

NATIONAL QUALITY FORUM

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SURGERY PHASE 3 STANDING COMMITTEE

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WEDNESDAY
AUGUST 17, 2016

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The Standing Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:00 a.m., Lee Fleisher and William Gunnar, Co-Chairs, presiding.

PRESENT:

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

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

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

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

ELISABETH EREKSON, MD, MPH, Dartmouth Hitchcock Medical Center

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

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

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

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

BARRY MARKMAN, MD, Senior Medical Director
 Medicaid, Aetna

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

LAWRENCE MOSS, MD, Surgeon-in-Chief, Nationwide
 Children's Hospital

AMY MOYER, Manager of Value Measurement, The
 Alliance

KEITH OLSEN, PharmD, FCCP, FCCM, Professor and
 Dean, College of Pharmacy, University of
 Arkansas for Medical Sciences

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

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

CHRISTOPHER SAIGAL, MD, MPH, Professor, UCLA

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

ALLAN SIPERSTEIN, MD, Chairman Endocrine
 Surgery, Cleveland Clinic

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

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

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

NQF STAFF:

HELEN BURSTIN, MD, MPH, Chief Scientific Officer
 ELISA MUNTHALI, MPH, Vice President, Quality
 Measurement
 MARCIA WILSON, PhD, MBA, Senior Vice President,
 Quality Measurement
 JASON GOLDWATER, MA, MPA, Senior Director
 KAREN JOHNSON, MS, Senior Director
 MELINDA MURPHY, RN, MS, Senior Director
 DESMIRRA QUINNONEZ, Project Analyst
 CHRISTY SKIPPER, MS, Project Manager
 KATHRYN STREETER, Senior Project Manager

ALSO PRESENT:

JAIMO AHN, MD, PhD, Orthopedic Trauma
 Association
 VINAY BADHWAR, MD, FACS, FACC, Society for
 Thoracic Surgery
 JULIA BERIAN, MD, American College of Surgeons
 MICHELLE DARDIS, MSN, MBA, RN-BC, The Joint
 Commission
 KATHY DOMZALSKI, MHA, BS, RN, The Joint
 Commission
 BRUCE HALL, MD, PhD, MBA, FACS, American College
 of Surgeons
 GAETANO PAONE, MD, MHSA, Society for Thoracic
 Surgery
 DAVID SHAHIAN, MD, Society for Thoracic Surgery
 ARYEH SHANDER, MD, FCCM, FCCP, Englewood
 Hospital and Medical Center*
 JONATHAN H. WATERS, MD, Magee Women's Hospital,
 University of Pittsburgh
 ANN WATT, MBA, RHIA, The Joint Commission

* present by teleconference

A G E N D A

Welcome, Recap of Day 1.6
Consideration of Candidate Measures (Continued)	
0134: Use of Internal Mammary Artery (AMI) in Coronary Artery Bypass Graft (CABG)19
0117: Beta Blockade at Discharge48
0127: Preoperative Beta Blockade57
3030: Individual Surgeon Composite Measure for Adult Cardiac Surgery.70
3031: STS Mitral Valve Repair/Replacement Composite Score.	109
3032: STS MVRR + Coronary Artery Bypass Graft Composite Score.	120
0697: Risk Adjusted Case Mix Adjusted Elderly Surgery Outcomes Measure - American College of Surgeons.	129
0706: Risk Adjusted Colon Surgery Outcome Measure - American College of Surgeons.	158
2998: Infection rate in bicondylar tibia plateau fracture - Orthopedic Trauma Association.	170
Overview of eMeasures.	207
Consideration of Candidate Measures (Cont'd)	
3016: PBM 01 Preoperative Anemia Screening - The Joint Commission.	245
NQF Member and Public Comment.	252

Consideration of Candidate Measures (Cont'd)

3017: PBM 02 Preoperative Hemoglobin

Level - The Joint Commission. 274

3019: PBM 03 Preoperative Blood Type

Testing and Antibody Screening - The
Joint Commission. 288

3020: PBM 04 Initial Transfusion

Threshold - The Joint Commission. 299

3021: PBM 05 Blood Usage in Selected

Elective Surgical Patients - The Joint
Commission. 343

NQF Member and Public Comment. 350

Next Steps/Committee Timeline. 350

Adjourn

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

2 8:00 a.m.

3 CO-CHAIR FLEISHER: Okay. Good
4 morning. It is 8:00 according to my iPhone
5 clock, so we are going to get started. I want to
6 thank everyone for coming on time. We have one
7 new member who has joined us this morning.

8 And can you identify yourself and any
9 disclosures?

10 You did the disclosure yesterday. I'm
11 sorry.

12 MEMBER WHITAKER: I did my disclosures
13 yesterday. I'm Barbee Whitaker from the American
14 Association of Blood Banks.

15 CO-CHAIR FLEISHER: Great. Well,
16 welcome.

17 And we do not have Dr. Cima on the
18 phone today. Is there anyone else? Are the
19 phone lines open? Yes?

20 OPERATOR: The line is open.

21 CO-CHAIR FLEISHER: Great. Do we have
22 anybody from the standing committee on the phone?

1 OPERATOR: No, we do not.

2 CO-CHAIR FLEISHER: Great. Thank you.

3 Incredibly productive yesterday. What
4 was most important is we actually touched on a
5 lot of cross-cutting and difficult issues. And
6 Barbara and I were talking about the need --

7 (Recorded music playing.)

8 CO-CHAIR FLEISHER: Yes. As long as
9 it's classical.

10 Some of the issues that were touched
11 on, we think the Committee did a fabulous job
12 outlining the issues and some of them have
13 actually brought up issues that we'll take to the
14 CSAC for more strategic questions. For example,
15 the last measure we went over yesterday.

16 We have two hours to get through our
17 colleagues from STS' measures. I would ask -- we
18 did a great job yesterday, but even today to be
19 more effective in limiting any additional
20 comments to not that I agree, which -- but that I
21 have a new area to actually question with regard
22 to the measure developers or for the discussion.

1 So if we can do that, I think we can get through
2 the entire day. And we must finish by 3:00 since
3 I know lots of people have planes, trains and
4 automobiles even before that.

5 So nothing further? Who's coming to
6 the table?

7 CO-CHAIR GUNNAR: Christy, did you
8 want to say anything?

9 MS. SKIPPER: No, just good morning
10 and welcome again to our second day of the
11 meeting and looking forward to an efficient and
12 productive meeting.

13 CO-CHAIR FLEISHER: And as always, we
14 want to thank NQF staff both for the preparation
15 before, which was outstanding, and all the work
16 done here.

17 So if you can introduce yourself and
18 we'll go through the measures. And someone has a
19 conference call. And, Larry, so we'd like to put
20 that first. So if you can identify yourselves.
21 And then if we can start with 134, that would be
22 fantastic.

1 DR. BADHWAR: Sure. Thank you for
2 your accommodation. My name is Vinay Badhwar.
3 I'm a professor of surgery at WVU, West Virginia
4 University, and I'm humbled by being the Chair of
5 Public Reporting for the STS.

6 And we thought, just because there's
7 a few new members, that a 90-second just preamble
8 on the STS Database, that it was established in
9 1989. We now have 6 million patients and over 95
10 percent of cardiac surgery performed in the
11 United States is registered by the database. The
12 database is a qualified clinical data registry by
13 CMS and for PQRS, and we've got a portfolio of
14 measures that are risk-adjusted outcome model-
15 based and long-standing NQF relationships, as you
16 know.

17 We have 36 measures, all of which are
18 used for ongoing feedback to our participants for
19 the purposes of quality measurement and quality
20 improvement, and many of these are included in
21 the PQRS system. The three areas to just briefly
22 touch on in 30 seconds are penetration,

1 completeness and accuracy and the suitability for
2 public reporting.

3 So the penetration, the database
4 compared to CMS has now 95 percent penetrance and
5 it's been implemented through a robust audit
6 process over the last decade. And now we have an
7 audit of 10 percent. And in the history of our
8 audits there have been no egregious absence and
9 essentially 100 percent, particularly on the most
10 important indicators such as mortality.

11 And then finally, all the six measures
12 we're going to discuss today are designated for
13 public reporting. And it's such an important
14 element in the STS Database that it's evidenced
15 by -- currently we have in the adult cardiac
16 surgical section 49 percent of sites are
17 participating in public reporting and 57.9
18 percent of all congenital sites are public
19 reporting voluntarily, which we believe is among
20 the highest in specialties in the United States.

21 And so today we'll touch upon six
22 measures: three process measures for CABG and

1 three composite measures, and Dr. Paone, Chief of
2 Cardiac Surgery at Henry Ford and our leader and
3 Chair of the Adult Cardiac Surgery Task Force is
4 going to kick us off.

5 DR. PAONE: Thank you. Good morning.
6 As Dr. Badhwar said, I have the honor of serving
7 as the Chair of the Task Force on Quality
8 Initiatives for the STS, and I guess we'll start
9 with Measure 134. It's a little out of order,
10 but I will start by saying that there have been
11 and continue to be significant advances in both
12 medical therapy and use of advanced percutaneous
13 catheter-based approaches for treating patients
14 with ischemic heart disease.

15 And as a result, the number of
16 coronary bypass procedures has decreased
17 significantly over the past two decades, but yet
18 continues to be the most common procedure that we
19 perform with over 150,000 procedures a year. I
20 might also add that in the opinion of many of us
21 it's by far the most highly scrutinized surgical
22 procedure in history.

1 The first measure that we'll discuss
2 is the use of the internal mammary artery in
3 coronary bypass surgery. This measure captures a
4 percentage of patients aged 18 and older
5 undergoing CABG who received an internal mammary
6 artery graft. There are reasons to exclude
7 patients from consideration, and these include
8 the subclavian artery stenosis, previous cardiac
9 or thoracic surgery, previous mediastinal
10 radiation; both of those may make harvest of the
11 artery difficult or impossible, patients who
12 undergo emergent or salvage procedures, and
13 finally if there is no significant or bypassable
14 disease of the LAD artery itself.

15 The IMA use has previously
16 been endorsed by NQF and is a very significant
17 component of our STS CABG composite score. Use
18 of the IMA to bypass the left anterior descending
19 artery, coronary artery during coronary bypass
20 surgery is a Class 1B recommendation of the 2011
21 ACCF/AHA Guidelines for Coronary Artery Bypass
22 Graft Surgery. And in those cases where for some

1 reason the left mammary is either unavailable or
2 unsuitable for use, it is then a Class 2C
3 recommendation that the right internal mammary
4 artery is probably indicated to bypass the LAD.

5 The superiority of internal mammary
6 arteries over saphenous vein grafts as coronary
7 artery bypass conduits and the evidence
8 supporting the short and long-term survival
9 benefits of using the left IMA specifically to
10 bypass the left anterior descending artery are
11 exhaustive and well-documented over what is now
12 approaching 30 years.

13 Long term patency rates of 10-plus
14 years for the LIMA graft when placed in the LAD
15 are routinely in excess of 90-plus percent
16 compared to saphenous vein patency, which
17 approximates 50 percent.

18 Most importantly, perhaps more than
19 any other --

20 CO-CHAIR FLEISHER: I think we're very
21 comfortable with the evidence of the superiority.

22 DR. PAONE: Okay.

1 CO-CHAIR FLEISHER: So what we're most
2 interested in; and thank you, is the gap and any
3 new evidence, because as you -- we can accept the
4 evidence as it is --

5 DR. PAONE: Excellent.

6 CO-CHAIR FLEISHER: -- unless there's
7 anything new that's come out.

8 DR. PAONE: Okay. Well, in fact then
9 there really hasn't been anything new that's come
10 out except for the fact that this remains really
11 the most important part of a coronary bypass
12 operation and we feel very strongly that it
13 should be continued to be endorsed because we
14 don't want to send a message anything other than
15 that.

16 CO-CHAIR FLEISHER: And anything on
17 gap that you can comment on? If not, I'm sure
18 the -- Larry, do you want to start --

19 MEMBER MOSS: Actually John is the
20 primary on this one.

21 CO-CHAIR FLEISHER: Okay. John?

22 MEMBER HANDY: Well, there isn't much

1 of a gap and it's a little bit tough to criticize
2 this particular process measure. It's a
3 maintenance process measure, so we don't even
4 really have to vote on the evidence, frankly,
5 just discuss the gap. The gap is listed in --

6 CO-CHAIR FLEISHER: Why don't we just
7 very quickly -- would anybody like to vote on
8 evidence?

9 (No audible response.)

10 CO-CHAIR FLEISHER: No? Okay.

11 Evidence passes.

12 MEMBER HANDY: Good. So the gap is
13 listed in a couple of different places. A little
14 bit variously on page 6 it's listed as a low
15 performer as 96 percent, high performer is 99
16 percent. In other words, the amount of volume
17 left internal mammary arteries used. Page 3293,
18 100 percent. So the worst is 93 percent. So
19 it's got a high penetrance in cardiac surgery.
20 It's adhered to. And that's true across the SDS
21 groups, too. The lowest was 98 percent. So
22 there isn't much of a gap.

1 And so, back to what I was getting
2 ready to say before we went and talked about
3 evidence is that it's so central to coronary
4 bypass it's a little difficult to discard it.

5 CO-CHAIR FLEISHER: Larry?

6 MEMBER MOSS: I agree completely. My
7 only comment or question was whether we should
8 consider reserve status, and if we did, whether
9 that would negatively impact the composite
10 measure that's so important.

11 CO-CHAIR FLEISHER: Yes?

12 MS. MURPHY: With respect to gap, one
13 of the things we talked about yesterday is for
14 some of these measures where the importance of
15 the measure in terms of precipitating or
16 contributing to an adverse event would cause you
17 to think potentially about it differently in
18 terms of retaining one in active endorsement with
19 a low gap.

20 The other thing is that if you make
21 the determination to put it into reserve status,
22 it is still an endorsed measure, still therefore

1 eligible to be an integral part of any composite.

2 DR. PAONE: Well, we would suggest
3 that -- we understand that putting it in reserve
4 does not take it away from the significance with
5 regard to the composite, however, we're not sure
6 that everyone understands the subtle difference
7 between being endorsed and being on reserve.

8 One of our colleagues has stated that
9 pretty much that probably the most important
10 thing we do as cardiac surgeons and coronary
11 surgeons is use the left internal mammary artery
12 to bypass the LAD, and that goes to evidence.
13 And I know we've accepted that, but we do think
14 that this is probably the most important process
15 measure in cardiac surgery and very strongly feel
16 that we'd benefit from having it re-endorsed
17 rather than just placed in reserve.

18 CO-CHAIR FLEISHER: Thank you. Amy?

19 MEMBER MOYER: So looking at the
20 public reporting, which I really appreciate you
21 have online, I know that you take great pains to
22 make sure that you're showing statistically

1 different -- statistically significant
2 differences. And I'm seeing a range of
3 performance among groups that are publicly
4 reporting on this measure alone, which to me
5 suggests there is gap that can be used to
6 distinguish performance. So I would support that
7 there be -- there's a meaningful gap there.

8 CO-CHAIR FLEISHER: Thank you for that
9 additional piece of information.

10 DR. PAONE: I think the average use is
11 very high, but there are still a not
12 insignificant number of outliers. So I think
13 that would be true.

14 CO-CHAIR FLEISHER: Helpful. Other
15 comments? Christy?

16 (No audible response.)

17 CO-CHAIR FLEISHER: No, call for a
18 vote.

19 MS. WILSON: Desmirra is going to be
20 helping with the vote.

21 CO-CHAIR FLEISHER: Oh, okay.

22 MS. QUINNONEZ: Okay. We are now

1 voting on Measure 0134, use of internal mammary
2 artery in coronary artery bypass graft. Voting
3 is now open for the evidence of 0134.

4 Sorry. Gaps. Yes, sorry. Voting is
5 now open for the gaps of Measure 0134. Option
6 No. 1 is high; option No. 2 is moderate; option
7 No. 3 is low; and option No. 4, insufficient.

8 (Voting.)

9 MEMBER GROVER: Just for the record I
10 want to state that I'm abstaining on all the STS
11 votes.

12 CO-CHAIR FLEISHER: Thank you. I just
13 wanted to ask staff if we think the gap is low
14 but we still want to -- but we don't want to go
15 to reserve status, do we -- how do we vote? In
16 other words, if we think that it's important to
17 not put it on reserve status. Elisa, if you can
18 help us.

19 MS. MUNTHALI: So you would vote on
20 performance gap regardless of your desire to have
21 the measure go into reserve status because for a
22 measure that's topped out, there's no opportunity

1 for improvement. It still needs to be -- all the
2 other criterion still need to be passed. So what
3 would happen is -- let's say you voted low or
4 insufficient. You may say should we consider
5 this measure for reserve status and vote on the
6 rest of the criterion and then come back to
7 answer the question on reserve status. Does that
8 make sense?

9 MEMBER KO: I just have a quick
10 question. Are there objective definitions,
11 criteria for reserve status? I know we did some
12 last time or a couple times ago, because like,
13 oh, that's topped out, that's -- but what -- is
14 there a definition for topped out?

15 MS. MUNTHALI: We do, and I don't --
16 Katie, could you pull that up? I think it would
17 be easier for everyone to see it.

18 MS. MURPHY: And while she's pulling
19 that up, there is one thing I wanted to say
20 because of something I heard. If a measure goes
21 into reserve status, number one, it is endorsed.
22 It is an endorsed measure in reserve status, so

1 it does not lose endorsement. In fact, as Elisa
2 just said, it goes through the entire process and
3 it is an endorsed measure placed in reserve
4 status because of a low gap.

5 MEMBER HANDY: So then what is the
6 natural history of a reserved measure? We've
7 talked about this a little bit in the past, too.
8 I mean, does it get periodically reviewed? I
9 know it doesn't have to be continuously supported
10 by data.

11 MS. MUNTHALI: So it doesn't go
12 through the three-year maintenance cycle, but
13 because you have ownership, the Surgery Committee
14 has ownership over the portfolio. You may want
15 to revisit it if in the particular topic area you
16 see that there might need to be a performance
17 measure to address certain elements to improve
18 care. So it's something that we will bring in
19 front of you again to look at the reserve status
20 list to see if any of those you would like to
21 revisit given new data, new evidence, anything
22 that you may have that would help to push that

1 forward.

2 MEMBER HANDY: And is there a sunset?

3 MS. MUNTHALI: So reserve status is
4 almost like a sunset. We're seeing the first
5 class of them. These are -- most of them are
6 process measures that have come through our
7 process early on. And so, but there may be an
8 opportunity for them to come back if we see that
9 improvements are going down. Maybe behavior has
10 changed. And so, yes. So we -- but we haven't
11 gotten there yet. This is like the first major
12 class of reserve status measures that have gone
13 through the NQF process.

14 MEMBER HANDY: Sure.

15 DR. BADHWAR: Brief comment. I
16 appreciate that definition. It's very helpful.
17 I just want to emphasize what Amy had mentioned,
18 that there is still some practice variability
19 that exists and this full endorsement is so
20 important to practicing surgeons that take a
21 shortcut. It is a little harder to do a mammary
22 artery than a vein graft, and I just wanted to

1 emphasize that one point.

2 MS. MUNTHALI: And we just want to
3 emphasize that the measure would still be
4 endorsed. You're not losing endorsement. It's
5 just that it wouldn't go through its periodic
6 maintenance review.

7 MEMBER HANDY: Thank you.

8 CO-CHAIR FLEISHER: Rick? Comment?

9 MEMBER DUTTON: Okay. Just a comment
10 on the reserve history. So we did this a couple
11 years ago with some of the antibiotic measures.
12 I don't know if it contributed or not, but
13 certainly within the next year CMS moved those
14 out of PQRS as being topped out. Is this still a
15 PQRS measure for you guys?

16 (No audible response.)

17 MEMBER DUTTON: Okay. That they also
18 told us, Anesthesia, that we had to take it out
19 of our QCDR measure set for CMS, because we
20 initially did that with it. And we did that for
21 one year, but then they told us we had to remove
22 it from that use.

1 We do still find that antibiotic
2 measure very useful. A lot of our members still
3 report it. It's useful for hospitals and
4 insurance companies and sort of internal quality
5 improvement, so lots of people are still
6 capturing it. But that's been what's happened to
7 the measures that we've --

8 CO-CHAIR FLEISHER: Thank you.

9 MEMBER DUTTON: -- seen on reserve.

10 CO-CHAIR FLEISHER: This is the
11 endorsement reserve status, and why don't we
12 vote? We're up to 20. Could people re-vote just
13 to make sure we get --

14 (Voting.)

15 CO-CHAIR FLEISHER: Barbara?

16 MEMBER LEVY: So I actually have a
17 question about our definition of a moderate/low
18 performance gap. I mean, is that -- are there
19 metrics that we're supposed to use? Because I
20 think it's quite different for us to look at a
21 gap in the STS Database that has penetrance of 95
22 percent versus a measure that's electively

1 reported by people who think they do a good job
2 with it. And when we've got 95 percent
3 penetrance and we do have a spectrum of people, I
4 think that's a different discussion than a
5 discussion about a topped out measure that's
6 voluntarily reported among whoever feels like
7 they want to report it.

8 CO-CHAIR FLEISHER: So I know of no
9 definitions that -- so I -- are you aware? I
10 mean, that's a good discussion that we'll put in
11 our report to send back to us, to you and I to
12 continue.

13 MEMBER LEVY: Thanks. We're really
14 creating a lot of work for ourselves, aren't we?

15 CO-CHAIR FLEISHER: Right. Allan?
16 Because I want to move forward.

17 MEMBER SIPERSTEIN: But I think
18 relative to an individual measure like this, I
19 think we really have to look at is there
20 opportunity for improvement and is there
21 variability? And we've had data presented that
22 says yes.

1 CO-CHAIR FLEISHER: Thank you.

2 MEMBER SIPERSTEIN: Even though the
3 number is high.

4 CO-CHAIR FLEISHER: So let's finish
5 the voting.

6 MS. QUINNONEZ: All votes are in and
7 voting is now closed. Okay. For performance
8 gaps of Measure 0134 the vote reads 10 percent
9 voted high; 52 percent voted moderate; 38 percent
10 voted low; and 0 percent for insufficient.

11 CO-CHAIR FLEISHER: So it passes,
12 correct?

13 MS. QUINNONEZ: Yes.

14 CO-CHAIR FLEISHER: Okay. So it's
15 still going forward for full endorsement.

16 Next, John?

17 MEMBER HANDY: Well, the rest of it's
18 pretty easy because the STS Database -- so
19 reliability with the track record, the construct
20 and the -- all the things that make the STS
21 Database an enviable thing. The reliability is
22 high.

1 CO-CHAIR FLEISHER: Can we vote?

2 MS. QUINNONEZ: Voting is now open for
3 the reliability of Measure 0134. Option 1 is
4 high; option 2 is moderate; option 3, low; and
5 option 4, insufficient.

6 (Voting.)

7 MS. QUINNONEZ: All votes are in and
8 voting is now closed. For the reliability of
9 Measure 0134, 81 percent voted high; 19 percent
10 voted moderate; 0 percent for low; and 0 percent
11 insufficient.

12 CO-CHAIR FLEISHER: So I just -- like
13 reliability will be the same for any of these
14 measures that are from the database. I would
15 like to -- no? I would like to know if anybody
16 would like to vote separately on reliability for
17 the measures. Or we -- as we come up to each
18 measure I will ask if anyone would like to vote
19 separately.

20 MEMBER PITZEN: I'm sorry. It was me
21 kind of shaking my head. I mean, the reliability
22 is dependent on the individual metric --

1 (Simultaneous speaking.)

2 CO-CHAIR FLEISHER: So we'll go by
3 each measure and say do we need to vote again or
4 can we take the previous vote?

5 Next.

6 MEMBER HANDY: So the same comments
7 about validity. The penetrance of the database
8 and the auditing habits or mandated auditing
9 characteristics of the database make it very
10 valid. And this is a very clear-cut. You either
11 did or you didn't use an IMA.

12 CO-CHAIR GUNNAR: Larry? Comments?

13 MEMBER MOSS: No.

14 CO-CHAIR FLEISHER: Any other
15 comments?

16 (No audible response.)

17 CO-CHAIR FLEISHER: Let's vote.

18 MS. QUINNONEZ: We are now voting on
19 the validity of Measure 0134. Option 1, high;
20 option 2, moderate; option 3, low; and option 4,
21 insufficient.

22 (Voting.)

1 MS. QUINNONEZ: All votes are in and
2 voting is now closed. For the validity of
3 Measure 0134, 86 percent voted high; 14 percent
4 voted moderate; 0 percent for low; and 0 percent
5 for insufficient.

6 CO-CHAIR FLEISHER: Next?

7 MEMBER HANDY: Same is true for
8 feasibility. Its penetrance in the adult cardiac
9 surgery arena in the United States is over 95
10 percent, so pretty much everybody is
11 participating in this database, so it's highly
12 feasible.

13 CO-CHAIR FLEISHER: Comments?

14 (No audible response.)

15 MS. QUINNONEZ: Voting is now open for
16 the feasibility of Measure 0134. Option 1 is
17 high; option 2, moderate; option 3, low; and
18 option 4, insufficient.

19 (Voting.)

20 MS. QUINNONEZ: All votes are in and
21 voting is now closed. For the feasibility of
22 Measure 0134, 67 percent voted high; 29 percent

1 voted moderate; 5 percent voted low; and 0
2 percent insufficient.

3 CO-CHAIR FLEISHER: John?

4 MEMBER HANDY: Usability also high.

5 CO-CHAIR FLEISHER: We heard it's
6 publicly reported.

7 MS. QUINNONEZ: Voting is now open for
8 the usability and use of Measure 0134. Option 1
9 is high; option 2, moderate; option 3, low; and
10 option 4, insufficient information.

11 (Voting.)

12 MS. QUINNONEZ: All votes are in and
13 voting is now closed. For the usability and use
14 of Measure 0134, 67 percent voted high; 29
15 percent voted moderate; 5 percent voted low; and
16 0 percent voted for insufficient information.

17 MEMBER HANDY: There's really no
18 competing measures for this one. There's a lot
19 of related measures, but none competing.

20 CO-CHAIR FLEISHER: So any comments
21 before we vote on suitability for endorsement?

22 (No audible response.)

1 CO-CHAIR FLEISHER: Okay.

2 MS. QUINNONEZ: Voting is now open for
3 the overall suitability for endorsement of
4 Measure 0134. Option 1 is yes; option 2 is no.

5 (Voting.)

6 MS. QUINNONEZ: All votes are in and
7 voting is now closed. For the overall
8 suitability for endorsement of Measure 0134, 100
9 percent voted yes; 0 percent voted no.

10 CO-CHAIR FLEISHER: Thank you very
11 much. We will go back to 117. So what I'd like
12 to focus on is any change in evidence and a
13 little bit on gap, and those would be the
14 primary --

15 DR. PAONE: Sure.

16 CO-CHAIR FLEISHER: -- focus to get
17 you --

18 DR. PAONE: Okay. Well, then I'll
19 eliminate most of what I was going to say and
20 suggest that there have been some recent data
21 that suggests that use of beta blockers post-
22 cardiac surgery has demonstrated a synergistic

1 and additive effect at reducing mortality when
2 combined with statins at both a year and longer
3 term at 11 years. And overall, patients -- it's
4 thought that in terms of secondary prevention
5 there's a survival advantage, not only in
6 patients with previous heart attacks or heart
7 failure, but also now those with normal heart
8 function. And so this essentially includes all
9 patients who undergo bypass surgery. The role of
10 discharge beta blockers remains a Level -- a
11 Class 1, Level B recommendation for patients with
12 atrial fibrillation to prevent atrial
13 fibrillation and the sequelae thereof.

14 In terms of a gap, this was considered
15 essentially topped out in 2012 at 95½ percent.
16 It was re-endorsed at that time. And since the
17 gap is really -- remains the same but similar to
18 the previous measure on IMAs, there is still a
19 lower tail, not as much with the discharge as
20 with the preoperative beta blockers that we'll
21 discuss subsequently, but there still remains a
22 little bit of a gap in use.

1 Added to that is there really is no
2 burden added to the capture of this measure. It
3 remains a component of our composite score and
4 one of 34 NQF-endorsed measures, and we believe
5 that removing it from active endorsement, like
6 the other measures, could suggest that its
7 importance has somewhat lessened. I know we
8 talked just a minute ago about the meaning of
9 "reserve status," that it maintains NQF
10 endorsement, but the added description of it sort
11 of being sunset I think is a little bit
12 concerning in terms of what that may at least
13 portray to those who don't understand the subtle
14 differences.

15 CO-CHAIR FLEISHER: Thank you. Lynn,
16 I think you're the primary and Kelsey is the
17 secondary.

18 MEMBER REEDE: Thank you. In
19 reference to the gap, it's still for the --

20 CO-CHAIR FLEISHER: How about just --

21 MEMBER REEDE: Okay. Well, he was --

22 CO-CHAIR FLEISHER: -- any comments on

1 evidence?

2 MEMBER REEDE: Evidence is fine. Good
3 to go.

4 MEMBER McCARTY: So I do have a
5 question about the evidence. The guidelines that
6 were submitted for this measure were from 2011,
7 and then this measure was endorsed in 2012.
8 There haven't been any updated guidelines since
9 then for CABG, but in 2014 the same group: ACC
10 and AHA, published guidelines for non-cardiac
11 surgery.

12 And so where I'm going with this is
13 that in those guidelines beta blockers given on
14 the day of surgery are flagged.

15 CO-CHAIR FLEISHER: I'm the Chair of
16 that Guideline committee --

17 MEMBER McCARTY: I saw that. I did.

18 CO-CHAIR FLEISHER: -- and it's not
19 relevant to this --

20 MEMBER McCARTY: It's not? Okay.

21 CO-CHAIR FLEISHER: -- population.

22 MEMBER McCARTY: So as a layperson

1 there's -- it perfectly makes sense why it would
2 be so effective --

3 CO-CHAIR FLEISHER: It's a
4 different --

5 MEMBER McCARTY: -- in CABG and
6 dangerous outside of that. Okay.

7 CO-CHAIR FLEISHER: And to disclose on
8 the task force that oversees all the guidelines,
9 this --

10 MEMBER McCARTY: That was my --

11 CO-CHAIR FLEISHER: -- they're not in
12 conflict.

13 MEMBER McCARTY: That was my question.

14 CO-CHAIR FLEISHER: So would anybody
15 like to vote on evidence or -- we'll continue.
16 Okay. Can you, Lynn, discuss gap?

17 MEMBER REEDE: So for gap it does
18 appear to be topped out except that in the 10th
19 decile it's gone from 73 percent in the 2013 to
20 '14 data down to 15 percent -- or 50 percent in
21 the '14 to '15 data. So there is some gap still
22 remaining in the measure.

1 CO-CHAIR FLEISHER: Kelsey, any
2 thoughts?

3 (No audible response.)

4 CO-CHAIR FLEISHER: Any comments?

5 (No audible response.)

6 MS. QUINNONEZ: Voting is now open.
7 We are voting on Measure 0 --

8 CO-CHAIR FLEISHER: Collette?

9 MEMBER PITZEN: I can comment now or
10 later. I just have a general comment about
11 performance gap in general and quality
12 improvement. And I know I'm in the minority. I
13 have a hard time with a measure that's nationally
14 at 98 percent, serving its purpose for moving
15 that quality needle forward. Granted, everybody
16 would want 100 percent, but when you're comparing
17 and trying to get better, it seems like there's a
18 lot of other places where we could be spending
19 our data collection resources and efforts. So
20 I'll try to refrain from those comments
21 throughout because I know everyone feels
22 differently.

1 CO-CHAIR FLEISHER: But it was
2 important to -- thank you for making the comment
3 as we --

4 DR. PAONE: I would just -- if I
5 could, just very quickly respond to that. And I
6 understand the idea of not wanting to waste
7 resources, but capturing this measure and
8 bringing it forth in our -- in data set really is
9 of no particular burden. It's in the same list
10 as three other medicines and it's on the same
11 data set, and I don't think the computer
12 recognizes that extra data variable as a burden
13 either.

14 CO-CHAIR GUNNAR: But as chair and as
15 a matter of process what defines a topped-out
16 measure? If that doesn't define a topped-out
17 measure, we'll be at a loss for defining a
18 topped-out measure.

19 CO-CHAIR FLEISHER: Barbara? And then
20 Kelsey.

21 MEMBER LEVY: So I think again we need
22 to look at the STS 95 percent penetrance

1 differently than we would look at other types of
2 measures. And I think a measure can be for
3 moving the needle, but it can also be for
4 maintaining the needle, to maintaining the
5 quality that we have established and holding
6 people accountable for a certain standard.

7 And so I think we need to think about
8 it, Collette, maybe just a little bit differently
9 in that I think the concern that I'm hearing is
10 that if it is in reserve status or not endorsed,
11 that that sends a public message that says this
12 is less important. And there are certain things
13 that we want people to do every single time. And
14 I think this may be one of those things.

15 DR. PAONE: I would just comment that
16 I think that's exactly what we think.

17 CO-CHAIR FLEISHER: Go ahead.

18 CO-CHAIR GUNNAR: But again, reserve
19 status and non-endorsement are 180 degrees from
20 one another.

21 CO-CHAIR GUNNAR: Lynn and Kelsey, did
22 you have other comments on this, or no?

1 MEMBER McCARTY: Slightly different
2 aspect of the gap. I was going to bring this up
3 in validity, but I think it overlaps with gap,
4 and that's that part of the measure allows the
5 surgeon to indicate that beta blockers are
6 contraindicated.

7 So my first question is can they just
8 write "contraindicated," or are there a set of
9 specific criteria that indicate that it's
10 contraindicated?

11 CO-CHAIR FLEISHER: Sounds like --
12 that's validity, correct?

13 MEMBER McCARTY: So the reason I bring
14 that up in gap is because I'm curious. If they
15 just write "contraindicated" and doesn't have to
16 be supported by a specific criteria, I'm curious
17 what percentage of the registry passes the
18 measure by listing that, because beta blockers
19 have kind of had a long history of controversy.
20 And so, if someone doesn't agree in giving it and
21 can just write that down as this -- it's
22 contraindicated -- and then I'm curious what the

1 reliability testing is around that. Then there
2 may actually be a larger opportunity for
3 improvement in giving beta blockers than this
4 percentage indicates.

5 DR. PAONE: Well, as is described,
6 there are clearly contraindications clinically to
7 the use of beta blockers. They generally are in
8 this analogy, which is fairly unusual, but the
9 clinical ones are basically bradycardia or in
10 some patients with lung disease reactive lung
11 disease that may be an issue for some of the beta
12 blockers. There is some data in the report that
13 describes looking at the measure with and without
14 the exclusions and there are some slight
15 differences, but nothing that would suggest on a
16 large scale that physicians are just randomly
17 deciding they don't like beta blockers and
18 writing "contraindicated."

19 Certainly in response to your first
20 question, yes, I mean, theoretically we can just
21 write a note in the chart that says it's
22 contraindicated. And the measure requires a

1 documentation, not just that it's
2 contraindicated, but the reason for that. And
3 so, I don't think that this is a particularly
4 large problem in terms of the measure itself.

5 CO-CHAIR FLEISHER: Cliff?

6 MEMBER KO: Just a short thing about
7 the topped out and reserve. I think that we have
8 to rework those -- the NQF should help us rework
9 those things, because if reserve is similar to
10 sunset, then this -- definitely not. But if this
11 reserve is topped out at 98 percent, all the
12 measures that we put on reserve status last time
13 were just these numbers exactly.

14 So when we think about it one way
15 versus the other, then we'll think about reserve
16 or not. For this, if we're thinking about
17 sunset, it probably should not be, but the
18 numbers would suggest that it should. So we need
19 some clarification from NQF.

20 CO-CHAIR FLEISHER: Great. So
21 unfortunately we don't have -- I think, Marcia,
22 we need to go back to the CSAC for some insights

1 on this, or do you have comments? It would
2 really be helpful.

3 DR. WILSON: What I will mention is we
4 hear this argument -- I shouldn't say that. We
5 hear this discussion in every committee meeting.
6 There are great concerns about putting measures
7 in reserve and what message that sends. As you
8 heard from my colleagues, reserve status does not
9 remove endorsement. It is an endorsed measure.
10 It can be brought back, as Elisa said, for review
11 or if something were to change about that
12 measure, or if there would be an indication that
13 performance on that measure was not maintained at
14 the level when it was put in reserve.

15 So I don't have an easy answer for you
16 because this is somewhat of a philosophical
17 divide that we see in the committees where
18 members are reluctant to put a measure in reserve
19 because of the message that it's sending, and yet
20 at the same time at -- the other argument would
21 be at 98 percent, as one of our Co-Chairs said,
22 this measure is topped out. So it is -- you have

1 to make the decision yourself, but it is a
2 philosophical divide that we see often in our
3 committees, if that helps.

4 MEMBER LEVY: So it helps and it
5 doesn't help. When we hear the consequences from
6 the NACOR registry that measures that were put in
7 reserve status were pulled out of PQRS and that
8 CMS has decided --

9 CO-CHAIR FLEISHER: I think CMS had
10 already signaled they were pulling it out when we
11 put it on reserve status.

12 MEMBER LEVY: Okay.

13 CO-CHAIR FLEISHER: Because I already
14 was aware, unless you are aware of something
15 different.

16 MEMBER LEVY: No, it like happened
17 like --

18 CO-CHAIR FLEISHER: Yes, because I was
19 already talking to CMS.

20 MEMBER DUTTON: Yes, I don't think
21 there's cause and effect there, more of a shared
22 perception. But the fact that we couldn't keep

1 it in the QCDR meant it had a huge economic
2 impact on our membership and that they had to go
3 find another measure to report for PQRS. And
4 that's the real elephant in the room here, is if
5 reserve status means that you can't report it for
6 your federal pay-for-performance requirements,
7 there is a huge impact on all of the physicians,
8 all of the eligible providers who have to report
9 these measures. And that's one of the reasons
10 the discussion gets so difficult.

11 DR. PAONE: If I could make just one
12 last comment, and that's even at 98 percent, if
13 that's what the average number is, it's still --
14 and there's many thousands of patients in the
15 database. And so, that's still a fair number of
16 patients that theoretically are being discharged
17 without beta blockers, without contraindications,
18 and at the present time the data is still fairly
19 significant that discharge beta blockers have a
20 survival advantage. So we would want to take
21 every opportunity to make certain that this stays
22 at the forefront and is an important part of our

1 composite and our data collection.

2 CO-CHAIR FLEISHER: So we have a
3 couple comments, and we want to get through all
4 the measures. My one advice to you, your last
5 statement's an interesting one that isn't in the
6 report, but when you come back it may be useful
7 to say the gap represents X number of patients
8 nationally. Would people agree? And that would
9 really help in defining that it's really not
10 topped out. It really -- opportunity for
11 improvement I guess is a different way of saying
12 -- and the implications for improvement.

13 Yes, Larry and then -- not, not Larry.
14 We've got A.J. and, yes, Allan.

15 MEMBER SIPERSTEIN: Okay. So the
16 whole reason this reserve status came about is
17 the whole way that we define the gap and
18 necessitating an opportunity for improvement as
19 opposed to thinking about it in a little bit of a
20 wider scope, saying this is an important area to
21 maintain or to continue to monitor even though
22 the compliance may be high. So I think we may

1 need to think about kind of broadening our
2 definition of, kind of, what constitutes a gap.

3 CO-CHAIR FLEISHER: A.J.?

4 MEMBER YATES: Yes, I think there's
5 more to it than just the number, 98 percent.
6 When we put the antibiotic process measure on
7 reserve, there was already literature in the
8 health economics literature showing that it
9 didn't improve inequality at any particular
10 hospital, that it was something that could be
11 done without improving quality and that it was
12 just a checklist sort of thing that you could do.

13 I would argue that the difference --
14 the average readmission and complication rates in
15 the joints that we talked about yesterday was 4
16 percent, so why is 98 percent so much different
17 than 96 percent? I'd love to argue top those
18 out, but I think there's a difference in terms of
19 there being performance and quality using that
20 measure.

21 The two things I would say about this
22 is, one, does the two percent non-compliance

1 track with less well-performing cardiac centers?
2 Are they lower-star centers? And the second
3 thing is, is that looking at the trend over the
4 last few years they actually had a worsening of
5 utilization of the beta blockers in those people
6 that -- in the lower 10th percentile, so they
7 were actually going backwards.

8 So we're not talking about a static
9 situation. We're talking about something that
10 hit the wall and came back and they're
11 retracting. And if it correlates with the
12 quality of the center, then I -- or their overall
13 quality, then I think it has some reason to be
14 continued to be captured.

15 CO-CHAIR FLEISHER: Okay. I would
16 like to move forward. Just remember that the
17 CSAC did say for -- if you consider this a never
18 or what should occur as a low-frequency event,
19 you can consider the gap being important. So
20 that's the counter-argument. Whether you think
21 never missing an antibiotic is one of those
22 events, that's how you should potentially think

1 about it.

2 Can we call for a vote?

3 MS. QUINNONEZ: We are now voting on
4 Measure 0117. Voting is now open for performance
5 gaps on Measure 0117. Option 1 is high; option
6 2, moderate; option 3, low; and option 4,
7 insufficient.

8 (Voting.)

9 MS. QUINNONEZ: All votes are in and
10 voting is now closed. For the performance gap of
11 Measure 0117, 0 percent voted high; 62 percent
12 voted moderate; 38 percent voted low; and 0
13 percent insufficient.

14 CO-CHAIR FLEISHER: Okay. We will
15 keep going. Next, Lynn?

16 MEMBER REEDE: Reliability?

17 CO-CHAIR FLEISHER: Yes, any
18 differences from the previous measure?

19 MEMBER REEDE: No. Looked at the
20 measure score. Signal-to-noise was good. Ready
21 to go.

22 CO-CHAIR FLEISHER: Okay.

1 MEMBER REEDE: It's not risk-adjusted.

2 CO-CHAIR FLEISHER: Any comments?

3 (No audible response.)

4 CO-CHAIR FLEISHER: Would anybody like
5 to vote on this separately from our previous
6 vote?

7 (No audible response.)

8 CO-CHAIR FLEISHER: No. Can we -- do
9 we have the right to continue our previous --
10 okay. Validity? Right?

11 MEMBER REEDE: Is that enough?

12 CO-CHAIR FLEISHER: Yes.

13 MEMBER REEDE: You want to discuss
14 more?

15 CO-CHAIR FLEISHER: Validity, any
16 comments?

17 MEMBER McCARTY: I have one more
18 question about validity. So I know this is
19 suggested to be a companion measure to
20 preoperative beta blockers. My question is that
21 for whatever reason if preoperative beta blockers
22 aren't given, and for the most part they are;

1 we'll get to that gap in a minute -- but is it
2 dangerous to prescribe a beta blocker where you
3 can't monitor the effects of what happens when
4 that patient goes home and takes it?

5 CO-CHAIR FLEISHER: Essentially
6 unintended consequences is what you're asking?

7 MEMBER McCARTY: I guess so.

8 DR. PAONE: I mean, I -- realistically
9 there's always potential consequences any time
10 that we prescribe a medicine to any patient at
11 any time. I'm not sure what that has to do with
12 the measure per se.

13 MEMBER McCARTY: Well, I guess I --
14 (Simultaneous speaking.)

15 DR. PAONE: We follow up. I mean, the
16 patients are followed by their surgeons, by their
17 cardiologists, by their internists after any
18 cardiac procedure, and we do take their heart
19 rate, their blood pressure, ask if there are any
20 problems. I'm not quite sure how else to answer
21 that. I mean, I can't --

22 MEMBER McCARTY: Let me rephrase the

1 question.

2 DR. PAONE: Sure.

3 MEMBER McCARTY: So I mean, I think
4 that the way that this has been studied has been
5 mostly like a beta-blocker regimen. So you start
6 it preoperatively. You continue it at discharge.
7 And is there any evidence to suggest that if the
8 first half of that process is missing that if
9 they don't start to get the drug in their system
10 prior to surgery that there is a risk of them
11 getting it after? So it's just a risk question
12 more than an unintended consequence question.

13 DR. BADHWAR: Brief response to that.
14 It's a good question, however, there's a dose-
15 response to any medicine, and particularly
16 starting post-operatively, it's well known that
17 we are cautious in discharge beta blockers. They
18 don't start them on the max dose if they've never
19 seen it before. So I would just respond to that
20 as dose response like any other medicine?

21 MEMBER McCARTY: Thank you.

22 CO-CHAIR FLEISHER: Okay. Would

1 people like to vote for -- would anybody like to
2 vote?

3 (No audible response.)

4 CO-CHAIR FLEISHER: Yes? No?

5 (No audible response.)

6 CO-CHAIR FLEISHER: No? Okay. We'll
7 carry on the previous vote for validity.

8 Next?

9 MEMBER REEDE: Feasibility. Collected
10 the same as the previous data.

11 CO-CHAIR FLEISHER: Any comments?

12 (No audible response.)

13 CO-CHAIR FLEISHER: No? Would anybody
14 like to vote separately on this measure?

15 (No audible response.)

16 CO-CHAIR FLEISHER: Okay. Next? Use
17 and usability.

18 MEMBER REEDE: Usability and use.
19 Same.

20 CO-CHAIR FLEISHER: Any difference?

21 (No audible response.)

22 CO-CHAIR FLEISHER: Anybody like to

1 vote separately?

2 (No audible response.)

3 CO-CHAIR FLEISHER: No. Okay. We're
4 next at suitability for endorsement.

5 So, Desmirra, can you --

6 MS. QUINNONEZ: We are now voting on
7 the overall suitability for endorsement of
8 Measure 0117. Option 1 is yes; option 2 is no.

9 (Voting.)

10 MS. QUINNONEZ: Looking -- all votes
11 are in and voting is now closed. For the overall
12 suitability for endorsement of Measure 0117, 100
13 percent voted yes; 0 percent voted no.

14 CO-CHAIR FLEISHER: Okay. Moving on
15 to 0127, preoperative. So any changes in
16 evidence and comments on the gap?

17 DR. PAONE: No particular changes in
18 evidence worth noting, but I will comment on the
19 gap. It remains actually more significant than
20 the previous two measures. I think the lower
21 levels are down in the low 80s despite the high
22 average. And so for reasons that we've discussed

1 for the previous two measures, but particularly
2 with regards to an ongoing gap I think we would
3 again strongly endorse, recommend endorsement.

4 As far as the -- well, I should go
5 back and say for different -- for new information
6 there is some controversy around this measure in
7 the sense that recent studies looking at patients
8 from the database have a large trial of over
9 500,000 patients looking at those with and
10 without beta blockers.

11 Preoperatively there really was little
12 difference in outcomes in that particular trial,
13 and in that same journal Dr. Shahian, who is here
14 in the audience today, had an invited commentary
15 where he addressed many of the issues related to
16 why those differences may have occurred.

17 One of the most significant
18 differences in the -- the fact of the incidence
19 of atrial fibrillation with and without beta
20 blockers, that's known to occur in 25 percent of
21 patients, carries a great deal of morbidity. And
22 over the years, 30-plus articles have clearly

1 defined beta blockers as being of benefit in that
2 population.

3 We have over the past iteration of the
4 data set, data collection vehicle, added an
5 additional data variable looking at beta blockers
6 for greater than two weeks preoperatively in
7 addition to the one that's before us here today,
8 which was less than 24 hours. And the reason for
9 adding that data point was to try to further
10 define the true benefits of this therapy. And in
11 addition to believing that beta blockers still
12 confer a benefit, the addition of that data set
13 will afford an opportunity to study this more
14 intensely going forward. And that's just another
15 reason that we would like to maintain focus on
16 this measure.

17 CO-CHAIR FLEISHER: Kelsey, any
18 comment?

19 MEMBER McCARTY: Nothing new to add on
20 evidence or gap.

21 CO-CHAIR FLEISHER: Lynn, David, do
22 you want to make any comments?

1 DR. SHAHIAN: No, I think --

2 CO-CHAIR FLEISHER: Okay. So would
3 anybody like to vote on evidence?

4 (No audible response.)

5 CO-CHAIR FLEISHER: No. Gap, Kelsey?

6 MEMBER McCARTY: Just, I mentioned
7 that it was in the 80s, the data that I had from
8 the measure worksheet is that it was in the 80s
9 back in 2012, but has risen to 93.5 now. So it
10 is quite a bit higher, but I still think that
11 shows opportunity for improvement.

12 CO-CHAIR FLEISHER: Okay. Any other
13 comments?

14 (No audible response.)

15 CO-CHAIR FLEISHER: No. Why don't we
16 vote?

17 MS. QUINNONEZ: We are now voting on
18 Measure 0127. Voting is now open for the
19 performance gap of Measure 0127. Option 1 is
20 high; option 2, moderate; option 3, low; and
21 option 4, insufficient.

22 (Voting.)

1 MS. QUINNONEZ: All votes are in and
2 voting is now closed. The results read 14
3 percent voted high; 81 percent voted moderate; 5
4 percent voted low; and 0 percent voted
5 insufficient.

6 CO-CHAIR FLEISHER: Sorry, Collette.
7 Did you have any comments? I'm sorry. I
8 missed --

9 MEMBER PITZEN: That's okay. My
10 previous comments about performance gap apply
11 here as well.

12 CO-CHAIR FLEISHER: And when the
13 report comes out, remember everybody gets to see
14 the report that goes to CSAC. Please, if there
15 are sections that you want to emphasize something
16 that the CSAC should consider either for this
17 measure or in a greater sense, please make sure
18 that that's clearly articulated in the report to
19 reflect your concerns.

20 Okay. We're now up to reliability.
21 Kelsey?

22 MEMBER McCARTY: Nothing new to add.

1 MEMBER PITZEN: I have a question. So
2 please describe to me the numerator with the beta
3 blocker less than 24 hours before discharge. Is
4 that an understanding perhaps that the patient is
5 on the beta blocker preoperatively and that's
6 continued in that dose the day of surgery given,
7 or what is that time frame? And when I'm looking
8 at the actual data in the database, unlike the
9 discharge medication this just simply has a check
10 box for contraindicated without any reference to
11 criteria.

12 DR. PAONE: So the numerator is all
13 patients who receive beta blockers within 24
14 hours of surgery, and that's whether they've had
15 it for two weeks, two months or just started the
16 day before.

17 MEMBER PITZEN: Okay. So is it likely
18 or not likely that they would be given a beta
19 blocker the morning of surgery or for a very
20 first dose?

21 DR. PAONE: Yes, that's a very good
22 question. It's a great question. It's -- the

1 ongoing controversy is in that question.

2 So in order to satisfy the measure, it
3 was not uncommon, and this was one of the
4 criticisms of the study that I mentioned is that
5 we don't know the difference between a patient --
6 the benefits of beta blockers in a patient who's
7 been on it for two weeks or two months versus a
8 patient who comes into the hospital the morning
9 of surgery and is given a dose a beta blocker.
10 We -- and that is not -- has not been uncommon,
11 frankly, because it does satisfy the data set.
12 And that's where the new data variable added will
13 hopefully provide additional information.

14 The thought among many is it's
15 probably not the dose necessarily or even the
16 medicine but the physiologic response, and so
17 there are other variables in terms of the
18 specific medication given, how it's given and
19 then whether or not the patient has responded to
20 it. So there are some questions with this that I
21 think really is why we'd like to maintain it as
22 an endorsed measure and enable us to continue to

1 look at this issue and study it further as the
2 number of patients increases in the database
3 given the new added variable.

4 MEMBER PITZEN: So the way it -- as it
5 is now, it could be an unintended consequence
6 that relates to patient safety. Is that correct,
7 or is that taking it too far? I'm just thinking
8 of the patients perhaps that have never been on a
9 beta blocker.

10 DR. PAONE: I mean, I guess
11 theoretically there's always a potential for an
12 unintended consequence, but that certainly hasn't
13 been the experience.

14 CO-CHAIR FLEISHER: Rick?

15 MEMBER DUTTON: Yes, I do this about
16 once a week, Collette. Same thing. Here's a
17 patient not on beta blockers scheduled for
18 surgery. It's indicated. There's a box in my
19 EHR that says I have to decide am I going to give
20 it or not. And different people play that
21 different ways.

22 Generally, we look at the patient. If

1 they're hypotensive or bradycardic already, we
2 would not give it and say contraindicated.
3 That's what that box means. But it can be for a
4 number of different reasons based on my
5 assessment. And there are some
6 anesthesiologists, honestly, who would give a
7 drop, a homeopathic dose to satisfy the
8 regulatory requirement, but not have any
9 different physiologic effect, if that makes
10 sense.

11 DR. PAONE: I will add just on a
12 practical basis, there are not that many patients
13 that come into the hospital for coronary bypass
14 surgery not on beta blockers without a
15 contraindication, and one of the reasons to give
16 that dose of medicine isn't necessarily that they
17 haven't been on it, but it's because you can't
18 document that they've taken their last dose
19 within 24 hours. So even though you know they're
20 on it, you just can't find that documentation
21 anyway. So the easiest thing to do is just give
22 them a dose and then you write the time down in

1 the medical record and now you've satisfied the
2 data set.

3 CO-CHAIR GUNNAR: Okay. Would anybody
4 like to vote on reliability?

5 Collette, would you like us to do a
6 separate vote on reliability? Does it matter?

7 MEMBER PITZEN: Sure.

8 CO-CHAIR FLEISHER: Sure. Why don't
9 we do it?

10 MS. QUINNONEZ: Voting is now open on
11 the reliability of Measure 0127. Option 1, high;
12 option 2, moderate; option 3, low; and option 4,
13 insufficient.

14 (Voting.)

15 MS. QUINNONEZ: All votes are in and
16 voting is now closed. For the reliability of
17 Measure 0127, 33 percent voted high; 57 percent
18 voted moderate; 10 percent voted low; and 0
19 percent for insufficient.

20 CO-CHAIR FLEISHER: Kelsey, validity?

21 MEMBER McCARTY: Nothing new to add.

22 CO-CHAIR FLEISHER: Since there was no

1 discussion, I will ask if the -- my habit now
2 will be is if there's discussion points, we'll
3 vote. If there's no discussion, we'll ask if
4 anyone would like to vote.

5 Is there any desire to vote?

6 (No audible response.)

7 CO-CHAIR FLEISHER: No. Let's move
8 on. So now we're onto feasibility.

9 MEMBER McCARTY: Same as before.

10 CO-CHAIR FLEISHER: Collette?

11 MEMBER PITZEN: May I just ask a
12 question again?

13 CO-CHAIR FLEISHER: Please.

14 MEMBER PITZEN: So when I think of
15 feasibility, I guess I'd like to ask the
16 developers how many of the participating
17 institutions have really a direct pass-through
18 from their electronic record to your registry,
19 because when I look at the data elements that are
20 collected in the registry, it assures my mind a
21 little bit if there's a lot of hospitals that
22 have this already built into their EHR without

1 the added abstraction that it would take to get
2 this information.

3 DR. PAONE: Well, I can answer that as
4 someone who works very closely with the data
5 manager at our institution, and we have over the
6 last two years instituted the use of the Epic
7 electronic health record. At our institution the
8 pass-through is zero at this point, but we are
9 actively working with our IT people to institute
10 that.

11 One of the issues for us actually,
12 unrelated and just very quickly, is we've just
13 had to change our data set. The manufacturer of
14 the program that we use has just changed, so
15 we're in a six-month process of just changing
16 over the data set.

17 But that's a great question. And
18 everyone that does this is looking for ways to
19 automate this, and we are as well, but I don't
20 know what it is, what the penetrance of automated
21 data transfer is nationally, but we don't do it.
22 I would guess it's very low, yes.

1 MEMBER PITZEN: Thank you. And the
2 reason I ask that question again is the cost-
3 benefit of data collection versus the output.
4 And there is -- you guys have great measures.
5 I'm just talking about some of the process ones
6 that are topped out and then the future potential
7 to build new great measures from your registry.

8 DR. PAONE: Yes, just very quickly I
9 would add for the same reason as the others,
10 there's really no added burden to checking off a
11 box for pre-op beta blockers.

12 CO-CHAIR FLEISHER: Yes, David?

13 DR. SHAHIAN: Just in terms of
14 automated extraction, it is an important point
15 and we have explored multiple avenues to make
16 that possible. Needless to say the EHR
17 manufacturers have not been particularly
18 interested in these efforts so far. We're
19 continuing to work with them. But there are
20 major differences between the unstructured data
21 fields in EHRs and the highly structured, highly
22 defined data fields we have in clinical

1 registries. That's what makes clinical
2 registries so powerful.

3 And we caution people about trying to
4 extract data from EHRs, particularly some of our
5 more complex definitions. It's very difficult to
6 do it even with natural language processing and
7 all those sorts of things. So it's an
8 interesting area. We'd like to reduce data
9 collection burden. It isn't happening much so
10 far. So, but good question. Thank you.

11 CO-CHAIR FLEISHER: Would you like --
12 shall we vote then, since there were questions?

13 (No audible response.)

14 CO-CHAIR FLEISHER: Go ahead.

15 MS. QUINNONEZ: Voting is now open for
16 the feasibility of Measure 0127. Option 1 is
17 high; option 2 is moderate; option 3 is low; and
18 option 4, insufficient.

19 (Voting.)

20 MS. QUINNONEZ: All votes are in and
21 voting is now closed. For the feasibility of
22 Measure 0127, 57 percent voted high; 38 percent

1 voted moderate; 5 percent voted low; and 0
2 percent for insufficient.

3 CO-CHAIR FLEISHER: Great. A.J.?

4 MEMBER YATES: This is not intended
5 just for STS, but STS routinely points out how
6 reasonable their price is to participate and how
7 it's underwritten and everything else, but that's
8 the cost of being in the registry. The cost of
9 uploading to the registry is not insignificant
10 and can run six figures in terms of the people
11 you have to support to do all that for you and
12 make sure that your i's are dotted and your t's
13 are crossed.

14 So I think for registry data that's
15 being put in that's not EMR direct pass-through,
16 which I would agree is not the sine qua non of
17 excellence; it may be that it's not as good as we
18 would like, it would be great if there was an
19 estimate of what the real true cost to the
20 hospital is for participating in the registry,
21 not just the cost to -- the contract cost with
22 STS. And I think that would be a reasonable

1 thing to expect from another developer, so I put
2 that out as one of the things on the wish list
3 that we can add to the conversation for down the
4 road.

5 CO-CHAIR FLEISHER: Thank you.

6 CO-CHAIR GUNNAR: Just for perspective
7 for the group, what's the number of data fields
8 that have to be extracted in place per case? I
9 think it was 178 this last time.

10 DR. PAONE: I honestly -- and maybe
11 David knows the exact number. It's probably more
12 than --

13 DR. SHAHIAN: About 200 --

14 DR. PAONE: Yes.

15 DR. SHAHIAN: -- or 250, something
16 like that.

17 DR. PAONE: Yes, I think so. Yes.

18 MEMBER YATES: Which I respect
19 immensely but -- and I think that's where
20 registries have to go, but I think you have to
21 recognize that there is a cost per each
22 institution, and it's not just the 3,000 for

1 being contracted with the registry.

2 DR. SHAHIAN: And I think for valve
3 repairs you've actually expanded that even
4 farther, right?

5 CO-CHAIR FLEISHER: So -- and we
6 recognize that it is fortunate the STS model is
7 to get the hospital to underwrite this. So I
8 think it's a very good point and we'll put it
9 into the report and you'll be responsible for
10 making sure it's well said as far as --

11 MEMBER YATES: Yes, sir, and I will
12 emphasize the fact that I really think the
13 hospital should pay for it.

14 (Laughter.)

15 CO-CHAIR FLEISHER: Thank you.

16 MEMBER YATES: For other registries as
17 well.

18 CO-CHAIR FLEISHER: And that's a --
19 the only reason is I hear that, but you guys were
20 -- you were the first, you were the best in
21 initiating.

22 Use and usability? Comments?

1 MEMBER McCARTY: Nothing to add.

2 CO-CHAIR FLEISHER: Nothing? Anybody
3 want to vote?

4 (No audible response.)

5 CO-CHAIR FLEISHER: Okay. So are we
6 up to voting for the measure?

7 (No audible response.)

8 CO-CHAIR FLEISHER: Okay. We are on
9 time.

10 MS. QUINNONEZ: We are now voting for
11 the overall suitability for endorsement of
12 Measure 0127. Option 1 is yes; option 2, no.

13 (Voting.)

14 MS. QUINNONEZ: All votes are in;
15 voting is now closed. For the overall
16 suitability for endorsement of Measure 0127, 95
17 percent voted yes; 5 percent voted no.

18 CO-CHAIR FLEISHER: Okay. Now we get
19 to actually the composite. So 3030.

20 DR. BADHWAR: So Composite Measure
21 3030 is a multi-procedural/multi-dimensional
22 composite measure on the STS individual surgeon

1 composite measure for adult cardiac surgery. It
2 includes five major operations: isolated coronary
3 bypass grafting; isolated aortic valve
4 replacement; AVR plus CABG; isolated mitral valve
5 repair or replacement, or what we term as MVRR;
6 and MVRR plus CABG, and it comprises a risk-
7 adjusted operative mortality domain and the risk-
8 adjusted major morbidity domain consistent with
9 all of our previous measures. And those domains
10 are five: major complication composite, prolonged
11 ventilation, deep sternal wound infection,
12 permanent stroke, renal failure and re-operations
13 of cardiac origin such as bleeding, coronary
14 graft occlusion, valve dysfunction, et cetera.

15 This includes seven previous NQF-
16 endorsed risk-adjusted mortality outcome measures
17 and five endorsed risk-adjusted complications as
18 noted. In the scientific aspects of this
19 composite, a lot of effort was made to assure its
20 reliability. In similar models it's a Markov
21 chain simulation, 95 percent Bayesian probability
22 interval. The evidence missing is only 0.4

1 percent for mortality and 0.3 percent for
2 morbidity. And the composite consists of the
3 reliability of each of these.

4 And just for frame of reference, which
5 I won't be duplicative in the next comments, for
6 CABG it was 0.77 reliability, isolated AVR 0.52,
7 AVR CABG 0.5, isolated MVRR 0.58, and MVRR plus
8 CABG is 0.5. And so this data set is three
9 years, from July 2011 to July -- sorry, June 2014
10 involving 2,286 surgeons, 621,489 cases, and it
11 is the highest reliability of all of our measures
12 ever performed at 0.81.

13 And so, with this the objective is --
14 it's an implicit weighted score, and we propose
15 this for our next composite measure for adult
16 cardiac surgery.

17 CO-CHAIR FLEISHER: Great. Thank you.
18 An important point; I just checked with Melinda,
19 while they do mention the Star Ratings, we do not
20 endorse the way they actually report it. We
21 endorse the measure. But whether it's one star,
22 two star and how they define the stars is not

1 part of our endorsement process.

2 DR. BADHWAR: I intentionally didn't
3 mention that.

4 CO-CHAIR FLEISHER: Thank you, but it
5 was sitting in front of me, so I had to make a
6 comment --

7 DR. BADHWAR: No problem.

8 CO-CHAIR FLEISHER: -- for the
9 Committee to recognize, because that would
10 probably take another three-hour debate about how
11 they actually defined that.

12 So we have -- our discussants are Karl
13 and Barbara. Karl?

14 MEMBER BILIMORIA: Great. So that was
15 a good overview and covers a lot of it. I think
16 under the evidence category, mortality is clearly
17 decreasing and they make a nice point about being
18 able to focus on quality of patients who survive.
19 And so this composite does that. The
20 complication rates still remain pretty high with
21 13.7 percent prolonged ventilation. Mortality
22 still remains 2.3 percent. So I think the

1 evidence is there for measuring these outcomes.
2 As mentioned, all 12 of the components are NQF-
3 endorsed already.

4 CO-CHAIR FLEISHER: So any comments,
5 because Barbara -- can we vote on evidence?

6 (No audible response.)

7 MS. QUINNONEZ: We are now voting on
8 the evidence for Measure 3030. Option 1 is yes;
9 option 2 is no.

10 (Voting.)

11 MS. QUINNONEZ: All votes are in and
12 voting is now closed. For the evidence of
13 Measure 3030, 100 percent voted yes; 0 percent
14 voted no.

15 MEMBER BILIMORIA: All right. So for
16 the performance gap I think it's pretty obvious
17 they had 9 percent of surgeons being noted to be
18 worse than expected and 18 percent better.
19 Clearly there's variability here that's
20 meaningful.

21 CO-CHAIR FLEISHER: Melinda is just
22 going to comment about one thing.

1 MS. MURPHY: The component measures
2 are specified for analysis at the group or
3 practice level, and this measure is applicable at
4 the individual physician level. So we had a fair
5 amount of discussion internally about that
6 because the question is the endorsement or the
7 consideration of the component measures. And the
8 discussion was, if it is suitable for use at a
9 group or practice level, you could have a group
10 or practice of two physicians and what is the
11 difference between applying it to two versus one?
12 So I only say that as a point of the way in which
13 the component measure is endorsed and the way
14 this measure will be used.

15 MEMBER BILIMORIA: I think it's more
16 about the specifications that have already been
17 well established in those prior metrics, and we
18 can talk a little bit about some of the
19 differences by surgeon as we move on for this
20 composite. But as I mentioned, we have a good
21 performance gap undoubtedly, so should we -- are
22 there any other comments?

1 CO-CHAIR FLEISHER: Comments?

2 MEMBER LEVY: Just in general, and
3 this is more of a clinical comment than an
4 evidence comment, but cardiac surgery is a team
5 sport. It's very unlikely that an outcome is
6 related, particularly a morbidity or mortality
7 outcome is related to an individual. And so, I
8 would just ask the developers why report this at
9 an individual level? Why did you decide to
10 report this at an individual level rather than at
11 the group level?

12 DR. BADHWAR: I will make a brief
13 comment on that. That's a very insightful
14 comment, and we agree with you that cardiac
15 surgery is a team sport. However, currently in
16 the United States, surgeon-level reporting using
17 claims data is going on, and it is an unfortunate
18 situation because that data is often not as
19 accurate as the STS Database and the clinical
20 registry that we have. And so we wanted to form
21 this in the most scientifically valid way we
22 possibly can to address that. And it's already

1 something that we are being asked for, and to do
2 so in the most responsible way forward is what
3 the objective was.

4 CO-CHAIR FLEISHER: Thank you. But
5 you also report it at the group level, correct?

6 DR. BADHWAR: This particular measure
7 is not. This is an individual surgeon measure.

8 CO-CHAIR FLEISHER: Okay. There is a
9 debate actually at the Board when I was briefly
10 on it of the consumerism approach of they want
11 individual practitioner-level measures. Most of
12 us around this table agree it's a team sport.
13 Being an anesthesiologist, very much a team sport
14 in many of these things. Intensivist. But that
15 debate is beyond the purview of this Committee
16 alone.

17 A.J.?

18 MEMBER YATES: Yes, I share the same
19 concerns as Barbara, and in the past, STS has
20 rejected the idea that they could do this at the
21 individual level because of small sample size
22 analysis and the like.

1 I have a question and then -- a real
2 quick question, then I want to just make a point.
3 What's the exclusion criteria by volume?

4 MEMBER LEVY: Yes, it's 100 cases over
5 3 years.

6 DR. BADHWAR: Thank you. Yes.

7 MEMBER YATES: Okay. So it has to be
8 100 over 3 years?

9 DR. BADHWAR: There's a minimum.

10 MEMBER YATES: So it's pretty low.
11 It's pretty low in terms of 50 a year?

12 DR. BADHWAR: Correct.

13 MEMBER YATES: Or, excuse me, 30 a
14 year.

15 DR. BADHWAR: Yes.

16 MEMBER YATES: My one question, and I
17 would have to delve into the actual measure
18 specifics more than time allows, but do you take
19 the sum total of reports from a particular
20 institution? And since you're not reporting this
21 by institution, do you take the sum total of the
22 results and then use that as a risk factor for

1 poorly performing institutions that may not have
2 the best intensive care units or the best
3 cardiologists or the best anesthesiologists; not
4 that any anesthesiologist isn't perfect, Dr.
5 Fleisher --

6 (Laughter.)

7 MEMBER YATES: -- but do you not -- do
8 you take -- do you do -- risk-adjust for the
9 environment that the surgeon is working in since
10 it is a team sport? And I -- because I would
11 think that that would be an important feedback
12 loop to make sure that they're not analyzed in
13 such a way that it takes the environment out of
14 the picture.

15 DR. BADHWAR: It's another insightful
16 comment. While we have site-specific data, this
17 is tracked directly to the surgeon ID number, and
18 there are many situations -- unlike major
19 academic institutions, there are many situations
20 where surgeons operate in different institutions
21 and this -- the purpose of this measure is to
22 track by surgeon, though your points are valid.

1 MEMBER YATES: Well, those effects of
2 those institutions though -- because they have to
3 be reporting registered institutions for those to
4 count, those could be proportionally weighted.

5 DR. BADHWAR: That's valid.

6 CO-CHAIR GUNNAR: So just to be clear,
7 the purpose of this, one of the purposes of this
8 was if I'm operating at four institutions, this
9 is a collection of all of my cases for that
10 period of time at all of those institutions?

11 DR. BADHWAR: Correct.

12 MEMBER YATES: I'm sorry to follow up
13 without being called on, but one of the
14 unintended consequences of not doing a -- risk-
15 adjusting for that is that, of those four
16 institutions, a really good surgeon realizes that
17 one of them is one where it's really hard to get
18 as good a result as he can other places, yet
19 that's an isolated location and his expertise is
20 all they're going to get. There's a chance that
21 he'll stop going to that institution if it's
22 going to bring down his reporting. And I just

1 throw that out for consideration.

2 CO-CHAIR GUNNAR: So this goes back to
3 NQF again about is the measure -- this measure is
4 -- actually at its core is about ongoing
5 professional practice evaluation. It's not about
6 quality improvement at any one institution. And
7 so philosophically is that in line with the
8 mission and vision of the NQF?

9 CO-CHAIR FLEISHER: See, I would
10 actually argue that that surgeon should stop
11 operating at that institution that's dragging
12 down his numbers, and that's what the public
13 wants. The public wants us to say, if I look bad
14 because of one institution, then I'm going to say
15 to the institution I can't operate there anymore.
16 You shouldn't be doing cardiac surgery unless
17 I'm --

18 (Simultaneous speaking.)

19 MEMBER YATES: -- administration of
20 that institution and say I'm taking my patients
21 and going elsewhere unless you improve the
22 quality of your ICU, your cardiac anesthesia and

1 so forth. So there is an opportunity to provide
2 quality improvement.

3 CO-CHAIR FLEISHER: Right. Thank you.
4 We're saying actually the same --

5 MEMBER YATES: Yes.

6 CO-CHAIR FLEISHER: -- thing. Rick
7 and --

8 (Simultaneous speaking.)

9 MEMBER DUTTON: Does your -- as you
10 present this as an individual result, does your
11 statistical model include hierarchical modeling
12 of the facility? So is the facility affecting
13 the risk-adjustment?

14 DR. BADHWAR: I believe so, yes.

15 MEMBER DUTTON: And asked the other
16 way, if you were reporting this at the facility
17 level; so you're reporting to a facility their
18 performance on this composite, would you adjust
19 it for the surgeon?

20 DR. BADHWAR: So at this point that's
21 not part of our formulation to have a surgeon-
22 level variable, though that's an interesting

1 point.

2 MEMBER BILIMORIA: No, I mean as I
3 think that the public wants it, surgeons want it,
4 this -- some things drive institutional
5 improvement, and this will drive surgeon-level
6 improvement even if you can't be responsible --

7 (Simultaneous speaking.)

8 CO-CHAIR GUNNAR: I don't know if
9 surgeons want it.

10 (Simultaneous speaking.)

11 MEMBER BILIMORIA: -- the entire
12 outcome --

13 (Simultaneous speaking.)

14 CO-CHAIR GUNNAR: There's no vote on
15 that. I mean, nobody raised their hand. I mean,
16 one of the interesting things about public
17 reporting -- what's the penetrance now for public
18 reporting requests?

19 DR. BADHWAR: Forty-nine percent
20 for --

21 (Simultaneous speaking.)

22 CO-CHAIR GUNNAR: Forty-nine percent.

1 And that's at the group or at the --

2 DR. BADHWAR: That's at a site
3 participant level.

4 CO-CHAIR GUNNAR: -- site participant
5 level.

6 DR. SHAHIAN: Can I just make one
7 comment?

8 CO-CHAIR FLEISHER: Yes, David, but it
9 would be -- go ahead. Can you come up? You're
10 allowed. He is a Board member.

11 (Laughter.)

12 CO-CHAIR FLEISHER: So if you could
13 come up here?

14 DR. SHAHIAN: Just informational, just
15 in terms of the philosophy of developing this
16 measure, the comments are absolutely correct that
17 we have historically avoided surgeon-level
18 measures for the exact reasons that were noted:
19 sample size and the fact that it's a team sport.
20 But the problem is that there are entities out
21 there that are publishing grossly flawed data and
22 we've seen two very good examples of it just in

1 the last year.

2 Several of us in the room have been
3 involved in critiques of some of these grossly
4 flawed measures, and we wanted to have something
5 that was scientifically valid that if we were in
6 a position of having to provide surgeon-level
7 data, we wanted to have the best possible
8 measure. That's what we've tried to do with this
9 measure which encompasses about 80 percent of a
10 typical cardiac surgeon's workload through these
11 five procedures. So having five procedures, two
12 domains, which each of them themselves have
13 multiple measures within them, and then three
14 years of data, that's why we have this very high
15 reliability.

16 So it's not a measure that frankly we
17 probably would have developed had not these other
18 forces beyond our control sort of pushed towards,
19 but we do have now a measure that we have a great
20 deal of confidence in.

21 CO-CHAIR GUNNAR: So are you currently
22 reporting the measure?

1 DR. SHAHIAN: No, our plan with this
2 measure is to provide this individually to
3 surgeons only, their own results, for 6 to 12
4 months and make sure that they're comfortable
5 with it, and that there's nothing that we haven't
6 thought of, although we've spent two years
7 developing this. So I think it's pretty
8 unlikely. But we're going to do this
9 confidentially to the surgeons for about a year,
10 and only then and probably only if we're pressed
11 are we going to start publicly reporting it. But
12 we want to have it ready. And I would not be at
13 all surprised that the way things are moving that
14 there will be public reporting of this measure
15 within a year.

16 CO-CHAIR FLEISHER: So just to -- in
17 the use and -- in the committee that looked at
18 intended use this idea of having the end user be
19 able to review the data was one of the major
20 themes that came out of it. So the process
21 you're talking about is actually this idea, if
22 I'm thinking -- remembering correctly -- Marcia

1 is shaking her head -- that this would be the
2 process that you might get to NQF endorsement-
3 plus, that we wanted the -- so you're actually
4 foreshadowing the idea that we want -- that once
5 measures are out, we'd like it publicly reported.
6 But that would be what could be the next stage of
7 the game is people being comfortable with the
8 data.

9 DR. SHAHIAN: Yes.

10 CO-CHAIR FLEISHER: Larry and Barry.
11 We need to keep moving because they have to
12 leave.

13 MEMBER MOSS: Just wanted to offer an
14 alternative point of view. I agree that surgery
15 is a team sport, but a patient goes to the
16 operating room not with an institution, but with
17 an individual surgeon and needs to choose an
18 individual surgeon. And every one of us knows in
19 this room, regardless of how uncomfortable it
20 might make us, that there is variation in
21 individual surgeons' talent and performance.

22 So I support what you're doing. I

1 think it's the right thing to do. We may not be
2 able to ideally compare surgeons, but it's a step
3 in the right direction and I support you.

4 DR. BADHWAR: Thank you.

5 CO-CHAIR FLEISHER: Thank you. And to
6 be clear, from the consumerism standpoint that's
7 the way they think about it. Who takes how to
8 look at the team and whether the surgeon has to
9 -- if they're not having a great result, look at
10 the whole team, so to the comment you made.

11 Barry?

12 MEMBER MARKMAN: Do you an education
13 process with poor outliers? I mean, you have the
14 data, so what do you plan to do with it?

15 DR. BADHWAR: That's part of the
16 process of feedback reports and looking at and
17 tracking quality improvement, but that's why this
18 is -- your point is important. We don't have an
19 answer yet, but maybe we will in a few years.

20 CO-CHAIR FLEISHER: So let's vote on
21 performance gap.

22 MS. QUINNONEZ: Voting is now open for

1 performance gaps of Measure 3030. Option 1 is
2 high; option 2 is moderate; option 3, low; and
3 option 4, insufficient.

4 (Voting.)

5 MS. QUINNONEZ: Looking for one more
6 vote. If you could resubmit your votes, please?

7 (Voting.)

8 CO-CHAIR FLEISHER: Okay.

9 MS. QUINNONEZ: Okay. Voting is now
10 closed. For performance gaps of Measure 3030, 60
11 percent voted high; 40 percent voted moderate; 0
12 percent for low; and 0 percent for insufficient.

13 CO-CHAIR FLEISHER: Okay. Next?

14 MEMBER BILIMORIA: So we need to touch
15 on the quality construct. Is that the next
16 piece?

17 (No audible response.)

18 MEMBER BILIMORIA: So I think --

19 CO-CHAIR FLEISHER: Next is --

20 MEMBER BILIMORIA: Yes, for the
21 composite.

22 CO-CHAIR FLEISHER: -- the composite.

1 MEMBER BILIMORIA: Yes, the quality
2 constructs of the composite.

3 CO-CHAIR FLEISHER: Right.

4 MEMBER BILIMORIA: So if it was -- as
5 mentioned, it gives a pretty comprehensive view
6 of the individual surgeon's practice. It's 80
7 percent of their practice. Clearly, mortality
8 and morbidity are important. The weighting and
9 the approach to putting together the composite is
10 well described, and we can talk about it below in
11 validity, but it was vetted by an expert panel.
12 And so, I think it's well described at this
13 point.

14 Any other points that we should touch
15 on in the composite construct?

16 CO-CHAIR FLEISHER: Any other
17 comments?

18 (No audible response.)

19 CO-CHAIR FLEISHER: Okay. Let's vote.

20 MS. QUINNONEZ: Voting is now open for
21 the composite quality construct of Measure 3030.
22 Option 1 is high; option 2 is moderate; option 3,

1 low; and option 4, insufficient.

2 (Voting.)

3 MS. QUINNONEZ: Voting is now closed.

4 For the composite of Measure 3030, 85 percent
5 voted high; 15 percent voted moderate; 0 percent
6 for low; and 0 percent insufficient.

7 CO-CHAIR FLEISHER: Karl, do you want
8 to continue?

9 MEMBER BILIMORIA: Yes, so moving on
10 to reliability. I think the specifications are
11 -- they're well specified. They're the same
12 specifications from prior NQF measures. They do
13 audits, as mentioned, on about 10 percent. And
14 in terms of formal reliability testing, that was
15 well covered here using multiple approaches. And
16 the reliability for surgeons with greater than
17 100 cases was 0.81. And so, I think that's
18 probably one of the best that we've seen so far.
19 So I have no issues on reliability.

20 CO-CHAIR FLEISHER: Do you think this
21 is different? It's a composite. So let's vote.

22 MS. QUINNONEZ: Voting is now open for

1 the reliability of Measure 3030. Option 1, high;
2 option 2, moderate; option 3, low; and option 4,
3 insufficient.

4 (Voting.)

5 MS. QUINNONEZ: All votes are in and
6 voting is now closed. For the reliability of
7 Measure 3030, 86 percent voted high; 14 percent
8 voted moderate; 0 percent, low; and 0 percent
9 insufficient.

10 MEMBER BILIMORIA: All right. Moving
11 on to validity, there are clearly significant and
12 meaningful differences in performance between
13 providers. Again, the expert panel reviewed
14 which measures were included under weights.
15 Missing data is a small problem at 0.4 percent.
16 Missing data and all the analyses around the
17 missing data do not really change the results.
18 It's a 0.99 correlation with and without the
19 missing data imputed.

20 The one question I had here was that
21 they mention that the SDS factors could not be
22 examined here, but they examined them in some of

1 the other subsequent factors. I know this is the
2 surgeon-level model, but I thought if you could
3 just comment on how you addressed -- or why you
4 didn't address the sociodemographic status.

5 DR. BADHWAR: So we wanted to focus
6 strictly on the major issues of complications and
7 mortality. And so, if I'm understanding your
8 question correctly, I mean, these are fairly
9 defined measures, and so we didn't delve into the
10 items that may or not have -- while I respect
11 your comment on socioeconomic factors influencing
12 outcome, we've done separate analyses on the
13 influence of that.

14 And in terms of the weighting of
15 importance for this type of measure, we actually
16 looked at different areas of the country and the
17 impact was not huge.

18 MEMBER BILIMORIA: I would agree that
19 the theoretical underpinning for -- to include
20 SDS is not there, but I was wondering if you did
21 examine it in this particular measure and see
22 whether it had an influence.

1 DR. SHAHIAN: We did not do it in the
2 manner we did it for example for our readmission
3 measure where I think there is a much more
4 plausible relationship between some of the
5 sociodemographic factors and the outcome. We
6 actually think that for morbidity and mortality
7 that relationship is a little more questionable.
8 And we've been working on this measure actually
9 for about two-and-a-half years and actually did
10 most of the original analytic work even before
11 NQF considered the possibility of including SES
12 factors. So we did not have it.

13 We could, although frankly dual-
14 eligible status, for example, for our readmission
15 measure showed essentially no impact. I think
16 the granularity of the data that we have and most
17 registries have for these sociodemographic
18 factors is probably inadequate to demonstrate a
19 difference and it's probably going to require
20 things like geocoding, which we don't have
21 available.

22 MEMBER BILIMORIA: To be clear, I

1 don't think that it is necessary here, but I just
2 wanted to bring it up since it was pointed out.

3 CO-CHAIR FLEISHER: Barbara and then
4 A.J.

5 MEMBER LEVY: I just think from a
6 theoretical standpoint the risk-adjustment for
7 clinical factors should correct for that.

8 CO-CHAIR FLEISHER: A.J.?

9 MEMBER YATES: Yes, unlike my concern
10 more about an urban population yesterday, my
11 concern here is geographic disparities in terms
12 of isolation. And having lived in Wyoming for a
13 while, I worry about a town like Billings or
14 Missoula or someplace like that where there may
15 -- those might even be too big, but there are
16 places where people with chest pain have to see a
17 cardiologist, have to have a cath and the cath
18 lab has to have a cardiac surgeon nearby. And if
19 it's a smaller hospital with very wide geographic
20 distances between it and the next center, there
21 is a risk of mortality or morbidity for not being
22 able to get the patient somewhere where this sort

1 of service exists. And you run the risk of those
2 isolated areas.

3 Maybe they score poorly. Maybe
4 they're one of the 18 percent of the cardiac
5 surgeons that score poorly and they realize that
6 they can't win there and they leave. Then the
7 cath lab shuts down and there's no cardiologist
8 anymore and all of a sudden there's a big hole in
9 the geography of the United States for that rural
10 environment.

11 So if I was to throw out anything as
12 being a potential risk of disparity, it would be
13 the question of geographic isolation. And there
14 are places where things like chest pain happen
15 even though you live way out on a farm somewhere
16 and it may not be possible to get to the next
17 state in time. And I would hate to see something
18 drive that availability. Even if it's at a
19 slightly little level of performance, let them
20 try and improve, but I worry about cardiac
21 surgeons leaving that environment because of
22 feeling chastised.

1 CO-CHAIR FLEISHER: Thank you. Other
2 comments?

3 (No audible response.)

4 MS. QUINNONEZ: Voting is now open for
5 the validity of Measure 3030. Option 1 is high;
6 option 2, moderate; option 3, low; and option 4,
7 insufficient.

8 (Voting.)

9 MS. QUINNONEZ: All votes are in and
10 voting is now closed. For the validity of
11 Measure 3030, 52 percent voted high; 48 percent
12 voted moderate; 0 percent low; and 0 percent
13 insufficient.

14 MEMBER BILIMORIA: In respect to the
15 scientific acceptability for the composite, they
16 did look at correlations between morbidity and
17 mortality and how much drove the overall score.
18 It was mostly driven by morbidity. That's also
19 where the weight is, but that also makes sense
20 given their underlying premise. Also, the
21 weights were done empirically and also then
22 validated by the expert panel, so I think there

1 is acceptability around how the weighting was
2 done for composite.

3 CO-CHAIR FLEISHER: Other comments?
4 Let's vote.

5 MS. QUINNONEZ: Voting is now open for
6 the composite scientific acceptability of measure
7 3030. Option 1 is high; option 2, moderate;
8 option 3, low; and option 4, insufficient.

9 (Voting.)

10 MS. QUINNONEZ: All votes are in and
11 voting is now closed. Seventy-one percent voted
12 high; 29 percent voted moderate; 0 percent, low;
13 and 0 percent, insufficient.

14 MEMBER BILIMORIA: Moving onto
15 feasibility. This captures most of the surgeons
16 in the country and most of the programs. All the
17 data are already collected and well demonstrated
18 to be collected in a standard fashion. Question?
19 Go ahead.

20 CO-CHAIR FLEISHER: Collette?

21 MEMBER PITZEN: I just have a general
22 comment. We had talked about the size of the STS

1 Database. I was pretty sure the cardiac data
2 elements was around 800. I just double checked
3 again. It is 800 data elements for the cardiac
4 surgery database. So again, as a comment in
5 general, not picking on STS, again the cost
6 benefit of collecting data. And I just want to
7 say really unrelated to this measure, I am
8 supportive of this composite.

9 DR. SHAHIAN: Very quick response.
10 There are probably more than 800 elements
11 available, but not every one of them is coded for
12 every case and for a typical CABG or valve, much
13 fewer than that. Many of the elements are child
14 fields of parents, so once the parent field is
15 coded as no, all those child fields go away.

16 MEMBER PITZEN: I understand that.
17 It's still resource time to look in the record
18 and verify that initial process that the fields
19 don't apply.

20 CO-CHAIR GUNNAR: That was A.J.'s
21 point. It requires an extractor.

22 CO-CHAIR FLEISHER: Interesting

1 question for NQF for how we put this in
2 perspective. I don't think we've ever looked at
3 cost as part of our mandate.

4 DR. SHAHIAN: Having just spent \$1.2
5 billion at partners to implement Epic, that is
6 not without cost either.

7 MEMBER DUTTON: Lee, just very
8 quickly, the metrics that could be on there for
9 developers to show would be very helpful. The
10 total number of fields has been discussed, but
11 also the throughput of one abstracter in a year.
12 How many cases does one abstracter look at in a
13 year or put another way, how many abstracters do
14 I need to hire?

15 DR. SHAHIAN: We know that. It
16 averages between 300 and 500 cases per year per
17 abstracter, depending on the overall complexity
18 of the case mix.

19 MEMBER PITZEN: Thank you.

20 MEMBER BILIMORIA: I think we should
21 be a little careful about what we criticize.
22 Yesterday, we were picking on administrative data

1 and now we're criticizing what we were calling
2 the gold standard yesterday. This is why we like
3 the registries.

4 CO-CHAIR FLEISHER: I was reminded by
5 Melinda and Lisa and this is under feasibility is
6 the cost and the burden and so it is something if
7 this committee wants to see and it sounds like we
8 do the next time, want to see that as part of our
9 considerations. But I also heard you, Collette
10 and Karl.

11 So other comments? No. Can we vote?

12 MS. QUINNONEZ: Voting is now open for
13 the feasibility of measure 3030. Option 1 is
14 high; option 2, moderate; option 3, low; and
15 option 4, insufficient.

16 (Voting.)

17 Looking for two more votes.

18 (Voting.)

19 All votes are in and voting is now
20 closed. For the feasibility of measure 3030, 48
21 percent voted high; 48 percent voted moderate; 5
22 percent voted low; and 0 percent voted

1 insufficient.

2 MEMBER BILIMORIA: And then with
3 respect to usability and use, again it's in use,
4 most surgeons. And there hasn't been sort of a
5 national revolt yet, so I think it's in good
6 shape.

7 CO-CHAIR FLEISHER: But not publicly
8 reported yet.

9 MEMBER BILIMORIA: Not publicly
10 reported, not this particular measure, but some
11 of the components are.

12 CO-CHAIR GUNNAR: When did you start
13 giving positions, this data?

14 DR. BADHWAR: This will commence in --

15 DR. SHAHIAN: Later this year.

16 CO-CHAIR GUNNAR: So it has not come
17 out to be clear.

18 CO-CHAIR FLEISHER: Amy.

19 MEMBER MOYER: So two things on this,
20 first, thank you for the measure. Hopefully, I
21 didn't need to disclose. We've been cheering
22 this on from the sidelines, but not involved in

1 the measure.

2 I have a pro and a con. One of the
3 things that I appreciate about STS is that you
4 allow people who participate in your registry to
5 use their data as they see fit. That's something
6 all registries do and so that makes it easier for
7 them to use it and for us to work with them to
8 use in our programs.

9 We've already been discussing with
10 organizations in our state how this might be
11 publicly reported and one of the things we've
12 heard back is that apparently there's a
13 significant cost to them to license the data from
14 STS to formally publicly report. I've heard this
15 from the Wisconsin Collaborative for Healthcare
16 Quality.

17 So for them, that's a usability factor
18 that they're at least pushing back on us with. I
19 know it's not free. I can't imagine how much it
20 costs to develop this, so what are you going to
21 do? But just throwing that out there.

22 DR. SHAHIAN: Once a program receives

1 its scores, they can do anything they want with
2 it. So, for example, if they state work a
3 mandate that to do cardiac surgery in your state
4 you have to provide the state with your data, you
5 have the right to do that. You can do with your
6 data, whatever you want.

7 MEMBER MOYER: And I think that's
8 awesome.

9 DR. SHAHIAN: Yes, okay.

10 CO-CHAIR FLEISHER: Allan.

11 MEMBER SIPERSTEIN: Specific question
12 for the developer on the unintended consequence
13 of surgeons being shy to operate on the very
14 sickest of the patients. I know that you address
15 that quite nicely for the individual components
16 of this measure when we last reviewed them, but
17 has that been looked at for this particular
18 measure? Particularly, because we're now dealing
19 with individual attribution.

20 DR. BADHWAR: A general comment that
21 the concept of risk aversion, of course, is ever
22 present and something of major consideration for

1 all of our measures in the entire public
2 reporting initiative to which your question
3 reflects, so it's an important one.

4 However, the robustness of the risk
5 models really adjusts for all these, the sort of
6 I do the highest risk operations, so I'm not
7 going to do it because I'm being publicly
8 scrutinized. And that's something of
9 communication we focus on. So the risk models
10 are very focused on adjusting for those types of
11 high-risk patients to avoid the risk-aversion
12 behavior.

13 DR. SHAHIAN: One of the things about
14 risk aversion is that we always think of it as
15 negative, but there are three things that can
16 happen in a risk-averse environment. One is that
17 you can avoid operating on patients who should be
18 operated on. That's bad. The second thing is,
19 however, that you can avoid those patients who
20 are hopelessly ill. And the third thing is that
21 there's evidence from New York State that in a
22 public reporting environment that patients are

1 better matched to programs and surgeons who are
2 able to take care of them. So you may make the
3 surgeon of lesser ability risk adverse to take on
4 a higher-risk patient, but that patient's
5 probably going to get taken care at a much better
6 place for their problem. So risk aversion -- we
7 had to be careful about how we defined that. It
8 sometimes has advantages actually.

9 CO-CHAIR FLEISHER: So what I'm
10 hearing, since this is about to be rolled out as
11 in their maintenance a year from now, we'd like
12 for you to address how the plan is rolled out and
13 the risk aversion issue as part of the one year
14 and when it comes back for maintenance. Those
15 should be in the database of what we want to see
16 for re-endorsement.

17 Other comments before we vote on use
18 and usability? We're defining excellent points
19 which I think is part of our job. Is a part of
20 our job.

21 MEMBER TEMPLE: I clearly missed
22 something. Why is it coming back in a year, this

1 measure?

2 CO-CHAIR FLEISHER: All measures come
3 back with a report from maintenance. It usually
4 just goes to staff.

5 MEMBER TEMPLE: I see.

6 CO-CHAIR FLEISHER: No?

7 (Laughter.)

8 MS. MUNTHALI: So we have an annual
9 update process which allows developers to come to
10 us if there are changes to the measure. They're
11 typically coding changes, minor changes that
12 won't change the specifications significantly.

13 If those changes do change the
14 specification significantly, that would trigger
15 an ad hoc review and that would come back to the
16 committee.

17 CO-CHAIR FLEISHER: Thank you. But
18 that points out as we define some of the things
19 we're concerned about, if there's a change, it
20 will come back to the committee. If it's on
21 track with addressing your concerns, then it
22 could be just signed off or we might hear about

1 it.

2 Are we ready to vote?

3 MS. QUINNONEZ: Voting is now open for
4 usability and use of measure 3030. Option 1,
5 high; option 2, moderate; option 3, low; and
6 option 4, insufficient information.

7 (Voting.)

8 All votes are in and voting is now
9 closed. For the usability and use of measure
10 3030, 43 percent voted high; 52 voted moderate; 5
11 percent voted low; and 0 percent insufficient
12 information.

13 CO-CHAIR FLEISHER: Okay, what's next?
14 Endorsement. Okay, voting for endorsement. Any
15 last comments? No. Let's --

16 MS. QUINNONEZ: Voting is now open for
17 the overall suitability for endorsement of
18 measure 3030. Option 1, yes; option 2, no.

19 (Voting.)

20 Okay, all votes are in and voting is
21 now closed. For the overall suitability for
22 endorsement of measure 3030, 95 percent voted

1 yes; 5 percent voted no.

2 CO-CHAIR FLEISHER: Thank you. We
3 have 15 minutes to get through the last two, so
4 3031. Robert and John.

5 DR. BADHWAR: Measure 3031 --

6 CO-CHAIR FLEISHER: Robert is not on
7 today, right?

8 MEMBER HANDY: I'm the primary
9 discussant therefore.

10 CO-CHAIR FLEISHER: Okay, 3031.

11 DR. BADHWAR: Measure 3031 involves
12 mitral valve repair and/or replacement as a
13 composite score. And after CABG/AVR, AVR/CABG,
14 isolated mitral valve operations are the most
15 common procedures performed.

16 From July 2011 to June of 2014, 62,118
17 patients underwent mitral valve repair or
18 replacement plus or minus tricuspid valve repair
19 or a surgical ablation procedure or a PFO or ASD
20 closure which is considered to be part of the
21 mitral operation. Further discussion can happen
22 on that if you wish.

1 Of those patients, we looked at a two
2 domain composite of operative mortality and
3 absence of major morbidity. I won't be
4 repetitive, it's the same morbidity items of 5 as
5 mentioned earlier.

6 The missing evidence of this data
7 field was 0.5 percent for mortality and 0.4
8 percent for morbidity. The c-statistic was .746
9 for morbidity and .807 for mortality. The
10 scaling of the measure was .74 for mortality and
11 .26 for major morbidity.

12 Looking at the three-year reliability
13 testing, we settled on one case per month or 36
14 cases involving 462 sites or 52,841 patients who
15 were arriving at a reliability of .58 for the
16 measure. That concludes my summary.

17 CO-CHAIR FLEISHER: John.

18 MEMBER HANDY: The evidence is good
19 for this. I mean it's just got face validity
20 with regard to this being a composite score that
21 covers all the adverse outcomes possible.

22 CO-CHAIR GUNNAR: As this is a new

1 measure, I think we have to vote on the evidence.

2 MS. QUINNONEZ: We are now voting on
3 measure 3031. Voting is now open for the
4 evidence. Option 1, yes; option 2, no.

5 (Voting.)

6 Okay, all votes are in and voting is
7 now closed. For the evidence of measure 3031,
8 100 percent voted yes; 0 percent no.

9 CO-CHAIR FLEISHER: Gap.

10 MEMBER HANDY: So for gap was the as-
11 expected performers had a respective mortality
12 and measure of 3.2 and 16.9 percent and the lower
13 than expected performers were double both of
14 those. So that's a substantial gap.

15 Actually, the higher than performers
16 were about half of each of those.

17 CO-CHAIR FLEISHER: Comments? Let's
18 vote.

19 MS. QUINNONEZ: Voting is now open for
20 performance gap of measure 3031. Option 1, high;
21 option 2, moderate; option 3, low; and option 4,
22 insufficient.

1 (Voting.)

2 All votes are in and voting is now
3 closed. For performance gap of measure 3031, 50
4 percent voted high; 50 percent voted moderate; 0
5 percent for low; and 0 percent insufficient.

6 MEMBER HANDY: So for the composite
7 construct, the reason for putting this measure
8 forward is that the mortality associated with
9 mitral valve surgery is low. And this gives you
10 a more protean picture of the surgical
11 experience. So I think this is a high quality
12 construct.

13 MEMBER EREKSON: So I have to say I
14 really like this measure in combining the
15 morbidity and mortality and giving us a little
16 bit more information. If I had a wish list of
17 everything that STS could do for us, when they
18 lead the way in showing us to look at these
19 quality metrics, I would love to see more
20 functional status six months and a year down the
21 road in future measures. And I know that's
22 probably something that you guys would love to

1 capture as well. But I really like this measure
2 in combining the mortality and the morbidity.

3 DR. BADHWAR: We share your comments.

4 CO-CHAIR FLEISHER: Great. Are we
5 ready to vote?

6 MS. QUINNONEZ: Voting is now open for
7 the composite for measure 3031. Option 1, high;
8 option 2, moderate; option 3, low; and option 4,
9 insufficient.

10 (Voting.)

11 Looking for three more, two more
12 votes. Okay, all votes are in and voting is now
13 closed. For the composite of measure 3031, 84
14 percent voted high; 16 percent voted moderate; 0
15 percent for low; and 0 percent insufficient.

16 CO-CHAIR FLEISHER: Yes, A.J.

17 MEMBER YATES: We're in middle of
18 this, but the disparity information could use a
19 real quick explanation because there's a lot of P
20 values less than .001 and it looks to me like
21 those are all correlating with being under 65.
22 But if we could go to the disparity list, it's

1 the chart with the -- it's under gap -- right
2 there. Go up.

3 And am I to understand that all those
4 things are patients under 65 or does ethnicity
5 have a significant factor?

6 DR. BADHWAR: So that goes into the
7 logistic regression model as you can see there.
8 So we adjust for those items to your point.

9 MEMBER YATES: Right. We're looking
10 at the order. I don't want to drag it out, but
11 is -- are we interpreting --

12 CO-CHAIR FLEISHER: Is race separate
13 from the insurance? So the insurance status is
14 one characteristic and then race is a separate
15 one, correct?

16 DR. BADHWAR: Correct.

17 CO-CHAIR FLEISHER: It's not related
18 to the above or below 65?

19 DR. BADHWAR: That's correct.

20 MEMBER YATES: So race did stand out
21 as something that was important in this case?

22 CO-CHAIR FLEISHER: Yes, but this is

1 what we want to see so that we can correct it and
2 be transparent about this.

3 DR. BADHWAR: Exactly correct.

4 MEMBER YATES: It went by. It was
5 hard to read the chart.

6 CO-CHAIR FLEISHER: Thank you.
7 Reliability.

8 MEMBER HANDY: Reliability was high
9 for the three years' worth of data that was
10 tested. You have to have a case cut off of 36
11 cases so it's about a case per month over 3 years
12 was 0.58.

13 CO-CHAIR FLEISHER: Other comments?
14 No. Shall we vote?

15 MS. QUINNONEZ: Voting is now open for
16 reliability of measure 3031. Option 1, high;
17 option 2, moderate; option 3, low; and option 4,
18 insufficient.

19 (Voting.)

20 CO-CHAIR FLEISHER: Validity.

21 MS. QUINNONEZ: All votes are in and
22 voting is now closed. For the reliability of

1 measure 3031, 79 percent voted high; 21 percent
2 voted moderate; 0 percent low; and 0 percent
3 insufficient.

4 MEMBER HANDY: So for validity that
5 was sort of demonstrated by looking at fairly
6 consistent performance over the two time frames
7 that were looked at. They were overlapping time
8 frames, 2011 to 2014 and 2012 to 2015. So that
9 was considered therefore valid.

10 CO-CHAIR FLEISHER: Comments? No.

11 MS. QUINNONEZ: Voting is now open for
12 validity of measure 3031. Option 1, high; option
13 2, moderate; option 3, low; and option 4,
14 insufficient.

15 (Voting.)

16 All votes are in and voting is now
17 closed. For the validity of measure 3031, 58
18 percent voted high; 42 percent voted moderate; 0
19 percent voted low; and 0 voted sufficient.

20 MEMBER HANDY: Nothing new to add
21 regarding feasibility.

22 CO-CHAIR FLEISHER: Would anybody like

1 to vote on that? Is it similar to the others?

2 MEMBER HANDY: Probably because it's
3 a new measure we --

4 CO-CHAIR FLEISHER: Okay, we'll go
5 ahead and vote.

6 MS. QUINNONEZ: Voting is now open for
7 feasibility of measure 3031. Option 1, high;
8 option 2, moderate; option 3, low; and option 4,
9 insufficient.

10 (Voting.)

11 All votes are in and voting is now
12 closed. For feasibility of measure 3031, 63
13 percent voted high; 26 percent voted moderate; 11
14 percent voted low; and 0 percent voted
15 insufficient.

16 MEMBER HANDY: Same is true for
17 usability.

18 MS. QUINNONEZ: Voting is now open for
19 usability and use of measure 3031. Option 1 is
20 high; option 2 is moderate; option 3 is low; and
21 option 4, insufficient information.

22 (Voting.)

1 All votes are in and voting is now
2 closed. For usability and use of measure 3031,
3 58 percent voted high; 42 percent voted moderate;
4 0 percent for low; and 0 percent for insufficient
5 information.

6 CO-CHAIR FLEISHER: Okay, Melinda
7 pointed out that many of these outcome measures
8 have face validity and therefore their validity
9 cannot be high. So the answer is that the
10 maximum is moderate.

11 Is there any who are uncomfortable
12 moving any high to moderate as a top level? So
13 essentially all high votes will now be reflected
14 as moderate votes where that is the top option.
15 Comments?

16 CO-CHAIR GUNNAR: Congratulations to
17 those who voted moderate.

18 CO-CHAIR FLEISHER: They got it right.

19 CO-CHAIR GUNNAR: They got it right.

20 CO-CHAIR FLEISHER: That gets them
21 another six years on this committee. No.

22 DR. SHAHIAN: Can I just make one

1 comment? I don't believe that face validity has
2 been the only type of validity demonstrated by
3 the developers.

4 Construct validity, for example, the
5 correlation of the rating categories with other
6 measures' predictive validity. And that was
7 mentioned. So I don't think face validity was
8 the only measure of validity that we
9 demonstrated.

10 MS. MURPHY: Okay, so we'll go back
11 and look. What we have from the submissions, as
12 we understand them is that that's where they sit
13 at this moment, but we'll go back and check and
14 if that is the case, we'll correct it with the
15 group and reflect that.

16 MEMBER BILIMORIA: I would agree with
17 that in the measures that we reviewed. It was
18 not just case validity. There were other things
19 mentioned in the documents.

20 CO-CHAIR FLEISHER: Next. Suitability
21 for endorsement. Please vote.

22 MS. QUINNONEZ: Voting is now open for

1 overall suitability for endorsement of measure
2 3031. Option 1 is yes. Option 2 is no.

3 (Voting.)

4 All votes are in and voting is now
5 closed. For overall suitability for endorsement
6 of measure 3031, 100 percent voted yes; 0 percent
7 voted no.

8 CO-CHAIR FLEISHER: Okay, we are now
9 down to the final measure, 3032. We have three
10 minutes within the time frame of when we're
11 supposed to be closed. So we'll assume that that
12 is an ex-surgical closure, so we have about 15
13 minutes left when we do the timing.

14 (Laughter.)

15 DR. BADHWAR: They have an hour to
16 wake up their patients.

17 CO-CHAIR FLEISHER: I know that, too.

18 DR. BADHWAR: We have faster PAs where
19 we are.

20 (Laughter.)

21 CO-CHAIR FLEISHER: We've been
22 exchanging this all week. So if you could just

1 briefly go into that.

2 DR. BADHWAR: So briefly after the
3 aforementioned operations previously discussed,
4 mitral valve repair/replacement plus CABG is the
5 next most common operative procedure for measure
6 3032. And this involves a similar data set from
7 July 2011 to June 2014 where 26,355 cases were
8 analyzed and for at least 10 patients over the 3-
9 year period.

10 The missing evidence was .55 for
11 mortality, .44 for morbidity, the same two domain
12 composite exactly as the previous measure.

13 The scalability of the composite was
14 .78 for mortality, .22 for morbidity with a c-
15 statistic of .708 for morbidity and .738 for
16 mortality, arriving at a reliability for 25 cases
17 over three years and 341 sites or 18,924 patients
18 at .50.

19 MEMBER HANDY: Me still. Nothing to
20 add. This is the same measure, just with
21 coronary bypass thrown in.

22 CO-CHAIR FLEISHER: So -- and this is

1 a new measure.

2 MEMBER HANDY: A new measure also.
3 New composite measure.

4 CO-CHAIR FLEISHER: So we will need to
5 vote.

6 MS. QUINNONEZ: Voting is now open for
7 measure 3032. We're voting on evidence. Option
8 1 is yes. Option 2 is now.

9 (Voting.)

10 Voting is now closed. One hundred
11 percent voted yes for the evidence of measure
12 3032 and 0 percent voted no.

13 CO-CHAIR FLEISHER: Next.

14 MEMBER HANDY: In the gap, this was as
15 expected performers had a mortality and morbidity
16 of 6.5 and 29 percent, respectively. And it was
17 for those that were lower than expected
18 performers. That was about double and for those
19 that were higher than expected it was not quite
20 half, actually. It was just somewhat approved,
21 4.3 versus 19.8 percent. So there is a gap.

22 CO-CHAIR FLEISHER: Any comments?

1 Ready to vote.

2 MS. QUINNONEZ: Voting is now open for
3 performance gap of measure 3032. Option 1, high;
4 option 2, moderate; option 3, low; option 4,
5 insufficient.

6 (Voting.)

7 All votes are in and voting is now
8 closed. For performance gap of measure 3032, 63
9 percent voted high; 37 percent voted moderate; 0
10 percent voted low; and 0 percent voted
11 insufficient.

12 MEMBER HANDY: So for the quality
13 construct the same comments apply to this
14 measure, too, is that mortality is low and
15 therefore a more global protean picture of
16 combined mortality and morbidity, gives you more
17 accurate picture of the performance. Quality
18 construct is good.

19 CO-CHAIR FLEISHER: Comments? No.

20 MS. QUINNONEZ: Voting is now open for
21 composite of measure 3032. Option 1, high;
22 option 2, moderate; option 3, low; option 4,

1 insufficient.

2 (Voting.)

3 All votes are in. Voting is now
4 closed. For the composite of measure 3032, 74
5 percent voted high; 26 percent voted moderate; 0
6 percent for low; and 0 percent insufficient.

7 MEMBER HANDY: So for reliability of
8 the three years' worth of data for the
9 participants that had at least 25 cases, the
10 reliability was 0.5.

11 CO-CHAIR FLEISHER: Is this any
12 different than --

13 MEMBER HANDY: A little smaller number
14 with the last measure I think it was 0.57.

15 CO-CHAIR FLEISHER: So do you
16 recommend voting?

17 MEMBER HANDY: Yes.

18 MS. QUINNONEZ: Voting is now open for
19 reliability of measure 3032. Option 1, high;
20 option 2, moderate; option 3, low; and option 4,
21 insufficient.

22 (Voting.)

1 All votes are in. Voting is now
2 closed. For the reliability of measure 3032, 55
3 percent voted high; 45 percent voted moderate; 0
4 percent for low; and 0 percent insufficient.

5 MEMBER HANDY: So the same comments
6 about validity for this measure apply for the
7 last two measures.

8 CO-CHAIR FLEISHER: Further comments
9 about our discussion with validity?

10 MS. MURPHY: They should go ahead and
11 vote. Given the discussion, you should -- if
12 you're voting as opposed to carrying the other
13 votes forward, you should continue to vote
14 high/moderate because there is the issue that we
15 have to resolve.

16 MS. QUINNONEZ: Voting is now open for
17 validity of measure 3032. Option 1, high; option
18 2, moderate; option 3, low; and option 4,
19 insufficient.

20 CO-CHAIR GUNNAR: But this is a test.

21 MS. QUINNONEZ: All votes are in and
22 voting is now closed. Sixty percent voted high;

1 40 percent voted moderate; 0 percent low; and 0
2 percent insufficient.

3 CO-CHAIR FLEISHER: Construct.

4 MEMBER HANDY: Same comments as the
5 last two measures.

6 MS. QUINNONEZ: Voting is open, is now
7 open for composite of scientific acceptability of
8 measure 3032. Option 1, high; option 2,
9 moderate; option 3, low; and option 4,
10 insufficient.

11 (Voting.)

12 Looking for two more votes.

13 (Voting.)

14 Voting is now closed. For the
15 composite construct of measure 3032, 78 percent
16 voted high; 22 percent voted moderate; 0 percent
17 voted low; and 0 percent voted insufficient.

18 MEMBER HANDY: So usability is high.
19 Sorry, I didn't really we jumped -- also high.

20 MS. QUINNONEZ: Voting is now open for
21 the feasibility of measure 3032. Option 1, high;
22 option 2, moderate; option 3, low; and option 4,

1 insufficient.

2 (Voting.)

3 Voting is now closed. For the
4 feasibility of measure 3032, 63 document voted
5 high; 26 percent voted moderate; 11 percent voted
6 low; and 0 percent insufficient.

7 CO-CHAIR FLEISHER: Any comments?

8 MS. QUINNONEZ: Voting is now open for
9 usability and use of measure 3032. Option 1,
10 high; option 2, moderate; option 3, low; and
11 option 4, insufficient information.

12 (Voting.)

13 All votes are in and voting is now
14 closed. For the usability and use of measure
15 3032, 63 document voted high; 376 percent voted
16 moderate; 0 percent voted low; and 0 percent
17 insufficient information.

18 CO-CHAIR FLEISHER: Any comments
19 before we vote on overall suitability? No,
20 please vote.

21 MS. QUINNONEZ: Voting is now open for
22 overall suitability for endorsement of measure

1 3032. Option 1 is yes. Option 2 is no.

2 CO-CHAIR FLEISHER: Cliff, you were
3 clearly right. I misjudged the end. The patient
4 is still asleep. So we actually beat our
5 anticipated time and we're only off 7 minutes
6 from being off an hour and 30 minutes.

7 (Voting.)

8 MS. QUINNONEZ: For the overall
9 suitability for endorsement of measure 3032, 100
10 percent voted yes; 0 percent voted no.

11 CO-CHAIR FLEISHER: So we will take a
12 break, a ten-minute break. And then we will get
13 Bruce, you're ready, you're up next.

14 DR. BADHWAR: Thanks very much.

15 CO-CHAIR FLEISHER: Thank you. Thank
16 you for staying. We really appreciate it.

17 (Whereupon, the above-entitled matter
18 went off the record at 10:06 a.m. and resumed at
19 10:17 a.m.)

20 CO-CHAIR GUNNAR: Yes, we already had
21 the two-minute warning, so coming back.

22 So Liz, you know you're on this solo?

1 Are we ready, Christy?

2 So the next measure is 0697, risk-
3 adjusted case mix adjusted elderly surgery
4 outcomes measure. American College of Surgeons
5 and developers, you have three minutes to provide
6 an overview.

7 DR. HALL: Thank you, Dr. Gunnar and
8 Dr. Fletcher. Thank you, committee. I'm Bruce
9 Hall. I'm a surgeon at Wash. U. in St. Louis and
10 the Vice President in the BJC HealthCare System.
11 I'm representing the American College of Surgeons
12 today with Dr. Julia Berian next to me, who is
13 one of our surgical scholars who has worked
14 intently on this work.

15 We also have our senior scientist on
16 the phone, Dr. Mark Cohen, and obviously, Dr. Ko
17 is here, but is abstaining from the discussion
18 with respect to this measure.

19 Dr. Fleisher and Dr. Gunner advised me
20 to make a few brief remarks. We'll be happy to
21 return to any category where there are more
22 specific questions.

1 We're starting with the first of two
2 measures in front of you for maintenance today,
3 the elderly measure which has been in use since
4 2011. It is a risk-adjusted measure of outcomes,
5 death or serious mortality. That's death,
6 returned to OR unanticipated, and 12 other
7 mortalities, rigorously defined.

8 And importantly, this is a measure of
9 30-day outcomes, strict 30-day time horizon which
10 really differentiates us from many other quality
11 measurement programs. This measure focuses on
12 patients 65 and older and has a denominator of
13 2900 CPT codes. Notably, we have removed VTE
14 from the prior specification of this measure
15 which we can describe in more detail, but that
16 was done because of the recently revealed bias in
17 that that has been widely published, and we
18 investigated, but did not add socio-demographic
19 factors which I'll be happy to comment on.

20 The NSQIP in the private sector has
21 been in place for 11 years or more and as you
22 know in the VA the parallel program has been in

1 place probably twice that long. We've had five
2 measures in front of the NQF and are just
3 discussing two today.

4 We don't feel, under the category of
5 importance, we don't feel there's major change to
6 evidence. We do continue to demonstrate a
7 variance in care. Almost 40 percent variance in
8 care and we do continue to demonstrate ability to
9 detect outliers.

10 In the category of scientific
11 criteria, in terms of both reliability and
12 validity, there are several aspects of how we
13 specify our data fields and our program that
14 yield high reliability and validity. That
15 includes rigorous definitions, trained data
16 collectors who are also examined, a community of
17 data collectors continuously exchanging best
18 practices.

19 We also audit nationally more than
20 12,000 data fields per year and have a national
21 community which meets annually. We importantly
22 provide feedback and revision from all national

1 users to our program in Chicago so that our data
2 fields and variables are constantly scrutinized
3 and revised over time and that includes some
4 variables that have been in place for 11 plus
5 years, as I mentioned.

6 Institutions also perform internal
7 inter-rater reliability auditing and that is fed
8 back to the college for continuous improvement of
9 all of our data fields.

10 In terms of validity specifically, we
11 have an outcome measure here which has inherent
12 face validity as you have mentioned, but we also
13 feel that we are representing an expert panel, so
14 to speak, of more than 30,000 surgeons who have
15 been using these data fields and this measure for
16 years now. And particularly in the geriatric
17 aspects of our program, we have a focused
18 steering group and expert panel that provides
19 sort of validity feedback, if you will, on all of
20 the aspects of these data fields in this measure.
21 And based on that, we've also shown widely across
22 the program the programmatic improvement. And so

1 again, evidence of validity of various kinds.

2 The risk adjustment for this measure
3 involves three main factors, the patient's ASA
4 class CPT code linear risk and the patient's
5 functional status. And so those represent both
6 the patient's biology, the procedural endogenous
7 risk, and then we turn those into obviously the
8 reported hospital effect. It is a hierarchical
9 adjustment scheme which does involve Bayesian
10 smoothing which has more or less become standard
11 across NQF measures nowadays.

12 And we are dealing with a focused
13 population here. Obviously, 65 and older,
14 largely Medicare covered and somewhat focused in
15 terms of biology and presentation. As I
16 mentioned, we investigated SDS and I've not
17 included which I can describe in more detail and
18 we have removed VTE.

19 In terms of feasibility, we have again
20 almost 800 hospitals and 30,000 surgeons using
21 this measure and like measures across the country
22 now. So we know that it's feasible and useable.

1 And for whatever burden is attached to the way we
2 specify data, I want to just emphasize that
3 because we're using a strict 30-day time horizon
4 which differentiates us from most every other
5 program in the country, that there is a bit of a
6 tradeoff there between burden and complexity and
7 unique added value of our program.

8 We do also know the true cost of
9 participation in our program. The subscription
10 fee in our program now varies between \$10,000 and
11 \$25,000 and you basically need some fraction of
12 an FTE varying between one quarter and one. And
13 if it's one, then you're going to pay that person
14 probably \$70,000. Then you are talking about a
15 participation cost annually of something like
16 \$75,000 to \$100,000. However, that covers 200
17 models across a variety of surgical specialties.
18 So to say that that's the true cost of this
19 measure in front of you would not be accurate.
20 This measure in front of you represents probably
21 less than a percent of everything that is
22 obtained by participation in our program. So the

1 true cost is actually substantially smaller than
2 what it might first appear to be.

3 With that, I'll pause and I'm happy to
4 take further questions as the categories arise.

5 CO-CHAIR GUNNAR: Dr. Erekson.

6 MEMBER EREKSON: So I think the first
7 thing to talk about, this is an already-approved
8 measure coming up for renewal, so the first thing
9 to talk about is evidence. One of the new pieces
10 of evidence that came out since this measure was
11 first approved was the joint statement from the
12 American College of Surgeons and the American
13 Geriatric Society about optimal preoperative
14 care. And I think that only advances that there
15 is good evidence that there are processes that we
16 can do to perform -- to affect quality
17 performance in this area.

18 The question from the NQF staffers is
19 why wasn't this measure inclusive of patients
20 younger than the age of 65, and then the other
21 question by people who completed the survey
22 before our meeting was why aren't we looking at

1 people over the age of -- higher age ranges.

2 So we're looking at patients who are 80 and
3 over; is that going to get us more bang for our
4 buck? I don't think there is the perfect age to
5 set that cutoff at. I think there is good data
6 to show that there is cognitive impact at the age
7 of 60 that undergoing surgery could have some
8 effects, and so I think the age of 65 is
9 acceptable. So we could vote on new evidence, or
10 we could leave it as is.

11 CO-CHAIR GUNNAR: So what's your
12 recommendation? Should we vote on evidence, Dr.
13 Erekson?

14 MEMBER EREKSON: I would say no.

15 CO-CHAIR GUNNAR: Okay, Dr. Dutton.

16 MEMBER DUTTON: Just a question for
17 any of the smart people in the room. We tossed
18 out DVT. I get that. But we also tossed out PE
19 with that. Is PE better defined? It's obviously
20 a very serious outcome for the patient. Should
21 that have been kept in?

22 DR. HALL: We can comment. The PE

1 side of that equation is much more rare than the
2 DVT side of that equation, so as a rare event it
3 has an even smaller impact on our assessments.
4 We do find that combined, there was an impact on
5 assessments, but we feel that it's a biased
6 impact. That was our decision for this program.

7 MEMBER BILIMORIA: The literature also
8 shows that the same surveillance bias is visit
9 for PE when examined separately, especially with
10 new CT scanners picking up smaller and smaller
11 sub-clinical PEs. So the same impact is seen as
12 DVT.

13 CO-CHAIR GUNNAR: Moving along, does
14 anyone feel that we need to vote on evidence?
15 Hearing none, we'll go to gap.

16 MEMBER EREKSON: So currently, in the
17 measure description, there are 460 hospitals that
18 participate in the ACS NSQIP which is not a full
19 penetrance across the country. But you have a
20 good spread of risk adjusted O/E ratios between
21 0.59 and 1.69.

22 In the body of the measure, the

1 measure developers cite that there are 49 low
2 outlying hospitals and 34 high-outlier hospitals
3 that are statistically significant, representing
4 a gap.

5 CO-CHAIR GUNNAR: Any additional
6 comments? We'll vote on gap.

7 MS. QUINNONEZ: We are now voting on
8 measure 0697. Voting is now open for performance
9 gap. Option 1, high; option 2, moderate; option
10 3, low; and option 4, insufficient.

11 (Voting.)

12 MS. QUINNONEZ: All votes are in.
13 Voting is now closed. For the performance gap of
14 measure 0697 45 percent voted high; 55 percent
15 voted moderate; 0 percent low; and 0 percent
16 insufficient.

17 CO-CHAIR GUNNAR: Next for
18 reliability.

19 MEMBER EREKSON: So for reliability
20 testing, I think we've already been presented
21 data showing the data element reliability of the
22 ACS NSQIP. What the authors and the developer

1 did in addition is they tested the reliability of
2 their modeling programs, and they actually
3 published this in the peer-reviewed literature
4 and included that article in this measure
5 submission.

6 For this measure, the sample size that
7 a hospital would need to achieve to have
8 reliability at a threshold of 0.4 which is what
9 they propose as moderate reliability is 180
10 cases, and they report that 85 percent of their
11 hospitals meet this threshold.

12 CO-CHAIR GUNNAR: Any other comments?

13 We can vote.

14 MS. QUINNONEZ: Okay, voting is now
15 open for reliability of measure 0697. Option 1,
16 high; option 2, moderate; option 3, low; and
17 option 4, insufficient.

18 (Voting.)

19 MS. QUINNONEZ: Voting is now closed.
20 For reliability of measure 0697, 53 percent voted
21 high; 47 percent voted moderate; 0 percent low;
22 and 0 percent insufficient.

1 CO-CHAIR GUNNAR: Validity, please.

2 MEMBER EREKSON: So I think this is
3 the appropriate place to talk about what the
4 NSQIP does monitor and doesn't monitor in terms
5 of outcomes. And when you look at outcomes in the
6 geriatric population, some of the things that are
7 very meaningful cannot be captured in the NSQIP.
8 That would include post-operative delirium that
9 has to be caught, and it's not very reliable to
10 find post-operative delirium in chart reviews.
11 That also includes falls outside of the hospital,
12 which are also not incorporated in the NSQIP.

13 What the NSQIP does very well is they
14 are incorporating functional status, and a lot of
15 the things that others, not even just the NSQIP,
16 have shown had been very predictive in these --
17 in geriatric surgery.

18 So the first thing is that while we
19 don't have everything that we would like to have
20 in a geriatric model of what surgery is, we have
21 a lot. And then when you go on to the validity
22 of the actual models, we have a c-statistic of

1 .75 to .77. And there is good data provided on
2 including the SE status, not including the SE
3 status and inclusion of the venous --

4 CO-CHAIR GUNNAR: Collette?

5 MEMBER PITZEN: Yes, I'm wondering if
6 you could comment a little bit about the validity
7 of the data that's collected in NSQIP versus
8 perhaps against the medical record?

9 DR. HALL: I will take that question
10 and I would like to just let Dr. Berian comment
11 on the last remark first if that's okay.

12 DR. BERIAN: So I did want to comment
13 for the record that we have a Geriatric Surgery
14 Pilot Project that includes 26 different
15 hospitals which are attempting to collect some of
16 those more kind of patient-centered variables
17 including things like delirium, mobility,
18 functional status later down the road after an
19 operation.

20 DR. HALL: In terms of the validity of
21 the fields that we do capture, again, we have
22 fields that have largely been in place for ten-

1 plus years and have been used by tens of
2 thousands of surgeons demonstrating that
3 improvement can occur using these fields, so I
4 think in terms of what you often see for validity
5 assessment is an expert panel. You may have
6 eight experts and six of them say yes, it looks
7 valid to me.

8 In fact, I think in this case, you've
9 got 30,000 surgeons who have said over the past
10 decade these are valid to us because we're
11 participating, we're using them, and we're
12 driving improvement with them. So I would say
13 whether you want to call that only isolated face
14 validity, or however you want to consider that, I
15 think it's good evidence of practical validity in
16 this case.

17 MEMBER PITZEN: Right. To clarify, I
18 was talking more about the data element validity.
19 So if you were looking for complications of wound
20 disruption or infection, deep incisional surgical
21 site, do you have some prior testing where you
22 are looking at a sample of what's submitted into

1 the registry versus what's reflected in the
2 patient record?

3 DR. HALL: Yes, I'm sorry. So in that
4 case, we would consider that a form of
5 reproducibility at the data element level, and as
6 I said, we audit programs annually across the
7 country. We shoot for between 5 and 10 percent
8 of all programs being audited annually which
9 means something like 10,000 to 15,000 fields get
10 audited. And across variables, our
11 reproducibility or our inter-rater reliability is
12 uniformly 97 to 98 percent.

13 MEMBER PITZEN: That's fabulous.
14 Probably for a future application, you could
15 include that, and I wouldn't have any questions.

16 DR. HALL: Thank you. I think it's
17 stated in one way or another in the material, but
18 we can clarify.

19 MEMBER PITZEN: Okay. Thank you.

20 DR. HALL: Thank you.

21 CO-CHAIR GUNNAR: Lee.

22 CO-CHAIR FLEISHER: I may have missed

1 the reliability, but after the 30-day mortality
2 in CABG I got lots of calls from The New York
3 Times, ended up in The Times, related to the
4 unintended consequence of cutting off the 30 days
5 and therefore potentially individuals at day 31
6 being put on palliative care. And I don't know
7 if that's validity or reliability. But have you
8 looked at whether or not your 30-day outcomes are
9 having unintended consequences?

10 DR. HALL: Well, that's a very
11 insightful and also complex question. What we
12 can tell you is that we have looked at the decay
13 function, the time decay function of different
14 outcomes over time. We know that no outcome is
15 100 percent captured at 30 days. But that the
16 rate of capture decays dramatically over time
17 with slightly different curves for different
18 outcomes.

19 And what we have decided over the
20 years is that the 30-day cutoff is a balance of
21 capturing enough of those signals to generate
22 good quality improvement versus the ongoing

1 burden of following patients longer and longer in
2 outlying settings. So that's part one.

3 Part two is --

4 CO-CHAIR FLEISHER: I'm talking about
5 inpatient, in other words, dying at day 31 in the
6 hospital.

7 DR. HALL: So yes, I think part two is
8 that we have not done a dedicated study on
9 whether patients are dying at day 31, but there
10 is such a study that's being -- that is coming
11 out in the literature now. It was not done by
12 our group. It was done by another group. So
13 there is a very good study appearing in the
14 literature now that indicates that there is no
15 such bias, but that was not done by us.

16 CO-CHAIR GUNNAR: Actually, I
17 published that study.

18 CO-CHAIR FLEISHER: Okay, good.

19 CO-CHAIR GUNNAR: In January.

20 CO-CHAIR FLEISHER: Can you send that?

21 CO-CHAIR GUNNAR: I can send it to
22 you. There is no bias.

1 DR. HALL: I didn't want to put you on
2 the spot.

3 CO-CHAIR FLEISHER: Where was it
4 published?

5 CO-CHAIR GUNNAR: JAMA Surgery.

6 CO-CHAIR FLEISHER: Thank you. When
7 they call us after this measure is approved --

8 DR. HALL: I didn't want to appear to
9 be sucking up to Dr. Gunnar.

10 (Laughter.)

11 CO-CHAIR GUNNAR: Any other -- Karl.

12 MEMBER EREKSON: I just had one other
13 comment for the developers. I didn't see because
14 this is a composite, so we lumped a bunch of
15 outcomes together to get to the composite score.
16 I didn't see in this measure submission what is
17 driving the composite.

18 Have you looked at, if you take out
19 let's say -- I know you looked at VTE, but did
20 you look at UTI? Is UTI driving the composite
21 because it's so much more common than some of
22 these other rare events? And can you comment on

1 whether or not those should be weighted in terms
2 of looking at the outcome or if they're not
3 weighted?

4 DR. HALL: Thank you, yes. So this is
5 what we refer to as an unweighted aggregate. We
6 don't consider this a composite. A true
7 composite would be where you actually model each
8 outcome, and then you aggregate the results of
9 those models. In fact, what we do is we create
10 an aggregate outcome. It's unweighted. Every
11 outcome in the aggregate is treated equally.

12 Over the years, based on experience
13 with hundreds of models across NSQIP, we have
14 removed a few things such as superficial
15 infections because superficial infections would
16 swamp other important events and drive the
17 composite.

18 And so we've reached this combination
19 of what we refer to as death or serious morbidity
20 based on the signals that we've seen across
21 hundreds of models over the last ten years.
22 They're not weighted. Each is treated equally,

1 so in answer to that part of your question, it's
2 an unweighted aggregate outcome. Does that
3 answer the question? Okay, thanks.

4 CO-CHAIR GUNNAR: A.J.

5 MEMBER YATES: Yes, I would just
6 second what was just said and others. Ideally,
7 the NQF's endorsed measures are patient-centric,
8 and so you would want to have some sense of what
9 has import to the patient. And I dare to say
10 that if you were to do a Delphi on this and count
11 7 to 10 as being dire outcomes to the patient,
12 they probably wouldn't rank an asymptomatic
13 urinary tract infection or an incidental pickup
14 of pneumonia on a chest x-ray as a dire outcome.

15 And so it really comes down to a lot
16 of the -- if you have a hospital that is very --
17 most of them are backing off now, but if you have
18 a hospital that's adamant about its fevers of
19 unknown origin, work up on post-update, too,
20 they're going to have a lot more little
21 pneumonias or over-called pneumonias and urinary
22 tract infections. It all depends on the

1 diagnostic intensity. So you don't have the
2 denominator of how many tests are being ordered
3 from one place or another. That's already been
4 addressed. It's not weighted. It's the way it
5 is. It's how you have your data over ten years.
6 It won't change probably. But I would just throw
7 out to you that it would be good to weight that
8 with patient preference or patient weighting of
9 that.

10 The one question that you might want
11 to answer or change would be, you exclude major
12 trauma. Is the major trauma exclusion based on a
13 trauma score, which you know, there's good
14 scoring for that. Or is that an arbitrary, this
15 is major, or that's minor? Because with trauma
16 scores that are out there, it would be easy
17 enough to make somebody, you know, above a 5
18 major, and below minor.

19 DR. HALL: Thank you, two great
20 insights. First on the aspects of the aggregate
21 that you mentioned, for instance, we don't
22 capture asymptomatic "UTIs". We don't capture

1 what are not true pneumonias. Our specifications
2 are fairly rigorous. And I think that goes part
3 way towards smoothing out that effect that you
4 mentioned of perhaps different importance for
5 different fields to patients. But that's not
6 unique to us.

7 We've just heard about combining death
8 and other morbidities for different cardiac
9 procedures as well. And weighting these outcomes
10 by patient-graded severity is something that our
11 profession as a whole is struggling with, and it
12 does apply to us, but it does not uniquely apply
13 to us. All of us in the profession are
14 struggling with that right now.

15 On the second aspect of your question,
16 which was?

17 MEMBER YATES: The fact that there's
18 trauma scores that exist, so are you delineating
19 major versus minor traumas by the score?

20 DR. HALL: We are not using trauma
21 score to do that. We're using a diagnosis
22 category to do that, so if the patient has a

1 diagnostic code of trauma, then they're excluded.
2 There are some minor traumas which we still
3 allow, such as an isolated fracture or same level
4 fall, but otherwise, any diagnostic code that
5 indicates major or multi-system trauma gets
6 excluded. In fact, we don't even -- it's not
7 excluded in terms of actually being captured and
8 then excluded. It's just they're not even
9 eligible for accrual.

10 Our patient population is a focused
11 population. It does not include transplant
12 surgery. It does not include major or multi-
13 system traumas.

14 DR. HALL: And I would just say that
15 even isolated fractures that come in, it depends
16 on how they arrive there, and if they come in by
17 chopper, and they were extracted, they may have
18 an isolated fracture when it's all said and done.
19 But in the meanwhile, they've got the three CT
20 scans are already done, cooked, and have to
21 billed for, and so they get coded out potentially
22 as a trauma.

1 MEMBER YATES: Yes, I don't disagree
2 that there are potential shortcomings in the way
3 we code in our profession absolutely. But any
4 diagnosis of major multi-system trauma would be
5 excluded.

6 DR. HALL: Ms. Whitaker.

7 MEMBER WHITAKER: Thank you. In the
8 numerator, are you including other -- if a
9 patient leaves the hospital where they had the
10 surgery and then is readmitted to another
11 hospital for one of those factors? Or dies at
12 home?

13 DR. HALL: We -- if we learn about a
14 death that occurred at home within the 30-day
15 time period, it would be included. Readmissions
16 are not part of this measure if that was your
17 question.

18 MEMBER WHITAKER: I understand, but
19 admissions for one of the morbidities.

20 DR. HALL: Yes.

21 MEMBER WHITAKER: So surgery, then
22 followed by pneumonia or something like that.

1 DR. HALL: Right. So if, in fact, the
2 outcome in question happened outside of the
3 original hospitalization, then we rely on them
4 either coming back to the same hospital, or we
5 rely on communicating directly with the patient
6 and family to determine that that occurred, yes.

7 MEMBER WHITAKER: Thank you.

8 CO-CHAIR GUNNAR: So as an aside, we
9 welcome Dr. Whitaker who's new to the committee.
10 We'll all get to know her over the next couple of
11 years.

12 So we're back to validity. Any other
13 comments? Amy.

14 MEMBER MOYER: I just want to make
15 sure I'm completely understanding the composite.
16 So the measure is the number of observed adverse
17 events. So if a patient has multiple things go
18 wrong, sometimes they start down the cascade, are
19 each of those separate events calculated into the
20 composite?

21 DR. HALL: So each of those different
22 separated events might be reported out under

1 different models, but in that case it would be
2 one case could only count as one event in the
3 overall model. But if a patient had pneumonia
4 and an MI, and we were modeling both of those in
5 separate models, we would report both. Overall,
6 they can only count once in the overall.

7 CO-CHAIR GUNNAR: Shall we vote on
8 validity?

9 MS. QUINNONEZ: Voting is now open for
10 validity of measure 0697. Option 1, moderate;
11 option 2, low; and option 3, insufficient.

12 (Voting.)

13 MS. QUINNONEZ: Voting is now closed.
14 For the validity of measure 0697, 68 percent
15 voted moderate; 32 percent voted low; and 0
16 percent voted insufficient.

17 CO-CHAIR GUNNAR: Moving on to
18 feasibility.

19 MS. JOHNSON: Excuse me. If you don't
20 mind, I'd like to just put in a little comment
21 here. The staff had originally assessed this as
22 an insufficient, mainly because the information

1 on testing was not included in the submission.
2 So you -- I'm assuming you have voted based on
3 what Dr. Hall mentioned in terms of their data
4 element testing. So what we will ask them to do
5 is go back. We will open up their forms so that
6 they can put that information into the
7 submission. We want everything to be very
8 transparent so that we understand why you guys
9 voted the way you did.

10 DR. HALL: And we did provide those
11 responses.

12 MS. JOHNSON: Did you go ahead and add
13 them into -- okay, yes, we need added into the
14 forms. Thank you very much.

15 CO-CHAIR GUNNAR: Feasibility.

16 MEMBER EREKSON: I think we've had a
17 lot of debate over the last day or two on claims
18 data versus registry data, and I don't have a lot
19 to add.

20 CO-CHAIR GUNNAR: Any other comments?
21 Go ahead and vote.

22 MS. QUINNONEZ: Voting is now open for

1 feasibility of measure 0697. Option 1, high;
2 option 2, moderate; option 3, low; and option 4,
3 insufficient.

4 (Voting.)

5 MS. QUINNONEZ: All votes are in.
6 Voting is now closed. For the feasibility of
7 measure 0697, 21 percent voted high; 79 percent
8 voted moderate; 0 percent voted low; and 0
9 percent voted insufficient.

10 CO-CHAIR GUNNAR: Moving on to use and
11 usability.

12 MEMBER EREKSON: As far as I can tell
13 from the submission, public reporting is an
14 aspect of this but is not required, so there's
15 currently 131 hospitals who publicly report out
16 of the 460 hospitals in the program.

17 DR. HALL: Correct, all of our
18 programs across the country are making use of
19 this information. And then inside of NSQIP, as
20 an institution, you can volunteer to publicly
21 report on Hospital Compare. So as you said, a
22 subpopulation of hospitals are already doing

1 that. But all the hospitals in the program are
2 making use of this information already.

3 CO-CHAIR GUNNAR: Any -- Collette.

4 MEMBER PITZEN: Just a quick question.
5 Are the participants in the database provided
6 back what happened for these patients so they can
7 drill down further on their data?

8 DR. HALL: Every case in this entire
9 -- in our entire registry program, if you will,
10 is transparent and visible to the institution.
11 You can reopen every single case and dive back
12 into all details.

13 MEMBER PITZEN: Right, so if I had
14 someone hit on this composite, I could drill down
15 at my own institution and see was it an MI; was
16 it a death, cardiac arrest, et cetera.

17 DR. HALL: Absolutely, yes.

18 MEMBER PITZEN: Thank you.

19 DR. HALL: The public can't do that.
20 That's not what you're asking, right? Okay.

21 CO-CHAIR GUNNAR: To -- yes, to
22 clarify, it's the extractor which is what -- it's

1 whoever has the data resource, they can drill
2 down.

3 MEMBER PITZEN: Yes, only comment to
4 the measures that I have grouped outcomes
5 together from a quality improvement standpoint to
6 the providers that are providing that care, if
7 they can understand their combined score better,
8 it can provide directions for them to work on.

9 DR. HALL: We agree. We absolutely
10 enable that.

11 CO-CHAIR GUNNAR: Any other comments
12 on usability and use? Hearing none.

13 MS. QUINNONEZ: Voting is now open for
14 usability and use of measure 0697. Option 1,
15 high; option 2, moderate; option 3, low; and
16 option 4, insufficient information.

17 (Voting.)

18 MS. QUINNONEZ: All votes are in.
19 Voting is now closed. For usability and use of
20 measure 0697, 57 percent voted high; 43 percent
21 voted moderate; 0 percent low; and 0 percent
22 insufficient information.

1 CO-CHAIR GUNNAR: Overall endorsement.

2 MS. QUINNONEZ: Voting is now open for
3 overall suitability for endorsement of measure
4 0697. Option 1, yes; option 2, no.

5 (Voting.)

6 MS. QUINNONEZ: All votes are in.
7 Voting is now closed. For the overall suitability
8 for endorsement of measure 0697, 100 percent voted
9 yes; 0 percent voted no.

10 CO-CHAIR GUNNAR: So we'll move on to
11 the second ACS measure which is for review which
12 is 0706, risk-adjusted colon surgery outcome
13 measure. This is a maintenance measure. Dr.
14 Hall?

15 DR. HALL: I can be even more brief.
16 This measure is very parallel to what we just
17 discussed. This is a maintenance measure that's
18 been in use since 2011. It is again a risk-
19 adjusted measurement of outcomes; the same death
20 or serious morbidity aggregate outcome at 30 days.
21 It's defined by a limited set of colon CPT codes.
22 Once again, we removed VTE from the prior

1 specification, and we investigated, but did not
2 add SDS factors.

3 My other comments are very parallel to
4 the prior, so I will just -- I'll stop there.

5 CO-CHAIR GUNNAR: Discussants are Drs.
6 Temple and Siperstein.

7 Clarissa.

8 MEMBER TEMPLE: I don't think we need
9 to review the evidence. We can move on.

10 CO-CHAIR GUNNAR: Yes, okay. Gap.
11 Anyone else want to vote on the evidence? Okay.

12 MEMBER TEMPLE: So there's clearly
13 differences in colon surgery outcomes. The
14 authors report differences in ethnicity, as well
15 as in socio-economic status and that there are
16 discrepancies in the country. They did not use --
17 Bruce, maybe you can clarify, but I didn't
18 actually see changes in this score between 2011
19 and now to sort of demonstrate an improvement
20 and/or that disparities exist with this O/E ratio.

21 DR. HALL: Right. Thank you. So the
22 odds ratio we see for this measure in the last

1 reporting period varies between about .66 and .14
2 at the 10/90 level. That's about a 40 percent
3 up/down, if you will. And within this measure, we
4 still do discriminate outliers even at the highest
5 statistical level, even at the 95 percent
6 confidence level. So if you convert that into
7 kind of a standardized rate which everyone knows
8 is just a construct and is not reality, but that
9 would reflect a standardized rate across the
10 country, that would vary from a 5 percent
11 complication rate to a 30-plus percent
12 complication rate. So that's the variance in
13 performance that we're talking about.

14 MEMBER TEMPLE: That's very, very
15 helpful. I just didn't see that. And so I think
16 that's clear, there's a very high performance gap.

17 CO-CHAIR GUNNAR: Dr. Siperstein,
18 anything else?

19 MEMBER SIPERSTEIN: I agree, there's a
20 high gap with this measure.

21 CO-CHAIR GUNNAR: Any other comments?
22 Go ahead and vote.

1 MS. QUINNONEZ: We are now voting on
2 measure 0706 for performance gap. Voting is now
3 open. Option 1, high; option 2, moderate; option
4 3, low; and option 4, insufficient.

5 (Voting.)

6 MS. QUINNONEZ: All votes are in.
7 Voting is now closed. For performance gap of
8 measure 0706, 94 percent voted high; 6 percent
9 voted moderate; 0 percent for low; and 0 percent
10 voted insufficient.

11 CO-CHAIR GUNNAR: All right, moving on
12 to reliability. Dr. Temple.

13 MEMBER TEMPLE: So again, the numerator
14 and denominator are clear. The only piece that
15 perhaps you'd want to comment on is that the
16 reliability of .04 is present when there are 99
17 colon cases -- 91 or 99 cases reported in a given
18 year in NSQIP. So given the way the data is
19 captured, sometimes less than 99 cases would be
20 collected, unless you are doing a disease-specific
21 data entry. So do you want to comment on that?

22 DR. HALL: Sure. That's a very

1 insightful comment. In an implementation,
2 obviously, we would strive to have the
3 implementation specified that X number of cases
4 would need to be accrued. As Dr. Temple
5 indicated, our number looks to be about 199.

6 It is still possible that some
7 hospitals in the country might not do that many
8 colectomies in a year. We've identified from the
9 AHA database that that probably is the case, but
10 that is a larger policy problem than the problem
11 of internally in this metric. If some hospitals
12 are not doing enough cases to be evaluated on
13 quality, then that needs to be addressed in a
14 different way.

15 MEMBER TEMPLE: So when you report out
16 the O/E ratios for the various institutions, do
17 you actually report out the confidence intervals
18 as well?

19 DR. HALL: We do.

20 MEMBER TEMPLE: Okay.

21 DR. HALL: Yes.

22 CO-CHAIR GUNNAR: Any other comments on

1 reliability? Go ahead and vote.

2 MS. QUINNONEZ: Voting is now open for
3 the reliability of measure 0706. Option 1, high;
4 option 2, moderate; option 3, low; and option 4,
5 insufficient.

6 (Voting.)

7 MS. QUINNONEZ: All votes are in.
8 Voting is now closed. For the reliability of
9 measure 0706, 52 percent voted high; 48 percent
10 voted moderate; 0 percent voted low; and 0 percent
11 voted insufficient.

12 CO-CHAIR GUNNAR: Regarding validity,
13 the same applies as before, Karen?

14 MS. JOHNSON: Yes, we would ask you to
15 -- we will open up your forms and ask you to
16 insert the information that you mentioned earlier,
17 if that's the same.

18 MEMBER TEMPLE: So my only comment is
19 the same as well in that 10 UTIs is very different
20 than 10 deaths, and the way this measure works is
21 it's the same score for those two outcomes based
22 on my understanding. And so I think that's the

1 standard of measurement today, but I'd like to see
2 the standard of measurement with NSQIP different
3 in five years.

4 The other piece with the validity is
5 that the risk model is sort of not available.
6 It's clearly proprietary, and so just to comment
7 there's several publications with the risk model,
8 but it's not in the public domain to look at.

9 DR. HALL: Thank you again for those
10 comments. So we agree again, severity weighting
11 of outcomes is a challenge for all of us, not
12 unique to us, but we agree that our profession
13 needs to make some progress on that.

14 Our risk elements in the model are
15 provided. We didn't provide coefficients on them,
16 but we do state that if this were implemented
17 publicly that we would provide those
18 specifications to the public if that's the intent
19 of the measure.

20 Yes, Larry?

21 MEMBER MOSS: To the developers,
22 patients under 18 years of age are excluded. And

1 I understand that there's a strong clinical
2 rationale why you wouldn't lump them in this
3 particular measure, but I think it's important for
4 measure development and specifications that it be
5 noted as an exclusion with a written rationale
6 why. And I'd further suggest that in the
7 committee's report, given the high morbidity of
8 colon surgery in children, that we make a note
9 that there's a gap there and an opportunity for
10 measure development.

11 DR. HALL: Thank you for that comment.
12 That's a NSQIP platform-wide cutoff. And we would
13 certainly agree that that calls out for more
14 development on the pediatric side.

15 MEMBER SIPERSTEIN: Larry, just to
16 comment, there is a separate pediatric NSQIP
17 program that addresses this.

18 MEMBER MOSS: No, I understand that
19 Allan. I think in NSQIP that's well understood,
20 but I would like to see the NQF not exclude
21 children as standard operating procedure, but
22 recognize when they're excluded. And if there's

1 a rationale, state the rationale, and if there's
2 a need, state the need.

3 CO-CHAIR GUNNAR: Any other comments
4 regarding validity? Dr. Siperstein? No. Shall
5 we vote?

6 MS. QUINNONEZ: Voting is now open for
7 validity of measure 0706. Option 1 is moderate;
8 option 2 is low; option 3 is insufficient.

9 (Voting.)

10 MS. QUINNONEZ: All votes are in, and
11 voting is now closed. For the validity of measure
12 0706, 90 percent voted moderate; 10 percent voted
13 low; 0 percent voted insufficient.

14 CO-CHAIR GUNNAR: Moving on to
15 feasibility.

16 MEMBER TEMPLE: I think the comments
17 from the previous discussion hold.

18 CO-CHAIR GUNNAR: Any other comments?

19 MEMBER MOYER: This is probably a
20 comment that may have gone better with the last
21 measure. Most of the business we do is in a state
22 that has a significant proportion of critical

1 access hospitals, and when I hear the overall
2 structure of this registry described, it really
3 sounds like something that would be very hard for
4 them to do. And while they're not doing
5 cardiothoracic surgery, good, they probably are
6 doing a lot of the -- a fair amount of procedures
7 that may be captured by a database like this. I
8 don't have a really good solution for that, but it
9 feels like there's a chunk of hospitals where
10 programs for which reporting those or tracking
11 this kind of data isn't an option.

12 DR. HALL: Thank you. That's a very
13 appropriate comment and I would say two things.
14 First of all, we do have a population of critical
15 access hospitals that participate in the program
16 now, so we know that it is feasible, and we do
17 reduce both the current cost and FTE requirement
18 for them. In the future, however, in an
19 implementation of this metric we would not require
20 hospitals to be NSQIP participants. We would just
21 guide them on the acquisition of these fields for
22 this metric or the prior metric.

1 MEMBER MOYER: Terrific. Thank you.

2 CO-CHAIR GUNNAR: Any other comments
3 regarding feasibility? Go ahead and vote.

4 MS. QUINNONEZ: Voting is now open for
5 feasibility of measure 0706. Option 1, high;
6 option 2, moderate; option 3, low; and option 4,
7 insufficient.

8 (Voting.)

9 MS. QUINNONEZ: All votes are in, and
10 voting is now closed. For the feasibility of
11 measure 0706, 35 percent voted high; 65 percent
12 voted moderate; 0 percent voted low; and 0 percent
13 voted insufficient.

14 CO-CHAIR GUNNAR: Usability and use.

15 MEMBER TEMPLE: I think the comments
16 are the same.

17 CO-CHAIR GUNNAR: Any other discussion?
18 Go ahead and vote.

19 MS. QUINNONEZ: Voting is now open for
20 usability and use of measure 0706. Option 1,
21 high; option 2, moderate; option 3, low; option 4,
22 insufficient information.

1 (Voting.)

2 MS. QUINNONEZ: All votes are in, and
3 voting is now closed for usability and use of
4 measure 0706. Fifty percent voted high; 50
5 percent moderate; 0 percent voted low; and 0
6 percent voted insufficient information.

7 CO-CHAIR GUNNAR: Voting for overall
8 suitability.

9 MS. QUINNONEZ: Voting is now open for
10 overall suitability for endorsement of measure
11 0706. Option 1, yes; option 2, no.

12 (Voting.)

13 MS. QUINNONEZ: All votes are in, and
14 voting is now closed for the overall suitability
15 for endorsement of measure 0706. 100 percent
16 voted yes; 0 percent voted no.

17 DR. HALL: Thank you for your
18 consideration.

19 CO-CHAIR GUNNAR: All right, next
20 measure for discussion is 2998, infection rate in
21 bicondylar tibial plateau. It is a new measure.
22 Developers are present at the table. If you'll

1 take three minutes to provide an overview.

2 DR. AHN: Good morning. My name is
3 Jaimo Ahn, and I'm an orthopedic trauma surgeon at
4 the University of Pennsylvania. And I am here on
5 behalf of the Orthopedic Trauma Association for a
6 measure regarding the measurement of infection
7 rates in bicondylar tibial plateau fractures.

8 I do want to emphasize that this has
9 been a collaborative effort within one of the
10 committees at the OTA. And Dr. Bill Obrebskey,
11 who has been one of the main shepherds of this,
12 was not able to be here today because he's at the
13 Metrics Consortium, which is a federally-funded
14 meeting that he had to attend.

15 So with that said, this is really the
16 OTA's foray into a national measure, so I wanted
17 to give you a little bit more background because
18 I think the measure itself is actually pretty
19 simple and won't require a lot of debate or
20 questions. I guess we'll see about that.

21 But in terms of the injury itself, many
22 of you may not have been exposed to this since you

1 were in training. It's a bicondylar tibial
2 plateau fracture, and very simply put, what that
3 means is the lower end of the knee or the upper
4 part of the tibia is shattered. And the
5 bicondylar means that it's both the inside and the
6 outside of the knee making this a pretty
7 significant injury.

8 And as the committee was talking about
9 measures potentially put forward to the NQF, the
10 reason this came up was multifold. One is that
11 it's a pretty devastating injury. Perhaps not as
12 quite life altering as a hip fracture, but you
13 have one of these fractures, and you're
14 essentially non-weight bearing for three months or
15 more. So it substantially changes your life. It
16 also puts you at future risk of degenerative
17 arthritis such that 20 percent or more will go on
18 to need a knee replacement at a later time. So we
19 thought that it was an important injury to think
20 about.

21 The reason that this specific fracture
22 pattern really came to our light is that even

1 though it's not terribly common, it's common
2 enough that everyone at community hospitals will
3 see it, and orthopedic surgeons at community
4 hospitals will treat it, but they won't really
5 understand their patterns because it's just rare
6 enough that they're not going to see too many at
7 their hospitals.

8 As the Level 1 trauma centers have been
9 informally tracking this, not as part of a
10 national initiative but just of our own accord,
11 one of the things that we realized is that the
12 infection rate is highly variable and really way
13 too high. So if you were to sustain a standard,
14 let's say an ankle fracture today and went to the
15 operating room for a surgery, your infection rate
16 would be maybe 1 percent, low single digits, in
17 some places less than 1 percent. With these
18 bicondylar tibial plateau fractures, we found that
19 the reported rates of infection, even at highly
20 specialized centers range somewhere from 8 to the
21 mid-20s or higher. So we realized there was a big
22 variance here in the discrepancy, and it's

1 something that we don't really know the answer to.

2 But the fact that the event rate is
3 relatively high and an injury that's not too
4 common, so it wouldn't be burdensome for the
5 people initially reporting, we felt would make a
6 good combination for a national measure such as
7 this.

8 In terms of the actual outcome that
9 we're trying to measure, infection, we would use
10 the CDC criteria for deep infection. And when
11 this involves implants, it actually goes up to a
12 year, and so our -- the obligation would be for
13 surgeons to track this for a year and report it,
14 during that year period.

15 And also to give you just a little more
16 background, the consequences of this infection is
17 not just to go and wash it out. It's actually
18 much more substantial because there's hardware
19 involved and a fracture involved. This often
20 means that you have to multiple stage
21 debridements. Sometimes removal of the hardware
22 and further reconstruction, so the burden isn't

1 just let's take care of the infection, you're on
2 your way; the burden is also very high.

3 So we felt that because there were so
4 many of these different elements incorporated:
5 there's a joint; there's the bone; there's
6 infection, that this measure as a starting point
7 for the Orthopedic Trauma Association would also
8 be good, not only in its simplicity, but the
9 implications that we could learn a lot about soft
10 tissues, how the joint is affected, the timing of
11 surgery, and I can get more into the variables
12 that we'd be interested in looking at in terms of
13 further improving what we do as fracture surgeons
14 as we go on.

15 So in terms of some of the nitty-
16 gritty, the numerator/denominator is relatively
17 simple. The numerator would be patients who
18 sustain a deep surgical site infection according
19 to CDC criteria. The numerator, we can discuss
20 the appropriateness of excluding patients 18 and
21 younger, but as for 18 and older that come in with
22 a specific type of tibial plateau fracture, the

1 bicondylar tibial fracture, these are easily
2 identified now using ICD-10 as well as CPT codes
3 for the fracture treatment. Even in the old
4 system, the ICD-9 would have identified it as
5 well. And we feel that this is going to be -- the
6 reliability and validity are going to be high.

7 The reliability we actually don't have
8 a registry to look at currently, but when we did
9 look at a larger study and applied some
10 reliability criteria, we found that we could
11 accurately, with both high sensitivity and
12 specificity apply the correct criteria so that we
13 would identify these injuries with a complication.
14 And that it's a -- it has face validity. We
15 understand already what the implications of
16 infection are because that's been studied for
17 these injuries for many, many years.

18 And the final thing that I think really
19 drew us to this, before I entertain questions, is
20 the fact that again because of the relatively high
21 event rate and our ability to look at factors such
22 as would a wound back potentially mitigate the

1 infection rate, because there was a small
2 randomized control trial suggesting that even the
3 way we dress the wound may affect the infection
4 rate. Do we have to rethink antibiotics for these
5 injuries because it's so high? Should we really
6 stop at 24 hours of prophylaxis? Is the timing of
7 surgery important? We know that it's important
8 for femoral shaft fractures. Is that going to be
9 important for these as well considering again the
10 soft tissue envelope, the joint, and some of the
11 implications of further treatment.

12 And with that, I will entertain
13 questions.

14 CO-CHAIR GUNNAR: Discussants are Dr.
15 Ko and Dr. Olsen. Dr. Ko.

16 DR. KO: Great. How much time do we
17 have?

18 (Laughter.)

19 CO-CHAIR GUNNAR: As much as you'd
20 like.

21 DR. KO: That's not a good sign.

22 CO-CHAIR GUNNAR: It's a new measure,

1 so evidence -- take your time with the evidence.

2 DR. KO: Okay, so this NQF measure
3 2998, the title of it is infection rate of
4 bicondylar tibial plateau fractures, and as was
5 just stated, this is an important clinical issue,
6 and this is a new measure, as Dr. Gunnar said.

7 This is an outcome measure, and in that
8 regard, there are likely processes that influence
9 the outcome. There are, as was stated, there is
10 a variation in the SSI rates. After this, ranging
11 from 8 to 30 or even higher, 8 to 30 percent, and
12 that's three peer-reviewed published studies. So
13 I think that's the evidence. Is there anything
14 further?

15 MEMBER DUTTON: I don't know where to
16 fit this in, so if you want to bring it back
17 later, that's fine. But I agree, the first thing
18 we need to know is just the demographics, the
19 incidence of the event across facilities. But
20 risk adjustment is going to be absolutely critical
21 in understanding these outcomes and particularly
22 open/closed, transfused/not transfused, age of

1 patient, nutritional status.

2 DR. KO: I think we'll talk about the
3 risk adjustment in the validity. At least I'll
4 bring it up then, so maybe we can do it then.

5 MEMBER DUTTON: Fair enough.

6 DR. KO: I'm sorry, who is the other
7 discussant?

8 CO-CHAIR GUNNAR: Dr. Keith Olsen.

9 DR. KO: Okay, sorry. Dr. Olsen, do
10 you have anything?

11 CO-CHAIR GUNNAR: A.J.

12 MEMBER YATES: As the only orthopedic
13 surgeon on the panel, I don't have any
14 relationship with OTA, but I'd like to just put
15 this in perspective as we discuss it. Orthopedics
16 is one of the gaps that was identified by the
17 panel last year, and the fact that one of the
18 specialty societies has responded to that gap
19 should be recognized.

20 The second thing is is that the -- we
21 may not be doing the injury justice, but as a
22 particular injury to gauge the quality of one

1 trauma center versus another or a set of
2 orthopedic trauma surgeons, they've picked a
3 disease that has a very high incidence and a very
4 difficult problem to adjust to, so I think they
5 should be applauded for that.

6 And the third thing to put it in
7 perspective is is that since this is a brand new
8 measure from a relatively young organization as
9 compared to say the American College of Surgeons,
10 it does have -- we do have the option of giving it
11 a provisional approval so that they can collect
12 the data and come back and seek a more permanent
13 endorsement or a more standing endorsement.

14 So with those things said, I just want
15 to make sure that the OTA has a chance just to put
16 this in perspective, what's your penetrance into
17 the trauma centers across the country? How many
18 people are members? How many people are expected
19 to respond?

20 And then the last question is -- and we
21 will come to risk adjustment -- but you say you
22 have no data for risk adjustment, but have you

1 established by consensus and literature review
2 what risk factors you are going to collect in
3 anticipation of establishing what may be high
4 correlates of bad outcomes through regression
5 analysis after you start to collect? So those
6 three things: penetrance, likelihood of response,
7 and have you established de novo through a
8 consensus process which risk factors are you going
9 to collect?

10 DR. KO: Can we just do the first two
11 and then we'll talk about the risk factors in the
12 validity?

13 MEMBER YATES: You can do that. I'm
14 just saying that -- it's -- I just want to know
15 what the homework is, just so you have a chance to
16 present that up front.

17 DR. AHN: So in terms of penetrance of
18 OTA members, essentially every Level 1 trauma
19 center is going to be covered by members of the
20 Orthopedic Trauma Association. In terms of
21 centers that don't have trauma designation and how
22 many members are OTA and what percentage would be

1 covered, I actually do not have that information
2 at my fingertips.

3 MEMBER YATES: And participation in a
4 registry?

5 DR. AHN: So participation in a
6 registry is something that the OTA members have
7 definitely expressed an interest in. In fact,
8 this grew out of a task force within the -- under
9 the Evidence Base Committee where there was a
10 strong interest in developing a database.

11 And so that's something that the OTA
12 has been working on, of having a registry. We do
13 have a fledgling registry, but it's something that
14 we wanted to nationalize and make something that
15 would have more of an impact. And by working with
16 NQF, for instance, we felt that we would increase
17 the compliance and be able to actually have more
18 people enter into the registry.

19 MEMBER YATES: And then I'll defer the
20 risk question as requested by Dr. Ko and then
21 these are Schatzker Vs and VIs or just Vs?

22 DR. AHN: These would be Schatzker Vs

1 and VIs. Anything that would be coded as being
2 bicondylar.

3 MEMBER YATES: And for the audience,
4 Schatzker VI means that it's not just split into
5 both condyles, but it's also fractured below in
6 the shaft of the tibia, so it's a disassociated
7 bicondylar fracture.

8 CO-CHAIR FLEISHER: So just for the
9 committee's purpose, there is no conditional
10 endorsement any longer. It's either endorsed or
11 not. And should we get that -- when we get there
12 and should we get there, I mean it's either
13 endorsed or not and if they need to come back
14 either short term or long term, we'll address
15 that. But the goal would be to focus on whether
16 or not this deserves endorsement.

17 MEMBER YATES: Am I correct in saying
18 that we used to have that?

19 CO-CHAIR FLEISHER: We did have a
20 conditional endorsement, but we now only endorse
21 or do not endorse.

22 MEMBER YATES: I think the handbook

1 needs to be updated then or maybe I missed
2 something.

3 CO-CHAIR GUNNAR: So from an evidence
4 point of view, A.J., is it your opinion that
5 what's presented is -- that clearly links these
6 infection outcomes to best practice and high
7 quality processes, that if measured would drive
8 that?

9 MEMBER YATES: The literature would
10 support that, yes. The evidence supports that.

11 CO-CHAIR GUNNAR: That is the
12 fundamental question that we are voting on in one
13 minute or in 30 seconds. Any other discussion?

14 MEMBER GROVER: I'm going to recuse
15 myself from the voting.

16 CO-CHAIR GUNNAR: Thank you. Very
17 good.

18 MS. QUINNONEZ: We are now voting on
19 measure 2998. Voting is now open for evidence.
20 Option 1, yes; option 2, no.

21 (Voting.)

22 MS. QUINNONEZ: All votes are in and

1 voting is now closed. For the evidence of measure
2 2998, 89 percent voted yes, and 11 percent voted
3 no.

4 CO-CHAIR GUNNAR: So carrying onto gap.
5 Dr. Ko.

6 DR. KO: So the studies that were
7 cited, there are three studies in the gap, in the
8 spread in the SSI rates after this procedure.
9 They range from 8 percent to 30 or above percent,
10 so that's the gap.

11 MEMBER YATES: I would say that I'm
12 struggling with that gap based on three
13 retrospective single center studies with --
14 involved less than 500 patients total.

15 CO-CHAIR GUNNAR: Any other comments?
16 Shall we vote?

17 (Off microphone comment.)

18 DR. AHN: The question was asked --
19 somebody was asking about the incidence of the
20 injury. It is a relatively low occurrence event.
21 So the best estimate is probably 1 in 100,000 per
22 year, so -- and it constitutes, we believe, to be

1 approximately 1 percent of all bony fractures.

2 So depending on how you estimate the
3 number of fractures in the U.S. a year, even
4 incidental ones could be up to -- in the millions,
5 up to ten million. So it does mean that there are
6 thousands across the U.S., but any given center --
7 it's not like a hip fracture where you have many,
8 many events, but we're measuring things for hip
9 fracture like in-hospital mortality and one-year
10 mortality. So I think that's very different than
11 looking at something like an infection.

12 And as the OTA thought about this,
13 that's why we migrated towards something that was
14 common enough so that the OTA members would not
15 feel burdened in terms of reporting it, but common
16 enough and yet have a complication rate with an
17 event rate that would be measurable and would be
18 meaningful.

19 CO-CHAIR GUNNAR: Collette.

20 MEMBER PITZEN: I just wanted to make
21 a couple comments. I applaud the Orthopedic
22 Trauma Association again for tackling what is a

1 known problem, high infection rates. And just a
2 comment that a registry doesn't have to be in
3 place in order to collect data and have a measure.

4 CO-CHAIR GUNNAR: Dr. Yates.

5 MEMBER YATES: Yes, my one statement is
6 is that the positive reported outcomes bias in
7 orthopedics borders around .7.

8 In terms of people wanting to -- in
9 terms of in the literature, people wanting to
10 report what their infection rates are for a
11 particular disease, if you're a high rate, you're
12 not reporting it on a pretty regular basis. The
13 fact that we have that big a spread in the
14 literature, even though it's sparse, it's the
15 literature and the problem is we don't have the
16 registry and we don't have a way of collecting
17 that through ICD-9 codes for the majority of
18 trauma patients that lay outside of the say CMS
19 databases.

20 DR. AHN: And if I may, one last thing,
21 the study by Barei that has the lowest in the
22 spread is from Harvard U Medical Center which in

1 the orthopedic trauma world is like the mecca,
2 right? That's where they strive for perfection.
3 They have -- they keep amazing records. That is
4 where they're trying to do -- sort of sets the
5 standard for the rest of the country. And when a
6 center like that reports a rate of over 8 percent
7 whereas a standard fracture at a standard
8 community hospital will have an infection SSI rate
9 of 1 percent or less, I think that also speaks to
10 what a problem this is.

11 CO-CHAIR GUNNAR: Any other discussion?
12 So we are voting on performance gap.

13 MS. QUINNONEZ: Voting is now open for
14 performance gap of measure 2998. Option 1, high;
15 option 2, moderate; option 3, low; and option 4,
16 insufficient.

17 (Voting.)

18 MS. QUINNONEZ: All votes are in and
19 voting is now closed. For performance gap of
20 measure 2998, 56 percent voted high; 39 percent
21 voted moderate; 0 percent voted low; and 6 percent
22 voted insufficient.

1 CO-CHAIR GUNNAR: Carrying forward to
2 reliability.

3 DR. KO: So here are some -- I'll
4 report the reliability issues and then maybe I
5 have some questions for the developer.

6 So first of all, this is a measure
7 that's 18 and over, and I'll save Dr. Moss the
8 time, why is it not the children? And the
9 inclusion is to have a fracture in an open
10 reduction internal fixation and there's one-year
11 follow up with three-year aggregate of the data.
12 So that's the data.

13 The numerator, it was a little
14 difficult to understand from the measure
15 description because there seemed to be three
16 options for numerators. So number one is a CPT
17 code of a post-op wound, irrigation, and
18 debridement. Number two was in the medical record
19 an irrigation debridement and a confirmed positive
20 culture. And number three was more like the CDC
21 where there was a deep-space SSI in the deep soft
22 tissue and it's purulent and all the clinical

1 things and constitutional symptoms of fever.

2 So it seemed like there were three
3 options for wound infection for the numerator and
4 so are they all three or is there just one that's
5 doing that? The denominator is relatively easy,
6 18 and over which, Dr. Moss, and then the
7 fracture.

8 The data source was a registry that is
9 from the OTA website that is seemingly a QCDR
10 registry, so that it's really made for the
11 providers to participate in the Quality Payment
12 Program with this, but it doesn't seem like this
13 is in there already. We can talk about either
14 here in reliability or feasibility, and that's the
15 data source.

16 The testing of reliability is largely
17 based on the two studies that have been quoted
18 previously which are, as Dr. Olsen said, single
19 institution retrospective studies of approximately
20 400 patients where it showed really good agreement
21 sensitivity and specificity and positive
22 predictive values. But it is in two retrospective

1 studies that are in the literature and not
2 necessarily with these definitions or a registry.

3 So let me stop there and those are the
4 issues of reliability.

5 DR. AHN: The age issue I think is a
6 relatively simple one. If we went -- I don't
7 think it's unreasonable to look at that population
8 at some point, but because of the physeal closure
9 and the timing of physeal closure depending on the
10 age, I think that would complicate the issue more.
11 So I think that would be a more advanced stage.

12 The other is some of these implants are
13 not actually acutely indicated for patients under
14 the age of 18, so that would also make it very
15 hard to capture these patients.

16 In terms of the multi-numerator, I
17 think that came out because there were multiple
18 surgeons having a discussion about this. What it
19 really comes down to is the CDC definition. And
20 the CDC definition, the one complication here or
21 not complication but modifier is the fact there is
22 hardware involved, so the typical shorter term

1 definition doesn't apply anymore and now it
2 applies to a year.

3 And of course, as orthopedic surgeons,
4 we have to sort of discuss and say okay, we
5 recognize that it's going to be up to a year. But
6 the other is that when there's a deep surgical
7 site infection that involves hardware, our
8 standard of care as OTA members is to debride it.

9 And so I think that's where some of the
10 confusion is, does it have to be debrided? Well,
11 technically, it doesn't, but our standard of care
12 right now is that we do debride it, so it should
13 be captured by a debridement CPT code. But that
14 -- as I look at this, that should not be a
15 necessary component, but just because it's a
16 standard of care.

17 The retrospective study, I'm going to
18 perhaps use that to implore all of you to consider
19 making this a more national prospective-type
20 collection. That is the state of orthopedic
21 trauma, especially in the U.S. Canadians have
22 been better, and other countries with national

1 registries have been much better at collecting
2 this data, but this is the state that we're in now
3 and we are trying to make that move of trying to
4 create more pre-thought out, pre-meditated
5 prospective registries.

6 CO-CHAIR GUNNAR: Dr. Dutton.

7 MEMBER DUTTON: Well, I admit to having
8 worked for many years at an inferior trauma center
9 in Baltimore, but we did do a lot of washouts,
10 routine washouts when there was associated soft
11 tissue injury. So that wouldn't necessarily be
12 infected -- or maybe would be, I'll ask the
13 orthopods here -- but how would you discriminate
14 that in the numerator, scheduled or planned washed
15 out for an open wound versus one done specifically
16 because there was a deep infection?

17 DR. AHN: It's actually -- it's nicely
18 built into the system because I use it a lot for
19 staged washouts. For an open fraction is a 1101X
20 code. So that would be easily distinguishable and
21 if the surgeon has any amount of detail in their
22 operative record, it will give the Gustilo-

1 Anderson classification or some openness.

2 The fact that they're doing a
3 debridement as well as a plan to return, but even
4 based on the procedural code itself, the code that
5 we use for an open fracture stage planned
6 debridement is very different than if there's an
7 infection and you're going in to treat that
8 infection.

9 CO-CHAIR GUNNAR: Dr. Moss.

10 MEMBER MOSS: I appreciate your
11 comments on the care of children, I just want to
12 make two additional comments.

13 The growth rate issues do increase the
14 complexity, but children do still have these
15 operations and they are at risk for infection.
16 There are very compelling data that the subset of
17 children who receive surgical care in adult
18 institutions in the United States is the trauma
19 population. So the injured children that have
20 these injuries are likely to be cared for by
21 members of your organization, so I think it's
22 particularly noteworthy to keep it under

1 consideration.

2 CO-CHAIR GUNNAR: So the other question
3 I had, we just verified that it is 90 days for CDC
4 follow-up. Would you modify your measure from one
5 year to within year of release, at least
6 recognizing that?

7 DR. AHN: So from what I saw that --
8 within one year if implant is in place and the
9 infection appears to be related to the operation,
10 so that's a modifier in the CDC definition. But
11 regardless of that modification, our plan --
12 because the general outcome -- now not relates
13 specifically for infection, but when we look at
14 patient-reported outcomes, the OTA has basically
15 decided that we would do a year and we thought
16 that coincided well with the modification of
17 implant in a year. And since we try striving for
18 patient-oriented outcomes collection at a year
19 that would be a good time frame.

20 CO-CHAIR GUNNAR: Dr. Ko, any other
21 comments regarding reliability?

22 DR. KO: No.

1 CO-CHAIR GUNNAR: Dr. Olsen? All
2 right. Ready to vote.

3 MS. QUINNONEZ: Voting is now open for
4 reliability of measure 2998. Option 1, high;
5 option 2, moderate; option 3, low; and option 4,
6 insufficient.

7 (Voting.)

8 MS. QUINNONEZ: All votes are in and
9 voting is now closed. The reliability of measure
10 2998, 5 percent voted high; 90 percent voted
11 moderate; 5 percent voted low; and 0 percent voted
12 insufficient.

13 CO-CHAIR GUNNAR: Moving on to
14 validity.

15 DR. KO: So validity, this is an
16 outcomes measure. The outcome, as we just heard,
17 is going to be aligned with the CDC definition
18 which I think most everyone uses for wound
19 infection. So that is a valid -- and that's
20 within the reliability, but the issue that Rick
21 brought up and A.J. brought up is the risk
22 adjustment.

1 This is a non-adjusted outcome measure
2 and so they do cite some potential items that can
3 be risk adjusted, but because this is not in place
4 and they don't have those factors, they have not
5 done the modeling to figure out if the modeling
6 makes a difference or not, so that might be the
7 reason why it's not risk adjusted and non-
8 stratified so if the developer could address that.

9 The data source, as was mentioned, is
10 an OTA certified QCDR which will be used and so
11 the operative word there is will. This is, as I
12 understand it, not in the registry yet, but
13 probably can be put into the registry.

14 As far as SDS, there's a quote in there
15 and I couldn't remember it, so I wrote it down:
16 SDS patient factors, injury factors have not been
17 consistently associated with differences in SSI
18 rates so those were not included.

19 Again, the testing for validity are
20 based on the two studies that have been previously
21 discussed. And as far as threats to validity,
22 again, no risk models, no risk adjustment. The

1 missing data issue, it's unknown because it's not
2 in the registry. The meaningful differences is
3 unknown, so reliability of distinction is unknown.
4 And there is -- the measure has a lot of good,
5 thoughtful planning in it, but nothing has been
6 demonstrated to date.

7 CO-CHAIR GUNNAR: Dr. Yates.

8 MEMBER YATES: And again, it's clear
9 that there's an intention to collect consensus
10 agreed upon risk factors that are listed in the
11 measure as submitted. And as noted, they can't
12 report on the reliability or the c-statistic of
13 those, but given the fact that it isn't collected
14 yet. But at face value, the injury itself has the
15 potential to -- because of its high rate of
16 infection, the injury itself may, in fact,
17 outweigh the risk factors. I mean it's a
18 devastating injury and very hard to take care of
19 in terms of avoiding complications.

20 You could almost do this study without
21 any risk adjustment in the first year and move the
22 needle in terms of the variabilities that are

1 brought out from having collected it for other
2 people to learn from. And if certain centers
3 perform or are doing something different than
4 other centers, then there may be an opportunity
5 for a best practice to evolve, even a non-risk
6 adjusted.

7 I would just point out that the CDC
8 criteria for hardware is a lot different than some
9 other CDC criteria in that bacteria are harbored
10 by prosthetics because of a number of reasons
11 including the propensity in a low-oxygen
12 environment for glycocalyxes and the like to form
13 and bacteria being resistant to antibiotics. But
14 on top of that, there are a number of these types
15 of infections in joint replacement as well as in
16 fractures that have hard to culture microbial
17 etiologies. And there's a number of low grade
18 skin bacteria. Propionibacteria is a classic that
19 might take up to 15 days to culture if your lab
20 even bothers to hold it that long.

21 So a draining sinus, purulence, and
22 elevated CRP and sed rate are some of the reasons

1 why the CDC will allow that to count as an
2 infection and would insist that it be counted as
3 an infection so that those aren't missed just
4 because they're culture negative.

5 CO-CHAIR GUNNAR: Collette.

6 MEMBER PITZEN: I'm just going back to
7 the earlier discussion from Cliff about the
8 specification of the numerator. Are we
9 comfortable -- me not being an orthopedic person,
10 I don't know if I from the discussion would
11 understand okay, how would I count this deep wound
12 infection? So I guess I would recommend a little
13 bit of clarity around that.

14 DR. AHN: As I reread what we have
15 proposed, I think there is a little bit of
16 confusion. I think they're overlapping -- the
17 Venn diagrams that overlap. I think as you start
18 taking away some of the factors like one of the
19 ones I stated which is an orthopedic surgeon as a
20 standard of care, if somebody meets the CDC
21 definition of a deep infection in the setting of
22 hardware and metal, we'll take them to surgery.

1 So I think that's why that was put in
2 because we were thinking of surgeons, but at the
3 end of the day, the numerator will be a deep
4 infection. Now whether a surgeon decides to go
5 against what's considered a standard of care and
6 not treat that appropriately, we can't really
7 control. But yes, the criteria should and will be
8 the CDC definition of deep infection.

9 MEMBER PITZEN: Perfect. Thank you.

10 CO-CHAIR GUNNAR: Cliff or Lee, you
11 had a comment.

12 CO-CHAIR FLEISHER: Yes, risk
13 adjustment still concerns me and I'm not concerned
14 about you -- it's great that you're creating a
15 registry and following these patients. And we're
16 from the same institution, obviously. But what
17 I'm concerned about is what NQF endorsement means
18 as opposed to when a registry is ready for
19 actually having an NQF endorsement.

20 So if it's not risk adjusted for the
21 purposes for public reporting, would it be good
22 for somebody to know what your rates are unrisk-

1 adjusted? Would that help anybody telling you
2 whether that's a good hospital or a bad hospital
3 if they get a trauma to be taken there?

4 Secondly, if you're talking about
5 comparison between hospitals, would it really tell
6 you enough without that risk adjustment? And the
7 third -- and looking through the report, there's
8 a whole bunch about negative pressure, vacuums,
9 and other things. You actually talk about this
10 treatment. I don't want NQF to be caught up in
11 what our mission is versus any agenda with regard
12 -- it was just interesting. I've never seen a
13 company get so focused on acknowledging their own
14 studies to support the measure as opposed to
15 acknowledging how important it is to do something.
16 It almost appeared like -- and I'll say it for
17 the record, that if they endorse this and you
18 don't have a good rate, non-risk adjusted, you
19 should be using our devices.

20 So that's my question. Why do you
21 think this is ready -- why do you think this -- if
22 this went out to the public, would you be

1 comfortable with Penn Presbyterian's rate, be
2 sitting out there unrisk-adjusted to drive the
3 public to whether or not they should come to us or
4 Rothman?

5 MEMBER MOYER: So related to that, if
6 this is trauma surgery, is the public choosing?
7 Probably, I'm guessing go where they're taken or
8 is this a surgery where there's a delay?

9 CO-CHAIR FLEISHER: Well, that's why I
10 actually said even comparing between hospitals so
11 they can drive each other, is it good enough to
12 risk adjust to drive improvement within a region?

13 DR. AHN: Our committee discussed this
14 at length and I've had numerous conversations with
15 Bill Obrebskey about this. And we do realize that
16 as it stands, not being able to risk stratify is
17 a weakness, but we believe part of -- we also had
18 a number of other measures that we were
19 concerning.

20 At least part of the decision to move
21 forward with something like this is because, for
22 better or for worse, the OTA has not been able to

1 create registries like the American College of
2 Surgeons, that because the event rate is high, we
3 believe that in the early time period that we'll
4 be able to collect the data to show the variation
5 and variability to be able to risk stratify.

6 But without being able to collect that
7 data, and without putting this on the national
8 agenda, orthopedic surgeons are not -- they
9 haven't been -- let's say the easiest -- my
10 colleagues haven't been the easiest to work with
11 in terms of driving those types of measures. So
12 I think this was our way of saying we can make
13 this an important thing for the OTA.

14 The OTA Board has certainly signed on
15 to it and to make this an important agenda where
16 by collecting data, then we can risk stratify.
17 But I do agree with you that without that risk
18 stratification, then it becomes very difficult to
19 interpret and that's something that orthopedic
20 traumatologists have been saying all the time.
21 Without having that data, we say we take care of
22 the most mangled and sick patients and fractures.

1 We can't be held accountable in the same way as
2 another center that doesn't have this complexity.

3 So I think that is something that is
4 foremost in our minds and that we hope by having
5 that data we'll be able to create that risk
6 stratification.

7 CO-CHAIR GUNNAR: We'll go Fred, Karl,
8 Chris, and then back to Cliff.

9 MEMBER GROVER: I mean I think it's a
10 reasonable strategy to collect data and have it
11 not risk adjusted until you have enough data to do
12 the model for risk adjustment. That's certainly
13 how we started the STS and you get a few thousand
14 patients or whatever it takes to develop your risk
15 model and then you go with that.

16 I guess the only question I would have
17 is now do you actually have people that are signed
18 up to do the database yet or not?

19 DR. AHN: Yes, our incipient OTA
20 database is something that people do contribute to
21 on a periodic active basis.

22 MEMBER GROVER: How many members are

1 signed up?

2 DR. AHN: That I don't know.

3 MEMBER GROVER: One question I would
4 have and I think this is a very reasonable thing.
5 The question is to me when does it merit NQF
6 approval? Do we want to see some evidence of what
7 the participation is and the consistency and
8 reliability of the data that you are collecting?
9 And I think at some point we probably have got to
10 touch on that.

11 CO-CHAIR GUNNAR: Karl.

12 MEMBER BILIMORIA: Yes, I guess I'd
13 have -- sort of the end of Dr. Grover's comment is
14 the same as mine. At what point are we ready for
15 NQF endorsement? It just seems like it's
16 premature. It's NQF supported, maybe. We all
17 like the idea. It's a good measure, but should it
18 get the stamp based on where it is now? And as
19 the newcomer, I would just pose that as a question
20 to the group.

21 CO-CHAIR GUNNAR: So just historically,
22 there was an avenue for having that --

1 MS. MUNTHALI: Yes. We no longer have
2 that. We have it for eMeasures that are not fully
3 spec'd. They don't have testing information.
4 You're going to hear from our colleague, Jason
5 Goldwater, who will talk about trial use, I think,
6 for this project. For other projects, claim-based
7 or otherwise, no, there is no path. It would have
8 to be fulfilled spec'd.

9 CO-CHAIR GUNNAR: Chris.

10 MEMBER SAIGAL: Just a follow up on Dr.
11 Fleisher's comment. Is there some kind of
12 secondary gain by a company that's being promoted
13 in this measure? The developer didn't really
14 address that. Is there some involvement of the
15 company or -- I just want to clarify what he said.

16 DR. AHN: To tell you perfectly
17 honestly, when Bill and I saw that, we thought it
18 was a little surprising too. We didn't really
19 understand why a -- why Smith & Nephew would come
20 out in that fashion. I can tell you that I use
21 Smith & Nephew products, but I have no
22 relationship with them. And certainly between

1 Bill and myself, we have no relationship with
2 Smith & Nephew wound care.

3 Maybe they saw it as an opportunity to
4 have some spotlight, but the -- and because it is
5 an infection and involves wounds, but yes, we do
6 not have any particular leaning toward the
7 utilization of a vac or any particular implant or
8 device.

9 DR. KO: So I didn't want to make
10 editorialized comments in the beginning to start
11 things off, but if I'm the last speaker for
12 validity, I will now. So -- oh, if I'm not the
13 last speaker, should I wait? Yes, wait? Okay.

14 CO-CHAIR GUNNAR: College, then Amy,
15 and then Cliff.

16 MEMBER PITZEN: This is Collette. I
17 just want to share my own experience. We have two
18 statewide orthopedic measures in Minnesota
19 implemented across all of the practices using a
20 direct data submission process from the practices,
21 so not a registry per se. But through the last
22 eight years that I've been working with NQF, I

1 have had the fortune of bringing forward a measure
2 that was almost done.

3 For example, we have a spine surgery
4 functional status measure and we were at the point
5 where we had picked variables for risk adjustment,
6 but we had not enough data yet to run that. And
7 like an ad hoc process was evoked when we had that
8 information, so I don't know if there's any
9 avenue. If risk adjustment is the only thing
10 that's holding us back from a validity standpoint,
11 I guess I'm asking staff direction. Thank you.

12 MS. MUNTHALI: If you feel the measure
13 is fully specified and there is this aspect of
14 validity that you have some concerns with, we
15 could possibly ask the developer to come back
16 during the annual update process that I mentioned
17 before. That would be a significant change to the
18 measure. We would bring it back in front of the
19 committee to evaluate, to see if they've met that
20 condition.

21 But that would only mean that the rest
22 of the criterion have passed and you feel that

1 they've met all of the conditions for endorsement.

2 CO-CHAIR GUNNAR: Amy.

3 MEMBER MOYER: From validity
4 perspectives, it sounded like today individuals
5 are submitting data to this registry kind of on a
6 voluntary -- it sounds like a little informal
7 basis. If you move to using a measure based on
8 that data, I think you would need to be able to
9 demonstrate that individuals who are being
10 measured are necessarily submitting all of the
11 data and submitting all of their cases to the
12 registry, and can you talk a little bit about how
13 you plan to account for that?

14 DR. AHN: I'm not sure there's a great
15 external way of enforcing that. I think we could
16 certainly do data biopsies and see how much of the
17 data we feel have been submitted. But with many
18 -- similar to many other measures and things that
19 the OTA has tried to do, I think it's going to be
20 very difficult to enforce that at an institution
21 level.

22 CO-CHAIR GUNNAR: Any other comments

1 except for Dr. Ko? Cliff.

2 DR. KO: So I tried to as objectively
3 talk about the validity and a big thing is the
4 risk adjustment and it's not just the risk
5 adjustment wasn't there and we just said it
6 doesn't need it. We just don't know. And we
7 don't know because there's no data and we don't
8 know there's data because there hasn't been any
9 data collected except for these prior two studies.

10 Looking at just the application
11 overall, I think that nobody denies that this is
12 an important clinical topic. It is. And the
13 numbers would specify that it is. And SSI is a
14 very important thing and so that's absolutely
15 true. This is almost like a first draft of a term
16 paper where you need to write seven drafts to have
17 your final -- maybe not seven, maybe three. But
18 I think these are important topics and the
19 validity is important and it's going down the
20 road, but we can't really decide on validity
21 because we don't have enough data.

22 And this is how it's kind of -- how

1 validity and feasibility is kind of linked because
2 we can't get validity, the data for validity,
3 until we address the feasibility of doing it
4 through a QCDR and all this stuff that was brought
5 up. It's voluntary and do people even do the QCDR
6 and it's self-reported and all that stuff about
7 feasibility.

8 So I think that this a great try and
9 it's a very worthy topic and that's why I think
10 A.J. said give it this status of keep going
11 because this is worthwhile. But it's probably not
12 -- it doesn't have -- we can't really address the
13 validity in a meaningful way because we don't have
14 enough data.

15 CO-CHAIR GUNNAR: Any other comments?
16 We will carry on.

17 MS. QUINNONEZ: Voting is now open for
18 the validity of measure 2998. Option 1, moderate;
19 option 2, low; option 3, insufficient.

20 (Voting.)

21 MS. QUINNONEZ: Voting is now closed.
22 For the validity of measure 2998, 0 percent voted

1 moderate; 16 percent voted low; and 84 percent
2 voted insufficient.

3 CO-CHAIR GUNNAR: So does that close?
4 Okay. So the measure does not pass, but I think
5 the message is to continue and collect the data
6 and work towards risk adjustment. Any other
7 comments anyone else would like to add?

8 CO-CHAIR FLEISHER: I'm just curious,
9 Cliff, can the college at all provide some
10 guidance?

11 DR. KO: Yes, I know that -- Fred and
12 I were talking about STS and the college would be
13 very happy to help because this is a very
14 worthwhile topic and so absolutely.

15 DR. AHN: Thank you for the feedback.

16 MEMBER MOYER: I'd just like to say in
17 addition to being clinically important, I was
18 really impressed with the organization of the
19 application and the materials and the
20 presentation. I think you did a terrific job for
21 a first time. Thank you.

22 CO-CHAIR WARREN: So we have a didactic

1 session next regarding eMeasures. Will someone
2 introduce -- okay, great. Welcome.

3 MR. GOLDWATER: So good afternoon,
4 everyone. My name is Jason Goldwater. I'm a
5 senior director here at NQF and I have a multiple
6 number of responsibilities --- oh hi, Melinda --
7 one of which is to oversee our eMeasure review and
8 acceptance cycle before these measures get to this
9 committee or any other committee.

10 I don't think it's a surprise to say
11 that the dawn of eMeasures is upon us. The
12 widespread implementation of electronic health
13 records, of data registries that has been growing
14 over the last several years has really led to a
15 greater increase in the number of measures being
16 submitted with electronic specifications.

17 I have been around this field long
18 enough -- 20-plus years, which I rarely admit to
19 people -- but long enough to know when CMS back in
20 the days when it was called HCFA was really trying
21 to move out of the chart abstraction into the
22 electronic measure form. And did not succeed as

1 much as they had hoped to largely because there
2 was such low EHR adoption.

3 Now we flash forward into 2016, and
4 roughly 80 percent of hospitals and 75 percent of
5 physician offices have electronic health records
6 and that continues to rise. So clearly, there is
7 a greater emphasis, not just from CMS, but from
8 the quality improvement community to learn how to
9 develop electronic measure specifications and to
10 measure clinical quality electronically with the
11 technology that is available to them.

12 So what I'm going to do in the next few
13 minutes is not get into an elongated history of
14 the electronic measurement world because I'm sure
15 as much as all of you would appreciate hearing
16 about that, recognizing that I am the speaker
17 standing between you and lunch, I'm certainly not
18 going to do that.

19 But what I do want to talk about is
20 sort of how we look at eMeasures, and in
21 particular, the eMeasures that you all will be
22 looking at and considering this afternoon. So

1 next slide.

2 Reviewing electronic clinical quality
3 measures, this particular project, surgery
4 project, includes the evaluation of five eMeasures
5 that are being considered for trial use. Now what
6 do we mean by that?

7 When eMeasures are submitted to NQF for
8 review and moving onto a committee, they can come
9 in through one of four ways. The first way is a
10 de novo measure, obviously a brand new measure
11 that has been electronically specified.

12 Another one is what we would call a
13 respecified measure. So a claims-based measure or
14 a chart-abstracted measure that an organization,
15 usually sponsored by CMS, is transitioning from
16 chart abstraction into electronic measurement and
17 mapping the specifications accordingly.

18 The third one is what we call legacy
19 measure which is a measure that's already used in
20 a national program. It's also chart abstracted
21 and they are moving that as well into an
22 electronic specification.

1 And the fourth one is what we are doing
2 now. Given as I've already said that there has
3 been significant rise in the amount of eMeasures
4 that are being submitted because there is such
5 rapid proliferation of electronic health record
6 adoption in hospitals and physician offices, there
7 is still an issue at times when measures are being
8 created, brand new measures. And that is that the
9 data that is available to test the measure is not
10 always easily accessible because, as some of you
11 may know that are familiar with this technology,
12 if you've seen one EHR system, you have seen one
13 EHR system.

14 Even if it's the same vendor, there are
15 very different EHR implementations. And one of
16 those issues is that the way data is structured or
17 the way the data is captured in an EHR, or even in
18 a registry, can vary. Some of it is unstructured
19 elements. Some of it is structured elements.
20 Some of it conforms to a national standard. Some
21 of it does not.

22 And so when someone is creating a brand

1 new measure that they want to use to fill what is
2 an obvious gap, particularly in surgery, they may
3 find it difficult when they get to the testing
4 part because they don't have the data necessary to
5 test the measure.

6 So do we stop the process then and
7 there and go well, that's too bad. We would like
8 to really put the kibosh on innovation and not let
9 you use your creativity to come up with something
10 that is needed. Obviously, the answer to that is
11 no. So we came up with the Trial Use Program.

12 The Trial Use Program is a path to
13 endorsement for new, innovative, electronically
14 specified measures that cannot at this time --
15 emphasis cannot at this time -- fully satisfy NQF
16 testing requirements for endorsement, but they can
17 be implemented in the real world. So they can be
18 implemented in hospitals.

19 They can be implemented in physician
20 offices. In this case, it would just be
21 hospitals, I guess. So they can be implemented,
22 but they don't or are not able to get enough data

1 for testing to adequately fulfill our criteria.

2 So we do not want to hinder that
3 measure because that data is not available. So
4 trial use is an ability to put the measure in the
5 field to be used and in essence, they are
6 collecting data while the measure is being used.

7 Approval for trial use is not -- and I
8 will reemphasize is not, and Elisa will quiz you
9 at the end of the day -- it is not NQF
10 endorsement. It is approval to continue to test
11 the measure. You are approving the measure to go
12 into the Trial Use Program, not for NQF
13 endorsement. It will not receive a number. It
14 will not be put into a national program. It will
15 not be considered endorsed. It will be considered
16 a trial use measure which means you're giving
17 approval for the measure to go into the field for
18 further testing.

19 The developer can then choose the sites
20 to put the measure in the field and they have a
21 three-year window to bring back the testing for
22 endorsement. So in other words, the measure

1 collects data while it's in the field. Once the
2 developer feels they have enough data because the
3 measure has been used, that it adequately
4 satisfies the testing criteria for NQF. They pull
5 the measure out of the Trial Use Program. They
6 evaluate the testing results from the data that's
7 been collected and then they resubmit the measure
8 for all of you to consider for endorsement at that
9 time.

10 Next slide. So approval for trial use.
11 This committee will consider the full NQF criteria
12 when reviewing these measures for approval, just
13 like you have been doing for the last day and a
14 half, but you'll only vote on selected criteria
15 due to limited testing data. You'll be looking at
16 evidence and performance gap, importance to
17 measure and report, and those are both voting
18 criteria for approval to trial use.

19 You'll vote on one portion of
20 scientific acceptability that the measure
21 specifications are consistent with evidence. This
22 is what we call a must pass criteria. This is

1 only what you will consider for trial use.
2 Feasibility and usability and use should also be
3 considered to determine if a measure should
4 receive approval for trial use. However, please
5 keep in mind what you're going to be looking in
6 terms of results is not necessarily real live
7 testing data.

8 What they have done is used a simulated
9 test data set to determine if the logic calculates
10 correctly and the measure is produced in the right
11 metric. And what they are using is the Bonnie
12 Tool that is developed and maintained by MITRE.

13 Brief aside, I always get asked this
14 question and this joke never fails. Everybody
15 generally asks me what does Bonnie mean? I have
16 absolutely no idea. It's not an acronym for
17 anything. If it is, nobody has told me. As a
18 former developer myself, we are very fond of
19 naming things after our pets or our children. I
20 would suspect that Bonnie is one of those two.

21 Bonnie is where you create a synthetic
22 test deck of patients that would normally be used

1 in the measure itself and they test to the measure
2 against that synthetic test to see if the logic is
3 calculating correctly. Now that being said, it
4 doesn't mean that they create a test deck of
5 patients that are always going to pass. They have
6 to be able to show you that the measure will use
7 the inclusion and exclusion criteria correctly so
8 that you know if the measure gets put into the
9 field it will calculate as it should.

10 Next slide.

11 So there are five measures that are
12 going to be considered for trial use. And these
13 are the five that are in front of you. So I'm
14 going to hang around for the first discussion in
15 case there's any questions that need to be
16 answered. But what I do want to emphasize are
17 three things. One is you're not reviewing for
18 endorsement. Again, you are not reviewing for
19 endorsement. You are reviewing for acceptance
20 into the program.

21 Number two, the criteria that you are
22 looking at is somewhat more limited than what you

1 have been using to date. And number three, if the
2 program, if the measure actually gets accepted
3 into the program, it will be placed into the field
4 where it will be tested, and once that data is
5 collected they will pull out, analyze the testing
6 results, and determine if the measure should come
7 back before this committee to be considered for
8 full endorsement if the measure passes and there
9 is always the possibility that the measure may
10 not.

11 With that in mind, do you have any
12 questions?

13 CO-CHAIR FLEISHER: Larissa.

14 MEMBER TEMPLE: So I remember a couple
15 of years ago, we looked at some measures that had
16 gone through some sort of different process and we
17 were -- at the time, we were told not to evaluate
18 the measures for their importance in the gap and
19 evidence. If these measures, today, if we look at
20 the importance, the evidence, and the gaps, will
21 we reevaluate when it comes back or would that be
22 considered completed today?

1 MR. GOLDWATER: That would be
2 completed, yes. What you're looking at when the
3 measure comes back are the results of the test --

4 MEMBER TEMPLE: So just reliability and
5 validity then?

6 MR. GOLDWATER: That's correct.

7 MEMBER TEMPLE: Thank you.

8 MEMBER SAIGAL: Just curious, that
9 ortho measure, couldn't that fall under this kind
10 of pilot testing? I mean why is this eMeasure
11 only? Is that a way to basically facilitate the
12 identification of measures before they're really
13 fully vetted, but they get the approval or the
14 endorsement of this group as being important and
15 then kind of like --

16 MR. GOLDWATER: I think your point is
17 well made. At this point, the program is only for
18 eMeasures. And the reason for that is because of
19 the great emphasis that CMS is putting on,
20 transitioning out of chart abstraction into
21 eMeasures themselves. That has been a directive
22 they've given to us and that is something that

1 certainly the quality measurement community is
2 trying to embrace. One of the difficulties,
3 however, is the lack of available testing data
4 which is why we've restricted this just to
5 eMeasures only.

6 CO-CHAIR FLEISHER: So maybe you can,
7 Jason, define what the program is which is I think
8 the difference. In other words, trial use, a lot
9 of things are. How is the program going to
10 evaluate how eMeasures work which changes the
11 equation?

12 MR. GOLDWATER: So the Trial Use
13 Program, there's a difference between the Trial
14 Use Program and what we had in the past which was
15 time limited endorsement which is no longer.

16 Trial use in the eMeasure program is
17 you're evaluating the measure initially on the
18 criteria that I went over, importance to measure.
19 You're looking at feasibility only through a very
20 narrow lens of synthetic test results. But the
21 program itself is allowing the measure to get put
22 into the field because it is filling at least if

1 the evidence is presented strongly enough, a
2 necessary gap in care in which a measure is
3 clearly needed. The difficulty with putting this
4 measure into endorsement is that they are unable
5 to get enough testing data in the time that they
6 had during the call for measures. So they decided
7 then to go this route which then allows them to
8 submit the measure that it can be evaluated on
9 some criteria minus the testing. It goes into the
10 field itself. Data is collected and essentially
11 the measure is tested in a real-life setting. And
12 then it is brought back out once enough data is
13 collected to determine whether it can be moved on
14 for further consideration for endorsement.

15 CO-CHAIR FLEISHER: So getting back to
16 the problem of why the last one failed to extend
17 your question was they didn't have data on risk
18 adjustment was probably the biggest question.

19 MR. GOLDWATER: Right.

20 CO-CHAIR FLEISHER: If we find that the
21 measure should be risk adjusted, let's make a
22 supposition, would that be -- and it's an

1 eMeasure, and they don't have a model. Should it
2 be approved or should it not be approved? Because
3 there's two different testing, testing of the
4 elements, obtaining it from an electronic record,
5 versus having built the correct model to allow --

6 MR. GOLDWATER: It's possible if they
7 want to resubmit for consideration for that
8 program, but generally, when measures come in to
9 us it's indicated by the developer that they want
10 to be considered for trial use because of the
11 testing limitations. So The Joint Commission
12 submitted these five measures because in the
13 process of development were unable to find enough
14 testing data to sufficiently fill the criteria.

15 The measure that is before these was
16 not asked to be considered for trial use. So we
17 did not look at it in that terms. If they want to
18 do that, that is a potential consideration.

19 CO-CHAIR FLEISHER: See --

20 MR. GOLDWATER: Was it an eMeasure? I
21 thought it was an eMeasure.

22 CO-CHAIR FLEISHER: No, it was not --

1 MR. GOLDWATER: If it's not an
2 eMeasure, then we don't look at it in terms of
3 trial use.

4 CO-CHAIR FLEISHER: But the second
5 question is if an eMeasure had a reason to be risk
6 adjusted, and they had no model built for risk
7 adjustment, should we approve that for trial use?
8 In other words, they may not have the data yet,
9 but suppose it was in a -- from a different data
10 source. I mean that's --

11 MR. GOLDWATER: You could consider that
12 for approval for trial use with the notation that
13 the data that they collect has to then be -- they
14 have to adequately risk adjust the measure once
15 the data has been collected.

16 CO-CHAIR FLEISHER: I think that would
17 concern me and perhaps others because that's not
18 testing. That's a threat to validity that we
19 would have concerns about. I would have concerns
20 about. So I'll let others -- Collette, Amy, and
21 then Fred. Do you have a comment you want to --

22 MEMBER GROVER: My question is is there

1 a reason that they can't just do this without
2 coming to NQF first and then come back after
3 they've done it showing that they're able to
4 collect the data and all the feasibility that
5 you're talking about?

6 MR. GOLDWATER: There's the
7 possibility, but there's also the possibility that
8 they may be contracted to develop these measures
9 and as a result of that do not have enough
10 available testing data to complete the process
11 which is why they're opting for the Trial Use
12 Program.

13 And I'm not aware of the situation. I
14 haven't inquired about that. But -- yes.

15 MS. WATT: I'm Ann Watt from The Joint
16 Commission. And this is our team you'll be
17 hearing from. We are not -- it's a very good
18 question. We've asked ourselves the same
19 question, why are we doing this? The answer is
20 because we have a great respect for the NQF
21 process and this is new for all of us.

22 These are not contracted measures.

1 These are measures that The Joint Commission has
2 chosen to develop because we feel that they are
3 important measures. We are very interested in
4 this process. We also feel that approval for
5 trial use gives us an opportunity, some leverage
6 with potential testing sites which nobody is
7 beating down our door these days to say yes, we'd
8 love to test your measures. And so we're hoping
9 that this would provide that incentive, too.

10 CO-CHAIR FLEISHER: Collette.

11 MEMBER PITZEN: Can staff put up the
12 slide of the criteria that we are going to be
13 talking about today? And if gap is one of them,
14 I have a hard time just making a decision about
15 that with no data. So I just want to understand
16 better.

17 CO-CHAIR FLEISHER: Can you actually
18 describe any measures that have gone through this
19 trial of how other committees have looked at this?

20 MR. GOLDWATER: So there are a few
21 measures that have been passed and moved on to
22 trial use. One of the most recent ones was a

1 hemolysis measure which I'm just blanking on the
2 exact specifications. But there was a strong
3 evidence base as to why there is a current gap,
4 why that process is not being used and the
5 outcomes it's leading to if the measure was not
6 implemented.

7 Unfortunately, there was not a lot of
8 data to collect around hemolysis that would
9 provide enough to go through for endorsements, so
10 the measure was brought up for potential inclusion
11 in trial use and was passed because there was
12 enough evidence indicating a clear measurement gap
13 indicating that quality performance would be
14 improved if the measure was implemented, a strong
15 evidence base about its importance to measure and
16 report as well.

17 There was a small scientific
18 acceptability in that the developer created the
19 specifications that were consistent with the
20 evidence and actually had had those conversations
21 with CDC prior to submitting the measure
22 submission form and they did do a fairly

1 comprehensive synthetic test deck in Bonnie to
2 look at feasibility. So yes, it was done. It has
3 been done.

4 MEMBER MOYER: So to follow up on that,
5 I think it would be useful to relook at
6 performance gap after the measure has been tested
7 because part of it is is there gap in practice.
8 But part of what we're also looking at, I believe,
9 as we're evaluating the measure is the measure's
10 ability as specified to identify and shed light on
11 that gap. So looking at it in the wild as it's
12 going to be used I think would be helpful for us
13 when we're actually endorsing it.

14 MR. GOLDWATER: Again, I do want to
15 emphasize this, again, you're not considering
16 endorsement. So this is not going to be an
17 endorsed measure.

18 CO-CHAIR FLEISHER: No, I think what's
19 been said is when it comes back.

20 MR. GOLDWATER: When it comes -- okay.

21 CO-CHAIR FLEISHER: Can that be defined
22 as part of the CDP process? Because the concern

1 is, at least what I'm hearing from the committee
2 is if this comes back we want to vote on certain
3 other areas or we do not feel that the CDP process
4 has been fulfilled. So can we make that as a
5 requirement, at least if it comes back to this
6 committee?

7 MS. MUNTHALI: A suggestion.

8 MR. GOLDWATER: A suggestion.

9 CO-CHAIR FLEISHER: Well, then we can
10 vote on -- we still vote on up or down if they
11 come back in for suitability for endorsement?

12 MS. MUNTHALI: Yes, we will do an
13 overall --

14 CO-CHAIR FLEISHER: We will do an
15 overall.

16 MS. MUNTHALI: An overall.

17 CO-CHAIR FLEISHER: So people still
18 have the -- so what's been clarified is at the
19 end, we can vote, even if we don't get to vote for
20 gap, we've only made a suggestion. We still have
21 the overall endorsement question.

22 MR. GOLDWATER: Right. We can still

1 endorse it. Not today, when it comes back from
2 trial.

3 CO-CHAIR FLEISHER: Who is next? Liz,
4 Barry, Cliff.

5 MEMBER EREKSON: So throughout the last
6 day and a half, we've been talking about how we're
7 supposed to separate how things that we endorse
8 then get applied. And what I'm struggling to wrap
9 my brain around is how does approval for trial use
10 then get applied in the next three years as these
11 developers are using their data? What are the
12 ramifications of that? So I'm just trying to kind
13 of put it in context because we know what NQF
14 endorsement means and how that gets applied.

15 MR. GOLDWATER: I mean what you're
16 looking at is -- the only thing when it comes to
17 trial use, the only thing that is incomplete is
18 the testing component of this because there's not
19 enough data to adequately do the reliability and
20 validity testing and they've made that case when
21 the application came in.

22 The other information that is on the

1 measure submission form is articulated about why
2 there is a gap, the evidence for the measure, its
3 importance to measure and report, what the metric
4 will produce, how the metric will improve quality.

5 So they don't have the testing data to
6 go through the criteria that we've established.
7 But the other criteria that is essential, they've
8 already addressed to that extent. So if the
9 measure is getting implemented, if you vote for
10 approval for trail use, and the measure gets put
11 into the field, the measure at that moment then is
12 filling the gap that they've articulated and they
13 are then collecting data to determine whether the
14 measure is reliable and valid and feasible.

15 That being said, there's always the
16 case that it may come back and it may not be.
17 That is the possibility. We are not saying that
18 every measure that goes through the Trial Use
19 Program is going to come back clean. It's just
20 not -- we can't possibly foresee that and neither
21 can the developer. But as I think Ann was
22 articulating, it provides a basis to collect data

1 that they otherwise would not be able to get. It
2 potentially makes it easier for them to implement
3 the measure in sites. And then it's possible to
4 evaluate whether the metric is driving potentially
5 systemic changes in quality that are needed that
6 they've articulated that are not there.

7 CO-CHAIR FLEISHER: So I spoke to other
8 staff. The way I would frame this is we have
9 clearly articulated from several people that you
10 would like to vote on additional areas when this
11 comes back. Since we are not the ones who can
12 approve that change in the current process, that
13 will be taken into consideration by NQF and we'll
14 get back. Today, we should vote on this process.

15 MR. GOLDWATER: Correct.

16 CO-CHAIR FLEISHER: But the concerns of
17 the committee were clearly heard today. It just
18 can't be answered today. Fair? So that's very
19 clear. And we do vote again during that process,
20 we do get to vote a final approval or non-
21 approval.

22 Barry?

1 MEMBER MARKMAN: Yes, I think it's
2 important that -- I mean this is the future. This
3 is coming into play, so I commend it, the forum to
4 -- in doing this. But it still has to meet the
5 importance and we can't stipulate, but we can make
6 suggestions that when they do come back in three
7 years, like risk adjustment, that they should
8 include that variable in the data set.

9 MR. GOLDWATER: Yes, you can make those
10 suggestions. I wouldn't stop you from doing that.

11 CO-CHAIR FLEISHER: That will be
12 clearly in the report to CSAC that the Board sees
13 the concerns.

14 Yes, Barbee.

15 MEMBER WHITAKER: So we're not supposed
16 to address usability and use, but some of the
17 things that are questioned there including
18 unintended consequences are not covered elsewhere.
19 And I think those are important for determining
20 the validity or the value of the measure overall.
21 So can we include those in our discussion prior to
22 that?

1 MR. GOLDWATER: Yes, you can include
2 those in the discussion, yes.

3 CO-CHAIR FLEISHER: So perhaps that
4 would be for when this comes back if we state
5 those concerns, they can be in the report so that
6 should the measure come back from The Joint
7 Commission, they should address these concerns and
8 that would be great to have in the report.

9 Larissa, then Collette.

10 MEMBER TEMPLE: So not to jump out of
11 turn, but there are some sort of scientific issues
12 with some of the measures that affect the
13 numerator and denominator which would
14 theoretically be within the discussion about
15 reliability. And I'm wondering where that
16 discussion will come up if we're not discussing
17 the testing characteristics because you'd hate
18 them to do something for three years and for us to
19 say the numerator and denominator were sort of
20 incorrect.

21 MR. GOLDWATER: Right, I understand.
22 So that's sort of where the Bonnie testing to some

1 extent comes into play because if the only
2 available test -- I mean what we ask the
3 developers to do is to use Bonnie as a baseline.
4 And if they are able to to the best of their
5 extent get a test data extract that actually have
6 allowed patients to use that as well.

7 MEMBER TEMPLE: So I'm actually talking
8 about the inclusion and exclusion criteria more
9 than the Bonnie testing. That's my question.

10 MR. GOLDWATER: Are you asking whether
11 -- I'm not sure what you're asking.

12 MEMBER TEMPLE: So if there's
13 discussion or concerns about the developers'
14 definitions for the numerator and denominator and
15 their choice of inclusion and exclusion, we
16 usually talk about that in the reliability section
17 of our discussions.

18 If we have concerns about the inclusion
19 and exclusion criteria, where do we put that in
20 the context of this trial?

21 MR. GOLDWATER: So they had to use
22 Bonnie as the test data for the

1 inclusion/exclusion criteria. So they will
2 discuss it at that point in time. If you've got
3 an issue with the inclusion/exclusion or the
4 numerator/denominator section, that's where it
5 should be discussed. When they do the
6 specifications --

7 MS. MUNTHALI: It's in the measure
8 specs, so even though you're not talking about
9 reliability and validity testing, you will talk
10 about it in specifications.

11 CO-CHAIR FLEISHER: Collette again, and
12 then Barbara.

13 MEMBER PITZEN: Did importance to
14 measure get added back into the criteria for
15 eMeasure review?

16 MR. GOLDWATER: Are you talking about
17 after the Bonnie -- after the approval for trial
18 use testing is completed to look at that?

19 MEMBER PITZEN: No, the high priority
20 importance to measure as a criteria, is that no
21 longer --

22 MR. GOLDWATER: You're going to look at

1 importance to measure.

2 CO-CHAIR FLEISHER: Barbara.

3 MEMBER LEVY: So I still have a little
4 bit of problem with the unintended consequences.
5 We could potentially look at some of that when we
6 look at the importance and the evidence. We could
7 bring it up in evidence, but I think it is
8 important for us to look at that before we say go
9 ahead and put these measures out there.

10 Similarly, when we look at feasibility
11 and look at cost of some of these measures
12 potentially, and it's not just the cost to collect
13 the measure, but it's also the cost of the
14 intervention. So I think there's some things that
15 we do need to discuss that don't fit exactly into
16 the evidence and importance, but that actually
17 need to come up in the discussion before we send
18 a measure out for trial use.

19 I don't think it's just the testing
20 piece that's missing.

21 CO-CHAIR FLEISHER: So -- did you have
22 a comment?

1 So how would you, either Lisa or Jason
2 or Melinda, we'll clearly go through the
3 traditional, but then what should we do before we
4 vote?

5 MR. GOLDWATER: I don't think there's
6 any issue with discussing unintended consequences
7 if you feel that there are going to -- if that's
8 potentially going to exist as a result of the
9 implementation of this measure. Clearly, if the
10 measure gets implemented in trial use, we don't --
11 there's nobody that wants an unintended
12 consequence, but those do need to be articulated
13 to determine whether or not that's significant
14 enough to delay or to reject the approval into the
15 program.

16 CO-CHAIR FLEISHER: So perhaps if we
17 continue the current way we do it, but not vote in
18 those areas --

19 MR. GOLDWATER: Right.

20 CO-CHAIR FLEISHER: So reliability,
21 validity, and usability, we will actually
22 structure our discussion that way, if that's okay

1 with everyone. But it's more to give The Joint
2 Commission our concerns when they bring it back.
3 There will not be a vote on -- is it those three
4 areas we do not vote on?

5 MR. GOLDWATER: That's right, because
6 you won't have enough testing data to do so.

7 CO-CHAIR FLEISHER: Great. Barbara.

8 MEMBER LEVY: So I agree that we don't
9 have enough data to vote on those things, but it
10 might influence my decision to vote up or down to
11 release something for trial use.

12 CO-CHAIR FLEISHER: I didn't say we
13 shouldn't have a full discussion and response.
14 All I'm saying is we don't per NQF rules vote on
15 them.

16 MR. GOLDWATER: I want to go to the
17 last bullet point which is you do need to consider
18 feasibility and usability of use. They are going
19 to have granted synthetic data to indicate
20 feasibility and whether you believe that can be
21 extrapolated into the field once it's put into the
22 program. So those are -- I mean if you look at

1 their Bonnie test results and think to yourself,
2 well, this just doesn't seem feasible to me. And
3 even with the way they structured this, this is
4 just simply not going to have any impact because
5 the data is not going to be available, the
6 structure data is simply not there, and we don't
7 think that the results of the Bonnie test could be
8 extrapolated into a real-life setting, that's the
9 discussion you need to have. I mean that's why
10 they have to do that testing.

11 CO-CHAIR FLEISHER: Shall we try one?
12 I think that's the best way. We have both Helen
13 back and we have Jason here.

14 MR. GOLDWATER: No, I'm going, bye-bye.

15 CO-CHAIR FLEISHER: No, you're not.
16 You had a lot of definitive comments. So if we
17 can ask our colleagues from The Joint Commission
18 to come up. One of the options is we all get the
19 food and -- good idea?

20 Okay, we will get food and in ten
21 minutes we will start.

22 (Whereupon, the above-entitled matter

1 went off the record at 12:21 p.m. and resumed at
2 12:34 p.m.)

3 CO-CHAIR FLEISHER: I essentially see
4 all of the standing committee back. So we will go
5 through these measures.

6 These are the new guidelines of how
7 we're going to actually have the discussion.
8 Importance to measure and report, we will vote on
9 evidence of the importance to measure and report
10 and performance gap. On the scientific
11 acceptability, we will only vote on the measure
12 specifications are consistent with the evidence.
13 We can discuss the other issues in that context
14 what the concerns of the committee are.
15 Feasibility, usability and use, and then overall
16 suitability.

17 So we'll start with, and we'll see how
18 this goes, the preoperative 3016, preoperative
19 anemia screening, and if you could introduce
20 yourselves and give us a short --

21 MS. DOMZALSKI: Good afternoon,
22 everyone. My name is Kathy Domzalski from The

1 Joint Commission. I'm the co-lead for the
2 project. The other co-lead is Michelle Dardis,
3 who is an informaticist. Also from The Joint
4 Commission, we have Ann Watt and JohnMarc Alban
5 who are project directors. And we're pleased to
6 have with us Dr. Jonathan Waters who is the
7 chairperson of our advisory panel.

8 Thank you for the opportunity to share
9 with you these five Joint Commission patient blood
10 management measures. Blood transfusion is the
11 most commonly performed procedure in hospitals
12 having increased 126 percent between 1997 and
13 2010. While it can be a life-saving procedure, it
14 does pose hazards such as risk of infection,
15 increased length of stay, decreased function at
16 discharge, and other associated complications. It
17 uses a resource that must be conserved for the
18 most urgent need and it has been unfortunately
19 assessed in one study to have a rate of
20 inappropriateness as high as 100 percent of the
21 time when the hemoglobin is over 8.0.

22 We have developed and assessed these

1 five evidence-based measures to assist hospitals
2 in identifying their opportunities to improve
3 blood management efforts. While there are those
4 efforts currently underway in some U.S. hospitals,
5 certainly it needs to spread to all U.S.
6 hospitals. And we look forward to your approval
7 for trial use.

8 MS. DARDIS: And an overview of all
9 five measures, I briefly wanted to address the
10 testing that was performed on these measures thus
11 far.

12 Kathy did introduce me. My name is
13 Michelle. I am a nurse informaticist working for
14 The Joint Commission on eCQMs. And I was
15 responsible for much of the testing effort for
16 this project.

17 In addition to a clinical advisory
18 panel for the measures, we also had a Technical
19 Advisory Committee and that was made up of
20 hospital clinical analysts, informaticists, and
21 blood project leads from hospitals who could
22 advise on feasibility of the measures. And we

1 also performed site visits with five hospitals
2 where we watched through their blood work flows to
3 assess how to structure the measures appropriately
4 for data capture with the EHR. So we'll be
5 sharing the results of those visits as well.

6 MS. DOMZALSKI: Measure 3016 concerns
7 preoperative anemia screening. And it assesses
8 the proportion of elective surgical patients who
9 had a timely preoperative anemia assessment. The
10 denominator is selected elective surgical patients
11 and the numerator is the number of them who had an
12 anemia assessment between 14 to 45 days prior to
13 the said scheduled surgical procedure.

14 Hospitals currently, by and large, do
15 anemia testing, but it is done so close to the
16 procedure that any assessment of the cause of
17 anemia or correction is virtually impossible to
18 effect.

19 The clinical intent is to ensure an
20 adequate preop time frame to assess and correct
21 anemia since uncorrected preop anemia really is
22 the biggest predictor of a perioperative

1 transfusion.

2 Thank you.

3 CO-CHAIR FLEISHER: Thank you. Okay.

4 Amy, are you the lead discussant member.

5 MEMBER MOYER: So I think I was
6 initially partially thrown by the title of the
7 measure which was preoperative anemia screening
8 which to me suggested what we were looking to
9 address was a lack of screening of patients prior.
10 But it almost sounds like from your description of
11 it it's not that screening isn't happening, it's
12 that it's not happening in a timely manner. And
13 that wasn't clear to me until actually right now.

14 So in terms of the evidence, there was
15 evidence supported that anemia screening is
16 important to perform in certain procedures and
17 certain populations. In looking through the code
18 set, it seems consistent with the evidence
19 supplied, which was at a high quality.

20 I don't know that there was evidence
21 that the specific time frame given, the 14 to 45
22 days, is set forth in the evidence, but it sounds

1 like that is the practicality of resolving the
2 anemia prior to the surgery and that's the
3 reasoning behind that. Those were my thoughts on
4 the science.

5 CO-CHAIR FLEISHER: Barbee, comments.

6 MEMBER WHITAKER: I don't really have
7 anything to add to that.

8 CO-CHAIR FLEISHER: Rick.

9 MEMBER DUTTON: I think we all agree
10 that unnecessary transfusion is bad and these are
11 a series of sort of stacked measures to get at
12 that problem one of which is you have to assess
13 the patient in a timely-enough fashion that you
14 can produce an intervention and so Amy, the time
15 limit is picked to how long does it take for oral
16 IN therapy, for example, to work in a patient that
17 it's going to work in.

18 My concern with this is the unintended
19 consequence. There's also very good evidence that
20 there's a huge amount of unnecessary preoperative
21 testing in anesthesia. Lee has written some of
22 that literature. And I am concerned that the

1 simplest response to a measure like this would be
2 well, let's just test everybody whether they need
3 it or not because we can't tell.

4 So I asked the developers already this
5 question. For me, this measure is going to very
6 strongly depend on exactly what surgeries we're
7 talking about which is going to be a moving target
8 over time. A knee replacement got transfused five
9 years ago. It doesn't today, for example.

10 And so having a SNOMED code for these
11 are the operations we're including and I
12 understand that's 2,000 very granular SNOMED
13 codes. I get that, but we do need to hear what
14 operations are we talking about here and how are
15 you going to put that out to the public in this
16 measure?

17 CO-CHAIR FLEISHER: So let's frame that
18 in the context of evidence as opposed to
19 specifications in that the evidence -- and I did
20 write some of the evidence -- that there's only
21 selected operations. But the way you, in some
22 ways, the way you specified it it says all

1 elective, your denominators are all elective
2 surgery.

3 MS. DOMZALSKI: It's all selected
4 elective surgical patients. That list are value
5 set because of the complexity of ICD-10 and SNOMED
6 coding contains approximately 2,000 procedures.
7 However, they are all major procedures. We're not
8 talking about any old hernia repairs here. We're
9 talking about abdominal aortic aneurysms, those
10 procedures likely to require blood replacement.

11 CO-CHAIR FLEISHER: I have a question,
12 but I will defer to the phone and then we'll go
13 Barbee, we'll just go with this side. I'll amend
14 that. On the phone?

15 OPERATOR: To make a comment, please
16 press star 1.

17 CO-CHAIR FLEISHER: No, this is not
18 open for comment. Is there anybody on the
19 standing committee --

20 OPERATOR: There are no committee
21 members on the phone at this time.

22 MEMBER WHITAKER: So I'm confused about

1 when to talk about the actual characteristics of
2 the measure. Is that now or is that at --

3 CO-CHAIR FLEISHER: This is just about
4 evidence. There is evidence supporting obtaining
5 a --

6 MEMBER WHITAKER: -- a timely.

7 CO-CHAIR FLEISHER: A timely
8 hemoglobin. Larissa.

9 MEMBER TEMPLE: So I guess what I'm
10 having troubles with is the supposition that all
11 patients preoperatively can be -- can go to the
12 operating room with normal hemoglobins and
13 particularly I think of the oncologic patients.
14 I don't think any patient undergoing ovarian
15 debulking will be anything but anemic. The
16 patients with pelvic radiation, colon cancer
17 surgeries, so I guess I'm having issues because I
18 don't know of any evidence that supports improving
19 preoperative hemoglobins in that kind of cohort.
20 And certainly, we wouldn't want to be advocating
21 Neupogen which is actually already black labeled
22 for cancer patients. So that's why I'm having

1 real problems with the evidence.

2 MS. DOMZALSKI: The measure only
3 requires an assessment to be made. It does not
4 require the correction to be made.

5 CO-CHAIR FLEISHER: I'll follow that up
6 so that you for Larissa's patients, should they
7 delay surgery to be able to meet the 14- to 35-day
8 window?

9 MS. DOMZALSKI: I don't see why that
10 would need to occur.

11 CO-CHAIR FLEISHER: I will tell you our
12 surgeons book things for within two days of seeing
13 a patient.

14 MS. DOMZALSKI: That has been a problem
15 across hospitals that we visited. The surgeons
16 want to operate quite quickly and this would
17 require a lengthier period of preoperative time in
18 order for an assessment to occur.

19 MEMBER TEMPLE: But that then implies
20 that I need to check the hemoglobin in these
21 patients and if it's low, I need to do something
22 about it before I take them to the operating room.

1 That's how I'm hearing this measure. And that's
2 what I'm hearing the rationale behind it. And I
3 completely support optimizing patients
4 preoperatively, but there are some patients that
5 you just cannot and it's a fairly big proportion
6 of patients.

7 MS. DOMZALSKI: I think that rationale
8 would apply to the next measure in which we look
9 at what the actual hemoglobin was prior to
10 surgery. But this measure only looks at the
11 assessment, that it's made in time.

12 CO-CHAIR FLEISHER: A.J. and then
13 Allan.

14 MEMBER MOYER: Can I just jump in
15 really quickly to help inform this?

16 CO-CHAIR FLEISHER: Yes.

17 MEMBER MOYER: They did actually
18 provide the full code set of the specifications.
19 It took me a while to find it, so if you go on the
20 SharePoint site under this measure, the last
21 spreadsheet listed has the SNOMED and the ICD-10
22 codes and everything for these code sets that

1 they're mentioning in the specification. It does
2 include joint replacement to the point that was
3 made earlier.

4 MEMBER YATES: It does not?

5 MEMBER MOYER: It does.

6 MEMBER YATES: It does include. Right.

7 On a facetious basis, I'm surprised your surgeons
8 wait two days, but a non-facetious -- I'm just
9 trying to tie the evidence to the measure. And in
10 the evidence they refer to hemoglobin as the test
11 and in the numerator in the measure is anemia
12 testing which is a very broad term. I mean I'm
13 not going to -- just to take it to hyperbole, I'm
14 not going to run sickle cell anemia tests or look
15 for macrocytic anemia or something like that with
16 Vitamin B12, etcetera, and serum iron levels.

17 Does the literature imply that you're
18 asking for an H&H sometime between 45 and 14 days?

19 MS. DOMZALSKI: Correct. That's
20 correct.

21 MEMBER YATES: Then I would argue that
22 as opposed to anemia screening, it would be much

1 better to say that hemoglobin screening would be
2 much more specific and much easier to understand.

3 MS. DOMZALSKI: Thank you.

4 MS. DARDIS: And the actual
5 specification and the numerator looks just for
6 hemoglobin screening.

7 MEMBER YATES: I know, but the way it's
8 phrased, anemia screening means a lot to -- it
9 means something a lot different to a hematologist
10 than it does to me.

11 MEMBER SIPERSTEIN: So my question is
12 kind of understanding the rationale of putting
13 together the numerator and the denominator. I
14 mean I understand the value of doing less
15 transfusions. I understand the value of doing
16 more anemia screening, but if you're following
17 this as a ratio over time, you may be in a system
18 where you have not cut down your transfusion rate
19 at all. You have simply quote gamed the system by
20 doing a bunch more screening. And that really
21 isn't -- you really haven't solved the problem
22 yet, even though your ratio has improved. So that

1 really is kind of my main problem in that the
2 number that you're going to follow really isn't
3 focusing on the key problem that is reducing
4 transfusions.

5 MS. DOMZALSKI: Well, according to what
6 our findings were, the current rate of anemia
7 detection is so low that it's not possible for
8 that anemia to be corrected before surgery at all.
9 So that by increasing the timely preoperative
10 anemia assessment and correcting the anemia,
11 you're therefore reducing the chances of a
12 perioperative transfusion.

13 CO-CHAIR FLEISHER: Fred.

14 MEMBER GROVER: I'll pass.

15 CO-CHAIR FLEISHER: Pass. Barb.

16 MEMBER LEVY: Yes, I do think -- first
17 of all, I have an issue with the timing. What if
18 it's 36 days or 38 days? I had patients who were
19 coming in from out of town, other places. You're
20 going to have outpatient data. You have no idea
21 when you go and survey a hospital what I have in
22 my office from a month ago or two months ago. For

1 my patients in GYN surgery, I've got a problem
2 because I've got an open spigot. And so anything
3 I do -- the surgery is going to stop the outflow.
4 Assessing her for anemia isn't really going to
5 help me. I know she's anemic. It's a question of
6 what am I going to stop it? What am I going to do
7 to fix it and how can I optimize it?

8 So I have a problem with the
9 specification for the timing. I have a problem in
10 the sense that there's an awful lot of outpatient
11 or office or distant evaluation being done and how
12 are we going to capture that because why would I
13 repeat it if it were done by somebody else in an
14 outlying area and I'm being referred the patient?
15 So there are a whole bunch of issues I think with
16 this particular measure that have some
17 difficulties that I'm having problems with.

18 MEMBER PITZEN: Hi, I have a technical
19 question. I don't know where the right place to
20 ask it, but in your eMeasure then, were you
21 planning on accessing lab values from the
22 practices when you were looking at that 45 to 14-

1 day window?

2 MS. DARDIS: Yes, and thank you for
3 bringing that up to build on what Barbara raised.
4 When we went out to the hospitals, it was really
5 important to us to assess the feasibility of
6 collecting that data from the practices because,
7 of course that's the automatic next question,
8 right, how likely are we to get that data?

9 We saw facilities where it was more
10 likely to collect the data where they had
11 integrated EHRs between the practice setting and
12 the inpatient that was not everywhere, of course.
13 There's different EHRs between practice and
14 inpatient. You have referring providers who
15 aren't in your system. We saw that many hospitals
16 have data that could be captured in the time
17 frame, but it comes to the hospital as a document
18 rather than a structure and then coded data we can
19 capture in an eCQM.

20 We did score the feasibility of
21 collecting this data in this time frame and shared
22 that in our submission. Overall, the hospitals we

1 visited which were demographically diverse,
2 financially diverse, some were academic, some were
3 not, felt that there were ways to address the lack
4 of data, whether it would be abstraction,
5 improving their interfaces, other ways of getting
6 the data into the inpatient EHR and this data
7 element was one of the key reasons we felt
8 approval for trial use would give us the
9 opportunity to further flesh out the issues with
10 bringing in that practice data.

11 CO-CHAIR FLEISHER: Sal?

12 MEMBER SCALI: I just wanted to echo
13 just the timing element. It is, for someone like
14 me to, you know, in AAA as your index cases you
15 sort of describe for aortic abdominal aneurysm and
16 lower extremity bypass is a big part of most
17 vascular surgeons' practices, for example.

18 So, you know, the timing -- that it
19 doesn't make a lot of sense with the supposition
20 that it will give you an opportunity to
21 potentially correct because, frankly, most anemia,
22 at least in the vascular patient populations, is

1 anemia of chronic disease.

2 It is true you can pick up iron
3 deficiency anemia for these elected patients but
4 then the unintended consequence, which I guess
5 we'll get to in a moment, you get this number that
6 you're supposed to react to.

7 So then you're doing a stool guaiac.
8 Now you're going to have to get additional lab
9 tests and a full iron study panel, probably an LFT
10 panel.

11 So now you're going to do an additional
12 work-up for the overwhelming majority of patients
13 that are -- it's going to make little impact in
14 terms of what the outcome to the surgery would be
15 for elective AAA patients unless the patient is
16 profoundly anemic.

17 So doing that screening at that time
18 point, 14 days pre-op or more, has little impact
19 and also operationalizing it as was already
20 described patients who get found, say, for a AAA
21 they get an ultrasound that's scheduled by their
22 provider, perhaps for screening, and then that may

1 be in some, you know, out of window time period
2 when they've had some routine lab work that was
3 done with their annual checkup.

4 They get referred to a surgeon and then
5 they get booked. And so you're not going to put
6 the breaks on that. It's just not -- that
7 behavior will not change and it doesn't make sense
8 to change it because I have -- you know, the
9 anemia prevalence in vascular patients, for
10 example, is extremely high, like 30 percent or
11 more depending on because the anemia chronic
12 illness, the renal insufficiency patients that we
13 see, et cetera.

14 And so I would say at least from a
15 vascular surgeon's perspective it doesn't make any
16 sense to screen -- have that designation of the
17 timing.

18 I do agree for major elective surgery
19 with risk of bleeding that having a hemoglobin
20 pre-op is critical. But the timing piece for me
21 just doesn't make a lot of sense. I don't see, at
22 least in our population, that there's any

1 literature to support that.

2 CO-CHAIR FLEISHER: Thank you.

3 Are there other comments? I'm going to
4 allow -- because Aryeh asked to speak too.

5 DR. WATERS: Aryeh does, yes. Of
6 course.

7 CO-CHAIR FLEISHER: But sure, please.

8 DR. WATERS: I just wanted to address
9 that 14 to 45 day window. The 14 days, as was
10 previously mentioned, was a time that was chosen
11 so that we would have time to fix it.

12 The 45 days was an interval that we
13 chose in association with the length of time that
14 a type and cross match was good for and then we
15 also figured that something that was longer than
16 that was probably not clinically relevant. So
17 that was some of the rationale for those
18 particular time limits.

19 I just wanted to mention a case that I
20 took care of when I was at the Cleveland Clinic
21 many years ago where we had a patient that came
22 for a total hip replacement and we did do

1 preoperative anemia screening for the patient and
2 she ended up having an occult anemia.

3 She also had a colorectal cancer that
4 was probably needing to be addressed more than she
5 needed her hip replaced. And so that was kind of
6 the initiation of this measure as something that
7 was important.

8 CO-CHAIR FLEISHER: Thank you. I want
9 to be careful about anecdotes to be honest. What
10 I would -- so we will be voting on evidence. The
11 one question I would ask the Joint Commission, it
12 was pointed out that you have a blood conservation
13 center of excellence program because it mentions
14 -- certification.

15 Can you mention how these measures fit
16 into that? Because you started with the statement
17 that this was to eventually go into other
18 programs. But it appears from your documentation
19 that there is something sooner in mind.

20 MS. DOMZALSKI: The Blood Management
21 Certification program is a new program for the
22 Joint Commission and a joint -- a number of other

1 certification programs such as in perinatal care
2 or acute heart failure and CHF management. And it
3 does denote a center of excellence, as you've
4 indicated.

5 This program just became effective in
6 the spring and currently, unlike other
7 certification programs, there is no requirement in
8 the blood program to have hospitals monitor and
9 report on the results of measures related to their
10 services.

11 However, should these measures be
12 approved for trial use we would then have those
13 measures available in the program and require
14 hospitals to report on a certain number of them in
15 order to maintain their certification.

16 CO-CHAIR FLEISHER: Thank you.

17 Any other comments about evidence? Can
18 we vote?

19 MEMBER KO: May I just ask a quick
20 question?

21 CO-CHAIR FLEISHER: Sure.

22 MEMBER KO: The last thing you

1 mentioned -- so if these do not pass you're not
2 going to do that?

3 MS. DOMZALSKI: Pardon me?

4 MEMBER KO: If these measures don't
5 pass you are not going to require it of the
6 certified centers?

7 MS. DOMZALSKI: That determination has
8 not been made yet.

9 MEMBER KO: But if they do pass you
10 will require it?

11 MS. DOMZALSKI: Yes.

12 MEMBER KO: Got it. Thank you.

13 CO-CHAIR FLEISHER: Okay. Evidence?

14 MS. QUINNONEZ: We are now voting on
15 Measure 3016. Voting is now open for evidence.
16 Option one, high, option two, moderate, option
17 three, low, and option four, insufficient.

18 All votes are in and voting is now
19 closed. For the evidence of Measure 3016, zero
20 percent voted high, 14 percent voted moderate, 48
21 percent voted low and 38 percent voted
22 insufficient.

1 CO-CHAIR FLEISHER: Next steps. Aryeh,
2 if you're on the -- if you can please -- a brief
3 comment, that would be great. Thank you.

4 DR. SHANDER: So, you know, you said no
5 anecdotes. But the discussion I'm hearing is
6 mostly anecdotal, because the fact that there's no
7 evidence I don't think is the correct way to put
8 this.

9 There is sufficient evidence on non-
10 cardiac patients, now looking at more than a
11 million encounters, of patients where anemia is
12 found to be an independent risk factor for, again,
13 outcomes of surgical patients, whether they're
14 vascular or not.

15 In the cardiac world this has been
16 established already for quite some time that
17 anemia is an independent risk factor in terms of
18 both complications, as well as the major one is
19 transfusion, which is, again, another independent
20 risk factor.

21 To state that, you know, that this
22 won't have any difference or that it's more work,

1 anemia is a condition. Some of us will say
2 anemia is actually a disease, and we screen for
3 other things which have less of a risk factor.

4 Anemia is an epidemic. There's more
5 than 2 billion people across the globe that suffer
6 from this condition and the majority of these are
7 not being screened at all.

8 So the argument that we're screening
9 for hemoglobin and not for anemia may be rational
10 in terms of the actual testing that we're doing,
11 but we are screening for low hemoglobin. And then
12 trying to, again, those patients, we selected out,
13 I think, in this particular measure, we're
14 selecting patients where we think we can reduce
15 the incidence of transfusion and therefore improve
16 their outcome.

17 So we're looking at patients who have
18 significant blood loss. And those patients, there
19 is data, both from Europe and now from the U.S.,
20 that mitigating this risk, or adjusting their risk
21 in terms of treating their anemia, which requires
22 some time prior to surgery. There's no question

1 about that.

2 Rick's comment about oral iron, we know
3 that oral iron, actually there's data now that's
4 been published in Hematology, as in the journal,
5 showing that oral iron in the first two to three
6 weeks actually increases hepcidin level, and that
7 blocks the absorption of oral iron.

8 So therefore, again, in these
9 situations, these patients, just like chemotherapy
10 and antibiotics, get sent to an infusion center
11 and do get their iron replenished.

12 Now, whether it's cancer, whether it's
13 renal failure, where there's just iron deficiency,
14 the therapy itself, with iron and erythropoietin,
15 has been demonstrated to, again, correct anemia in
16 these patients.

17 The data that's completely -- not
18 completely missing at this point, because there is
19 some European data that's been published -- is
20 does that improve their outcome? There's one
21 thing that is unequivocal, and that is reduces
22 another independent risk factor, which is

1 transfusion.

2 And therefore we come back and we're
3 doing two things -- number one, we're looking at
4 patients who are anemic and trying to rectify that
5 as a risk. And, two, there has been significant
6 data -- again, I think that both European, as well
7 as now Australian, as well as the Pacific Rim, as
8 well as U.S. -- that it reduces the other risk,
9 which is transfusion.

10 So I just want to make the comment that
11 there is sufficient data even though the vote went
12 the different way. There are a lot of anecdotes
13 in terms of what to do with patients who have
14 cancer, and I will tell you that even those
15 patients can benefit from their anemia to be
16 treated. And there is now -- the EU is looking at
17 it, and there's a new publication that is right
18 now in review looking at the treatment of anemia
19 in patients who are going for surgical for -- who
20 have cancer and are going of surgery. That is,
21 cancer surgery.

22 So I just want to make those comments.

1 So I think it's an important measure that we get
2 this on the books, because everybody else around
3 the world is starting to look at it in a different
4 -- in a different eye, and we're still lagging in
5 terms of implementation of any kind of anemia
6 assessment in hospitalized patients in the U.S.

7 CO-CHAIR FLEISHER: Thank you, Aryeh.

8 DR. SHANDER: Thank you for the
9 opportunity.

10 CO-CHAIR FLEISHER: Thank you very
11 much. I will take a motion. Would anybody like
12 -- Allan, do you want to comment first?

13 MEMBER SIPERSTEIN: Yes, I just want to
14 make a comment back to the developers, and just
15 make it very clear, from my perspective, you know,
16 your enumerator is a very laudable goal, and your
17 denominator independently is a very laudable goal.
18 Expressing it as a ratio has no clinical meaning
19 to me. So I think you should, you know, go back
20 and rethink how you want to, you know, affect your
21 improvement.

22 CO-CHAIR FLEISHER: Fred?

1 MEMBER GROVER: I think virtually
2 everybody -- and you and Anastasia can correct me
3 if I'm wrong -- that has a major operative
4 procedure gets a preoperative hemoglobin. And a
5 lot of this is the question of the timing, and to
6 have everybody -- a lot of us practice in areas
7 where patients come from 500 miles -- you can get
8 these things checked. But that isn't practical.
9 And patients like to -- a lot of time when a
10 decision is made for a major procedure, for
11 anxiety reasons they want to get it over with with
12 the family.

13 So what we do now, if we have somebody
14 that we're really concerned about, we pick that up
15 and we only have to delay their operation, we
16 aren't putting everybody else through that
17 inconvenience of waiting a certain period of time
18 or an extra clinic visit.

19 So, that's one of my issues. We are
20 getting preoperative hemoglobin. It's more a
21 question of timing and then breaking up the
22 efficiency of what the patients want. Our

1 patients usually want to be treated rather
2 quickly.

3 CO-CHAIR FLEISHER: So, does anyone
4 want to reopen and revote on this after hearing
5 the comments from Dr. Shander, who is an expert in
6 blood transfusion, anesthesiologist at Englewood
7 Hospital, or the comments here? If anybody makes
8 a motion, we will reopen.

9 Hearing none, we will go forward.

10 MS. DOMZALSKI: Measure two, the
11 preoperative hemoglobin level is Measure 3017.
12 The measure is designed to allow transfusion or
13 blood use review committees to identify patients
14 undergoing elective surgery with suboptimal
15 uncorrected hemoglobin levels that may have led to
16 a peri-op transfusion.

17 It assesses via stratification pre-op
18 hemoglobin levels immediately prior to the
19 selected elective surgical procedure. Thank you.

20 CO-CHAIR FLEISHER: Thank you.
21 Larissa? Or Barbee, you want to go first?

22 MEMBER WHITAKER: Okay. So this

1 measure is designed to identify patients who could
2 have benefitted from pre-surgical treatment to
3 enhance their iron stores and to reverse anemia.

4 Identified in the measure are the
5 numbers of patients who are anemic, had
6 hemoglobins lower than 12 grams per deciliter
7 prior to elective surgery, of the elective
8 surgical patients receiving a transfusion during
9 or within five days after transfusion.

10 Obviously, unnecessary blood
11 transfusions are undesirable and perioperative
12 optimization of anemia is preferred. But the data
13 is not clear on the true cut point of 12, and
14 there's some other areas of performance gap, if we
15 get to that.

16 Larissa, do you want to pick up from
17 there?

18 MEMBER TEMPLE: I'll just make the
19 comment that, you know, I look forward to seeing
20 that paper that's under review published about
21 showing how oncologic patients can be optimized
22 with iron preoperatively.

1 But I think it's a fairly large cohort
2 of patients who present with anemia that's either
3 from chronic disease and/or from oncological cause
4 that is quite challenging to improve in the period
5 of time where the disease isn't progressing. And,
6 clearly, there is certainly some concerns about
7 anything but iron in those patients.

8 So I think that the issue, to me, is
9 the evidence gap and demonstrating, again, that
10 all patients can be optimized to a hemoglobin of
11 12 preoperatively. And I think it's a fairly big
12 -- it's a substantial subgroup that cannot be
13 optimized, and that's -- maybe if they wanted to
14 rethink the new way or show us the new paper
15 that's about to be published.

16 MS. DOMZALSKI: The aim of the measure
17 is not to say that all patients should be
18 optimized. The aim of the measure is to profile
19 for blood use review committees and clinicians who
20 can review those who have not been optimized to
21 see if that was possible.

22 Over time, there should be a reduction

1 in the number of preoperative anemic patients.
2 The idea is for hospitals to formulate educational
3 interventions for practitioners who have not
4 optimized a patient who is optimizable, so that
5 the reduction in preoperative anemia will occur.

6 MEMBER TEMPLE: Will there be -- I
7 would imagine, though, at some point these numbers
8 will be compared between hospitals, and obviously
9 the different case mixes, whether it's an
10 orthopedic hospital where you would think
11 optimization is possible versus other types of
12 facilities where there's a more blended mix.

13 So I worry that -- initially, it's just
14 a percentage, but I worry that that's not the
15 ultimate goal if we're looking at quality, because
16 we want to be not just intra-institutional but
17 also between.

18 CO-CHAIR FLEISHER: Barbara?

19 MEMBER LEVY: So, help me understand
20 why a blood utilization committee would need this
21 measure when they have access to the chart, they
22 have access to these data already? So how is this

1 helping the blood utilization committee?

2 MS. DOMZALSKI: You're saying that
3 they've asked for the data already?

4 MEMBER LEVY: I'm saying, when I sit on
5 a blood utilization committee I've got the chart
6 and I'm looking clinically at the scenario to
7 assess why did we transfuse this patient, what was
8 going on with this patient?

9 So I'm trying to understand why I need
10 a measure that holds everyone to a standard that
11 perhaps a subset of patients actually need -- and
12 I may not know that. So, just help me understand
13 how the measure helps the blood utilization
14 committee.

15 MS. DOMZALSKI: I guess most simply,
16 not all blood transfusion committees operate the
17 same, and while that may be the procedure in your
18 facility that's certainly not the procedure in a
19 number of facilities.

20 So we would like to present for these
21 committees who are not looking at charts and who
22 are not taking clinical conditions into

1 consideration, a profile, if you will, of what
2 patients are going to surgery with what
3 hemoglobins and they should be looking at those
4 prior to going with suboptimal hemoglobins, to
5 see, A, are these people optimizable; B, did they
6 really have a preoperative assessment; and C, what
7 educational interventions -- is it an individual,
8 is it a department, is it a group of individuals,
9 what educational interventions will help in
10 raising those preoperative hemoglobin levels?
11 Because some hospitals just look at the number of
12 units they transfuse and call it a day or a month.

13 MEMBER LEVY: So, I appreciate that.

14 I guess I'm still seeing an unintended consequence
15 when you create a number that says 12, hemoglobin
16 of 12, that that sets a -- you know, if a hospital
17 is not sophisticated enough to look at who they're
18 transfusing, then to set a number that says
19 "hemoglobin of 12," my concern is that that's
20 setting a benchmark that says that that is an
21 optimal level. And I'm not sure we have the
22 evidence to support that.

1 You know, chronic anemia is different
2 than acute anemia. We have different thresholds
3 for transfusion. The threshold for transfusion is
4 as important as the preoperative hemoglobin, in my
5 experience, to determine whether a transfusion
6 occurs or doesn't.

7 CO-CHAIR FLEISHER: Okay. Other
8 comments, because Dr. Shander -- we're going to
9 consider him your developer, or part of the
10 development team. Is that an accurate
11 consideration?

12 DR. WATERS: Part of the team.

13 CO-CHAIR FLEISHER: So, Operator, if
14 you can open it up, and Aryeh, if you will have a
15 brief comment.

16 DR. SHANDER: Is it open? Is it open?

17 CO-CHAIR FLEISHER: It is.

18 OPERATOR: Your line is open.

19 DR. SHANDER: Oh, okay. Yes, it feels
20 muzzled. But anyway, I just wanted to make a
21 couple of points. In terms of the discussion that
22 just went on for this particular measure, which,

1 you know, again, I really don't know what I can
2 add to the discussions going on, other than,
3 again, there was some mention about optimizing
4 patients preoperatively and that some patients are
5 just going to have anemia and that's all we could
6 do about that.

7 Well, I think we need to relook at this
8 because there is very good evidence that you don't
9 have to have all of the amount of time that you're
10 looking for to -- that is, all the 14 days to 49
11 days -- even a few days prior to, especially
12 oncologic patients where you want to minimize
13 transfusion, because, again, there has been risks
14 associated with that in terms of that particular
15 surgical population.

16 So even earlier intervention, if you
17 can, and there now -- as I said already, there is
18 data to suggest that even short intervals of
19 therapy prior to surgery raise hemoglobin and
20 reduce the chance of the patient being transfused.

21 The review on 3017 I don't know what
22 else I can add to the discussion back and forth on

1 that. Thank you.

2 CO-CHAIR FLEISHER: Thank you.

3 MEMBER WHITAKER: I think another one
4 of these measures gets to the point about trying
5 to optimize them, you know, the optimization
6 issue.

7 But I do think that this issue is
8 actually better managed through guidelines and
9 standards than measures, because, as Barbara said,
10 if you're not in a sophisticated blood utilization
11 committee and you go in and you say, oh, well,
12 we've been transfusing too much at 9 or 10 and
13 just apply a blanket requirement to change, I
14 think you need to look at the clinical profile of
15 each patient.

16 So guidelines and standards can
17 describe and recommend how to implement a blood
18 utilization review committee that would have a
19 better impact, I believe.

20 MEMBER SIPERSTEIN: So, a question for
21 the developer. Explain to me the clinical meaning
22 of your result -- I mean, the numerator and the

1 denominator statement. So, explain to me how the
2 data would be presented. So, in a report, then
3 you would have four different ratios, one for each
4 of the hemoglobin ranges, correct?

5 MS. DARDIS: So you would see an
6 overall rate. So you would first see an overall
7 rate, what is the numerator rate of patients who
8 received a transfusion.

9 Then you would see the strata and the
10 strata would break out which cases were in a range
11 of eight to nine, nine to ten, and so on. And so
12 this would allow a committee to say, okay, here is
13 the patient populations that fell into this range
14 and this range and let's dig into the specific
15 cases.

16 MEMBER SIPERSTEIN: I mean, I
17 understand going through the granular data but I
18 don't understand the clinical significance of the
19 ratio, particularly, you know, as the numerator is
20 the number of patients and the denominator is that
21 subset that's transfused. So this ratio is going
22 to be greater than one.

1 MS. DARDIS: And, again, the intent of
2 the measure was for the blood utilization or the
3 blood management committee, not the ratio or rate.
4 The value is really which patients fell into which
5 strata and where do we want to focus our efforts
6 based on what we know our challenges are?

7 MEMBER SIPERSTEIN: Right. Again, I
8 understand that's a laudable goal, but the way the
9 measure is written, the key number that's coming
10 out, this ratio, like looking at mortality, I
11 understand what a mortality rate is.

12 When I look at this number, it doesn't
13 have any -- it doesn't have cleaning meaning or
14 significance. I understand how the bits and
15 pieces would be used, but as the measure is
16 written, again, I'd like you to try to explain or
17 justify that how -- why you're expressing the data
18 that way.

19 CO-CHAIR FLEISHER: Rick.

20 MEMBER DUTTON: So I'm a big fan of
21 internal quality improvement, understand how this
22 can do. But NQF measures are intended for public

1 reporting and there's going to be a real strong
2 reluctance for anybody to report something that
3 makes them look bad when it's not their fault.

4 So if I'm reporting this measure, I
5 transfused a hundred patients last month and 20 of
6 them had a low hematocrit before the surgery. So
7 an opportunity for improvement, perhaps. But that
8 ratio is completely meaningless without an
9 understanding of the risk adjustment of that: how
10 many of them were oncologic patients, how many of
11 them had renal failure, how many of them were just
12 post-trauma, whatever.

13 And I'm not going to want to see that
14 number publicly reported unless I am certain that
15 that assessment is a fair comparison of me to
16 other facilities.

17 Similarly, it's not useful for your
18 internal benchmark unless it can be a comparison
19 of apples to apples across multiple centers. So
20 what are your plans for the risk adjustment of
21 this model or the presentation of this data?

22 MS. DARDIS: So, currently, the measure

1 does exclude a number of populations, including
2 traumatic injury, obstetric procedures and
3 diagnoses, sickle cell disease and patients on
4 ECMO, because those were identified as populations
5 that had unique needs and that would obscure the
6 numbers we received in the strata.

7 I don't know if you want to build on
8 that, Dr. Waters.

9 DR. WATERS: Well, I think the measure
10 was primarily developed to raise awareness of
11 anemia as something that we need to manage.

12 In my particular facility, from a
13 women's hospital where we do a large number of
14 hysterectomies, we take care of a large OB
15 population. And in those particular segments of
16 the population you have widespread iron deficiency
17 anemia, whereas if you're working in a different
18 kind of facility you might see a different patient
19 population with a different spread of hemoglobin
20 values. So it gives you an opportunity or an
21 awareness of where you stand relative to different
22 hospitals.

1 CO-CHAIR FLEISHER: Barbee, do you
2 still have comments?

3 MEMBER WHITAKER: The exclusions, it
4 seemed that there -- sorry, I can't talk about
5 this? Okay. Oh, he brought it up so -- or she
6 brought it up. Yes. So I was just going to say
7 that if you were going to include trauma you ought
8 to include other emergency surgeries where there
9 could be a lot of blood loss, for ruptured
10 aneurysm or things like that.

11 CO-CHAIR FLEISHER: So, Allan, did you
12 still have -- no? Collette.

13 MEMBER PITZEN: I just have a technical
14 suggestion based on what Allan was saying, and
15 being that it's an electronic measure that you're
16 pulling from a large population, perhaps your
17 denominator would be patients with selected
18 surgical procedures and taking into the feedback
19 that the surgeons have given. But the denominator
20 being surgical procedures and the numerator being
21 those that received transfusion. And then, of
22 course, you can stratify by pre-op hemoglobin.

1 Just a suggestion.

2 CO-CHAIR FLEISHER: Thank you. Any
3 other comments before we vote on evidence?

4 MS. QUINNONEZ: We are now voting on
5 Measure 3017. Voting is now open for evidence.
6 Option one, high, option two, moderate, option
7 three, low and option four, insufficient.

8 All votes are in and voting is now
9 closed. For the evidence of Measure 3017, zero
10 percent voted high, 14 percent voted moderate, 57
11 percent voted low and 29 percent voted
12 insufficient.

13 CO-CHAIR FLEISHER: Thank you. So we
14 will not be going forward on this measure.

15 3019, Preoperative Blood Type Testing
16 and Antibody Screening.

17 MS. DOMZALSKI: The intent of this
18 measure is to assess the proportion of, again,
19 selected elective surgical adult patients who had
20 a type and cross match or a type and screen
21 completed prior to the procedure -- completed
22 prior to the procedure.

1 The denominator is adult elective
2 surgeries. The numerator is the number who had a
3 type and cross or type and screen anytime within
4 the 45 days prior to the procedure to the start of
5 the procedure, and that type and screen or type
6 and cross needs to be completed. That's what
7 we're measuring here.

8 There is some evidence that there is
9 occasional non-completion of those procedures
10 prior to performance of the procedure.

11 CO-CHAIR FLEISHER: Barbee, and then
12 Barry.

13 MEMBER WHITAKER: Okay. So there is
14 some evidence, although the evidence is fairly
15 low, with the gap. It was one percent of the time
16 that they weren't completed. And I question
17 whether the -- okay, so the measure follows from
18 clinical guidelines cited by the developer, that
19 in order to effectively utilize resources, pre-
20 transfusion testing should be completed. However,
21 the desired outcome is that the patient get an
22 appropriate unit of blood if transfusion is

1 required.

2 And I would like to ask whether you
3 considered using a numerator of elective surgery
4 patients receiving un-cross-matched blood, rather
5 than the possible unintended consequence of having
6 a lot of type and cross and type and screens that
7 were never required.

8 CO-CHAIR FLEISHER: Do you want to make
9 comments, Barry?

10 MEMBER MARKMAN: I get the eMeasures.
11 I think they're great, as I said before, and I
12 think this is your barrier. You know, in terms of
13 conservation, the numerator, those who had a type
14 and cross match, and the denominator are selected
15 elective surgical procedures.

16 I did not see the list of surgical
17 procedures, but from what I hear they're major
18 surgical procedures. Okay.

19 It was one percent. However, there are
20 other studies that say it's as high as 7 percent.
21 You have the longest measure I've ever seen.

22 However, one of the comments that you

1 make in this that stood out in my mind is that --
2 is by the College of American Pathologists. It's
3 108 public and private participating institutions.
4 And of the type and screens for these major
5 elective procedures, 64 -- or 65 percent were
6 collected prior to the day of surgery and then
7 there were a number, 23 percent after the start of
8 surgery. And of those samples that were sent off
9 late or close to late, 79 percent were considered
10 clinically significant positive in their antibody
11 screens.

12 So here we have major surgery, the type
13 and screen is collected either the day of the
14 surgery or during the surgery, and I think, you
15 know, that the evidence is strong that there's a
16 quality issue with that, to go into major surgery
17 and send off the type and screen. And that's from
18 the American College of Pathologists. I think the
19 evidence is there that this is a quality measure.

20 CO-CHAIR FLEISHER: Okay. Well, I know
21 Aryeh wants to make comments, but anybody --

22 DR. SHANDER: No, I just want to

1 support the argument. That argument is absolutely
2 the reason for this measure, and you don't want
3 somebody who can have a type and cross done where
4 they're matched for a unit of blood receive un-
5 cross-matched blood. That's for elective cases or
6 any cases where you're planning significant blood
7 loss.

8 You want to make sure that the type and
9 cross is performed, or type and screen is
10 performed, and concluded prior to surgery, because
11 if there are antibodies and you need more time,
12 surgery should not start.

13 That's the spirit behind this
14 particular, and I think that what you quoted from
15 the American College of Pathologists is clearly
16 the data that will support this being universal.

17 CO-CHAIR FLEISHER: Any comments?
18 Barbee?

19 MEMBER WHITAKER: I'd just like to
20 consider it as an outcome measure rather than a
21 process measure, because ultimately the goal is to
22 assess your patient carefully, determine whether

1 they will need a type and cross or a type and
2 screen and then do it in the appropriate time.

3 So a little tweaking to both the
4 numerator and the denominator would make this a
5 much better measure.

6 MEMBER MARKMAN: In the 45 days. I
7 mean, we'll go to suggestions, because that's what
8 we were instructed to do. Forty-five days
9 sometimes is hard to, you know -- Yes, 45 days.

10 CO-CHAIR FLEISHER: Other comments from
11 around the room from the standing committee?
12 Barbara?

13 MEMBER LEVY: Yes, I just think -- I
14 really like reformatting this as an outcome
15 measure because the unintended consequence is
16 driving type and screen or type and cross match in
17 a large proportion of patients who don't need it
18 at all. And so we really want to capture those
19 patients who clearly did need it and it was done
20 inappropriately. That's really a good outcome
21 measure.

22 But the unintended consequence of

1 hospitals deciding that they're going to have to
2 go back to doing type and screen or type and cross
3 match for a large proportion of patients who
4 really don't need them, that's expensive. It
5 utilizes resources that need to be used in some
6 other way, and it's really, I think, a problem.

7 DR. WATERS: There is something called
8 a MSBOS, or maximum surgical blood ordering
9 schedule, that basically does what you suggest,
10 which is to focus your resources on not
11 unnecessarily cross-matching or screening
12 patients. And I think the measure's surgical
13 procedures that we selected fall within generally
14 accepted procedures where there is greater than 25
15 percent of blood being needed.

16 We looked at this particular measure at
17 the University of Pittsburgh and found that we had
18 11 patients in the course of one year that got to
19 the operating room without appropriate
20 preoperative testing. And these particular
21 patients ended up having antibodies that made it
22 difficult to get blood to them. And in two of the

1 11 patients, they dropped down below three grams
2 per deciliter of hemoglobin before appropriate
3 blood was available for them.

4 So it's the severity of this particular
5 measure: what we're trying to prevent with this
6 measure is fairly significant.

7 CO-CHAIR FLEISHER: A.J., you had a
8 comment now?

9 MEMBER YATES: I just had a question.
10 Good to see you. We're both from the same
11 institution. The MSBOS is something that came
12 about in the last two years, last year,
13 thereabout.

14 DR. WATERS: That's actually not
15 correct. It's been around since 1971.

16 MEMBER YATES: But the current one that
17 we're -- the updated one --

18 DR. WATERS: Yes, we have a data-driven
19 MSBOS now, and previously it was an opinion
20 guided. But we and several other facilities in
21 the United States have moved towards a data-driven
22 MBOS.

1 MEMBER YATES: And our data driven one,
2 I would actually argue that for a total knee
3 replacement I don't even need a type and screen.

4 DR. WATERS: Yes, absolutely.

5 MEMBER YATES: And so my question is --
6 two questions. Where is the list of which
7 surgeries? Which list are you using, MSBOS, the
8 most data driven one, the most recent?

9 And the second question is, the
10 literature talking about the gap in this -- I know
11 we're not to gap yet -- but the literature on the
12 gap is limited to around 2004 in terms of time.
13 So is there any current literature or data showing
14 a gap using the new MSBOS?

15 MS. DOMZALSKI: I'll address the last
16 question first. Hospitals are not particularly
17 fond of publicizing their errors and their
18 difficulties and their failures. For example,
19 their need to transfuse un-cross-matched blood
20 because they didn't complete a procedure. So,
21 when doing the literature review we found all the
22 literature we possibly could.

1 As for the MSBOS, the list of
2 procedures that are covered are covered in a value
3 set here, and it resembles the selective elective
4 surgical procedure list, except that it is minus
5 certain maxillofacial procedures, certain
6 gynecological procedures, and others that are not
7 likely to require blood replacement.

8 MEMBER YATES: And just out of
9 ignorance, which section is the value set listed?
10 Is it in one of the additional sets?

11 MS. DARDIS: It's a part of the
12 specifications. I'm not sure where NQF packaged
13 it in the package you received.

14 MEMBER YATES: Okay. Well, I'll have
15 to search for it. Thanks.

16 CO-CHAIR FLEISHER: Thank you. Rick?

17 MEMBER DUTTON: Amy found the list.
18 Knee replacement is on it.

19 CO-CHAIR FLEISHER: Thank you. So --

20 MEMBER LEVY: So is LAVH, and the
21 current data show an average blood loss of
22 laparoscopically-assisted vaginal hysterectomy at

1 less than 100 cc's.

2 CO-CHAIR FLEISHER: So the issue is for
3 evidence, unless anybody else has other comments,
4 that we vote on evidence as currently constructed.
5 So in the specs that we were given. And if we can
6 call it.

7 MS. QUINNONEZ: We are now voting on
8 Measure 2019. Voting is now open for evidence.
9 Option number two is moderate. Option number
10 three, low. Option number four, insufficient.
11 Option number two, moderate. Option number three,
12 low. Option number four, insufficient.

13 All votes are in and voting is now
14 closed. For the evidence of Measure 3019, 24
15 percent voted moderate, 48 percent voted low and
16 29 percent voted insufficient.

17 CO-CHAIR FLEISHER: Okay. I was just
18 clarified, given this didn't meet on evidence,
19 although several people had suggestions for The
20 Joint Commission on other ways to assess this, we
21 will be moving forward to the next.

22 3020, Initial Transfusion Threshold.

1 MS. DOMZALSKI: Once again, this
2 measure has been constructed for transfusion
3 committees to have a sense and see how their blood
4 transfusion administration is occurring. And as
5 you are probably all familiar with, a restrictive
6 transfusion strategy is supported rather than
7 transfusing patients at a higher level of
8 hemoglobin or hematocrit.

9 And so this measure gives those
10 transfusion committees a profile of blood usage in
11 their institution by showing them the hemoglobin
12 values of each patient immediately prior to the
13 first unit of a transfusion.

14 There are exclusions in the measure,
15 such things as emergency room patients, et cetera.
16 The denominator is all hospitalized adult patients
17 who get a red blood cell transfusion, and we're
18 looking at the first unit only.

19 The numerator is stratified by
20 hemoglobin values in one gram per dL increments in
21 a range from an aggregate of less than seven
22 through an aggregate of 10 or greater.

1 CO-CHAIR FLEISHER: Okay. Barbee?

2 MEMBER WHITAKER: Okay. This measure
3 is to monitor proportions of patients transfused
4 at initial hemoglobin levels from less than seven
5 to greater than ten. The evidence, while
6 moderate, is sufficiently strong to introduce a
7 program of monitoring with the intent of having
8 more transfusions occur at the lower, more
9 restrictive end of the spectrum than at the
10 higher, liberal end.

11 The blood utilization committee or the
12 transfusion committee will have a metric from
13 which to investigate transfusion practice. I
14 think there's always a question of what you do
15 with the metric. We have evidence through a
16 survey that we conducted at AABB that indicates
17 that many hospitals, most hospitals, have policies
18 for transfusing between seven and eight and eight
19 and nine for different circumstances, but that
20 their actual transfusion values don't always meet
21 those policies to which they intend to adhere.

22 So this measure would allow measurement

1 of the adherence to that policy -- to their
2 internal policies, but I would say that for an
3 investigational purpose, a self-monitoring
4 purpose.

5 CO-CHAIR FLEISHER: Great. And Lynn,
6 you're the second. Any additional comments?

7 MEMBER REEDE: Just one small comment.
8 As far as evidence from STS and also from the
9 Society of Cardiovascular -- or Anesthesiologist
10 guidelines, they recommended, and the developer
11 noted this in their rationale, that also
12 underlying cardiac disease post-operative status
13 in clinical conditions might be considered because
14 there is not good evidence to support keeping
15 those patients at a seven hemoglobin.

16 So just that the exclusion did not
17 include, like in other ones we've had
18 contraindications, kind of a general decision
19 process for the clinician.

20 CO-CHAIR FLEISHER: Thanks.
21 Christopher?

22 MEMBER SAIGAL: Yes. I think that the

1 rationale behind using these measures for
2 developing evidence was that they were using the
3 EMR and there was specified fields and three types
4 of fields and it was more complicated to develop
5 evidence.

6 This sounds like it's really a research
7 project to understand what the prevalence of
8 transfusion rates are in the country or different
9 levels.

10 So as a quality measure, I don't see
11 how this would be implemented because it sounds
12 like there's different standards locally. There's
13 no agreement.

14 So I don't think this really fits the
15 idea of a quality measure. It fits the idea of a
16 research or survey project.

17 CO-CHAIR FLEISHER: Rick and then Liz.

18 MEMBER DUTTON: I've worked in a number
19 of hospitals that routinely look at all
20 transfusions to see what the hemoglobin level was
21 when we gave the blood for purposes of quality
22 improvement, and I've looked at a lot of

1 exceptions as to why that might have happened.

2 I am very concerned about the
3 unintended consequence in this measure of delaying
4 transfusion in a patient who needs it while you
5 wait for a hemoglobin value. If there's a hole in
6 the aorta, I don't care what the hemoglobin is.
7 The patient should be transfused.

8 MEMBER EREKSON: So I think this is
9 also --

10 DR. SHANDER: I think that's excluded
11 already.

12 MEMBER EREKSON: In the exclusion
13 criteria, one of the things that I notice is
14 pregnancy is not an exclusion, although major
15 trauma is. And when you're having a patient who
16 is having a massive bleeding, hemorrhage
17 postpartum, that I would equate to some of the
18 trauma patients, and so that might be considered.

19 CO-CHAIR FLEISHER: So that --

20 MS. DOMZALSKI: I'm sorry. In the
21 world of e-specifications it's very difficult to
22 find in a chart the items that would exclude or

1 necessarily explain why a patient had received a
2 transfusion outside the accepted parameters.

3 For example, it's generally agreed in
4 the guidelines that heart failure or heart
5 difficulties are reason for transfusing the
6 patient at a higher hemoglobin level. But in an
7 electronic record, you really cannot find that.
8 It will be in the problem list, but it will be
9 undated. So you don't know if that heart problem
10 preceded the transfusion or followed the
11 transfusion.

12 In addition, there's an imprecise
13 definition of what heart failure is. Is that
14 heart failure 20 years ago or is it heart failure
15 yesterday? There is no precise definition.

16 Similarly, a patient with a hole in the
17 aorta may be described as having active bleeding.
18 But if you ask a number of clinicians what is
19 active bleeding, the interpretation of that is
20 going to vary.

21 Is it 4 ABD's in an hour or is it a
22 Hemovac full inside of 30 minutes? What is active

1 bleeding?

2 So because of the imprecise
3 definitions, we did want transfusion committees to
4 look at the clinical record and make a clinical
5 determination rather than to subject the outcome
6 of a measure or a publicly reported item to what
7 is in an electronic record that may be imprecise.

8 CO-CHAIR FLEISHER: So, just as a
9 reminder, the evidence criteria is that a process
10 or intermediate outcome is based on a systematic
11 review in grading the body of empirical evidence
12 where the specific focus of the evidence matches
13 what is being measured.

14 There's a lot of concerns I had about
15 specification that I'm hearing from the committee,
16 which would be -- we could address after the
17 evidence, correct? Sal?

18 MEMBER SCALI: I guess just a
19 clarification. So, as a quality measure, one of
20 the points that was raised about sort of how there
21 are different thresholds, so how would this
22 number, if it ever were to be reported, because if

1 one center uses seven, another uses eight, is it
2 just a relative percent of where you are with your
3 threshold at your center? Or is there some agreed
4 upon threshold that the centers are being held to
5 in terms of how you're determining the numerator
6 and denominator?

7 I guess that was my first question in
8 terms of clarification. Two, clarification of the
9 measure, is it for the entire episode of care or
10 only inter-op transfusion?

11 If it includes the entire episode of
12 care, you've got your open AAA repair and then on
13 post-op day four somebody pulled the trigger and
14 said give them a blood transfusion. But, oh wait,
15 the patient's having an MI and the hemoglobin was
16 eight and cardiology said to go ahead and
17 transfuse, but the institutional trigger is seven.
18 So how does that sort of get factored?

19 Three, for patients who undergo
20 contemporary aortic surgery actually there's
21 compelling evidence to suggest that restrictive
22 transfusion leads to higher rates of spinal cord

1 ischemia. And so actually liberal transfusion is
2 now becoming the standard, many of the times, for
3 patients who undergo open thoracical abdominal
4 aneurysm repair and if you're trying to do
5 preemptive protocols to prevent spinal ischemia
6 risk.

7 Lastly, Jehovah's Witness, I didn't see
8 that that was an exclusion for trigger. So if you
9 would address those.

10 MS. DOMZALSKI: Spinal surgery patients
11 --

12 MEMBER SCALI: Patients at risk of
13 spinal cord ischemia after open aortic surgery.

14 DR. SHANDER: No good data for that for
15 transfusion, by the way.

16 MEMBER SCALI: I disagree.

17 DR. SHANDER: You may, but you can
18 quote the data then, because I think that making
19 a statement like that for preemptive transfusion,
20 that would change, I think, the whole transfusion
21 world, in a sense, knowing that that was effective
22 in prevention.

1 I think that the data comes from
2 retrospective data in terms of prone patients and
3 --

4 CO-CHAIR FLEISHER: Let's -- let's --
5 let's focus on the question at hand, which is
6 evidence or whether or not the measure does what
7 its specification is.

8 MEMBER GROVER: Well, I don't think
9 you're collecting enough data that we would
10 consider -- I don't know whether this is under
11 evidence or not -- but that we would consider it
12 important, or reliable data that we'd consider
13 important.

14 We have, personally, a cut-off of less
15 than seven hemoglobin in our cardiac surgery
16 patients, but we factor in the age. We factor in
17 if they have COPD. We factor in if it's an
18 incomplete revascularization, all of those things
19 where a hemoglobin, a higher hemoglobin might
20 alleviate the patient.

21 We also factor in whether the patient
22 is so tired they can't get up and walk and they

1 may be at risk for a pulmonary embolism if we
2 don't give them a transfusion.

3 There are several things that come in
4 to -- which you, you know, when you receive the
5 patient at bedside, that affect your judgment.
6 It's not gaming and it's trying -- I mean, we try
7 to really conserve and we've driven down our blood
8 utilization. But you're at risk in this of not
9 capturing those types of things and penalizing or
10 misidentifying people that are abusing the blood
11 transfusions.

12 MS. DOMZALSKI: And that's why we
13 wanted the clinician to look at the record and
14 factor in all of those types of things that you
15 mentioned, rather than to make a cut-off judgment.

16 And to answer your previous question,
17 yes, this does cover the entire episode of care.
18 But, again, it's the first unit of any
19 transfusion. It's only one unit per person.

20 And your first question -- I'm sorry --
21 could you repeat that again?

22 MEMBER BILIMORIA: So we've been

1 looking at -- we've done this with about 45
2 hospitals and implemented a blood use measure.

3 It's a registry measure, and then based
4 on the NSQIP data you can tell what -- sort of
5 whether they have CHF and whatnot and so you have
6 some validated definitions to combine. It's a
7 registry measure. It's extremely intensive, but
8 we find a lot of the inappropriate blood use is
9 beyond the first transfusion as well and you can
10 set different thresholds but you can give people
11 a lot of information by setting one.

12 I was particularly interested in an
13 eMeasure for this because the extraction burden is
14 extremely high. It's the one that gets that most
15 complaints. So maybe there's some way to put
16 these two together in some fashion.

17 MS. DARDIS: I would like to thank you
18 for bringing that up. I think that one of the
19 unique advantages of an eMeasure for this kind of
20 thing and the reason we've structured this as a
21 tool for performance improvement rather than a
22 metric that is for comparison is the fact that

1 you're using that real-time clinical data and you
2 can use the same data that you're using to present
3 measures to the board to provide the clinician
4 with decision support.

5 And so that maybe on a facility level
6 you're working with specific conditions and you
7 have specific thresholds for specific conditions
8 you can use common data elements for measurement
9 and for your specific modifications for your
10 facility and so I think it's an opportunity with
11 eMeasures that we need to explore further.

12 The other is the reduction of burden in
13 the data collection that you're using the EHR data
14 and we don't have 200 data points in this measure
15 to capture every single condition but we are able
16 to provide some information real-time to the
17 facility.

18 CO-CHAIR FLEISHER: Fred, did you have
19 another comment? No? Okay. So we are voting on
20 evidence.

21 DR. WATERS: Can I say one more thing?

22 CO-CHAIR FLEISHER: Sure.

1 DR. WATERS: This measure -- part of
2 the intent was to get people to give red cell
3 transfusions based on quantitative data rather
4 than guessing, which is kind of the current
5 standard is that guesswork -- if somebody has a
6 hemoglobin and it doesn't really matter what that
7 particular value is, dependent upon the
8 circumstance, but I mean it should be a
9 quantitative decision rather than guesswork.

10 CO-CHAIR FLEISHER: Thank you.

11 MS. QUINNONEZ: We are now voting on
12 measure 3020. Voting is now open for evidence.
13 Option one, high, option two, moderate, option
14 three, low, option four, insufficient.

15 (Voting.)

16 MS. QUINNONEZ: All votes are in and
17 voting is now closed. For the evidence of measure
18 3020, 5 percent voted high, 58 percent voted
19 moderate, 26 percent voted low and 11 percent
20 voted insufficient.

21 CO-CHAIR FLEISHER: Okay. We can move
22 on with the discussion. So it passed on evidence.

1 Performance gap -- do we discuss that? Okay.

2 Barbee?

3 MEMBER WHITAKER: Okay. So there's not
4 a lot of data for a performance gap but based on
5 our own experience with the AABB there is a gap
6 with what people say they're going to do and what
7 they do. So I think that it's definitely a
8 measure that is worthy of monitoring.

9 CO-CHAIR FLEISHER: Lynn, any further
10 -- Barry?

11 MEMBER MARKMAN: Yes. There's also a
12 bigger gap in terms of using an eMeasure and it's
13 not -- it's more in the macro sense of how you
14 capture this data in an eMeasure and subsequently
15 disperse it in a coordinated care center.

16 So, I mean, we could look at the
17 specific measure and say, you know, there's a gap
18 or not, but there's a gap with this technology.
19 There really is a true gap with this technology
20 and it's in a bigger sense and it's for, you know,
21 for quality care of patients. I'm just going to
22 put that out as a -- as a general comment.

1 CO-CHAIR FLEISHER: Amy?

2 MEMBER MOYER: I'm struggling a little
3 with the concept of gap as it relates to this
4 measure. I think what we'll find when the results
5 come back are there differences in transfusion
6 thresholds and where people are being transfused?
7 It sure sounds like it from around the room but I
8 think the bigger question is is there in
9 appropriate variation and that are, you know,
10 relevant to what.

11 Just saying, okay, there's variance
12 there -- that's one thing. But what's the gap and
13 what are we looking for?

14 CO-CHAIR FLEISHER: Comments?

15 DR. WATERS: I'd like to say that the
16 gap is huge. At the University of Pittsburgh
17 we've looked at a number of different surgical
18 procedures. Primarily or at least orthopedic
19 total joint replacements has been an area of focus
20 and for primary total hip replacement for
21 arthritis we saw a variability from one surgeon
22 who transfused 100 percent of his patients to a

1 different surgeon that transfused 1 percent.

2 So if you're using gap as a measure of
3 -- as a word for variability, the variability is
4 huge. Fortunately, we've made huge strides in
5 narrowing that gap where most of our surgeons are
6 now down under 5 percent for transfusing total
7 hips, but there is a big opportunity here.

8 MS. DOMZALSKI: When we place these
9 measures out for public comment, we had about 140
10 hospitals respond and one of the questions was is
11 there a gap between what this measure asked you to
12 do and what you're currently doing.

13 Well, more than two-thirds of them
14 reported, yes, there is a difference between what
15 you're expecting and what we're doing and as we
16 were going around to test these at various
17 hospitals every hospital could put their finger
18 exactly on where the problem was in terms of
19 people being transfused over a hemoglobin of nine.

20 In one hospital it was an OB/Gyn who
21 did it. In another, it was a particular
22 orthopedic surgeon. So yes, there's a gap. It's

1 apparent at every hospital that we were at.

2 CO-CHAIR FLEISHER: A.J.?

3 MEMBER YATES: My understanding is that
4 the tool is -- or the measure is made to help the
5 blood bank do its job better, correct?

6 MS. DOMZALSKI: Not necessarily the
7 blood bank but the blood transfusion --

8 MEMBER YATES: Well, the committee.
9 The blood --

10 MS. DOMZALSKI: Yes.

11 MEMBER YATES: I stand corrected. The
12 blood transfusion committee. At least where we
13 practice, and again, the University of Pittsburgh
14 -- the act of ordering the blood requires the
15 insertion of the hemoglobin and hematocrit and the
16 indication, that being ongoing bleeding, et
17 cetera, such that that automatically goes to the
18 blood bank.

19 Is that not a common scenario or is --
20 are we -- are we talking about much less
21 sophisticated electronic medical records
22 elsewhere?

1 MS. DARDIS: You are special. Yes. We
2 looked up the literature that exists for clinical
3 decision support and order sets for blood use.
4 There are a few medical sites -- UPMC, University
5 of Iowa where those order sets exist and you have
6 to enter a condition.

7 There is not standardization around
8 that. We did not see that everywhere we visited
9 just among five hospitals I think one had that
10 built into their ordering. There's a lot of fear
11 in EHR implementation as an -- I guess this is
12 kind of an aside but there's a lot of fear about
13 what you put in front of the physician as a
14 requirement in ordering and I think this is an
15 area where we heard a lot of that.

16 And so we actually had some excitement
17 in seeing this measure as a way to bring those
18 things into their practice because they've heard
19 about them but they haven't implemented them
20 themselves.

21 MS. DOMZALSKI: At one of our test
22 hospitals they do have CPOE and they do have

1 decision support tools and it was described to us
2 that every time they have a new groups of
3 residents their blood utilization goes up because
4 the resident is bypassing all those decision
5 support tools by giving in indication of other for
6 the transfusion.

7 And so it takes a lot of intervening
8 with each of the residents to stop that other as
9 being an option for transfusion.

10 CO-CHAIR FLEISHER: Okay. Barbee, do
11 you want to make another comment?

12 MEMBER WHITAKER: I'd just like to
13 comment that there's no -- there's no category for
14 hemoglobin not measured before first unit
15 transfused and it might be valuable to kind of get
16 at the work-up not being complete prior to -- I
17 mean, not just the type and screen but the H&H,
18 anything that would not be complete prior to the
19 first transfusion or maybe that doesn't happen but
20 it seems like there could be circumstances where
21 you could push the practice to be making sure that
22 there is a hemoglobin on everyone before they do

1 get a transfusion.

2 MS. DOMZALSKI: Thank you.

3 CO-CHAIR FLEISHER: Great. So why
4 don't we vote on gap?

5 MS. QUINNONEZ: Voting is now open for
6 a performance gap of measure 3020. Option one is
7 high, option two, moderate, option three, low and
8 option four, insufficient.

9 (Voting.)

10 MS. QUINNONEZ: All votes are in and
11 voting is now closed. For performance gap of
12 measure 3020, 10 percent voted high, 65 percent
13 voted moderate, 0 percent voted low and 25 percent
14 voted insufficient.

15 CO-CHAIR FLEISHER: Great. So we will
16 continue. So next what do we have -- what else
17 are we -- okay. Now it's actually the
18 specifications -- a discussion.

19 MEMBER WHITAKER: So like the numerator
20 and the denominator?

21 CO-CHAIR FLEISHER: Correct, and the
22 exclusions and the comment about, you know --

1 MEMBER WHITAKER: Okay.

2 CO-CHAIR FLEISHER: -- some of the
3 comments I heard about, you know,
4 interoperatively, massive bleeding and how the
5 specifications --

6 MEMBER WHITAKER: Okay. So thank you.
7 Regarding the numerator, I would suggest adding
8 the additional not captured categorization and
9 then --

10 CO-CHAIR FLEISHER: So let me just get
11 some clarification, either Melinda or Elisa. When
12 we're voting, we're voting as it is but -- and
13 it's a -- and it's a must pass criteria. However,
14 if it doesn't pass and the Joint Commission is
15 willing to make changes that can occur in --
16 during the call or no?

17 MS. MUNTHALI: It depends on how
18 significant those changes are and how quickly the
19 Joint Commission can turn those around. So we'd
20 have to get an agreement from you today to say
21 that you can make those changes by the post-
22 comment call.

1 CO-CHAIR FLEISHER: We'll probably vote
2 as is or as is with modification might be
3 something we can discuss if it doesn't pass. But
4 we'll first -- but please, as is and things that
5 are -- they should do or must do from your
6 perspective.

7 MEMBER WHITAKER: Okay. I'd like to
8 comment that patients under the age of 18 can
9 benefit from hemoglobin optimization so would like
10 to see it extended to pediatric patients. I don't
11 know if that's the standard of care -- for the
12 quality measures here but obviously that would be
13 optimal.

14 And then regarding exclusions, other
15 emergent surgeries which may have high blood loss,
16 if there's not time to get a hemoglobin in advance
17 might be an exclusion and then the emergency
18 department -- I question whether they should be
19 given an opt out categorically and whether they
20 could also wait or, you know, benefit from paying
21 attention to hemoglobin levels before they
22 transfuse.

1 MS. DARDIS: I'm sorry. Can I ask for
2 a clarification? Would you like to see emergency
3 department excluded from the measure or included?

4 MEMBER WHITAKER: Included.

5 MS. DARDIS: Okay. Thank you.

6 CO-CHAIR GUNNAR: Fred?

7 MEMBER GROVER: I'm concerned under
8 your specifications for who's included just as a
9 hemoglobin again and it doesn't included
10 hemorrhagic shock, bleeding, current active
11 bleeding -- some of those things we talked about
12 earlier which are obvious indications for a
13 transfusion regardless of the hemoglobin.

14 CO-CHAIR GUNNAR: Barry? Any other
15 comments? Amy?

16 MEMBER MOYER: I apologize for
17 timeliness. I'm just going to ask instead of
18 trying to look this up. So a denominator
19 exclusion is patients whose first unit of whole
20 blood was given while in an emergency department.
21 If these are elective surgeries shouldn't
22 admission source emergency department perhaps be

1 excluded entirely?

2 MS. DARDIS: This measure is for all
3 patients, not elective surgicals.

4 CO-CHAIR FLEISHER: Lynn? Did Lynn
5 already go? Nothing? Anybody else have any
6 comments on the specifications?

7 MS. QUINNONEZ: Voting is now open for
8 eMeasure specifications for measure 3020. Option
9 one, high, option two, moderate, option three, low
10 and option four, insufficient.

11 (Voting.)

12 MS. QUINNONEZ: All votes are in and
13 voting is now closed. For the eMeasure approval
14 for trial use for measure specifications of
15 measure 3020, 5 percent voted high, 37 percent
16 voted moderate, 47 percent voted low and 11
17 percent voted insufficient.

18 CO-CHAIR FLEISHER: So this is
19 consensus not reached, which means we will
20 continue to evaluate the measure. One of the
21 questions is is the Joint Commission interested in
22 working with some of the things they heard today

1 to potentially change it during the phone call.

2 MS. DARDIS: I think from a time frame
3 perspective, yes. I think it's unclear -- and
4 Ann, jump in -- but I think it's unclear which
5 changes that were suggested are the changes that
6 are most of import to the group. I think any
7 changes we make we want to take back to our
8 advisory panel.

9 CO-CHAIR FLEISHER: Sure, Barbee, do
10 you have a -- or maybe in the next couple days we
11 can get some consensus on -- can you work with
12 staff to give some significant recommendations of
13 what is most concerning?

14 MS. WATT: I was going to say this is
15 Ann, you know that. I'm sort of confused actually
16 about what the ask is.

17 It was our understanding as you're
18 looking at the HQMF specifications you were
19 actually looking at the construct of the eMeasure
20 as opposed -- the technical construct as opposed
21 to the content of the measure itself.

22 And so as I'm listening to the

1 conversation I'm understanding that you are asking
2 us to change the clinical content of the
3 specifications irrespective of the HQMF
4 specification. Is that correct?

5 CO-CHAIR FLEISHER: Can you be
6 specific? Can someone articulate? Because I
7 missed the --

8 MS. SKIPPER: I felt like I heard a
9 committee member ask for the measure to be
10 extended to the pediatric population and then also
11 --

12 CO-CHAIR FLEISHER: That's not a
13 critical issue. That's a typical ask of this
14 committee.

15 MS. WATT: Yes, I understand that.

16 CO-CHAIR FLEISHER: So I think I'll
17 take chair prerogative in saying if that doesn't
18 happen that's -- we'd like it to be. Anything
19 else that was asked, Barbee?

20 CO-CHAIR GUNNAR: I think the -- Fred's
21 -- his --

22 MEMBER GROVER: Yes, I mean, my concern

1 was that there's more than the hemoglobin that's
2 a trigger to transfusion and at least on some of
3 the major ones, such as active bleeding
4 hemorrhagic shock, if you're just looking at
5 hemoglobin you're going to miss a fair amount of
6 things. Even in the operating room, you can have
7 things that you aren't expecting on elective cases
8 that require them. So I think --

9 CO-CHAIR GUNNAR: How will the -- how
10 will the threshold reflect the clinical condition?

11 MEMBER GROVER: Yes.

12 CO-CHAIR GUNNAR: And is it reflective
13 of current variable practice across health care
14 facilities?

15 MEMBER GROVER: Right. There is
16 variation in what your hemoglobin level is but if
17 people are bleeding significantly and they're in
18 shock there's very little variation in that, I
19 would think.

20 MS. DOMZALSKI: The number in the
21 threshold by itself is insufficient to determine
22 if a transfusion could have been avoided. It does

1 need to be evaluated by a clinician in
2 relationship to the clinical signs and symptoms,
3 which is why this is being done for the
4 transfusion or blood usage committee to review.

5 As before, it's very difficult to
6 specify what active bleeding is. Every clinician
7 has a different concept of what that is and that's
8 why we'd like the committee to look at this when
9 it turns out that a transfusion was given above a
10 threshold whether it be seven in your facility or
11 eight or nine. And so that's why we'd like the
12 committee to look at it. We recognize that that
13 would be perhaps understandable.

14 DR. WATERS: I've got to say that
15 measuring a hemoglobin in the operating room takes
16 10 microliters in about 20 seconds. So I don't
17 know how it would interfere with the process of
18 getting a patient blood.

19 MEMBER GROVER: Well, if you wait for
20 a hemoglobin change in somebody who's bleeding
21 rapidly, they could be dead.

22 CO-CHAIR GUNNAR: Exactly. Hemoglobin

1 will be normal when you're providing active
2 transfusions to an actively bleeding patient.

3 CO-CHAIR FLEISHER: Liz?

4 MEMBER EREKSON: So I had said this
5 before but just to remind, in pregnant patients
6 undergoing postpartum hemorrhage they may be
7 considered, like, traumatic injury and you may
8 want to exclude them or consider them in a
9 different measure.

10 CO-CHAIR FLEISHER: So -- Allan?

11 MEMBER SIPERSTEIN: Yes. So again, the
12 ratio as expressed, as I've said before, doesn't
13 make clinical sense, but let me play devil's
14 advocate for a minute.

15 You bring all your patients to anemia
16 screening. Nobody ever goes to the operating room
17 with a crit, you know, less than -- or a
18 hemoglobin less than 10. Well, if you look at
19 your measure a couple years from now, all of your
20 transfusions will have been in patients who are
21 over 10 because they've had, has been nicely
22 expressed, unexpected bleeding in the operating

1 room. And so it's not really clear to me how
2 you're going to use this number over time to
3 monitor quality improvement.

4 Again, as I've said, each of the
5 numerator and denominator are laudable goals but
6 the end result as expressed does not make clinical
7 sense to me.

8 DR. SHANDER: Well, from your lips to
9 God's ear, as they say, but because I don't think
10 we're there yet. But I think that if that is the
11 consequence of anemia management is that
12 transfusions are -- you know, we're going to have
13 to relook at this measure at some point.

14 I think the idea -- and I think was
15 already mentioned -- is this is basically just to
16 trigger a review. If there is justification for
17 a transfusion at high level of hemoglobin, meaning
18 that the patient is hemorrhaging, I don't think
19 there's going to be an argument and that's not the
20 intent. The intent is really to have a measure
21 for somebody to start in terms of a threshold for
22 the transfusion.

1 Once you've identified that hemoglobin
2 is not the indication for a transfusion, as we all
3 talked about was hemorrhage, then I don't think
4 that there is an issue and to some extent I think
5 that's -- there is some comments on the exclusion
6 on that, if I recall.

7 CO-CHAIR FLEISHER: So let me throw out
8 something to the Joint Commission on what I'm
9 hearing. I actually think if you stratified this
10 by an intraoperative transfusion versus a post-
11 operative transfusion, you might get some interest
12 -- it might have some more validity or some other
13 ways to get to some of the concerns.

14 I don't know whether others think about
15 that but that may be a way to -- because what I'm
16 hearing from the committee, and I actually -- I
17 don't want to have to worry about getting a
18 hemoglobin level and I'll say 10, that'll actually
19 it would be the hemoglobin level -- it'd be the
20 pre-op hemoglobin level and that will make it very
21 different to compare to, you know, a transfusion.

1 But if I said intraoperatively, there
2 is a preoperative hemoglobin level and that's why
3 we see some screwy data that doesn't make sense.
4 Post-operatively, I think, most of the time we
5 usually have time to get a hemoglobin level unless
6 they're acutely bleeding. So I don't know if
7 that's something.

8 MS. DARDIS: I understand the concern
9 of the intra-op setting. One thing I'd like to
10 raise is that this is an all -- again, this is an
11 all patients measure. It's part of the set that
12 we brought to the surgical committee. This
13 specific measure is for all hospitalized patients,
14 not just surgical patients.

15 So the strata might have to look at
16 something different, but the intent was to improve
17 blood management for all patients with this
18 measure, not just the surgical. So I'm wondering
19 if another option -- I'm not the clinical expert
20 on this -- would be to exclude the intra-op
21 transfusion.

22 CO-CHAIR FLEISHER: Is that of -- or

1 stratified, which would be the other way to do it.
2 Barbee, did you have another comment?

3 MEMBER WHITAKER: My other comment was
4 just the value of having an eMeasure for this to
5 establish the infrastructure to be able to monitor
6 and report internally.

7 I think that eMeasure process would be
8 very valuable for everyone even if -- even if it's
9 not -- if we could keep it from being something
10 that you're -- something that you're looking at
11 but not something that you're held to.

12 CO-CHAIR FLEISHER: And thank you.

13 Comment? Rick?

14 MEMBER DUTTON: I think some of the
15 reaction of the committee is to the very arbitrary
16 nature of this: transfusion judged on a hemoglobin
17 level. The measures that have done better here,
18 just in the last two days, have been ones that are
19 measuring physician or practitioner judgment.

20 So if you could get at the underlying
21 physiology of this and, say, create an outcome
22 measure where, of the transfusions given, what

1 percent were indicated because of bleeding or
2 ischemia or a clinical indication for the
3 transfusion.

4 Do I know how to e-specify that? No.
5 But that's where we would like to see a good
6 quality measure appear.

7 MS. DARDIS: Understood, that is not a
8 eCQM.

9 MEMBER MOSS: I just want to ask if you
10 could help talk us through how this would sort of
11 play out in the real world. So you do these
12 thresholds.

13 A certain number of patients meet them.
14 That will trigger a local review. Each case will
15 be looked at on an individual basis with a
16 clinical decision whether it was appropriate or
17 not. Then we come back next year and do these
18 thresholds again.

19 We don't know whether they should go up
20 or down or stay the same. How will we know if
21 this is working?

22 DR. WATERS: Well, getting back to the

1 University of Pittsburgh, what we've done for our
2 anesthesiology department is we've made this
3 measure for -- it's a value measure for our
4 anesthesiologists and how they get paid.

5 What we found from hospital to hospital
6 is that one hospital will transfuse 95 percent of
7 their patients in the operating room with a
8 hemoglobin less than eight, whereas another
9 hospital in our system will transfuse their
10 patients only 45 percent of the time with a
11 hemoglobin less than eight. So there's huge
12 cultural variation from institution to
13 institution, or rather, hospital to hospital.

14 But the opportunity here is to decrease
15 that variability from hospital to hospital and I
16 think there's a large opportunity there.

17 CO-CHAIR FLEISHER: Okay. So we're
18 worried about losing our quorum. So Barry,
19 specifically --

20 MEMBER MARKMAN: Yes, just one
21 question. Now, this is for a trial, right?

22 CO-CHAIR FLEISHER: Yes.

1 MEMBER MARKMAN: And then they'll come
2 back -- I mean, can they tweak or, you know --

3 CO-CHAIR FLEISHER: So the answer is I
4 would hope that a few people over the next couple
5 days can send to Melinda if they have specific
6 questions for the Joint Commission to consider in
7 how they specify, correct?

8 And if the Joint Commission is
9 interested in addressing them then potentially we
10 could go from this gray area to get it back into
11 where it would be -- would pass the criteria. Am
12 I accurately -- at the time of the discussion,
13 yes.

14 MS. WATT: I'm sorry, and I think that
15 maybe, Jason, this is a question for you. It was
16 our understanding that this category had to do
17 with the appropriateness of the technical
18 specification of the measures, not the clinical
19 content of the specifications but the way that
20 they're represented for collection by an
21 electronic record.

22 What we are talking about has nothing

1 to do with that, and so I'm a little confused as
2 to what -- we would be happy to look at making
3 modifications to the clinical specifications but
4 I'm not sure how that relates to this criterion
5 for the HQMF specifications and we're hoping,
6 Jason, that you can clarify.

7 MR. GOLDWATER: So Ann, you're correct
8 that this part of the feasibility really is
9 talking about being the electronic construction
10 the HQM on the format of the measure, the sources
11 the data collection could be implemented as not
12 referencing the clinical specifications. She's
13 correct.

14 MS. MURPHY: But the piece of the
15 measure, Jason -- if you'd help us just a minute
16 -- the piece of the measure that they're talking
17 about and that they are -- they voted on are the
18 specifications of the measure.

19 MR. GOLDWATER: That was the path that
20 they just voted on. Correct.

21 CO-CHAIR FLEISHER: Right.

22 MS. MURPHY: Yes, that's what we're

1 talking about.

2 MR. GOLDWATER: Those were the clinical
3 specifications, right.

4 MS. MURPHY: Yes.

5 CO-CHAIR FLEISHER: Yes, we voted
6 correctly from your perspective if we had concerns
7 about the clinical specifications or --

8 MR. GOLDWATER: That's correct. Right.
9 This -- this section, what we were just at,
10 feasibility is talking about the electronic
11 development of the measure. That's correct.

12 MS. MURPHY: And the first part of the
13 feasibility are the specifications. That's the
14 one piece that we understood that the committee
15 was to vote on were those specifications of the
16 measure that in fact are listed in the feasibility
17 section.

18 MR. GOLDWATER: That this -- the
19 electronic specifications of the measure lead to
20 the metric that matches the purpose and intent.
21 That's correct. The specifications that were
22 voted on before are clinical in nature.

1 MS. WATT: You're talking about the
2 evidence and the gap that we voted -- that were
3 voted on previously -- the content of the measure.

4 MR. GOLDWATER: That's correct. That's
5 what you just voted on recently.

6 CO-CHAIR FLEISHER: And then
7 specifications.

8 MR. GOLDWATER: That's passed, right.
9 The electronics that you were just on in the
10 feasibility part in specifications, is the
11 construction of the measure electronically, will
12 it lead to the metric that matches the intent of
13 the measure?

14 CO-CHAIR FLEISHER: So the concerns of
15 many of the committee is whether the clinical
16 specifications were valid to -- it's almost
17 validity if we were in a different measure.
18 Where do we put that in this construct?

19 Because what we were told is when you
20 come back, we don't vote on that again. So I
21 think what you're hearing is some confabulation.

22 MR. GOLDWATER: So, I mean, I think if

1 there's concerns about the clinical nature --
2 clinical specifications of the measure then -- I
3 don't know, that's kind of a -- you have to sort
4 of balance that, I guess.

5 If you've got concerns about the
6 clinical specs and you're not sure about whether
7 or not it's conducive or not to, I guess,
8 improving overall quality based on the objective
9 and intent of the measure, then when you get to
10 this feasibility part all you're really looking at
11 there is, you know, electronically speaking was it
12 constructed in such a way that it matches the
13 overall intent?

14 So if you've got a problem with the
15 intent, subsequently, there may be an issue with
16 the way the measure is designed.

17 CO-CHAIR FLEISHER: I'm not sure if
18 that helped you.

19 MS. WATT: Thanks. We'll look forward
20 to hearing what Melinda shares with us.

21 MS. MURPHY: So I think -- and Christy,
22 will help -- if they send the comments to surgery

1 --

2 MS. SKIPPER: Yes.

3 Surgery@qualityforum.org. Any comments or input
4 and provided to the Joint Commission on this
5 measure.

6 CO-CHAIR FLEISHER: Let me be specific.

7 What we want is comments, not to change the whole
8 measure. If there are tweaks to the way
9 inclusion, exclusion -- and please correct me if
10 I'm overstating my interpretation.

11 MS. SKIPPER: It's clinical content.

12 CO-CHAIR FLEISHER: Clinical content

13 that they could take back to their TEP to see
14 whether or not they agree with us. That might
15 change how we vote on the November call. That's
16 what we're looking for over the next three to four
17 days.

18 MR. GOLDWATER: And then whatever

19 changes -- if there are recommended changes or
20 changes that are made, then subsequently, the
21 electronic specifications may also be changed as
22 well, potentially. Right.

1 CO-CHAIR FLEISHER: Fred?

2 MEMBER GROVER: I'm just a -- I think
3 we've got it backwards here because what we're
4 trying to do -- at least my thought was when we
5 got into this -- was to streamline this for you so
6 we could give you this advice up front because if
7 you go with what you've got now, I'll tell you,
8 when this comes back this doesn't meet, you know,
9 what we understand are the important variables.

10 There's a big disconnect there. You'd
11 be wasting your time and if you get it -- if we
12 tell you now what we think is important, then when
13 you go to the electronic thing you've hopefully
14 got it as close together so we don't come back a
15 year from now and say why did you do this and
16 start all over again.

17 CO-CHAIR FLEISHER: Thank you. Okay.
18 We should continue. Feasibility.

19 MEMBER WHITAKER: I don't have an
20 comments on feasibility.

21 CO-CHAIR FLEISHER: Okay.

22 MS. QUINNONEZ: Voting is now open for

1 the feasibility of measure 3020. Option one,
2 high, option two, moderate, option three, low and
3 option four, insufficient.

4 (Pause.)

5 MS. QUINNONEZ: Looking for one more
6 vote. If you could resubmit your votes please and
7 point them this way.

8 (Voting.)

9 MS. QUINNONEZ: Voting is now closed.
10 Feasibility for measure 3020 reads 18 percent
11 voted high, 35 percent voted moderate, 35 percent
12 voted low and 12 percent voted insufficient.
13 Consensus not reached.

14 Are there any further comments on use
15 and usability? We are now voting for use --
16 usability and use of measure 3020. Option one,
17 high, option two, moderate, option three, low and
18 option four, insufficient information.

19 (Voting.)

20 MS. QUINNONEZ: All votes are in and
21 voting is now closed. For the usability and use
22 of measure 3020, 0 percent voted high, 29 percent

1 voted moderate, 35 percent voted low and 35
2 percent voted for insufficient information.

3 CO-CHAIR FLEISHER: Not a must pass.
4 So next. So okay, so vote on that. So we are
5 done with this measure? Right, and we can't vote
6 on that, given -- right.

7 So since consensus is not reached we
8 will not vote on this. We will be voting, going
9 through this again on the November call and
10 hopefully we'll be able to get those comments in
11 to make it -- that the committee is interested in
12 going forward.

13 So the last measure is 3021, blood
14 usage.

15 MS. DOMZALSKI: Measure 3021 looks at
16 blood usage in general in selected elective
17 surgical patients. It has a denominator of
18 patients who had the timely pre-op assessment that
19 is between 14 and 45 days prior to the procedure.

20 And by identifying which of these
21 patients had pre-op transfusions, which is the
22 numerator, there is an opportunity again for the

1 blood management review committee by review of the
2 case to identify any other blood conservation
3 methods that should have been undertaken in order
4 to avoid that transfusion.

5 Whether those methods are preoperative
6 anemia correction, use of a Cell Saver or other
7 technologies or education in general to what
8 restrictive transfusion strategies encompass that
9 would be a matter of determination for each
10 hospital's committee to decide.

11 Again, it may confirm that no
12 additional education efforts are needed. But it
13 was for that particular month or that particular
14 time frame a number of patients whose transfusions
15 were unavoidable.

16 But we do want the transfusion
17 committee to look at those patients who had
18 transfusions with an eye towards a more
19 restrictive strategy.

20 CO-CHAIR FLEISHER: Okay. Larissa?
21 Barbee, either one?

22 MEMBER WHITAKER: Thank you. So this

1 measure is intended to assess the effectiveness of
2 the preoperative anemia screening by identifying
3 those patients who had been appropriately screened
4 but still required a perioperative blood
5 transfusion. So not as -- the effectiveness of
6 actual -- the actual screening but the treatment
7 after the screening.

8 I had a little trouble with this
9 because it seems like there's still a big gap in
10 the denominator whether there would be sufficient
11 14 to 45-day preoperative anemia screening because
12 we had the whole discussion about the
13 appropriateness of that.

14 So that's really my comment on this
15 particular measure. I do have some comments on
16 numerator and that I think nonautologous shouldn't
17 be mentioned at all.

18 CO-CHAIR FLEISHER: So I'm going to
19 actually ask staff to comment. Since we didn't
20 pass that first one, it makes it difficult to look
21 at the issue of in those who got transfused was it
22 appropriate. So what's the best way to address

1 that? It's a question, Barbee, for you too. Yes,
2 Barry?

3 MEMBER MARKMAN: Can I just take that
4 variable out and still proceed with the data
5 collection?

6 CO-CHAIR FLEISHER: So I guess that's
7 a question to the Joint Commission because I think
8 what I'm -- one question is without that being
9 passed, how do people feel about the rest of the
10 measure? It's up to you whether you want us to
11 vote with or without that question.

12 MEMBER WHITAKER: You take that out.

13 MEMBER MARKMAN: It doesn't mean -- I
14 mean, in the measure itself, I mean, I don't know.
15 There's certain variables that you're looking at.
16 I mean, this is more of a data collection type of
17 measure.

18 CO-CHAIR FLEISHER: Other comments?

19 (Pause.)

20 CO-CHAIR FLEISHER: So I'm told that we
21 don't have a quorum. So we -- for this measure,
22 unfortunately, so we will not be voting. No, this

1 is not Chicago. So why don't we --

2 MEMBER MARKMAN: Yes. Yes, can we call
3 them?

4 CO-CHAIR FLEISHER: How many do we
5 need? Call Rick? I don't know if I have Rick's
6 cell.

7 MS. DOMZALSKI: I have his.

8 CO-CHAIR FLEISHER: You have it? Can
9 you tell him to dial in? He's not on the phone.
10 I don't have Barbara's -- I don't think I have
11 Barbara's cell. Other comments regarding
12 evidence?

13 DR. SHANDER: Lee, I can't -- I can't
14 vote. I would love to but I can't.

15 CO-CHAIR FLEISHER: Any comments from
16 the committee on this measure?

17 MEMBER SIPERSTEIN: I mean, this
18 discussion parallels exactly 3016 and so we've
19 already been through this. There's the rub.

20 CO-CHAIR FLEISHER: So your suggestion,
21 Allan, is --

22 MEMBER SIPERSTEIN: Well, if there's

1 not a quorum, we'd have to follow this with a
2 phone conversation but I think a good chunk of the
3 discussion it would just be, you know, repetitive
4 to redo the discussion at this point. If we need
5 to vote, we can vote on the phone conference.

6 CO-CHAIR FLEISHER: Yes, we can and we
7 can do the evidence review. We can do the
8 evidence on this, or just actually if you give it
9 to -- if Christy can take his vote over the -- the
10 hand. Okay. We have a quorum. Can you call the
11 vote?

12 MS. QUINNONEZ: I can. We are now
13 voting --

14 CO-CHAIR FLEISHER: Wait one second.

15 (Pause.)

16 CO-CHAIR FLEISHER: So one important
17 thing is they actually don't say the fact -- it's
18 not fully linked, this measure, to 3016. They use
19 the term -- use the term timely preoperative
20 screening, but it's -- is it defined in the
21 specifications as 3016? It does say that in the
22 specifications? Okay. So why don't we call the

1 vote?

2 MS. QUINNONEZ: We are now voting on
3 measure 3021. Voting is now open for evidence.
4 Option number one is -- actually there is no
5 option number one.

6 Option number two is moderate. Option
7 number three is low and option number four is
8 insufficient. Option two, moderate. Option
9 three, low, and option four insufficient.

10 (Voting.)

11 MS. QUINNONEZ: All votes are in.
12 Voting is now closed. For the evidence of measure
13 3021, 25 percent voted moderate, 44 percent voted
14 low and 31 percent voted insufficient.

15 CO-CHAIR FLEISHER: So this measure
16 does not go forward. It would be great from my
17 perspective to get feedback on how people think
18 about this trial measure and then maybe, Jason, we
19 can continue the discussion with some input from
20 the --

21 MR. GOLDWATER: Always welcome.

22 CO-CHAIR FLEISHER: Can we -- can we

1 open the phones for public comment?

2 OPERATOR: Thank you. At this time, if
3 you'd like to make a comment please press star
4 one. We'll pause for just a moment.

5 (Pause.)

6 OPERATOR: And there are no public
7 comments at this time.

8 MS. SKIPPER: Thank you, everyone. We
9 have successfully made a recommendation on almost
10 all of the measures but I'm glad that we were able
11 to get through this last one.

12 I just wanted to share that we do have
13 a post-meeting call next Thursday, August 25th,
14 from 2:00 to 4:00 p.m., and then the next call
15 that we would have as a group is our post-draft
16 comment call. So once we do put the report
17 together and put it out for comment, we'll bring
18 you all back to respond to the comments and vote
19 on any measures where consensus is not reached.

20 Finally, I want to say that for our new
21 committee members, to Karl, Barbee and -- I'm
22 drawing a blank -- Sal, yes, sorry about that --

1 we will be asking you to pull a number from our
2 magic bowl down here to select your committee
3 term.

4 New committee members may serve --
5 well, you'll pick a number and either you'll be
6 assigned a two-year term or a three-year term and
7 after your first term, you may elect to serve a
8 second term. And for all remaining and continuing
9 committee members, I'll be in touch with
10 information on your next term.

11 So right now I'm going to go around and
12 have our new committee members select their term
13 and state that for the record.

14 CO-CHAIR FLEISHER: Before we all
15 leave, I'd like to say a thank you to the staff.
16 Really appreciate it, Christy and the team.

17 (Applause.)

18 CO-CHAIR FLEISHER: For Melinda also
19 for leading us and appreciate Elisa, please send
20 our thanks to Marcia and Helen for coming in and
21 helping us out when we got into quandaries.

22 MEMBER SCALI: For the record it's two

1 years -- Sal Scali.

2 MEMBER BILIMORIA: Karl Bilimoria --
3 two years.

4 MEMBER WHITAKER: Barbee Whitaker --
5 three years.

6 (Whereupon, the above-entitled matter
7 went off the record at 2:34 p.m.)
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A	ACCF/AHA 12:21	305:16 307:9 345:22	affect 135:16 177:3
A.J. 2:20 45:14 46:3	accommodation 9:2	addressed 54:15 93:3	238:12 272:20 309:5
67:3 77:17 95:4,8	accord 173:10	149:4 163:13 235:8	afford 55:13
113:16 148:4 179:11	account 210:13	265:4	aforementioned 121:3
184:4 196:21 212:10	accountable 38:6 205:1	addresses 166:17	afternoon 214:3 215:22
255:12 295:7 316:2	accrual 151:9	addressing 107:21	245:21
A.J.'s 99:20	accrued 163:4	335:9	age 135:20 136:1,1,4,6
a.m. 1:9 6:2 128:18,19	accuracy 10:1	adequate 248:20	136:8 165:22 178:22
AAA 261:14 262:15,20	accurate 76:19 123:17	adequately 219:1 220:3	191:5,10,14 308:16
306:12	134:19 280:10	228:14 234:19	321:8
AABB 300:16 313:5	accurately 176:11	adhere 300:21	aged 12:4
ABD's 304:21	335:12	adhered 15:20	agenda 202:11 204:8
abdominal 252:9	achieve 139:7	adherence 301:1	204:15
261:15 307:3	acknowledging 202:13	Adjourn 5:22	aggregate 147:5,8,10
ability 106:3 131:8	202:15	adjust 82:18 114:8	147:11 148:2 149:20
176:21 219:4 232:10	acquisition 168:21	180:4 203:12 228:14	159:20 189:11 299:21
ablation 109:19	acronym 221:16	adjusted 4:12,12,14	299:22
able 73:18 86:19 88:2	ACS 137:18 138:22	71:7,8 129:3,3 137:20	ago 20:12 23:11 33:8
95:22 106:2 171:12	159:11	159:19 197:3,7 199:6	223:15 251:9 258:22
182:17 203:16,22	act 316:14	201:20 202:1,18	258:22 264:21 304:14
204:4,5,6 205:5 210:8	active 16:18 33:5	205:11 226:21 228:6	agree 7:20 16:6 39:20
218:22 222:6 229:3	205:21 304:17,19,22	adjusting 80:15 105:10	45:8 67:16 76:14
236:1 239:4 254:7	322:10 326:3 327:6	269:20	77:12 87:14 93:18
311:15 332:5 343:10	328:1	adjustment 133:2,9	119:16 158:9 161:19
350:10	actively 64:9 328:2	178:20 179:3 180:21	165:10,12 166:13
above-entitled 128:17	actual 58:8 78:17	180:22 196:22 197:22	178:17 204:17 243:8
244:22 352:6	140:22 174:8 253:1	198:21 201:13 202:6	250:9 263:18 340:14
absence 10:8 110:3	255:9 257:4 269:10	205:12 209:5,9 211:4	agreed 198:10 304:3
absolutely 84:16 152:3	300:20 345:6,6	211:5 213:6 226:18	306:3
157:17 158:9 178:20	acute 266:2 280:2	228:7 237:7 285:9,20	agreement 190:20
211:14 213:14 221:16	acutely 191:13 331:6	adjusts 105:5	302:13 320:20
292:1 296:4	ad 107:15 209:7	administration 1:14	AHA 34:10 163:9
absorption 270:7	adamant 148:18	81:19 299:4	ahead 38:17 66:14 84:9
abstaining 19:10	add 11:20 55:19 57:22	administrative 100:22	98:19 117:5 125:10
129:17	61:11 62:21 65:9 68:3	admission 322:22	155:12,21 161:22
abstracted 216:20	70:1 116:20 121:20	admissions 152:19	164:1 169:3,18 241:9
abstracter 100:11,12	130:18 155:12,19	admit 193:7 214:18	306:16
100:17	160:2 213:7 250:7	adoption 215:2 217:6	Ahn 3:9 171:2,3 181:17
abstracters 100:13	281:2,22	adult 4:8 10:15 11:3	182:5,22 185:18
abstraction 64:1	added 33:1,2,10 55:4	29:8 71:1 72:15	187:20 191:5 193:17
214:21 216:16 224:20	59:12 60:3 64:1 65:10	194:17 288:19 289:1	195:7 200:14 203:13
261:4	134:7 155:13 240:14	299:16	205:19 206:2 207:16
abusing 309:10	adding 55:9 320:7	advance 321:16	210:14 213:15
academic 79:19 261:2	addition 55:7,11,12	advanced 11:12 191:11	aim 276:16,18
ACC 34:9	139:1 213:17 247:17	advances 11:11 135:14	Alban 246:4
accept 14:3	304:12	advantage 32:5 44:20	aligned 196:17
acceptability 97:15	additional 7:19 18:9	advantages 106:8	Allan 2:17 25:15 45:14
98:1,6 126:7 220:20	55:5 59:13 138:5	310:19	104:10 166:19 255:13
231:18 245:11	194:12 236:10 262:8	adverse 16:16 106:3	272:12 287:11,14
acceptable 136:9	262:11 297:10 301:6	110:21 153:16	328:10 347:21
acceptance 214:8	320:8 344:12	advice 45:4 341:6	alleviate 308:20
222:19	additive 32:1	advise 247:22	Alliance 2:10
accepted 17:13 223:2	address 21:17 76:22	advised 129:19	allow 103:4 151:3 200:1
294:14 304:2	93:4 104:14 106:12	advisory 246:7 247:17	227:5 264:4 274:12
access 168:1,15 277:21	183:14 197:8 207:14	247:19 324:8	283:12 300:22
277:22	212:3,12 237:16	advocate 328:14	allowed 84:10 239:6
accessible 217:10	238:7 247:9 249:9	advocating 253:20	allowing 225:21
accessing 259:21	261:3 264:8 296:15	Aetna 2:6	allows 39:4 78:18 107:9

226:7
already-approved 135:7
altering 172:12
alternative 87:14
amazing 188:3
amend 252:13
American 1:21 2:2,3,5 2:14,19 3:11,14 4:13 4:14 6:13 129:4,11 135:12,12 180:9 204:1 291:2,18 292:15
AMI 4:4
amount 15:16 75:5 168:6 193:21 217:3 250:20 281:9 326:5
Amy 2:9 17:18 22:17 102:18 153:13 208:14 210:2 228:20 249:4 250:14 297:17 314:1 322:15
analogy 40:8
analyses 92:16 93:12
analysis 75:2 77:22 181:5
Analyst 3:6
analysts 247:20
analytic 94:10
analyze 223:5
analyzed 79:12 121:8
Anastasia 273:2
and/or 109:12 160:20 276:3
Anderson 194:1
anecdotal 268:6
anecdotes 265:9 268:5 271:12
anemia 4:19 245:19 248:7,9,12,15,17,21 248:21 249:7,15 250:2 256:11,14,15 256:22 257:8,16 258:6,8,10,10 259:4 261:21 262:1,3 263:9 263:11 265:1,2 268:11,17 269:1,2,4,9 269:21 270:15 271:15 271:18 272:5 275:3 275:12 276:2 277:5 280:1,2 281:5 286:11 286:17 328:15 329:11 344:6 345:2,11
anemic 253:15 259:5 262:16 271:4 275:5 277:1
anesthesia 1:17 2:8 23:18 81:22 250:21

anesthesiologist 77:13 79:4 274:6 301:9
anesthesiologists 1:13 2:14 61:6 79:3 334:4
anesthesiology 1:12 334:2
aneurysm 261:15 287:10 307:4
aneurysms 252:9
ankle 173:14
Ann 3:18 229:15 235:21 246:4 324:4,15 336:7
annual 107:8 209:16 263:3
annually 131:21 134:15 143:6,8
answer 20:7 42:15 50:20 64:3 88:19 118:9 148:1,3 149:11 174:1 218:10 229:19 309:16 335:3
answered 222:16 236:18
anterior 12:18 13:10
antibiosis 177:4
antibiotic 23:11 24:1 46:6 47:21
antibiotics 199:13 270:10
antibodies 292:11 294:21
antibody 5:8 288:16 291:10
anticipated 128:5
anticipation 181:3
anxiety 273:11
anybody 6:22 15:7 27:15 35:14 49:4 52:1 52:13,22 56:3 62:3 70:2 116:22 202:1 252:18 272:11 274:7 285:2 291:21 298:3 323:5
anymore 81:15 96:8 192:1
anytime 289:3
anyway 61:21 280:20
aorta 303:6 304:17
aortic 71:3 252:9 261:15 306:20 307:13
apologize 322:16
apparent 316:1
apparently 103:12
appear 35:18 135:2 146:8 333:6
appeared 202:16
appearing 145:13
appears 195:9 265:18

applaud 186:21
applauded 180:5
Applause 351:17
apples 285:19,19
applicable 75:3
application 143:14 211:10 213:19 234:21
applied 176:9 234:8,10 234:14
applies 164:13 192:2
apply 57:10 99:19 123:13 125:6 150:12 150:12 176:12 192:1 255:8 282:13
applying 75:11
appreciate 17:20 22:16 103:3 128:16 194:10 215:15 279:13 351:16 351:19
approach 77:10 90:9
approaches 11:13 91:15
approaching 13:12
appropriate 140:3 168:13 289:22 293:2 294:19 295:2 314:9 333:16 345:22
appropriately 201:6 248:3 345:3
appropriateness 175:20 335:17 345:13
approval 180:11 206:6 219:7,10,17 220:10 220:12,18 221:4 224:13 228:12 230:4 234:9 235:10 236:20 236:21 240:17 242:14 247:6 261:8 323:13
approve 228:7 236:12
approved 122:20 135:11 146:7 227:2,2 266:12
approving 219:11
approximately 186:1 190:19 252:6
approximates 13:17
arbitrary 149:14 332:15
area 7:21 21:15 45:20 66:8 135:17 259:14 314:19 317:15 335:10
areas 9:21 93:16 96:2 233:3 236:10 242:18 243:4 273:6 275:14
arena 29:9
argue 46:13,17 81:10 256:21 296:2
argument 42:4,20 269:8 292:1,1 329:19

Arkansas 2:11
arrest 157:16
arrive 151:16
arriving 110:15 121:16
arteries 13:6 15:17
artery 4:3,4,10 12:2,6,8 12:11,14,19,19,21 13:4,7,10 17:11 19:2 19:2 22:22
arthritis 172:17 314:21
article 139:4
articles 54:22
articulate 325:6
articulated 57:18 235:1 235:12 236:6,9 242:12
articulating 235:22
Aryeh 3:16 264:4,5 268:1 272:7 280:14 291:21
as- 111:10
ASA 133:3
ASD 109:19
aside 153:8 221:13 317:12
asked 77:1 82:15 185:18 221:13 227:16 229:18 251:4 264:4 278:3 315:11 325:19
asking 50:6 157:20 185:19 209:11 239:10 239:11 256:18 325:1 351:1
asks 221:15
asleep 128:4
aspect 39:2 150:15 156:14 209:13
aspects 71:18 131:12 132:17,20 149:20
assess 248:3,20 250:12 260:5 278:7 288:18 292:22 298:20 345:1
assessed 154:21 246:19,22
assesses 248:7 274:17
Assessing 259:4
assessment 61:5 142:5 248:9,12,16 254:3,18 255:11 258:10 272:6 279:6 285:15 343:18
assessments 137:3,5
assigned 351:6
assist 247:1
Assistant 2:15
Associate 2:20
associated 112:8 193:10 197:17 246:16 281:14

association 2:14,20
3:10 4:17 6:14 171:5
175:7 181:20 186:22
264:13

assume 120:11

assuming 155:2

assure 71:19

assures 63:20

asymptomatic 148:12
149:22

atrial 32:12,12 54:19

attached 134:1

attacks 32:6

attempting 141:15

attend 171:14

attention 321:21

attribution 104:19

audible 15:9 18:16
23:16 28:16 29:14
30:22 36:3,5 49:3,7
52:3,5,12,15,21 53:2
56:4,14 63:6 66:13
70:4,7 74:6 89:17
90:18 97:3

audience 54:14 183:3

audit 10:5,7 131:19

143:6

audited 143:8,10

auditing 28:8,8 132:7

audits 10:8 91:13

August 1:6 350:13

Australian 271:7

authors 138:22 160:14

automate 64:19

automated 64:20 65:14

automatic 260:7

automatically 316:17

automobiles 8:4

availability 96:18

available 94:21 99:11

165:5 215:11 217:9

219:3 225:3 229:10

239:2 244:5 266:13

295:3

avenue 206:22 209:9

avenues 65:15

average 18:10 44:13

46:14 53:22 297:21

averages 100:16

aversion 104:21 105:14

106:6,13

avoid 105:11,17,19

344:4

avoided 84:17 326:22

avoiding 198:19

AVR 71:4 72:6,7

AVR/CABG 109:13

aware 25:9 43:14,14

229:13

awareness 286:10,21

awesome 104:8

awful 259:10

B

B 32:11 279:5

B12 256:16

back 16:1 20:6 22:8

25:11 31:11 41:22

42:10 45:6 47:10 54:5

56:9 81:2 103:12,18

106:14,22 107:3,15

107:20 119:10,13

128:21 132:8 153:4

153:12 155:5 157:6

157:11 176:22 178:16

180:12 183:13 200:6

205:8 209:10,15,18

214:19 219:21 223:7

223:21 224:3 226:12

226:15 229:2 232:19

233:2,5,11 234:1

235:16,19 236:11,14

237:6 238:4,6 240:14

243:2 244:13 245:4

271:2 272:14,19

281:22 294:2 314:5

324:7 333:17,22

335:2,10 338:20

340:13 341:8,14

350:18

background 171:17

174:16

backing 148:17

backwards 47:7 341:3

bacteria 199:9,13,18

bad 81:13 105:18 181:4

202:2 218:7 250:10

285:3

Badhwar 3:10 9:1,2

11:6 22:15 51:13

70:20 73:2,7 76:12

77:6 78:6,9,12,15

79:15 80:5,11 82:14

82:20 83:19 84:2 88:4

88:15 93:5 102:14

104:20 109:5,11

113:3 114:6,16,19

115:3 120:15,18

121:2 128:14

balance 144:20 339:4

Baltimore 193:9

bang 136:3

bank 316:5,7,18

Banks 2:20 6:14

Barb 258:15

Barbara 2:4 7:6 24:15

37:19 73:13 74:5

77:19 95:3 240:12

241:2 243:7 260:3

277:18 282:9 293:12

Barbara's 347:10,11

Barbee 2:19 6:13

237:14 250:5 252:13

274:21 287:1 289:11

292:18 300:1 313:2

318:10 324:9 325:19

332:2 344:21 346:1

350:21 352:4

Barei 187:21

barrier 290:12

Barry 2:6 87:10 88:11

234:4 236:22 289:12

290:9 313:10 322:14

334:18 346:2

base 182:9 231:3,15

based 9:15 61:4 132:21

147:12,20 149:12

155:2 164:21 185:12

190:17 194:4 197:20

206:18 210:7 284:6

287:14 305:10 310:3

312:3 313:4 339:8

baseline 239:3

basically 40:9 134:11

195:14 224:11 294:9

329:15

basis 61:12 187:12

205:21 210:7 235:22

256:7 333:15

Bayesian 71:21 133:9

bearing 172:14

beat 128:4

beating 230:7

becoming 307:2

bedside 309:5

beginning 208:10

behalf 171:5

behavior 22:9 105:12

263:7

believe 10:19 33:4

82:14 119:1 185:22

203:17 204:3 232:8

243:20 282:19

believing 55:11

benchmark 279:20

285:18

benefit 17:16 55:1,12

65:3 99:6 271:15

321:9,20

benefits 13:9 55:10

59:6

benefitted 275:2

Berian 3:11 129:12

141:10,12

best 69:20 79:2,2,3

85:7 91:18 131:17

184:6 185:21 199:5

239:4 244:12 345:22

beta 4:5,6 31:21 32:10

32:20 34:13 39:5,18

40:3,7,11,17 44:17,19

47:5 49:20,21 50:2

51:17 54:10,19 55:1,5

55:11 58:2,5,13,18

59:6,9 60:9,17 61:14

65:11

beta-blocker 51:5

better 36:17 74:18

106:1,5 136:19 158:7

167:20 192:22 193:1

203:22 230:16 257:1

282:8,19 293:5 316:5

332:17

beyond 77:15 85:18

310:9

bias 130:16 137:8

145:15,22 187:6

biased 137:5

bicondylar 4:16 170:21

171:7 172:1,5 173:18

176:1 178:4 183:2,7

big 95:15 96:8 173:21

187:13 211:3 255:5

261:16 276:11 284:20

315:7 341:10 345:9

bigger 313:12,20 314:8

biggest 226:18 248:22

Billimoria 1:15 73:14

74:15 75:15 83:2,11

89:14,18,20 90:1,4

91:9 92:10 93:18

94:22 97:14 98:14

100:20 102:2,9

119:16 137:7 206:12

309:22 352:2,2

Bill 171:10 203:15

207:17 208:1

billed 151:21

Billings 95:13

billion 100:5 269:5

biology 133:6,15

biopsies 210:16

bit 15:1,14 21:7 31:13

32:22 33:11 38:8

45:19 56:10 63:21

75:18 112:16 134:5

141:6 171:17 200:13

200:15 210:12 241:4

bits 284:14

BJC 129:10

black 253:21

blank 350:22

blanket 282:13
blanking 231:1
bleeding 71:13 263:19
 303:16 304:17,19
 305:1 316:16 320:4
 322:10,11 326:3,17
 327:6,20 328:2,22
 331:6 333:1
blended 277:12
Blockade 4:5,6
blocker 50:2 58:3,5,19
 59:9 60:9
blockers 31:21 32:10
 32:20 34:13 39:5,18
 40:3,7,12,17 44:17,19
 47:5 49:20,21 51:17
 54:10,20 55:1,5,11
 58:13 59:6 60:17
 61:14 65:11
blocks 270:7
blood 2:20 5:7,14 6:14
 50:19 246:9,10 247:3
 247:21 248:2 252:10
 265:12,20 266:8
 269:18 274:6,13
 275:10 276:19 277:20
 278:1,5,13,16 282:10
 282:17 284:2,3 287:9
 288:15 289:22 290:4
 292:4,5,6 294:8,15,22
 295:3 296:19 297:7
 297:21 299:3,10,17
 300:11 302:21 306:14
 309:7,10 310:2,8
 316:5,7,9,12,14,18
 317:3 318:3 321:15
 322:20 327:4,18
 331:17 343:13,16
 344:1,2 345:4
board 77:9 84:10
 204:14 237:12 311:3
body 137:22 305:11
bone 175:5
Bonnie 221:11,15,20,21
 232:1 238:22 239:3,9
 239:22 240:17 244:1
 244:7
bony 186:1
book 254:12
booked 263:5
books 272:2
borders 187:7
bothers 199:20
bowl 351:2
box 58:10 60:18 61:3
 65:11
bradycardia 40:9
bradycardic 61:1

brain 234:9
brand 180:7 216:10
 217:8,22
break 128:12,12 283:10
breaking 273:21
breaks 263:6
brief 22:15 51:13 76:12
 129:20 159:15 221:13
 268:2 280:15
briefly 9:21 77:9 121:1
 121:2 247:9
bring 21:18 39:2,13
 80:22 95:2 178:16
 179:4 209:18 219:21
 241:7 243:2 317:17
 328:15 350:17
bringing 37:8 209:1
 260:3 261:10 310:18
broad 256:12
broadening 46:1
brought 7:13 42:10
 196:21,21 199:1
 212:4 226:12 231:10
 287:5,6 331:12
Bruce 3:14 128:13
 129:8 160:17
BS 3:13
BSN 2:12
buck 136:4
build 65:7 260:3 286:7
built 63:22 193:18
 227:5 228:6 317:10
bullet 243:17
bunch 146:14 202:8
 257:20 259:15
burden 33:2 37:9,12
 65:10 66:9 101:6
 134:1,6 145:1 174:22
 175:2 310:13 311:12
burdened 186:15
burdensome 174:4
BURSTIN 3:2
business 167:21
bye-bye 244:14
bypass 4:4,10 11:16
 12:3,18,19,21 13:4,7
 13:10 14:11 16:4
 17:12 19:2 32:9 61:13
 71:3 121:21 261:16
bypassable 12:13
bypassing 318:4

C

C 279:6
c- 121:14
c-statistic 110:8 140:22
 198:12
CABG 4:4 10:22 12:5

12:17 34:9 35:5 71:4
 71:6 72:6,7,8 99:12
 121:4 144:2
CABG/AVR 109:13
calculate 222:9
calculated 153:19
calculates 221:9
calculating 222:3
call 8:19 18:17 48:2
 142:13 146:7 216:12
 216:18 220:22 226:6
 279:12 298:6 320:16
 320:22 324:1 340:15
 343:9 347:2,5 348:10
 348:22 350:13,14,16
called 80:13 214:20
 294:7
calling 101:1
calls 144:2 166:13
Canadians 192:21
cancer 2:19 253:16,22
 265:3 270:12 271:14
 271:20,21
Candidate 4:3,19 5:1
capture 33:2 113:1
 141:21 144:16 149:22
 149:22 191:15 248:4
 259:12 260:19 293:18
 311:15 313:14
captured 47:14 140:7
 144:15 151:7 162:19
 168:7 192:13 217:17
 260:16 320:8
captures 12:3 98:15
capturing 24:6 37:7
 144:21 309:9
cardiac 4:8 9:10 10:15
 11:2,3 12:8 15:19
 17:10,15 29:8 31:22
 47:1 50:18 71:1,13
 72:16 76:4,14 81:16
 81:22 85:10 95:18
 96:4,20 99:1,3 104:3
 150:8 157:16 268:10
 268:15 301:12 308:15
cardiologist 95:17 96:7
cardiologists 50:17
 79:3
cardiology 306:16
cardiothoracic 1:19
 168:5
Cardiovascular 301:9
care 2:2 21:18 79:2
 106:2,5 131:7,8
 135:14 144:6 158:6
 175:1 192:8,11,16
 194:11,17 198:18
 200:20 201:5 204:21

208:2 226:2 264:20
 266:1 286:14 303:6
 306:9,12 309:17
 313:15,21 321:11
 326:13
cared 194:20
careful 100:21 106:7
 265:9
carefully 292:22
carries 54:21
carry 52:7 212:16
carrying 125:12 185:4
 189:1
cascade 153:18
case 4:12 68:8 99:12
 100:18 110:13 114:21
 115:10,11 119:14,18
 129:3 142:8,16 143:4
 154:1,2 157:8,11
 163:9 218:20 222:15
 234:20 235:16 264:19
 277:9 333:14 344:2
cases 12:22 72:10 78:4
 80:9 91:17 100:12,16
 110:14 115:11 121:7
 121:16 124:9 139:10
 162:17,17,19 163:3
 163:12 210:11 261:14
 283:10,15 292:5,6
 326:7
categorically 321:19
categories 119:5 135:4
categorization 320:8
category 73:16 129:21
 131:4,10 150:22
 318:13 335:16
cath 95:17,17 96:7
catheter-based 11:13
caught 140:9 202:10
cause 16:16 43:21
 248:16 276:3
caution 66:3
cautious 51:17
cc's 298:1
CDC 174:10 175:19
 189:20 191:19,20
 195:3,10 196:17
 199:7,9 200:1,20
 201:8 231:21
CDP 232:22 233:3
cell 256:14 286:3
 299:17 312:2 344:6
 347:6,11
center 1:15,18 2:19,22
 3:17 47:12 95:20
 180:1 181:19 185:13
 186:6 187:22 188:6
 193:8 205:2 265:13

266:3 270:10 306:1,3
313:15
centers 47:1,2 173:8,20
180:17 181:21 199:2
199:4 267:6 285:19
306:4
central 16:3
certain 21:17 38:6,12
44:21 199:2 233:2
249:16,17 266:14
273:17 285:14 297:5
297:5 333:13 346:15
certainly 23:13 40:19
60:12 166:13 204:14
205:12 207:22 210:16
215:17 225:1 247:5
253:20 276:6 278:18
certification 265:14,21
266:1,7,15
certified 197:10 267:6
cetera 71:14 157:16
263:13 299:15 316:17
chain 71:21
chair 1:11,15 9:4 11:3,7
34:15 37:14 325:17
Chairman 2:17,21
chairperson 246:7
challenge 165:11
challenges 284:6
challenging 276:4
chance 80:20 180:15
181:15 281:20
chances 258:11
change 31:12 42:11
64:13 92:17 107:12
107:13,19 131:5
149:6,11 209:17
236:12 263:7,8
282:13 307:20 324:1
325:2 327:20 340:7
340:15
changed 22:10 64:14
340:21
changes 53:15,17
107:10,11,11,13
160:18 172:15 225:10
236:5 320:15,18,21
324:5,5,7 340:19,19
340:20
changing 64:15
characteristic 114:14
characteristics 28:9
238:17 253:1
chart 40:21 114:1 115:5
140:10 214:21 216:16
216:20 224:20 277:21
278:5 303:22
chart-abstracted

216:14
charts 278:21
chastised 96:22
check 58:9 119:13
254:20
checked 72:18 99:2
273:8
checking 65:10
checklist 46:12
checkup 263:3
cheering 102:21
chemotherapy 270:9
chest 1:22 95:16 96:14
148:14
CHF 266:2 310:5
Chicago 132:1 347:1
Chief 1:17 3:2 11:1
child 99:13,15
children 166:8,21 189:8
194:11,14,17,19
221:19
Children's 2:9
choice 239:15
choose 87:17 219:19
choosing 203:6
chopper 151:17
chose 264:13
chosen 230:2 264:10
Chris 205:8 207:9
Christopher 2:15
301:21
Christy 3:6 8:7 18:15
129:1 339:21 348:9
351:16
chronic 262:1 263:11
276:3 280:1
chunk 168:9 348:2
Cima 6:17
circumstance 312:8
circumstances 300:19
318:20
cite 138:1 197:2
cited 185:7 289:18
claim-based 207:6
claims 76:17 155:17
claims-based 216:13
clarification 41:19
305:19 306:8,8
320:11 322:2
clarified 233:18 298:18
clarify 142:17 143:18
157:22 160:17 207:15
336:6
Clarissa 160:7
clarity 200:13
class 12:20 13:2 22:5
22:12 32:11 133:4
classic 199:18

classical 7:9
classification 194:1
clean 235:19
cleaning 284:13
clear 80:6 88:6 94:22
102:17 161:16 162:14
198:8 231:12 236:19
249:13 272:15 275:13
329:1
clear-cut 28:10
clearly 40:6 54:22
57:18 73:16 74:19
90:7 92:11 106:21
128:3 160:12 165:6
184:5 215:6 226:3
236:9,17 237:12
242:2,9 276:6 292:15
293:19
Cleveland 2:17 264:20
Cliff 41:5 128:2 200:7
201:10 205:8 208:15
211:1 213:9 234:4
CLIFFORD 2:1
clinic 2:17 264:20
273:18
clinical 2:12 9:12 40:9
65:22 66:1 76:3,19
95:7 166:1 178:5
189:22 211:12 215:10
216:2 247:17,20
248:19 272:18 278:22
282:14,21 283:18
289:18 301:13 305:4
305:4 311:1 317:2
325:2 326:10 327:2
328:13 329:6 331:19
333:2,16 335:18
336:3,12 337:2,7,22
338:15 339:1,2,6
340:11,12
clinically 40:6 213:17
264:16 278:6 291:10
clinician 301:19 309:13
311:3 327:1,6
clinicians 276:19
304:18
clock 6:5
close 213:3 248:15
291:9 341:14
closed 26:7 27:8 29:2
29:21 30:13 31:7
48:10 53:11 57:2
62:16 66:21 70:15
74:12 89:10 91:3 92:6
97:10 98:11 101:20
108:9,21 111:7 112:3
113:13 115:22 116:17
117:12 118:2 120:5

120:11 122:10 123:8
124:4 125:2,22
126:14 127:3,14
138:13 139:19 154:13
156:6 158:19 159:7
162:7 164:8 167:11
169:10 170:3,14
185:1 188:19 196:9
212:21 267:19 288:9
298:14 312:17 319:11
323:13 342:9,21
349:12
closely 64:4
closure 109:20 120:12
191:8,9
CMS 9:13 10:4 23:13,19
43:8,9,19 187:18
214:19 215:7 216:15
224:19
Co-Chair 1:11,13 6:3,15
6:21 7:2,8 8:7,13
13:20 14:1,6,16,21
15:6,10 16:5,11 17:18
18:8,14,17,21 19:12
23:8 24:8,10,15 25:8
25:15 26:1,4,11,14
27:1,12 28:2,12,14,17
29:6,13 30:3,5,20
31:1,10,16 33:15,20
33:22 34:15,18,21
35:3,7,11,14 36:1,4,8
37:1,14,19 38:17,18
38:21 39:11 41:5,20
43:9,13,18 45:2 46:3
47:15 48:14,17,22
49:2,4,8,12,15 50:5
51:22 52:4,6,11,13,16
52:20,22 53:3,14
55:17,21 56:2,5,12,15
57:6,12 60:14 62:3,8
62:20,22 63:7,10,13
65:12 66:11,14 67:3
68:5,6 69:5,15,18
70:2,5,8,18 72:17
73:4,8 74:4,21 76:1
77:4,8 80:6 81:2,9
82:3,6 83:8,14,22
84:4,8,12 85:21 86:16
87:10 88:5,20 89:8,13
89:19,22 90:3,16,19
91:7,20 95:3,8 97:1
98:3,20 99:20,22
101:4 102:7,12,16,18
104:10 106:9 107:2,6
107:17 108:13 109:2
109:6,10 110:17,22
111:9,17 113:4,16
114:12,17,22 115:6

115:13,20 116:10,22
 117:4 118:6,16,18,19
 118:20 119:20 120:8
 120:17,21 121:22
 122:4,13,22 123:19
 124:11,15 125:8,20
 126:3 127:7,18 128:2
 128:11,15,20 135:5
 136:11,15 137:13
 138:5,17 139:12
 140:1 141:4 143:21
 143:22 145:4,16,18
 145:19,20,21 146:3,5
 146:6,11 148:4 153:8
 154:7,17 155:15,20
 156:10 157:3,21
 158:11 159:1,10
 160:5,10 161:17,21
 162:11 163:22 164:12
 167:3,14,18 169:2,14
 169:17 170:7,19
 177:14,19,22 179:8
 179:11 183:8,19
 184:3,11,16 185:4,15
 186:19 187:4 188:11
 189:1 193:6 194:9
 195:2,20 196:1,13
 198:7 200:5 201:10
 201:12 203:9 205:7
 206:11,21 207:9
 208:14 210:2,22
 212:15 213:3,8,22
 223:13 225:6 226:15
 226:20 227:19,22
 228:4,16 230:10,17
 232:18,21 233:9,14
 233:17 234:3 236:7
 236:16 237:11 238:3
 240:11 241:2,21
 242:16,20 243:7,12
 244:11,15 245:3
 249:3 250:5,8 251:17
 252:11,17 253:3,7
 254:5,11 255:12,16
 258:13,15 261:11
 264:2,7 265:8 266:16
 266:21 267:13 268:1
 272:7,10,22 274:3,20
 277:18 280:7,13,17
 282:2 284:19 287:1
 287:11 288:2,13
 289:11 290:8 291:20
 292:17 293:10 295:7
 297:16,19 298:2,17
 300:1 301:5,20
 302:17 303:19 305:8
 308:4 311:18,22
 312:10,21 313:9

314:1,14 316:2
 318:10 319:3,15,21
 320:2,10 321:1 322:6
 322:14 323:4,18
 324:9 325:5,12,16,20
 326:9,12 327:22
 328:3,10 330:7
 331:22 332:12 334:17
 334:22 335:3 336:21
 337:5 338:6,14
 339:17 340:6,12
 341:1,17,21 343:3
 344:20 345:18 346:6
 346:18,20 347:4,8,15
 347:20 348:6,14,16
 349:15,22 351:14,18
Co-Chairs 1:9 42:21
co-lead 246:1,2
code 133:4 151:1,4
 152:3 189:17 192:13
 193:20 194:4,4
 249:17 251:10 255:18
 255:22
coded 99:11,15 151:21
 183:1 260:18
codes 130:13 159:21
 176:2 187:17 251:13
 255:22
coding 107:11 252:6
coefficients 165:15
cognitive 136:6
Cohen 129:16
cohort 253:19 276:1
coincided 195:16
colectomies 163:8
collaborative 103:15
 171:9
colleague 207:4
colleagues 7:17 17:8
 42:8 204:10 244:17
collect 141:15 180:11
 181:2,5,9 187:3 198:9
 204:4,6 205:10 213:5
 228:13 229:4 231:8
 235:22 241:12 260:10
collected 52:9 63:20
 98:17,18 141:7
 162:20 198:13 199:1
 211:9 220:7 223:5
 226:10,13 228:15
 291:6,13
collecting 99:6 187:16
 193:1 204:16 206:8
 219:6 235:13 260:6
 260:21 308:9
collection 36:19 45:1
 55:4 65:3 66:9 80:9
 192:20 195:18 311:13

335:20 336:11 346:5
 346:16
collectors 131:16,17
collects 220:1
college 1:22 2:2,3,5,11
 3:11,14 4:13,14 129:4
 129:11 132:8 135:12
 180:9 204:1 208:14
 213:9,12 291:2,18
 292:15
Collette 2:12 36:8 38:8
 57:6 60:16 62:5 63:10
 98:20 101:9 141:4
 157:3 186:19 200:5
 208:16 228:20 230:10
 238:9 240:11 287:12
colon 4:14 159:12,21
 160:13 162:17 166:8
 253:16
Colorado 1:20
colorectal 2:18 265:3
combination 147:18
 174:6
combine 310:6
combined 32:2 123:16
 137:4 158:7
combining 112:14
 113:2 150:7
come 14:7,9 20:6 22:6
 22:8 27:17 45:6 61:13
 84:9,13 102:16 107:2
 107:9,15,20 151:15
 151:16 175:21 180:12
 180:21 183:13 203:3
 207:19 209:15 216:8
 218:9 223:6 227:8
 229:2 233:11 235:16
 235:19 237:6 238:6
 238:16 241:17 244:18
 271:2 273:7 309:3
 314:5 333:17 335:1
 338:20 341:14
comes 57:13 59:8
 106:14 148:15 191:19
 223:21 224:3 232:19
 232:20 233:2,5 234:1
 234:16 236:11 238:4
 239:1 260:17 308:1
 341:8
comfortable 13:21 86:4
 87:7 200:9 203:1
coming 6:6 8:5 106:22
 128:21 135:8 145:10
 153:4 229:2 237:3
 258:19 284:9 351:20
commence 102:14
commend 237:3
comment 4:21 5:18

14:17 16:7 22:15 23:8
 23:9 36:9,10 37:2
 38:15 44:12 53:18
 55:18 73:6 74:22 76:3
 76:4,13,14 79:16 84:7
 88:10 93:3,11 98:22
 99:4 104:20 119:1
 130:19 136:22 141:6
 141:10,12 146:13,22
 154:20 158:3 162:15
 162:21 163:1 164:18
 165:6 166:11,16
 167:20 168:13 185:17
 187:2 201:11 206:13
 207:11 228:21 241:22
 252:15,18 268:3
 270:2 271:10 272:12
 272:14 275:19 280:15
 295:8 301:7 311:19
 313:22 315:9 318:11
 318:13 319:22 320:22
 321:8 332:2,3,13
 345:14,19 350:1,3,16
 350:17
commentary 54:14
comments 7:20 18:15
 28:6,12,15 29:13
 30:20 33:22 36:4,20
 38:22 42:1 45:3 49:2
 49:16 52:11 53:16
 55:22 56:13 57:7,10
 69:22 72:5 74:4 75:22
 76:1 84:16 90:17 97:2
 98:3 101:11 106:17
 108:15 111:17 113:3
 115:13 116:10 118:15
 122:22 123:13,19
 125:5,8 126:4 127:7
 127:18 138:6 139:12
 153:13 155:20 158:11
 160:3 161:21 163:22
 165:10 167:3,16,18
 169:2,15 185:15
 186:21 194:11,12
 195:21 208:10 210:22
 212:15 213:7 244:16
 250:5 264:3 266:17
 271:22 274:5,7 280:8
 287:2 288:3 290:9,22
 291:21 292:17 293:10
 298:3 301:6 314:14
 320:3 322:15 323:6
 330:5 339:22 340:3,7
 341:20 342:14 343:10
 345:15 346:18 347:11
 347:15 350:7,18
Commission 3:12,13
 3:18 4:20 5:4,9,12,16

227:11 229:16 230:1 238:7 243:2 244:17 246:1,4,9 247:14 265:11,22 298:20 320:14,19 323:21 330:8 335:6,8 340:4 346:7	complaints 310:15 complete 229:10 296:20 318:16,18 completed 135:21 223:22 224:2 240:18 288:21,21 289:6,16 289:20 completely 16:6 153:15 255:3 270:17,18 285:8 completeness 10:1 complex 66:5 144:11 complexity 100:17 134:6 194:14 205:2 252:5 compliance 45:22 182:17 complicate 191:10 complicated 302:4 complication 46:14 71:10 73:20 161:11 161:12 176:13 186:16 191:20,21 complications 71:17 93:6 142:19 198:19 246:16 268:18 component 12:17 33:3 75:1,7,13 192:15 234:18 components 74:2 102:11 104:15 composite 4:7,9,11 11:1 12:17 16:9 17:1 17:5 33:3 45:1 70:19 70:20,22 71:1,10,19 72:2,15 73:19 75:20 82:18 89:21,22 90:2,9 90:15,21 91:4,21 97:15 98:2,6 99:8 109:13 110:2,20 112:6 113:7,13 121:12,13 122:3 123:21 124:4 126:7 126:15 146:14,15,17 146:20 147:6,7,17 153:15,20 157:14 comprehensive 90:5 232:1 comprises 71:6 computer 37:11 con 103:2 concept 104:21 314:3 327:7 concern 38:9 95:9,11 228:17 232:22 250:18 279:19 325:22 331:8 concerned 107:19 201:13,17 250:22	273:14 303:2 322:7 concerning 33:12 203:19 324:13 concerns 42:6 57:19 77:19 107:21 201:13 209:14 228:19,19 236:16 237:13 238:5 238:7 239:13,18 243:2 245:14 248:6 276:6 305:14 330:13 337:6 338:14 339:1,5 concluded 292:10 concludes 110:16 condition 209:20 269:1 269:6 311:15 317:6 326:10 conditional 183:9,20 conditions 210:1 278:22 301:13 311:6 311:7 conductive 339:7 conducted 300:16 conduits 13:7 condyles 183:5 confabulation 338:21 confer 55:12 conference 1:8 8:19 348:5 confidence 85:20 161:6 163:17 confidentially 86:9 confirm 344:11 confirmed 189:19 conflict 35:12 conforms 217:20 confused 252:22 324:15 336:1 confusion 192:10 200:16 congenital 10:18 Congratulations 118:16 consensus 181:1,8 198:9 323:19 324:11 342:13 343:7 350:19 consequence 51:12 60:5,12 104:12 144:4 242:12 250:19 262:4 279:14 290:5 293:15 293:22 303:3 329:11 consequences 43:5 50:6,9 80:14 144:9 174:16 237:18 241:4 242:6 conservation 265:12 290:13 344:2 conserve 309:7 conserved 246:17	consider 16:8 20:4 47:17,19 57:16 142:14 143:4 147:6 192:18 220:8,11 221:1 228:11 243:17 280:9 292:20 308:10 308:11,12 328:8 335:6 consideration 4:3,19 5:1 12:7 75:7 81:1 104:22 170:18 195:1 226:14 227:7,18 236:13 279:1 280:11 considerations 101:9 considered 32:14 94:11 109:20 116:9 201:5 216:5 219:15,15 221:3 222:12 223:7 223:22 227:10,16 290:3 291:9 301:13 303:18 328:7 considering 177:9 215:22 232:15 consistency 206:7 consistent 71:8 116:6 220:21 231:19 245:12 249:18 consistently 197:17 consists 72:2 Consortium 171:13 constantly 132:2 constitutes 46:2 185:22 constitutional 190:1 construct 26:19 89:15 90:15,21 112:7,12 119:4 123:13,18 126:3,15 161:8 324:19,20 338:18 constructed 298:4 299:2 339:12 construction 336:9 338:11 constructs 90:2 consumerism 77:10 88:6 Cont'd 4:19 5:1 contains 252:6 contemporary 306:20 content 324:21 325:2 335:19 338:3 340:11 340:12 context 234:13 239:20 245:13 251:18 continue 11:11 25:12 35:15 45:21 49:9 51:6 59:22 91:8 125:13 131:6,8 213:5 219:10 242:17 319:16 323:20
---	--	--	--

341:18 349:19
continued 4:3 14:13
 47:14 58:6
continues 11:18 215:6
continuing 65:19 351:8
continuous 132:8
continuously 21:9
 131:17
contract 67:21
contracted 69:1 229:8
 229:22
contraindicated 39:6,8
 39:10,15,22 40:18,22
 41:2 58:10 61:2
contraindication 61:15
contraindications 40:6
 44:17 301:18
contribute 205:20
contributed 23:12
contributing 16:16
control 85:18 177:2
 201:7
controversy 39:19 54:6
 59:1
conversation 68:3
 325:1 348:2
conversations 203:14
 231:20
convert 161:6
cooked 151:20
coordinated 313:15
COPD 308:17
cord 306:22 307:13
core 81:4
coronary 4:4,10 11:16
 12:3,19,19,21 13:6
 14:11 16:3 17:10 19:2
 61:13 71:2,13 121:21
correct 26:12 39:12
 60:6 77:5 78:12 80:11
 84:16 95:7 114:15,16
 114:19 115:1,3
 119:14 156:17 176:12
 183:17 224:6 227:5
 236:15 248:20 256:19
 256:20 261:21 268:7
 270:15 273:2 283:4
 295:15 305:17 316:5
 319:21 325:4 335:7
 336:7,13,20 337:8,11
 337:21 338:4 340:9
corrected 258:8 316:11
correcting 258:10
correction 248:17
 254:4 344:6
correctly 86:22 93:8
 221:10 222:3,7 337:6
correlates 47:11 181:4

correlating 113:21
correlation 92:18 119:5
correlations 97:16
cost 67:8,8,19,21,21
 68:21 99:5 100:3,6
 101:6 103:13 134:8
 134:15,18 135:1
 168:17 241:11,12,13
cost- 65:2
costs 103:20
count 80:4 148:10
 154:2,6 200:1,11
counted 200:2
counter-argument
 47:20
countries 192:22
country 93:16 98:16
 133:21 134:5 137:19
 143:7 156:18 160:16
 161:10 163:7 180:17
 188:5 302:8
couple 15:13 20:12
 23:10 45:3 153:10
 186:21 223:14 280:21
 324:10 328:19 335:4
course 104:21 192:3
 260:7,12 264:6
 287:22 294:18
cover 309:17
covered 91:15 133:14
 181:19 182:1 237:18
 297:2,2
covers 73:15 110:21
 134:16
CPHQ 2:12
CPOE 317:22
CPT 130:13 133:4
 159:21 176:2 189:16
 192:13
create 147:9 193:4
 204:1 205:5 221:21
 222:4 279:15 332:21
created 217:8 231:18
creating 25:14 201:14
 217:22
creativity 218:9
crit 328:17
criteria 20:11 39:9,16
 58:11 78:3 131:11
 174:10 175:19 176:10
 176:12 199:8,9 201:7
 219:1 220:4,11,14,18
 220:22 222:7,21
 225:18 226:9 227:14
 230:12 235:6,7 239:8
 239:19 240:1,14,20
 303:13 305:9 320:13
 335:11

criterion 20:2,6 209:22
 336:4
critical 167:22 168:14
 178:20 263:20 325:13
criticisms 59:4
criticize 15:1 100:21
criticizing 101:1
critiques 85:3
CRNA 2:13
cross 264:14 288:20
 289:3,6 290:6,14
 292:3,9 293:1,16
 294:2
cross-cutting 7:5
cross-matched 292:5
cross-matching 294:11
crossed 67:13
CRP 199:22
CSAC 7:14 41:22 47:17
 57:14,16 237:12
CT 137:10 151:19
cultural 334:12
culture 189:20 199:16
 199:19 200:4
curious 39:14,16,22
 213:8 224:8
current 168:17 231:3
 236:12 242:17 258:6
 295:16 296:13 297:21
 312:4 322:10 326:13
currently 10:15 76:15
 85:21 137:16 156:15
 176:8 247:4 248:14
 266:6 285:22 298:4
 315:12
curves 144:17
cut 115:10 257:18
 275:13
cut-off 308:14 309:15
cutoff 136:5 144:20
 166:12
cutting 144:4
cycle 21:12 214:8

D

D 4:1
D.C 1:9
dangerous 35:6 50:2
Dardis 3:12 246:2 247:8
 257:4 260:2 283:5
 284:1 285:22 297:11
 310:17 317:1 322:1,5
 323:2 324:2 331:8
 333:7
dare 148:9
Dartmouth 1:18
data 9:12 21:10,21
 25:21 31:20 35:20,21

36:19 37:8,11,12
 40:12 44:18 45:1
 52:10 55:4,4,5,9,12
 56:7 58:8 59:11,12
 62:2 63:19 64:4,13,16
 64:21 65:3,20,22 66:4
 66:8 67:14 68:7 72:8
 76:17,18 79:16 84:21
 85:7,14 86:19 87:8
 88:14 92:15,16,17,19
 94:16 98:17 99:1,3,6
 100:22 102:13 103:5
 103:13 104:4,6 110:6
 115:9 121:6 124:8
 131:13,15,17,20
 132:1,9,15,20 134:2
 136:5 138:21,21
 141:1,7 142:18 143:5
 149:5 155:3,18,18
 157:7 158:1 162:18
 162:21 168:11 180:12
 180:22 187:3 189:11
 189:12 190:8,15
 193:2 194:16 197:9
 198:1 204:4,7,16,21
 205:5,10,11 206:8
 208:20 209:6 210:5,8
 210:11,16,17 211:7,8
 211:9,21 212:2,14
 213:5 214:13 217:9
 217:16,17 218:4,22
 219:3,6 220:1,2,6,15
 221:7,9 223:4 225:3
 226:5,10,12,17
 227:14 228:8,9,13,15
 229:4,10 230:15
 231:8 234:11,19
 235:5,13,22 237:8
 239:5,22 243:6,9,19
 244:5,6 248:4 258:20
 260:6,8,10,16,18,21
 261:4,6,6,10 269:19
 270:3,17,19 271:6,11
 275:12 277:22 278:3
 281:18 283:2,17
 284:17 285:21 292:16
 296:1,8,13 297:21
 307:14,18 308:1,2,9
 308:12 310:4 311:1,2
 311:8,13,13,14 312:3
 313:4,14 331:3
 336:11 346:4,16
data-driven 295:18,21
database 9:8,11,12
 10:3,14 24:21 26:18
 26:21 27:14 28:7,9
 29:11 44:15 54:8 58:8
 60:2 76:19 99:1,4

106:15 157:5 163:9
168:7 182:10 205:18
205:20
databases 187:19
date 198:6 223:1
David 3:16 55:21 65:12
68:11 84:8
dawn 214:11
day 4:2 8:2,10 34:14
58:6,16 144:5 145:5,9
155:17 201:3 219:9
220:13 234:6 260:1
264:9 279:12 291:6
291:13 306:13
days 144:4,15 159:20
195:3 199:19 214:20
230:7 248:12 249:22
254:12 256:8,18
258:18,18 262:18
264:9,12 275:9
281:10,11,11 289:4
293:6,8,9 324:10
332:18 335:5 340:17
343:19
de 181:7 216:10
dead 327:21
deal 54:21 85:20
dealing 104:18 133:12
Dean 2:11
death 130:5,5 147:19
150:7 152:14 157:16
159:19
deaths 164:20
debate 73:10 77:9,15
155:17 171:19
debride 192:8,12
debrided 192:10
debridement 189:18,19
192:13 194:3,6
debridements 174:21
debulking 253:15
decade 10:6 142:10
decades 11:17
decay 144:12,13
decays 144:16
decide 60:19 76:9
211:20 344:10
decided 43:8 144:19
195:15 226:6
decides 201:4
deciding 40:17 294:1
decile 35:19
deciliter 275:6 295:2
decision 43:1 137:6
203:20 230:14 243:10
273:10 301:18 311:4
312:9 317:3 318:1,4
333:16

deck 221:22 222:4
232:1
decrease 334:14
decreased 11:16
246:15
decreasing 73:17
dedicated 145:8
deep 71:11 142:20
174:10 175:18 189:21
192:6 193:16 200:11
200:21 201:3,8
deep-space 189:21
defer 182:19 252:12
deficiency 262:3
270:13 286:16
define 37:16 45:17
55:10 72:22 107:18
225:7
defined 55:1 65:22
73:11 93:9 106:7
130:7 136:19 159:21
232:21 348:20
defines 37:15
defining 37:17 45:9
106:18
definitely 41:10 182:7
313:7
definition 20:14 22:16
24:17 46:2 191:19,20
192:1 195:10 196:17
200:21 201:8 304:13
304:15
definitions 20:10 25:9
66:5 131:15 191:2
239:14 305:3 310:6
definitive 244:16
degenerative 172:16
degrees 38:19
delay 203:8 242:14
254:7 273:15
delaying 303:3
delineating 150:18
delirium 140:8,10
141:17
Delphi 148:10
delve 78:17 93:9
demographically 261:1
demographics 178:18
demonstrate 94:18
131:6,8 160:19 210:9
demonstrated 31:22
98:17 116:5 119:2,9
198:6 270:15
demonstrating 142:2
276:9
denies 211:11
denominator 130:12
149:2 162:14 190:5

238:13,19 239:14
248:10 257:13 272:17
283:1,20 287:17,19
289:1 290:14 293:4
299:16 306:6 319:20
322:18 329:5 343:17
345:10
denominators 252:1
denote 266:3
department 2:2,7,18,21
279:8 321:18 322:3
322:20,22 334:2
depend 251:6
dependent 27:22 312:7
depending 100:17
186:2 191:9 263:11
depends 148:22 151:15
320:17
descending 12:18
13:10
describe 58:2 130:15
133:17 230:18 261:15
282:17
described 40:5 90:10
90:12 168:2 262:20
304:17 318:1
describes 40:13
description 33:10
137:17 189:15 249:10
deserves 183:16
designated 10:12
designation 181:21
263:16
designed 274:12 275:1
339:16
desire 19:20 63:5
desired 289:21
Desmirra 3:6 18:19
53:5
despite 53:21
detail 130:15 133:17
193:21
details 157:12
detect 131:9
detection 258:7
determination 16:21
267:7 305:5 344:9
determine 153:6 221:3
221:9 223:6 226:13
235:13 242:13 280:5
292:22 326:21
determining 237:19
306:5
devastating 172:11
198:18
develop 103:20 205:14
215:9 229:8 230:2
302:4

developed 85:17
221:12 246:22 286:10
developer 68:1 104:12
138:22 189:5 197:8
207:13 209:15 219:19
220:2 221:18 227:9
231:18 235:21 280:9
282:21 289:18 301:10
developers 7:22 63:16
76:8 100:9 107:9
119:3 129:5 138:1
146:13 165:21 170:22
234:11 239:3 251:4
272:14
developers' 239:13
developing 84:15 86:7
182:10 302:2
development 2:12
166:4,10,14 227:13
280:10 337:11
device 208:8
devices 202:19
devil's 328:13
diagnoses 286:3
diagnosis 150:21 152:4
diagnostic 149:1 151:1
151:4
diagrams 200:17
dial 347:9
didactic 213:22
dies 152:11
difference 17:6 46:13
46:18 52:20 54:12
59:5 75:11 94:19
197:6 225:8,13
268:22 315:14
differences 18:2 33:14
40:15 48:18 54:16,18
65:20 75:19 92:12
160:13,14 197:17
198:2 314:5
different 15:13 18:1
24:20 25:4 35:4 39:1
43:15 45:11 46:16
54:5 60:20,21 61:4,9
79:20 91:21 93:16
124:12 141:14 144:13
144:17,17 150:4,5,8
153:21 154:1 163:14
164:19 165:2 175:4
186:10 194:6 199:3,8
217:15 223:16 227:3
228:9 257:9 260:13
271:12 272:3,4 277:9
280:1,2 283:3 286:17
286:18,19,21 300:19
302:8,12 305:21
310:10 314:17 315:1

327:7 328:9 330:21
331:16 338:17
differentiates 130:10
134:4
differently 16:17 36:22
38:1,8
difficult 7:5 12:11 16:4
44:10 66:5 180:4
189:14 204:18 210:20
218:3 294:22 303:21
327:5 345:20
difficulties 225:2
259:17 296:18 304:5
difficulty 226:3
dig 283:14
digits 173:16
dire 148:11,14
direct 63:17 67:15
208:20
direction 88:3 209:11
directions 158:8
directive 224:21
directly 79:17 153:5
director 1:13,15 2:1,6
2:13,19 3:4,5,5 214:5
directors 246:5
disagree 152:1 307:16
disassociated 183:6
discard 16:4
discharge 4:5 32:10,19
44:19 51:6,17 58:3,9
246:16
discharged 44:16
disclose 35:7 102:21
disclosure 6:10
disclosures 6:9,12
disconnect 341:10
discrepancies 160:16
discrepancy 173:22
discriminate 161:4
193:13
discuss 10:12 12:1
15:5 32:21 35:16
49:13 175:19 179:15
192:4 240:2 241:15
245:13 313:1 321:3
discussant 109:9 179:7
249:4
discussants 73:12
160:5 177:14
discussed 53:22
100:10 121:3 159:17
197:21 203:13 240:5
discussing 103:9 131:3
238:16 242:6
discussion 7:22 25:4,5
25:10 42:5 44:10 63:1
63:2,3 75:5,8 109:21

125:9,11 129:17
167:17 169:17 170:20
184:13 188:11 191:18
200:7,10 222:14
237:21 238:2,14,16
239:13 241:17 242:22
243:13 244:9 245:7
268:5 280:21 281:22
312:22 319:18 335:12
345:12 347:18 348:3
348:4 349:19
discussions 239:17
281:2
disease 11:14 12:14
40:10,11 180:3
187:11 262:1 269:2
276:3,5 286:3 301:12
disease-specific
162:20
disfunction 71:14
disparities 95:11
160:20
disparity 96:12 113:18
113:22
disperse 313:15
disruption 142:20
distances 95:20
distant 259:11
distinction 198:3
distinguish 18:6
distinguishable 193:20
dive 157:11
diverse 261:1,2
divide 42:17 43:2
Division 2:1
dL 299:20
DNP 2:13
document 61:18 127:4
127:15 260:17
documentation 41:1
61:20 265:18
documents 119:19
doing 80:14 81:16
87:22 156:22 162:20
163:12 168:4,6
179:21 190:5 194:2
199:3 212:3 217:1
220:13 229:19 237:4
237:10 257:14,15,20
262:7,17 269:10
271:3 294:2 296:21
315:12,15
domain 71:7,8 110:2
121:11 165:8
domains 71:9 85:12
Domzalski 3:13 245:21
245:22 248:6 252:3
254:2,9,14 255:7

256:19 257:3 258:5
265:20 267:3,7,11
274:10 276:16 278:2
278:15 288:17 296:15
299:1 303:20 307:10
309:12 315:8 316:6
316:10 317:21 319:2
326:20 343:15 347:7
door 230:7
dose 51:18,20 58:6,20
59:9,15 61:7,16,18,22
dose- 51:14
dotted 67:12
double 99:2 111:13
122:18
Dr 6:17 9:1 11:1,5,6
13:22 14:5,8 17:2
18:10 22:15 31:15,18
37:4 38:15 40:5 42:3
44:11 50:8,15 51:2,13
53:17 54:13 56:1
58:12,21 60:10 61:11
64:3 65:8,13 68:10,13
68:14,15,17 69:2
70:20 73:2,7 76:12
77:6 78:6,9,12,15
79:4,15 80:5,11 82:14
82:20 83:19 84:2,6,14
86:1 87:9 88:4,15
93:5 94:1 99:9 100:4
100:15 102:14,15
103:22 104:9,20
105:13 109:5,11
113:3 114:6,16,19
115:3 118:22 120:15
120:18 121:2 128:14
129:7,7,8,12,16,16,19
129:19 135:5 136:12
136:15,22 141:9,10
141:12,20 143:3,16
143:20 144:10 145:7
146:1,8,9 147:4
149:19 150:20 151:14
152:6,13,20 153:1,9
153:21 155:3,10
156:17 157:8,17,19
158:9 159:13,15
160:21 161:17 162:12
162:22 163:4,19,21
165:9 166:11 167:4
168:12 170:17 171:2
171:10 177:14,15,15
177:16,21 178:2,6
179:2,6,8,9,9 181:10
181:17 182:5,20,22
185:5,6,18 187:4,20
189:3,7 190:6,18
191:5 193:6,17 194:9

195:7,20,22 196:1,15
198:7 200:14 203:13
205:19 206:2,13
207:10,16 208:9
210:14 211:1,2
213:11,15 246:6
264:5,8 268:4 272:8
274:5 280:8,12,16,19
286:8,9 291:22 294:7
295:14,18 296:4
303:10 307:14,17
311:21 312:1 314:15
327:14 329:8 333:22
347:13

draft 211:15
drafts 211:16
drag 114:10
dragging 81:11
draining 199:21
dramatically 144:16
drawing 350:22
dress 177:3
drew 176:19
drill 157:7,14 158:1
drive 83:4,5 96:18
147:16 184:7 203:2
203:11,12
driven 97:18 296:1,8
309:7
driving 142:12 146:17
146:20 204:11 236:4
293:16
drop 61:7
dropped 295:1
drove 97:17
Drs 160:5
drug 51:9
dual- 94:13
due 220:15
duplicative 72:5
Dutton 1:17 23:9,17
24:9 43:20 60:15 82:9
82:15 100:7 136:15
136:16 178:15 179:5
193:6,7 250:9 284:20
297:17 302:18 332:14
DVT 136:18 137:2,12
dying 145:5,9

E

E 4:1
e-specifications 303:21
e-specify 333:4
ear 329:9
earlier 110:5 164:16
200:7 256:3 281:16
322:12
early 22:7 204:3

easier 20:17 103:6
236:2 257:2
easiest 61:21 204:9,10
easily 176:1 193:20
217:10
easy 26:18 42:15
149:16 190:5
echo 261:12
ECMO 286:4
economic 44:1
economics 46:8
eCQM 260:19 333:8
eCQMs 247:14
editorialized 208:10
education 88:12 344:7
344:12
educational 277:2
279:7,9
effect 32:1 43:21 61:9
133:8 150:3 248:18
effective 7:19 35:2
266:5 307:21
effectively 289:19
effectiveness 345:1,5
effects 50:3 80:1 136:8
efficiency 273:22
efficient 8:11
effort 71:19 171:9
247:15
efforts 36:19 65:18
247:3,4 284:5 344:12
egregious 10:8
EHR 60:19 63:22 65:16
215:2 217:12,13,15
217:17 248:4 261:6
311:13 317:11
EHRs 65:21 66:4
260:11,13
eight 142:6 208:22
283:11 300:18,18
306:1,16 327:11
334:8,11
either 13:1 28:10 37:13
57:16 100:6 153:4
183:10,12,14 190:13
242:1 276:2 291:13
320:11 344:21 351:5
elderly 4:12 129:3
130:3
elect 351:7
elected 262:3
elective 5:15 248:8,10
252:1,1,4 262:15
263:18 274:14,19
275:7,7 288:19 289:1
290:3,15 291:5 292:5
297:3 322:21 323:3
326:7 343:16

electively 24:22
electronic 63:18 64:7
214:12,16,22 215:5,9
215:14 216:2,16,22
217:5 227:4 287:15
304:7 305:7 316:21
335:21 336:9 337:10
337:19 340:21 341:13
electronically 215:10
216:11 218:13 338:11
339:11
electronics 338:9
element 10:14 138:21
142:18 143:5 155:4
261:7,13
elements 21:17 63:19
99:2,3,10,13 165:14
175:4 217:19,19
227:4 311:8
elephant 44:4
elevated 199:22
eligible 17:1 44:8 94:14
151:9
eliminate 31:19
Elisa 3:2 19:17 21:1
42:10 219:8 320:11
351:19
ELISABETH 1:18
elongated 215:13
embolism 309:1
embrace 225:2
eMeasure 214:7 224:10
225:16 227:1,20,21
228:2,5 240:15
259:20 310:13,19
313:12,14 323:8,13
324:19 332:4,7
eMeasures 4:18 207:2
214:1,11 215:20,21
216:4,7 217:3 224:18
224:21 225:5,10
290:10 311:11
emergency 287:8
299:15 321:17 322:2
322:20,22
emergent 12:12 321:15
emphasis 215:7 218:15
224:19
emphasize 22:17 23:1
23:3 57:15 69:12
134:2 171:8 222:16
232:15
empirical 305:11
empirically 97:21
EMR 67:15 302:3
enable 59:22 158:10
encompass 344:8
encompasses 85:9

encounters 268:11
ended 144:3 265:2
294:21
Endocrine 2:17
endogenous 133:6
endorse 54:3 72:20,21
183:20,21 202:17
234:1,7
endorsed 12:16 14:13
16:22 17:7 20:21,22
21:3 23:4 34:7 38:10
42:9 59:22 71:16,17
74:3 75:13 148:7
183:10,13 219:15
232:17
endorsement 16:18
21:1 22:19 23:4 24:11
26:15 30:21 31:3,8
33:5,10 42:9 53:4,7
53:12 54:3 70:11,16
73:1 75:6 108:14,14
108:17,22 119:21
120:1,5 127:22 128:9
159:1,3,8 170:10,15
180:13,13 183:10,16
183:20 201:17,19
206:15 210:1 218:13
218:16 219:10,13,22
220:8 222:18,19
223:8 224:14 225:15
226:4,14 232:16
233:11,21 234:14
endorsement- 87:2
endorsements 231:9
endorsing 232:13
enforce 210:20
enforcing 210:15
Englewood 3:16 274:6
enhance 275:3
ensure 248:19
enter 182:18 317:6
entertain 176:19 177:12
entire 8:2 21:2 83:11
105:1 157:8,9 306:9
306:11 309:17
entirely 323:1
entities 84:20
entry 162:21
enumerator 272:16
envelope 177:10
enviable 26:21
environment 79:9,13
96:10,21 105:16,22
199:12
Epic 64:6 100:5
epidemic 269:4
episode 306:9,11
309:17

equally 147:11,22
equate 303:17
equation 137:1,2
225:11
Erekson 1:18 112:13
135:5,6 136:13,14
137:16 138:19 140:2
146:12 155:16 156:12
234:5 303:8,12 328:4
errors 296:17
erythropoietin 270:14
especially 137:9 192:21
281:11
essence 219:5
essential 235:7
essentially 10:9 32:8
32:15 50:5 94:15
118:13 172:14 181:18
226:10 245:3
establish 332:5
established 9:8 38:5
75:17 181:1,7 235:6
268:16
establishing 181:3
estimate 67:19 185:21
186:2
et 71:14 157:16 263:13
299:15 316:16
etcetera 256:16
ethnicity 114:4 160:14
etiologies 199:17
EU 271:16
Europe 269:19
European 270:19 271:6
evaluate 209:19 220:6
223:17 225:10 236:4
323:20
evaluated 163:12 226:8
327:1
evaluating 225:17
232:9
evaluation 81:5 216:4
259:11
event 16:16 47:18
137:2 154:2 174:2
176:21 178:19 185:20
186:17 204:2
events 47:22 146:22
147:16 153:17,19,22
186:8
eventually 265:17
everybody 29:10 36:15
57:13 221:14 251:2
272:2 273:2,6,16
evidence 13:7,21 14:3
14:4 15:4,8,11 16:3
17:12 19:3 21:21
31:12 34:1,2,5 35:15

51:7 53:16,18 55:20
 56:3 71:22 73:16 74:1
 74:5,8,12 76:4 105:21
 110:6,18 111:1,4,7
 121:10 122:7,11
 131:6 133:1 135:9,10
 135:15 136:9,12
 137:14 142:15 160:9
 160:11 178:1,1,13
 182:9 184:3,10,19
 185:1 206:6 220:16
 220:21 223:19,20
 226:1 231:3,12,15,20
 235:2 241:6,7,16
 245:9,12 249:14,15
 249:18,20,22 250:19
 251:18,19,20 253:4,4
 253:18 254:1 256:9
 256:10 265:10 266:17
 267:13,15,19 268:7,9
 276:9 279:22 281:8
 288:3,5,9 289:8,14,14
 291:15,19 298:3,4,8
 298:14,18 300:5,15
 301:8,14 302:2,5
 305:9,11,12,17
 306:21 308:6,11
 311:20 312:12,17,22
 338:2 347:12 348:7,8
 349:3,12
evidence-based 247:1
evidenced 10:14
evoked 209:7
evolve 199:5
ex-surgical 120:12
exact 68:11 84:18 231:2
exactly 38:16 41:13
 115:3 121:12 241:15
 251:6 315:18 327:22
 347:18
examine 93:21
examined 92:22,22
 131:16 137:9
example 7:14 94:2,14
 104:2 119:4 209:3
 250:16 251:9 261:17
 263:10 296:18 304:3
examples 84:22
excellence 67:17
 265:13 266:3
excellent 14:5 106:18
exceptions 303:1
excess 13:15
exchanging 120:22
 131:17
excitement 317:16
exclude 12:6 149:11
 166:20 286:1 303:22

328:8 331:20
excluded 151:1,6,7,8
 152:5 165:22 166:22
 303:10 322:3 323:1
excluding 175:20
exclusion 78:3 149:12
 166:5 222:7 239:8,15
 239:19 301:16 303:12
 303:14 307:8 321:17
 322:19 330:5 340:9
exclusions 40:14 287:3
 299:14 319:22 321:14
excuse 78:13 154:19
exhaustive 13:11
exist 150:18 160:20
 242:8 317:5
exists 22:19 96:1 317:2
expanded 69:3
expect 68:1
expected 74:18 111:11
 111:13 122:15,17,19
 180:18
expecting 315:15 326:7
expensive 294:4
experience 60:13
 112:11 147:12 208:17
 280:5 313:5
expert 90:11 92:13
 97:22 132:13,18
 142:5 274:5 331:19
expertise 80:19
experts 142:6
explain 282:21 283:1
 284:16 304:1
explanation 113:19
explore 311:11
explored 65:15
exposed 171:22
expressed 182:7
 328:12,22 329:6
expressing 272:18
 284:17
extend 226:16
extended 321:10
 325:10
extent 235:8 239:1,5
 330:4
external 210:15
extra 37:12 273:18
extract 66:4 239:5
extracted 68:8 151:17
extraction 65:14 310:13
extractor 99:21 157:22
extrapolated 243:21
 244:8
extremely 263:10 310:7
 310:14
extremity 261:16

eye 272:4 344:18

F

fabulous 7:11 143:13
FACC 3:10
face 110:19 118:8 119:1
 119:7 132:12 142:13
 176:14 198:14
facetious 256:7
facilitate 224:11
facilities 178:19 260:9
 277:12 278:19 285:16
 295:20 326:14
facility 82:12,12,16,17
 278:18 286:12,18
 311:5,10,17 327:10
FACOG 2:4
FACS 2:1,4 3:10,14
fact 14:8,10 21:1 43:22
 54:18 69:12 84:19
 142:8 147:9 150:17
 151:6 153:1 174:2
 176:20 179:17 182:7
 187:13 191:21 194:2
 198:13,16 268:6
 310:22 337:16 348:17
factor 78:22 103:17
 114:5 268:12,17,20
 269:3 270:22 308:16
 308:16,17,21 309:14
factored 306:18
factors 92:21 93:1,11
 94:5,12,18 95:7
 130:19 133:3 152:11
 160:2 176:21 181:2,8
 181:11 197:4,16,16
 198:10,17 200:18
failed 226:16
fails 221:14
failure 32:7 71:12 266:2
 270:13 285:11 304:4
 304:13,14,14
failures 296:18
fair 44:15 75:4 168:6
 179:5 236:18 285:15
 326:5
fairly 40:8 44:18 93:8
 116:5 150:2 231:22
 255:5 276:1,11
 289:14 295:6
fall 151:4 224:9 294:13
falls 140:11
familiar 217:11 299:5
family 153:6 273:12
fan 284:20
fantastic 8:22
far 11:21 54:4 60:7
 65:18 66:10 69:10

91:18 156:12 197:14
 197:21 247:11 301:8
farm 96:15
farther 69:4
fashion 98:18 207:20
 250:13 310:16
faster 120:18
fault 285:3
FCCM 2:10 3:16
FCCP 2:10 3:16
fear 317:10,12
feasibility 29:8,16,21
 52:9 63:8,15 66:16,21
 98:15 101:5,13,20
 116:21 117:7,12
 126:21 127:4 133:19
 154:18 155:15 156:1
 156:6 167:15 169:3,5
 169:10 190:14 212:1
 212:3,7 221:2 225:19
 229:4 232:2 241:10
 243:18,20 245:15
 247:22 260:5,20
 336:8 337:10,13,16
 338:10 339:10 341:18
 341:20 342:1,10
feasible 29:12 133:22
 168:16 235:14 244:2
fed 132:7
federal 44:6
federally-funded
 171:13
fee 134:10
feedback 9:18 79:11
 88:16 131:22 132:19
 213:15 287:18 349:17
feel 14:12 17:15 131:4,5
 132:13 137:5,14
 176:5 186:15 209:12
 209:22 210:17 230:2
 230:4 233:3 242:7
 346:9
feeling 96:22
feels 25:6 36:21 168:9
 220:2 280:19
fell 283:13 284:4
felt 174:5 175:3 182:16
 261:3,7 325:8
femoral 177:8
fever 190:1
fevers 148:18
fewer 99:13
fibrillation 32:12,13
 54:19
field 99:14 110:7
 214:17 219:5,17,20
 220:1 222:9 223:3
 225:22 226:10 235:11

243:21
fields 65:21,22 68:7
 99:14,15,18 100:10
 131:13,20 132:2,9,15
 132:20 141:21,22
 142:3 143:9 150:5
 168:21 302:3,4
Fifty 170:4
figure 197:5
figured 264:15
figures 67:10
fill 218:1 227:14
filling 225:22 235:12
final 120:9 176:18
 211:17 236:20
finally 10:11 12:13
 350:20
financially 261:2
find 24:1 44:3 61:20
 137:4 140:10 218:3
 226:20 227:13 255:19
 303:22 304:7 310:8
 314:4
findings 258:6
fine 34:2 178:17
finger 315:17
fingertips 182:2
finish 8:2 26:4
first 8:20 12:1 22:4,11
 39:7 40:19 51:8 58:20
 69:20 102:20 130:1
 135:2,6,8,11 140:18
 141:11 149:20 168:14
 178:17 181:10 189:6
 198:21 211:15 213:21
 216:9 222:14 229:2
 258:16 270:5 272:12
 274:21 283:6 296:16
 299:13,18 306:7
 309:18,20 310:9
 318:14,19 321:4
 322:19 337:12 345:20
 351:7
fit 103:5 178:16 241:15
 265:15
fits 302:14,15
five 71:2,10,17 85:11,11
 131:1 165:3 216:4
 222:11,13 227:12
 246:9 247:1,9 248:1
 251:8 275:9 317:9
fix 259:7 264:11
fixation 189:10
flagged 34:14
flash 215:3
flawed 84:21 85:4
fledgling 182:13
Fleisher 1:9,11 6:3,15

6:21 7:2,8 8:13 13:20
 14:1,6,16,21 15:6,10
 16:5,11 17:18 18:8,14
 18:17,21 19:12 23:8
 24:8,10,15 25:8,15
 26:1,4,11,14 27:1,12
 28:2,14,17 29:6,13
 30:3,5,20 31:1,10,16
 33:15,20,22 34:15,18
 34:21 35:3,7,11,14
 36:1,4,8 37:1,19
 38:17 39:11 41:5,20
 43:9,13,18 45:2 46:3
 47:15 48:14,17,22
 49:2,4,8,12,15 50:5
 51:22 52:4,6,11,13,16
 52:20,22 53:3,14
 55:17,21 56:2,5,12,15
 57:6,12 60:14 62:8,20
 62:22 63:7,10,13
 65:12 66:11,14 67:3
 68:5 69:5,15,18 70:2
 70:5,8,18 72:17 73:4
 73:8 74:4,21 76:1
 77:4,8 79:5 81:9 82:3
 82:6 84:8,12 86:16
 87:10 88:5,20 89:8,13
 89:19,22 90:3,16,19
 91:7,20 95:3,8 97:1
 98:3,20 99:22 101:4
 102:7,18 104:10
 106:9 107:2,6,17
 108:13 109:2,6,10
 110:17 111:9,17
 113:4,16 114:12,17
 114:22 115:6,13,20
 116:10,22 117:4
 118:6,18,20 119:20
 120:8,17,21 121:22
 122:4,13,22 123:19
 124:11,15 125:8
 126:3 127:7,18 128:2
 128:11,15 129:19
 143:22 145:4,18,20
 146:3,6 183:8,19
 201:12 203:9 213:8
 223:13 225:6 226:15
 226:20 227:19,22
 228:4,16 230:10,17
 232:18,21 233:9,14
 233:17 234:3 236:7
 236:16 237:11 238:3
 240:11 241:2,21
 242:16,20 243:7,12
 244:11,15 245:3
 249:3 250:5,8 251:17
 252:11,17 253:3,7
 254:5,11 255:12,16

258:13,15 261:11
 264:2,7 265:8 266:16
 266:21 267:13 268:1
 272:7,10,22 274:3,20
 277:18 280:7,13,17
 282:2 284:19 287:1
 287:11 288:2,13
 289:11 290:8 291:20
 292:17 293:10 295:7
 297:16,19 298:2,17
 300:1 301:5,20
 302:17 303:19 305:8
 308:4 311:18,22
 312:10,21 313:9
 314:1,14 316:2
 318:10 319:3,15,21
 320:2,10 321:1 323:4
 323:18 324:9 325:5
 325:12,16 328:3,10
 330:7 331:22 332:12
 334:17,22 335:3
 336:21 337:5 338:6
 338:14 339:17 340:6
 340:12 341:1,17,21
 343:3 344:20 345:18
 346:6,18,20 347:4,8
 347:15,20 348:6,14
 348:16 349:15,22
 351:14,18
Fleisher's 207:11
flesh 261:9
Fletcher 129:8
Floor 1:8
Florida- 2:16
flows 248:2
focus 31:12,16 55:15
 73:18 93:5 105:9
 183:15 284:5 294:10
 305:12 308:5 314:19
focused 105:10 132:17
 133:12,14 151:10
 202:13
focuses 130:11
focusing 258:3
follow 50:15 80:12
 189:11 207:10 232:4
 254:5 258:2 348:1
follow-up 195:4
followed 50:16 152:22
 304:10
following 145:1 201:15
 257:16
follows 289:17
fond 221:18 296:17
food 244:19,20
foray 171:16
force 11:3,7 35:8 182:8
forces 85:18

Ford 11:2
forefront 44:22
foremost 205:4
foresee 235:20
foreshadowing 87:4
form 76:20 143:4
 199:12 214:22 231:22
 235:1
formal 91:14
formally 103:14
format 336:10
former 221:18
forms 155:5,14 164:15
formulate 277:2
formulation 82:21
forth 37:8 82:1 249:22
 281:22
fortunate 69:6
Fortunately 315:4
fortune 209:1
Forty-five 293:8
Forty-nine 83:19,22
forum 1:1,8 237:3
forward 8:11 22:1 25:16
 26:15 36:15 47:16
 55:14 77:2 112:8
 125:13 172:9 189:1
 203:21 209:1 215:3
 247:6 274:9 275:19
 288:14 298:21 339:19
 343:12 349:16
found 173:18 176:10
 262:20 268:12 294:17
 296:21 297:17 334:5
four 80:8,15 216:9
 267:17 283:3 288:7
 298:10,12 306:13
 312:14 319:8 323:10
 340:16 342:3,18
 349:7,9
fourth 217:1
fraction 134:11 193:19
fracture 4:16 151:3,18
 172:2,12,21 173:14
 174:19 175:13,22
 176:1,3 183:7 186:7,9
 188:7 189:9 190:7
 194:5
fractured 183:5
fractures 151:15 171:7
 172:13 173:18 177:8
 178:4 186:1,3 199:16
 204:22
frame 58:7 72:4 120:10
 195:19 236:8 248:20
 249:21 251:17 260:17
 260:21 324:2 344:14
frames 116:6,8

frankly 15:4 59:11
 85:16 94:13 261:21
Fred 205:7 213:11
 228:21 258:13 272:22
 311:18 322:6 341:1
Fred's 325:20
FREDERICK 1:19
free 103:19
front 21:19 73:5 130:2
 131:2 134:19,20
 181:16 209:18 222:13
 317:13 341:6
FTE 134:12 168:17
fulfill 219:1
fulfilled 233:4
full 22:19 26:15 137:18
 220:11 223:8 243:13
 255:18 262:9 304:22
fulled 207:8
fully 207:2 209:13
 218:15 224:13 348:18
function 32:8 144:13,13
 246:15
functional 112:20 133:5
 140:14 141:18 209:4
fundamental 184:12
further 8:5 55:9 60:1
 109:21 125:8 135:4
 157:7 166:6 174:22
 175:13 177:11 178:14
 219:18 226:14 261:9
 311:11 313:9 342:14
future 65:6 112:21
 143:14 168:18 172:16
 237:2

G

G 4:1
GAETANO 3:15
gain 207:12
Gainesville 2:16
game 87:7
gamed 257:19
gaming 309:6
gap 14:2,17 15:1,5,5,12
 15:22 16:12,19 18:5,7
 19:13,20 21:4 24:18
 24:21 31:13 32:14,17
 32:22 33:19 35:16,17
 35:21 36:11 39:2,3,14
 45:7,17 46:2 47:19
 48:10 50:1 53:16,19
 54:2 55:20 56:5,19
 57:10 74:16 75:21
 88:21 111:9,10,14,20
 112:3 114:1 122:14
 122:21 123:3,8
 137:15 138:4,6,9,13

160:10 161:16,20
 162:2,7 166:9 179:18
 185:4,7,10,12 188:12
 188:14,19 218:2
 220:16 223:18 226:2
 230:13 231:3,12
 232:6,7,11 233:20
 235:2,12 245:10
 275:14 276:9 289:15
 296:10,11,12,14
 313:1,4,5,12,17,18,19
 314:3,12,16 315:2,5
 315:11,22 319:4,6,11
 338:2 345:9
gaps 19:4,5 26:8 48:5
 89:1,10 179:16
 223:20
gauge 179:22
general 2:8 36:10,11
 76:2 98:21 99:5
 104:20 195:12 301:18
 313:22 343:16 344:7
generally 40:7 60:22
 221:15 227:8 294:13
 304:3
generate 144:21
geocoding 94:20
geographic 95:11,19
 96:13
geography 96:9
geriatric 132:16 135:13
 140:6,17,20 141:13
getting 16:1 51:11
 226:15 235:9 261:5
 273:20 327:18 330:17
 333:22
give 60:19 61:2,6,15,21
 171:17 174:15 193:22
 212:10 243:1 245:20
 261:8,20 306:14
 309:2 310:10 312:2
 324:12 341:6 348:8
given 21:21 34:13
 49:22 58:6,18 59:9,18
 59:18 60:3 97:20
 125:11 162:17,18
 166:7 186:6 198:13
 217:2 224:22 249:21
 287:19 298:5,18
 321:19 322:20 327:9
 332:22 343:6
gives 90:5 112:9 123:16
 230:5 286:20 299:9
giving 39:20 40:3
 102:13 112:15 180:10
 219:16 318:5
glad 350:10
global 123:15

globe 269:5
glycocalyxes 199:12
go 8:18 19:14,21 21:11
 23:5 28:2 31:11 34:3
 38:17 41:22 44:2
 48:21 54:4 66:14
 68:20 84:9 98:19
 99:15 113:22 114:2
 117:4 119:10,13
 121:1 125:10 137:15
 140:21 153:17 155:5
 155:12,21 161:22
 164:1 169:3,18
 172:17 174:17 175:14
 201:4 203:7 205:7,15
 218:7 219:11,17
 226:7 231:9 235:6
 241:8 242:2 243:16
 245:4 252:12,13
 253:11 255:19 258:21
 265:17 272:19 274:9
 274:21 282:11 291:16
 293:7 294:2 306:16
 323:5 333:19 335:10
 341:7,13 349:16
 351:11
goal 183:15 272:16,17
 277:15 284:8 292:21
goals 329:5
God's 329:9
goes 17:12 20:20 21:2
 50:4 57:14 81:2 87:15
 107:4 114:6 150:2
 174:11 226:9 235:18
 245:18 316:17 318:3
 328:16
going 6:5 10:12 11:4
 18:19 22:9 26:15
 31:19 34:12 39:2 47:7
 48:15 55:14 60:19
 74:22 76:17 80:20,21
 80:22 81:14,21 86:8
 86:11 94:19 103:20
 105:7 106:5 134:13
 136:3 148:20 173:6
 176:5,6 177:8 178:20
 181:2,8,19 184:14
 192:5,17 194:7
 196:17 200:6 207:4
 210:19 211:19 212:10
 215:12,18 221:5
 222:5,12,14 225:9
 230:12 232:12,16
 235:19 240:22 242:7
 242:8 243:18 244:4,5
 244:14 245:7 250:17
 251:5,7,15 256:13,14
 258:2,20 259:3,4,6,6

259:12 262:8,11,13
 263:5 264:3 267:2,5
 271:19,20 278:8
 279:2,4 280:8 281:2,5
 283:17,21 285:1,13
 287:6,7 288:14 294:1
 304:20 313:6,21
 315:16 322:17 324:14
 326:5 329:2,12,19
 343:8,12 345:18
 351:11
gold 101:2
Goldwater 3:4 207:5
 214:3,4 224:1,6,16
 225:12 226:19 227:6
 227:20 228:1,11
 229:6 230:20 232:14
 232:20 233:8,22
 234:15 236:15 237:9
 238:1,21 239:10,21
 240:16,22 242:5,19
 243:5,16 244:14
 336:7,19 337:2,8,18
 338:4,8,22 340:18
 349:21
good 6:3 8:9 11:5 15:12
 25:1,10 34:2 48:20
 51:14 58:21 66:10
 67:17 69:8 73:15
 75:20 80:16,18 84:22
 102:5 110:18 123:18
 135:15 136:5 137:20
 141:1 142:15 144:22
 145:13,18 149:7,13
 168:5,8 171:2 174:6
 175:8 177:21 184:17
 190:20 195:19 198:4
 201:21 202:2,18
 203:11 206:17 214:3
 229:17 244:19 245:21
 250:19 264:14 281:8
 293:20 295:10 301:14
 307:14 333:5 348:2
gotten 22:11
grade 199:17
grading 305:11
graft 4:4,11 12:6,22
 13:14 19:2 22:22
 71:14
grafting 71:3
grafts 13:6
gram 299:20
grams 275:6 295:1
granted 36:15 243:19
granular 251:12 283:17
granularity 94:16
gray 335:10
great 6:15,21 7:2,18

17:21 41:20 42:6
 54:21 58:22 64:17
 65:4,7 67:3,18 72:17
 73:14 85:19 88:9
 113:4 149:19 177:16
 201:14 210:14 212:8
 214:2 224:19 229:20
 238:8 243:7 268:3
 290:11 301:5 319:3
 319:15 349:16
greater 55:6 57:17
 91:16 214:15 215:7
 283:22 294:14 299:22
 300:5
grew 182:8
gritty 175:16
grossly 84:21 85:3
group 34:9 68:7 75:2,9
 75:9 76:11 77:5 84:1
 119:15 132:18 145:12
 145:12 206:20 224:14
 279:8 324:6 350:15
grouped 158:4
groups 15:21 18:3
 318:2
GROVER 1:19 19:9
 184:14 205:9,22
 206:3 228:22 258:14
 273:1 308:8 322:7
 325:22 326:11,15
 327:19 341:2
Grover's 206:13
growing 214:13
growth 194:13
guaiac 262:7
guess 11:8 45:11 50:7
 50:13 60:10 63:15
 64:22 171:20 200:12
 205:16 206:12 209:11
 218:21 253:9,17
 262:4 278:15 279:14
 305:18 306:7 317:11
 339:4,7 346:6
guessing 203:7 312:4
guesswork 312:5,9
guidance 213:10
guide 168:21
guided 295:20
Guideline 34:16
guidelines 12:21 34:5,8
 34:10,13 35:8 245:6
 282:8,16 289:18
 301:10 304:4
Gunnar 1:9,13 8:7
 28:12 37:14 38:18,21
 62:3 68:6 80:6 81:2
 83:8,14,22 84:4 85:21
 99:20 102:12,16

110:22 118:16,19
 125:20 128:20 129:7
 135:5 136:11,15
 137:13 138:5,17
 139:12 140:1 141:4
 143:21 145:16,19,21
 146:5,9,11 148:4
 153:8 154:7,17
 155:15,20 156:10
 157:3,21 158:11
 159:1,10 160:5,10
 161:17,21 162:11
 163:22 164:12 167:3
 167:14,18 169:2,14
 169:17 170:7,19
 177:14,19,22 178:6
 179:8,11 184:3,11,16
 185:4,15 186:19
 187:4 188:11 189:1
 193:6 194:9 195:2,20
 196:1,13 198:7 200:5
 201:10 205:7 206:11
 206:21 207:9 208:14
 210:2,22 212:15
 213:3 322:6,14
 325:20 326:9,12
 327:22
Gunner 129:19
Gustilo- 193:22
guys 23:15 65:4 69:19
 112:22 155:8
GYN 259:1
gynecological 297:6
Gynecologists 2:5

H

H 3:17
H&H 256:18 318:17
habit 63:1
habits 28:8
half 51:8 111:16 122:20
 220:14 234:6
Hall 3:14 129:7,9
 136:22 141:9,20
 143:3,16,20 144:10
 145:7 146:1,8 147:4
 149:19 150:20 151:14
 152:6,13,20 153:1,21
 155:3,10 156:17
 157:8,17,19 158:9
 159:14,15 160:21
 162:22 163:19,21
 165:9 166:11 168:12
 170:17
hand 83:15 308:5
 348:10
handbook 183:22
HANDY 1:21 14:22

15:12 21:5 22:2,14
 23:7 26:17 28:6 29:7
 30:4,17 109:8 110:18
 111:10 112:6 115:8
 116:4,20 117:2,16
 121:19 122:2,14
 123:12 124:7,13,17
 125:5 126:4,18
hang 222:14
happen 20:3 96:14
 105:16 109:21 318:19
 325:18
happened 24:6 43:16
 153:2 157:6 303:1
happening 66:9 249:11
 249:12
happens 50:3
happy 129:20 130:19
 135:3 213:13 336:2
harbored 199:9
hard 36:13 80:17 115:5
 168:3 191:15 198:18
 199:16 230:14 293:9
harder 22:21
hardware 174:18,21
 191:22 192:7 199:8
 200:22
Harvard 187:22
harvest 12:10
hate 96:17 238:17
hazards 246:14
HCFA 214:20
he'll 80:21
head 27:21 87:1
health 1:14 2:5 46:8
 64:7 214:12 215:5
 217:5 326:13
Healthcare 103:15
 129:10
hear 42:4,5 43:5 69:19
 107:22 168:1 207:4
 251:13 290:17
heard 20:20 30:5 42:8
 101:9 103:12,14
 150:7 196:16 236:17
 317:15,18 320:3
 323:22 325:8
hearing 38:9 106:10
 137:15 158:12 215:15
 229:17 233:1 255:1,2
 268:5 274:4,9 305:15
 330:9,16 338:21
 339:20
heart 11:14 32:6,6,7
 50:18 266:2 304:4,4,9
 304:13,14,14
held 205:1 306:4
 332:11

Helen 3:2 244:12
 351:20
help 19:18 21:22 41:8
 43:5 45:9 202:1
 213:13 255:15 259:5
 277:19 278:12 279:9
 316:4 333:10 336:15
 339:22
helped 339:18
helpful 18:14 22:16
 42:2 100:9 161:15
 232:12
helping 18:20 278:1
 351:21
helps 43:3,4 278:13
hematocrit 285:6 299:8
 316:15
hematologist 257:9
Hematology 270:4
hemoglobin 5:3 246:21
 253:8 254:20 255:9
 256:10 257:1,6
 263:19 269:9,11
 273:4,20 274:11,15
 274:18 276:10 279:10
 279:15,19 280:4
 281:19 283:4 286:19
 287:22 295:2 299:8
 299:11,20 300:4
 301:15 302:20 303:5
 303:6 304:6 306:15
 308:15,19,19 312:6
 315:19 316:15 318:14
 318:22 321:9,16,21
 322:9,13 326:1,5,16
 327:15,20,22 328:18
 329:17 330:1,18,19
 330:20 331:2,5
 332:16 334:8,11
hemoglobins 253:12
 253:19 275:6 279:3,4
hemolysis 231:1,8
hemorrhage 303:16
 328:6 330:3
hemorrhagic 322:10
 326:4
hemorrhaging 329:18
Hemovac 304:22
Henry 11:2
hepcidin 270:6
hernia 252:8
hi 214:6 259:18
hierarchical 82:11
 133:8
high 15:15,19 18:11
 19:6 26:3,9,22 27:4,9
 28:19 29:3,17,22 30:4
 30:9,14 45:22 48:5,11

53:21 56:20 57:3
 62:11,17 66:17,22
 73:20 85:14 89:2,11
 90:22 91:5 92:1,7
 97:5,11 98:7,12
 101:14,21 108:5,10
 111:20 112:4,11
 113:7,14 115:8,16
 116:1,12,18 117:7,13
 117:20 118:3,9,12,13
 123:3,9,21 124:5,19
 125:3,17,22 126:8,16
 126:18,19,21 127:5
 127:10,15 131:14
 138:9,14 139:16,21
 156:1,7 158:15,20
 161:16,20 162:3,8
 164:3,9 166:7 169:5
 169:11,21 170:4
 173:13 174:3 175:2
 176:6,11,20 177:5
 180:3 181:3 184:6
 187:1,11 188:14,20
 196:4,10 198:15
 204:2 240:19 246:20
 249:19 263:10 267:16
 267:20 288:6,10
 290:20 310:14 312:13
 312:18 319:7,12
 321:15 323:9,15
 329:17 342:2,11,17
 342:22
high-outlier 138:2
high-risk 105:11
high/moderate 125:14
higher 56:10 111:15
 122:19 136:1 173:21
 178:11 299:7 300:10
 304:6 306:22 308:19
higher-risk 106:4
highest 10:20 72:11
 105:6 161:4
highly 11:21 29:11
 65:21,21 173:12,19
hinder 219:2
hip 172:12 186:7,8
 264:22 265:5 314:20
hips 315:7
hire 100:14
historically 84:17
 206:21
history 10:7 11:22 21:6
 23:10 39:19 215:13
hit 47:10 157:14
Hitchcock 1:18
hoc 107:15 209:7
hold 167:17 199:20
holding 38:5 209:10

holds 278:10
hole 96:8 303:5 304:16
home 50:4 152:12,14
homeopathic 61:7
homework 181:15
honest 265:9
honestly 61:6 68:10
 207:17
honor 11:6
hope 205:4 335:4
hoped 215:1
hopefully 59:13 102:20
 341:13 343:10
hopelessly 105:20
hoping 230:8 336:5
horizon 130:9 134:3
hospital 2:8,9 3:17,17
 46:10 59:8 61:13
 67:20 69:7,13 95:19
 133:8 139:7 140:11
 145:6 148:16,18
 152:9,11 153:4
 156:21 188:8 202:2,2
 247:20 258:21 260:17
 274:7 277:10 279:16
 286:13 315:17,20
 316:1 334:5,5,6,9,13
 334:13,15,15
hospital's 344:10
hospitalization 153:3
hospitalized 272:6
 299:16 331:13
hospitals 24:3 63:21
 133:20 137:17 138:2
 138:2 139:11 141:15
 156:15,16,22 157:1
 163:7,11 168:1,9,15
 168:20 173:2,4,7
 202:5 203:10 215:4
 217:6 218:18,21
 246:11 247:1,4,6,21
 248:1,14 254:15
 260:4,15,22 266:8,14
 277:2,8 279:11
 286:22 294:1 296:16
 300:17,17 302:19
 310:2 315:10,17
 317:9,22
hour 120:15 128:6
 304:21
hours 7:16 55:8 58:3,14
 61:19 177:6
HQM 336:10
HQMF 324:18 325:3
 336:5
huge 44:1,7 93:17
 250:20 314:16 315:4
 315:4 334:11

humbled 9:4
hundred 122:10 285:5
hundreds 147:13,21
hyperbole 256:13
hypotensive 61:1
hysterectomies 286:14
hysterectomy 297:22

I

i's 67:12
ICD-10 176:2 252:5
 255:21
ICD-9 176:4 187:17
ICU 81:22
ID 79:17
idea 37:6 77:20 86:18
 86:21 87:4 206:17
 221:16 244:19 258:20
 277:2 302:15,15
 329:14
ideally 88:2 148:6
identification 224:12
identified 163:8 176:2,4
 179:16 275:4 286:4
 330:1
identify 6:8 8:20 176:13
 232:10 274:13 275:1
 344:2
identifying 247:2
 343:20 345:2
ignorance 297:9
ill 105:20
illness 263:12
IMA 12:15,18 13:9
 28:11
imagine 103:19 277:7
IMAs 32:18
immediately 274:18
 299:12
immensely 68:19
impact 16:9 44:2,7
 93:17 94:15 136:6
 137:3,4,6,11 182:15
 244:4 262:13,18
 282:19
implant 195:8,17 208:7
implants 174:11 191:12
implement 100:5 236:2
 282:17
implementation 163:1
 163:3 168:19 214:12
 242:9 272:5 317:11
implementations
 217:15
implemented 10:5
 165:16 208:19 218:17
 218:18,19,21 231:6
 231:14 235:9 242:10
 302:11 310:2 317:19
 336:11
implications 45:12
 175:9 176:15 177:11
implicit 72:14
implies 254:19
implore 192:18
imply 256:17
import 148:9 324:6
importance 16:14 33:7
 93:15 131:5 150:4
 220:16 223:18,20
 225:18 231:15 235:3
 237:5 240:13,20
 241:1,6,16 245:8,9
important 7:4 10:10,13
 14:11 16:10 17:9,14
 19:16 22:20 37:2
 38:12 44:22 45:20
 47:19 65:14 72:18
 79:11 88:18 90:8
 105:3 114:21 147:16
 166:3 172:19 177:7,7
 177:9 178:5 202:15
 204:13,15 211:12,14
 211:18,19 213:17
 224:14 230:3 237:2
 237:19 241:8 249:16
 260:5 265:7 272:1
 280:4 308:12,13
 341:9,12 348:16
importantly 13:18
 130:8 131:21
impossible 12:11
 248:17
imprecise 304:12 305:2
 305:7
impressed 213:18
improve 21:17 46:9
 81:21 96:20 235:4
 247:2 269:15 270:20
 276:4 331:16
improved 231:14
 257:22
improvement 9:20 20:1
 24:5 25:20 36:12 40:3
 45:11,12,18 56:11
 81:6 82:2 83:5,6
 88:17 132:8,22 142:3
 142:12 144:22 158:5
 160:19 203:12 215:8
 272:21 284:21 285:7
 302:22 310:21 329:3
improvements 22:9
improving 46:11
 175:13 253:18 261:5
 339:8
imputed 92:19

in-hospital 186:9	indication 42:12 316:16 318:5 330:2 333:2	initiating 69:21	126:2,10,17 127:1,6
inadequate 94:18	indications 322:12	initiation 265:6	127:11,17 138:10,16
inappropriate 310:8	indicators 10:10	initiative 105:2 173:10	139:17,22 154:11,16
inappropriately 293:20	individual 4:7 25:18	Initiatives 11:8	154:22 156:3,9
inappropriateness 246:20	27:22 70:22 75:4 76:7	injured 194:19	158:16,22 162:4,10
incentive 230:9	76:9,10 77:7,11,21	injuries 176:13,17	164:5,11 167:8,13
incidence 54:18 178:19	82:10 87:17,18,21	177:5 194:20	169:7,13,22 170:6
180:3 185:19 269:15	90:6 104:15,19 279:7	injury 171:21 172:7,11	188:16,22 196:6,12
incidental 148:13 186:4	333:15	172:19 174:3 179:21	212:19 213:2 267:17
incipient 205:19	individually 86:2	179:22 185:20 193:11	267:22 288:7,12
incisional 142:20	individuals 144:5 210:4	197:16 198:14,16,18	298:10,12,16 312:14
include 12:7 82:11	210:9 279:8	286:2 328:7	312:20 319:8,14
93:19 140:8 143:15	inequality 46:9	innovation 218:8	323:10,17 326:21
151:11,12 237:8,21	infected 193:12	innovative 218:13	342:3,12,18 343:2
238:1 256:2,6 287:7,8	infection 4:16 71:11	inpatient 145:5 260:12	349:8,9,14
301:17	142:20 148:13 170:20	260:14 261:6	insurance 24:4 114:13
included 9:20 92:14	171:6 173:12,15,19	input 340:3 349:19	114:13
133:17 139:4 152:15	174:9,10,16 175:1,6	inquired 229:14	integral 17:1
155:1 197:18 322:3,4	175:18 176:16 177:1	insert 164:16	integrated 260:11
322:8,9	177:3 178:3 184:6	insertion 316:15	intend 300:21
includes 32:8 71:2,15	186:11 187:1,10	inside 156:19 172:5	intended 67:4 86:18
131:15 132:3 140:11	188:8 190:3 192:7	304:22	284:22 345:1
141:14 216:4 306:11	193:16 194:7,8,15	insightful 76:13 79:15	intensely 55:14
including 94:11 141:2,2	195:9,13 196:19	144:11 163:1	intensity 149:1
141:17 152:8 199:11	198:16 200:2,3,12,21	insights 41:22 149:20	intensive 79:2 310:7
237:17 251:11 286:1	201:4,8 208:5 246:14	insignificant 18:12 67:9	Intensivist 77:14
inclusion 141:3 189:9	infections 147:15,15	insist 200:2	intent 165:18 248:19
222:7 231:10 239:8	148:22 199:15	instance 149:21 182:16	284:1 288:17 300:7
239:15,18 340:9	inferior 193:8	institute 64:9	312:2 329:20,20
inclusion/exclusion	influence 93:13,22	instituted 64:6	331:16 337:20 338:12
240:1,3	178:8 243:10	institution 64:5,7 68:22	339:9,13,15
inclusive 135:19	influencing 93:11	78:20,21 80:21 81:6	intention 198:9
incomplete 234:17	inform 255:15	81:11,14,15,20 87:16	intentionally 73:2
308:18	informal 210:6	156:20 157:10,15	intently 129:14
inconvenience 273:17	informally 173:9	190:19 201:16 210:20	inter-op 306:10
incorporated 140:12	informaticist 246:3	295:11 299:11 334:12	inter-rater 132:7 143:11
175:4	247:13	334:13	interest 182:7,10
incorporating 140:14	informaticists 247:20	institutional 83:4	330:11
incorrect 238:20	information 18:9 30:10	306:17	interested 14:2 65:18
increase 182:16 194:13	30:16 54:5 59:13 64:2	institutions 63:17 79:1	175:12 230:3 310:12
214:15	108:6,12 112:16	79:19,20 80:2,3,8,10	323:21 335:9 343:11
increased 246:12,15	113:18 117:21 118:5	80:16 132:6 163:16	interesting 45:5 66:8
increases 60:2 270:6	127:11,17 154:22	194:18 291:3	82:22 83:16 99:22
increasing 258:9	155:6 156:19 157:2	instructed 293:8	202:12
Incredibly 7:3	158:16,22 164:16	insufficiency 263:12	interfaces 261:5
increments 299:20	169:22 170:6 182:1	insufficient 19:7 20:4	interfere 327:17
independent 268:12,17	207:3 209:8 234:22	26:10 27:5,11 28:21	intermediate 305:10
268:19 270:22	310:11 311:16 342:18	29:5,18 30:2,10,16	internal 4:3 12:2,5 13:3
independently 272:17	343:2 351:10	48:7,13 56:21 57:5	13:5 15:17 17:11 19:1
index 261:14	informational 84:14	62:13,19 66:18 67:2	24:4 132:6 189:10
indicate 39:5,9 243:19	infrastructure 332:5	89:3,12 91:1,6 92:3,9	284:21 285:18 301:2
indicated 13:4 60:18	infusion 270:10	97:7,13 98:8,13	internally 75:5 163:11
163:5 191:13 227:9	inherent 132:11	101:15 102:1 108:6	332:6
266:4 333:1	initial 5:11 99:18	108:11 111:22 112:5	internists 50:17
indicates 40:4 145:14	298:22 300:4	113:9,15 115:18	interoperatively 320:4
151:5 300:16	initially 23:20 174:5	116:3,14 117:9,15,21	interpret 204:19
indicating 231:12,13	225:17 249:6 277:13	118:4 123:5,11 124:1	interpretation 304:19
		124:6,21 125:4,19	340:10

interpreting 114:11
interval 71:22 264:12
intervals 163:17 281:18
intervening 318:7
intervention 241:14
 250:14 281:16
interventions 277:3
 279:7,9
intra-institutional
 277:16
intra-op 331:9,20
intraoperative 330:10
intraoperatively 331:1
introduce 8:17 214:2
 245:19 247:12 300:6
investigate 300:13
investigated 130:18
 133:16 160:1
investigational 301:3
invited 54:14
involve 133:9
involved 85:3 102:22
 174:19,19 185:14
 191:22
involvement 207:14
involves 109:11 121:6
 133:3 174:11 192:7
 208:5
involving 72:10 110:14
iowa 317:5
iPhone 6:4
iron 256:16 262:2,9
 270:2,3,5,7,11,13,14
 275:3,22 276:7
 286:16
irrespective 325:3
irrigation 189:17,19
ischemia 307:1,5,13
 333:2
ischemic 11:14
isolated 71:2,3,4 72:6,7
 80:19 96:2 109:14
 142:13 151:3,15,18
isolation 95:12 96:13
issue 40:11 60:1 106:13
 125:14 178:5 191:5
 191:10 196:20 198:1
 217:7 240:3 242:6
 258:17 276:8 282:6,7
 291:16 298:2 325:13
 330:4 339:15 345:21
issues 7:5,10,12,13
 54:15 64:11 91:19
 93:6 189:4 191:4
 194:13 217:16 238:11
 245:13 253:17 259:15
 261:9 273:19
it'd 330:19

item 305:6
items 93:10 110:4
 114:8 197:2 303:22
iteration 55:3

J

Jaimo 3:9 171:3
JAMA 146:5
January 145:19
Jason 3:4 207:4 214:4
 225:7 242:1 244:13
 335:15 336:6,15
 349:18
JD 1:13
Jehovah's 307:7
job 7:11,18 25:1 106:19
 106:20 213:20 316:5
John 1:21 14:19,21
 26:16 30:3 109:4
 110:17
JohnMarc 246:4
JOHNSON 3:5 154:19
 155:12 164:14
joined 6:7
joint 3:12,13,18 4:20
 5:4,9,12,15 135:11
 175:5,10 177:10
 199:15 227:11 229:15
 230:1 238:6 243:1
 244:17 246:1,3,9
 247:14 256:2 265:11
 265:22,22 298:20
 314:19 320:14,19
 323:21 330:8 335:6,8
 340:4 346:7
joints 46:15
joke 221:14
Jonathan 3:17 246:6
journal 54:13 270:4
judged 332:16
judgment 309:5,15
 332:19
Julia 3:11 129:12
July 72:9,9 109:16
 121:7
jump 238:10 255:14
 324:4
jumped 126:19
June 72:9 109:16 121:7
justice 179:21
justification 329:16
justify 284:17

K

Karen 3:5 164:13
Karl 1:15 73:12,13 91:7
 101:10 146:11 205:7
 206:11 350:21 352:2

KATHRYN 3:7
Kathy 3:13 245:22
 247:12
Katie 20:16
keep 43:22 48:15 87:11
 188:3 194:22 212:10
 221:5 332:9
keeping 301:14
Keith 2:10 179:8
Kelsey 2:7 33:16 36:1
 37:20 38:21 55:17
 56:5 57:21 62:20
kept 136:21
Kettering 2:19
key 258:3 261:7 284:9
kibosh 218:8
kick 11:4
kind 27:21 39:19 46:1,2
 141:16 161:7 168:11
 207:11 210:5 211:22
 212:1 224:9,15
 234:12 253:19 257:12
 258:1 265:5 272:5
 286:18 301:18 310:19
 312:4 317:12 318:15
 339:3
kinds 133:1
knee 172:3,6,18 251:8
 296:2 297:18
know 8:3 9:16 17:13,21
 20:11 21:9 23:12 25:8
 27:15 33:7 36:12,21
 49:18 59:5 61:19
 64:20 83:8 93:1
 100:15 103:19 104:14
 112:21 120:17 128:22
 130:22 133:22 134:8
 144:6,14 146:19
 149:13,17 153:10
 168:16 174:1 177:7
 178:15,18 181:14
 200:10 201:22 206:2
 209:8 211:6,7,8
 213:11 214:19 217:11
 222:8 234:13 249:20
 253:18 257:7 259:5
 259:19 261:14,18
 263:1,8 268:4,21
 270:2 272:15,19,20
 275:19 278:12 279:16
 280:1 281:1,1,21
 282:5 283:19 284:6
 286:7 290:12 291:15
 291:20 293:9 296:10
 304:9 308:10 309:4
 313:17,20 314:9
 319:22 320:3 321:11
 321:20 324:15 327:17

 328:17 329:12 330:14
 330:21 331:6 333:4
 333:19,20 335:2
 339:3,11 341:8
 346:14 347:5 348:3
knowing 307:21
known 51:16 54:20
 187:1
knows 68:11 87:18
 161:7
Ko 2:1 20:9 41:6 129:16
 177:15,15,16,21
 178:2 179:2,6,9
 181:10 182:20 185:5
 185:6 189:3 195:20
 195:22 196:15 208:9
 211:1,2 213:11
 266:19,22 267:4,9,12

L

lab 95:18 96:7 199:19
 259:21 262:8 263:2
labeled 253:21
lack 225:3 249:9 261:3
LAD 12:14 13:4,14
 17:12
lagging 272:4
language 66:6
laparoscopically-ass...
 297:22
large 40:16 41:4 54:8
 248:14 276:1 286:13
 286:14 287:16 293:17
 294:3 334:16
largely 133:14 141:22
 190:16 215:1
larger 40:2 163:10
 176:9
Larissa 2:18 223:13
 238:9 253:8 274:21
 275:16 344:20
Larissa's 254:6
Larry 8:19 14:18 16:5
 28:12 45:13,13 87:10
 165:20 166:15
Lastly 307:7
late 291:9,9
laudable 272:16,17
 284:8 329:5
Laughter 69:14 79:6
 84:11 107:7 120:14
 120:20 146:10 177:18
LAVH 297:20
LAWRENCE 2:8
lay 187:18
layperson 34:22
lead 112:18 249:4
 337:19 338:12

leader 11:2
leading 231:5 351:19
leads 247:21 306:22
leaning 208:6
learn 152:13 175:9
 199:2 215:8
leave 87:12 96:6 136:10
 351:15
leaves 152:9
leaving 96:21
led 214:14 274:15
Lee 1:9,11 100:7 143:21
 201:10 250:21 347:13
left 12:18 13:1,9,10
 15:17 17:11 120:13
legacy 216:18
length 203:14 246:15
 264:13
lengthier 254:17
lens 225:20
lessened 33:7
lesser 106:3
let's 20:3 26:4 28:17
 63:7 88:20 90:19
 91:21 98:4 108:15
 111:17 146:19 173:14
 175:1 204:9 226:21
 251:2,17 283:14
 308:4,4,5
level 5:4 32:10,11 42:14
 75:3,4,9 76:9,10,11
 77:5,21 82:17,22 84:3
 84:5 96:19 118:12
 143:5 151:3 161:2,5,6
 173:8 181:18 210:21
 270:6 274:11 279:21
 299:7 302:20 304:6
 311:5 326:16 329:17
 330:18,19,20 331:2,5
 332:17
levels 53:21 256:16
 274:15,18 279:10
 300:4 302:9 321:21
leverage 230:5
LEVY 2:4 24:16 25:13
 37:21 43:4,12,16 76:2
 78:4 95:5 241:3 243:8
 258:16 277:19 278:4
 279:13 293:13 297:20
LFT 262:9
liberal 300:10 307:1
license 103:13
life 172:12,15
life-saving 246:13
light 172:22 232:10
likelihood 181:6
LIMA 13:14
limit 250:15

limitations 227:11
limited 159:21 220:15
 222:22 225:15 296:12
limiting 7:19
limits 264:18
line 6:20 81:7 280:18
linear 133:4
lines 6:19
linked 212:1 348:18
links 184:5
lips 329:8
Lisa 101:5 242:1
list 21:20 37:9 68:2
 112:16 113:22 252:4
 290:16 296:6,7 297:1
 297:4,17 304:8
listed 15:5,13,14
 198:10 255:21 297:9
 337:16
listening 324:22
listing 39:18
literature 46:7,8 137:7
 139:3 145:11,14
 181:1 184:9 187:9,14
 187:15 191:1 250:22
 256:17 264:1 296:10
 296:11,13,21,22
 317:2
little 11:9 15:1,13 16:4
 21:7 22:21 31:13
 32:22 33:11 38:8
 45:19 54:11 63:21
 75:18 94:7 96:19
 100:21 112:15 124:13
 141:6 148:20 154:20
 171:17 174:15 189:13
 200:12,15 207:18
 210:6,12 241:3
 262:13,18 293:3
 314:2 326:18 336:1
 345:8
live 96:15 221:6
lived 95:12
Liz 128:22 234:3 302:17
 328:3
local 333:14
locally 302:12
location 80:19
logic 221:9 222:2
logistic 114:7
long 7:8 13:13 39:19
 131:1 183:14 199:20
 214:17,19 250:15
long-standing 9:15
long-term 13:8
longer 32:2 145:1,1
 183:10 207:1 225:15
 240:21 264:15

longest 290:21
look 21:19 24:20 25:19
 37:22 38:1 60:1,22
 63:19 81:13 88:8,9
 97:16 99:17 100:12
 112:18 119:11 140:5
 146:20 165:8 176:8,9
 176:21 191:7 192:14
 195:13 215:20 223:19
 227:17 228:2 232:2
 240:18,22 241:5,6,8
 241:10,11 243:22
 247:6 255:8 256:14
 272:3 275:19 279:11
 279:17 282:14 284:12
 285:3 302:19 305:4
 309:13 313:16 322:18
 327:8,12 328:18
 331:15 336:2 339:19
 344:17 345:20
looked 48:19 86:17
 93:16 100:2 104:17
 110:1 116:7 144:8,12
 146:18,19 223:15
 230:19 294:16 302:22
 314:17 317:2 333:15
looking 8:11 17:19
 40:13 47:3 53:10 54:7
 54:9 55:5 58:7 64:18
 88:16 89:5 101:17
 110:12 113:11 114:9
 116:5 126:12 135:22
 136:2 142:19,22
 147:2 175:12 186:11
 202:7 211:10 215:22
 220:15 221:5 222:22
 224:2 225:19 232:8
 232:11 234:16 249:8
 249:17 259:22 268:10
 269:17 271:3,16,18
 277:15 278:6,21
 279:3 281:10 284:10
 299:18 310:1 314:13
 324:18,19 326:4
 332:10 339:10 340:16
 342:5 346:15
looks 113:20 142:6
 163:5 255:10 257:5
 343:15
loop 79:12
lose 21:1
losing 23:4 334:18
loss 37:17 269:18 287:9
 292:7 297:21 321:15
lot 7:5 24:2 25:14 30:18
 36:18 63:21 71:19
 73:15 113:19 140:14
 140:21 148:15,20

155:17,18 168:6
 171:19 175:9 193:9
 193:18 198:4 199:8
 225:8 231:7 244:16
 257:8,9 259:10
 261:19 263:21 271:12
 273:5,6,9 287:9 290:6
 302:22 305:14 310:8
 310:11 313:4 317:10
 317:12,15 318:7
lots 8:3 24:5 144:2
Louis 129:9
love 46:17 112:19,22
 230:8 347:14
low 15:14 16:19 19:7,13
 20:3 21:4 26:10 27:4
 27:10 28:20 29:4,17
 30:1,9,15 48:6,12
 53:21 56:20 57:4
 62:12,18 64:22 66:17
 67:1 78:10,11 89:2,12
 91:1,6 92:2,8 97:6,12
 98:8,12 101:14,22
 108:5,11 111:21
 112:5,9 113:8,15
 115:17 116:2,13,19
 117:8,14,20 118:4
 123:4,10,14,22 124:6
 124:20 125:4,18
 126:1,9,17,22 127:6
 127:10,16 138:1,10
 138:15 139:16,21
 154:11,15 156:2,8
 158:15,21 162:4,9
 164:4,10 167:8,13
 169:6,12,21 170:5
 173:16 185:20 188:15
 188:21 196:5,11
 199:17 212:19 213:1
 215:2 254:21 258:7
 267:17,21 269:11
 285:6 288:7,11
 289:15 298:10,12,15
 312:14,19 319:7,13
 323:9,16 342:2,12,17
 343:1 349:7,9,14
low-frequency 47:18
low-oxygen 199:11
lower 32:19 47:6 53:20
 111:12 122:17 172:3
 261:16 275:6 300:8
lower-star 47:2
lowest 15:21 187:21
lump 166:2
lumped 146:14
lunch 215:17
lung 40:10,10
Lynn 2:13 33:15 35:16

38:21 48:15 55:21
301:5 313:9 323:4,4

M

MA 3:4
macro 313:13
macrocytic 256:15
Magee 3:17
magic 351:2
main 133:3 171:11
258:1
maintain 45:21 55:15
59:21 266:15
maintained 42:13
221:12
maintaining 38:4,4
maintains 33:9
maintenance 15:3
21:12 23:6 106:11,14
107:3 130:2 159:13
159:17
major 22:11 65:20 71:2
71:8,10 79:18 86:19
93:6 104:22 110:3,11
131:5 149:11,12,15
149:18 150:19 151:5
151:12 152:4 252:7
263:18 268:18 273:3
273:10 290:17 291:4
291:12,16 303:14
326:3
majority 187:17 262:12
269:6
making 37:2 69:10
156:18 157:2 172:6
192:19 230:14 307:18
318:21 336:2
mammary 4:3 12:2,5
13:1,3,5 15:17 17:11
19:1 22:21
manage 286:11
managed 282:8
management 2:21
246:10 247:3 265:20
266:2 284:3 329:11
331:17 344:1
manager 2:7,9 3:6,7
64:5
mandate 100:3 104:3
mandated 28:8
mangled 204:22
manner 94:2 249:12
manufacturer 64:13
manufacturers 65:17
mapping 216:17
Marcia 3:3 41:21 86:22
351:20
Mark 129:16

MARKMAN 2:6 88:12
237:1 290:10 293:6
313:11 334:20 335:1
346:3,13 347:2
Markov 71:20
Massachusetts 2:8
massive 303:16 320:4
match 264:14 288:20
290:14 293:16 294:3
matched 106:1 292:4
matches 305:12 337:20
338:12 339:12
material 143:17
materials 213:19
matter 37:15 62:6
128:17 244:22 312:6
344:9 352:6
max 51:18
maxillofacial 297:5
maximum 118:10 294:8
MBA 1:17 2:7,13 3:3,12
3:14,18
MBOS 295:22
McCARTY 2:7 34:4,17
34:20,22 35:5,10,13
39:1,13 49:17 50:7,13
50:22 51:3,21 55:19
56:6 57:22 62:21 63:9
70:1
MD 1:11,13,15,17,18,19
1:21 2:1,4,6,8,15,15
2:17,18,20 3:2,9,10
3:11,14,15,16,16,17
mean 21:8 24:18 25:10
27:21 40:20 50:8,15
50:21 51:3 60:10 83:2
83:15,15 88:13 93:8
110:19 183:12 186:5
198:17 205:9 209:21
216:6 221:15 222:4
224:10 228:10 234:15
237:2 239:2 243:22
244:9 256:12 257:14
282:22 283:16 293:7
309:6 312:8 313:16
318:17 325:22 335:2
338:22 346:13,14,14
346:16 347:17
meaning 33:8 272:18
282:21 284:13 329:17
meaningful 18:7 74:20
92:12 140:7 186:18
198:2 212:13
meaningless 285:8
means 44:5 61:3 143:9
172:3,5 174:20 183:4
201:17 219:16 234:14
257:8,9 323:19

meant 44:1
measurable 186:17
measure 2:12 4:8,12,14
7:15,22 11:9 12:1,3
15:2,3 16:10,15,22
17:15 18:4 19:1,5,21
19:22 20:5,20,22 21:3
21:6,17 23:3,15,19
24:2,22 25:5,18 26:8
27:3,9,18 28:3,19
29:3,16,22 30:8,14
31:4,8 32:18 33:2
34:6,7 35:22 36:7,13
37:7,16,17,18 38:2
39:4,18 40:13,22 41:4
42:9,12,13,18,22 44:3
46:6,20 48:4,5,11,18
48:20 49:19 50:12
52:14 53:8,12 54:6
55:16 56:8,18,19
57:17 59:2,22 62:11
62:17 66:16,22 70:6
70:12,16,20,22 71:1
72:15,21 74:8,13 75:3
75:13,14 77:6,7 78:17
79:21 81:3,3 84:16
85:8,9,16,19,22 86:2
86:14 89:1,10 90:21
91:4 92:1,7 93:15,21
94:3,8,15 97:5,11
98:6 99:7 101:13,20
102:10,20 103:1
104:16,18 107:1,10
108:4,9,18,22 109:5
109:11 110:10,16
111:1,3,7,12,20 112:3
112:7,14 113:1,7,13
115:16 116:1,12,17
117:3,7,12,19 118:2
119:8 120:1,6,9 121:5
121:12,20 122:1,2,3,7
122:11 123:3,8,14,21
124:4,14,19 125:2,6
125:17 126:8,15,21
127:4,9,14,22 128:9
129:2,4,18 130:3,4,8
130:11,14 132:11,15
132:20 133:2,21
134:19,20 135:8,10
135:19 137:17,22
138:1,8,14 139:4,6,15
139:20 146:7,16
152:16 153:16 154:10
154:14 156:1,7
158:14,20 159:3,8,11
159:13,13,16,17
160:22 161:3,20
162:2,8 164:3,9,20

165:19 166:3,4,10
167:7,11,21 169:5,11
169:20 170:4,10,15
170:20,21 171:6,16
171:18 174:6,9 175:6
177:22 178:2,6,7
180:8 184:19 185:1
187:3 188:14,20
189:6,14 195:4 196:4
196:9,16 197:1 198:4
198:11 202:14 206:17
207:13 209:1,4,12,18
210:7 212:18,22
213:4 214:22 215:9
215:10 216:10,10,13
216:13,14,19,19
217:9 218:1,5 219:3,4
219:6,11,11,16,17,20
219:22 220:3,5,7,17
220:20 221:3,10
222:1,1,6,8 223:2,6,8
223:9 224:3,9 225:17
225:18,21 226:2,4,8
226:11,21 227:15
228:14 231:1,5,10,14
231:15,21 232:6,9,17
235:1,2,3,9,10,11,14
235:18 236:3 237:20
238:6 240:7,14,20
241:1,13,18 242:9,10
245:8,9,11 248:6
249:7 251:1,5,16
253:2 254:2 255:1,8
255:10,20 256:9,11
259:16 265:6 267:15
267:19 269:13 272:1
274:10,11,12 275:1,4
276:16,18 277:21
278:10,13 280:22
284:2,9,15 285:4,22
286:9 287:15 288:5,9
288:14,18 289:17
290:21 291:19 292:2
292:20,21 293:5,15
293:21 294:16 295:5
295:6 298:8,14 299:2
299:9,14 300:2,22
302:10,15 303:3
305:6,19 306:9 308:6
310:2,3,7 311:14
312:1,12,17 313:8,17
314:4 315:2,11 316:4
317:17 319:6,12
322:3 323:2,8,14,15
323:20 324:21 325:9
328:9,19 329:13,20
331:11,13,18 332:22
333:6 334:3,3 336:10

336:15,16,18 337:11
 337:16,19 338:3,11
 338:13,17 339:2,9,16
 340:5,8 342:1,10,16
 342:22 343:5,13,15
 345:1,15 346:10,14
 346:17,21 347:16
 348:18 349:3,12,15
 349:18
measure's 232:9
 294:12
measured 184:7 210:10
 305:13 318:14
measurement 2:9,13
 3:3,4 9:19 130:11
 159:19 165:1,2 171:6
 215:14 216:16 225:1
 231:12 300:22 311:8
measures 4:3,19 5:1
 7:17 8:18 9:14,17
 10:11,22,22 11:1
 16:14 22:6,12 23:11
 24:7 27:14,17 30:18
 30:19 33:4,6 38:2
 41:12 42:6 43:6 44:9
 45:4 53:20 54:1 65:4
 65:7 71:9,16 72:11
 75:1,7 77:11 84:18
 85:4,13 87:5 91:12
 92:14 93:9 105:1
 107:2 112:21 118:7
 119:17 125:7 126:5
 130:2 131:2 133:11
 133:21 148:7 158:4
 172:9 203:18 204:11
 208:18 210:18 214:8
 214:15 216:3 217:7,8
 218:14 220:12 222:11
 223:15,18,19 224:12
 226:6 227:8,12 229:8
 229:22 230:1,3,8,18
 230:21 238:12 241:9
 241:11 245:5 246:10
 247:1,9,10,18,22
 248:3 250:11 265:15
 266:9,11,13 267:4
 282:4,9 284:22 302:1
 311:3 315:9 321:12
 332:17 335:18 350:10
 350:19
measures' 119:6
measuring 74:1 186:8
 289:7 327:15 332:19
mecca 188:1
mediastinal 12:9
Medicaid 2:6
medical 1:18 2:6,11,22
 3:17 11:12 62:1 141:8

187:22 189:18 316:21
 317:4
Medicare 133:14
medication 58:9 59:18
medicine 1:16,20 2:3,4
 50:10 51:15,20 59:16
 61:16
medicines 37:10
meet 139:11 237:4
 254:7 298:18 300:20
 333:13 341:8
meeting 8:11,12 42:5
 135:22 171:14
meets 131:21 200:20
Melinda 3:5 72:18
 74:21 101:5 118:6
 214:6 242:2 320:11
 335:5 339:20 351:18
member 4:21 5:18 6:7
 6:12 14:19,22 15:12
 16:6 17:19 19:9 20:9
 21:5 22:2,14 23:7,9
 23:17 24:9,16 25:13
 25:17 26:2,17 27:20
 28:6,13 29:7 30:4,17
 33:18,21 34:2,4,17,20
 34:22 35:5,10,13,17
 36:9 37:21 39:1,13
 41:6 43:4,12,16,20
 45:15 46:4 48:16,19
 49:1,11,13,17 50:7,13
 50:22 51:3,21 52:9,18
 55:19 56:6 57:9,22
 58:1,17 60:4,15 62:7
 62:21 63:9,11,14 65:1
 67:4 68:18 69:11,16
 70:1 73:14 74:15
 75:15 76:2 77:18 78:4
 78:7,10,13,16 79:7
 80:1,12 81:19 82:5,9
 82:15 83:2,11 84:10
 87:13 88:12 89:14,18
 89:20 90:1,4 91:9
 92:10 93:18 94:22
 95:5,9 97:14 98:14,21
 99:16 100:7,19,20
 102:2,9,19 104:7,11
 106:21 107:5 109:8
 110:18 111:10 112:6
 112:13 113:17 114:9
 114:20 115:4,8 116:4
 116:20 117:2,16
 119:16 121:19 122:2
 122:14 123:12 124:7
 124:13,17 125:5
 126:4,18 135:6
 136:14,16 137:7,16
 138:19 140:2 141:5

142:17 143:13,19
 146:12 148:5 150:17
 152:1,7,18,21 153:7
 153:14 155:16 156:12
 157:4,13,18 158:3
 160:8,12 161:14,19
 162:13 163:15,20
 164:18 165:21 166:15
 166:18 167:16,19
 169:1,15 178:15
 179:5,12 181:13
 182:3,19 183:3,17,22
 184:9,14 185:11
 186:20 187:5 193:7
 194:10 198:8 200:6
 201:9 203:5 205:9,22
 206:3,12 207:10
 208:16 210:3 213:16
 223:14 224:4,7,8
 228:22 230:11 232:4
 234:5 237:1,15
 238:10 239:7,12
 240:13,19 241:3
 243:8 249:4,5 250:6,9
 252:22 253:6,9
 254:19 255:14,17
 256:4,5,6,21 257:7,11
 258:14,16 259:18
 261:12 266:19,22
 267:4,9,12 272:13
 273:1 274:22 275:18
 277:6,19 278:4
 279:13 282:3,20
 283:16 284:7,20
 287:3,13 289:13
 290:10 292:19 293:6
 293:13 295:9,16
 296:1,5 297:8,14,17
 297:20 300:2 301:7
 301:22 302:18 303:8
 303:12 305:18 307:12
 307:16 308:8 309:22
 313:3,11 314:2 316:3
 316:8,11 318:12
 319:19 320:1,6 321:7
 322:4,7,16 325:9,22
 326:11,15 327:19
 328:4,11 332:3,14
 333:9 334:20 335:1
 341:2,19 344:22
 346:3,12,13 347:2,17
 347:22 351:22 352:2
 352:4
members 9:7 24:2
 42:18 180:18 181:18
 181:19,22 182:6
 186:14 192:8 194:21
 205:22 252:21 350:21

351:4,9,12
membership 44:2
Memorial 2:18
mention 42:3 72:19
 73:3 92:21 264:19
 265:15 281:3
mentioned 22:17 56:6
 59:4 74:2 75:20 90:5
 91:13 110:5 119:7,19
 132:5,12 133:16
 149:21 150:4 155:3
 164:16 197:9 209:16
 264:10 267:1 309:15
 329:15 345:17
mentioning 256:1
mentions 265:13
merit 206:5
message 14:14 38:11
 42:7,19 213:5
met 1:8 209:19 210:1
metal 200:22
methods 344:3,5
metric 27:22 163:11
 168:19,22,22 221:11
 235:3,4 236:4 300:12
 300:15 310:22 337:20
 338:12
metrics 24:19 75:17
 100:8 112:19 171:13
MHA 3:13
MHSA 3:15
MI 154:4 157:15 306:15
Michelle 3:12 246:2
 247:13
microbial 199:16
microliters 327:16
microphone 185:17
mid-20s 173:21
middle 113:17
migrated 186:13
miles 273:7
million 9:9 186:5
 268:11
millions 186:4
mind 63:20 154:20
 221:5 223:11 265:19
 291:1
minds 205:4
mine 206:14
minimize 281:12
minimum 78:9
Minnesota 2:12 208:18
minor 107:11 149:15,18
 150:19 151:2
minority 36:12
minus 109:18 226:9
 297:4
minute 33:8 50:1

184:13 328:14 336:15
minutes 109:3 120:10
 120:13 128:5,6 129:5
 171:1 215:13 244:21
 304:22
misidentifying 309:10
misjudged 128:3
missed 57:8 106:21
 143:22 184:1 200:3
 325:7
missing 47:21 51:8
 71:22 92:15,16,17,19
 110:6 121:10 198:1
 241:20 270:18
mission 81:8 202:11
Missoula 95:14
mitigate 176:22
mitigating 269:20
mitral 4:9 71:4 109:12
 109:14,17,21 112:9
 121:4
MITRE 221:12
mix 4:12 100:18 129:3
 277:12
mixes 277:9
mobility 141:17
model 69:6 82:11 93:2
 114:7 140:20 147:7
 154:3 165:5,7,14
 205:12,15 227:1,5
 228:6 285:21
model- 9:14
modeling 82:11 139:2
 154:4 197:5,5
models 71:20 105:5,9
 134:17 140:22 147:9
 147:13,21 154:1,5
 197:22
moderate 19:6 26:9
 27:4,10 28:20 29:4,17
 30:1,9,15 48:6,12
 56:20 57:3 62:12,18
 66:17 67:1 89:2,11
 90:22 91:5 92:2,8
 97:6,12 98:7,12
 101:14,21 108:5,10
 111:21 112:4 113:8
 113:14 115:17 116:2
 116:13,18 117:8,13
 117:20 118:3,10,12
 118:14,17 123:4,9,22
 124:5,20 125:3,18
 126:1,9,16,22 127:5
 127:10,16 138:9,15
 139:9,16,21 154:10
 154:15 156:2,8
 158:15,21 162:3,9
 164:4,10 167:7,12

169:6,12,21 170:5
 188:15,21 196:5,11
 212:18 213:1 267:16
 267:20 288:6,10
 298:9,11,15 300:6
 312:13,19 319:7,13
 323:9,16 342:2,11,17
 343:1 349:6,8,13
moderate/low 24:17
modification 195:11,16
 321:2
modifications 311:9
 336:3
modifier 191:21 195:10
modify 195:4
moment 119:13 235:11
 262:5 350:4
monitor 45:21 50:3
 140:4,4 266:8 300:3
 329:3 332:5
monitoring 300:7 313:8
month 110:13 115:11
 258:22 279:12 285:5
 344:13
months 58:15 59:7 86:4
 112:20 172:14 258:22
morbidity 150:8
 152:19
morbidity 54:21 71:8
 72:2 76:6 90:8 94:6
 95:21 97:16,18 110:3
 110:4,8,9,11 112:15
 113:2 121:11,14,15
 122:15 123:16 147:19
 159:20 166:7
morning 6:4,7 8:9 11:5
 58:19 59:8 171:2
mortalities 130:7
mortality 10:10 32:1
 71:7,16 72:1 73:16,21
 76:6 90:7 93:7 94:6
 95:21 97:17 110:2,7,9
 110:10 111:11 112:8
 112:15 113:2 121:11
 121:14,16 122:15
 123:14,16 130:5
 144:1 186:9,10
 284:10,11
Moss 2:8 14:19 16:6
 28:13 87:13 165:21
 166:18 189:7 190:6
 194:9,10 333:9
motion 272:11 274:8
move 25:16 47:16 63:7
 75:19 159:10 160:9
 193:3 198:21 203:20
 210:7 214:21 312:21
moved 23:13 226:13

230:21 295:21
moving 36:14 38:3
 53:14 86:13 87:11
 91:9 92:10 98:14
 118:12 137:13 154:17
 156:10 162:11 167:14
 196:13 216:8,21
 251:7 298:21
MOYER 2:9 17:19
 102:19 104:7 153:14
 167:19 169:1 203:5
 210:3 213:16 232:4
 249:5 255:14,17
 256:5 314:2 322:16
MPA 3:4
MPH 1:18 2:15 3:2,2
MSBOS 294:8 295:11
 295:19 296:7,14
 297:1
MSHS 2:1
MSN 3:12
multi- 151:12
multi-numerator
 191:16
multi-procedural/mul...
 70:21
multi-system 151:5
 152:4
multifold 172:10
multiple 65:15 85:13
 91:15 153:17 174:20
 191:17 214:5 285:19
MUNTHALI 3:2 19:19
 20:15 21:11 22:3 23:2
 107:8 207:1 209:12
 233:7,12,16 240:7
 320:17
MURPHY 3:5 16:12
 20:18 75:1 119:10
 125:10 336:14,22
 337:4,12 339:21
music 7:7
muzzled 280:20
MVRR 4:10 71:5,6 72:7
 72:7

N

N 4:1
N.W 1:9
NACOR 43:6
name 9:2 171:2 214:4
 245:22 247:12
naming 221:19
narrow 225:20
narrowing 315:5
national 1:1,8,14 102:5
 131:20,22 171:16
 173:10 174:6 192:19

192:22 204:7 216:20
 217:20 219:14
nationalize 182:14
nationally 36:13 45:8
 64:21 131:19
Nationwide 2:8
natural 21:6 66:6
nature 332:16 337:22
 339:1
nearby 95:18
necessarily 59:15
 61:16 191:2 193:11
 210:10 221:6 304:1
 316:6
necessary 95:1 192:15
 218:4 226:2
necessitating 45:18
need 7:6 20:2 21:16
 28:3 37:21 38:7 41:18
 41:22 46:1 87:11
 89:14 100:14 102:21
 122:4 134:11 137:14
 139:7 155:13 160:8
 163:4 167:2,2 172:18
 178:18 183:13 210:8
 211:6,16 222:15
 241:15,17 242:12
 243:17 244:9 246:18
 251:2,13 254:10,20
 254:21 277:20 278:9
 278:11 281:7 282:14
 286:11 292:11 293:1
 293:17,19 294:4,5
 296:3,19 311:11
 327:1 347:5 348:4
needed 218:10 226:3
 236:5 265:5 294:15
 344:12
needing 265:4
needle 36:15 38:3,4
 198:22
Needless 65:16
needs 20:1 87:17
 163:13 165:13 184:1
 247:5 286:5 289:6
 303:4
negative 105:15 200:4
 202:8
negatively 16:9
neither 235:20
Nephew 207:19,21
 208:2
Neupogen 253:21
never 47:17,21 51:18
 60:8 202:12 221:14
 290:7
new 6:7 7:21 9:7 14:3,7
 14:9 21:21,21 54:5

55:19 57:22 59:12	218:15 219:9,12	163:16	160:10,11 163:20
60:3 62:21 65:7	220:4,11 229:2,20	OB 286:14	178:2 179:9 192:4
105:21 110:22 116:20	234:13 236:13 243:14	OB/Gyn 315:20	200:11 208:13 213:4
117:3 122:1,2,3 135:9	284:22 297:12	objective 20:10 72:13	214:2 232:20 242:22
136:9 137:10 144:2	NQF's 148:7	77:3 339:8	244:20 249:3 267:13
153:9 170:21 177:22	NQF- 71:15 74:2	objectively 211:2	274:22 280:7,19
178:6 180:7 216:10	NQF-endorsed 33:4	obligation 174:12	283:12 287:5 289:13
217:8 218:1,13	NSQIP 130:20 137:18	Obremskey 171:10	289:17 290:18 291:20
229:21 245:6 265:21	138:22 140:4,7,12,13	203:15	297:14 298:17 300:1
271:17 276:14,14	140:15 141:7 147:13	obscure 286:5	300:2 311:19 312:21
296:14 318:2 350:20	156:19 162:18 165:2	observed 153:16	313:1,3 314:11
351:4,12	166:12,16,19 168:20	obstetric 286:2	318:10 319:17 320:1
newcomer 206:19	310:4	Obstetricians 2:5	320:6 321:7 322:5
nice 73:17	number 11:15 18:12	obtained 134:22	334:17 341:17,21
nicely 104:15 193:17	20:21 26:3 44:13,15	obtaining 227:4 253:4	343:4 344:20 348:10
328:21	45:7 46:5 60:2 61:4	obvious 74:16 218:2	348:22
nine 283:11,11 300:19	68:7,11 79:17 100:10	322:12	old 176:3 252:8
315:19 327:11	124:13 153:16 163:3	obviously 129:16 133:7	older 12:4 130:12
nitty- 175:15	163:5 186:3 189:16	133:13 136:19 163:2	133:13 175:21
non 67:16	189:18,20 199:10,14	201:16 216:10 218:10	Olsen 2:10 177:15
non- 197:7 236:20	199:17 203:18 214:6	275:10 277:8 321:12	179:8,9 190:18 196:1
268:9	214:15 219:13 222:21	occasional 289:9	once 60:16 87:4 99:14
non-adjusted 197:1	223:1 248:11 258:2	occlusion 71:14	103:22 154:6 159:22
non-cardiac 34:10	262:5 265:22 266:14	occult 265:2	220:1 223:4 226:12
non-completion 289:9	271:3 277:1 278:19	occur 47:18 54:20	228:14 243:21 299:1
non-compliance 46:22	279:11,15,18 283:20	142:3 254:10,18	330:1 350:16
non-endorsement	284:9,12 285:14	277:5 300:8 320:15	oncologic 253:13
38:19	286:1,13 289:2 291:7	occurred 54:16 152:14	275:21 281:12 285:10
non-facetious 256:8	298:9,9,10,11,11,12	153:6	oncological 276:3
non-risk 199:5 202:18	302:18 304:18 305:22	occurrence 185:20	one-year 186:9 189:10
non-weight 172:14	314:17 326:20 329:2	occurring 299:4	ones 40:9 65:5 186:4
nonautologous 345:16	333:13 344:14 349:4	occurs 280:6	200:19 230:22 236:11
normal 32:7 253:12	349:5,6,7,7 351:1,5	odds 160:22	301:17 326:3 332:18
328:1	numbers 41:13,18	offer 87:13	ongoing 9:18 54:2 59:1
normally 221:22	81:12 211:13 275:5	office 1:14 258:22	81:4 144:22 316:16
Northwestern 1:16,16	277:7 286:6	259:11	online 17:21
Notably 130:13	numerator 58:2,12	Officer 1:17 3:2	open 6:19,20 19:3,5
notation 228:12	152:8 162:13 175:17	offices 215:5 217:6	27:2 29:15 30:7 31:2
note 40:21 166:8	175:19 189:13 190:3	218:20	36:6 48:4 56:18 62:10
noted 71:18 74:17	193:14 200:8 201:3	oh 18:21 20:13 208:12	66:15 88:22 90:20
84:18 166:5 198:11	238:13,19 239:14	214:6 280:19 282:11	91:22 97:4 98:5
301:11	248:11 256:11 257:5	287:5 306:14	101:12 108:3,16
noteworthy 194:22	257:13 282:22 283:7	okay 6:3 13:22 14:8,21	111:3,19 113:6
notice 303:13	283:19 287:20 289:2	15:10 18:21,22 23:9	115:15 116:11 117:6
noting 53:18	290:3,13 293:4	23:17 26:7,14 31:1,18	117:18 119:22 122:6
November 340:15	299:19 306:5 319:19	33:21 34:20 35:6,16	123:2,20 124:18
343:9	320:7 329:5 343:22	43:12 45:15 47:15	125:16 126:6,7,20
novo 181:7 216:10	345:16	48:14,22 49:10 51:22	127:8,21 138:8
nowadays 133:11	numerator/denomina...	52:6,16 53:3,14 56:2	139:15 154:9 155:5
NQF 3:1 4:21 5:18 8:14	175:16 240:4	56:12 57:9,20 58:17	155:22 158:13 159:2
9:15 12:16 22:13 33:9	numerators 189:16	62:3 70:5,8,18 77:8	162:3 164:2,15 167:6
41:8,19 81:3,8 87:2	numerous 203:14	78:7 89:8,9,13 90:19	169:4,19 170:9
91:12 94:11 100:1	nurse 2:14 247:13	104:9 108:13,14,20	184:19 188:13 189:9
131:2 133:11 135:18	nut 348:20	109:10 111:6 113:12	193:15,19 194:5
166:20 172:9 178:2	nutritional 179:1	117:4 118:6 119:10	196:3 212:17 252:18
182:16 201:17,19		120:8 136:15 139:14	259:2 267:15 280:14
202:10 206:5,15,16	O	141:11 143:19 145:18	280:16,16,18 288:5
208:22 214:5 216:7	O/E 137:20 160:20	148:3 155:13 157:20	298:8 306:12 307:3

307:13 312:12 319:5
323:7 341:22 349:3
350:1
open/closed 178:22
openness 194:1
operate 79:20 81:15
104:13 254:16 278:16
operated 105:18
operating 80:8 81:11
87:16 105:17 166:21
173:15 253:12 254:22
294:19 326:6 327:15
328:16,22 334:7
operation 14:12 109:21
141:19 195:9 273:15
operationalizing
262:19
operations 71:2 105:6
109:14 121:3 194:15
251:11,14,21
operative 71:7 110:2
121:5 193:22 197:11
273:3 330:11
Operator 6:20 7:1
252:15,20 280:13,18
350:2,6
opinion 11:20 184:4
295:19
opportunities 247:2
opportunity 19:22 22:8
25:20 40:2 44:21
45:10,18 55:13 56:11
82:1 166:9 199:4
208:3 230:5 246:8
261:9,20 272:9 285:7
286:20 311:10 315:7
334:14,16 343:22
opposed 45:19 125:12
201:18 202:14 251:18
256:22 324:20,20
opt 321:19
optimal 2:1 135:13
279:21 321:13
optimizable 277:4
279:5
optimization 275:12
277:11 282:5 321:9
optimize 259:7 282:5
optimized 275:21
276:10,13,18,20
277:4
optimizing 255:3 281:3
opting 229:11
option 19:5,6,6,7 27:3,4
27:4,5 28:19,20,20,20
29:16,17,17,18 30:8,9
30:9,10 31:4,4 48:5,5
48:6,6 53:8,8 56:19

56:20,20,21 62:11,12
62:12,12 66:16,17,17
66:18 70:12,12 74:8,9
89:1,2,2,3 90:22,22
90:22 91:1 92:1,2,2,2
97:5,6,6,6 98:7,7,8,8
101:13,14,14,15
108:4,5,5,6,18,18
111:4,4,20,21,21,21
113:7,8,8,8 115:16,17
115:17,17 116:12,12
116:13,13 117:7,8,8,8
117:19,20,20,21
118:14 120:2,2 122:7
122:8 123:3,4,4,4,21
123:22,22,22 124:19
124:20,20,20 125:17
125:17,18,18 126:8,8
126:9,9,21,22,22,22
127:9,10,10,11 128:1
128:1 138:9,9,9,10
139:15,16,16,17
154:10,11,11 156:1,2
156:2,2 158:14,15,15
158:16 159:4,4 162:3
162:3,3,4 164:3,4,4,4
167:7,8,8 168:11
169:5,6,6,6,20,21,21
169:21 170:11,11
180:10 184:20,20
188:14,15,15,15
196:4,5,5,5 212:18,19
212:19 267:16,16,16
267:17 288:6,6,6,7
298:9,9,10,11,11,12
312:13,13,13,14
318:9 319:6,7,7,8
323:8,9,9,10 331:19
342:1,2,2,3,16,17,17
342:18 349:4,5,6,6,7
349:8,8,9
options 189:16 190:3
244:18
oral 250:15 270:2,3,5,7
order 11:9 59:2 114:10
187:3 254:18 266:15
289:19 317:3,5 344:3
ordered 149:2
ordering 294:8 316:14
317:10,14
organization 180:8
194:21 213:18 216:14
organizations 103:10
origin 71:13 148:19
original 94:10 153:3
originally 154:21
ortho 224:9
orthopedic 2:21 3:9

4:16 171:3,5 173:3
175:7 179:12 180:2
181:20 186:21 188:1
192:3,20 200:9,19
204:8,19 208:18
277:10 314:18 315:22
orthopedics 179:15
187:7
orthopods 193:13
OTA 171:10 179:14
180:15 181:18,22
182:6,11 186:12,14
190:9 192:8 195:14
197:10 203:22 204:13
204:14 205:19 210:19
OTA's 171:16
ought 287:7
outcome 4:14 9:14
71:16 76:5,7 83:12
93:12 94:5 118:7
132:11 136:20 144:14
147:2,8,10,11 148:2
148:14 153:2 159:12
159:20 174:8 178:7,9
195:12 196:16 197:1
262:14 269:16 270:20
289:21 292:20 293:14
293:20 305:5,10
332:21
outcomes 1:15 4:12
54:12 74:1 110:21
129:4 130:4,9 140:5,5
144:8,14,18 146:15
148:11 150:9 158:4
159:19 160:13 164:21
165:11 178:21 181:4
184:6 187:6 195:14
195:18 196:16 231:5
268:13
outflow 259:3
outliers 18:12 88:13
131:9 161:4
outlining 7:12
outlying 138:2 145:2
259:14
outpatient 258:20
259:10
output 65:3
outside 35:6 140:11
153:2 172:6 187:18
304:2
outstanding 8:15
outweigh 198:17
ovarian 253:14
over-called 148:21
overall 31:3,7 32:3
47:12 53:7,11 70:11
70:15 97:17 100:17

108:17,21 120:1,5
127:19,22 128:8
154:3,5,6 159:1,3,7
168:1 170:7,10,14
211:11 233:13,15,16
233:21 237:20 245:15
260:22 283:6,6 339:8
339:13
overlap 200:17
overlapping 116:7
200:16
overlaps 39:3
oversee 214:7
oversees 35:8
overstating 340:10
overview 4:18 73:15
129:6 171:1 247:8
overwhelming 262:12
ownership 21:13,14

P

P 113:19
P-R-O-C-E-E-D-I-N-G-S
6:1
p.m 245:1,2 350:14
352:7
Pacific 271:7
package 297:13
packaged 297:12
page 15:14,17
paid 334:4
pain 95:16 96:14
pains 17:21
palliative 144:6
panel 90:11 92:13
97:22 132:13,18
142:5 179:13,17
246:7 247:18 262:9
262:10 324:8
Paone 3:15 11:1,5
13:22 14:5,8 17:2
18:10 31:15,18 37:4
38:15 40:5 44:11 50:8
50:15 51:2 53:17
58:12,21 60:10 61:11
64:3 65:8 68:10,14,17
paper 211:16 275:20
276:14
parallel 130:22 159:16
160:3
parallels 347:18
parameters 304:2
Pardon 267:3
parent 99:14
parents 99:14
part 14:11 17:1 39:4
44:22 49:22 73:1
82:21 88:15 100:3

101:8 106:13,19,19
 109:20 145:2,3,7
 148:1 150:2 152:16
 172:4 173:9 203:17
 203:20 218:4 232:7,8
 232:22 261:16 280:9
 280:12 297:11 312:1
 331:11 336:8 337:12
 338:10 339:10
partially 249:6
participant 84:3,4
participants 9:18 124:9
 157:5 168:20
participate 67:6 103:4
 137:18 168:15 190:11
participating 10:17
 29:11 63:16 67:20
 142:11 291:3
participation 134:9,15
 134:22 182:3,5 206:7
particular 15:2 21:15
 37:9 46:9 53:17 54:12
 77:6 78:19 93:21
 102:10 104:17 166:3
 179:22 187:11 208:6
 208:7 215:21 216:3
 259:16 264:18 269:13
 280:22 281:14 286:12
 286:15 292:14 294:16
 294:20 295:4 312:7
 315:21 344:13,13
 345:15
particularly 10:9 41:3
 51:15 54:1 65:17 66:4
 76:6 104:18 132:16
 178:21 194:22 218:2
 253:13 283:19 296:16
 310:12
partners 1:17 100:5
PAs 120:18
pass 213:4 220:22
 222:5 258:14,15
 267:1,5,9 320:13,14
 321:3 335:11 343:3
 345:20
pass-through 63:17
 64:8 67:15
passed 20:2 209:22
 230:21 231:11 312:22
 338:8 346:9
passes 15:11 26:11
 39:17 223:8
patency 13:13,16
path 207:7 218:12
 336:19
Pathologists 291:2,18
 292:15
patient 2:1 50:4,10 58:4

59:5,6,8,19 60:6,17
 60:22 87:15 95:22
 106:4 128:3 136:20
 143:2 148:9,11 149:8
 149:8 150:22 151:10
 152:9 153:5,17 154:3
 179:1 197:16 246:9
 250:13,16 253:14
 254:13 259:14 261:22
 262:15 264:21 265:1
 277:4 278:7,8 281:20
 282:15 283:13 286:18
 289:21 292:22 299:12
 303:4,7,15 304:1,6,16
 308:20,21 309:5
 327:18 328:2 329:18
patient's 106:4 133:3,4
 133:6 306:15
patient-centered
 141:16
patient-centric 148:7
patient-graded 150:10
patient-oriented 195:18
patient-reported
 195:14
patients 5:15 9:9 11:13
 12:4,7,11 32:3,6,9,11
 40:10 44:14,16 45:7
 50:16 54:7,9,21 58:13
 60:2,8 61:12 73:18
 81:20 104:14 105:11
 105:17,19,22 109:17
 110:1,14 114:4
 120:16 121:8,17
 130:12 135:19 136:2
 145:1,9 150:5 157:6
 165:22 175:17,20
 185:14 187:18 190:20
 191:13,15 201:15
 204:22 205:14 221:22
 222:5 239:6 248:8,10
 249:9 252:4 253:11
 253:13,16,22 254:6
 254:21 255:3,4,6
 258:18 259:1 262:3
 262:12,15,20 263:9
 263:12 268:10,11,13
 269:12,14,17,18
 270:9,16 271:4,13,15
 271:19 272:6 273:7,9
 273:22 274:1,13
 275:1,5,8,21 276:2,7
 276:10,17 277:1
 278:11 279:2 281:4,4
 281:12 283:7,20
 284:4 285:5,10 286:3
 287:17 288:19 290:4
 293:17,19 294:3,12

294:18,21 295:1
 299:7,15,16 300:3
 301:15 303:18 306:19
 307:3,10,12 308:2,16
 313:21 314:22 321:8
 321:10 322:19 323:3
 328:5,15,20 331:11
 331:13,14,17 333:13
 334:7,10 343:17,18
 343:21 344:14,17
 345:3
pattern 172:22
patterns 173:5
pause 135:3 342:4
 346:19 348:15 350:4
 350:5
pay 69:13 134:13
pay-for-performance
 44:6
paying 321:20
Payment 190:11
PBM 4:19 5:3,7,11,14
PE 136:18,19,22 137:9
pediatric 166:14,16
 321:10 325:10
peer-reviewed 139:3
 178:12
pelvic 253:16
penalizing 309:9
penetrance 10:4 15:19
 24:21 25:3 28:7 29:8
 37:22 64:20 83:17
 137:19 180:16 181:6
 181:17
penetration 9:22 10:3
Penn 203:1
Pennsylvania 171:4
Pennsylvania/Ameri...
 1:12
people 8:3 24:5,12 25:1
 25:3 38:6,13 45:8
 47:5 52:1 60:20 64:9
 66:3 67:10 87:7 95:16
 103:4 135:21 136:1
 136:17 174:5 180:18
 180:18 182:18 187:8
 187:9 199:2 205:17
 205:20 212:5 214:19
 233:17 236:9 269:5
 279:5 298:19 309:10
 310:10 312:2 313:6
 314:6 315:19 326:17
 335:4 346:9 349:17
percent 9:10 10:4,7,9
 10:16,18 13:15,17
 15:15,16,18,18,21
 24:22 25:2 26:8,9,9
 26:10 27:9,9,10,10

29:3,3,4,4,10,22,22
 30:1,2,14,15,15,16
 31:9,9 32:15 35:19,20
 35:20 36:14,16 37:22
 41:11 42:21 44:12
 46:5,16,16,17,22
 48:11,11,12,13 53:13
 53:13 54:20 57:3,3,4
 57:4 62:17,17,18,19
 66:22,22 67:1,2 70:17
 70:17 71:21 72:1,1
 73:21,22 74:13,13,17
 74:18 83:19,22 85:9
 89:11,11,12,12 90:7
 91:4,5,5,6,13 92:7,7,8
 92:8,15 96:4 97:11,11
 97:12,12 98:11,12,12
 98:13 101:21,21,22
 101:22 108:10,11,11
 108:22 109:1 110:7,8
 111:8,8,12 112:4,4,5
 112:5 113:14,14,15
 113:15 116:1,1,2,2,18
 116:18,19 117:13,13
 117:14,14 118:3,3,4,4
 120:6,6 122:11,12,16
 122:21 123:9,9,10,10
 124:5,5,6,6 125:3,3,4
 125:4,22 126:1,1,2,15
 126:16,16,17 127:5,5
 127:6,15,16,16
 128:10,10 131:7
 134:21 138:14,14,15
 138:15 139:10,20,21
 139:21,22 143:7,12
 144:15 154:14,15,16
 156:7,7,8,9 158:20,20
 158:21,21 159:8,9
 161:2,5,10,11 162:8,8
 162:9,9 164:9,9,10,10
 167:12,12,13 169:11
 169:11,12,12 170:4,5
 170:5,6,15,16 172:17
 173:16,17 178:11
 185:2,2,9,9 186:1
 188:6,9,20,20,21,21
 196:10,10,11,11
 212:22 213:1,1 215:4
 215:4 246:12,20
 263:10 267:20,20,21
 267:21 288:10,10,11
 288:11 289:15 290:19
 290:20 291:5,7,9
 294:15 298:15,15,16
 306:2 312:18,18,19
 312:19 314:22 315:1
 315:6 319:12,12,13
 319:13 323:15,15,16

323:17 333:1 334:6
 334:10 342:10,11,11
 342:12,22,22 343:1,2
 349:13,13,14
percentage 12:4 39:17
 40:4 181:22 277:14
percentile 47:6
perception 43:22
percutaneous 11:12
perfect 79:4 136:4
 201:9
perfection 188:2
perfectly 35:1 207:16
perform 11:19 132:6
 135:16 199:3 249:16
performance 18:3,6
 19:20 21:16 24:18
 26:7 36:11 42:13
 46:19 48:4,10 56:19
 57:10 74:16 75:21
 82:18 87:21 88:21
 89:1,10 92:12 96:19
 111:20 112:3 116:6
 123:3,8,17 135:17
 138:8,13 161:13,16
 162:2,7 188:12,14,19
 220:16 231:13 232:6
 245:10 275:14 289:10
 310:21 313:1,4 319:6
 319:11
performed 9:10 72:12
 109:15 246:11 247:10
 248:1 292:9,10
performer 15:15,15
performers 111:11,13
 111:15 122:15,18
performing 79:1
peri-op 274:16
perinatal 266:1
period 80:10 121:9
 152:15 161:1 174:14
 204:3 254:17 263:1
 273:17 276:4
periodic 23:5 205:21
periodically 21:8
perioperative 248:22
 258:12 275:11 345:4
permanent 71:12
 180:12
person 134:13 200:9
 309:19
personally 308:14
perspective 68:6 100:2
 179:15 180:7,16
 263:15 272:15 321:6
 324:3 337:6 349:17
perspectives 210:4
PEs 137:11

pets 221:19
PFO 109:19
Pharmacy 2:11
PharmD 2:10
PHASE 1:3
PhD 2:19 3:3,9,14
philosophical 42:16
 43:2
philosophically 81:7
philosophy 84:15
phone 6:18,19,22
 129:16 252:12,14,21
 324:1 347:9 348:2,5
phones 350:1
phrased 257:8
physeal 191:8,9
physician 75:4 215:5
 217:6 218:19 317:13
 332:19
physicians 1:22 40:16
 44:7 75:10
physiologic 59:16 61:9
physiology 332:21
pick 262:2 273:14
 275:16 351:5
picked 180:2 209:5
 250:15
picking 99:5 100:22
 137:10
pickup 148:13
picture 79:14 112:10
 123:15,17
piece 18:9 89:16 162:14
 165:4 241:20 263:20
 336:14,16 337:14
pieces 135:9 284:15
pilot 141:14 224:10
Pittsburgh 2:22 3:18
 294:17 314:16 316:13
 334:1
PITZEN 2:12 27:20 36:9
 57:9 58:1,17 60:4
 62:7 63:11,14 65:1
 98:21 99:16 100:19
 141:5 142:17 143:13
 143:19 157:4,13,18
 158:3 186:20 200:6
 201:9 208:16 230:11
 240:13,19 259:18
 287:13
place 68:8 106:6 130:21
 131:1 132:4 140:3
 141:22 149:3 187:3
 195:8 197:3 259:19
 315:8
placed 13:14 17:17
 21:3 223:3
places 15:13 36:18

80:18 95:16 96:14
 173:17 258:19
plan 86:1 88:14 106:12
 194:3 195:11 210:13
planes 8:3
planned 193:14 194:5
planning 198:5 259:21
 292:6
plans 285:20
plateau 4:16 170:21
 171:7 172:2 173:18
 175:22 178:4
platform-wide 166:12
plausible 94:4
play 60:20 237:3 239:1
 328:13 333:11
playing 7:7
please 57:14,17 58:2
 63:13 89:6 119:21
 127:20 140:1 221:4
 252:15 264:7 268:2
 321:4 340:9 342:6
 350:3 351:19
pleased 246:5
plus 71:4,6 72:7 87:3
 109:18 121:4 132:4
 142:1
pneumonia 148:14
 152:22 154:3
pneumonias 148:21,21
 150:1
point 23:1 55:9 64:8
 65:14 69:8 72:18
 73:17 75:12 78:2
 82:20 83:1 87:14
 88:18 90:13 99:21
 114:8 175:6 184:4
 191:8 199:7 206:9,14
 209:4 224:16,17
 240:2 243:17 256:2
 262:18 270:18 275:13
 277:7 282:4 329:13
 342:7 348:4
pointed 95:2 118:7
 265:12
points 63:2 67:5 79:22
 90:14 106:18 107:18
 280:21 305:20 311:14
policies 300:17,21
 301:2
policy 2:5 163:10 301:1
poor 88:13
poorly 79:1 96:3,5
population 34:21 55:2
 95:10 133:13 140:6
 151:10,11 168:14
 191:7 194:19 263:22
 281:15 286:15,16,19

287:16 325:10
populations 249:17
 261:22 283:13 286:1
 286:4
portfolio 9:13 21:14
portion 220:19
portray 33:13
pose 206:19 246:14
position 85:6
positions 102:13
positive 187:6 189:19
 190:21 291:10
possibility 94:11 223:9
 229:7,7 235:17
possible 65:16 85:7
 96:16 110:21 163:6
 227:6 236:3 258:7
 276:21 277:11 290:5
possibly 76:22 209:15
 235:20 296:22
post- 31:21 320:21
 330:10
post-draft 350:15
post-meeting 350:13
post-op 189:17 306:13
post-operative 140:8
 140:10 301:12
post-operatively 51:16
 331:4
post-trauma 285:12
post-update 148:19
postpartum 303:17
 328:6
potential 50:9 60:11
 65:6 96:12 152:2
 197:2 198:15 227:18
 230:6 231:10
potentially 16:17 47:22
 144:5 151:21 172:9
 176:22 236:2,4 241:5
 241:12 242:8 261:21
 324:1 335:9 340:22
powerful 66:2
PQRS 9:13,21 23:14,15
 43:7 44:3
practical 61:12 142:15
 273:8
practicality 250:1
practice 2:14 22:18
 75:3,9,10 81:5 90:6,7
 184:6 199:5 232:7
 260:11,13 261:10
 273:6 300:13 316:13
 317:18 318:21 326:13
practices 131:18
 208:19,20 259:22
 260:6 261:17
practicing 22:20

practitioner 332:19
practitioner-level 77:11
practitioners 277:3
pre- 289:19
pre-meditated 193:4
pre-op 65:11 262:18
 263:20 274:17 287:22
 330:20 343:18,21
pre-surgical 275:2
pre-thought 193:4
preamble 9:7
preceded 304:10
precipitating 16:15
precise 304:15
predictive 119:6 140:16
 190:22
predictor 248:22
preemptive 307:5,19
preference 149:8
preferred 275:12
pregnancy 303:14
pregnant 328:5
premature 206:16
premise 97:20
preop 248:20,21
preoperative 4:6,19 5:3
 5:7 32:20 49:20,21
 53:15 135:13 245:18
 245:18 248:7,9 249:7
 250:20 253:19 254:17
 258:9 265:1 273:4,20
 274:11 277:1,5 279:6
 279:10 280:4 288:15
 294:20 331:2 344:5
 345:2,11 348:19
preoperatively 51:6
 54:11 55:6 58:5
 253:11 255:4 275:22
 276:11 281:4
preparation 8:14
prerogative 325:17
Presbyterian's 203:1
prescribe 50:2,10
present 1:11 3:8,22
 44:18 82:10 104:22
 162:16 170:22 181:16
 276:2 278:20 311:2
presentation 133:15
 213:20 285:21
presented 25:21 138:20
 184:5 226:1 283:2
President 2:4 3:2,3
 129:10
presiding 1:10
press 252:16 350:3
pressed 86:10
pressure 50:19 202:8
pretty 17:9 26:18 29:10

73:20 74:16 78:10,11
 86:7 90:5 99:1 171:18
 172:6,11 187:12
prevalence 263:9 302:7
prevent 32:12 295:5
 307:5
prevention 32:4 307:22
previous 12:8,9 28:4
 32:6,18 48:18 49:5,9
 52:7,10 53:20 54:1
 57:10 71:9,15 121:12
 167:17 309:16
previously 12:15 121:3
 190:18 197:20 264:10
 295:19 338:3
price 67:6
primarily 286:10 314:18
primary 14:20 31:14
 33:16 109:8 314:20
prior 51:10 75:17 91:12
 130:14 142:21 159:22
 160:4 168:22 211:9
 231:21 237:21 248:12
 249:9 250:2 255:9
 269:22 274:18 275:7
 279:4 281:11,19
 288:21,22 289:4,10
 291:6 292:10 299:12
 318:16,18 343:19
priority 240:19
private 130:20 291:3
pro 103:2
probability 71:21
probably 13:4 17:9,14
 41:17 59:15 68:11
 73:10 85:17 86:10
 91:18 94:18,19 99:10
 106:5 112:22 117:2
 131:1 134:14,20
 143:14 148:12 149:6
 163:9 167:19 168:5
 185:21 197:13 203:7
 206:9 212:11 226:18
 262:9 264:16 265:4
 299:5 321:1
problem 41:4 73:7
 84:20 92:15 106:6
 163:10,10 180:4
 187:1,15 188:10
 226:16 241:4 250:12
 254:14 257:21 258:1
 258:3 259:1,8,9 294:6
 304:8,9 315:18
 339:14
problems 50:20 254:1
 259:17
procedural 133:6 194:4
procedure 11:18,22

50:18 109:19 121:5
 166:21 185:8 246:11
 246:13 248:13,16
 273:4,10 274:19
 278:17,18 288:21,22
 289:4,5,10 296:20
 297:4 343:19
procedures 11:16,19
 12:12 85:11,11
 109:15 150:9 168:6
 249:16 252:6,7,10
 286:2 287:18,20
 289:9 290:15,17,18
 291:5 294:13,14
 297:2,5,6 314:18
proceed 346:4
process 10:6,22 15:2,3
 17:14 21:2 22:6,7,13
 37:15 46:6 51:8 64:15
 65:5 73:1 86:20 87:2
 88:13,16 99:18 107:9
 181:8 208:20 209:7
 209:16 218:6 223:16
 227:13 229:10,21
 230:4 231:4 232:22
 233:3 236:12,14,19
 292:21 301:19 305:9
 327:17 332:7
processes 135:15
 178:8 184:7
processing 66:6
produce 235:4 250:14
produced 221:10
productive 7:3 8:12
products 207:21
profession 150:11,13
 152:3 165:12
professional 2:14 81:5
professor 1:11,19 2:10
 2:15,15,20 9:3
profile 276:18 279:1
 282:14 299:10
profoundly 262:16
program 1:14 2:7 64:14
 103:22 130:22 131:13
 132:1,17,22 134:5,7,9
 134:10,22 137:6
 156:16 157:1,9
 166:17 168:15 190:12
 216:20 218:11,12
 219:12,14 220:5
 222:20 223:2,3
 224:17 225:7,9,13,14
 225:16,21 227:8
 229:12 235:19 242:15
 243:22 265:13,21,21
 266:5,8,13 300:7
programmatic 132:22

programs 98:16 103:8
 106:1 130:11 139:2
 143:6,8 156:18
 168:10 265:18 266:1
 266:7
progress 165:13
progressing 276:5
project 3:6,6,7 141:14
 207:6 216:3,4 246:2,5
 247:16,21 302:7,16
projects 207:6
proliferation 217:5
prolonged 71:10 73:21
promoted 207:12
prone 308:2
propensity 199:11
prophylaxis 177:6
Propionibacteria
 199:18
proportion 167:22
 248:8 255:5 288:18
 293:17 294:3
proportionally 80:4
proportions 300:3
propose 72:14 139:9
proposed 200:15
proprietary 165:6
prospective 193:5
prospective-type
 192:19
prosthetics 199:10
protean 112:10 123:15
protocols 307:5
provide 59:13 82:1 85:6
 86:2 104:4 129:5
 131:22 155:10 158:8
 165:15,17 171:1
 213:9 230:9 231:9
 255:18 311:3,16
provided 141:1 157:5
 165:15 340:4
provider 262:22
providers 44:8 92:13
 158:6 190:11 260:14
provides 132:18 235:22
providing 158:6 328:1
provisional 180:11
public 4:21 5:18 9:5
 10:2,13,17,18 17:20
 38:11 81:12,13 83:3
 83:16,17 86:14 105:1
 105:22 156:13 157:19
 165:8,18 201:21
 202:22 203:3,6
 251:15 284:22 291:3
 315:9 350:1,6
publication 271:17
publications 165:7

publicizing 296:17
publicly 18:3 30:6
 86:11 87:5 102:7,9
 103:11,14 105:7
 156:15,20 165:17
 285:14 305:6
published 34:10 130:17
 139:3 145:17 146:4
 178:12 270:4,19
 275:20 276:15
publishing 84:21
pull 20:16 220:4 223:5
 351:1
pulled 43:7 306:13
pulling 20:18 43:10
 287:16
pulmonary 309:1
purpose 36:14 79:21
 80:7 183:9 301:3,4
 337:20
purposes 9:19 80:7
 201:21 302:21
purulence 199:21
purulent 189:22
purview 77:15
push 21:22 318:21
pushed 85:18
pushing 103:18
put 8:19 16:21 19:17
 25:10 41:12 42:14,18
 43:6,11 46:6 67:15
 68:1 69:8 100:1,13
 144:6 146:1 154:20
 155:6 172:2,9 179:14
 180:6,15 197:13
 201:1 218:8 219:4,14
 219:20 222:8 225:21
 230:11 234:13 235:10
 239:19 241:9 243:21
 251:15 263:5 268:7
 310:15 313:22 315:17
 317:13 338:18 350:16
 350:17
puts 172:16
putting 17:3 42:6 90:9
 112:7 204:7 224:19
 226:3 257:12 273:16

Q

QCDR 23:19 44:1 190:9
 197:10 212:4,5
QI 1:15
qua 67:16
qualified 9:12
quality 1:1,8,16,17 2:7
 2:21 3:2,4 9:19,19
 11:7 24:4 36:11,15
 38:5 46:11,19 47:12

47:13 73:18 81:6,22
 82:2 88:17 89:15 90:1
 90:21 103:16 112:11
 112:19 123:12,17
 130:10 135:16 144:22
 158:5 163:13 179:22
 184:7 190:11 215:8
 215:10 216:2 225:1
 231:13 235:4 236:5
 249:19 277:15 284:21
 291:16,19 302:10,15
 302:21 305:19 313:21
 321:12 329:3 333:6
 339:8

quandaries 351:21

quantitative 312:3,9

quarter 134:12

question 7:21 16:7 20:7

20:10 24:17 34:5
 35:13 39:7 40:20
 49:18,20 51:1,11,12
 51:14 58:1,22,22 59:1
 63:12 64:17 65:2
 66:10 75:6 78:1,2,16
 92:20 93:8 96:13
 98:18 100:1 104:11
 105:2 135:18,21
 136:16 141:9 144:11
 148:1,3 149:10
 150:15 152:17 153:2
 157:4 180:20 182:20
 184:12 185:18 195:2
 202:20 205:16 206:3
 206:5,19 221:14
 226:17,18 228:5,22
 229:18,19 233:21
 239:9 251:5 252:11
 257:11 259:5,19
 260:7 265:11 266:20
 269:22 273:5,21
 282:20 289:16 295:9
 296:5,9,16 300:14
 306:7 308:5 309:16
 309:20 314:8 321:18
 334:21 335:15 346:1
 346:7,8,11

questionable 94:7

questioned 237:17

questions 7:14 59:20
 66:12 129:22 135:4
 143:15 171:20 176:19
 177:13 189:5 222:15
 223:12 296:6 315:10
 323:21 335:6

quick 20:9 78:2 99:9

113:19 157:4 266:19

quickly 15:7 37:5 64:12
 65:8 100:8 254:16

255:15 274:2 320:18
QUINNONEZ 3:6 18:22
 26:6,13 27:2,7 28:18
 29:1,15,20 30:7,12
 31:2,6 36:6 48:3,9
 53:6,10 56:17 57:1
 62:10,15 66:15,20
 70:10,14 74:7,11
 88:22 89:5,9 90:20
 91:3,22 92:5 97:4,9
 98:5,10 101:12 108:3
 108:16 111:2,19
 113:6 115:15,21
 116:11 117:6,18
 119:22 122:6 123:2
 123:20 124:18 125:16
 125:21 126:6,20
 127:8,21 128:8 138:7
 138:12 139:14,19
 154:9,13 155:22
 156:5 158:13,18
 159:2,6 162:1,6 164:2
 164:7 167:6,10 169:4
 169:9,19 170:2,9,13
 184:18,22 188:13,18
 196:3,8 212:17,21
 267:14 288:4 298:7
 312:11,16 319:5,10
 323:7,12 341:22
 342:5,9,20 348:12
 349:2,11
quite 24:20 50:20 56:10
 104:15 122:19 172:12
 254:16 268:16 276:4
quiz 219:8
quorum 334:18 346:21
 348:1,10
quote 197:14 257:19
 307:18
quoted 190:17 292:14

R

race 114:12,14,20
radiation 12:10 253:16
raise 281:19 286:10
 331:10
raised 83:15 260:3
 305:20
raising 279:10
ramifications 234:12
randomized 177:2
randomly 40:16
range 18:2 173:20
 185:9 283:10,13,14
 299:21
ranges 136:1 283:4
ranging 178:10
rank 148:12

rapid 217:5
rapidly 327:21
rare 137:1,2 146:22
 173:5
rarely 214:18
rate 4:16 50:19 144:16
 161:7,9,11,12 170:20
 173:12,15 174:2
 176:21 177:1,4 178:3
 186:16,17 187:11
 188:6,8 194:13
 198:15 199:22 202:18
 203:1 204:2 246:19
 257:18 258:6 283:6,7
 283:7 284:3,11
rates 13:13 46:14 73:20
 171:7 173:19 178:10
 185:8 187:1,10
 197:18 201:22 302:8
 306:22
rating 119:5
Ratings 72:19
ratio 160:20,22 257:17
 257:22 272:18 283:19
 283:21 284:3,10
 285:8 328:12
rational 269:9
rationale 166:2,5 167:1
 167:1 255:2,7 257:12
 264:17 301:11 302:1
ratios 137:20 163:16
 283:3
re-endorsed 17:16
 32:16
re-endorsement 106:16
re-operations 71:12
re-vote 24:12
reached 147:18 323:19
 342:13 343:7 350:19
react 262:6
reaction 332:15
reactive 40:10
read 57:2 115:5
readmission 46:14 94:2
 94:14
Readmissions 152:15
readmitted 152:10
reads 26:8 342:10
ready 16:2 48:20 86:12
 108:2 113:5 123:1
 128:13 129:1 196:2
 201:18 202:21 206:14
real 44:4 67:19 78:1
 113:19 218:17 221:6
 254:1 285:1 333:11
real-life 226:11 244:8
real-time 311:1,16
realistically 50:8

reality 161:8	recognizing 195:6 215:16	regardless 19:20 87:19 195:11 322:13	196:20 198:3,12 206:8 224:4 234:19 238:15 239:16 240:9 242:20
realize 96:5 203:15	recommend 54:3 124:16 200:12 282:17	regards 54:2	reliable 140:9 235:14 308:12
realized 173:11,21	recommendation 12:20 13:3 32:11 136:12 350:9	regimen 51:5	relook 232:5 281:7 329:13
realizes 80:16	recommendations 324:12	region 203:12	reluctance 285:2
really 14:9,10 15:4 17:20 25:13,19 30:17 32:17 33:1 37:8 42:2 45:9,9,10 54:11 59:21 63:17 65:10 69:12 80:16,17 92:17 99:7 105:5 112:14 113:1 126:19 128:16 130:10 148:15 168:2,8 171:15 172:22 173:4 173:12 174:1 176:18 177:5 190:10,20 191:19 201:6 202:5 207:13,18 211:20 212:12 213:18 214:14 214:20 218:8 224:12 248:21 250:6 255:15 257:20,21 258:1,2 259:4 260:4 273:14 279:6 281:1 284:4 293:14,18,20 294:4,6 302:6,14 304:7 309:7 312:6 313:19 329:1 329:20 336:8 339:10 345:14 351:16	recommended 301:10 340:19	registries 66:1,2 68:20 69:16 94:17 101:3 103:6 193:1,5 204:1 214:13	reluctant 42:18
reason 13:1 39:13 41:2 45:16 47:13 49:21 55:8,15 65:2,9 69:19 112:7 172:10,21 197:7 224:18 228:5 229:1 292:2 304:5 310:20	reconstruction 174:22	registry 9:12 39:17 43:6 63:18,20 65:7 67:8,9 67:14,20 69:1 76:20 103:4 143:1 155:18 157:9 168:2 176:8 182:4,6,12,13,18 187:2,16 190:8,10 191:2 197:12,13 198:2 201:15,18 208:21 210:5,12 217:18 310:3,7	rely 153:3,5
reasonable 67:6,22 205:10 206:4	record 19:9 26:19 62:1 63:18 64:7 99:17 128:18 141:8,13 143:2 189:18 193:22 202:17 217:5 227:4 245:1 304:7 305:4,7 309:13 335:21 351:13 351:22 352:7	regression 114:7 181:4	remain 73:20
reasoning 250:3	Recorded 7:7	regular 187:12	remaining 35:22 351:8
reasons 12:6 44:9 53:22 61:4,15 84:18 199:10,22 261:7 273:11	records 188:3 214:13 215:5 316:21	regulatory 61:8	remains 14:10 32:10,17 32:21 33:3 53:19 73:22
recall 330:6	rectify 271:4	reject 242:14	remark 141:11
Recap 4:2	recuse 184:14	rejected 77:20	remarks 129:20
receive 58:13 194:17 219:13 221:4 292:4 309:4	red 299:17 312:2	related 30:19 54:15 76:6,7 114:17 144:3 195:9 203:5 266:9	remember 47:16 57:13 197:15 223:14
received 12:5 283:8 286:6 287:21 297:13 304:1	redo 348:4	relates 60:6 195:12 314:3 336:4	remembering 86:22
receives 103:22	reduce 66:8 168:17 269:14 281:20	relationship 94:4,7 179:14 207:22 208:1 327:2	remind 328:5
receiving 275:8 290:4	reduces 270:21 271:8	relationships 9:15	reminded 101:4
recognize 68:21 69:6 73:9 166:22 192:5 327:12	reduction 189:10 276:22 277:5 311:12	relative 25:18 286:21 306:2	reminder 305:9
recognizes 37:12	REEDE 2:13 33:18,21 34:2 35:17 48:16,19 49:1,11,13 52:9,18 301:7	relatively 174:3 175:16 176:20 180:8 185:20 190:5 191:6	removal 174:21
	refer 147:5,19 256:10	release 195:5 243:11	remove 23:21 42:9
	reference 33:19 58:10 72:4	relevant 34:19 264:16 314:10	removed 130:13 133:18 147:14 159:22
	referencing 336:12	reliability 26:19,21 27:3 27:8,13,16,21 40:1 48:16 57:20 62:4,6,11 62:16 71:20 72:3,6,11 85:15 91:10,14,16,19 92:1,6 110:12,15 115:7,8,16,22 121:16 124:7,10,19 125:2 131:11,14 132:7 138:18,19,21 139:1,8 139:9,15,20 143:11 144:1,7 162:12,16 164:1,3,8 176:6,7,10 189:2,4 190:14,16 191:4 195:21 196:4,9	removing 33:5
	referred 259:14 263:4		renal 71:12 263:12 270:13 285:11
	referring 260:14		renewal 135:8
	reflect 57:19 119:15 161:9 326:10		reopen 157:11 274:4,8
	reflected 118:13 143:1		repair 71:5 109:12,17 109:18 306:12 307:4
	reflective 326:12		repair/replacement 4:9 121:4
	reflects 105:3		repairs 69:3 252:8
	reformatting 293:14		repeat 259:13 309:21
	refrain 36:20		repetitive 110:4 348:3
	regard 7:21 17:5 110:20 178:8 202:11		rephrase 50:22
	regarding 116:21 164:12 167:4 169:3 171:6 195:21 214:1 320:7 321:14 347:11		replaced 265:5
			replacement 71:4,5 109:12,18 172:18 199:15 251:8 252:10 256:2 264:22 296:3 297:7,18 314:20
			replacements 314:19
			replenished 270:11
			report 24:3 25:7,11 40:12 44:3,5,8 45:6 57:13,14,18 69:9 72:20 76:8,10 77:5 103:14 107:3 139:10 154:5 156:15,21 160:14 163:15,17 166:7 174:13 187:10 189:4 198:12 202:7

220:17 231:16 235:3
 237:12 238:5,8 245:8
 245:9 266:9,14 283:2
 285:2 332:6 350:16
reported 25:1,6 30:6
 87:5 102:8,10 103:11
 133:8 153:22 162:17
 173:19 187:6 285:14
 305:6,22 315:14
reporting 9:5 10:2,13
 10:17,19 17:20 18:4
 76:16 78:20 80:3,22
 82:16,17 83:17,18
 85:22 86:11,14 105:2
 105:22 156:13 161:1
 168:10 174:5 186:15
 187:12 201:21 285:1
 285:4
reports 78:19 88:16
 188:6
represent 133:5
represented 335:20
representing 129:11
 132:13 138:3
represents 45:7 134:20
reproducibility 143:5
 143:11
requested 182:20
requests 83:18
require 94:19 168:19
 171:19 252:10 254:4
 254:17 266:13 267:5
 267:10 297:7 326:8
required 156:14 290:1
 290:7 345:4
requirement 61:8
 168:17 233:5 266:7
 282:13 317:14
requirements 44:6
 218:16
requires 40:22 99:21
 254:3 269:21 316:14
reread 200:14
research 2:1 302:6,16
resembles 297:3
reserve 16:8,21 17:3,7
 17:17 19:15,17,21
 20:5,7,11,21,22 21:3
 21:19 22:3,12 23:10
 24:9,11 33:9 38:10,18
 41:7,9,11,12,15 42:7
 42:8,14,18 43:7,11
 44:5 45:16 46:7
reserved 21:6
resident 318:4
residents 318:3,8
resistant 199:13
resolve 125:15

resolving 250:1
resource 99:17 158:1
 246:17
resources 36:19 37:7
 289:19 294:5,10
respecified 216:13
respect 16:12 68:18
 93:10 97:14 102:3
 129:18 229:20
respective 111:11
respectively 122:16
respond 37:5 51:19
 180:19 315:10 350:18
responded 59:19
 179:18
response 15:9 18:16
 23:16 28:16 29:14
 30:22 36:3,5 40:19
 49:3,7 51:13,15,20
 52:3,5,12,15,21 53:2
 56:4,14 59:16 63:6
 66:13 70:4,7 74:6
 89:17 90:18 97:3 99:9
 181:6 243:13 251:1
responses 155:11
responsibilities 214:6
responsible 69:9 77:2
 83:6 247:15
rest 20:6 26:17 188:5
 209:21 346:9
restricted 225:4
restrictive 299:5 300:9
 306:21 344:8,19
resubmit 89:6 220:7
 227:7 342:6
result 11:15 80:18
 82:10 88:9 229:9
 242:8 282:22 329:6
results 57:2 78:22 86:3
 92:17 147:8 220:6
 221:6 223:6 224:3
 225:20 244:1,7 248:5
 266:9 314:4
resumed 128:18 245:1
retaining 16:18
rethink 177:4 272:20
 276:14
retracting 47:11
retrospective 185:13
 190:19,22 192:17
 308:2
return 129:21 194:3
returned 130:6
revascularization
 308:18
revealed 130:16
reverse 275:3
review 23:6 42:10 86:19

107:15 159:11 160:9
 181:1 214:7 216:8
 240:15 271:18 274:13
 275:20 276:19,20
 281:21 282:18 296:21
 305:11 327:4 329:16
 333:14 344:1,1 348:7
reviewed 21:8 92:13
 104:16 119:17
reviewing 216:2 220:12
 222:17,18,19
reviews 140:10
revised 132:3
revision 131:22
revisit 21:15,21
revolt 102:5
revote 274:4
rework 41:8,8
RHIA 3:18
RICHARD 1:17
Rick 23:8 60:14 82:6
 196:20 250:8 284:19
 297:16 302:17 332:13
 347:5
Rick's 270:2 347:5
right 13:3 25:15 49:9,10
 69:4 74:15 82:3 88:1
 88:3 90:3 92:10 104:5
 109:7 114:1,9 118:18
 118:19 128:3 142:17
 150:14 153:1 157:13
 157:20 160:21 162:11
 170:19 188:2 192:12
 196:2 221:10 226:19
 233:22 238:21 242:19
 243:5 249:13 256:6
 259:19 260:8 271:17
 284:7 326:15 334:21
 336:21 337:3,8 338:8
 340:22 343:5,6
 351:11
rigorous 131:15 150:2
rigorously 130:7
Rim 271:7
rise 215:6 217:3
risen 56:9
risk 4:12,14 51:10,11
 78:22 95:21 96:1,12
 104:21 105:4,6,9,14
 106:3,6,13 133:2,4,7
 137:20 165:5,7,14
 172:16 178:20 179:3
 180:21,22 181:2,8,11
 182:20 194:15 196:21
 197:3,7,22,22 198:10
 198:17,21 201:12,20
 202:6 203:12,16
 204:5,16,17 205:5,11

205:12,14 209:5,9
 211:4,4 213:6 226:17
 226:21 228:5,6,14
 237:7 246:14 263:19
 268:12,17,20 269:3
 269:20,20 270:22
 271:5,8 285:9,20
 307:6,12 309:1,8
risk- 71:6,7 80:14 129:2
 159:18
risk-adjust 79:8
risk-adjusted 9:14 49:1
 71:16,17 130:4
 159:12
risk-adjustment 82:13
 95:6
risk-averse 105:16
risk-aversion 105:11
risks 281:13
RN 2:12 3:5,13
RN-BC 3:12
road 68:4 112:21
 141:18 211:20
Robert 109:4,6
robust 10:5
robustness 105:4
role 32:9
rolled 106:10,12
room 1:8 44:4 85:2
 87:16,19 136:17
 173:15 253:12 254:22
 293:11 294:19 299:15
 314:7 326:6 327:15
 328:16 329:1 334:7
Rothman 203:4
roughly 215:4
route 226:7
routine 193:10 263:2
routinely 13:15 67:5
 302:19
rub 347:19
rules 243:14
run 67:10 96:1 209:6
 256:14
ruptured 287:9
rural 96:9

S

safety 2:7 60:6
SAIGAL 2:15 207:10
 224:8 301:22
Sal 261:11 305:17
 350:22 352:1
salvage 12:12
SALVATORE 2:15
sample 77:21 84:19
 139:6 142:22
samples 291:8

saphenous 13:6,16
satisfied 62:1
satisfies 220:4
satisfy 59:2,11 61:7
 218:15
save 189:7
Saver 344:6
saw 34:17 195:7 207:17
 208:3 260:9,15
 314:21
saying 11:10 45:11,20
 82:4 181:14 183:17
 204:12,20 235:17
 243:14 278:2,4
 287:14 314:11 325:17
says 25:22 38:11 40:21
 60:19 251:22 279:15
 279:18,20
scalability 121:13
scale 40:16
Scali 2:15 261:12
 305:18 307:12,16
 351:22 352:1
scaling 110:10
scanners 137:10
scans 151:20
scenario 278:6 316:19
Schatzker 182:21,22
 183:4
schedule 294:9
scheduled 60:17
 193:14 248:13 262:21
scheme 133:9
scholars 129:13
School 1:20 2:3,3
science 250:4
Sciences 2:11
scientific 3:2 71:18
 97:15 98:6 126:7
 131:10 220:20 231:17
 238:11 245:10
scientifically 76:21
 85:5
scientist 129:15
scope 45:20
score 4:9,11 12:17 33:3
 48:20 72:14 96:3,5
 97:17 109:13 110:20
 146:15 149:13 150:19
 150:21 158:7 160:18
 164:21 260:20
scores 104:1 149:16
 150:18
scoring 149:14
screen 263:16 269:2
 288:20 289:3,5
 291:13,17 292:9
 293:2,16 294:2 296:3

318:17
screened 269:7 345:3
screening 4:20 5:8
 245:19 248:7 249:7,9
 249:11,15 256:22
 257:1,6,8,16,20
 262:17,22 265:1
 269:8,11 288:16
 294:11 328:16 345:2
 345:6,7,11 348:20
screens 290:6 291:4,11
screwy 331:3
scrutinized 11:21 105:8
 132:2
SDS 15:20 92:21 93:20
 133:16 160:2 197:14
 197:16
se 50:12 141:2,2 208:21
search 297:15
second 8:10 47:2
 105:18 148:6 150:15
 159:11 179:20 228:4
 296:9 301:6 348:14
 351:8
secondary 32:4 33:17
 207:12
Secondly 202:4
seconds 9:22 184:13
 327:16
section 10:16 239:16
 240:4 297:9 337:9,17
sections 57:15
sector 130:20
sed 199:22
see 20:17 21:16,20 22:8
 42:17 43:2 57:13 81:9
 93:21 95:16 96:17
 101:7,8 103:5 106:15
 107:5 112:19 114:7
 115:1 142:4 146:13
 146:16 157:15 160:18
 160:22 161:15 165:1
 166:20 171:20 173:3
 173:6 206:6 209:19
 210:16 222:2 227:19
 245:3,17 254:9
 263:13,21 276:21
 279:5 283:5,6,9
 285:13 286:18 290:16
 295:10 299:3 302:10
 302:20 307:7 317:8
 321:10 322:2 331:3
 333:5 340:13
seeing 18:2 22:4
 254:12 275:19 279:14
 317:17
seek 180:12
seemingly 190:9

seen 24:9 51:19 84:22
 91:18 137:11 147:20
 202:12 217:12,12
 290:21
sees 237:12
segments 286:15
select 351:2,12
selected 5:14 220:14
 248:10 251:21 252:3
 269:12 274:19 287:17
 288:19 290:14 294:13
 343:16
selecting 269:14
selective 297:3
self-monitoring 301:3
self-reported 212:6
send 14:14 25:11
 145:20,21 241:17
 291:17 335:5 339:22
 351:19
sending 42:19
sends 38:11 42:7
senior 2:6,7,13 3:3,4,5
 3:5,7 129:15 214:5
sense 20:8 35:1 54:7
 57:17 61:10 97:19
 148:8 259:10 261:19
 263:7,16,21 299:3
 307:21 313:13,20
 328:13 329:7 331:3
sensitivity 176:11
 190:21
sent 270:10 291:8
separate 62:6 93:12
 114:12,14 153:19
 154:5 166:16 234:7
separated 153:22
separately 27:16,19
 49:5 52:14 53:1 137:9
sequelae 32:13
series 250:11
serious 130:5 136:20
 147:19 159:20
serum 256:16
serve 351:4,7
service 2:18 96:1
services 266:10
serving 11:6 36:14
SES 94:11
session 214:1
set 23:19 37:8,11 39:8
 55:4,12 59:11 62:2
 64:13,16 72:8 121:6
 136:5 159:21 180:1
 221:9 237:8 249:18
 249:22 252:5 255:18
 279:18 297:3,9
 310:10 331:11

sets 188:4 255:22
 279:16 297:10 317:3
 317:5
setting 200:21 226:11
 244:8 260:11 279:20
 310:11 331:9
settings 145:2
settled 110:13
seven 71:15 211:16,17
 299:21 300:4,18
 301:15 306:1,17
 308:15 327:10
Seventy-one 98:11
severity 150:10 165:10
 295:4
shaft 177:8 183:6
Shahian 3:16 54:13
 56:1 65:13 68:13,15
 69:2 84:6,14 86:1
 87:9 94:1 99:9 100:4
 100:15 102:15 103:22
 104:9 105:13 118:22
shaking 27:21 87:1
Shander 3:16 268:4
 272:8 274:5 280:8,16
 280:19 291:22 303:10
 307:14,17 329:8
 347:13
shape 102:6
share 77:18 113:3
 208:17 246:8 350:12
shared 43:21 260:21
SharePoint 255:20
shares 339:20
sharing 248:5
shattered 172:4
shed 232:10
shepherds 171:11
shock 322:10 326:4,18
shoot 143:7
short 13:8 41:6 183:14
 245:20 281:18
shortcomings 152:2
shortcut 22:21
shorter 191:22
show 100:9 136:6 204:4
 222:6 276:14 297:21
showed 94:15 190:20
showing 17:22 46:8
 112:18 138:21 229:3
 270:5 275:21 296:13
 299:11
shown 132:21 140:16
shows 56:11 137:8
shuts 96:7
shy 104:13
sick 204:22
sickest 104:14

sickle 256:14 286:3	sites 10:16,18 110:14 121:17 219:19 230:6 236:3 317:4	282:10 316:21	240:6,10 245:12
side 137:1,2 166:14 252:13	sitting 73:5 203:2	sorry 6:11 19:4,4 27:20 57:6,7 72:9 80:12	251:19 255:18 297:12
sidelines 102:22	situation 47:9 76:18 229:13	126:19 143:3 179:6,9 287:4 303:20 309:20	319:18 320:5 322:8
sign 177:21	situations 79:18,19 270:9	322:1 335:14 350:22	323:6,8,14 324:18
Signal-to-noise 48:20	six 10:11,21 67:10 112:20 118:21 142:6	sort 24:4 33:10 46:12 85:18 95:22 102:4	325:3 335:19 336:3,5
signaled 43:10	six-month 64:15	105:5 116:5 132:19 160:19 165:5 188:4	336:12,18 337:3,7,13
signals 144:21 147:20	Sixty 125:22	192:4 206:13 215:20 223:16 238:11,19,22	337:15,19,21 338:7
signed 107:22 204:14 205:17 206:1	size 77:21 84:19 98:22 139:6	250:11 261:15 305:20 306:18 310:4 324:15	338:10,16 339:2
significance 17:4 283:18 284:14	skin 199:18	333:10 339:3	340:21 348:21,22
significant 11:11 12:13 12:16 18:1 44:19	SKIPPER 3:6 8:9 325:8 340:2,11 350:8	sorts 66:7	specificity 176:12 190:21
53:19 54:17 92:11	slide 216:1 220:10 222:10 230:12	sounded 210:4	specifics 78:18
103:13 114:5 138:3	slight 40:14	sounds 39:11 101:7 168:3 210:6 249:10	specified 75:2 91:11
167:22 172:7 209:17	slightly 39:1 96:19 144:17	249:22 302:6,11 314:7	163:3 209:13 216:11
217:3 242:13 269:18	Sloan- 2:18	source 190:8,15 197:9 228:10 322:22	218:14 232:10 251:22 302:3
271:5 291:10 292:6	small 77:21 92:15 177:1 231:17 301:7	sources 336:10	specify 131:13 134:2 211:13 327:6 335:7
295:6 320:18 324:12	smaller 95:19 124:13 135:1 137:3,10,10	sparse 187:14	specs 240:8 298:5 339:6
significantly 11:17 107:12,14 326:17	smart 136:17	speak 132:14 264:4	spectrum 25:3 300:9
signs 327:2	Smith 207:19,21 208:2	speaker 208:11,13 215:16	spending 36:18
similar 32:17 41:9 71:20 117:1 121:6	smoothing 133:10 150:3	speaking 28:1 50:14 81:18 82:8 83:7,10,13	spent 86:6 100:4
210:18	SNOMED 251:10,12 252:5 255:21	83:21 339:11	spigot 259:2
Similarly 241:10 285:17 304:16	societies 179:18	speaks 188:9	spinal 306:22 307:5,10 307:13
simple 171:19 175:17 191:6	Society 1:12 3:10,15,16 135:13 301:9	spec'd 207:3,8	spine 209:3
simplest 251:1	socio-demographic 130:18	special 317:1	spirit 292:13
simplicity 175:8	socio-economic 160:15	specialized 173:20	split 183:4
simply 58:9 172:2 244:4,6 257:19	sociodemographic 93:4 94:5,17	specialties 10:20 134:17	spoke 236:7
278:15	socioeconomic 93:11	specialty 179:18	sponsored 216:15
simulated 221:8	soft 175:9 177:10 189:21 193:10	specific 39:9,16 59:18 104:11 129:22 172:21	sport 76:5,15 77:12,13 79:10 84:19 87:15
simulation 71:21	solo 128:22	175:22 249:21 257:2	spot 146:2
Simultaneous 28:1 50:14 81:18 82:8 83:7	solution 168:8	283:14 305:12 311:6	spotlight 208:4
83:10,13,21	solved 257:21	311:7,7,9 313:17	spread 137:20 185:8 187:13,22 247:5 286:19
sine 67:16	somebody 149:17 185:19 200:20 201:22	325:6 331:13 335:5 340:6	spreadsheet 255:21
single 38:13 157:11 173:16 185:13 190:18	259:13 273:13 292:3	specifically 13:9 132:10 193:15 195:13	spring 266:6
311:15	306:13 312:5 327:20 329:21	334:19	SSI 178:10 185:8 188:8 189:21 197:17 211:13
sinus 199:21	someplace 95:14	specification 107:14 130:14 160:1 200:8	St 129:9
Siperstein 2:17 25:17 26:2 45:15 104:11	somewhat 33:7 42:16 122:20 133:14 222:22	216:22 256:1 257:5	stacked 250:11
160:6 161:17,19	sooner 265:19	259:9 305:15 308:7	staff 3:1 8:14 19:13 107:4 154:21 209:11
166:15 167:4 257:11	sophisticated 279:17	325:4 335:18	230:11 236:8 324:12 345:19 351:15
272:13 282:20 283:16		specifications 75:16 91:10,12 107:12	staffers 135:18
284:7 328:11 347:17		150:1 165:18 166:4	stage 87:6 174:20 191:11 194:5
347:22		214:16 215:9 216:17	staged 193:19
sir 69:11		220:21 231:2,19	stamp 206:18
sit 119:12 278:4			stand 114:20 286:21 316:11
site 84:2,4 142:21 175:18 192:7 248:1			standard 38:6 98:18 101:2 133:10 165:1,2 166:21 173:13 188:5
255:20			
site-specific 79:16			

188:7,7 192:8,11,16
200:20 201:5 217:20
278:10 307:2 312:5
321:11
standardization 317:7
standardized 161:7,9
standards 282:9,16
302:12
standing 1:3,8 6:22
180:13 215:17 245:4
252:19 293:11
standpoint 88:6 95:6
158:5 209:10
stands 203:16
star 72:19,21,22 252:16
350:3
stars 72:22
start 8:21 11:8,10 14:18
51:5,9,18 86:11
102:12 153:18 181:5
200:17 208:10 244:21
245:17 289:4 291:7
292:12 329:21 341:16
started 6:5 58:15
205:13 265:16
starting 51:16 130:1
175:6 272:3
state 19:10 96:17
103:10 104:2,3,4
105:21 165:16 167:1
167:2,21 192:20
193:2 238:4 268:21
351:13
stated 17:8 143:17
178:5,9 200:19
statement 135:11 187:5
265:16 283:1 307:19
statement's 45:5
States 1:17 9:11 10:20
29:9 76:16 96:9
194:18 295:21
statewide 208:18
static 47:8
statins 32:2
statistic 121:15
statistical 82:11 161:5
statistically 17:22 18:1
138:3
status 16:8,21 19:15,17
19:21 20:5,7,11,21,22
21:4,19 22:3,12 24:11
33:9 38:10,19 41:12
42:8 43:7,11 44:5
45:16 93:4 94:14
112:20 114:13 133:5
140:14 141:2,3,18
160:15 179:1 209:4
212:10 301:12

stay 246:15 333:20
staying 128:16
stays 44:21
steering 132:18
stenosis 12:8
step 88:2
steps 268:1
Steps/Committee 5:20
sternal 71:11
stipulate 237:5
stood 291:1
stool 262:7
stop 80:21 81:10 160:4
177:6 191:3 218:6
237:10 259:3,6 318:8
stores 275:3
strata 283:9,10 284:5
286:6 331:15
strategic 7:14
strategies 344:8
strategy 205:10 299:6
344:19
stratification 204:18
205:6 274:17
stratified 197:8 299:19
330:9 332:1
stratify 203:16 204:5,16
287:22
streamline 341:5
Street 1:9
STREETER 3:7
strict 130:9 134:3
strictly 93:6
strides 315:4
strive 163:2 188:2
striving 195:17
stroke 71:12
strong 166:1 182:10
231:2,14 285:1
291:15 300:6
strongly 14:12 17:15
54:3 226:1 251:6
structure 168:2 242:22
244:6 248:3 260:18
structured 65:21
217:16,19 244:3
310:20
struggling 150:11,14
185:12 234:8 314:2
STS 4:9,10 9:5,8 10:14
11:8 12:17 19:10
24:21 26:18,20 37:22
67:5,5,22 69:6 70:22
76:19 77:19 98:22
99:5 103:3,14 112:17
205:13 213:12 301:8
STS' 7:17
studied 51:4 176:16

studies 54:7 178:12
185:6,7,13 190:17,19
191:1 197:20 202:14
211:9 290:20
study 55:13 59:4 60:1
145:8,10,13,17 176:9
187:21 192:17 198:20
246:19 262:9
stuff 212:4,6
sub-clinical 137:11
subclavian 12:8
subgroup 276:12
subject 305:5
submission 139:5
146:16 155:1,7
156:13 208:20 231:22
235:1 260:22
submissions 119:11
submit 226:8
submitted 34:6 142:22
198:11 210:17 214:16
216:7 217:4 227:12
submitting 210:5,10,11
231:21
suboptimal 274:14
279:4
subpopulation 156:22
subscription 134:9
subsequent 93:1
subsequently 32:21
313:14 339:15 340:20
subset 194:16 278:11
283:21
substantial 111:14
174:18 276:12
substantially 135:1
172:15
subtle 17:6 33:13
succeed 214:22
successfully 350:9
sucking 146:9
sudden 96:8
suffer 269:5
sufficient 116:19 268:9
271:11 345:10
sufficiently 227:14
300:6
suggest 17:2 31:20
33:6 40:15 41:18 51:7
166:6 281:18 294:9
306:21 320:7
suggested 49:19 249:8
324:5
suggesting 177:2
suggestion 233:7,8,20
287:14 288:1 347:20
suggestions 237:6,10
293:7 298:19

suggests 18:5 31:21
suitability 10:1 30:21
31:3,8 53:4,7,12
70:11,16 108:17,21
119:20 120:1,5
127:19,22 128:9
159:3,7 170:8,10,14
233:11 245:16
suitable 75:8
sum 78:19,21
summary 110:16
sunset 22:2,4 33:11
41:10,17
superficial 147:14,15
superiority 13:5,21
supplied 249:19
support 18:6 67:11
87:22 88:3 184:10
202:14 255:3 264:1
279:22 292:1,16
301:14 311:4 317:3
318:1,5
supported 21:9 39:16
206:16 249:15 299:6
supporting 13:8 253:4
supportive 99:8
supports 184:10
253:18
suppose 228:9
supposed 24:19 120:11
234:7 237:15 262:6
supposition 226:22
253:10 261:19
sure 9:1 14:17 17:5,22
22:14 24:13 31:15
50:11,20 51:2 57:17
62:7,8 67:12 69:10
79:12 86:4 99:1
153:15 162:22 180:15
210:14 215:14 239:11
264:7 266:21 279:21
292:8 297:12 311:22
314:7 318:21 324:9
336:4 339:6,17
surgeon 1:21 4:7 39:5
70:22 75:19 77:7 79:9
79:17,22 80:16 81:10
82:19 87:17,18 88:8
95:18 106:3 129:9
171:3 179:13 193:21
200:19 201:4 263:4
314:21 315:1,22
surgeon's 85:10 90:6
263:15
surgeon- 82:21
Surgeon-in-Chief 2:8
surgeon-level 76:16
83:5 84:17 85:6 93:2

surgeons 3:11,14 4:13
4:15 17:10,11 22:20
50:16 72:10 74:17
79:20 83:3,9 86:3,9
88:2 91:16 96:5,21
98:15 102:4 104:13
106:1 129:4,11
132:14 133:20 135:12
142:2,9 173:3 174:13
175:13 180:2,9
191:18 192:3 201:2
204:2,8 254:12,15
256:7 287:19 315:5
surgeons' 87:21 261:17
Surgeons/Professor
2:2
Surgeons/UCLA 2:3
surgeries 251:6 253:17
287:8 296:7 321:15
322:21
surgery 1:3,14,19 2:2,3
2:16,17,18,21 3:11,15
3:16 4:8,12,14 9:3,10
11:2,3 12:3,9,20,22
15:19 17:15 21:13
29:9 31:22 32:9 34:11
34:14 51:10 58:6,14
58:19 59:9 60:18
61:14 71:1 72:16 76:4
76:15 81:16 87:14
99:4 104:3 112:9
129:3 136:7 140:17
140:20 141:13 146:5
151:12 152:10,21
159:12 160:13 166:8
168:5 173:15 175:11
177:7 200:22 203:6,8
209:3 216:3 218:2
250:2 252:2 254:7
255:10 258:8 259:1,3
262:14 263:18 269:22
271:20,21 274:14
275:7 279:2 281:19
285:6 290:3 291:6,8
291:12,14,14,16
292:10,12 306:20
307:10,13 308:15
339:22
Surgery@qualityforu...
340:3
surgical 1:15 5:15
10:16 11:21 109:19
112:10 129:13 134:17
142:20 175:18 192:6
194:17 248:8,10,13
252:4 268:13 271:19
274:19 275:8 281:15
287:18,20 288:19

290:15,16,18 294:8
294:12 297:4 314:17
331:12,14,18 343:17
surgicals 289:2 323:3
surprise 214:10
surprised 86:13 256:7
surprising 207:18
surveillance 137:8
survey 135:21 258:21
300:16 302:16
survival 13:8 32:5
44:20
survive 73:18
suspect 221:20
sustain 173:13 175:18
swamp 147:16
symptoms 190:1 327:2
synergistic 31:22
synthetic 221:21 222:2
225:20 232:1 243:19
system 9:21 51:9
129:10 151:13 176:4
193:18 217:12,13
257:17,19 260:15
334:9
systematic 305:10
systemic 236:5

T

T 2:15
t's 67:12
table 8:6 77:12 170:22
tackling 186:22
tail 32:19
take 7:13 17:4,21 22:20
23:18 28:4 44:20
50:18 64:1 73:10
78:18,21 79:8 106:2,3
128:11 135:4 141:9
146:18 171:1 175:1
178:1 198:18 199:19
200:22 204:21 250:15
254:22 256:13 272:11
286:14 324:7 325:17
340:13 346:3,12
348:9
taken 61:18 106:5
202:3 203:7 236:13
takes 50:4 79:13 88:7
205:14 318:7 327:15
talent 87:21
talk 75:18 90:10 135:7,9
140:3 179:2 181:11
190:13 202:9 207:5
210:12 211:3 215:19
239:16 240:9 253:1
287:4 333:10
talked 16:2,13 21:7

33:8 46:15 98:22
322:11 330:3
talking 7:6 43:19 47:8,9
65:5 86:21 134:14
142:18 145:4 161:13
172:8 202:4 213:12
229:5 230:13 234:6
239:7 240:8,16 251:7
251:14 252:8,9
296:10 316:20 335:22
336:9,16 337:1,10
338:1
target 251:7
task 11:3,7 35:8 182:8
team 76:4,15 77:12,13
79:10 84:19 87:15
88:8,10 229:16
280:10,12 351:16
technical 247:18
259:18 287:13 324:20
335:17
technically 192:11
technologies 344:7
technology 215:11
217:11 313:18,19
teleconference 3:22
tell 144:12 156:12 202:5
207:16,20 251:3
254:11 271:14 310:4
341:7,12 347:9
telling 202:1
Temple 2:18 106:21
107:5 160:6,8,12
161:14 162:12,13
163:4,15,20 164:18
167:16 169:15 223:14
224:4,7 238:10 239:7
239:12 253:9 254:19
275:18 277:6
ten 147:21 149:5 186:5
244:20 283:11 300:5
ten- 141:22
ten-minute 128:12
tens 142:1
TEP 340:13
term 13:13 32:3 71:5
183:14,14 191:22
211:15 256:12 348:19
348:19 351:3,6,6,7,8
351:10,12
terms 16:15,18 32:4,14
33:12 41:4 46:18
59:17 65:13 67:10
78:11 84:15 91:14
93:14 95:11 131:11
132:10 133:15,19
140:4 141:20 142:4
147:1 151:7 155:3

171:21 174:8 175:12
175:15 181:17,20
186:15 187:8,9
191:16 198:19,22
204:11 221:6 227:17
228:2 249:14 262:14
268:17 269:10,21
271:13 272:5 280:21
281:14 290:12 296:12
306:5,8 308:2 313:12
315:18 329:21
terribly 173:1
terrific 169:1 213:20
test 125:20 217:9 218:5
219:10 221:9,22
222:1,2,4 224:3
225:20 230:8 232:1
239:2,5,22 244:1,7
251:2 256:10 315:16
317:21
tested 115:10 139:1
223:4 226:11 232:6
testing 5:8 40:1 91:14
110:13 138:20 142:21
155:1,4 190:16
197:19 207:3 218:3
218:16 219:1,18,21
220:4,6,15 221:7
223:5 224:10 225:3
226:5,9 227:3,3,11,14
228:18 229:10 230:6
234:18,20 235:5
238:17,22 239:9
240:9,18 241:19
243:6 244:10 247:10
247:15 248:15 250:21
256:12 269:10 288:15
289:20 294:20
tests 149:2 256:14
262:9
thank 6:6 7:2 8:14 9:1
11:5 14:2 17:18 18:8
19:12 23:7 24:8 26:1
31:10 33:15,18 37:2
51:21 65:1 66:10 68:5
69:15 72:17 73:4 77:4
78:6 82:3 88:4,5 97:1
100:19 102:20 107:17
109:2 115:6 128:15
128:15 129:7,8
143:16,19,20 146:6
147:4 149:19 152:7
153:7 155:14 157:18
160:21 165:9 166:11
168:12 169:1 170:17
184:16 201:9 209:11
213:15,21 224:7
246:8 249:2,3 257:3

260:2 264:2 265:8
 266:16 267:12 268:3
 272:7,8,10 274:19,20
 282:1,2 288:2,13
 297:16,19 310:17
 312:10 319:2 320:6
 322:5 332:12 341:17
 344:22 350:2,8
 351:15
thanks 25:13 128:14
 148:3 297:15 301:20
 339:19 351:20
themes 86:20
theoretical 93:19 95:6
theoretically 40:20
 44:16 60:11 238:14
therapy 11:12 55:10
 250:16 270:14 281:19
thereabout 295:13
thereof 32:13
thing 16:20 17:10 20:19
 26:21 41:6 46:12 47:3
 60:16 61:21 68:1
 74:22 82:6 88:1
 105:18,20 135:7,8
 140:18 176:18 178:17
 179:20 180:6 187:20
 204:13 206:4 209:9
 211:3,14 234:16,17
 266:22 270:21 310:20
 311:21 314:12 331:9
 341:13 348:17
things 16:13 26:20
 38:12,14 41:9 46:21
 66:7 68:2 77:14 83:4
 83:16 86:13 94:20
 96:14 102:19 103:3
 103:11 105:13,15
 107:18 114:4 119:18
 140:6,15 141:17
 147:14 153:17 168:13
 173:11 180:14 181:6
 186:8 190:1 202:9
 208:11 210:18 221:19
 222:17 225:9 234:7
 237:17 241:14 243:9
 254:12 269:3 271:3
 273:8 287:10 299:15
 303:13 308:18 309:3
 309:9,14 317:18
 321:4 322:11 323:22
 326:6,7
think 7:11 8:1 13:20
 16:17 17:13 18:10,12
 19:13,16 20:16 24:20
 25:1,4,17,19 33:11,16
 37:11,21 38:2,7,9
 38:14,16,16 39:3 41:3

41:7,14,15,21 43:9,20
 45:22 46:1,4,18 47:13
 47:20,22 51:3 53:20
 54:2 56:1,10 59:21
 63:14 67:14,22 68:9
 68:17,19,20 69:2,8,12
 73:15,22 74:16 75:15
 79:11 83:3 86:7 88:1
 88:7 89:18 90:12
 91:10,17,20 94:3,6,15
 95:1,5 97:22 100:2,20
 102:5 104:7 105:14
 106:19 111:1 112:11
 119:7 124:14 135:6
 135:14 136:4,5,8
 138:20 140:2 142:4,8
 142:15 143:16 145:7
 150:2 155:16 160:8
 161:15 164:22 166:3
 166:19 167:16 169:15
 171:18 172:19 176:18
 178:13 179:2 180:4
 183:22 186:10 188:9
 191:5,7,10,11,17
 192:9 194:21 196:18
 200:15,16,17 201:1
 202:21,21 204:12
 205:3,9 206:4,9 207:5
 210:8,15,19 211:11
 211:18 212:8,9 213:4
 213:20 214:10 224:16
 225:7 228:16 232:5
 232:12,18 235:21
 237:1,19 241:7,14,19
 242:5 244:1,7,12
 249:5 250:9 253:13
 253:14 255:7 258:16
 259:15 268:7 269:13
 269:14 271:6 272:1
 272:19 273:1 276:1,8
 276:11 277:10 281:7
 282:3,7,14 286:9
 290:11,12 291:14,18
 292:14 293:13 294:6
 294:12 300:14 301:22
 302:14 303:8,10
 307:18,20 308:1,8
 310:18 311:10 313:7
 314:4,8 317:9,14
 324:2,3,4,6 325:16,20
 326:8,19 329:9,10,14
 329:14,18 330:3,4,9
 330:14 331:4 332:7
 332:14 334:16 335:14
 338:21,22 339:21
 341:2,12 345:16
 346:7 347:10 348:2
 349:17

thinking 41:16 45:19
 60:7 86:22 201:2
third 105:20 180:6
 202:7 216:18
thoracic 1:21 3:11,15
 3:16 12:9
thoracical 307:3
thought 9:6 32:4 59:14
 86:6 93:2 172:19
 186:12 195:15 207:17
 227:21 341:4
thoughtful 198:5
thoughts 36:2 250:3
thousand 205:13
thousands 44:14 142:2
 186:6
threat 228:18
threats 197:21
three 9:21 10:22 11:1
 37:10 72:8 85:13
 105:15 113:11 115:9
 120:9 121:17 124:8
 129:5 133:3 151:19
 171:1 172:14 178:12
 181:6 185:7,12
 189:15,20 190:2,4
 211:17 222:17 223:1
 234:10 237:6 238:18
 243:3 267:17 270:5
 288:7 295:1 298:10
 298:11 302:3 306:19
 312:14 319:7 323:9
 340:16 342:2,17
 349:7,9 352:5
three-hour 73:10
three-year 21:12
 110:12 189:11 219:21
 351:6
threshold 5:12 139:8
 139:11 280:3 298:22
 306:3,4 326:10,21
 327:10 329:21
thresholds 280:2
 305:21 310:10 311:7
 314:6 333:12,18
throughput 100:11
throw 81:1 96:11 149:6
 330:7
throwing 103:21
thrown 121:21 249:6
Thursday 350:13
tibia 4:16 172:4 183:6
tibial 170:21 171:7
 172:1 173:18 175:22
 176:1 178:4
tie 256:9
time 6:6 20:12 32:16
 36:13 38:13 41:12

42:20 44:18 50:9,11
 58:7 61:22 68:9 70:9
 78:18 80:10 96:17
 99:17 101:8 116:6,7
 120:10 128:5 130:9
 132:3 134:3 144:13
 144:14,16 152:15
 172:18 177:16 178:1
 189:8 195:19 204:3
 204:20 213:21 218:14
 218:15 220:9 223:17
 225:15 226:5 230:14
 240:2 246:21 248:20
 249:21 250:14 251:8
 252:21 254:17 255:11
 257:17 260:16,21
 262:17 263:1 264:10
 264:11,13,18 268:16
 269:22 273:9,17
 276:5,22 281:9
 289:15 292:11 293:2
 296:12 318:2 321:16
 324:2 329:2 331:4,5
 334:10 335:12 341:11
 344:14 350:2,7
Timeline 5:20
timeliness 322:17
timely 248:9 249:12
 253:6,7 258:9 343:18
 348:19
timely-enough 250:13
times 20:12 144:3,3
 217:7 307:2
timing 120:13 175:10
 177:6 191:9 258:17
 259:9 261:13,18
 263:17,20 273:5,21
tired 308:22
tissue 177:10 189:22
 193:11
tissues 175:10
title 178:3 249:6
today 6:18 7:18 10:12
 10:21 54:14 55:7
 109:7 129:12 130:2
 131:3 165:1 171:12
 173:14 210:4 223:19
 223:22 230:13 234:1
 236:14,17,18 251:9
 320:20 323:22
told 23:18,21 221:17
 223:17 338:19 346:20
tool 221:12 310:21
 316:4
tools 318:1,5
top 46:17 118:12,14
 199:14
topic 21:15 211:12

212:9 213:14
topics 211:18
topped 19:22 20:13,14
 23:14 25:5 32:15
 35:18 41:7,11 42:22
 45:10 65:6
topped-out 37:15,16,18
tossed 136:17,18
total 78:19,21 100:10
 185:14 264:22 296:2
 314:19,20 315:6
touch 9:22 10:21 89:14
 90:14 206:10 351:9
touched 7:4,10
tough 15:1
town 95:13 258:19
track 26:19 47:1 79:22
 107:21 174:13
tracked 79:17
tracking 88:17 168:10
 173:9
tract 148:13,22
tradeoff 134:6
traditional 242:3
trail 235:10
trained 131:15
training 172:1
trains 8:3
transfer 64:21
transfuse 278:7 279:12
 296:19 306:17 321:22
 334:6,9
transfused 178:22
 251:8 281:20 283:21
 285:5 300:3 303:7
 314:6,22 315:1,19
 318:15 345:21
transfused/not 178:22
transfusing 279:18
 282:12 299:7 300:18
 304:5 315:6
transfusion 5:11
 246:10 249:1 250:10
 257:18 258:12 268:19
 269:15 271:1,9 274:6
 274:12,16 275:8,9
 278:16 280:3,3,5
 281:13 283:8 287:21
 289:20,22 298:22
 299:2,4,6,10,13,17
 300:12,13,20 302:8
 303:4 304:2,10,11
 305:3 306:10,14,22
 307:1,15,19,20 309:2
 309:19 310:9 314:5
 316:7,12 318:6,9,19
 319:1 322:13 326:2
 326:22 327:4,9

329:17,22 330:2,10
 330:11,21 331:21
 332:16 333:3 344:4,8
 344:16 345:5
transfusions 257:15
 258:4 275:11 300:8
 302:20 309:11 312:3
 328:2,20 329:12
 332:22 343:21 344:14
 344:18
transitioning 216:15
 224:20
transparent 115:2
 155:8 157:10
transplant 151:11
trauma 3:9 4:17 149:12
 149:12,13,15 150:18
 150:20 151:1,5,22
 152:4 171:3,5 173:8
 175:7 180:1,2,17
 181:18,20,21 186:22
 187:18 188:1 192:21
 193:8 194:18 202:3
 203:6 287:7 303:15
 303:18
traumas 150:19 151:2
 151:13
traumatic 286:2 328:7
traumatologists 204:20
treat 173:4 194:7 201:6
treated 147:11,22
 271:16 274:1
treating 11:13 269:21
treatment 176:3 177:11
 202:10 271:18 275:2
 345:6
trend 47:3
trial 54:8,12 177:2
 207:5 216:5 218:11
 218:12 219:4,7,12,16
 220:5,10,18 221:1,4
 222:12 225:8,12,13
 225:16 227:10,16
 228:3,7,12 229:11
 230:5,19,22 231:11
 234:2,9,17 235:18
 239:20 240:17 241:18
 242:10 243:11 247:7
 261:8 266:12 323:14
 334:21 349:18
tricuspid 109:18
tried 85:8 210:19 211:2
trigger 107:14 306:13
 306:17 307:8 326:2
 329:16 333:14
trouble 345:8
troubles 253:10
true 15:20 18:13 29:7

55:10 67:19 117:16
 134:8,18 135:1 147:6
 150:1 211:15 262:2
 275:13 313:19
try 36:20 55:9 96:20
 195:17 212:8 244:11
 284:16 309:6
trying 36:17 66:3 174:9
 188:4 193:3,3 214:20
 225:2 234:12 256:9
 269:12 271:4 278:9
 282:4 295:5 307:4
 309:6 322:18 341:4
turn 133:7 238:11
 320:19
turns 327:9
tweak 335:2
tweaking 293:3
tweaks 340:8
twice 131:1
two 7:16 11:17 46:21,22
 53:20 54:1 55:6 58:15
 58:15 59:7,7 64:6
 72:22 75:10,11 84:22
 85:11 86:6 101:17
 102:19 109:3 110:1
 113:11 116:6 121:11
 125:7 126:5,12 130:1
 131:3 145:3,7 149:19
 155:17 164:21 168:13
 181:10 189:18 190:17
 190:22 194:12 197:20
 208:17 211:9 221:20
 222:21 227:3 254:12
 256:8 258:22 267:16
 270:5 271:3,5 274:10
 288:6 294:22 295:12
 296:6 298:9,11 306:8
 310:16 312:13 319:7
 323:9 332:18 342:2
 342:17 349:6,8
 351:22 352:3
two-and-a-half 94:9
two-minute 128:21
two-thirds 315:13
two-year 351:6
type 5:7 93:15 119:2
 175:22 264:14 288:15
 288:20,20 289:3,3,5,5
 290:6,6,13 291:4,12
 291:17 292:3,8,9
 293:1,1,16,16 294:2,2
 296:3 318:17 346:16
types 38:1 105:10
 199:14 204:11 277:11
 302:3 309:9,14
typical 85:10 99:12
 191:22 325:13

typically 107:11

U

U 129:9 187:22
U.S 186:3,6 192:21
 247:4,5 269:19 271:8
 272:6
UCLA 2:3,15
ultimate 277:15
ultimately 292:21
ultrasound 262:21
un- 292:4
un-cross-matched
 290:4 296:19
unable 226:4 227:13
unanticipated 130:6
unavailable 13:1
unavoidable 344:15
unclear 324:3,4
uncomfortable 87:19
 118:11
uncommon 59:3,10
uncorrected 248:21
 274:15
undated 304:9
undergo 12:12 32:9
 306:19 307:3
undergoing 12:5 136:7
 253:14 274:14 328:6
underlying 97:20
 301:12 332:20
underpinning 93:19
understand 17:3 33:13
 37:6 99:16 114:3
 119:12 152:18 155:8
 158:7 166:1,18 173:5
 176:15 189:14 197:12
 200:11 207:19 230:15
 238:21 251:12 257:2
 257:14,15 277:19
 278:9,12 283:17,18
 284:8,11,14,21 302:7
 325:15 331:8 341:9
understandable 327:13
understanding 58:4
 93:7 153:15 164:22
 178:21 257:12 285:9
 316:3 324:17 325:1
 335:16
understands 17:6
understood 166:19
 333:7 337:14
undertaken 344:3
underway 247:4
underwent 109:17
underwrite 69:7
underwritten 67:7
undesirable 275:11

undoubtedly 75:21
unequivocal 270:21
unexpected 328:22
unfortunate 76:17
unfortunately 41:21
 231:7 246:18 346:22
uniformly 143:12
unintended 50:6 51:12
 60:5,12 80:14 104:12
 144:4,9 237:18 241:4
 242:6,11 250:18
 262:4 279:14 290:5
 293:15,22 303:3
unique 134:7 150:6
 165:12 286:5 310:19
uniquely 150:12
unit 289:22 292:4
 299:13,18 309:18,19
 318:14 322:19
United 1:17 9:11 10:20
 29:9 76:16 96:9
 194:18 295:21
units 79:2 279:12
universal 292:16
University 1:12,16,19
 2:11,16,22 3:18 9:4
 171:4 294:17 314:16
 316:13 317:4 334:1
unknown 148:19 198:1
 198:3,3
unnecessarily 294:11
unnecessary 250:10,20
 275:10
unreasonable 191:7
unrelated 64:12 99:7
unrisk- 201:22
unrisk-adjusted 203:2
unstructured 65:20
 217:18
unsuitable 13:2
unusual 40:8
unweighted 147:5,10
 148:2
up/down 161:3
update 107:9 209:16
updated 34:8 184:1
 295:17
uploading 67:9
UPMC 317:4
upper 172:3
urban 95:10
urgent 246:18
urinary 148:13,21
usability 30:4,8,13
 52:17,18 69:22 102:3
 103:17 106:18 108:4
 108:9 117:17,19
 118:2 126:18 127:9

127:14 156:11 158:12
 158:14,19 169:14,20
 170:3 221:2 237:16
 242:21 243:18 245:15
 342:15,16,21
usage 5:14 299:10
 327:4 343:14,16
use 4:3 11:12 12:2,15
 12:17 13:2 17:11
 18:10 19:1 23:22
 24:19 28:11 30:8,13
 31:21 32:22 40:7
 52:16,18 64:6,14
 69:22 75:8 78:22
 86:17,18 102:3,3
 103:5,7,8 106:17
 108:4,9 113:18
 117:19 118:2 127:9
 127:14 130:3 156:10
 156:18 157:2 158:12
 158:14,19 159:18
 160:16 169:14,20
 170:3 174:9 192:18
 193:18 194:5 207:5
 207:20 216:5 218:1,9
 218:11,12 219:4,7,12
 219:16 220:5,10,18
 221:1,2,4 222:6,12
 225:8,12,14,16
 227:10,16 228:3,7,12
 229:11 230:5,22
 231:11 234:9,17
 235:10,18 237:16
 239:3,6,21 240:18
 241:18 242:10 243:11
 243:18 245:15 247:7
 261:8 266:12 274:13
 276:19 310:2,8 311:2
 311:8 317:3 323:14
 329:2 342:14,15,16
 342:21 344:6 348:18
 348:19
useable 133:22
useful 24:2,3 45:6
 232:5 285:17
user 86:18
users 132:1
uses 196:18 246:17
 306:1,1
usually 107:3 216:15
 239:16 274:1 331:5
UTI 146:20,20
utilization 47:5 208:7
 277:20 278:1,5,13
 282:10,18 284:2
 300:11 309:8 318:3
utilize 289:19
utilizes 294:5

UTIs 149:22 164:19

V

VA 130:22
vac 208:7
vacuums 202:8
vaginal 297:22
valid 28:10 76:21 79:22
 80:5 85:5 116:9 142:7
 142:10 196:19 235:14
 338:16
validated 97:22 310:6
validity 28:7,19 29:2
 39:3,12 49:10,15,18
 52:7 62:20 90:11
 92:11 97:5,10 110:19
 115:20 116:4,12,17
 118:8,8 119:1,2,4,6,7
 119:8,18 125:6,9,17
 131:12,14 132:10,12
 132:19 133:1 140:1
 140:21 141:6,20
 142:4,14,15,18 144:7
 153:12 154:8,10,14
 164:12 165:4 167:4,7
 167:11 176:6,14
 179:3 181:12 196:14
 196:15 197:19,21
 208:12 209:10,14
 210:3 211:3,19,20
 212:1,2,2,13,18,22
 224:5 228:18 234:20
 237:20 240:9 242:21
 330:12 338:17
valuable 318:15 332:8
value 2:9 134:7 198:14
 237:20 252:4 257:14
 257:15 284:4 297:2,9
 303:5 312:7 332:4
 334:3
values 113:20 190:22
 259:21 286:20 299:12
 299:20 300:20
valve 4:9 69:2 71:3,4,14
 99:12 109:12,14,17
 109:18 112:9 121:4
variabilities 198:22
variability 22:18 25:21
 74:19 204:5 314:21
 315:3,3 334:15
variable 37:12 55:5
 59:12 60:3 82:22
 173:12 237:8 326:13
 346:4
variables 59:17 132:2,4
 141:16 143:10 175:11
 209:5 341:9 346:15
variance 131:7,7
 161:12 173:22 314:11
variation 87:20 178:10
 204:4 314:9 326:16
 326:18 334:12
varies 134:10 161:1
variety 134:17
various 133:1 163:16
 315:16
variously 15:14
vary 161:10 217:18
 304:20
varying 134:12
vascular 2:16 261:17
 261:22 263:9,15
 268:14
vehicle 55:4
vein 13:6,16 22:22
vendor 217:14
Venn 200:17
venous 141:3
ventilation 71:11 73:21
verified 195:3
verify 99:18
versus 24:22 41:15
 59:7 65:3 75:11
 122:21 141:7 143:1
 144:22 150:19 155:18
 180:1 193:15 202:11
 227:5 277:11 330:10
Veterans 1:14
vett 90:11 224:13
VI 183:4
Vice 1:15 2:4,20 3:2,3
 129:10
view 87:14 90:5 184:4
Vinay 3:10 9:2
Virginia 9:3
virtually 248:17 273:1
VIs 182:21 183:1
visible 157:10
vision 81:8
visit 137:8 273:18
visited 254:15 261:1
 317:8
visits 248:1,5
Vitamin 256:16
volume 15:16 78:3
voluntarily 10:19 25:6
voluntary 210:6 212:5
volunteer 156:20
vote 15:4,7 18:18,20
 19:15,19 20:5 24:12
 26:8 27:1,16,18 28:3
 28:4,17 30:21 35:15
 48:2 49:5,6 52:1,2,7
 52:14 53:1 56:3,16
 62:4,6 63:3,4,5 66:12
 70:3 74:5 83:14 88:20

89:6 90:19 91:21 98:4
 101:11 106:17 108:2
 111:1,18 113:5
 115:14 117:1,5
 119:21 122:5 123:1
 125:11,13 127:19,20
 136:9,12 137:14
 138:6 139:13 154:7
 155:21 160:11 161:22
 164:1 167:5 169:3,18
 185:16 196:2 220:14
 220:19 233:2,10,10
 233:19,19 235:9
 236:10,14,19,20
 242:4,17 243:3,4,9,10
 243:14 245:8,11
 266:18 271:11 288:3
 298:4 319:4 321:1
 337:15 338:20 340:15
 342:6 343:4,5,8
 346:11 347:14 348:5
 348:5,9,11 349:1
 350:18
voted 20:3 26:9,9,10
 27:9,10 29:3,4,22
 30:1,1,14,15,15,16
 31:9,9 48:11,12,12
 53:13,13 57:3,3,4,4
 62:17,18,18 66:22
 67:1,1 70:17,17 74:13
 74:14 89:11,11 91:5,5
 92:7,8 97:11,12 98:11
 98:12 101:21,21,22
 101:22 108:10,10,11
 108:22 109:1 111:8
 112:4,4 113:14,14
 116:1,2,18,18,19,19
 117:13,13,14,14
 118:3,3,17 120:6,7
 122:11,12 123:9,9,10
 123:10 124:5,5 125:3
 125:3,22 126:1,16,16
 126:17,17 127:4,5,5
 127:15,15,16 128:10
 128:10 138:14,15
 139:20,21 154:15,15
 154:16 155:2,9 156:7
 156:8,8,9 158:20,21
 159:8,9 162:8,9,10
 164:9,10,10,11
 167:12,12,13 169:11
 169:12,12,13 170:4,5
 170:6,16,16 185:2,2
 188:20,21,21,22
 196:10,10,11,11
 212:22 213:1,2
 267:20,20,21,21
 288:10,10,11,11

298:15,15,16 312:18
 312:18,19,20 319:12
 319:13,13,14 323:15
 323:16,16,17 336:17
 336:20 337:5,22
 338:2,3,5 342:11,11
 342:12,12,22 343:1,1
 343:2 349:13,13,14
votes 19:11 26:6 27:7
 29:1,20 30:12 31:6
 48:9 53:10 57:1 62:15
 66:20 70:14 74:11
 89:6 92:5 97:9 98:10
 101:17,19 108:8,20
 111:6 112:2 113:12
 113:12 115:21 116:16
 117:11 118:1,13,14
 120:4 123:7 124:3
 125:1,13,21 126:12
 127:13 138:12 156:5
 158:18 159:6 162:6
 164:7 167:10 169:9
 170:2,13 184:22
 188:18 196:8 267:18
 288:8 298:13 312:16
 319:10 323:12 342:6
 342:20 349:11
voting 19:1,2,4,8 24:14
 26:5,7 27:2,6,8 28:18
 28:22 29:2,15,19,21
 30:7,11,13 31:2,5,7
 36:6,7 48:3,4,8,10
 53:6,9,11 56:17,18,22
 57:2 62:10,14,16
 66:15,19,21 70:6,10
 70:13,15 74:7,10,12
 88:22 89:4,7,9 90:20
 91:2,3,22 92:4,6 97:4
 97:8,10 98:5,9,11
 101:12,16,18,19
 108:3,7,8,14,16,19,20
 111:2,3,5,6,19 112:1
 112:2 113:6,10,12
 115:15,19,22 116:11
 116:15,16 117:6,10
 117:11,18,22 118:1
 119:22 120:3,4 122:6
 122:7,9,10 123:2,6,7
 123:20 124:2,3,16,18
 124:22 125:1,12,16
 125:22 126:6,11,13
 126:14,20 127:2,3,8
 127:12,13,21 128:7
 138:7,8,11,13 139:14
 139:18,19 154:9,12
 154:13 155:22 156:4
 156:6 158:13,17,19
 159:2,5,7 162:1,2,5,7

164:2,6,8 167:6,9,11
 169:4,8,10,19 170:1,3
 170:7,9,12,14 184:12
 184:15,18,19,21
 185:1 188:12,13,17
 188:19 196:3,7,9
 212:17,20,21 220:17
 265:10 267:14,15,18
 288:4,5,8 298:7,8,13
 311:19 312:11,12,15
 312:17 319:5,9,11
 320:12,12 323:7,11
 323:13 341:22 342:8
 342:9,15,19,21 343:8
 346:22 348:13 349:2
 349:3,10,12
Vs 182:21,21,22
VTE 130:13 133:18
 146:19 159:22

W

wait 208:13,13 256:8
 303:5 306:14 321:20
 327:19 348:14
waiting 273:17
wake 120:16
walk 308:22
wall 47:10
want 6:5 8:8,14 14:14
 14:18 19:10,14,14
 21:14 22:17 23:2 25:7
 25:16 36:16 38:13
 44:20 45:3 49:13
 55:22 57:15 70:3
 77:10 78:2 83:3,9
 86:12 87:4 91:7 99:6
 101:8 104:1,6 106:15
 114:10 115:1 134:2
 141:12 142:13,14
 146:1,8 148:8 149:10
 153:14 155:7 160:11
 162:15,21 171:8
 178:16 180:14 181:14
 194:11 202:10 206:6
 207:15 208:9,17
 215:19 218:1 219:2
 222:16 227:7,9,17
 228:21 230:15 232:14
 233:2 243:16 253:20
 254:16 265:8 271:10
 271:22 272:12,13,20
 273:11,22 274:1,4,21
 275:16 277:16 281:12
 284:5 285:13 286:7
 290:8 291:22 292:2,8
 293:18 305:3 318:11
 324:7 328:8 330:17
 333:9 340:7 344:16

346:10 350:20
wanted 19:13 20:19
 22:22 76:20 85:4,7
 87:3,13 93:5 95:2
 171:16 182:14 186:20
 247:9 261:12 264:8
 264:19 276:13 280:20
 309:13 350:12
wanting 37:6 187:8,9
wants 81:13,13 83:3
 101:7 242:11 291:21
warning 128:21
WARREN 213:22
wash 129:9 174:17
washed 193:14
Washington 1:9
washouts 193:9,10,19
wasn't 135:19 211:5
 249:13
waste 37:6
wasting 341:11
watched 248:2
Waters 3:17 246:6
 264:5,8 280:12 286:8
 286:9 294:7 295:14
 295:18 296:4 311:21
 312:1 314:15 327:14
 333:22
Watt 3:18 229:15,15
 246:4 324:14 325:15
 335:14 338:1 339:19
way 41:14 45:11,17
 51:4 60:4 72:20 75:12
 75:13 76:21 77:2
 79:13 82:16 86:13
 88:7 96:15 100:13
 112:18 134:1 143:17
 149:4 150:3 152:2
 155:9 162:18 163:14
 164:20 173:12 175:2
 177:3 187:16 204:12
 205:1 210:15 212:13
 216:9 217:16,17
 224:11 236:8 242:17
 242:22 244:3,12
 251:21,22 257:7
 268:7 271:12 276:14
 284:8,18 294:6
 307:15 310:15 317:17
 330:15 332:1 335:19
 339:12,16 340:8
 342:7 345:22
ways 60:21 64:18 216:9
 251:22 261:3,5
 298:20 330:13
we'll 7:13 8:18 10:21
 11:8 12:1 25:10 28:2
 32:20 35:15 37:17

41:15 50:1 52:6 63:2
63:3 69:8 117:4
119:10,13,14 120:11
129:20 137:15 138:6
153:10 159:10 171:20
179:2 181:11 183:14
200:22 204:3 205:5,7
236:13 242:2 245:17
245:17 248:4 252:12
252:13 262:5 293:7
314:4 321:1,4 339:19
343:10 350:4,17
we're 10:12 13:20 14:1
17:5 22:4 24:12,19
25:13 41:16 47:8,9
53:3 57:20 63:8 64:15
65:18 82:4 86:8,10
101:1 104:18 106:18
107:19 113:17 114:9
120:10 122:7 128:5
130:1 134:3 136:2
142:10,11,11 150:21
153:12 161:13 174:9
186:8 193:2 201:15
230:8 232:8,9,13
234:6 237:15 238:16
245:7 246:5 251:6,11
252:7,8 269:8,10,13
269:17 271:2,3 272:4
273:14 277:15 280:8
289:7 295:5,10,17
296:11 299:17 315:15
320:12,12 329:10,12
334:17 336:5,22
340:16 341:3
we've 9:13 17:13 21:6
24:7 25:2,21 45:14
53:22 64:12 84:22
85:8 86:6 91:18 93:12
94:8 100:2 102:21
103:9,11 120:21
131:1 132:21 138:20
147:18,20 150:7
155:16 163:8 225:4
229:18 233:20 234:6
235:6 282:12 301:17
309:7,22 310:1,20
314:17 315:4 334:1,2
341:3 347:18
weakness 203:17
website 190:9
WEDNESDAY 1:5
week 60:16 120:22
weeks 55:6 58:15 59:7
270:6
weight 97:19 149:7
weighted 72:14 80:4
147:1,3,22 149:4

weighting 90:8 93:14
98:1 149:8 150:9
165:10
weights 92:14 97:21
welcome 4:2 6:16 8:10
153:9 214:2 349:21
well-documented
13:11
well-performing 47:1
went 7:15 16:2 115:4
128:18 173:14 191:6
202:22 225:18 245:1
260:4 271:11 280:22
352:7
weren't 289:16
West 9:3
whatnot 310:5
Whitaker 2:19 6:12,13
152:6,7,18,21 153:7,9
237:15 250:6 252:22
253:6 274:22 282:3
287:3 289:13 292:19
300:2 313:3 318:12
319:19 320:1,6 321:7
322:4 332:3 341:19
344:22 346:12 352:4
352:4
wide 95:19
widely 130:17 132:21
wider 45:20
widespread 214:12
286:16
wild 232:11
William 1:9,13
willing 320:15
WILSON 3:3 18:19 42:3
win 96:6
window 219:21 254:8
260:1 263:1 264:9
Wisconsin 103:15
wish 68:2 109:22
112:16
Witness 307:7
women's 3:17 286:13
wondering 93:20 141:5
238:15 331:18
word 197:11 315:3
words 15:16 19:16
145:5 219:22 225:8
228:8
work 8:15 25:14 65:19
94:10 103:7 104:2
129:14 148:19 158:8
204:10 213:6 225:10
248:2 250:16,17
263:2 268:22 324:11
work-up 262:12 318:16
worked 129:13 193:8

302:18
working 64:9 79:9 94:8
182:12,15 208:22
247:13 286:17 311:6
323:22 333:21
workload 85:10
works 64:4 164:20
worksheet 56:8
world 188:1 215:14
218:17 268:15 272:3
303:21 307:21 333:11
worried 334:18
worry 95:13 96:20
277:13,14 330:17
worse 74:18 203:22
worsening 47:4
worst 15:18
worth 53:18 115:9
124:8
worthwhile 212:11
213:14
worthy 212:9 313:8
wouldn't 23:5 143:15
148:12 166:2 174:4
193:11 237:10 253:20
wound 71:11 142:19
176:22 177:3 189:17
190:3 193:15 196:18
200:11 208:2
wounds 208:5
wrap 234:8
write 39:8,15,21 40:21
61:22 211:16 251:20
writing 40:18
written 166:5 250:21
284:9,16
wrong 153:18 273:3
wrote 197:15
WVU 9:3
Wyoming 95:12

X

X 45:7 163:3
x-ray 148:14

Y

Yates 2:20 46:4 67:4
68:18 69:11,16 77:18
78:7,10,13,16 79:7
80:1,12 81:19 82:5
95:9 113:17 114:9,20
115:4 148:5 150:17
152:1 179:12 181:13
182:3,19 183:3,17,22
184:9 185:11 187:4,5
198:7,8 256:4,6,21
257:7 295:9,16 296:1
296:5 297:8,14 316:3

316:8,11
year 11:19 23:13,21
32:2 78:11,14 85:1
86:9,15 100:11,13,16
102:15 106:11,13,22
112:20 121:9 131:20
162:18 163:8 174:12
174:13,14 179:17
185:22 186:3 192:2,5
195:5,5,8,15,17,18
198:21 294:18 295:12
333:17 341:15
years 13:12,14 23:11
32:3 47:4 54:22 64:6
72:9 78:5,8 85:14
86:6 88:19 94:9
115:11 118:21 121:17
130:21 132:5,16
142:1 144:20 147:12
147:21 149:5 153:11
165:3,22 176:17
193:8 208:22 214:14
214:18 223:15 234:10
237:7 238:18 251:9
264:21 295:12 304:14
328:19 352:1,3,5
years' 115:9 124:8
yesterday 6:10,13 7:3
7:15,18 16:13 46:15
95:10 100:22 101:2
304:15
yield 131:14
York 105:21 144:2
young 180:8
younger 135:20 175:21

Z

zero 64:8 267:19 288:9

0

0 26:10 27:10,10 29:4,4
30:1,16 31:9 36:7
48:11,12 53:13 57:4
62:18 67:1 74:13
89:11,12 91:5,6 92:8
92:8 97:12,12 98:12
98:13 101:22 108:11
111:8 112:4,5 113:14
113:15 116:2,2,18,19
117:14 118:4,4 120:6
122:12 123:9,10
124:5,6 125:3,4 126:1
126:1,16,17 127:6,16
127:16 128:10 138:15
138:15 139:21,22
154:15 156:8,8
158:21,21 159:9
162:9,9 164:10,10

167:13 169:12,12
 170:5,5,16 188:21
 196:11 212:22 319:13
 342:22
0.3 72:1
0.4 71:22 92:15 110:7
 139:8
0.5 72:7,8 110:7 124:10
0.52 72:6
0.57 124:14
0.58 72:7 115:12
0.59 137:21
0.77 72:6
0.81 72:12 91:17
0.99 92:18
001 113:20
01 4:19
0117 4:5 48:4,5,11 53:8
 53:12
0127 4:6 53:15 56:18,19
 62:11,17 66:16,22
 70:12,16
0134 4:3 19:1,3,5 26:8
 27:3,9 28:19 29:3,16
 29:22 30:8,14 31:4,8
02 5:3
03 5:7
04 5:11 162:16
05 5:14
0697 4:12 129:2 138:8
 138:14 139:15,20
 154:10,14 156:1,7
 158:14,20 159:4,8
0706 4:14 159:12 162:2
 162:8 164:3,9 167:7
 167:12 169:5,11,20
 170:4,11,15

1

1 4:2 19:6 27:3 28:19
 29:16 30:8 31:4 32:11
 48:5 53:8 56:19 62:11
 66:16 70:12 74:8 89:1
 90:22 92:1 97:5 98:7
 101:13 108:4,18
 111:4,20 113:7
 115:16 116:12 117:7
 117:19 120:2 122:8
 123:3,21 124:19
 125:17 126:8,21
 127:9 128:1 138:9
 139:15 154:10 156:1
 158:14 159:4 162:3
 164:3 167:7 169:5,20
 170:11 173:8,16,17
 181:18 184:20 185:21
 186:1 188:9,14 196:4
 212:18 252:16 315:1

1.2 100:4
1.69 137:21
10 10:7 26:8 62:18
 91:13 121:8 143:7
 148:11 164:19,20
 167:12 282:12 299:22
 319:12 327:16 328:18
 328:21 330:18
10-plus 13:13
10,000 134:10 143:9
10/90 161:2
10:06 128:18
10:17 128:19
100 10:9 15:18 31:8
 36:16 53:12 74:13
 78:4,8 91:17 111:8
 120:6 128:9 144:15
 159:8 170:15 246:20
 298:1 314:22
100,000 134:16 185:21
1030 1:8
108 291:3
109 4:9
10th 35:18 47:6
11 32:3 117:13 127:5
 130:21 132:4 185:2
 294:18 295:1 312:19
 323:16
1101X 193:19
117 31:11
12 74:2 86:3 130:6
 275:6,13 276:11
 279:15,16,19 342:12
12,000 131:20
12:21 245:1
12:34 245:2
120 4:11
126 246:12
129 4:13
13.7 73:21
131 156:15
134 8:21 11:9
14 29:3 35:20,21 57:2
 92:7 161:1 248:12
 249:21 256:18 262:18
 264:9,9 267:20
 281:10 288:10 343:19
 345:11
14- 254:7 259:22
140 315:9
15 35:20,21 91:5 109:3
 120:12 199:19
15,000 143:9
150,000 11:19
158 4:15
15th 1:9
16 113:14 213:1
16.9 111:12

17 1:6
170 4:17
178 68:9
18 12:4 74:18 96:4
 165:22 175:20,21
 189:7 190:6 191:14
 321:8 342:10
18,924 121:17
180 38:19 139:9
19 4:4 27:9
19.8 122:21
1971 295:15
1989 9:9
199 163:5
1997 246:12
1B 12:20

2

2 19:6 27:4 28:20 29:17
 30:9 31:4 48:6 53:8
 56:20 62:12 66:17
 70:12 74:9 89:2 90:22
 92:2 97:6 98:7 101:14
 108:5,18 111:4,21
 113:8 115:17 116:13
 117:8,20 120:2 122:8
 123:4,22 124:20
 125:18 126:8,22
 127:10 128:1 138:9
 139:16 154:11 156:2
 158:15 159:4 162:3
 164:4 167:8 169:6,21
 170:11 184:20 188:15
 196:5 212:19 269:5
2,000 251:12 252:6
2,286 72:10
2.3 73:22
2:00 350:14
2:34 352:7
20 24:12 172:17 285:5
 304:14 327:16
20-plus 214:18
200 68:13 134:16
 311:14
2004 296:12
2010 246:13
2011 12:20 34:6 72:9
 109:16 116:8 121:7
 130:4 159:18 160:18
2012 32:15 34:7 56:9
 116:8
2013 35:19
2014 34:9 72:9 109:16
 116:8 121:7
2015 116:8
2016 1:6 215:3
2019 298:8
207 4:18

21 116:1 156:7
22 121:14 126:16
23 291:7
24 55:8 58:3,13 61:19
 177:6 298:14
245 4:20
25 54:20 121:16 124:9
 294:14 319:13 349:13
25,000 134:11
250 68:15
252 4:21
25th 350:13
26 110:11 117:13 124:5
 127:5 141:14 312:19
26,355 121:7
274 5:4
288 5:9
29 29:22 30:14 98:12
 122:16 288:11 298:16
 342:22
2900 130:13
299 5:12
2998 4:16 170:20 178:3
 184:19 185:2 188:14
 188:20 196:4,10
 212:18,22
2C 13:2

3

3 1:3 19:7 27:4 28:20
 29:17 30:9 48:6 56:20
 62:12 66:17 78:5,8
 89:2 90:22 92:2 97:6
 98:8 101:14 108:5
 111:21 113:8 115:11
 115:17 116:13 117:8
 117:20 123:4,22
 124:20 125:18 126:9
 126:22 127:10 138:10
 139:16 154:11 156:2
 158:15 162:4 164:4
 167:8 169:6,21
 188:15 196:5 212:19
3- 121:8
3,000 68:22
3.2 111:12
3:00 8:2
30 9:22 13:12 78:13
 128:6 144:4,15
 159:20 178:11,11
 184:13 185:9 263:10
 304:22
30-day 130:9,9 134:3
 144:1,8,20 152:14
30-plus 54:22 161:11
30,000 132:14 133:20
 142:9
300 100:16

3016 4:19 245:18 248:6
 267:15,19 347:18
 348:18,21
3017 5:3 274:11 281:21
 288:5,9
3019 5:7 288:15 298:14
3020 5:11 298:22
 312:12,18 319:6,12
 323:8,15 342:1,10,16
 342:22
3021 5:14 343:13,15
 349:3,13
3030 4:7 70:19,21 74:8
 74:13 89:1,10 90:21
 91:4 92:1,7 97:5,11
 98:7 101:13,20 108:4
 108:10,18,22
3031 4:9 109:4,5,10,11
 111:3,7,20 112:3
 113:7,13 115:16
 116:1,12,17 117:7,12
 117:19 118:2 120:2,6
3032 4:10 120:9 121:6
 122:7,12 123:3,8,21
 124:4,19 125:2,17
 126:8,15,21 127:4,9
 127:15 128:1,9
31 144:5 145:5,9 349:14
32 154:15
3293 15:17
33 62:17
34 33:4 138:2
341 121:17
343 5:16
35 169:11 342:11,11
 343:1,1
35-day 254:7
350 5:18,20
36 9:17 110:13 115:10
 258:18
37 123:9 323:15
376 127:15
38 26:9 48:12 66:22
 258:18 267:21
39 188:20

4

4 19:7 27:5 28:20 29:18
 30:10 46:15 48:6
 56:21 62:12 66:18
 89:3 91:1 92:2 97:6
 98:8 101:15 108:6
 111:21 113:8 115:17
 116:13 117:8,21
 123:4,22 124:20
 125:18 126:9,22
 127:11 138:10 139:17
 156:2 158:16 162:4

164:4 169:6,21
 188:15 196:5 304:21
4.3 122:21
4:00 350:14
40 89:11 126:1 131:7
 161:2
400 190:20
42 116:18 118:3
43 108:10 158:20
44 121:11 349:13
45 125:3 138:14 248:12
 249:21 256:18 259:22
 264:9,12 289:4 293:6
 293:9 310:1 334:10
 343:19
45-day 345:11
460 137:17 156:16
462 110:14
47 139:21 323:16
48 4:5 97:11 101:20,21
 164:9 267:20 298:15
49 10:16 138:1 281:10

5

5 30:1,15 57:3 67:1
 70:17 101:21 108:10
 109:1 110:4 143:7
 149:17 161:10 196:10
 196:11 312:18 315:6
 323:15
50 13:17 35:20 78:11
 112:3,4 121:18 170:4
500 100:16 185:14
 273:7
500,000 54:9
52 26:9 97:11 108:10
 164:9
52,841 110:14
53 139:20
55 121:10 125:2 138:14
56 188:20
57 4:6 62:17 66:22
 158:20 288:10
57.9 10:17
58 110:15 116:17 118:3
 312:18

6

6 4:2 9:9 15:14 86:3
 162:8 188:21
6.5 122:16
60 89:10 136:7
62 48:11
62,118 109:16
621,489 72:10
63 117:12 123:8 127:4
 127:15
64 291:5

65 113:21 114:4,18
 130:12 133:13 135:20
 136:8 169:11 291:5
 319:12
66 161:1
67 29:22 30:14
68 154:14

7

7 128:5 148:11 187:7
 290:20
70 4:8
70,000 134:14
708 121:15
73 35:19
738 121:15
74 110:10 124:4
746 110:8
75 141:1 215:4
75,000 134:16
77 141:1
78 121:14 126:15
79 116:1 156:7 291:9

8

8 173:20 178:11,11
 185:9 188:6
8.0 246:21
8:00 1:9 6:2,4
80 85:9 90:6 136:2
 215:4
800 99:2,3,10 133:20
807 110:9
80s 53:21 56:7,8
81 27:9 57:3
84 113:13 213:1
85 91:4 139:10
86 29:3 92:7
89 185:2

9

9 74:17 282:12
90 167:12 195:3 196:10
90-plus 13:15
90-second 9:7
91 162:17
93 15:18
93.5 56:9
94 162:8
95 9:9 10:4 24:21 25:2
 29:9 32:15 37:22
 70:16 71:21 108:22
 161:5 334:6
96 15:15 46:17
97 143:12
98 15:21 36:14 41:11
 42:21 44:12 46:5,16
 143:12

99 15:15 162:16,17,19
9th 1:8

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In the matter of: Surgery Phase 3
Standing Committee

Before: NQF

Date: 08-17-16

Place: Washington, DC

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