliminary analysis, do you want  
14 to get to evidence?

15                  MS. MARINELARENA: Yes.

16                  MEMBER CIMA: Okay.

17                  MS. MARINELARENA: Yes, we're  
18 discussing evidence and you can talk about the  
19 star rating in both validity under meaningful  
20 differences and usability as well.

21                  MEMBER CIMA: Oh that was what I was  
22 getting at.

1 MS. MARINELARENA: Yes.

2 MEMBER CIMA: So evidence. I think  
3 they have demonstrated in the evidence the  
4 volumes are important, and there still remains a  
5 performance gap which is in the order of a  
6 reasonable amount of considering the volume and  
7 the degree of severity of the complications,  
8 there is a reasonable gap that would indicate  
9 that, it should -- it is important to measure.

10 Other than that, the quality of the  
11 data is good. The methodology is  
12 well-established and has been refined over  
13 decades. And so I did have the comment there  
14 about, you know, going back to the whole issue  
15 of, if we're really going to pull these apart,  
16 then they should be separate endorsed measures,  
17 but I defer to the rest of the Committee on that,  
18 but I felt it was preliminary composite rationale  
19 was high.

20 CO-CHAIR GUNNAR: So just to get us,  
21 because this will get us the first voting.  
22 Everybody's on the -- make sure everybody's on

1 the website, right, on the link?

2 MS. SKIPPER: Yes. So you all should  
3 be logged into the Poll Everywhere link, sent via  
4 email, yesterday. Should the vote be coming up?

5 MEMBER SAIGAL: I don't see anything  
6 on the screen yet, is it --

7 CO-CHAIR GUNNAR: Yes, it's just the  
8 blue screen right now, right? Or are we in --  
9 do we have a poll just --

10 MS. SKIPPER: It should be a blue  
11 screen.

12 CO-CHAIR GUNNAR: Just this?

13 (Simultaneous speaking.)

14 MEMBER DUTTON: I've got a blue  
15 screen.

16 MS. SKIPPER: I haven't activated  
17 anything yet.

18 MEMBER DUTTON: Can, I ask a quick  
19 question, while we're waiting to activate this?

20 For the developers, are any of these  
21 measures today, but, this one included, have you  
22 advanced any of them to MIPS --- to CMS for MIPS

1 reporting, or do you use them in your QCDR, or so  
2 STS to MIPS, for reporting?

3 DR. BADHWAR: The point of order of  
4 MIPS is for individuals that are --

5 (Off-microphone comments.)

6 MEMBER DUTTON: Yes, it's not, it's  
7 not hospital reporting, it would be physician  
8 reporting, but that, but those are publically  
9 reported measures, which is why I asked.

10 DR. BADHWAR: We have not, as a  
11 society, done that yet.

12 (Off-microphone comments.)

13 MEMBER DUTTON: Any of them? Because  
14 that, that is publically reporting, right? I  
15 mean that's headed for public reporting, even if  
16 it hasn't happened yet?

17 MR. ANTMAN: So we do have a number of  
18 STS measures that are part of the MIPS Program.  
19 I don't have a list of those specifically; we can  
20 certainly access them.

21 I don't think any of the 15 -- the --  
22 I don't know if the 15 measures that we're

1 looking at today specifically are, but we can  
2 certainly look that up.

3 And that's actually on the website, I  
4 think, under the -- if you search under QCDR, I  
5 think it'll actually list the measures. I  
6 actually think a few of them may be. It's a good  
7 point, though.

8 MS. KOSURI: We do have a Member who  
9 stepped away, so we'll do a test run just to make  
10 sure that we have quorum before we proceed to the  
11 actual vote, if that's okay? So I have activated  
12 the poll, as you can see. And if you can click  
13 the link and input your vote.

14 CO-CHAIR GUNNAR: So everybody's bar  
15 is working? Everybody -- anyone not --

16 MS. KOSURI: So as far as, you know,  
17 we only have 12.

18 MS. SKIPPER: And if you're not by a  
19 computer, there's also a Poll Everywhere App that  
20 you could download on your phone to vote. And if  
21 anybody's having trouble that's on the phone, you  
22 can definitely chat us and we can resend the link

1 to you.

2 MEMBER JARRETT: This is Mark on the  
3 phone. What we should be seeing is that it says  
4 response recorded, right, underneath it, under  
5 the test?

6 MS. KOSURI: That should -- that  
7 should be it. That's the indication.

8 MEMBER JARRETT: Okay. Thank you.

9 MS. KOSURI: Yes.

10 DR. PAONE: This -- while you're  
11 testing that, if I can just follow-up the  
12 question about MIPS and NCDR? The website does  
13 list, it has a page where it does list 11 cardiac  
14 measures and one, two, three, four, five, six  
15 thoracic measures, which can be reported for  
16 MIPS.

17 It would be surgeon-specific and it's  
18 requested by surgeons, so it's --

19 (Off-microphone comments.)

20 DR. PAONE: And QCDR.

21 (Off-microphone comments.)

22 DR. PAONE: If it's requested,

1 correct.

2 DR. BADHWAR: These are the QCDR?

3 DR. PAONE: QCDRs.

4 DR. BADHWAR: QCDRs, yes.

5 DR. BADHWAR: Yes. Yes.

6 MEMBER DUTTON: Yes that seems pretty  
7 obvious, public reporting news of these measures.

8 DR. PAONE: Exactly, yes.

9 DR. BADHWAR: And the question, on the  
10 phone, about the breakdowns, sort of,  
11 post-approval question, about percentages, so the  
12 Bayesian analysis in general for all these  
13 measures, it's essentially 80 percent are as  
14 expected, and there are 10 percent that are  
15 higher than expected, 10 percent lower than  
16 expected.

17 And it varies by measure, particularly  
18 those that are less frequent operations, it's a  
19 little bit more of a tighter bell curve, but it's  
20 roughly that. It can be 70 percent is as expected  
21 and a little higher, three-star a little higher,  
22 one star, but it's not as, who's on the phone,



1 but it's not 98 percent three-star and one  
2 percent one star, it's, it's still -- it's a bell  
3 curve of Bayesian statistics.

4 MEMBER CIMA: Great, thank you.

5 DR. BADHWAR: You're welcome.

6 (Off-microphone comments.)

7 CO-CHAIR GUNNAR: Hey, there, if we're  
8 coming back live, we should use our mics and, if  
9 we're not --

10 (Off-microphone comments.)

11 CO-CHAIR GUNNAR: Okay, so we don't  
12 have a quorum. So unless somebody has not voted  
13 online, the way it works is we will vote here and  
14 they will, but they will not display the vote  
15 results, and we'll just spend the day voting and  
16 then online with the Survey Monkey, the  
17 additional people will vote, and we will know the  
18 results at a later date, correct?

19 MS. SKIPPER: Right.

20 CO-CHAIR GUNNAR: Yes.

21 (Laughter.)

22 CO-CHAIR GUNNAR: Except we're still

1       playing.

2                   MS. SKIPPER: All right, we're going  
3       to just take a quick break.

4                   (Simultaneous speaking.)

5                   CO-CHAIR FLEISHER: Can we do a -- so  
6       who's connected on the -- do we have people, on  
7       the phone, that can just, sort of, raise their  
8       hand, do we know?

9                   MS. SKIPPER: We missed Dr. Handy, he  
10      had to step away.

11                  PARTICIPANT: Is he going to come  
12      back?

13                  CO-CHAIR GUNNAR: So we're at 14,  
14      we're still at 12.

15                  CO-CHAIR FLEISHER: No we're at 13.

16                  MS. SKIPPER: We've gotten to 13.

17                  CO-CHAIR GUNNAR: But, I mean, so --

18                  CO-CHAIR FLEISHER: So why don't we  
19      take a five-minute break, while we figure this  
20      out?

21                  (Whereupon, the above-entitled matter  
22      went off the record at 10:08 a.m. and resumed at

1 10:19 a.m.)

2 MS. SKIPPER: So we are going to be  
3 voting on evidence for Measure 2561. And voting  
4 is now open.

5 (Pause.)

6 MS. KOSURI: So I think we have all  
7 the votes. So for Measure 2561, STS Aortic Valve  
8 Replacement Composite Score, for the evidence  
9 portion we have passed this measure for the  
10 evidence part with 14 votes passing. So that is  
11 100 percent. Thank you.

12 MS. SKIPPER: And we can now move on  
13 to the discussion of gap. If there is not  
14 anything -- yes, discussion of gap.

15 MEMBER CIMA: As I mentioned earlier,  
16 there is, you know, a small band of performance  
17 that sort of -- you know, we are doing well  
18 across the country but there still is some gaps.  
19 And given the severity of this, both the  
20 scientific team and -- and my view of this, if I  
21 wanted to know what -- if I were having cardiac  
22 surgery, I think there is data to support

1 continued measurement of this because of the  
2 implications of it. So --

3 CO-CHAIR FLEISHER: Thank you. I  
4 think particularly we have a lot of measures and  
5 they are very similar and we have been here  
6 before -- that unless there is a significant  
7 concern -- perhaps in the discussion, if you feel  
8 there is gap, unless anybody else feels we need  
9 much discussion, we can just go forward and say  
10 it's -- there is a gap. Elizabeth?

11 MEMBER EREKSON: I just have a  
12 question about penetrance because that has been a  
13 question that we have raised about the STS  
14 database before and I think -- I believe in the  
15 measure that I reviewed there was a bump in  
16 participants from this kind of 900 into the 1,000  
17 range. And did you guys get a bump either by  
18 adding sites or -- where is your penetrance now?

19 DR. BADHWAR: So it is a very  
20 interesting question. So you are talking overall  
21 in the database in terms of volunteer public  
22 reporting, correct? So if that -- or -

1 MEMBER EREKSON: Participation.

2 DR. BADHWAR: Yes, in public  
3 reporting.

4 MEMBER EREKSON: Participation in the  
5 database.

6 DR. BADHWAR: Oh, in the entire  
7 database?

8 MEMBER EREKSON: Yes, in STS -- in  
9 this measure.

10 DR. BADHWAR: In this particular  
11 measure? So there -- several things. The answer  
12 is two-fold. One is, programs are growing still.  
13 Second is that approximately five years ago, we  
14 had an alignment with U.S. News and World Report  
15 and that the process of a program voluntarily  
16 publicly reporting through a clinical registry  
17 was credited with a small number -- a numerical  
18 credit, and the U.S. News and World Report  
19 Cardiovascular and Heart Surgery Guidelines  
20 score, and that was communicated to all  
21 participants and perhaps -- though we don't know  
22 for sure exactly what changed -- it further

1 encouraged in our pathway towards voluntary  
2 participation on all of the measures. Second  
3 part of that -- third part of that is that in  
4 this particular isolated AVR is relatively still  
5 newish compared to CABG. And it is a three-year  
6 rolling participation and so programs that are  
7 early on, it takes them three years to accumulate  
8 data to actually participate, as opposed to the  
9 CABG one.

10 MEMBER EREKSON: So the question is  
11 how many -- we have heard before that it is 95  
12 percent of hospitals performing these procedures  
13 are participating in this database. Is that your  
14 current estimation as well?

15 DR. BADHWAR: Yes, that is correct.  
16 It is approximately 95 percent overall. Some of  
17 the VAs don't participate, but essentially nearly  
18 everyone else, because it is an important measure  
19 to participate in a clinical registry. And so it  
20 is actually higher than 95 percent.

21 MS. SKIPPER: Okay, are we ready to  
22 vote on gap for 2561? Okay.

1 MS. KOSURI: Voting is now open.

2 (Pause.)

3 CO-CHAIR FLEISHER: Put this on the  
4 record. So the question -- will you rephrase the  
5 question.

6 MEMBER YATES: Are TAVRs considered  
7 part of the measure?

8 DR. BADHWAR: No, currently TAVRs are  
9 not considered part of the AVR measure. These  
10 are surgical AVR measures. We are working  
11 collectively with our cardiology colleagues at  
12 the American College of Cardiology in developing  
13 a risk model for public reporting with TAVR,  
14 which is ongoing right now. And that will soon  
15 be presented to NQF.

16 CO-CHAIR FLEISHER: Results?

17 MS. KOSURI: For measure 2561 for  
18 performance gap, we have 14 people voting  
19 moderate and one person voting high out of 15  
20 people who voted.

21 CO-CHAIR GUNNAR: So the measure  
22 passes on performance. Shall we go to --

1 MS. SKIPPER: Composite construct.

2 (Pause.)

3 MS. SKIPPER: So you all are voting on  
4 the quality construct and rationale -- is it  
5 explicit -- explicitly articulated and logical?  
6 I think we talked a little bit about that this  
7 morning. Is there anything else, Bob, you would  
8 like to add? Or anyone else in the room?

9 MEMBER CIMA: No, it is -- it is based  
10 off the STS. So we have done this multiple  
11 times. The methodology is sound and very  
12 reliable.

13 CO-CHAIR GUNNAR: Right, I was -- just  
14 as an aside, I was going to streamline that for  
15 future discussion. If there is no new evidence  
16 and the evidence is still the same basis for  
17 which it -- then we can sort of state that and  
18 move on. Same here. I mean, we have seen this  
19 measure before. So I -- any other discussion?

20 (No response.)

21 CO-CHAIR GUNNAR: If not, we will  
22 vote.



1 MS. KOSURI: Voting is now open for  
2 the composite portion of measure 2561.

3 (Pause.)

4 MS. KOSURI: We are still waiting for  
5 one more vote.

6 (Pause.)

7 CO-CHAIR GUNNAR: But to be clear, 14  
8 is quorum. So if we hit the 14, we are good,  
9 right? Fourteen apparently is just fine. We  
10 have 15 that are voting.

11 MS. GOODWIN: Just to put it on the  
12 record, the reason why we went from 15 to 14 is  
13 because we are not counting Dr. Grover in the  
14 denominator because he is abstaining.

15 CO-CHAIR GUNNAR: Correct. So we are  
16 there now. And it -- and it looks like it  
17 passes. Okay, sorry. Go ahead.

18 MS. KOSURI: No worries. With -- for  
19 measure 2561, for the composite portion, we have  
20 8 people who voted high and 6 people who voted  
21 moderate with a total of 14 people. And so this  
22 passes.

1 CO-CHAIR GUNNAR: And next is  
2 reliability. Anything you want to say about  
3 reliability, Dr. Cima?

4 MEMBER CIMA: No. I thought we were  
5 streamlining these.

6 CO-CHAIR GUNNAR: Yes, I agree. But  
7 anything to add?

8 MEMBER CIMA: No. The data speak for  
9 themselves. The association and the analysis  
10 shows that it is very reliable over time.

11 CO-CHAIR GUNNAR: Yes, let me rephrase  
12 the question. Since our last discussion of this,  
13 is there anyone who has changed their mind on  
14 reliability?

15 (No response.)

16 CO-CHAIR GUNNAR: Seeing no comments  
17 in the room --

18 MS. MARINELARENA: Actually this  
19 measure was retested. They have to test the  
20 composite construct. The methods panel reviewed  
21 the measure and did provide some -- their  
22 ratings. For reliability, you can choose to

1 accept that rating and not vote. There were some  
2 recommendations that they made here and some  
3 issues that they want the committee to discuss.  
4 I don't think the -- it is on page 8 of the  
5 measure -- of the preliminary analysis. The full  
6 specifications were included. So I don't think  
7 that was an issue.

8           The subgroup members have concerns  
9 about the inclusion of SDS doctors -- well, that  
10 is validity. But in the risk adjustment model  
11 the standing committee should review and  
12 determine if SDS factors are appropriate. You do  
13 have to vote on validity because they did not  
14 reach consensus on validity of the measure. So  
15 you need to discuss validity and determine if the  
16 results are acceptable. And then again, like I  
17 mentioned earlier, we need to seek clarification  
18 from the developer on the levels of analysis that  
19 were tested and which testing results correspond  
20 with each level of testing -- whether it is  
21 facility level or clinician level. So the  
22 methods panel did not have a problem with the

1 reliability. You can choose to accept the  
2 moderate rating, but we do have to discuss  
3 validity and then vote.

4 CO-CHAIR GUNNAR: So we are on  
5 reliability at this point. And we will discuss  
6 validity next. So any other further discussion  
7 on reliability?

8 (No response.)

9 CO-CHAIR GUNNAR: Go ahead and vote  
10 then.

11 MS. KOSURI: Voting is now open for  
12 reliability.

13 (Pause.)

14 MEMBER YATES: Just for the record,  
15 the SDS question -- I mean, all that was included  
16 was race and gender. And I am not -- I am not  
17 aware of gender being an SDS question or -- and  
18 race is separate.

19 CO-CHAIR GUNNAR: Hold those thoughts.

20 MEMBER YATES: Okay.

21 CO-CHAIR GUNNAR: Hold those thoughts  
22 for just one moment. Let's get to -- that's

1 next, though.

2 MEMBER YATES: I saw it in front of  
3 me.

4 (Laughter.)

5 CO-CHAIR GUNNAR: We are just shouting  
6 out things now. All right. What do we have for  
7 this one? Reliability?

8 MS. KOSURI: So for reliability we  
9 have five people who voted high, and ten  
10 individuals who voted moderate, with a total of  
11 15 people.

12 VICE-CHAIR GUNNAR: Very good. So it  
13 passes. Now we will go to validity. And Dr.  
14 Cima then Dr. Yates.

15 MEMBER CIMA: Well this -- this sort  
16 of went to my question about the star ratings  
17 because I also was wondering about that. I think  
18 the group that reviewed this was also concerned  
19 about the star rating as being the publicly  
20 reported aspect of this. And that's what I was  
21 getting at but I was -- I was -- you know, I  
22 think the developer needs to discuss that if that

1 is a valid way of doing it, given it's just sort  
2 of so generic. But the -- that's what they asked  
3 us. And I also wasn't quite clear on what they -  
4 - why they wanted to separate out some of those  
5 risk factors. So I was going to defer to the  
6 group because I am not sure we have actually good  
7 measures to inform the database on this. But  
8 those are the two issues that came up under  
9 validity. And then my -- my main focus was on  
10 the star rating.

11 VICE-CHAIR GUNNAR: So Dr. Yates and  
12 then the developers?

13 MEMBER YATES: Correct me if I am  
14 wrong, but it's -- the two things they found  
15 disparity in was that higher rates of -- for  
16 women and for blacks, or African Americans, and  
17 the -- the logic being that that's a  
18 physiological or genetic issue as opposed to  
19 SDS/SES per se. And you know, people don't like  
20 including SDS in some things because they feel  
21 like it is going to reward hospitals that are  
22 performing poorly as opposed to being an actual

1 risk factor. But I think for the purposes of  
2 this specific technical measure, it really  
3 doesn't make a difference. And we are not  
4 talking about poverty per se. People use African  
5 American race as a surrogate for poverty, but it  
6 is not necessarily, you know, a risk factor in  
7 this particular case. I would be interested in  
8 how the measure developers feel about that.

9 VICE-CHAIR GUNNAR: STS? Do you want  
10 to ---

11 MR. ANTMAN: So if I may confirm, I  
12 believe our lead statisticians are on the line  
13 with us, Sean O'Brien and Maria, and they can  
14 speak to specific questions related to  
15 reliability and validity.

16 DR. BADHWAR: While they are chiming  
17 in, I will just comment that there's obvious  
18 validity -- there's statistical validity, of  
19 course, but then the face validity of this  
20 measure, I think everyone is aware -- in terms of  
21 how we approach people -- to address your other  
22 question on the social disparity issue. As we go

1 through model development and the amount of hours  
2 that go into parsing out each risk factor and the  
3 coefficient of how that impacts the overall  
4 model, each of these items are addressed. And we  
5 go through one at a time -- age, sex and race.  
6 And to this date, those haven't parsed out to be  
7 significant yet. We are continuing to observe  
8 those. So hopefully that addresses your  
9 question, particularly as you made those mention.  
10 But I will have -- and I think Sean O'Brien and  
11 he can comment on the statistical validity  
12 calculations.

13 MR. O'BRIEN: Sure. This is Sean  
14 O'Brien from Duke University. With respect to  
15 the race and sex question, I had not remembered  
16 that that was raised in the context of validity  
17 that it's -- as it relates to the risk adjustment  
18 procedure and the rationale for having factors in  
19 the model that are associated with socioeconomic  
20 status and disparities issues. And our framework  
21 for approaching the risk adjustment is to -- is  
22 to think about minimizing confounding in the



1 sense that we would like to -- it is not  
2 practical to think about a randomized trial, or  
3 randomizing patients to go to a particular  
4 provider in order to obtain an unbiased  
5 assessment, but we would like to ask the  
6 question, how would results at one particular  
7 participant -- how -- what would those results be  
8 hypothetically if the mix of patients was similar  
9 between that participant and the reference  
10 population that they're being compared to --  
11 which is the overall STS?

12 And you know, a requirement for  
13 unbiased estimation is that all the -- all the  
14 factors -- you have measured and accounted for  
15 all the factors that are potential confounders.  
16 So we are kind of agnostic with respect to what  
17 variables are potential confounders and to  
18 satisfy the assumptions that are required for  
19 unbiased estimation. You are more likely to meet  
20 those -- I feel like you are more likely to meet  
21 those assumptions, which inherently can't be  
22 verified, if you adjust for a large number of

1 factors. So it wasn't -- they were not in there  
2 or out, specifically, because they were somehow  
3 connected to STS-related variables therein,  
4 because they are one of the dozens of factors  
5 that are measured on patients, but in principle  
6 we would like to balance all of the potentially  
7 important factors across participants when they  
8 are being assessed in comparison to the -- to the  
9 benchmark. And I will keep going unless there's  
10 -- unless I am interrupted for questions. I am  
11 happy to be.

12 CO-CHAIR FLEISHER: So to be clear,  
13 race is or is not in the model?

14 (No response.)

15 CO-CHAIR FLEISHER: Race is in the  
16 model, which presents a problem.

17 DR. SHAHIAN: Can I respond, Dr.  
18 Fleisher?

19 (No response.)

20 DR. SHAHIAN: We -- you know, putting  
21 -- putting on my NQF hat now for a second, I  
22 think NQF is now open to considering

1 socioeconomic or socio-demographic factors when  
2 there is a plausible association between those  
3 factors and the outcome. And for example, we did  
4 a very extensive study of socioeconomic factors  
5 in readmission because we think there is a very  
6 clear potential there.

7           On the other hand, for mortality, we  
8 see no particular reason why there should be an  
9 expectation that Medicaid or dual-eligible status  
10 or any of the other markers for socioeconomic  
11 status should affect mortality. Now, why is race  
12 in the model? I think race is in the model  
13 because historically we have had it. And we  
14 can't parse out the genetic or physiologic  
15 aspects of being, for example, African American.  
16 That population has a higher prevalence of  
17 hypertension. Hypertension happens to be a risk  
18 factor. So -- so there are potential socio-  
19 demographic factors associated with race, but  
20 also genetic factors. And we have just taken the  
21 agnostic view that, you know, this has an impact.  
22 We know it has an impact. We are not considering

1       it because of its socioeconomic association, but  
2       because of the potential for racial differences  
3       in risk like hypertension and things like that.  
4       So that is kind of the rationale for that.

5               MS. MUNTHALI:   So thank you for  
6       clarifying that.   And I just wanted to clarify  
7       for the committee, Dr. Shahian is right that we  
8       are looking at socio-demographic factors and  
9       social risk within risk models differently than  
10      we did before.   So prior to three years ago we  
11      prohibited the inclusion of social risk factors  
12      in our risk models.   We also have said that race  
13      should not be used as a proxy for social risk or  
14      socio-demographic factors.   But it can be used to  
15      make some genetic inferences.   So that  
16      clarification was important for us because we  
17      would have had some challenges trying to look at  
18      the measure as it currently is specified.

19              MEMBER YATES:   And I would argue that  
20      it would be better if they use the AHRQ ZIP code  
21      poverty index, or dual-eligibility as an index.  
22      Because I don't think people have more

1 complications because of the color of their skin,  
2 per se. Now, maybe the association of somebody's  
3 skin color with -- as was put items such as --  
4 or, conditions such as hypertension and the like  
5 -- would be important. And from a genetic  
6 perspective, then I think it is reasonable from a  
7 medical risk adjustment to conclude it.

8 MS. MUNTHALI: And I think you're right  
9 there. And one other thing I did not mention is,  
10 as we are asking developers about the connection  
11 of these socio-demographic factors and risk  
12 factors to the outcome, we are asking them to lay  
13 out a conceptual model of what that would look  
14 like and to then validate it with empirical  
15 testing. So that's -- and -- and because of the  
16 testing, or whether or not there is a conceptual  
17 relationship, the data or the evidence may not  
18 show that. That is why we are asking them to  
19 kind of lay out this entire rationale in their  
20 submission to us.

21 CO-CHAIR GUNNAR: So with that  
22 background, any more discussion on validity?

1 Amy?

2 MEMBER MOYER: Yes, I guess have a  
3 question conceptually about if the reason for  
4 including race in the risk adjustment model is  
5 the higher prevalence of these clinical factors,  
6 wouldn't those clinical factors already be  
7 accounted for and taken into account in the risk-  
8 adjustment model? Wouldn't that perhaps -- is  
9 that like a double impact potentially? I am a  
10 little confused by the separate influence of the  
11 two factors.

12 VICE-CHAIR GUNNAR: Comments?

13 MEMBER SAIGAL: It sounds like it to  
14 me. I mean, basically it's -- intent is not to  
15 have race in the model. Race is in the model. I  
16 mean -- you know.

17 (Simultaneous speaking.)

18 DR. SHAHIAN: I used hypertension as  
19 an example, but -- Sean may want to expand on it  
20 -- but I think there are potentially numerous  
21 genetic factors and racial factors that we may  
22 not account for in the model. And given its

1 impact on -- in previous analyses on outcomes, we  
2 decided to leave it in, again, without using it  
3 as a proxy for socio-demographic status -- or  
4 socioeconomic status, but using it because of  
5 potential genetic and physiologic factors. And  
6 Sean, you may want to expand on that.

7 MR. O'BRIEN: Well, I mean, our  
8 approach to assessing its inclusion or exclusion  
9 was empirical. So the model does adjust for a  
10 very large number of risk factors -- close to 40  
11 -- but empirically, in the case of the morbidity  
12 component -- and there is a clear association  
13 even after adjusting for those variables --  
14 between race and the morbidity outcomes. So it  
15 was included. I think that it was not included  
16 in the mortality portion of the adjustment for  
17 the mortality component in the case of the ADR  
18 measure. But we see empirically -- we don't know  
19 the underlying reasons for the association, but  
20 we know that race may be associated with, you  
21 know, any number of unmeasured factors. And so  
22 the idea is that we -- to the extent that there

1 is unmeasured factors that could be explaining  
2 the observed differences between the participant  
3 who is being evaluated and other participants, we  
4 need to try to maximize -- measure those. And so  
5 to measure -- to measure variables that are  
6 proxies in the sense of being associated with --  
7 with underlying causal factors is adequate to  
8 minimize confounding that would be there if you  
9 didn't at least adjust to the variables --

10 (Simultaneous speaking.)

11 MEMBER SAIGAL: Can I follow up on  
12 that? Because -- so are there measures of SES in  
13 the model? Dual-eligibility? Is that right?

14 (No response.)

15 MEMBER SAIGAL: No? So then basically,  
16 I mean, there known risk factors that are  
17 associated with race are already in the model and  
18 you are saying something else is accounting for  
19 the impact of race, and it sounds like it is SES.  
20 I mean, genetic factors are undefined. So  
21 logically that sounds what it is. So now -- and  
22 basically it is the intent is not to have race



1 used in this way. It is being used in this way  
2 in my mind. So I would say it is a problem  
3 unless you can change it.

4 DR. BADHWAR: Can I make a comment  
5 just to add to the genetic -- just to give a  
6 clinical, real-world example? So, East Asian  
7 Indian males of lower than average body weight  
8 but higher preponderance of small-vessel coronary  
9 disease, just to give an example -- patients such  
10 as those have a little bit more difficult  
11 coronary anastomoses to be done. There is no way  
12 of grading that in -- in -- using the current  
13 risk models that exist. Difficult small-vessel  
14 coronaries -- that is not a factor that we have  
15 on our database. But an example of that -- and  
16 there are many other that -- why race can be  
17 important and used in a -- in an instructive --

18 MEMBER SAIGAL: But in India, if all  
19 those guys have small vessels -- in India, all  
20 the Indians in India are having this problem? I  
21 mean, it doesn't make sense to me. How do we  
22 know that that's true across the entire

1 population of Southeast Asians? It is an  
2 impression.

3 DR. BADHWAR: I will respond by saying  
4 just from -- I am just using that as one example.  
5 It's a fairly well accepted -- within our --  
6 within the cardiac surgical community, when you  
7 see someone of a certain ethnicity, you are  
8 expecting a certain variable in the operating  
9 room. It is not measurable by current ways -- we  
10 don't have a defined way of measuring X, Y and Z,  
11 but it is an inference. But that is why race is  
12 in the model. Not by any kind of socially --  
13 social inference, but by other factors that we  
14 can't account for.

15 MEMBER SAIGAL: Right, I understand  
16 the intent is that. But the impact, actually, it  
17 sounds like they're measuring SES, especially if  
18 they are African American. I mean that's --  
19 that's who you are loading on there because you  
20 already have the other factors incorporated that  
21 we know matter in terms of the outcomes here.  
22 The --

1 (Simultaneous speaking.)

2 DR. BADHWAR: That is assuming that  
3 you have in fact included every other potential  
4 confounder in your model, which -- I am sure we  
5 haven't. There are -- you know, we can only  
6 account for a certain number of confounders that  
7 we routinely measure. I would not assume that  
8 all the delta between what is in the model and  
9 not is SES. That's our point. And I think  
10 that's what Sean was saying as well.

11 MEMBER YATES: Yes, in defense of STS,  
12 they took a lot of different variables and then  
13 they threw them into multi-variable regression  
14 analysis and they came up with things that made a  
15 difference. And race happens to empirically make  
16 a difference. And that -- unfortunately, I have  
17 to mix two meanings of the word black, but it's a  
18 black box in the sense that you don't know what  
19 is causing that difference to the Nth detail.  
20 But there is enough multiple different things  
21 that are different for that to make it an  
22 important risk factor and it has to be included.

1 I mean, in -- I have to use an  
2 orthopedic analogy, but, you know, we would need  
3 to use gender as a risk factor for hip  
4 replacement because it is -- we know that the  
5 shape of their acetabulae are different and they  
6 have a smaller pelvis. And we know that they are  
7 more osteoporotic. And -- but there's also data  
8 to show that there is a different ligamentous --  
9 a different tension to their ligaments, a  
10 different propensity to ligamentous tears and the  
11 like, and so we are -- we are left with some  
12 things that we -- are so poorly defined, we can't  
13 use them as individual risk adjustments, but when  
14 added together they become a composite risk. And  
15 I think it is reasonable when it is used for this  
16 purpose -- and especially for black and white,  
17 again I am using the word black in a different  
18 context, in a black and white outcome of these  
19 type of morbidities and this -- and mortality, I  
20 think it is an important thing to include. And  
21 it's not going -- it is not expected that the  
22 socioeconomic component of race, or the overlay

1 of that, is affecting these very clear-cut  
2 outcomes. And that's where I would argue --

3 (Simultaneous speaking.)

4 MEMBER SAIGAL: Well, why is it not  
5 expected? Why is -- how can it not be expected?  
6 It should be expected.

7 MEMBER YATES: The -- because, again,  
8 I don't think that -- I don't think that the --  
9 necessarily the definition of race in and of  
10 itself is dragging poverty into this particular  
11 question. You know, people use race as a  
12 surrogate for poverty, and I don't think that is  
13 an appropriate use for it in this case. That is  
14 my opinion and I think it would be justified by  
15 statistical analysis.

16 MEMBER SAIGAL: Well in my view it has  
17 not been justified by this analysis. I think --  
18 I mean, I think this is a fantastic registry and  
19 project. I don't think it should go down for  
20 this, but I think it is notable that this has not  
21 been addressed in a meaningful way. So I would  
22 just make that in a note on this measure that it

1 has not been addressed.

2 MEMBER EREKSON: I would like to  
3 support what you just said. And I would also  
4 like to say that as we consider these socio-  
5 demographic risk factors, there's just better  
6 variables to measure it than race as a surrogate.  
7 And so, if we are accounting for all the knowns  
8 and we are putting race in the model, then it  
9 would really be nice to see these other things  
10 considered or not considered as -- as a note for  
11 the record and for the future that, you know, all  
12 of the things that we've already discussed -- the  
13 dual-eligible, the Medicaid -- all of the things  
14 that we can easily obtain out of billing data  
15 that doesn't include adding more variables to an  
16 already cumbersome data collection, would be  
17 helpful for us to be able to review in the  
18 future.

19 CO-CHAIR GUNNAR: Dr. Stein?

20 MEMBER STEIN: I am not arguing  
21 against -- I think it is fine to keep race in the  
22 model, but an easy solution is just also do a

1 stratified analysis by race, right?

2 DR. SHAHIAN: We have those data  
3 available. And it -- and it is not being -- just  
4 again to repeat -- we are not using it as a  
5 socio-demographic variable or proxy. That is not  
6 its purpose in this model.

7 MS. MARINELARENA: I just wanted to  
8 point out too that Hispanic is part of the model.  
9 Hispanic is not a race even from -- for a  
10 clinical perspective, Hispanic is not a race, it  
11 is an ethnicity. So it is not clear what  
12 clinical issues we associated with Hispanics.

13 DR. BADHWAR: Just a final response to  
14 Dr. Saigal's comment that -- again, that this is  
15 -- it is definitely not a surrogate for socio-  
16 demographic profiling. That is not at all the  
17 intent of this. But certain races or  
18 demographics do have a higher preponderance of  
19 diabetes -- a higher preponderance of poorly  
20 controlled diabetes and secondary effects that  
21 are covered in the model, but it is -- as Dr.  
22 Yates mentioned, it's a multi-variable factor

1       that came out in the calculations.

2                   MEMBER SAIGAL: I totally get that  
3       that is -- not the intent. I completely hear  
4       everyone's comment -- not the intent. But  
5       logically, it is the impact. I mean, Indians  
6       don't show up as a special risk model -- factor  
7       in the risk model, although they have a smaller  
8       set of coronary arteries that apparently,  
9       according to consensus. So I mean, something  
10      else is driving it. Logically it has got to be  
11      SES. In other models, that is what it is -- that  
12      is what it loads on. So I would just say it has  
13      to be looked at. And as -- I think the  
14      suggestions on the committee are really important  
15      because I don't know if we should or shouldn't  
16      put this in as a -- as a -- in the risk models,  
17      but NQF says we shouldn't, so as a committee we  
18      have to sort of discuss that. And that's just --  
19      I think it is a glaring example of what has not  
20      been happening.

21                   MEMBER YATES: I would argue that  
22      there would be an unintended consequence of



1 dropping it from the model. If it is thought to  
2 be an important risk factor, you run the risk of  
3 patient avoidance and not -- you know, lemon-  
4 dropping by surgeons. And there would be less  
5 access to care. And I -- at this point in time,  
6 I really think that we are arguing apples and  
7 oranges. Not to mix it in with the lemons.

8 MEMBER STEIN: I would just encourage  
9 the developers to put in the material they are  
10 sharing with us the stratified results. I think  
11 that would help.

12 MS. MUNTHALI: And I would second that  
13 because that is actually a requirement. So we  
14 ask for not just the risk adjustment based on the  
15 SDS, but also -- or SES -- but also  
16 stratification so that we can see the differences  
17 between groups.

18 CO-CHAIR FLEISHER: So my question is  
19 actually hypothetical depending on where this  
20 goes. But if you wanted to show us that  
21 inclusion in the model did not have a negative  
22 effect on adverse selection, and actually

1 institutionalizing any kind of racial profiling,  
2 or -- who would you do that? Have you thought  
3 about that? Because that's the concern is that  
4 it is institutionalizing differences. So have  
5 you seen over time -- has the race Hispanic or --  
6 since that is not a race -- or African Americans  
7 have changed and the influence of that? Or --  
8 and as well as the influence of detecting the  
9 extent of disease? Because what I am hearing is  
10 disease is here and your argument is actually  
11 severity rather than presence. Because you have  
12 a lot of these kind of risk factors that are  
13 associated with differences between different  
14 racial groups. So is it severity of detection?

15 DR. PAONE: I am not exactly sure how  
16 to answer this, but you know -- considering  
17 socioeconomic status has become in vogue over the  
18 past few years -- and I don't say that lightly --  
19 it is clearly not an easy thing to define. I  
20 think -- depending upon what you look at, it  
21 becomes controversial in one way or another. You  
22 look at geography -- and if you look at

1 geography, is their ZIP code enough? Or a city?  
2 Or do you have to go down to the street or  
3 apartment level, right? Before you actually get  
4 reliable data that's usable?

5 You know, the concept of dual-  
6 eligibles I think is a good one at the patient  
7 level because I do think there is some evidence  
8 that at the individual patient level, the  
9 outcomes are a little worse for dual-eligibles  
10 than for others. But if I remember correctly, we  
11 did a pilot study of this at STS a few years  
12 back, and the numbers are relatively small, so  
13 that it really doesn't drive any changes in the  
14 star ratings overall from that perspective. And  
15 so --

16 CO-CHAIR GUNNAR: So let me be very  
17 clear, you have analyzed one star -- one-, two-,  
18 and three-star facilities and socioeconomic  
19 factors are not driving those ratings?

20 DR. PAONE: I think we have -- I  
21 believe we have done that, including dual-  
22 eligibles as an SES variable -- in a pilot study.

1 David, is that not correct?

2 (No response.)

3 DR. PAONE: I am sorry? Oh, that was  
4 for readmissions. I apologize. But -

5 CO-CHAIR FLEISHER: I didn't look --  
6 how strong is -- what is the coefficient of the  
7 influence of African American race as well as  
8 Hispanic in your model? Is it, you know, 1.02?  
9 Or 1.0 -- you know --

10 (Simultaneous speaking.)

11 DR. PAONE: I don't have that  
12 information. I would ask Sean, he is on the  
13 line, if he knows --

14 CO-CHAIR FLEISHER: Yes, I am asking  
15 --

16 (Simultaneous speaking.)

17 (Pause.)

18 PARTICIPANT: Sean, are you on the  
19 line? The question was, what the coefficient was  
20 for race, if you are looking that up, perhaps.

21 MR. O'BRIEN: Apologies, I was on  
22 mute. So -- so in the morbidity endpoint

1 component the odds ratio comparing patients with  
2 black race compared to other races including  
3 white was 1.27, in other words a 27% increase in  
4 risk. And as I mentioned -- race was not a  
5 factor in the mortality risk adjustment.

6 DR. PAONE: Let me just add a more  
7 personal sort of practical approach to this is --  
8 I don't know any surgeon who has ever looked at a  
9 patient and said, their risk is higher and  
10 therefore I am not going to operate on them --  
11 because they're -- because they're black which  
12 means they are likely poor. It just doesn't  
13 happen in the real world that I am aware of.

14 MEMBER YATES: On the contrary, saying  
15 any surgeon would be fine if you were saying any  
16 cardiothoracic surgeon, because you are dealing  
17 with situations that aren't truly elective.  
18 Whereas, when there is the opportunity to perform  
19 elective surgery, unfortunately there is biased  
20 lemon-dropping and cherry-picking in elective  
21 surgeries that leads to loss of access. So I --  
22 in the real world, that really does happen. And

1 I can tell you people that -- there are surgeons  
2 that just refuse to see Medicaid, and not just  
3 for medical -- not just because of reimbursement.

4 DR. PAONE: Well then I will accept  
5 that and understand it, but change my comment to  
6 say in the real world of cardiac surgery, then.  
7 And I would believe that very strongly.

8 MEMBER YATES: And to STS's credit,  
9 the case complexity mix, which is another way of  
10 looking at risk avoidance, has gone up slightly  
11 in the STS database. And to the STS database  
12 credit, partly because you guys are risk-  
13 adjusting, which does make it an even playing  
14 field for all surgeons, so they don't feel like  
15 they are being unduly measured for taking on  
16 complex cases. So kudos to the STS for doing  
17 that.

18 MEMBER JARRETT: This is Mark. I  
19 raised my hand a little while back, but I guess  
20 that's part of the punishment for not physically  
21 being there. You know, I am listening to this  
22 discussion, you know, our health system is very

1 much involved now through one of our leaders in  
2 looking at social determinants and all of these  
3 issues. And I think -- we all agree that I think  
4 STS needs to move to, you know, a better  
5 mechanism to include social determinants. And I  
6 don't think we know what the impact of race is --  
7 whether it is genetic, whether we are really  
8 looking at a proxy for access and other social  
9 determinants. But we have to realize, we are  
10 really at a point in the science of this that we  
11 really don't have great social determinants. I  
12 mean, you know, dual-eligibility is a poor proxy  
13 for it, quite frankly. Doesn't that account for  
14 a lot of the population that has no insurance?  
15 And I think that we really need -- you know, need  
16 to sit back and say this is the status of where  
17 we are today, and it may not be ideal, but it  
18 does provide information that, if it is  
19 publically reported, does help the public, which  
20 is where we are going -- as well as help  
21 performance improvement. But saying that we  
22 expect that STS will come out -- because I -- I

1 had the same concerns about the measures that I  
2 looked at, that they need to come out with a --  
3 with a viewpoint on how they are moving forward  
4 with social determinants and other things more  
5 quickly.

6 The other thing -- I will make a  
7 comment -- also, depending on what's written in  
8 the medical record as race and ethnicity -- when  
9 we did an analysis of this and an audit of this,  
10 it is kind of frightening. And I have a feeling  
11 in a lot of hospitals and other places around the  
12 country, this is often got by a registrar who  
13 usually has no concept, is afraid to ask, or puts  
14 down, you know, miscellaneous or other -- things  
15 like that. So I worry, also, about the validity  
16 of what -- of actually what is written,  
17 especially as you move from white versus African  
18 American to anything else.

19 DR. SHAHIAN: Could I respond to the  
20 question about where we are heading in exploring  
21 this at STS? We are very close to signing a  
22 contract with an academic institution that will



1 provide us with the ability to geocode every  
2 single patient in the STS database. And for  
3 those of you that aren't familiar with this, most  
4 people think this is probably the single best way  
5 to assess overall socioeconomic or socio-  
6 demographic status -- gets you down -- it takes  
7 the patient's address, converts it to a very  
8 highly specific latitude and longitude, and gets  
9 you to a block-level, or Census-track level  
10 socio-demographic status. We will do this with  
11 every patient. And then we can explore some of  
12 these questions that have been raised  
13 empirically. So that's -- that is something that  
14 we hope to have within a year.

15 MEMBER YATES: And ideally you would  
16 cover that as a continuous variable across the  
17 entire population as opposed to using a cutoff,  
18 which cuts out the community effect because --  
19 you know, my observation is, it's the social  
20 topology of the neighborhood that makes it a  
21 tough deal in terms of getting good healthcare  
22 and getting access. And there is a big

1 difference between living in some parts of the  
2 Bronx versus living in Palo Alto.

3 DR. BADHWAR: Just a comment on -- not  
4 representing STS, but just as a healthcare  
5 researcher in general -- I mean, as all of you --  
6 that the data is just not there yet, but these  
7 types of issues like geocoding are evolving  
8 rapidly. Another one is distressed community  
9 index and what that -- how that would influence  
10 outcome. And so, as these types of variables are  
11 becoming more accessible for our healthcare  
12 analyses, perhaps one day -- to address Dr.  
13 Saigal's earlier comments that -- which are very  
14 valued, that yes, it's incumbent upon us as a  
15 society, regardless of what specialty it is, to  
16 have a more robust analysis before making a  
17 conclusion of connection.

18 CO-CHAIR FLEISHER: So I actually have  
19 a question, Lisa. I am going to put you on the  
20 spot in that, as we think through this and try to  
21 make determinations -- and as the committee,  
22 which owns this portfolio, weighs a decision on

1       this particular issue, is this a up-or-down  
2       because of what we think about how they included  
3       those particular variables? Is this a clear  
4       message, then, when this comes back -- do we have  
5       the option to say if this comes back, we have to  
6       change to what we hope will be the next -- next  
7       time, with a clear signal? Is there any clarity  
8       from your perspective on how the committee is  
9       clearly concerned about the inclusion of African  
10      American and Hispanic in the model?

11                   MS. MUNTHALI: Yes, it is a good  
12      question. We are struggling with that now. I  
13      mean, as it clearly is included in the  
14      specifications, it does go against our policy as  
15      part of this SDS trial. It is a five-year trial.  
16      We are finding the developers, to the point that  
17      is just made, are having a hard time getting  
18      access to the right data -- merging those SDS  
19      data with clinical data. It has been a  
20      challenge. So they are using perhaps less than  
21      optimal, less than desired data to make  
22      inferences about social demographic factors and

1       their relationship to outcomes.

2               With that said, I think the committee  
3 needs to send a strong message because it is part  
4 of our criteria. We are in -- we are all in a  
5 period of discovery with the influence of risk  
6 factors on health outcomes and the impact of  
7 those factors that are outside the clinical care  
8 delivery system. But we would like to see that  
9 variable not in the risk model as a proxy. If it  
10 is indeed -- I was getting a little confused  
11 about whether or not it was and wasn't. I think  
12 the CSAC will have some challenges with that if  
13 it is used as a proxy for SDS. So I think with  
14 the comments that were made -- and I can't  
15 remember who made them down there -- about just  
16 very strong caution to the developer, to -- I  
17 think somebody said they wouldn't vote it down,  
18 but very strong caution that you come back soon  
19 with --

20               CO-CHAIR FLEISHER: So the irony is,  
21 if we weren't in the SDS period and this was  
22 approved years ago, this was probably in the

1 model, but because we are in the SDS period, it  
2 has actually popped up as a potential surrogate -  
3 - although we heard David's comment that this was  
4 not originally put in the model for surrogate  
5 purposes. So it is a -- just to articulate -- it  
6 is a confusing question of how much do we buy  
7 into the genetics or severity of disease  
8 argument. But we are now in SDS where there has  
9 been a -- in a trial period where there is a very  
10 clear signal that that is not acceptable, but it  
11 was when we first looked at this measure because  
12 it wasn't considered an SDS variable. It was  
13 considered --

14 MS. MUNTHALI: Right, because we  
15 thought at the time that we would be masking  
16 disparities, as many do on the other side. So --  
17 but we are in this period now. So this is what  
18 we hold. This is the standard we hold all  
19 outcome measures to that come through NQF.

20 CO-CHAIR FLEISHER: So what I am  
21 hearing is that if we decide to approve it, that  
22 we are giving a very clear signal that it

1       probably wouldn't be approved in the next time,  
2       and that is only an if. That we want them to  
3       look into this issue.

4               MS. MARINELARENA: Sure. So when you  
5       are considering risk adjustment, you are looking  
6       at the threats to validity. So does -- do these  
7       two risk factors, are they a risk to -- a threat  
8       to the validity of the measure?

9               DR. BADHWAR: May I raise one point?  
10      Just to add to the confusion slightly. That if  
11      we consider, say, African American race to the  
12      odds ratio of 1.27 -- I think as Sean had said --  
13      it is a statistical input. It is not being used  
14      for racial profiling or that type of more  
15      egregious type of effort. However, if you think  
16      about it in a different way, if the concern is  
17      that a provider may see an elevated risk for a --  
18      a race and maybe have risk aversion, which is the  
19      issue, technically if that is a higher risk for a  
20      certain race, it actually advantages by risk  
21      adjustment to take care of that person. So --

22              CO-CHAIR FLEISHER: That is actually

1 -- we should stop, but that actually is not the  
2 argument of why we said it shouldn't be in. What  
3 it says it is masking that a hospital can do  
4 worse in an African American patient -- for  
5 example in this case -- because it gets risk-  
6 adjusted out. It is not the argument that  
7 somebody -- so, I think you are confusing why we  
8 made a clear, concerted effort at the CSAC of  
9 saying why we didn't want race placed there --

10 MEMBER YATES: In the past.

11 CO-CHAIR FLEISHER: In the past.

12 MEMBER YATES: Right, that was the  
13 paradigm of the past and now the paradigm is, at  
14 least present data to show that it shouldn't be a  
15 risk adjustment.

16 CO-CHAIR FLEISHER: But it should be  
17 stratified --

18 MEMBER YATES: Right.

19 CO-CHAIR FLEISHER: To show us. We  
20 should vote.

21 CO-CHAIR GUNNAR: All right, can we  
22 move on to validity? And just to torture this

1 one a little bit, how do -- does this come to a  
2 note to our decision? Whatever the decision is?  
3 Let's vote, and then we will get to that next  
4 step. So we are voting on validity.

5 MS. KOSURI: Voting is now open.

6 (Pause.)

7 MS. KOSURI: We are still waiting for  
8 a couple more votes.

9 (Pause.)

10 MS. KOSURI: Okay, we have the 14  
11 votes. One of our members had to step off, so -

12 CO-CHAIR FLEISHER: Can I make a  
13 motion -- I don't know how the committee -- that  
14 we get stratification by race in the maintenance  
15 at one year? Because I think there is enough  
16 concern ---

17 PARTICIPANT: Was consensus reached?

18 MS. KOSURI: No, it is 64 --

19 CO-CHAIR FLEISHER: It is reached, but  
20 there is lots of concerns.

21 (Simultaneous speaking.)

22 MS. KOSURI: We beat 60 percent. Do



1       you mind if I announce it for a second?

2                   MS. MUNTHALI: To Lee's motion, the  
3       reason he mentioned a year -- it is because it is  
4       the annual update of the measure, so we want to  
5       make sure it is within process. We will work  
6       with the SDS to make sure this happens -- and  
7       looked at by the committee.

8                   CO-CHAIR FLEISHER: Does the committee  
9       agree with my motion?

10                  MEMBER SAIGAL: Second.

11                  CO-CHAIR GUNNAR: Just -- for those on  
12       the phone, if you would like to vote no, just  
13       email your vote in. Any -- just hand vote here -  
14       - anybody in opposition?

15                  Seeing none, I think we have -- the  
16       recommendation from the -- in within a year, back  
17       from the developer.

18                  MS. KOSURI: So I just wanted to --  
19                   (Simultaneous speaking.)

20                  MS. KOSURI: So for measure 2561 for  
21       validity we have nine votes with moderate and  
22       five votes with low for a total of 14 votes. And

1       that is above the 60 percent. It is 64 percent,  
2       so it passes.

3                   CO-CHAIR GUNNAR: So this passes on  
4       validity with, in my opinion, clear question to  
5       it by the fact that it is 30-some percent low.  
6       And a request -- a strong requirement that --  
7       appended to this decision that the developer come  
8       back with how they are going to address this  
9       issue going forward. So we can move on to use --  
10      is that is what is next? If I am --

11                  MS. KOSURI: Composite construction.

12                  CO-CHAIR GUNNAR: All right. Dr.  
13      Cima, any --

14                  MEMBER CIMA: No.

15                  CO-CHAIR GUNNAR: Any comments from  
16      anyone?

17                  (No response.)

18                  CO-CHAIR GUNNAR: Can we carry on to  
19      the vote? And this should --

20                  (Pause.)

21                  MS. KOSURI: Voting is now open for  
22      the composite construction.

1 CO-CHAIR GUNNAR: Yes.

2 (Pause.)

3 MS. KOSURI: Voting is now closed with  
4 -- with six votes for high and eight votes for  
5 moderate, for a total of 14 votes. The composite  
6 construction part of measure 2561 has passed.

7 CO-CHAIR GUNNAR: So the -- you  
8 announced, it passed. We move on to -- now do we  
9 get to use?

10 CO-CHAIR FLEISHER: Just for the -- to  
11 help the room think about for the -- for all the  
12 other measures we are going to look at, we  
13 discussed the fact that any measure that is built  
14 on this measure, if the votes are going to be the  
15 same, we will be able to ask if anyone wants to  
16 pull the measure for individual voting, which  
17 there is no problem doing -- that is actually the  
18 approach we take for the math. But if you think  
19 you are going to have the same questions about  
20 any other of these measures, we use these votes  
21 and carry them to the next discussion.

22 CO-CHAIR GUNNAR: That was jumping

1 ahead.

2 CO-CHAIR FLEISHER: Yes.

3 (Laughter.)

4 CO-CHAIR GUNNAR: Let's -- let's -- we  
5 are just trying to get through our first measure  
6 by 11:30.

7 (Laughter.)

8 CO-CHAIR FLEISHER: And our second  
9 measure by 11:40.

10 CO-CHAIR GUNNAR: All right. So where  
11 are we headed next? Feasibility?

12 MS. KOSURI: Yes, voting is now open  
13 for feasibility.

14 CO-CHAIR GUNNAR: Dr. Cima, any  
15 comments before we move on to ---

16 MEMBER CIMA: No.

17 CO-CHAIR GUNNAR: Any comments in the  
18 room? Dr. Cima, we can carry on and vote.

19 MEMBER CIMA: Vote -- let's vote.

20 CO-CHAIR GUNNAR: Yes.

21 (Pause.)

22 MS. KOSURI: Waiting on one more vote.

1 (Pause.)

2 MS. KOSURI: Okay, with seven votes  
3 for high and seven votes for moderate, with a  
4 total of 14 votes, we have -- for measure 2561  
5 for feasibility -- has passed.

6 CO-CHAIR GUNNAR: Very good. Next?  
7 Usability, right?

8 MS. KOSURI: And now it is usability.

9 CO-CHAIR GUNNAR: So, use -- any  
10 comments, Dr. Cima? Anyone in the group?

11 MEMBER CIMA: No, it just goes back to  
12 the question that was raised quite a while ago  
13 about, is it being used the way we want it to be  
14 used? The public reporting aspect of it -- that  
15 was my main concern. That -- is it enough to  
16 just be what it is -- voluntary? Although a lot  
17 of people are doing it, and the star rating -- as  
18 we discussed, we are not here to comment on it --  
19 but is that useful information? And we had that  
20 long discussion about it. That was my one  
21 concern as an individual, is -- are we moving the  
22 bar for usability? Or is it the same thing we

1 have been doing for the last decade with these  
2 measures?

3 (Pause.)

4 CO-CHAIR GUNNAR: Any further  
5 discussion? Impressions? Elisabeth?

6 MEMBER EREKSON: I would just say, to  
7 add to the conversation that we have already had,  
8 is perhaps the developer could go and actually  
9 conduct patient focus groups to get a little bit  
10 more information on what patients want to see on  
11 the website. And I think -- you know, I have  
12 been on the website this morning already, and  
13 there is definitely columns, and it is very clear  
14 to understand. You can definitely make the  
15 morbidity -- the composite measures look bigger,  
16 but still include some of that other data. The  
17 other comment I would have is that I feel that  
18 all surgeons feel that their outcomes are better  
19 than they are when those are good outcomes, and  
20 they have less of the bad outcomes than they  
21 actually do. Just like all surgeons, if you ask  
22 them what their volume is, tend to overestimate

1       how much they are doing. And so, to -- and that  
2       is just a truth in surgery because we all want to  
3       do a good job by our patients -- I think to have  
4       the onus for public reporting go to the patient  
5       level where the patient has to ask her or his  
6       surgeon what their -- their data is, takes away  
7       from the public reporting. So I just would say  
8       that I like some of the pathways that have been  
9       proposed. I think we have other measures that  
10      are QCDR measures, and that is how we are talking  
11      about public reporting. But it is something that  
12      -- but I don't think the onus should be on the  
13      patient and the individual surgeon because those  
14      data are not as good as what a transparent public  
15      reporting is.

16                   CO-CHAIR GUNNAR: Dr. Stein and then  
17      Rick.

18                   MEMBER STEIN: I have a question for  
19      the developer, did -- for the 67 percent that are  
20      publically reporting, since you -- since you know  
21      where they lie in the zero to 100 percent, are  
22      they -- do they tend to be the highest 67

1       percent? Or -- have you looked at that?

2               DR. PAONE: So the answer to that is  
3 we see what the public sees. The STS is a  
4 voluntary -- participation in the database is  
5 voluntary, public reporting is voluntary. The  
6 data is housed at the Duke Clinical Research  
7 Institute, not at the STS. And so we don't know  
8 of the 1,091 centers, which are three stars or  
9 two stars for any particular outcomes. That is  
10 not information that we have. That information  
11 is obviously with the institution. So of the --  
12 so, on the website, 67 percent report -- or 69.9  
13 percent now report. The star ratings are  
14 available for them individually. If you go to  
15 that website, you can actually organize them in -  
16 - depending on how you click the categories, you  
17 can have them pop up in order from three stars  
18 for mortality or three stars down -- or click  
19 them again and the one-star programs will pop up  
20 to the top for the individual categories. But if  
21 they are not publicly reported, STS has no way of  
22 knowing. In fact, I can tell you a year and a



1 half ago there were -- when we added the five --  
2 when we added the composites for the surgery,  
3 there were three programs in the country who were  
4 three stars for all five categories. We had no  
5 idea who they were and had no way of finding out  
6 unless they came forward -- and one did and so we  
7 knew who one was. That is just -- again, the  
8 nature of the voluntary aspect of this.

9 DR. SHAHIAN: Let me expand on that  
10 question, though. We did actually look at this  
11 as a research endeavor. And I presented this to  
12 the American Surgical Association about three  
13 years ago. We had access on a research basis to  
14 all the programs in the country, and we looked at  
15 the performance of publicly reporting programs  
16 versus non-publicly reporting programs. You can  
17 go to PubMed and you can see the abstract. But  
18 very striking that publicly reporting programs  
19 uniformly for all nine reporting periods that we  
20 studied between 2010 and 2014 -- every single  
21 reporting period -- publicly reporting programs  
22 had lower risk-adjusted mortality and higher

1 composite scores for every rating period. And  
2 again, you can go to PubMed and see the detailed  
3 results.

4 MEMBER DUTTON: So obviously you can  
5 slice that either way around, but it is  
6 interesting. I have a different question for the  
7 developers about the science of this. Obviously  
8 STS existed for a long time before the public  
9 reporting started as a quality improvement tool  
10 for surgeons and hospitals and you have -- I  
11 believe you have documented substantial  
12 improvement over that period with the measurement  
13 and reporting as a quality improvement tool. How  
14 did that change when you started public  
15 reporting? Did the vector of change defer? Do  
16 -- did it cause a drop-off in overall  
17 improvement, or an increase? In other words, did  
18 the public reporting help?

19 DR. SHAHIAN: Behind that question is  
20 the presumption that the main goal of public  
21 reporting is improvement, and some people would  
22 argue it is the only way to improve. In fact, I

1 think there are many examples of improvement  
2 without public reporting -- one of the best of  
3 which is the Northern New England Cardiovascular  
4 Disease Study Group. And there are many other  
5 examples.

6 We think the main reason to do public  
7 reporting is public accountability and  
8 transparency. I think there are many ways to  
9 improve. And we have -- you know, we were  
10 improving before public reporting, and I don't --  
11 as I recall, for most of the measures, the  
12 trajectory for improvement did not change  
13 dramatically when we started publically  
14 reporting. Because we have been working on this  
15 for years before and after. And those graphs are  
16 actually also in that article if you want to look  
17 at it. But in most cases, you know, we have just  
18 been improving steadily over the years.

19 DR. BADHWAR: If I can comment to  
20 enhance Dave's comment. At the institutional  
21 level, if you think about the overarching  
22 objective of what public reporting is -- and the

1 aspects of, once you sign up to voluntarily  
2 public report -- the arc of improvement is  
3 increasing because everybody is trying to get to  
4 that two- and three-star rating. And by being  
5 able to compartmentalize each of the  
6 subcomponents of where you are not three stars is  
7 the, you know, issue du jour at every cardiac  
8 surgical program that is publicly reporting -- to  
9 define, how can you improve? And so lessons  
10 through some of the task forces -- one of which  
11 that Gae chairs -- is how do we take those  
12 lessons from those three-star programs and share  
13 it in terms of quality improvement? So I would -  
14 - I would say to your question that yes, there is  
15 a gradual improvement at multiple sites that are  
16 participating in public reporting.

17 CO-CHAIR GUNNAR: So we are at use.

18 Any other discussion or comments around use?

19 (No audible response.)

20 CO-CHAIR GUNNAR: If not, then we will  
21 vote.

22 MS. KOSURI: Voting is now open.

1 (Pause.)

2 MS. KOSURI: Okay, for use, with a  
3 total of 14 votes, we have 12 who voted to pass  
4 and 2 who voted to not pass. So this -- this --  
5 it passes for measure 2561.

6 CO-CHAIR GUNNAR: Very good. Our next  
7 is usability. Any discussion about usability?

8 (No response.)

9 CO-CHAIR GUNNAR: Hearing none, it is  
10 open for a vote.

11 (Pause.)

12 MS. KOSURI: Waiting for one more  
13 vote.

14 (Pause.)

15 MS. KOSURI: Okay. With a total of 14  
16 votes, we have 2 votes for high, 10 votes for  
17 moderate and 2 votes for low. So for measure  
18 2561, usability, we have passed -- the measure  
19 has passed.

20 CO-CHAIR GUNNAR: Very well. Now we  
21 move to overall endorsement. Any further  
22 discussion, comments before we vote on this

1 measure for endorsement?

2 (No response.)

3 CO-CHAIR GUNNAR: recognizing the  
4 discussion and caveats that we have already come  
5 to -- very good.

6 (Pause.)

7 MS. KOSURI: We are still waiting for  
8 two more votes.

9 CO-CHAIR GUNNAR: He will certainly  
10 present the amicus brief at the --

11 MS. KOSURI: For measure 2561 for  
12 overall suitability, this measure has passed with  
13 14 votes for yes out of the total of 14 votes.

14 CO-CHAIR GUNNAR: Okay, and -- and I  
15 think we have given appropriate direction as to  
16 what needs to be the addendum to this decision?  
17 All right, very well. Now, our next is virtually  
18 the same. So the next is 2563. It is STS -- is  
19 that correct? STS aortic valve replacement and  
20 coronary bypass graft composite score. And the  
21 discussants are -- Allan is not with us, right?

22 MEMBER SIPERSTEIN: Yes, I am here.

1 CO-CHAIR GUNNAR: Allan, great. So  
2 let me ask, is there anything you would like -- I  
3 mean, it is virtually the same -- it is identical  
4 to the process we just completed, right? It -

5 MEMBER SIPERSTEIN: Correct, yes. So  
6 -- but first I just want to put in my two cents  
7 on a lot of that last discussion. I think the  
8 whole discussion on race and socio-demographic is  
9 very, very important. And just to editorialize,  
10 I think it just reflects our maturation in terms  
11 of measures and outcomes. Whereas previously we  
12 were ecstatic to be able to risk adjust  
13 mortality. And it simply shows the  
14 sophistication in what has gone on. And I think  
15 the real importance for the patient is to  
16 identify modifiable risk factors, both at a  
17 personal level and a societal level, and so are  
18 quality efforts to move that forward.

19 So that -- now that I have gotten my  
20 two cents in -- so exactly. This measure is  
21 exceptionally parallel to the measure we just  
22 discussed, simply for aortic valves with CABG

1       being done. My question -- I will try to focus  
2       this for the developer -- is obviously we are  
3       dealing with a lower-volume procedure with a  
4       higher overall mortality and complication rate.  
5       And I just want to get their input on how they  
6       think this impacts the validity and usability of  
7       the measure.

8                   DR. PAONE: So I think that is a  
9       reasonable point to make. However it -- AVR CABG  
10      is -- fewer numbers than isolated AVR, although  
11      that may not be the case a few years from now  
12      with the advent and continued exponential growth  
13      of trans-catheter aortic valve replacement. But  
14      having said that, it is still the third most  
15      common procedure. It is -- and its complexity is  
16      such that it is a different procedure from the  
17      aortic valve replacement. And so I do think it  
18      is very reasonable to have a separate composite  
19      score for this. We have provided the graphs that  
20      show that -- from the composite have been updated  
21      and I believe they have been sent to the  
22      committee -- that demonstrates that there are



1 differences in the spread of morbidity and  
2 mortality outcomes for these two measures. And  
3 so I do think it is very reasonable to have this  
4 be a separate composite. And it is part of a  
5 group of outcome composite scores, which frankly  
6 are part of, now, the individual surgeon  
7 composite. So we need these mortalities  
8 particularly -- as well as for the hospital-based  
9 composite, which we are in the process of  
10 developing.

11 DR. BADHWAR: And one additional point  
12 to Dr. Paone's is that for isolated aortic valve  
13 replacement, these are often and increasingly  
14 more commonly performed as a minimally invasive  
15 procedure, and not an entire sternotomy, whereas  
16 AVR CABG -- it is -- it necessitates an entire  
17 sternotomy. So there might be some inherent  
18 differences, and hence the reason why these two  
19 measures are independent of each other. They are  
20 obviously parallel, but that should be a stand-  
21 alone measure.

22 MEMBER SIPERSTEIN: But again, with

1 the construct of those -- the procedure, the risk  
2 adjustment, the data collection -- exactly  
3 parallels what we have just been discussing for  
4 the last hour and a half.

5 CO-CHAIR GUNNAR: So do we -- can we  
6 -- do you want us to run through all the votes?  
7 Or does anybody think that they are going to  
8 change? Or would like the opportunity to change  
9 their vote from the previous measure? And is  
10 that -- are we allowed to do that, or not? Can  
11 we -- can we just move to pass or no pass on the  
12 -- or do you want us to run through all of it.

13 MS. MARINELARENA: So you don't have  
14 to vote for evidence because that's a maintenance  
15 measure. We are okay with that. Gap, if there  
16 is any issues with it -- because we do require  
17 that they submit new performance data. Staff did  
18 provide a rating of moderate. You can choose to  
19 accept that. You don't have to vote. Composite  
20 construct as well, you can choose to accept the  
21 rating that staff gave it. You don't have to  
22 vote. Reliability -- there was a rating of the

1 methods panel -- rated it as moderate. You don't  
2 have to vote. Consensus was not reached on this  
3 one as well -- same issues as the other one. We  
4 can carry the vote over and include it in the  
5 discussion. Feasibility -- you have to vote, but  
6 it is the same issue. We can carry it over.  
7 Same for use and usability. And then do a -

8 CO-CHAIR GUNNAR: I guess I am asking,  
9 is it -- it is probably easier just to forge  
10 ahead and run through the voting line. And then  
11 you've got it documented. And then same --  
12 attachment or addendum to this decision as --

13 CO-CHAIR FLEISHER: I will ask it  
14 different. Does anybody want to poll any one  
15 aspect of what was just discussed by Melissa?

16 CO-CHAIR GUNNAR: But she just said we  
17 can't do that.

18 CO-CHAIR FLEISHER: No, she just said  
19 we could.

20 MS. MARINELARENA: You don't have to  
21 vote on every individual -- you can choose to  
22 accept the ratings that we provided.

1 CO-CHAIR GUNNAR: No, I want to accept  
2 the ratings that we -- I -- is there anyone who  
3 would change their vote in any -- can we go and  
4 carry the same votes forward? Not -- not -- not  
5 the -

6 MS. MARINELARENA: I think they are  
7 the same. Yes, they are the same.

8 CO-CHAIR GUNNAR: But -- but you only  
9 have the -- you will actually have the vote count  
10 then.

11 MS. MARINELARENA: Yes, okay.

12 CO-CHAIR GUNNAR: See what I am  
13 saying?

14 MEMBER SIPERSTEIN: Yes, Allan here,  
15 I feel comfortable using the same vote.

16 (Simultaneous speaking.)

17 PARTICIPANT: Agree.

18 CO-CHAIR GUNNAR: Okay, let's just see  
19 if we can run through this. Let's go through the  
20 first -- what do we have to do? Vote first is  
21 what?

22 PARTICIPANT: Thirteen.

1 CO-CHAIR GUNNAR: No, no, no. What's  
2 the first thing we vote on?

3 MS. SKIPPER: The first criteria is  
4 evidence.

5 CO-CHAIR GUNNAR: Okay, would anyone  
6 change their vote on evidence if we take that --  
7 the answer is no. So can we adopt that what we  
8 did for the previous measure -

9 MS. SKIPPER: I just want to make sure  
10 everyone in the room understands what we're --  
11 and it's okay? Okay. I am just looking at -

12 (Simultaneous speaking.)

13 CO-CHAIR GUNNAR: Anyone who has a --  
14 has a -- if there is one vote who is not  
15 comfortable with this, we will go -- start from  
16 the beginning, okay? I don't have a -- all  
17 right.

18 (Simultaneous speaking.)

19 CO-CHAIR GUNNAR: Yes, exactly. Next,  
20 so evidence passed same vote percentage carried  
21 forward. What is next?

22 MS. SKIPPER: Gap.

1 CO-CHAIR GUNNAR: Gap. Anyone  
2 changing their gap vote for this measure versus  
3 the previous one?

4 (No response.)

5 CO-CHAIR GUNNAR: None? Or would like  
6 to take that vote?

7 (No response.)

8 CO-CHAIR GUNNAR: No, hearing none,  
9 next. Adopt that.

10 MS. SKIPPER: Composite construction.

11 CO-CHAIR GUNNAR: Composite  
12 construction. I don't see any -- so we will just  
13 adopt whatever the vote percentage and say --  
14 every -- no one would change their vote. Next?

15 MS. SKIPPER: Reliability.

16 CO-CHAIR GUNNAR: Reliability. Any  
17 new discussion on reliability? Anything  
18 different from what we've --

19 (No response.)

20 CO-CHAIR GUNNAR: Very good. Next?

21 MS. SKIPPER: Validity.

22 CO-CHAIR GUNNAR: Validity.

1 (No response.)

2 CO-CHAIR GUNNAR: Hearing none, move  
3 forward.

4 MS. SKIPPER: The composite. Validity  
5 composite.

6 CO-CHAIR GUNNAR: Oh, yes. It -- same  
7 vote.

8 MS. SKIPPER: There -- you have to  
9 take three separate votes under scientific  
10 acceptability for a composite.

11 CO-CHAIR GUNNAR: Okay.

12 MS. SKIPPER: So now we are looking at  
13 the composite construction.

14 CO-CHAIR GUNNAR: Anyone want to  
15 change their composite construction vote?

16 (No response.)

17 CO-CHAIR GUNNAR: Or would like to re-  
18 vote on it. That's a bad way to put it. Anyone  
19 would like to re-vote on that -- on that measure?

20 (No response.)

21 CO-CHAIR GUNNAR: Okay, next?

22 MS. SKIPPER: Feasibility.

1 CO-CHAIR GUNNAR: Feasibility?

2 (No response.)

3 CO-CHAIR GUNNAR: Hearing none, carry  
4 one.

5 MS. SKIPPER: Use.

6 CO-CHAIR GUNNAR: Use?

7 (No response.)

8 CO-CHAIR GUNNAR: Hearing none.

9 MS. SKIPPER: Usability.

10 CO-CHAIR GUNNAR: Usability?

11 (No response.)

12 CO-CHAIR GUNNAR: And we will -- just  
13 for -- to make all of us better, let's go ahead  
14 and actually vote for whether we would endorse  
15 this. So let's take that vote.

16 (Laughter.)

17 CO-CHAIR GUNNAR: Yes. A.J., that's as  
18 good as it gets. I think we're -- we're -- as  
19 long as -- as long as we can do that, we are  
20 going to see a lot of that today. We are going  
21 to be done pretty -- there is so much redundancy  
22 in what we have to do for -- and we have seen



1       these measures twice over -- we have lived with  
2       these measures now for 12 years, right? All  
3       right. So here we are. I didn't get a -- I  
4       didn't -- it didn't sign me in.

5                       (Simultaneous speaking.)

6               PARTICIPANT: If you could refresh,  
7       that would --

8               CO-CHAIR GUNNAR: Oh, here it goes.  
9       It finally came through. Very good.

10                      (Simultaneous speaking.)

11               MEMBER JARRETT: And while we are  
12       voting I am just going to make an off-hand  
13       comment that anybody who said that they want to  
14       go through everything again would be like  
15       somebody from the old movie 12 Angry Men.

16                      (Laughter.)

17               MEMBER JARRETT: For those of you who  
18       remember it.

19               CO-CHAIR GUNNAR: Actually, did it win  
20       that year -- Academy -- I think it actually won  
21       that year, didn't it? Did 12 Angry Men win Best  
22       Picture for ---

1 (Pause.)

2 (Laughter.)

3 MEMBER JARRETT: It was nominated for  
4 three, but it didn't.

5 CO-CHAIR GUNNAR: It did not, okay.  
6 There you go. Please -- it's been a couple years  
7 since I saw it.

8 MS. KOSURI: We are still waiting for  
9 two more votes.

10 CO-CHAIR GUNNAR: We need a couple  
11 more votes.

12 PARTICIPANT: Are we taking a lunch  
13 break?

14 CO-CHAIR GUNNAR: No, no we are going  
15 to keep -- we are going to -- lunch is going to  
16 be very brief, okay?

17 PARTICIPANT: Well, it is a working  
18 lunch.

19 CO-CHAIR GUNNAR: All right, we've got  
20 14 votes. Very good. It passes and we can move  
21 -- do -- do you want a quick break?

22 MS. KOSURI: We are just going to read

1 the votes off for one second. So for measure  
2 2563, the committee has voted to pass this  
3 measure for overall suitability for endorsement  
4 with 14 votes out of a total of 14 votes.

5 CO-CHAIR GUNNAR: Go ahead.

6 CO-CHAIR FLEISHER: So we are going to  
7 -- what we thought is, we would take a break till  
8 12 -- or a little -- and bring -- five after 12?  
9 Take like a 20-minute break? Twenty-five minute  
10 break? Let's just -- we can do 12, okay. Amy,  
11 you were getting me concerned. We are going to  
12 take a break till 12 to bring our lunch back,  
13 stretch and we can have a working lunch so that  
14 we can keep moving, since this is the committee  
15 of surgeons and anesthesiologists. Sorry for the  
16 non-surgeons and anesthesiologists. We are used  
17 to this.

18 (Whereupon, the above-entitled matter  
19 went off the record at 11:43 a.m. and resumed at  
20 12:05 p.m.)

21 CO-CHAIR FLEISHER: So we are  
22 rejoining the discussion and we are going to skip

1 a couple of measures because of the availability  
2 of someone to lead the discussion, correct,  
3 Christy? So do you want to tell us what's going  
4 on and keep us on track?

5 MS. SKIPPER: Okay, so we've moved the  
6 discussion of 0122. There is a discussant who  
7 has to step away for a surgery, so we'd like to  
8 discuss this measure. Also we'll have quorum, so  
9 it just made sense to go ahead and move it around  
10 and discuss this measure, so thank you all for  
11 your flexibility.

12 And I think Dr. Handy, I don't know if  
13 you can come back to the line, but you, Dr.  
14 Yates, and Dr. Scali are discussants for 0122.

15 MEMBER YATES: Are we waiting for Dr.  
16 Handy?

17 MS. SKIPPER: But if one of you could  
18 go ahead and start, and he'll chime in?

19 MEMBER YATES: Well, how about before  
20 we start, should we let the developers present  
21 it? Isn't that usually what we do, or is it  
22 because it's for re-endorsement and we're going

1 to just press ahead?

2 MS. SKIPPER: That is usually what we  
3 do. Thank you. So Mark and team, could you tell  
4 us about 0122?

5 MR. ANTMAN: So I'm happy to introduce  
6 this measure briefly. Again, 0122 is the risk-  
7 adjusted operative mortality for mitral valve  
8 replacement plus CABG.

9 This is the operative mortality  
10 measure that constitutes the mortality domain for  
11 the mitral plus CABG composite, which is that  
12 mitral plus CABG composite is NQF endorsed and it  
13 is publicly reported.

14 I'll note that just skipping ahead a  
15 bit, this committee will also be looking at 01,  
16 sorry, 1501, I'm sorry again, 1502, which is the  
17 operative mortality for MV repair plus CABG.

18 The MV replacement and the MV repair  
19 components are actually combined in the mortality  
20 domain of the mitral valve and CABG surgery  
21 composite, hence our reference to that composite  
22 as the MVRR composite, so just to explain why

1 mitral valve replacements and mitral valve repair  
2 are separated out.

3 I'll defer to my surgeons if they want  
4 to add anything further. Okay, thank you.

5 MS. SKIPPER: All right, so if there's  
6 nothing else to add, then our lead discussants,  
7 Dr. Handy, Dr. Yates, Dr. Scali, you can start  
8 with the measure discussion.

9 MEMBER SCALI: Yeah, I'm happy to take  
10 us through it. So thank you for that  
11 introduction. Just to clarify, the level of  
12 analysis for this measure is clinician groups and  
13 facilities. This is a maintenance evaluation.  
14 It was originally endorsed in 2007, re-endorsed  
15 in 2015.

16 The review of evidence was not  
17 required. However, the developer did provide  
18 ample references from the literature that  
19 documents that this particular procedure has one  
20 of the highest known mortality rates for all  
21 surgical procedures.

22 There was a question for the committee

1 to consider in the pre-work up by the reviewing  
2 group from NQF. The question for the committee  
3 is, "Is there at least one thing that the  
4 provider can do to achieve a change in the  
5 measure of results?"

6 And I think that sort of goes to the  
7 fact that as they're getting feedback on these  
8 measures quarterly, and so I think that they can  
9 obviously act on these results to sort of improve  
10 patient restratification and patient selection,  
11 and certainly the patient counseling.

12 And the second question to the  
13 committee was, "If derived from a patient report,  
14 does the target population value the measured  
15 outcome and is it meaningful?" and I think the  
16 answer to that is yes given the fact that it's  
17 looking at mortality.

18 So I don't know if there's anything  
19 else that you wanted to add, A.J., in terms of  
20 evidence?

21 MEMBER YATES: I have little to add.  
22 One of the comments was that someone had

1 mentioned the fact that it presents small numbers  
2 making it harder to detect real differences in  
3 performance.

4           However, the mortality of the rate  
5 gives it gravitas enough for the work group, the  
6 people who were doing this basically a  
7 recommendation, endorsement.

8           MS. SKIPPER: And I believe Dr. Handy  
9 joined the line. Is there anything you'd like to  
10 add, Dr. Handy, to evidence, or share of the  
11 evidence for this measure?

12           MEMBER HANDY: I just logged on, so I  
13 don't know what A.J. said, but I'm assuming you  
14 guys are cooking through these things here since  
15 my schedule had that this was to be talked about  
16 around 10:00 my time here, so you guys must have  
17 considerably abbreviated the discussion a la some  
18 of the preamble. Is that true?

19           MEMBER YATES: You have no idea.

20           MEMBER HANDY: Good, I'm not against  
21 it.

22           MEMBER YATES: I move to vote.



1 MS. SKIPPER: All right, did I miss  
2 someone? Okay, we're now voting on evidence for  
3 measure 0122.

4 MS. KOSURI: Voting is now open for  
5 0122.

6 MS. SKIPPER: And we see that we have  
7 100 percent votes. We just want to read the  
8 number for the record if we can, so just bear  
9 with us for a second.

10 And so I suppose while we figure that  
11 out, if we could move onto discussion of gap.

12 MEMBER SCALI: So pertaining to gap,  
13 the developer did provide comparative data from  
14 the STS database between two different reporting  
15 time periods of 2011 and 2014 compared to 2014  
16 and 2017.

17 They describe the odds ratio greater  
18 than one being undesirable and that it implied  
19 participant increases of patient risk for  
20 experiencing the outcome if they have a value  
21 greater than one. There was a value of eight to  
22 13 percent on average with a median of 9.1

1 percent in the era of 2011 and 2014.

2 This was relatively static in the era  
3 of 2014 and 2017 still demonstrating that there  
4 is evidence for improvement and there is  
5 variation in the outcome, and I think the  
6 committee had given a moderate gap rating, which  
7 I think was appropriate.

8 MEMBER YATES: Nothing to add.

9 MEMBER HANDY: I agree. That second  
10 to last comment is mine. The mortality  
11 disparities also were evident across sex, age,  
12 and race/ethnicity.

13 MS. KOSURI: We're just going to  
14 announce the evidence, but for one second. So  
15 with 14 votes, out of a total of 14 votes, the  
16 evidence criteria has passed for measure 0122.

17 MS. SKIPPER: And now we'll take a  
18 vote on gap in just a moment for 0122.

19 MS. KOSURI: Voting is now open for  
20 measure 0122 for performance gap. Okay, with a  
21 total of 14 votes, we have four votes for high  
22 and, oh, 15 votes now. We have four votes for

1 high and 11 votes for moderate for the  
2 performance gap criteria for measure 0122, and so  
3 it has passed.

4 CO-CHAIR FLEISHER: I think we're  
5 going onto reliability next. So for reliability,  
6 the score is the rate or proportion of cases that  
7 are meeting the criteria of the specifications  
8 and numerator statement.

9 The numerator statement is the number  
10 of patients age 18 years or older undergoing  
11 combined mitral valve replacement and CABG who  
12 die, including both all deaths occurring during  
13 the hospitalization in which the operation is  
14 performed or even after 30 days, and then two,  
15 deaths that occur after discharge from the  
16 hospital, but within 30 days of the procedure.

17 The denominator statement is all  
18 patients undergoing CABG MVR. The exclusions are  
19 none. The data source is a registry, the STS  
20 registry.

21 The question that was posed to the  
22 committee was, "Do we have any concerns about

1 whether the measure can be consistently  
2 implemented?" Personally, I do not. It's  
3 already being used and it's already being  
4 implemented at centers for quality improvement.

5 Relative to the reliability testing,  
6 this was a maintenance measure, so less emphasis  
7 was on this, but there is no score level testing  
8 that was done, so the highest achievable rating  
9 was moderate.

10 This is a mortality end point, so  
11 certainly it's a highly repeatable outcome  
12 measure. It's very clear and very unambiguous.

13 The developer provides agreement rates  
14 from a 2014 audit of 108 STS adult cardiac  
15 surgery participants and demonstrated an overall  
16 agreement of 95.73 percent.

17 Again, the level of analysis was there  
18 were two potential levels and there was a  
19 question about clarification from the developers  
20 about clinician group versus facility.

21 This was a question that was brought  
22 up in the morning discussions about how the

1       overwhelming majority of centers are now at the  
2       facility level because those are the people who  
3       are in the STS database. It's really the  
4       minority of clinician groups that are  
5       participating. It's really at the center level.

6               And then the panel's recommendation  
7       was moderate reliability, which again seemed  
8       prudent given the caveats already given.

9               MEMBER YATES: Again, it's a measure  
10       that's known to us and we've seen before, and for  
11       re-endorsement, I don't see any major challenges  
12       to the reliability or validity, and I will defer.  
13       I would argue that the debate we had previously  
14       on STS should hold for this as well and not be  
15       reopened.

16              CO-CHAIR GUNNAR: So I have a question  
17       though. Have you examined the 31-day, you know,  
18       this concept that you have somebody alive until  
19       day 30, but only to discharge them from the  
20       hospital and get them home to beat the metric?

21              Have you examined post-30 days and  
22       post -- particularly if somebody has now lingered

1 in the hospital because your definition isn't  
2 just 30 days. If they stayed 45 days and then  
3 died, you're still counting them. So the  
4 question is are they discharged? Is there  
5 evidence that you discharge people past 30 days?

6 DR. BADHWAR: So if I can just  
7 interpret your question, I think the clarity is  
8 that the measure is 30 days or in hospital. So  
9 if a patient is there for three months and they  
10 die in hospital, that still counted.

11 PARTICIPANT: Correct.

12 CO-CHAIR GUNNAR: But are you finding  
13 evidence that people, to game it, then discharge  
14 somebody off the acute care ward to beat the  
15 mortality? Do you have any evidence? Have you  
16 ever looked at that?

17 PARTICIPANT: We don't have evidence  
18 that further clarifies that type of gaming if  
19 that was to occur, at least in these measures.  
20 If you're asking in general across the board,  
21 that's a more detailed question, but at least in  
22 this special, we don't have that information.

1                   MEMBER JARRETT: Yeah, this is Mark  
2                   Jarrett. I had a question and on my measure,  
3                   it's the same issue on mortality, that it's not  
4                   even trying to gain the system, but the reality  
5                   is the patient may spend two months in the  
6                   hospital.

7                   They're really a train wreck. They're  
8                   not getting better and it's decided to move them  
9                   to, you know, a nursing home, and, you know, and  
10                  they succumb two weeks later, but now it's more  
11                  than 30 days after the surgery and it's right  
12                  after their discharge from, you know, and they've  
13                  already been discharged from the hospital, but  
14                  clearly their death is related to their  
15                  complications following the surgery, and that's a  
16                  reality that can really happen. So it's not a  
17                  matter of gaming. It's just missing mortalities.

18                 DR. PAONE: I don't know if we have a  
19                 way of capturing that information specifically.  
20                 I think we have in the past looked at the number  
21                 of deaths and the reliability of in hospital 30-  
22                 day mortalities versus the percentage of

1 patients, of data sets that had increasing  
2 numbers that were not reported for the out of  
3 hospital deaths.

4 This is an issue for certain for every  
5 single mortality measure, the possibility of, as  
6 you say, either gaming or just the natural  
7 history of some very sick patients, particularly  
8 with these LTACs where patients get transferred,  
9 as you say, 40 days, 50 days, 60 days to a  
10 facility and then die a week or two later.

11 I would suspect, and I think we've  
12 looked at this, that the number of patients that  
13 fall into that category is quite small, so even  
14 if we're not capturing them, I don't think it  
15 changes the outcomes to any specific degree,  
16 although it's an ongoing problem and it's an  
17 important issue to pay attention to, and there is  
18 the need to follow up to 30 days post-discharge,  
19 and so that would capture some of those that  
20 don't have that information.

21 Now, you need to have 98 percent  
22 capture on that metric in order to be able to



1 receive a star rating, so there's been some  
2 significant improvement in how many of those are  
3 captured.

4 MEMBER YATES: It wouldn't answer the  
5 question directly, but as a surrogate, do you  
6 keep track in the registry as to discharge  
7 disposition?

8 DR. PAONE: The answer is yes. There  
9 is a category in the database for where the  
10 patients are discharged.

11 MEMBER YATES: Because you would then  
12 be able to assess the risk of loss information by  
13 looking at discharge after 30 days to a skilled  
14 nursing facility or hospice as opposed to home,  
15 and if that occurs only one percent of the time,  
16 then the data, the bleed out on the data wouldn't  
17 be that much.

18 MEMBER JARRETT: Well, this is Mark.  
19 I agree with that, but I'm still concerned  
20 because even though the numbers are small, the  
21 numerators for especially some of the mortality  
22 statistics on some of the other measures are also

1       small.

2                       So adding one or two to a given  
3       facility or a given group might really truly  
4       impact their standing. So I'm just saying I  
5       think that's something you need to look at going  
6       forward.

7                       DR. BADHWAR: So this is a very  
8       important constructive comment. A couple of  
9       things just as a broad issue, as Guy just  
10      mentioned, we're really trying to police the  
11      mortality variable at 30 days for all participant  
12      sites to make sure that they have contributed  
13      that, and almost making the record incomplete in  
14      some of the measures if they don't provide a  
15      mortality number such as missing this.

16                      The second thing, and this is not  
17      particularly relevant to this right now, but  
18      we're in the process of looking at NDI through a  
19      research mechanism and mapping that as part of a  
20      research enterprise to see if we can use that to  
21      validate 30-day outcome to make sure that it's  
22      accurate.

1                   MEMBER GROVER: Let me just say at one  
2 point we were hoping to use the Social Security,  
3 and an attorney in the Social Security is dealing  
4 with another issue not related to any specialty  
5 or trying to get data has blocked that, and that  
6 way we could have 100 percent. I mean, if you  
7 wanted to, you could have a 60-day and six months  
8 even to verify it.

9                   So if there's anything that, I can get  
10 you more details on that, or if there's anything  
11 NQF could do as a group to lobby to reverse that  
12 decision, that would be very helpful because  
13 that's really stupid and it's hurting, I think,  
14 every database in terms of seeing how the  
15 outcomes are.

16                  DR. PAONE: Perhaps unrelated to this,  
17 but I think we all recognize the growing need  
18 for, you know, value in our outcomes, and so  
19 there's a lot of work going on now in trying to  
20 figure out how to do one year outcome not just  
21 30-day outcomes, and that question goes back to  
22 the Social Security Death Index and access to it,

1 so.

2 CO-CHAIR FLEISHER: Right, so I  
3 actually want to commend STS because we had a  
4 debate several years ago and our concern about  
5 the CMS mortality measure was that it was not in  
6 hospital plus, and for those who were here, we  
7 actually preferred this over the CMS, that we  
8 need Bill's paper and continue to do that  
9 research, but I acknowledge without that Social  
10 Security link, that makes it difficult, so I want  
11 to say thank you.

12 If you get that data, it's great, but  
13 it may be worth scanning the literature,  
14 including my colleagues' papers, to put it into  
15 the data given that you're not linked to any kind  
16 of death registry.

17 MEMBER JARRETT: This is Mark. Just  
18 on the issue, just for everybody's information on  
19 death registries, we've been looking at it for  
20 our own mortality around CMS stars and everything  
21 else.

22 Unfortunately, it turns out, New York

1 state has not been reporting for over three-and-  
2 a-half years to the Social Security  
3 Administration their deaths.

4 Now, how Social Security knows how to  
5 stop the checks, don't ask me, but they do not  
6 report it officially into Social Security, and I  
7 don't know if any other states do the same thing.

8 MEMBER DUTTON: I just wanted to throw  
9 out, Fred, this would a great issue for the NQF  
10 to take on because everybody would benefit from  
11 it. I've tried to get Social Security master  
12 death file information as well, and it exists for  
13 credit card companies, not for science.

14 CO-CHAIR GUNNAR: Any further  
15 discussion? If not, we can --

16 MS. MARINELARENA: Before you vote,  
17 because the question was asked through multiple,  
18 on all of the measures and it was posed to the  
19 Methods Panel, does the committee have any issues  
20 with the fact that the measure is specified at  
21 two different levels of analysis?

22 I know that STS provides an

1 explanation of why, because of, you know, most  
2 surgeons are in the hospital. Is that sufficient  
3 for you? And in the future, we can ask them to,  
4 you know, clarify that up front, or do you  
5 recommend in the future, do you think that they  
6 need to provide an analysis at the hospital  
7 level?

8 CO-CHAIR FLEISHER: Fred, this may be  
9 actually the time to talk about the influence of  
10 the hospital CEOs that you were discussing  
11 because I think reporting at the hospital level  
12 probably has the most profound effect on  
13 improvement, correct?

14 MEMBER GROVER: Is this on? Yeah,  
15 they're kind of two different issues, but when we  
16 originally set up the STS database back in 1989,  
17 it was -- and it's different from the ACC because  
18 the ACC is with the hospital or the institution.  
19 We made it for our members.

20 And at that time, there were a fair  
21 number of hospitals that had more than one group  
22 of cardiothoracic surgeons operating in them,

1 mostly obviously in the private area, not the  
2 university area, but, so for that reason, we made  
3 it group specific, so it goes to the surgeon.

4 Now, the hospitals see the data.  
5 They're all shared because they're obviously  
6 picking up at this point the cost of the data  
7 manager, so it's all shared now, but that's how  
8 we got on that.

9 But in practicality, I'm not sure what  
10 percent of, how many hospitals now have more than  
11 one group. That would be something we could try  
12 to figure out.

13 I don't know that I -- I think it's  
14 probably so small that it's probably immaterial.  
15 I mean, it's probably not worth fretting over at  
16 this point. There are bigger issues to take care  
17 of, I think.

18 DR. SHAHIAN: I think this is largely  
19 a semantic issue, Dr. Fleisher. It's a surgical  
20 group, and in some cases, the surgical group is  
21 organized within a hospital. In some instances,  
22 it may be a private group in multiple hospitals,

1 but it would probably help all of you if we were  
2 simply to say, "This is a measure designed for a  
3 surgical group."

4 And I think in terms of testing, it  
5 doesn't make, frankly, it shouldn't make any  
6 difference whether that surgical group happens to  
7 be organized within a hospital or a private  
8 practice group working in multiple hospitals. We  
9 get all of their cases, and that's the critical  
10 issue.

11 MEMBER YATES: Just to follow up on  
12 that for clarity, earlier we heard that it's  
13 possible for MIPS reporting for several of the  
14 measures. Do you capture the surgeons' MPI  
15 and/or their 10?

16 DR. SHAHIAN: Yes.

17 MEMBER YATES: All right, well, if  
18 they have the MPI and 10, then the 10 would give  
19 you an idea as to what groups are which within  
20 the institution and across institutions if they  
21 go to more than one hospital.

22 DR. SHAHIAN: And if our composite



1 report, if you go to our website, you'll see that  
2 even if a group is reporting as a, and Mark can  
3 correct me on this, but even if you're reporting  
4 in one or the other of those two methods that I  
5 just indicated, you have the option of actually  
6 getting --

7 We've actually gone through that  
8 exercise of taking multiple groups and combining  
9 them at the hospital level for the purposes of  
10 reporting, so we give you the option both ways.

11 DR. PAONE: If I could just sort of  
12 try a real world quickly here, I'm from Michigan.  
13 I participate in the Michigan Society of Thoracic  
14 and Cardiovascular Surgery, which is a quality  
15 collaborative of 33, all 33 hospitals, all 33  
16 public, non-federal hospitals that do cardiac  
17 surgery in the state of Michigan.

18 And two examples, there's one hospital  
19 that has two separate groups operating in it  
20 still, and they report as one hospital, and then  
21 there are several hospitals, there are two  
22 surgical groups that operate at several different

1 hospitals and their results get reported to the  
2 state collaborative per hospital, not for the  
3 surgical group.

4 Now, I suspect there may be  
5 circumstances still, although very few, where a  
6 surgical group may operate at three or four  
7 hospitals and collate all of that into one group.  
8 I don't know that for certain, but I would, as  
9 Dr. Badhwar said earlier, I think that would be  
10 decidedly unusual at this point.

11 CO-CHAIR FLEISHER: I'd actually be  
12 curious, both Elizabeth and your comment, and to  
13 mine and yours, from a patient perspective, and  
14 I'm not talking about today, but from a patient  
15 perspective, do they want to know is that group  
16 going to that hospital, how you make a decision  
17 getting back to the focus group that was  
18 previously suggested, or is it you go to the  
19 surgeon and you don't care which hospital they  
20 take you to?

21 So, you know, I know that's a -- your  
22 database was set up for one reason. We're now

1 asking for public reporting. So any thoughts on  
2 -- because it's not testing in the way I think  
3 people are asking, which is which hospital should  
4 I go to and surgical group?

5 MEMBER EATMON: From a patient's  
6 perspective, I know when I was looking for my  
7 surgeon actually in Atlanta, I chose a particular  
8 doctor, but did not realize that I had a breast  
9 surgeon and a reconstruction surgeon, and one  
10 surgeon could operate in one hospital group and  
11 then other surgeon didn't have the credentials to  
12 operate in the same one.

13 So then at that point, from a  
14 patient's perspective, who do you drop off? Who  
15 do you need the most? But overall, it's about  
16 accessibility.

17 If you don't have the accessibility to  
18 make that decision, which I found through a lot  
19 of other groups that most people don't have that  
20 accessibility, and then when you start talking  
21 about people that are not from metropolitan  
22 Atlanta that are in rural Georgia, that

1 accessibility goes even further down.

2 And just like I spoke about, we're  
3 going on getting research. We just want the  
4 doctor, but then when we find out that they may  
5 not be part of that group, that has a different  
6 effect on us.

7 And it kind of brings on some other  
8 stressors and things of that nature because you  
9 think you're going to this one group that's in  
10 the hospital with your example where there could  
11 be two separate groups, but when you get there,  
12 they're like, "Oh, on Wednesdays, only group B  
13 operates," and you need the surgery.

14 So it is imperative or important  
15 rather, from a patient's perspective, and  
16 accessibility is definitely key with some of  
17 those decisions that we make.

18 MEMBER MOYER: I would just throw out  
19 there we had a centers of excellence program  
20 around CABG, and the discussions that we had with  
21 our membership and with patients was they're  
22 really interested in a surgeon at a hospital

1 together.

2 Because they kind of felt like, "Well,  
3 I don't know what I should look for in a hospital  
4 or what I should look for over here, but I want  
5 the whole group working together and I want to  
6 know how they do together."

7 And for a lot of our groups, it is one  
8 group at one hospital, but I think we've got a  
9 fair amount of hospitals where someone, say, from  
10 an academic medical center comes in every once in  
11 a while, and I think that's a little different  
12 situation than that surgeon operating in their  
13 home academic institution.

14 CO-CHAIR FLEISHER: So can I make a  
15 suggestion independent of the vote that you may  
16 want to test it at the hospital level for any  
17 future --

18 Correct, it's not tested at the  
19 hospital level as was suggested, but it would be  
20 great for any kind of maintenance or certainly  
21 for the update to see the data that essentially,  
22 Amy, you're asking for. Are people in agreement

1 with that for --

2 DR. BADHWAR: Perhaps it's a comment  
3 to those questions raised. Obviously for cardiac  
4 surgery, it's a team sport and that's the whole  
5 principle behind that as opposed to gall bladder  
6 operations and things like that may not  
7 necessarily rely on critical care and nursing in  
8 a more robust way, and so that's the basis of all  
9 of our models.

10 And so just from a restoring faith in  
11 the process from a patient perspective, we as a  
12 society truly feel that it's yes, obviously the  
13 surgeon is of great importance, but so is the  
14 entire team, and that really drives almost all of  
15 our models and the principles in which we base  
16 them as a concept. I just wanted to get that out  
17 there from a patient advocacy perspective.

18 MEMBER GROVER: There are some old  
19 articles, I don't know whether they still apply,  
20 from the Northern New England Group back in the  
21 late '80s and early '90s where they found that, I  
22 think it was a small number, but some surgeons

1 got better results when they operated at one  
2 hospital as compared to another hospital.

3 And I don't know whether that's still  
4 true because there's not that many that do it  
5 now, but that is an interesting question because  
6 just as you said, it's a heart team. It's your  
7 anesthesiologist, your perfusionist, and the  
8 whole bit unless you carry them with you, unless  
9 you take them all with you to these hospitals,  
10 which would be awfully expensive for a practice  
11 in this day and age.

12 MS. MARINELARENA: So just a better  
13 clarification, from the NQF process perspective,  
14 the measure has to be the specifications and the  
15 testing have to match.

16 If the measure is endorsed in the way  
17 that it looks now, it would look like it's  
18 endorsed at the facility level and at the  
19 clinician level, so the public thinks that this  
20 measure, or will interpret it that it is endorsed  
21 at the facility level.

22 It is not because it's not tested at

1 the facility level. We can take that off and  
2 then it's implemented. The way it's used, it  
3 could be used -- you know, you could say it's  
4 reported this way, you know, and the explanation  
5 that STS has provided, how it's used with  
6 surgical groups is fine, but it cannot be  
7 specified at the facility level until it is  
8 tested, and, you know, we've captured that  
9 recommendation, and STS can, you know, look into  
10 that if they'd like.

11 MEMBER YATES: I move that we vote.

12 CO-CHAIR FLEISHER: Any further  
13 discussion?

14 MS. KOSURI: Voting is now open for  
15 measure 0122. Okay, voting is now closed for  
16 measure 0122 for the reliability portion of the  
17 measure criteria where 13 people voted moderate  
18 and two people voted high. This means that 87  
19 percent have passed the vote. With 87 percent,  
20 the vote has passed. I apologize.

21 CO-CHAIR GUNNAR: So validity next?

22 MEMBER SCALI: So with respect to



1 validity, I echo Dr. Yates' commentary about the  
2 validity discussion and some of the  
3 sociodemographic factors that are implicated in  
4 these models just like they were in the previous  
5 things that we did this morning, so I think we've  
6 had that discussion.

7 Nonetheless, there was new face  
8 validity and empirical validity testing of the  
9 measure that was performed by the developers.  
10 However, the Methods Panel expressed concerns  
11 about the face validity testing that was  
12 submitted since it did not meet NQF criteria. So  
13 I don't know if there's any additional comment  
14 about that.

15 MEMBER YATES: My only comment is that  
16 we have endorsed this before with the same  
17 questions and I don't see any reason to not  
18 endorse it this time or at least vote for this  
19 being acceptable.

20 CO-CHAIR GUNNAR: Voting is open.

21 MS. KOSURI: Voting is open. Voting  
22 is now closed with a total of 15 votes. Thirteen

1 people have voted moderate and two people have  
2 voted high for the validity portion of the  
3 measure criteria for measure 0122. This is 100  
4 percent who have passed the vote.

5 MEMBER SCALI: Does that mean  
6 feasibility is next?

7 MS. KOSURI: Yes.

8 MEMBER SCALI: The data elements are  
9 routinely generated and collected by the  
10 healthcare team. The measure has already -- it's  
11 a maintenance measure. The data abstraction is  
12 done by a provider other than the person who gets  
13 the original information. Most if not all of the  
14 variables are available in the electronic health  
15 record.

16 There are moderate costs associated  
17 which we've all been aware of in the past, and  
18 again, the data collection is already in use, so  
19 I believe it's highly feasible because it's  
20 already happening.

21 CO-CHAIR GUNNAR: So my only comment  
22 is I know in the interim, since 2014, you've

1 added like a considerable number of data fields,  
2 particularly for the mitral valve, right? Is  
3 that correct?

4 Yeah, and so the question, are you  
5 getting any feedback from the poor individual who  
6 has got to put all of that information in because  
7 it's now pages, particularly for the mitral  
8 valve?

9 DR. BADHWAR: It's actually mitral  
10 valve and aortic valve. There are multiple  
11 fields that were added initially for research  
12 purposes, but I'll just give you an example  
13 within the details of the field.

14 It really surrounds around anterior  
15 leaflet and posterior leaflet repair, and for the  
16 field, I know Dr. Gunnar knows this and Dr.  
17 Grover, but there's substantial evidence to note  
18 the level of complexity when the repair involves  
19 both leaflets versus just one leaflet, that the  
20 outcomes are fair to be worse, either longer  
21 operative times --

22 CO-CHAIR GUNNAR: I guess I'm not

1 asking specifically about, you know, justifying  
2 why you did it. It's really about the, in a  
3 feasibility perspective, it's gotten to the point  
4 where any time studies on what it takes to  
5 actually complete one of these records now,  
6 because they're, I forget the number of pages and  
7 the number of fields. It's pretty stunning.

8 DR. BADHWAR: Yeah, there's about 400  
9 data elements, and so it does take several hours  
10 for one data manager to enter the fields. So we  
11 have received feedback, frankly, and your  
12 impression is correct.

13 However, we do have fairly good  
14 adoption of those fields, particularly those that  
15 are doing these types of operations.

16 MEMBER STEIN: I have a follow-up  
17 question. When some of the sites are entering  
18 this information, I understand the electronic  
19 health record, some as a hybrid and some  
20 manually, is that correct?

21 DR. PAONE: The desire certainly is at  
22 some point going forward is to be able to

1 directly download as much information as possible  
2 from the electronic health record into the  
3 database. I think that's obvious as to why that  
4 would be.

5 Some data elements obviously lend  
6 themselves more to that than others, and we had  
7 this conversation on a conference call about a  
8 week-and-a-half or two weeks ago talking about  
9 the future of AI and the ability to intelligently  
10 read the reports and even download most of the  
11 information.

12 I suspect that's true to whatever  
13 extent various institutions use the health  
14 records that they have and the ability to  
15 transfer that information, so I don't know the  
16 specifics of that and I don't know if any of my  
17 colleagues do as to what percentage of centers  
18 are doing that.

19 Right now, what's most likely to be  
20 able to be downloaded from the electronic health  
21 record are sort of the easy things, which helps a  
22 little bit, but not a lot.

1                   In reference to the question about  
2           increasing the number of data points in the  
3           recent spec upgrade of the database, the extra  
4           work is case specific. If you're doing a  
5           coronary bypass operation, there hasn't been much  
6           change in what's been added or subtracted.

7                   On the other hand, the issues that are  
8           more technical related to aortic surgery, aortic  
9           valve surgeries, atrial fibrillation and maze  
10          procedures, and complex mitral valve repairs, and  
11          truthfully, the extent to which that causes more  
12          or less work is really specific to the  
13          institution depending upon the relationship  
14          between the data manager and the surgeon, how  
15          much data the surgeon enters directly into the  
16          worksheet and how much time the data manager may  
17          have to spend looking through the record or  
18          tracking down the surgeon.

19                   So it's quite variable. It's an issue  
20          that we're well aware of and paying great  
21          attention to in trying to simplify the data  
22          requests going forward and also automate as much

1 as possible, but the truth is that's a little bit  
2 a ways yet before it becomes, I think, done in a  
3 manner that will actually make a difference.

4 MEMBER STEIN: So one of the other  
5 measures that I was reviewing, it said that some  
6 were, the data was coming in through EMR, some as  
7 a hybrid, and some manual, and I guess my  
8 suggestion would be that you may want to put in  
9 your risk adjustment model how the data is being  
10 entered because that may impact performance or  
11 proposed performance.

12 MEMBER YATES: As someone who is  
13 really concerned about data collection within my  
14 own institution and who values registry data far  
15 more than administrative data sets, a lot of it  
16 has to do with how you set up the data fields in  
17 your EMR.

18 You can have EMRs that contribute  
19 nothing to the STS or you can have EMRs that as  
20 things are entered from the outpatient arena or  
21 the inpatient arena, then automatically go into  
22 the STS database because it's been set up the

1 right way.

2           So a lot of that is going to be  
3 variable, but it doesn't mean that the data is  
4 not legitimate because it was hand entered, if  
5 you will, or physically entered at the point of  
6 contact, but those were many, many points of  
7 contact rather than somebody retrospectively  
8 trying to capture that.

9           The fact of the matter is that this is  
10 a tiered problem, and tautologically speaking, it  
11 is what it is because it happens, so it must be  
12 feasible because all of these hospitals are  
13 replying, but there's going to be, you know,  
14 there's going to be plateaus that you're going to  
15 reach, and right now having one person who is  
16 totally dedicated to making sure that your  
17 hospital's database is up to date for STS, that's  
18 one FTE that you're paying for.

19           If they were to double the amount of  
20 data that has to be collected, you're then  
21 hitting a different plateau, and so far, I don't  
22 think they've hit the second level of plateau and



1 they're fully utilizing the person that's already  
2 been assigned to make it happen.

3 So I would argue that we could argue  
4 about the fact that yeah, it's expensive to be in  
5 it, but the benefits from it have obviously been  
6 costed out by the hospital and they've decided  
7 that it's worth doing.

8 MEMBER STEIN: I think my concern is  
9 that the ones getting three stars, it's because  
10 they're entering the data in a certain way versus  
11 the two stars that are using some other approach,  
12 and that's why I'm suggesting to at least explore  
13 it, if not adjust for it.

14 MEMBER YATES: Well, that's why they  
15 have the 10 percent audit.

16 DR. BADHWAR: Yeah, I was just going  
17 to mention I think the discussion is interesting,  
18 of course, but however, we have a fairly robust  
19 audit process, and if the issue is going to be is  
20 the data accurate, there is a 10 percent audit  
21 process, and the outcome of that is in the 98th  
22 to 99th percent accurate in general.

1 CO-CHAIR GUNNAR: So let's hold that  
2 for validity. Let's vote on feasibility and  
3 carry forward, right, because we're still on  
4 feasibility, right?

5 MS. SKIPPER: We're on feasibility and  
6 we already voted on validity.

7 CO-CHAIR GUNNAR: Yes, sorry.

8 MS. SKIPPER: So, yeah, you're correct  
9 we're on feasibility.

10 CO-CHAIR GUNNAR: So we already voted  
11 on validity, so we can bring it up next time when  
12 we want to talk about validity again on the next  
13 measure 12 more times. Let's get to feasibility.  
14 Any other discussion on feasibility? And if not,  
15 then let's vote.

16 MS. KOSURI: Voting is now open for  
17 feasibility for measure 0122.

18 MEMBER STEIN: While we're voting, I  
19 just want to follow up. It's not a matter of  
20 accuracy. That's not the concern that I'm  
21 having. It's the ability to capture everything  
22 at granular detail of someone manually entering

1 in these in the EMR, entering it in, and whether  
2 that might be affecting the parameters.

3 MS. MARINELARENA: Use your mics,  
4 please.

5 DR. BADHWAR: Thank you. So honestly,  
6 personally, I hear you completely. You know, I  
7 think you raise a very important point. This is  
8 something that the data managers sweat about on a  
9 daily basis and communicate to us.

10 The real issue is the precision of the  
11 data collection is what you're commenting on, so  
12 I totally respect what you're saying.

13 In fact, STS as a whole is actually  
14 undergoing a full review right now of our data  
15 warehouse mechanisms and how can we make the user  
16 experience better, and this gets to Dr. Gunnar's  
17 point of the large number of variables and how we  
18 refine the process.

19 So, yes, some vendors are actually  
20 extracting data from the EMRs and supplementing  
21 it. However, some do not use that process. We  
22 hope to evolve the database much like this whole

1 discussion all day today as how are we evolving  
2 to make it more precise, and more accurate, and  
3 better for the user experience.

4 And we're actually working on that  
5 very diligently and actively now, including  
6 looking at the whole technological experience of  
7 data precision. So your point is very well taken  
8 and actually being addressed.

9 MS. KOSURI: Voting is now closed for  
10 the feasibility portion of the measure criteria  
11 for measure 0122. We had a total of 15 votes  
12 where 11 people voted moderate and four  
13 individuals voted high, which means that the  
14 committee has passed this portion of the  
15 criteria.

16 CO-CHAIR GUNNAR: We'll move onto use.

17 MEMBER SCALI: So with respect to use,  
18 there was some information that was provided by  
19 the developers about improvement over time. They  
20 developed reports on operative mortality rates.  
21 They were saying that they were trending slightly  
22 lower. The overall event rates in the last three

1 12-month periods were 9.9, 9.3 and then 9.45  
2 percent.

3 They did not address potential  
4 unintended consequences such as sicker or higher  
5 risk patients being potentially shifted to other  
6 institutions, but did state that the benefits of  
7 tracking the measure outweigh the theoretical  
8 risk.

9 And then with respect to the  
10 usability, again, we hit the same snag we  
11 discussed this morning about the public reporting  
12 caveat. Technically in the write up, obviously  
13 the public accountability program was thought to  
14 be unclear, but public reporting is planned as of  
15 January '19 for the developer.

16 With regard to feedback, all of the  
17 end users get reports quarterly and they can  
18 provide assistance with interpretation, and users  
19 give feedback to the developer and the feedback  
20 is considered when there is changes that are  
21 incorporated on the measure. There is no  
22 facility level testing that was provided, so the

1 measure can only be used for the provider level.

2 And preliminary rating of usability  
3 was a no pass similar to what we saw this morning  
4 as it was originally endorsed in 2007, but, since  
5 it has not been an accountability application or  
6 in public reporting, but I believe it's part of a  
7 composite measure elsewhere, so again, this is  
8 the same discussion from this morning.

9 CO-CHAIR GUNNAR: Correct, so this is  
10 the first test that will carry us through all of  
11 the other, any other -- it's not part of a  
12 composite or is it?

13 MEMBER HANDY: It is.

14 MR. ANTMAN: And to add to what Dr.  
15 Scali said a moment ago, yes, the public  
16 reporting of the mitral composites was planned  
17 for January '19 and it did go live last month.

18 CO-CHAIR GUNNAR: So to bring back  
19 this morning, this decision here will set us on a  
20 path of one or two options? This one is being  
21 public, so we're good here, got it, yes, no  
22 challenge to this one.

1 MS. MARINELARENA: No, this measure  
2 individually is not being publicly reported. It  
3 is part of a component. It is a component of a  
4 composite. The composite is being publicly  
5 reported, correct?

6 CO-CHAIR GUNNAR: No, no, no, to  
7 clarify so everybody is on common understanding  
8 here, this, what we're voting on is a measure  
9 that when it was endorsed initially, knowingly  
10 was done so with the understanding it was going  
11 to be publicly reported in three years, correct?

12 When it was endorsed initially, the  
13 understanding between NQF and the developer was  
14 that there would need to be, this would have to  
15 be publicly reported within three years, is that  
16 correct?

17 MS. MUNTHALI: For six years or a plan  
18 for public reporting.

19 MS. MARINELARENA: So our criteria  
20 says --

21 DR. PAONE: Can I clarify just to make  
22 sure everyone understands what this measure, how

1       it's reported? It's reported as part of --  
2       there's a mitral valve repair or replacement  
3       composite which includes mortality and  
4       morbidity for isolated mitral valve repairs and  
5       mitral replacement.

6               There is a second mitral valve  
7       composite for mitral valve repair or replacement  
8       with coronary bypass, which is what this MVR CABG  
9       mortality is reported as part of the mortality  
10      component of that. It's not separately reported.

11             CO-CHAIR GUNNAR: Correct, and this is  
12      a theme that's going to exist for all of the next  
13      measures that we approach. And as we discussed  
14      earlier, so this is a part of a composite that's  
15      reported, but not independently reported.

16             MEMBER YATES: But for clarification,  
17      it's only two components within the composite,  
18      the publicly reported composite.

19             DR. PAONE: The publicly reported  
20      composite for mitral valve repair or  
21      replacement/coronary bypass surgery, for  
22      instance, includes data for isolate mitral valve,



1 I'm sorry, for mitral valve repair/CABG and  
2 mitral valve replacement/CABG.

3 The mortality component of that  
4 composite includes mortalities for both  
5 procedures combined, not separately. It's  
6 probably not something I should be saying so  
7 clearly, but given this conversation, but it's  
8 the fact. The volumes are required in order to  
9 be able to become more reliable and more valid.

10 MEMBER YATES: So it's one degree of  
11 separation from being reported separately.

12 MEMBER HANDY: So this is John Handy  
13 and I'm going to show my enduring confusion. So  
14 when you go to the STS site and you look at the  
15 mitral valve CABG composite score as was  
16 mentioned earlier by my colleagues in the room,  
17 it's listed in three parts, overall score,  
18 absence of mortality, and then absence of major  
19 morbidity.

20 And I thought our sticking point this  
21 morning was the absence of major morbidity, each  
22 one of which individually, all five of them, are

1 NQF approved end points, but we're conglomerating  
2 them all together.

3 So actually if you look at the  
4 website, there is public reporting of the absence  
5 of operative mortality separated out from the  
6 overall composite score, and the absence of  
7 operative mortality as we're talking about right  
8 now is an NQF endorsed measure.

9 CO-CHAIR FLEISHER: Can I ask a  
10 question? So I heard a statement that's  
11 important, whether or not the robustness and the  
12 stability of individually reporting this metric  
13 is sufficient. If you report it, you're worried  
14 about the stability.

15 There is one thing to say that  
16 statement. There is another thing to actually  
17 document it because my question to you is we've  
18 heard today from our patient phasing that it  
19 would be great to report this out in a year.

20 And I'll actually make a proposal that  
21 within the year, can we get a plan and  
22 maintenance back that either you do report this

1 out or you give us good documentation of why  
2 there's unintended consequences of publicly  
3 reporting this independently that we could take  
4 back?

5 I don't know if that's a fair question  
6 because it says if you have a plan for public  
7 reporting, that's good, but I really -- I want  
8 more than --

9 CO-CHAIR GUNNAR: That's a new  
10 credible plan.

11 CO-CHAIR FLEISHER: Well, that's why  
12 I'm saying it's one year to sort of come up with  
13 documentation of why there's unintended negative  
14 consequences of publicly reporting this.

15 DR. SHAHIAN: Could I respond to that,  
16 Dr. Fleisher? We actually, in 2007, when we  
17 started doing composite measures, we had a two-  
18 part article called quality measurement in adult  
19 cardiac surgery 1 and 2, and that paper was for  
20 CABG, but similar arguments would apply to these  
21 other procedures.

22 One of the problems is as mortality

1 rates have fallen for almost all cardiac surgical  
2 procedures, trying to differentiate quality based  
3 just on mortality is very difficult.

4 We found that using mortality alone,  
5 that you could identify about one percent of STS  
6 providers as being outliers. When you used a  
7 composite measure, it went up to about 20 percent  
8 that you could identify as outliers.

9 That's right in the paper and that's  
10 12 years ago that we showed that. I have no  
11 reason to believe that would be any different  
12 today.

13 That is, I think, the main rationale  
14 in my mind or one of the main rationales is just  
15 to have a better chance of discriminating levels  
16 of performance. It's a statistical issue related  
17 to sample size and number of end points  
18 available.

19 And then the other thing is that, as  
20 somebody alluded to earlier, if you're just  
21 looking at mortality, that's only one aspect of  
22 being a survivor. Most people want to know not

1 just if they're going to survive, but am I going  
2 to survive with a life altering complication like  
3 dialysis-dependent renal failure or a  
4 debilitating stroke?

5 So the composite provides a more  
6 multidimensional approach to quality, so if  
7 there's a statistical and a sort of qualitative  
8 reason for reporting the two together we think.

9 CO-CHAIR GUNNAR: So let me add to  
10 that again going back to the strategy here. The  
11 strategy here is if it is, my esteemed colleague,  
12 is passed with an addendum with a clear  
13 understanding within a year, that it's the  
14 message to STS.

15 I will propose the second strategy  
16 which is to fail. Let STS go back. And this is  
17 just not this measure. It's the other measures  
18 that make up. Come back to the committee with a  
19 justification and a plan forward that we can  
20 review and vote on before we endorse or make our  
21 decision forward to NQF, CSAC , and above, right?

22 The benefit of my argument for the

1       latter is STS may come back and say, "You know,  
2       let's rethink all of this. Maybe we don't need  
3       to report one and two or whatever publicly.  
4       Let's back off. Put our focus on the composites.  
5       We've justified their use and people are actually  
6       relying on them," as opposed to from a public  
7       facing point of view.

8                 Alternatively, they could say, "Here  
9       is our plan and this is our plan going forward to  
10       immediately begin to publicly report, for those  
11       who are willing to publicly report the individual  
12       pieces of this, and here is our strategy to do  
13       that."

14                So those are the two options, I think,  
15       unless someone else has a different option,  
16       option three, but we're going to know, I think,  
17       if there's any -- is there any further discussion  
18       or a need for understanding? Amy?

19                MEMBER MOYER: I guess the only thing  
20       I'd throw out there, so for instance, I have the  
21       anti-lipid treatment discharge. I would not  
22       mistake anything on the STS site for a single

1 reporting of that measure.

2 CO-CHAIR GUNNAR: No, no, no, we're  
3 doing just this one.

4 MS. MARINELARENA: Let me finish. I  
5 do this for a living and I would not have noticed  
6 that extra R in your online reported measure  
7 versus what's NQF endorsed if we hadn't had this  
8 discussion. That's really confusing. I just  
9 wanted to throw that out there.

10 CO-CHAIR GUNNAR: Any other comment?

11 MS. MARINELARENA: This is Melissa.  
12 Just a process issue. The composites that this  
13 is a part of are not up for endorsement right  
14 now; you endorsed those in 2017. The measure  
15 under discussion is the one before you right now.

16 MEMBER SAIGAL: Can I clarify what  
17 we're talking about? Basically the issue is that  
18 these individual measures are being reported  
19 directly or rather as part of a composite that  
20 doesn't meet the criteria and what do you do  
21 about that; that's the issue. And personally I  
22 think that if they're being reported in some way

1 as part of a composite, that's good enough for  
2 me. So I accept that as a form of public  
3 reporting of them, even though I specifically  
4 call that individually.

5 DR. BADHWAR: May I just respond to  
6 this, because it's somewhat of a similar  
7 argument. And Amy, I hear your comment. The  
8 MVRR just for clarity because I think you had  
9 some blank looks, that's mitral valve repair or  
10 replacement, but to Melissa's point that that's a  
11 previous measure, that is being public reported.  
12 To Dr. Saigal's point, these are being reported  
13 to the individual sites, and like the previous  
14 argument to give a very clinical point, to  
15 improve quality at the site level, they need that  
16 information and that's how they're being much  
17 more focused on their replacements versus the  
18 repairs. So it's the same argument before, it's  
19 still applicable with this measure.

20 CO-CHAIR GUNNAR: Any other -- oh,  
21 Joshua, anything?

22 MEMBER STEIN: I don't know. I think



1 your last comment goes back to my earlier  
2 question which is if we want the developer to  
3 make changes to our suggestions, do we have to  
4 vote it down to be able to get that versus  
5 accepting it if they do make those edits.

6 MS. MUNTHALI: So you've voting on the  
7 measure as it's currently specified. So I don't  
8 know if that helps.

9 CO-CHAIR FLEISHER: And when does this  
10 measure lose endorsement?

11 MS. MUNTHALI: Now. If you vote no --  
12 or yeah, do not pass, it would lose endorsement.

13 MS. MARINELARENA: But just to be  
14 clear, the composite that this is a part of will  
15 not lose endorsement, because the components do  
16 not need to be endorsed.

17 CO-CHAIR GUNNAR: But the developer  
18 can come back to the committee based on this non-  
19 endorsement decision with a rebuttal that we can  
20 then review and make a new vote on, yes or no?

21 MS. MUNTHALI: They could, but I think  
22 this is where we have to have dialogue with the

1 developer. So how soon could you come back to  
2 the committee? We do have a path forward if the  
3 measure is not passed or recommended for passing,  
4 because it has to be upheld by the CSAT. And Amy  
5 and both Lee are on the CSAT. So we do have  
6 recourse if you want to reconsider, if you want a  
7 reconsideration request of the standing  
8 committee's decision today prior to the end of  
9 the comment period. But it all depends on how  
10 quickly revisions can be made.

11 DR. BADHWAR: May I just ask a  
12 question just for point of order; this is the  
13 same argument from the previous discussion, and  
14 so if a decision on this is different than the  
15 previous discussion, does it not go back and it's  
16 still applicable to all of our measures, if you  
17 then separate the individual elements from the  
18 composite and vote against one or any of them?  
19 Speaking in broad generalities because the  
20 validity, specificity, face validity of these  
21 items and the statistical aspects of all these  
22 are all similar to -- the same thing for the

1 aortic valve sub-components. So I just wanted to  
2 be clear on how we would approach things.

3 MS. MARINELARENA: No, so this is  
4 different criteria. The conversation started  
5 before the composite, but it was just the general  
6 conversation. The composites refine 2561 and  
7 2563 because they are publicly reported. We just  
8 got a little bit ahead of ourselves talking about  
9 this. Again, this is an individual measure that  
10 is not publicly reported by itself, which is the  
11 issue.

12 CO-CHAIR GUNNAR: And the time from  
13 its initial endorsement has passed, from which  
14 there was an agreement at the get-go that it  
15 would be publicly reported.

16 MEMBER YATES: And I would argue that  
17 SDS is within their rights to feel like they are  
18 using public reporting in a sense that it's part  
19 of a composite. And I agree with Dr. Fleisher  
20 from his earlier comments that I don't think that  
21 the Central Committee would actually consider  
22 this scenario when they started to -- or when

1 they decided to start enforcing the public  
2 reporting as being a requirement for re-  
3 endorsement. And I think this is a very  
4 different and separate environment, and I think  
5 we're well within our rights to prove it and say  
6 that it's -- or say yes to this vote and yes to  
7 endorsement. And with the proviso that it's with  
8 Dr. Fleisher's addendum and also with the proviso  
9 that it's not what they intended, or it wasn't  
10 what we think they meant. I would, however,  
11 point out that I think Dr. Fleisher has moved  
12 into a living constitution type of philosophy and  
13 away from originalism with his comments.

14 DR. SHAHIAN: I could respond from a  
15 developer standpoint that I think you should vote  
16 up or down based on the measure as you see it. I  
17 would not anticipate that there are going to be  
18 significant changes on our part. We've been  
19 doing this now for, this is our ninth year public  
20 reporting. There is no organization in the  
21 United States or perhaps worldwide that does more  
22 exhaustive public reporting than we do. We

1 report these measures as part of a composite, we  
2 publicly report them. We think for the public  
3 that it's much more useful to have the measure as  
4 we currently provide it. So like it or don't  
5 like it, but I think this is what it's going to  
6 be.

7 CO-CHAIR GUNNAR: Any other  
8 discussion?

9 All right, vote.

10 MS. KOSURI: Voting is now open for  
11 the use part of the criteria for Measure 0122.

12 I think we're still waiting for one  
13 more vote.

14 Oh, so we have 15.

15 Okay, for the use part of the measure  
16 criteria for Measure 0122 we have a total of 15  
17 votes with 8 voting to pass and 7 voting to not  
18 pass. And the percentage -- give me one second -  
19 - is 53 voting to pass and 47 voting for no pass  
20 which indicates consensus not reached.

21 CO-CHAIR FLEISHER: Which is actually  
22 back to my comment that that means by the post

1 call we have to reach consensus, so is there any  
2 information that people want from the developer?  
3 We heard David talk to help them make a  
4 determination by the call, because we continue to  
5 talk, right, with consensus not reached?

6 PARTICIPANT: Mm-hmm.

7 CO-CHAIR FLEISHER: We continue to  
8 vote on the rest --

9 PARTICIPANT: We don't get a final  
10 vote.

11 MS. MUNTHALI: We don't do a final  
12 vote.

13 CO-CHAIR FLEISHER: But everything  
14 else --

15 MS. MUNTHALI: Yes, and part of the  
16 reason we wait for the post-comment call is to  
17 see if the public comments will help to inform  
18 your final vote, to help you get over the  
19 consensus not reached decision here.

20 MR. ANTMAN: May I just ask what is  
21 the threshold for consensus, what percentage?

22 MS. MUNTHALI: You needed to get 61

1 percent or more.

2 MR. ANTMAN: Thank you.

3 MEMBER YATES: I would ask STS -- this  
4 is a reasonable ask for the next two weeks or  
5 whenever we have our post call; I would ask that  
6 they provide a written statement just explaining  
7 why there would be adverse outcomes for reporting  
8 it separately as opposed to continuing to use it  
9 primarily in a composite.

10 MS. SKIPPER: And our post-meeting  
11 call is next Wednesday, so if you are able to  
12 come up with that, we would need it for the call  
13 on February 20th.

14 MS. MARINELARENA: Actually, what I  
15 would recommend is this is consensus not reached,  
16 we're not going to have an overall vote. This  
17 will go out for the 30-day public commenting  
18 period. That would be when STS should submit  
19 that comment to the public and then we ask for  
20 comments from all of the public. And then after  
21 the post-comment call that is when you will vote  
22 again and consider STS' statement and any other

1 public comments that we receive. So it won't be  
2 on the next immediate call, but in 30-some days.  
3 We will outline all of this for you.

4 CO-CHAIR FLEISHER: So the important  
5 part about that is since it's the public issue  
6 that we have here, the clearer the explanation  
7 and if there are other groups that either support  
8 or refute your explanation, that informs this  
9 discussion at the call. So we take all public  
10 comments very seriously, so.

11 MS. SKIPPER: Call your friends.

12 CO-CHAIR FLEISHER: Well, no. So if  
13 there is a group that actually can talk to how  
14 these measures are utilized, including -- well,  
15 we can do that offline. That would be very  
16 helpful.

17 CO-CHAIR GUNNAR: I think we're --  
18 what did we do -- we just did vote overall,  
19 right, to endorse or not endorse; is that what  
20 we're doing?

21 MS. SKIPPER: No, not for this one.

22 CO-CHAIR GUNNAR: Not for this one.



1 We'll just stop and move on, right?

2 MS. MARINELARENA: So we'll go back to

3 --

4 CO-CHAIR GUNNAR: Can we go --

5 MS. SKIPPER: Yeah, we do usability  
6 but not in overall recommendation.

7 CO-CHAIR GUNNAR: Okay, from a  
8 strategy point of view now there's a line of  
9 measures that are going to get us to this  
10 decision point for all of those measures. How do  
11 you want to handle this? You want to just go  
12 through it like we normally do and just march  
13 through them?

14 MS. SKIPPER: For the record.

15 CO-CHAIR GUNNAR: For the record we're  
16 going to march through -- and where would you  
17 like to go next? That leaves the lipid, the  
18 process measure for last -- unless you want to do  
19 the process measure now and then bunch all the  
20 other ones later. We either got to --

21 MS. SKIPPER: So we can have the  
22 discussion on usability if there's nothing else

1 to add for 0122 and then we'll move on. And then  
2 we can start with the 0114.

3 CO-CHAIR GUNNAR: So is there any  
4 further discussion on usability --

5 MS. SKIPPER: Mm-hmm, for 0122. So  
6 you can have the discussion now; we're not going  
7 to vote on it. But if there's anything else  
8 you'd like to add for the record now, that will  
9 be put out in the report for public comment.

10 CO-CHAIR GUNNAR: Hearing none, carry  
11 onto the next.

12 MS. SKIPPER: Yes, Measure 0114 and  
13 the developer will introduce it. I'm sending an  
14 email now with some additional material the  
15 developer did provide and I'll also be screen-  
16 sharing it. So, Mark?

17 MR. ANTMAN: Yes, thank you. While  
18 we're waiting for that screen-share to come up --  
19 Measure 0114 is the STS risk-adjusted  
20 postoperative renal failure measure. So this is  
21 the first of five component measures of the  
22 morbidity domain for the CABG composite to be

1 reviewed today. And again, this individual  
2 measure along with the other four components of  
3 morbidity are statistically rolled up together to  
4 create the morbidity component that goes into the  
5 CABG composite. Now that the edit is on the  
6 screen I'll explain that -- and I apologize for  
7 not being able to get this into the materials for  
8 the committee review earlier. It's just within  
9 the last month, approximately, that based on some  
10 feedback from STS database participants we  
11 realized that there was a need for clarification  
12 in our exclusion for this measure. Christy or  
13 other staff can -- thank you. The previous  
14 wording of the denominator exclusion, as you see  
15 here, was patients with documented history of  
16 renal failure baseline serum creatinine of 4.0 or  
17 higher. Some STS database participants  
18 questioned how they can account for this because  
19 there isn't actually a history of renal failure  
20 element, data element in the STS database.  
21 Participants have all along been simply reporting  
22 the data elements that exist, baseline serum

1 creatinine or patient undergoing dialysis,  
2 specifically currently prior to surgery  
3 undergoing dialysis. So this edit is simply  
4 intended to match the language of the exclusion  
5 to the data elements that exist in the database;  
6 it doesn't represent any significant change to  
7 the measure; it's simply an edit to the  
8 exclusion, as I said, to match the data elements.

9 And Christy, if you'll scroll down to  
10 the next page, then you can see under the  
11 denominator exclusion, so there's the edit.  
12 We've eliminated documented history of renal  
13 failure, baseline serum creatinine remains as it  
14 was is simply edited to say greater than or equal  
15 to 4.0. And again, adding the phrase "Or  
16 currently prior to surgery undergoing dialysis,"  
17 because that in fact is the data element that's  
18 collected.

19 So we're happy to answer any questions  
20 about that.

21 MEMBER JARRETT: This is Mark. The  
22 other Mark. The baseline is collected considered

1 at what time before the surgery -- excuse my  
2 ignorance on that -- and does that represent,  
3 what about somebody with acute kidney injury  
4 where their baseline is normally 0.9, they come  
5 in with some heart failure and other issues and  
6 they have some renal insufficiency and their  
7 creatinine is high, but in reality that does not  
8 represent major intrinsic renal disease?

9 DR. PAONE: I'm sorry; could you just  
10 repeat that again? I only heard half of it.

11 MEMBER JARRETT: I'm sorry; I  
12 apologize. So I assume that 4.0 represents the  
13 last baseline creatinine prior to surgery, but  
14 how does that reflect the delta if somebody had,  
15 came in needing surgery but had acute heart  
16 failure associated with, had some pre-renal  
17 disease or acute kidney injury, and let's say  
18 even from dye or whatever and really does not  
19 reflect their intrinsic renal disease but  
20 reflects either pre-renal or acute kidney injury?  
21 Does this really differentiate between those, or  
22 have you evaluated whether that makes a

1 difference?

2 DR. PAONE: No, that's a good  
3 question. The intention is to eliminate patients  
4 with chronic renal failure of significance so  
5 that you're not -- and someone with a creatinine  
6 over 4.0 is very likely to go on and require  
7 dialysis, and so that's intended not to include  
8 those patients, although they're very small in  
9 the outcome measure. But you're right; I don't  
10 know how to account for that. I suspect the  
11 number is fairly small, but I don't know that  
12 we've looked at that specifically. It is  
13 something to think about as we go forward in  
14 terms of trying to make sure that we capture all  
15 those who need to be captured with this. But I  
16 don't know that we've actually looked  
17 specifically at that, it is a very good question.

18 DR. BADHWAR: I'd add to that, though,  
19 and say that the concept of the actual domain is  
20 to be, again, more stringent to detect anyone  
21 because from a patient advocate or a hospital,  
22 whether you get renal failure post-operative, if

1       you go on new dialysis, that's bad, regardless if  
2       you had pre-renal disease or not. And so we're  
3       actually being more stringent or penalizing sites  
4       for the negative outcome. And so you can look at  
5       it in two ways; I would advocate that looking at  
6       it from the benefit of how to avoid this measure  
7       and if you had that patient that had AKI  
8       preoperatively from all the data that comes out,  
9       so from a dye issue, those are the patients you  
10      should probably wait and not actually operate on  
11      right away. And so I would just advocate that  
12      the reason this has been edited like this, it's  
13      actually making it more stringent.

14               CO-CHAIR GUNNAR: All right, our  
15      discussants, are we headed to evidence now -- hm?

16               PARTICIPANT: Discussions with Dr.  
17      Saigal --

18               CO-CHAIR GUNNAR: Dr. Saigal, Stein  
19      and Barbara's not on, so. So evidence?

20               MEMBER SAIGAL: Right, so this is  
21      outcome measure and, you know, I guess evidence  
22      requirements aren't that significant, but there's

1 a spread in performance 0.8 to 9.94 percent.  
2 It's a significant problem, there's at least one  
3 thing a surgeon can do to mitigate the outcome,  
4 so it's pretty reasonable. There's a gap in  
5 care, the report what's mentioned they also talk  
6 about the risk for this outcome being worse among  
7 black patients and a little worse in men. So  
8 that's the evidence.

9 Would you like to vote on that?

10 CO-CHAIR GUNNAR: Yes, we need to go  
11 through the votes. So, evidence. Any other  
12 discussion on evidence -- Dr. Stein, anything  
13 further?

14 MEMBER STEIN: I think the developer  
15 -- I thought the developer provided extensive  
16 evidence supporting the rationale for the measure  
17 and there are ways to reduce this measure during  
18 the perioperative period and I'm unaware of any  
19 new studies to change the evidence, so I think  
20 there's sufficient evidence.

21 CO-CHAIR GUNNAR: Can we vote then?

22 MS. KOSURI: Voting is now open for



1 the evidence portion of the measure criteria for  
2 Measure 0114.

3 I think we're waiting for one more.

4 Okay, so I think we'll -- voting is  
5 now closed for the evidence portion of the  
6 measure criteria for Measure 0114 where a total  
7 of 14 people voted to pass this measure, so the  
8 committee passes the evidence portion of this  
9 measure.

10 CO-CHAIR GUNNAR: I guess we'll go to  
11 gap.

12 MEMBER SAIGAL: I mentioned gap  
13 already.

14 CO-CHAIR GUNNAR: So we can proceed,  
15 unless there's any other discussion on gap, let's  
16 go and -- Joshua?

17 MEMBER STEIN: Actually, this is the  
18 first time I'm looking at this measure and I  
19 thought the information the developer provided in  
20 their Table 1B4 both for this measure and the  
21 other one that I reviewed, I think you need a  
22 statistician to look at this information. I

1 thought it was incredibly confusing and I think  
2 it's very difficult to interpret without  
3 additional information, at least for me to say  
4 whether there's gaps; specifically there are a  
5 whole bunch of odds ratios, there's no  
6 information as to what it's comparing the odds  
7 of, is it males versus females, one time period  
8 versus another time period, there's no confidence  
9 intervals provided. Odds ratios without  
10 confidence intervals to me are completely  
11 useless, so both this measure and the other one I  
12 reviewed, and probably all the measures it seems  
13 like the data's being presented the same way.  
14 And I think if a statistician looked at this,  
15 they could clarify and present it in a manner  
16 that we could make use of.

17 MEMBER SAIGAL: The reporting odds  
18 ratios that are significant, that was my  
19 assumption, and I don't know if that's true.  
20 Good question.

21 MR. O'BRIEN: This is Sean O'Brien; do  
22 you want me to jump in and try to give an

1 explanation of what was presented?

2 MEMBER SAIGAL: Yeah.

3 MR. O'BRIEN: So with respect to  
4 disparities, the intent there with that question,  
5 the measure designed to assess performance for  
6 participant level, and as it's designed it's  
7 already estimating outcomes in a way that's  
8 averaged over different types of patients. But  
9 the question is raised, is it possible to look at  
10 performance across participants in sub-groups of  
11 participants who may be subject to disparities.  
12 When we talk about stratifying results to look at  
13 disparities, these measures aren't designed to  
14 compare performance across the sub-groups;  
15 they're designed to compare participants across  
16 participants in comparison to the national  
17 benchmark. So when it comes to stratifying,  
18 rather than saying here are outcomes for black  
19 patients and white patients and males and  
20 females, we're asking the question is there  
21 variation across participants in their  
22 performance when you look at different sub-groups

1 of patients. So one participant in theory could  
2 have excellent outcomes for one type of patient  
3 or one set of, based on characteristics but  
4 different performance for different types of  
5 patients. So we've done an analysis, how much  
6 variation do we see when we look at patients  
7 separated by males and females, black and non-  
8 black race, et cetera just as an attempt to  
9 basically provide information that was requested  
10 by NQF related to disparities.

11 MEMBER SAIGAL: But you didn't do  
12 tests on those variation data to see if they were  
13 significant, did you report whatever you came out  
14 with? You didn't actually see if the confidence  
15 intervals were crossing one, or what was the --

16 MR. O'BRIEN: So, each participant,  
17 anytime we'd ever report a measure of participant  
18 level performance, that's always accompanied by a  
19 measure of uncertainty like a confidence  
20 interval. But now we're talking about  
21 summarizing results for 1,000 hospitals, and so  
22 what we're doing is saying each hospital gets a

1 point estimate of their estimated performance and  
2 how much variation is there across participants.  
3 So each person has an odds ratio and they're  
4 summarizing the distribution of those point  
5 estimates of odds ratios, so there's not a great  
6 way to summarize -- we could summarize the  
7 distribution of the lower limit of the confidence  
8 interval or the upper limit of the confidence  
9 interval, but basically -- yeah, we're basically  
10 just saying how much do we see differences in our  
11 estimates of performance across participants.  
12 That's why there's no confidence intervals  
13 associated with them.

14 MEMBER SAIGAL: That doesn't make any  
15 sense to me. I don't know if anyone follows  
16 that. Can you explain it to me?

17 MEMBER DUTTON: They're not actually  
18 doing a comparison; they're showing the  
19 distribution

20 MS. SKIPPER: Can you speak to the  
21 mic, please?

22 MEMBER DUTTON: I'll try that in

1 English. They're not actually doing a  
2 comparison, so there's no statistical comparison  
3 of the point estimate, as he says; rather, this  
4 graphic on the screen is just a distribution of  
5 their sites. This is what the curve looks like  
6 for the variability in the data. I actually find  
7 that very useful to know how the percentiles lay  
8 out.

9 MEMBER STEIN: I really have no idea  
10 what they're showing. I mean, here it says 2016  
11 or 2017, then there's information 2011 to 2012,  
12 then there's a bunch of summary statistics. And  
13 then if you scroll down more, there's a bunch of  
14 odds ratios, but there's no explanation as to  
15 what they are.

16 MR. ANTMAN: May I comment on that  
17 table, please?

18 Excuse me. This table was originally  
19 submitted in an appendix to our application  
20 because we realized that if we had to put this  
21 table into the submission form itself, the  
22 columns would get confused and it would be

1 impossible to read. So, NQF staff, if it's  
2 possible to pull up the appendix we originally  
3 submitted, that will show this data much more  
4 clearly. I was asked by staff to put this into  
5 the form itself, which I agreed to, but knowing  
6 that it would be very confusing without the  
7 columns of the table being clearly distributed.  
8 So in the appendix you'll be able to read this  
9 data much more clearly.

10 MEMBER SAIGAL: So just to clarify  
11 this; so basically there's a spread in  
12 performance, so there's a gap, the questions  
13 about disparities, and what I'm understanding  
14 from the statistician is that there is a  
15 difference in post-operative renal failure if  
16 you're black versus you're white, and that is a  
17 meaningful statement to make; is that correct?

18 MR. O'BRIEN: No, that's not what this  
19 is looking at.

20 MEMBER SAIGAL: Okay, that's fine.  
21 Thank you. So basically we can't say if there's  
22 a disparity in the outcomes as presented here, so

1       there's no comments you can make about it, I  
2       guess.

3               MEMBER STEIN: Right, that was the  
4       conclusion I came to as well. There's not enough  
5       information provided.

6               MEMBER SAIGAL: Okay, so not enough  
7       information for that.

8               CO-CHAIR GUNNAR: Are we ready to --  
9       any other discussion?

10              If not, then we'll vote on performance  
11       gap.

12              MS. KOSURI: Voting is now open for  
13       the performance gap portion of the measure  
14       criteria for Measure 0114.

15              CO-CHAIR FLEISHER: Has everybody  
16       voted? We need one more. Did we lose --

17              MS. KOSURI: I think we have the 14  
18       people we need. So with a total of 14 votes, 2  
19       votes for high, 10 votes for moderate, and 2  
20       votes for low, the committee has passed the  
21       performance gap portion of the measure criteria  
22       for Measure 0114.



1                   MEMBER SAIGAL:   Okay, the next one is  
2   validity.

3                   CO-CHAIR GUNNAR:   Reliability.   I got  
4   my cheat sheet here.

5                   MEMBER SAIGAL:   Okay, so I guess these  
6   data have been contracted several times; there's  
7   like a 10 percent contraction rate that seems  
8   pretty reliable to me.   I don't know if anybody  
9   has questions about that?

10                  CO-CHAIR FLEISHER:   So are we ready to  
11   vote?   Any comments?

12                  Let's vote.

13                  MS. KOSURI:   Okay.   Voting is now open  
14   for the reliability portion of the measure  
15   criteria for Measure 0114.

16                  Okay, voting is now closed with a  
17   total of 14 votes where 4 people voted high and  
18   10 individuals voted moderate.   The reliability  
19   portion of the measure criteria for Measure 0114  
20   has passed by the committee.

21                  MEMBER SAIGAL:   Now validity?

22                  Okay, so I think the only issues here

1 are -- one of the tests of validity was whether  
2 performance in one period predicted performance  
3 in a later period. And it did, but then again  
4 you would hope that there would be improvements  
5 over time in these scores, so it's a question  
6 about whether that's a good test of validity or  
7 actually it's just showing you nothing's  
8 happening in terms of quality improvement. The  
9 other issue is that it does include race in the  
10 risk adjustment model; we already discussed that,  
11 so same I guess caution is there. But overall, I  
12 would not mark it as valid personally.

13 MEMBER STEIN: Yes, I had a similar  
14 concern about comparing past to current  
15 performance; I think in a way that's good, but  
16 then it also suggests providers can't do better.  
17 I also had some questions about whether the  
18 developer looks at outliers. There was someone  
19 who had like a 20 percent rate of acute renal  
20 failure which to me seemed very high to see  
21 whether that was like a problem with data input  
22 versus the fact they really had that kind of

1 rate.

2 Do you guys look at outliers to see  
3 whether you're confident that it's not just how  
4 it's being reported?

5 DR. BADHWAR: Your question's about  
6 outlier determination as a whole or just for this  
7 particular measure in terms of the creatinines of  
8 10 or something like that, right?

9 CO-CHAIR GUNNAR: So this gets to  
10 audit question about -- so the validity and how  
11 do you go back and ensure that outliers or  
12 anybody is inputting valid information?

13 DR. BADHWAR: Sean can probably chime  
14 in to just talk in concept of the variable of say  
15 a creatinine is 111, something like that; that's  
16 immediately deleted as an obvious one. I'll let  
17 Sean answer overarching issues with the data  
18 entry in that large determination.

19 Sean, can you chime in?

20 MR. O'BRIEN: Yeah, the participants  
21 receive a very detailed data quality feedback  
22 report that's separate from the feedback report

1 reporting outcomes. I don't really remember the  
2 exact length and all the content of the report,  
3 but it's several dozen pages and very detailed.  
4 So missing values, but the raise checks on values  
5 are incorporated up front in the harvest process  
6 as well. So there are checks in place. When it  
7 comes to looking at outlier values for outcome  
8 rates, I think that most sites are paying very,  
9 very close attention to their outcome rates, and  
10 so have an opportunity to detect if their  
11 performance is in line with what they think it  
12 should be. So that outlier -- an outlier renal  
13 failure rate is not in the data quality report  
14 but is in their feedback report. So beyond that  
15 I'm not sure I have data to address the question  
16 about outliers.

17 CO-CHAIR GUNNAR: Let me ask a  
18 specific question; do you impute values for empty  
19 data, missing data fields?

20 DR. BADHWAR: Not for an outcome  
21 measure like that. If it's, for example, for  
22 renal failure -- this comes to the audit process

1 -- it's actually a chart examination of the data  
2 field. So for example, did they have renal  
3 failure or not have renal failure, did they go on  
4 dialysis or not go on dialysis. That is part of  
5 the audit process.

6 MEMBER STEIN: So if someone has a  
7 renal failure rate say of 20 percent, because  
8 that was I think the highest reported -- unless  
9 that provider comes back to you and says, "Hey,  
10 I'm surprised that my rate is so high," like do  
11 you guys go and look at the ones on the extremes  
12 and see whether they legitimately are on the  
13 extremes versus some sort of inputting error with  
14 how the data's being entered or something?

15 MR. O'BRIEN: We do with internal  
16 process of review, but we don't have a set  
17 criterion for assessing outliers like that with  
18 respect to renal failure and other outcome rates.

19 MEMBER STEIN: One other comment and  
20 this is not just to the specific measure; in  
21 terms of your risk adjustment methodology, it  
22 seems like you adjust for many different medical

1 conditions, and I know we already talked about  
2 things like race, but do you guys consider  
3 putting into your risk adjustment things like  
4 whether the patient's from an urban or rural  
5 location, whether the care's at an academic or  
6 tertiary facility. There are a bunch of non-  
7 medical factors that it would seem to be useful  
8 to build into risk adjustment models, so I'm  
9 wondering, are you planning on putting those in  
10 or are they being put in?

11 DR. BADHWAR: That's a very good  
12 question and this is a general question; those  
13 are fields that are actually in the database, and  
14 so they are being recorded. Whether they parsed  
15 out depending on the risk model as relevant in  
16 the multi-variable regression, it changes, but  
17 those are captured. So that's a good question.

18 DR. SHAHIAN: I can expand on that a  
19 little; I don't think those would be appropriate  
20 for a risk model being used to assess the  
21 performance of an institution. That kind of risk  
22 model -- and Sean, you can chime in as well --

1       that should be based on patient characteristics,  
2       not on the characteristics of the institution or  
3       where it lies. A patient may be -- well, I'll  
4       just leave it at that -- I could go into a lot of  
5       detail but historically and traditionally those  
6       are not included in models used to assess  
7       performance. Now, there are people that say, and  
8       this is being argued in some of the hospital  
9       compare measures, that hospitals should be  
10      compared to "like" hospitals; that's a different  
11      question. But in terms of adjusting procedural  
12      performance, I would argue that those things  
13      don't belong in a risk model, even though they  
14      may have an impact on it, they don't belong in a  
15      quality performance model.

16               Sean, do you want to comment on that?

17               MR. O'BRIEN: I think just leave it  
18      there, but I can answer questions.

19               CO-CHAIR GUNNAR: So we are ready to  
20      vote on validity, unless there's further  
21      discussion?

22               MS. KOSURI: Voting is now open for

1 the validity portion of the measure criteria for  
2 Measure 0114.

3 Waiting on one more.

4 Okay, with a total of 14 votes we have  
5 2 votes for high, 9 votes for moderate and 3  
6 votes for low. The validity portion of the  
7 measure criteria passes for Measure 0114.

8 I'll check that -- and the percentage  
9 is 78 percent; it passes by 78 percent.

10 MEMBER SAIGAL: Okay, so then  
11 feasibility. I mean, proof's in the pudding;  
12 it's widely used, people are doing it as  
13 expensive to the hospital, I think. I don't know  
14 if we need to belabor that more?

15 MEMBER STEIN: Yeah, I thought the  
16 feasibility was fine. You know, I think the  
17 developer should consider risk adjusting for how  
18 the data's being inputted in, whether it's via  
19 EMR versus hybrid versus manual entry, because I  
20 think that probably is affecting the outcomes, as  
21 I mentioned earlier. But besides that, I think  
22 it's otherwise feasible.



1 CO-CHAIR GUNNAR: Any other  
2 discussion?

3 Let's go ahead and vote.

4 MS. KOSURI: Voting is now open for  
5 the feasibility portion of the measure criteria  
6 for Measure 0114.

7 Voting is now closed with a total of  
8 14 votes where 6 voted for high and 8 voted for  
9 moderate. Measure 0114 passes for the  
10 feasibility portion of the measure criteria.

11 MEMBER SAIGAL: Okay, then usability;  
12 so I think this is the same issue we're  
13 discussing in terms of whether one of the single  
14 measure is not directly reported counts; under  
15 public reporting my personal view is that it  
16 does. It may be used as part of a composite but  
17 others disagree, so I don't know if we need to  
18 belabor that more or more discussion is needed.

19 CO-CHAIR GUNNAR: Any further  
20 discussion?

21 Go ahead and vote.

22 MEMBER DUTTON: Actually, I did have

1 a comment on that. This is one of the measures  
2 that is reportable by individual physicians under  
3 MIPS, so in their QCDR, so this measure is  
4 publicly reported.

5 PARTICIPANT: But it's not the same  
6 measure through MIPS. It would be --

7 PARTICIPANT: That's only if those  
8 physicians choose to use it, right?

9 DR. BADHWAR: And the QCDR it is  
10 reported as part of CABG as a separate item for  
11 renal failure. It's on the website. It's --

12 MEMBER YATES: It's the reporting  
13 level.

14 MS. KOSURI: Could you put your  
15 speaker on?

16 MEMBER DUTTON: So I see what Dr.  
17 Yates is saying that it is the -- as presented  
18 here it is a hospital or group level of reporting  
19 as opposed to a physician level of reporting. So  
20 that does not count as publicly reported even  
21 though it's the same data being calculated in the  
22 same model?

1 CO-CHAIR FLEISHER: So that's your  
2 determination.

3 MEMBER DUTTON: Okay.

4 CO-CHAIR FLEISHER: Remember, they  
5 have not defined what accountability and public  
6 reporting is in the way which the line is  
7 written.

8 MEMBER YATES: Right, but we haven't  
9 had any -- we're not being presented with a  
10 distribution of results and outcomes for surgery  
11 specific data which may be very different than  
12 what were being presented for site specific, so  
13 we can't really use that as a surrogate for  
14 reported. What goes out in MIPS is going to be  
15 different.

16 CO-CHAIR GUNNAR: The other is at the  
17 time when the measure was initially endorsed. It  
18 wasn't a common understanding between NQF and STS  
19 developers that we'll rely on a second set of  
20 individuals to report this publically and then I  
21 get to bootstrap that.

22 DR. BADHWAR: So just for clarity,

1       it's on the STS website.

2                   CO-CHAIR FLEISHER: Thank you. So we  
3       should just vote.

4                   CO-CHAIR GUNNAR: We're voting.

5                   MS. KOSURI: Voting is now open for  
6       the use portion of the measure criteria for  
7       Measure 0114.

8                   I think we had an additional vote who  
9       voted early, so -- a voter who voted early, so  
10      make sure you can check and try again.

11                   Okay, voting is now closed. For the  
12      use portion of the measure criteria for Measure  
13      0114 there were a total of 14 votes where 6 voted  
14      to pass and 8 voted to not pass, and this is  
15      consensus not reached with 43 percent.

16                   CO-CHAIR FLEISHER: So we continue,  
17      because consensus is not reached.

18                   CO-CHAIR GUNNAR: We continue with the  
19      voting on usability.

20                   I thought we went to -- oh, no. We go  
21      to --

22                   MS. KOSURI: No voting.

1 CO-CHAIR GUNNAR: Any further  
2 discussion on this measure?

3 Hearing none --

4 CO-CHAIR FLEISHER: I urge a five-  
5 minute sun salutation, whatever you feel to get  
6 up and move around.

7 MS. SKIPPER: And to correct for the  
8 record, the reliability on this vote, 4 high, 10  
9 moderate, because the measure score testing was  
10 not completed, high should not have been an  
11 option given to you all. We apologize for that.  
12 So for those of you who voted high for  
13 reliability for this measure, is there any  
14 protest if we move your 4 votes to the moderate?

15 MEMBER SAIGAL: I'm going to freak  
16 out.

17 (Laughter.)

18 MS. SKIPPER: Hearing no  
19 disagreement, we'll --

20 And the same for 0122, we'll move your  
21 high votes to the moderate vote, if there are no  
22 objections to that.

1 PARTICIPANT: Why?

2 MS. SKIPPER: Measure score testing  
3 was not completed. The highest rating possible  
4 in that situation is moderate.

5 MEMBER YATES: What if we're rebels?

6 (Laughter.)

7 MEMBER YATES: I've got to point out  
8 that we're about to wipe out about a half of the  
9 endorsements for the STS measures that make up 30  
10 of our inventory. And we're now going to take 13  
11 of 30 out of being endorsed, and I think we're  
12 doing it on the basis of semantics of what  
13 qualifies for public reporting. And I'm just  
14 going on the record that I find this to be very  
15 frustrating and I'm not sure that this should not  
16 have been foreseen and addressed in advance if  
17 communications at the central committee is an  
18 issue. It's somewhat mystifying to me.

19 CO-CHAIR FLEISHER: So we don't have  
20 a central committee.

21 MEMBER YATES: But it's starting to  
22 feel like one.

1 CO-CHAIR FLEISHER: So one of the  
2 questions is in the four weeks during public  
3 comment, right, this will still go out for public  
4 comment?

5 MS. MUNTHALI: Yes, this will go out  
6 for public comment which is -- we have quite a  
7 bit of time.

8 CO-CHAIR FLEISHER: So part of my  
9 question is can we get CSAC or some other body to  
10 weigh in on A.J.'s concerns?

11 MS. MUNTHALI: The CSAC would be  
12 weighing in. The CSAC takes in not just the  
13 standing committee's recommendations but also the  
14 public comments, so you don't want to unfairly  
15 influence them. We don't know if there's going  
16 to be an issue. These are discussions that are  
17 happening. This is going to be shared with the  
18 CSAC; they're going to review the report as well.  
19 Your co-chairs will be at the CSAC to talk about  
20 the discussion. But yes, you guys should talk  
21 about the portfolio at large and what this means  
22 to it, and where there may be measure gaps, do

1       you have the right measures in your portfolio; I  
2       think all of those discussions should be  
3       happening at the standing committee level.

4               MEMBER SAIGAL:   I'm confused.   So  
5       we're saying that because of the non-agreement on  
6       that one issue that we're not going to -- there's  
7       a follow-up call to this that we're all on that  
8       we can still further discuss it, or is that's it?

9               MS. MUNTHALI:   All of the  
10       recommendations whether the measures pass or not  
11       are included in our report which goes up for  
12       public comment.   And then you will meet on a  
13       post-comment call to reach consensus where you  
14       didn't, and then all of your recommendations from  
15       there will go to the CSAC.

16              MEMBER SAIGAL:   Okay, I do second what  
17       A.J.'s concerned about; I think it sounds like a  
18       semantic issue and some very valuable measures  
19       are at risk, in my mind.

20              CO-CHAIR FLEISHER:   So we have a  
21       chance in a month, post-public comment to re-vote  
22       and to get -- I mean, it would be useful to have



1 people after this is posted to discuss what  
2 public comment means including the public. So if  
3 there are public-facing entities that want to  
4 make comment if they are on this call or you know  
5 them, that would be helpful to guide us whichever  
6 direction.

7 Fred?

8 MEMBER GROVER: I would just like to  
9 see the complete NQF definition of public  
10 reporting before we leave today.

11 MS. MUNTHALI: We can share that with  
12 you.

13 MEMBER YATES: And given the fact that  
14 we're going to have a fairly long day or  
15 afternoon for the post-public reporting phone  
16 call. Just do me a favor, Christy and company,  
17 have you guys already put out the Outlook  
18 invitation for that?

19 MS. SKIPPER: Yeah, so the post-  
20 comment call is May 8th. Is that what you're  
21 asking?

22 MEMBER YATES: That'll help me to just

1 make sure that I block out my schedule.

2 MS. SKIPPER: Yes, and the report goes  
3 for comment March 21st.

4 MS. MUNTHALI: So the CSAC will meet  
5 in July and what we do prior to every meeting  
6 they have is prime them about the issues. So  
7 this will be something we talk to them about in  
8 addition to them receiving your report, and some  
9 members of the CSAC may join the post-comment  
10 call. We welcome that as well so that they can  
11 hear the discussion from you directly.

12 DR. BADHWAR: Respectfully, may I ask  
13 a question, Elisa, just from a process point?  
14 Would you desire a response from STS in the  
15 public reporting period or as a separate  
16 communication directly to NQF? How would you  
17 like us to respond to these issues?

18 MS. MUNTHALI: In the period, yes.

19 DR. BADHWAR: Okay.

20 DR. PAONE: If I can just echo what  
21 Dr. Yates said, I'm sure it's apparent at this  
22 point, but essentially 10 of the 15 measures

1       today will have been failed on the basis of this  
2       question as we go forward.

3               MS. MUNTHALI:   So just because  
4       consensus wasn't reached, it doesn't mean that  
5       you have a final decision, it doesn't mean that  
6       they're failed yet.   The committee has to vote on  
7       whether or not they pass during the public  
8       comment period, so I wouldn't take it as the last  
9       word.

10              DR. PAONE:   I guess I meant for the  
11       purposes of today's session, but 10 of the 15  
12       will all have that same issue as you discussed  
13       needs to be addressed going forward.

14              DR. SHAHIAN:   Dr. Fleisher, can I make  
15       a comment?   I apologize; I have to leave fairly  
16       soon for the airport, so I won't be able to join  
17       the rest of the discussion.   But I'd just like to  
18       thank Dr. Yates for saying what I would have  
19       liked to have said; I think this is an unfair  
20       black mark against measures we have been using,  
21       and in our opinion in good faith publicly  
22       reporting for close to a decade.   Based solely on

1 a semantic issue I've tried to outline the  
2 scientific reasons why we've done what we've  
3 done, and we will put this into a formal  
4 document, but to discredit these measures has  
5 implications that are far-reaching. These  
6 measures are components of our composites,  
7 probably the most widely regarded measures in, at  
8 least in surgery right now, and whether you no  
9 longer require NQF endorsement for the individual  
10 components of a composite, there's no question  
11 that when and if NQF endorsement is withdrawn  
12 from measures that are part of the composite, it  
13 will cast doubt on the overall system of  
14 measurement, and I think that's unfair. So I  
15 would like to express my strong discomfort with  
16 the approach that's been taken today. We will  
17 respond and I hope that folks on reflection will  
18 come around.

19 I will also distribute the original  
20 paper that we based this approach on, a set of  
21 papers so that you can read in detail the degree  
22 of discussion that went into whether or not and

1       how to include these individual components of  
2       morbidity. This was not some willy-nilly  
3       decision; this was based on a lot of analyses and  
4       I hope that you'll take the opportunity to read  
5       that.

6               So thanks for the opportunity to make  
7       that comment.

8               CO-CHAIR FLEISHER: Thank you. I'd  
9       actually like a brief discussion here to follow  
10      up on AJ's, and then let others. If we ignored  
11      what the words say but get to the intent, I mean,  
12      do people have strong feelings about whether or  
13      not these are publicly reported?

14              You know, because I'm curious about,  
15      are people voting no because of the way it's  
16      phrased, or people feel that the absence of a  
17      public reporting, independent of what the words  
18      are, is sufficient to vote it down? Could I  
19      get -- Amy?

20              MEMBER MOYER: So, I'm kind of  
21      thinking this through. To me, we're not saying  
22      those measures are failures, or that they

1 don't -- they're not acceptable.

2 I think, to me, it's somewhat a  
3 question of what types of measures need to be  
4 individually reviewed and endorsed by NQF. And  
5 so, it may be perfectly appropriate these  
6 measures aren't individually, publicly reported.

7 And so, then, do we need to review  
8 them as individual standalone measures that  
9 aren't going to be publicly recorded or used  
10 separately, because we're still looking at the  
11 composite. The composite would still be  
12 endorsed, it would still be something reexamined.

13 But instead of looking at, I don't  
14 know, 18 measures, maybe we have a really in-  
15 depth look at three composites. Because I think  
16 it's still important, but I'm wondering if the --  
17 I don't know if the takeaway message -- I don't  
18 know that it's necessarily intended to be, no,  
19 you've got to like report all of these.

20 But maybe it's just a looking at, you  
21 know, what needs that individual level of review  
22 and that individual level of endorsement, for

1 things like --

2 CO-CHAIR FLEISHER: I'm going to get  
3 the CSATs. Did you have a comment?

4 MEMBER EREKSON: Yeah, I wanted to  
5 just comment on -- so, we're not in a point of  
6 consensus. And so, I think now is the time to  
7 say, well, what would help us change our route  
8 and what would help us get to consensus.

9 CO-CHAIR FLEISHER: Right.

10 MEMBER EREKSON: And I clearly heard  
11 the scientific basis of why the participants in  
12 the STS database want to publicly report in the  
13 way that they're publicly reporting. But what I  
14 haven't heard is how that public reporting is  
15 used by the public, or how that public reporting  
16 is used by the patient, or where the patient's  
17 voice is in all that.

18 And that would absolutely change how  
19 I'm considering this and how I think -- how we  
20 could even advise NQF on the public reporting  
21 measures over the month if I get more information  
22 on that, because that's where I'm really

1 struggling today. Not that I -- that's just  
2 where I'm struggling today.

3 CO-CHAIR FLEISHER: Rick?

4 MEMBER DUTTON: Amen, Fred. I feel as  
5 if NQF has made a major philosophical or policy  
6 shift by the seams here that we're just now  
7 catching up to.

8 I think NQF has had enormous value as  
9 a steward of measures for quality improvement,  
10 that would be the Q in NQF, and a shift to  
11 public, to emphasize in public reporting, is a  
12 somewhat different mission, and I believe there  
13 are potential and intended consequences there to  
14 how the measures are used and their value,  
15 honestly.

16 It's why I asked the question a day  
17 earlier, David, about what their experience with  
18 public reporting has been.

19 So, these are measures that have had  
20 a long history of really improving healthcare.  
21 They're about the best technical measures we have  
22 in our entire portfolio. I think they are still



1 enormously valuable for improving healthcare at  
2 the hospital and physician level.

3 Now, it seems like this isn't the kind  
4 of measure we want at all. And that's what's  
5 bothering me.

6 MEMBER GROVER: I was wondering for  
7 the SDS-advocated. We'd complied with NQF on  
8 this issue, plus the fact that I thought it was  
9 the right thing to do for our patients and the  
10 public.

11 Quite frankly, maybe we didn't read  
12 the fine print well enough in the definition, but  
13 we assume that since these were a part of the  
14 composite measures, they were participating in  
15 the public reporting effort.

16 This is a -- if this goes out for  
17 public comment, news in some very important  
18 opportunities to actually, potentially connect  
19 with CMS for physicians-based reimbursement,  
20 which would actually follow data instead of -- or  
21 follow the most accurate way, and this could be  
22 very, very damaging.

1                   And if there's any way we can solve  
2                   this issue, if it's solvable, before the  
3                   public -- it's released to the public, it would  
4                   be very helpful.

5                   CO-CHAIR FLEISHER: Thank you. I'm  
6                   going to speak on behalf of myself, not as Chair  
7                   or a member of the Board, because I am trying to  
8                   think through the implications of what we  
9                   actually said at a high level, that it's okay to  
10                  look at the composite, but not the individual  
11                  measures.

12                  And I don't know if we've ever looked  
13                  close enough at the individual measures within a  
14                  composite to actually say they're good enough,  
15                  compared to the composite. We'd actually be just  
16                  looking at the composite as whether or not that's  
17                  valid, rather than looking at the measure of  
18                  renal failure and individual mortality.

19                  So, I'm actually concerned that I  
20                  think Rick and others -- and AJ, you  
21                  articulated -- the unintended consequences of  
22                  making it easier not to endorse individual

1 measures could make the quality worse of the  
2 measures.

3 The positive of this is getting to  
4 measures that matter. So, perversely, I actually  
5 think what the STS did is the composites of the  
6 measures that matter.

7 The individual components, I wish  
8 there was some other means to say, these have  
9 been fully vetted by NQF, they're really  
10 important, they meet every criteria from  
11 stringency perspective. But they're not the  
12 measures that matter, because we actually agreed  
13 with you, or I do agree with you, that all that's  
14 important to put out is the ones you put on  
15 public reporting.

16 So, you know, I don't know where that  
17 goes within the organization, but it's good that  
18 potential -- I think when they thought of  
19 composite measures, they never thought of the  
20 positives of getting the composites proofed, but  
21 not since --

22 MS. MUNTHALI: Yeah. No, I think you

1       raise --

2                   CO-CHAIR FLEISHER:  -- and the  
3       components.

4                   MS. MUNTHALI:  The components.  Yeah,  
5       you raised very good points.  When we convened  
6       the composite framework technical expert can on  
7       2014, use was not must-pass.  So, these sort of  
8       discussions were -- they weren't on the table.  
9       Things, as quality measurement is evolving, we're  
10      evolving our criteria vows.

11                   I know this doesn't give you much  
12      comfort.  It is what it is right now.  But this  
13      is where we're taking it to say maybe we need to  
14      re-look about -- look at how you squeeze in the  
15      individual components, vis-a-vis the entire  
16      composite.

17                   And that's something we would do  
18      rather quickly.  But it is, unfortunately, the  
19      criteria as it is right now.  It is up to -- the  
20      degree to which, though, the measures and the  
21      composites meet the criteria, is up to you as a  
22      committee to decide.  And I think you did take

1 the vote, but some are not -- there's no  
2 consensus that's been reached yet.

3 MEMBER YATES: I agree 100 percent  
4 with you in terms of the challenge to the quality  
5 of the composites is the elements of the  
6 composites are given a free pass on a regular  
7 basis, in that having the elements of the  
8 composites go through this process and be  
9 endorsed, only makes the composites stronger.

10 But I have two things to add, and they  
11 have to do with just basic fairness. These  
12 measure have already been endorsed before, and  
13 usability was part of that endorsement. And the  
14 potential target for its usability was presented  
15 probably before as being part of a composite  
16 measure.

17 And this committee and the NQF at  
18 large accepted that use as being acceptable at  
19 that time, and we're changing the definition.  
20 This is was similar to Lucy pulling the football  
21 out before Charlie Brown tries to kick it. I  
22 think this is, you know, sort of last second

1 changes.

2 The implications of this are that a  
3 whole bunch of things that are endorsed out there  
4 that include some of the Yale core measures that  
5 CMS uses, they're part of composites of reporting  
6 for value-based purchasing and for hospital  
7 compare, but not necessarily readily transparent  
8 or seen by the consumer or by the potential  
9 patient.

10 But we're not questioning those  
11 measures that CMS is using that are buried within  
12 complicated scores and outcomes. All of the HARQ  
13 hack-size scores would also fall out because  
14 those aren't transparent to patients. They get a  
15 star rating for the hospital and that's about it.

16 Now, I would argue that -- you could  
17 argue that maybe someone with incredible  
18 sophistication could dig into that and find it.

19 But they could also dig into the  
20 hospitals data by asking for it, with as much  
21 effort as it would take to go into those other  
22 measures that are still sitting out there that

1 really aren't being publicly reported.

2 But we've approved them for use within  
3 CMS's value-based purchasing, readmission rates,  
4 hack-side, all of those other ones that are out  
5 there.

6 So, this is opening up a can of worms  
7 as to what defines usability, and I think we gave  
8 people the reason to expect that a composite  
9 measure being reported was being used, or public  
10 reporting. So, I'm off my soap box.

11 CO-CHAIR GUNNAR: So, I just want to  
12 go on saying this. I was all in for connecting  
13 the dots between publicly reporting -- a  
14 composite measure is fundamentally publicly  
15 reporting -- until I understood, the way I  
16 understand it, is that I could still be a one-  
17 star in stroke if I could, if you will, two-star  
18 and the other four morbidity components, and be a  
19 two-star facility.

20 That means that fundamentally, I'm not  
21 publicly reported. I can't draw that association  
22 the way I understand it. Does that make sense?

1 If, as a consumer, I could go online and be  
2 assured that if I went to a two-star cardiac  
3 surgeon and whatever that -- I'm looking for an  
4 aortic valve enquiring bypass -- and it's two-  
5 star, then I can be assured that it's two-star  
6 both in mortality, as well as each component of  
7 that, that they don't have a heightened level of  
8 stroke or a heightened level of renal failure,  
9 that gets buried in that analysis.

10 And my understanding is that that's  
11 not true, unless I'm corrected.

12 DR. BADHWAR: May I just respond to  
13 that specific question first? So, again, this is  
14 an all-or-none phenomenon. If there is an  
15 outlier that has a very high level of stroke,  
16 that's not going to get buried statistically in a  
17 two-star issue. This is actually going to drag  
18 them down.

19 So, that's point one. Point two is  
20 more philosophical. Speaking on behalf of health  
21 systems here, as well as my role in STS as  
22 Council Chair, and speaking on behalf of STS, I



1 would say the answer is two-fold.

2 I would question, given the close  
3 alignment and sort of attached-at-the-hip  
4 partnership and public reporting transparency  
5 that STS and NQF have had over the years --  
6 decade -- the risk of sort of disapproval of any  
7 one NQF-endorsed measure, as a hospital chair,  
8 when one goes through the quality aspects and  
9 sees that STS is no longer -- it's been sort of  
10 like the Moody downgrade -- that it's no longer  
11 that valued, and many of our quality officers sit  
12 on NQF or are on committees, including my own,  
13 was on just last week, how does -- what's the  
14 optics of that in terms of the reliability and  
15 the brand of STS quality?

16 The quality aspects of the database  
17 and its contribution is at the very center of  
18 what STS values as most important. And if we're  
19 a Moody downgrade because of this issue -- now,  
20 first of all, I'm saying, we would totally  
21 respect NQF and what you decide, but just  
22 remember the public trust and what that might do

1 in terms of optics, if we're now downgrading.

2 It's not maybe the most valued quality  
3 measuring tool, and does that actually help what  
4 we're all trying to achieve?

5 MEMBER CIMA: Can I make a comment?

6 CO-CHAIR FLEISHER: Yeah, make a -- go  
7 ahead.

8 MEMBER CIMA: We just --

9 CO-CHAIR FLEISHER: Before we keep --  
10 I'd just like to get Rissa to comment, and then  
11 we'll continue the comments from the rest of the  
12 committee, because I think NQF should have a  
13 chance to respond.

14 MS. MUNTHALI: Yes, so I really do  
15 appreciate all of the comments, and I think it  
16 does show the strength of NQF endorsement.  
17 Really, what you're saying is, by having that  
18 signal, it signals something to the field. And  
19 that we take pride in.

20 But we also take pride in -- we're not  
21 making the decisions. We have constituted this  
22 multi-stakeholder committee with different

1 perspectives, and I don't think that every  
2 perspective is swaying in the same direction.

3 And so, this is not -- we are trying  
4 to be neutral in this, giving you the opportunity  
5 to see how you're interpreting the criteria and  
6 applying the criteria to the measures.

7 And so, this diverse committee is  
8 signaling that they're not quite sure where  
9 they're going, and this is -- I understand  
10 there's some strong viewpoints here.

11 I think we have to let the process  
12 weigh out. I think the ultimate outcome may not  
13 be as dire as you think. It is important for us  
14 to get, especially now, where we don't really  
15 have a definitive decision, to get others to  
16 weigh in, as well. So, I hope that helps.

17 We can't change, you know, the vote.  
18 The vote wasn't made by NQF, it was made by the  
19 committee members. So, I think what you started  
20 to do to get a sense of where people were feeling  
21 angst is a good thing, because I think it'll give  
22 you some general sense of the trouble spots and

1       what you may have to overcome by the post-comment  
2       call.

3                   CO-CHAIR FLEISHER:   Who would like to  
4       speak up from --

5                   MEMBER JARRETT:   Hi.

6                   CO-CHAIR FLEISHER:   Yeah, please.

7                   MEMBER JARRETT:   Hi.   This is Mark  
8       Jarrett.   So, first of all, following up with  
9       NQF's just, you know, what was just said, I think  
10      this offers up an opportunity rather than, you  
11      know, just a challenge.   It's a really good  
12      opportunity.

13                   Clearly, we're all -- you know, we all  
14      recognize that STS provides a great performance  
15      and quality improvement database that allows us  
16      to really move the needle.

17                   The question really comes about of how  
18      we're defining publicly reported, which is an  
19      issue about composite scores.   And quite frankly,  
20      here we're talking about this, but those of us  
21      who deal also with, you know, CMS stars, with,  
22      you know, three-year rolling averages that are

1 four years old, and other composite scores, like  
2 PSI-90, this is not an unusual discussion, so  
3 actually, I see this as an opportunity to bring  
4 this to, you know, on a national basis forward,  
5 because we have to make a decision, because we're  
6 either going to do, you know, follow science and  
7 say what's right and what really improves care,  
8 or get caught up in the lexicon of, well, if it's  
9 not defined publicly reported this way, then we  
10 don't want that measure.

11 Because that really kind of avoids the  
12 question of why we're measuring these things.  
13 And yes, transparency and giving the public the  
14 right information is really critical. But we  
15 have to make sure we're giving them the right  
16 information.

17 As I said before, if a composite score  
18 has invalid components to it, whether it be one  
19 or three out of seven or ten, then really that  
20 composite score may not be valid all together,  
21 and we need to address both the individual  
22 components, as well as the composite.

1                   So, I don't -- I see this as more than  
2                   an intellectual discussion. I see this as really  
3                   the opportunity, maybe on a national basis, that  
4                   we really address really basic issues going  
5                   forward, because I'm sure it's not going to be  
6                   just related to STS as NQF moves with other  
7                   measures and other fields.

8                   CO-CHAIR GUNNAR: Thank you, Mark.  
9                   Any other comments?

10                  MEMBER SAIGAL: Yes. Can I make one  
11                  comment? And this -- Bill, what you were saying  
12                  about -- I want to clarify that. The reason you  
13                  changed your mind was because you're concerned  
14                  that the two-star rating could cover up poor  
15                  performance in one of the sub-measures?

16                  MEMBER JARRETT: Correct.

17                  MEMBER SAIGAL: And so, that an  
18                  important thing to understand. So, basically --  
19                  but that's morbidity measure is a binary thing.  
20                  So, if you fail one, you fail the whole thing.  
21                  And is it possible to get a two-star rating if  
22                  you fail morbidity?

1 DR. PAONE: Sean, can you answer that  
2 more definitively than I can. I would imagine  
3 that you can probably have a sort of high one-  
4 star rating and get an overall two-star rating.  
5 I don't know how often that occurs, if at all.  
6 Sean, do you know that from the statistical data?

7 MR. O'BRIEN: I don't know how -- I  
8 know for a fact that it can occur. I don't know  
9 how frequently. And I'd just say conceptually,  
10 we don't assume that a site's performance is  
11 exactly the same, that they perform well on  
12 mortality and exactly that much better on each  
13 individual endpoint.

14 The composite measures are averaging  
15 over the different measures, and of course  
16 there's some information lost when you try to sum  
17 up performance on multiple endpoints and multiple  
18 dimensions into a single number.

19 And so, there's not a -- so yeah,  
20 that's an area that's possible.

21 DR. PAONE: You know, I mean, I can  
22 certainly imagine that you can have every one of

1 your morbidities is in one or the other  
2 categories, and you would technically fail that  
3 if it were reported individually. But yet,  
4 overall, it becomes a two-star composite. I can  
5 imagine that that would happen.

6 I just -- what I -- I must admit, as  
7 I sit and listen to this, what I'm not quite so  
8 clear about is, we're not saying the measures are  
9 not important. We're not saying the measured  
10 outcomes aren't important. We're not even saying  
11 they're the wrong measures.

12 I think there's wide agreement that  
13 after all of the study that went into this, that  
14 these are the appropriate measures to be part of  
15 this composite, and many, many randomized trials  
16 and all sorts of reports. So, I'd use composite  
17 measures as outcomes for a variety of reasons,  
18 including statistical ones.

19 What's sort of, I guess, a little  
20 confounding to me is what we're really sitting  
21 here discussing is a changed definition of what  
22 public reporting is.



1           That seems to be basically the entire  
2           issue at hand, particularly for the mortality  
3           outcomes in the mitral categories, and all of the  
4           composite measures, because they're not  
5           specifically and individually reported. Rather,  
6           as part of a composite.

7           I just don't know, at least in my own  
8           mind, and I'm not the most experienced person in  
9           this group, but whether that should be reason to  
10          take these measures, which have been approved for  
11          a very long time, have been vetted and have been  
12          continuously upgraded, to change their status.  
13          It just -- I will admit sitting here, I just  
14          don't quite frankly understand that.

15                 MEMBER SAIGAL: I agree with that and  
16           I. It's a great point, though, that those  
17           identified for the public's use. It isn't like a  
18           killer problem for the measure in my mind. It's  
19           just like a -- it's an important observation that  
20           can be used to improve public reporting, I think.  
21           But not necessarily -- it's not fatal to what is  
22           happening right now, I think.

1 DR. BADHWAR: I would say that these  
2 points are very valid in terms of the question.  
3 But if we look at the robustus (phonetic) of each  
4 of these measures, as you've attested to and  
5 voted on, these are not some random skin  
6 infection issues. These are major morbidity  
7 outcome measures.

8 And we're valuing each of them  
9 independently. And they all have importance.  
10 It's unlikely -- highly unlikely -- that any one  
11 site can be gaming and have a super high stroke  
12 rate and zero renal failure, to have a volume  
13 that would actually attest to public reporting.

14 Remember a couple of things. Just  
15 because you sign up for public reporting and you  
16 have -- you want to participate, if your volume  
17 thresholds are too low, you do not get public  
18 reported.

19 And so, those types of outlier  
20 determination questions that Dr. Gunnar raised,  
21 that's where those types of hospitals may come  
22 up, when they have to do ten of a certain

1 operation and they have a high stroke rate. Yes,  
2 that's a percentage.

3 However, they're not going to get  
4 public reported because they don't meet the  
5 volume threshold. So, the public trust is  
6 protected in that regard.

7 The second thing, let's raise one of  
8 the markers in the composite, and that's deep  
9 sternal wound infection. When this whole process  
10 started a few years ago, deep sternal wound  
11 infection was fairly high and relatively common.

12 And now, we learned about diabetic  
13 management and, you know, how you manage the  
14 sternum, preoperative antibiotics and all of  
15 these other quality instruments that we've done.

16 Deep sternal wound infection now is so  
17 negligible its weight in its contribution is so  
18 minimal. We're down to like the one percent  
19 range across the country because of the value of  
20 each of these measures.

21 And so, it gets back to the previous  
22 argument. If one degrades or takes away the

1 importance at a hospital level, there may not  
2 even be public reporting, or just learning or  
3 tending to how are they going to improve if it's  
4 not an endorsed entity.

5 DR. PAONE: If I could just take one  
6 more second and use an example here that Mark  
7 just pulled up from the website that may  
8 illustrate some of the questions about the value  
9 of the individual components I'm staring at for  
10 the AVR composite, there is one site that has two  
11 stars for operative mortality, one star for  
12 morbidity, who is a two-star program overall.

13 At least in this brief look there are  
14 four sites who have two stars for mortality, but  
15 one star for morbidity, who are one-star  
16 programs.

17 And so, I think that points to the  
18 effectiveness of the morbidity composite and  
19 being able to identify a lesser functioning or a  
20 core outcome facility, and I think actually  
21 confirms the value of the composite over  
22 individuals.

1                   Because I would suspect the -- and I  
2                   have no way of knowing from this data, and maybe  
3                   that's part of the concern and I get that, but  
4                   it's not unlikely that they -- each individual  
5                   component may be a low two-star, but it's a one-  
6                   star composite, as well as in the other  
7                   direction. So, that's just an example of why I  
8                   think that this is valuable.

9                   MEMBER GROVER: Just a question moving  
10                  forward. Would it help if -- and I don't know  
11                  that this would be approved at the higher levels  
12                  of STS -- if we did this, the morbidities and the  
13                  incidents at each site and the mortality you've  
14                  already got on there, is that what you all are  
15                  after?

16                 So, what if we go ahead, in addition  
17                 to having the composite, do we know the results  
18                 that go into that composite? What percent --  
19                 stroke percent -- renal failure percent  
20                 mortality, that type of thing?

21                 MEMBER EATMON: Yes, that would be  
22                 something more aligned to what a patient is

1 looking for to kind of see, in terms of making  
2 the decisions, or just being educated themselves.  
3 And so, if that was a percentage number, they  
4 could have a realistic view of what the  
5 probability was.

6 MEMBER GROVER: So, was that  
7 implied -- was the NQF definition of public  
8 reporting for this?

9 CO-CHAIR FLEISHER: Yeah, that would  
10 be an example in the -- you know, the complicated  
11 question is, you know, if you look at CMS  
12 hospital compare, they don't -- I mean, you can  
13 get to some of the data, but a lot of times they  
14 say no different.

15 So, it might be, you know, whether STS  
16 comes up with a plan of how they want to present  
17 it. I mean, I'm just throwing it out there that,  
18 you know, the composite, if it fails, why does it  
19 fail? Where does, you know, if they have higher-  
20 than-expected stroke or something that's behind  
21 the numbers, how it's displayed is not what NQF  
22 endorses.

1                   It's more of that they have a plan  
2                   that we except to make this public reporting in  
3                   some manner. And then, we vote on what that  
4                   manner is.

5                   DR. BADHWAR: So, if I might, I think  
6                   the concept is an excellent one. The  
7                   practicality is where I think we'll have some  
8                   challenges. And I'm not speaking on behalf of  
9                   STS yet, because we have to actually do the  
10                  analysis.

11                  But having been involved in a lot of  
12                  these risk models and developing them, the good  
13                  thing is that the incidents -- the actual hard  
14                  incidents -- of many of these morbidity endpoints  
15                  is so low that in order to develop a risk-  
16                  adjusted model for an outcome, such as stroke or  
17                  such as deep sternal wound infection, the actual  
18                  data that's going to be required and the length  
19                  of that, so right now we have a three-year  
20                  composite for AVR.

21                  If we develop a separate model to  
22                  public report these items for a stroke, I mean,

1 Sean can potentially speak to this, or we can  
2 come back with an answer, I'm a little concerned  
3 that we might not have the actual sample size of  
4 the one event to be able to report risk-adjusted  
5 outcome. It might take like a five-year  
6 reportable issue.

7 CO-CHAIR FLEISHER: But this is an  
8 endorsed -- these individuals. So, all I'm --  
9 again, as an individual asking, if you said this  
10 is an outlier, I don't know whether the committee  
11 would accept or not.

12 But it's really, you're asking for a  
13 plan of how you would publicly report without  
14 being specific in the way public reporting is  
15 defined for the individual components. AJ, did  
16 you have a comment? Or Chris, did you have a  
17 comment?

18 MEMBER HANDY: This is John Handy.  
19 So, I am kind of bugged by the fact that it seems  
20 like it's the prerogative of this committee to  
21 define what public reporting is.

22 I mean, we've had a definition in



1 front of us for about 30 or 40 minutes right now,  
2 but each of us is interpreting a little bit  
3 differently.

4 Some of us have felt that the public  
5 reporting is acceptable in its present form, and  
6 others feel that it needs to be more granular.  
7 Are we not working that out right now?

8 CO-CHAIR FLEISHER: So, I'm sorry, I  
9 didn't hear all, but what we were just discussing  
10 is, it is this committee's prerogative in the  
11 surgical space of what is acceptable public  
12 reporting.

13 So, NQF, at a higher level in the  
14 composite, did not say all public reporting is  
15 the same. It all must be hospital compare. What  
16 it's saying, in our domain do we feel that STS,  
17 for usability, has done public reporting that we  
18 find is a benefit to patients?

19 I know that's a really --- I need  
20 to -- I mean, but parsing how -- it's -- we are  
21 individually responsible in each of the standing  
22 committees.

1                   MEMBER MOYER: So, I'm torn on this  
2                   for so many reasons, because I think, well yes,  
3                   we define it for the surgical area. I think  
4                   consistency across the committees is a reasonable  
5                   expectation as a measure developer.

6                   And while we look at all the STS  
7                   measures, if you're like an NC2A or a joint  
8                   commission, where they're going to a bunch of  
9                   different committees, I think it's important that  
10                  you could have the same expectation of the same  
11                  result.

12                  As a purchaser, I'm always going to go  
13                  for the composite. You know, I like it rolled  
14                  up, I like the differentiation that comes with  
15                  that. Gee, I'm really -- if I were to put my  
16                  patient hat on, I like to see everything. I like  
17                  digging into the details.

18                  Whether that's actually useful I don't  
19                  know, but I like to be able to see it, as a  
20                  patient, which I don't know what -- I know I  
21                  don't represent my organization, but I don't know  
22                  if I officially represent my stakeholder ground.

1       So --

2                   CO-CHAIR FLEISHER:   So, we -- I know  
3       that my colleague is leaving at 3:30.   Are other  
4       people leaving?

5                   PARTICIPANT:   I'm leaving at 3:00, but  
6       I'll be on the phone.

7                   CO-CHAIR FLEISHER:   Yeah, and I'm  
8       leaving at 4:15 on the phone.   But -- so, we need  
9       to be done between -- in the next hour or so.  
10      Elisa?

11                   MS. MUNTHALI:   So, you know, I do want  
12      to clear the air.   This decision to make this  
13      criterion of use must-pass was a very thoughtful  
14      one.   Since you last met and maybe had a very  
15      substantive discussion about it, quality  
16      measurement has changed, accountability has  
17      changed.

18                   The burden of measurement has  
19      increased, and one of the reasons we have made  
20      this must-pass is because we got so much critique  
21      from so many in Quality about just looking at the  
22      scientific merits of measures is not enough.   You

1       need to look at the implementation of those  
2       measures, the context in which they're used.

3               And so, this is one way in which we're  
4       demonstrating that to say -- not to say -- to put  
5       limits on you, but to try to quantify all of  
6       this. That is quality measurement. Not just  
7       looking at the reliability and validity of  
8       measures. We understand that's important.

9               But if these are going to be put out  
10      as national standards that can be picked up by  
11      any entity, we need to make sure that to the  
12      extent possible, that there is transparency to  
13      the extent possible, and that is where the  
14      committee can decide that.

15              But Amy is right. Within all of this  
16      it is you as a committee determining the degree  
17      to which it's meeting that.

18              MEMBER YATES: I've got to add one  
19      thing. There's a consequence here, and the  
20      consequence is, is that as you become more  
21      granular, as you start to -- if you start to  
22      destabilize the composite measures by reporting

1 the individual parts of the measures, and  
2 scientifically if there's concerns from the  
3 collecting group or registry that if reported  
4 individually, they lose validity and reliability  
5 in terms of the risk adjustments and everything  
6 else that goes into the composite, you run the  
7 risk that people -- the surgeons, the providers,  
8 will no longer trust what's being reported.

9 I don't trust what's being reported in  
10 my specialty through two measures that were  
11 endorsed here, because of absolute lack of risk  
12 adjustment. But I'm held subject to it,  
13 regardless of the seats assessment being 0.67.

14 As that gets down to surgeon-specific,  
15 it becomes even less risk-adjusted and it  
16 becomes -- and the more granularity they get, the  
17 harder the risk adjustment and the harder the  
18 fairness.

19 And what you do is, you drive away  
20 care and access to care for those patients that  
21 are at the margin of acceptable risk because  
22 everyone is going to go through gang theory and

1 try to avoid risk.

2 And you're going to end up with less  
3 patients getting less care and it's going to hurt  
4 the most vulnerable patients first, and I think  
5 you have to be very careful how granular you  
6 want, because the public's crying for  
7 granularity, but the more granular you get, the  
8 more the people at risk are left out of the  
9 discussion.

10 DR. BADHWAR: To echo that interesting  
11 comment, I would also say that it's also  
12 applicable to the actual participant sites that  
13 actually are doing the voluntary public  
14 reporting.

15 And if there's a question on some of  
16 those validity issues, the subcomponents, which  
17 we will take back and we will respond as fully  
18 respectful to this process.

19 But I'd raise that secondary question.  
20 What happens if the sites say, well, I don't want  
21 to public report now? Then, it actually  
22 decreases the entire purpose of what we're trying

1 to do here together.

2 CO-CHAIR FLEISHER: So, we've got a  
3 lot of theoreticals. The question is, what's --  
4 we've only got about an hour to an hour-and-a-  
5 half left of the meeting. Fred, you had a  
6 comment first?

7 MEMBER GROVER: I'll shut up because  
8 I'm not supposed to talk much, but I'm looking at  
9 this definition and nowhere in here do I see that  
10 it says that if you put -- if approved measure is  
11 part -- publicly reported by being a part of a  
12 composite measure, that that's not public  
13 reporting. And I think, in all fairness, we  
14 assumed it was.

15 And I think the definition lacks  
16 specificity and that needs to be considered. I  
17 really -- it really ticks me off.

18 MEMBER YATES: And what I just said  
19 isn't theoretical. It's actually happening, and  
20 I know that from polling within the American  
21 Association of Hip and Knee Surgeons.

22 And I also know that it's -- there are

1       surgeons in our community that scan who they're  
2       going to see in their office by their BMI. And  
3       if their BMI is over 35, they don't even get an  
4       appointment.

5               So, there -- and that has a lot to do  
6       with the question of reporting and perceptions of  
7       quality.

8               CO-CHAIR FLEISHER: So, are we still  
9       at the same place for everybody who's voted?  
10      Okay, so we're not going to call another vote  
11      unless somebody -- so, we need clarity and -- or  
12      we'll have more discussions for comment, as well  
13      as discussions internally, just so that --

14              (Off-microphone comments.)

15              CO-CHAIR FLEISHER: No, not criteria.  
16      But I think we should make the CSAC chairs aware  
17      of --

18              PARTICIPANT: They will be. Yes.

19              CO-CHAIR FLEISHER: -- what's going  
20      on. So, the question is --

21              CO-CHAIR GUNNAR: So we all know,  
22      there's one measure that's a process measure we



1       should go that's not -- doesn't line up under  
2       this.

3                   CO-CHAIR FLEISHER: Right. So, we  
4       should -- people need to stretch? Or they just  
5       want to go to the -- go ahead.

6                   PARTICIPANT: So, the process measure.

7                   CO-CHAIR FLEISHER: All right. That  
8       process measure is -- it's 118, Anti-Lipid  
9       Treatment Discharge. And Keith's not with us  
10      today and it's Amy and TeMaya for discussions.  
11      So, the developers want to introduce this first?

12                  MR. ANTMAN: Yes, thank you. As has  
13      already been said, this is the anti-lipid  
14      treatment discharge measure. It is worth  
15      pointing out, this is one of the morbidity  
16      components for the CABG composite. So, although  
17      this differs from the other measures under review  
18      today --

19                  DR. PAONE: I apologize. It's not one  
20      of the morbidity measures. It's one of the  
21      perioperative medications which the CABG group  
22      has the two process measures, which are the use

1 of the use of the internal mammary artery and  
2 perioperative medications.

3 MR. ANTMAN: Yes. Thanks to Dr. Paone  
4 for that correction. Yes, it is part of a  
5 different domain in the CABG composite. The  
6 domain is labeled Receipt of Required  
7 Perioperative Medications.

8 But it is not immune to the concerns  
9 that were expressed before, because although when  
10 the CABG composite is publicly reported, there  
11 are domain scores and domain star ratings for  
12 each of the domains on the public reporting site.

13 You cannot drill down from the receipt  
14 of required perioperative medications domain to  
15 the individual, to the four or five individual  
16 perioperative medication measures. So, it is  
17 subject to that same concern.

18 That said, we'll welcome discussion of  
19 this measure.

20 CO-CHAIR GUNNAR: So, for evidence.

21 MEMBER MOYER: I don't believe there  
22 was any updates to the evidence since the last

1 submission, and that's fine.

2 CO-CHAIR GUNNAR: Any other  
3 discussion? And we vote.

4 MS. KOSURI: Voting is now open for  
5 the evidence portion of the measure criteria for  
6 Measure 0118.

7 MS. SKIPPER: And note, so those of  
8 you are voting high, recast your vote. The  
9 highest this measure can get is moderate, since  
10 no QQC was submitted.

11 CO-CHAIR GUNNAR: We may not have a  
12 quorum. Do we not have a quorum now? Do we kick  
13 this one down the road?

14 MS. KOSURI: So, give people another  
15 moment or two. And we're just waiting on two  
16 more votes.

17 (Off-microphone comments.)

18 MS. KOSURI: Okay, voting is now  
19 closed for Measure 0118. For the evidence  
20 portion of the measure criteria, 14 people have  
21 voted moderate out of 14 total votes. Thank you.

22 CO-CHAIR GUNNAR: So, we move on to

1 gap.

2 MEMBER MOYER: So, this presents a  
3 perennial topic and actually another interesting  
4 discussion around composites. The median value  
5 for participants on this was 99 percent.

6 So, I know my co-presenter isn't here,  
7 but I think both of our worksheets, we expressed  
8 a concern over the measure being topped out.  
9 That said, if it's part of an all-or-none  
10 composite, that could still be a meaningful  
11 component as part of that composite. So --

12 CO-CHAIR GUNNAR: Right. So,  
13 there's -- this gives -- to bring history to this  
14 committee, we were the first committee to  
15 recommend endorsed-but-reserved status on a  
16 topped out measure where the gap didn't exist  
17 anymore.

18 So, that's one possible direction for  
19 this particular measure going forward And I  
20 forget how we get there. We vote on gap and if  
21 there's no gap low, then we can make the  
22 recommendation for reserved status. Is that

1       how -- but endorsed? How do we do this?

2                   MS. MARINELARENA: According to our  
3 guidance, this measure is not eligible for  
4 reserve status because reliability has not been  
5 demonstrated for the measure score. So, we only  
6 have data element reliability testing.

7                   CO-CHAIR GUNNAR: So, the answer to  
8 this is, we follow the path through the voting  
9 process and if we get to a place where we stop,  
10 then that's where it stops, with no opportunity  
11 for reserve status, apparently. Yes.

12                  PARTICIPANT: How did we do it last  
13 time?

14                  PARTICIPANT: What's that?

15                  CO-CHAIR GUNNAR: I can't remember the  
16 measures that we put in reserve, and --

17                  PARTICIPANT: We put in the antibiotic  
18 skip measures, which obviously are extremely  
19 important measures.

20                  CO-CHAIR GUNNAR: Right.

21                  CO-CHAIR FLEISHER: I'm just curious  
22 about -- given the compliance. Does this make

1 any difference in your composite anymore?

2 DR. PAONE: I wouldn't --

3 statistically -- Sean, are you still on the line?

4 Can you address that? Since it's an all-or-none,

5 I would think just a couple -- I mean, overall

6 it's a good thing that this composite has, you

7 know, a very small gap. There is still a

8 difference between the lowest and the highest.

9 I will point out in terms of the

10 specifics of lipid therapy, that this is a 1A

11 guideline for cholesterol in the recent

12 cholesterol guidelines for patients with

13 atherosclerotic disease, and certainly anyone

14 having undergone coronary bypass surgery falls

15 into that category.

16 So, it's an important measure,

17 certainly from that standpoint. I mean, it makes

18 as much difference as the pre-op beta blocker and

19 the -- you know, pre -- I'm sorry, the post-op

20 data blocker and the pre-op aspirin.

21 So, I don't know. Statistically,

22 Sean, is there -- do you have any thoughts on

1       that?

2                   MR. O'BRIEN:  Yeah.  I don't know to  
3       the extent which it drives the composite.  And I  
4       think we don't assume that it's a major driver of  
5       the composite.

6                   But I think we justify it based on it  
7       being a safeguard, whereby if a site did have  
8       substantially lower performance on this measure  
9       than that would contribute to the composite being  
10      lower.

11                  So, it's not a major driver, but it's  
12      not adding noise to it, either, and it's there  
13      for accountability.

14                  MEMBER YATES:  One point of  
15      clarification.  Ninety-nine percent -- a lot of  
16      hospitals are 99 percent compliant for all their  
17      patients.  How many hospitals are not 99 percent?  
18      That's the question.

19                  Because I see on here there's still  
20      some scores in the low 90, and that's the  
21      institutions' response.  Being -- you know, a  
22      whole lot of hospitals being perfect at it

1 doesn't mean there's not a gap.

2 DR. BADHWAR: That's absolutely right.

3 In fact, because it's in the composite and  
4 because we value that as important, I will flip  
5 around it.

6 So, you're 100 percent right in your  
7 statement. Flip it round the other way. If it  
8 wasn't in the composite, then human behavior  
9 takes effect and the likelihood of them focusing  
10 on discharging someone with high-dose lipid  
11 therapy may be skipped. And then, it does do --  
12 may have a negative impact, since it is a  
13 guideline recommended point. But --

14 MEMBER YATES: So, what percentage of  
15 the hospitals fail?

16 DR. BADHWAR: Yeah, I think it's a low  
17 percentage. But since it's also an all-or-  
18 none --

19 MEMBER YATES: Right.

20 DR. BADHWAR: Then, we'd have to break  
21 down that data.

22 MEMBER YATES: Well, is it two, three,



1 four percent?

2 DR. BADHWAR: I'd say that's probably  
3 accurate.

4 MEMBER YATES: Okay. Well, two,  
5 three, four percent would be adequate gap for  
6 something. That's a -- I think a two or three,  
7 four percent hospital failure rate on this would  
8 be a major problem for a 1A recommendation.

9 Do we have that data, as we scroll  
10 back on the screen there?

11 MEMBER MOYER: Now to where? Where  
12 are we looking? I missed that.

13 MEMBER YATES: I'm not asking -- you  
14 know, the hospitals are performing 99 percent,  
15 but which hospitals -- what percentage of the  
16 hospitals don't do that?

17 CO-CHAIR GUNNAR: They want the data  
18 for that gap.

19 MEMBER YATES: There we go, for  
20 performance. So, there's still -- am I incorrect  
21 in saying that there's still a range there?

22 MR. O'BRIEN: The STS provided some

1 data looking at variation and performance across  
2 categories of performance.

3 So, we looked at categories of  
4 hospitals based on their past performance in one  
5 time period and look at their compliance rate for  
6 anti-lipid medication at a more recent period,  
7 and across the low-, mid- and high-performance  
8 groups, the percentage of anti-lipid medication  
9 increased from 89.8 percent to 99.8 percent.

10 So, that's the degree of differences  
11 across the performance groups.

12 MEMBER MOYER: It's actually further  
13 down in the document. It's another one of those  
14 funky tables. But if I'm reading this right, the  
15 bottom ten percent of hospitals has a 46 percent  
16 compliance with this. And then, the next decile  
17 starts at 94 percent. It reaches 99 percent out  
18 of like 50 percentile. So, for those bottom  
19 hospitals -- what page is this, it's page 19,  
20 there.

21 So, I mean, for those bottom  
22 hospitals, that is a pretty significant gap.

1 They're less than 50 percent.

2 MEMBER YATES: Yeah. And again, for  
3 a level-1A recommendation, obviously there's  
4 excellent evidence for it being beneficial. Any  
5 kind of gap in this one I would think still would  
6 warrant some consideration for being at least  
7 moderate evidence for gap.

8 CO-CHAIR GUNNAR: Any other  
9 discussion? Vote for gap?

10 MS. KOSURI: Voting is now open for  
11 performance gap for Measure 0118. Okay. Okay,  
12 voting is now closed. For a total of 14 votes,  
13 we had 12 votes for moderate and two votes for  
14 low.

15 For the performance gap portion of the  
16 measure criteria, for Measure 118 I will also  
17 apply the percentage. So, 86 voted for moderate  
18 and 14 voted for low. So, this portion of the  
19 measure is passed by the committee.

20 DR. BADHWAR: Drs. Gunnar and  
21 Fletcher, if I might, I just want to thank  
22 everybody. I have to depart. I'll leave

1 responses in the fine hands of Mark Antman and  
2 Gae Paone.

3 CO-CHAIR GUNNAR: Thank you for all  
4 your presence and your input today. Thank you so  
5 much.

6 CO-CHAIR FLEISHER: And your  
7 willingness to engage --

8 CO-CHAIR GUNNAR: Yes.

9 DR. BADHWAR: Anytime.

10 CO-CHAIR FLEISHER: -- in complex  
11 issues that we're still grappling with.

12 DR. BADHWAR: We're all on the same  
13 page. Thank you.

14 PARTICIPANT: Go Mountaineers.

15 PARTICIPANT: That's right, go  
16 Mountaineers.

17 MS. SKIPPER: So, we're ready for the  
18 discussion of the reliability for 0118.

19 MEMBER MOYER: The only concern that  
20 I had and that I saw mentioned was that potential  
21 level of analysis question, which seemed to be a  
22 kind of non-issue in a previous measure. So --

1 CO-CHAIR GUNNAR: TeMaya, any  
2 question? Anyone else? All right, we will vote  
3 on reliability.

4 MS. KOSURI: Voting is now open for  
5 the reliability portion of the measure criteria  
6 for Measure 118.

7 PARTICIPANT: So, that's the problem.

8 MS. KOSURI: Okay. Voting is now  
9 closed. For a total of 14 votes we have 13 votes  
10 for moderate and one vote for low.

11 For the reliability portion of the  
12 measure criteria for Measure 118, the committee  
13 has passed this measure with -- let me provide  
14 the percentage.

15 CO-CHAIR GUNNAR: Move on to validity?

16 MEMBER MOYER: It looks like there was  
17 some question around the method of validity  
18 testing used.

19 I think we discussed this on a  
20 previous measure, as well, that it looked at  
21 stability and performance over time frames where  
22 you might expect to see an improvement in

1 performance, although, honestly, given the  
2 performance distributions in the two time frames,  
3 I'm not sure how much improvement you would have  
4 seen. So --

5 CO-CHAIR GUNNAR: Any other comments?  
6 We'll vote on validity.

7 MS. KOSURI: Voting is now open for  
8 the validity portion of the measure criteria for  
9 Measure 118.

10 (Off-microphone comments.)

11 MEMBER CIMA: I don't have it active  
12 on my screen.

13 MS. KOSURI: It should be active.

14 PARTICIPANT: I had to refresh my  
15 screen, Bob.

16 MEMBER CIMA: I just did that and it  
17 didn't do anything.

18 MS. SKIPPER: If you're still having  
19 trouble, you can chat in your vote and we'll  
20 record it.

21 MEMBER TEMPLE: This can be a big  
22 component, I would rank it as a moderate.

1 MEMBER MOYER: Okay, thank you,  
2 Larissa.

3 (Off-microphone comments.)

4 PARTICIPANT: I'll put it as moderate.  
5 I just lost the screen now. I'm going to re-log  
6 on completely.

7 MS. KOSURI: So, voting is now closed.  
8 We have 14 votes for which -- for moderate for  
9 the validity portion of the measure criteria for  
10 Measure 118.

11 CO-CHAIR GUNNAR: Feasibility is next,  
12 right? Yep. No additional comments? It's  
13 feasible, all the reasons? All right. Vote.

14 MS. KOSURI: Voting is now open for  
15 the feasibility portion of Measure 118. And,  
16 Larissa, if you're still having an issue, feel  
17 free to chat. We can see how you vote via chat.  
18 Or, verbally is fine, as well.

19 MEMBER TEMPLE: It's working now.  
20 Thanks.

21 MS. KOSURI: Just waiting on two more  
22 votes. Voting is now closed for the feasibility

1       portion of the measure criteria for Measure 118.  
2       With a total of 14 votes, we have 11 voting for  
3       moderate and three voting for high, which means  
4       the committee has passed this portion of the  
5       measure.

6                   CO-CHAIR GUNNAR:   And now, to use and  
7       usability.

8                   MEMBER MOYER: Really there's the same  
9       pattern issue we've been discussing. It's not  
10      individually reported but it is part of the  
11      composite. That composite seems to show a lot of  
12      variation on the website, so it's kind of --  
13      seems useful to me, but the individual measure  
14      itself isn't listed up there.

15                  CO-CHAIR GUNNAR:   So, what's the  
16      composite that's -- can you explain a little bit  
17      more about the composite, how it's used and  
18      what --

19                  DR. PAONE:   The composite is the three  
20      medications. It's anti-platelet agents, it's  
21      postoperative use of beta blockers, and it's  
22      post-discharge. That's four. I'm sorry, it's



1 four.

2 It's preoperative beta blocker and  
3 discharge beta blocker, anti-platelet medication  
4 at discharge, and anti-lipid treatment at  
5 discharge.

6 CO-CHAIR GUNNAR: Can you talk about  
7 the -- and do you give star ratings for these, as  
8 well?

9 DR. PAONE: There's a star rating for  
10 the composite, currently two or three stars.

11 CO-CHAIR GUNNAR: And given what sort  
12 of gaps exist, I mean, we understand that gaps  
13 for this generally. Is there --

14 DR. PAONE: For the -- the gap overall  
15 is actually -- and I don't remember exactly.  
16 It's broader than the gap for any medicine  
17 individually, as you might imagine. Because if  
18 you're missing any one of them, it's -- again,  
19 it's a dichotomous composite.

20 You either get all of them or you get,  
21 you know, it's a zero or one report. I don't  
22 remember off the top of my head what the

1 difference is, but it is -- clearly it has to be  
2 larger than the gap, obviously, for any one of  
3 the medicines, because it's a summation,  
4 essentially, of the four.

5 And so, to the extent that, you  
6 know -- and this goes back to the discussion  
7 we've been having. All right? I mean, we've had  
8 this. If usability is defined as being  
9 individually publicly reported on our website --

10 CO-CHAIR GUNNAR: This one is not.

11 DR. PAONE: It's not. I mean, we've  
12 had that conversation. I can't make an argument  
13 that it is. It is not.

14 There are other ways that are  
15 important that the data is used. It's used  
16 individually by centers, it's used by hospitals  
17 to look at, it's used by surgeons.

18 As a division head I can tell you, for  
19 me this was an important domain that we worked  
20 very hard at getting to 100 percent on for many,  
21 many years.

22 And when somebody missed one, we

1 investigated why that patient didn't go home on  
2 lipids, or didn't go home on aspirin, because we  
3 know these outcomes are important to the  
4 subsequent longer-term benefits of the operation.

5 CO-CHAIR GUNNAR: So -- so --

6 DR. PAONE: But I can't -- I -- I  
7 don't mean to interrupt you, but --

8 CO-CHAIR GUNNAR: No, no, no, this is  
9 exactly right.

10 DR. PAONE: -- your point is -- what  
11 you're going to make is exactly -- is, if the  
12 argument or the discussion or the conversation is  
13 going to be, is it publicly reported, the answer  
14 is, individually it is not.

15 CO-CHAIR GUNNAR: No, actually, it  
16 wasn't, actually.

17 DR. PAONE: Okay.

18 CO-CHAIR GUNNAR: I don't mean to talk  
19 over you, Gae. I just wanted -- I want you to  
20 understand that if -- it depends on how this  
21 is -- you know, either the entire thing is topped  
22 out -- I mean, we already know that the variance

1 for this particular component of it is really  
2 bumping up against 100 percent. Right? I mean,  
3 you're at 99 percent. Your IQR is limited.  
4 Right?

5 And the piece is, is that it's like an  
6 assumption that that's going to be 100 percent  
7 virtually in the -- in a way, it's -- that I have  
8 a more comfortable feeling with saying, it's  
9 virtually publicly reported, but it's not --  
10 maybe you just need to take it out of the whole  
11 thing. Right?

12 It's really not adding to the -- maybe  
13 it should just be the other three. I'm bringing  
14 this up just -- this gets back to either we have  
15 a demonstrable gap that we're trying to get to,  
16 one person or one facility not being 100 percent  
17 is a facility that makes it one star.

18 It must be, right? To be a one-star  
19 means that you're virtually not 100 percent. If  
20 I'm tracking this particular measure, you're not  
21 meeting it if you're not 100 percent, basically.

22 MEMBER HANDY: John Handy. When you

1 go to the website and actually look at this  
2 particular category, it's receipt of required  
3 perioperative medications, so the conglomerate  
4 that was mentioned before, that's got the most  
5 variability with regard to three and one stars,  
6 of all the four columns that are there, five  
7 columns that are there.

8 CO-CHAIR GUNNAR: And so, the question  
9 on the table -- that's great, John -- is, what  
10 impact did this particular measure have on that  
11 analysis?

12 DR. PAONE: I can't answer that  
13 sitting here. But I'm looking at a one-star  
14 program in medications that is at 59.2 percent of  
15 the patients receive all four of these  
16 medications.

17 The argument that I would make in  
18 terms of, you know, not taking this one out if  
19 it's topped off, is because we think they're all  
20 important. They're all equally important. And  
21 if you take this one out and then the next three  
22 get -- you know, you look -- or get better, or --

1       presumably, the composite would get worse.

2               But then, one more would get topped  
3       out, and now you've got a composite of two. And  
4       then, eventually, you've got one, you don't have  
5       a composite. Now, you're looking at an  
6       individual number.

7               Does this matter at all? Does this  
8       whole perioperative medication, is this important  
9       enough to be part of it?

10              Well, we obviously think so. It's  
11       been part of it. This was the -- one of the  
12       first -- right? -- was the CABG mortality  
13       composite. And it's publicly reported and, you  
14       know, it's -- I lost my train of thought here for  
15       a second. I apologize.

16              CO-CHAIR GUNNAR: So, we'll -- any  
17       other comments? Thank you for that, Gae. Mark,  
18       do you -- other question, or another comment?

19              MR. ANTMAN: Yes. If I may add, and  
20       I apologize, I think it was I who interrupted  
21       Dr. Paone's train of thought.

22              For what it's worth, looking onto the

1 website, again, it's not possible to drill down  
2 to determine how many, or, excuse me, which of  
3 the one-star hospitals, again for the  
4 perioperative medication domain, it's not  
5 possible on the website to determine exactly why  
6 they're one star, for which of the four  
7 medication measures they have failed, or  
8 potentially more than one.

9 But it may be worth noting that  
10 looking as -- after sorting by the star rating  
11 for perioperative medications, there are  
12 approximately 60 centers that scored a one-star  
13 for perioperative medications.

14 So, it's clearly a problem, even  
15 though it's -- the performance is 99 percent for  
16 this one medication.

17 Again, we don't know where the centers  
18 are failing for the other medications, but  
19 clearly, for an all-or-none domain, an all-or-  
20 none composite of perioperative medications, it's  
21 a significant quality issue that there are that  
22 many centers that are just getting one star.

1                   If I may add briefly, Dr. Gunnar,  
2           this -- from the STS staff perspective, having  
3           heard the patient perspective today of what is  
4           valuable and what is understandable on the  
5           website or not, I will note that I have realized  
6           in looking at our public reporting pages, that  
7           although we've explained multiple times in this  
8           meeting what we mean by the major morbidity  
9           domain and the perioperative medication domain,  
10          and what goes into those domains, at the bottom  
11          of the page, Amy, I think you referenced what we  
12          say at the bottom of the page earlier.

13                   We say, absence of major morbidity,  
14          patients who do not experience any major  
15          morbidity. We define major morbidity elsewhere  
16          on our website, but we don't define it here. The  
17          same with required perioperative medications.

18                   When I go back home to Chicago  
19          tonight, and when I'm back in the office  
20          tomorrow, I'm going to make sure that my  
21          colleagues who work on the website will realize  
22          that we need that definition on this page, so



1       that, at least, is understandable.

2               So, in that respect this discussion  
3       has been very valuable for me.

4               DR. PAONE: Let me -- I got my train  
5       of thought back with the perioperative  
6       medications. One of the points I wanted to make  
7       was, it's a smaller component of the overall  
8       composite score, but it's not an insignificant  
9       one.

10              There are a fair number of programs,  
11       and I don't know exactly how many, but it is  
12       not -- it is very possible to be two stars in  
13       mortality, two stars in morbidity, three stars in  
14       perioperative medications.

15              And because of the small -- and this  
16       is one of the reasons for the multi-dimensional  
17       domain -- a composite score, that three-star in  
18       perioperative medications can drive you to be a  
19       three-star program overall for the composite.

20              Now, you can't be one star in  
21       mortality or one star in morbidity, and be a  
22       three-star program, because of your medications.

1                   But it is another differentiator in an  
2                   environment where we're trying, in as simplistic  
3                   a manner with this three-star composite rating,  
4                   not ranking, program, to differentiate programs  
5                   that otherwise would be really gapped together  
6                   quite closely.

7                   MR. ANTMAN: Thank you. I actually --  
8                   sorry. Go ahead, Josh.

9                   MEMBER STEIN: I was just going to  
10                  say, in my field there are some quality metrics  
11                  that are like never-events, and, you know, this  
12                  kind of reminds me of some of those.

13                  And it seems like we're being tasked  
14                  to evaluate and show, you know, a spread in  
15                  differences in performance on something that  
16                  should be a never-event. So, you know, if all  
17                  the hospitals are doing great at it, there can be  
18                  consequences of taking that off.

19                  I guess it puts us in a -- as people  
20                  trying to review these measures in a difficult  
21                  position if we're being asked to potentially ding  
22                  a measure because it's not showing us enough

1       variability, when it's supposed to be a never-  
2       event type of thing.

3                   MR. O'BRIEN:   This is Sean O'Brien.  
4       Can I jump in and just ask whether the bar charts  
5       have been displayed that show the performance  
6       gaps across the low-, mid- and high-performance  
7       groups?   Because my impression is that we provide  
8       a data that does demonstrate a performance gap.

9                   On a relative scale, there's a 50-fold  
10       difference in the frequency of patients who do  
11       not receive anti-lipid medications across  
12       hospitals in the highest performance group  
13       compared to the lowest performance group, but I  
14       just want to make sure those data have been  
15       presented on everyone's radar when you're  
16       thinking about evidence of gap.

17                   CO-CHAIR FLEISHER:   Thank you.   You  
18       know, Mark, I want to thank you for your last  
19       comment.   And I'm thinking back to Amy and TeMaya  
20       and Elizabeth.   And where I came from, this in a  
21       more -- specific to the language perspective.

22                   But what I've learned today also, is

1       that David's comments that the public knows how  
2       to use this website, as well as how to ask the  
3       physicians for more data why they're an outlier,  
4       or why they're not a top hospital, doesn't exist.

5               And the question -- you've always been  
6       leaders. You know, it's interesting that there  
7       was a law that was before Congress to actually  
8       make transparency of quality metrics on  
9       individual hospital websites. And I asked Nancy  
10      Foster why HA was not supportive, and they said,  
11      there needs to be a national website.

12             So, I'm -- you know, dating back to  
13      what I asked in the beginning, but really  
14      reframing it from a patient perspective, if you  
15      can teach patients how to use your website on  
16      your website and how to ask the right questions  
17      and understand the components and why you should  
18      say, if you're a one-star hospital, or even a  
19      two-star hospital, ask them why, and you could  
20      get to that other data, that would be a huge  
21      advantage from a public reporting perspective.

22             So, I don't know how you get there

1 quickly, but that's what I just learned in your  
2 response to Amy's comment. And that -- then, to  
3 be honest, you would do a great service to the  
4 public and to this entire field.

5 MR. ANTMAN: And I'll add, if I may,  
6 the STS has a separate patient portal. I don't  
7 know offhand, we could look quickly, I'm not sure  
8 what is said on that patient portal with stars  
9 explaining these metrics and what goes into these  
10 metrics, but that's certainly one thing that I  
11 and my colleagues will be looking at closely, be  
12 sure that adequate explanations are provided  
13 there.

14 CO-CHAIR FLEISHER: Yeah, because that  
15 actually could be part of the plan.

16 MR. ANTMAN: Yes.

17 CO-CHAIR FLEISHER: Because, I mean,  
18 from my perspective, although I'm supportive,  
19 that would make me feel very good that the  
20 usability of your data changes overnight by  
21 making patients understand how to use the data  
22 and how to drill down, even if it's not -- even

1       for explanatory purposes.

2                   And all the reasons that David nicely  
3       outlined and you did, why the composite's the  
4       right place to start. It's sort of, you start  
5       with the composite.

6                   If you don't look good, you ask. But  
7       if you look great, there's actually no reason --  
8       if you're a three-star hospital, there's no  
9       reason to go any further, I assume.

10                  DR. PAONE: I just -- I have to  
11       comment on that. I don't think that because of a  
12       hospital -- did I misunderstand you? I hope I  
13       did, that if a hospital's a three-star program,  
14       that is absolutely not a reason not to go further  
15       in any variety of ways that -- I'm sure I  
16       misunderstood you.

17                  CO-CHAIR FLEISHER: I -- yeah, I said  
18       it incorrectly. That doesn't mean you can't  
19       continue to improve. And one of the nice things  
20       is, you've shown how improvement -- all I'm  
21       suggesting is that the patient may have, from a  
22       patient perspective, of trying to dig down

1 further may be different than the provider always  
2 trying to get better.

3 MEMBER YATES: Question. Do you still  
4 affiliate with Consumer Report?

5 DR. PAONE: We are not, no longer.

6 MEMBER YATES: When did that stop?

7 DR. PAONE: I don't remember exactly.  
8 In the last year.

9 MEMBER YATES: It used to be that it  
10 was reported on Consumer Report.

11 DR. PAONE: That's correct. And it's  
12 not any longer.

13 MEMBER YATES: Because that interface  
14 was probably more consumer-friendly, no pun  
15 intended.

16 DR. PAONE: Yeah.

17 MR. ANTMAN: I can explain that a  
18 little bit. We heard from consumer reports in  
19 the spring of 2018. Not deciding to do away with  
20 STS star ratings specifically, but letting us  
21 know that they were closing their health rating  
22 center all together.

1                   So, although they still publish  
2                   information -- they still publish health-related  
3                   information, they decided that they were no  
4                   longer going to publish any health ratings,  
5                   whether it be physician or surgeon ratings, or  
6                   hospital ratings, or other ratings data that may  
7                   have been provided by other organizations,  
8                   because, as they explained to me, they decided  
9                   that it wasn't of sufficient interest to their  
10                  readership.

11                 MEMBER YATES: US News and World  
12                  Report is moving in to the surgeon-specific  
13                  sphere.

14                 DR. PAONE: Yes, we're aware of that.

15                 MEMBER YATES: So are we.

16                 DR. PAONE: I know we're running late,  
17                  but I just want to follow up again on the three-  
18                  star thing and make a quick comment. I -- even  
19                  from the patients' perspective, because the  
20                  program's a three-star program, they should still  
21                  consider the website and its information as a  
22                  starting point and not the end point, and should



1 be prepared to ask questions in any area that  
2 they wish.

3 I've got patients who come see me with  
4 a folder full of papers from -- and we all do --  
5 from various websites on the Internet, most of  
6 which tell them nothing. And I oftentimes --  
7 I've had patients come, and you all have, who  
8 said, I researched you on the Internet and, you  
9 know, absolutely that's why I'm here.

10 And when I asked them what they found,  
11 none of what they found is the reason that they  
12 should be coming to see me. So, we just implore  
13 patients in general to get as much information  
14 from as many sources as possible, starting with  
15 our website.

16 CO-CHAIR FLEISHER: Thank you.

17 CO-CHAIR GUNNAR: Any other comments?  
18 Discussion? All right. Usability and use.

19 MS. KOSURI: We are now voting on the  
20 use portion for Measure 0118. Voting is now  
21 open. The options are possible, no-pos.

22 (Off-microphone comments.)

1 MS. SKIPPER: And we're still waiting.  
2 Just two votes.

3 MS. KOSURI: Mm-hmm.

4 MS. SKIPPER: And, Chris, if you're on  
5 the phone and you can hear us, just type in your  
6 vote via the app, or you can speak it to us.

7 So, just one vote shy, so we'll need  
8 to reach out and collect the final vote for this  
9 measure. But we can still go on and discuss --  
10 well, people are packing up. So --

11 DR. PAONE: I don't want to be out of  
12 place here, but as a point of order, the  
13 majority, there's a number of other measures.  
14 There are four more individual composite  
15 measures, there are three more mitral measures,  
16 that are going to have the same exact issue that  
17 we've been discussing all along, on use and  
18 usability.

19 So, I don't know that we need to go  
20 through this whole conversation, and I leave it  
21 up to all of you to decide. But there are -- the  
22 aortic and CABG mortality measures, which won't

1 suffer those, because they are individually  
2 reported mortality issues.

3 So, perhaps we could focus on those  
4 and get through those, and then work to the  
5 others, if necessary.

6 CO-CHAIR FLEISHER: That would be  
7 great, but we can discuss that.

8 DR. PAONE: We don't have enough  
9 votes. I get it. Okay.

10 CO-CHAIR FLEISHER: So, there's a  
11 couple of interesting things. By having a lack  
12 of a quorum, in effect the other measures don't  
13 go down at all. They have to go for a call in  
14 which we can get --

15 MS. MARINELARENA: We already have it  
16 scheduled.

17 CO-CHAIR FLEISHER: We already have it  
18 scheduled?

19 MS. MARINELARENA: Mm-hmm.

20 CO-CHAIR FLEISHER: So, at that call,  
21 if we get any insights from Mark, back from STS,  
22 where we get insights internally, we will have an

1 opportunity to vote again on usability, but  
2 there's no -- for the new measures we haven't  
3 discussed.

4 MS. MARINELARENA: We will be voting  
5 on the measures we have not discussed.

6 CO-CHAIR FLEISHER: Correct.

7 MS. MARINELARENA: On February 20th  
8 from 12:00 to 2 p.m., Eastern.

9 CO-CHAIR FLEISHER: That's --

10 MS. MARINELARENA: I don't know when  
11 it is. I have no idea when it is.

12 CO-CHAIR FLEISHER: That's next  
13 Wednesday. Okay, I'll be in California. I'll be  
14 on the call.

15 MS. MARINELARENA: Then, it will be  
16 9 a.m. for you.

17 CO-CHAIR FLEISHER: Yes. I will miss  
18 one conference. Okay. So, do we want to  
19 continue discussion, or put it all on the call?

20 MS. MARINELARENA: Let's put it on the  
21 call, because if we continue discussion, the rest  
22 of the committee that is not here --

1 CO-CHAIR FLEISHER: Will not hear that.

2 MS. MARINELARENA: Yes.

3 CO-CHAIR FLEISHER: Okay. And, AJ,  
4 your comments are acknowledged.

5 MS. SKIPPER: So just as Melissa said,  
6 our next call is scheduled for Wednesday,  
7 February 20th from 12:00 to 2 p.m., where we will  
8 be discussing the remaining measures.

9 Following that, we'll be writing up a  
10 report of your recommendations. And that'll,  
11 again, be posted for a 30-day comment period,  
12 opening on March 21st.

13 And then, we'll bring you all back on  
14 May 8th for the post-comment call. Anything else  
15 to add, Melissa?

16 MS. MARINELARENA: No. I just want to  
17 thank everyone. I know these are really  
18 difficult discussions to have. I know internally  
19 as a team we have struggled with this. We've  
20 worked a lot with STS. So, we commend you for  
21 struggling with this, and, you know you'll help  
22 NQF work through these issues.

1                   We appreciate STS being here today and  
2                   we're glad that you were here in person. It  
3                   makes that much easier to have these  
4                   conversations around these really complex issues  
5                   and really complex measures.

6                   So, we really appreciate your time and  
7                   your contribution, and we look forward to talking  
8                   to you next week. And if there's anything we can  
9                   do, you can resend the information.

10                  If there's anything that you need from  
11                  us to make it easier to get through the  
12                  conversation, just reach out to the team and  
13                  we're happy to put something together.

14                  And, of course, thank you to Lee, who  
15                  will be in California, so don't really feel bad  
16                  for him, and to Bill, who just left, for leading  
17                  us today. Thank you all very much.

18                  MS. SKIPPER: And just one more thing  
19                  before we close. If there is anyone on the line  
20                  who'd like to make a public comment, we'd  
21                  definitely like to give you the opportunity to do  
22                  so now.

1 DR. PAONE: If I could, then, just  
2 take this opportunity, as well, on behalf of the  
3 STS and my colleagues, to thank everyone for  
4 their time put in before they got here, in  
5 addition to the conversation today.

6 We don't -- the fact that we had some  
7 disagreements on process doesn't mean that we're  
8 not completely committed to making this the best  
9 possible outcome for everyone involved, and we  
10 thank everyone for their efforts.

11 CO-CHAIR FLEISHER: And thank you very  
12 much. You did engage the group incredibly well,  
13 and appreciate that, and of course, always  
14 appreciate the NQF team for the outstanding work  
15 in preparing us and taking us through this  
16 difficult conversation.

17 We will huddle before next Wednesday  
18 to help with the discussion. Fred, thank you for  
19 not voting but being here to give guidance, as  
20 always.

21 (Whereupon, the above-entitled matter  
22 went off the record at 3:32 p.m.)

A			
<b>a-half</b> 189:2	<b>accessibility</b> 195:16,17	<b>addition</b> 4:21 42:2	78:12 238:21 239:5
<b>A.J</b> 26:12 34:12,13,15	195:20 196:1,16	53:10 266:8 293:16	239:11
74:11 77:16 168:17	<b>accessible</b> 73:17	343:5	<b>affect</b> 115:11
175:19 176:13	138:11	<b>additional</b> 42:2 51:20	<b>affiliate</b> 335:4
<b>A.J.'s</b> 263:10 264:17	<b>accompanied</b> 244:18	63:20 83:7 97:17	<b>afraid</b> 136:13
<b>a.m</b> 1:7 4:2 98:22 99:1	<b>account</b> 118:7,22	161:11 201:13 234:14	<b>African</b> 110:16 111:4
171:19 340:16	122:14 123:6 135:13	242:3 260:8 319:12	115:15 122:18 130:6
<b>abbreviated</b> 176:17	235:18 238:10	<b>address</b> 15:8 46:19	132:7 136:17 139:9
<b>abilities</b> 27:10	<b>accountability</b> 24:11	53:20 71:6,8 111:21	142:11 143:4
<b>ability</b> 76:2 84:1,16	25:7,13 27:22 28:11	137:7 138:12 146:8	<b>afternoon</b> 265:15
137:1 205:9,14	28:17 29:5,15 38:20	213:3 252:15 285:21	<b>age</b> 112:5 178:11
210:21	155:7 213:13 214:5	286:4 310:4	179:10 199:11
<b>able</b> 18:7 21:16 28:5	259:5 299:16 311:13	<b>addressed</b> 112:4	<b>agents</b> 320:20
32:6 57:2 60:19 68:15	<b>accountable</b> 45:7	125:21 126:1 212:8	<b>agnostic</b> 113:16 115:21
68:21 69:7 126:17	<b>accounted</b> 113:14	262:16 267:13	<b>ago</b> 30:22 74:22 101:13
147:15 156:5 159:12	118:7	<b>addresses</b> 112:8	116:10 140:22 149:12
184:22 185:12 204:22	<b>accounting</b> 120:18	<b>adds</b> 45:10,10 56:4	153:1,13 188:4 205:8
205:20 217:9 225:4	126:7	<b>adequate</b> 120:7 313:5	214:15 220:10 291:10
231:11 235:7 247:8	<b>accumulate</b> 102:7	333:12	<b>agree</b> 34:12 35:10 44:5
267:16 292:19 296:4	<b>accuracy</b> 210:20	<b>adequately</b> 17:14	106:6 135:3 145:9
298:19	<b>accurate</b> 186:22 209:20	<b>Adjourn</b> 3:17	164:17 178:9 185:19
<b>above-entitled</b> 98:21	209:22 212:2 273:21	<b>adjust</b> 113:22 119:9	227:19 275:13 277:3
171:18 343:21	313:3	120:9 159:12 209:13	289:15
<b>absence</b> 81:10,11,19	<b>acetabulae</b> 124:5	253:22	<b>agreed</b> 247:5 275:12
81:19 82:22 83:5 87:6	<b>achievable</b> 180:8	<b>adjusted</b> 72:18 83:1	<b>agreement</b> 180:13,16
217:18,18,21 218:4,6	<b>achieve</b> 34:9 175:4	87:7 143:6 173:7	197:22 227:14 288:12
269:16 328:13	282:4	295:16	<b>ahead</b> 39:10 60:2
<b>absolute</b> 301:11	<b>achieving</b> 21:12	<b>adjusting</b> 119:13	105:17 108:9 148:1
<b>absolutely</b> 38:8 71:9	<b>acknowledge</b> 188:9	134:13 255:11 256:17	163:10 168:13 171:5
271:18 312:2 334:14	<b>acknowledged</b> 341:4	<b>adjustment</b> 76:14,21	172:9,18 173:1,14
337:9	<b>act</b> 11:12 33:10 55:17	107:10 112:17,21	227:8 257:3,21 282:7
<b>abstaining</b> 105:14	175:9	117:7 118:4,8 119:16	293:16 305:5 330:8
<b>abstract</b> 153:17	<b>acting</b> 16:1 17:7 47:21	129:14 133:5 142:5	<b>AHRQ</b> 44:11 116:20
<b>abstraction</b> 202:11	<b>activate</b> 92:19	142:21 143:15 162:2	<b>AI</b> 205:9
<b>academic</b> 136:22	<b>activated</b> 92:16 94:11	207:9 250:10 253:21	<b>air</b> 299:12
197:10,13 254:5	<b>active</b> 318:11,13	254:3,8 301:12,17	<b>airport</b> 267:16
<b>Academy</b> 169:20	<b>actively</b> 212:5	<b>adjustments</b> 124:13	<b>airports</b> 15:13
<b>ACC</b> 190:17,18	<b>activities</b> 7:11,22	301:5	<b>AJ</b> 274:20 296:15 341:3
<b>accept</b> 26:20 107:1	<b>actual</b> 38:18 94:11	<b>Administration</b> 9:1	<b>AJ's</b> 269:10
108:1 134:4 162:19	110:22 238:19 295:13	11:10 189:3	<b>AKI</b> 239:7
162:20 163:22 164:1	295:17 296:3 302:12	<b>administrative</b> 207:15	<b>algorithm</b> 66:16
224:2 296:11	<b>acute</b> 182:14 237:3,15	<b>admit</b> 288:6 289:13	<b>aligned</b> 293:22
<b>acceptability</b> 16:21	237:17,20 250:19	<b>Adolph</b> 1:21 10:4,21	<b>alignment</b> 101:14 281:3
20:13,18 167:10	<b>add</b> 56:7 68:5 83:22	<b>adopt</b> 165:7 166:9,13	<b>alive</b> 181:18
<b>acceptable</b> 25:2 28:12	104:8 106:7 121:5	<b>adoption</b> 204:14	<b>all-or-</b> 312:17 327:19
30:7,8,15 34:10	133:6 142:10 150:7	<b>ADR</b> 64:21,21 119:17	<b>all-or-none</b> 280:14
107:16 141:10 201:19	174:4,6 175:19,21	<b>adult</b> 48:12 71:15	308:9 310:4 327:19
270:1 277:18 297:5	176:10 178:8 214:14	180:14 219:18	<b>Allan</b> 1:19 13:15,16
297:11 301:21	221:9 234:1,8 238:18	<b>advance</b> 22:16 262:16	158:21 159:1 164:14
<b>accepted</b> 25:12 122:5	277:10 300:18 326:19	<b>advanced</b> 92:22	<b>Alliance</b> 1:17 9:22
277:18	328:1 333:5 341:15	<b>advantage</b> 59:2 332:21	<b>allow</b> 39:15 52:4
<b>accepting</b> 225:5	<b>added</b> 124:14 153:1,2	<b>advantages</b> 142:20	<b>allowed</b> 69:11 75:12
<b>access</b> 19:20 22:16	203:1,11 206:6	<b>advent</b> 160:12	162:10
32:5 44:21 74:17	<b>addendum</b> 158:16	<b>adverse</b> 129:22 231:7	<b>allowing</b> 48:5 60:14
93:20 129:5 133:21	163:12 221:12 228:8	<b>advise</b> 271:20	<b>allows</b> 40:3 67:14
135:8 137:22 139:18	<b>adding</b> 58:16 100:18	<b>Advisor</b> 11:21	284:15
153:13 187:22 301:20	126:15 186:2 236:15	<b>advocacy</b> 198:17	<b>alluded</b> 220:20
	311:12 324:12	<b>advocate</b> 1:12 9:18	<b>altering</b> 221:2



<b>Alternatively</b> 39:13 222:8	309:7 323:13 325:12	343:13,14	197:22 204:1 243:20
<b>Alto</b> 138:2	<b>anterior</b> 203:14	<b>approach</b> 30:15 111:21	265:21 278:20 296:9
<b>Amen</b> 272:4	<b>anti-lipid</b> 3:12 49:10	119:8 133:7 147:18	296:12 313:13
<b>Amendment</b> 37:20	222:21 305:8,13	209:11 216:13 221:6	<b>aspect</b> 56:16 77:18
<b>American</b> 1:15 103:12	314:6,8 321:4 331:11	227:2 268:16,20	109:20 149:14 153:8
111:5 115:15 122:18	<b>anti-platelet</b> 320:20	<b>approached</b> 31:6	163:15 220:21
132:7 136:18 139:10	321:3	<b>approaching</b> 112:21	<b>aspects</b> 48:2 56:9
142:11 143:4 153:12	<b>antibiotic</b> 309:17	<b>appropriate</b> 57:22	115:15 156:1 226:21
303:20	<b>antibiotics</b> 291:14	87:22 107:12 125:13	281:8,16
<b>Americans</b> 110:16	<b>anticipate</b> 228:17	158:15 178:7 254:19	<b>aspirin</b> 310:20 323:2
130:6	<b>Antman</b> 2:7 47:2,10,12	270:5 288:14	<b>assess</b> 137:5 185:12
<b>amicus</b> 158:10	47:15,16 52:5,10	<b>appropriately</b> 44:1	243:5 254:20 255:6
<b>amount</b> 91:6 112:1	93:17 111:11 173:5	<b>approval</b> 36:10 52:1	<b>assessed</b> 114:8
197:9 208:19	214:14 230:20 231:2	<b>approve</b> 141:21	<b>assessing</b> 119:8
<b>ample</b> 174:18	234:17 246:16 305:12	<b>approved</b> 64:15 140:22	253:17
<b>Amy</b> 1:17 9:21 42:14	306:3 316:1 326:19	142:1 218:1 279:2	<b>assessment</b> 38:15
68:4 71:22 118:1	330:7 333:5,16	289:10 293:11 303:10	113:5 301:13
171:10 197:22 222:18	335:17	<b>approximately</b> 101:13	<b>assigned</b> 209:2
224:7 226:4 269:19	<b>anybody</b> 100:8 145:14	102:16 235:9 327:12	<b>assistance</b> 85:3 213:18
300:15 305:10 328:11	162:7 163:14 169:13	<b>arc</b> 156:2	<b>associated</b> 87:8 112:19
331:19	249:8 251:12	<b>area</b> 191:1,2 287:20	115:19 119:20 120:6
<b>Amy's</b> 70:17 333:2	<b>anybody's</b> 94:21	298:3 337:1	120:17 127:12 130:13
<b>analogy</b> 124:2	<b>anymore</b> 75:3 308:17	<b>arena</b> 207:20,21	202:16 237:16 245:13
<b>analyses</b> 119:1 138:12	310:1	<b>argue</b> 27:7 35:9,21	<b>association</b> 64:9,10
269:3	<b>anytime</b> 244:17 316:9	116:19 125:2 128:21	106:9 115:2 116:1
<b>analysis</b> 16:8 69:15	<b>aortic</b> 3:7,8 46:3 77:22	154:22 181:13 209:3	117:2 119:12,19
81:5 85:16,22 88:9	87:2 99:7 158:19	209:3 227:16 255:12	153:12 279:21 303:21
90:13 96:12 106:9	159:22 160:13,17	278:16,17	<b>assume</b> 123:7 237:12
107:5,18 123:14	161:12 203:10 206:8	<b>argued</b> 255:8	273:13 287:10 311:4
125:15,17 127:1	206:8 227:1 280:4	<b>arguing</b> 37:19 126:20	334:9
136:9 138:16 174:12	338:22	129:6	<b>assumed</b> 303:14
180:17 189:21 190:6	<b>apart</b> 58:8 67:2 91:15	<b>argument</b> 130:10 141:8	<b>assuming</b> 41:12 123:2
244:5 280:9 295:10	<b>apartment</b> 131:3	143:2,6 221:22 224:7	176:13
316:21 325:11	<b>Apologies</b> 132:21	224:14,18 226:13	<b>assumption</b> 242:19
<b>Analyst</b> 2:4	<b>apologize</b> 13:5 132:4	291:22 322:12 323:12	324:6
<b>analyzed</b> 131:17	200:20 235:6 237:12	325:17	<b>assumptions</b> 113:18,21
<b>anastomoses</b> 121:11	261:11 267:15 305:19	<b>arguments</b> 219:20	<b>assured</b> 280:2,5
<b>and/or</b> 192:15	326:15,20	<b>armed</b> 79:21	<b>atherosclerotic</b> 310:13
<b>Anesthesia</b> 1:12 10:16	<b>app</b> 94:19 338:6	<b>army</b> 88:10	<b>Atlanta</b> 195:7,22
<b>anesthesiologist</b> 10:15	<b>apparent</b> 266:21	<b>arteries</b> 128:8	<b>atrial</b> 206:9
199:7	<b>apparently</b> 105:9 128:8	<b>artery</b> 3:8 306:1	<b>attached-at-the-hip</b>
<b>anesthesiologists</b>	309:11	<b>article</b> 155:16 219:18	281:3
171:15,16	<b>appended</b> 146:7	<b>articles</b> 198:19	<b>attachment</b> 163:12
<b>Angeles</b> 1:18	<b>appendix</b> 246:19 247:2	<b>articulate</b> 28:10 141:5	<b>attempt</b> 244:8
<b>Angry</b> 169:15,21	247:8	<b>articulated</b> 104:5	<b>attend</b> 18:1
<b>angst</b> 283:21	<b>apples</b> 129:6	274:21	<b>attending</b> 47:20
<b>announce</b> 18:8 145:1	<b>applicable</b> 224:19	<b>Asian</b> 121:6	<b>attention</b> 55:22 56:3
178:14	226:16 302:12	<b>Asians</b> 122:1	184:17 206:21 252:9
<b>announced</b> 147:8	<b>application</b> 214:5	<b>aside</b> 104:14	<b>attest</b> 290:13
<b>annoyed</b> 84:20	246:19	<b>asked</b> 7:8,9 69:19 93:9	<b>attested</b> 290:4
<b>annual</b> 145:4	<b>applied</b> 44:1	110:2 189:17 247:4	<b>attorney</b> 187:3
<b>answer</b> 51:15 57:9 65:6	<b>apply</b> 198:19 219:20	272:16 330:21 332:9	<b>audible</b> 13:10,12,14
68:21 73:13,18 77:17	315:17	332:13 337:10	40:5 156:19
101:11 130:16 152:2	<b>applying</b> 283:6	<b>asking</b> 7:13 58:15	<b>audit</b> 136:9 180:14
165:7 175:16 185:4,8	<b>appointment</b> 304:4	64:19 72:1,3,4,5,8	209:15,19,20 251:10
236:19 251:17 255:18	<b>appreciate</b> 33:21 48:7	75:18 80:7 86:4	252:22 253:5
281:1 287:1 296:2	59:8 67:4 89:10	117:10,12,18 132:14	<b>automate</b> 206:22
	282:15 342:1,6	163:8 182:20 195:1,3	<b>automatically</b> 207:21

**availability** 72:2 81:16  
82:5 172:1  
**available** 44:18,20 45:7  
61:12,14,19 63:14  
68:20 70:9,14 71:18  
73:11 74:4 75:19 81:8  
82:3 127:3 152:14  
202:14 220:18  
**average** 121:7 177:22  
**averaged** 243:8  
**averages** 284:22  
**averaging** 287:14  
**aversion** 142:18  
**avoid** 239:6 302:1  
**avoidance** 129:3  
134:10  
**avoids** 285:11  
**AVR** 3:7,8 49:22,22  
50:13,13 59:3,4 60:20  
60:21 88:2 102:4  
103:9,10 160:9,10  
161:16 292:10 295:20  
**aware** 108:17 111:20  
133:13 202:17 206:20  
304:16 336:14  
**awfully** 199:10

---

## B

---

**B** 196:12  
**back** 6:15 19:16 27:9  
30:3 31:5 37:18 38:2  
39:17 40:2,11 44:7  
48:10 50:20 54:1  
60:11,12 67:9 76:15  
76:19 84:9 86:17 89:3  
91:14 97:8 98:12  
131:12 134:19 135:16  
139:4,5 140:18  
145:16 146:8 149:11  
171:12 172:13 187:21  
190:16 194:17 198:20  
214:18 218:22 219:4  
221:10,16,18 222:1,4  
225:1,18 226:1,15  
229:22 233:2 251:11  
253:9 291:21 296:2  
302:17 313:10 322:6  
324:14 328:18,19  
329:5 331:19 332:12  
339:21 341:13  
**background** 68:3  
117:22  
**bad** 10:12 46:18 57:3  
69:21 150:20 167:18  
239:1 342:15  
**Badhwar** 2:7 47:19 50:6  
56:6,6 60:3,4 74:21  
77:15 80:19 93:3,10

96:2,4,5,9 97:5  
100:19 101:2,6,10  
102:15 103:8 111:16  
121:4 122:3 123:2  
127:13 138:3 142:9  
155:19 161:11 182:6  
186:7 194:9 198:2  
203:9 204:8 209:16  
211:5 224:5 226:11  
238:18 251:5,13  
252:20 254:11 258:9  
259:22 266:12,19  
280:12 290:1 295:5  
302:10 312:2,16,20  
313:2 315:20 316:9  
316:12  
**balance** 114:6  
**band** 99:16  
**bar** 94:14 149:22 331:4  
**Barb** 13:9  
**Barbara** 13:11 46:5,6  
**Barbara's** 239:19  
**base** 18:11 198:15  
**based** 30:3 31:13 48:11  
60:15 104:9 129:14  
220:2 225:18 228:16  
235:9 244:3 255:1  
267:22 268:20 269:3  
311:6 314:4  
**baseline** 235:16,22  
236:13,22 237:4,13  
**basic** 277:11 286:4  
**basically** 51:16 58:2  
88:1 118:14 120:15  
120:22 176:6 223:17  
244:9 245:9,9 247:11  
247:21 286:18 289:1  
324:21  
**basis** 39:11 54:5 104:16  
153:13 198:8 211:9  
262:12 267:1 271:11  
277:7 285:4 286:3  
**Bayesian** 81:5 96:12  
97:3  
**bear** 177:8  
**beat** 144:22 181:20  
182:14  
**becoming** 138:11  
**began** 56:15  
**beginning** 85:4 165:16  
332:13  
**behalf** 274:6 280:20,22  
295:8 343:2  
**behavior** 312:8  
**belabor** 256:14 257:18  
**believe** 15:22 28:5 29:6  
42:16 67:20 100:14  
111:12 131:21 134:7

154:11 160:21 176:8  
202:19 214:6 220:11  
272:12 306:21  
**bell** 96:19 97:2  
**belong** 255:13,14  
**benchmark** 74:8 114:9  
243:17  
**beneficial** 56:5 315:4  
**benefit** 59:1 189:10  
221:22 239:6 297:18  
**benefits** 209:5 213:6  
323:4  
**best** 60:10 84:1 137:4  
155:2 169:21 272:21  
343:8  
**beta** 310:18 320:21  
321:2,3  
**better** 29:3 52:16 53:14  
62:14 69:22 75:12,14  
81:2 116:20 126:5  
135:4 150:18 168:13  
183:8 199:1,12  
211:16 212:3 220:15  
250:16 287:12 325:22  
335:2  
**beyond** 24:21 48:6 54:9  
65:17 87:17 252:14  
**biased** 16:1 133:19  
**big** 137:22 318:21  
**bigger** 150:15 191:16  
**Bill** 8:21 286:11 342:16  
**Bill's** 188:8  
**billing** 126:14  
**binary** 286:19  
**bit** 6:7 23:18 41:12  
69:14 85:6 96:19  
104:6 121:10 144:1  
150:9 173:15 199:8  
205:22 207:1 227:8  
263:7 297:2 320:16  
335:18  
**black** 123:17,18 124:16  
124:17,18 133:2,11  
240:7 243:18 244:7,8  
247:16 267:20  
**blacks** 110:16  
**bladder** 198:5  
**blank** 224:9  
**bleed** 185:16  
**block** 266:1  
**block-level** 137:9  
**blocked** 187:5  
**blocker** 310:18,20  
321:2,3  
**blockers** 320:21  
**blogs** 80:1  
**blowback** 35:2  
**blue** 92:8,10,14

**BMI** 304:2,3  
**board** 23:13 79:5  
182:20 274:7  
**Bob** 12:14,18 57:12  
86:22 104:7 318:15  
**body** 43:21 121:7 263:9  
**bootstrap** 259:21  
**bothering** 273:5  
**bottom** 79:2 314:15,18  
314:21 328:10,12  
**box** 123:18 279:10  
**boxes** 22:22  
**brand** 281:15  
**break** 78:4 98:3,19  
170:13,21 171:7,9,10  
171:12 312:20  
**breakdown** 74:19 76:2  
**breakdowns** 96:10  
**breaking** 34:20  
**breast** 195:8  
**brief** 6:5 16:5 18:18  
158:10 170:16 269:9  
292:13  
**briefly** 4:17,17 173:6  
328:1  
**bring** 28:4 46:14 171:8  
171:12 210:11 214:18  
285:3 308:13 341:13  
**bringing** 324:13  
**brings** 40:2 63:8 196:7  
**broad** 186:9 226:19  
**broaden** 58:17  
**broader** 38:15 321:16  
**broadest** 87:20  
**broken** 35:13,14  
**Bronx** 138:2  
**brought** 180:21  
**Brown** 277:21  
**bugged** 296:19  
**build** 254:8  
**built** 147:13  
**bump** 100:15,17  
**bumping** 324:2  
**bunch** 10:10 233:19  
242:5 246:12,13  
254:6 278:3 298:8  
**burden** 299:18  
**buried** 62:7 278:11  
280:9,16  
**busy** 54:16  
**buy** 141:6  
**bypass** 3:8 81:9 158:20  
206:5 216:8,21 280:4  
310:14

---

## C

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**CABG** 3:9,11 49:3,3,6,8  
49:14,15,18,22 50:1

50:13 64:22 77:22 102:5,9 159:22 160:9 161:16 173:8,11,12 173:17,20 179:11,18 196:20 216:8 217:15 219:20 234:22 235:5 258:10 305:16,21 306:5,10 326:12 338:22 <b>calculated</b> 48:9 258:21 <b>calculation</b> 66:11 <b>calculations</b> 112:12 128:1 <b>California</b> 1:18 340:13 342:15 <b>call</b> 5:3 6:6 8:20 21:22 22:5 40:14 46:13 205:7 224:4 230:1,4 230:16 231:5,11,12 231:21 232:2,9,11 264:7,13 265:4,16,20 266:10 284:2 304:10 339:13,20 340:14,19 340:21 341:6,14 <b>called</b> 19:15,19 219:18 <b>cancer</b> 1:21 9:18 <b>Candidate</b> 3:6 <b>capability</b> 45:9 <b>capture</b> 17:14 31:19 32:6 42:9 87:21 184:19,22 192:14 208:8 210:21 238:14 <b>captured</b> 185:3 200:8 238:15 254:17 <b>capturing</b> 183:19 184:14 <b>card</b> 189:13 <b>cardiac</b> 16:11 34:3,4 48:12,15,19 71:15 88:18 95:13 99:21 122:6 134:6 156:7 180:14 193:16 198:3 219:19 220:1 280:2 <b>cardiology</b> 103:11,12 <b>cardiothoracic</b> 133:16 190:22 <b>Cardiovascular</b> 101:19 155:3 193:14 <b>care</b> 27:11 28:4 34:7 43:13 54:19 61:10 68:18 129:5 140:7 142:21 182:14 191:16 194:19 198:7 240:5 285:7 301:20,20 302:3 <b>care's</b> 254:5 <b>careful</b> 302:5 <b>carried</b> 165:20	<b>carry</b> 34:21 146:18 147:21 148:18 163:4 163:6 164:4 168:3 199:8 210:3 214:10 234:10 <b>case</b> 34:11 37:7,15 42:14,18 43:20 62:16 70:2 111:7 119:11,17 125:13 134:9 143:5 160:11 206:4 <b>cases</b> 43:11 134:16 155:17 179:6 191:20 192:9 <b>cast</b> 268:13 <b>catching</b> 272:7 <b>categories</b> 152:16,20 153:4 288:2 289:3 314:2,3 <b>category</b> 184:13 185:9 310:15 325:2 <b>caught</b> 285:8 <b>causal</b> 120:7 <b>cause</b> 154:16 <b>causes</b> 206:11 <b>causing</b> 123:19 <b>caution</b> 140:16,18 250:11 <b>caveat</b> 213:12 <b>caveats</b> 158:4 181:8 <b>CBA</b> 87:9 <b>Census-track</b> 137:9 <b>center</b> 1:21,22 10:6 181:5 197:10 281:17 335:22 <b>centers</b> 55:2,16,17 152:8 180:4 181:1 196:19 205:17 322:16 327:12,17,22 <b>central</b> 227:21 262:17 262:20 <b>cents</b> 159:6,20 <b>CEOs</b> 190:10 <b>certain</b> 55:7 79:11 122:7,8 123:6 127:17 142:20 184:4 194:8 209:10 290:22 <b>certainly</b> 34:12 35:22 58:22 64:20 76:1,3 93:20 94:2 158:9 175:11 180:11 197:20 204:21 287:22 310:13 310:17 333:10 <b>cetera</b> 244:8 <b>chair</b> 11:12,17 274:6 280:22 281:7 <b>chairs</b> 14:14 156:11 304:16 <b>challenge</b> 139:20	214:22 277:4 284:11 <b>challenges</b> 116:17 140:12 181:11 295:8 <b>challenging</b> 43:17 <b>chance</b> 220:15 264:21 282:13 <b>change</b> 121:3 134:5 139:6 154:14,15 155:12 162:8,8 164:3 165:6 166:14 167:15 175:4 206:6 236:6 240:19 271:7,18 283:17 289:12 <b>changed</b> 23:18 24:10 25:2 31:1 43:5 101:22 106:13 130:7 286:13 288:21 299:16,17 <b>changes</b> 131:13 184:15 213:20 225:3 228:18 254:16 278:1 333:20 <b>changing</b> 166:2 277:19 <b>characteristics</b> 244:3 255:1,2 <b>charge</b> 17:8 <b>Charlie</b> 277:21 <b>chart</b> 253:1 <b>charts</b> 331:4 <b>chat</b> 6:13 18:4 94:22 318:19 319:17,17 <b>cheat</b> 249:4 <b>check</b> 256:8 260:10 <b>checked</b> 85:17 <b>checks</b> 189:5 252:4,6 <b>cherry-picking</b> 133:20 <b>Chest</b> 1:15 <b>Chicago</b> 328:18 <b>Chief</b> 10:16 13:4 <b>chime</b> 15:9 172:18 251:13,19 254:22 <b>chiming</b> 111:16 <b>cholesterol</b> 310:11,12 <b>choose</b> 74:18 77:3 106:22 108:1 162:18 162:20 163:21 258:8 <b>chose</b> 195:7 <b>Chris</b> 11:1,4 296:16 338:4 <b>CHRISTOPHER</b> 1:17 <b>Christy</b> 2:3 4:9 5:5,10 15:16 17:2 45:3 172:3 235:12 236:9 265:16 <b>chronic</b> 238:4 <b>Cima</b> 1:11 12:14,14 44:3,5 46:6,9,10,16 57:11,12 59:8 64:1 67:3 86:21,22 90:1,16 90:21 91:2 97:4 99:15 104:9 106:3,4,8	109:14,15 146:13,14 148:14,16,18,19 149:10,11 282:5,8 318:11,16 <b>circuit</b> 35:4 <b>circumstances</b> 194:5 <b>city</b> 131:1 <b>clarification</b> 71:4 73:21 74:13 89:15 107:17 116:16 180:19 199:13 216:16 235:11 311:15 <b>clarifies</b> 182:18 <b>clarify</b> 63:1 72:20 116:6 174:11 190:4 215:7 215:21 223:16 242:15 247:10 286:12 <b>clarifying</b> 24:7 70:11 72:9 116:6 <b>clarity</b> 60:10 72:3 80:21 139:7 182:7 192:12 224:8 259:22 304:11 <b>class</b> 29:20 36:4 <b>clear</b> 37:3 39:7 42:14 43:3,9 45:13 65:20 71:1 105:7 110:3 114:12 115:6 119:12 127:11 131:17 139:3 139:7 141:10,22 143:8 146:4 150:13 180:12 221:12 225:14 227:2 288:8 299:12 <b>clear-cut</b> 125:1 <b>clearer</b> 232:6 <b>clearly</b> 130:19 139:9,13 183:14 217:7 247:4,7 247:9 271:10 284:13 322:1 327:14,19 <b>Cleveland</b> 1:19 13:17 <b>click</b> 94:12 152:16,18 <b>clickers</b> 19:14 <b>Cliff</b> 46:4,5,6 <b>Clinic</b> 1:11,19 13:17 <b>clinical</b> 48:12 101:16 102:19 118:5,6 121:6 127:10,12 139:19 140:7 152:6 224:14 <b>clinician</b> 85:18 107:21 174:12 180:20 181:4 199:19 <b>clinician-level-testing</b> 86:3,9 <b>close</b> 119:10 136:21 252:9 267:22 274:13 281:2 342:19 <b>closed</b> 12:16 147:3 200:15 201:22 212:9 241:5 249:16 257:7 260:11 307:19 315:12
---	---	---	---

317:9 319:7,22  
**closely** 330:6 333:11  
**closer** 20:2  
**closing** 335:21  
**CMS** 92:22 188:5,7,20  
 273:19 278:5,11  
 284:21 294:11  
**CMS's** 279:3  
**co-chairs** 1:8 8:14  
 15:22 263:19  
**co-presenter** 308:6  
**code** 116:20 131:1  
**coefficient** 112:3 132:6  
 132:19  
**collaborative** 193:15  
 194:2  
**collate** 194:7  
**colleague** 221:11 299:3  
**colleagues** 15:16 16:1  
 103:11 205:17 217:16  
 328:21 333:11 343:3  
**colleagues'** 188:14  
**collect** 338:8  
**collected** 202:9 208:20  
 236:18,22  
**collecting** 301:3  
**collection** 126:16 162:2  
 202:18 207:13 211:11  
**collectively** 39:19  
 103:11  
**College** 1:15 103:12  
**color** 117:1,3  
**Colorado** 1:14  
**columns** 150:13 246:22  
 247:7 325:6,7  
**combine** 7:6  
**combined** 81:14 173:19  
 179:11 217:5  
**combining** 193:8  
**come** 38:21 39:17 50:9  
 76:19 89:3 98:11  
 135:22 136:2 140:18  
 141:19 144:1 146:7  
 158:4 172:13 219:12  
 221:18 222:1 225:18  
 226:1 231:12 234:18  
 237:4 268:18 290:21  
 296:2 337:3,7  
**comes** 139:4,5 197:10  
 239:8 243:17 252:7  
 252:22 253:9 284:17  
 294:16 298:14  
**comfort** 276:12  
**comfortable** 164:15  
 165:15 324:8  
**coming** 46:22 92:4 97:8  
 207:6 337:12  
**commend** 188:3 341:20

**comment** 5:3 22:3 44:4  
 63:2 64:1 88:15 91:13  
 111:17 112:11 121:4  
 127:14 128:4 134:5  
 136:7 138:3 141:3  
 149:18 150:17 155:19  
 155:20 169:13 178:10  
 186:8 194:12 198:2  
 201:13,15 202:21  
 223:10 224:7 225:1  
 226:9 229:22 231:19  
 234:9 246:16 253:19  
 255:16 258:1 263:3,4  
 263:6 264:12,21  
 265:2,4,20 266:3  
 267:8,15 269:7 271:3  
 271:5 273:17 282:5  
 282:10 286:11 296:16  
 296:17 302:11 303:6  
 304:12 326:18 331:19  
 333:2 334:11 336:18  
 341:11 342:20  
**commentary** 33:1,16  
 201:1  
**commenting** 211:11  
 231:17  
**comments** 3:15,15 11:6  
 14:10,16 16:3 17:19  
 18:10 19:4,17 22:6,15  
 22:21 26:5,9 35:6  
 46:20 60:1 71:9 74:10  
 86:17 93:5,12 95:19  
 95:21 97:6,10 106:16  
 118:12 138:13 140:14  
 146:15 148:15,17  
 149:10 156:18 157:22  
 175:22 227:20 228:13  
 230:17 231:20 232:1  
 232:10 248:1 249:11  
 263:14 282:11,15  
 286:9 304:14 307:17  
 318:5,10 319:3,12  
 326:17 332:1 337:17  
 337:22 341:4  
**commercial** 10:11  
**commission** 298:8  
**commitment** 9:13  
**committed** 343:8  
**committee** 1:3,6 7:8,12  
 7:17,20 9:9,13 11:12  
 15:7,11 17:1,6 18:21  
 19:5 21:13,14 22:3  
 25:1,5 27:19 31:20  
 32:15 35:2 39:18,20  
 40:1,4,16,20 42:19  
 48:4 49:17 62:20 65:7  
 67:6 68:3 86:4 91:17  
 107:3,11 116:7

128:14,17 138:21  
 139:8 140:2 144:13  
 145:7,8 160:22 171:2  
 171:14 173:15 174:22  
 175:2,13 178:6  
 179:22 189:19 212:14  
 221:18 225:18 226:2  
 227:21 235:8 241:8  
 248:20 249:20 262:17  
 262:20 264:3 267:6  
 276:22 277:17 282:12  
 282:22 283:7,19  
 296:10,20 300:14,16  
 308:14,14 315:19  
 317:12 320:4 340:22  
**committee's** 4:5 27:20  
 43:7 226:8 263:13  
 297:10  
**committees** 10:10,21  
 11:20 43:13 281:12  
 297:22 298:4,9  
**common** 75:5 160:15  
 215:7 259:18 291:11  
**commonly** 161:14  
**communicate** 211:9  
**communicated** 101:20  
**communication** 266:16  
**communications**  
 262:17  
**community** 122:6  
 137:18 138:8 304:1  
**companies** 189:13  
**company** 265:16  
**comparative** 177:13  
**compare** 83:4 86:7  
 243:14,15 255:9  
 278:7 294:12 297:15  
**compared** 102:5 113:10  
 133:2 177:15 199:2  
 255:10 274:15 331:13  
**comparing** 133:1 242:6  
 250:14  
**comparison** 114:8  
 243:16 245:18 246:2  
 246:2  
**compartmentalize**  
 156:5  
**competing** 41:17,19  
 42:6  
**complete** 204:5 265:9  
**completed** 159:4  
 261:10 262:3  
**completely** 73:11 128:3  
 211:6 242:10 319:6  
 343:8  
**complex** 16:17,21  
 66:15 134:16 206:10  
 316:10 342:4,5

**complexity** 134:9  
 160:15 203:18  
**compliance** 309:22  
 314:5,16  
**compliant** 311:16  
**complicated** 52:19  
 278:12 294:10  
**complication** 58:21  
 66:10 160:4 221:2  
**complications** 53:4  
 66:9 91:7 117:1  
 183:15  
**complied** 273:7  
**component** 49:2,9 50:8  
 51:7 65:8,9,13 71:15  
 87:22 119:12,17  
 124:22 133:1 215:3,3  
 216:10 217:3 234:21  
 235:4 280:6 293:5  
 308:11 318:22 324:1  
 329:7  
**components** 30:19  
 31:1 34:18 38:17,21  
 41:20 52:6 57:17 62:6  
 62:12 63:7 65:3 68:6  
 68:8,13 173:19  
 216:17 225:15 235:2  
 268:6,10 269:1 275:7  
 276:3,4,15 279:18  
 285:18,22 292:9  
 296:15 305:16 332:17  
**composite's** 36:20  
 334:3  
**composites** 26:16 30:4  
 35:12 38:17 41:21  
 42:3 49:22 51:1,8  
 82:8,8 83:9 153:2  
 214:16 222:4 223:12  
 227:6 268:6 270:15  
 275:5,20 276:21  
 277:5,6,8,9 278:5  
 308:4  
**comprehending** 78:22  
**computation** 62:8  
**computer** 19:22 94:19  
**concept** 35:20 53:1  
 131:5 136:13 181:18  
 198:16 238:19 251:14  
 295:6  
**conceptual** 117:13,16  
**conceptually** 39:11  
 53:9 118:3 287:9  
**concern** 64:8 87:18  
 100:7 130:3 142:16  
 144:16 149:15,21  
 188:4 209:8 210:20  
 250:14 293:3 306:17  
 308:8 316:19

<b>concerned</b> 47:6 109:18 139:9 171:11 185:19 207:13 264:17 274:19 286:13 296:2	267:4 271:6,8 277:2	<b>continuously</b> 289:12	<b>country</b> 28:21 34:4 61:14 99:18 136:12 153:3,14 291:19
<b>concerns</b> 107:8 136:1 144:20 179:22 201:10 263:10 301:2 306:8	<b>consent</b> 71:21	<b>contract</b> 136:22	<b>countryside</b> 12:4
<b>concerted</b> 143:8	<b>consequence</b> 128:22 300:19,20	<b>contracted</b> 249:6	<b>counts</b> 257:14
<b>concise</b> 18:10	<b>consequences</b> 213:4 219:2,14 272:13 274:21 330:18	<b>contraction</b> 249:7	<b>couple</b> 4:10 5:17 7:16 20:16 68:19 144:8 170:6,10 172:1 186:8 290:14 310:5 339:11
<b>conclude</b> 117:7	<b>consider</b> 25:8 34:10 53:16,18 126:4 142:11 175:1 227:21 231:22 254:2 256:17 336:21	<b>contrary</b> 133:14	<b>course</b> 18:11 57:5 61:2 111:19 209:18 287:15 342:14 343:13
<b>conclusion</b> 138:17 248:4	<b>considerable</b> 203:1	<b>contribute</b> 207:18 311:9	<b>court</b> 6:9 35:4 57:7
<b>concur</b> 28:15	<b>considerably</b> 176:17	<b>contributed</b> 186:12	<b>courts</b> 30:12
<b>condition</b> 33:15,18	<b>consideration</b> 3:6 315:6	<b>contribution</b> 281:17 291:17 342:7	<b>Cove</b> 46:5
<b>conditions</b> 52:1 117:4 254:1	<b>considered</b> 43:22 103:6 103:9 126:10,10 141:12,13 213:20 236:22 303:16	<b>control</b> 44:19	<b>cover</b> 137:16 286:14
<b>conduct</b> 33:4 150:9	<b>considering</b> 83:4 91:6 114:22 115:22 130:16 142:5 271:19	<b>controlled</b> 127:20	<b>covered</b> 127:21
<b>conference</b> 1:7 205:7 340:18	<b>consistency</b> 298:4	<b>controversial</b> 130:21	<b>create</b> 60:14 235:4
<b>confidence</b> 62:5 65:11 242:8,10 244:14,19 245:7,8,12	<b>consistently</b> 180:1	<b>convened</b> 276:5	<b>creatinine</b> 235:16 236:1 236:13 237:7,13 238:5 251:15
<b>confident</b> 251:3	<b>consists</b> 16:18	<b>conversation</b> 27:19 31:18 42:8 56:15 83:21 85:13 150:7 205:7 217:7 227:4,6 322:12 323:12 338:20 342:12 343:5,16	<b>creatinines</b> 251:7
<b>confirm</b> 111:11	<b>constituted</b> 282:21	<b>conversations</b> 44:16 342:4	<b>credentials</b> 195:11
<b>confirmed</b> 88:22	<b>constitutes</b> 173:10	<b>converts</b> 137:7	<b>credible</b> 219:10
<b>confirms</b> 292:21	<b>constitution</b> 30:1 228:12	<b>cooking</b> 176:14	<b>credit</b> 101:18 134:8,12 189:13
<b>conflict</b> 8:4 9:2 10:6 14:3 15:18	<b>constitutional</b> 9:5 29:19 36:4	<b>cooperative</b> 10:1	<b>credited</b> 101:17
<b>conflicts</b> 9:19 10:11,19 11:11,19 12:9,17,21 13:7,18 14:1	<b>construct</b> 20:17 104:1 104:4 106:20 162:1 162:20	<b>core</b> 56:20 278:4 292:20	<b>criteria</b> 18:13 19:2 20:7 20:13 24:4,10,17 28:12 30:13 31:15,15 32:9 41:13,15 43:6,7 44:1 85:12 140:4 165:3 178:16 179:2,7 200:17 201:12 202:3 212:10,15 215:19 223:20 227:4 229:11 229:16 241:1,6 248:14,21 249:15,19 256:1,7 257:5,10 260:6,12 275:10 276:10,19,21 283:5,6 304:15 307:5,20 315:16 317:5,12 318:8 319:9 320:1
<b>confounder</b> 123:4	<b>construction</b> 146:11,22 147:6 166:10,12 167:13,15	<b>coronaries</b> 121:14	<b>criterion</b> 17:10,13 253:17 299:13
<b>confounders</b> 113:15,17 123:6	<b>constructive</b> 186:8	<b>coronary</b> 3:8 81:9 121:8,11 128:8 158:20 206:5 216:8 310:14	<b>critical</b> 28:22 29:5 192:9 198:7 285:14
<b>confounding</b> 112:22 120:8 288:20	<b>consumer</b> 75:18 77:13 278:8 280:1 335:4,10 335:18	<b>correct</b> 26:17 29:12 33:12 38:14 52:1 55:11 61:17 71:3 89:18 96:1 97:18 100:22 102:15 105:15 110:13 132:1 158:19 159:5 172:2 182:11 190:13 193:3 197:18 203:3 204:12,20 210:8 214:9 215:5,11 215:16 216:11 247:17 261:7 286:16 335:11 340:6	<b>critique</b> 299:20
<b>confuse</b> 41:11	<b>consumer-friendly</b> 335:14	<b>corrected</b> 280:11	<b>crossing</b> 244:15
<b>confused</b> 118:10 140:10 246:22 264:4	<b>consumers</b> 44:14	<b>correction</b> 306:4	<b>crying</b> 302:6
<b>confusing</b> 81:22 141:6 143:7 223:8 242:1 247:6	<b>contact</b> 208:6,7	<b>correctly</b> 59:3 131:10	<b>CSAC</b> 4:10 29:12,14 30:5 37:8 40:1 42:21 43:9,18 140:12 143:8 221:21 263:9,11,12 263:18,19 264:15 266:4,9 304:16
<b>confusion</b> 142:10 217:13	<b>contains</b> 48:15	<b>correspond</b> 107:19	<b>CSAT</b> 226:4,5
<b>congenital</b> 71:16	<b>content</b> 252:2	<b>cost</b> 191:6	
<b>conglomerate</b> 325:3	<b>CONTENTS</b> 3:1	<b>costed</b> 209:6	
<b>conglomerating</b> 218:1	<b>context</b> 112:16 124:18 300:2	<b>costs</b> 202:16	
<b>Congress</b> 332:7	<b>continue</b> 188:8 230:4,7 260:16,18 282:11 334:19 340:19,21	<b>Council</b> 280:22	
<b>connect</b> 273:18	<b>continued</b> 100:1 160:12	<b>counseling</b> 175:11	
<b>connected</b> 98:6 114:3	<b>continuing</b> 55:20 112:7 231:8	<b>Counselor</b> 35:8	
<b>connecting</b> 279:12	<b>continuous</b> 137:16	<b>count</b> 164:9 258:20	
<b>connection</b> 117:10 138:17		<b>counted</b> 182:10	
<b>consensus</b> 21:12,21 35:22 107:14 128:9 144:17 163:2 229:20 230:1,5,19,21 231:15 260:15,17 264:13		<b>counting</b> 105:13 182:3	

**CSATs** 271:3  
**cumbersome** 126:16  
**curious** 194:12 269:14  
 309:21  
**current** 73:1 102:14  
 121:12 122:9 250:14  
**currently** 61:17,21 78:2  
 103:8 116:18 225:7  
 229:4 236:2,16  
 321:10  
**curve** 96:19 97:3 246:5  
**cutoff** 137:17  
**cuts** 137:18

## D

**D** 1:20  
**D.C** 1:7 9:6 12:4  
**daily** 211:9  
**Dallas** 10:15  
**damaging** 273:22  
**Dartmouth-Hitchcock**  
 1:13 11:16  
**data's** 71:11 242:13  
 253:14 256:18  
**database** 48:13,14  
 75:20 76:1,10 77:5,6  
 82:12,18 100:14,21  
 101:5,7 102:13 110:7  
 121:15 134:11,11  
 137:2 152:4 177:14  
 181:3 185:9 187:14  
 190:16 194:22 205:3  
 206:3 207:22 208:17  
 211:22 235:10,17,20  
 236:5 254:13 271:12  
 281:16 284:15  
**date** 97:18 112:6  
 208:17  
**dating** 332:12  
**Dave** 47:20  
**Dave's** 155:20  
**David** 2:11 132:1 230:3  
 272:17 334:2  
**David's** 141:3 332:1  
**day** 97:15 138:12  
 181:19 183:22 199:11  
 212:1 265:14 272:16  
**days** 87:15,17 179:14  
 179:16 181:21 182:2  
 182:2,5,8 183:11  
 184:9,9,9,18 185:13  
 186:11 232:2  
**de-endorse** 31:8  
**deal** 84:21 137:21  
 284:21  
**dealing** 133:16 160:3  
 187:3  
**Dean** 29:22

**death** 66:7 183:14  
 187:22 188:16,19  
 189:12  
**deaths** 179:12,15  
 183:21 184:3 189:3  
**debate** 181:13 188:4  
**debilitating** 221:4  
**decade** 150:1 267:22  
 281:6  
**decades** 91:13  
**decide** 25:1 141:21  
 276:22 281:21 300:14  
 338:21  
**decided** 35:3 119:2  
 183:8 209:6 228:1  
 336:3,8  
**decidedly** 194:10  
**deciding** 335:19  
**decile** 314:16  
**decision** 39:18,20  
 61:21 138:22 144:2,2  
 146:7 158:16 163:12  
 187:12 194:16 195:18  
 214:19 221:21 225:19  
 226:8,14 230:19  
 233:10 267:5 269:3  
 283:15 285:5 299:12  
**decisionable** 30:10  
**decisions** 44:17 196:17  
 282:21 294:2  
**deck** 4:22  
**decreases** 302:22  
**dedicated** 208:16  
**deemed** 16:17  
**deep** 53:8 60:21 87:10  
 291:8,10,16 295:17  
**defense** 123:11  
**defer** 52:10 53:16 91:17  
 110:5 154:15 174:3  
 181:12  
**define** 28:2 44:8 130:19  
 156:9 296:21 298:3  
 328:15,16  
**defined** 25:14 29:11,13  
 29:17,18 30:2 73:6  
 122:10 124:12 259:5  
 285:9 296:15 322:8  
**defines** 279:7  
**defining** 284:18  
**definitely** 60:18 94:22  
 127:15 150:13,14  
 196:16 342:21  
**definition** 26:20 27:6  
 32:4 42:20,22 43:1,2  
 45:4 88:6 125:9 182:1  
 265:9 273:12 277:19  
 288:21 294:7 296:22  
 303:9,15 328:22

**definitions** 80:22 82:1  
**definitive** 283:15  
**definitively** 287:2  
**degrades** 291:22  
**degree** 91:7 184:15  
 217:10 268:21 276:20  
 300:16 314:10  
**degrees** 27:21  
**deleted** 251:16  
**delivery** 140:8  
**delta** 123:8 237:14  
**demographic** 115:19  
 126:5 127:16 137:6  
 139:22  
**demographics** 127:18  
**demonstrable** 324:15  
**demonstrate** 331:8  
**demonstrated** 91:3  
 180:15 309:5  
**demonstrates** 160:22  
**demonstrating** 178:3  
 300:4  
**denominator** 105:14  
 179:17 235:14 236:11  
**Denver** 14:5  
**depart** 315:22  
**Department** 11:18  
**depending** 129:19  
 130:20 136:7 152:16  
 206:13 254:15  
**depends** 226:9 323:20  
**depth** 270:15  
**derived** 84:2 175:13  
**describe** 89:12 177:17  
**designed** 59:17 192:2  
 243:5,6,13,15  
**desire** 82:13 204:21  
 266:14  
**desired** 139:21  
**destabilize** 300:22  
**detail** 123:19 210:22  
 255:5 268:21  
**detailed** 88:9 154:2  
 182:21 251:21 252:3  
**details** 187:10 203:13  
 298:17  
**detect** 176:2 238:20  
 252:10  
**detecting** 130:8  
**detection** 130:14  
**determinants** 135:2,5,9  
 135:11 136:4  
**determination** 230:4  
 251:6,18 259:2  
 290:20  
**determinations** 138:21  
**determine** 52:21 107:12  
 107:15 327:2,5

**determining** 89:22  
 300:16  
**develop** 295:15,21  
**developed** 37:9 52:15  
 53:10,20 59:18  
 212:20  
**developer** 18:20 25:6  
 28:10 32:16 33:2  
 57:12 107:18 109:22  
 140:16 145:17 146:7  
 150:8 151:19 160:2  
 174:17 177:13 180:13  
 213:15,19 215:13  
 225:2,17 226:1  
 228:15 230:2 234:13  
 234:15 240:14,15  
 241:19 250:18 256:17  
 298:5  
**developers** 4:8 18:15  
 21:8 25:3 39:16 88:5  
 89:5,11 92:20 110:12  
 111:8 117:10 129:9  
 139:16 154:7 172:20  
 180:19 201:9 212:19  
 259:19 305:11  
**developing** 51:19  
 103:12 161:10 295:12  
**development** 10:22  
 112:1  
**diabetes** 127:19,20  
**diabetic** 291:12  
**diagnosis** 80:6  
**dialog** 39:3  
**dialogue** 225:22  
**dialysis** 53:7 236:1,3,16  
 238:7 239:1 253:4,4  
**dialysis-dependent**  
 221:3  
**dichotomous** 66:1,11  
 88:5 321:19  
**die** 179:12 182:10  
 184:10  
**died** 182:3  
**dies** 66:8  
**difference** 24:14 53:6  
 58:19 111:3 123:15  
 123:16,19 138:1  
 192:6 207:3 238:1  
 247:15 310:1,8,18  
 322:1 331:10  
**differences** 90:20 116:2  
 120:2 129:16 130:4  
 130:13 161:1,18  
 176:2 245:10 314:10  
 330:15  
**different** 28:4 32:14  
 62:2 70:3 123:12,20  
 123:21 124:5,8,9,10

124:17 130:13 142:16  
 154:6 160:16 163:14  
 166:18 177:14 189:21  
 190:15,17 193:22  
 196:5 197:11 208:21  
 220:11 222:15 226:14  
 227:4 228:4 243:8,22  
 244:4,4 253:22  
 255:10 259:11,15  
 272:12 282:22 287:15  
 294:14 298:9 306:5  
 335:1  
**differentiate** 220:2  
 237:21 330:4  
**differentiation** 69:3  
 298:14  
**differentiator** 330:1  
**differently** 116:9 297:3  
**differs** 305:17  
**difficult** 54:17 121:10  
 121:13 188:10 220:3  
 242:2 330:20 341:18  
 343:16  
**difficulty** 82:14  
**dig** 278:18,19 334:22  
**digging** 298:17  
**diligently** 212:5  
**dimensions** 287:18  
**ding** 330:21  
**dire** 283:13  
**direction** 158:15 265:6  
 283:2 293:7 308:18  
**directly** 185:5 205:1  
 206:15 223:19 257:14  
 266:11,16  
**Director** 2:2 5:17  
**disagree** 257:17  
**disagreement** 261:19  
**disagreements** 343:7  
**disapproval** 281:6  
**discharge** 3:12 179:15  
 181:19 182:5,13  
 183:12 185:6,13  
 222:21 305:9,14  
 321:3,4,5  
**discharged** 182:4  
 183:13 185:10  
**discharging** 312:10  
**disclose** 7:14 8:3,19  
**disclosed** 45:7  
**disclosures** 3:3 4:17  
 6:18 7:6 8:11,11 10:2  
 11:2 23:13  
**discomfort** 268:15  
**discovery** 140:5  
**discredit** 268:4  
**discretion** 27:21  
**discriminating** 220:15

**discuss** 19:10 21:2  
 35:20 51:17 63:15  
 86:4 107:3,15 108:2,5  
 109:22 128:18 172:8  
 172:10 264:8 265:1  
 338:9 339:7  
**discussant** 172:6  
**discussants** 18:22 19:3  
 158:21 172:14 174:6  
 239:15  
**discussed** 11:18 49:17  
 88:15 126:12 147:13  
 149:18 159:22 163:15  
 213:11 216:13 250:10  
 267:12 317:19 340:3  
 340:5  
**discussing** 15:6 33:17  
 90:18 162:3 190:10  
 257:13 288:21 297:9  
 320:9 338:17 341:8  
**discussion** 17:11,15  
 18:10,15 19:1,10 20:6  
 20:11 25:15 37:7  
 38:22 39:2 42:5,10  
 49:1 50:5,10 51:22  
 86:11 99:13,14 100:7  
 100:9 104:15,19  
 106:12 108:6 117:22  
 134:22 147:21 149:20  
 150:5 156:18 157:7  
 157:22 158:4 159:7,8  
 163:5 166:17 171:22  
 172:2,6 174:8 176:17  
 177:11 189:15 200:13  
 201:2,6 209:17  
 210:14 212:1 214:8  
 222:17 223:8,15  
 226:13,15 229:8  
 232:9 233:22 234:4,6  
 240:12 241:15 248:9  
 255:21 257:2,18,20  
 261:2 263:20 266:11  
 267:17 268:22 269:9  
 285:2 286:2 299:15  
 302:9 306:18 307:3  
 308:4 315:9 316:18  
 322:6 323:12 329:2  
 337:18 340:19,21  
 343:18  
**discussions** 89:2  
 180:22 196:20 239:16  
 263:16 264:2 276:8  
 304:12,13 305:10  
 341:18  
**disease** 121:9 130:9,10  
 141:7 155:4 237:8,17  
 237:19 239:2 310:13  
**diseases** 13:6

**disparities** 90:7 112:20  
 141:16 178:11 243:4  
 243:11,13 244:10  
 247:13  
**disparity** 110:15 111:22  
 247:22  
**display** 97:14  
**displayed** 64:12 89:18  
 294:21 331:5  
**disposition** 185:7  
**distinguish** 79:13  
**distressed** 138:8  
**distribute** 268:19  
**distributed** 247:7  
**distribution** 89:7 245:4  
 245:7,19 246:4  
 259:10  
**distributions** 318:2  
**diverse** 283:7  
**division** 322:18  
**doctor** 195:8 196:4  
**doctors** 80:8 107:9  
**doctrine** 56:12  
**document** 218:17 268:4  
 314:13  
**documentation** 219:1  
 219:13  
**documented** 154:11  
 163:11 235:15 236:12  
**documents** 174:19  
**doing** 44:22 59:10 63:5  
 63:10 64:5 77:10  
 99:17 110:1 134:16  
 147:17 149:17 150:1  
 151:1 176:6 204:15  
 205:18 206:4 209:7  
 219:17 223:3 228:19  
 232:20 244:22 245:18  
 246:1 256:12 262:12  
 302:13 330:17  
**domain** 50:16 51:3,4,5  
 65:22 66:3,14,19,20  
 67:14 72:7 79:3  
 173:10,20 234:22  
 238:19 297:16 306:5  
 306:6,11,11,14  
 322:19 327:4,19  
 328:9,9 329:17  
**domains** 50:16,19  
 51:14 67:7 73:13  
 306:12 328:10  
**dots** 279:13  
**double** 77:22 118:9  
 208:19  
**doubt** 268:13  
**downgrade** 281:10,19  
**downgrading** 282:1  
**download** 94:20 205:1

205:10  
**downloaded** 205:20  
**dozen** 252:3  
**dozens** 114:4  
**drag** 280:17  
**dragging** 125:10  
**dramatically** 155:13  
**draw** 279:21  
**drill** 306:13 327:1  
 333:22  
**drill-down** 63:21  
**drive** 131:13 301:19  
 329:18  
**driver** 311:4,11  
**drives** 198:14 311:3  
**driving** 54:7 128:10  
 131:19  
**drop** 195:14  
**drop-off** 154:16  
**dropping** 129:1,4  
**drove** 12:2  
**Drs** 315:20  
**du** 156:7  
**dual-** 131:5,21  
**dual-eligibility** 116:21  
 120:13 135:12  
**dual-eligible** 115:9  
 126:13  
**dual-eligibles** 131:9  
**Duke** 2:10 112:14 152:6  
**Dumb** 22:14  
**Dutton** 1:11 10:14,14  
 22:13,14 23:1,4,6  
 33:21 92:14,18 93:6  
 93:13 96:6 154:4  
 189:8 245:17,22  
 257:22 258:16 259:3  
 272:4  
**Dutton's** 44:7  
**dye** 237:18 239:9

---

**E**


---

**earlier** 61:1 68:9 82:4  
 84:13 89:3 99:15  
 107:17 138:13 192:12  
 194:9 216:14 217:16  
 220:20 225:1 227:20  
 235:8 256:21 272:17  
 328:12  
**early** 102:7 198:21  
 260:9,9  
**easier** 163:9 274:22  
 342:3,11  
**easily** 70:9 126:14  
**East** 121:6  
**Eastern** 340:8  
**easy** 126:22 130:19  
 205:21

**Eatmon** 1:12 9:12,17,17  
78:11 195:5 293:21  
**echo** 77:16 201:1  
266:20 302:10  
**ecstatic** 159:12  
**edit** 235:5 236:3,7,11  
**edited** 236:14 239:12  
**editorialize** 159:9  
**edits** 225:5  
**educated** 294:2  
**effect** 129:22 137:18  
190:12 196:6 312:9  
339:12  
**effective** 44:13  
**effectiveness** 292:18  
**effects** 127:20  
**effort** 14:20 25:6 33:22  
142:15 143:8 273:15  
278:21  
**efforts** 159:18 343:10  
**egregious** 142:15  
**eight** 49:13 147:4  
177:21  
**either** 20:10 30:5 66:1,2  
66:7,9 70:15 72:9  
84:4 88:7 100:17  
154:5 184:6 203:20  
218:22 232:7 233:20  
237:20 285:6 311:12  
321:20 323:21 324:14  
**elective** 133:17,19,20  
**electronic** 202:14  
204:18 205:2,20  
**element** 64:4 235:20,20  
236:17 309:6  
**elements** 202:8 204:9  
205:5 226:17 235:22  
236:5,8 277:5,7  
**elevated** 65:17 142:17  
**eligible** 309:3  
**eligibles** 131:6,22  
**eliminate** 39:22 238:3  
**eliminated** 236:12  
**Elisa** 2:2 5:7,12 6:18  
16:4 27:17 29:10  
37:10 38:13 266:13  
299:10  
**Elisabeth** 1:13 11:15  
12:2 78:10 85:8 86:12  
150:5  
**Elizabeth** 100:10  
194:12 331:20  
**email** 20:3,4 92:4  
145:13 234:14  
**emphasis** 180:6  
**emphasize** 272:11  
**empirical** 117:14 119:9  
201:8

**empirically** 119:11,18  
123:15 137:13  
**employee** 73:8  
**employer** 7:18  
**empty** 14:14 252:18  
**EMR** 207:6,17 211:1  
256:19  
**EMRs** 207:18,19 211:20  
**enables** 84:13  
**encompasses** 63:4  
**encourage** 129:8  
**encouraged** 6:13 102:1  
**endeavor** 153:11  
**ended** 70:2  
**endorse** 27:3,5 37:13  
39:9 40:10 57:19  
59:11 168:14 201:18  
221:20 232:19,19  
274:22  
**endorsed** 24:1,2 33:11  
34:18 35:1,14 36:18  
40:18,19,22 41:3,6,6  
41:9 42:7 56:4 58:2,7  
58:7,12 59:16 60:15  
65:4 91:16 173:12  
174:14 199:16,18,20  
201:16 214:4 215:9  
215:12 218:8 223:7  
223:14 225:16 259:17  
262:11 270:4,12  
277:9,12 278:3 292:4  
296:8 301:11 309:1  
**endorsed-but-reserv...**  
308:15  
**endorsement** 17:16  
21:4 24:12,19 25:11  
33:19 34:21 36:9  
41:16 64:10 89:17,20  
157:21 158:1 171:3  
176:7 223:13 225:10  
225:12,15,19 227:13  
228:3,7 268:9,11  
270:22 277:13 282:16  
**endorsements** 262:9  
**endorses** 294:22  
**endpoint** 132:22 287:13  
**endpoints** 88:4 287:17  
295:14  
**enduring** 217:13  
**enforcing** 228:1  
**engage** 316:7 343:12  
**engaged** 18:9  
**England** 155:3 198:20  
**English** 246:1  
**enhance** 32:16 155:20  
**enormous** 272:8  
**enormously** 273:1  
**enquiring** 280:4

**ensure** 16:19 17:14  
43:21 251:11  
**enter** 87:13 204:10  
**entered** 207:10,20  
208:4,5 253:14  
**entering** 204:17 209:10  
210:22 211:1  
**enterprise** 71:13  
186:20  
**enters** 206:15  
**entire** 38:15 43:10  
67:13 101:6 117:19  
121:22 137:17 161:15  
161:16 198:14 272:22  
276:15 289:1 302:22  
323:21 333:4  
**entirety** 67:7  
**entities** 45:7 265:3  
**entity** 292:4 300:11  
**entry** 251:18 256:19  
**environment** 228:4  
330:2  
**equal** 236:14  
**equally** 325:20  
**equals** 80:15  
**ER** 11:12  
**era** 73:1 178:1,2  
**Erekson** 1:13 11:15,16  
100:11 101:1,4,8  
102:10 126:2 150:6  
271:4,10  
**error** 253:13  
**erudite** 56:13  
**especially** 122:17  
124:16 136:17 185:21  
283:14  
**essentially** 71:19 96:13  
102:17 197:21 266:22  
322:4  
**established** 36:7  
**esteemed** 221:11  
**estimate** 245:1 246:3  
**estimated** 245:1  
**estimates** 245:5,11  
**estimating** 243:7  
**estimation** 102:14  
113:13,19  
**et** 244:8  
**ethnicity** 122:7 127:11  
136:8  
**evaluate** 17:9 62:21  
69:7 330:14  
**evaluated** 59:15 64:15  
85:20 120:3 237:22  
**evaluation** 3:5 4:19  
16:20 17:10 18:11,12  
19:2,4 45:14 174:13  
**event** 66:11 212:22

296:4 331:2  
**eventually** 326:4  
**everybody** 34:1 94:15  
156:3 189:10 215:7  
248:15 304:9 315:22  
**everybody's** 91:22,22  
94:14 188:18  
**everyone's** 128:4  
331:15  
**evidence** 20:10 32:10  
90:14,18 91:2,3 99:3  
99:8,10 104:15,16  
117:17 131:7 162:14  
165:4,6,20 174:16  
175:20 176:10,11  
177:2 178:4,14,16  
182:5,13,15,17  
203:17 239:15,19,21  
240:8,11,12,16,19,20  
241:1,5,8 306:20,22  
307:5,19 315:4,7  
331:16  
**evident** 178:11  
**evolve** 211:22  
**evolving** 138:7 212:1  
276:9,10  
**exact** 252:2 338:16  
**exactly** 67:15 96:8  
101:22 130:15 159:20  
162:2 165:19 287:11  
287:12 321:15 323:9  
323:11 327:5 329:11  
335:7  
**examination** 253:1  
**examined** 181:17,21  
**example** 60:20 81:8,16  
115:3,15 118:19  
121:6,9,15 122:4  
128:19 143:5 196:10  
203:12 252:21 253:2  
292:6 293:7 294:10  
**examples** 155:1,5  
193:18  
**excellence** 196:19  
**excellent** 56:15 244:2  
295:6 315:4  
**exceptionally** 159:21  
**exclusion** 119:8 235:12  
235:14 236:4,8,11  
**exclusions** 179:18  
**excuse** 49:9 87:11  
237:1 246:18 327:2  
**exercise** 27:2 42:1  
193:8  
**exhaustive** 228:22  
**exist** 121:13 216:12  
235:22 236:5 308:16  
321:12 332:4



**existed** 154:8  
**exists** 73:8 189:12  
**expand** 118:19 119:6  
 153:9 254:18  
**expanding** 23:19  
**expect** 135:22 279:8  
 317:22  
**expectation** 70:7 115:9  
 298:5,10  
**expected** 65:17 67:12  
 80:21 81:2,3 96:14,15  
 96:16,20 124:21  
 125:5,5,6  
**expecting** 122:8  
**expensive** 199:10  
 209:4 256:13  
**experience** 78:2 88:3  
 211:16 212:3,6  
 272:17 328:14  
**experienced** 289:8  
**experiencing** 177:20  
**expert** 10:22 43:12  
 276:6  
**expertise** 16:19  
**experts** 28:3 43:14  
**explain** 24:3 173:22  
 235:6 245:16 320:16  
 335:17  
**explained** 328:7 336:8  
**explaining** 120:1 231:6  
 333:9  
**explanation** 24:7 86:10  
 190:1 200:4 232:6,8  
 243:1 246:14  
**explanations** 333:12  
**explanatory** 334:1  
**explicit** 63:10 104:5  
**explicitly** 63:19 104:5  
**explore** 137:11 209:12  
**exploring** 136:20  
**exponential** 160:12  
**express** 17:20 268:15  
**expressed** 201:10  
 306:9 308:7  
**extensive** 115:4 240:15  
**extent** 17:13 43:9 45:5  
 76:22 119:22 130:9  
 205:13 206:11 300:12  
 300:13 311:3 322:5  
**extra** 35:18 206:3 223:6  
**extracting** 211:20  
**extremely** 309:18  
**extremes** 253:11,13

## F

**FACC** 2:7  
**face** 9:10 111:19 201:7  
 201:11 226:20

**face-to-face** 5:20  
**faced** 36:22  
**facilitate** 19:9  
**facilities** 69:11 131:18  
 174:13  
**facility** 70:6,16 72:10  
 85:18 86:2,6 107:21  
 180:20 181:2 184:10  
 185:14 186:3 199:18  
 199:21 200:1,7  
 213:22 254:6 279:19  
 292:20 324:16,17  
**facility-to-facility** 86:8  
**facing** 222:7  
**FACOG** 1:13  
**FACS** 1:13,18 2:7  
**fact** 30:3 34:16 37:1  
 40:18,20 51:6,8 53:10  
 63:2 84:20 123:3  
 146:5 147:13 152:22  
 154:22 175:7,16  
 176:1 189:20 208:9  
 209:4 211:13 217:8  
 236:17 250:22 265:13  
 273:8 287:8 296:19  
 312:3 343:6  
**factor** 89:22 111:1,6  
 112:2 115:18 121:14  
 123:22 124:3 127:22  
 128:6 129:2 133:5  
**factors** 107:12 110:5  
 112:18 113:14,15  
 114:1,4,7 115:1,3,4  
 115:19,20 116:8,11  
 116:14 117:11,12  
 118:5,6,11,21,21  
 119:5,10,21 120:1,7  
 120:16,20 122:13,20  
 126:5 130:12 131:19  
 139:22 140:6,7 142:7  
 159:16 201:3 254:7  
**fail** 24:18 66:5 221:16  
 286:20,20,22 288:2  
 294:19 312:15  
**failed** 267:1,6 327:7  
**failing** 327:18  
**fails** 25:20 36:13 294:18  
**failure** 53:7 60:20 65:13  
 66:4 67:11 82:6 87:12  
 88:6 221:3 234:20  
 235:16,19 236:13  
 237:5,16 238:4,22  
 247:15 250:20 252:13  
 252:22 253:3,3,7,18  
 258:11 274:18 280:8  
 290:12 293:19 313:7  
**failures** 269:22  
**fair** 190:20 197:9

203:20 219:5 329:10  
**fairly** 122:5 204:13  
 209:18 238:11 265:14  
 267:15 291:11  
**fairness** 277:11 301:18  
 303:13  
**faith** 25:6 198:10  
 267:21  
**fall** 16:11 49:7 89:8  
 184:13 278:13  
**fallen** 220:1  
**falls** 21:20 310:14  
**familiar** 23:17 137:3  
**family** 57:1 68:19  
**fantastic** 125:18  
**far** 47:5 75:6 94:16  
 207:14 208:21  
**far-reaching** 268:5  
**fashion** 76:17  
**fatal** 289:21  
**favor** 265:16  
**feasibility** 20:19 148:11  
 148:13 149:5 163:5  
 167:22 168:1 202:6  
 204:3 210:2,4,5,9,13  
 210:14,17 212:10  
 256:11,16 257:5,10  
 319:11,15,22  
**feasible** 202:19 208:12  
 256:22 319:13  
**February** 1:5 231:13  
 340:7 341:7  
**feedback** 6:7 175:7  
 203:5 204:11 213:16  
 213:19,19 235:10  
 251:21,22 252:14  
**feel** 30:4,13 33:5 82:13  
 100:7 110:20 111:8  
 113:20 134:14 150:17  
 150:18 164:15 198:12  
 227:17 261:5 262:22  
 269:16 272:4 297:6  
 297:16 319:16 333:19  
 342:15  
**feeling** 136:10 283:20  
 324:8  
**feelings** 269:12  
**feels** 100:8  
**felt** 52:16 91:18 197:2  
 297:4  
**females** 242:7 243:20  
 244:7  
**fewer** 160:10  
**fibrillation** 206:9  
**field** 37:13 134:14  
 203:13,16 253:2  
 282:18 330:10 333:4  
**fields** 203:1,11 204:7

204:10,14 207:16  
 252:19 254:13 286:7  
**figure** 98:19 177:10  
 187:20 191:12  
**file** 189:12  
**fill** 7:9  
**filled** 22:14  
**final** 127:13 230:9,11  
 230:18 267:5 338:8  
**finally** 21:3 169:9  
**financial** 11:11  
**find** 23:7 27:9 33:22  
 55:8 61:6,13 78:20  
 79:22 84:21 85:1  
 196:4 246:6 262:14  
 278:18 297:18  
**finding** 139:16 153:5  
 182:12  
**fine** 19:18 23:6 105:9  
 126:21 133:15 200:6  
 247:20 256:16 273:12  
 307:1 316:1 319:18  
**finish** 223:4  
**first** 5:19 8:13 9:8 20:2  
 20:7 26:22 36:22 39:1  
 39:8 45:14,17 49:4,4  
 50:2,11 55:1 60:3  
 63:1 79:15,17,19 81:1  
 91:21 141:11 148:5  
 159:6 164:20,20  
 165:2,3 214:10  
 234:21 241:18 280:13  
 281:20 284:8 302:4  
 303:6 305:11 308:14  
 326:12  
**five** 18:19 26:21 62:6  
 67:7,14 88:3 95:14  
 101:13 109:9 145:22  
 153:1,4 171:8 217:22  
 234:21 306:15 325:6  
**five-** 261:4  
**five-minute** 98:19  
**five-year** 139:15 296:5  
**Fleisher's** 35:8 61:1  
 228:8  
**Fletcher** 315:21  
**flew** 14:5  
**flexibility** 172:11  
**flip** 312:4,7  
**Floor** 1:7  
**Florida** 11:9  
**Florida-Gainesville**  
 1:19  
**focus** 110:9 150:9  
 160:1 194:17 222:4  
 339:3  
**focused** 18:11 224:17  
**focusing** 312:9

**folder** 337:4  
**folks** 268:17  
**follow** 34:15 39:13  
 56:11 120:11 184:18  
 192:11 210:19 269:9  
 273:20,21 285:6  
 309:8 336:17  
**follow-on** 25:17  
**follow-up** 95:11 204:16  
 264:7  
**followed** 20:20  
**following** 183:15 284:8  
 341:9  
**follows** 245:15  
**football** 277:20  
**forces** 156:10  
**Ford** 55:6  
**foreseen** 262:16  
**forge** 163:9  
**forget** 204:6 308:20  
**form** 7:9,15 54:5 75:10  
 76:2 81:15 224:2  
 246:21 247:5 297:5  
**formal** 268:3  
**forms** 71:21  
**fortitude** 9:5  
**fortunate** 18:16  
**Forum** 1:1,7  
**forward** 20:5 22:2 24:18  
 28:9 37:13 39:22  
 42:12 43:20 52:4  
 86:17 100:9 136:3  
 146:9 153:6 159:18  
 164:4 165:21 167:3  
 186:6 204:22 206:22  
 210:3 221:19,21  
 222:9 226:2 238:13  
 267:2,13 285:4 286:5  
 293:10 308:19 342:7  
**Foster** 332:10  
**found** 110:14 195:18  
 198:21 220:4 337:10  
 337:11  
**founders** 38:7  
**four** 62:6 66:19 95:14  
 178:21,22 194:6  
 212:12 235:2 263:2  
 279:18 285:1 292:14  
 306:15 313:1,5,7  
 320:22 321:1 322:4  
 325:6,15 327:6  
 338:14  
**Fourteen** 105:9  
**Fourteenth** 37:20  
**frames** 317:21 318:2  
**framework** 112:20  
 276:6  
**frankly** 53:17 54:13

56:2 72:22 135:13  
 161:5 192:5 204:11  
 273:11 284:19 289:14  
**freak** 261:15  
**Fred** 13:20 14:2,5 15:5  
 189:9 190:8 265:7  
 272:4 303:5 343:18  
**FREDERICK** 1:14  
**free** 19:10 57:2 277:6  
 319:17  
**frequency** 331:10  
**frequent** 96:18  
**frequently** 43:12 287:9  
**fretting** 191:15  
**friend** 68:18  
**friends** 232:11  
**frightening** 136:10  
**front** 8:1 40:1 109:2  
 190:4 252:5 297:1  
**frustrating** 262:15  
**FTE** 208:18  
**full** 107:5 211:14 337:4  
**fully** 209:1 275:9  
 302:17  
**fun** 19:13  
**function** 18:4  
**functioning** 292:19  
**fundamental** 54:10  
**fundamentally** 36:21  
 40:2,15 62:11,17  
 279:14,20  
**funky** 314:14  
**further** 63:6 64:13 65:1  
 101:22 108:6 150:4  
 157:21 174:4 182:18  
 189:14 196:1 200:12  
 222:17 234:4 240:13  
 255:20 257:19 261:1  
 264:8 314:12 334:9  
 334:14 335:1  
**further** 55:20  
**future** 53:19 104:15  
 126:11,18 190:3,5  
 197:17 205:9

## G

**Gae** 47:18 54:6 56:17  
 156:11 316:2 323:19  
 326:17  
**GAETANO** 2:9  
**gain** 183:4  
**Gainesville** 11:9  
**gall** 198:5  
**game** 182:13  
**gaming** 182:18 183:17  
 184:6 290:11  
**gang** 301:22  
**gap** 20:11 32:10 91:5,8

99:13,14 100:8,10  
 102:22 103:18 162:15  
 165:22 166:1,2  
 177:11,12 178:6,18  
 178:20 179:2 240:4  
 241:11,12,15 247:12  
 248:11,13,21 308:1  
 308:16,20,21 310:7  
 312:1 313:5,18  
 314:22 315:5,7,9,11  
 315:15 321:14,16  
 322:2 324:15 331:8  
 331:16  
**gapped** 330:5  
**gaps** 90:8 99:18 242:4  
 263:22 321:12,12  
 331:6  
**Gee** 298:15  
**gender** 108:16,17 124:3  
**general** 47:13 96:12  
 138:5 182:20 209:22  
 227:5 254:12 283:22  
 337:13  
**generalities** 226:19  
**generally** 321:13  
**generate** 78:3  
**generated** 71:11 202:9  
**generic** 110:2  
**genetic** 110:18 115:14  
 115:20 116:15 117:5  
 118:21 119:5 120:20  
 121:5 135:7  
**genetics** 141:7  
**geocode** 137:1  
**geocoding** 138:7  
**geography** 130:22  
 131:1  
**Georgia** 195:22  
**get-go** 227:14  
**getting** 25:4 90:22  
 109:21 137:21,22  
 139:17 140:10 171:11  
 175:7 183:8 193:6  
 194:17 196:3 203:5  
 209:9 275:3,20 302:3  
 322:20 327:22  
**give** 5:7 7:16 35:4 41:15  
 58:18 64:5 67:1 72:12  
 84:19 86:5 121:5,9  
 192:18 193:10 203:12  
 213:19 219:1 224:14  
 229:18 242:22 276:11  
 283:21 307:14 321:7  
 342:21 343:19  
**given** 50:4 60:6 99:19  
 110:1 118:22 158:15  
 175:16 178:6 181:8,8  
 186:2,3 188:15 217:7

261:11 265:13 277:6  
 281:2 309:22 318:1  
 321:11  
**gives** 61:15 176:5  
 308:13  
**giving** 33:5 62:19 64:17  
 65:7 87:19 141:22  
 283:4 285:13,15  
**glad** 342:2  
**glaring** 128:19  
**goal** 154:20  
**Goodwin** 2:3 6:1,2 17:2  
 19:18 22:7 44:2  
 105:11  
**gosh** 29:21  
**gotten** 98:16 159:19  
 204:3  
**graded** 66:21  
**grading** 121:12  
**gradual** 156:15  
**graft** 3:8 158:20  
**grandchildren** 13:6  
**granted** 79:14 80:3  
**granular** 210:22 297:6  
 300:21 302:5,7  
**granularity** 301:16  
 302:7  
**graphic** 246:4  
**graphs** 155:15 160:19  
**grappling** 316:11  
**Grau-Sepulveda** 48:1  
**gravitas** 176:5  
**gray** 21:21  
**greater** 21:18 177:17,21  
 236:14  
**ground** 17:22 298:22  
**group** 16:8 30:11 37:1  
 70:15,19 72:10,11  
 109:18 110:6 149:10  
 155:4 161:5 175:2  
 176:5 180:20 186:3  
 187:11 190:21 191:3  
 191:11,20,20,22  
 192:3,6,8 193:2 194:3  
 194:6,7,15,17 195:4  
 195:10 196:5,9,12  
 197:5,8 198:20  
 232:13 258:18 289:9  
 301:3 305:21 331:12  
 331:13 343:12  
**groups** 34:19 48:10,18  
 48:20 50:21 57:18  
 73:4 129:17 130:14  
 150:9 174:12 181:4  
 192:19 193:8,19,22  
 195:19 196:11 197:7  
 200:6 232:7 314:8,11  
 331:7

**Grover** 1:14 13:20 14:2  
14:2,8 105:13 187:1  
190:14 198:18 203:17  
265:8 273:6 293:9  
294:6 303:7

**growing** 101:12 187:17

**growth** 160:12

**guess** 23:14 54:10

88:21 118:2 134:19  
163:8 203:22 207:7  
222:19 239:21 241:10  
248:2 249:5 250:11  
267:10 288:19 330:19

**guidance** 18:13 309:3

343:19

**guide** 19:9 44:17 265:5

**guideline** 310:11

312:13

**guidelines** 101:19

310:12

**guilt** 64:9

**Gunnar's** 82:4 211:16

## H

**HA** 332:10

**hack-side** 279:4

**hack-size** 278:13

**half** 153:1 162:4 237:10

262:8 303:5

**hand** 86:11 98:8 115:7

134:19 145:13 206:7

208:4 289:2

**handful** 16:13

**handle** 233:11

**hands** 316:1

**Handy** 1:15 12:19,20,20

98:9 172:12,16 174:7

176:8,10,12,20 178:9

214:13 217:12,12

296:18,18 324:22,22

**happen** 133:13,22

183:16 209:2 288:5

**happened** 65:1 93:16

**happening** 128:20

202:20 250:8 263:17

264:3 289:22 303:19

**happens** 31:16 115:17

123:15 145:6 192:6

208:11 302:20

**happy** 34:1 50:7 51:15

70:4 114:11 173:5

174:9 236:19 342:13

**hard** 69:16 139:17

295:13 322:20

**harder** 72:19 176:2

301:17,17

**HARQ** 278:12

**harvest** 252:5

**harvestry** 57:7

**hat** 114:21 298:16

**hate** 41:2 68:21

**he'll** 172:18

**head** 34:2 321:22

322:18

**headed** 93:15 148:11

239:15

**heading** 136:20

**health** 1:16 9:1 11:10

12:7 13:4 134:22

140:6 202:14 204:19

205:2,13,20 280:20

335:21 336:4

**health-related** 336:2

**healthcare** 10:1 44:17

137:21 138:4,11

202:10 272:20 273:1

**hear** 5:4 6:6 128:3

211:6 224:7 266:11

297:9 338:5 341:1

**heard** 57:16 59:20

102:11 141:3 192:12

218:10,18 230:3

237:10 271:10,14

328:3 335:18

**hearing** 130:9 141:21

157:9 166:8 167:2

168:3,8 234:10 261:3

261:18

**heart** 101:19 199:6

237:5,15

**heck** 69:20

**heightened** 280:7,8

**held** 301:12

**help** 16:19 24:7 25:16

25:17 31:5 44:15,17

68:18 84:7 88:11

129:11 135:19,20

147:11 154:18 192:1

230:3,17,18 265:22

271:7,8 282:3 293:10

341:21 343:18

**helpful** 23:20 52:3

62:20 65:7 67:5 68:2

68:3 69:6 126:17

187:12 232:16 265:5

274:4

**helping** 7:3

**helps** 51:15 205:21

225:8 283:16

**Henry** 55:6

**hey** 69:19 97:7 253:9

**hi** 4:9 7:2 11:15 12:6

13:3,16 22:13 56:6

284:5,7

**high** 65:14 82:9 91:19

103:19 105:20 109:9

147:4 149:3 157:16

178:21 179:1 200:18

202:2 212:13 237:7

248:19 249:17 250:20

253:10 256:5 257:8

261:8,10,12,21 274:9

280:15 287:3 290:11

291:1,11 307:8 320:3

**high-dose** 312:10

**high-performance**

314:7 331:6

**higher** 16:19 30:12 31:7

40:20 53:16 67:11

96:15,21,21 102:20

110:15 115:16 118:5

121:8 127:18,19

133:9 142:19 153:22

160:4 213:4 235:17

293:11 297:13

**higher-** 294:19

**highest** 151:22 174:20

180:8 253:8 262:3

307:9 310:8 331:12

**highlight** 19:6

**highly** 137:8 180:11

202:19 290:10

**highways** 12:15

**hip** 124:3 303:21

**Hispanic** 127:8,9,10

130:5 132:8 139:10

**Hispanics** 127:12

**historically** 115:13

255:5

**history** 184:7 235:15,19

236:12 272:20 308:13

**hit** 105:8 208:22 213:10

**hitting** 208:21

**hm** 239:15

**hold** 6:6 41:7 108:19,21

141:18,18 181:14

210:1

**holistic** 78:1

**home** 26:21 34:12 53:3

181:20 183:9 185:14

197:13 323:1,2

328:18

**honest** 333:3

**honestly** 211:5 272:15

318:1

**hope** 51:14 85:6 137:14

139:6 211:22 250:4

268:17 269:4 283:16

334:12

**hopefully** 33:3 112:8

**hoping** 187:2

**hospice** 185:14

**hospital** 57:2 63:13

70:3 72:5,22 73:9,22

74:17 75:6,18 93:7

143:3 179:16 181:20

182:1,8,10 183:6,13

183:21 184:3 188:6

190:2,6,10,11,18

191:21 192:7,21

193:9,18,20 194:2,16

194:19 195:3,10

196:10,22 197:3,8,16

197:19 199:2,2 209:6

238:21 244:22 255:8

256:13 258:18 273:2

278:6,15 281:7 292:1

294:12 297:15 313:7

332:4,9,18,19 334:8

334:12 336:6

**hospital's** 208:17

334:13

**hospital-based** 161:8

**hospitalgov.com** 32:2

**hospitalization** 87:16

179:13

**hospitals** 34:4 73:9

75:2 83:3 102:12

110:21 136:11 154:10

190:21 191:4,10,22

192:8 193:15,16,21

194:1,7 197:9 199:9

208:12 244:21 255:9

255:10 278:20 290:21

311:16,17,22 312:15

313:14,15,16 314:4

314:15,19,22 322:16

327:3 330:17 331:12

**hour** 162:4 299:9 303:4

**hour-and-a-** 303:4

**hour-and-a-half** 12:2

**hours** 112:1 204:9

**housed** 152:6

**Housekeeping** 3:2

**huddle** 343:17

**huge** 332:20

**human** 312:8

**hurt** 302:3

**hurting** 187:13

**hybrid** 204:19 207:7

256:19

**hypertension** 115:17

115:17 116:3 117:4

118:18

**hypothetical** 129:19

**hypothetically** 113:8

## I

**idea** 119:22 153:5

176:19 192:19 246:9

340:11

**ideal** 135:17

<b>ideally</b> 137:15	122:2 204:12 331:7	<b>incumbent</b> 138:14	130:8 132:7 138:9
<b>identical</b> 159:3	<b>impressions</b> 150:5	<b>independent</b> 54:4	140:5 190:9 263:15
<b>identifiable</b> 45:6	<b>improve</b> 34:7 154:22	161:19 197:15 269:17	<b>inform</b> 30:12 31:5 44:15
<b>identified</b> 289:17	155:9 156:9 175:9	<b>independently</b> 24:6	110:7 230:17
<b>identify</b> 159:16 220:5,8	224:15 289:20 292:3	25:19 216:15 219:3	<b>information</b> 44:15,18
292:19	334:19	290:9	52:22 55:3 61:16
<b>ignorance</b> 237:2	<b>improved</b> 64:11	<b>index</b> 87:16 116:21,21	62:19 63:20,21 68:15
<b>ignored</b> 269:10	<b>improvement</b> 11:22	138:9 187:22	68:20 70:5 72:6,11,17
<b>illustrate</b> 292:8	33:4 50:22 60:15	<b>India</b> 121:18,19,20	74:13 77:19 78:19,20
<b>imagine</b> 287:2,22 288:5	135:21 154:9,12,13	<b>Indian</b> 121:7	79:22 80:4 82:2,2,14
321:17	154:17,21 155:1,12	<b>Indians</b> 121:20 128:5	84:11,14,19,22
<b>immaterial</b> 191:14	156:2,13,15 178:4	<b>indicate</b> 17:12 91:8	132:12 135:18 149:19
<b>immediate</b> 232:2	180:4 185:2 190:13	<b>indicated</b> 193:5	150:10 152:10,10
<b>immediately</b> 222:10	212:19 250:8 272:9	<b>indicates</b> 229:20	182:22 183:19 184:20
251:16	284:15 317:22 318:3	<b>indication</b> 95:7	185:12 188:18 189:12
<b>immune</b> 306:8	334:20	<b>individual</b> 7:18 16:9	202:13 203:6 204:18
<b>impact</b> 115:21,22 118:9	<b>improvements</b> 250:4	25:18 31:4 34:21	205:1,11,15 212:18
119:1 120:19 122:16	<b>improves</b> 285:7	36:17 37:2 39:14	224:16 230:2 241:19
128:5 135:6 140:6	<b>improving</b> 155:10,18	41:20 50:8 52:5 54:2	241:22 242:3,6 244:9
186:4 207:10 255:14	272:20 273:1	54:13 60:17 61:12,20	246:11 248:5,7
312:12 325:10	<b>impute</b> 252:18	63:7 64:3 65:2 66:5,6	251:12 271:21 285:14
<b>impacts</b> 112:3 160:6	<b>in-</b> 270:14	66:7,8 68:7 69:17	285:16 287:16 336:2
<b>impassioned</b> 80:20	<b>in-person</b> 4:5 9:8	70:5,6,17 72:4 75:4	336:3,21 337:13
<b>imperative</b> 196:14	<b>incentive</b> 32:18 33:9	76:8,10,18 77:1,2	342:9
<b>implementation</b> 43:15	<b>incident</b> 53:11	83:12 124:13 131:8	<b>informs</b> 232:8
300:1	<b>incidents</b> 293:13	147:16 149:21 151:13	<b>inherent</b> 161:17
<b>implemented</b> 180:2,4	295:13,14	152:20 161:6 163:21	<b>inherently</b> 113:21
200:2	<b>include</b> 25:11 49:2 86:6	203:5 222:11 223:18	<b>initial</b> 25:11 36:9 38:7
<b>implicated</b> 201:3	124:20 126:15 135:5	224:13 226:17 227:9	227:13
<b>implication</b> 65:2	150:16 163:4 238:7	235:1 258:2 268:9	<b>initially</b> 203:11 215:9
<b>implications</b> 100:2	250:9 269:1 278:4	269:1 270:8,21,22	215:12 259:17
268:5 274:8 278:2	<b>included</b> 76:3 92:21	274:10,13,18,22	<b>initiation</b> 37:4
<b>implied</b> 177:18 294:7	107:6 108:15 119:15	275:7 276:15 285:21	<b>Initiative</b> 11:14
<b>implore</b> 337:12	119:15 123:3,22	287:13 292:9 293:4	<b>Initiatives</b> 47:17
<b>implying</b> 64:13	139:2,13 255:6	296:9,15 301:1	<b>injury</b> 237:3,17,20
<b>importance</b> 31:9 60:6	264:11	306:15,15 320:13	<b>inpatient</b> 16:7 207:21
66:19 159:15 198:13	<b>includes</b> 216:3,22	326:6 332:9 338:14	<b>input</b> 33:3 94:13 142:13
290:9 292:1	217:4	<b>individually</b> 36:18	160:5 250:21 316:4
<b>important</b> 8:2 18:5 20:8	<b>including</b> 110:20 118:4	39:12 55:3,9,16,17	<b>inputted</b> 256:18
30:5 39:3 52:21 54:2	131:21 133:2 179:12	57:6 152:14 215:2	<b>inputting</b> 251:12
54:20 56:8,17 60:5	188:14 212:5 232:14	217:22 218:12 224:4	253:13
63:9 77:16 80:20	265:2 281:12 288:18	270:4,6 288:3 289:5	<b>insight</b> 86:5
85:14 91:4,9 102:18	<b>inclusion</b> 107:9 116:11	297:21 301:4 320:10	<b>insights</b> 339:21,22
114:7 116:16 117:5	119:8 129:21 139:9	321:17 322:9,16	<b>insignificant</b> 329:8
121:17 123:22 124:20	<b>incomplete</b> 186:13	323:14 339:1	<b>instance</b> 54:15 82:18
128:14 129:2 159:9	<b>incorporated</b> 22:21	<b>individuals</b> 16:18 47:22	216:22 222:20
184:17 186:8 196:14	122:20 213:21 252:5	75:3 93:4 109:10	<b>instances</b> 191:21
211:7 218:11 232:4	<b>incorrect</b> 313:20	212:13 249:18 259:20	<b>Institute</b> 152:7
270:16 273:17 275:10	<b>incorrectly</b> 334:18	292:22 296:8	<b>institution</b> 68:14 75:22
275:14 281:18 283:13	<b>increase</b> 62:7 133:3	<b>infection</b> 53:8 55:10	76:15,20 136:22
286:18 288:9,10	154:17	60:22 87:11 290:6	152:11 190:18 192:20
289:19 298:9 300:8	<b>increased</b> 299:19 314:9	291:9,11,16 295:17	197:13 206:13 207:14
309:19 310:16 312:4	<b>increases</b> 177:19	<b>infectious</b> 13:6	254:21 255:2
322:15,19 323:3	<b>increasing</b> 156:3 184:1	<b>inference</b> 82:2 122:11	<b>institution-specific</b>
325:20,20 326:8	206:2	122:13	77:8
<b>importantly</b> 66:21	<b>increasingly</b> 161:13	<b>inferences</b> 116:15	<b>institutional</b> 155:20
<b>impossible</b> 247:1	<b>incredible</b> 278:17	139:22	<b>institutionalizing</b> 130:1
<b>impression</b> 64:6,17	<b>incredibly</b> 242:1 343:12	<b>influence</b> 118:10 130:7	130:4

**institutions** 75:2 89:8  
90:4 192:20 205:13  
213:6  
**institutions'** 311:21  
**instructive** 121:17  
**instruments** 291:15  
**insufficiency** 237:6  
**insurance** 135:14  
**intellectual** 286:2  
**intelligently** 205:9  
**intended** 19:9 84:7,9  
228:9 236:4 238:7  
270:18 272:13 335:15  
**intent** 38:7,10,13 52:2  
118:14 120:22 122:16  
127:17 128:3,4 243:4  
269:11  
**intention** 64:21 238:3  
**interest** 3:3 4:17 6:19  
7:6 8:4,11 9:2,20 10:3  
10:7,12,19 11:19  
12:10,22 336:9  
**interested** 7:21 82:11  
111:7 196:22  
**interesting** 61:6 100:20  
154:6 199:5 209:17  
302:10 308:3 332:6  
339:11  
**interface** 335:13  
**interference** 5:22 8:6  
8:12 14:7,22 15:3  
29:9  
**interim** 11:17 202:22  
**intermittently** 42:15  
**internal** 27:8 44:19  
60:21 253:15 306:1  
**internally** 28:21 34:6  
304:13 339:22 341:18  
**Internet** 337:5,8  
**interpret** 24:8 54:17  
60:19 69:15 72:19  
182:7 199:20 242:2  
**interpretation** 81:18  
213:18  
**interpreted** 43:6 56:14  
71:10  
**interpreting** 283:5  
297:2  
**interrupt** 323:7  
**interrupted** 114:10  
326:20  
**interval** 244:20 245:8,9  
**intervals** 242:9,10  
244:15 245:12  
**intestinal** 9:4  
**intrinsic** 237:8,19  
**introduce** 5:7 6:22 8:15  
8:17 13:21 18:20

46:18 47:4,8 173:5  
234:13 305:11  
**introduction** 18:18 47:6  
174:11  
**introductions** 3:3 4:16  
6:18 7:7  
**introspection** 60:6  
**invalid** 285:18  
**invasive** 161:14  
**inventory** 262:10  
**investigated** 323:1  
**invitation** 265:18  
**invited** 18:17  
**involved** 10:9 135:1  
295:11 343:9  
**involves** 203:18  
**IQR** 324:3  
**irony** 140:20  
**irrelevant** 79:18  
**isolate** 216:22  
**isolated** 49:14 60:20,21  
67:1 88:2 102:4  
160:10 161:12 216:4  
**issue** 36:21 46:19 91:14  
107:7 110:18 111:22  
139:1 142:3,19 146:9  
156:7 163:6 183:3  
184:4,17 186:9 187:4  
188:18 189:9 191:19  
192:10 206:19 209:19  
211:10 220:16 223:12  
223:17,21 227:11  
232:5 239:9 250:9  
257:12 262:18 263:16  
264:6,18 267:12  
268:1 273:8 274:2  
280:17 281:19 284:19  
289:2 296:6 319:16  
320:9 327:21 338:16  
**issues** 53:21 85:11  
107:3 110:8 112:20  
127:12 135:3 138:7  
162:16 163:3 189:19  
190:15 191:16 206:7  
237:5 249:22 251:17  
266:6,17 286:4 290:6  
302:16 316:11 339:2  
341:22 342:4  
**it'll** 94:5 283:21  
**item** 57:7 258:10  
**items** 112:4 117:3  
226:21 295:22

---

**J**

---

**January** 213:15 214:17  
**Jarrett** 1:16 13:2,3,3  
28:14,14 95:2,8  
134:18 169:11,17

170:3 183:1,2 185:18  
188:17 236:21 237:11  
284:5,7,8 286:16  
**JD** 1:10  
**job** 45:1 87:19 151:3  
**John** 1:15 12:18,20  
217:12 296:18 324:22  
325:9  
**join** 266:9 267:16  
**joined** 13:20 23:9 47:18  
176:9  
**joint** 298:7  
**Josh** 9:7 330:8  
**Joshua** 1:20 12:7  
224:21 241:16  
**jour** 156:7  
**Judge** 35:8  
**July** 266:5  
**jump** 4:20 16:5 45:14  
242:22 331:4  
**jumping** 147:22  
**justification** 31:20 32:7  
43:17 221:19  
**justified** 125:14,17  
222:5  
**justify** 311:6  
**justifying** 204:1

---

**K**

---

**KATHRYN** 2:3  
**Katy** 6:2 16:22 44:2  
**keep** 4:12 18:10 114:9  
126:21 170:15 171:14  
172:4 185:6 282:9  
**Keith** 13:13  
**Keith's** 305:9  
**key** 196:16  
**kick** 39:9 277:21 307:12  
**kidney** 237:3,17,20  
**killer** 289:18  
**Knee** 303:21  
**knew** 153:7  
**knowing** 152:22 247:5  
293:2  
**knowingly** 215:9  
**knowledge** 43:16  
**known** 120:16 174:20  
181:10  
**knowns** 126:7  
**knows** 132:13 189:4  
203:16 332:1  
**Kosuri** 2:4 7:2,3 94:8  
94:16 95:6,9 99:6  
103:1,17 105:1,4,18  
108:11 109:8 144:5,7  
144:10,18,22 145:18  
145:20 146:11,21  
147:3 148:12,22

149:2,8 156:22 157:2  
157:12,15 158:7,11  
170:8,22 177:4  
178:13,19 200:14  
201:21 202:7 210:16  
212:9 229:10 240:22  
248:12,17 249:13  
255:22 257:4 258:14  
260:5,22 307:4,14,18  
315:10 317:4,8 318:7  
318:13 319:7,14,21  
337:19 338:3  
**kudos** 134:16

---

**L**

---

**L.A** 11:4  
**la** 176:17  
**labeled** 306:6  
**lack** 301:11 339:11  
**lacks** 303:15  
**land** 28:5  
**language** 33:22 85:21  
236:4 331:21  
**large** 10:17 73:4 113:22  
119:10 211:17 251:18  
263:21 277:18  
**largely** 191:18  
**larger** 322:2  
**Larissa** 1:20 15:11  
319:2,16  
**late** 198:21 336:16  
**latitude** 137:8  
**Laughter** 11:5 14:11,18  
97:21 109:4 148:3,7  
168:16 169:16 170:2  
261:17 262:6  
**launched** 48:14  
**law** 29:19 30:1 36:4  
332:7  
**lay** 117:12,19 246:7  
**lead** 18:22 19:3 111:12  
172:2 174:6  
**leaders** 52:11 135:1  
332:6  
**leading** 342:16  
**leads** 133:21  
**leaflet** 203:15,15,19  
**leaflets** 203:19  
**learned** 83:21 291:12  
331:22 333:1  
**learning** 80:7 292:2  
**leave** 119:2 255:4,17  
265:10 267:15 315:22  
338:20  
**leaves** 233:17  
**leaving** 299:3,4,5,8  
**Lee** 1:8,10 23:8,10,11  
226:5 342:14

**Lee's** 8:16 33:22 145:2  
**leeway** 44:9  
**left** 124:11 302:8 303:5  
 342:16  
**legitimate** 208:4  
**legitimately** 253:12  
**lemon-** 129:3  
**lemon-dropping**  
 133:20  
**lemons** 129:7  
**lend** 205:5  
**length** 252:2 295:18  
**lengthy** 7:9  
**lesser** 292:19  
**lessons** 156:9,12  
**let's** 37:13 45:16 108:22  
 144:3 148:4,4,19  
 164:18,19 168:13,15  
 171:10 210:1,2,13,15  
 222:2,4 237:17  
 241:15 249:12 257:3  
 291:7 340:20  
**letting** 335:20  
**level** 16:7,9,20 54:22  
 75:17 81:1 82:9 85:16  
 86:2 107:20,21,21  
 131:3,7,8 137:9 151:5  
 155:21 159:17,17  
 174:11 180:7,17  
 181:2,5 190:7,11  
 193:9 197:16,19  
 199:18,19,21 200:1,7  
 203:18 208:22 213:22  
 214:1 224:15 243:6  
 244:18 258:13,18,19  
 264:3 270:21,22  
 273:2 274:9 280:7,8  
 280:15 292:1 297:13  
 316:21  
**level-1A** 315:3  
**levels** 86:6 107:18  
 180:18 189:21 220:15  
 293:11  
**Levy** 13:11 46:5  
**lexicon** 285:8  
**lie** 151:21  
**lies** 255:3  
**lieu** 77:17  
**life** 27:10 221:2  
**ligamentous** 124:8,10  
**ligaments** 124:9  
**light** 22:22  
**lightly** 130:18  
**liked** 267:19  
**likelihood** 312:9  
**Likewise** 15:22  
**limbo** 40:11  
**limit** 48:7 245:7,8

**limited** 324:3  
**limits** 62:5 65:11 300:5  
**line** 13:9 57:7 62:12  
 111:12 132:13,19  
 163:10 172:13 176:9  
 233:8 252:11 259:6  
 305:1 310:3 342:19  
**lingered** 181:22  
**link** 5:2 19:19,21 20:5  
 92:1,3 94:13,22  
 188:10  
**linked** 188:15  
**lipid** 233:17 310:10  
 312:10  
**lipids** 323:2  
**Lisa** 138:19  
**list** 93:19 94:5 95:13,13  
**listed** 70:19 217:17  
 320:14  
**listen** 32:18,20 61:3  
 288:7  
**listened** 56:12  
**listening** 134:21  
**literally** 79:16  
**literature** 174:18  
 188:13  
**little** 6:7 23:18 41:12  
 69:6,14 70:20 72:18  
 74:5 85:6 88:5,10  
 96:19,21,21 104:6  
 118:10 121:10 131:9  
 134:19 140:10 144:1  
 150:9 171:8 175:21  
 197:11 205:22 207:1  
 227:8 240:7 254:19  
 288:19 296:2 297:2  
 320:16 335:18  
**live** 97:8 214:17  
**lived** 169:1  
**lives** 66:8  
**living** 138:1,2 223:5  
 228:12  
**loading** 122:19  
**loads** 128:12  
**lobby** 187:11  
**local** 28:21  
**location** 254:5  
**logged** 4:22 5:1 92:3  
 176:12  
**logic** 110:17  
**logical** 104:5  
**logically** 120:21 128:5  
 128:10  
**long** 4:13,14 149:20  
 154:8 168:19,19  
 265:14 272:20 289:11  
**longer** 19:13 34:16  
 36:14 53:12 203:20

268:9 281:9,10 301:8  
 335:5,12 336:4  
**longer-term** 323:4  
**longitude** 137:8  
**look** 6:16 33:17,18 39:3  
 41:16 52:20 55:17  
 62:20 63:11 69:19  
 82:19 90:7,8 94:2  
 116:17 117:13 130:20  
 130:22,22 132:5  
 142:3 147:12 150:15  
 153:10 155:16 186:5  
 197:3,4 199:17 200:9  
 217:14 218:3 239:4  
 241:22 243:9,12,22  
 244:6 251:2 253:11  
 270:15 274:10 276:14  
 290:3 292:13 294:11  
 298:6 300:1 314:5  
 322:17 325:1,22  
 333:7 334:6,7 342:7  
**looked** 128:13 133:8  
 136:2 141:11 145:7  
 152:1 153:14 182:16  
 183:20 184:12 238:12  
 238:16 242:14 274:12  
 314:3 317:20  
**looking** 10:8 38:17 79:5  
 80:6,14 82:21 83:4  
 84:3 94:1 116:8  
 132:20 134:10 135:2  
 135:8 142:5 165:11  
 167:12 173:15 175:17  
 185:13 186:18 188:19  
 195:6 206:17 212:6  
 220:21 239:5 241:18  
 247:19 252:7 270:10  
 270:13,20 274:16,17  
 280:3 294:1 299:21  
 300:7 303:8 313:12  
 314:1 325:13 326:5  
 326:22 327:10 328:6  
 333:11  
**looks** 40:21 105:16  
 199:17 224:9 246:5  
 250:18 317:16  
**loose** 32:4  
**loosely** 25:14  
**Los** 1:18  
**lose** 18:7 225:10,12,15  
 248:16 301:4  
**loser** 66:2  
**loss** 133:21 185:12  
**lost** 287:16 319:5  
 326:14  
**lot** 22:15,15 80:4 100:4  
 123:12 130:12 135:14  
 136:11 149:16 159:7

168:20 187:19 195:18  
 197:7 205:22 207:15  
 208:2 255:4 269:3  
 294:13 295:11 303:3  
 304:5 311:15,22  
 320:11 341:20  
**lots** 10:21 144:20  
**low** 145:22 146:5  
 157:17 248:20 256:6  
 290:17 293:5 295:15  
 308:21 311:20 312:16  
 315:14,18 317:10  
**low-** 314:7 331:6  
**lower** 35:15 53:11 81:3  
 81:20 96:15 121:7  
 153:22 212:22 245:7  
 311:8,10  
**lower-volume** 160:3  
**lowest** 310:8 331:13  
**LTACs** 184:8  
**Lucy** 277:20  
**lunch** 170:12,15,18  
 171:12,13

---

**M**


---

**MA** 1:11  
**main** 17:8 110:9 149:15  
 154:20 155:6 220:13  
 220:14  
**maintain** 25:22  
**maintenance** 20:21,22  
 24:15,17 33:4 144:14  
 162:14 174:13 180:6  
 197:20 202:11 218:22  
**major** 53:3 58:20 81:11  
 83:5 87:7,8 88:1,3  
 181:11 217:18,21  
 237:8 272:5 290:6  
 311:4,11 313:8 328:8  
 328:13,14,15  
**majority** 16:10 26:14  
 34:3 73:1,9 74:22  
 181:1 338:13  
**making** 17:16 25:6  
 35:12 58:8 65:20 77:9  
 77:10 138:16 176:2  
 186:13 208:16 239:13  
 274:22 282:21 294:1  
 333:21 343:8  
**males** 121:7 242:7  
 243:19 244:7  
**mammary** 306:1  
**manage** 39:12 291:13  
**management** 291:13  
**manager** 2:3,3 4:10 6:3  
 9:22 47:16 191:7  
 204:10 206:14,16  
**managers** 211:8

**Manchester** 12:3  
**manner** 16:2 44:22  
 207:3 242:15 295:3,4  
 330:3  
**manual** 207:7 256:19  
**manually** 204:20  
 210:22  
**mapping** 186:19  
**march** 233:12,16 266:3  
 341:12  
**margin** 301:21  
**Maria** 48:1 111:13  
**Marinelarena** 2:2 5:15  
 5:16 24:9 25:10 26:2  
 26:6,10,17 31:17 41:8  
 41:11 45:2,16,20 46:1  
 47:7,11,14 85:9 86:15  
 90:15,17 91:1 106:18  
 127:7 142:4 162:13  
 163:20 164:6,11  
 189:16 199:12 211:3  
 215:1,19 223:4,11  
 225:13 227:3 231:14  
 233:2 309:2 339:15  
 339:19 340:4,7,10,15  
 340:20 341:2,16  
**mark** 1:16 2:7 13:1,3  
 28:14 47:16 95:2  
 134:18 173:3 183:1  
 185:18 188:17 193:2  
 234:16 236:21,22  
 250:12 267:20 284:7  
 286:8 292:6 316:1  
 326:17 331:18 339:21  
**markers** 115:10 291:8  
**masking** 141:15 143:3  
**Massachusetts** 12:3  
**master** 189:11  
**match** 86:1 199:15  
 236:4,8  
**material** 129:9 234:14  
**materials** 235:7  
**math** 147:18  
**matter** 66:3 98:21  
 122:21 171:18 183:17  
 208:9 210:19 275:4,6  
 275:12 326:7 343:21  
**maturation** 159:10  
**maximize** 120:4  
**Mayo** 1:11  
**maze** 206:9  
**MBA** 1:11,16  
**MD** 1:10,10,11,11,13,14  
 1:15,16,17,18,19,20  
 1:20,21 2:7,9,11  
**mean** 8:3 31:13 32:1  
 36:20 37:12 44:11,19  
 54:1 57:14 64:11

67:18 69:20 85:6 87:3  
 93:15 98:17 104:18  
 108:15 118:14,16  
 119:7 120:16,20  
 121:21 122:18 124:1  
 125:18 128:5,9  
 135:12 138:5 139:13  
 159:3 187:6 191:15  
 202:5 208:3 246:10  
 256:11 264:22 267:4  
 267:5 269:11 287:21  
 294:12,17 295:22  
 296:22 297:20 310:5  
 310:17 312:1 314:21  
 321:12 322:7,11  
 323:7,18,22 324:2  
 328:8 333:17 334:18  
 343:7  
**meaningful** 69:2 90:19  
 125:21 175:15 247:17  
 308:10  
**meaningless** 84:2  
**meanings** 123:17  
**means** 20:9 22:1 32:5  
 83:1 133:12 200:18  
 212:13 229:22 263:21  
 265:2 275:8 279:20  
 320:3 324:19  
**meant** 228:10 267:10  
**measurable** 122:9  
**measured** 45:9 113:14  
 114:5 134:15 175:14  
 288:9  
**measurement** 9:22  
 100:1 154:12 219:18  
 268:14 276:9 299:16  
 299:18 300:6  
**Measurements** 5:13  
**measuring** 18:12  
 122:10,17 282:3  
 285:12  
**mechanism** 135:5  
 186:19  
**mechanisms** 211:15  
**med** 80:9  
**median** 177:22 308:4  
**Medicaid** 115:9 126:13  
 134:2  
**medical** 1:22 10:6  
 117:7 134:3 136:8  
 197:10 253:22 254:7  
**medication** 306:16  
 314:6,8 321:3 326:8  
 327:4,7,16 328:9  
**medications** 305:21  
 306:2,7,14 320:20  
 325:3,14,16 327:11  
 327:13,18,20 328:17

329:6,14,18,22  
 331:11  
**medicine** 1:14 321:16  
**medicines** 322:3  
**meet** 24:16 25:21 28:12  
 31:15,21 32:8 41:14  
 42:18 113:19,20  
 201:12 223:20 264:12  
 266:4 275:10 276:21  
 291:4  
**meeting** 4:5,11 5:19  
 6:16 9:8 15:16 17:5  
 17:22 18:1 22:11  
 23:10 48:7 179:7  
 266:5 300:17 303:5  
 324:21 328:8  
**meets** 27:22 30:13  
 41:12  
**Melissa** 2:2 5:16 30:18  
 45:2 78:9 85:7 163:15  
 223:11 341:5,15  
**Melissa's** 27:20 224:10  
**members** 17:7,18 18:21  
 19:5 21:14 107:8  
 144:11 190:19 266:9  
 283:19  
**membership** 17:8,17  
 196:21  
**Memorial** 1:20  
**men** 169:15,21 240:7  
**mention** 112:9 117:9  
 209:17  
**mentioned** 53:21 73:3  
 74:22 99:15 107:17  
 127:22 133:4 145:3  
 176:1 186:10 217:16  
 240:5 241:12 256:21  
 316:20 325:4  
**merging** 139:18  
**merits** 299:22  
**message** 139:4 140:3  
 221:14 270:17  
**met** 1:6 17:13 299:14  
**method** 17:17  
**methodologic** 16:19  
**methodology** 23:20  
 59:17 64:14 91:11  
 104:11 253:21  
**methods** 16:17 85:20  
 106:20 107:22 163:1  
 189:19 193:4 201:10  
**metric** 181:20 184:22  
 218:12  
**metrics** 27:8 47:17  
 330:10 332:8 333:9  
 333:10  
**metropolitan** 195:21  
**mic** 245:21

**Michigan** 1:20 12:9  
 193:12,13,17  
**microphone** 6:8  
**mics** 97:8 211:3  
**mid-** 314:7 331:6  
**million** 48:15  
**mind** 53:4 62:2 106:13  
 121:2 145:1 220:14  
 264:19 286:13 289:8  
 289:18  
**mine** 178:10 194:13  
**minimal** 291:18  
**minimally** 56:8 161:14  
**minimize** 120:8  
**minimizing** 112:22  
**Minnesota** 12:15  
**minority** 181:4  
**minute** 171:9 261:5  
**minutes** 18:19 26:21  
 297:1  
**MIPS** 92:22,22 93:2,4  
 93:18 95:12,16  
 192:13 258:3,6  
 259:14  
**miscellaneous** 136:14  
**missed** 6:21 98:9  
 313:12 322:22  
**missing** 15:15 183:17  
 186:15 252:4,19  
 321:18  
**mission** 54:9 56:20  
 272:12  
**mistake** 222:22  
**misunderstand** 334:12  
**misunderstood** 334:16  
**mitigate** 240:3  
**mitral** 3:10 77:22 173:7  
 173:11,12,20 174:1,1  
 179:11 203:2,7,9  
 206:10 214:16 216:2  
 216:4,5,6,7,20,22  
 217:1,2,15 224:9  
 289:3 338:15  
**mix** 113:8 123:17 129:7  
 134:9  
**model** 103:13 107:10  
 112:1,4,19 114:13,16  
 115:12,12 117:13  
 118:4,8,15,15,22  
 119:9 120:13,17  
 122:12 123:4,8 126:8  
 126:22 127:6,8,21  
 128:6,7 129:1,21  
 132:8 139:10 140:9  
 141:1,4 207:9 250:10  
 254:15,20,22 255:13  
 255:15 258:22 295:16  
 295:21

**models** 73:8 116:9,12  
121:13 128:11,16  
198:9,15 201:4 254:8  
255:6 295:12  
**moderate** 103:19  
105:21 108:2 109:10  
145:21 147:5 149:3  
157:17 162:18 163:1  
178:6 179:1 180:9  
181:7 200:17 202:1  
202:16 212:12 248:19  
249:18 256:5 257:9  
261:9,14,21 262:4  
307:9,21 315:7,13,17  
317:10 318:22 319:4  
319:8 320:3  
**modifiable** 159:16  
**moment** 9:3 74:22  
108:22 178:18 214:15  
307:15  
**money** 56:13  
**monitoring** 6:12  
**Monkey** 97:16  
**month** 214:17 235:9  
264:21 271:21  
**months** 68:19 182:9  
183:5 187:7  
**Moody** 281:10,19  
**morbidities** 87:8 88:1  
124:19 216:4 288:1  
293:12  
**morbidity** 50:15 51:4  
51:13,13 54:3 56:22  
57:19 59:4,22 62:6  
63:4 65:8,12,14,15,19  
65:21 66:14,20 67:1,7  
67:13 72:7 73:13  
78:15 79:1,8,11,13  
80:15 81:11,18,20  
83:6,9 87:7 88:3  
119:11,14 132:22  
150:15 161:1 217:19  
217:21 234:22 235:3  
235:4 269:2 279:18  
286:19,22 290:6  
292:12,15,18 295:14  
305:15,20 328:8,13  
328:15,15 329:13,21  
**morning** 4:4,6,13 5:11  
5:15 6:1 11:7 23:10  
47:15 104:7 150:12  
180:22 201:5 213:11  
214:3,8,19 217:21  
**mortalities** 161:7  
183:17,22 217:4  
**mortality** 3:10 49:14  
50:16 51:4,6,11,12  
57:18 58:17 59:5,21

62:5 63:4 66:18,21  
73:13 78:15 79:1,7,10  
79:13 80:15 81:10,17  
81:21 82:20,22 83:1  
83:12 84:4,5 87:6,7  
87:15 115:7,11  
119:16,17 124:19  
133:5 152:18 153:22  
159:13 160:4 161:2  
173:7,9,10,17,19  
174:20 175:17 176:4  
178:10 180:10 182:15  
183:3 184:5 185:21  
186:11,15 188:5,20  
212:20 216:3,9,9  
217:3,18 218:5,7  
219:22 220:3,4,21  
274:18 280:6 287:12  
289:2 292:11,14  
293:13,20 326:12  
329:13,21 338:22  
339:2  
**motion** 144:13 145:2,9  
**Mountaineers** 316:14  
316:16  
**move** 20:12,19 22:2  
24:18 37:12 47:1  
86:16 99:12 104:18  
135:4 136:17 143:22  
146:9 147:8 148:15  
157:21 159:18 162:11  
167:2 170:20 172:9  
176:22 177:11 183:8  
200:11 212:16 233:1  
234:1 261:6,14,20  
284:16 307:22 317:15  
**moved** 172:5 228:11  
**moves** 286:6  
**movie** 169:15  
**moving** 136:3 149:21  
171:14 293:9 336:12  
**Moyer** 1:17 9:21,21  
68:17 72:8 118:2  
196:18 222:19 269:20  
298:1 306:21 308:2  
313:11 314:12 316:19  
317:16 319:1 320:8  
**Moyer's** 71:22  
**MPH** 1:13,17 2:4  
**MPI** 192:14,18  
**multi-dimensional**  
329:16  
**multi-stakeholder** 17:8  
282:22  
**multi-variable** 123:13  
127:22 254:16  
**multidimensional**  
221:6

**multiple** 42:11 70:18  
87:9 104:10 123:20  
156:15 189:17 191:22  
192:8 193:8 203:10  
287:17,17 328:7  
**Munthali** 2:2 5:10,12  
6:20 7:5 8:7,13 9:15  
12:11,18 13:1,8,11,13  
13:15,19 14:17,19  
15:1,4,14 27:18 29:13  
29:17,21 30:8,17,22  
32:21 33:8,14 38:14  
43:8 116:5 117:8  
129:12 139:11 141:14  
145:2 215:17 225:6  
225:11,21 230:11,15  
230:22 263:5,11  
264:9 265:11 266:4  
266:18 267:3 275:22  
276:4 282:14 299:11  
**must-pass** 276:7  
299:13,20  
**must-pass-criteria** 20:9  
20:21  
**must-pass-criterion**  
24:15  
**mute** 6:7 87:1 132:22  
**MV** 3:10 173:17,18,18  
**MVR** 179:18 216:8  
**MVRR** 173:22 224:8  
**mystifying** 262:18

---

**N**


---

**name** 4:9 5:5,11,16  
6:11,14 8:21 9:10  
11:7 18:8  
**named** 7:8  
**Nancy** 332:9  
**narrow** 37:15  
**national** 1:1,6 10:17  
11:21 243:16 285:4  
286:3 300:10 332:11  
**natural** 184:6  
**nature** 153:8 196:8  
**NC2A** 298:7  
**NCDR** 95:12  
**NDI** 186:18  
**nearly** 102:17  
**necessarily** 22:17 58:6  
111:6 125:9 198:7  
270:18 278:7 289:21  
**necessary** 34:17 339:5  
**necessitates** 161:16  
**need** 5:1 18:2,6 19:21  
26:3 31:2,19 32:6  
42:1,10,10 44:13  
46:14 47:5 59:6 62:19  
63:18 86:1 100:8

107:15,17 120:4  
124:2 135:15,15  
136:2 161:7 170:10  
184:18,21 186:5  
187:17 188:8 190:6  
195:15 196:13 215:14  
222:2,18 224:15  
225:16 231:12 235:11  
238:15 240:10 241:21  
248:16,18 256:14  
257:17 270:3,7  
276:13 285:21 297:19  
299:8 300:1,11  
304:11 305:4 324:10  
328:22 338:7,19  
342:10  
**needed** 19:7 52:17  
55:13 230:22 257:18  
**needing** 237:15  
**needle** 284:16  
**needs** 44:12 109:22  
135:4 140:3 158:16  
267:13 270:21 297:6  
303:16 332:11  
**negative** 129:21 219:13  
239:4 312:12  
**negligible** 291:17  
**neighborhood** 137:20  
**Network** 11:22  
**neutral** 283:4  
**never** 37:14 80:9 88:12  
275:19  
**never-** 331:1  
**never-event** 330:16  
**never-events** 330:11  
**new** 9:12 15:12 19:12  
19:15 32:14 77:13  
104:15 155:3 162:17  
166:17 188:22 198:20  
201:7 219:9 225:20  
239:1 240:19 340:2  
**newish** 102:5  
**news** 10:12,12 69:5  
96:7 101:14,18  
273:17 336:11  
**nice** 9:10 126:9 334:19  
**nicely** 334:2  
**nine** 145:21 153:19  
**Ninety-nine** 311:15  
**ninth** 228:19  
**nit-picky** 58:10  
**no-pos** 337:21  
**noise** 311:12  
**nominated** 7:19 170:3  
**non-** 225:18 244:7  
254:6  
**non-agreement** 264:5  
**non-federal** 193:16



**non-issue** 316:22  
**non-profit** 10:2  
**non-publicly** 153:16  
**non-support** 17:20  
**non-surgeons** 171:16  
**normally** 31:12 86:7  
 87:4 233:12 237:4  
**North** 1:16  
**Northern** 155:3 198:20  
**Northwell** 13:4  
**notable** 125:20  
**note** 4:21 6:5 19:6 21:9  
 81:18 89:19 125:22  
 126:10 144:2 173:14  
 203:17 307:7 328:5  
**noted** 68:8,8  
**nothing's** 250:7  
**notice** 55:22  
**noticed** 223:5  
**noting** 327:9  
**NQF** 2:1 3:7,8,10,12  
 15:21 17:7,17,18 19:7  
 19:8 22:3 29:13 31:13  
 31:15 34:16 39:10  
 45:3 48:5 49:7 60:13  
 89:15 103:15 114:21  
 114:22 128:17 141:19  
 173:12 175:2 187:11  
 189:9 199:13 201:12  
 215:13 218:1,8  
 221:21 223:7 244:10  
 247:1 259:18 265:9  
 266:16 268:9,11  
 270:4 271:20 272:5,8  
 272:10 273:7 275:9  
 277:17 281:5,12,21  
 282:12,16 283:18  
 286:6 294:7,21  
 297:13 341:22 343:14  
**NQF's** 284:9  
**NQF-endorsed** 26:4,8  
 30:20 31:2 54:4 55:20  
 56:9 57:5 58:9 64:6  
 64:18 65:3 281:7  
**Nth** 123:19  
**number** 7:10 8:9 11:20  
 16:12 76:4 79:4 83:14  
 83:22 84:2 88:10  
 93:17 101:17 113:22  
 119:10,21 123:6  
 177:8 179:9 183:20  
 184:12 186:15 190:21  
 198:22 203:1 204:6,7  
 206:2 211:17 220:17  
 238:11 287:18 294:3  
 326:6 329:10 338:13  
**numbers** 73:18 83:5  
 131:12 160:10 176:1

184:2 185:20 294:21  
**numerator** 179:8,9  
**numerators** 87:12  
 185:21  
**numerical** 101:17  
**numerous** 118:20  
**nursing** 183:9 185:14  
 198:7  
**NW** 1:7  


---

**O**  
**O'Brien** 2:10 48:1 66:17  
 111:13 112:10,13,14  
 119:7 132:21 242:21  
 242:21 243:3 244:16  
 247:18 251:20 253:15  
 255:17 287:7 311:2  
 313:22 331:3,3  
**O/E** 77:1,17  
**OB/GYN** 11:18  
**objections** 261:22  
**objective** 155:22  
**observation** 137:19  
 289:19  
**observe** 112:7  
**observed** 120:2  
**observer** 2:11 47:21  
**obtain** 113:4 126:14  
**obvious** 96:7 111:17  
 205:3 251:16  
**obviously** 14:3 53:13  
 152:11 154:4,7 160:2  
 161:20 175:9 191:1,5  
 198:3,12 205:5 209:5  
 213:12 309:18 315:3  
 322:2 326:10  
**occasionally** 14:9  
**occur** 67:14 179:15  
 182:19 287:8  
**occurring** 179:12  
**occurs** 185:15 287:5  
**odds** 133:1 142:12  
 177:17 242:5,6,9,17  
 245:3,5 246:14  
**off-hand** 169:12  
**Off-microphone** 19:17  
 22:6 26:5,9 35:6  
 46:20 60:1 74:10 93:5  
 93:12 95:19,21 97:6  
 97:10 304:14 307:17  
 318:10 319:3 337:22  
**offers** 284:10  
**offhand** 333:7  
**office** 304:2 328:19  
**Officer** 10:16 13:4  
**officers** 281:11  
**officially** 189:6 298:22  
**offline** 232:15

**oftentimes** 337:6  
**OG's** 11:21  
**old** 169:15 198:18  
 285:1  
**older** 179:10  
**Olsen** 13:13  
**once** 65:5 70:19 75:8  
 78:12 156:1 197:10  
**one-** 131:17 279:16  
 287:3 293:5  
**one-star** 62:16 65:19  
 152:19 292:15 324:18  
 325:13 327:3,12  
 332:18  
**ones** 87:8 89:6 209:9  
 233:20 253:11 275:14  
 279:4 288:18  
**ongoing** 103:14 184:16  
**online** 97:13,16 223:6  
 280:1  
**onus** 84:9 151:4,12  
**open** 5:3 19:21 20:3  
 35:22 51:19 99:4  
 103:1 105:1 108:11  
 114:22 144:5 146:21  
 148:12 156:22 157:10  
 177:4 178:19 200:14  
 201:20,21 210:16  
 229:10 240:22 248:12  
 249:13 255:22 257:4  
 260:5 307:4 315:10  
 317:4 318:7 319:14  
 337:21  
**opening** 3:2 279:6  
 341:12  
**openly** 19:11  
**openness** 8:8  
**operate** 133:10 193:22  
 194:6 195:10,12  
 239:10  
**operated** 199:1  
**operates** 196:13  
**operating** 122:8 190:22  
 193:19 197:12  
**operation** 53:3 78:4  
 179:13 206:5 291:1  
 323:4  
**operation-specific**  
 77:20  
**operations** 49:16 96:18  
 198:6 204:15  
**operative** 3:10 49:14  
 81:10 82:19,22 173:7  
 173:9,17 203:21  
 212:20 218:5,7  
 292:11  
**ophthalmologist** 12:7  
**opinion** 35:4 39:22 40:3

41:7 125:14 146:4  
 267:21  
**opportunities** 273:18  
**opportunity** 17:18  
 68:11 133:18 162:8  
 252:10 269:4,6 283:4  
 284:10,12 285:3  
 286:3 309:10 340:1  
 342:21 343:2  
**opposed** 60:21 102:8  
 110:18,22 137:17  
 185:14 198:5 222:6  
 231:8 258:19  
**opposition** 145:14  
**optics** 281:14 282:1  
**optimal** 139:21  
**option** 40:13 51:21  
 139:5 193:5,10  
 222:15,16 261:11  
**options** 214:20 222:14  
 337:21  
**orally** 7:14  
**oranges** 129:7  
**order** 19:22 21:17 26:14  
 31:12 46:14 91:5 93:3  
 113:4 152:17 184:22  
 217:8 226:12 295:15  
 338:12  
**Oregon** 12:21  
**organization** 228:20  
 275:17 298:21  
**organizations** 9:19  
 45:8 336:7  
**organize** 152:15  
**organized** 191:21 192:7  
**original** 38:10,13  
 202:13 268:19  
**originalism** 228:13  
**originally** 88:19 141:4  
 174:14 190:16 214:4  
 246:18 247:2  
**orthopedic** 10:5,9  
 124:2  
**osteoporotic** 124:7  
**outcome** 16:12 49:10  
 54:14 57:3 115:3  
 117:12 124:18 138:10  
 141:19 161:5 175:15  
 177:20 178:5 180:11  
 186:21 187:20 209:21  
 238:9 239:4,21 240:3  
 240:6 252:7,9,20  
 253:18 283:12 290:7  
 292:20 295:16 296:5  
 343:9  
**outcomes** 52:20 53:12  
 55:8 76:4 77:2 82:12  
 119:1,14 122:21

125:2 131:9 140:1,6  
 150:18,19,20 152:9  
 159:11 161:2 184:15  
 187:15,18,21 203:20  
 231:7 243:7,18 244:2  
 247:22 252:1 256:20  
 259:10 278:12 288:10  
 288:17 289:3 323:3  
**outlier** 251:6 252:7,12  
 252:12 280:15 290:19  
 296:10 332:3  
**outliers** 220:6,8 250:18  
 251:2,11 252:16  
 253:17  
**outline** 232:3 268:1  
**outlined** 56:18 57:6  
 334:3  
**Outlook** 265:17  
**outpatient** 207:20  
**outside** 34:18 45:8  
 140:7  
**outstanding** 343:14  
**outweigh** 213:7  
**overall** 21:3 24:19  
 41:15 63:3 65:4 66:14  
 72:5 74:5 78:1 79:2  
 80:14 81:8,9,20  
 100:20 102:16 112:3  
 113:11 131:14 137:5  
 154:16 157:21 158:12  
 160:4 171:3 180:15  
 195:15 212:22 217:17  
 218:6 231:16 232:18  
 233:6 250:11 268:13  
 287:4 288:4 292:12  
 310:5 321:14 329:7  
 329:19  
**overarching** 155:21  
 251:17  
**overcome** 284:1  
**overestimate** 150:22  
**overlay** 124:22  
**overload** 55:13 80:4  
**overnight** 333:20  
**override** 39:10  
**overrule** 43:1  
**overruled** 41:3,4  
**overseeing** 43:9  
**oversight** 43:11,21  
**overturn** 43:12  
**overview** 3:4,4 4:19  
 23:16 50:4  
**overwhelming** 74:22  
 181:1  
**owns** 138:22

---

**P**


---

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

4:1  
**p.m** 171:20 340:8 341:7  
 343:22  
**packing** 338:10  
**page** 95:13 107:4  
 236:10 314:19,19  
 316:13 328:11,12,22  
**pages** 55:7 203:7 204:6  
 252:3 328:6  
**paid** 7:21  
**Palo** 138:2  
**panel** 16:17,18 85:21  
 106:20 107:22 163:1  
 189:19 201:10  
**panel's** 181:6  
**Paone** 2:9 47:18 50:6  
 52:12 54:12 56:18  
 57:6 58:14 60:2 68:5  
 71:5,8 72:20 74:21  
 75:21 76:9,16,22 77:6  
 82:10 95:10,20,22  
 96:3,8 130:15 131:20  
 132:3,11 133:6 134:4  
 152:2 160:8 183:18  
 185:8 187:16 193:11  
 204:21 215:21 216:19  
 237:9 238:2 266:20  
 267:10 287:1,21  
 292:5 305:19 306:3  
 310:2 316:2 320:19  
 321:9,14 322:11  
 323:6,10,17 325:12  
 329:4 334:10 335:5,7  
 335:11,16 336:14,16  
 338:11 339:8 343:1  
**Paone's** 77:16 161:12  
 326:21  
**paper** 188:8 219:19  
 220:9 268:20  
**papers** 188:14 268:21  
 337:4  
**paradigm** 143:13,13  
**parallel** 159:21 161:20  
**parallels** 162:3  
**parameters** 211:2  
**parse** 115:14  
**parsed** 112:6 254:14  
**parsing** 37:17 76:13,21  
 112:2 297:20  
**part** 24:5 25:15,18 26:3  
 26:6,7,15 30:4 33:1,6  
 33:16 34:22 36:17,19  
 37:11,16 41:21 42:17  
 43:3 49:17 51:22  
 55:15 65:15 80:13  
 89:19 93:18 99:10  
 102:3,3 103:7,9 127:8  
 134:20 139:15 140:3

147:6 161:4,6 186:19  
 196:5 214:6,11 215:3  
 216:1,9,14 219:18  
 223:13,19 224:1  
 225:14 227:18 228:18  
 229:1,11,15 230:15  
 232:5 253:4 257:16  
 258:10 263:8 268:12  
 273:13 277:13,15  
 278:5 288:14 289:6  
 293:3 303:11,11  
 306:4 308:9,11  
 320:10 326:9,11  
 333:15  
**participant** 57:8 60:12  
 60:14 72:5,21,21 73:5  
 73:6 98:11 113:7,9  
 120:2 132:18 144:17  
 164:17,22 169:6  
 170:12,17 177:19  
 182:11,17 186:11  
 230:6,9 239:16 243:6  
 244:1,16,17 258:5,7  
 262:1 299:5 302:12  
 304:18 305:6 309:12  
 309:14,17 316:14,15  
 317:7 318:14 319:4  
**participants** 70:15 73:2  
 100:16 101:21 114:7  
 120:3 180:15 235:10  
 235:17,21 243:10,11  
 243:15,16,21 245:2  
 245:11 251:20 271:11  
 308:5  
**participate** 10:21 14:20  
 34:5 48:21 71:21  
 102:8,17,19 193:13  
 290:16  
**participating** 4:7 46:7  
 48:10 50:20 102:13  
 156:16 181:5 273:14  
**participation** 48:17  
 101:1,4 102:2,6 152:4  
**particular** 36:12 65:12  
 66:3 79:20 101:10  
 102:4 111:7 113:3,6  
 115:8 125:10 139:1,3  
 152:9 174:19 195:7  
 251:7 308:19 324:1  
 324:20 325:2,10  
**particularly** 31:4 83:9  
 96:17 100:4 112:9  
 161:8 181:22 184:7  
 186:17 203:2,7  
 204:14 289:2  
**partly** 134:12  
**Partners** 1:12 10:17  
**partnership** 281:4

**parts** 34:21 35:13 138:1  
 217:17 301:1  
**pass** 10:13 20:10,15  
 21:17 22:8 31:14  
 32:16,17,19 36:3  
 39:10,13 157:3,4  
 162:11,11 171:2  
 214:3 225:12 229:17  
 229:18,19,19 241:7  
 260:14,14 264:10  
 267:7 277:6  
**passed** 36:20 41:13  
 42:22 99:9 147:6,8  
 149:5 157:18,19  
 158:12 165:20 178:16  
 179:3 200:19,20  
 202:4 212:14 221:12  
 226:3 227:13 248:20  
 249:20 315:19 317:13  
 320:4  
**passes** 31:19 36:14  
 103:22 105:17,22  
 109:13 146:2,3 157:5  
 170:20 241:8 256:7,9  
 257:9  
**passing** 32:7 99:10  
 226:3  
**path** 39:8,21 40:1,9,11  
 214:20 226:2 309:8  
**paths** 39:8  
**pathway** 102:1  
**pathways** 151:8  
**patient** 1:12 9:12,18  
 52:16,20 53:2 57:1  
 58:20,21 61:10 66:5,6  
 66:7,8 68:11,16 69:17  
 70:8 72:9,12 74:1  
 78:12,13,18,19 79:6  
 79:15 80:12 82:1  
 83:12 84:10 85:3  
 129:3 131:6,8 133:9  
 137:2,11 143:4 150:9  
 151:4,5,13 159:15  
 175:10,10,11,13  
 177:19 182:9 183:5  
 194:13,14 198:11,17  
 218:18 236:1 238:21  
 239:7 244:2 255:1,3  
 271:16 278:9 293:22  
 298:16,20 323:1  
 328:3 332:14 333:6,8  
 334:21,22  
**patient's** 54:18 137:7  
 195:5,14 196:15  
 254:4 271:16  
**patients** 27:12 83:8,14  
 84:3 87:21 89:8 113:3  
 113:8 114:5 121:9

133:1 150:10 151:3  
 179:10,18 184:1,7,8  
 184:12 185:10 196:21  
 213:5 235:15 238:3,8  
 239:9 240:7 243:8,19  
 243:19 244:1,5,6  
 273:9 278:14 297:18  
 301:20 302:3,4  
 310:12 311:17 325:15  
 328:14 331:10 332:15  
 333:21 337:3,7,13  
**patients'** 336:19  
**pattern** 320:9  
**Pause** 99:5 103:2 104:2  
 105:3,6 108:13  
 132:17 144:6,9  
 146:20 147:2 148:21  
 149:1 150:3 157:1,11  
 157:14 158:6 170:1  
**pay** 55:22 56:3 184:17  
**payers** 44:16  
**paying** 206:20 208:18  
 252:8  
**peer** 74:1  
**pelvis** 124:6  
**penalizing** 239:3  
**penetrance** 100:12,18  
**people** 8:10 34:7 55:21  
 56:3 70:12 97:17 98:6  
 103:18,20 105:20,20  
 105:21 109:9,11  
 110:19 111:4,21  
 116:22 125:11 134:1  
 137:4 149:17 154:21  
 176:6 181:2 182:5,13  
 195:3,19,21 197:22  
 200:17,18 202:1,1  
 212:12 220:22 222:5  
 230:2 241:7 248:18  
 249:17 255:7 256:12  
 265:1 269:12,15,16  
 279:8 283:20 299:4  
 301:7 302:8 305:4  
 307:14,20 330:19  
 338:10  
**people's** 68:21  
**percent** 21:13,19,20  
 22:9 35:10 48:17,18  
 48:22 55:9,10 69:20  
 70:14,20 71:3,13 83:2  
 83:19,20,20 84:4,5  
 88:18 90:3,4 96:13,14  
 96:15,20 97:1,2 99:11  
 102:12,16,20 144:22  
 146:1,1,5 151:19,21  
 152:1,12,13 177:7,22  
 178:1 180:16 184:21  
 185:15 187:6 191:10

200:19,19 202:4  
 209:15,20,22 213:2  
 220:5,7 231:1 240:1  
 249:7 250:19 253:7  
 256:9,9 260:15 277:3  
 291:18 293:18,19,19  
 308:5 311:15,16,17  
 312:6 313:1,5,7,14  
 314:9,9,15,15,17,17  
 315:1 322:20 324:2,3  
 324:6,16,19,21  
 325:14 327:15  
**percentage** 89:7 165:20  
 166:13 183:22 205:17  
 229:18 230:21 256:8  
 291:2 294:3 312:14  
 312:17 313:15 314:8  
 315:17 317:14  
**percentages** 96:11  
**percentile** 314:18  
**percentiles** 246:7  
**perceptions** 304:6  
**perennial** 308:3  
**perfect** 311:22  
**perfectly** 270:5  
**perform** 133:18 287:11  
**performance** 45:6,9,10  
 91:5 99:16 103:18,22  
 135:21 153:15 162:17  
 176:3 178:20 179:2  
 207:10,11 220:16  
 240:1 243:5,10,14,22  
 244:4,18 245:1,11  
 247:12 248:10,13,21  
 250:2,2,15 252:11  
 254:21 255:7,12,15  
 284:14 286:15 287:10  
 287:17 311:8 313:20  
 314:1,2,4,11 315:11  
 315:15 317:21 318:1  
 318:2 327:15 330:15  
 331:5,8,12,13  
**performed** 161:14  
 179:14 201:9  
**performing** 48:19  
 102:12 110:22 313:14  
**perfusionist** 199:7  
**period** 36:13 37:3 140:5  
 140:21 141:1,9,17  
 153:21 154:1,12  
 226:9 231:18 240:18  
 242:7,8 250:2,3  
 266:15,18 267:8  
 314:5,6 341:11  
**periods** 153:19 177:15  
 213:1  
**perioperative** 240:18  
 305:21 306:2,7,14,16

325:3 326:8 327:4,11  
 327:13,20 328:9,17  
 329:5,14,18  
**person** 5:14 9:10 13:5  
 14:20 18:17 103:19  
 142:21 202:12 208:15  
 209:1 245:3 289:8  
 324:16 342:2  
**personal** 55:4 133:7  
 159:17 257:15  
**personally** 29:5 180:2  
 211:6 223:21 250:12  
**perspective** 31:7 37:9  
 48:11 78:18 117:6  
 127:10 131:14 139:8  
 194:13,15 195:6,14  
 196:15 198:11,17  
 199:13 204:3 275:11  
 283:2 328:2,3 331:21  
 332:14,21 333:18  
 334:22 336:19  
**perspectives** 28:4  
 283:1  
**pertaining** 177:12  
**pertains** 71:22  
**perversely** 275:4  
**phasing** 218:18  
**phenomena** 83:10,13  
**phenomenon** 280:14  
**philosophical** 272:5  
 280:20  
**philosophy** 228:12  
**phone** 4:7 5:14 6:5,12  
 8:10,20 12:12 15:1,8  
 18:3 21:15 28:15 44:3  
 47:22 48:2 63:2 83:16  
 94:20,21 95:3 96:10  
 96:22 98:7 145:12  
 265:15 299:6,8 338:5  
**phonetic** 46:5 290:3  
**phrase** 236:15  
**phrased** 269:16  
**physically** 134:20 208:5  
**physician** 61:11 93:7  
 258:19 273:2 336:5  
**physicians** 1:15 258:2  
 258:8 332:3  
**physicians-based**  
 273:19  
**physiologic** 115:14  
 119:5  
**physiological** 110:18  
**picked** 300:10  
**picking** 58:3 191:6  
**picture** 87:20 169:22  
**piece** 52:22 61:15 72:6  
 324:5  
**pieces** 222:12

**pilot** 131:11,22  
**pink** 22:22  
**Pittsburgh** 1:21 10:6  
**place** 28:5 79:15,17,19  
 79:22 252:6 304:9  
 309:9 334:4 338:12  
**placed** 143:9  
**places** 54:8 80:2 136:11  
**plan** 28:7,10 51:19 52:2  
 52:5,13 215:17  
 218:21 219:6,10  
 221:19 222:9,9  
 294:16 295:1 296:13  
 333:15  
**plane** 12:4  
**planned** 213:14 214:16  
**planning** 254:9  
**plateau** 208:21,22  
**plateaus** 208:14  
**platform** 4:22 19:12,15  
**plausible** 115:2  
**playing** 98:1 134:13  
**please** 6:6,7,10 18:1,2,8  
 170:6 211:4 245:21  
 246:17 284:6  
**pleasure** 5:19  
**plus** 49:15,18,21 50:1  
 50:13 173:8,11,12,17  
 188:6 273:8  
**point** 11:4 12:1 14:4  
 26:14 27:20 31:11  
 39:18 40:10 44:7 63:9  
 68:9 70:11,17 71:4  
 72:3 73:21 74:12,14  
 74:19 77:10 79:20  
 81:6,7 82:4 83:7  
 84:12 89:17 93:3 94:7  
 108:5 123:9 127:8  
 129:5 135:10 139:16  
 142:9 160:9 161:11  
 180:10 187:2 191:6  
 191:16 194:10 195:13  
 204:3,22 208:5 211:7  
 211:17 212:7 217:20  
 222:7 224:10,12,14  
 226:12 228:11 233:8  
 233:10 245:1,4 246:3  
 262:7 266:13,22  
 271:5 280:19,19  
 289:16 310:9 311:14  
 312:13 323:10 336:22  
 336:22 338:12  
**pointed** 88:4  
**pointing** 12:5 14:12,15  
 305:15  
**points** 206:2 208:6  
 218:1 220:17 276:5  
 290:2 292:17 329:6

<b>police</b> 186:10	<b>post-op</b> 310:19	76:5 143:14 158:10	179:16
<b>policy</b> 139:14 272:5	<b>post-operative</b> 87:12	172:20 242:15 294:16	<b>procedures</b> 102:12
<b>poll</b> 5:1 19:19,20 92:3,9	238:22 247:15	297:5	174:21 206:10 217:5
94:12,19 163:14	<b>post-public</b> 264:21	<b>presented</b> 58:12 103:15	219:21 220:2
<b>polling</b> 303:20	265:15	153:11 242:13 243:1	<b>proceed</b> 86:18 94:10
<b>poor</b> 66:13 133:12	<b>posted</b> 265:1 341:11	247:22 258:17 259:9	241:14
135:12 203:5 286:14	<b>posterior</b> 203:15	259:12 277:14 331:15	<b>process</b> 3:5 4:19 7:15
<b>poorly</b> 110:22 124:12	<b>postoperative</b> 234:20	<b>presents</b> 114:16 176:1	8:8 16:14 17:5 18:14
127:19	320:21	308:2	22:10 23:17 25:3 33:6
<b>pop</b> 152:17,19	<b>potential</b> 41:4 113:15	<b>President</b> 2:2 5:12	40:9 43:19,22 49:11
<b>popped</b> 141:2	113:17 115:6,18	<b>presiding</b> 1:8	49:12 60:5 81:11 85:4
<b>population</b> 113:10	116:2 119:5 123:3	<b>press</b> 173:1	101:15 145:5 159:4
115:16 122:1 135:14	141:2 180:18 213:3	<b>presumably</b> 326:1	161:9 186:18 198:11
137:17 175:14	272:13 275:18 277:14	<b>presumption</b> 154:20	199:13 209:19,21
<b>portal</b> 333:6,8	278:8 316:20	<b>pretty</b> 7:9 40:21 45:13	211:18,21 223:12
<b>portfolio</b> 3:4 4:18 16:6	<b>potentially</b> 68:10 114:6	52:19 85:10 96:6	233:18,19 252:5,22
16:13 38:16 43:10	118:9,20 213:5	168:21 204:7 240:4	253:5,16 266:13
138:22 263:21 264:1	273:18 296:1 327:8	249:8 314:22	277:8 283:11 291:9
272:22	330:21	<b>prevalence</b> 115:16	302:18 304:22 305:6
<b>portion</b> 24:8 99:9 105:2	<b>poverty</b> 111:4,5 116:21	118:5	305:8,22 309:9 343:7
105:19 119:16 200:16	125:10,12	<b>previous</b> 89:6 119:1	<b>professional</b> 7:10
202:2 212:10,14	<b>powers</b> 39:12	162:9 165:8 166:3	<b>profiling</b> 127:16 130:1
241:1,5,8 248:13,21	<b>practical</b> 54:22 113:2	201:4 224:11,13	142:14
249:14,19 256:1,6	133:7	226:13,15 235:13	<b>profound</b> 190:12
257:5,10 260:6,12	<b>practicality</b> 191:9 295:7	291:21 316:22 317:20	<b>program</b> 24:12 25:8,13
307:5,20 315:15,18	<b>practice</b> 10:15,18 16:8	<b>previously</b> 159:11	28:11 38:20 63:16,21
317:5,11 318:8 319:9	70:16,19 192:8	181:13 194:18	81:16 84:15 93:18
319:15 320:1,4	199:10	<b>pride</b> 282:19,20	101:15 156:8 196:19
337:20	<b>practices</b> 45:8 75:4	<b>primarily</b> 231:9	213:13 292:12 325:14
<b>Portland</b> 12:21	<b>practicing</b> 70:18	<b>prime</b> 266:6	329:19,22 330:4
<b>pose</b> 85:15	<b>pre</b> 310:19	<b>principle</b> 114:5 198:5	334:13 336:20
<b>posed</b> 179:21 189:18	<b>pre-meeting</b> 19:4	<b>principles</b> 198:15	<b>program's</b> 336:20
<b>position</b> 330:21	<b>pre-op</b> 310:18,20	<b>print</b> 273:12	<b>programs</b> 75:1,2 88:18
<b>positive</b> 275:3	<b>pre-renal</b> 237:16,20	<b>prior</b> 18:8 116:10 226:8	101:12 102:6 152:19
<b>positives</b> 275:20	239:2	236:2,16 237:13	153:3,14,15,16,18,21
<b>possibility</b> 184:5	<b>pre-work</b> 175:1	266:5	156:12 292:16 329:10
<b>possible</b> 35:18 62:4	<b>preamble</b> 45:13 176:18	<b>private</b> 10:17 191:1,22	330:4
66:12 67:10,21 78:21	<b>preceding</b> 50:5	192:7	<b>prohibited</b> 116:11
87:20 192:13 205:1	<b>precise</b> 212:2	<b>probability</b> 294:5	<b>project</b> 2:3,3,4 4:10 5:8
207:1 243:9 247:2	<b>precision</b> 211:10 212:7	<b>probably</b> 7:7 8:2 47:7,8	6:2 125:19
262:3 286:21 287:20	<b>predicted</b> 250:2	48:17 80:10 85:10	<b>projects</b> 5:18
300:12,13 308:18	<b>preferred</b> 188:7	89:3 137:4 140:22	<b>promise</b> 80:5
327:1,5 329:12	<b>preliminary</b> 19:7 85:22	142:1 163:9 190:12	<b>proof's</b> 256:11
337:14,21 343:9	90:13 91:18 107:5	191:14,14,15 192:1	<b>proofed</b> 275:20
<b>possibly</b> 79:21	214:2	217:6 239:10 242:12	<b>propensity</b> 124:10
<b>post</b> 181:22 229:22	<b>preoperative</b> 291:14	251:13 256:20 268:7	<b>proportion</b> 48:20 179:6
231:5	321:2	277:15 287:3 313:2	<b>proposal</b> 218:20
<b>post-</b> 265:19	<b>preoperatively</b> 239:8	335:14	<b>propose</b> 221:15
<b>post-30</b> 181:21	<b>prepared</b> 46:9 337:1	<b>problem</b> 107:22 114:16	<b>proposed</b> 151:9 207:11
<b>post-approval</b> 96:11	<b>preparing</b> 343:15	121:2,20 147:17	<b>proprietary</b> 72:16 74:9
<b>post-comment</b> 22:5	<b>preponderance</b> 121:8	184:16 208:10 240:2	<b>protected</b> 291:6
230:16 231:21 264:13	127:18,19	250:21 289:18 313:8	<b>protest</b> 261:14
266:9 284:1 341:14	<b>prerogative</b> 296:20	317:7 327:14	<b>prove</b> 228:5
<b>post-discharge</b> 184:18	297:10	<b>problems</b> 219:22	<b>provide</b> 18:17 44:14
320:22	<b>presence</b> 130:11 316:4	<b>procedural</b> 255:11	63:6 68:11,15 69:2
<b>post-endorsement</b>	<b>present</b> 1:9 2:6,17 18:5	<b>procedure</b> 17:5 48:16	77:17 82:15 84:11
89:17	21:8,15 36:8 46:9	112:18 160:3,15,16	85:3 86:10 106:21
<b>post-meeting</b> 231:10	53:14 63:3 64:21,22	161:15 162:1 174:19	135:18 137:1 162:18

174:17 177:13 186:14  
 190:6 213:18 229:4  
 231:6 234:15 244:9  
 317:13 331:7  
**provided** 7:14 76:6  
 160:19 163:22 200:5  
 212:18 213:22 240:15  
 241:19 242:9 248:5  
 313:22 333:12 336:7  
**provider** 113:4 142:17  
 175:4 202:12 214:1  
 253:9 335:1  
**providers** 44:16 220:6  
 250:16 301:7  
**provides** 68:14 180:13  
 189:22 221:5 284:14  
**providing** 19:3  
**proviso** 228:7,8  
**proxies** 120:6  
**proxy** 17:7 116:13  
 119:3 127:5 135:8,12  
 140:9,13  
**prudent** 181:8  
**PSI-90** 285:2  
**public's** 289:17 302:6  
**public-facing** 265:3  
**publically** 24:6,13,22  
 25:4,7,13,20 26:16  
 27:1,16 28:7 29:1,7  
 32:2 36:12 37:2 38:19  
 39:15 42:16 48:11  
 49:5,19 50:9 51:2,3,9  
 51:18 52:6,14 53:18  
 60:13,17 63:17 66:22  
 70:13,20,21 71:14  
 73:10,14,17 75:10  
 90:10 93:8,14 135:19  
 151:20 155:13 259:20  
**publications** 63:18  
**publicly** 101:16 109:19  
 152:21 153:15,18,21  
 156:8 173:13 215:2,4  
 215:11,15 216:18,19  
 219:2,14 222:3,10,11  
 227:7,10,15 229:2  
 258:4,20 267:21  
 269:13 270:6,9  
 271:12,13 279:1,13  
 279:14,21 284:18  
 285:9 296:13 303:11  
 306:10 322:9 323:13  
 324:9 326:13  
**publish** 336:1,2,4  
**PubMed** 153:17 154:2  
**pudding** 256:11  
**pull** 41:18 91:15 147:16  
 247:2  
**pulled** 64:7 78:7 292:7

**pulling** 45:3 57:14,17  
 58:3,8 277:20  
**pun** 335:14  
**punishment** 134:20  
**purchaser** 69:12 72:13  
 72:14 298:12  
**purchasing** 10:1 278:6  
 279:3  
**purpose** 58:16 124:16  
 127:6 302:22  
**purposes** 50:22 111:1  
 141:5 193:9 203:12  
 267:11 334:1  
**purview** 43:7 90:11  
**push** 29:11 30:3  
**pushing** 37:18 38:1  
**put** 6:6 9:10 22:15  
 40:11 55:13 63:17,19  
 75:8 103:3 105:11  
 117:3 128:16 129:9  
 138:19 141:4 159:6  
 167:18 188:14 203:6  
 207:8 222:4 234:9  
 246:20 247:4 254:10  
 258:14 265:17 268:3  
 275:14,14 298:15  
 300:4,9 303:10  
 309:16,17 319:4  
 340:19,20 342:13  
 343:4  
**puts** 136:13 330:19  
**putting** 114:20,21 126:8  
 254:3,9

## Q

**QCDR** 93:1 94:4 95:20  
 96:2 151:10 258:3,9  
**QCDRs** 96:3,4  
**QQC** 307:10  
**qualifies** 262:13  
**qualitative** 221:7  
**quality** 1:1,7 5:13 10:16  
 11:12,14,21 13:4  
 20:17 27:8 31:9 34:7  
 44:19 47:17 50:21  
 54:7 55:7 60:14 82:12  
 91:10 104:4 154:9,13  
 156:13 159:18 180:4  
 193:14 219:18 220:2  
 221:6 224:15 250:8  
 251:21 252:13 255:15  
 272:9 275:1 276:9  
 277:4 281:8,11,15,16  
 282:2 284:15 291:15  
 299:15,21 300:6  
 304:7 327:21 330:10  
 332:8  
**quantify** 300:5

**quarterly** 175:8 213:17  
**question's** 60:4 251:5  
**questioned** 235:18  
**questioning** 278:10  
**questions** 7:10 15:7  
 22:10 42:1,4 51:15,19  
 57:13 68:21 71:5 80:8  
 84:17,20 85:15 88:12  
 111:14 114:10 137:12  
 147:19 198:3 201:17  
 236:19 247:12 249:9  
 250:17 255:18 263:2  
 290:20 292:8 332:16  
 337:1  
**quick** 92:18 98:3  
 170:21 336:18  
**quickly** 136:5 193:12  
 226:10 276:18 333:1  
 333:7  
**quirky** 74:5  
**quite** 14:13 17:3 53:17  
 72:22 110:3 135:13  
 149:12 184:13 206:19  
 263:6 273:11 283:8  
 284:19 288:7 289:14  
 330:6  
**quorum** 18:6,7 21:13  
 21:15,19 22:9 94:10  
 97:12 105:8 172:8  
 307:12,12 339:12  
**quoted** 83:22

## R

**R** 223:6  
**race** 108:16,18 111:5  
 112:5,15 114:13,15  
 115:11,12,19 116:12  
 118:4,15,15 119:14  
 119:20 120:17,19,22  
 121:16 122:11 123:15  
 124:22 125:9,11  
 126:6,8,21 127:1,9,10  
 130:5,6 132:7,20  
 133:2,4 135:6 136:8  
 142:11,18,20 143:9  
 144:14 159:8 244:8  
 250:9 254:2  
**race/ethnicity** 178:12  
**races** 127:17 133:2  
**racial** 116:2 118:21  
 130:1,14 142:14  
**radar** 331:15  
**raise** 98:7 142:9 211:7  
 252:4 276:1 291:7  
 302:19  
**raised** 100:13 112:16  
 134:19 137:12 149:12  
 198:3 243:9 276:5

290:20  
**random** 290:5  
**randomized** 113:2  
 288:15  
**randomizing** 113:3  
**range** 100:17 291:19  
 313:21  
**rank** 318:22  
**ranking** 330:4  
**rapidly** 138:8  
**rate** 65:15 66:4 67:11  
 160:4 176:4 179:6  
 249:7 250:19 251:1  
 252:13 253:7,10  
 290:12 291:1 313:7  
 314:5  
**rated** 66:19 163:1  
**rates** 110:15 174:20  
 180:13 212:20,22  
 220:1 252:8,9 253:18  
 279:3  
**rating** 17:12 19:7,8  
 51:12,14 59:21,22  
 62:3,13 65:8,19 66:15  
 67:2 71:18 72:4 81:4  
 81:8 82:19 88:14  
 90:19 107:1 108:2  
 109:19 110:10 149:17  
 154:1 156:4 162:18  
 162:21,22 178:6  
 180:8 185:1 214:2  
 262:3 278:15 286:14  
 286:21 287:4,4 321:9  
 327:10 330:3 335:21  
**ratings** 63:7 69:12  
 70:13 89:16 106:22  
 109:16 131:14,19  
 152:13 163:22 164:2  
 306:11 321:7 335:20  
 336:4,5,6,6  
**ratio** 133:1 142:12  
 177:17 245:3  
**rational** 17:12 31:20  
 42:11 58:5 91:18  
 104:4 112:18 116:4  
 117:19 220:13 240:16  
**rationales** 220:14  
**ratios** 77:1,17 242:5,9  
 242:18 245:5 246:14  
**raw** 69:13 72:17  
**re-** 167:17 228:2  
**re-discuss** 22:4  
**re-endorsed** 174:14  
**re-endorsement** 25:12  
 27:15 172:22 181:11  
**re-exploration** 87:10  
**re-log** 319:5  
**re-look** 276:14

**re-vote** 22:4 167:19  
 264:21  
**reach** 107:14 208:15  
 230:1 264:13 338:8  
 342:12  
**reached** 21:21 144:17  
 144:19 163:2 229:20  
 230:5,19 231:15  
 260:15,17 267:4  
 277:2  
**reaches** 314:17  
**read** 27:13 170:22  
 177:7 205:10 247:1,8  
 268:21 269:4 273:11  
**readership** 336:10  
**readily** 73:16 278:7  
**reading** 67:9 314:14  
**readmission** 115:5  
 279:3  
**readmissions** 132:4  
**ready** 18:5 35:14  
 102:21 248:8 249:10  
 255:19 316:17  
**real** 133:13,22 134:6  
 159:15 176:2 193:12  
 211:10  
**real-time** 15:20  
**real-world** 121:6  
**realistic** 294:4  
**reality** 28:22 83:8 183:4  
 183:16 237:7  
**realize** 135:9 195:8  
 328:21  
**realized** 235:11 246:20  
 328:5  
**reason** 25:2 60:22 83:8  
 105:12 115:8 118:3  
 145:3 155:6 161:18  
 191:2 194:22 201:17  
 220:11 221:8 230:16  
 239:12 279:8 286:12  
 289:9 334:7,9,14  
 337:11  
**reasonable** 35:3 70:7  
 91:6,8 117:6 124:15  
 160:9,18 161:3 231:4  
 240:4 298:4  
**reasons** 24:22 74:6  
 119:19 268:2 288:17  
 298:2 299:19 319:13  
 329:16 334:2  
**rebels** 262:5  
**rebuttal** 225:19  
**recall** 155:11  
**recast** 307:8  
**receipt** 306:6,13 325:2  
**receive** 75:8 185:1  
 232:1 251:21 325:15

331:11  
**received** 204:11  
**receiving** 266:8  
**recognize** 53:5 187:17  
 284:14  
**recognizing** 158:3  
**recollection** 37:6  
**recommend** 190:5  
 231:15 308:15  
**recommendation** 21:4  
 22:2 24:19 33:15 35:8  
 39:6,20 41:15 145:16  
 176:7 181:6 200:9  
 233:6 308:22 313:8  
 315:3  
**recommendations**  
 17:17,19 18:12 21:7  
 21:10 32:22 33:6,10  
 107:2 263:13 264:10  
 264:14 341:10  
**recommended** 21:18  
 22:8 226:3 312:13  
**reconsider** 226:6  
**reconsideration** 226:7  
**reconstruction** 195:9  
**record** 11:6 14:10,16  
 16:3 47:4 77:13 98:22  
 103:4 105:12 108:14  
 126:11 136:8 171:19  
 177:8 186:13 202:15  
 204:19 205:2,21  
 206:17 233:14,15  
 234:8 261:8 262:14  
 318:20 343:22  
**recorded** 95:4 254:14  
 270:9  
**records** 48:16 204:5  
 205:14  
**recourse** 226:6  
**recused** 15:5  
**reduce** 240:17  
**redundancy** 168:21  
**reexamined** 270:12  
**refer** 36:1  
**reference** 113:9 173:21  
 206:1  
**referenced** 328:11  
**references** 174:18  
**refine** 211:18 227:6  
**refined** 91:12  
**reflect** 237:14,19  
**reflected** 39:4,5  
**reflection** 268:17  
**reflects** 159:10 237:20  
**reframing** 332:14  
**refresh** 169:6 318:14  
**refuse** 134:2  
**refute** 232:8

**Reg** 26:12  
**regard** 77:8 213:16  
 291:6 325:5  
**regarded** 268:7  
**regardless** 138:15  
 239:1 301:13  
**regionalist** 38:6  
**registrar** 136:12  
**registries** 188:19  
**registry** 72:18 101:16  
 102:19 125:18 179:19  
 179:20 185:6 188:16  
 207:14 301:3  
**regression** 123:13  
 254:16  
**regular** 277:6  
**reimbursement** 134:3  
 273:19  
**rejoining** 171:22  
**related** 7:11 41:17,19  
 42:6 50:5 111:14  
 183:14 187:4 206:8  
 220:16 244:10 286:6  
**relates** 112:17  
**relation** 19:1 61:13  
**relationship** 117:17  
 140:1 206:13  
**relative** 180:5 331:9  
**relatively** 32:14 53:11  
 102:4 131:12 178:2  
 291:11  
**released** 274:3  
**relevant** 7:22 10:7 12:9  
 89:16 186:17 254:15  
**reliability** 20:14 58:17  
 106:2,3,14,22 108:1,5  
 108:7,12 109:7,8  
 111:15 162:22 166:15  
 166:16,17 179:5,5  
 180:5 181:7,12  
 183:21 200:16 249:3  
 249:14,18 261:8,13  
 281:14 300:7 301:4  
 309:4,6 316:18 317:3  
 317:5,11  
**reliable** 28:20 32:11  
 104:12 106:10 131:4  
 217:9 249:8  
**rely** 198:7 259:19  
**relying** 222:6  
**remain** 18:9  
**remaining** 50:1 341:8  
**remains** 91:4 236:13  
**Remarks** 3:2  
**remember** 7:7 15:18  
 22:17 38:13 89:13  
 131:10 140:15 169:18  
 252:1 259:4 281:22

290:14 309:15 321:15  
 321:22 335:7  
**remembered** 112:15  
**remind** 15:17 17:4  
**reminder** 8:3 17:6,18  
 19:8 20:8 21:5,12  
**reminders** 7:16  
**reminds** 330:12  
**remote** 19:13  
**renal** 53:7 60:20 65:13  
 66:4 67:10 82:6 87:12  
 88:6 221:3 234:20  
 235:16,19 236:12  
 237:6,8,19 238:4,22  
 247:15 250:19 252:12  
 252:22 253:2,3,7,18  
 258:11 274:18 280:8  
 290:12 293:19  
**reopened** 181:15  
**repair** 173:17,18 174:1  
 203:15,18 216:2,7,20  
 224:9  
**repair/CABG** 217:1  
**repairs** 206:10 216:4  
 224:18  
**repeat** 127:4 237:10  
**repeatable** 180:11  
**rephrase** 103:4 106:11  
**replacement** 3:7,8,11  
 46:3 87:2 99:8 124:4  
 158:19 160:13,17  
 161:13 173:8,18  
 179:11 216:2,5,7  
 224:10  
**replacement/CABG**  
 217:2  
**replacement/coronary**  
 216:21  
**replacements** 174:1  
 224:17  
**replying** 208:13  
**report** 17:15 20:8 21:9  
 29:2 42:21 52:14 55:3  
 55:16 57:22 59:19,21  
 60:10 63:14 67:1  
 68:14 69:5 71:14,20  
 72:14 74:3 76:14  
 101:14,18 152:12,13  
 156:2 175:13 189:6  
 193:1,20 218:13,19  
 218:22 222:3,10,11  
 229:1,2 234:9 240:5  
 244:13,17 251:22,22  
 252:2,13,14 259:20  
 263:18 264:11 266:2  
 266:8 270:19 271:12  
 295:22 296:4,13  
 302:21 321:21 335:4

335:10 336:12 341:10  
**reportable** 87:22 258:2  
 296:6  
**reported** 24:6,13,22  
 25:4,7,14,20 26:16,20  
 27:1,8,16 28:7 29:7  
 36:13 37:2 38:19  
 39:15 42:16 48:9,11  
 49:5,20 50:9,20 51:2  
 51:3,9,18 52:6 54:14  
 55:9 59:12 64:3 69:1  
 70:14 73:14 75:22  
 87:9 93:9 95:15  
 109:20 135:19 152:21  
 173:13 184:2 194:1  
 200:4 215:2,5,11,15  
 216:1,1,9,10,15,15,18  
 216:19 217:11 223:6  
 223:18,22 224:11,12  
 227:7,10,15 251:4  
 253:8 257:14 258:4  
 258:10,20 259:14  
 269:13 270:6 279:1,9  
 279:21 284:18 285:9  
 288:3 289:5 290:18  
 291:4 301:3,8,9  
 303:11 306:10 320:10  
 322:9 323:13 324:9  
 326:13 335:10 339:2  
**reportedly** 59:12  
**reporter** 6:10  
**reports** 33:1 44:13  
 69:10 76:5 205:10  
 212:20 213:17 288:16  
 335:18  
**represent** 7:18 75:1  
 236:6 237:2,8 298:21  
 298:22  
**representative** 9:12  
 77:14  
**Representatives** 46:14  
**representing** 47:19  
 138:4  
**represents** 48:16 79:3  
 237:12  
**request** 146:6 226:7  
**requested** 95:18,22  
 244:9  
**requests** 206:22  
**require** 24:11 29:14  
 36:16 162:16 238:6  
 268:9  
**required** 30:19 69:14  
 89:1 113:18 174:17  
 217:8 295:18 306:6  
 306:14 325:2 328:17  
**requirement** 113:12  
 129:13 146:6 228:2

**requirements** 239:22  
**requires** 21:18  
**requiring** 53:7  
**research** 152:6 153:11  
 153:13 186:19,20  
 188:9 196:3 203:11  
**researched** 337:8  
**researcher** 12:8 138:5  
**researching** 80:6,11  
**resend** 94:22 342:9  
**reserve** 309:4,11,16  
**reserved** 308:22  
**respect** 50:11 60:8  
 112:14 113:16 200:22  
 211:12 212:17 213:9  
 243:3 253:18 281:21  
 329:2  
**respectful** 302:18  
**Respectfully** 266:12  
**respond** 39:16 114:17  
 122:3 136:19 219:15  
 224:5 228:14 266:17  
 268:17 280:12 282:13  
 302:17  
**response** 13:10,12,14  
 40:5 86:19 95:4  
 104:20 106:15 108:8  
 114:14,19 120:14  
 127:13 132:2 146:17  
 156:19 157:8 158:2  
 166:4,7,19 167:1,16  
 167:20 168:2,7,11  
 266:14 311:21 333:2  
**responses** 316:1  
**responsible** 84:10  
 297:21  
**rest** 5:8 61:14 91:17  
 230:8 267:17 282:11  
 340:21  
**restoring** 198:10  
**restratification** 175:10  
**restrict** 73:21  
**restriction** 75:11  
**result** 77:8 298:11  
**results** 45:6,10 63:13  
 68:12 74:5,7,8 82:18  
 97:15,18 103:16  
 107:16,19 113:6,7  
 129:10 154:3 175:5,9  
 194:1 199:1 243:12  
 244:21 259:10 293:17  
**resumed** 98:22 171:19  
**retested** 106:19  
**rethink** 222:2  
**retrospectively** 208:7  
**reverse** 187:11  
**review** 4:18 16:5 21:1  
 49:7,12 50:3,12,21

51:7 89:15 107:11  
 126:17 174:16 211:14  
 221:20 225:20 235:8  
 253:16 263:18 270:7  
 270:21 305:17 330:20  
**reviewed** 48:6 89:6  
 100:15 106:20 109:18  
 235:1 241:21 242:12  
 270:4  
**reviewing** 4:20 16:16  
 175:1 207:5  
**revisions** 226:10  
**reward** 110:21  
**Richard** 1:11 10:13  
 22:13  
**Rick** 10:14 22:12 33:20  
 35:10 151:17 272:3  
 274:20  
**rights** 227:17 228:5  
**risk** 34:18 72:18 76:13  
 76:20 79:10,11 82:6,6  
 83:17 87:7 103:13  
 107:10 110:5 111:1,6  
 112:2,17,21 115:17  
 116:3,9,9,11,12,13  
 117:7,11 118:4  
 119:10 120:16 121:13  
 123:22 124:3,13,14  
 126:5 128:6,7,16  
 129:2,2,14 130:12  
 133:4,5,9 134:10  
 140:5,9 142:5,7,7,17  
 142:18,19,20 143:15  
 159:12,16 162:1  
 177:19 185:12 207:9  
 213:5,8 240:6 250:10  
 253:21 254:3,8,15,20  
 254:21 255:13 256:17  
 264:19 281:6 295:12  
 301:5,7,11,17,21  
 302:1,8  
**risk-** 118:7 134:12  
 143:5 173:6 295:15  
**risk-adjusted** 3:10  
 77:18 78:6 153:22  
 234:19 296:4 301:15  
**risks** 52:18  
**Rissa** 282:10  
**road** 307:13  
**Robert** 1:11 12:13 44:3  
 46:6,8,8  
**robust** 138:16 198:8  
 209:18  
**robustness** 218:11  
**robustus** 290:3  
**Rochester** 12:15 15:12  
**role** 280:21  
**roles** 17:1

**rolled** 235:3 298:13  
**rolling** 102:6 284:22  
**room** 1:7 4:6 6:13 8:13  
 8:20 12:12 13:21  
 14:14 21:16 104:8  
 106:17 122:9 147:11  
 148:18 165:10 217:16  
**roughly** 96:20  
**round** 24:2 312:7  
**route** 271:7  
**routinely** 123:7 202:9  
**RPVI** 1:18  
**rule** 36:1,15  
**rules** 17:22 29:11 31:13  
 36:7,11 39:10,13  
**Ruling** 36:2  
**run** 94:9 129:2 162:6,12  
 163:10 164:19 301:6  
**running** 336:16  
**runs** 34:18  
**rural** 195:22 254:4

---

**S**


---

**safeguard** 311:7  
**Saigal** 1:17 11:1,1 92:5  
 118:13 120:11,15  
 121:18 122:15 125:4  
 125:16 128:2 145:10  
 223:16 239:17,18,20  
 241:12 242:17 243:2  
 244:11 245:14 247:10  
 247:20 248:6 249:1,5  
 249:21 256:10 257:11  
 261:15 264:4,16  
 286:10,17 289:15  
**Saigal's** 127:14 138:13  
 224:12  
**Sal** 11:8  
**salutation** 261:5  
**SALVATORE** 1:18  
**sample** 220:17 296:3  
**satisfy** 35:5,7 52:2  
 113:18  
**saw** 109:2 170:7 214:3  
 316:20  
**saying** 15:5 30:14  
 34:20 38:6 40:21 41:5  
 44:9 58:4,9 59:11  
 61:7 72:11 77:12  
 79:17 120:18 122:3  
 123:10 133:14,15  
 135:21 143:9 164:13  
 186:4 211:12 212:21  
 217:6 219:12 243:18  
 244:22 245:10 258:17  
 264:5 267:18 269:21  
 279:12 281:20 282:17  
 286:11 288:8,9,10

297:16 313:21 324:8  
**says** 44:12 79:2 82:22  
 95:3 128:17 143:3  
 215:20 219:6 246:3  
 246:10 253:9 303:10  
**scale** 331:9  
**Scali** 1:18 11:7,8  
 172:14 174:7,9  
 177:12 200:22 202:5  
 202:8 212:17 214:15  
**scan** 304:1  
**scanning** 188:13  
**scenario** 227:22  
**schedulary** 35:19  
**schedule** 176:15 266:1  
**scheduled** 22:5 50:3  
 339:16,18 341:6  
**school** 1:14 30:1 80:9  
**science** 135:10 154:7  
 189:13 285:6  
**scientific** 16:16,20  
 20:12,17 23:20 99:20  
 167:9 268:2 271:11  
 299:22  
**scientifically** 301:2  
**scientifically-proven**  
 28:20  
**score** 3:7,9 46:4 50:13  
 50:14,17,19 51:3,11  
 51:13 53:13,20 57:15  
 59:18,19 63:3 64:22  
 65:4,14 66:13 67:8  
 68:7 69:4 78:14,16  
 79:3 80:16 81:10  
 82:20 99:8 101:20  
 158:20 160:19 179:6  
 180:7 217:15,17  
 218:6 261:9 262:2  
 285:17,20 309:5  
 329:8,17  
**score's** 79:7,7,8  
**scored** 327:12  
**scores** 31:5 63:6 68:7  
 79:3 154:1 161:5  
 250:5 278:12,13  
 284:19 285:1 306:11  
 311:20  
**screen** 92:6,8,11,15  
 235:6 246:4 313:10  
 318:12,15 319:5  
**screen-** 234:15  
**screen-share** 234:18  
**scroll** 79:1 83:3 236:9  
 246:13 313:9  
**scrutinizability** 60:7  
**SDS** 34:5 107:9,12  
 108:15,17 110:20  
 129:15 139:15,18

140:13,21 141:1,8,12  
 145:6 227:17  
**SDS-advocated** 273:7  
**SDS/SES** 110:19  
**se** 79:8 110:19 111:4  
 117:2  
**seams** 272:6  
**Sean** 2:10 47:22 66:17  
 111:13 112:10,13  
 118:19 119:6 123:10  
 132:12,18 142:12  
 242:21 251:13,17,19  
 254:22 255:16 287:1  
 287:6 296:1 310:3,22  
 331:3  
**search** 94:4  
**searchable** 73:12  
**seats** 301:13  
**second** 23:21 24:2 40:1  
 74:16 101:13 102:2  
 114:21 129:12 145:1  
 145:10 148:8 171:1  
 175:12 177:9 178:9  
 178:14 186:16 208:22  
 216:6 221:15 229:18  
 259:19 264:16 277:22  
 291:7 292:6 326:15  
**secondary** 127:20  
 302:19  
**Security** 187:2,3,22  
 188:10 189:2,4,6,11  
**seeing** 78:14 95:3  
 106:16 145:15 187:14  
**seek** 107:17  
**seen** 24:20 78:12 80:9  
 104:18 130:5 168:22  
 181:10 278:8 318:4  
**sees** 152:3 281:9  
**selection** 129:22  
 175:10  
**semantic** 191:19  
 264:18 268:1  
**semantics** 262:12  
**send** 19:19 22:19 39:11  
 39:21 40:19 140:3  
**sending** 40:17 234:13  
**Senior** 2:2,2,3,3 4:9  
 5:12,16 6:2 47:16  
**sense** 40:4 54:8 58:6  
 65:20 82:9,15 85:5  
 90:3 113:1 120:6  
 121:21 123:18 172:9  
 227:18 245:15 279:22  
 283:20,22  
**sent** 16:16 41:3 92:3  
 160:21  
**separate** 19:21 32:13  
 42:8 51:11,12,13

57:17 58:1 59:4,12,20  
 91:16 108:18 110:4  
 118:10 160:18 161:4  
 167:9 193:19 196:11  
 226:17 228:4 251:22  
 258:10 266:15 295:21  
 333:6  
**separated** 59:6 174:2  
 218:5 244:7  
**separately** 51:9 52:7  
 54:14 57:9,18,22 58:2  
 58:4 59:10,12,13,15  
 59:16 64:16 216:10  
 217:5,11 231:8  
 270:10  
**separating** 59:5  
**separation** 217:11  
**seriously** 232:10  
**serum** 235:16,22  
 236:13  
**serve** 54:9  
**service** 40:20 333:3  
**services** 12:8  
**SES** 120:12,19 122:17  
 123:9 128:11 129:15  
 131:22  
**session** 267:11  
**set** 18:18 42:4 128:8  
 190:16 194:22 207:16  
 207:22 214:19 244:3  
 253:16 259:19 268:20  
**sets** 27:11 184:1 207:15  
**seven** 49:2,8 149:2,3  
 285:19  
**severity** 91:7 99:19  
 130:11,14 141:7  
**sex** 112:5,15 178:11  
**Shahian** 2:11 47:20  
 62:22 64:20 65:21  
 67:15,20 73:20 84:12  
 114:17,20 116:7  
 118:18 127:2 136:19  
 153:9 154:19 191:18  
 192:16,22 219:15  
 228:14 254:18 267:14  
**shape** 124:5  
**share** 69:11 72:15,17  
 73:22,22 74:1,7,8,18  
 74:20 75:7,7,10  
 156:12 176:10 265:11  
**shared** 57:7 74:18  
 191:5,7 263:17  
**sharing** 129:10 234:16  
**sheet** 45:18 249:4  
**shift** 272:6,10  
**shifted** 213:5  
**Shore-LIJ** 1:16  
**short** 57:9

**shouting** 109:5  
**show** 117:18 124:8  
 128:6 129:20 143:14  
 143:19 160:20 217:13  
 247:3 282:16 320:11  
 330:14 331:5  
**showed** 220:10  
**showing** 245:18 246:10  
 250:7 330:22  
**shown** 334:20  
**shows** 106:10 159:13  
**shut** 303:7  
**shy** 338:7  
**sic** 35:19  
**sick** 184:7  
**sicker** 213:4  
**side** 71:19 141:16  
**sign** 71:21 156:1 169:4  
 290:15  
**signal** 139:7 141:10,22  
 282:18  
**signaling** 283:8  
**signals** 282:18  
**signed** 70:21 73:5,10  
 73:15  
**significance** 55:21  
 238:4  
**significant** 100:6 112:7  
 185:2 228:18 236:6  
 239:22 240:2 242:18  
 244:13 314:22 327:21  
**signing** 136:21  
**similar** 47:9 100:5  
 113:8 214:3 219:20  
 224:6 226:22 250:13  
 277:20  
**similarly** 83:5  
**simplify** 206:21  
**simplistic** 84:7 330:2  
**simply** 159:13,22 192:2  
 235:21 236:3,7,14  
**Simultaneous** 23:2  
 33:13 38:11 52:8  
 67:17,22 75:16 76:11  
 92:13 98:4 118:17  
 120:10 123:1 125:3  
 132:10,16 144:21  
 145:19 164:16 165:12  
 165:18 169:5,10  
**single** 35:21 58:7 59:17  
 63:3 65:15 79:4 137:2  
 137:4 153:20 184:5  
 222:22 257:13 287:18  
**Siperstein** 1:19 13:16  
 13:17 158:22 159:5  
 161:22 164:14  
**sit** 7:17 11:20 135:16  
 281:11 288:7



<b>site</b> 51:10 60:12 61:5,9 61:16 69:1 72:21,22 77:11 217:14 222:22 224:15 259:12 290:11 292:10 293:13 306:12 311:7	<b>329:7</b>	109:15 110:1 128:18 133:7 175:6,9 193:11 205:21 219:12 221:7 253:13 276:7 277:22 281:3,6,9 287:3 288:19 321:11 334:4	225:7
<b>site's</b> 287:10	<b>smarter</b> 22:18	<b>sorting</b> 327:10	<b>spend</b> 97:15 183:5 206:17
<b>site-specific</b> 74:13	<b>smoother</b> 36:2	<b>sorts</b> 55:10 288:16	<b>spent</b> 82:11 84:21
<b>sites</b> 28:22 31:4 57:8 60:14 61:8,20 70:18 77:18 78:7 100:18 156:15 186:12 204:17 224:13 239:3 246:5 252:8 292:14 302:12 302:20	<b>snag</b> 213:10	<b>sound</b> 104:11	<b>sphere</b> 336:13
<b>sitting</b> 80:10 278:22 288:20 289:13 325:13	<b>snowed</b> 15:13	<b>sounds</b> 118:13 120:19 120:21 122:17 264:17	<b>spirit</b> 8:8 34:8
<b>situation</b> 197:12 262:4	<b>snowy</b> 12:3	<b>source</b> 60:9 179:19	<b>split</b> 67:2
<b>situations</b> 133:17	<b>soap</b> 279:10	<b>sources</b> 337:14	<b>spoke</b> 78:17 196:2
<b>six</b> 24:13,21 49:8,14 95:14 147:4 187:7 215:17	<b>social</b> 111:22 116:9,11 116:13 122:13 135:2 135:5,8,11 136:4 137:19 139:22 187:2 187:3,22 188:9 189:2 189:4,6,11	<b>Southeast</b> 122:1	<b>sport</b> 198:4
<b>size</b> 220:17 296:3	<b>socially</b> 122:12	<b>space</b> 297:11	<b>spot</b> 70:9 138:20
<b>skill</b> 27:11	<b>societal</b> 159:17	<b>speak</b> 6:10,11,13,14 15:19 16:2 30:12 47:12 48:2 50:7 54:8 66:18 106:8 111:14 245:20 274:6 284:4 296:1 338:6	<b>spots</b> 283:22
<b>skilled</b> 185:13	<b>society</b> 2:7,9 11:13 53:17 93:11 138:15 193:13 198:12	<b>speaker</b> 28:16 258:15	<b>spread</b> 161:1 240:1 247:11 330:14
<b>skin</b> 117:1,3 290:5	<b>socio-</b> 115:18 126:4 127:15 137:5	<b>speaking</b> 6:15 18:9 23:2 33:13 38:11 52:8 53:11 67:17,22 75:16 76:11 92:13 98:4 118:17 120:10 123:1 125:3 132:10,16 144:21 145:19 164:16 165:12,18 169:5,10 208:10 226:19 280:20 280:22 295:8	<b>sprinkle</b> 335:19
<b>skip</b> 171:22 309:18	<b>socio-demographic</b> 115:1 116:8,14 117:11 119:3 127:5 137:10 159:8	<b>spec</b> 206:3	<b>squeeze</b> 276:14
<b>skipped</b> 312:11	<b>sociodemographic</b> 201:3	<b>special</b> 128:6 182:22	<b>stability</b> 218:12,14 317:21
<b>Skipper</b> 2:3 4:3,9 5:6 6:4 16:4 22:19 23:3,5 23:8 27:17 92:2,10,16 94:18 97:19 98:2,9,16 99:2,12 102:21 104:1 104:3 165:3,9,22 166:10,15,21 167:4,8 167:12,22 168:5,9 172:5,17 173:2 174:5 176:8 177:1,6 178:17 210:5,8 231:10 232:11,21 233:5,14 233:21 234:5,12 245:20 261:7,18 262:2 265:19 266:2 307:7 316:17 318:18 338:1,4 341:5 342:18	<b>socioeconomic</b> 112:19 115:1,4,10 116:1 119:4 124:22 130:17 131:18 137:5	<b>specialists</b> 80:8	<b>staff</b> 2:1 15:21 19:7,8 48:5 162:17,21 235:13 247:1,4 328:2
<b>skipping</b> 173:14	<b>solely</b> 267:22	<b>specialty</b> 138:15 187:4 301:10	<b>stakeholder</b> 298:22
<b>slice</b> 154:5	<b>solo</b> 46:9	<b>specific</b> 15:7 68:13 72:6 111:2,14 137:8 184:15 191:3 206:4 206:12 252:18 253:20 259:11,12 280:13 296:14 331:21	<b>stand-</b> 161:20
<b>slide</b> 4:22	<b>solution</b> 126:22	<b>specifically</b> 49:22 52:13,15 53:20 65:10 93:19 94:1 114:2 183:19 204:1 224:3 236:2 238:12,17 242:4 289:5 335:20	<b>standalone</b> 270:8
<b>slightly</b> 43:6 134:10 142:10 212:21	<b>solvable</b> 274:2	<b>specifications</b> 85:22 107:6 139:14 179:7 199:14	<b>standard</b> 4:16 141:18
<b>Sloan-Kettering</b> 1:20	<b>solve</b> 274:1	<b>specified</b> 85:17 88:3 116:18 189:20 200:7	<b>standards</b> 300:10
<b>small</b> 99:16 101:17 121:19 131:12 176:1 184:13 185:20 186:1 191:14 198:22 238:8 238:11 310:7 329:15	<b>somebody</b> 15:8 66:12 66:13 97:12 140:17 143:7 169:15 181:18 181:22 182:14 208:7 220:20 237:3,14 304:11 322:22		<b>standing</b> 1:3,6 4:5 7:12 17:1,6 19:5 25:5 107:11 186:4 226:7 263:13 264:3 297:21
<b>small-vessel</b> 121:8,13	<b>somebody's</b> 117:2		<b>standpoint</b> 30:15 54:18 228:15 310:17
<b>smaller</b> 124:6 128:7	<b>someday</b> 35:13		<b>star</b> 51:12,13 59:21,22 62:3,8 63:6 65:7 67:2 69:3,12 70:13 71:2,17 72:4,14 81:3 88:14 89:8,15 90:4,5,19 96:22 97:2 109:16,19 110:10 131:14,17 149:17 152:13 185:1 278:15 279:17 280:5 287:4 292:11,15 293:6 306:11 321:7,9 324:17 327:6,10,22 329:20,21 335:20 336:18
	<b>somewhat</b> 84:7 224:6 262:18 270:2 272:12		<b>staring</b> 292:9
	<b>soon</b> 85:10 103:14 140:18 226:1 267:16		<b>stars</b> 75:13,13 80:21 81:2,3,17,17 152:8,9 152:17,18 153:4 156:6 188:20 209:9 209:11 284:21 292:11 292:14 321:10 325:5 329:12,13,13 333:8
	<b>sophistication</b> 159:14 278:18		<b>start</b> 5:6 8:10,14 12:12 85:10,11 165:15 172:18,20 174:7 195:20 228:1 234:2 300:21,21 334:4,4
	<b>sorry</b> 8:7 15:15 37:6 45:20 46:2 74:11 105:17 132:3 171:15 173:16,16 210:7 217:1 237:9,11 297:8 310:19 320:22 330:8		
	<b>sort</b> 55:12 58:17 64:5,8 70:11 83:20 96:10 98:7 99:17 104:17		

**started** 86:13 154:9,14  
155:13 219:17 227:4  
227:22 283:19 291:10  
**starting** 20:7 262:21  
336:22 337:14  
**starts** 314:17  
**state** 52:13 104:17  
189:1 193:17 194:2  
213:6  
**statement** 44:12 88:22  
179:8,9,17 218:10,16  
231:6,22 247:17  
312:7  
**statements** 88:13  
**states** 1:11 67:3 189:7  
228:21  
**static** 178:2  
**statistical** 67:13 69:14  
88:9 111:18 112:11  
125:15 142:13 220:16  
221:7 226:21 246:2  
287:6 288:18  
**statistically** 81:6,14  
84:3 235:3 280:16  
310:3,21  
**statistician** 66:17  
241:22 242:14 247:14  
**statisticians** 88:11  
111:12  
**statistics** 97:3 185:22  
246:12  
**status** 112:20 115:9,11  
119:3,4 130:17  
135:16 137:6,10  
289:12 308:15,22  
309:4,11  
**stayed** 182:2  
**steadily** 155:18  
**Stein** 1:20 9:7 12:6,7  
32:13 33:7,9 126:19  
126:20 129:8 151:16  
151:18 204:16 207:4  
209:8 210:18 224:22  
239:18 240:12,14  
241:17 246:9 248:3  
250:13 253:6,19  
256:15 330:9  
**step** 18:2 63:6 64:13  
65:1 98:10 144:4,11  
172:7  
**stepped** 94:9  
**steps** 5:4  
**sternal** 53:8,8 87:10,11  
291:9,10,16 295:17  
**sternotomy** 161:15,17  
**sternum** 291:14  
**steward** 87:3 272:9  
**sticking** 217:20

**stop** 20:11 31:16 143:1  
189:5 233:1 309:9  
335:6  
**stops** 309:10  
**straightforward** 87:13  
**strategy** 221:10,11,15  
222:12 233:8  
**stratification** 129:16  
144:14  
**stratified** 127:1 129:10  
143:17  
**stratifying** 243:12,17  
**streamline** 104:14  
**streamlining** 106:5  
**street** 1:7 131:2  
**strength** 282:16  
**strengthens** 59:1  
**stressors** 196:8  
**stretch** 171:13 305:4  
**strict** 88:6  
**striking** 153:18  
**stringency** 275:11  
**stringent** 56:19 238:20  
239:3,13  
**stroke** 53:6 55:9 61:10  
61:12 62:7 65:13  
67:11 82:6 221:4  
279:17 280:8,15  
290:11 291:1 293:19  
294:20 295:16,22  
**strong** 132:6 140:3,16  
140:18 146:6 268:15  
269:12 283:10  
**stronger** 35:12 277:9  
**strongly** 134:7  
**structure** 16:14  
**struggled** 341:19  
**struggling** 139:12  
272:1,2 341:21  
**STS'** 231:22  
**STS's** 49:4 87:2 134:8  
**STS-related** 114:3  
**studied** 153:20  
**studies** 204:4 240:19  
**study** 115:4 131:11,22  
155:4 288:13  
**stuff** 58:3 80:7,7  
**stunning** 204:7  
**stupid** 187:13  
**sub-components** 227:1  
**sub-criteria** 20:14  
**sub-groups** 243:10,14  
243:22  
**sub-measures** 286:15  
**subcomponents** 56:10  
57:4 72:2 81:7 156:6  
302:16  
**subgroup** 107:8

**subject** 243:11 301:12  
306:17  
**submission** 117:20  
246:21 307:1  
**submit** 17:19 162:17  
231:18  
**submitted** 19:5 48:12  
49:6 201:12 246:19  
247:3 307:10  
**subsequent** 323:4  
**substantial** 154:11  
203:17  
**substantially** 45:11  
311:8  
**substantive** 299:15  
**substantively** 62:18  
**subtracted** 206:6  
**succumb** 183:10  
**suffer** 339:1  
**sufficient** 190:2 218:13  
240:20 269:18 336:9  
**suggest** 35:17 54:12  
84:22  
**suggested** 194:18  
197:19  
**suggesting** 209:12  
334:21  
**suggestion** 197:15  
207:8  
**suggestions** 32:15,19  
32:20,22 61:2 128:14  
225:3  
**suggests** 250:16  
**suitability** 158:12 171:3  
**sum** 287:16  
**summarize** 245:6,6  
**summarizing** 244:21  
245:4  
**summary** 19:4 246:12  
**summation** 322:3  
**sun** 261:5  
**sunny** 13:18  
**super** 290:11  
**supplementing** 211:20  
**support** 17:20 99:22  
126:3 232:7  
**supporting** 240:16  
**supportive** 332:10  
333:18  
**suppose** 56:1 177:10  
**supposed** 31:16 303:8  
331:1  
**surgeon** 10:5 11:8  
12:21 48:19 52:10  
63:13 68:12 69:9,19  
70:5 72:10,10 74:19  
75:20 77:12,18,21  
78:2,6 84:14,18 85:1

133:8,15,16 151:6,13  
161:6 191:3 194:19  
195:7,9,9,10,11  
196:22 197:12 198:13  
206:14,15,18 240:3  
280:3 336:5  
**surgeon-specific** 74:15  
75:21 76:4,19 95:17  
301:14 336:12  
**surgeons** 2:7,9 27:9  
31:5 34:4 69:10 71:12  
71:14 77:2 83:15  
95:18 129:4 134:1,14  
150:18,21 154:10  
171:15 174:3 190:2  
190:22 198:22 301:7  
303:21 304:1 322:17  
**surgeons'** 192:14  
**surgeries** 133:21 206:9  
**surgery** 1:3 3:11 4:4  
7:11 16:6,11,12 34:3  
48:13,15 52:18 84:16  
99:22 101:19 133:19  
134:6 151:2 153:2  
172:7 173:20 180:15  
183:11,15 193:14,17  
196:13 198:4 206:8  
216:21 219:19 236:2  
236:16 237:1,13,15  
259:10 268:8 310:14  
**Surgery's** 11:13  
**surgical** 28:3 43:13  
48:10,18,20 50:20  
73:4 75:2,4 87:10  
103:10 122:6 153:12  
156:8 174:21 191:19  
191:20 192:3,6  
193:22 194:3,6 195:4  
200:6 220:1 297:11  
298:3  
**surprised** 253:10  
**surrogate** 111:5 125:12  
126:6 127:15 141:2,4  
185:5 259:13  
**surrounds** 203:14  
**Survey** 97:16  
**surveys** 22:14  
**survive** 221:1,2  
**survives** 58:20,21  
**survivor** 220:22  
**suspect** 184:11 194:4  
205:12 238:10 293:1  
**swaying** 283:2  
**sweat** 211:8  
**system** 1:16 62:8 69:22  
70:3 71:2 134:22  
140:8 183:4 268:13  
**systems** 280:21

T			
<b>tab</b> 19:22	<b>ten</b> 109:9 285:19	<b>theoretical</b> 303:3	<b>threw</b> 123:13
<b>table</b> 83:16 241:20	290:22 314:15	<b>theory</b> 244:1 301:22	<b>throw</b> 84:9 189:8
246:17,18,21 247:7	<b>tend</b> 29:6 150:22	<b>therapy</b> 310:10 312:11	196:18 222:20 223:9
276:8 325:9	151:22	<b>they'd</b> 200:10	<b>throwing</b> 294:17
<b>tables</b> 314:14	<b>tending</b> 292:3	<b>things</b> 9:7 29:1 36:2	<b>ticks</b> 303:17
<b>tackle</b> 34:2	<b>tension</b> 124:9	55:10 59:6 61:6 63:11	<b>tiered</b> 208:10
<b>takeaway</b> 270:17	<b>term</b> 53:13	63:15 68:22 74:5	<b>tighter</b> 96:19
<b>taken</b> 65:18 115:20	<b>terms</b> 27:10 35:16	79:12 82:17 84:6	<b>till</b> 171:7,12
118:7 212:7 268:16	56:13,21 60:18 69:3,6	101:11 109:6 110:14	<b>timely</b> 44:14,21
<b>takes</b> 102:7 137:6 151:6	70:8 71:10 74:7,14	110:20 116:3 123:14	<b>times</b> 17:4 18:1 66:19
204:4 263:12 291:22	80:21,22 81:4 100:21	123:20 124:12 126:9	104:11 203:21 210:13
312:9	111:20 122:21 137:21	126:12,13 136:4,14	249:6 294:13 328:7
<b>talk</b> 4:14 21:2 27:21	156:13 159:10 175:19	176:14 186:9 196:8	<b>today</b> 4:15 5:2 6:10 7:4
32:11 69:9 83:11	187:14 192:4 238:14	198:6 201:5 205:21	7:13 10:8,20 11:20
84:14 85:18 87:14	250:8 251:7 253:21	207:20 227:2 254:2,3	14:3,6 16:16 17:9
90:18 190:9 210:12	255:11 257:13 277:4	255:12 271:1 276:9	18:17 19:13 21:1,6
230:3,5 232:13 240:5	281:14 282:1 290:2	277:10 278:3 285:12	26:15 47:21 48:6 49:1
243:12 251:14 263:19	294:1 301:5 310:9	290:14 334:19 339:11	49:12 50:3 51:7,22
263:20 266:7 303:8	325:18	<b>thinks</b> 199:19	92:21 94:1 135:17
321:6 323:18	<b>tertiary</b> 254:6	<b>third</b> 40:8 102:3 160:14	168:20 194:14 212:1
<b>talked</b> 88:16 104:6	<b>test</b> 94:9 95:5 106:19	<b>Thirteen</b> 164:22 201:22	218:18 220:12 226:8
176:15 254:1	197:16 214:10 250:6	<b>thoracic</b> 2:7,9 12:20	235:1 265:10 267:1
<b>talking</b> 26:15 81:1 90:9	<b>tested</b> 107:19 197:18	95:15 193:13	268:16 272:1,2
100:20 111:4 151:10	199:22 200:8	<b>thought</b> 22:20 37:8,15	305:10,18 316:4
194:14 195:20 205:8	<b>testing</b> 86:1,1,6,7,11	58:22 80:9 90:12	328:3 331:22 342:1
218:7 223:17 227:8	95:11 107:19,20	106:4 129:1 130:2	342:17 343:5
244:20 284:20 342:7	117:15,16 180:5,7	141:15 171:7 213:13	<b>today's</b> 17:5,22 18:14
<b>target</b> 175:14 277:14	192:4 195:2 199:15	217:20 240:15 241:19	22:10 267:11
<b>task</b> 156:10	201:8,11 213:22	242:1 256:15 260:20	<b>tomorrow</b> 328:20
<b>tasked</b> 330:13	261:9 262:2 309:6	273:8 275:18,19	<b>tonight</b> 328:19
<b>tautologically</b> 208:10	317:18	326:14,21 329:5	<b>tool</b> 154:9,13 282:3
<b>TAVR</b> 103:13	<b>tests</b> 244:12 250:1	<b>thoughtful</b> 299:13	<b>top</b> 152:20 321:22
<b>TAVRs</b> 103:6,8	<b>than-expected</b> 294:20	<b>thoughts</b> 108:19,21	332:4
<b>teach</b> 332:15	<b>thank</b> 5:10,13,20 6:20	195:1 310:22	<b>topic</b> 308:3
<b>team</b> 5:9 99:20 173:3	7:5 9:6,13,15 12:11	<b>threat</b> 142:7	<b>topology</b> 137:20
198:4,14 199:6	12:18 13:1,8,19 14:19	<b>threats</b> 142:6	<b>topped</b> 308:8,16 323:21
202:10 341:19 342:12	15:14 16:2,4 23:12,14	<b>three</b> 18:18 24:12 75:13	325:19 326:2
343:14	48:4 63:22 80:19 95:8	81:2,17 90:5 95:14	<b>torn</b> 298:1
<b>teammates</b> 6:22	97:4 99:11 100:3	102:7 116:10 152:8	<b>torture</b> 143:22
<b>tears</b> 124:10	116:5 172:10 173:3	152:17,18 153:3,4,12	<b>total</b> 105:21 109:10
<b>technical</b> 10:22 48:2	174:4,10 188:11	156:6 167:9 170:4	145:22 147:5 149:4
74:6 111:2 206:8	211:5 231:2 234:17	182:9 194:6 209:9	157:3,15 158:13
272:21 276:6	235:13 247:21 260:2	212:22 215:11,15	171:4 178:15,21
<b>technically</b> 24:16	267:18 269:8 274:5	217:17 222:16 270:15	201:22 212:11 229:16
142:19 213:12 288:2	286:8 305:12 307:21	285:19 312:22 313:5	241:6 248:18 249:17
<b>technological</b> 212:6	315:21 316:3,4,13	313:6 320:3,19	256:4 257:7 260:13
<b>teleconference</b> 2:17	319:1 326:17 330:7	321:10 324:13 325:5	307:21 315:12 317:9
<b>Telephonic</b> 5:22 8:6,12	331:17,18 337:16	325:21 329:13 338:15	320:2
14:7,22 15:3 29:9	341:17 342:14,17	<b>three-</b> 336:17	<b>totally</b> 60:8 73:14 128:2
<b>tell</b> 55:1 83:19 134:1	343:3,10,11,18	<b>three-and-</b> 189:1	208:16 211:12 281:20
152:22 172:3 173:3	<b>thanks</b> 6:4 17:2 23:16	<b>three-star</b> 89:9 96:21	<b>touch</b> 15:21
322:18 337:6	269:6 306:3 319:20	97:1 131:18 156:4,12	<b>tough</b> 137:21
<b>TeMaya</b> 1:12 9:11,16,17	<b>theme</b> 216:12	329:17,19,22 330:3	<b>track</b> 172:4 185:6
78:9,9 85:14 305:10	<b>then,we'll</b> 6:11	334:8,13 336:20	<b>tracking</b> 40:7,7 206:18
317:1 331:19	<b>theoretical</b> 213:7	<b>three-year</b> 102:5	213:7 324:20
<b>Temple</b> 1:20 15:10,11	303:19	284:22 295:19	<b>traditionally</b> 255:5
318:21 319:19	<b>theoretically</b> 67:21	<b>threshold</b> 230:21 291:5	<b>train</b> 23:12 183:7
	68:10 83:2	<b>thresholds</b> 290:17	326:14,21 329:4

**trajectory** 155:12  
**trans-catheter** 160:13  
**transcriber** 6:9  
**transcript** 6:16  
**transfer** 205:15  
**transferred** 184:8  
**transparency** 8:9 28:17  
 45:4,5,11 56:22 155:8  
 281:4 285:13 300:12  
 332:8  
**transparent** 44:14,22  
 61:19 151:14 278:7  
 278:14  
**travel** 9:5  
**treated** 65:22 66:10  
**treatment** 3:12 49:10  
 67:13 222:21 305:9  
 305:14 321:4  
**trending** 212:21  
**trial** 113:2 139:15,15  
 141:9  
**trials** 288:15  
**tried** 189:11 268:1  
**tries** 277:21  
**trouble** 94:21 283:22  
 318:19  
**troublesome** 27:14  
**true** 121:22 176:18  
 199:4 205:12 242:19  
 280:11  
**truly** 133:17 186:3  
 198:12  
**trust** 44:15 281:22  
 291:5 301:8,9  
**truth** 151:2 207:1  
**truthfully** 206:11  
**try** 4:15 6:7 52:21 120:4  
 138:20 160:1 191:11  
 193:12 242:22 245:22  
 260:10 287:16 300:5  
 302:1  
**trying** 15:9 34:9 37:12  
 80:13 82:14 84:10,21  
 87:20 116:17 148:5  
 156:3 183:4 186:10  
 187:5,19 206:21  
 208:8 220:2 238:14  
 274:7 282:4 283:3  
 302:22 324:15 330:2  
 330:20 334:22 335:2  
**turn** 5:6 6:17 9:16 15:16  
 27:3 62:3  
**turned** 43:5  
**turning** 16:22  
**turns** 188:22  
**Twenty-five** 171:9  
**twice** 169:1  
**two** 9:7 16:15 20:13

39:8 49:21 50:1,11  
 51:8 57:18 58:8 59:5  
 61:6 75:13 79:3,7,7,8  
 80:21 81:3,7,17 85:19  
 95:14 110:8,14  
 118:11 123:17 142:7  
 152:9 158:8 159:6,20  
 161:2,18 170:9  
 177:14 179:14 180:18  
 183:5,10 184:10  
 186:2 189:21 190:15  
 193:4,18,19,21  
 196:11 200:18 202:1  
 205:8 209:11 214:20  
 216:17 221:8 222:3  
 222:14 231:4 239:5  
 277:10 280:19 292:10  
 292:14 301:10 305:22  
 307:15,15 312:22  
 313:4,6 315:13 318:2  
 319:21 321:10 326:3  
 329:12,13 338:2  
**two-** 131:17 156:4  
 219:17 280:4  
**two-fold** 101:12 281:1  
**two-star** 62:13 65:16  
 66:15 67:12 82:19  
 279:17,19 280:2,5,17  
 286:14,21 287:4  
 288:4 292:12 293:5  
 332:19  
**type** 22:1 56:22 80:1  
 124:19 142:14,15  
 182:18 228:12 244:2  
 293:20 331:2 338:5  
**types** 138:7,10 204:15  
 243:8 244:4 270:3  
 290:19,21

---

**U**


---

**U.S** 10:16 48:19 69:5  
 101:14,18  
**UCLA** 11:2  
**ultimate** 283:12  
**unadulterated** 58:13  
**unambiguous** 180:12  
**unaware** 240:18  
**unbiased** 113:4,13,19  
**uncertainty** 244:19  
**unclear** 213:14  
**undefined** 120:20  
**undergoing** 179:10,18  
 211:14 236:1,3,16  
**undergone** 310:14  
**underlying** 119:19  
 120:7  
**underneath** 95:4  
**underpins** 71:2

**underscore** 30:18  
**understand** 8:16 25:17  
 27:14 43:15 44:19,21  
 53:5 58:5,10,14 59:9  
 61:8 69:15 79:9 80:5  
 80:13,17 122:15  
 134:5 150:14 204:18  
 279:16,22 283:9  
 286:18 289:14 300:8  
 321:12 323:20 332:17  
 333:21  
**understandable** 328:4  
 329:1  
**understanding** 23:19  
 67:6 69:10 72:16  
 215:7,10,13 221:13  
 222:18 247:13 259:18  
 280:10  
**understands** 165:10  
 215:22  
**understood** 59:3  
 279:15  
**undesirable** 177:18  
**unduly** 134:15  
**unfair** 267:19 268:14  
**unfairly** 263:14  
**unfortunately** 10:11  
 15:12 123:16 133:19  
 188:22 276:18  
**uniformly** 153:19  
**unintended** 128:22  
 213:4 219:2,13  
 274:21  
**United** 1:11 228:21  
**university** 1:14,17,18  
 1:20,21 2:8,10 10:5  
 11:9 12:8 56:7 112:14  
 191:2  
**unmeasured** 119:21  
 120:1  
**unpaid** 8:1  
**unrelated** 187:16  
**unruly** 60:18  
**unusual** 194:10 285:2  
**up-front** 36:8  
**up-or-down** 139:1  
**update** 145:4 197:21  
**updated** 160:20  
**updates** 306:22  
**upgrade** 206:3  
**upgraded** 289:12  
**upheld** 29:14 226:4  
**uphold** 30:5  
**upper** 245:8  
**upstairs** 39:9,11  
**urban** 254:4  
**urge** 261:4  
**urogynecologist** 11:17

**urologist** 11:2  
**usability** 21:3 40:10  
 90:2,6,20 149:7,8,22  
 157:7,7,18 160:6  
 163:7 168:9,10  
 213:10 214:2 233:5  
 233:22 234:4 257:11  
 260:19 277:13,14  
 279:7 297:17 320:7  
 322:8 333:20 337:18  
 338:18 340:1  
**usable** 131:4  
**use** 20:20 24:3,8,9,10  
 24:14 25:21 31:13,15  
 32:12 33:3 34:10  
 35:16 36:14 37:15  
 39:10 41:1,13,14  
 42:14,18,20,22 43:1,5  
 43:5,6 60:7 62:21  
 93:1 97:8 111:4  
 116:20 124:1,3,13  
 125:11,13 146:9  
 147:9,20 149:9  
 156:17,18 157:2  
 163:7 168:5,6 186:20  
 187:2 202:18 205:13  
 211:3,21 212:16,17  
 222:5 229:11,15  
 231:8 242:16 258:8  
 259:13 260:6,12  
 276:7 277:18 279:2  
 288:16 289:17 292:6  
 299:13 305:22 306:1  
 320:6,21 332:2,15  
 333:21 337:18,20  
 338:17  
**useful** 51:22 90:10  
 149:19 229:3 246:7  
 254:7 264:22 298:18  
 320:13  
**useless** 242:11  
**user** 211:15 212:3  
**users** 213:17,18  
**uses** 81:12 278:5  
**usual** 48:6  
**usually** 136:13 172:21  
 173:2  
**utilized** 232:14  
**utilizing** 209:1

---

**V**


---

**Vaish** 7:5  
**Vaishnavi** 2:4 7:3  
**valid** 28:19 32:11 110:1  
 217:9 250:12 251:12  
 274:17 285:20 290:2  
**validate** 117:14 186:21  
**validity** 20:14 53:12

56:5 88:12 90:19  
 107:10,13,14,15  
 108:3,6 109:13 110:9  
 111:15,18,18,19  
 112:11,16 117:22  
 136:15 142:6,8  
 143:22 144:4 145:21  
 146:4 160:6 166:21  
 166:22 167:4 181:12  
 200:21 201:1,2,8,8,11  
 202:2 210:2,6,11,12  
 226:20,20 249:2,21  
 250:1,6 251:10  
 255:20 256:1,6 300:7  
 301:4 302:16 317:15  
 317:17 318:6,8 319:9  
**valuable** 29:8 264:18  
 273:1 293:8 328:4  
 329:3  
**value** 9:22 35:11,15  
 57:5 59:1 60:16  
 175:14 177:20,21  
 187:18 272:8,14  
 291:19 292:8,21  
 308:4 312:4  
**value-based** 278:6  
 279:3  
**valued** 138:14 281:11  
 282:2  
**values** 207:14 252:4,4,7  
 252:18 281:18  
**valuing** 290:8  
**valve** 3:7,8,10 46:3  
 49:15,15,18,18,21,21  
 77:22,22 78:1 87:2  
 99:7 158:19 160:13  
 160:17 161:12 173:7  
 173:20 174:1,1  
 179:11 203:2,8,10,10  
 206:9,10 216:2,4,6,7  
 216:20,22 217:1,2,15  
 224:9 227:1 280:4  
**valves** 159:22  
**variability** 246:6 325:5  
 331:1  
**variable** 122:8 127:5  
 131:22 137:16 140:9  
 141:12 186:11 206:19  
 208:3 251:14  
**variables** 113:17 114:3  
 119:13 120:5,9  
 123:12 126:6,15  
 138:10 139:3 202:14  
 211:17  
**variance** 62:15 323:22  
**variation** 178:5 243:21  
 244:6,12 245:2 314:1  
 320:12

**varies** 96:17  
**variety** 52:20 288:17  
 334:15  
**various** 205:13 337:5  
**VAs** 102:17  
**vascular** 11:8,13,13  
 16:11  
**vast** 26:14 34:3 73:1,1,1  
 73:8  
**vector** 154:15  
**vendors** 211:19  
**verbally** 319:18  
**verified** 113:22  
**verify** 45:9 187:8  
**versus** 79:1 80:1 89:9  
 136:17 138:2 153:16  
 166:2 180:20 183:22  
 203:19 209:10 223:7  
 224:17 225:4 242:7,8  
 247:16 250:22 253:13  
 256:19,19  
**vessels** 121:19  
**Veterans** 9:1 11:10  
**vetted** 275:9 289:11  
**Vice** 2:2 5:12  
**VICE-CHAIR** 109:12  
 110:11 111:9 118:12  
**view** 99:20 115:21  
 125:16 222:7 233:8  
 257:15 294:4  
**viewpoint** 136:3  
**viewpoints** 283:10  
**Vinay** 2:7 47:18 56:6  
 60:4  
**Virginia** 2:7 56:7  
**virtually** 158:17 159:3  
 324:7,9,19  
**vis-a-vis** 276:15  
**vision** 51:17  
**vogue** 130:17  
**voice** 271:17  
**volume** 91:6 150:22  
 290:12,16 291:5  
**volumes** 91:4 217:8  
**voluntarily** 49:4,19 74:1  
 101:15 156:1  
**voluntary** 48:21 71:12  
 88:17,20 89:1 102:1  
 149:16 152:4,5,5  
 153:8 302:13  
**volunteer** 71:20 100:21  
**voted** 97:12 103:20  
 105:20,20 109:9,10  
 157:3,4 171:2 200:17  
 200:18 202:1,2 210:6  
 210:10 212:12,13  
 241:7 248:16 249:17  
 249:18 257:8,8 260:9

260:9,13,14 261:12  
 290:5 304:9 307:21  
 315:17,18  
**voter** 260:9  
**votes** 21:19 22:9 99:7  
 99:10 144:8,11  
 145:21,22,22 147:4,4  
 147:5,14,20 149:2,3,4  
 157:3,16,16,16,17  
 158:8,13,13 162:6  
 164:4 167:9 170:9,11  
 170:20 171:1,4,4  
 177:7 178:15,15,21  
 178:21,22,22 179:1  
 201:22 212:11 229:17  
 240:11 248:18,19,19  
 248:20 249:17 256:4  
 256:5,5,6 257:8  
 260:13 261:14,21  
 307:16,21 315:12,13  
 315:13 317:9,9 319:8  
 319:22 320:2 338:2  
 339:9  
**voting** 7:4 14:6 15:6  
 19:12 20:17 21:5,10  
 21:14 22:10 89:12  
 91:21 97:15 99:3,3  
 103:1,18,19 104:3  
 105:1,10 108:11  
 144:4,5 146:21 147:3  
 147:16 148:12 156:22  
 163:10 169:12 177:2  
 177:4 178:19 200:14  
 200:15 201:20,21,21  
 210:16,18 212:9  
 215:8 225:6 229:10  
 229:17,17,19,19  
 240:22 241:4 248:12  
 249:13,16 255:22  
 257:4,7 260:4,5,11,19  
 260:22 269:15 307:4  
 307:8,18 309:8  
 315:10,12 317:4,8  
 318:7 319:7,14,22  
 320:2,3 337:19,20  
 340:4 343:19  
**vows** 276:10  
**vulnerable** 302:4

---

**W**

---

**wait** 230:16 239:10  
**waiting** 92:19 105:4  
 144:7 148:22 157:12  
 158:7 170:8 172:15  
 229:12 234:18 241:3  
 256:3 307:15 319:21  
 338:1  
**walk** 20:1 57:2 79:18

**wanted** 5:13 6:22 7:16  
 11:3 15:2,17 17:4  
 23:9 63:1 76:3 99:21  
 110:4 116:6 127:7  
 129:20 145:18 175:19  
 187:7 189:8 198:16  
 223:9 227:1 271:4  
 323:19 329:6  
**wants** 53:2 75:7 147:15  
**ward** 182:14  
**warehouse** 211:15  
**warm** 13:18  
**warrant** 315:6  
**Washington** 1:7  
**wasn't** 58:6 64:15 110:3  
 114:1 140:11 141:12  
 228:9 259:18 267:4  
 283:18 312:8 323:16  
 336:9  
**way** 8:16 22:16 28:9  
 30:6 31:12 32:6 39:21  
 44:20 53:14 62:2  
 67:19 68:2 69:1 82:15  
 84:7 85:2 97:13 110:1  
 121:1,1,11 122:10  
 125:21 130:21 134:9  
 137:4 142:16 149:13  
 152:21 153:5 154:5  
 154:22 167:18 183:19  
 187:6 195:2 198:8  
 199:16 200:2,4 208:1  
 209:10 223:22 242:13  
 243:7 245:6 250:15  
 259:6 269:15 271:13  
 273:21 274:1 279:15  
 279:22 285:9 293:2  
 296:14 300:3 312:7  
 324:7  
**ways** 32:15 122:9 155:8  
 193:10 207:2 239:5  
 240:17 322:14 334:15  
**WebMD** 80:1  
**website** 54:15 55:7,14  
 63:20 67:3 68:6 71:18  
 71:20 73:11 78:12,13  
 82:3,5 92:1 94:3  
 95:12 150:11,12  
 152:12,15 193:1  
 218:4 258:11 260:1  
 292:7 320:12 322:9  
 325:1 327:1,5 328:5  
 328:16,21 332:2,11  
 332:15,16 336:21  
 337:15  
**websites** 55:4 75:9  
 332:9 337:5  
**Wednesday** 1:5 231:11  
 340:13 341:6 343:17

**Wednesdays** 196:12  
**week** 184:10 281:13  
 342:8  
**week-and-a-half** 205:8  
**weeks** 183:10 205:8  
 231:4 263:2  
**weigh** 14:8 40:3,15  
 263:10 283:12,16  
**weighing** 263:12  
**weighs** 138:22  
**weight** 34:21 58:18  
 121:7 291:17  
**welcome** 4:4 5:11,17  
 6:2 9:3,9,11,16 23:9  
 46:21 47:3 97:5  
 266:10 306:18  
**well-aware** 77:11  
**well-established** 91:12  
**well-over** 48:18  
**well-recognized** 36:8  
**went** 60:16 69:4 87:5  
 98:22 105:12 109:16  
 171:19 220:7 260:20  
 268:22 280:2 288:13  
 343:22  
**weren't** 40:22 140:21  
 276:8  
**West** 2:7 56:7  
**whichever** 265:5  
**white** 124:16,18 133:3  
 136:17 243:19 247:16  
**wide** 288:12  
**widely** 256:12 268:7  
**William** 1:8,10 8:22  
 15:5  
**willing** 222:11  
**willingness** 316:7  
**willy-nilly** 269:2  
**win** 169:19,21  
**winner** 66:2  
**wipe** 262:8  
**wish** 19:11 76:5 275:7  
 337:2  
**withdrawn** 268:11  
**withhold** 33:5  
**women** 110:16  
**won** 169:20  
**wondering** 57:21 88:21  
 90:2 109:17 254:9  
 270:16 273:6  
**word** 123:17 124:17  
 267:9  
**wording** 235:14  
**words** 61:18 133:3  
 154:17 269:11,17  
**work** 7:22 11:16 31:12  
 145:5 176:5 187:19  
 206:4,12 328:21

339:4 341:22 343:14  
**workbook** 22:20  
**worked** 322:19 341:20  
**working** 94:15 103:10  
 155:14 170:17 171:13  
 192:8 197:5 212:4  
 297:7 319:19  
**works** 97:13  
**worksheet** 88:16  
 206:16  
**worksheets** 308:7  
**world** 29:6 69:5 101:14  
 101:18 133:13,22  
 134:6 193:12 336:11  
**worldwide** 228:21  
**worms** 279:6  
**worried** 218:13  
**worries** 105:18  
**worry** 136:15  
**worse** 131:9 143:4  
 203:20 240:6,7 275:1  
 326:1  
**worth** 188:13 191:15  
 209:7 305:14 326:22  
 327:9  
**wouldn't** 33:14 61:16  
 62:2 80:4 118:6,8  
 140:17 142:1 185:4  
 185:16 267:8 310:2  
**wound** 53:8 60:21  
 87:10,11 291:9,10,16  
 295:17  
**wreck** 183:7  
**write** 213:12  
**writing** 341:9  
**written** 63:12 136:7,16  
 231:6 259:7  
**wrong** 28:18 110:14  
 288:11  
**wrote** 22:18

---

**X**

---

**X** 122:10

---

**Y**

---

**Y** 122:10  
**Yale** 278:4  
**Yates** 1:21 10:4,4 26:13  
 26:18 34:14,15 35:7  
 36:5 40:8,17 41:5,10  
 56:11 74:12 75:17  
 76:7,12,18 77:4,7  
 103:6 108:14,20  
 109:2,14 110:11,13  
 116:19 123:11 125:7  
 127:22 128:21 133:14  
 134:8 137:15 143:10  
 143:12,18 172:14,15

172:19 174:7 175:21  
 176:19,22 178:8  
 181:9 185:4,11  
 192:11,17 200:11  
 201:15 207:12 209:14  
 216:16 217:10 227:16  
 231:3 258:12,17  
 259:8 262:5,7,21  
 265:13,22 266:21  
 267:18 277:3 300:18  
 303:18 311:14 312:14  
 312:19,22 313:4,13  
 313:19 315:2 335:3,6  
 335:9,13 336:11,15  
**Yates'** 201:1  
**year** 49:7 137:14  
 144:15 145:3,16  
 152:22 169:20,21  
 187:20 218:19,21  
 219:12 221:13 228:19  
 335:8  
**years** 4:11 24:12,13,21  
 30:22 82:11 83:22  
 101:13 102:7 116:10  
 130:18 131:11 140:22  
 153:13 155:15,18  
 160:11 169:2 170:6  
 179:10 188:4 189:2  
 215:11,15,17 220:10  
 281:5 285:1 291:10  
 322:21  
**yesterday** 12:16 92:4  
**York** 15:13 188:22  
**young** 78:19

---

**Z**

---

**Z** 122:10  
**zero** 84:4 151:21  
 290:12 321:21  
**ZIP** 116:20 131:1  
**zone** 21:21

---

**0**

---

**0.67** 301:13  
**0.8** 240:1  
**0.9** 237:4  
**01** 173:15  
**0114** 45:18 234:2,12,19  
 241:2,6 248:14,22  
 249:15,19 256:2,7  
 257:6,9 260:7,13  
**0118** 3:12 307:6,19  
 315:11 316:18 337:20  
**0122** 3:10 172:6,14  
 173:4,6 177:3,5  
 178:16,18,20 179:2  
 200:15,16 202:3  
 210:17 212:11 229:11

229:16 234:1,5  
 261:20

---

**1**

---

**1,000** 75:1 100:16  
 244:21  
**1,091** 152:8  
**1.0** 132:9  
**1.02** 132:8  
**1.27** 133:3 142:12  
**10** 83:20 96:14,15  
 157:16 192:15,18,18  
 209:15,20 248:19  
 249:7,18 251:8 261:8  
 266:22 267:11  
**10:00** 176:16  
**10:08** 98:22  
**10:19** 99:1  
**100** 35:10 71:3 84:5  
 99:11 151:21 177:7  
 187:6 202:3 277:3  
 312:6 322:20 324:2,6  
 324:16,19,21  
**1030** 1:7  
**108** 180:14  
**11** 95:13 179:1 212:12  
 320:2  
**11:30** 148:6  
**11:40** 148:9  
**11:43** 171:19  
**111** 251:15  
**118** 305:8 315:16 317:6  
 317:12 318:9 319:10  
 319:15 320:1  
**12** 94:17 98:14 157:3  
 169:2,15,21 171:8,8  
 171:10,12 210:13  
 220:10 315:13  
**12-month** 213:1  
**12:00** 340:8 341:7  
**12:05** 171:20  
**13** 1:5 98:15,16 177:22  
 200:17 262:10 317:9  
**14** 3:5 98:13 99:10  
 103:18 105:7,8,12,21  
 144:10 145:22 147:5  
 149:4 157:3,15  
 158:13,13 170:20  
 171:4,4 178:15,15,21  
 241:7 248:17,18  
 249:17 256:4 257:8  
 260:13 307:20,21  
 315:12,18 317:9  
 319:8 320:2  
**15** 4:13,15 21:14 48:5  
 49:1,12 50:2 93:21,22  
 103:19 105:10,12  
 109:11 178:22 201:22

212:11 229:14,16  
 266:22 267:11  
**1501** 173:16  
**1502** 173:16  
**15th** 1:7  
**173** 3:11  
**18** 179:10 270:14  
**19** 213:15 214:17  
 314:19  
**1989** 48:14 190:16  
**1A** 310:10 313:8  
**1B4** 241:20

---

**2**


---

**2** 40:13 83:19 157:4,16  
 157:17 219:19 248:18  
 248:19 256:5 340:8  
 341:7  
**2.3** 83:1  
**20** 220:7 250:19 253:7  
**20-minute** 171:9  
**200-page** 74:2  
**2007** 24:2 174:14 214:4  
 219:16  
**2010** 49:3 153:20  
**2011** 177:15 178:1  
 246:11  
**2012** 246:11  
**2014** 24:1 153:20  
 177:15,15 178:1,3  
 180:14 202:22 276:7  
**2015** 174:15  
**2016** 246:10  
**2017** 177:16 178:3  
 223:14 246:11  
**2018** 335:19  
**2019** 1:5  
**20th** 231:13 340:7  
 341:7  
**21st** 266:3 341:12  
**2561** 3:7 45:21 46:3  
 47:9 50:12 86:21 87:2  
 99:3,7 102:22 103:17  
 105:2,19 145:20  
 147:6 149:4 157:5,18  
 158:11 227:6  
**2563** 3:8 47:9 50:12  
 158:18 171:2 227:7  
**27%** 133:3  
**2A** 40:14  
**2B** 40:14

---

**3**


---

**3** 256:5  
**3:00** 299:5  
**3:30** 299:3  
**3:32** 343:22  
**30** 87:15,17 179:14,16

181:19 182:2,5,8  
 183:11 184:18 185:13  
 186:11 262:9,11  
 297:1  
**30-** 183:21  
**30-day** 186:21 187:21  
 231:17 341:11  
**30-some** 146:5 232:2  
**30,000-foot** 81:1  
**305** 3:13  
**31-day** 181:17  
**33** 193:15,15,15  
**342** 3:15  
**343** 3:17  
**35** 304:3

---

**4**


---

**4** 3:2 83:19 249:17  
 261:8,14  
**4.0** 235:16 236:15  
 237:12 238:6  
**4:15** 299:8  
**40** 21:20 22:9 119:10  
 184:9 297:1  
**400** 204:8  
**43** 260:15  
**45** 3:7,9 182:2  
**46** 314:15  
**47** 229:19

---

**5**


---

**50** 184:9 314:18 315:1  
**50-fold** 331:9  
**53** 229:19  
**59.2** 325:14

---

**6**


---

**6** 105:20 257:8 260:13  
**6.5** 48:15  
**60** 21:18,20 144:22  
 146:1 184:9 327:12  
**60-day** 187:7  
**61** 230:22  
**64** 144:18 146:1  
**66** 21:13  
**67** 70:14,20 71:3 151:19  
 151:22 152:12  
**69.9** 71:13 152:12

---

**7**


---

**7** 229:17  
**70** 48:22 96:20  
**78** 256:9,9

---

**8**


---

**8** 3:3 105:20 107:4  
 229:17 257:8 260:14  
**8:30** 1:7 4:2

**80** 96:13  
**80s** 198:21  
**86** 315:17  
**87** 200:18,19  
**89** 69:20  
**89.8** 314:9  
**8th** 265:20 341:14

---

**9**


---

**9** 256:5 340:16  
**9.1** 177:22  
**9.3** 213:1  
**9.45** 213:1  
**9.9** 213:1  
**9.94** 240:1  
**90** 48:17,18 311:20  
**90-plus** 88:18  
**900** 100:16  
**90s** 198:21  
**94** 314:17  
**95** 102:11,16,20  
**95.73** 180:16  
**97.7** 82:22  
**98** 97:1 184:21  
**98th** 209:21  
**99** 308:5 311:16,17  
 313:14 314:17 324:3  
 327:15  
**99.8** 314:9  
**99th** 209:22  
**9th** 1:7

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In the matter of: Surgery Standing Committee

Before: NQF

Date: 02-13-19

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