

NATIONAL QUALITY FORUM

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SURGERY STANDING COMMITTEE

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FRIDAY

MARCH 20, 2015

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

COMMITTEE MEMBERS:

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

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 Surgery, Cleveland Clinic

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

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

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

NQF STAFF:

HELEN BURSTIN, MD, MPH, Chief Scientific Officer

MARCIA WILSON, Senior Vice President, Quality
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JULIET FELDMAN, Project Manager, Stakeholder
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KAREN JOHNSON, Senior Director

ANDREW LYZENGA, Senior Project Manager

MELINDA MURPHY, Senior Director

YETUNDE ALEXANDRA OGUNGBEMI, Project Analyst

ALSO PRESENT:

MAX HE, The Society of Thoracic Surgeons

JEFFREY P. JACOBS, M.D., The Society of Thoracic
Surgeons

JANE HAN, The Society of Thoracic Surgeons,
Senior Manager of Quality Metrics and
Initiatives

JAMIE YAP, The Society of Thoracic Surgeons, STS
National Database Assistant

* present by teleconference

CONTENTS

Welcome, Recap of Day 1. 5

Consideration of Candidates Concepts/Measures

073252
2683	120
073395
0115	132
0130	158

Break

Consideration of Candidates Concepts/Measures

0116	166
0118	182
0123	201
0121	224

Public Comment 197

Working Lunch

Consideration of Candidates Concepts/Measures

0122	235
1501	232
1502	245
0696	248

Public Comment 265

Adjourn

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

(8:30 a.m.)

DR. GUNNAR: So, I think the first time we went through this we didn't finish the first day's agenda in the first day. So congratulations to us and our ability to, you know, iron-chair our way through to almost a little after 6 o'clock. So I think the first day is always the toughest because you sort of reintroduce yourself to the process but we are now full into the agenda. And today's is really centered on all of the STS measures that you can see. And for that reason we've, and I think wisely, the NQF staff has brought the developers from STS here for just a full day event and walk through it rather than split it up.

So I know there are a couple of topics we wanted to get to before we have the developers join us, but introduce Helen Burstin, so our leader in this effort. So, Helen, do you want to say a few words?

DR. BURSTIN: Good morning, everybody.

1 Nice to see everybody again. I am Helen Burstin.
2 I am the Chief Scientific Officer here at NQF.
3 Apologies for missing yesterday; I was actually
4 in an all-day meeting at the American College of
5 Surgeons. How appropriate. It's hard to be in
6 two places at once. Actually Dave Shahian from
7 STS was there as well. So, delighted to be here
8 with you and I know you are in great hands, so I
9 am glad to be here today.

10 DR. GUNNAR: So, Lee, how do you want
11 to -- we wanted to talk about a couple of
12 concepts before we open this?

13 DR. FLEISHER: So first, good morning.
14 I just wanted to say thank you. One of the
15 things we talked about as we start today is the
16 idea that Patrick Romano mentioned and actually
17 the major reason through the Kaizan that Helen
18 and the NQF team developed these standing
19 committees is to create memory so that as we
20 actually -- and have a consistency so that Andrew
21 really will be talking with all of you and
22 thinking through as you see these measures coming

1 through the final report, calling out,
2 particularly those who reviewed them, anything
3 you would like to see the developer do over the
4 years in which the measures are being utilized or
5 if they came back.

6 So, for example, the last measure
7 yesterday, there were a lot of thoughts about
8 what kind of testing might have to happen with
9 that new measure for admission after outpatient
10 surgery or other sort of process measures, what
11 would have to be demonstrated for the committee
12 to continue endorsement at the next stage. It
13 will be important to sort of identify those
14 specifically so that even if we were not on this
15 committee then the process would have memory. So
16 I think that's going to be -- Andrew working with
17 Juliet is going to do that.

18 The other thing, just because I am
19 leaving early, is I didn't want to forget to say
20 thank you to the staff as always, because they
21 have been tremendous and really helped guide us.
22 So I wanted to say thank you. Yes.

1 (Applause.)

2 DR. FLEISHER: Do we --

3 DR. GUNNAR: I have a couple of things
4 before we go.

5 DR. FLEISHER: Okay. Do you want to
6 say those?

7 DR. GUNNAR: So today I appreciate
8 that Fred Grover has recused himself. He will be
9 in attendance but not voting for any of the
10 measures today because of his past deep history
11 with the STS. There are other cardiac surgeons,
12 including myself, who are -- and just a show of
13 hands, who is a cardiac surgeon, just so you
14 know?

15 DR. GUNNAR: John. Dr. Roth.

16 But I think it's important to just
17 kind of foundationally know that you carry bias
18 into these. And it's important to try to --
19 there is a fine line between bias and conflict
20 sometimes, and I appreciate that Dr. Grover has
21 presented his conflict. But we will just keep
22 that in mind as we carry forward in the

1 discussions.

2 Yes, Helen?

3 DR. BURSTIN: And just to follow up on
4 that, again bias is a funny word; it's pretty
5 subjective. I mean don't, I don't want us to
6 confuse expertise and bias. Some of you here are
7 cardiac surgeons at the table, we want you to
8 engage. That's why you are around this table.
9 So, you know, bias is subjective but expertise is
10 important. And, again, you know we really want
11 you to speak and participate in the
12 conversations.

13 DR. FLEISHER: Yes, I guess in the
14 same way yesterday when the beta blocker
15 discussion occurred and I had to be a content
16 expert, I felt appropriate to make a content
17 comment, not about the measure but about the
18 content. So if you have content expertise in
19 particular, we would like that to be articulated.

20 DR. GUNNAR: So for those on the
21 phone, Dr. Fleisher looked at Dr. Grover and
22 said, you are a content expert. So don't, don't

1 hesitate in providing content expertise.

2 Correct, Helen? Okay.

3 DR. FLEISHER: So, Melinda, would it
4 be best, one of the things that we wanted to have
5 a discussion of is the potential unintended
6 consequences of 30-day mortality, should we do
7 that in the context of STS presenting that
8 measure or just have a general discussion? The
9 New York Times -- I know, right. So should we do
10 that first or just within the content; what do
11 you think would be the best approach?

12 MS. MURPHY: I would say in STS so
13 that you don't need ---

14 DR. GUNNAR: Okay. So to frame this,
15 I think anybody who has read the paper recently
16 regarding this topic is there is a -- there are
17 experts in palliative care and end of life care
18 who are presenting an opinion that would
19 discourage any metric from measuring to a single-
20 day outcome, and in this case 30-day outcome,
21 mortality outcome. And there have been papers
22 written in peer review journals regarding the

1 risk of any one patient being adversely impacted
2 by that for failure to provide comfort care when
3 an inevitable outcome is clear but you are trying
4 to reach a 30-day metric such that if it was
5 clear that my loved one was not -- had a terrible
6 complication following a procedure -- was not
7 going to clearly make it to 30 days and the
8 systems prevented that death, that naturally
9 expected death, to just meet a 30-day measure.

10 And so I think I framed it correctly.
11 Helen, that was what you were faced with, and
12 Lee, when you were confronted by the media,
13 correct, to respond?

14 DR. FLEISHER: I think that was part
15 of the question was would there be individuals
16 who are kept alive and denied palliative care on
17 day 22 in order to make the 30-day mortality.
18 And we were just talking with the STS folks and
19 whether or not there's ways to mitigate that by
20 looking at operative mortality and what defines
21 operative mortality.

22 The second question, which is an

1 interesting one, is that they argued people would
2 not operate on patients because 30-day mortality
3 was too high. la some of the discussions
4 yesterday about shared decision making in
5 patient-reported outcomes, I'd like to hear
6 people's opinions on whether or not that is a
7 good or bad thing once people think about
8 operative mortality, whether there is unintended
9 consequences that they would not have a shared
10 decision discussion but really present risk
11 benefits and think about it.

12 So I guess we can start with John. We
13 wanted to have a robust discussion so by the time
14 STS comes we can sort of have a shorter
15 discussion. I guess, Rick, you are the first?

16 DR. DUTTON: The second point, I
17 agree, it's going to be difficult. There's
18 gamesmanship possible in any publicly reported
19 measure. So, for instance, if we changed the
20 measures to say that if the patient agrees to a
21 risky operation then the mortality doesn't count,
22 you can imagine how that might be. That might

1 adversely affect practice as well.

2 But on the first point, I notice this
3 time, and maybe it's been true all along and I
4 just caught on, that a lot of the STS 30-day
5 mortality measures are now written so that it's
6 any mortality occurring in a hospital, even up to
7 a million days still counts. And then the 30 day
8 is only if the patient gets discharged and it's
9 within 30 days. I thought that was a really
10 significant improvement in how these were
11 written. And I think that's something NQF should
12 encourage all of the mortality measure developers
13 to look at. That can still be gamed, obviously;
14 you can send the person home, you can transfer
15 them to the hospice, and there are still going to
16 be issues. But I think this clears up one
17 important point.

18 DR. FLEISHER: Interesting we can hear
19 how --- whether transfers to hospice counts or
20 doesn't count in operative mortality and ask that
21 question of STS.

22 DR. GUNNAR: The other question there

1 is what is the percentage of deaths that occur
2 out of hospital versus in the primary index
3 hospitalization? So those are the -- how many
4 are in those two buckets?

5 DR. HANDY: So I was going to make
6 exactly Dr. Dutton's point, except for the fact
7 that, a point of clarification, that is not a new
8 definition by the STS. This has been a
9 longstanding definition, either 30-day deaths --
10 well, it's actually taking more responsibility
11 because if you walk out three days after your
12 discharge and you get hit by a bus you're still
13 considered an operative mortality as an
14 outpatient.

15 So this has been the consistent
16 definition from the STS.

17 DR. YATES: As to your second point it
18 extends, in addition to mortality it extends to
19 the 30-day re-admission and some of the HAC,
20 hospital acquired condition risks, in that
21 especially in something as elective as total knee
22 and total hip replacement, the collective

1 response of people honing back on their risk,
2 risky patients, and not offering surgery to
3 patients with ill-defined ranges of risk because
4 that ill-defined range of risk may not be as
5 adequately risk adjusted or fair to the hospital,
6 and that the leverage that's being used in some
7 of the payments and value-based payments are so
8 high for that one basket of admissions, you are
9 seeing patients being denied surgery for ill-
10 defined classes of risk such as morbid obesity.
11 And I think it's a slippery slope until things
12 like lupus and rheumatoid arthritis get told that
13 they are not quite ready for surgery or they are
14 not really appropriate for surgery. And they try
15 to reduce their risk at the door.

16 I have heard, I have heard executives
17 from large centers flat-out say that they are
18 going to restrict their surgeons in terms of who
19 they can operate on to reduce that risk. And so
20 I think it's only natural that the mortality risk
21 would also be that much more likely to be
22 invoked. If it's being invoked at elective

1 surgeries for just re-admissions, I think it's
2 very likely that that type of gamesmanship will
3 happen at the mortality level.

4 DR. FLEISHER: So one of the things we
5 can do here is if people have thought about ways
6 that we can ask the developers of these measures
7 how to look at those consequences, that's one of
8 the things that this committee can help define.
9 So if you have any thoughts on that.

10 Allan?

11 DR. SIPERSTEIN: Yes. In preparation
12 for this meeting I polled some of my cardiac
13 surgeons at the Cleveland Clinic about some of
14 these measures and unintended consequences, and
15 they echoed exactly that, that the very highest
16 risk patients, they are getting push-back in
17 terms of operating on them. Obviously they
18 understand that they are overall mortality
19 statistics, they understand that things are risk
20 adjusted, but there is a concern that at the
21 extremes, the risk adjustment methods may not
22 work.

1 And what they were really asking for
2 was some carve-out or exclusion for the sickest
3 several percent, you know, to be excluded from
4 these metrics.

5 DR. FLEISHER: I think we will ask
6 Helen in the end if she will comment. But Chris?

7 DR. SAIGAL: I just wanted to say I
8 think all --- whatever we do is going to be gamed
9 in one direction or the other. I think that we
10 have to ask for, you know, I guess --- that this
11 -- do we want to have audits to make sure we're
12 measuring would actually be happening. I mean my
13 system games things all the time. So it's the
14 natural function of measurement. And we have to
15 marry measurement with auditing to make it
16 effective I think.

17 DR. FLEISHER: Kelsey?

18 MS. MCCARTY: Yesterday there was a
19 metrical reviewing in which DNR came up. And I
20 think we had given a suggestion to that reviewer
21 to consider excluding patients in which a DNR box
22 might be checked from the mortality metric. I'm

1 sure there's a lot more to that that would need
2 to be discussed and fleshed out. But perhaps
3 something around that as a starting point for any
4 exclusion criteria might help with this.

5 DR. LEVY: So another thing we talked
6 about yesterday was a patient-reported outcome
7 measure and finding some way to get information
8 from the patient side about what their value
9 system is and being able to marry that to our
10 measure in some way. And a composite might be
11 the best way to prevent a lot of the gaming.
12 Because we are looking at it all from our side,
13 and how to optimize a metric. And, clearly,
14 having a mortality rate that's zero if you've got
15 patients in there that are very high risk is not
16 going to happen.

17 So it might be a U curve where if
18 they're doing the right kind of care for patients
19 that, you know, you've got patients at both ends,
20 patients with very low mortality but you have
21 some patients that you would expect a certain
22 mortality rate and that your quality rating goes

1 down if that's too low. I mean, that's one way
2 to look at it.

3 But another way to look at it is to
4 really recognize that patient-reported outcomes
5 and the experience of the patient and shared
6 decision making are critical points. And it's
7 really that shared decision making piece that we
8 can't report on; the patient has to report on
9 those. And finding a metric, finding a way to
10 incorporate that into our mortality measure so
11 that we are capturing what our job really is,
12 which is to fully inform the patient about those
13 risks might be the best way for us to get off
14 this dime.

15 DR. GUNNAR: So I want to add to
16 Barbara's point because I think it's an important
17 one about what role does 30-day mortality with
18 regard to cardiac surgery play, as opposed to
19 composite. As an isolated endorsed measure over
20 the past decade, whether it's related or not, the
21 mortality in cardiac surgery has gone down
22 dramatically. And you will see today when we

1 look at the distinction between low performers
2 and high performers that the difference is --
3 here is relatively small.

4 I'm not trying to tee up performance,
5 I'm just trying to say -- performance gap -- I'm
6 just trying to say that there have been dramatic
7 decreases in these operations, mortality 30-day
8 in-house and 30-day out-of-house mortality. The
9 question is where does this fit into this? And I
10 think the composite discussion is going to be a
11 big one for us, whether you have to keep every
12 component of that composite alive and well or
13 whether the composite can drive, can do the same
14 thing. And actually in that sense of ---
15 potentially even avoid this ethical conundrum.

16 And then the last thing I want to say,
17 just because I've got the mike open is, you know,
18 I have personally lived with, you know, having
19 been participating in cardiac surgery -- an early
20 adopter of STS back in the '90s and as a
21 participant, 30-day mortality was, sure, yes,
22 should be measured on 30-day mortality. And

1 never would have thought that I or anyone on my
2 team of providers would have ever allowed some
3 sort of, you know, delayed care or anything.
4 That's beyond me conceptually.

5 But I understand the argument. That
6 being said, I do believe isn't that a local
7 issue? Does that --- isn't that really an
8 ethical issue at the local level and shouldn't
9 somebody be raising their hand? And so I pose
10 that as the --- as maybe an argument for
11 discussion.

12 So Dr. Yates?

13 DR. YATES: It is not just the
14 developers, it's how it's used. And the problem
15 is is that certainly I don't want to come back to
16 my example of joint replacement, but the way it's
17 used in our re-admissions package is with CMS in
18 terms of value-based payments, it's a moving
19 benchmark. And we all experienced the moving
20 benchmark of SCIP which rolls right up to the top
21 and topped out so that almost everybody could hit
22 it and it became a process measure, but one

1 patient made a difference.

2 Well, we are at a point now where it
3 may be one surgeon's practice or one set of
4 patients that makes a difference in a moving
5 benchmark as that quality squeezes to less and
6 less variability, like you just said, and greater
7 and greater improvement as that quality moves to
8 the left. So to keep it in the cardiac mortality
9 ranks, if somebody has a 1 percent risk, a normal
10 risk of cardiac mortality, of post-CABG
11 mortality, yet there is another patient that has
12 a 2 percent risk because of co-morbidities, be it
13 morbid obesity or diabetes or the like, there
14 will be, there will be pressure, not just
15 regionally or locally, to delimit that, because
16 it's going to put you at risk for significant
17 payment penalties that will cause pressure from
18 those people that run hospitals to not want you
19 to operate on them.

20 And I think that is something that has
21 to be resisted but it's hard to do if you're --
22 everyone else is doing the same thing. And I

1 think you are going to see those mortality curves
2 moving to the left and squeezing up against
3 actuarial risk. And that's what I fear.

4 Value in medicine was defined by
5 Michael Porter as the outcome divided by the
6 cost. If you take care of less risky patients,
7 you are more likely to have a great outcome and
8 less cost. But if everyone is measuring you for
9 your value, you may create pockets of patients
10 that are treated as a class and not as
11 individuals, and that's the definition of
12 discrimination. And when that happens then we
13 have to protect those patients from becoming
14 value refugees.

15 And what I would like to see is some
16 way of creating the exclusions. That would be
17 one way of protecting certain classes of patients
18 that have hard-to-define risk; it may be the
19 patients with diabetes, it may be some other way
20 of doing it. And if we can get to patient
21 populations, we would define quality as the
22 outcome over the cost times the people that could

1 have been helped divided by the -- or the people
2 that could have been helped divided by the people
3 that weren't.

4 I'm sorry to go long but I think
5 that's --

6 DR. GUNNAR: Are you arguing against
7 a composite measure which actually extends a
8 wider net? As we look at the composite measures
9 it will actually -- the failure-to-meet criteria
10 will be met by a wider number of --

11 DR. YATES: I think the composite
12 measures should measure the population being
13 treated by that hospital. And that should be one
14 part of the composite measure is that the overall
15 -- and that's hard to know because you never know
16 what the denominator could have been. But if
17 there was a way to capture what the denominator
18 could have been then you could say that they did
19 their best to take care of everybody.

20 DR. FLEISHER: Great. Larissa?

21 DR. TEMPLE: I just had a couple of
22 comments. I mean I think that ultimately we are

1 going to have to come up with some sort of
2 composite score that incorporates the patient's
3 values and preferences and the time to getting
4 geriatrics or the hospice involved. I mean we
5 grapple with this in oncology. And I believe
6 that in oncology we sort of started to think
7 about developing a metric where we got hospice
8 three days before patients passed away. So I
9 think we have a long way to go before we can
10 start putting these patient preferences into our
11 models.

12 But I wondered about when we think
13 about maintenance of our measures, and we talked
14 of this a bit last night, that when people come
15 back for maintenance, it's an opportunity for us
16 to ask them to give us some data about potential
17 unintended consequences to see if there's
18 variations in the patterns of care. And when we
19 look at these measures for maintenance we are not
20 asking them to give -- we need to push them to
21 the next level: show us how these measures are
22 helping. Kind of give us some data to suggest

1 that there is or isn't gaming, and what kind of
2 gaming is going on. Because it's an opportunity
3 for us -- tell us what happens when a measure is
4 for institutional quality improvement versus when
5 it becomes for public reporting.

6 I mean I think we are starting to see
7 more gaming when we go to public reporting. And
8 so I sort of think we should think a little bit
9 more about what we do with measure maintenance.
10 And I think that -- it won't get us to the
11 composite score we want but it will get us a
12 little further than we are now.

13 DR. FLEISHER: Thanks. And it's going
14 to be important that we put those in the report
15 so that the measure developers --

16 Amy?

17 MS. MOYER: A couple of things. I
18 think one of the things I was struck by was, both
19 in, you know, in the comments and in the article,
20 there was a lack of understanding about what was
21 actually being measured. And part of that is,
22 you know, we need to have this fits-on-one-line

1 name for the measure that doesn't capture
2 everything.

3 And so I think when we are talking
4 about, well, we could tweak the measure this way,
5 tweak the measure that way, do this, I think
6 people are reacting to what they think the
7 measure is instead of what's actually involved in
8 it.

9 And I think I forgot my second point.

10 Oh, you know, we set a bar of a
11 certain amount of evidence to have a measure.
12 And I would also question then, I guess, are we
13 reacting to anecdotes and stories or are we
14 reacting to actual evidence that these unintended
15 consequences are occurring?

16 DR. FLEISHER: Rick, did you have
17 another?

18 DR. DUTTON: A question for the NQF.
19 I am a little surprised we haven't seen any
20 patient-reported outcomes show up here yet
21 because certainly lots of people are working on
22 these for things like total joint replacement

1 and, you know, at six months are you happy, does
2 your leg work, that kind of thing. Are those
3 coming to this committee, or will they when
4 they're in the surgical area?

5 DR. BURSTIN: So the question --- to
6 date they have been part of the Parsons Center
7 Care Committee which is looking at all those sort
8 of functional status measures together. But one
9 thought might be to bring things that are more
10 surgical perhaps for a second opinion to this
11 group to kind of weigh in on the more surgical
12 risk oriented perspectives as well.

13 DR. GUNNAR: And I think that would be
14 helpful just because where this topic came up.
15 So the -- and I can't remember what the actual
16 measures were that we endorsed as a standing
17 committee to go forward as CSAC. They were then
18 approved by the committee. It then went for
19 public comment and the 30-day mortality metrics
20 were appealed by this consortium of interested
21 parties.

22 Lee and I met with NQF staff because

1 it was literally we had a 2 or 3-day window to be
2 able to present our opinion to the CSAC along
3 with -- and the developers presented as well, Dr.
4 Jacobs I believe was on the phone, and in essence
5 we supported their -- what you will see is their
6 response today in that moment in time.

7 What we are doing now, just to be
8 clear, is we are bringing this back to the
9 committee for essentially discussion and
10 potentially a position. And so I want to be
11 clear I think as to where this discussion is
12 headed. And if it needs more discussion or more
13 context or a -- potentially a debate, I don't
14 know where we would -- I would encourage that.

15 So just wanted to put that in context.
16 Dr. Erekson?

17 DR. EREKSON: So I think one thing
18 that's really important to remember when we look
19 at surgical rates is surgical rates vary widely
20 across the country. They vary widely at hospitals
21 across all procedures. And they do not
22 correspond to the underlying health in the

1 community at large. You can have a surgical rate
2 in the county next door that's completely
3 different than in your county.

4 So when we are thinking about offering
5 surgery, not offering surgery, gaming the system,
6 I think this plays off of a lot of other comments
7 that the committee has already given today which
8 is we really have to get into this patient
9 preference and the shared decision-making because
10 currently, the underlying health of the
11 population doesn't explain all the variation that
12 we see in the surgical rates.

13 DR. MOSS: So this is a little bit
14 philosophical but I just wanted to talk about the
15 tone of the discussion. A) this is a, you know,
16 this is a visible group that speaks fairly loudly
17 for surgical quality in this country. And I
18 think we need to be careful not to be drawn into
19 a discussion where we are put on the opposite
20 side of the patient. And I kind of see that
21 potential here. And I think that, you know, in
22 25 years of doing this it's exceedingly,

1 exceedingly rare that I have seen somebody in
2 medicine make a decision for any other reason
3 than his or her conscience.

4 You know, there's always isolated
5 anecdotes of everything, but I think we need to
6 be careful to argue really vigorously for the
7 integrity of the practitioners and say we will
8 work with you, no measure is perfect, any measure
9 can be gamed, but let's not get on the wrong side
10 of the table or be pushed to the wrong side of
11 the table in the discussion.

12 DR. SAIGAL: I wanted to comment that
13 I do think we've been talking a lot about patient
14 preferences and shared decision-making and it may
15 be time to really look at that quite seriously to
16 let us address some of the concerns you just
17 raised in terms of our concern for the patient.
18 I'm not sure that they can be measured in claims
19 but I think e-measures are a way in which you can
20 report what's happening.

21 I think some employers are using it,
22 sort of just making it a requirement now in their

1 ACOs. I know Boeing is doing that and a few
2 others groups are -- Madison are doing that. So
3 there's probably ways for us to capture that that
4 happened as a way to safeguard against some
5 gaming. We should take it quite seriously I
6 think.

7 I don't know if there is a plan to do
8 that, Helen, or is there a -- are we just sort of
9 talking about that right now or is there a --

10 DR. FLEISHER: Melissa?

11 MS. THOMASON: And really it's been
12 pointed out, just like Dr. Moss was saying, so
13 from a patient's perspective -- and I'm new to
14 the measures conversation, I mean obviously --
15 but from a patient's perspective I think it's
16 just about when I go see my surgeon, when I come
17 out of all of the procedures, what I was
18 expecting. So I want my idea of success to align
19 with his idea of success. So I want the outcome
20 that he's being measured by to be what I was
21 looking for, otherwise we are working towards
22 different ends. And it seems like a slippery

1 slope.

2 DR. FLEISHER: Kelsey is next.

3 MS. MCCARTY: So this idea of
4 including patient choice more has come up a lot
5 recently with the New York Times article. There
6 was another New York Times article about
7 suffering. Atul Gawande has a new book about
8 this and is making the rounds. And I feel like
9 this Committee gets it and wants to include
10 patient choice but we were also talking about we
11 didn't really have a chance to have the full
12 discussion yesterday, but gap measures or
13 measures that we need to close the gap, and I
14 feel like the pinch that we are feeling is like
15 we get it, we want to make sure that what the
16 patient wanted is what was executed on and that
17 we are not penalizing people for making really
18 good choices about patient care, but I don't
19 think that we know how to do that.

20 And so if we are thinking about
21 pushing people to bring forward to us measures
22 that will help the work of this committee then

1 maybe we should put a really strong RFP out there
2 on how do we do this? How do we capture patient
3 choice in the medical record or in some form of
4 documentation so we can incorporate that into
5 measures going forward. I'm not sure that we are
6 going to resolve this conversation unless we see
7 some kind of methodology which I don't know if
8 that exists today.

9 DR. FLEISHER: Great, Fred, did you
10 have a --

11 DR. GROVER: I just wanted to --
12 mention we actually sent a letter in to the New
13 York Times that they haven't seen fit to publish
14 yet. But, you know, obviously we are very
15 concerned, I think, if any of our measures in the
16 STS are being used for gaming purposes. And like
17 Bill, I would hope we are hearing about some
18 isolated incidences of it.

19 And a lot of which I think --- their
20 point is that when people aren't doing well post-
21 operatively that sometimes their care is
22 prolonged because of this. It could also be

1 surgeon's pride. I mean, there are a lot of
2 factors that go into sometimes not being totally
3 realistic. I'm sure I've been in that boat too,
4 and most surgeons in this room probably have
5 where you keep hoping the patient can turn
6 around.

7 But I think to go away from data
8 that's well-adjusted becomes a little anti-
9 intellectual. We use that when we counsel our
10 patients. And they sign and they agree to this.
11 But I always have told my patients with what I
12 think their estimated -- I don't put it in that
13 words -- but what's your likelihood of survival
14 or not survival, what your likelihood of
15 complications are, and what the potential
16 benefits are so that you have shared decision-
17 making. And it's very valuable to use that.

18 We can't control how everybody in the
19 world interprets that. And what you're talking
20 about at Pittsburgh, I mean they don't even need
21 a database if they are telling you that they
22 don't want you to operate on --

1 DR. YATES: No, no, let me correct
2 that. No one has told me to do anything in
3 Pittsburgh.

4 DR. GROVER: Yes. But anyway --

5 DR. YATES: No.

6 DR. GROVER: -- or whatever your
7 colleagues are seeing. But, you know, so that
8 could just be people make up their idea of what a
9 high risk patient is.

10 But the other point is that there are
11 some patients who are best served by not
12 operating. And this helps you make that judgment
13 with them where the risks outweigh the benefits.

14 And the other thing that was just
15 brought up here a few minutes ago is there is a
16 difference in performance, different across
17 hospitals and across regions, and it may be that
18 if your hospital is having difficulty with some
19 of these patients they ought to be referred to
20 another center. So I think we have to keep all
21 of these things in mind. And -- but the idea
22 perhaps of trying to develop some metrics further

1 down where a patient isn't doing well, to measure
2 whether life is being prolonged, there's a
3 decision -- decision-making in the post-operative
4 period is probably an important one I think.

5 DR. GUNNAR: I think we are going to
6 -- just to put a time -- 9:15. If we are not
7 done we are going to cut it off at 9:15 --- off
8 this. And I don't want to, I don't want to
9 present a leading question but I appreciate what
10 you said. The STS does audits, I mean. The
11 question is is that is this an answerable --- is
12 this a -- in the audit process is it possible to
13 gather this kind of reflection on cases that are
14 actually, are, you know, die in the house? I
15 don't know. That is -- I'm sorry -- I think
16 there is a potential way to investigate this and
17 from a developer point of view, or any study
18 point of view. But I don't -- I just, I say that
19 rhetorically I guess, so anyway --

20 DR. FLEISHER: Well, I think Collette
21 has yet to make a comment.

22 DR. GUNNAR: Yes.

1 DR. FLEISHER: And given the time, I'd
2 like people to send more comments. Well, yes,
3 you and Marcia too. So if you have more comments
4 I think we can add them to the report or on the
5 phone call. But Collette has yet to speak so we
6 will just leave it.

7 MS. PITZEN: Thanks. Just a couple of
8 thoughts. Maybe we need to have recognition that
9 mortality measures in and of themselves are not
10 the end-all for a measuring our surgical
11 populations. And really encourage and start
12 looking at some functional status measures that
13 would be important to patients. How well can I
14 expect to be doing six months or one year out
15 from having this procedure? What is my
16 anticipated quality of life?

17 I know we've been working with a lot
18 of patient-reported outcome tools to put these
19 kind of measures in place to understanding our
20 surgical populations.

21 DR. FLEISHER: Thanks. Really, really
22 short.

1 DR. YATES: Well, that's got to be
2 really important because absolutely, in a public
3 forum, my medical center has told me take care of
4 the patient. And that's from top down, we take
5 care of the patient. And we have not drawn any
6 lines in the sand.

7 I am very fully aware of other people
8 who have spoken in public forums in front of
9 large audiences saying they were drawing lines in
10 the sand at a BMI of 40, and practices in the
11 surrounding areas that have drawn lines in the
12 sand and very openly saying they are doing it
13 because of concerns over payments.

14 Directly to the mortality question,
15 since it is a registry, it is entirely possible
16 for the Society for Thoracic Surgeons to add
17 another checkbox in their registry saying the
18 patient was made DNR and allowed to pass away.
19 And that would be a way of capturing perhaps the
20 compassion of cardiac surgeons that may be out
21 there as much as -- it may alleviate the fears of
22 other societies.

1 DR. FLEISHER: That is a great idea
2 that we can ask them to address when they talk
3 about the measures.

4 Helen?

5 DR. BURSTIN: Thanks. That's a great
6 discussion and it makes me feel like we need to
7 do more of this. And one thought might be to
8 actually just go ahead and schedule a separate
9 call on this to really just have a couple-hour
10 discussion, potentially even inviting some of the
11 folks from our Palliative Care Committee to join
12 this discussion. I think there is a real
13 opportunity here to have both, you know,
14 especially more patients as well to bring that
15 point. But I thought you just captured that
16 beautifully in terms of making sure your goals
17 align.

18 I think there are some things we could
19 do. And I want to just make a couple points. I
20 think there are -- first of all, the CSAC did
21 weigh this appeal. It has already been completed
22 and done and approved by the board. So

1 ultimately the measures were upheld because there
2 was a sense that the benefits still exceed the
3 risks. We have not heard any substantial data
4 beyond the anecdote of, you know, the plural of
5 anecdote being data. That this is a real
6 concern.

7 But I think very much there's sense
8 that this is something we need to monitor going
9 forward. And some of this relates to the fact
10 that measures have taken on higher stakes,
11 particularly the financial higher stakes. And we
12 need to recognize that the environment has
13 certainly changed over the last five years in
14 that respect.

15 So I guess one question might be, and
16 one thing perhaps to tee up for a subsequent
17 discussion is, you know, to hear from you and
18 perhaps with the palliative care folks, are there
19 ways we can help mitigate this risk? You know,
20 I've heard a couple of discussion points today.
21 Audits: what's involved in the audits? Does some
22 of this get captured? Are there ways to build

1 additional items into audits that may help with
2 that?

3 The other thing is, again, the point
4 Collette just made, it's not just 30-day
5 mortality, it's in the context of a lot of other
6 measures that give you a sense of how overall it
7 went. Are there balancing measures that you
8 might put in place to go along with this that may
9 in fact show there may be something coming out in
10 a different direction that's not intended? The
11 patient-reported measures piece I think is
12 absolutely great, both in terms of functional
13 status, but also the shared decision-making
14 piece. This has been an ongoing discussion for a
15 while. Chris, we'd very much like to think about
16 what we could move forward in that space. Still
17 haven't been a lot of measures coming forward
18 yet, but very much hopeful.

19 And it's now a requirement in
20 Washington state that they are going to be -- if
21 any of you are from Washington -- that they are
22 going to be certifying these patient decision

1 aids. And I will be sitting on their panel in
2 May when they actually come up with some
3 criteria.

4 So, again, I think there is some
5 movement in this direction. It's a whole lot
6 slower than we'd like.

7 And, lastly, I think there are efforts
8 around the measures itself, what you could do in
9 terms of the measures: exclusions, composites,
10 whatever the case may be.

11 And, lastly, to the point raised, I
12 think it was Larissa, about measure maintenance,
13 we actually are proposing next -- in just a
14 couple of weeks to our CSAC in fact a pretty
15 radical redesign of measure maintenance where we
16 de-emphasize a lot of rework, which is what it
17 feels like to us at least, and I think to the
18 committee chairs we have talked to, around, you
19 know, the constant emphasis on re-looking at
20 evidence and instead use you, as standing
21 committee, to help us attest to the fact that
22 evidence is still okay. Ask the developers, ask

1 you, but not necessarily spend a lot of time on
2 that. Not unless you require re-testing, unless
3 you've changed, for example, a data source or a
4 level of analysis or things along those lines,
5 and put a lot more emphasis on asking the
6 developers when they come back for maintenance to
7 really focus in on use and usefulness. Is the
8 measure moving a needle? Is it having unintended
9 consequences? And how do we find out how?

10 And that's still a real issue for us.
11 And just interestingly, I spent an hour on the
12 phone with that reporter from the New York Times
13 explaining these measures to her, Collette. So
14 to Amy's point, so it is not -- this is complex
15 stuff. It's really hard to explain. So I think
16 anything we can do collectively to do that.

17 So I will just offer I would love to
18 have this conversation continue. If we'd like to
19 do it offline not to disrupt your flow, but
20 offline and perhaps even involve some of the
21 palliative care folks, I think that would be a
22 great way to further this discussion because it's

1 going to keep coming up again and again and
2 again. So thanks.

3 DR. FLEISHER: As always, very
4 thoughtful. And that was after I spent 45
5 minutes with the reporter, so --

6 So how many people would be willing to
7 have that phone call attributed to this? I think
8 it's unanimous, Andrew.

9 Helen, if you can work, and Marcia,
10 with our palliative care colleagues to invite
11 them to our call.

12 What I would actually suggest, given
13 that A.J. and others have already started
14 proposing ways to mitigate these risks is can we
15 create a sandbox, Juliet and Andrew, of ideas for
16 discussion on the call because I think that would
17 facilitate, rather than just having an open call.
18 We can talk about some of these ideas, put them
19 into buckets. And then we can push out and
20 really have maybe even lead discussions on
21 certain ideas and whether they would work. And
22 we'll work with Marcia and Helen.

1 DR. GUNNAR: Can we work out, reach
2 out to the appellants, to the people who -- and
3 have them participate as well?

4 DR. TEMPLE: It also might be helpful
5 to have the patients' family center group as
6 well, especially since we're talking about these
7 issues.

8 DR. FLEISHER: Fantastic. I'm sure
9 that will be well-appreciated by CSAC and the
10 board to approach this so thoughtfully.

11 Should we start?

12 MR. LYZENGA: So in the interest of
13 sort of time and efficiency today, and given that
14 just about all of the STS measures have very
15 consistent methodology across them, particularly
16 in terms of the way the data is collected so, you
17 know, a lot of the -- we sort of, you know,
18 determined that a lot of these issues, or
19 specifically around feasibility and usability are
20 probably pretty similar across the measures, if
21 not exactly the same. So we are going to try to
22 kind of reduce the amount of voting that we have

1 to do by we will go through the first measure and
2 we will take a vote. And then for the remaining
3 measures on the day I think for feasibility and
4 usability we are just going to ask you to give us
5 an okay if we can just carry over that first vote
6 for the rest of the measures for each one.

7 And then we will -- there are some
8 differences related to the scientific
9 acceptability of the evidence for each measure,
10 so we will have to go through each of those. But
11 we are going to try to kind of run through the
12 others.

13 So does anybody have any comments or
14 questions on that?

15 DR. FLEISHER: Amy?

16 MS. MOYER: I felt like the first one
17 was a little different from the rest since it was
18 kind of a structural measure versus the rest were
19 more process and open.

20 MR. LYZENGA: That is true. Maybe we
21 should instead of the first one have the second
22 measure carry over. So we'll go through the

1 first one, second one and then carry over.

2 DR. FLEISHER: Great.

3 MR. LYZENGA: Thanks, Amy, that's a
4 good point.

5 DR. FLEISHER: So I guess Robert and
6 -- okay, let's have the status.

7 MR. LYZENGA: Yes.

8 DR. FLEISHER: Are there first
9 discussions? Correct? Yes, okay, 3-minute
10 presentation on the measure.

11 DR. JACOBS: So which measure are we
12 doing, just so I know?

13 So my name is Jeff Jacobs. I am up
14 here with Max. And Max is a statistician from
15 DCRI and I am a heart surgeon at Johns Hopkins,
16 also The Heart Institute in St. Pete, Florida.
17 And from 2006 to 2014 I chaired the STS
18 Congenital Heart Surgery Database.

19 DR. FLEISHER: And can you mention who
20 else is in the room?

21 DR. JACOBS: So in the back we have
22 Dave Shahian who is the Chair of the STS National

1 Database Work Force and a member of the board of
2 NQF. And we have Jane Han who is the coordinator
3 of a huge amount of the work that we do with the
4 STS database. And we also have -- she stepped
5 out for a minute -- but we have Jamie Yap who is
6 also STS staff working with us.

7 DR. FLEISHER: Thanks. If you want to
8 give a quick introduction of the first measure?

9 DR. JACOBS: Sure. So we are going to
10 -- we are starting with surgical volume for
11 pediatric and general heart surgery stratified by
12 the STAT categories.

13 Right, so the first three measures on
14 this list come from the STS Congenital Heart
15 Surgery Database. A brief introduction to the
16 STS Congenital Heart Surgery Database is that we
17 know from manpower studies that 125 hospitals in
18 the United States perform pediatric heart
19 surgery, and currently 120 of those hospitals are
20 submitting data to the STS database. So that's a
21 penetrance of over 95 percent.

22 And we know that the data in the

1 database is quite good from a rigorous audit
2 process where 10 percent of the sites are audited
3 with site visits every year. And the results of
4 that audit shows that the data is quite good and
5 believable, and especially when it comes to data
6 that goes into our risk models and into diagnosis
7 procedure and mortality.

8 The first measure is surgical volume
9 stratified by five -- what we now call STAT
10 categories which are STS EACTS congenital heart
11 surgery mortality categories. And what the STAT
12 categories are, I guess to understand that the
13 first thing is to take a step back and think of
14 pediatric heart surgery in comparison to adult
15 heart surgery. With adult heart surgery if you
16 think about coronary artery bypass grafting,
17 aortic valve replacement and mitral valve
18 replacement and combinations of those, that's
19 going to get 80 to 90 percent of the adult heart
20 surgery, even more at some institutions.

21 In pediatric heart surgery, to capture
22 80 to 90 percent of the operations one would need

1 to include about 125 different types of
2 operations that have a tremendous range in
3 complexity and range in expected outcomes. So
4 rather than initially developing risk models for
5 each individual operation, a strategy was evolved
6 to group operations into categories that were
7 similar in overall operative risk.

8 And initially these categories were
9 developed based on expert opinion where a group
10 of surgeons and cardiologists sat around at a
11 table, looked at all the different operations,
12 and grouped operations into category 1, 2, 3, 4,
13 5. The STAT categories are different because
14 they are developed based on objective data of an
15 analysis of 77,000 operations in the STS and
16 EACTS databases. And this allowed us to group
17 all 100-plus operations into five categories of
18 increasing complexity.

19 Category 1 operations there is a less
20 than 1 percent chance of dying before going home.

21 Category 5 operations it's about a 20
22 percent or one in five chance of dying before

1 going home.

2 And this first measure is a measure
3 that asks if a given hospital can capture all the
4 operations that they do and stratify them into
5 the five STAT categories.

6 MR. LYZENGA: Dr. Sawin, are you on
7 the phone?

8 DR. SAWIN: I am. I'm a little bit
9 stymied here because I can't get into the
10 website, so --

11 MR. LYZENGA: Do you want to get us
12 started, Dr. Markman?

13 DR. MARKMAN: Okay. This is measure
14 0732. It's surgical volume of pediatric and
15 congenital heart surgery. And as Dr. Jacobs
16 eloquently mentioned, it's a relatively new
17 measure. It was -- original endorsement was in
18 November of 2011. And it is a structural measure
19 type.

20 And the recommendation from the
21 committee in terms of the evidence was that it
22 should be paired, because of the volume, with

1 another measure. And in terms of the evidence,
2 my question to Dr. Jacobs is with the pairing has
3 it improved in terms of the evidence? Are you
4 familiar with the pairing of these?

5 DR. JACOBS: Yes. Right, so --

6 DR. MARKMAN: So how is that going?

7 DR. JACOBS: -- we're going to discuss
8 this measure later with a companion measure which
9 talks about operative mortality stratified by
10 these five categories. And obviously that's
11 going to be a topic that we'll discuss in the
12 future.

13 But the question on the table is has
14 results improved? And Max was able to run some
15 analyses over the past week where we looked at
16 outcome stratified by the STAT categories on an
17 annual basis going from 1998 up until 2014. And
18 there's a very impressive decline in discharge
19 mortality and operative mortality across all five
20 categories, most notable in the most complex
21 category, Category 5, on a year by year basis.

22 And we also stratified that analysis

1 into 4-year analytic windows. And both looking
2 at 4-year analytic windows and in an annual
3 basis, operative mortality has declined across
4 each of the STAT categories, most significantly
5 in the highest level.

6 DR. FLEISHER: Rick?

7 DR. DUTTON: Just a dumb question to
8 start. What is pediatric and congenital surgery?

9 DR. JACOBS: Right. That's a great
10 question.

11 DR. DUTTON: So how old do you have to
12 be or not be or yes --

13 DR. JACOBS: Right. So what we
14 capture in the STS Congenital Heart Surgery
15 Database is pediatric and congenital heart
16 surgery. And what we use to define that is the
17 concept of pediatric and congenital cardiac
18 disease.

19 So pediatric cardiac disease is any
20 disease of the heart that exists in a patient
21 under the age of 18. So that includes anything
22 from being born with a hole in the heart to being

1 stabbed in the heart.

2 DR. DUTTON: Okay.

3 DR. JACOBS: And so congenital or
4 acquired.

5 Now, congenital heart disease is
6 something you are born with. And that's any
7 disease that you are born with at any age. So in
8 our database we capture all acquired disease in
9 patients less than the age of 18 and we capture
10 congenital disease at any age.

11 So, for example, a patient at the age
12 of one year has a repair of Tetralogy of Fallot
13 and then comes back at the age of 22 for a
14 pulmonary valve insertion and right ventricular
15 outflow tract reconstruction, that's an operation
16 that most commonly is done by a congenital heart
17 surgeon and ends up in the STS Congenital Heart
18 Surgery Database.

19 DR. DUTTON: Perfect. Thank you.

20 DR. GUNNAR: If I have a heart
21 transplant for my --- as a result of my
22 congenital heart disease at any age is that

1 included as well?

2 DR. JACOBS: Yes.

3 DR. FLEISHER: Kelsey, did you have a

4 --

5 MS. MCCARTY: Oh. No.

6 DR. FLEISHER: Okay. Any other
7 comments before we vote on evidence?

8 DR. EREKSON: I'm sorry, I'm not as
9 familiar. But in general I think my impression
10 is that congenital and pediatric cardiac surgery
11 is not necessarily elective, that you are not
12 going to be offering these patients non-surgical
13 treatments. Is that correct?

14 DR. JACOBS: Well, I'd say that's a
15 great question. For some of the most complex
16 forms of congenital heart disease that require
17 surgery in the first weeks of life, and without
18 surgery there is no chance of survival, some of
19 those with the highest risk, prior to operating,
20 it's not uncommon to have a conference with the
21 family and say, Okay, without surgery the chances
22 of survival are essentially zero, with surgery

1 the chances of survival are 50 percent. And a
2 discussion takes place as to whether or not the
3 family is willing to take on these very high
4 risks for that operation.

5 So there are a very small subset of
6 patients who are treated non-operatively with
7 comfort care and they don't survive. That's less
8 and less common as results are improving, but it
9 does happen.

10 DR. EREKSON: And I guess this gets to
11 in this specific case these are not necessarily
12 procedures where people would be gaming the
13 system and pushing patients towards surgical
14 treatment. At least it seems like that. Are you
15 monitoring for those types of --

16 DR. JACOBS: Well, I think any measure
17 is subject to gaming. That's a fact. But I
18 think it's probably not so easy to sit down with
19 a mother and a father with a sick little baby and
20 do anything but what's best for that little baby.
21 And the database has a fairly intense audit
22 process that covers a variety of domains of

1 what's in the database, but I think that the
2 likelihood of counseling a mother and a father to
3 do anything but what's best for the baby is
4 pretty close to zero.

5 MR. MARKMAN: Just one more question.
6 I noted in here that are you collaborating with
7 the European association? What percentage of
8 that contributes toward your database?

9 DR. JACOBS: Right. So the STS
10 Congenital Heart Surgery Database is purely
11 hospitals in the United States and Canada. We
12 also receive some data from a few other countries
13 that they use for their internal work, but when
14 we do an analysis of the STS aggregate data it's
15 only United States and Canada.

16 The EACTS database is a separate
17 database that's maintained in Warsaw, Poland.
18 And that database has the same exact fields, same
19 exact data definitions, and it's basically a
20 sister database.

21 When we do our benchmarking within
22 North America it's only based on North American

1 data. But when we do research projects on rare
2 lesions we will pool our data with the European
3 data.

4 DR. HANDY: I'm not sure this is the
5 right time to ask but since your application
6 states that the relationship between surgical
7 volume for pediatric congenital heart surgery at
8 a center and quality care is unclear and
9 controversial, why is the STS promoting this
10 structural measure when you already have two
11 outcome measures which take into account more or
12 less the same thing, not the volume but you're
13 tying the mortality to the volume --

14 DR. JACOBS: Right.

15 DR. HANDY: -- for the STAT
16 categories?

17 DR. JACOBS: Well, nowhere in this
18 measure do we say that more volume is a sign of
19 high quality. That's not the argument for this
20 measure. But we have published several papers
21 using the STS Congenital Heart Surgery Database
22 that shows that there is some form of

1 relationship between volume and outcome that's
2 more amplified at high-complexity operations.

3 And there's dozens of papers that have
4 been written about this. If someone asked me to
5 summarize them I would say that on the whole,
6 evidence shows that high volume centers tend to
7 perform better, especially with more complex
8 operations. But there's plenty of low volume
9 centers that achieve excellent results. That's a
10 two sentence summary of the volume outcome
11 relationship in congenital heart surgery fusing
12 together multiple papers.

13 Now, this measure is not being put
14 forth as a measure to say that volume is a
15 surrogate for quality, this measure is being put
16 forth that programs that have the ability to
17 capture data and stratify them by these five STAT
18 categories have in place a mechanism to track
19 outcomes. And that activity of being able to
20 capture all of your operations, put them into
21 buckets of complexity and get them into a
22 database, that we believe is a sign of quality

1 because you're measuring.

2 DR. FLEISHER: Just a quick question
3 then, Robert.

4 Did you have a follow-up?

5 DR. HANDY: Yes. I mean is that
6 necessary, considering you have 95 percent
7 penetrance in the STS database which is more
8 granular than this?

9 DR. JACOBS: Yes, so that's a great
10 question. So when this measure was put forth the
11 penetrance was a lot less than 95 percent. When
12 we put forth this measure the first time it was
13 probably 60 or 70 percent. Now it's 95 percent.
14 This measure is one of the facts that helped
15 increase that penetrance.

16 It's not unusual for a surgeon to sit
17 in a meeting room with some hospital middle
18 managers that are asking for justification about
19 why they should invest the resources necessary to
20 capture all these operations and stratify them
21 into these categories of complexity. And when
22 one says, well, this is an NQF-endorsed measure,

1 that is very helpful to getting them to write the
2 check to pay for the resources to capture the
3 data.

4 DR. HANDY: Maybe you just started
5 answering the performance gap question.

6 DR. FLEISHER: And remember that we do
7 have with performance gap, reserve status, which
8 this committee used frequently to say the
9 evidence exists but the gap does not but we
10 thought it was an important measure.

11 Robert?

12 DR. CIMA: Yes. That was going to be
13 my question that John followed up on is that
14 yesterday we had this discussion about pairing
15 volume and mortality with esophagectomy and we
16 actually did away with one of them and accepted
17 the other. You know, this is basically a measure
18 that says we measure. And you have other
19 measures that, as John points out, directly
20 related to this that are actual outcomes. And
21 the evidence, as Dr. Jacobs said, is not as clear
22 as it is with an esophagectomy. And so I'm just,

1 you know, again trying to simplify and look for
2 value in a measure.

3 I mean if you are looking for outcomes
4 you have pediatric outcomes. And I know we have
5 discussed this before. I'm not sure the NQF
6 should be in the fact of endorsing measures so
7 that it makes business sense for people to join a
8 registry. And I'm just saying what value does
9 this add?

10 DR. FLEISHER: Okay. We want to stay
11 with evidence. We also want, the one question
12 is, is this, is STS saying this is paired, such
13 that if one goes down, and we have Helen here and
14 Marcia.

15 If one goes down, the other goes down,
16 or is this a standalone measure because we had --

17 DR. BURSTIN: Standalone.

18 DR. FLEISHER: This is a standalone?

19 DR. BURSTIN: I mean if they're paired
20 and one goes down, I guess the question for the
21 committee remaining would be is the other as a
22 standalone sufficient to keep it going.

1 DR. JACOBS: So I, the comments that
2 I wanted to make is that even though the
3 penetrance is down 95 percent. If one is a
4 mother or a father who's bringing a baby to a
5 hospital, it's in the 5 percent that's not this.

6 That's a big deal, and I think
7 encouraging the remaining 5 percent to meet the
8 gap, that's a good thing.

9 I also think that removing this
10 measure could have some unintended consequences
11 as well because we're in an environment of very
12 limited healthcare resources. And there's middle
13 managers in every hospital that are trying to do
14 their job better by cutting the budget.

15 And when this, if this measure were to
16 be removed, this gives a tool for a middle
17 manager to limit the support of the database and
18 the data collection enterprise by saying NQF just
19 removed endorsement of this measure. Therefore,
20 we don't need to provide the support to collect
21 the data anymore. I think we should be careful.

22 DR. FLEISHER: Let me be careful also.

1 When we put on reserve, it's still endorsed.
2 It's just in reserved status for the committee.
3 Evidence only because I want to vote. Evidence,
4 Larry?

5 DR. MOSS: I think this is evidence.
6 As someone who's lived in the world of children's
7 survey since before the STS database existed,
8 this model has been extraordinarily valuable.

9 And it's transformed the field. And
10 you can qualify for this measure just by showing
11 up, but I would vigorously argue against this
12 going away. I mean it has worked. It is
13 working, and it's going to continue to work.

14 DR. FLEISHER: So that's endorsement
15 evidence.

16 MS. PITZEN: I just have a question.
17 I didn't hear paired or standalone. This
18 measure, is it standalone?

19 MS. MURPHY: This measure has been
20 identified as paired.

21 MS. PITZEN: What is it paired with?

22 MS. MURPHY: It's paired with a

1 mortality measure.

2 MS. PITZEN: I see.

3 DR. FLEISHER: So what does that mean
4 for us as we vote?

5 MS. MURPHY: What is has meant in
6 conversations of committee and in endorsement
7 practice over time is that the position has been
8 that a volume measure alone cannot stand alone.

9 There should be something with it, and
10 that has traditionally been a mortality measure.
11 So the sense has been that a volume measure would
12 not be endorsed alone.

13 And I think yesterday what happened
14 was that the measure that went down was the
15 mortality measure. So then that would have left
16 a volume measure alone. So it took down the
17 volume measure with it.

18 DR. GUNNAR: The other way around.

19 MS. MURPHY: They both went down.

20 DR. GUNNAR: They retracted them when
21 they admitted that they were paired.

22 DR. FLEISHER: They are going to try

1 to come back with a combined measure.

2 DR. JACOBS: So when these measures
3 went through the cycle of endorsement the first
4 time around, the reason, one of the arguments in
5 favor of both of these is kind of a subtle
6 argument but an important argument.

7 This measure talks about tracking
8 surgical volume for all pediatric and congenital
9 heart surgery and pediatric and congenital heart
10 surgery stratified by STAT categories.

11 The mortality measure that we'll talk
12 about later just talks about tracking mortality
13 stratified by STAT categories. And that subtle
14 difference deals with the fact that about 97-98
15 percent of operations are classifiable by the
16 STAT categories.

17 Then there's 2 to 3 percent of
18 operations that are not classifiable by the STAT
19 system because they're performed rarely, and
20 there's no data to put them into the STAT system.

21 So this measure, the volume measure,
22 required a program to not only keep track of the

1 volume for all their STAT categories but also the
2 volume of everything that they do, whereas the
3 second measure only looked at mortality
4 stratified by STAT categories because the overall
5 volume, the overall mortality is really not quite
6 as meaningful because it varies so much based on
7 case mix.

8 DR. CIMA: Is that an operational
9 issue? I just want to know for this. If you're
10 a member of the STS, and you're a children's
11 hospital, you would put in all your cases no
12 matter what. And then does the STS do this in
13 the background?

14 DR. JACOBS: That's a great question.
15 So this measure is written to be independent of
16 whether or not one participates in the STS
17 database.

18 So this measure is written that any
19 program can do it independently or as part of the
20 STS database. So if one is at a hospital that's
21 participating in the STS database, one could
22 still track all your outcomes, track all your

1 outcomes stratified by STAT categories and
2 comply.

3 But those hospitals that participate
4 in the STS database, which is now 95 percent,
5 they'll send all their data to STS with the
6 procedure of every operation and their
7 classification of which STAT category it would be
8 in. STS, at the level of DCRI, goes through all
9 those procedures and assures that the STAT
10 categorization is uniformly applied across all
11 centers.

12 So it's done both at the individual
13 hospital and at DCRI. And when DCRI, Duke
14 Clinical Research Institute, does multi-
15 institutional outcomes analysis, they do that
16 analysis based on cleansed and adjudicated data
17 to assure that the STAT categorization's applied
18 uniformly across centers.

19 DR. FLEISHER: So let's vote on
20 evidence. And we will get to the issue of what
21 we do with the measure itself. So please vote.
22 All right, go ahead, voting on evidence. We have

1 a couple more votes, just real quickly. Let's
2 call it.

3 MR. LYZENGA: We've got 45 percent
4 high, 35 percent moderate, 20 percent low, zero
5 insufficient and one abstention. So the measure
6 passes on evidence, and we can move to
7 performance gap.

8 DR. FLEISHER: So Robert, do you want
9 to comment? Are you in yet?

10 DR. SAWIN: Yes, so as mentioned, the
11 penetrance of this measure is already high. I
12 think we just had the discussion about, from Dr.
13 Jacobs about the potential value of getting that
14 last 5 percent involved.

15 DR. FLEISHER: Other comments on the
16 performance gap?

17 DR. MARKMAN: Yes, I think the
18 performance gap, after you explained it Dr.
19 Jacobs, I mean it's almost inherent in the
20 complexity of what you're doing in terms of the
21 STAT categories.

22 And I still believe that there is a

1 performance gap and that you have moved the
2 needle, according to what you were status, with
3 your status. And you can move it more, and I
4 think that because of the complexity of what
5 you're doing, I still believe that there is a
6 performance gap.

7 DR. JACOBS: I agree completely. If
8 one's child is having surgery at a hospital
9 that's in the 5 percent that's not doing this,
10 that's a sub-optimal setup.

11 I think that in and of itself is a
12 performance gap. I think that this measure has
13 been one of many reasons why the numbers went
14 from 30 percent to 50 percent to now 95 percent
15 penetrance.

16 And I do believe that withdrawing this
17 measure or retiring this measure could
18 potentially have an unintended consequence of
19 decreasing the funding to support the enterprise.

20 DR. FLEISHER: We shouldn't --

21 DR. JACOBS: I mean I used the wrong
22 word because I couldn't think of the right word.

1 DR. FLEISHER: But no, not the reserve
2 status but --

3 DR. JACOBS: That's what I was looking
4 for.

5 DR. FLEISHER: We shouldn't, the
6 funding for the enterprise should be different.
7 The question that I think Helen and I were
8 discussing is if this measure goes away, but the
9 other measure stands, is the measures together
10 weaker --

11 DR. JACOBS: Yes.

12 DR. FLEISHER: -- in the way we report
13 it to the public, because you're saying it's
14 paired.

15 DR. JACOBS: Right, I think to answer
16 the question, is the measure weaker, yes. It's
17 weaker because if we only had the mortality
18 measure, we would not know the answer of the
19 overall programmatic volume because the mortality
20 measure just stratifies mortality by five STAT
21 categories.

22 This measure has volume by five STAT

1 categories and overall volume.

2 DR. FLEISHER: So how should we think
3 about this as we vote?

4 DR. BURSTIN: I guess, I'm sorry, just
5 coming in late to this conversation. But it
6 sounds like high penetration is not necessarily a
7 bad thing. You'd like to, in fact, have many
8 centers participating so you've actually got data
9 from 95 percent of facilities on volume.

10 I guess one question might be, is
11 there a reason beyond having the risk-adjusted
12 mortality by, stratified by category in which
13 volume is incorporated, is there an additional
14 benefit to having volume paired with this
15 measure? And I guess one question might be from
16 a consumer, purchaser perspective.

17 Would it be useful to know volume
18 along with mortality, not in and of itself, but
19 if it's a paired measure and you get both, I
20 would think a fair number of consumers would like
21 to see this, institution of this, a lot of my
22 procedure, just as a thought.

1 DR. JACOBS: I would agree with that.
2 This is a publically reported measure. If you go
3 to the STS website, this information is on the
4 STS website as a publically reported measure.

5 And I think one way to say this is
6 imagine you're a mother, and you have a little
7 baby that needs a complex operation. And if you
8 knew that the mortality of a given center was 18
9 percent for that complex operation, that would be
10 useful.

11 Now if you also knew that the
12 mortality for that center was 18 percent, but
13 they had only done ten operations in the last
14 four years, eleven operations in the last four
15 years and another center that had the same
16 mortality but did, had done 150, that's useful
17 information for that mother and father to know.

18 So I think that it's publically
19 reported, and it does provide useful information.

20 MS. MURPHY: I have a question. I
21 thought from the submission there was information
22 that said that volume is not publically reported,

1 that that particular parameter is not publically
2 reported.

3 DR. JACOBS: On the STS website, we
4 report the number of operations done and the
5 mortality for all the STAT categories.

6 DR. GUNNAR: Do you run the risk of
7 limiting access to care where small volume
8 centers could be providing excellent care?

9 DR. JACOBS: Well, I think I would
10 agree that there's several small volume centers
11 that do provide excellent care. And there's also
12 some small volume centers that are outliers on
13 the side of low performance. We know that.

14 I think that there's, best as I know,
15 nowhere in the United States that a little baby
16 has a hole in the heart and needs heart surgery,
17 that they're not going to be able to get it.

18 There's not limited access. There's
19 countries where that exists. When Fred Grover or
20 when I go to Jamaica, there's places where a baby
21 has a hole in the heart, and they don't get it
22 fixed.

1 But there's no such thing as that not
2 happening in the United States. There's always a
3 way for a little baby who has a pediatric heart
4 problem to end up in a heart center and have it,
5 have the operation done.

6 When you're in a state like North
7 Dakota or South Dakota, one might have to travel
8 a little bit further. But probably it makes
9 sense to travel a little further to go to a
10 center that does a reasonable amount of heart
11 surgery than to have it done in a place that only
12 does maybe one pediatric heart operation a month,
13 which is what a state like North Dakota might
14 generate.

15 DR. FLEISHER: Barbara, Amy.

16 DR. LEVY: So I just think we need to
17 be thinking about this category, and maybe it's
18 outlived its purpose in some ways. Performance
19 gap is all about quality improvement.

20 But these measures are used for much
21 more than quality improvement as Jeff has been
22 talking to us about. They're for public

1 reporting. They're for patient decision making.

2 They're for a lot of other purposes,
3 and so I think when we're talking about retiring
4 a measure because the performance gap has been
5 improved to the point where we don't see a lot of
6 quality improvement opportunity in the measure, I
7 think we've limited ourselves. And we need to
8 broaden, perhaps, this voting metric that we look
9 at as a committee.

10 DR. FLEISHER: So Helen are we allowed
11 to, or Marcia, are we allowed to say not
12 applicable? I mean because I think what you're
13 suggesting, Barbara, is it's hard to put it into
14 that list.

15 DR. LEVY: I think if you can explain
16 it, that's great.

17 DR. JACOBS: Can I make a slight
18 clarification, too, because it was brought up
19 that the measure submission form says that volume
20 is not publically reported?

21 And I've just received a message that
22 that's an error, and volume is publically

1 reported. And that was just an error in the
2 measure submission form, which I think is
3 understandable because this is the book of all
4 our measure submission forms.

5 DR. FLEISHER: Okay. If you can send
6 an addendum. I think that's probably our only
7 error.

8 DR. SAIGAL: Can I ask a question?
9 Maybe what we could do is have, if a measure
10 doesn't have a performance gap, but it still has,
11 you know, and in a usability area, it's still
12 important for consumer decision making or
13 purchaser decision making, you can still pass.

14 DR. FLEISHER: Andrew, how do you want
15 to do this?

16 MR. LYZENGA: I think we have enough
17 discussion to go and address this issue.

18 DR. FLEISHER: Yes. So are we making
19 the determination that we do not need to vote on
20 performance gap? Is that --

21 DR. BURSTIN: I'm sorry. I'm still
22 having sidebars here with my methodologist. I'm

1 not sure I think this is the gap issue.

2 Performance gap really is intended to
3 say, is there variation in performance, or is
4 there significant performance gap. It's not the
5 same thing as seeing that a lot of institutions
6 are doing it.

7 So I guess the question might be, is
8 there still a gap, i.e. there is variation in
9 volume across these institutions, such that this
10 information is useful.

11 I mean we should talk about the
12 content of the measure. I think we're getting
13 confused about the 95 percent number, which in
14 the past, some of the structural measures we have
15 seen from STS -- and we've had plenty of debates
16 about this as Dave Shahian knows well --
17 participation in pediatric cardiac surgery
18 database should be a different story.

19 If that's topped out, you could say
20 sure, I'll look at the mortality measure. I
21 think in this instance it's a different measure.
22 It's not, 95 percent doesn't reflect performance.

1 It reflects submission of data, and if the
2 measure is publically reported, that's really, I
3 think, the issue. So I'm not sure there's
4 actually a gap question.

5 DR. FLEISHER: So just by a show of
6 hands, are people comfortable that when they
7 vote, they will vote on Helen's definition of
8 performance gap, which we will put into the body
9 of the report that that's how we approached this?

10 DR. DUTTON: So the gap is that
11 there's a variability between --

12 DR. FLEISHER: Yes, that there's a
13 gap, that there's variability.

14 DR. DUTTON: Between facility volume,
15 okay.

16 DR. FLEISHER: Anybody uncomfortable
17 voting for that? So let's vote --

18 DR. BURSTIN: They're waving their
19 voting wand.

20 DR. FLEISHER: Okay. Let's vote based
21 upon that, and we will put clearly in the
22 document what this vote meant, rather than doing

1 not applicable.

2 MR. LYZENGA: Okay. Voting on
3 performance gap.

4 MALE PARTICIPANT: So we're just
5 recognizing that there's variability?

6 DR. BURSTIN: Yes, that's one of the
7 definitions of gap.

8 MALE PARTICIPANT: And that's how we
9 defined it.

10 MR. LYZENGA: All right, so we have 50
11 percent high, 40 percent moderate, 10 percent
12 low, zero insufficient. The measure passes on
13 performance gap. We will go on to reliability
14 now. I'm sorry -- yes, reliability.

15 DR. SAWIN: So I think as presented,
16 this data is very reliable. It's audited by the
17 STS. I don't think there's any question that
18 it's high quality data and highly valued by
19 congenital heart surgeons who participate in it.

20 MR. LYZENGA: Any other comments on
21 reliability? Does not sound like it. Let's go
22 ahead and vote. Okay, if we can have the vote.

1 79 percent high, 21 percent moderate, zero low,
2 zero insufficient.

3 Measure passes on reliability. We'll
4 move to validity. Dr. Sawin, or anybody else
5 have any comments on validity?

6 DR. SAWIN: I'm sorry. I was on mute.
7 The validity has also been well established.
8 Again, the data is audited, and the data
9 abstractors are well trained. So it's a given
10 that it's high validity.

11 DR. FLEISHER: So going forward for
12 validity of any of the database measures, we will
13 ask prior to voting. And if --- are you okay
14 with that? And if anyone agrees that we should
15 vote separately for validity on any measure.

16 MR. LYZENGA: I think validity is one
17 that we want to continue to do votes for.

18 DR. FLEISHER: Okay.

19 MR. LYZENGA: Reliability may be a
20 different question because it seems like the
21 audit process is what's being referred to here,
22 and that's consistent across the measures.

1 I don't know. Can we have some, what
2 do you think about that? Melinda, Karen?

3 FEMALE PARTICIPANT: Scientific
4 acceptability --

5 MR. LYZENGA: It's the scientific
6 acceptability as a whole we're going to --

7 (Simultaneous speaking)

8 MALE PARTICIPANT: You can reliably
9 measure. If they have it measured, doesn't mean
10 it's valid.

11 MR. LYZENGA: Right. Yes, we'll
12 definitely do validity.

13 DR. FLEISHER: So validity we'll vote.
14 Please vote. Amy, do you want to hold the vote?
15 Amy and Collette?

16 MS. MOYER: So I'm reading what's on
17 the screen in front of me, and it says one of
18 the things we're supposed to be looking at is
19 that the measure score correctly reflects the
20 quality of care provided.

21 And it sounded to me like that was
22 unclear, that this volume necessarily reflected a

1 difference in quality of care. I mean that was
2 pretty much what was said.

3 I'm still a little boggled by the
4 votes results on the evidence. I have to be
5 honest.

6 DR. JACOBS: So what I would say
7 again, to summarize the data about the volume
8 outcome relationship, most people will feel that
9 quality of care at pediatric cardiac programs is
10 higher at high volume centers.

11 That difference is especially notable
12 in the most complex of operations. There's
13 plenty of papers published that support those two
14 facts. But the caveat is that excellent care is
15 delivered at some low volume programs. So one
16 cannot say that all low volume programs are not
17 good because some low volume programs are
18 absolutely fine.

19 It's just that if we're going to find
20 a low performance outlier, it's more likely to be
21 in a low volume program than in a high volume
22 program.

1 That's, I think, the summary of the
2 evidence of why volume is associated, at least in
3 some important ways, with outcome.

4 DR. SAIGAL: Can I mention, yesterday
5 we voted on a measure that had no evidence. We
6 specifically said that there was no evidence for
7 the measure. It was a thought process, and we
8 approved it. So to be consistent --

9 MR. LYZENGA: That was for an outcome
10 measure. There are different requirements for an
11 outcome measure as opposed to a structure,
12 process or intermediate outcome.

13 DR. SAIGAL: Okay, but still --

14 MR. LYZENGA: We do require a higher
15 sort of level of evidence for a process or
16 structure measure.

17 DR. FLEISHER: All right, Collette.

18 MS. PITZEN: Sorry. I just have a
19 technical question. In terms of validating that
20 the results are accurate, what kind of checks and
21 balances are in place for determining that the
22 volumes that the groups are reporting are

1 accurate.

2 DR. JACOBS: So that's a great
3 question, and I think we could address that now,
4 and it'll apply to every measure we talk about
5 for the rest of today.

6 Ten percent of the sites in the STS
7 database are randomly selected for audit on an
8 annual basis. This applies to the congenital
9 heart surgery database and adult cardiac surgery
10 database.

11 That audit includes reviewing the
12 operative log of the hospital to see how many
13 cases were done and reviewing the database to see
14 that all those cases were actually put into the
15 database.

16 So that's one component of a much
17 larger picture of the audit. But to answer your
18 question, that -- I think that answers your
19 question.

20 MS. PITZEN: Perfect. Thanks. It
21 just wasn't part of the application.

22 MR. LYZENGA: Shall we vote? We're

1 voting on validity now, 60 percent high, 30
2 percent moderate, 10 percent low, zero
3 insufficient. The measure passes on validity.
4 So we'll go ahead to feasibility.

5 DR. FLEISHER: Robert?

6 DR. SAWIN: Like all the registries,
7 there is the expense issue, the FTE involved in
8 having the clinical data abstractor. The fees
9 are relatively moderate at four to five thousand
10 dollars. But overall, I think the feasibility is
11 reasonable.

12 MR. LYZENGA: Any additional comments
13 or questions on feasibility? All right, let's go
14 ahead and vote, 71 percent high, 29 percent, and
15 zero low, zero insufficient. The measure passes
16 on feasibility. Go ahead to usability.

17 DR. SAWIN: So I just wanted to
18 clarify from Dr. Jacobs. So this data is
19 publically reported?

20 DR. JACOBS: Yes.

21 DR. SAWIN: So I think usability is
22 also good in both consumers and providers can

1 access the data. I'm not aware of any, other
2 than the issues we talked about earlier with 30
3 day mortality, I'm not aware of any unintended
4 consequences. Again, the audit process here is
5 very rigorous.

6 DR. MARKMAN: Just a quick question
7 for Dr. Jacobs. I'm not, on your site, how in
8 depth do you go into these STAT categories for
9 the public?

10 DR. JACOBS: So I could demonstrate.
11 I can either demonstrate or just describe it
12 because the site's up and running. They were
13 just looking at it over here.

14 But basically, for any program, you'll
15 get a table that has for rows, overall
16 programmatic volume STAT category one, two, three
17 four and five.

18 And the numerator will be patients who
19 met the definition of operative mortality. The
20 denominator will be the overall programmatic
21 volume for that category.

22 And then a percentage will be reported

1 for what the mortality is. And then after that,
2 there's an O/E ratio and a risk adjusted
3 mortality that's calculated.

4 DR. MARKMAN: Do you explain in
5 layman's terms the difference in the stat?

6 DR. JACOBS: Yes, absolutely. So what
7 we did was when we wrote this website and the
8 entire STS public reporting website, our team was
9 assigned the task of putting explanatory text on
10 the website that could be understood by somebody
11 with a fifth grade education.

12 And I think we've done a pretty good
13 job of achieving that goal.

14 DR. CIMA: Just for public record, Dr.
15 Jacobs and I were talking offline. I just want
16 to make sure how they define public reporting in
17 STS --

18 DR. JACOBS: Right.

19 DR. CIMA: -- because it's not
20 necessarily what everyone thinks.

21 DR. JACOBS: Yes, I don't think this
22 is news because this is the way the adult cardiac

1 surgery public reporting initiative works as
2 well.

3 First, the program needs to choose
4 whether or not to participate in the database.
5 So that's optional. There's no mandatory rule
6 that we can require people to participate in the
7 database.

8 But we know that in the adult
9 database, the penetration is over 90 percent and
10 the congenital database, 95 percent. Then, once
11 in the database, one has to decide whether or not
12 they're willing to publically report. And not
13 all programs that participate in the database
14 publically report, but what we have found is that
15 each year, more and more programs are opting into
16 public reporting.

17 DR. FLEISHER: Yes, Melissa?

18 MS. THOMASON: So I am the patient
19 voice on this board. First of all, I want to
20 commend you. The entire time you've spoke of
21 keeping it into the perspective of real lives,
22 real patients.

1 And thank you so much. I'm really
2 interested in the information you're putting out
3 there publically, and just really want to know if
4 you know how often patients are accessing your
5 information. Do you guys have numbers with that?

6 And how do you disseminate this
7 information? So how does the public know that
8 this is even available for their use?

9 DR. JACOBS: Right, so those are also
10 some very good questions. First of all, off the
11 top of my head, I do not know the number of
12 people who have accessed the website, but would
13 clearly be very easy information to obtain.

14 Regarding how we share this
15 information, if we focus first on the congenital
16 database, where public reporting is a new thing,
17 we rolled out public reporting in the congenital
18 database in January of 2015. So we've just
19 started it in the congenital database.

20 We've partnered with several advocacy
21 groups that are parent advocacy groups. There's
22 Pediatric Congenital Heart Association

1 especially. And they are actively helping us
2 wordsmith some of the text that describes the
3 information so that we can really be sure that
4 we're meeting our goal of explaining at the level
5 of a fifth grade education.

6 They are also in the process of
7 putting together their own website that explains
8 it in even more detail, and they're talking about
9 having some oral video presentations describing
10 it.

11 And this group, which is basically
12 parents of children who have had heart surgery or
13 adults who have had heart surgery as children,
14 this group is working on all of this.

15 And there's several STS members that
16 are on a committee that are helping them create
17 even more educational information. In fact, we
18 just had a phone conference Tuesday night about
19 this very topic.

20 So we're working to get the
21 information out in collaboration with disease
22 specific patient advocacy groups, I guess is the

1 answer to your question in one sentence.

2 DR. FLEISHER: Collette?

3 MS. PITZEN: Just a question of
4 curiosity. Is there a plan to use the STS
5 measures in a PQRS program in the future?

6 DR. JACOBS: I think that would be a
7 great idea.

8 MS. PITZEN: I mean you have great
9 penetration across the country. It would be a
10 great avenue for your cardiac surgeons to get
11 credit within those modules.

12 DR. FLEISHER: Thank you. Any other
13 comments, usability? Please vote.

14 MR. LYZENGA: We have 85 percent high,
15 10 percent moderate, 5 percent low and zero
16 insufficient information. It passes on usability
17 and use.

18 So that means we can go ahead and move
19 to overall suitability for endorsement. Any
20 additional comments or questions? Hearing none,
21 let's go ahead and vote. Overall suitability for
22 endorsement, yes or no.

1 DR. FLEISHER: We need a few more
2 votes. Okay, and we're set.

3 MR. LYZENGA: We have 90 percent yes,
4 10 percent no. Measure passes.

5 DR. FLEISHER: Great.

6 DR. JACOBS: I just want to bring a
7 piece of clarification about the PQRS. So I was
8 answering that specifically related to the
9 congenital database when I said that would be a
10 great idea.

11 We already do that with several of our
12 adult measures, okay. So I just interpreted that
13 you were asking about the pediatric measures, but
14 STS already has several of the adult measures
15 that are through the PQRS deal.

16 MR. LYZENGA: Okay. So we're moving
17 on to Measure 2683, Risk Adjusted Operative
18 Mortality for Pediatric and Congenital Heart
19 Surgery.

20 DR. JACOBS: Can I make -- this might
21 be out of order. I don't know, but I would
22 suggest if you did 0733 first. 0733 is a

1 building block for 2683. So --

2 MR. LYZENGA: Sure. That makes sense.

3 DR. JACOBS: If we discussed that
4 first, then it would be a building block for the
5 other one.

6 MR. LYZENGA: Sure. All right, so
7 we're going to switch the sequence up a little
8 bit. We'll go with 0733 first. This is
9 operative mortality stratified by the five STAT
10 mortality categories. And Collette and, let's
11 have --

12 DR. JACOBS: So briefly, we've already
13 discussed in detail what the STAT categories are.
14 This is just reporting operative mortality
15 stratified by the STAT categories.

16 I'd like to spend just 60 seconds
17 addressing the concept of operative mortality in
18 general just to get a few points on the record.

19 And this relates a lot to the
20 discussion that was held earlier about operative
21 mortality. And I just want to make four points.
22 Each will be one sentence long.

1 First of all, by using operative
2 mortality instead of 30 day mortality, that
3 mitigates against the problem of perversely
4 incentivizing providers to keep a patient alive
5 until 31 days.

6 So the measure of 30 day mortality
7 alone could have unintended consequences, which
8 are mitigated by using operative mortality, which
9 is a combination of 30 day mortality and
10 discharge mortality.

11 Second of all, by using robust risk
12 adjustment, that risk adjustment mitigates
13 against the fear to operate on high risk
14 patients.

15 So there was discussion before about
16 could a mortality measure have the perverse
17 unintended consequence of not wanting to operate
18 on high risk patients. Well, good risk
19 adjustment models will prevent that, and I
20 believe that the STS risk adjustment models
21 prevent that.

22 Third, in general, the STS has taken

1 the approach that mortality is one element of a
2 multi-domain outcome analysis that includes
3 mortality and morbidity components. And I
4 believe in the future should include patient
5 reported outcomes as well. So we're not saying
6 mortality is the only measure. We're saying it's
7 an important piece of a multi-domain measure.

8 And fourth, there was discussion
9 before about how do we assure that lives are not
10 unnecessarily being prolonged to comply with the
11 measure or to game the system. And I think
12 there's two answers to that. Number one, by
13 using operative mortality instead of 30 day
14 mortality, we eliminate the perverse incentive to
15 keep somebody alive 31 days.

16 But also, I think we could develop a
17 mechanism, that through the audit process, we can
18 assure as best as possible the unnecessarily
19 prolonging life purely to do on a measure doesn't
20 occur.

21 It's hard to believe it occurs that
22 often as somebody who operates on patients

1 everyday. But I think the audit process could
2 address that. So that's my comments related to
3 mortality. As Helen said, this is complex stuff,
4 but if we're going to talk about a mortality
5 measure, I think we have to get all those facts
6 out on the table.

7 Now specifically, this mortality
8 measure stratifies mortality by the five STAT
9 categories. There's multiple publications in the
10 peer review literature that shows substantial
11 variation across institution for mortality in
12 each of these five categories and especially in
13 the higher levels, four and five. And I think
14 that's why this is important.

15 MS. PITZEN: Great. Thanks very much.
16 This is measure 0733, Operative mortality
17 stratified by the five STAT mortality categories.
18 Apologies for my voice.

19 This measure includes pediatric
20 patients or congenital heart surgery patients
21 with an indexed surgery who have died, all deaths
22 during the hospitalization, any time frame, even

1 after 30 days or deaths after discharge but
2 within 30 days.

3 And just a comment, this is
4 incorporating neonates, infants, pediatric
5 patients and adult patients that have congenital
6 repairs that are occurring. The level of
7 analysis is group practice or facility.

8 I can talk a little bit about
9 evidence. The developers states critical
10 evaluation of operative mortality allows one to
11 evaluate the risk associated with a given
12 procedure for various patient characteristics.

13
14 And more importantly, aggressively
15 research ways to minimize that risk. I just want
16 to add that processes of care are involved,
17 including patient selection for appropriateness
18 of procedure, surgical technique and post-
19 operative care related to the avoidance of the
20 outcome of mortality. So I would rate the
21 evidence as really high.

22 DR. FLEISHER: Larry?

1 DR. GUNNAR: Just a reminder, this was
2 originally endorsed in 2011.

3 MR. LYZENGA: So we'll vote on
4 evidence. Go ahead and vote. I think we can
5 call it. Unanimous yes. The measure passes on
6 evidence. So we'll go to performance gaps.

7 DR. GUNNAR: Dr. Jacobs, do you have
8 anything to say about performance?

9 DR. JACOBS: I would just say that
10 there's multiple papers in the peer reviewed
11 literature, some of which I've written, that
12 document that the operative mortality varies
13 substantially from institution to institution at
14 all STAT categories and especially at the highest
15 STAT categories.

16 MR. LYZENGA: Collette?

17 MS. PITZEN: Great. Thanks. The
18 current mortality rate is at 3.4 percent. The
19 variation over time is best described by a table
20 provided by the measure developer.

21 Within that table, especially in the
22 Category 1, the least severe, there was

1 improvement from 0.75 percent to 0.38 percent.

2 And in the highest mortality category, from 18.8
3 percent mortality down to 12.75. So it is
4 demonstrating improvement over time.

5 MR. LYZENGA: So we'll vote on
6 performance gap. Oh, I'm sorry. Rick?

7 DR. DUTTON: Yes, this applies to a
8 lot of the measures with low volume, so valve
9 CABG ones that come up later will apply as well.
10 So you have 100 centers doing 2100 cases a year,
11 so about 200 cases per center for the mean. So a
12 death rate of 3.4 percent is seven deaths a year.
13 So with those low numbers, the ability to
14 discriminate high and low providers is almost
15 zero.

16 And I think you reported that 90
17 something percent wind up in the can't
18 discriminate from average category. So, it gets
19 to the discussion we were having yesterday.

20 I think as a quality improvement
21 measure, this has very little value because you
22 can't show a big difference. But I think as a

1 public accountability measure, obviously,
2 mortality after congenital heart surgery is very
3 important.

4 And I would endorse it for that
5 reason, but I wanted to hear you --

6 DR. JACOBS: You're raising some great
7 points. The feedback reports of the STS
8 congenital heart surgery database go back to
9 participants every six months.

10 In that six month feedback report,
11 those participants receive data that's analyzed
12 both in a one year and a four year analytic
13 window. So the one year analytic window reflects
14 a picture of most recently what's happening.

15 But has the problem that you just
16 pointed out, that if you're doing 200 cases a
17 year, there's only about seven children that die,
18 which is good. But then it's hard to
19 differentiate.

20 The four year analytic window now
21 narrows the confidence intervals and allows for
22 identification of outliers.

1 If we look at the four year analytic
2 window across the whole STS database, using 95
3 percent confidence intervals, we can identify
4 about 12.5 percent of programs as low performing
5 outliers, 12.5 percent as high performing
6 outliers, and about 75 percent as as expected
7 performing.

8 So by using a four year analytic
9 window, we can increase our sample size and
10 identify more outliers. By also reporting it to
11 the participants in a one year analytic window at
12 the same time, they can get a picture as to
13 what's happening most recently.

14 DR. GUNNAR: Just to clarify, not all
15 sites that participate are signed up for public
16 reporting.

17 DR. JACOBS: Correct. All sites that
18 participate get the feedback report that they can
19 use internally for quality improvement. Public
20 reporting in the congenital database especially,
21 is a new thing and only went live about eight
22 weeks ago.

1 And not all sites participate. If we
2 go online, we can see who's participating now and
3 who's not. If this is anything like what we saw
4 in the adult database, every year more and more
5 sites will publically participate.

6 DR. DUTTON: Jeff, is that Lake
7 Woebegone? Are the people who choose to
8 publically report the ones that have good
9 results?

10 DR. JACOBS: No, well, so that's also
11 a good question, and I think the best way to do
12 that would be to think about the adult cardiac
13 database.

14 In the adult cardiac database, we know
15 that about 75 percent of programs are two star,
16 12.5 percent one star and three star. And if we
17 look at the distribution of star ratings amongst
18 publically reported programs, it's quite
19 different.

20 But there are one star programs that
21 are publically reporting, and there are two start
22 and there are three star. It's just that it's

1 not 12.5, 75, 12.5. I would guess it's more like
2 5 percent are one star instead of 12.5 percent
3 are one star.

4 DR. DUTTON: And at some point the
5 fact that you're not publically reporting will be
6 taken as evidence --

7 DR. JACOBS: In and of itself as a
8 sign of poor quality.

9 DR. DUTTON: -- of low, so the public
10 good is still served. I get that.

11 DR. JACOBS: Absolutely.

12 MR. LYZENGA: Larry?

13 DR. MOSS: I was going to make this
14 comment yesterday about volume when we were
15 talking about the esophageal resection measure.

16 Essentially, all measures in
17 children's surgery are going to suffer from this
18 low volume issue. It's the nature of the field,
19 and we found it across specialties, that
20 mortality will not be a good discriminator of
21 quality in children's surgery.

22 But nevertheless, you can't not report

1 mortality, and none of our stakeholders in other
2 programs wanted us to not report mortality,
3 despite the fact that it's not an ideal
4 discriminator.

5 Other comment about volume with this
6 database here, this is not a low volume sample.
7 These are all the cases, so it isn't that there
8 are more out there to capture. This is the
9 universe of cases, so the numbers are the
10 numbers.

11 MR. LYZENGA: Any additional comments
12 on performance gap? Hearing none, let's go ahead
13 and vote.

14 DR. GUNNAR: So just maybe a question.
15 When you're so low, and a single event can be
16 tracked to a patient, is there a risk of
17 offending HIPAA in this?

18 DR. JACOBS: So we've -- STS has
19 invested a fair amount of time and money working
20 with some really world-class HIPAA lawyers that
21 are based in Chicago to make sure that everything
22 we're doing is compliant with HIPAA.

1 And just as I'm confident that it's
2 snowing here, and it's not snowing in St. Pete,
3 Florida, I'm confident that what we're doing is
4 HIPAA compliant.

5 MR. LYZENGA: All right, let's go
6 ahead and vote on performance gap.

7 Forty-two percent high, 53 percent
8 moderate, 5 percent low, zero insufficient.
9 Measure passes on performance gap. We'll move to
10 reliability.

11 DR. GUNNAR: Collette?

12 MS. PITZEN: Just a couple comments on
13 reliability. The numerator statement is clear.
14 The denominator includes an extensive procedure
15 list created and classified by STS.

16 Just a comment in the measurement
17 world, many times, procedures are defined by CPT
18 procedure codes or standard billing codes. This
19 measure does require participation in the STS
20 database and reliance on the categories that were
21 created by STS.

22 There was no reliability performance

1 score testing recorded for this measure.

2 However, that data element testing showed good
3 agreement with 97.5 percent accuracy rate.

4 DR. JACOBS: So I guess regarding the
5 reliability testing, my understanding of the
6 measure submission process is that there's two
7 choices.

8 One is to do it with the reliability
9 testing that we did not do in the others through
10 the audit, and we chose to save it through the
11 audit.

12 We know that measurement of
13 reliability is quite accurate -- measurement of
14 mortality is quite reliable. That's a better way
15 to say that. So we chose the option of doing
16 this through the audit, and I think that proves
17 that we have pretty good reliability.

18 MS. PITZEN: Just an additional
19 comment, oftentimes doing, the reliability
20 performance score testing does give us an idea
21 about capturing the variability between groups
22 and understanding if it's a good predictor.

1 So just a comment overall on all of
2 the individual measures that we're looking at
3 today, we don't know what those reliability
4 scores are except for your composite measure.

5 DR. JACOBS: So first, let me take a
6 step back. I forgot to answer one of your
7 previous comments about the list of procedures
8 that are eligible.

9 So that list of procedures that are
10 eligible has been cross-mapped to both CPT and
11 ICD-9 codes. And although it's probably
12 technically easier to do this participation in
13 the STS database, it's certainly possible to do
14 this without participating in the STS database.

15 And it's possible to do it using ICD-9
16 or CPT codes, a methodology which I think would
17 be less accurate and precise but certainly
18 doable.

19 MS. PITZEN: Just a quick following,
20 so do you have that crosswalk available?

21 DR. JACOBS: Yes.

22 MS. PITZEN: Okay. I just didn't see

1 it.

2 DR. JACOBS: I thought it was in here,
3 but if it's not, it certainly can be put in
4 there.

5 MS. PITZEN: Okay. Thank you.

6 DR. GUNNAR: Larry and then Greg? All
7 right, Greg.

8 DR. DUTTON: Not trying to pick on
9 you, but I always enjoy the chance to learn. Do
10 you want to comment on the no preemie PDAs --

11 DR. JACOBS: Yes.

12 DR. DUTTON: -- exclusion because --

13 DR. JACOBS: Right. That's a great
14 question.

15 DR. DUTTON: -- don't preemies need
16 love, too?

17 DR. JACOBS: No, they totally do. I
18 think, in fact I do a lot of those preemie PDA
19 ligations, and I love them all.

20 So the goal here is to have a measure
21 of mortality that's reflective of the
22 programmatic performance of a pediatric and

1 congenital cardiac surgery program.

2 The trick with premature PDAs is that
3 it's an operation that takes 15 minutes. It's a
4 very small blip in a hospitalization that might
5 be several months.

6 And oftentimes, when those premature
7 babies die, they die months after the surgery of
8 an event totally unrelated to the operation, like
9 necrotizing enterocolitis or sepsis or some other
10 miserable problem with prematurity.

11 So when we developed this measure, it
12 just didn't seem like mortality after a premature
13 duct ligation is reflective of the programmatic
14 performance of the cardiac surgery program.

15 Now the STS database captures that,
16 and we can look on any given time within the STS
17 database what is the mortality after premature
18 PDA ligation at any participant in the database
19 or across the whole database.

20 It's just that we don't include that
21 in this particular measure because we don't think
22 that mortality is reflective of the programmatic

1 performance of the cardiac surgical program.

2 DR. GUNNAR: Any additional comments?
3 Let's go ahead and vote on reliability.

4 MR. LYZENGA: A misfire. I think we
5 may have to revote on this one.

6 DR. GUNNAR: Okay. Vote again. Is
7 that ready?

8 MR. LYZENGA: Not quite. It's just a
9 second. Ready. Go ahead, voting on reliability.
10 We have 76 percent high, 19 percent moderate, 5
11 percent low, zero insufficient. Measure passes
12 on reliability. We'll go ahead to validity.

13 MS. PITZEN: The developer provided
14 great data element validity. Accuracy rates in
15 the 97 percent. Just wanted to comment. It
16 appears to me that this measure is not risk-
17 adjusted, rather stratified by the five STAT
18 categories. And so C statistics were provided
19 for those five STAT categories as well.

20 Additionally for validity. They did
21 a nice job of comparing over time levels of
22 provider performance and consistency across time.

1 DR. JACOBS: The only thing I would
2 add is that we believe that stratification across
3 STAT categories is risk adjustment by definition.

4 DR. GUNNAR: Any other comments?

5 DR. YATES: One comment for all the
6 rest of the STS measures we go at because we
7 discussed today, and this is relevant to the
8 mortality question that came up earlier.

9 At any point does the registry capture
10 the unusual circumstance, albeit in children, but
11 might be applicable to all the rest of the
12 measures, does it capture DNR status going into
13 surgery, which would be atypical? And does it
14 capture the creation of DNR status after surgery?

15 DR. JACOBS: So this is a very complex
16 question you're asking, which we could spend the
17 next several hours on.

18 To try to answer it in two sentences,
19 in my career I've done over 3000 pediatric and
20 congenital cardiac operations, and I've never
21 once taken somebody to the operating room with a
22 DNR status when we started the operation. I've

1 just not seen that happen.

2 Now, on the other side of the
3 spectrum, I would say that 90 percent of the
4 children who die after heart surgery are DNR at
5 the time that they die, at least 90 percent.
6 Because eventually, through the grieving process
7 of the family and the overall horribleness of
8 watching a baby die, there's multiple meetings
9 with the healthcare team, the nurses, all the
10 family members.

11 And we gradually work our way through
12 this grieving process where the first discussion
13 is it seems unlikely that your baby is going to
14 survive and that it may be time to shift the
15 focus of our care from survival to comfort.

16 And after several more discussions and
17 however many discussions the family requires,
18 which might be one or might be 20, eventually,
19 the child reaches a point where they're put on
20 DNR.

21 And usually even there then some
22 levels of support are withdrawn. So it's unusual

1 for a child to die after pediatric heart surgery
2 not being a DNR.

3 So we could track those things, and I
4 think it would be interesting to track. But I
5 would think that on the side of DNR before
6 pediatric heart surgery, it's going to be close
7 to zero. In DNR at the time of death, it's going
8 to be almost all of them.

9 DR. YATES: Again, the question wasn't
10 asked specifically for pediatric. It was meant
11 to just clear the air for the rest of the day,
12 and I would, if it's not captured, it would
13 certainly be a valuable thing to be able to
14 report on if questioned by outside parties.

15 And I think it would ameliorate some
16 of the concerns that were expressed in the
17 earlier conversation where it does happen and
18 people, and that's there's normal behavior.

19 Again, that ties into broad questions
20 about cardiac going forward for validity. Thank
21 you.

22 DR. GUNNAR: Larry?

1 DR. MOSS: So I think Dr. Yates raises
2 an excellent point, but just also for the record,
3 there is a vigorous national debate about DNR in
4 patients with congenital anomalies.

5 And it remains to be resolved. It's
6 not the national standard of care to take
7 patients for any operation, congenital heart or
8 not who are not, who don't have the DNR status
9 removed but what to do in the post-operative
10 period and how to define that is being looked at
11 and not yet defined.

12 DR. GUNNAR: Any other comments?
13 We'll vote on validity.

14 MR. LYZENGA: We have 81 percent high,
15 14 percent moderate, 5 percent low, zero
16 insufficient. Measure passes on validity, so
17 we'll go ahead to feasibility.

18 So yes, is this -- and there was some
19 question of whether the first measure, which was
20 a volume measure, would be applicable across the
21 rest of them.

22 Do we have some consensus that it is?

1 Does anybody want to discuss feasibility or vote,
2 or are you comfortable turning the vote --

3 MALE PARTICIPANT: We should vote. We
4 don't have to --

5 MR. LYZENGA: All right, we're voting.
6 So go ahead and cast your vote on feasibility.
7 We have 75 percent high, 20 percent moderate, 5
8 percent low, zero insufficient. So we'll move on
9 to usability.

10 DR. GUNNAR: Discussion? Dr. Yates,
11 you have your, okay. Collette, go ahead.

12 MS. PITZEN: I know this is late.
13 It's just a comment. The STS database has great
14 penetration. It's being used across the country,
15 but it also can be a very burdensome thing.

16 The data collection form for the
17 congenital pediatric database is 32 pages long.
18 So I just think in a general sense, at some point
19 in time, we need to weigh the value of burden and
20 feasibility against the value of the metric that
21 we're collecting and outputting.

22 DR. JACOBS: I think you're absolutely

1 correct. One thing about those 32 pages though
2 is that huge portions of that are parent/child
3 fields.

4 So if a given field applies to an
5 operation, you click yes, and you enter the
6 children of all that. If not, you enter no, and
7 you bypass all the pages associated with that
8 child.

9 And several portions of that are just
10 lists of diagnoses, procedures, complications, so
11 32 pages might sounds very overwhelming. But I
12 know that essentially, everybody doesn't do it by
13 paper now.

14 They do it electronically, and in our
15 own hospital, the time it takes to enter the
16 information from a given operation by the team t
17 that enters the data is about 20 minutes per
18 operation at most.

19 DR. GUNNAR: What's the complete
20 number of data fields?

21 DR. JACOBS: I don't know that off the
22 top of my head. I'd have to go back and look

1 that up.

2 DR. GUNNAR: For the adults, it's
3 about 680 or something with the new format.

4 DR. JACOBS: Yes, I mean there's no
5 doubt that it takes time, effort and money to
6 collect these data. But it's money well spent.

7 DR. SAWIN: And there's value, too,
8 from a quality improvement standpoint. There's
9 all kinds of data that can be generated by this
10 registry, so it's very valuable for things much
11 wider than mortality.

12 DR. GUNNAR: Any other comments? Vote
13 on usability?

14 MR. LYZENGA: Go ahead and vote. I
15 think we can call it. We have 70 percent high,
16 25 percent moderate, 5 percent low, zero
17 insufficient. Measure passes on usability and
18 use.

19 So we will go ahead to overall
20 suitability for endorsement. Any additional
21 comments? Hearing none, we'll vote on overall
22 suitability for endorsement.

1 Unanimous yes, 100 percent. The
2 measure passes, and I think we are going to go
3 ahead and take a break now. If you could come
4 back here at 10:45. Thanks everyone.

5 (Whereupon, the above-entitled matter
6 went off the record at 10:29 a.m. and resumed at
7 10:48 a.m.)

8 DR. FLEISHER: Okay, we are going to
9 get started. I've been talking to Helen and
10 Marcia, I mean I think this morning's discussion
11 and where we ended up really is a new direction
12 for how we get ahead of some of these discussion
13 and help shape them. So, it's really fantastic
14 and we look forward to that call.

15 And I guess they'll decide whether
16 that will be an open call? Yes, and they'll get
17 back to us. So, we'll hopefully decide.

18 So, we are up to, is it 2683? Okay.

19 DR. JACOBS: So, this is a measure
20 from the STS Congenital Heart Surgery Database
21 that I think I'm most proud of out of everything
22 in the congenital database that we've done. It's

1 a tool that uses everything we've talked about so
2 far as building blocks.

3 And we talked earlier that
4 categorizing operations into STAT categories is a
5 form of risk adjustment. But, one could then
6 argue that any given patient in STAT Category 5
7 might not be the same as any other patient.

8 So, you can have a STAT Category 5
9 patient undergoing an Norwood Operation that had
10 a prenatal diagnosis that was electively
11 delivered that goes to the operating room
12 extubated and eating.

13 Then you can have another patient
14 having a Norwood Operation that is born in shock,
15 gets put on ECMO and goes to the operating
16 theater on mechanical circulatory support.

17 And the STS Congenital Health Surgery
18 Database has only matured recently to a point
19 where we have the capability of finely
20 differentiating these preoperative factors.

21 This risk model that we're putting
22 forward is a new measure and what it does is it

1 provides risk adjusted operative mortality based
2 on a number of variables which include the
3 operation that's performed, the STAT category of
4 that operation, a variety of preoperative factors
5 that include chromosomal abnormalities, syndromes
6 that the child is born with, non-cardiac
7 abnormalities like gastroschisis or omphalocele
8 that the child is born with, preoperative factors
9 like whether or not the baby's on the ventilator,
10 on mechanical circulatory support, has
11 preoperative renal failure or a preoperative
12 neurologic deficit and previous cardiac surgery.

13 And all of those factors are then put
14 into a multivariable model that allows one to
15 calculate risk adjusted mortality and observe to
16 expected mortality rates. And those can then be
17 reported back stratified by STAT categories,
18 stratified by age groups or stratified by both
19 STAT categories and age groups.

20 So, this is our newest measure of
21 reporting risk adjusted operative mortality in
22 the STS Congenital Heart Surgery Database. It is

1 publically reported on the STS website and it's a
2 new measure that we're putting forward for
3 endorsement.

4 DR. FLEISHER: Fantastic. So,
5 evidence? This is clearly an outcome, so, Larry,
6 any comments about?

7 DR. MOSS: So, things to talk about
8 about the measure but with respect to the link
9 between risk adjusted mortality and processes and
10 structure of care, I think it's pretty self-
11 evident, so I don't have anything more to say
12 about that.

13 DR. FLEISHER: Shall we vote?

14 Any comments on evidence?

15 Let's vote. Get the vote?

16 MR. LYZENGA: Unanimous yes and passes
17 on evidence. So, go to performance gap.

18 DR. MOSS: So, one just quick
19 additional comment about evidence before we jump
20 into that.

21 We've commented that mortality is a
22 less than ideal discriminator in the pediatric

1 world. The state of the field in infant outcomes
2 is evolved to neurodevelopmental outcomes.

3 I'm interested whether there's
4 anything in the pipeline or whether you will be
5 bringing us anything in the future in that area?

6 DR. JACOBS: Yes, that's a great
7 question.

8 So, we have an NIH funded R01 grant
9 that's funding research into developing a multi-
10 domain composite that will be based on risk
11 adjusted mortality and a variety of risk adjusted
12 morbidities that will include postoperative
13 strokes, postoperative renal failure,
14 postoperative respiratory failure, postoperative
15 mechanical circulatory support.

16 We're moving in that direction. We've
17 published some papers about that already where we
18 have STAT morbidity categories that is a parallel
19 initiative to the STAT mortality categories.

20 And through an NIH funded grant, we're
21 developing a multi-domain composite. We're
22 working with Dave Shahian, Sara Pasquali whose an

1 Outcomes Investigator at University of Michigan,
2 Sean O'Brien and Max and the DCRI team, that's
3 where we're headed.

4 Hopefully, I'll be back here to tell
5 you guys about that soon.

6 DR. FLEISHER: Fantastic. I mean
7 perversely, it would be interesting if there was
8 a gap in care identified in our document and
9 somebody put in a grant, they could actually cite
10 our document as something to support that.

11 So, this idea of what people are
12 bringing up again, the value of a standing
13 committee, would be useful. So, Andrew, we'll
14 make sure that's in the document.

15 DR. JACOBS: Yes, I think that's
16 great.

17 DR. MOSS: So, with respect to
18 performance gap, the risk adjustment process is
19 well described and we'll discuss that under
20 validity.

21 But, in the model, there were 86 cites
22 with 12 high outliers and seven low outliers, so

1 22 percent were statistical outliers. So, there
2 does seem to be a significant opportunity for
3 improvement and the data do seem to outline that.

4 DR. FLEISHER: Okay, any other
5 comments? Questions?

6 Let's vote. Can we see the vote?

7 MR. LYZENGA: Fifty-seven percent
8 high, 43 percent moderate. The measure passes
9 performance gap.

10 So, we'll move to reliability.

11 DR. MOSS: We've talked about the
12 audit process, that's the relevant issue here. I
13 won't repeat that unless people want to discuss
14 it.

15 DR. FLEISHER: Rick?

16 DR. DUTTON: One quick request. For
17 all of the -- it applies to about half of the STS
18 measures, but includes all the mortality ones.
19 The anesthesia ghetto down here would love to
20 have you list the anesthesia CPT codes for these
21 same operations.

22 Are they same operation, same patient?

1 Same results? Same outcome? There's an
2 anesthesia provider there as well. We would love
3 to have you list our CPT codes with these so they
4 can be reported.

5 DR. JACOBS: Yes, I think that that's
6 very doable and we would be happy to do it.

7 Just so you know, there is a
8 Congenital Cardiac Anesthesia Society and the
9 Congenital Cardiac Anesthesia Society has
10 partnered with the STS Congenital Heart Surgery
11 Database and there's a specific anesthetic module
12 of the STS Congenital Heart Surgery Database.

13 That initiative is led by David Vener
14 at Texas Children's Hospital and we partnered
15 with anesthesia for a variety of issues and it's
16 been very good and we're starting to publish some
17 papers together.

18 There's this Optional Anesthesia
19 module that has increasing penetrance and we're
20 really moving in that direction in multiple
21 domains.

22 DR. FLEISHER: Thank you.

1 No other comments?

2 Let's vote.

3 MR. LYZENGA: Eighty-six percent high,
4 14 percent moderate, zero low, zero insufficient.

5 So it passes reliability. And we're
6 going to go validity.

7 DR. MOSS: So, I think the most
8 relevant issue for validity is the risk
9 adjustment model and the developers were kind
10 enough to provide a line by line mathematical
11 proof of that model which, I think, you did to
12 intimidate the reviewers and it worked.

13 You talk about the logistic regression
14 model and my interpretation in reading through
15 what's provided, it seems to me the biggest risk
16 in this kind of analysis is nesting of cases in
17 individual institutions because of the unique
18 processes of care associated with congenital
19 heart surgery.

20 It was my interpretation that this was
21 a hierarchical model, I'm just confirming that
22 with you and your statistician.

1 MR. HE: Yes, this is a hierarchical
2 model, but unlike the more hierarchical model you
3 will see in some other measures, the hierarchical
4 part for this model is actually not to
5 accommodate the participant level of variation.
6 It's actually to accommodate the procedure level
7 of variation.

8 So, Jeff already mentioned that we
9 have the STAT category in this model. We
10 actually have finer categories. We included all
11 the procedures that have more than 50 cases. So,
12 we have more than five categories of procedures
13 in this model.

14 To accommodate that large number of
15 categories, we can now use all the different
16 procedures that may affect the model, so inside
17 we pulled out all of those as a separate level so
18 that we have a hierarchical structure.

19 DR. MOSS: So, pardon me for my -- if
20 this is a statistically naive question, but could
21 you explain to us, if we don't adjust for nesting
22 of cases within institutions or nesting of

1 patient outcomes within institutions, we could
2 potentially overestimate the difference in
3 outcomes. How does this model address that?

4 MR. HE: Sorry, could you explain it
5 in maybe another way for me?

6 DR. MOSS: How does this model address
7 variation within a center versus variation
8 between centers?

9 MR. HE: So, this model is to provide
10 a baseline prediction for patients that come in
11 for a pediatric or congenital heart surgery.

12 So, I think it's called a marginal
13 model. So, we try to just to give an estimate at
14 the population average level.

15 DR. MOSS: I'll just add to that for
16 the committee that the outcome of all that is
17 pretty good reliability. It was 0.55 for the
18 institutions with less than 200 cases and 0.88
19 with institutions with more than 800 cases and
20 0.69 overall.

21 DR. FLEISHER: Thank you, important
22 information.

1 Any other questions, comments?

2 Let's vote.

3 MR. LYZENGA: We have 62 percent high,
4 38 percent moderate. The measure passes on
5 validity.

6 So, we'll go ahead to feasibility.

7 DR. MOSS: Again, I think this is an
8 issue we've covered and if there's discussion,
9 please go ahead.

10 DR. FLEISHER: Would anybody like to
11 vote or can we carry this over? Anybody
12 disagree? Okay.

13 MR. LYZENGA: All right, we will carry
14 over the vote from the previous measure on
15 feasibility.

16 Any comments or desire to vote on
17 usability? All right, we will also carry over
18 the votes from the last measure on this one.

19 And we will take a vote now on overall
20 suitability for endorsement.

21 One hundred percent yes. The measure
22 passes.

1 We'll go on to the next one.

2 Next, we'll be moving to 0115, Risk
3 Adjusted Surgical Re-exploration.

4 Dr. Jacobs?

5 DR. JACOBS: Yes. So, now we're
6 moving into the STS Adult Cardiac Surgery
7 Database and this measure is the percent of
8 patients age 18 or older undergoing coronary
9 artery bypass grafting who require reintervention
10 during the current hospitalization for
11 mediastinal bleeding with or without tamponade,
12 graft occlusion, valve dysfunction or other
13 cardiac reasons.

14 So, basically, patients who require
15 surgical re-exploration for a cardiac reason.

16 DR. GUNNAR: I didn't have it, is this
17 a new measure or is this -- what is it?

18 DR. JACOBS: This is an old measure.

19 DR. GUNNAR: It is a maintenance
20 because I didn't have it in my documents.

21 DR. JACOBS: It's maintenance of an
22 old measure which ultimately becomes part of our

1 multi-domain composite for coronary artery bypass
2 grafting.

3 DR. FLEISHER: And Barry?

4 MR. MARKMAN: Yes, it was first
5 introduced in 2007 and it's one of the 11
6 component measures of the STS CABG composite.

7 It's an outcome measure and my
8 question is, I mean the risk adjustment is very
9 important and it's one of 11 of them. What's so
10 important about having these individual risk
11 adjusted within the composite itself?

12 DR. JACOBS: Right. So, well, first
13 of all, it's nice to know that each element of
14 the composite is also an NQF endorsed measure.
15 So, that when we look at a composite, you can say
16 that every single piece of that composite has
17 been evaluated individually and is endorsed by
18 NQF.

19 So, that's a general principle as to
20 why all the different pieces of the composite
21 that we'll talk about later are also individual
22 NQF endorsed measures, some of which are coming

1 up for maintenance during today.

2 DR. GUNNAR: So, just for my -- when
3 you sign on for public reporting, do you sign on
4 for the whole whatever STS has decided that
5 they're going to report or is it a la carte or --

6 DR. JACOBS: So, the way it works
7 right now is that when one signs on for public
8 reporting, there is a consent form with a variety
9 of check boxes. And what the check boxes include
10 is, you can report for CABG, you can report for
11 aortic valve replacement, you can report for
12 aortic valve replacement combined with CABG.

13 So, if you agree to report for CABG,
14 you get the whole CABG composite. If you agree
15 to report for AVR or AVR CABG, same thing.

16 So, you can't select a component of a
17 composite to report, but you can select the
18 operative subgroup that you would report.

19 DR. GUNNAR: So, flip that is, are the
20 components reported or just --

21 DR. JACOBS: Both.

22 DR. GUNNAR: So, both the composite --

1 all the components --

2 DR. JACOBS: Right.

3 DR. GUNNAR: -- the composite and the
4 composite is reported.

5 DR. JACOBS: Correct, correct. So,
6 you start out by getting the composite but then
7 the user of the website, the patient, the parent,
8 the family has the ability to drill down into
9 more detail should they desire, both with star
10 ratings and with point estimates with components
11 and rules or credible indices.

12 MR. MARKMAN: Do you continually data
13 mine this and for new uses and new findings based
14 upon your database? I see that you have
15 something with ethnicity in your little summary.

16 So, as you continually data mine, have
17 you done anything new or different with this?

18 DR. JACOBS: Well, there's the quality
19 arm and the research arm and the research arm is
20 active, ongoing arm of the database that leads to
21 dozens of peer review publications every year.

22 I mean it's the range of the entire

1 spectrum of cardiothoracic surgery.

2 MR. MARKMAN: Yes, so, it's ongoing
3 performance. And, you know, I mean you're really
4 using that.

5 DR. JACOBS: Absolutely. Like on the
6 quality side, participants get feedback in the
7 Adult Cardiac Surgery Database every three months
8 with a feedback report that provides the
9 information in these measures plus the whole pile
10 of other information.

11 And then on the research side, there's
12 probably 25 to 30 ongoing studies right now to
13 try to improve the state of care.

14 MR. MARKMAN: And I also noticed that,
15 I don't know if this goes back to usability, but
16 I think the evidence does come into play here.

17 You have a pretty stable number of
18 participants but there is some variation. I mean
19 do some hospitals drop out?

20 DR. JACOBS: Well, some hospitals stop
21 doing heart surgery, other hospitals start doing
22 heart surgery and, you know, so it changes every

1 harvest. Some of the changes probably related to
2 hospitals dropping out or hospitals coming in,
3 but once you're over 90 percent penetrance,
4 that's not the huger part.

5 In an era of shifting health care
6 economics, there's new places that are starting
7 to do open heart surgery and there's other places
8 that are deciding not to.

9 DR. CIMA: On the evidence section,
10 you report over two 12-month periods, but I just
11 want to know, since this has been an older
12 measure, is there data on overall performance? I
13 mean this is a bleeding measure, so are there
14 fewer -- has this moved people over time?

15 DR. JACOBS: Yes. I know that the
16 overall performance in the composite has gotten
17 better over time. Our overall mortality has
18 gotten better over time. I don't know the answer
19 specifically how the rate of re-exploration for
20 bleeding has changed over time, but the rate of
21 re-exploration overall has changed over time.

22 That's certainly something we can look

1 at.

2 DR. GUNNAR: Barbara, you -- I think
3 you had backup to this. Is there anything else
4 you wanted to add?

5 DR. LEVY: No.

6 DR. GUNNAR: Can we go ahead and vote
7 on the evidence?

8 MR. LYZENGA: So, voting on whether a
9 rationale supports the relationship of the health
10 outcome to at least one health care service
11 process intervention or service. Your options
12 are yes and no.

13 I think we can close it out. Ninety-
14 five percent yes, five percent no. The measure
15 passes on evidence.

16 So, we'll move to opportunity for
17 improvement performance gap.

18 MR. MARKMAN: So, why do you only have
19 90 percent and, I mean you still have room to
20 enlist more hospitals?

21 DR. JACOBS: So, we're talking
22 penetrance. Why do we only have 90 percent of

1 the hospitals in the country participating in the
2 database right now?

3 MR. MARKMAN: Right.

4 DR. JACOBS: You know, I think my
5 guess is it's higher. When the last STS CMS link
6 penetrance paper went up to 2012, right, so the
7 way we're calculating penetrance is based on the
8 number of CMS providing hospitals that perform
9 CABG and how many of those participate in the STS
10 database. Because, essentially, everybody that
11 does CABG participates in Medicare.

12 So, we have to calculate the
13 denominator. We have to use the latest link to
14 Medicare data. And we have now access to a link
15 of STS data to Medicare data up through 2012 and
16 every year the penetrance has gone up for the
17 last 12 years so that it's now 90 percent as of
18 2012. And my guess is in 2015, it's even higher,
19 but I can't say that as a fact until we have more
20 recent CMS data.

21 DR. GUNNAR: But to be clear, you
22 could have three groups operating at a particular

1 facility, theoretically, and only one of the
2 groups participate?

3 DR. JACOBS: Yes, so, when we
4 publically report our outcomes, we publically
5 report our outcomes stratified both by
6 participant group and by hospital.

7 So, we can go to the STS public
8 reporting website or the public reporting website
9 on Consumers Report and we can say we want the
10 outcomes for all the hospitals or all the groups.

11 In most cases, that's a one to one
12 relationship. There's one hospital that's got
13 one group. But, in some cases, it's one to many
14 or many to one. So, one group can operate at
15 many hospitals and a given hospital can have many
16 groups.

17 And what the strategy of allowing
18 access to the data both stratified by hospital
19 and by group is to deal with that issue. And
20 even though some hospitals have many groups or
21 some groups go to many hospitals, by allowing
22 access to the data with both ways, we can really

1 answer questions for both approaches.

2 DR. GUNNAR: Any other discussion
3 regarding performance?

4 Can we -- what has happened in this
5 arena regarding performance for this particular
6 measure over the last --

7 DR. JACOBS: Right, so I think that
8 somebody else just asked that. I don't know the
9 answer to how re-exploration for bleeding has
10 changed over time.

11 I think that we know that risk
12 adjusted mortality has decreased over time and
13 performance on the composite has changed over
14 time and we certainly could investigate how this
15 particular domain of the composite has changed
16 over time, but I couldn't tell you that right
17 now.

18 DR. GUNNAR: So, as a matter of
19 process, and I'm -- believe me, without that
20 evidence it may be the desire of this committee
21 to say that this is topped out and without that
22 information, we can't make that determination.

1 So, as a matter of --

2 DR. JACOBS: They're getting it.

3 DR. GUNNAR: Okay. Do you want to
4 move to the next measure and come back to that?
5 Because I don't know that we can fundamentally
6 vote on performance gap without the information.

7 DR. LEVY: Well, there is a
8 discrepancy between the high performing and the
9 low performing places. I mean there is
10 definitely gap that's still there that they've
11 reported in the submission.

12 DR. JACOBS: Right. I think there's
13 definitely evidence that there's variation, I
14 just can't tell you if it's better now than it
15 was two years ago.

16 DR. GUNNAR: And what's the
17 relationship between the high performing and the
18 low performing? Is the difference between --

19 DR. LEVY: It's one percent to five
20 percent, something like that.

21 DR. GUNNAR: Okay, that's kind of what
22 I needed to know.

1 DR. JACOBS: Okay.

2 DR. GROVER: It's 1.4 to 9.2 percent

3 and --

4 DR. GUNNAR: Very good, and then we'll

5 save that other comment about what's happened

6 over time for --

7 DR. JACOBS: We'll have that for you

8 --

9 (off mic comments)

10 DR. GUNNAR: Thank you.

11 Any other discussion on performance?

12 Let's go ahead and vote.

13 MR. LYZENGA: Voting on performance

14 gap, data demonstrate considerable variation or

15 overall less than optimal performance across

16 providers.

17 DR. GUNNAR: While we're waiting for

18 that, just a point, at some point, this, you

19 know, the hope of all these, right, is that

20 they'll all go into reserve status at some point

21 in the future, right, that's the ultimate goal,

22 right?

1 David? Well, here is the question, as
2 a component, does it matter to a composite
3 measure whether a component of that composite
4 measure is in reserve status? Just a matter of -
5 - I don't think it does from an NQF perspective.

6 MR. LYZENGA: From an NQF perspective,
7 components of a composite do not need to be
8 endorsed, so it can be in reserve status, it
9 could not be endorsed.

10 DR. GUNNAR: John?

11 DR. HANDY: Although, I hadn't thought
12 about it until Dr. Jacobs said it, it does -- if
13 a specialty group just sort of arbitrarily
14 chooses points of care to say this is good care,
15 there is more standing if the points of care that
16 have been chosen to make up the composite have
17 been separately endorsed by the NQF.

18 I also had the same question and never
19 had considered it in that light.

20 DR. JACOBS: Yes, I mean I think -- I
21 mean that's our belief. We like to be able to
22 say when people question the basis of our

1 composite that every element within the composite
2 has been vetted through NQF and endorsed.

3 MS. MURPHY: And one thing that I
4 would add and look to Helen about this is my
5 memory of it over the time of developing the
6 guidance for composite measures and the
7 endorsement is that the individual measures did
8 not have to be endorsed but they were to be
9 vetted through the process.

10 DR. BURSTIN: That's still correct,
11 yes.

12 MS. JOHNSON: There's a couple little
13 details on that. Without going into too much
14 details, sometimes individual measures aren't
15 quite reliable enough to make it through on their
16 own but they actually do contribute to the
17 composite.

18 So, that might be one reason why a
19 measure couldn't be individually endorsed by NQF,
20 but would be a very valid part of the composite.

21 MR. LYZENGA: In other words, the
22 reliability of a composite can be greater than

1 the reliability of its components.

2 DR. HANDY: So, regarding that, I find
3 that a little confusing.

4 So, if you have a proposed composite
5 score then we individually go through the
6 different parts and say are these clinically
7 plausible and relevant and have some relationship
8 to quality, but not to the level of endorsement?

9 MS. MURPHY: That's correct. There is
10 not the requirement that each individual measure
11 be endorsed but that it be vetted as a valid
12 measure for inclusion in a composite.

13 DR. BURSTIN: And sometimes some of
14 that's because on its own, an individual measure
15 may not have enough heft when you put it
16 together, for example, with other similar
17 measures in a domain, they logically hang
18 together in a way that they may not individually
19 be able to stand on their own.

20 DR. GROVER: But I think if you -- one
21 of the values in the public reporting is the
22 composite, but also breaking down in the public

1 report the relative performance on each of the
2 measures that are in the composite.

3 And so, I would think that it would be
4 good when you're publically reporting these to
5 have the endorsement of the NQF.

6 MR. LYZENGA: All right, so we voted
7 on performance gap. The results are 57 percent
8 high, 43 percent moderate, zero percent low, zero
9 insufficient.

10 So, the measure passes on performance
11 gap. And we'll move to reliability.

12 DR. GUNNAR: Lynn?

13 MS. REEDE: Do you want me to ask my
14 question or wait for that question?

15 DR. SHAHIAN: We'll send this to you
16 but over the last decade the rate of decline in
17 re-operations is 9.2 percent in the STS database.
18 So, we'll send you the paper.

19 DR. GUNNAR: Thank you, Dr. Shahian.

20 Did -- Lynn, did you have a comment
21 before we vote reliability?

22 MS. REEDE: Yes, it was a question

1 about the modeling. Will we continue to have
2 variation in the measures and the composite
3 because of the way the risk adjusted
4 stratification is set up so we'll always have
5 outliers at each end though the bell curve may
6 move? When we use that as part of our
7 performance gap, I'm just asking that question,
8 will it continue to create that variation?

9 MR. HE: So, currently the performance
10 groups are defined first by constructing those
11 confidence interval, a 95 percent confidence
12 interval.

13 So, hypothetically, if there's just no
14 true variation at all, then all the centers,
15 using the correct measures, all the centers will
16 not be labeled as performance outliers.

17 MS. REEDE: Well, you're still going
18 to have a star rating eventually. You'll still
19 have one, two and three star identified in the
20 model, is that correct?

21 MR. HE: Yes, but, again,
22 hypothetically, if there's not true variation

1 then everybody will be a two star.

2 MS. REEDE: Thank you.

3 MR. LYZENGA: Any other comments on
4 reliability? Seeing none, we'll go ahead and
5 vote.

6 So, this is -- we're voting on whether
7 the measure is precisely specified, can be
8 collected, the data can be collected consistently
9 and that it has been tested within appropriate
10 method and scope with adequate results.

11 DR. GUNNAR: So, here's where the --
12 I mean just to go back, are these reliability?
13 Can we think of these as sort of the continuum
14 for the adult measures on reliability, validity?

15 We've heard from previous discussion
16 how they're collected and their audit process and
17 --

18 MR. LYZENGA: Yes, I think that the
19 reliability submission is pretty consistent
20 across the submissions. But, I think that's a
21 question for the committee whether you feel
22 comfortable carrying over your votes on

1 reliability.

2 DR. GUNNAR: So, does anybody object?
3 We'll take the unanimous vote as a requirement?

4 DR. FLEISHER: I would just like, we
5 did it on the pediatric, it's a separate
6 database. Let's just vote once on the adult
7 would make me comfortable and then -- because
8 this is correct, a different database?

9 DR. GUNNAR: Correct.

10 DR. FLEISHER: So, we can just vote
11 once and then anything that, if you could tell us
12 is this the same database then I would feel
13 comfortable going forward.

14 MS. JOHNSON: And I would also say
15 you'd want to be sure that the reliability
16 results are similar across measures to be able to
17 carry over that vote even if the methods, et
18 cetera are the same.

19 MR. LYZENGA: If I'm not mistaken, the
20 audit results are presented in reliability and
21 those are the same across the measures as the 97
22 percent agreement rate of the data elements.

1 DR. GUNNAR: It's agreed.

2 Cliff?

3 DR. KO: So, are we talking about
4 reliability in terms of validation and audit of
5 the data, that reliability? Or do we talk about
6 reliability of distinction of the measure of
7 distinguishing hospitals for whatever the measure
8 is, re-operation or mortality when we talk about
9 reliability?

10 Because if it's the latter, then I
11 don't think we can vote all together. If it's
12 the former, we can.

13 MR. LYZENGA: And there is -- it
14 depends on if you're doing reliability, I think,
15 at the data element versus the performance score
16 level.

17 If it was done at the performance
18 score level, then we would be getting to the
19 question of variation within the, you know,
20 hospital as opposed to variation and
21 discrimination at the data element level which is
22 what they provided here.

1 It's just a question of the sort of
2 reliability of the collection of the data
3 elements. And we do have some inner guidance. I
4 think our guidance suggests that reliability is
5 generally considered, you know, that the voting
6 on reliability should be sort of higher for
7 performance score reliability. Or we would
8 prefer that be provided, but we certainly accept
9 data element reliability.

10 And, in this instance, it appears
11 they've, you know, provided the same results
12 across and it's just sort of a report on their
13 audit process.

14 MS. JOHNSON: Just to remind you, in
15 your algorithm for reliability, you'll notice
16 that if developers show you reliability at the
17 score level, it's eligible for a high rating. If
18 it's only at the data element level, a moderate
19 rating should be the highest that it would get.

20 DR. GUNNAR: Collette?

21 MS. PITZEN: Karen, thanks for that
22 point. I was going to suggest that, too,

1 especially if our votes are going to carry over
2 for several measures.

3 There isn't -- many of them do not
4 have the performance score reliability.

5 DR. GUNNAR: I guess as chair, given
6 the discussion, despite the -- I think we're
7 almost set to -- we have to vote on each one.
8 What are your thoughts?

9 MR. LYZENGA: I don't know that that's
10 the case. I think if we can vote once and if the
11 committee is comfortable carrying those votes
12 over, that's acceptable.

13 MS. JOHNSON: Yes, so just to recap,
14 since all of them used data element reliability,
15 well, data element validity which carries over
16 for data element reliability, it's all the same
17 in all the measures. Once you vote once, then it
18 would be fine to carry over.

19 DR. GUNNAR: Anyone on the committee
20 uncomfortable with that? Hearing none, we'll
21 vote on reliability and validity and those votes
22 will carry over for these like measures or

1 measures that have like data collection.

2 MR. LYZENGA: So, we have 71 percent
3 high, 29 percent moderate, zero low, zero
4 insufficient.

5 The measure passes on reliability.
6 These results will be carried over to subsequent
7 measures.

8 DR. GUNNAR: Validity? Again, Dr.
9 Markman?

10 MR. LYZENGA: I think on validity,
11 we'll have to vote individually. This one's not
12 going to carry through.

13 DR. GUNNAR: This will not carry
14 through? Okay. Understood.

15 All right, Barry, any comments?

16 MR. MARKMAN: Well, I mean it's the
17 same database as the composite, so I think it
18 shows validity in the outcome of bleeding.

19 MR. LYZENGA: There's also -- they did
20 the data element and validity testing, I'll just
21 note. But they also provided some testing
22 results on the distribution of participants to

1 the end tertiles and --

2 DR. GUNNAR: Percentiles, yes.

3 MR. LYZENGA: But they showed some
4 data that showed consistency in scores across
5 time, I should say. I would ask the developers
6 to provide any clarification, if possible.

7 But they're showing that registry
8 participants and providers who are in the middle
9 tertile or in the, you know, get one score in one
10 year typically stay the same in the next year is
11 basically. And that is intended to demonstrate
12 that the measure is valid.

13 DR. YATES: I have a validity question
14 and it's -- and the reason I'm asking it is that
15 people can choose to be adamant about not having
16 a mediastinal bleed and having to go back for
17 bleeding versus doing a lot of anticoagulation
18 with abovian (phonetic) and then having something
19 squeeze out the toothpaste tube the other way
20 which would be mediastinitis.

21 And I'm pretty sure I know the answer
22 already, but you do capture mediastinitis rates

1 as well, correct?

2 DR. JACOBS: Yes.

3 DR. YATES: So, that would be the one
4 confounding factor that is addressed in this
5 instance, that's part of their complex of things
6 they measure, then that doesn't get -- there's no
7 undue problem with that.

8 DR. GUNNAR: Agreed.

9 Any other -- Larry?

10 DR. MOSS: Does re-exploration in the
11 ICU count or does this necessitate going to the
12 operating room?

13 DR. JACOBS: It's regardless of
14 geographic location.

15 DR. GUNNAR: Dr. Yates, are you okay.

16 All right, ready to vote. We're
17 voting on validity kind of slowly apparently.

18 MR. LYZENGA: Yes, voting on validity,
19 so specifications consistent with the evidence,
20 testing appropriate with an appropriate method
21 and scope with adequate results, appropriate
22 exclusions, appropriate method of risk adjustment

1 and stratification, demonstrating meaningful
2 differences in performances and so on.

3 I think we've got everybody.

4 Eighty percent high, 20 percent
5 moderate, zero low, zero insufficient.

6 The measure passes on validity. So,
7 we will move to feasibility and usability and I
8 think we will be voting on these once for the
9 adult measures, is that correct? We'll take this
10 vote or did we already do a vote? We did not.
11 We should do a vote on this one and then we will
12 carry these votes over to the subsequent
13 measures.

14 DR. GUNNAR: So, any discussion on
15 feasibility? Hearing none, let's go ahead and
16 vote.

17 MR. LYZENGA: Sixty-eight percent
18 high, 27 percent moderate, five percent low, zero
19 insufficient.

20 The measure passes on feasibility.
21 We'll move to usability. This will also be the
22 vote that carries across the adult outcome

1 measures.

2 DR. GUNNAR: Any discussion before we
3 vote? Hearing none, go ahead.

4 MR. LYZENGA: We'll have to redo this
5 one again, sorry. Just one moment.

6 Okay, one more time, if you'd submit
7 your vote on usability and use. Again, this will
8 carry over to the remaining STS adult outcome
9 measures.

10 Eighty-two percent high, 18 percent
11 moderate, zero percent low, zero percent
12 insufficient.

13 The measure passes on usability and
14 use. And we will go ahead to overall suitability
15 for endorsement.

16 Any additional comments or questions?
17 Hearing none, let's go ahead and vote.

18 Does the measure meet NQF criteria for
19 endorsement, yes or no?

20 We have a unanimous yes. The measure
21 passes. We'll move on to the next one.

22 Next we have 0130, Risk Adjusted Deep

1 Sternal Wound Infection Rate.

2 DR. JACOBS: Right, so this is what
3 was brought up before, percent of patients 18
4 years or older undergoing isolated coronary
5 bypass grafting who develop mediastinitis or deep
6 sternal wound infection within 30 days of cardiac
7 surgery.

8 DR. FLEISHER: So, evidence, any
9 comments from Rick or Keith?

10 DR. DUTTON: So, this is an outcome
11 measure. It's reported at the clinician group
12 and facility level. The outcome is strongly
13 influenced by processes of care, so it's an
14 outcome we can change.

15 I guess I'll just hit my generic
16 comments so we can go through this quicker.

17 The gap is minimal. High performers
18 are at -- was the number 0.2 percent, so two in a
19 thousand low performers are at about 1.1 percent
20 in the last year. So, you could argue that's
21 five times higher, but this is a very important
22 outcome that you don't want to have.

1 It's important for the composite and
2 it's important because it's the backside to the
3 re-exploration measure just discussed.

4 But, again, the number of high and low
5 groups on this measure by itself is very small.
6 It's, I think, two percent are outliers either
7 high or low.

8 DR. FLEISHER: Keith, any comments?

9 DR. OLSEN: None.

10 DR. FLEISHER: Okay. Let's just vote
11 and then I'll ask if there's comments between
12 each -- did you want to make a comment?

13 DR. JACOBS: Yes, I was just going to
14 say that although it's a rare event, it's a big
15 deal. I mean, you know, people die from this and
16 not only that, but if one is in a low performing
17 outlier, there's clear interventions that can
18 take place that can solve the problem.

19 So, the stakes are high and, although
20 it's a rare problem, it's a fixable problem.

21 MR. LYZENGA: Okay, voting on
22 evidence. The question is whether a rationale

1 supports the relationship of this health outcome,
2 and in this case, deep sternal wound infection to
3 at least one health care structure process
4 intervention or service.

5 Dr. Ko?

6 DR. KO: Well, just maybe we can get
7 the vote done and then I just have a question.

8 MR. LYZENGA: Okay.

9 Unanimous yes. The measure passes on
10 evidence.

11 Go ahead, Dr. Ko.

12 DR. KO: I think it's insightful for
13 Jeff to say that, you know, first of all, that
14 there's two percent on each side but it's a very
15 important -- it's a severe thing if somebody gets
16 a sternal wound infection.

17 Is there a way that the NQF looks at
18 that more objectively than saying it's a really
19 serious thing for this? Because, you know, the
20 two percent on each side, I'm not sure that that
21 would pass. But, the fact that this is a really
22 important topic, sternal wound infection is.

1 So, how do we -- where is that cut
2 point of what's important versus, you know, if
3 this was a hemorrhoid then that two percent would
4 not pass. But if this is sternal wound
5 infection, it does.

6 Is there a way that the NQF --

7 DR. FLEISHER: I think that's us.

8 DR. KO: Oh, we just kind of
9 internally implicitly figure this out?

10 DR. FLEISHER: I think that's why you
11 have a -- and you can correct me, Marcia and
12 Karen -- but I think that we are, I mean and
13 that's why the CSAC and I think the consumers and
14 all the councils get to see the vote out of this
15 body, the exact vote, not just it passed, to see
16 how strongly a group of 23 of us believe this is
17 an important measure.

18 DR. YATES: I'd like to comment on
19 that because it's an outcomes measure, so it's
20 not like a process measure where if it's only two
21 percent, we think it's topped out.

22 As an outcomes measure, we live in a

1 world of trying to decrease infection rates to
2 less than one percent. We're trying to get
3 infection rates to half a percentage point.

4 And for those particular infections
5 such as mediastinitis or an infected total joint,
6 the impact to the patient is tremendous. The
7 cost is tremendous. The morbidity and mortality
8 from repeat surgeries to correct the problem are
9 tremendous.

10 So, there's a world of difference
11 between a two percent infection rate and one
12 percent. And I think that has to be kept in mind
13 that when we're talking outcomes, infection
14 rates, you're talking in half a percentage points
15 as being important.

16 DR. DUTTON: This also gets to our
17 discussion yesterday about the uses of the
18 measure and that's something that CSAC, I know,
19 is going to take up.

20 It's much less useful as a quality
21 improvement measure because it's not very
22 discriminatory but it's very important as a

1 public accountability measure.

2 DR. FLEISHER: I think those are
3 excellent comments and I think if we continue to
4 place in the public record, you know, the
5 definition of a superficial, you know, a little
6 bit of redness in a wound, if this group did not
7 feel that was worthy of putting out there because
8 it wasn't important enough or it was, that's part
9 of the voting of this body.

10 MR. LYZENGA: And will be reflected in
11 the report. I remember, I think, the last cycle
12 we had another similar measure postoperative
13 stroke, it had the same kind of questions, rare
14 event, very severe, many consequences for the
15 patient and we communicated that in the report
16 that the concerns about the, you know, low volume
17 of the event but it's severity.

18 DR. FLEISHER: So, vote on performance
19 gap unless --

20 MR. LYZENGA: We have 38 percent high,
21 57 percent moderate, five percent low, zero
22 insufficient.

1 The measure passes on performance gap.

2 So, we'll move to reliability. I
3 believe this is one where we're going to carry
4 over, so unless there are any objections, we will
5 carry over the previous vote.

6 DR. FLEISHER: Any objections?

7 MR. LYZENGA: Hearing none, we'll go
8 to the validity.

9 DR. DUTTON: Yes, I have nothing
10 further to add, I put my comments in.

11 DR. FLEISHER: Keith? Anything?
12 Anybody have any comments?

13 Let's vote on validity.

14 MR. LYZENGA: Okay, go ahead and cast
15 your votes on validity.

16 Sixty-seven percent high, 33 percent
17 moderate, zero low, zero insufficient.

18 The measure passes on validity.

19 And we will move to -- well,
20 feasibility and usability and unless there are
21 any additional comments or questions or
22 objections from the committee, we'll carry over

1 the feasibility and usability votes.

2 Seeing none, we'll vote on overall
3 suitability for endorsement.

4 I know this slide isn't quite correct,
5 but you guys get the gist, we're voting on
6 overall suitability.

7 All right, give us a moment here.
8 Okay, voting.

9 Unanimous yes, the measure passes.

10 So, we'll move on to the next.
11 Starting to get pretty efficient here.

12 0116 is the next measure, Anti-
13 platelet Medication at Discharge. This is a
14 process measure, so I don't believe we'll be able
15 to carry over our votes on this one.

16 DR. JACOBS: So, this is one of the
17 next two that are process measures, this one
18 anti-platelet medication the next one anti-lipid
19 medication.

20 This one is the percentage of patients
21 over the age of 18, isolated CABG, discharged
22 home on a lipid lowering statin.

1 There's ample evidence in the peer
2 review literature how this is associated with
3 outcome and the references are provided in the
4 packet.

5 DR. GUNNAR: Chris?

6 DR. SAIGAL: Okay, so, as just
7 discussed, the evidence for this is strong.
8 There's consistent level one evidence of benefit.
9 It's incorporated into clinical practice
10 guidelines, so I think in terms of evidence, the
11 process outcome link is met.

12 DR. GUNNAR: Any other comments?

13 DR. DUTTON: Just quickly. Prescribed
14 versus given or prescription filled versus
15 actually taken, nobody's ever figured how to
16 measure the last one. But this is a
17 prescription, so an order for the drug exists.

18 DR. GUNNAR: I think we can go ahead
19 -- any other comments? We can go ahead and vote,
20 evidence.

21 MR. LYZENGA: Voting on evidence.

22 We have 67 percent high, 33 percent

1 moderate, zero low, zero insufficient.

2 The measure passes on evidence. And
3 we'll move to performance gap.

4 DR. SAIGAL: Okay, so there's a very
5 small gap even at the 20th percentile the
6 performance is like 98 percent.

7 They grouped them by high versus low
8 performers that we discussed by baseline
9 significant, variance on the group mean. The
10 high performers achieved 99.9 percent performance
11 while low performers achieved about 95 percent
12 performance.

13 It's statistically meaningful,
14 probably not that clinically meaningful. I'm not
15 sure how many cardiac events are being prevented
16 with a three or four percent gap in the end. But
17 it is statistically meaningful.

18 DR. GUNNAR: Jeff, do you want to
19 comment?

20 DR. JACOBS: I think, again, this is
21 a -- it's a re-endorsement of a previous measure
22 that's part of the composite which kind of

1 explains why we want to have this brought forward
2 again.

3 I think that there's data that shows
4 that it's associated with outcome. I think there
5 is increased compliance with it over time which,
6 therefore, is going to mean less variability.

7 DR. GUNNAR: But to be clear, as we
8 discussed before, if we determine that this is no
9 longer -- if there is no longer a gap, it can go
10 to reserve status. We vote on reserve status.

11 MR. LYZENGA: If we vote -- if we get
12 a low or insufficient vote on performance gap, we
13 may vote on whether to put it in reserve status
14 and we would move through the rest of the
15 criteria in that case.

16 DR. GUNNAR: Correct. Dr. Handy?

17 DR. HANDY: So, I know that we talked
18 a lot about reserve status last time. We haven't
19 this time and I'm not sure I recall all the
20 things that we said.

21 So, reserve status means still NQF
22 endorsed but what does it imply for the

1 institution? Are they, therefore, relieved of
2 the collection responsibilities, there's no more
3 data being gathered? I mean what does reserve
4 entail?

5 MR. LYZENGA: Well, NQF endorsement
6 doesn't really entail any sort of or compel
7 anybody to do anything to report on anything. In
8 general, it just is a sort of judgment on the
9 scientific sort of merit of the measure itself.

10 Sorry, I kind of lost my train of
11 thought.

12 DR. FLEISHER: So one example would
13 be, since this would be collected as part of the
14 STS database, the committee would essentially be
15 saying there is not sufficient gap to keep it
16 endorsed -- to keep it as going through the
17 maintenance process.

18 However, if STS ever came back and
19 said there was a large performance gap, then it
20 still exists in the set of measures -- correct,
21 Karen and Marcia -- and therefore, they wouldn't
22 have to go through a new submission because it

1 exists. We believe it's evidence is important.

2 At least this is the way CSAC was
3 thinking about it.

4 MR. LYZENGA: So, it remains endorsed,
5 it's just kind of an indication that it's just
6 sort of an asterisk in a way, this is topped out
7 but it remains endorsed. It can be used.

8 DR. HANDY: So it's success, but does
9 endorsement have a sunset? I mean does reserve
10 status have a sunset? In other words, you can
11 sort of stick it in there and say, well, I've got
12 an NQF endorsed thing forever now.

13 DR. FLEISHER: We haven't gone to
14 that. That's an excellent question we'll have to
15 address. But certainly, reserve status doesn't
16 require maintenance, if I remember correctly.

17 MR. LYZENGA: No, I believe it does,
18 yes. I think it should still go through
19 maintenance. We'll confirm that, but I believe
20 every three years it will still need to come up.

21 So, there is no requirement for
22 maintenance of reserve status measures?

1 MS. JOHNSON: Yes. Let me read you a
2 couple of -- can somebody turn off their mic?
3 Thank you.

4 I'll just read you a couple of
5 sentences from our guidance.

6 Endorsement with reserve status
7 retains these measures in the NQF portfolio for
8 periodic monitoring while also communicating to
9 potential users that the measure is no longer
10 addressed high leverage areas for accountability
11 purposes.

12 So, it's not saying you shouldn't use
13 it or you can't use it, but it's kind of
14 signaling that, you know, it's not high leverage
15 anymore like maybe it was before.

16 But if they do not go through periodic
17 maintenance -- but the standing committee will
18 periodically review measures in reserve status
19 for any change in evidence, evidence of
20 deterioration in performance or unintended
21 consequences or any other concerns related to the
22 measure.

1 The standing committee may remove a
2 measure from inactive endorsement status or
3 reserve status if the measure no longer meets NQF
4 endorsement criteria.

5 The maintenance review may occur upon
6 request from the standing committee or measure
7 steward to return the measure to active
8 endorsement.

9 So, it's pretty much in your court
10 what you would want to do with it.

11 DR. GUNNAR: Amy and then Cliff?

12 MS. MOYER: I want to make sure I'm
13 remembering this correctly.

14 So, you know, earlier we talked about
15 paired measures and if one is kicked out,
16 whatever, voted off the island, the other one has
17 to stand alone.

18 For a composite, though, decisions we
19 make about the individual measures do not affect
20 the overall composite and its endorsement status
21 and it's used in that, right?

22 MR. LYZENGA: No, the composite may

1 remain endorsed even if its components are de-
2 endorsed.

3 DR. FLEISHER: I would think they may
4 you might think about this is the composite might
5 be endorsed but putting this out alone, what
6 we're signaling is a simple measure of this in a
7 public reporting space, we believe it's topped
8 out and is not as critical to be out there as a
9 measure independently, but has nothing to do with
10 the composite.

11 DR. GROVER: Could I ask you a follow-
12 up on that?

13 I mean if, again, you have the
14 composite score out there and then you want to
15 have each of the components of that in the public
16 reporting, this doesn't preclude that, right? I
17 mean we can we still --

18 DR. FLEISHER: No, it's still an NQF
19 endorsed measure that happens to be on reserve
20 status because we don't think -- I mean it's more
21 of a signal to the outside world that if you
22 alone made this an accountability measure, it's

1 not good enough to be a solitary accountability
2 measure.

3 I would think -- would that be an
4 accurate -- what you would think about it,
5 Marcia?

6 MS. WILSON: Yes.

7 DR. GUNNAR: But to get to your point
8 specifically, the STS is free to put out their
9 menu of publically reported components regardless
10 of NQF endorsement.

11 So, if this result turns out that
12 there's, based on the evidence, that there's no
13 performance gap and we vote it low, then there'll
14 be a decision about reserve status or no status.

15 In either of those cases, it doesn't
16 impact the composite or the ability of the STS to
17 report independently what they would like on
18 public reporting sites. They just can't assign
19 NQF endorsement.

20 The question, I think, that's left is,
21 if it's in reserve status, can they still report
22 that it's NQF endorsed? And the answer is

1 resoundingly, yes.

2 But I think we've -- have we finally
3 laid this one down?

4 DR. FLEISHER: To be very clear, this
5 is the committee that's ahead of the curve in
6 actually defining it. So, in many ways, although
7 CSAC is the decision making body, how we did it,
8 how you did it, actually helped inform CSAC and
9 will further inform CSAC should any of these
10 measures go in reserve status.

11 DR. KO: Can you remind us, because it
12 seemed like the last committee meeting we had, we
13 just, ah, reserve, reserve, reserve. How many
14 measures are in reserve status and which -- is
15 there like five or six of them that went there?

16 DR. CIMA: That was the SCIP measures.
17 I mean those are the ones --

18 DR. KO: That's all the SCIP measures
19 in what, 60 minutes?

20 DR. CIMA: Pretty much, and that's
21 what I was saying, you know, we topped out like -
22 - yes, I don't think anyone would disagree that

1 there is strong evidence that antibiotics within
2 an hour of incision for almost any surgery that
3 requires antibiotics is important. And that was
4 the concern last year when we put it in reserve
5 was what's going to happen to it.

6 And the topped out was about 98
7 percent, you know, and so, that's why I was just
8 wondering, you know, this is a process measure
9 that's at 98 percent. It's a standalone process
10 measure.

11 I mean we sort of set a precedent last
12 year and I just want to know if the rationale is
13 different now?

14 DR. KO: But I wanted to clarify, even
15 the discontinuation of antibiotic one was
16 reserved?

17 MR. LYZENGA: I think we removed
18 endorsement from one or two but the rest of them
19 remained endorsed with reserve status.

20 DR. SIPERSTEIN: I actually have the
21 list in front of me, Cliff. There were nine
22 measures that we put on reserve status, eight of

1 those dealt with antibiotics, one of them had to
2 do with participation in a database for cardiac
3 surgery.

4 MR. LYZENGA: And I think we can pull
5 up the number of total reserve measures and just
6 doing that now.

7 MS. FELDMAN: There's 14 endorsed
8 reserved measures.

9 DR. GUNNAR: In total or for just the
10 surgery --

11 MR. LYZENGA: In total.

12 MR. GUNNAR: And we own --

13 MR. LYZENGA: We own nine of them.

14 MR. GUNNAR: -- nine of them, maybe
15 ten.

16 Can we vote on --

17 DR. SIPERSTEIN: I just want one
18 follow-up comment about just helping to think
19 about reserve status.

20 I mean I think after our discussion,
21 it prompted discussion in other committees about
22 how to think about this concept of reserve

1 status.

2 And just from a procedural point of
3 view, one of the statements was that in the
4 absence of having this as an option, the measure
5 would otherwise lose endorsement. It meets all
6 of the criteria except opportunity for
7 improvement is no longer met.

8 And so, I think just thinking about
9 the process, you know, if we went through our
10 routine process, we'd end up voting no in the end
11 and this allows a measure that otherwise is
12 entirely valid, but has been a success to still
13 be recognized in that category, but at the same
14 time, says if you've got limited health care
15 resources, don't put your team measuring this, go
16 look at something else that has a little more
17 traction.

18 DR. GUNNAR: Any other discussion?
19 Hearing none, let's vote on performance gap.

20 MR. LYZENGA: Okay, so we have five
21 percent high, 14 percent moderate, 77 percent
22 low, and five percent insufficient.

1 The measure does not pass performance
2 gap which makes it eligible for reserve status.

3 And can we take a vote on that?

4 DR. GUNNAR: Well, why don't we got
5 through the other --

6 MS. JOHNSON: Yes, you'll go through
7 the rest of them and then you'll come back and
8 vote.

9 MR. LYZENGA: We'll go through the
10 rest of the criteria and then we'll come back.
11 Okay.

12 DR. GUNNAR: So, I think we've already
13 -- reliability, we move on, right?

14 MR. LYZENGA: So, can we do
15 reliability? I think it's the same, well, can we
16 get some input from the developers? Is there any
17 difference in the reliability?

18 DR. JACOBS: Same.

19 MR. LYZENGA: Same, so --

20 MS. JOHNSON: Any concerns about the
21 specs and how they're put out, any of that kind
22 of stuff?

1 DR. SAIGAL: I don't think so. The
2 exclusions are appropriate. It's pretty clear.

3 MR. LYZENGA: All right, so we'll
4 carry over the reliability vote as well on this
5 one unless anyone objects.

6 Seeing no objections, we'll go to
7 validity. And again, I think we'll want to vote
8 on this.

9 DR. GUNNAR: Any discussion? Seeing
10 none, go ahead.

11 MR. LYZENGA: Okay, voting on
12 validity.

13 Just in general, this is voting on
14 whether this measure is a valid and accurate
15 reflection of quality care.

16 We have 60 percent high, 35 percent
17 moderate, five percent low, zero insufficient.

18 The measure passes on validity.

19 Feasibility and usability I think
20 we'll also be able to carry over here.

21 DR. GUNNAR: Any objections?

22 MR. LYZENGA: Also using the registry,

1 any objection to carrying feasibility and
2 usability over?

3 Seeing none, we will do so. And we'll
4 move to an overall vote or vote on overall
5 suitability for endorsement.

6 DR. GUNNAR: Reserve status.

7 MR. LYZENGA: Yes, you're right.

8 So, here, we're voting on -- there we
9 go.

10 So voting on endorsement --

11 DR. GUNNAR: Any final --

12 MR. LYZENGA: -- with reserve status.

13 DR. GUNNAR: -- questions? Seeing
14 none, go ahead and vote. I think we've led the
15 field in discussing reserve status.

16 MR. LYZENGA: I think we can close it
17 out.

18 Unanimous yes. The measure is
19 endorsed with reserve status.

20 Thank you all.

21 And now we'll move to 0118 Anti-lipid
22 Treatment at Discharge.

1 DR. GUNNAR: So, since my partner is
2 also discussant, I'll take on this.

3 So, Jeff, did you want to make any
4 comments opening up?

5 DR. JACOBS: So, I think this is going
6 to be a fairly identical discussion to the
7 previous one. It's the same exact measure just
8 different set of drugs.

9 DR. FLEISHER: My only question,
10 looking at the evidence is, a lot of the evidence
11 is extrapolated from -- there's no guideline
12 specific to the cardiovascular patient -- to the
13 surgical patient, if I'm not mistaken. It's all
14 guidelines related to cardiovascular disease.
15 So, I was just questioning the absolute link.

16 DR. JACOBS: I think it's a fair
17 extrapolation, because the population here is
18 isolated to coronary artery bypass grafting, and
19 clearly, those patients are all patients with
20 cardiovascular disease.

21 DR. GUNNAR: Any other -- oh,
22 Collette?

1 MS. PITZEN: This is in terms of the
2 measure construction related to the evidence.

3 The ACC/AHA guidelines recommend
4 starting a statin for AS/CVD age 21 and older.
5 So there is no support for that 18- to 20-year-
6 old patient. So, I would recommend either
7 changing the age of the measure to be consistent
8 with the guidelines.

9 DR. JACOBS: Well, I think it's
10 probably because it's never been studied in those
11 patients between the ages of 18 to 21, and it's
12 pretty rare, but if you're coming to a coronary
13 artery bypass graft operation as a 19-year-old
14 because of atherosclerotic coronary artery
15 disease, probably it makes sense to follow this
16 measure.

17 I think that the lack of evidence in
18 the published literature doesn't mean that
19 there's a lack of justification in applying this
20 measure to patients between the ages of 18 and
21 21.

22 MS. PITZEN: Right. This is Collette

1 again. I agree that it is rare. I'm also coming
2 from the perspective of we did a complete
3 redesign around appropriate statin use for
4 patients with vascular disease and we did need to
5 write in kind of an exception for that age range.

6 So, if we're going to be consistent
7 with what currently is published, I think that
8 needs to be considered.

9 DR. JACOBS: It seems to me that it
10 makes sense that if you're getting coronary
11 artery bypass graft operation at the age of 19
12 for the atherosclerotic artery disease, it makes
13 sense to be on these medicines.

14 DR. FLEISHER: I think we're asking
15 two different questions, which is, does it make
16 sense, as opposed to is there evidence? And I
17 think Collette and I are both articulating it
18 would be great if there was some evidence to show
19 that it --

20 DR. GROVER: It would have to be
21 something like a familial hypolipidemia, and
22 you'd never have it. And then it would allow you

1 to probably justify -- I mean do the usual
2 justification in this.

3 DR. FLEISHER: So, Dr. Shahian?

4 DR. SHAHIAN: We'd be happy to change
5 that to 21 if that'll settle the issue. Would
6 that -- yeah, that's fine.

7 DR. YATES: We're going back to the
8 very same question you just asked, which is that
9 we're using inferred implications from non-
10 cardiac surgery patient studies, and we're
11 talking about guidelines for heart patients in
12 general.

13 I think that the subcategory of those
14 heart patients that end up having a CABG are a
15 sine qua non for having cardiovascular disease.
16 And as such, it's fair to make that leap from the
17 generalized literature to coronary artery
18 disease.

19 If they decided the day of surgery to
20 cancel surgery, they'd still be better doctors if
21 they were to put those patients on statins based
22 on guidelines. And I would argue that if an 18

1 to 21-year-old, I would agree with Dr. Jacobs,
2 that if for some reason some patient comes in
3 needing a bypass surgery 18 to 21, they've
4 declared themselves part of that population in a
5 special way that is beyond -- I think we're
6 dancing -- we're asking a lot of angels to dance
7 on a pinhead here.

8 I don't know that we have to ask them
9 to change -- their measures across the board are
10 all 18 and over and I think that horse sense
11 would say that it's okay just to leave it as is
12 and not to change what is very consistent
13 classification of adult.

14 DR. GUNNAR: So, from a matter of
15 process, there's, I think, one of two things that
16 could be done here.

17 The first is to have STS provide
18 whatever impact that would make with regard to
19 this measure. So, what is the number of 18- to
20 21-year-olds that are operated on for coronary
21 artery disease? Which would give the relevant
22 impact to that cohort on the measure.

1 Or we ask, I think, how do you amend
2 -- what's the process for amending? This measure
3 now gets amended and comes back, which would be
4 just process here.

5 MR. LYZENGA: If the committee wants
6 the age range to be changed to 21, we can just
7 sort of accept that now with the understanding
8 that we'll coordinate with the developer to do
9 that, and you can vote on the measure, assuming
10 that it will be specified for 21 and older.

11 It's not clear to me that that's what
12 the whole committee wants to do yet.

13 DR. JACOBS: I mean, certainly, STS,
14 as Dave said, we could change this to 21 if
15 that's what the Committee wants. My own take on
16 this is it doesn't -- it's not very logical.

17 There's very, very few patients
18 between the ages of 18 and 21 that require
19 coronary artery bypass grafting for coronary
20 artery disease. Those that do probably really
21 should be on these medicines.

22 DR. GUNNAR: So, let's have a --

1 Collette -- and then we'll take a -- I think
2 we'll take a vote on after that whether the
3 Committee would like the developer to change or
4 whether they're happy with the current language.

5 So, Collette?

6 MS. PITZEN: I'm not trying to be
7 difficult, honestly. The ACC/AHA came out with
8 four very specific at-risk groups. One of them
9 was age 21 and older with AS/CVD, diabetic
10 patients age 40 to 75, anyone with an LDL age 21
11 and older with an LDL greater than 190, and the
12 fourth category was based on a risk calculator.

13 So, I'm just raising the question to
14 be consistent with the current guidelines that
15 are based on random control trials.

16 Thanks.

17 DR. GUNNAR: And I don't know that --
18 I think the Committee can still view those as
19 true and unrelated with regard to this measure.

20 So, Lee, do you want to --

21 DR. FLEISHER: No, my only comment,
22 and A.J., thanks for the comments, but an

1 accountability measure, in my mind, and looking
2 at the evidence, is a little different than what
3 a doctor wants to do with his 18- to 21-year-
4 olds.

5 And I think that's consistent with
6 Collette's comments. I think the will of the
7 Committee is the will of the Committee. I mean I
8 just felt it was important from a process
9 standpoint that we articulate what those
10 guidelines said.

11 DR. GUNNAR: So, accepted.

12 Amy?

13 MS. MOYER: So, from a process
14 standpoint, if I followed this correctly, we're
15 potentially talking about, if we didn't change
16 the age, a rate of insufficient evidence with
17 exception. What would be the impact of that? Is
18 that a still pass or it doesn't pass? Okay.

19 MS. JOHNSON: And, sorry, Andrew, just
20 to -- it gets really complicated the way our
21 criteria are set up sometimes and it's hard to
22 parse what you're talking about.

1 But I think, really, this discussion
2 is a little bit more about validity and how the
3 specs line up with evidence. So, technically, I
4 think you'd be fine to vote on evidence without
5 thinking about the 18 to 20. You can think about
6 it again under validity, see what you think.

7 But it gets even a little bit more
8 complicated because we already know -- well, we
9 don't know how many -- but you also are thinking
10 about in terms of feasibility and usability and
11 use. You're thinking possibly changing a measure
12 that all the other ones are similar to.

13 And I think, you know, I'm not going
14 to tell you guys what to do, but it'd be really
15 interesting to know how many operations there and
16 does that even change anything?

17 DR. JACOBS: Yeah, I mean, it's
18 probably exceedingly rare, but we obviously don't
19 have a number at the tip of our tongues here.

20 DR. GUNNAR: I mean, I did 4,000
21 operations. I can't remember. Fred? I mean,
22 anybody collectively in the room? Dr. Shahian,

1 how many patients with coronary disease did you
2 operate on between 18 to 21? How many 18- to 21-
3 year-old have you operated on?

4 DR. SHAHIAN: May I just comment
5 additionally on the rationale?

6 Certainly, secondary prevention in
7 this population of patients with atherosclerotic
8 coronary artery disease is one rationale. But we
9 also know that, you know, statins reduce re-
10 operation for occluded grafts. There is a
11 randomized trial showing a very substantial
12 reduction in graft closure.

13 And we also know the pleiotropic
14 effects of statins decrease, post-operative
15 stroke, atrial fibrillation and a number of other
16 issues relating to the systemic inflammatory
17 effects of cardiopulmonary bypass.

18 So there are a variety of reasons that
19 statin drugs are particularly efficacious.

20 Dr. Fleisher, I'll forward a paper to
21 you that reviews --

22 DR. FLEISHER: Yes, I would actually

1 -- and I'm on the Oversight Committee for
2 Practice Guidelines for the ACC/AHA. So, I think
3 it would be great for them to -- for STS to, the
4 next time we have an update, or that this gets
5 addressed in the update, even it's a lower level
6 of evidence, it would just be helpful.

7 DR. SIPERSTEIN: Yeah, I would just
8 suggest, it's such a small group, we really have
9 no data and we just move forward.

10 DR. GUNNAR: Collette? Your card is
11 -- oh.

12 All right, I think we vote on the
13 evidence.

14 MR. LYZENGA: All right, voting on
15 evidence.

16 This is -- oh, I'm sorry, yes. So,
17 let's hold off on the vote. Go to the next
18 slide. Apologies, thanks for the correction.
19 This is a process measure, so we're voting on
20 evidence now, high, moderate, low or
21 insufficient.

22 We have 32 percent high, 47 percent

1 moderate, 16 percent low, five percent
2 insufficient evidence with exception.

3 The measure passes on evidence. So we
4 will go ahead and move to performance gap.

5 DR. GUNNAR: Lee?

6 DR. FLEISHER: They show, I mean,
7 pretty high but not -- I mean, they're 95.5
8 percent. So, it's actually the interesting
9 question when this comes back is how many
10 patients remained on statins?

11 I mean, this is just, as Rick pointed
12 out, a single point that, whether they were
13 ordered, essentially, and it would be great to
14 know that if it's possible from any other data
15 source.

16 DR. HANDY: Well, I think this is a
17 little different than the platelets. If you look
18 at the submitted information more in the
19 appendices, the different in the anti-platelet
20 between the low performing tercile and the high
21 performing tercile was 95 versus 99 percent.

22 In this particular tercile, it's 89

1 percent versus 99. So, I mean, it's still pretty
2 high but 11 percent is a lot less than four
3 percent.

4 DR. GUNNAR: Any other discussion?
5 We'll vote on performance gap.

6 MR. LYZENGA: Voting on performance
7 gap.

8 Ten percent high, 71 percent moderate,
9 19 percent low, zero insufficient.

10 So, the measure passes performance
11 gap. And unless there are any objections, we
12 will again carry over our votes on feasibility
13 and usability -- oh, I'm sorry, reliability, my
14 mistake. I'm getting ahead of myself.

15 So, we'll carry over the vote on
16 reliability and we'll still hold the vote on
17 validity. So, that's what is under discussion
18 right now, measure validity. Any comments?

19 DR. FLEISHER: None.

20 DR. GUNNAR: Same.

21 MR. LYZENGA: Seeing no comments,
22 we'll vote on validity. We can close it out, I

1 think.

2 Fifty-nine percent high, 41 percent
3 moderate, zero low, zero insufficient.

4 The measure passes validity. And now
5 we will carry over our votes for feasibility and
6 usability unless there are any objections from
7 the committee.

8 Seeing no objections, we will move on
9 to a vote on overall suitability for endorsement.

10 DR. GUNNAR: Any discussion? Hearing
11 none.

12 MR. LYZENGA: Ninety-five percent yes,
13 five percent no.

14 The measure passes.

15 And we move on to another outcome
16 measure. This is Risk Adjusted Operative
17 Mortality for Aortic Valve Replacement. Unless
18 we actually --

19 DR. FLEISHER: We have listed NQF
20 member and public comment for 12:15.

21 MR. LYZENGA: You're right.

22 DR. FLEISHER: Perhaps we should open

1 the phones.

2 MR. LYZENGA: We should do that.

3 Operator, could you open the lines for
4 public comment?

5 OPERATOR: At this time, if you would
6 like to make a public comment, please press star
7 then the number one on your telephone keypad.

8 And there are no public comments at
9 this time.

10 MR. LYZENGA: Thank you.

11 Are there any public comments from
12 members in the audience? No, okay.

13 So, we can move on. So, we're back to
14 outcome measures. This is Risk Adjusted
15 Operative Mortality for Aortic Valve Replacement.

16 DR. JACOBS: So, now we're
17 transitioning into a group of outcome measures
18 that are going to be risk adjusted operative
19 mortality, first for aortic valve then aortic
20 valve and CABG, then mitral valve and then mitral
21 valve and CABG starting with repair and then
22 replacement.

1 And this will all follow a very
2 similar theme. The definition is operative
3 morality. The discussion regarding operative
4 mortality this morning, I think, will suffice.

5 And I think we just move on and start
6 working our way through these operative mortality
7 measures.

8 MS MCCARTY: Okay, so this measure was
9 first approved in 2007 and re-endorsed by the
10 committee in 2011. It applies to all patients 18
11 years and older and it is stratified to either
12 include, as Rick pointed out this morning, the
13 adjustment that they made is to include all
14 deaths that happen within the hospital regardless
15 of the days out from surgery in which they
16 happen, or to include deaths within 30 days even
17 if the patient is discharged.

18 In terms of the evidence, we had a
19 lengthy discussion about that this morning, so I
20 don't know if I have anything to add to that.

21 DR. FLEISHER: So, any other comments
22 on evidence?

1 Hearing none, why don't we vote?

2 MR. LYZENGA: Ninety-five percent yes,
3 five percent no.

4 The measure passes evidence. We'll
5 move to performance gap.

6 MS. MCCARTY: And in terms of
7 performance gap, there has been measurable
8 improvement in the outcome for this metric. They
9 current mortality rates are about two and half
10 percent.

11 And, again, given this morning's
12 discussion, I'm not really sure what to make of
13 that number. Maybe that's exactly where it needs
14 to be, it's hard to say, but there -- I mean we
15 certainly don't expect zero, I would think, on
16 this measure.

17 There is some variability between
18 institutions where that goes all the way up to, I
19 think, about 12 percent with the highest outlier.
20 So, there is some variability.

21 DR. FLEISHER: Comments?

22 LYZENGA: Okay, let's vote on

1 performance gap.

2 Thirty-six percent high, 64 percent
3 moderate, zero low, zero insufficient.

4 So, the measure passes on performance
5 gap.

6 And unless there are any objections
7 from the Committee, we'll carry over our previous
8 vote on reliability.

9 Seeing no objections, we'll go to
10 validity.

11 Any comments or questions on validity
12 for this measure?

13 DR. FLEISHER: Seeing none.

14 MR. LYZENGA: Let's vote on validity.

15 Seventy-six percent high, 24 percent
16 moderate, zero low, zero insufficient.

17 The measure passes on validity.

18 And unless there are any objections
19 from the Committee, we will carry over our
20 previous votes on feasibility and usability.

21 Seeing no objections, we'll vote on
22 overall suitability for endorsement.

1 Go ahead and cast your vote.

2 Unanimous yes, 100 percent, the
3 measure passes.

4 Next is?

5 DR. GUNNER: The next is 0123, Risk
6 Adjusted Operative Mortality for AVR and CABG.

7 DR. JACOBS: Right, so this is the
8 same exact except it's for the population of
9 patients who had an aortic valve replacement
10 combined with coronary bypass grafting.

11 The issues are the same and the
12 details are going to be very much the same.

13 DR. FLEISHER: So, my only comment, in
14 the overall measure, because it's the same, is,
15 as far as performance gap, 4.81 initially to 4.19
16 during the latter evaluation period, and you have
17 a range now of 1.68 to 8.51.

18 DR. JACOBS: Right. So, I think it
19 makes the performance gap criteria based on
20 variability, for sure.

21 DR. FLEISHER: Yes.

22 DR. HANDY: Well, that's exactly what

1 I was going to comment, too, is that the seminal
2 piece of information is very deep into the
3 application.

4 It's on Page 30 where you, typically,
5 in all these applications, where you have
6 terciles of performers, and that's really where
7 the performance gap is, not in the mean.

8 And the mean is reported up-front.
9 It's kind of what we're talking about and seeing,
10 yet that's the seminal information. So, I would
11 just say move it up.

12 DR. FLEISHER: I would actually just
13 really credit staff, because if you look at the
14 measure worksheet, it's really nicely outlined
15 there. I mean, Helen, and we have to give a lot
16 of credit to that change in process to the staff.
17 And they did a fantastic job. It was easy to
18 find and really answered --

19 DR. JACOBS: I couldn't agree more.
20 That was a huge tool to time-saving.

21 MR. LYZENGA: Sure, can we vote on
22 evidence?

1 Ninety-five percent yes and five
2 percent no.

3 The measure passes evidence.

4 We'll move to performance gap.

5 DR. GUNNAR: I think we already
6 discussed performance gap, but if anybody else
7 has any? Go ahead and vote.

8 MR. LYZENGA: Voting on performance
9 gap.

10 DR. GUNNAR: We should be done by
11 1:00.

12 DR. JACOBS: I think it's all building
13 blocks. We've built all the building blocks and
14 now it's just going through the process with the
15 building blocks.

16 MR. LYZENGA: All right, we've got 48
17 percent high, 48 percent moderate, 5 percent low.

18 The measure passes performance gap.

19 And unless there are any objections
20 from the Committee, we'll carry over our previous
21 vote on reliability.

22 Seeing none, we'll go ahead to

1 validity.

2 DR. GUNNAR: Any discussion on
3 validity? Hearing none, let's go ahead and vote.

4 MR. LYZENGA: Eighty-two percent high,
5 18 percent moderate, zero percent low, zero
6 insufficient.

7 The measure passes on validity.

8 And unless we have any objections from
9 our Committee members, we'll carry over our votes
10 on feasibility and usability.

11 Seeing none, we will vote on overall
12 suitability for endorsement.

13 Unanimous yes, the measure passes.

14 DR. FLEISHER: How about if we grab
15 lunch and come back to our seats? Yes?

16 DR. MOSS: I just wanted to ask a
17 general question. This is my second time through
18 this process and we've seen many, many STS
19 measures sail through, which obviously speaks to
20 the quality of the organization and the good
21 work.

22 But it seems to be almost a

1 disproportionate representation across American
2 healthcare, and we saw the gynecologists come
3 last year and then come back again a year later,
4 and then the bariatric surgeons were here last
5 year and didn't come back this year.

6 I'm just wondering, is there anything
7 we should be doing as a committee to be more
8 accessible or more available to groups out there
9 that want to do this kind of work?

10 DR. FLEISHER: So, I actually would
11 say the Committee -- well, I would defer to staff
12 because it's usually not the Committee that does
13 it, it's --

14 DR. BURSTIN: Well, it's actually a
15 great question and some of this is also the
16 growth of registries in the surgery space. And
17 some registries -- and Dave and I, we talked
18 about this just yesterday at the ACS vetting.

19 Some registries have not brought their
20 measures traditionally through NQF and some have.
21 So, you know, we've been delighted STS has made
22 that commitment. But I guess one question might

1 be, as you work with your individual specialists
2 or other groups to think about if there are
3 really good measures out there, you think it
4 would be useful to bring through this process,
5 we'd be very open to finding who they are and we
6 could work with those developers certainly to
7 bring them through.

8 But, again, I think there are a fair
9 number of specialty areas that are not bringing
10 them through. And, again, some of them are also
11 in different committees, and maybe one thing we
12 could do going forward is share the list of all
13 of the sort of surgical-related measures, like
14 functional status and things like that, that may
15 be living in other committees, with this group
16 for input.

17 DR. MOSS: It seems like the part of
18 it is there is very good back and forth
19 relationship between the NQF and the STS. And
20 I'm just wondering if that could exist with other
21 groups.

22 DR. FLEISHER: Helen, do you want to

1 talk about the incubator? Because isn't that the
2 space?

3 DR. BURSTIN: Why don't take other
4 comments first? Just to wrap it up.

5 DR. GROVER: I was pretty involved a
6 number of years ago on the professional council,
7 the ones that had the physicians in it, and I
8 really tried to encourage at those meetings all
9 the other specialties with professional
10 organizations to be involved with this process
11 and develop databases and kind of take charge for
12 their own area of the quality improvement and be
13 a resource to their members and to the patients
14 that they operate on.

15 And it was hard. Maybe there's more
16 now, but I think we have always offered, and Dave
17 can say this too, within the STS, and Jeff too,
18 if people want advice from us or anything we can
19 do to help them get cranked up and get going,
20 we'd be glad to do.

21 But I think we just happen to be the
22 first ones involved back 14 years ago or 12 or

1 whatever it was.

2 DR. FLEISHER: Barbara?

3 DR. LEVY: Well, as someone who is in
4 charge of quality and safety for our specialty
5 association, I will tell you that the big barrier
6 is not an interest or a desire to do it, it is
7 the funding to do it. And the funding is an
8 overwhelming barrier. You know, to do this well
9 is millions and millions of dollars. Our members
10 don't support that. So, we survive on membership
11 dues.

12 And unlike STS, we're not driven -- we
13 weren't driven 15 or 20 years ago with the public
14 reporting.

15 There's definitely some public
16 reporting, particularly of obstetrical outcomes,
17 but it's at the facility level. It's not at the
18 individual provider level.

19 And so there's no drive from our
20 members to support these activities. And very
21 honestly, without some other source of funding
22 that's going to help us drive this, I don't know

1 how to get it done. I can't get it through my
2 board and get that kind of support.

3 DR. FLEISHER: A.J.?

4 DR. YATES: At the ACS meeting, you
5 now have, I mean, the 800 pound gorilla in the
6 room in NSQIP which is obviously a huge, you
7 know, sample registry. But, obviously, they're
8 going to create measures from that. Do they
9 intend to take those measures through NQF or is
10 there intention to somehow not go through NQF and
11 bypass the CMS pathway?

12 DR. BURSTIN: I'm going to ask Cliff
13 to answer that one. Although I will point out,
14 we have endorsed NSQIP measures in the past and
15 would obviously be delighted to bring those
16 through again.

17 DR. YATES: You know, in smaller
18 specialties, again, cost and inertia are a big
19 deal. But, obviously, the best answer for a lot
20 of us would be more robust registries.

21 And I will now let Cliff answer.

22 DR. KO: Thank you for asking that.

1 Yes, absolutely. To Barbara's point, it does
2 take a fair amount of resource, but the College
3 is committed to that, so we are putting stuff
4 together not just with NSQIP, but bariatric as
5 well. That one should not have been submitted at
6 that point last year, but putting together stuff
7 with that. So, yes.

8 MR. LYZENGA: Yeah, I was just going
9 to say, the bariatric group still remains
10 interested. We didn't drive them off completely,
11 they weren't quite ready to submit during this
12 cycle, but they do intend to bring some measures
13 back.

14 DR. CIMA: But the one issue becomes,
15 as Cliff knows and we talked about this, is, you
16 know, STS has been very open about making
17 available the risk adjustment and stuff even
18 though it's very onerous.

19 I mean, for someone not -- to want to
20 do this individually, without having an
21 established -- NSQIP is not in every hospital.
22 It's what, 450 hospitals now, Cliff? And some of

1 that stuff is proprietary, so it's not like you
2 can do it your own.

3 DR. FLEISHER: So, I think what we did
4 was for the other, the prior endorsed measures is
5 that we just felt there was an important thing we
6 put out to the whole risk adjustment modeling so
7 that everyone knew what that was.

8 And in order to be used, then, people
9 just have to collect those And we made the
10 models very small and easy so that if somebody
11 weren't in that database that they could collect
12 these things.

13 What's difficult is the rigor with
14 which they're collected is variable. And that's
15 where the STS is -- I mean, having one registry
16 do everything is great. And our work with the
17 CDC when we harmonized an SSI measure made it
18 parsimonious where you have SSI and only like
19 three -- I think there were five risk factors,
20 and it was good metrics or good reliability and
21 validity of the measure.

22 The vehicle to do the measurement was

1 different. People were getting different answers
2 whether they used NSQIP or NHSN or a third
3 registry.

4 And so all of these things need to be
5 taken care of or addressed. You know, it's not
6 endorsement of the measure but how it's going to
7 be implemented. And that is a big deal when it
8 ultimately gets used, if it ultimately gets used.

9 DR. FLEISHER: So, one of the
10 questions in this gap analysis, as we write it,
11 there is expertise on different types of measures
12 from different developers that we have identified
13 over the years.

14 I wouldn't want to put David or any
15 other group on the spot, but in addition to NQF
16 staff, we may be able to identify resources in
17 the developer community, in the surgical space,
18 that could serve as potentially point people who
19 have gotten through NQF.

20 DR. JACOBS: Right. That's what I was
21 going to comment on.

22 I think there's no doubt, developing

1 measures is expensive and the time to develop a
2 body of knowledge to develop the measure and the
3 registry to track the measure, it's time
4 consuming and it's expensive.

5 And STS is lucky now because,
6 initially, under Fred's leadership and then
7 Dave's leadership, we have this whole measure
8 development team. We have Jane Han here who here
9 who could produce this 800-plus page book of
10 measures. And it takes time to develop that.

11 STS is currently in dialogue with the
12 neurosurgical societies to partner with them to
13 develop neurosurgery quality measures, and we've
14 had several preliminary phone conferences with
15 actually came out of the last meeting of this
16 group, and then some discussions with
17 neurosurgery and STS after that.

18 And I think that's something our group
19 is willing to do. And if there's other
20 professional societies that are at a point where
21 they have the time, money and energy to do this,
22 and they need the intellectual input, there's

1 people in our team that could work with those
2 other societies and we'd be happy to be worked as
3 a resource to do that.

4 DR. ASHER: Hi, this is Tony Asher.
5 I'm on the line. I'm sorry I can't be there in
6 person, but I just want to chime in.

7 The neurosurgery societies have really
8 appreciated STS' input, not only in terms of our
9 registry development but also in terms of our
10 ambitions to develop measures.

11 You know, everybody has mentioned the
12 challenges related to resources, and they're
13 substantial. And in particular, when you're not
14 looking at this in terms of individual measures,
15 I mean, you know, right now CMS is insisting on
16 the use of several, you know, at least nine
17 measures to satisfactorily participate in
18 something like PQRS.

19 And so when you're starting with no
20 specialty-specific measures, it's already
21 daunting to think about getting your first
22 through, through a process like NQF has set up.

1 But to think about developing nine so
2 that you could have your members using all
3 measures that are really relevant to what you're
4 doing every day becomes difficult.

5 So, you know, assuring resources for
6 measure development, at least benefitting from
7 the experience of groups like STS, and having a
8 tool kit available, will be critically important
9 for smaller specialty societies.

10 If I could just make one other
11 comment, the other thing that's complicating our
12 decisions as to whether or not to move forward
13 with an individual measure development right now
14 is the fact that there is a QCDR method which,
15 frankly, is a lower bar with respect to measure
16 development.

17 I'm sure that that's going to change
18 over time. But right now, it's a very attractive
19 mechanism for groups like ours that do have an
20 existing registry, want to have measures that are
21 more specific to what we do every day, but can't
22 right now either because of expenses or just time

1 considerations, come up with multiple measures
2 and get them through the NQF process.

3 In the short term, I think it's going
4 to be a great way for us to at least get in the
5 game. But we do recognize the importance and
6 value of having measures vetted for more general
7 use outside of, for example, our own specific
8 registries.

9 DR. SHAHIAN: Could I just make one
10 comment, Dr. Fleisher?

11 Just with respect to the cost of
12 developing measures, the biggest cost of
13 developing a measure is not on any society's
14 balance sheet. It's the investment of hundreds,
15 in the case of STS, volunteers who are on calls
16 at 6:00 in the morning and 9:00 at night, who
17 have taken the time to make themselves really
18 experts in some of these methodological issues.

19 The contribution of those individuals
20 cannot be -- I really can't adequately express
21 it. But it is far greater than the actual cost
22 that you see on a balance sheet.

1 And I think any society that wants to
2 get in this game really has to develop that cadre
3 of people who are really committed to doing this.
4 That's the key to our success, I think.

5 DR. FLEISHER: We'll go with a couple
6 quick comments.

7 Rick, did you want to say -- and we're
8 going to end where it all began with Fred.

9 DR. DUTTON: Very quickly, I will echo
10 what Lee said about the -- we were here last year
11 as a new measure developer, had a miserable time,
12 but the staff really stepped up to help us this
13 year and it was much -- has been a much better
14 process.

15 I think that's the barrier I would put
16 on the table for societies just getting into
17 this.

18 To echo the other comments, I think
19 having a registry is pretty much critical at this
20 point if you're going to have the data in order
21 to build measures, and we are slowly developing
22 that.

1 I agree with what Dr. Asher said about
2 the QCDR, but we look at it slightly differently.
3 That's our farm team, that's where we can develop
4 the measures in a very specialty-specific way and
5 get the data we need to advance into the NQF, and
6 that's our intention with what we have in that
7 pipeline now.

8 DR. FLEISHER: Great.

9 DR. ASHER: I think we'd view QCDR the
10 same way.

11 DR. FLEISHER: Great. Fred's going to
12 make a comment and then Helen's going to finish.

13 DR. GROVER: Yes, I'd just like to say
14 that I obviously -- our group was stimulated, as
15 mentioned, in the '80s. But Karl Hammermeister,
16 my cardiology colleague, when worked developing
17 the VA database, always made the point, and I
18 think it's true and it's been true over the
19 years, that when physicians come forward
20 themselves with things they want to measure for
21 quality, they take ownership over that and
22 they're probably more likely to rise to the

1 occasion and try to improve on their performance
2 when it's something that originates within their
3 own group and has meaning with their group so it
4 has credibility and validity.

5 But I think what you really need in
6 these, as Dave mentioned, is some leaders that
7 really take this to heart and really want to do
8 it and have fun with it, and the STS leadership
9 always supported this, even when we were getting
10 started.

11 It cost us several hundred thousand
12 dollars when we changed over in the mid '90s for
13 two or three years in a row. But then we became
14 -- when we built our number of people
15 participating, groups and hospitals obviously, we
16 got rid of that deficit.

17 But you have to have a champion. And
18 we would be willing or there'd be people, like
19 Dave or Jeff in our group, that would be willing
20 to go to a national meeting or a meeting of the
21 leadership of these professional societies to try
22 to stimulate some enthusiasm. Because if you

1 don't have the data and have some control over
2 what you're doing yourself, somebody else will do
3 it for you.

4 And a lot of times, there'd be these
5 people that have no intent of ever going through
6 NQF. That's the for-profits in the sky. And
7 then you're feeling like you're a victim and none
8 of us want to be a victim.

9 DR. FLEISHER: Well, it's clear to see
10 why everyone followed you, Fred.

11 So, Helen, did you want to make?

12 DR. BURSTIN: Just a couple of
13 comments. I know I'm between you and lunch.

14 So, I'm pleased to hear from Rick that
15 things are improved because we really have been
16 trying to do as much as we can with up front
17 support, hand holding.

18 Our goal, just to make it clear, is to
19 get these measures through. We want to make sure
20 that whatever comes through the process is good
21 make it through. We don't want to have a
22 "gotcha" feeling. It really is the intent.

1 The better something comes through the
2 process, the easier it'll have going through.
3 So, up front support, we're very invested in
4 that.

5 And I think part of what we'd love to
6 also know from the surgical societies, in
7 particular, is what do you need to succeed? I
8 mean, as we're moving towards e-measures, for
9 example, are there particular elements that would
10 be really useful?

11 So, we've got a new project HHS has
12 funded for us with NLM on coming up with an
13 approach to harmonize value sets, the kind of
14 building blocks of, you know, this is cardiac
15 surgery or this is post-op just to make it very
16 clear, more plug-and-play over time. And, again,
17 we'd love to have further conversations with you
18 on that.

19 The other thing is I know, Marcia
20 mentioned it yesterday, we're going to be
21 convening an extra panel in the next few months
22 to think through this issue of moving for

1 endorsement for intended use, or at least some
2 grades of endorsement, fully recognizing that,
3 you know, farm team measures may not need to
4 reach the same level of rigor, if you're going to
5 be using it for QI and benchmarking as a measure
6 that might be in a penalty program or a payment
7 program. So, more on that to follow, certainly.

8 But we recognize the field has
9 changed, the idea that a QI measure is held to
10 the same, you know, standards is something as
11 that might be used for public reporting for
12 patients to make decisions, purchasers to make
13 decisions or penalties just doesn't seem logical
14 anymore.

15 And then lastly, Lee gave us hints to
16 the fact that we also, the Board did approve our
17 proposal recently that we would move to try to
18 develop a measure incubator, and we've moved
19 pretty far along that process.

20 And the idea there would be that we
21 would never endorse measures. That's not our
22 role -- I mean, develop measures, sorry -- we

1 will continue to endorse measures. There you go,
2 there you go.

3 (Laughter.)

4 But we would not develop measures but
5 there seems to be a need for some entity to help
6 facilitate development. So, we're trying to
7 think about how we can bring to the table folks
8 who have ideas for measures, and that can
9 certainly include the specialty societies, hook
10 you up with both test beds, experts and just kind
11 of move the process along and see if we can
12 really kind of disrupt the measure development
13 cycle a bit, move things through more fast and
14 more quickly and particularly give access to data
15 from the concepts stage. As you're developing a
16 measure, here's your test bed. Can you move that
17 along more rapidly, get the outcomes you want?
18 So, certainly more on that to follow.

19 But, again, trying to be very much
20 responsive to what we recognize as a rapidly
21 changing measure development and use world and
22 trying to keep up.

1 So, thanks.

2 DR. FLEISHER: Okay, well, let's get
3 lunch. If we could maybe try to get back here
4 around 1:00 and we'll kind of have a working
5 lunch, that'll be great.

6 (Whereupon, the above-entitled matter
7 went off the record at 12:40 p.m. and resumed at
8 12:59 p.m.)

9 DR. GUNNAR: Now that we're in a
10 rhythm. The next measure is 0121, if I have it
11 right. Risk Adjusted Operative Mortality for
12 Mitral Valve Replacement.

13 DR. JACOBS: Yes. So again, we're
14 working our way through the risk adjusted
15 operative mortality measures. And now we're
16 going to have four of them related to the mitral
17 valve.

18 The first two are mitral valve
19 replacement. One without and one with CABG. And
20 then the next two are mitral valve repair for the
21 same.

22 Again, the details are really going to

1 be very similar to the previous operative
2 mortality measures. And the data is basically
3 similar but valve-specific.

4 DR. GUNNAR: And the model is all
5 based on a 2009 publication.

6 DR. JACOBS: Correct.

7 DR. GUNNAR: All right. So, Dr. Roth?

8 DR. ROTH: Yes, let's see if we can
9 get that momentum re-going again. This was
10 previously endorsed in December 2011. It's a
11 maintenance. It's risk adjusted operative
12 mortality for mitral valve replacement. Percent
13 of patients age 18 years and older undergoing
14 mitral valve replacement who died, both including
15 all deaths during the hospitalization in which
16 the procedure was performed, even if after 30
17 days, and those deaths occurring after discharge
18 from the hospital, but within 30 days of the
19 procedure.

20 Again, this is just replacement. It
21 does not include repair. Repair is another
22 discussion. It's an outcomes measure, of course.

1 Evidence is pretty much as discussed this
2 morning.

3 DR. GUNNAR: Any other discussion on
4 the evidence?

5 (No response)

6 DR. GUNNAR: Hearing none, shall we
7 vote?

8 MR. LYZENGA: Voting on evidence. Go
9 ahead and cast your vote.

10 Unanimous yes. The measure passes on
11 evidence. So we'll move to performance gap.

12 DR. ROTH: There were two groups that
13 were reviewed December of 2008 -- I'm sorry, July
14 of 2008 through June of 2011. And then again
15 July 2011 through June of 2014.

16 Average rate was 5.85 percent for the
17 first time period. 5.26 percent for the second
18 time period. But the range was somewhat
19 different. The first time period, 2.7 percent to
20 12.7 percent. So, quite a bit of variability.
21 And then the second time period, 5.26 percent to
22 11.5 percent. Again, somewhat of a variation

1 between the two time periods, but very similar.

2 DR. GUNNAR: So the question I have
3 is, does the STS recognize the gender
4 distinctions in relationship to their modeling,
5 and that's why the two are separated? Is that --
6 or why -- you don't throw them in the same
7 bucket. Or do you distinguish the gap based on
8 gender, but gender doesn't impact the model by
9 definition, right?

10 MR. HE: Yes, we use the same model
11 for both genders. And gender itself is actually
12 a covariant, a predictor in the model. But we
13 provide the results by gender. We provide all
14 the evaluation statistics by gender so that the
15 requirement of the form is met. So we don't do
16 anything differently for male and female.

17 DR. GUNNAR: Yes. I asked it poorly,
18 probably. But the model isn't a separate model
19 for male or a separate model for female? It's a
20 combined model.

21 MR. HE: Yes.

22 DR. GUNNAR: You've just identified a

1 performance gap between gender, correct?

2 MR. HE: Yes. So, for most of the
3 predictors, like ejection fraction, we don't
4 assume that there is a different effect between
5 gender groups. So the same effect is used.

6 The only exception is body surface
7 area. So, for body surface area, a male and
8 female have different effect size. But that's
9 the only exception.

10 DR. GUNNAR: Which leads to the
11 missing data conversation. And you've improved
12 over time, but it's still pretty much the same.
13 EF is your highest component of missing data.
14 It's small, but just for -- and you do your best
15 to apply really the lowest impact data element if
16 there's a missing piece of data.

17 MR. HE: Yes.

18 DR. GUNNAR: I just wanted to -- any
19 other questions about performance gap?

20 (No response)

21 DR. GUNNAR: Hearing none, go ahead
22 and vote.

1 MR. LYZENGA: Voting on the performance
2 gap. Variation in performance or overall less
3 than optimal performance.

4 We have 48 percent high, 52 percent
5 moderate, zero low, zero insufficient. The
6 measure passes performance gap.

7 And barring any objections from our
8 Committee, we will carry over our votes on
9 reliability and move to validity.

10 (No response)

11 MR. LYZENGA: Seeing none, let's
12 discuss validity. Or is there any discussion on
13 validity? Any comments or questions?

14 DR. ROTH: Actually, I don't have any
15 additional comments on it. You know, it's 19,000
16 operations with 989 participants. It's a pretty
17 large number.

18 DR. GUNNAR: Let's go ahead and vote
19 on validity.

20 MR. LYZENGA: So, again, voting on
21 validity. The question is whether the measure is
22 an accurate representation of quality care in

1 this area.

2 We have 65 percent high, 35 percent
3 moderate, zero low, zero insufficient. The
4 measure passes on validity.

5 And if there are no objections from
6 the Committee, we will carry over our votes on
7 feasibility and usability.

8 (No response)

9 MR. LYZENGA: Seeing no objections, we
10 will vote on overall suitability for endorsement.
11 Go ahead and cast your vote.

12 And we have a unanimous yes. The
13 measure passes.

14 So, next we'll move to --

15 DR. GUNNAR: So, we wanted to -- the
16 question is, could we just do the repair next?
17 Because that's mine. I'm discussing, but also it
18 is a mirror of this, literally. There are
19 different numbers obviously, but -- and so the
20 question is begged: why did you separate mitral
21 valve replacement from mitral valve repair?

22 DR. JACOBS: Right. And that's a

1 great question. I think the operative mortality
2 in the short and long term outcomes are different
3 in the two subsets. And probably the patients
4 that get one versus the other are different. So
5 it makes sense to have separate models for the
6 two.

7 Some patients are candidates for both.
8 Some patients are clearly only candidates for
9 replacement. But we felt that the patient
10 subsets were different enough and their outcomes
11 were different enough that it makes sense to
12 create two models.

13 So the measure is, as you said, the
14 same that we just discussed for replacement, but
15 now for patients who undergo repair of the mitral
16 valve.

17 DR. GUNNAR: Do you want to say this
18 is 1501?

19 MR. LYZENGA: Yes. To clarify, we're
20 on 1501 now. Risk Adjusted Operative Mortality
21 for Mitral Valve Repair.

22 DR. FLEISHER: So, any other comments

1 or questions from the Committee?

2 (No response)

3 DR. FLEISHER: So, from the patient's
4 perspective, if they're coming in, they should
5 look at both? I'm just curious, from a gap
6 analysis, from a --

7 DR. JACOBS: Yeah. I think, from the
8 patient's perspective, step one is to have a
9 detailed heart to heart discussion with your
10 surgeon about what operations you might end up
11 getting. And what's the likelihood of having a
12 replacement? What's the likelihood of having a
13 repair?

14 And I think some patients go to the
15 operating room where the plan is 100 percent to
16 replace the valve. Other patients go to the
17 operating room that we're going to do our very
18 best to do a repair and only replace it if we
19 have to.

20 Those patients who go with the plan
21 we're going to do our very best to do a repair
22 and only replace it if we have to, some have an

1 anatomic substrate that it's almost close to, but
2 not exactly 100 percent chance that they'll get a
3 repair. Others have an anatomic substrate that's
4 50/50.

5 So, based on all that, you know, which
6 data they look at, they should talk to their
7 surgeon. And then probably look at both sets of
8 data. And they'll go in there having a good idea
9 what it's going to be, but not knowing for sure
10 sometimes.

11 DR. FLEISHER: Yes, Melissa?

12 MS. THOMASON: That's exactly the
13 conversation I had to have with my surgeon. So
14 that's exactly how it went down. But I would
15 have wanted to go see information for both and
16 see them separately. In having the valve
17 entirely replaced, first it's repaired, was an
18 entirely different set of long term implications
19 for me and all of that, so.

20 DR. FLEISHER: Thank you. And thank
21 you for the honesty to provide us with your
22 story.

1 Given the similarity, are there any
2 comments about any aspect? Or should we just
3 vote continuously?

4 (No response)

5 DR. FLEISHER: Hearing no comments,
6 Andrew, take us through it.

7 MR. LYZENGA: Let's vote. All right,
8 so we're voting first time evidence, whether a
9 rationale supports the relationship of the health
10 outcome to at least one healthcare structure,
11 process, intervention or service.

12 We have a unanimous yes on evidence.
13 And we'll go to performance gap. Unless there
14 are any objections, we'll go ahead and vote.

15 Voting on performance gap.

16 We have 29 percent high, 71 percent
17 moderate, zero low, zero insufficient. If there
18 are no objections from the Committee, we'll carry
19 over our votes on reliability and move to
20 validity.

21 Any comments or questions on validity?

22 (No response)

1 MR. LYZENGA: Seeing none, let's go
2 ahead and vote.

3 73 percent high, 27 percent moderate,
4 zero low, zero insufficient. And unless there
5 are any objections, we will carry over our votes
6 from feasibility and usability.

7 Seeing none, we will go ahead and vote
8 on overall suitability for endorsement.

9 Unanimous yes. Measure passes. So
10 now we're going --

11 DR. GUNNAR: So, let's go back to
12 0122. Which is Operative Mortality Mitral Valve
13 Replacement and CABG. And again, Dr. Handy, do
14 you have any other?

15 DR. HANDY: It's the same as before.
16 It's just a question of magnitude.

17 So, jumping way ahead, if you look at
18 the performance gap, whereas the highest tercile
19 of mortality in the mitral valve repair was three
20 percent, this is 20.6 percent. So, 21 percent
21 versus the lowest tercile, which is 2.3.

22 Other than that, it's the same. Just

1 proportional risk.

2 DR. JACOBS: Sure. And it makes
3 sense. It's a bigger operation with higher risk.

4 DR. GUNNAR: So, just to go back, and
5 they showed two periods of time. And in the
6 mitral valve world, if I read them all right,
7 there's been more incremental increase or
8 improvement in men than there has been in
9 females. In both mitral valve and mitral valve
10 repair. And I didn't review this one. Were the
11 sexes, did gender make a difference in the level
12 of improvement across risk groups?

13 DR. HANDY: I don't know. I didn't
14 look at it -- I didn't look for that, Bill.

15 DR. GUNNAR: I just thought we'd have
16 some dialogue because we've gone through so many
17 today.

18 (Laughter)

19 DR. GUNNAR: Trying to slow us down.

20 DR. JACOBS: The nice thing is that,
21 with the discussion we had this morning about
22 operative mortality and some of the other

1 building blocks, it just sets all this up.
2 Because this is now just all based on a variety
3 of building blocks that we put together to put
4 these measures together. And then the composites
5 are the next set of building blocks.

6 DR. GUNNAR: We're headed towards the
7 composite. But I did want to sort of -- if you
8 had any reflections on sort of the gap or the
9 improvement.

10 From an NQF perspective, these
11 measures are supposed to, you know, at least push
12 improvement. And so the question here is, did
13 it? And can you show any?

14 DR. JACOBS: You know, I mean, I think
15 the issue of mitral valve surgery in women is a
16 complex issue. But maybe the simplest way to
17 look at it is that, in general, women are
18 smaller. Their hearts are smaller. Their mitral
19 valve is smaller. The mitral valve annulus is
20 smaller. Getting a good prosthesis in there is
21 more difficult. And doing a repair on a smaller
22 mitral valve is a little bit more challenging.

1 That's not based on a lot of data.

2 That's based on doing a lot of surgery.

3 DR. GUNNAR: Yeah, and mine was merely
4 an observation. And I think that you've
5 confirmed that it exists. It's just, you know,
6 there is no current explanation for it. But
7 there is signs of improvement over the periods of
8 measurement.

9 DR. JACOBS: Yes. Agreed.

10 DR. GUNNAR: Okay. All right.

11 MR. LYZENGA: Okay. Let's vote on
12 evidence.

13 We have a unanimous yes. So we'll
14 move onto performance gap. Any comments or
15 questions?

16 DR. KO: I just have quick question.
17 There's a table, and I feel so moronic because I
18 can't understand the table.

19 But the mean, it says, and this is on
20 page four at the top where it says 953 STS
21 participants. And it's the mean, N is 7.7 and
22 the percent -- in the column, percent operative

1 mortality is 12 percent, 11.9. So that is the
2 mean mortality rate of this procedure? This
3 combined procedure?

4 DR. HANDY: We're trying to locate the
5 table.

6 It's a common methodology across all
7 these applications. And what they do is, this is
8 that particular one, Cliff, is looking at the
9 consistency of your operative mortality tercile
10 in the earlier time period versus the second time
11 period.

12 And so, in general, what you see is
13 that the best performers stay best, and the worst
14 stay worst. But in this particular case, they
15 actually flipped.

16 And that's the one that you're looking
17 at, I believe. It's the 8.6, 11.1, 9.4. Is that
18 what we're talking about? This is on page 28 of
19 the empirical validity. It's a graphic.

20 DR. KO: Is that what you're talking
21 about? You're talking about on page four?

22 DR. HANDY: I think that's the word --

1 DR. KO: On the top of page four, the
2 word -- it says calculation of MV replacement and
3 CABG operative mortality.

4 DR. HANDY: Yes. We're there.

5 DR. KO: You see 36 months. Do you
6 see it?

7 MR. HE: Yes, so that table actually
8 summarizes both the sample size, the denominator
9 size of each hospital, of all the hospitals. And
10 also the raw observable operative mortality rates
11 across all hospitals.

12 So if you look at a mean role, so it
13 basically means the average sample size across
14 all hospitals is 7.7. And the average mortality
15 rates across all hospitals -- and by the way,
16 this is hospital level average, it's 11.9.

17 Does that clarify?

18 DR. KO: Yes. And then the
19 percentages down the left side, it looks like 50
20 percent of the samples have zero percent
21 mortality? Is that what that means?

22 MR. HE: Yeah. Those are the

1 percentiles. So, right, that means 50 percent of
2 the participants didn't have any patient
3 experience in the mortality event.

4 DR. KO: Okay. Thank you.

5 DR. DUTTON: That shouldn't be
6 surprising since the average center did nine of
7 these cases in the year and one of them died.

8 DR. HANDY: Correct.

9 DR. DUTTON: So, half the centers
10 would have no mortality, predictably.

11 DR. HANDY: Exactly.

12 MR. LYZENGA: Any other comments on
13 performance gap, or questions?

14 (No response)

15 MR. LYZENGA: Seeing none, let's go
16 ahead and vote on performance gap. The question
17 is whether there is variation or overall less
18 than optimal performance across providers.

19 We have 43 percent high, 57 percent
20 moderate and zero low and zero insufficient. The
21 measure passes on performance gap.

22 And unless there are any objections

1 from the Committee, we will carry over our
2 reliability voting results.

3 Seeing none, we'll go to validity.

4 Any comments on validity?

5 Hearing none, we'll go ahead and vote.

6 Voting now on validity.

7 Sixty-three percent high, 37 percent
8 moderate, zero low, zero insufficient. The
9 measure passes validity.

10 Unless there are any objections from
11 the Committee, we'll carry over our votes for
12 feasibility and usability.

13 (No response)

14 MR. LYZENGA: Seeing none, let's vote
15 on overall suitability for endorsement.

16 MS. THOMASON: I have a question.

17 MR. LYZENGA: Yes, go ahead.

18 MS. THOMASON: I just wanted to
19 clarify. So all of the measures we've talked
20 about this morning, are they still at this point
21 publicly reported information disseminated just
22 like we talked about before?

1 DR. JACOBS: Yeah. So, let's take it
2 from the beginning. All of the three congenital
3 measures are publicly reported.

4 The adult measures are publicly
5 reported as composite scores, with the ability to
6 then drill down to the components of the
7 composite. But the status of the different
8 measures are a little bit different.

9 So, CABG and all the CABG related
10 measures have been publicly reported through the
11 CABG composite since 2010. And STS has made the
12 commitment to roll out at least one new measure
13 every year, because it takes time to roll them
14 out for public reporting.

15 So, right now we're publicly reporting
16 isolated CABG, isolated aortic valve replacement,
17 aortic valve replacement combined with CABG, and
18 the congenital measures. The next ones on the
19 schedule to be rolled out are the mitral valve
20 measures and some general thoracic measures.

21 So, the short answer to your question
22 is, everything is currently publicly reported

1 that we've talked about today except for the
2 mitral valve measures, and the mitral valve
3 measures we anticipate being rolled out within
4 the next year on public reporting.

5 DR. GUNNAR: But to clarify, if you go
6 to your hospital, they may not, even though they
7 do aortic valve and mitral valves, they may not
8 report the valve bundles. They'll report their
9 CABG bundle if they've signed onto it.

10 DR. JACOBS: Right. So the point
11 there is that STS is a professional medical
12 society and not the government. We can't mandate
13 anybody to do this. We can just create the
14 service to publicly report. And each hospital
15 and each cardiac surgical program has to decide
16 whether or not they're going to do it.

17 Every year the number of programs who
18 are doing it is increasing. And there's huge
19 efforts within STS to get more programs to sign
20 up and participate.

21 And those efforts range from blast
22 emails to webinars to telephone campaigns where

1 Fred and Dave and several STS leaders even
2 divided up the names of non-reporting programs
3 and called them.

4 So, we're working on getting more and
5 more programs to report. And it's getting better
6 every year. But you're absolutely right, not
7 everybody is publicly reporting.

8 And when they publicly report, they do
9 not necessarily have to publicly report each
10 measure. But it's getting better every year.

11 MR. LYZENGA: All right. If anybody
12 has not voted, yet for overall suitability for
13 endorsement, please do so now.

14 And we have a unanimous yes. The
15 measure passes. And I think now we're onto our
16 composite. The last measure of the day.

17 DR. GUNNAR: No, we've got one more.

18 MR. LYZENGA: One more. My mistake.

19 DR. GUNNAR: Right, 1502, exactly.

20 This is exactly as was just said. This is the
21 last iteration. This is repair plus CABG.

22 Everything we said so far stands. And

1 nothing new to add.

2 DR. YATES: As the reviewer, I concur.
3 It's an outcomes measure. You can -- and there's
4 performance gap.

5 DR. GUNNAR: And the rarity of event?
6 The channel -- what is the average per center?

7 DR. YATES: The average per center has
8 stayed the same over two time periods of around
9 five percent. The range has become less over
10 time from the high going from around 13 percent
11 down to eight percent. But still represents two
12 and a half full difference from the low in the
13 range of about three percent. So there's a wide
14 range. And it remains in according to
15 performance gap.

16 DR. DUTTON: And this is way more
17 common than replacement. There are 14 per
18 center, per year in this.

19 DR. GUNNAR: Originally. So there's
20 a significant performance gap I believe.

21 So we're voting on evidence.

22 DR. YATES: There is evidence first.

1 It's an outcomes measure. They did provide
2 evidence, but it wasn't required.

3 DR. LYZENGA: So, voting on evidence
4 first. Go ahead and cast your vote.

5 And we have a unanimous yes. And is
6 there any discussion on performance gap? Or
7 should we go ahead and vote? Let's vote.

8 Forty-seven percent high, 53 moderate,
9 zero low, zero insufficient. Measure passes on
10 performance gap.

11 If there are no objections from the
12 Committee, we'll carry over our reliability
13 voting and move to validity. Any comments or
14 questions on validity of this measure?

15 Seeing none, we'll go ahead and vote.
16 Voting now on validity.

17 Fifty-eight percent high, 42 percent
18 moderate, zero low, zero insufficient. The
19 measure passes on validity.

20 Baring objection from the Committee,
21 we will carry it forward, our votes on
22 feasibility and usability.

1 Seeing no objection, we'll move to
2 overall suitability for endorsement. Any
3 comments or questions before we vote? No? All
4 right. Voting now on overall suitability for
5 endorsement.

6 And we have a unanimous yes. The
7 measure passes.

8 And now on for a composite.

9 DR. GUNNAR: So the next measure up is
10 0696, STS CABG composite score. So Jeff, do you
11 have any comments for that?

12 DR. JACOBS: Right. So now we're
13 moving into -- yes, we're moving into a different
14 type of measure, a composite measure.

15 And this is the STS CABG composite
16 score. And it's based on a combination of 11 NQF
17 endorsed process and outcome measures.

18 The composite is divided into four
19 domains. Domain number one is the absence of
20 operative mortality. Domain number two is the
21 absence of major morbidity, which is defined as
22 patients who do not experience any major

1 morbidity.

2 The morbidities include re-operation
3 for any cardiac reasons, which we discussed
4 earlier today; renal failure; deep sternal wound
5 infection, which we discussed earlier today;
6 prolonged mechanical ventilation; and
7 cerebrovascular accident or permanent stroke. So
8 it's an absence of all of those major
9 complications.

10 The third is a process measure, which
11 is use of the internal mammary artery. Which is
12 a process measure that's been shown to be
13 associated with improved short term and long term
14 outcomes after coronary bypass grafting.

15 And then the fourth domain is a
16 perioperative medications bundle that is the
17 proportion of patients who receive all of the
18 required perioperative medications. Including
19 preoperative beta blockade, discharge
20 antiplatelet medication, discharge beta blockade
21 therapy and discharge anti-lipid medication. Two
22 of those four we discussed today.

1 All four of those and really all the
2 components are previously endorsed NQF measures.
3 So what's new here is that we take these 11
4 previously endorsed NQF measures and put them
5 into a statistical model. Which then allows
6 reporting publicly the programs stratified.

7 And the way we're doing it is into a
8 star system. Programs are assigned one star, two
9 star or three stars. About 75 percent of the
10 programs are two star programs. And about 12 .5
11 percent are one star and three stars.

12 And this is the first STS measure that
13 has been publicly reported. And it's been
14 publicly reported since 2010.

15 And that's a rapid summary of how this
16 works. And I'd be happy to answer any questions.

17 DR. GUNNAR: I think the only other
18 thing we had before we roll it out, Lynn, is the
19 fact that we endorsed which composite measures
20 last? I think we endorsed AVR and AVR CABG on
21 our last round if I'm not mistaken.

22 DR. YATES: We also did renal failure

1 and prolonged ventilation/intubation as outcomes,
2 separately.

3 DR. GUNNAR: Yes.

4 DR. YATES: And I think CVA.

5 DR. GUNNAR: Okay. So, Lynn?

6 MS. REEDE: I believe we've discussed
7 the evidence on this measure as well. It's been
8 audited in the same the other measures were
9 inside the composite.

10 DR. GUNNAR: Any other discussion?

11 All right. We'll vote on the
12 evidence.

13 MR. LYZENGA: Okay, we have one more
14 on the phone there. Yes. Got it. 95 percent
15 yes, five percent no. Measure passes evidence.

16 We'll move to performance gap.

17 DR. GUNNAR: Any comments Lynn?

18 MS. REEDE: Nothing new.

19 DR. JACOBS: Yes, I think the star
20 system along shows there's a performance gap when
21 there's about 12.5 is one star, 12 and a half is
22 three star.

1 DR. GUNNAR: And that's based on a 95
2 percent confidence interval on these measurement
3 assess -- on the measurement assessments, right?

4 MR. HE: This one actually used a 98
5 percent Bayesian type credible integral. And the
6 choice of 98 over 95 is the course of isolated
7 CABG population is pretty large --- very large
8 actually.

9 And we are combining four domains. So
10 that gives us more accuracy. So we want to
11 divide the hospitals more reliably in a sense.
12 So we're using more strict criteria.

13 DR. JACOBS: Yes. The -- I'm going to
14 venture into statistical territory, which is a
15 little dangerous here. But --

16 DR. GUNNAR: We encourage that Jeff.

17 DR. JACOBS: The quote that I've heard
18 that explains this to most -- that surgeons like,
19 is that by using a 98 percent Bayesian credible
20 index, it means that the outliers that are
21 identified were 99 percent certain that they're
22 true outliers.

1 So that's how those numbers came
2 about. And I think people who are identified as
3 outliers like to know that there's a 99 percent
4 certainty statistically that they really are an
5 outlier. Did I say that right?

6 DR. GUNNAR: Yes. And it exceeds
7 beyond a reasonable doubt. There's no doubt.

8 Liz?

9 DR. EREKSON: Oh, sorry. So this is
10 one of the measures that's been publicly reported
11 for the longest amount of time. Can you guys
12 comment on unintended consequences of public
13 reporting?

14 Or because this public reporting is in
15 effect, are you seeing centers moving away from
16 more surgery? Or dropping out of the database?
17 Anything like that as a consequence of the five
18 years of public reporting experience?

19 DR. JACOBS: Great. So that's a
20 really important question you're asking. I think
21 there's many potential unintended consequences of
22 public reporting.

1 And it's in general, very important to
2 keep our eye on those potential unintended
3 consequences. Because everybody in this room I
4 think, believes that on the whole public
5 reporting is a good thing. And we don't want to
6 have bad things happen because we're doing
7 something we believe is a good thing.

8 I think the most feared unintended
9 consequence is risk aversion. To state that
10 simply, a surgeon or a hospital doesn't want to
11 operate on a high risk patient because they could
12 look bad on a publicly reported report card.

13 And the solution to risk aversion is
14 having solid risk adjustment methodologies that
15 level the playing field and credit providers,
16 surgeons and hospitals for caring for the high
17 risk patients. And those are the patients that
18 may actually benefit the most from surgery.

19 So I think although risk aversion is
20 a potential unintended consequence, we mitigate
21 against that risk by having what I would believe
22 are the best risk adjustment models in all of

1 medicine within this composite.

2 And to date, no one has shown us any
3 evidence that risk aversion is taking place
4 because of public reporting and we've not seen
5 any evidence that that's taking place.

6 DR. SHAHIAN: I can add a little bit
7 to that too, Jeff. We've going to be publishing
8 our work. We're presenting it next month at the
9 American Surgical on our first four years of
10 experience with public reporting.

11 And we looked specifically at the
12 question of risk aversion. And found that there
13 has been essentially zero change in the expected
14 mortality rates over that four year period of
15 public reporting.

16 And in fact, some of the most
17 important risk predictors have actually increased
18 in frequency. Like preoperative renal failure,
19 severe chronic obstructive pulmonary disease,
20 have actually gone up a little bit.

21 And so, there has really been no
22 evidence that programs overall are shying away

1 from the more difficult cases. That was
2 certainly one of the things that we wanted to
3 confirm.

4 DR. YATES: Is there the positive
5 possibility that the trust in your risk
6 stratification, your risk adjustment model is so
7 good that surgeons feel more comfortable taking
8 on higher risk patients then maybe they did in
9 the earlier part of the process?

10 DR. SHAHIAN: I would hope so. We
11 just recently published another paper. The lead
12 author is Englund. Showing that -- and this is
13 in over a half a million patients over the last
14 three years.

15 If you stratify them by quintiles of
16 expected mortality risk, the O/E ratio was
17 essentially unity for each of those categories
18 except the very highest risk group of hospitals.
19 The ones that were doing the most difficult
20 cases. And it turns out their O/E ratio was .8.

21 So actually the risk modes over
22 predict mortality at the high end by a little

1 bit. And actually give more credit than is
2 probably warranted to programs that are doing
3 very high risk.

4 And if you take all the high -- the
5 highest risk cases from the hospitals, three
6 years of experience and compress them into one
7 year, in a sort of a thought experiment. And
8 look at the O/E ratio for that nightmare year,
9 which occasionally can happen, there's still --
10 they still have an O/E ratio that's about one.

11 So, I think the adequacy of risk
12 adjustment has been demonstrated. I hope that
13 we're getting that message across to our
14 participants. I think we are.

15 DR. GUNNAR: When you do your audits
16 and you got that four percent that's -- your rate
17 of reliability is not met, did they tend to up-
18 code or down -- or underestimate or overestimate?
19 Or is that anything you can say about the five
20 year outcome.

21 DR. SHAHIAN: I'm not sure I've
22 noticed a consistent trend. Jane, do you recall

1 or Jeff?

2 DR. JACOBS: No, I don't know. I
3 didn't see that.

4 DR. GUNNAR: My hypothesis would be,
5 is that people don't game that. They'd probably
6 under represent their comorbidity. And that's
7 what -- you know, they leave things out.

8 So, you may want to look at that. It
9 would be interesting to --

10 DR. SHAHIAN: No, that would be a very
11 important question to look at a little bit
12 further. I think that --

13 DR. GROVER: Yes, with the VADs -- the
14 VADs have had a great improvement over the past
15 several years with the nonpulsatile VADs. And
16 ECMO being used even more in the temporary VADs.

17 And it may be that some of these
18 people in the risk models based, you know, in the
19 last couple of years. And we re-up it every
20 what? Every three years? Every two years? We
21 re -- every three, calculate it.

22 But it may be that some of the

1 technologies are ahead of our re-upping that
2 which is affecting it as well. I mean, we have
3 some incredibly high people that come into our
4 place from out -- other hospitals that are just
5 moribund that respond to ECMO for example. Get a
6 coronary bypass and walk out.

7 DR. GUNNER: Go then, Cliff?

8 DR. KO: Oh, I don't know, oh, here I
9 am. I don't know where this question belongs in
10 terms of all these things. But, are these
11 weighted? Are the domains weighted? Or are they
12 just all equal?

13 MR. HE: Yes. They are weighted. So
14 the mortality domain has a larger -- largest
15 weight amount of the four domains.

16 And the way we weighted them, so we
17 designed different weights to different domains.
18 And the goal is that the final values made
19 clinical sense. So even though in the measure
20 development, we derived those weights using the
21 statistical method.

22 And we actually just used one over the

1 standard deviation of the specific domain. So
2 the domain with the larger variation, was
3 assigned the lower weight. That's how we
4 started.

5 Actually, when we -- when we developed
6 the measure, we look at different ways. That's
7 the one we choose. And we make sure that the
8 number makes clinical sense. And we continuously
9 make sure that makes sense and reflects the
10 current clinical practice.

11 I think one example is that -- so, IMA
12 when the measure was first developed, the IMA
13 usage was not very consistent across the board.
14 But it gets really consistent right now.

15 So, almost everybody who is getting
16 IMA, it's really good. So the IMA's variation
17 gets really small. But we are not giving IMA our
18 larger weight just because of that. We keep
19 using our original weight because we think that
20 makes clinical sense.

21 MR. LYZENGA: And I'll just note that
22 we actually have an opportunity to vote on that.

1 We'll have two additional questions for
2 composite.

3 One, in just a moment, on the
4 conceptual basis for the composite measure
5 construction. And then one a little bit later on
6 the empirical results around their construction.

7 DR. GUNNAR: Dr. Dutton?

8 DR. DUTTON: Yes, so, based on a lot
9 of experience with trauma registry scoring over
10 decades, once you set a benchmark, you would
11 expect as science marches on, everybody to get
12 better. And I think you said you're seeing that
13 in the data.

14 And that's why the .8 O/E in the
15 highest group. How often are you resetting the
16 benchmark in this data?

17 DR. JACOBS: The model is recalibrated
18 every three years.

19 MR. HE: I think we use the last three
20 years of data to recalibrate the model. That way
21 we actually recalibrate the model every time the
22 measure was calculated.

1 So we used the latest three year as
2 the benchmark.

3 DR. JACOBS: What he said.

4 MR. LYZENGA: Any more comments on
5 performance gap?

6 DR. GUNNAR: Test the vote? Yes.

7 MR. LYZENGA: Let's go ahead and vote
8 on performance gap.

9 Fifty-six percent high, 44 percent
10 moderate and zero low, zero insufficient. The
11 measure passes on performance gap.

12 And Alexandra, if you would skip over
13 high priority. But there will be one more here,
14 1D. There we go, composite.

15 So this is the -- the question here is
16 whether the conceptual basis for the composite
17 construction, weighting methodology, that sort of
18 thing, is explicitly articulated and logical or
19 that the sort of quality construct makes sense.
20 And then there's a rationale for distinctive
21 additive value of the composite itself.

22 Any discussion? Comments or

1 questions?

2 Okay. Let's go ahead and vote.

3 Eighty-four percent high, 16 percent
4 moderate, zero low, zero insufficient. So, the
5 measure passes on importance to measuring report.

6 And we'll go ahead and move to
7 reliability.

8 DR. GUNNAR: Lynn, any comments on
9 reliability?

10 MS. REEDE: So, reliability, I think
11 we discussed. Again, it's been audited over the
12 last few periods of time. The risk prediction
13 model has been good.

14 And I really have nothing more to add.

15 DR. GUNNAR: Any discussion?

16 It will be in vote.

17 MR. LYZENGA: Okay. We're voting on
18 reliability.

19 Okay, with 74 percent high, 26 percent
20 moderate. The measure passes reliability. And
21 we'll go to validity.

22 DR. GUNNAR: Any further discussion?

1 Let's go ahead and vote.

2 MR. LYZENGA: Okay. We're voting on
3 validity.

4 We have 63 percent high, 37 percent
5 moderate, zero low, zero insufficient. The
6 measure passes on validity.

7 And we got one more composite specific
8 here in just a moment. There we go. So this is
9 again, we just looked at the conceptual basis of
10 the composite. And now we're -- the question is
11 whether the empirical analysis supports the
12 composite construction.

13 MS. REEDE: So, signal to noise ratio
14 was used to look at this particular measure for
15 reliability. So that it looked at the
16 differences between hospital versus random
17 statistical fluctuations, making the measure
18 valid.

19 DR. GUNNAR: Any other comments?

20 Let's go ahead and vote.

21 MR. LYZENGA: Voting on the scientific
22 acceptability of the composite measure

1 properties.

2 79 percent high, 21 percent moderate
3 and zero low, zero insufficient. The measure
4 passes scientific acceptability.

5 And we'll go to feasibility. Any
6 additional comments same? Everybody all right
7 with this? Or do we vote? Or can we carry
8 forward?

9 DR. GUNNAR: You can carry forward.

10 MR. LYZENGA: All right. We'll carry
11 forward our votes on feasibility and usability
12 for this one was well.

13 And go to overall suitability for
14 endorsement. Any comments or questions before we
15 vote?

16 Hearing none, let's go ahead and vote.

17 Unanimous yes. The measure passes.
18 And that will do it for our measures today. Well
19 done. Good work everyone.

20 So actually we should take a moment
21 for public comment. Operator, could you open the
22 lines?

1 DR. GUNNAR: We vetted it at 2:30, but
2 do we wait or what happens?

3 MR. LYZENGA: We can open it up right
4 now and see if there's anybody who wants to.

5 (Laughter)

6 MR. LYZENGA: Operator, is there
7 anybody on the line who wants to make public
8 comment?

9 OPERATOR: Okay, at this time if you
10 would like to make a public comment, please press
11 star then the number one.

12 There are no public comments at this
13 time.

14 MR. LYZENGA: Thank you. So that will
15 do it for our measure review.

16 Juliet, do you want to talk about next
17 steps for a moment? Just give us a --

18 MS. FELDMAN: So, as we presented at
19 the start of our meeting, we have a post-meeting
20 webinar scheduled for next Friday the 27th. We
21 will discuss as a project team whether we think
22 that it's still needed, given that we've gone --

1 we got through all the measures today.

2 I know we didn't have a thorough
3 discussion of gaps. So, we'll determine whether
4 that can be done via email or whether it's worth
5 meeting during that time.

6 MR. LYZENGA: Keep the call in on your
7 books, on your schedule for now.

8 MS. FELDMAN: And we'll be in touch
9 early next week. And then we will get to writing
10 the draft report. So, we will keep you posted on
11 our progress with that. And we will likely be
12 following up with you.

13 Are there any questions regarding next
14 steps in the process?

15 MS. MURPHY: We will also have a
16 summary of the discussion of related and
17 competing, which we'll bring back to the group.

18 MS. MOYER: Do we have that one AHRQ
19 measure that might have been coming back for the
20 call?

21 MR. LYZENGA: Yes. Thank you for the
22 reminder. We will be coordinating with AHRQ and

1 it's still I think a question of whether it will
2 be feasible for them to bring it back within this
3 cycle.

4 But we'll be -- they're I think
5 investigating that as we speak. And we'll be
6 talking to them and let you know what the plan
7 is.

8 And as Juliet mentioned, we would like
9 to have some more discussion about gaps in the
10 surgery portfolio. Gaps in surgical measurement.
11 We did create a little document that we can kind
12 of pass out to you right now. That you can take
13 a look at on your ride home.

14 And that offers a few spaces. It's
15 broken out by topic area. So the current
16 measures are separated out into general topic
17 areas.

18 And we would just ask you to take a
19 look at what's there currently. And then there
20 are a few spaces at the bottom of each little
21 section, each table, where we -- we'll send you
22 an electronic copy of this document.

1 And we'll ask you to just fill in a
2 couple of potential measure concepts if you can
3 think of any in that particular area. Or just if
4 there are gaps in measurement, you could identify
5 those there.

6 And if you do know of any potential
7 measure developers in the area, you could just
8 list those out. And that could give us sort of a
9 lead for reaching out to measure developers. And
10 helping coordinate measure development in that
11 area.

12 So, we'd appreciate your feedback
13 there. Any other comments? Go ahead, Helen?

14 DR. BURSTIN: So I just want to thank
15 everybody. But I also want to make an
16 announcement.

17 It just seems timely since this is the
18 Surgery Standing Committee, that next week we are
19 delighted to in fact present the Eisenberg Award
20 for patient safety to NSQIP. So Cliff and the
21 folks from ACS will be coming to our meeting and
22 I just wanted to offer that congratulations.

1 (Applause)

2 DR. BURSTIN: For a big honor,
3 especially for somebody like me who spent years
4 working under the tutelage of Dr. John Eisenberg.
5 So, huge honor. He would be delighted to hear
6 that NSQIP got this award.

7 MR. LYZENGA: Thanks everybody for a
8 great meeting. And safe travels.

9 (Whereupon, the above-entitled matter
10 was concluded at 1:51 p.m.)
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A			
A.J 2:21 45:13 189:22 209:3	activities 208:20	187:13 243:4	algorithm 152:15
a.m 1:8 5:2 120:6,7	activity 60:19	adults 92:13 119:2	align 32:18 40:17
ability 5:6 60:16 101:13 135:8 175:16 243:5	actual 27:14 28:15 62:20 216:21	advance 218:5	alive 11:16 20:12 96:4 97:15
able 18:9 29:2 53:14 60:19 75:17 115:13 144:21 146:19 150:16 166:14 181:20 212:16	actuarial 23:3	adversely 11:1 13:1	all-day 6:4
abnormalities 122:5,7	adamant 155:15	advice 207:18	Allan 2:17 16:10
above-entitled 120:5 224:6 270:9	add 19:15 38:4 39:16 63:9 99:16 113:2 130:15 138:4 145:4 165:10 198:20 246:1 255:6 263:14	Advisor 2:20	alleviate 39:21
abovian 155:18	addendum 78:6	advocacy 91:20,21 92:22	Alliance 2:9
absence 179:4 248:19 248:21 249:8	addition 14:18 212:15	Aetna 2:5	allow 185:22
absolute 183:15	additional 42:1 73:13 87:12 93:20 106:11 108:18 112:2 119:20 123:19 158:16 165:21 229:15 261:1 265:6	affect 13:1 129:16 173:19	allowed 21:2 39:18 51:16 77:10,11
absolutely 39:2 42:12 84:18 89:6 105:11 117:22 136:5 210:1 245:6	additionally 112:20 192:5	age 54:21 55:7,9,10,11 55:13,22 122:18,19 132:8 166:21 184:4,7 185:5,11 188:6 189:9 189:10,10 190:16 225:13	allowing 140:17,21
abstention 70:5	additive 262:21	agenda 5:5,11	allows 99:10 102:21 122:14 179:11 250:5
abstractor 87:8	address 31:16 40:2 78:17 86:3 98:2 130:3 130:6 171:15	ages 184:11,20 188:18	ambitions 214:10
abstractors 82:9	addressed 156:4 172:10 193:5 212:5	aggregate 58:14	ameliorate 115:15
ACC/AHA 184:3 189:7 193:2	addressing 95:17	aggressively 99:14	amend 188:1
accept 152:8 188:7	adequacy 257:11	ago 36:15 103:22 142:15 207:6,22 208:13	amended 188:3
acceptability 47:9 83:4 83:6 264:22 265:4	adequate 149:10 156:21	agree 12:17 35:10 71:7 74:1 75:10 134:13,14 185:1 187:1 202:19 218:1	amending 188:2
acceptable 153:12	adequately 15:5 216:20	agreed 151:1 156:8 238:9	America 58:22
accepted 62:16 190:11	Adjourn 4:22	agreement 108:3 150:22	American 1:12,19 2:2,4 2:11,13 6:4 58:22 205:1 255:9
access 75:7,18 88:1 139:14 140:18,22 223:14	adjudicated 69:16	agrees 12:20 82:14	amount 27:11 46:22 49:3 76:10 106:19 210:2 253:11 259:15
accessed 91:12	adjust 129:21	ah 176:13	ample 167:1
accessible 205:8	adjusted 15:5 16:20 89:2 94:17 112:17 122:1,15,21 123:9 124:11,11 132:3 133:11 141:12 148:3 158:22 196:16 197:14 197:18 201:6 224:11 224:14 225:11 231:20	ahead 40:8 69:22 81:22 87:4,14,16 93:18,21 100:4 106:12 107:6 112:3,9,12 116:17 117:6,11 119:14,19 120:3,12 131:6,9 138:6 143:12 149:4 157:15 158:3,14,17 161:11 165:14 167:18 167:19 176:5 181:10 182:14 194:4 195:14 201:1 203:7,22 204:3 226:9 228:21 229:18 230:11 234:14 235:2 235:7,17 241:16 242:5,17 247:4,7,15 259:1 262:7 263:2,6 264:1,20 265:16 269:13	amplified 60:2
accessing 91:4	adjustment 16:21 96:12 96:12,19,20 113:3 121:5 125:18 128:9 133:8 156:22 198:13 210:17 211:6 254:14 254:22 256:6 257:12	AHRQ 267:18,22	Amy 2:8 26:16 47:15 48:3 76:15 83:14,15 173:11 190:12
accident 249:7	Administration 1:14	aids 43:1	Amy's 44:14
accommodate 129:5,6 129:14	admission 7:9	air 115:11	analyses 53:15
account 59:11	admissions 15:8	albeit 113:10	analysis 44:4 51:15 53:22 58:14 69:15,16 97:2 99:7 128:16 212:10 232:6 264:11
accountability 102:1 164:1 172:10 174:22 175:1 190:1	admitted 66:21	Alexandra 3:6 262:12	Analyst 3:6
accuracy 108:3 112:14 252:10	adopter 20:20		analytic 54:1,2 102:12 102:13,20 103:1,8,11
accurate 85:20 86:1 108:13 109:17 175:4 181:14 229:22	adult 50:14,15,19 86:9 89:22 90:8 94:12,14 99:5 104:4,12,14 132:6 136:7 149:14 150:6 157:9,22 158:8		analyzed 102:11
achieve 60:9			anatomic 233:1,3
achieved 168:10,11			Andrew 3:5 6:20 7:16 45:8,15 78:14 125:13 190:19 234:6
achieving 89:13			anecdote 41:4,5
ACOs 32:1			anecdotes 27:13 31:5
acquired 14:20 55:4,8			anesthesia 1:17 2:7 126:19,20 127:2,8,9 127:15,18
ACS 205:18 209:4 269:21			Anesthesiologists 1:13
active 135:20 173:7			Anesthesiology 1:12
actively 92:1			anesthetic 127:11
			Anesthetists 2:14
			angels 187:6
			announcement 269:16
			annual 53:17 54:2 86:8
			annulus 237:19

anomalies 116:4	applying 184:19	Associate 2:21	back 7:5 15:1 20:20
answer 72:15,18 86:17	appreciate 8:7,20 37:9	associated 85:2 99:11	21:15 25:15 29:8 44:6
93:1 109:6 113:18	269:12	118:7 128:18 167:2	48:21 50:13 55:13
137:18 141:1,9	appreciated 214:8	169:4 249:13	67:1 102:8 109:6
155:21 175:22 209:13	approach 10:11 46:10	Associates 1:15	118:22 120:4,17
209:19,21 243:21	97:1 221:13	association 2:13 58:7	122:17 125:4 136:15
250:16	approached 80:9	91:22 208:5	142:4 149:12 155:16
answerable 37:11	approaches 141:1	assume 228:4	170:18 180:7,10
answered 202:18	appropriate 6:5 9:16	assuming 188:9	186:7 188:3 194:9
answering 62:5 94:8	15:14 149:9 156:20	assure 69:17 97:9,18	197:13 204:15 205:3
answers 86:18 97:12	156:20,21,22 181:2	assures 69:9	205:5 206:18 207:22
212:1	185:3	assuring 215:5	210:13 224:3 235:11
ANTHONY 1:15	appropriateness 99:17	asterisk 171:6	236:4 267:17,19
anti 35:8 166:12	approve 222:16	at-risk 189:8	268:2
anti-lipid 166:18 182:21	approved 28:18 40:22	atherosclerotic 184:14	background 68:13
249:21	85:8 198:9	185:12 192:7	backside 160:2
anti-platelet 166:18	arbitrarily 144:13	atrial 192:15	backup 138:3
194:19	area 28:4 78:11 124:5	attendance 8:9	bad 12:7 73:7 254:6,12
antibiotic 177:15	207:12 228:7,7 230:1	attest 43:21	balance 216:14,22
antibiotics 177:1,3	268:15 269:3,7,11	attractive 215:18	balances 85:21
178:1	areas 39:11 172:10	attributed 45:7	balancing 42:7
anticipate 244:3	206:9 268:17	Atul 33:7	bar 27:10 215:15
anticipated 38:16	arena 141:5	atypical 113:13	Barbara 2:4 76:15
anticoagulation 155:17	argue 31:6 65:11 121:6	audience 197:12	77:13 138:2 208:2
antiplatelet 249:20	159:20 186:22	audiences 39:9	Barbara's 19:16 210:1
anybody 10:15 47:13	argued 12:1	audit 37:12 50:1,4	bariatric 205:4 210:4,9
80:16 82:4 117:1	arguing 24:6	57:21 82:21 86:7,11	Baring 247:20
131:10,11 150:2	argument 21:5,10	86:17 88:4 97:17 98:1	barrier 208:5,8 217:15
165:12 170:7 191:22	59:19 67:6,6	108:10,11,16 126:12	barring 229:7
203:6 244:13 245:11	arguments 67:4	149:16 150:20 151:4	Barry 2:5 133:3 154:15
266:4,7	arm 135:19,19,19,20	152:13	based 51:9,14 58:22
anymore 64:21 172:15	artery 50:16 132:9	audited 50:2 81:16 82:8	68:6 69:16 80:20
222:14	133:1 183:18 184:13	251:8 263:11	106:21 122:1 124:10
anyway 36:4 37:19	184:14 185:11,12	auditing 17:15	135:13 139:7 175:12
aortic 50:17 134:11,12	186:17 187:21 188:19	audits 17:11 37:10	186:21 189:12,15
196:17 197:15,19,19	188:20 192:8 249:11	41:21,21 42:1 257:15	201:19 225:5 227:7
201:9 243:16,17	arthritis 15:12	author 256:12	233:5 237:2 238:1,2
244:7	article 26:19 33:5,6	available 91:8 109:20	248:16 252:1 258:18
Apologies 6:3 98:18	articulate 190:9	205:8 210:17 215:8	261:8
193:18	articulated 9:19 262:18	avenue 93:10	baseline 130:10 168:8
apparently 156:17	articulating 185:17	average 101:18 130:14	basically 58:19 62:17
appeal 40:21	AS/CVD 184:4 189:9	226:16 240:13,14,16	88:14 92:11 132:14
appealed 28:20	Asher 1:15 214:4,4	241:6 246:6,7	155:11 225:2 240:13
appears 112:16 152:10	218:1,9	aversion 254:9,13,19	basis 53:17,21 54:3
appellants 46:2	asked 60:4 115:10	255:3,12	86:8 144:22 261:4
appendices 194:19	141:8 186:8 227:17	avoid 20:15	262:16 264:9
Applause 8:1 270:1	asking 17:1 25:20 44:5	avoidance 99:19	basket 15:8
applicable 77:12 81:1	61:18 94:13 113:16	AVR 134:15,15 201:6	Bayesian 252:5,19
113:11 116:20	148:7 155:14 185:14	250:20,20	beautifully 40:16
application 59:5 86:21	187:6 209:22 253:20	award 269:19 270:6	becoming 23:13
202:3	asks 52:3	aware 39:7 88:1,3	bed 223:16
applications 202:5	aspect 234:2		beds 223:10
239:7	assess 252:3		began 217:8
applied 69:10,17	assessments 252:3		begged 230:20
applies 86:8 101:7	assign 175:18		beginning 243:2
118:4 126:17 198:10	assigned 89:9 250:8		behavior 115:18
apply 86:4 101:9	260:3		belief 144:21
228:15	Assistant 3:17		believable 50:5

B

babies 111:7
baby 57:19,20 58:3
64:4 74:7 75:15,20
76:3 114:8,13
baby's 122:9

believe 21:6 25:5 29:4 60:22 70:22 71:5,16 96:20 97:4,21 113:2 141:19 162:16 165:3 166:14 171:1,17,19 174:7 239:17 246:20 251:6 254:7,21	203:15 221:14 237:1 237:3,5 BMI 39:10 board 40:22 46:10 49:1 90:19 187:9 209:2 222:16 260:13 boat 35:3 body 80:8 162:15 164:9 176:7 213:2 228:6,7 Boeing 32:1 boggled 84:3 book 33:7 78:3 213:9 books 267:7 born 54:22 55:6,7 121:14 122:6,8 bottom 268:20 box 17:21 boxes 134:9,9 break 4:6 120:3 breaking 146:22 brief 49:15 briefly 95:12 bring 28:9 33:21 40:14 94:6 206:4,7 209:15 210:12 223:7 267:17 268:2 bringing 29:8 64:4 124:5 125:12 206:9 broad 115:19 broaden 77:8 broken 268:15 brought 5:14 36:15 77:18 159:3 169:1 205:19 BSN 2:12 bucket 227:7 buckets 14:4 45:19 60:21 budget 64:14 build 41:22 217:21 building 95:1,4 121:2 203:12,13,15 221:14 237:1,3,5 built 203:13 219:14 bundle 244:9 249:16 bundles 244:8 burden 117:19 burdensome 117:15 Burstin 3:2 5:19,22 6:1 9:3 28:5 40:5 63:17 63:19 73:4 78:21 80:18 81:6 145:10 146:13 205:14 207:3 209:12 220:12 269:14 270:2 bus 14:12 business 63:7 bypass 50:16 118:7	132:9 133:1 159:5 183:18 184:13 185:11 187:3 188:19 192:17 201:10 209:11 249:14 259:6 <hr/> C <hr/> C 112:18 CABG 101:9 133:6 134:10,12,13,14,15 139:9,11 166:21 186:14 197:20,21 201:6 224:19 235:13 240:3 243:9,9,11,16 243:17 244:9 245:21 248:10,15 250:20 252:7 cadre 217:2 calculate 122:15 139:12 258:21 calculated 89:3 261:22 calculating 139:7 calculation 240:2 calculator 189:12 call 38:5 40:9 45:7,11 45:16,17 50:9 70:2 100:5 119:15 120:14 120:16 267:6,20 called 130:12 245:3 calling 7:1 calls 216:15 campaigns 244:22 Canada 58:11,15 cancel 186:20 Cancer 2:19 candidates 4:3,7,14 231:7,8 capability 121:19 capture 24:17 27:1 32:3 34:2 50:21 52:3 54:14 55:8,9 60:17,20 61:20 62:2 106:8 113:9,12 113:14 155:22 captured 40:15 41:22 115:12 captures 111:15 capturing 19:11 39:19 108:21 card 193:10 254:12 cardiac 8:11,13 9:7 16:12 19:18,21 20:19 22:8,10 39:20 54:17 54:19 56:10 79:17 84:9 86:9 89:22 93:10 104:12,14 111:1,14 112:1 113:20 115:20 122:12 127:8,9 132:6 132:13,15 136:7	159:6 168:15 178:2 186:10 221:14 244:15 249:3 cardiologists 51:10 cardiology 218:16 cardiopulmonary 192:17 cardiothoracic 1:20 136:1 cardiovascular 183:12 183:14,20 186:15 care 2:2 10:17,17 11:2 11:16 18:18 21:3 23:6 24:19 25:18 28:7 33:18 34:21 39:3,5 40:11 41:18 44:21 45:10 57:7 59:8 75:7 75:8,11 83:20 84:1,9 84:14 99:16,19 114:15 116:6 123:10 125:8 128:18 136:13 137:5 138:10 144:14 144:14,15 159:13 161:3 179:14 181:15 212:5 229:22 career 113:19 careful 30:18 31:6 64:21,22 caring 254:16 Carolina 1:15 carried 154:6 carries 153:15 157:22 carry 8:17,22 47:5,22 48:1 131:11,13,17 150:17 153:1,18,22 154:12,13 157:12 158:8 165:3,5,22 166:15 181:4,20 195:12,15 196:5 200:7,19 203:20 204:9 229:8 230:6 234:18 235:5 242:1 242:11 247:12,21 265:7,9,10 carrying 149:22 153:11 182:1 carte 134:5 carve-out 17:2 case 10:20 43:10 57:11 68:7 153:10 161:2 169:15 216:15 239:14 cases 37:13 68:11 86:13,14 101:10,11 102:16 106:7,9 128:16 129:11,22 130:18,19 140:11,13 175:15 241:7 256:1 256:20 257:5
---	---	---	---

cast 117:6 165:14 201:1
226:9 230:11 247:4
categories 49:12 50:10
50:11,12 51:6,8,13,17
52:5 53:10,16,20 54:4
59:16 60:18 61:21
67:10,13,16 68:1,4
69:1 70:21 72:21 73:1
75:5 88:8 95:10,13,15
98:9,12,17 100:14,15
107:20 112:18,19
113:3 121:4 122:17
122:19 124:18,19
129:10,12,15 256:17
categorization 69:10
categorization's 69:17
categorizing 121:4
category 51:12,19,21
53:21,21 69:7 73:12
76:17 88:16,21
100:22 101:2,18
121:6,8 122:3 129:9
179:13 189:12
caught 13:4
cause 22:17
caveat 84:14
CDC 211:17
center 1:18 2:10,15,19
2:21 28:6 36:20 39:3
46:5 59:8 74:8,12,15
76:4,10 101:11 130:7
241:6 246:6,7,18
centered 5:12
centers 15:17 60:6,9
69:11,18 73:8 75:8,10
75:12 84:10 101:10
130:8 148:14,15
241:9 253:15
cerebrovascular 249:7
certain 18:21 23:17
27:11 45:21 252:21
certainly 21:15 27:21
41:13 109:13,17
110:3 115:13 137:22
141:14 152:8 171:15
188:13 192:6 199:15
206:6 222:7 223:9,18
256:2
certainty 253:4
certifying 42:22
cetera 150:18
chair 1:12 2:10 48:22
153:5
chaired 48:17
Chairman 2:17
chairs 43:18
challenges 214:12
challenging 237:22

champion 219:17
chance 33:11 51:20,22
56:18 110:9 233:2
chances 56:21 57:1
change 159:14 172:19
186:4 187:9,12
188:14 189:3 190:15
191:16 202:16 215:17
255:13
changed 12:19 41:13
44:3 137:20,21
141:10,13,15 188:6
219:12 222:9
changes 136:22 137:1
changing 184:7 191:11
223:21
channel 246:6
characteristics 99:12
charge 207:11 208:4
check 62:2 134:9,9
checkbox 39:17
checked 17:22
checks 85:20
Chest 1:19
Chicago 106:21
Chief 3:2 6:2
child 71:8 114:19 115:1
118:8 122:6,8
children 92:12,13
102:17 113:10 114:4
118:6
children's 2:8,16,17
65:6 68:10 105:17,21
127:14
chime 214:6
choice 33:4,10 34:3
252:6
choices 33:18 108:7
choose 90:3 104:7
155:15 260:7
chooses 144:14
chose 108:10,15
chosen 144:16
Chris 17:6 42:15 167:5
CHRISTOPHER 2:15
chromosomal 122:5
chronic 255:19
CIMA 1:16 62:12 68:8
89:14,19 137:9
176:16,20 210:14
circulatory 121:16
122:10 124:15
circumstance 113:10
cite 125:9
cites 125:21
claims 31:18
clarification 14:7 77:18
94:7 155:6

clarify 87:18 103:14
177:14 231:19 240:17
242:19 244:5
class 23:10
classes 15:10 23:17
classifiable 67:15,18
classification 69:7
187:13
classified 107:15
cleansed 69:16
clear 11:3,5 29:8,11
62:21 107:13 115:11
139:21 160:17 169:7
176:4 181:2 188:11
220:9,18 221:16
clearly 11:7 18:13
80:21 91:13 123:5
183:19 231:8
clears 13:16
Cleveland 2:18 16:13
click 118:5
Cliff 151:2 173:11
177:21 209:12,21
210:15,22 239:8
259:7 269:20
CLIFFORD 2:1
Clinic 1:16 2:18 16:13
clinical 2:12 69:14 87:8
167:9 259:19 260:8
260:10,20
clinically 146:6 168:14
clinician 159:11
close 33:13 58:4 115:6
138:13 182:16 195:22
233:1
closure 192:12
CMS 21:17 139:5,8,20
209:11 214:15
Co-Chair 1:11,13
Co-Chairs 1:9
co-morbidities 22:12
code 257:18
codes 107:18,18
109:11,16 126:20
127:3
cohort 187:22
collaborating 58:6
collaboration 3:4 92:21
colleague 218:16
colleagues 36:7 45:10
collect 64:20 119:6
211:9,11
collected 46:16 149:8,8
149:16 170:13 211:14
collecting 117:21
collection 64:18 117:16
152:2 154:1 170:2
collective 14:22

collectively 44:16
191:22
College 1:19 2:2,4 6:4
210:2
Collette 2:12 37:20 38:5
42:4 44:13 83:15
85:17 93:2 95:10
100:16 107:11 117:11
152:20 183:22 184:22
185:17 189:1,5
193:10
Collette's 190:6
Colorado 1:20
Colorectal 2:18
column 238:22
combination 96:9
248:16
combinations 50:18
combined 67:1 134:12
201:10 227:20 239:3
243:17
combining 252:9
come 21:15 25:1,14
32:16 33:4 43:2 44:6
49:14 67:1 101:9
120:3 130:10 136:16
142:4 171:20 180:7
180:10 204:15 205:2
205:3,5 216:1 218:19
259:3
comes 12:14 50:5
55:13 187:2 188:3
194:9 220:20 221:1
comfort 11:2 57:7
114:15
comfortable 80:6 117:2
149:22 150:7,13
153:11 256:7
coming 6:22 28:3 42:9
42:17 45:1 73:5
133:22 137:2 184:12
185:1 221:12 232:4
267:19 269:21
commend 90:20
comment 4:10,20 9:17
17:6 28:19 31:12
37:21 70:9 99:3
105:14 106:5 107:16
108:19 109:1 110:10
112:15 113:5 117:13
123:19 143:5 147:20
160:12 162:18 168:19
178:18 189:21 192:4
196:20 197:4,6
201:13 202:1 212:21
215:11 216:10 218:12
253:12 265:21 266:8
266:10

commented 123:21	comparison 50:14	4:3,7,14	considerable 143:14
comments 24:22 26:19	compassion 39:20	conceptual 261:4	Consideration 4:3,7,14
30:6 38:2,3 47:13	compel 170:6	262:16 264:9	considerations 216:1
56:7 64:1 70:15 81:20	competing 267:17	conceptually 21:4	considered 14:13
82:5 87:12 93:13,20	complete 118:19 185:2	concern 16:20 31:17	144:19 152:5 185:8
98:2 106:11 107:12	completed 40:21	41:6 177:4	considering 61:6
109:7 112:2 113:4	completely 30:2 71:7	concerned 34:15	consistency 6:20
116:12 119:12,21	210:10	concerns 31:16 39:13	112:22 155:4 239:9
123:6,14 126:5 128:1	complex 44:14 53:20	115:16 164:16 172:21	consistent 14:15 46:15
131:1,16 143:9 149:3	56:15 60:7 74:7,9	180:20	82:22 85:8 149:19
154:15 158:16 159:9	84:12 98:3 113:15	concluded 270:10	156:19 167:8 184:7
159:16 160:8,11	156:5 237:16	concur 246:2	185:6 187:12 189:14
164:3 165:10,12,21	complexity 51:3,18	condition 14:20	190:5 257:22 260:13
167:12,19 183:4	60:21 61:21 70:20	conference 1:8 56:20	260:14
189:22 190:6 195:18	71:4	92:18	consistently 149:8
195:21 197:8,11	compliance 169:5	conferences 213:14	consortium 28:20
198:21 199:21 200:11	compliant 106:22 107:4	confidence 102:21	constant 43:19
207:4 217:6,18	complicated 190:20	103:3 148:11,11	construct 262:19
220:13 229:13,15	191:8	252:2	constructing 148:10
231:22 234:2,5,21	complicating 215:11	confident 107:1,3	construction 184:2
238:14 241:12 242:4	complication 11:6	confirm 171:19 256:3	261:5,6 262:17
247:13 248:3,11	complications 35:15	confirmed 238:5	264:12
251:17 262:4,22	118:10 249:9	confirming 128:21	consumer 73:16 78:12
263:8 264:19 265:6	comply 69:2 97:10	conflict 8:19,21	consumers 73:20 87:22
265:14 266:12 269:13	component 20:12	confounding 156:4	140:9 162:13
commitment 205:22	86:16 133:6 134:16	confronted 11:12	consuming 213:4
243:12	144:2,3 228:13	confuse 9:6	content 9:15,16,18,18
committed 210:3 217:3	components 97:3	confused 79:13	9:22 10:1,10 79:12
committee 1:3,7,10,11	134:20 135:1,10	confusing 146:3	CONTENTS 4:1
1:13 7:11,15 16:8	144:7 146:1 174:1,15	congenital 48:18 49:14	context 10:7 29:13,15
28:3,7,17,18 29:9	175:9 243:6 250:2	49:16 50:10 52:15	42:5
30:7 33:9,22 40:11	composite 18:10 19:19	54:8,14,15,17 55:3,5	continually 135:12,16
43:18,21 52:21 62:8	20:10,12,13 24:7,8,11	55:10,16,17,22 56:10	continue 7:12 44:18
63:21 65:2 66:6 77:9	24:14 25:2 26:11	56:16 58:10 59:7,21	65:13 82:17 148:1,8
92:16 125:13 130:16	109:4 124:10,21	60:11 67:8,9 81:19	164:3 223:1
141:20 149:21 153:11	133:1,6,11,14,15,16	86:8 90:10 91:15,17	continuously 234:3
153:19 165:22 170:14	133:20 134:14,17,22	91:19,22 94:9,18	260:8
172:17 173:1,6 176:5	135:3,4,6 137:16	98:20 99:5 102:2,8	continuum 149:13
176:12 188:5,12,15	141:13,15 144:2,3,7	103:20 111:1 113:20	contribute 145:16
189:3,18 190:7,7	144:16 145:1,1,6,17	116:4,7 117:17	contributes 58:8
193:1 196:7 198:10	145:20,22 146:4,12	120:20,22 121:17	contribution 216:19
200:7,19 203:20	146:22 147:2 148:2	122:22 127:8,9,10,12	control 35:18 189:15
204:9 205:7,11,12	154:17 160:1 168:22	128:18 130:11 243:2	220:1
229:8 230:6 232:1	173:18,20,22 174:4	243:18	controversial 59:9
234:18 242:1,11	174:10,14 175:16	congratulations 5:6	conundrum 20:15
247:12,20 269:18	237:7 243:5,7,11	269:22	convening 221:21
committees 6:19	245:16 248:8,10,14	conscience 31:3	conversation 32:14
178:21 206:11,15	248:15,18 250:19	consensus 116:22	34:6 44:18 73:5
common 57:8 239:6	251:9 255:1 261:2,4	consent 134:8	115:17 228:11 233:13
246:17	262:14,16,21 264:7	consequence 71:18	conversations 9:12
commonly 55:16	264:10,12,22	96:17 253:17 254:9	66:6 221:17
communicated 164:15	composites 43:9 237:4	254:20	coordinate 188:8
communicating 172:8	compress 257:6	consequences 10:6	269:10
community 2:12 30:1	concept 54:17 95:17	12:9 16:7,14 25:17	coordinating 267:22
212:17	178:22	27:15 44:9 64:10 88:4	coordinator 49:2
comorbidity 258:6	concepts 6:12 223:15	96:7 164:14 172:21	copy 268:22
companion 53:8	269:2	253:12,21 254:3	coronary 50:16 132:8
comparing 112:21	Concepts/Measures	consider 17:21	133:1 159:4 183:18

184:12,14 185:10
 186:17 187:20 188:19
 188:19 192:1,8
 201:10 249:14 259:6
correct 10:2 11:13 36:1
 48:9 56:13 103:17
 118:1 135:5,5 145:10
 146:9 148:15,20
 150:8,9 156:1 157:9
 162:11 163:8 166:4
 169:16 170:20 225:6
 228:1 241:8
correction 193:18
correctly 11:10 83:19
 171:16 173:13 190:14
correspond 29:22
cost 23:6,8,22 163:7
 209:18 216:11,12,21
 219:11
council 207:6
councils 162:14
counsel 35:9
counseling 58:2
count 12:21 13:20
 156:11
countries 58:12 75:19
country 29:20 30:17
 93:9 117:14 139:1
counts 13:7,19
county 30:2,3
couple 5:17 6:11 8:3
 24:21 26:17 38:7
 40:19 41:20 43:14
 70:1 107:12 145:12
 172:2,4 217:5 220:12
 258:19 269:2
couple-hour 40:9
course 225:22 252:6
court 173:9
covariant 227:12
covered 131:8
covers 57:22
CPHQ 2:12
CPT 107:17 109:10,16
 126:20 127:3
cranked 207:19
create 6:19 23:9 45:15
 92:16 148:8 209:8
 231:12 244:13 268:11
created 107:15,21
creating 23:16
creation 113:14
credibility 219:4
credible 135:11 252:5
 252:19
credit 93:11 202:13,16
 254:15 257:1
criteria 18:4 24:9 43:3

158:18 169:15 173:4
 179:6 180:10 190:21
 201:19 252:12
critical 19:6 99:9 174:8
 217:19
critically 215:8
CRNA 2:13
cross-mapped 109:10
crosswalk 109:20
CSAC 28:17 29:2 40:20
 43:14 46:9 162:13
 163:18 171:2 176:7,8
 176:9
curiosity 93:4
curious 232:5
current 100:18 132:10
 189:4,14 199:9 238:6
 260:10 268:15
currently 30:10 49:19
 148:9 185:7 213:11
 243:22 268:19
curve 18:17 148:5
 176:5
curves 23:1
cut 37:7 162:1
cutting 64:14
CVA 251:4
cycle 67:3 164:11
 210:12 223:13 268:3

D

D.C 1:8
Dakota 76:7,7,13
dance 187:6
dancing 187:6
dangerous 252:15
Dartmouth 1:18
data 25:16,22 35:7 41:3
 41:5 44:3 46:16 49:20
 49:22 50:4,5 51:14
 58:12,14,19 59:1,2,3
 60:17 62:3 64:18,21
 67:20 69:5,16 73:8
 80:1 81:16,18 82:8,8
 84:7 87:8,18 88:1
 102:11 108:2 112:14
 117:16 118:17,20
 119:6,9 126:3 135:12
 135:16 137:12 139:14
 139:15,15,20 140:18
 140:22 143:14 149:8
 150:22 151:5,15,21
 152:2,9,18 153:14,15
 153:16 154:1,20
 155:4 169:3 170:3
 193:9 194:14 217:20
 218:5 220:1 223:14
 225:2 228:11,13,15

228:16 233:6,8 238:1
 261:13,16,20
database 3:17 35:21
 48:18 49:1,4,15,16,20
 50:1 54:15 55:8,18
 57:21 58:1,8,10,16,17
 58:18,20 59:21 60:22
 61:7 64:17 65:7 68:17
 68:20,21 69:4 79:18
 82:12 86:7,9,10,13,15
 90:4,7,9,10,11,13
 91:16,18,19 94:9
 102:8 103:2,20 104:4
 104:13,14 106:6
 107:20 109:13,14
 111:15,17,18,19
 117:13,17 120:20,22
 121:18 122:22 127:11
 127:12 132:7 135:14
 135:20 136:7 139:2
 139:10 147:17 150:6
 150:8,12 154:17
 170:14 178:2 211:11
 218:17 253:16
databases 51:16
 207:11
date 28:6 255:2
daunting 214:21
Dave 6:6 48:22 79:16
 124:22 188:14 205:17
 207:16 219:6,19
 245:1
Dave's 213:7
David 127:13 144:1
 212:14
day 4:2 5:5,8,15 10:20
 11:17 13:7 47:3 88:3
 96:2,6,9 97:13 115:11
 186:19 215:4,21
 245:16
day's 5:5
days 11:7 13:7,9 14:11
 25:8 96:5 97:15 99:1
 99:2 159:6 198:15,16
 225:17,18
DCRI 48:15 69:8,13,13
 125:2
de 174:1
de-emphasize 43:16
deal 64:6 94:15 140:19
 160:15 209:19 212:7
deals 67:14
dealt 178:1
death 11:8,9 101:12
 115:7
deaths 14:1,9 98:21
 99:1 101:12 198:14
 198:16 225:15,17

debate 29:13 116:3
debates 79:15
decade 19:20 147:16
decades 261:10
December 225:10
 226:13
decide 90:11 120:15,17
 244:15
decided 134:4 186:19
deciding 137:8
decision 12:4,10 19:6,7
 31:2 35:16 37:3 42:22
 77:1 78:12,13 175:14
 176:7
decision-making 30:9
 31:14 37:3 42:13
decisions 173:18
 215:12 222:12,13
declared 187:4
decline 53:18 147:16
declined 54:3
decrease 163:1 192:14
decreased 141:12
decreases 20:7
decreasing 71:19
deep 8:10 158:22 159:5
 161:2 202:2 249:4
defer 205:11
deficit 122:12 219:16
define 16:8 23:21 54:16
 89:16 116:10
defined 15:10 23:4 81:9
 107:17 116:11 148:10
 248:21
defines 11:20
defining 176:6
definitely 83:12 142:10
 142:13 208:15
definition 14:8,9,16
 23:11 80:7 88:19
 113:3 164:5 198:2
 227:9
definitions 58:19 81:7
delayed 21:3
delighted 6:7 205:21
 209:15 269:19 270:5
delimit 22:15
delivered 84:15 121:11
demonstrate 88:10,11
 143:14 155:11
demonstrated 7:11
 257:12
demonstrating 101:4
 157:1
denied 11:16 15:9
denominator 24:16,17
 88:20 107:14 139:13
 240:8

Department 2:3,6,10,19
depends 151:14
depth 88:8
derived 259:20
describe 88:11
described 100:19
125:19
describes 92:2
describing 92:9
designed 259:17
desire 131:16 135:9
141:20 208:6
despite 106:3 153:6
detail 92:8 95:13 135:9
detailed 232:9
details 145:13,14
201:12 224:22
deterioration 172:20
determination 78:19
141:22
determine 169:8 267:3
determined 46:18
determining 85:21
develop 36:22 97:16
159:5 207:11 213:1,2
213:10,13 214:10
217:2 218:3 222:18
222:22 223:4
developed 6:18 51:9,14
111:11 260:5,12
developer 2:12 7:3
37:17 100:20 112:13
188:8 189:3 212:17
217:11
developers 5:14,18
13:12 16:6 21:14
26:15 29:3 43:22 44:6
99:9 128:9 152:16
155:5 180:16 206:6
212:12 269:7,9
developing 25:7 51:4
124:9,21 145:5
212:22 215:1 216:12
216:13 217:21 218:16
223:15
development 213:8
214:9 215:6,13,16
223:6,12,21 259:20
269:10
deviation 260:1
diabetes 22:13 23:19
diabetic 189:9
diagnoses 118:10
diagnosis 50:6 121:10
dialogue 213:11 236:16
die 37:14 102:17 111:7
111:7 114:4,5,8 115:1
160:15

died 98:21 225:14
241:7
difference 20:2 22:1,4
36:16 67:14 84:1,11
89:5 101:22 130:2
142:18 163:10 180:17
236:11 246:12
differences 47:8 157:2
264:16
different 30:3 32:22
36:16 42:10 47:17
51:1,11,13 72:6 79:18
79:21 82:20 85:10
104:19 129:15 133:20
135:17 146:6 150:8
177:13 183:8 185:15
190:2 194:17,19
206:11 212:1,1,11,12
226:19 228:4,8
230:19 231:2,4,10,11
233:18 243:7,8
248:13 259:17,17
260:6
differentiate 102:19
differentiating 121:20
differently 218:2
227:16
difficult 12:17 189:7
211:13 215:4 237:21
256:1,19
difficulty 36:18
dime 19:14
direction 17:9 42:10
43:5 120:11 124:16
127:20
directly 39:14 62:19
Director 1:14,17 2:1,5
2:13,15 3:4,5
disagree 131:12 176:22
discharge 14:12 53:18
96:10 99:1 166:13
182:22 225:17 249:19
249:20,21
discharged 13:8 166:21
198:17
discontinuation 177:15
discourage 10:19
discrepancy 142:8
discriminate 101:14,18
discrimination 23:12
151:21
discriminator 105:20
106:4 123:22
discriminatory 163:22
discuss 53:7,11 117:1
125:19 126:13 229:12
266:21
discussant 183:2

discussed 18:2 63:5
95:3,13 113:7 160:3
167:7 168:8 169:8
203:6 226:1 231:14
249:3,5,22 251:6
263:11
discussing 72:8 182:15
230:17
discussion 9:15 10:5,8
12:10,13,15 20:10
21:11 29:9,11,12
30:15,19 31:11 33:12
40:6,10,12 41:17,20
42:14 44:22 45:16
57:2 62:14 70:12
78:17 95:20 96:15
97:8 101:19 114:12
117:10 120:10,12
131:8 141:2 143:11
149:15 153:6 157:14
158:2 163:17 178:20
178:21 179:18 181:9
183:6 191:1 195:4,17
196:10 198:3,19
199:12 204:2 225:22
226:3 229:12 232:9
236:21 247:6 251:10
262:22 263:15,22
267:3,16 268:9
discussions 9:1 12:3
45:20 48:9 114:16,17
213:16
disease 54:18,19,20
55:5,7,8,10,22 56:16
92:21 183:14,20
184:15 185:4,12
186:15,18 187:21
188:20 192:1,8
255:19
disproportionate 205:1
disrupt 44:19 223:12
disseminate 91:6
disseminated 242:21
disstination 20:1 151:6
distinctions 227:4
distinctive 262:20
distinguish 227:7
distinguishing 151:7
distribution 104:17
154:22
divide 252:11
divided 23:5 24:1,2
245:2 248:18
Division 2:1
DNP 2:13
DNR 17:19,21 39:18
113:12,14,22 114:4
114:20 115:2,5,7

116:3,8
doable 109:18 127:6
doctor 190:3
doctors 186:20
document 80:22 100:12
125:8,10,14 268:11
268:22
documentation 34:4
documents 132:20
doing 18:18 22:22
23:20 29:7 30:22 32:1
32:2 34:20 37:1 38:14
39:12 48:12 70:20
71:5,9 79:6 80:22
101:10 102:16 106:22
107:3 108:15,19
136:21,21 151:14
155:17 178:6 205:7
215:4 217:3 220:2
237:21 238:2 244:18
250:7 254:6 256:19
257:2
dollars 87:10 208:9
219:12
domain 124:10 141:15
146:17 248:19,20
249:15 259:14 260:1
260:2
domains 57:22 127:21
248:19 252:9 259:11
259:15,17
door 15:15 30:2
doubt 119:5 212:22
253:7,7
dozens 60:3 135:21
Dr 5:3,22 6:10,13 8:2,3
8:5,7,15,15,20 9:3,13
9:20,21,21 10:3,14
11:14 12:16 13:18,22
14:5,6,17 16:4,11
17:5,7,17 18:5 19:15
21:12,13 24:6,11,20
24:21 26:13 27:16,18
28:5,13 29:3,16,17
30:13 31:12 32:10,12
33:2 34:9,11 36:1,4,5
36:6 37:5,20,22 38:1
38:21 39:1 40:1,5
45:3 46:1,4,8 47:15
48:2,5,8,11,19,21
49:7,9 52:6,8,12,13
52:15 53:2,5,6,7 54:6
54:7,9,11,13 55:2,3
55:19,20 56:2,3,6,8
56:14 57:10,16 58:9
59:4,14,15,17 61:2,5
61:9 62:4,6,12,21
63:10,17,18,19 64:1

64:22 65:5,14 66:3,18
 66:20,22 67:2 68:8,14
 69:19 70:8,10,12,15
 70:17,18 71:7,20,21
 72:1,3,5,11,12,15
 73:2,4 74:1 75:3,6,9
 76:15,16 77:10,15,17
 78:5,8,14,18,21 80:5
 80:10,12,14,16,18,20
 81:6,15 82:4,6,11,18
 83:13 84:6 85:4,13,17
 86:2 87:5,6,17,18,20
 87:21 88:6,7,10 89:4
 89:6,14,14,18,19,21
 90:17 91:9 93:2,6,12
 94:1,5,6,20 95:3,12
 99:22 100:1,7,7,9
 101:7 102:6 103:14
 103:17 104:6,10
 105:4,7,9,11,13
 106:14,18 107:11
 108:4 109:5,21 110:2
 110:6,8,11,12,13,15
 110:17 112:2,6 113:1
 113:4,5,15 115:9,22
 116:1,1,12 117:10,10
 117:22 118:19,21
 119:2,4,7,12 120:8,19
 123:4,7,13,18 124:6
 125:6,15,17 126:4,11
 126:15,16 127:5,22
 128:7 129:19 130:6
 130:15,21 131:7,10
 132:4,5,16,18,19,21
 133:3,12 134:2,6,19
 134:21,22 135:2,3,5
 135:18 136:5,20
 137:9,15 138:2,5,6,21
 139:4,21 140:3 141:2
 141:7,18 142:2,3,7,12
 142:16,19,21 143:1,2
 143:4,7,10,17 144:10
 144:11,12,20 145:10
 146:2,13,20 147:12
 147:15,19,19 149:11
 150:2,4,9,10 151:1,3
 152:20 153:5,19
 154:8,8,13 155:2,13
 156:2,3,8,10,13,15,15
 157:14 158:2 159:2,8
 159:10 160:8,9,10,13
 161:5,6,11,12 162:7,8
 162:10,18 163:16
 164:2,18 165:6,9,11
 166:16 167:5,6,12,13
 167:18 168:4,18,20
 169:7,16,16,17
 170:12 171:8,13

173:11 174:3,11,18
 175:7 176:4,11,16,18
 176:20 177:14,20
 178:9,17 179:18
 180:4,12,18 181:1,9
 181:21 182:6,11,13
 183:1,5,9,16,21 184:9
 185:9,14,20 186:3,3,4
 186:7 187:1,14
 188:13,22 189:17,21
 190:11 191:17,20,22
 192:4,20,22 193:7,10
 194:5,6,16 195:4,19
 195:20 196:10,19,22
 197:16 198:21 199:21
 200:13 201:5,7,13,18
 201:21,22 202:12,19
 203:5,10,12 204:2,14
 204:16 205:10,14
 206:17,22 207:3,5
 208:2,3 209:3,4,12,17
 209:22 210:14 211:3
 212:9,20 214:4 216:9
 216:10 217:5,9 218:1
 218:8,9,11,13 220:9
 220:12 224:2,9,13
 225:4,6,7,7,8 226:3,6
 226:12 227:2,17,22
 228:10,18,21 229:14
 229:18 230:15,22
 231:17,22 232:3,7
 233:11,20 234:5
 235:11,13,15 236:2,4
 236:13,15,19,20
 237:6,14 238:3,9,10
 238:16 239:4,20,22
 240:1,4,5,18 241:4,5
 241:8,9,11 243:1
 244:5,10 245:17,19
 246:2,5,7,16,19,22
 247:3 248:9,12
 250:17,22 251:3,4,5
 251:10,17,19 252:1
 252:13,16,17 253:6,9
 253:19 255:6 256:4
 256:10 257:15,21
 258:2,4,10,13 259:7,8
 261:7,7,8,17 262:3,6
 263:8,15,22 264:19
 265:9 266:1 269:14
 270:2,4
draft 267:10
dramatic 20:6
dramatically 19:22
drawing 39:9
drawn 30:18 39:5,11
drill 135:8 243:6
drive 20:13 208:19,22

210:10
driven 208:12,13
drop 136:19
dropping 137:2 253:16
drug 167:17
drugs 183:8 192:19
duct 111:13
dues 208:11
Duke 69:13
dumb 54:7
Dutton 1:17 12:16
 27:18 54:7,11 55:2,19
 80:10,14 101:7 104:6
 105:4,9 110:8,12,15
 126:16 159:10 163:16
 165:9 167:13 217:9
 241:5,9 246:16 261:7
 261:8
Dutton's 14:6
dying 51:20,22
dysfunction 132:12

E

e-measures 31:19
 221:8
EACTS 50:10 51:16
 58:16
earlier 88:2 95:20 113:8
 115:17 121:3 173:14
 239:10 249:4,5 256:9
early 7:19 20:19 267:9
easier 109:12 221:2
easy 57:18 91:13
 202:17 211:10
eating 121:12
echo 217:9,18
echoed 16:15
ECMO 121:15 258:16
 259:5
economics 137:6
education 89:11 92:5
educational 92:17
EF 228:13
effect 228:4,5,8 253:15
effective 17:16
effects 192:14,17
efficacious 192:19
efficiency 46:13
efficient 166:11
effort 5:20 119:5
efforts 43:7 244:19,21
eight 103:21 177:22
 246:11
Eighty 157:4
Eighty-four 263:3
Eighty-six 128:3
Eighty-two 158:10
 204:4
Eisenberg 269:19
 270:4
either 14:9 88:11 160:6
 175:15 184:6 198:11
 215:22
ejection 228:3
elective 14:21 15:22
 56:11
electively 121:10
electronic 268:22
electronically 118:14
element 97:1 108:2
 112:14 133:13 145:1
 151:15,21 152:9,18
 153:14,15,16 154:20
 228:15
elements 150:22 152:3
 221:9
eleven 74:14
eligible 109:8,10
 152:17 180:2
eliminate 97:14
ELISABETH 1:18
eloquently 52:16
email 267:4
emails 244:22
emphasis 43:19 44:5
empirical 239:19 261:6
 264:11
employers 31:21
encourage 13:12 29:14
 38:11 207:8 252:16
encouraging 64:7
end-all 38:10
ended 120:11
Endocrine 2:17
endorse 102:4 222:21
 223:1
endorsed 19:19 28:16
 65:1 66:12 100:2
 133:14,17,22 144:8,9
 144:17 145:2,8,19
 146:11 169:22 170:16
 171:4,7,12 174:1,2,5
 174:19 175:22 177:19
 178:7 182:19 209:14
 211:4 225:10 248:17
 250:2,4,19,20
endorsement 7:12
 52:17 64:19 65:14
 66:6 67:3 93:19,22
 119:20,22 123:3
 131:20 145:7 146:8
 147:5 158:15,19
 166:3 170:5 171:9
 172:6 173:2,4,8,20
 175:10,19 177:18
 179:5 182:5,10 196:9

200:22 204:12 212:6
 222:1,2 230:10 235:8
 242:15 245:13 248:2
 248:5 265:14
endorsing 63:6
ends 18:19 32:22 55:17
energy 213:21
engage 9:8
Englund 256:12
enjoy 110:9
enlist 138:20
entail 170:4,6
enter 118:5,6,15
enterocolitis 111:9
enterprise 64:18 71:19
 72:6
enters 118:17
enthusiasm 219:22
entire 89:8 90:20
 135:22
entirely 39:15 179:12
 233:17,18
entity 223:5
environment 41:12
 64:11
equal 259:12
era 137:5
Erekson 1:18 29:16,17
 56:8 57:10 253:9
error 77:22 78:1,7
esophageal 105:15
esophagectomy 62:15
 62:22
especially 14:21 40:14
 46:6 50:5 60:7 84:11
 92:1 98:12 100:14,21
 103:20 153:1 270:3
essence 29:4
essentially 29:9 56:22
 105:16 118:12 139:10
 170:14 194:13 255:13
 256:17
established 82:7
 210:21
estimate 130:13
estimated 35:12
estimates 135:10
et 150:17
ethical 20:15 21:8
ethnicity 135:15
European 58:7 59:2
evaluate 99:11
evaluated 133:17
evaluation 99:10
 201:16 227:14
event 5:15 106:15
 111:8 160:14 164:14
 164:17 241:3 246:5

events 168:15
eventually 114:6,18
 148:18
everybody 5:22 6:1
 21:21 24:19 35:18
 118:12 139:10 149:1
 157:3 214:11 245:7
 254:3 260:15 261:11
 265:6 269:15 270:7
everyday 98:1
evidence 27:11,14
 43:20,22 47:9 52:21
 53:1,3 56:7 60:6 62:9
 62:21 63:11 65:3,3,5
 65:15 69:20,22 70:6
 84:4 85:2,5,6,15 99:9
 99:21 100:4,6 105:6
 123:5,14,17,19
 136:16 137:9 138:7
 138:15 141:20 142:13
 156:19 159:8 160:22
 161:10 167:1,7,8,10
 167:20,21 168:2
 171:1 172:19,19
 175:12 177:1 183:10
 183:10 184:2,17
 185:16,18 190:2,16
 191:3,4 193:6,13,15
 193:20 194:2,3
 198:18,22 199:4
 202:22 203:3 226:1,4
 226:8,11 234:8,12
 238:12 246:21,22
 247:2,3 251:7,12,15
 255:3,5,22
evident 123:11
evolved 51:5 124:2
exact 58:18,19 162:15
 183:7 201:8
exactly 14:6 16:15
 46:21 199:13 201:22
 233:2,12,14 241:11
 245:19,20
example 7:6 21:16 44:3
 55:11 146:16 170:12
 216:7 221:9 259:5
 260:11
exceed 41:2
exceedingly 30:22 31:1
 191:18
exceeds 253:6
excellent 60:9 75:8,11
 84:14 116:2 164:3
 171:14
exception 185:5 190:17
 194:2 228:6,9
excluded 17:3
excluding 17:21

exclusion 17:2 18:4
 110:12
exclusions 23:16 43:9
 156:22 181:2
executed 33:16
Executive 1:17
executives 15:16
exist 206:20
existed 65:7
existing 215:20
exists 34:8 54:20 62:9
 75:19 167:17 170:20
 171:1 238:5
expect 18:21 38:14
 199:15 261:11
expected 11:9 51:3
 103:6 122:16 255:13
 256:16
expecting 32:18
expense 87:7
expenses 215:22
expensive 213:1,4
experience 19:5 215:7
 241:3 248:22 253:18
 255:10 257:6 261:9
experienced 21:19
experiment 257:7
expert 9:16,22 51:9
expertise 9:6,9,18 10:1
 212:11
experts 10:17 216:18
 223:10
explain 30:11 44:15
 77:15 89:4 129:21
 130:4
explained 70:18
explaining 44:13 92:4
explains 92:7 169:1
 252:18
explanation 238:6
explanatory 89:9
explicitly 262:18
express 216:20
expressed 115:16
extends 14:18,18 24:7
extensive 107:14
extra 221:21
extraordinarily 65:8
extrapolated 183:11
extrapolation 183:17
extremes 16:21
extubated 121:12
eye 254:2

F

FAANS 1:15
faced 11:11
facilitate 45:17 223:6

facilities 73:9
facility 80:14 99:7
 140:1 159:12 208:17
FACOG 2:4
FACOS 2:14
FACS 1:15 2:1,4,14
fact 14:6 41:9 42:9
 43:14,21 57:17 63:6
 67:14 73:7 92:17
 105:5 106:3 110:18
 139:19 161:21 215:14
 222:16 250:19 255:16
 269:19
factor 156:4
factors 35:2 121:20
 122:4,8,13 211:19
facts 61:14 84:14 98:5
failure 11:2 122:11
 124:13,14 249:4
 250:22 255:18
failure-to-meet 24:9
fair 15:5 73:20 106:19
 183:16 186:16 206:8
 210:2
fairly 30:16 57:21 183:6
Fallot 55:12
familial 185:21
familiar 53:4 56:9
family 46:5 56:21 57:3
 114:7,10,17 135:8
fantastic 46:8 120:13
 123:4 125:6 202:17
far 121:2 201:15 216:21
 222:19 245:22
farm 218:3 222:3
fast 223:13
father 57:19 58:2 64:4
 74:17
favor 67:5
FCCM 2:9,14
FCCP 2:9
fear 23:3 96:13
feared 254:8
fears 39:21
feasibility 46:19 47:3
 87:4,10,13,16 116:17
 117:1,6,20 131:6,15
 157:7,15,20 165:20
 166:1 181:19 182:1
 191:10 195:12 196:5
 200:20 204:10 230:7
 235:6 242:12 247:22
 265:5,11
feasible 268:2
feedback 102:7,10
 103:18 136:6,8
 269:12
feel 33:8,14 40:6 84:8

149:21 150:12 164:7
238:17 256:7
feeling 33:14 220:7,22
feels 43:17
fees 87:8
FELDMAN 3:3 178:7
266:18 267:8
felt 9:16 47:16 190:8
211:5 231:9
female 83:3 227:16,19
228:8
females 236:9
fewer 137:14
fibrillation 192:15
field 65:9 105:18 118:4
124:1 182:15 222:8
254:15
fields 58:18 118:3,20
fifth 89:11 92:5
Fifty-eight 247:17
Fifty-nine 196:2
Fifty-seven 126:7
Fifty-six 262:9
figure 162:9
figured 167:15
fill 269:1
filled 167:14
final 7:1 182:11 259:18
finally 176:2
financial 41:11
find 44:9 84:19 146:2
202:18
finding 18:7 19:9,9
206:5
findings 135:13
fine 8:19 84:18 153:18
186:6 191:4
finely 121:19
finer 129:10
finish 5:4 218:12
first 5:3,5,5,8 6:13
10:10 12:15 13:2
40:20 47:1,5,16,21
48:1,8 49:8,13 50:8
50:13 52:2 56:17
61:12 67:3 90:3,19
91:10,15 94:22 95:4,8
96:1 109:5 114:12
116:19 133:4,12
148:10 161:13 187:17
197:19 198:9 207:4
207:22 214:21 224:18
226:17,19 233:17
234:8 246:22 247:4
250:12 255:9 260:12
fit 20:9 34:13
fits-on-one-line 26:22
five 41:13 50:9 51:17,22

52:5 53:10,19 60:17
72:20,22 87:9 88:17
95:9 98:8,12,13,17
112:17,19 129:12
138:14,14 142:19
157:18 159:21 164:21
176:15 179:20,22
181:17 194:1 196:13
199:3 203:1 211:19
246:9 251:15 253:17
257:19
fixable 160:20
fixed 75:22
flat-out 15:17
Fleisher 1:9,11 6:13 8:2
8:5 9:13,21 10:3
11:14 13:18 16:4 17:5
17:17 24:20 26:13
27:16 32:10 33:2 34:9
37:20 38:1,21 40:1
45:3 46:8 47:15 48:2
48:5,8,19 49:7 54:6
56:3,6 61:2 62:6
63:10,18 64:22 65:14
66:3,22 69:19 70:8,15
71:20 72:1,5,12 73:2
76:15 77:10 78:5,14
78:18 80:5,12,16,20
82:11,18 83:13 85:17
87:5 90:17 93:2,12
94:1,5 99:22 120:8
123:4,13 125:6 126:4
126:15 127:22 130:21
131:10 133:3 150:4
150:10 159:8 160:8
160:10 162:7,10
164:2,18 165:6,11
170:12 171:13 174:3
174:18 176:4 183:9
185:14 186:3 189:21
192:20,22 194:6
195:19 196:19,22
198:21 199:21 200:13
201:13,21 202:12
204:14 205:10 206:22
208:2 209:3 211:3
212:9 216:10 217:5
218:8,11 220:9 224:2
231:22 232:3 233:11
233:20 234:5
fleshed 18:2
flip 134:19
flipped 239:15
Floor 1:8
Florida 48:16 107:3
flow 44:19
fluctuations 264:17
focus 44:7 91:15

114:15
folks 11:18 40:11 41:18
44:21 223:7 269:21
follow 9:3 174:11
184:15 198:1 222:7
223:18
follow-up 61:4 178:18
followed 62:13 190:14
220:10
following 11:6 109:19
267:12
for-profits 220:6
Force 49:1
forever 171:12
forgot 7:19
forgot 27:9 109:6
form 34:3 59:22 77:19
78:2 117:16 121:5
134:8 227:15
format 119:3
former 151:12
forms 56:16 78:4
forth 60:14,16 61:10,12
206:18
Forty-seven 247:8
Forty-two 107:7
forum 1:1,8 39:3
forums 39:8
forward 8:22 28:17
33:21 34:5 41:9 42:16
42:17 82:11 115:20
120:14 121:22 123:2
150:13 169:1 192:20
193:9 206:12 215:12
218:19 247:21 265:8
265:9,11
found 90:14 105:19
255:12
foundationally 8:17
four 74:14,14 87:9
88:17 95:21 98:13
102:12,20 103:1,8
168:16 189:8 195:2
224:16 238:20 239:21
240:1 248:18 249:22
250:1 252:9 255:9,14
257:16 259:15
fourth 97:8 189:12
249:15
fraction 228:3
frame 10:14 98:22
framed 11:10
frankly 215:15
Fred 8:8 34:9 75:19
191:21 217:8 220:10
245:1
Fred's 213:6 218:11
FREDERICK 1:20

free 175:8
frequency 255:18
frequently 62:8
Friday 1:5 266:20
front 39:8 83:17 177:21
220:16 221:3
FTE 87:7
full 5:11,15 33:11
246:12
fully 19:12 39:7 222:2
fun 219:8
function 17:14
functional 28:8 38:12
42:12 206:14
fundamentally 142:5
funded 124:8,20 221:12
funding 71:19 72:6
124:9 208:7,7,21
funny 9:4
further 26:12 36:22
44:22 76:8,9 165:10
176:9 221:17 258:12
263:22
fusing 60:11
future 53:12 93:5 97:4
124:5 143:21

G

game 97:11 216:5
217:2 258:5
gamed 13:13 17:8 31:9
games 17:13
gamesmanship 12:18
16:2
gaming 18:11 26:1,2,7
30:5 32:5 34:16 57:12
57:17
gap 20:5 33:12,13 62:5
62:7,9 64:8 70:7,16
70:18 71:1,6,12 76:19
77:4 78:10,20 79:1,2
79:4,8 80:4,8,10,13
81:3,7,13 101:6
106:12 107:6,9
123:17 125:8,18
126:9 138:17 142:6
142:10 143:14 147:7
147:11 148:7 159:17
164:19 165:1 168:3,5
168:16 169:9,12
170:15,19 175:13
179:19 180:2 194:4
195:5,7,11 199:5,7
200:1,5 201:15,19
202:7 203:4,6,9,18
212:10 226:11 227:7
228:1,19 229:2,6
232:5 234:13,15

235:18 237:8 238:14
 241:13,16,21 246:4
 246:15,20 247:6,10
 251:16,20 262:5,8,11
gaps 100:6 267:3 268:9
 268:10 269:4
GARY 2:14
gastroschisis 122:7
gather 37:13
gathered 170:3
Gawande 33:7
gender 227:3,8,11,13
 227:14 228:1,5
 236:11
genders 227:11
general 2:7 10:8 49:11
 56:9 95:18 96:22
 117:18 133:19 170:8
 181:13 186:12 204:17
 216:6 237:17 239:12
 243:20 254:1 268:16
generalized 186:17
generally 152:5
generate 76:14
generated 119:9
generic 159:15
geographic 156:14
geriatrics 25:4
getting 16:16 25:3 62:1
 70:13 79:12 135:6
 142:2 151:18 185:10
 195:14 212:1 214:21
 217:16 219:9 232:11
 237:20 245:4,5,10
 257:13 260:15
ghetto 126:19
gist 166:5
give 25:16,20,22 42:6
 47:4 49:8 108:20
 130:13 166:7 187:21
 202:15 223:14 257:1
 266:17 269:8
given 17:20 30:7 38:1
 45:12 46:13 52:3 74:8
 82:9 99:11 111:16
 118:4,16 121:6
 140:15 153:5 167:14
 199:11 234:1 266:22
gives 64:16 252:10
giving 260:17
glad 6:9 207:20
go 8:4 24:4 25:9 26:7
 28:17 32:16 35:2,7
 40:8 42:8 47:1,10,22
 69:22 74:2 75:20 76:9
 78:17 81:13,21 87:4
 87:13,16 88:8 93:18
 93:21 95:8 100:4,6

102:8 104:2 106:12
 107:5 112:3,9,12
 113:6 116:17 117:6
 117:11 118:22 119:14
 119:19 120:2 123:17
 128:6 131:6,9 132:1
 138:6 140:7,21
 143:12,20 146:5
 149:4,12 155:16
 157:15 158:3,14,17
 159:16 161:11 165:7
 165:14 167:18,19
 169:9 170:22 171:18
 172:16 176:10 179:15
 180:6,9 181:6,10
 182:9,14 193:17
 194:4 200:9 201:1
 203:7,22 204:3
 209:10 217:5 219:20
 223:1,2 226:8 228:21
 229:18 230:11 232:14
 232:16,20 233:8,15
 234:13,14 235:1,7,11
 236:4 241:15 242:3,5
 242:17 244:5 247:4,7
 247:15 259:7 262:7
 262:14 263:2,6,21
 264:1,8,20 265:5,13
 265:16 269:13
goal 89:13 92:4 110:20
 143:21 220:18 259:18
goals 40:16
goes 18:22 50:6 63:13
 63:15,15,20 69:8 72:8
 121:11,15 136:15
 199:18
going 7:16,17 11:7
 12:17 13:15 14:5
 15:18 17:8 18:16
 20:10 22:16 23:1 25:1
 26:2,13 34:5,6 37:5,7
 41:8 42:20,22 45:1
 46:21 47:4,11 49:9
 50:19 51:20 52:1 53:6
 53:7,11,17 56:12
 62:12 63:22 65:12,13
 66:22 75:17 82:11
 83:6 84:19 95:7 98:4
 105:13,17 113:12
 114:13 115:6,7,20
 120:2,8 128:6 134:5
 145:13 148:17 150:13
 152:22 153:1 154:12
 156:11 160:13 163:19
 165:3 169:6 170:16
 177:5 183:5 185:6
 186:7 191:13 197:18
 201:12 202:1 203:14

206:12 207:19 208:22
 209:8,12 210:8 212:6
 212:21 215:17 216:3
 217:8,20 218:11,12
 220:5 221:2,20 222:4
 224:16,22 232:17,21
 233:9 235:10 244:16
 246:10 252:13 255:7
good 5:22 6:13 12:7
 33:18 48:4 50:1,4
 64:8 84:17 87:22
 89:12 91:10 96:18
 102:18 104:8,11
 105:10,20 108:2,17
 108:22 127:16 130:17
 143:4 144:14 147:4
 175:1 204:20 206:3
 206:18 211:20,20
 220:20 233:8 237:20
 254:5,7 256:7 260:16
 263:13 265:19
gorilla 209:5
gotcha 220:22
gotten 137:16,18
 212:19
government 244:12
grab 204:14
grade 89:11 92:5
grades 222:2
gradually 114:11
graft 132:12 184:13
 185:11 192:12
grafting 50:16 132:9
 133:2 159:5 183:18
 188:19 201:10 249:14
grafts 192:10
grant 124:8,20 125:9
granular 61:8
graphic 239:19
grapple 25:5
great 6:8 23:7 24:20
 34:9 40:1,5 42:12
 44:22 48:2 54:9 56:15
 61:9 68:14 77:16 86:2
 93:7,8,10 94:5,10
 98:15 100:17 102:6
 110:13 112:14 117:13
 124:6 125:16 185:18
 193:3 194:13 205:15
 211:16 216:4 218:8
 218:11 224:5 231:1
 253:19 258:14 270:8
greater 22:6,7 145:22
 189:11 216:21
Greg 110:6,7
grieving 114:6,12
group 28:11 30:16 46:5
 51:6,9,16 92:11,14

99:7 140:6,13,14,19
 144:13 159:11 162:16
 164:6 168:9 193:8
 197:17 206:15 210:9
 212:15 213:16,18
 218:14 219:3,3,19
 256:18 261:15 267:17
grouped 51:12 168:7
groups 32:2 85:22
 91:21,21 92:22
 108:21 122:18,19
 139:22 140:2,10,16
 140:20,21 148:10
 160:5 189:8 205:8
 206:2,21 215:7,19
 219:15 226:12 228:5
 236:12
Grover 1:20 8:8,20 9:21
 34:11 36:4,6 75:19
 143:2 146:20 174:11
 185:20 207:5 218:13
 258:13
growth 205:16
guess 9:13 12:12,15
 17:10 27:12 37:19
 41:15 48:5 50:12
 57:10 63:20 73:4,10
 73:15 79:7 92:22
 105:1 108:4 120:15
 139:5,18 153:5
 159:15 205:22
guidance 145:6 152:3,4
 172:5
guide 7:21
guideline 183:11
guidelines 167:10
 183:14 184:3,8
 186:11,22 189:14
 190:10 193:2
Gunnar 1:9,13 5:3 6:10
 8:3,7,15 9:20 10:14
 13:22 19:15 24:6
 28:13 37:5,22 46:1
 55:20 66:18,20 75:6
 100:1,7 103:14
 106:14 107:11 110:6
 112:2,6 113:4 115:22
 116:12 117:10 118:19
 119:2,12 132:16,19
 134:2,19,22 135:3
 138:2,6 139:21 141:2
 141:18 142:3,16,21
 143:4,10,17 144:10
 147:12,19 149:11
 150:2,9 151:1 152:20
 153:5,19 154:8,13
 155:2 156:8,15
 157:14 158:2 167:5

167:12,18 168:18
 169:7,16 173:11
 175:7 178:9,12,14
 179:18 180:4,12
 181:9,21 182:6,11,13
 183:1,21 187:14
 188:22 189:17 190:11
 191:20 193:10 194:5
 195:4,20 196:10
 203:5,10 204:2 224:9
 225:4,7 226:3,6 227:2
 227:17,22 228:10,18
 228:21 229:18 230:15
 231:17 235:11 236:4
 236:15,19 237:6
 238:3,10 244:5
 245:17,19 246:5,19
 248:9 250:17 251:3,5
 251:10,17 252:1,16
 253:6 257:15 258:4
 261:7 262:6 263:8,15
 263:22 264:19 265:9
 266:1
GUNNER 201:5 259:7
guys 91:5 125:5 166:5
 191:14 253:11
gynecologists 2:5
 205:2

H

HAC 14:19
half 126:17 163:3,14
 199:9 241:9 246:12
 251:21 256:13
Hammermeister 218:15
Han 3:13 49:2 213:8
hand 21:9 220:17
hands 6:8 8:13 80:6
Handy 1:19 14:5 59:4
 59:15 61:5 62:4
 144:11 146:2 169:16
 169:17 171:8 194:16
 201:22 235:13,15
 236:13 239:4,22
 240:4 241:8,11
hang 146:17
happen 7:8 16:3 18:16
 57:9 114:1 115:17
 177:5 198:14,16
 207:21 254:6 257:9
happened 32:4 66:13
 141:4 143:5
happening 17:12 31:20
 76:2 102:14 103:13
happens 23:12 26:3
 174:19 266:2
happy 28:1 127:6 186:4
 189:4 214:2 250:16

hard 6:5 22:21 24:15
 44:15 77:13 97:21
 102:18 190:21 199:14
 207:15
hard-to-define 23:18
harmonize 221:13
harmonized 211:17
harvest 137:1
head 91:11 118:22
headed 29:12 125:3
 237:6
health 1:14 2:4,20
 29:22 30:10 121:17
 137:5 138:9,10 161:1
 161:3 179:14 234:9
Health-System 2:11
healthcare 64:12 114:9
 205:2 234:10
hear 12:5 13:18 41:17
 65:17 102:5 220:14
 270:5
heard 15:16,16 41:3,20
 149:15 252:17
hearing 34:17 93:20
 106:12 119:21 153:20
 157:15 158:3,17
 165:7 179:19 196:10
 199:1 204:3 226:6
 228:21 234:5 242:5
 265:16
heart 48:15,16,18 49:11
 49:14,16,18 50:10,14
 50:15,15,19,21 52:15
 54:14,15,20,22 55:1,5
 55:16,17,20,22 56:16
 58:10 59:7,21 60:11
 67:9,9 75:16,16,21
 76:3,4,10,12 81:19
 86:9 91:22 92:12,13
 94:18 98:20 102:2,8
 114:4 115:1,6 116:7
 120:20 122:22 127:10
 127:12 128:19 130:11
 136:21,22 137:7
 186:11,14 219:7
 232:9,9
hearts 237:18
heft 146:15
held 95:20 222:9
Helen 3:2 5:19,20 6:1
 6:17 9:2 10:2 11:11
 17:6 32:8 40:4 45:9
 45:22 63:13 72:7
 77:10 98:3 120:9
 145:4 202:15 206:22
 220:11 269:13
Helen's 80:7 218:12
help 16:8 18:4 33:22

41:19 42:1 43:21
 120:13 207:19 208:22
 217:12 223:5
helped 7:21 24:1,2
 61:14 176:8
helpful 28:14 46:4 62:1
 193:6
helping 25:22 92:1,16
 178:18 269:10
helps 36:12
hemorrhoid 162:3
hesitate 10:1
HHS 221:11
Hi 214:4
hierarchical 128:21
 129:1,2,3,18
high 12:3 15:8 18:15
 20:2 36:9 57:3 59:19
 60:6 70:4,11 73:6
 81:11,18 82:1,10
 84:10,21 87:1,14
 93:14 96:13,18 99:21
 101:14 103:5 107:7
 112:10 116:14 117:7
 119:15 125:22 126:8
 128:3 131:3 142:8,17
 147:8 152:17 154:3
 157:4,18 158:10
 159:17 160:4,7,19
 164:20 165:16 167:22
 168:7,10 172:10,14
 179:21 181:16 193:20
 193:22 194:7,20
 195:2,8 196:2 200:2
 200:15 203:17 204:4
 229:4 230:2 234:16
 235:3 241:19 242:7
 246:10 247:8,17
 254:11,16 256:22
 257:3,4 259:3 262:9
 262:13 263:3,19
 264:4 265:2
high-complexity 60:2
higher 41:10,11 84:10
 85:14 98:13 139:5,18
 152:6 159:21 236:3
 256:8
highest 16:15 54:5
 56:19 100:14 101:2
 152:19 199:19 228:13
 235:18 256:18 257:5
 261:15
highly 81:18
hints 222:15
hip 14:22
HIPAA 106:17,20,22
 107:4
history 8:10

hit 14:12 21:21 159:15
Hitchcock 1:18
hold 83:14 193:17
 195:16
holding 220:17
hole 54:22 75:16,21
home 13:14 51:20 52:1
 166:22 268:13
honest 84:5
honestly 189:7 208:21
honesty 233:21
honing 15:1
honor 270:2,5
hook 223:9
hope 34:17 143:19
 256:10 257:12
hopeful 42:18
hopefully 120:17 125:4
hoping 35:5
Hopkins 48:15
horribleness 114:7
horse 187:10
hospice 13:15,19 25:4
 25:7
hospital 2:7,8,16,17
 13:6 14:2,20 15:5
 24:13 36:18 52:3
 61:17 64:5,13 68:11
 68:20 69:13 71:8
 86:12 118:15 127:14
 140:6,12,15,18
 151:20 198:14 210:21
 225:18 240:9,16
 244:6,14 254:10
 264:16
hospitalization 14:3
 98:22 111:4 132:10
 225:15
hospitals 22:18 29:20
 36:17 49:17,19 58:11
 69:3 136:19,20,21
 137:2,2 138:20 139:1
 139:8 140:10,15,20
 140:21 151:7 210:22
 219:15 240:9,11,14
 240:15 252:11 254:16
 256:18 257:5 259:4
hour 44:11 177:2
hours 113:17
house 37:14
huge 49:3 118:2 202:20
 209:6 244:18 270:5
huger 137:4
hundred 131:21 219:11
hundreds 216:14
hypolipidemia 185:21
hypothesis 258:4
hypothetically 148:13

148:22	138:17 163:21 179:7	infected 163:5	intended 42:10 79:2
	199:8 207:12 236:8	infection 159:1,6 161:2	155:11 222:1
I	236:12 237:9,12	161:16,22 162:5	intense 57:21
i.e 79:8	238:7 258:14	163:1,3,11,13 249:5	intent 220:5,22
ICD-9 109:11,15	improving 57:8	infections 163:4	intention 209:10 218:6
ICU 156:11	in-house 20:8	inferred 186:9	interest 46:12 208:6
idea 6:16 32:18,19 33:3	inactive 173:2	inflammatory 192:16	interested 28:20 91:2
36:8,21 40:1 93:7	incentive 97:14	influenced 159:13	124:3 210:10
94:10 108:20 125:11	incentivizing 96:4	inform 19:12 176:8,9	interesting 12:1 13:18
222:9,20 233:8	incidences 34:18	information 18:7 74:3	115:4 125:7 191:15
ideal 106:3 123:22	incision 177:2	74:17,19,21 79:10	194:8 258:9
ideas 45:15,18,21 223:8	include 33:9 51:1 97:4	91:2,5,7,13,15 92:3	interestingly 44:11
identical 183:6	111:20 122:2,5	92:17,21 93:16	intermediate 85:12
identification 102:22	124:12 134:9 198:12	118:16 130:22 136:9	internal 58:13 249:11
identified 65:20 125:8	198:13,16 223:9	136:10 141:22 142:6	internally 103:19 162:9
148:19 212:12 227:22	225:21 249:2	194:18 202:2,10	interpretation 128:14
252:21 253:2	included 56:1 129:10	233:15 242:21	128:20
identify 7:13 103:3,10	includes 54:21 86:11	inherent 70:19	interpreted 94:12
212:16 269:4	97:2 98:19 107:14	initially 51:4,8 201:15	interprets 35:19
ill 15:9	126:18	213:6	interval 148:11,12
ill-defined 15:3,4	including 8:12 33:4	initiative 90:1 124:19	252:2
IMA 260:11,12,16,17	99:17 225:14 249:18	127:13	intervals 102:21 103:3
IMA's 260:16	inclusion 146:12	Initiatives 3:15	intervention 138:11
imagine 12:22 74:6	incorporate 19:10 34:4	inner 152:3	161:4 234:11
impact 163:6 175:16	incorporated 73:13	input 180:16 206:16	interventions 160:17
187:18,22 190:17	167:9	213:22 214:8	intimidate 128:12
227:8 228:15	incorporates 25:2	insertion 55:14	introduce 5:19
impacted 11:1	incorporating 99:4	inside 129:16 251:9	introduced 133:5
implemented 212:7	increase 61:15 103:9	insightful 161:12	introduction 49:8,15
implications 186:9	236:7	insisting 214:15	invest 61:19
233:18	increased 169:5 255:17	instance 12:19 79:21	invested 106:19 221:3
implicitly 162:9	increasing 51:18	152:10 156:5	investigate 37:16
imply 169:22	127:19 244:18	Institute 1:17 48:16	141:14
importance 216:5	incredibly 259:3	69:14	investigating 268:5
263:5	incremental 236:7	institution 73:21 98:11	Investigator 125:1
important 7:13 8:16,18	incubator 207:1 222:18	100:13,13 170:1	investment 216:14
9:10 13:17 19:16	independent 68:15	institutional 26:4 69:15	invite 45:10
26:14 29:18 37:4	independently 68:19	institutions 50:20 79:5	inviting 40:10
38:13 39:2 62:10 67:6	174:9 175:17	79:9 128:17 129:22	invoked 15:22,22
78:12 85:3 97:7 98:14	index 14:2 252:20	130:1,18,19 199:18	involve 44:20
102:3 130:21 133:9	indexed 98:21	insufficient 70:5 81:12	involved 25:4 27:7
133:10 159:21 160:1	indication 171:5	82:2 87:3,15 93:16	41:21 70:14 87:7
160:2 161:15,22	indices 135:11	107:8 112:11 116:16	99:16 207:5,10,22
162:2,17 163:15,22	individual 51:5 69:12	117:8 119:17 128:4	iron-chair 5:7
164:8 171:1 177:3	109:2 128:17 133:10	147:9 154:4 157:5,19	island 173:16
190:8 211:5 215:8	133:21 145:7,14	158:12 164:22 165:17	isolated 19:19 31:4
253:20 254:1 255:17	146:10,14 173:19	168:1 169:12 179:22	34:18 159:4 166:21
258:11	206:1 208:18 214:14	181:17 190:16 193:21	183:18 243:16,16
importantly 99:14	215:13	194:2 195:9 196:3	252:6
impression 56:9	individually 133:17	200:3,16 204:6 229:5	issue 21:7,8 44:10 68:9
impressive 53:18	145:19 146:5,18	230:3 234:17 235:4	69:20 78:17 79:1 80:3
improve 136:13 219:1	154:11 210:20	241:20 242:8 247:9	87:7 105:18 126:12
improved 53:3,14 77:5	individuals 11:15 23:11	247:18 262:10 263:4	128:8 131:8 140:19
220:15 228:11 249:13	216:19	264:5 265:3	186:5 210:14 221:22
improvement 13:10	inertia 209:18	integral 252:5	237:15,16
22:7 26:4 76:19,21	inevitable 11:3	integrity 31:7	issues 13:16 46:7,18
77:6 101:1,4,20	infant 124:1	intellectual 35:9 213:22	88:2 127:15 192:16
103:19 119:8 126:3	infants 99:4	intend 209:9 210:12	201:11 216:18

it'd 191:14
it'll 86:4 221:2
items 42:1
iteration 245:21

J

Jacobs 3:11 29:4 48:11
48:13,21 49:9 52:15
53:2,5,7 54:9,13 55:3
56:2,14 57:16 58:9
59:14,17 61:9 62:21
64:1 67:2 68:14 70:13
70:19 71:7,21 72:3,11
72:15 74:1 75:3,9
77:17 84:6 86:2 87:18
87:20 88:7,10 89:6,15
89:18,21 91:9 93:6
94:6,20 95:3,12 100:7
100:9 102:6 103:17
104:10 105:7,11
106:18 108:4 109:5
109:21 110:2,11,13
110:17 113:1,15
117:22 118:21 119:4
120:19 124:6 125:15
127:5 132:4,5,18,21
133:12 134:6,21
135:2,5,18 136:5,20
137:15 138:21 139:4
140:3 141:7 142:2,12
143:1,7 144:12,20
156:2,13 159:2
160:13 166:16 168:20
180:18 183:5,16
184:9 185:9 187:1
188:13 191:17 197:16
201:7,18 202:19
203:12 212:20 224:13
225:6 230:22 232:7
236:2,20 237:14
238:9 243:1 244:10
248:12 251:19 252:13
252:17 253:19 258:2
261:17 262:3
Jamaica 75:20
Jamie 3:16 49:5
Jane 3:13 49:2 213:8
257:22
January 91:18
Jeff 48:13 76:21 104:6
129:8 161:13 168:18
183:3 207:17 219:19
248:10 252:16 255:7
258:1
JEFFREY 3:11
job 19:11 64:14 89:13
112:21 202:17
John 1:19 8:15 12:12

62:13,19 144:10
270:4
Johns 48:15
JOHNSON 3:4 145:12
150:14 152:14 153:13
172:1 180:6,20
190:19
join 5:19 40:11 63:7
joint 21:16 27:22 163:5
journals 10:22
judgment 36:12 170:8
Juliet 3:3 7:17 45:15
266:16 268:8
July 226:13,15
jump 123:19
jumping 235:17
June 226:14,15
justification 61:18
184:19 186:2
justify 186:1

K

Kaizan 6:17
Karen 3:4 83:2 152:21
162:12 170:21
Karl 218:15
keep 8:21 20:11 22:8
35:5 36:20 45:1 63:22
67:22 96:4 97:15
170:15,16 223:22
254:2 260:18 267:6
267:10
keeping 90:21
Keith 2:9 159:9 160:8
165:11
Kelsey 2:6 17:17 33:2
56:3
kept 11:16 163:12
key 217:4
keypad 197:7
Keystone 2:15
kicked 173:15
kind 7:8 8:17 18:18
25:22 26:1 28:2,11
30:20 34:7 37:13
38:19 46:22 47:11,18
67:5 85:20 128:9,16
142:21 156:17 162:8
164:13 168:22 170:10
171:5 172:13 180:21
185:5 202:9 205:9
207:11 209:2 221:13
223:10,12 224:4
268:11
kinds 119:9
kit 215:8
knee 14:21
knew 74:8,11 211:7

know 5:7,17 6:8 8:14,17
9:9,10 10:9 17:3,10
18:19 20:17,18 21:3
24:15,15 26:19,22
27:10 28:1 29:14
30:15,21 31:4 32:1,7
33:19 34:7,14 36:7
37:14,15 38:17 40:13
41:4,17,19 43:19
46:17,17 48:12 49:17
49:22 62:17 63:1,4
68:9 72:18 73:17
74:17 75:13,14 78:11
83:1 90:8 91:3,4,7,11
94:21 104:14 108:12
109:3 117:12 118:12
118:21 127:7 133:13
136:3,15,22 137:11
137:15,18 139:4
141:8,11 142:5,22
143:19 151:19 152:5
152:11 153:9 155:9
155:21 160:15 161:13
161:19 162:2 163:18
164:4,5,16 166:4
169:17 172:14 173:14
176:21 177:7,8,12
179:9 187:8 189:17
191:8,9,13,15 192:9,9
192:13 194:14 198:20
205:21 208:8,22
209:7,17 210:16
212:5 214:11,15,16
215:5 220:13 221:6
221:14,19 222:3,10
229:15 233:5 236:13
237:11,14 238:5
253:3 258:2,7,18
259:8,9 267:2 268:6
269:6
knowing 233:9
knowledge 213:2
knows 79:16 210:15
Ko 2:1 151:3 161:5,6,11
161:12 162:8 176:11
176:18 177:14 209:22
238:16 239:20 240:1
240:5,18 241:4 259:8

L

la 12:3 134:5
labeled 148:16
lack 26:20 184:17,19
laid 176:3
Lake 104:6
language 189:4
large 15:17 30:1 39:9
129:14 170:19 229:17

252:7,7
larger 86:17 259:14
260:2,18
largest 259:14
Larissa 2:18 24:20
43:12
Larry 65:4 99:22 105:12
110:6 115:22 123:5
156:9
lastly 43:7,11 222:15
late 73:5 117:12
latest 139:13 262:1
Laughter 223:3 236:18
266:5
LAWRENCE 2:7
lawyers 106:20
layman's 89:5
LDL 189:10,11
lead 45:20 256:11 269:9
leader 5:20
leaders 219:6 245:1
leadership 213:6,7
219:8,21
leading 37:9
leads 135:20 228:10
leap 186:16
learn 110:9
leave 38:6 187:11 258:7
leaving 7:19
led 127:13 182:14
Lee 1:8,11 6:10 11:12
28:22 189:20 194:5
217:10 222:15
left 22:8 23:2 66:15
175:20 240:19
leg 28:2
lengthy 198:19
lesions 59:2
let's 31:9 48:6 69:19
70:1 80:17,20 81:21
87:13 93:21 95:10
106:12 107:5 112:3
123:15 126:6 128:2
131:2 143:12 150:6
157:15 158:17 160:10
165:13 179:19 188:22
193:17 199:22 200:14
204:3 224:2 225:8
229:11,18 234:7
235:1,11 238:11
241:15 242:14 243:1
247:7 262:7 263:2
264:1,20 265:16
letter 34:12
level 16:3 21:8 25:21
44:4 54:5 69:8 85:15
92:4 99:6 129:5,6,17
130:14 146:8 151:16

151:18,21 152:17,18
 159:12 167:8 193:5
 208:17,18 222:4
 236:11 240:16 254:15
levels 98:13 112:21
 114:22
leverage 15:6 172:10
 172:14
LEVY 2:4 18:5 76:16
 77:15 138:5 142:7,19
 208:3
life 10:17 37:2 38:16
 56:17 97:19
ligation 111:13,18
ligations 110:19
light 144:19
likelihood 35:13,14
 58:2 232:11,12
limit 64:17
limited 64:12 75:18
 77:7 179:14
limiting 75:7
line 8:19 128:10,10
 191:3 214:5 266:7
lines 39:6,9,11 44:4
 197:3 265:22
link 123:8 139:5,13,14
 167:11 183:15
lipid 166:22
list 49:14 77:14 107:15
 109:7,9 126:20 127:3
 177:21 206:12 269:8
listed 196:19
lists 118:10
literally 29:1 230:18
literature 98:10 100:11
 167:2 184:18 186:17
little 5:8 26:8,12 27:19
 30:13 35:8 47:17 52:8
 57:19,20 74:6 75:15
 76:3,8,9 84:3 95:7
 99:8 101:21 135:15
 145:12 146:3 164:5
 179:16 190:2 191:2,7
 194:17 237:22 243:8
 252:15 255:6,20
 256:22 258:11 261:5
 268:11,20
live 103:21 162:22
lived 20:18 65:6
lives 90:21 97:9
living 206:15
Liz 253:8
local 21:6,8
locally 22:15
locate 239:4
location 156:14
log 86:12

logical 188:16 222:13
 262:18
logically 146:17
logistic 128:13
long 24:4 25:9 95:22
 117:17 231:2 233:18
 249:13
longer 169:9,9 172:9
 173:3 179:7
longest 253:11
longstanding 14:9
look 13:13 16:7 19:2,3
 20:1 24:8 25:19 29:18
 31:15 63:1 77:8 79:20
 103:1 104:17 111:16
 118:22 120:14 133:15
 137:22 145:4 179:16
 194:17 202:13 218:2
 232:5 233:6,7 235:17
 236:14,14 237:17
 240:12 254:12 257:8
 258:8,11 260:6
 264:14 268:13,19
looked 9:21 51:11
 53:15 68:3 116:10
 255:11 264:9,15
looking 11:20 18:12
 28:7 32:21 38:12 54:1
 63:3 72:3 83:18 88:13
 109:2 183:10 190:1
 214:14 239:8,16
looks 161:17 240:19
lose 179:5
lost 170:10
lot 7:7 13:4 18:1,11
 30:6 31:13 33:4 34:19
 35:1 38:17 42:5,17
 43:5,16 44:1,5 46:17
 46:18 61:11 73:21
 77:2,5 79:5 95:19
 101:8 110:18 155:17
 169:18 183:10 187:6
 195:2 202:15 209:19
 220:4 238:1,2 261:8
lots 27:21
loudly 30:16
love 44:17 110:16,19
 126:19 127:2 221:5
 221:17
loved 11:5
low 18:20 19:1 20:1
 60:8 70:4 75:13 81:12
 82:1 84:15,16,17,20
 84:21 87:2,15 93:15
 101:8,13,14 103:4
 105:9,18 106:6,15
 107:8 112:11 116:15
 117:8 119:16 125:22

128:4 142:9,18 147:8
 154:3 157:5,18
 158:11 159:19 160:4
 160:7,16 164:16,21
 165:17 168:1,7,11
 169:12 175:13 179:22
 181:17 193:20 194:1
 194:20 195:9 196:3
 200:3,16 203:17
 204:5 229:5 230:3
 234:17 235:4 241:20
 242:8 246:12 247:9
 247:18 262:10 263:4
 264:5 265:3
lower 193:5 215:15
 260:3
lowering 166:22
lowest 228:15 235:21
lucky 213:5
lunch 4:12 204:15
 220:13 224:3,5
lupus 15:12
Lynn 2:13 147:12,20
 250:18 251:5,17
 263:8
LYZENG 3:5 46:12
 47:20 48:3,7 52:6,11
 70:3 78:16 81:2,10,20
 82:16,19 83:5,11 85:9
 85:14 86:22 87:12
 93:14 94:3,16 95:2,6
 100:3,16 101:5
 105:12 106:11 107:5
 112:4,8 116:14 117:5
 119:14 123:16 126:7
 128:3 131:3,13 138:8
 143:13 144:6 145:21
 147:6 149:3,18
 150:19 151:13 153:9
 154:2,10,19 155:3
 156:18 157:17 158:4
 160:21 161:8 164:10
 164:20 165:7,14
 167:21 169:11 170:5
 171:4,17 173:22
 177:17 178:4,11,13
 179:20 180:9,14,19
 181:3,11,22 182:7,12
 182:16 188:5 193:14
 195:6,21 196:12,21
 197:2,10 199:2,22
 200:14 202:21 203:8
 203:16 204:4 210:8
 226:8 229:1,11,20
 230:9 231:19 234:7
 235:1 238:11 241:12
 241:15 242:14,17
 245:11,18 247:3

251:13 260:21 262:4
 262:7 263:17 264:2
 264:21 265:10 266:3
 266:6,14 267:6,21
 270:7

M

M.D 3:11
MA 1:16
Madison 32:2
magnitude 235:16
maintained 58:17
maintenance 25:13,15
 25:19 26:9 43:12,15
 44:6 132:19,21 134:1
 170:17 171:16,19,22
 172:17 173:5 225:11
major 6:17 248:21,22
 249:8
making 12:4 19:6,7
 31:22 33:8,17 35:17
 40:16 77:1 78:12,13
 78:18 176:7 210:16
 264:17
male 81:4,8 83:8 117:3
 227:16,19 228:7
mammary 249:11
manager 2:6,8 3:3,5,14
 64:17
managers 61:18 64:13
mandate 244:12
mandatory 90:5
manpower 49:17
MARCH 1:5
marches 261:11
Marcia 3:2 38:3 45:9,22
 63:14 77:11 120:10
 162:11 170:21 175:5
 221:19
marginal 130:12
Markman 2:5 52:12,13
 53:6 58:5 70:17 88:6
 89:4 133:4 135:12
 136:2,14 138:18
 139:3 154:9,16
marry 17:15 18:9
Massachusetts 2:7
mathematical 128:10
matter 68:12 120:5
 141:18 142:1 144:2,4
 187:14 224:6 270:9
matured 121:18
Max 3:10 48:14,14
 53:14 125:2
Mayo 1:16
MBA 1:17 2:6,13
McCARTY 2:6 17:18
 33:3 56:5 198:8 199:6

MD 1:11,13,15,16,17,18
 1:19,20 2:1,4,5,7,15
 2:16,17,18,21 3:2
mean 9:5 17:12 19:1
 24:22 25:4 26:6 32:14
 35:1,20 37:10 61:5
 63:3,19 65:12 66:3
 70:19 71:21 77:12
 79:11 83:9 84:1 93:8
 101:11 119:4 120:10
 125:6 133:8 135:22
 136:3,18 137:13
 138:19 142:9 144:20
 144:21 149:12 154:16
 160:15 162:12 168:9
 169:6 170:3 171:9
 174:13,17,20 176:17
 177:11 178:20 184:18
 186:1 188:13 190:7
 191:17,20,21 194:6,7
 194:11 195:1 199:14
 202:7,8,15 209:5
 210:19 211:15 214:15
 221:8 222:22 237:14
 238:19,21 239:2
 240:12 259:2
meaning 219:3
meaningful 68:6 157:1
 168:13,14,17
means 93:18 169:21
 240:13,21 241:1
 252:20
meant 66:5 80:22
 115:10
measurable 199:7
measure 2:12 7:6,9
 9:17 10:8 11:9 12:19
 13:12 18:7,10 19:10
 19:19 21:22 24:7,12
 24:14 26:3,9,15 27:1
 27:4,5,7,11 31:8,8
 37:1 43:12,15 44:8
 47:1,9,18,22 48:10,11
 49:8 50:8 52:2,2,13
 52:17,18 53:1,8,8
 57:16 59:10,18,20
 60:13,14,15 61:10,12
 61:14,22 62:10,17,18
 63:2,16 64:10,15,19
 65:10,18,19 66:1,8,10
 66:11,14,15,16,17
 67:1,7,11,21,21 68:3
 68:15,18 69:21 70:5
 70:11 71:12,17,17
 72:8,9,16,18,20,22
 73:15,19 74:2,4 77:4
 77:6,19 78:2,4,9
 79:12,20,21 80:2

81:12 82:3,15 83:9,19
 85:5,7,10,11,16 86:4
 87:3,15 94:4,17 96:6
 96:16 97:6,7,11,19
 98:5,8,16,19 100:5,20
 101:21 102:1 105:15
 107:9,19 108:1,6
 109:4 110:20 111:11
 111:21 112:11,16
 116:16,19,20 119:17
 120:2,19 121:22
 122:20 123:2,8 126:8
 131:4,14,18,21 132:7
 132:17,18,22 133:7
 133:14 137:12,13
 138:14 141:6 142:4
 144:3,4 145:19
 146:10,12,14 147:10
 149:7 151:6,7 154:5
 155:12 156:6 157:6
 157:20 158:13,18,20
 159:11 160:3,5 161:9
 162:17,19,20,22
 163:18,21 164:1,12
 165:1,18 166:9,12,14
 167:16 168:2,21
 170:9 172:9,22 173:2
 173:3,6,7 174:6,9,19
 174:22 175:2 177:8
 177:10 179:4,11
 180:1 181:14,18
 182:18 183:7 184:2,7
 184:16,20 187:19,22
 188:2,9 189:19 190:1
 191:11 193:19 194:3
 195:10,18 196:4,14
 196:16 198:8 199:4
 199:16 200:4,12,17
 201:3,14 202:14
 203:3,18 204:7,13
 211:17,21 212:6
 213:2,3,7 215:6,13,15
 216:13 217:11 218:20
 222:5,9,18 223:12,16
 223:21 224:10 225:22
 226:10 229:6,21
 230:4,13 231:13
 235:9 241:21 242:9
 243:12 245:10,15,16
 246:3 247:1,9,14,19
 248:7,9,14,14 249:10
 249:12 250:12 251:7
 251:15 259:19 260:6
 260:12 261:4,22
 262:11 263:5,20
 264:6,14,17,22 265:3
 265:17 266:15 267:19
 269:2,7,9,10

measured 20:22 26:21
 31:18 32:20 83:9
measurement 2:8,12
 3:3 17:14,15 107:16
 108:12,13 211:22
 238:8 252:2,3 268:10
 269:4
measures 5:12 6:22 7:4
 7:10 8:10 12:20 13:5
 16:6,14 24:8,12 25:13
 25:19,21 28:8,16
 32:14 33:12,13,21
 34:5,15 38:9,12,19
 40:3 41:1,10 42:6,7
 42:11,17 43:8,9 44:13
 46:14,20 47:3,6 49:13
 59:11 62:19 63:6 67:2
 72:9 76:20 79:14
 82:12,22 93:5 94:12
 94:13,14 101:8
 105:16 109:2 113:6
 113:12 126:18 129:3
 133:6,22 136:9 145:6
 145:7,14 146:17
 147:2 148:2,15
 149:14 150:16,21
 153:2,17,22 154:1,7
 157:9,13 158:1,9
 166:17 170:20 171:22
 172:7,18 173:15,19
 176:10,14,16,18
 177:22 178:5,8 187:9
 197:14,17 198:7
 204:19 205:20 206:3
 206:13 209:8,9,14
 210:12 211:4 212:11
 213:1,10,13 214:10
 214:14,17,20 215:3
 215:20 216:1,6,12
 217:21 218:4 220:19
 222:3,21,22 223:1,4,8
 224:15 225:2 237:4
 237:11 242:19 243:3
 243:4,8,10,18,20,20
 244:2,3 248:17 250:2
 250:4,19 251:8
 253:10 265:18 267:1
 268:16
measuring 10:19 17:12
 23:8 38:10 61:1
 179:15 263:5
mechanical 121:16
 122:10 124:15 249:6
mechanism 60:18
 97:17 215:19
media 11:12
mediastinal 132:11
 155:16

mediastinitis 155:20,22
 159:5 163:5
medical 1:18 2:5,10,14
 2:21 34:3 39:3 244:11
Medicare 139:11,14,15
medication 166:13,18
 166:19 249:20,21
medications 249:16,18
medicine 1:21 2:3 23:4
 31:2 255:1
medicines 185:13
 188:21
meet 11:9 64:7 158:18
meeting 6:4 16:12
 61:17 92:4 176:12
 209:4 213:15 219:20
 219:20 266:19 267:5
 269:21 270:8
meetings 114:8 207:8
meets 173:3 179:5
Melinda 3:5 10:3 83:2
Melissa 2:20 32:10
 90:17 233:11
member 49:1 68:10
 196:20
members 1:10 92:15
 114:10 197:12 204:9
 207:13 208:9,20
 215:2
membership 208:10
Memorial 2:19
memory 6:19 7:15
 145:5
men 236:8
mention 34:12 48:19
 85:4
mentioned 6:16 52:16
 70:10 129:8 214:11
 218:15 219:6 221:20
 268:8
menu 175:9
merely 238:3
merit 170:9
message 77:21 257:13
met 1:7 24:10 28:22
 88:19 167:11 179:7
 227:15 257:17
method 149:10 156:20
 156:22 215:14 259:21
methodological 216:18
methodologies 254:14
methodologist 78:22
methodology 34:7
 46:15 109:16 239:6
 262:17
methods 16:21 150:17
metric 10:19 11:4 17:22
 18:13 19:9 25:7 77:8

117:20 199:8
metrical 17:19
metrics 3:14 17:4 28:19
 36:22 211:20
MHA 2:15
mic 143:9 172:2
Michael 23:5
Michigan 125:1
mid 219:12
middle 61:17 64:12,16
 155:8
mike 20:17
million 13:7 256:13
millions 208:9,9
mind 8:22 36:21 163:12
 190:1
mine 135:13,16 230:17
 238:3
minimal 159:17
minimize 99:15
minute 49:5
minutes 36:15 45:5
 111:3 118:17 176:19
mirror 230:18
miserable 111:10
 217:11
misfire 112:4
missing 6:3 228:11,13
 228:16
mistake 195:14 245:18
mistaken 150:19
 183:13 250:21
mitigate 11:19 41:19
 45:14 254:20
mitigated 96:8
mitigates 96:3,12
mitral 50:17 197:20,20
 224:12,16,18,20
 225:12,14 230:20,21
 231:15,21 235:12,19
 236:6,9,9 237:15,18
 237:19,22 243:19
 244:2,2,7
mix 68:7
MN 2:12
model 65:8 121:21
 122:14 125:21 128:9
 128:11,14,21 129:2,2
 129:4,9,13,16 130:3,6
 130:9,13 148:20
 225:4 227:8,10,12,18
 227:18,19,20 250:5
 256:6 261:17,20,21
 263:13
modeling 148:1 211:6
 227:4
models 25:11 50:6 51:4
 96:19,20 211:10

231:5,12 254:22
 258:18
moderate 70:4 81:11
 82:1 87:2,9 93:15
 107:8 112:10 116:15
 117:7 119:16 126:8
 128:4 131:4 147:8
 152:18 154:3 157:5
 157:18 158:11 164:21
 165:17 168:1 179:21
 181:17 193:20 194:1
 195:8 196:3 200:3,16
 203:17 204:5 229:5
 230:3 234:17 235:3
 241:20 242:8 247:8
 247:18 262:10 263:4
 263:20 264:5 265:2
modes 256:21
module 127:11,19
modules 93:11
moment 29:6 158:5
 166:7 261:3 264:8
 265:20 266:17
momentum 225:9
money 106:19 119:5,6
 213:21
monitor 41:8
monitoring 57:15 172:8
month 76:12 102:10
 255:8
months 28:1 38:14
 102:9 111:5,7 136:7
 221:21 240:5
morality 198:3
morbid 15:10 22:13
morbidities 124:12
 249:2
morbidity 97:3 124:18
 163:7 248:21 249:1
moribund 259:5
morning 5:22 6:13
 198:4,12,19 216:16
 226:2 236:21 242:20
morning's 120:10
 199:11
moronic 238:17
mortality 10:6,21 11:17
 11:20,21 12:2,8,21
 13:5,6,12,20 14:13,18
 15:20 16:3,18 17:22
 18:14,20,22 19:10,17
 19:21 20:7,8,21,22
 22:8,10,11 23:1 28:19
 38:9 39:14 42:5 50:7
 50:11 53:9,19,19 54:3
 59:13 62:15 66:1,10
 66:15 67:11,12 68:3,5
 72:17,19,20 73:12,18

74:8,12,16 75:5 79:20
 88:3,19 89:1,3 94:18
 95:9,10,14,17,21 96:2
 96:2,6,8,9,10,16 97:1
 97:3,6,13,14 98:3,4,7
 98:8,11,16,17 99:10
 99:20 100:12,18
 101:2,3 102:2 105:20
 106:1,2 108:14
 110:21 111:12,17,22
 113:8 119:11 122:1
 122:15,16,21 123:9
 123:21 124:11,19
 126:18 137:17 141:12
 151:8 163:7 196:17
 197:15,19 198:4,6
 199:9 201:6 224:11
 224:15 225:2,12
 231:1,20 235:12,19
 236:22 239:1,2,9
 240:3,10,14,21 241:3
 241:10 248:20 255:14
 256:16,22 259:14
Moss 2:7 30:13 32:12
 65:5 105:13 116:1
 123:7,18 125:17
 126:11 128:7 129:19
 130:6,15 131:7
 156:10 204:16 206:17
mother 57:19 58:2 64:4
 74:6,17
move 42:16 70:6 71:3
 82:4 93:18 107:9
 117:8 126:10 138:16
 142:4 147:11 148:6
 157:7,21 158:21
 165:2,19 166:10
 168:3 169:14 180:13
 182:4,21 193:9 194:4
 196:8,15 197:13
 198:5 199:5 202:11
 203:4 215:12 222:17
 223:11,13,16 226:11
 229:9 230:14 234:19
 238:14 247:13 248:1
 251:16 263:6
moved 71:1 137:14
 222:18
movement 43:5
moves 22:7
moving 21:18,19 22:4
 23:2 44:8 94:16
 124:16 127:20 132:2
 132:6 221:8,22
 248:13,13 253:15
MOYER 2:8 26:17 47:16
 83:16 173:12 190:13
 267:18

MPH 1:13,18 2:15 3:2
MSHS 2:1
multi 69:14 124:9
multi-domain 97:2,7
 124:21 133:1
multiple 60:12 98:9
 100:10 114:8 127:20
 216:1
multivariable 122:14
MURPHY 3:5 10:12
 65:19,22 66:5,19
 74:20 145:3 146:9
 267:15
mute 82:6
MV 240:2

N

N 238:21
N.W 1:8
naive 129:20
name 27:1 48:13
names 245:2
narrows 102:21
national 1:1,7,14 3:17
 48:22 116:3,6 219:20
Nationwide 2:7
natural 15:20 17:14
naturally 11:8
nature 105:18
Nebraska 2:10
necessarily 44:1 56:11
 57:11 73:6 83:22
 89:20 245:9
necessary 61:6,19
necessitate 156:11
necrotizing 111:9
need 10:13 18:1 25:20
 26:22 30:18 31:5
 33:13 35:20 38:8 40:6
 41:8,12 50:22 64:20
 76:16 77:7 78:19 94:1
 110:15 117:19 144:7
 171:20 185:4 212:4
 213:22 218:5 219:5
 221:7 222:3 223:5
needed 142:22 266:22
needing 187:3
needle 44:8 71:2
needs 29:12 74:7 75:16
 90:3 185:8 199:13
neonates 99:4
nesting 128:16 129:21
 129:22
net 24:8
neurodevelopmental
 124:2
neurologic 122:12
neurosurgery 1:15

213:13,17 214:7
neurosurgical 213:12
never 21:1 24:15
 113:20 144:18 184:10
 185:22 222:21
nevertheless 105:22
new 7:9 10:9 14:7 32:13
 33:5,6,7 34:12 44:12
 52:16 91:16 103:21
 119:3 120:11 121:22
 123:2 132:17 135:13
 135:13,17 137:6
 170:22 217:11 221:11
 243:12 246:1 250:3
 251:18
newest 122:20
news 89:22
NHSN 212:2
nice 6:1 112:21 133:13
 236:20
nicely 202:14
night 25:14 92:18
 216:16
nightmare 257:8
NIH 124:8,20
nine 177:21 178:13,14
 214:16 215:1 241:6
Ninety 138:13
Ninety-five 196:12
 199:2 203:1
NLM 221:12
nobody's 167:15
noise 264:13
non 186:9,15
non-cardiac 122:6
non-operatively 57:6
non-reporting 245:2
non-surgical 56:12
nonpulsatile 258:15
normal 22:9 115:18
North 58:22,22 76:6,13
Norwood 121:9,14
notable 53:20 84:11
note 154:21 260:21
noted 58:6
notice 13:2 152:15
noticed 136:14 257:22
November 52:18
NQF 3:1 5:14 6:2,18
 13:11 27:18 28:22
 49:2 63:5 64:18
 133:14,18,22 144:5,6
 144:17 145:2,19
 147:5 158:18 161:17
 162:6 169:21 170:5
 171:12 172:7 173:3
 174:18 175:10,19,22
 196:19 205:20 206:19

209:9,10 212:15,19
 214:22 216:2 218:5
 220:6 237:10 248:16
 250:2,4
NQF-endorsed 61:22
NSQIP 209:6,14 210:4
 210:21 212:2 269:20
 270:6
number 24:10 73:20
 75:4 79:13 91:11
 97:12 118:20 122:2
 129:14 136:17 139:8
 159:18 160:4 178:5
 187:19 191:19 192:15
 197:7 199:13 206:9
 207:6 219:14 229:17
 244:17 248:19,20
 260:8 266:11
numbers 71:13 91:5
 101:13 106:9,10
 230:19 253:1
numerator 88:18
 107:13
Nurse 2:14
nurses 114:9

O

O'Brien 125:2
o'clock 5:8
O/E 89:2 256:16,20
 257:8,10 261:14
obesity 15:10 22:13
object 150:2
objection 182:1 247:20
 248:1
objections 165:4,6,22
 181:6,21 195:11
 196:6,8 200:6,9,18,21
 203:19 204:8 229:7
 230:5,9 234:14,18
 235:5 241:22 242:10
 247:11
objective 51:14
objectively 161:18
objects 181:5
observable 240:10
observation 238:4
observe 122:15
obstetrical 208:16
Obstetricians 2:5
obstructive 255:19
obtain 91:13
obviously 13:13 16:17
 32:14 34:14 53:10
 102:1 191:18 204:19
 209:6,7,15,19 218:14
 219:15 230:19
occasion 219:1

occasionally 257:9
occluded 192:10
occlusion 132:12
occur 14:1 97:20 173:5
occurred 9:15
occurring 13:6 27:15
 99:6 225:17
occurs 97:21
offending 106:17
offer 44:17 269:22
offered 207:16
offering 15:2 30:4,5
 56:12
offers 268:14
Office 1:14
Officer 3:2 6:2
offline 44:19,20 89:15
oftentimes 108:19
 111:6
OGUNGBEMI 3:6
oh 27:10 56:5 101:6
 162:8 183:21 193:11
 193:16 195:13 253:9
 259:8,8
okay 8:5 10:2,14 43:22
 47:5 48:6,9 52:13
 55:2 56:6,21 63:10
 78:5 80:15,20 81:2,22
 82:13,18 85:13 94:2
 94:12,16 109:22
 110:5 112:6 117:11
 120:8,18 126:4
 131:12 142:3,21
 143:1 154:14 156:15
 158:6 160:10,21
 161:8 165:14 166:8
 167:6 168:4 179:20
 180:11 181:11 187:11
 190:18 197:12 198:8
 199:22 224:2 238:10
 238:11 241:4 251:5
 251:13 263:2,17,19
 264:2 266:9
old 54:11 132:18,22
 184:6
older 132:8 137:11
 159:4 184:4 188:10
 189:9,11 198:11
 225:13
olds 190:4
OLSEN 2:9 160:9
omphalocele 122:7
once 6:6 12:7 90:10
 113:21 137:3 150:6
 150:11 153:10,17,17
 157:8 261:10
oncology 25:5,6
one's 71:8 154:11

onerous 210:18
ones 101:9 104:8
 126:18 176:17 191:12
 207:7,22 243:18
 256:19
ongoing 42:14 135:20
 136:2,12
online 104:2
open 6:12 20:17 45:17
 47:19 120:16 137:7
 196:22 197:3 206:5
 210:16 265:21 266:3
opening 183:4
openly 39:12
operate 12:2 15:19
 22:19 35:22 96:13,17
 140:14 192:2 207:14
 254:11
operated 187:20 192:3
operates 97:22
operating 16:17 36:12
 56:19 113:21 121:11
 121:15 139:22 156:12
 232:15,17
operation 12:21 51:5
 55:15 57:4 69:6 74:7
 74:9 76:5,12 111:3,8
 113:22 116:7 118:5
 118:16,18 121:9,14
 122:3,4 126:22
 184:13 185:11 192:10
 236:3
operational 68:8
operations 20:7 50:22
 51:2,6,11,12,15,17,19
 51:21 52:4 60:2,8,20
 61:20 67:15,18 74:13
 74:14 75:4 84:12
 113:20 121:4 126:21
 191:15,21 229:16
 232:10
operative 11:20,21 12:8
 13:20 14:13 51:7 53:9
 53:19 54:3 86:12
 88:19 94:17 95:9,14
 95:17,20 96:1,8 97:13
 98:16 99:10,19
 100:12 122:1,21
 134:18 196:16 197:15
 197:18 198:2,3,6
 201:6 224:11,15
 225:1,11 231:1,20
 235:12 236:22 238:22
 239:9 240:3,10
 248:20
operatively 34:21
Operator 197:3,5
 265:21 266:6,9

opinion 10:18 28:10
29:2 51:9
opinions 12:6
opportunity 25:15 26:2
40:13 77:6 126:2
138:16 179:6 260:22
opposed 19:18 85:11
151:20 185:16
opposite 30:19
optimal 2:1 143:15
229:3 241:18
optimize 18:13
opting 90:15
option 108:15 179:4
optional 90:5 127:18
options 138:11
oral 92:9
order 11:17 94:21
167:17 211:8 217:20
ordered 194:13
organization 2:16
204:20
organizations 207:10
oriented 28:12
original 52:17 260:19
originally 100:2 246:19
originates 219:2
ought 36:19
out-of-house 20:8
outcome 10:20,20,21
11:3 18:6 23:5,7,22
32:19 38:18 53:16
59:11 60:1,10 84:8
85:3,9,11,12 97:2
99:20 123:5 127:1
130:16 133:7 138:10
154:18 157:22 158:8
159:10,12,14,22
161:1 167:3,11 169:4
196:15 197:14,17
199:8 234:10 248:17
257:20
outcomes 12:5 19:4
27:20 51:3 60:19
62:20 63:3,4 68:22
69:1,15 97:5 124:1,2
125:1 130:1,3 140:4,5
140:10 162:19,22
163:13 208:16 223:17
225:22 231:2,10
246:3 247:1 249:14
251:1
outflow 55:15
outlier 84:20 160:17
199:19 253:5
outliers 75:12 102:22
103:5,6,10 125:22,22
126:1 148:5,16 160:6

252:20,22 253:3
outline 126:3
outlined 202:14
outlived 76:18
outpatient 7:9 14:14
outputting 117:21
outside 115:14 174:21
216:7
outweigh 36:13
overall 16:18 24:14
42:6 51:7 68:4,5
72:19 73:1 87:10
88:15,20 93:19,21
109:1 114:7 119:19
119:21 130:20 131:19
137:12,16,17,21
143:15 158:14 166:2
166:6 173:20 182:4,4
196:9 200:22 201:14
204:11 229:2 230:10
235:8 241:17 242:15
245:12 248:2,4
255:22 265:13
overestimate 130:2
257:18
Oversight 193:1
overwhelming 118:11
208:8
ownership 218:21

P

P 3:11
P-R-O-C-E-E-D-I-N-G-S
5:1
p.m 224:7,8 270:10
package 21:17
packet 167:4
page 202:4 213:9
238:20 239:18,21
240:1
pages 117:17 118:1,7
118:11
paired 52:22 63:12,19
65:17,20,21,22 66:21
72:14 73:14,19
173:15
pairing 53:2,4 62:14
palliative 10:17 11:16
40:11 41:18 44:21
45:10
panel 43:1 221:21
paper 10:15 118:13
139:6 147:18 192:20
256:11
papers 10:21 59:20
60:3,12 84:13 100:10
124:17 127:17
parallel 124:18

parameter 75:1
pardon 129:19
parent 91:21 135:7
parent/child 118:2
parents 92:12
parse 190:22
parsimonious 211:18
Parsons 28:6
part 11:14 24:14 26:21
28:6 68:19 86:21
129:4 132:22 137:4
145:20 148:6 156:5
164:8 168:22 170:13
187:4 206:17 221:5
256:9
participant 20:21 81:4
81:8 83:3,8 111:18
117:3 129:5 140:6
participants 102:9,11
103:11 136:6,18
154:22 155:8 229:16
238:21 241:2 257:14
participate 9:11 46:3
69:3 81:19 90:4,6,13
103:15,18 104:1,5
139:9 140:2 214:17
244:20
participates 68:16
139:11
participating 20:19
68:21 73:8 104:2
109:14 139:1 219:15
participation 79:17
107:19 109:12 178:2
particular 9:19 75:1
111:21 139:22 141:5
141:15 163:4 194:22
214:13 221:7,9 239:8
239:14 264:14 269:3
particularly 7:2 41:11
46:15 192:19 208:16
223:14
parties 28:21 115:14
partner 183:1 213:12
partnered 91:20 127:10
127:14
parts 146:6
Pasquali 124:22
pass 39:18 78:13
161:21 162:4 180:1
190:18,18 268:12
passed 25:8 162:15
passes 70:6 81:12 82:3
87:3,15 93:16 94:4
100:5 107:9 112:11
116:16 119:17 120:2
123:16 126:8 128:5
131:4,22 138:15

147:10 154:5 157:6
157:20 158:13,21
161:9 165:1,18 166:9
168:2 181:18 194:3
195:10 196:4,14
199:4 200:4,17 201:3
203:3,18 204:7,13
226:10 229:6 230:4
230:13 235:9 241:21
242:9 245:15 247:9
247:19 248:7 251:15
262:11 263:5,20
264:6 265:4,17
pathway 209:11
patient 2:1 11:1 12:20
13:8 18:8 19:5,8,12
22:1,11 23:20 25:10
30:8,20 31:13,17 33:4
33:10,16,18 34:2 35:5
36:9 37:1 39:4,5,18
42:22 54:20 55:11
77:1 90:18 92:22 96:4
97:4 99:12,17 106:16
121:6,7,9,13 126:22
130:1 135:7 163:6
164:15 183:12,13
184:6 186:10 187:2
198:17 231:9 241:2
254:11 269:20
patient's 25:2 32:13,15
232:3,8
patient-reported 12:5
18:6 19:4 27:20 38:18
42:11
Patient/Family 2:20
patients 12:2 15:2,3,9
16:16 17:21 18:15,18
18:19,20,21 22:4 23:6
23:9,13,17,19 25:8
35:10,11 36:11,19
38:13 40:14 46:5 55:9
56:12 57:6,13 88:18
90:22 91:4 96:14,18
97:22 98:20,20 99:5,5
116:4,7 130:10 132:8
132:14 159:3 166:20
183:19,19 184:11,20
185:4 186:11,14,21
188:17 189:10 192:1
192:7 194:10 198:10
201:9 207:13 222:12
225:13 231:3,7,8,15
232:14,16,20 248:22
249:17 254:17,17
256:8,13
Patrick 6:16
patterns 25:18
pay 62:2

payment 22:17 222:6
payments 15:7,7 21:18 39:13
PDA 110:18 111:18
PDA's 110:10 111:2
pediatric 49:11,18 50:14,21 52:14 54:8 54:15,17,19 56:10 59:7 63:4 67:8,9 76:3 76:12 79:17 84:9 91:22 94:13,18 98:19 99:4 110:22 113:19 115:1,6,10 117:17 123:22 130:11 150:5
peer 10:22 98:10 100:10 135:21 167:1
penalizing 33:17
penalties 22:17 222:13
penalty 222:6
penetrance 49:21 61:7 61:11,15 64:3 70:11 71:15 127:19 137:3 138:22 139:6,7,16
penetration 73:6 90:9 93:9 117:14
Pennsylvania 1:12
people 12:1,7 15:1 16:5 22:18 23:22 24:1,2 25:14 27:6,21 33:17 33:21 34:20 36:8 38:2 39:7 45:6 46:2 57:12 63:7 80:6 84:8 90:6 91:12 104:7 115:18 125:11 126:13 137:14 144:22 155:15 160:15 207:18 211:8 212:1 212:18 214:1 217:3 219:14,18 220:5 253:2 258:5,18 259:3
people's 12:6
percent 17:3 22:9,12 49:21 50:2,19,22 51:20,22 57:1 61:6,11 61:13,13 64:3,5,7 67:15,17 69:4 70:3,4 70:4,14 71:9,14,14,14 73:9 74:9,12 79:13,22 81:11,11,11 82:1,1 86:6 87:1,2,2,14,14 90:9,10 93:14,15,15 94:3,4 100:18 101:1,1 101:3,12,17 103:3,4,5 103:6 104:15,16 105:2,2 107:7,7,8 108:3 112:10,10,11 112:15 114:3,5 116:14,15,15 117:7,7 117:8 119:15,16,16

120:1 126:1,7,8 128:3 128:4 131:3,4,21 132:7 137:3 138:14 138:14,19,22 139:17 142:19,20 143:2 147:7,8,8,17 148:11 150:22 154:2,3 157:4 157:4,17,18,18 158:10,10,11,11 159:3,18,19 160:6 161:14,20 162:3,21 163:2,11,12 164:20 164:21,21 165:16,16 167:22,22 168:6,10 168:11,16 177:7,9 179:21,21,21,22 181:16,16,17 193:22 193:22 194:1,1,8,21 195:1,2,3,8,8,9 196:2 196:2,12,13 199:2,3 199:10,19 200:2,2,15 200:15 201:2 203:1,2 203:17,17,17 204:4,5 204:5 225:12 226:16 226:17,19,20,21,22 229:4,4 230:2,2 232:15 233:2 234:16 234:16 235:3,3,20,20 235:20 238:22,22 239:1 240:20,20 241:1,19,19 242:7,7 246:9,10,11,13 247:8 247:17,17 250:9,11 251:14,15 252:2,5,19 252:21 253:3 257:16 262:9,9 263:3,3,19,19 264:4,4 265:2,2
percentage 14:1 58:7 88:22 163:3,14 166:20
percentages 240:19
percentile 168:5
percentiles 155:2 241:1
perfect 31:8 55:19 86:20
perform 49:18 60:7 139:8
performance 20:4,5 36:16 62:5,7 70:7,16 70:18 71:1,6,12 75:13 76:18 77:4 78:10,20 79:2,3,4,22 80:8 81:3 81:13 84:20 100:6,8 101:6 106:12 107:6,9 107:22 108:20 110:22 111:14 112:1,22 123:17 125:18 126:9 136:3 137:12,16

138:17 141:3,5,13 142:6 143:11,13,15 147:1,7,10 148:7,9,16 151:15,17 152:7 153:4 164:18 165:1 168:3,6,10,12 169:12 170:19 172:20 175:13 179:19 180:1 194:4 195:5,6,10 199:5,7 200:1,4 201:15,19 202:7 203:4,6,8,18 219:1 226:11 228:1 228:19 229:1,2,3,6 234:13,15 235:18 238:14 241:13,16,18 241:21 246:4,15,20 247:6,10 251:16,20 262:5,8,11
performances 157:2
performed 67:19 122:3 225:16
performers 20:1,2 159:17,19 168:8,10 168:11 202:6 239:13
performing 103:4,5,7 142:8,9,17,18 160:16 194:20,21
period 37:4 116:10 201:16 226:17,18,19 226:21 239:10,11 255:14
periodic 172:8,16
periodically 172:18
periods 137:10 227:1 236:5 238:7 246:8 263:12
perioperative 249:16 249:18
permanent 249:7
person 13:14 214:6
personally 20:18
perspective 32:13,15 73:16 90:21 144:5,6 185:2 232:4,8 237:10
perspectives 28:12
perverse 96:16 97:14
perversely 96:3 125:7
Pete 48:16 107:2
Pharmacists 2:11
Pharmacy 2:10
PharmD 2:9
philosophical 30:14
phone 9:21 29:4 38:5 44:12 45:7 52:7 92:18 213:14 251:14
phones 197:1
phonetic 155:18
physicians 1:19 207:7

218:19
pick 110:8
picture 86:17 102:14 103:12
piece 19:7 42:11,14 94:7 97:7 133:16 202:2 228:16
pieces 133:20
pile 136:9
pinch 33:14
pinhead 187:7
pipeline 124:4 218:7
Pittsburgh 2:21 35:20 36:3
PITZEN 2:12 38:7 65:16 65:21 66:2 85:18 86:20 93:3,8 98:15 100:17 107:12 108:18 109:19,22 110:5 112:13 117:12 152:21 184:1,22 189:6
place 38:19 42:8 57:2 60:18 76:11 85:21 160:18 164:4 255:3,5 259:4
places 6:6 75:20 137:6 137:7 142:9
plan 32:7 93:4 232:15 232:20 268:6
platelet 166:13
platelets 194:17
plausible 146:7
play 19:18 136:16
playing 254:15
plays 30:6
please 69:21 83:14 93:13 131:9 197:6 245:13 266:10
pleased 220:14
pleiotropic 192:13
plenty 60:8 79:15 84:13
plug-and-play 221:16
plural 41:4
plus 136:9 245:21
PMP 2:20
pockets 23:9
point 12:16 13:2,17 14:6,7,17 18:3 19:16 22:2 27:9 34:20 36:10 37:17,18 40:15 42:3 43:11 44:14 48:4 77:5 105:4 113:9 114:19 116:2 117:18 121:18 135:10 143:18,18,20 152:22 162:2 163:3 175:7 179:2 194:12 209:13 210:1,6 212:18 213:20 217:20

218:17 242:20 244:10
pointed 32:12 102:16
 194:11 198:12
points 19:6 40:19 41:20
 62:19 95:18,21 102:7
 144:14,15 163:14
Poland 58:17
Policy 2:4
polled 16:12
pool 59:2
poor 105:8
poorly 227:17
population 24:12 30:11
 130:14 183:17 187:4
 192:7 201:8 252:7
populations 23:21
 38:11,20
Porter 23:5
portfolio 172:7 268:10
portions 118:2,9
pose 21:9
position 29:10 66:7
positive 256:4
possibility 256:5
possible 12:18 37:12
 39:15 97:18 109:13
 109:15 155:6 194:14
possibly 191:11
post 34:20 99:18
post-CABG 22:10
post-meeting 266:19
post-op 221:15
post-operative 37:3
 116:9 192:14
posted 267:10
postoperative 124:12
 124:13,14,14 164:12
potential 10:5 25:16
 30:21 35:15 37:16
 70:13 172:9 253:21
 254:2,20 269:2,6
potentially 20:15 29:10
 29:13 40:10 71:18
 130:2 190:15 212:18
pound 209:5
PQRS 93:5 94:7,15
 214:18
practice 2:10,13 13:1
 22:3 66:7 99:7 167:9
 193:2 260:10
practices 39:10
practitioners 31:7
precedent 177:11
precise 109:17
precisely 149:7
preclude 174:16
predict 256:22
predictably 241:10

prediction 130:10
 263:12
predictor 108:22
 227:12
predictors 228:3
 255:17
preemie 110:10,18
preemies 110:15
prefer 152:8
preference 30:9
preferences 25:3,10
 31:14
preliminary 213:14
premature 111:2,6,12
 111:17
prematurity 111:10
prenatal 121:10
preoperative 121:20
 122:4,8,11,11 249:19
 255:18
preparation 16:11
Prescribed 167:13
prescription 167:14,17
present 3:8,22 12:10
 29:2 37:9 269:19
presentation 48:10
presentations 92:9
presented 8:21 29:3
 81:15 150:20 266:18
presenting 10:7,18
 255:8
President 2:4 3:2
presiding 1:9
press 197:6 266:10
pressure 22:14,17
pretty 9:4 43:14 46:20
 58:4 84:2 89:12
 108:17 123:10 130:17
 136:17 149:19 155:21
 166:11 173:9 176:20
 181:2 184:12 194:7
 195:1 207:5 217:19
 222:19 226:1 228:12
 229:16 252:7
prevent 18:11 96:19,21
prevented 11:8 168:15
prevention 192:6
previous 109:7 122:12
 131:14 149:15 165:5
 168:21 183:7 200:7
 200:20 203:20 225:1
previously 225:10
 250:2,4
pride 35:1
primary 14:2
principle 133:19
prior 56:19 82:13 211:4
priority 262:13

probably 32:3 35:4 37:4
 46:20 57:18 61:13
 76:8 78:6 109:11
 136:12 137:1 168:14
 184:10,15 186:1
 188:20 191:18 218:22
 227:18 231:3 233:7
 257:2 258:5
problem 21:14 76:4
 96:3 102:15 111:10
 156:7 160:18,20,20
 163:8
procedural 179:2
procedure 11:6 38:15
 50:7 69:6 73:22 99:12
 99:18 107:14,18
 129:6 225:16,19
 239:2,3
procedures 29:21
 32:17 57:12 69:9
 107:17 109:7,9
 118:10 129:11,12,16
process 5:10 7:10,15
 21:22 37:12 47:19
 50:2 57:22 82:21 85:7
 85:12,15 88:4 92:6
 97:17 98:1 108:6
 114:6,12 125:18
 126:12 138:11 141:19
 145:9 149:16 152:13
 161:3 162:20 166:14
 166:17 167:11 170:17
 177:8,9 179:9,10
 187:15 188:2,4 190:8
 190:13 193:19 202:16
 203:14 204:18 206:4
 207:10 214:22 216:2
 217:14 220:20 221:2
 222:19 223:11 234:11
 248:17 249:10,12
 256:9 267:14
processes 99:16 123:9
 128:18 159:13
produce 213:9
professional 2:13
 207:6,9 213:20
 219:21 244:11
Professor 1:11,16,20
 2:2,9,15,21
program 1:14 2:6 67:22
 68:19 84:21,22 88:14
 90:3 93:5 111:1,14
 112:1 222:6,7 244:15
programmatic 72:19
 88:16,20 110:22
 111:13,22
programs 60:16 84:9
 84:15,16,17 90:13,15

103:4 104:15,18,20
 106:2 244:17,19
 245:2,5 250:6,8,10,10
 255:22 257:2
progress 267:11
project 3:3,5,6 221:11
 266:21
projects 59:1
prolonged 34:22 37:2
 97:10 249:6 251:1
prolonging 97:19
promoting 59:9
prompted 178:21
proof 128:11
properties 265:1
proportion 249:17
proportional 236:1
proposal 222:17
proposed 146:4
proposing 43:13 45:14
proprietary 211:1
prosthesis 237:20
protect 23:13
protecting 23:17
proud 120:21
proves 108:16
provide 11:2 64:20
 74:19 75:11 128:10
 130:9 155:6 187:17
 227:13,13 233:21
 247:1
provided 83:20 100:20
 112:13,18 128:15
 151:22 152:8,11
 154:21 167:3
provider 112:22 127:2
 208:18
providers 21:2 87:22
 96:4 101:14 143:16
 155:8 241:18 254:15
provides 122:1 136:8
providing 10:1 75:8
 139:8
public 4:10,20 26:5,7
 28:19 39:2,8 72:13
 76:22 88:9 89:8,14,16
 90:1,16 91:7,16,17
 102:1 103:15,19
 105:9 134:3,7 140:7,8
 146:21,22 164:1,4
 174:7,15 175:18
 196:20 197:4,6,8,11
 208:13,15 222:11
 243:14 244:4 253:12
 253:14,18,22 254:4
 255:4,10,15 265:21
 266:7,10,12
publically 74:2,4,18,22

75:1 77:20,22 80:2
 87:19 90:12,14 91:3
 104:5,8,18,21 105:5
 123:1 140:4,4 147:4
 175:9
publication 225:5
publications 98:9
 135:21
publicly 12:18 242:21
 243:3,4,10,15,22
 244:14 245:7,8,9
 250:6,13,14 253:10
 254:12
publish 34:13 127:16
published 59:20 84:13
 124:17 184:18 185:7
 256:11
publishing 255:7
pull 178:4
pulled 129:17
pulmonary 55:14
 255:19
purchaser 73:16 78:13
purchasers 222:12
purely 58:10 97:19
purpose 76:18
purposes 34:16 77:2
 172:11
push 25:20 45:19
 237:11
push-back 16:16
pushed 31:10
pushing 33:21 57:13
put 22:16 26:14 29:15
 30:19 34:1 35:12 37:6
 38:18 42:8 44:5 45:18
 60:13,15,20 61:10,12
 65:1 67:20 68:11
 77:13 80:8,21 86:14
 110:3 114:19 121:15
 122:13 125:9 146:15
 165:10 169:13 175:8
 177:4,22 179:15
 180:21 186:21 211:6
 212:14 217:15 237:3
 237:3 250:4
putting 25:10 89:9 91:2
 92:7 121:21 123:2
 164:7 174:5 210:3,6

Q

QCDR 215:14 218:2,9
QI 222:5,9
qua 186:15
qualify 65:10
quality 1:1,7,17 2:6 3:2
 3:14 18:22 22:5,7
 23:21 26:4 30:17

38:16 59:8,19 60:15
 60:22 76:19,21 77:6
 81:18 83:20 84:1,9
 101:20 103:19 105:8
 105:21 119:8 135:18
 136:6 146:8 163:20
 181:15 204:20 207:12
 208:4 213:13 218:21
 229:22 262:19
question 11:15,22
 13:21,22 20:9 27:12
 27:18 28:5 37:9,11
 39:14 41:15 53:2,13
 54:7,10 56:15 58:5
 61:2,10 62:5,13 63:11
 63:20 65:16 68:14
 72:7,16 73:10,15
 74:20 78:8 79:7 80:4
 81:17 82:20 85:19
 86:3,18,19 88:6 93:1
 93:3 104:11 106:14
 110:14 113:8,16
 115:9 116:19 124:7
 129:20 133:8 144:1
 144:18,22 147:14,14
 147:22 148:7 149:21
 151:19 152:1 155:13
 160:22 161:7 171:14
 175:20 183:9 186:8
 189:13 194:9 204:17
 205:15,22 227:2
 229:21 230:16,20
 231:1 235:16 237:12
 238:16 241:16 242:16
 243:21 253:20 255:12
 258:11 259:9 262:15
 264:10 268:1
questioned 115:14
questioning 183:15
questions 47:14 87:13
 91:10 93:20 115:19
 126:5 131:1 141:1
 158:16 164:13 165:21
 182:13 185:15 200:11
 212:10 228:19 229:13
 232:1 234:21 238:15
 241:13 247:14 248:3
 250:16 261:1 263:1
 265:14 267:13
quick 49:8 61:2 88:6
 109:19 123:18 126:16
 217:6 238:16
quicker 159:16
quickly 70:1 167:13
 217:9 223:14
quintiles 256:15
quite 15:13 31:15 32:5
 50:1,4 68:5 104:18

108:13,14 112:8
 145:15 166:4 210:11
 226:20
quote 252:17

R

R01 124:8
radical 43:15
raised 31:17 43:11
raises 116:1
raising 21:9 102:6
 189:13
random 189:15 264:16
randomized 192:11
randomly 86:7
range 15:4 51:2,3
 135:22 185:5 188:6
 201:17 226:18 244:21
 246:9,13,14
ranges 15:3
ranks 22:9
rapid 250:15
rapidly 223:17,20
rare 31:1 59:1 160:14
 160:20 164:13 184:12
 185:1 191:18
rarely 67:19
rarity 246:5
rate 18:14,22 30:1
 99:20 100:18 101:12
 108:3 137:19,20
 147:16 150:22 159:1
 163:11 190:16 226:16
 239:2 257:16
rates 29:19,19 30:12
 112:14 122:16 155:22
 163:1,3,14 199:9
 240:10,15 255:14
rating 18:22 148:18
 152:17,19
ratings 104:17 135:10
ratio 89:2 256:16,20
 257:8,10 264:13
rational 138:9 160:22
 177:12 192:5,8 234:9
 262:20
raw 240:10
re-admission 14:19
re-admissions 16:1
 21:17
re-endorsed 198:9
re-endorsement 168:21
re-exploration 132:3,15
 137:19,21 141:9
 156:10 160:3
re-going 225:9
re-looking 43:19
re-operation 151:8

249:2
re-operations 147:17
re-testing 44:2
re-up 258:19
re-upping 259:1
reach 11:4 46:1 222:4
reaches 114:19
reaching 269:9
reacting 27:6,13,14
read 10:15 172:1,4
 236:6
reading 83:16 128:14
ready 15:13 112:7,9
 156:16 210:11
real 40:12 41:5 44:10
 70:1 90:21,22
realistic 35:3
really 5:11 6:21 7:21
 9:10 12:10 13:9 15:14
 17:1 19:4,7,11 21:7
 29:18 30:8 31:6,15
 32:11 33:11,17 34:1
 38:11,21,21 39:2 40:9
 44:7,15 45:20 68:5
 79:2 80:2 91:1,3 92:3
 99:21 106:20 120:11
 120:13 127:20 136:3
 140:22 161:18,21
 170:6 188:20 190:20
 191:1,14 193:8
 199:12 202:6,13,14
 202:18 206:3 207:8
 214:7 215:3 216:17
 216:20 217:2,3,12
 219:5,7,7 220:15,22
 221:10 223:12 224:22
 228:15 250:1 253:4
 253:20 255:21 260:14
 260:16,17 263:14
reason 5:13 6:17 31:2
 67:4 73:11 102:5
 132:15 145:18 155:14
 187:2
reasonable 76:10 87:11
 253:7
reasons 71:13 132:13
 192:18 249:3
recalibrate 261:20,21
recalibrated 261:17
recall 169:19 257:22
recap 4:2 153:13
receive 58:12 102:11
 249:17
received 77:21
recognition 38:8
recognize 19:4 41:12
 216:5 222:8 223:20
 227:3

recognized 179:13
recognizing 81:5 222:2
recommend 184:3,6
recommendation 52:20
reconstruction 55:15
record 34:3 89:14 95:18
 116:2 120:6 164:4
 224:7
recorded 108:1
recused 8:8
redesign 43:15 185:3
redness 164:6
redo 158:4
reduce 15:15,19 46:22
 192:9
reduction 192:12
REEDE 2:13 147:13,22
 148:17 149:2 251:6
 251:18 263:10 264:13
references 167:3
referred 36:19 82:21
reflect 79:22
reflected 83:22 164:10
reflection 37:13 181:15
reflections 237:8
reflective 110:21
 111:13,22
reflects 80:1 83:19
 102:13 260:9
refugees 23:14
regard 19:18 187:18
 189:19
regarding 10:16,22
 91:14 108:4 141:3,5
 146:2 198:3 267:13
regardless 156:13
 175:9 198:14
regionally 22:15
regions 36:17
registries 87:6 205:16
 205:17,19 209:20
 216:8
registry 39:15,17 63:8
 113:9 119:10 155:7
 181:22 209:7 211:15
 212:3 213:3 214:9
 215:20 217:19 261:9
regression 128:13
reintervention 132:9
reintroduce 5:10
related 19:20 47:8
 62:20 94:8 98:2 99:19
 137:1 172:21 183:14
 184:2 214:12 224:16
 243:9 267:16
relates 41:9 95:19
relating 192:16
relationship 59:6 60:1

60:11 84:8 138:9
 140:12 142:17 146:7
 161:1 206:19 227:4
 234:9
relative 147:1
relatively 20:3 52:16
 87:9
relevant 113:7 126:12
 128:8 146:7 187:21
 215:3
reliability 81:13,14,21
 82:3,19 107:10,13,22
 108:5,8,13,17,19
 109:3 112:3,9,12
 126:10 128:5 130:17
 145:22 146:1 147:11
 147:21 149:4,12,14
 149:19 150:1,15,20
 151:4,5,6,9,14 152:2
 152:4,6,7,9,15,16
 153:4,14,16,21 154:5
 165:2 180:13,15,17
 181:4 195:13,16
 200:8 203:21 211:20
 229:9 234:19 242:2
 247:12 257:17 263:7
 263:9,10,18,20
 264:15
reliable 81:16 108:14
 145:15
reliably 83:8 252:11
reliance 107:20
relieved 170:1
remain 174:1
remained 177:19
 194:10
remaining 47:2 63:21
 64:7 158:8
remains 116:5 171:4,7
 210:9 246:14
remember 28:15 29:18
 62:6 164:11 171:16
 191:21
remembering 173:13
remind 152:14 176:11
reminder 100:1 267:22
remove 173:1
removed 64:16,19
 116:9 177:17
removing 64:9
renal 122:11 124:13
 249:4 250:22 255:18
repair 55:12 197:21
 224:20 225:21,21
 230:16,21 231:15,21
 232:13,18,21 233:3
 235:19 236:10 237:21
 245:21

repaired 233:17
repairs 99:6
repeat 126:13 163:8
replace 232:16,18,22
replaced 233:17
replacement 14:22
 21:16 27:22 50:17,18
 134:11,12 196:17
 197:15,22 201:9
 224:12,19 225:12,14
 225:20 230:21 231:9
 231:14 232:12 235:13
 240:2 243:16,17
 246:17
report 7:1 19:8,8 26:14
 31:20 38:4 72:12 75:4
 80:9 90:12,14 102:10
 103:18 104:8 105:22
 106:2 115:14 134:5
 134:10,10,11,13,15
 134:17,18 136:8
 137:10 140:4,5,9
 147:1 152:12 164:11
 164:15 170:7 175:17
 175:21 244:8,8,14
 245:5,8,9 254:12
 263:5 267:10
reported 12:18 74:2,4
 74:19,22 75:2 77:20
 78:1 80:2 87:19 88:22
 97:5 101:16 104:18
 122:17 123:1 127:4
 134:20 135:4 142:11
 159:11 175:9 202:8
 242:21 243:3,5,10,22
 250:13,14 253:10
 254:12
reporter 44:12 45:5
reporting 26:5,7 77:1
 85:22 89:8,16 90:1,16
 91:16,17 95:14
 103:10,16,20 104:21
 105:5 122:21 134:3,8
 140:8,8 146:21 147:4
 174:7,16 175:18
 208:14,16 222:11
 243:14,15 244:4
 245:7 250:6 253:13
 253:14,18,22 254:5
 255:4,10,15
reports 102:7
represent 258:6
representation 205:1
 229:22
represents 246:11
request 126:16 173:6
require 44:2 56:16
 85:14 90:6 107:19

132:9,14 171:16
 188:18
required 67:22 247:2
 249:18
requirement 31:22
 42:19 146:10 150:3
 171:21 227:15
requirements 85:10
requires 114:17 177:3
research 2:1 59:1 69:14
 99:15 124:9 135:19
 135:19 136:11
resection 105:15
reserve 62:7 65:1 72:1
 143:20 144:4,8
 169:10,10,13,18,21
 170:3 171:9,15,22
 172:6,18 173:3
 174:19 175:14,21
 176:10,13,13,13,14
 177:4,19,22 178:5,19
 178:22 180:2 182:6
 182:12,15,19
reserved 65:2 177:16
 178:8
resetting 261:15
resisted 22:21
resolve 34:6
resolved 116:5
resoundingly 176:1
resource 207:13 210:2
 214:3
resources 61:19 62:2
 64:12 179:15 212:16
 214:12 215:5
respect 41:14 123:8
 125:17 215:15 216:11
respiratory 124:14
respond 11:13 259:5
response 15:1 29:6
 226:5 228:20 229:10
 230:8 232:2 234:4,22
 241:14 242:13
responsibilities 170:2
responsibility 14:10
responsive 223:20
rest 47:6,17,18 86:5
 113:6,11 115:11
 116:21 169:14 177:18
 180:7,10
restrict 15:18
result 55:21 175:11
results 50:3 53:14 57:8
 60:9 84:4 85:20 104:9
 127:1 147:7 149:10
 150:16,20 152:11
 154:6,22 156:21
 227:13 242:2 261:6

resumed 120:6 224:7
retains 172:7
retiring 71:17 77:3
retracted 66:20
return 173:7
review 10:22 98:10
 135:21 167:2 172:18
 173:5 236:10 266:15
reviewed 7:2 100:10
 226:13
reviewer 17:20 246:2
reviewers 128:12
reviewing 17:19 86:11
 86:13
reviews 192:21
revote 112:5
rework 43:16
RFP 34:1
rhetorically 37:19
rheumatoid 15:12
rhythm 224:10
RICHARD 1:17
Rick 12:15 27:16 54:6
 101:6 126:15 159:9
 194:11 198:12 217:7
 220:14
rid 219:16
ride 268:13
right 10:9 18:18 21:20
 32:9 49:13 53:5 54:9
 54:13 55:14 58:9 59:5
 59:14 69:22 71:22
 72:15 81:10 83:11
 85:17 87:13 89:18
 91:9 95:6 107:5 110:7
 110:13 117:5 131:13
 131:17 133:12 134:7
 135:2 136:12 139:2,3
 139:6 141:7,16
 142:12 143:19,21,22
 147:6 154:15 156:16
 159:2 166:7 173:21
 174:16 180:13 181:3
 182:7 184:22 193:12
 193:14 195:18 196:21
 201:7,18 203:16
 212:20 214:15 215:13
 215:18,22 224:11
 225:7 227:9 230:22
 234:7 236:6 238:10
 241:1 243:15 244:10
 245:6,11,19 248:4,12
 251:11 252:3 253:5
 260:14 265:6,10
 266:3 268:12
rigor 211:13 222:4
rigorous 50:1 88:5
rise 218:22

risk 11:1 12:10 15:1,3,4
 15:5,10,15,19,20
 16:16,19,21 18:15
 22:9,10,12,16 23:3,18
 28:12 36:9 41:19 50:6
 51:4,7 56:19 75:6
 89:2 94:17 96:11,12
 96:13,18,18,20 99:11
 99:15 106:16 112:16
 113:3 121:5,21 122:1
 122:15,21 123:9
 124:10,11 125:18
 128:8,15 132:2 133:8
 133:10 141:11 148:3
 156:22 158:22 189:12
 196:16 197:14,18
 201:5 210:17 211:6
 211:19 224:11,14
 225:11 231:20 236:1
 236:3,12 254:9,11,13
 254:14,17,19,21,22
 255:3,12,17 256:5,6,8
 256:16,18,21 257:3,5
 257:11 258:18 263:12
risk-adjusted 73:11
risks 14:20 19:13 36:13
 41:3 45:14 57:4
risky 12:21 15:2 23:6
RN 2:12
Robert 1:16 2:16 48:5
 61:3 62:11 70:8 87:5
robust 12:13 96:11
 209:20
role 19:17 222:22
 240:12
roll 243:12,13 250:18
rolled 91:17 243:19
 244:3
rolls 21:20
Romano 6:16
room 1:8 35:4 48:20
 61:17 113:21 121:11
 138:19 156:12 191:22
 209:6 232:15,17
 254:3
Roth 2:14 8:15 225:7,8
 226:12 229:14
round 250:21
rounds 33:8
routine 179:10
row 219:13
rows 88:15
rule 90:5
rules 135:11
run 22:18 47:11 53:14
 75:6
running 88:12

S

safe 270:8
safeguard 32:4
safety 2:6 208:4 269:20
SAIGAL 2:15 17:7
 31:12 78:8 85:4,13
 167:6 168:4 181:1
sail 204:19
sample 103:9 106:6
 209:7 240:8,13
samples 240:20
sand 39:6,10,12
sandbox 45:15
Sara 124:22
sat 51:10
satisfactorily 214:17
save 108:10 143:5
saw 104:3 205:2
Sawin 2:16 52:6,8
 70:10 81:15 82:4,6
 87:6,17,21 119:7
saying 32:12 39:9,12
 39:17 63:8,12 64:18
 72:13 97:5,6 161:18
 170:15 172:12 176:21
says 61:22 62:18 77:19
 83:17 179:14 238:19
 238:20 240:2
schedule 40:8 243:19
 267:7
scheduled 266:20
School 1:20 2:3
science 261:11
scientific 3:2 6:2 47:8
 83:3,5 170:9 264:21
 265:4
SCIP 21:20 176:16,18
scope 149:10 156:21
score 25:2 26:11 83:19
 108:1,20 146:5
 151:15,18 152:7,17
 153:4 155:9 174:14
 248:10,16
scores 109:4 155:4
 243:5
scoring 261:9
screen 83:17
Sean 125:2
seats 204:15
Seattle 2:16
second 11:22 12:16
 14:17 27:9 28:10
 47:21 48:1 68:3 96:11
 112:9 204:17 226:17
 226:21 239:10
secondary 192:6
seconds 95:16
section 137:9 268:21

see 5:13 6:1,22 7:3
 19:22 23:1,15 25:17
 26:6 29:5 30:12,20
 32:16 34:6 66:2 73:21
 77:5 86:12,13 104:2
 109:22 126:6 129:3
 135:14 162:14,15
 191:6 216:22 220:9
 223:11 225:8 233:15
 233:16 239:12 240:5
 240:6 258:3 266:4
seeing 15:9 36:7 79:5
 149:4 166:2 181:6,9
 182:3,13 195:21
 196:8 200:9,13,21
 202:9 203:22 204:11
 229:11 230:9 235:1,7
 241:15 242:3,14
 247:15 248:1 253:15
 261:12
seen 27:19 31:1 34:13
 79:15 114:1 204:18
 255:4
select 134:16,17
selected 86:7
selection 99:17
self 123:10
seminal 202:1,10
send 13:14 38:2 69:5
 78:5 147:15,18
 268:21
Senior 2:5,6,13 3:2,4,5
 3:5,14
sense 20:14 41:2,7 42:6
 63:7 66:11 76:9 95:2
 117:18 184:15 185:10
 185:13,16 187:10
 231:5,11 236:3
 252:11 259:19 260:8
 260:9,20 262:19
sent 34:12
sentence 60:10 93:1
 95:22
sentences 113:18
 172:5
separate 40:8 58:16
 129:17 150:5 227:18
 227:19 230:20 231:5
separated 227:5 268:16
separately 82:15
 144:17 233:16 251:2
sepsis 111:9
sequence 95:7
serious 161:19
seriously 31:15 32:5
serve 212:18
served 36:11 105:10
service 2:18 138:10,11

161:4 234:11 244:14
set 22:3 27:10 94:2
 148:4 153:7 170:20
 177:11 183:8 190:21
 214:22 233:18 237:5
 261:10
sets 221:13 233:7 237:1
settle 186:5
setup 71:10
seven 101:12 102:17
 125:22
Seventy-six 200:15
severe 100:22 161:15
 164:14 255:19
severity 164:17
sexes 236:11
Shahian 6:6 48:22
 79:16 124:22 147:15
 147:19 186:3,4
 191:22 192:4 216:9
 255:6 256:10 257:21
 258:10
shape 120:13
share 91:14 206:12
shared 12:4,9 19:5,7
 30:9 31:14 35:16
 42:13
sheet 216:14,22
shift 114:14
shifting 137:5
shock 121:14
short 38:22 216:3 231:2
 243:21 249:13
shorter 12:14
show 8:12 25:21 27:20
 42:9 80:5 101:22
 152:16 185:18 194:6
 237:13
showed 108:2 155:3,4
 236:5
showing 65:10 155:7
 192:11 256:12
shown 249:12 255:2
shows 50:4 59:22 60:6
 98:10 154:18 169:3
 251:20
shying 255:22
sick 57:19
sickest 17:2
side 18:8,12 30:20 31:9
 31:10 75:13 114:2
 115:5 136:6,11
 161:14,20 240:19
sidebars 78:22
sign 35:10 59:18 60:22
 105:8 134:3,3 244:19
signal 174:21 264:13
signaling 172:14 174:6

signed 103:15 244:9
significant 13:10 22:16
 79:4 126:2 168:9
 246:20
significantly 54:4
signs 134:7 238:7
similar 46:20 51:7
 146:16 150:16 164:12
 191:12 198:2 225:1,3
 227:1
similarity 234:1
simple 174:6
simplest 237:16
simplify 63:1
simply 254:10
Simultaneous 83:7
sine 186:15
single 10:19 106:15
 133:16 194:12
SIPERSTEIN 2:17
 16:11 177:20 178:17
 193:7
sister 58:20
sit 57:18 61:16
site 50:3 88:7
site's 88:12
sites 50:2 86:6 103:15
 103:17 104:1,5
 175:18
sitting 43:1
six 28:1 38:14 102:9,10
 176:15
Sixty-eight 157:17
Sixty-seven 165:16
Sixty-three 242:7
size 103:9 228:8 240:8
 240:9,13
skip 262:12
sky 220:6
slide 166:4 193:18
slight 77:17
slightly 218:2
slippery 15:11 32:22
Sloan-Kettering 2:19
slope 15:11 33:1
slow 236:19
slower 43:6
slowly 156:17 217:21
small 20:3 57:5 75:7,10
 75:12 111:4 160:5
 168:5 193:8 211:10
 228:14 260:17
smaller 209:17 215:9
 237:18,18,19,20,21
snowing 107:2,2
societies 39:22 213:12
 213:20 214:2,7 215:9
 217:16 219:21 221:6

223:9
society 1:12 2:11 3:10
 3:11,13,16 39:16
 127:8,9 217:1 244:12
society's 216:13
solid 254:14
solitary 175:1
solution 254:13
solve 160:18
somebody 21:9 22:9
 31:1 89:10 97:15,22
 113:21 125:9 141:8
 161:15 172:2 211:10
 220:2 270:3
somewhat 226:18,22
soon 125:5
sorry 24:4 37:15 56:8
 73:4 78:21 81:14 82:6
 85:18 101:6 130:4
 158:5 170:10 190:19
 193:16 195:13 214:5
 222:22 226:13 253:9
sort 5:9 7:10,13 12:14
 21:3 25:1,6 26:8 28:7
 31:22 32:8 46:13,17
 85:15 144:13 149:13
 152:1,6,12 170:6,8,9
 171:6,11 177:11
 188:7 206:13 237:7,8
 257:7 262:17,19
 269:8
sound 81:21
sounded 83:21
sounds 73:6 118:11
source 44:3 194:15
 208:21
South 76:7
space 42:16 174:7
 205:16 207:2 212:17
spaces 268:14,20
speak 9:11 38:5 268:5
speaking 83:7
speaks 30:16 204:19
special 187:5
specialists 206:1
specialties 105:19
 207:9 209:18
specialty 144:13 206:9
 208:4 215:9 223:9
specialty-specific
 214:20 218:4
specific 57:11 92:22
 127:11 183:12 189:8
 215:21 216:7 260:1
 264:7
specifically 7:14 46:19
 85:6 94:8 98:7 115:10
 137:19 175:8 255:11

specifications 156:19
specified 149:7 188:10
specs 180:21 191:3
spectrum 114:3 136:1
spend 44:1 95:16
 113:16
spent 44:11 45:4 119:6
 270:3
Spine 1:15
split 5:16
spoke 90:20
spoken 39:8
spot 212:15
squeeze 155:19
squeezes 22:5
squeezing 23:2
SSI 211:17,18
St 48:16 107:2
stabbed 55:1
stable 136:17
staff 3:1 5:14 7:20
 28:22 49:6 202:13,16
 205:11 212:16 217:12
stage 7:12 223:15
Stakeholder 3:3
stakeholders 106:1
stakes 41:10,11 160:19
stand 66:8 146:19
 173:17
standalone 63:16,17,18
 63:22 65:17,18 177:9
standard 107:18 116:6
 260:1
standards 222:10
standing 1:3 6:18 28:16
 43:20 125:12 144:15
 172:17 173:1,6
 269:18
standpoint 119:8 190:9
 190:14
stands 72:9 245:22
star 104:15,16,16,17,20
 104:22 105:2,3 135:9
 148:18,19 149:1
 197:6 250:8,8,9,10,11
 251:19,21,22 266:11
stars 250:9,11
start 6:15 12:12 25:10
 38:11 46:11 54:8
 104:21 135:6 136:21
 198:5 266:19
started 25:6 45:13
 52:12 62:4 91:19
 113:22 120:9 219:10
 260:4
starting 18:3 26:6 49:10
 127:16 137:6 166:11
 184:4 197:21 214:19

stat 49:12 50:9,11
 51:13 52:5 53:16 54:4
 59:15 60:17 67:10,13
 67:16,18,20 68:1,4
 69:1,7,9,17 70:21
 72:20,22 75:5 88:8,16
 89:5 95:9,13,15 98:8
 98:17 100:14,15
 112:17,19 113:3
 121:4,6,8 122:3,17,19
 124:18,19 129:9
state 42:20 76:6,13
 124:1 136:13 254:9
statement 107:13
statements 179:3
states 49:18 58:11,15
 59:6 75:15 76:2 99:9
statin 166:22 184:4
 185:3 192:19
statins 186:21 192:9,14
 194:10
statistical 126:1 250:5
 252:14 259:21 264:17
statistically 129:20
 168:13,17 253:4
statistician 48:14
 128:22
statistics 16:19 112:18
 227:14
status 28:8 38:12 42:13
 48:6 62:7 65:2 71:2,3
 72:2 113:12,14,22
 116:8 143:20 144:4,8
 169:10,10,13,18,21
 171:10,15,22 172:6
 172:18 173:2,3,20
 174:20 175:14,14,21
 176:10,14 177:19,22
 178:19 179:1 180:2
 182:6,12,15,19
 206:14 243:7
stay 63:10 155:10
 239:13,14
stayed 246:8
step 50:13 109:6 232:8
stepped 49:4 217:12
steps 266:17 267:14
sternal 159:1,6 161:2
 161:16,22 162:4
 249:4
steward 173:7
stick 171:11
stimulate 219:22
stimulated 218:14
stop 136:20
stories 27:13
story 79:18 233:22
strategy 51:5 140:17

stratification 113:2
 148:4 157:1 256:6
stratified 49:11 50:9
 53:9,16,22 67:10,13
 68:4 69:1 73:12 95:9
 95:15 98:17 112:17
 122:17,18,18 140:5
 140:18 198:11 250:6
stratifies 72:20 98:8
stratify 52:4 60:17
 61:20 256:15
Street 1:8
strict 252:12
stroke 164:13 192:15
 249:7
strokes 124:13
strong 34:1 167:7 177:1
strongly 159:12 162:16
struck 26:18
structural 47:18 52:18
 59:10 79:14
structure 85:11,16
 123:10 129:18 161:3
 234:10
STS 3:16 5:12,15 6:7
 8:11 10:7,12 11:18
 12:14 13:4,21 14:8,16
 20:20 34:16 37:10
 46:14 48:17,22 49:4,6
 49:14,16,20 50:10
 51:15 54:14 55:17
 58:9,14 59:9,21 61:7
 63:12 65:7 68:10,12
 68:16,20,21 69:4,5,8
 74:3,4 75:3 79:15
 81:17 86:6 89:8,17
 92:15 93:4 94:14
 96:20,22 102:7 103:2
 106:18 107:15,19,21
 109:13,14 111:15,16
 113:6 117:13 120:20
 121:17 122:22 123:1
 126:17 127:10,12
 132:6 133:6 134:4
 139:5,9,15 140:7
 147:17 158:8 170:14
 170:18 175:8,16
 187:17 188:13 193:3
 204:18 205:21 206:19
 207:17 208:12 210:16
 211:15 213:5,11,17
 214:8 215:7 216:15
 219:8 227:3 238:20
 243:11 244:11,19
 245:1 248:10,15
 250:12
studied 184:10
studies 49:17 136:12

186:10
study 37:17
stuff 44:15 98:3 180:22
 210:3,6,17 211:1
stymied 52:9
sub-optimal 71:10
subcategory 186:13
subgroup 134:18
subject 57:17
subjective 9:5,9
submission 74:21
 77:19 78:2,4 80:1
 108:6 142:11 149:19
 170:22
submissions 149:20
submit 158:6 210:11
submitted 194:18 210:5
submitting 49:20
subsequent 41:16
 154:6 157:12
subset 57:5
subsets 231:3,10
substantial 41:3 98:10
 192:11 214:13
substantially 100:13
substrate 233:1,3
subtle 67:5,13
succeed 221:7
success 32:18,19 171:8
 179:12 217:4
suffer 105:17
suffering 33:7
suffice 198:4
sufficient 63:22 170:15
suggest 25:22 45:12
 94:22 152:22 193:8
suggesting 77:13
suggestion 17:20
suggests 152:4
suitability 93:19,21
 119:20,22 131:20
 158:14 166:3,6 182:5
 196:9 200:22 204:12
 230:10 235:8 242:15
 245:12 248:2,4
 265:13
summarize 60:5 84:7
summarizes 240:8
summary 60:10 85:1
 135:15 250:15 267:16
sunset 171:9,10
superficial 164:5
support 64:17,20 71:19
 84:13 114:22 121:16
 122:10 124:15 125:10
 184:5 208:10,20
 209:2 220:17 221:3
supported 29:5 219:9

supports 138:9 161:1
 234:9 264:11
supposed 83:18 237:11
sure 17:11 18:1 20:21
 31:18 33:15 34:5 35:3
 40:16 46:8 49:9 59:4
 63:5 79:1,20 80:3
 89:16 92:3 95:2,6
 106:21 125:14 150:15
 155:21 161:20 168:15
 169:19 173:12 199:12
 201:20 202:21 215:17
 220:19 233:9 236:2
 257:21 260:7,9
surface 228:6,7
surgeon 1:19 8:13
 32:16 48:15 55:17
 61:16 232:10 233:7
 233:13 254:10
surgeon's 22:3 35:1
Surgeon-in-Chief 2:7
 2:16
surgeons 2:2 3:10,12
 3:13,16 6:5 8:11 9:7
 15:18 16:13 35:4
 39:16,20 51:10 81:19
 93:10 205:4 252:18
 254:16 256:7
Surgeons-in-Chief 2:17
surgeries 16:1 163:8
surgery 1:3,14,16,20
 2:2,3,18,19 7:10 15:2
 15:9,13,14 19:18,21
 20:19 30:5,5 48:18
 49:11,15,16,19 50:11
 50:14,15,15,20,21
 52:15 54:8,14,16
 55:18 56:10,17,18,21
 56:22 58:10 59:7,21
 60:11 67:9,10 71:8
 75:16 76:11 79:17
 86:9,9 90:1 92:12,13
 94:19 98:20,21 102:2
 102:8 105:17,21
 111:1,7,14 113:13,14
 114:4 115:1,6 120:20
 121:17 122:12,22
 127:10,12 128:19
 130:11 132:6 136:1,7
 136:21,22 137:7
 159:7 177:2 178:3,10
 186:10,19,20 187:3
 198:15 205:16 221:15
 237:15 238:2 253:16
 254:18 268:10 269:18
surgical 28:4,10,11
 29:19,19 30:1,12,17
 38:10,20 49:10 50:8

52:14 57:13 59:6 67:8
 99:18 112:1 132:3,15
 183:13 212:17 221:6
 244:15 255:9 268:10
surgical-related 206:13
surprised 27:19
surprising 241:6
surrogate 60:15
surrounding 39:11
survey 65:7
survival 35:13,14 56:18
 56:22 57:1 114:15
survive 57:7 114:14
 208:10
switch 95:7
syndromes 122:5
system 17:13 18:9 30:5
 57:13 67:19,20 97:11
 250:8 251:20
systemic 192:16
systems 11:8

T

t 118:16
table 9:7,8 31:10,11
 51:11 53:13 88:15
 98:6 100:19,21
 217:16 223:7 238:17
 238:18 239:5 240:7
 268:21
take 23:6 24:19 32:5
 39:3,4 47:2 50:13
 57:3 59:11 109:5
 116:6 120:3 131:19
 150:3 157:9 160:18
 163:19 180:3 183:2
 188:15 189:1,2 207:3
 207:11 209:9 210:2
 218:21 219:7 234:6
 243:1 250:3 257:4
 265:20 268:12,18
taken 41:10 96:22
 105:6 113:21 167:15
 212:5 216:17
takes 57:2 111:3 118:15
 119:5 213:10 243:13
talk 6:11 30:14 40:2
 45:18 67:11 79:11
 86:4 98:4 99:8 123:7
 128:13 133:21 151:5
 151:8 207:1 233:6
 266:16
talked 6:15 18:5 25:13
 43:18 88:2 121:1,3
 126:11 169:17 173:14
 205:17 210:15 242:19
 242:22 244:1
talking 6:21 11:18 27:3

31:13 32:9 33:10
 35:19 46:6 76:22 77:3
 89:15 92:8 105:15
 120:9 138:21 151:3
 163:13,14 186:11
 190:15,22 202:9
 239:18,20,21 268:6
talks 53:9 67:7,12
tamponade 132:11
task 89:9
team 6:18 21:2 89:8
 114:9 118:16 125:2
 179:15 213:8 214:1
 218:3 222:3 266:21
technical 85:19
technically 109:12
 191:3
technique 99:18
technologies 259:1
tee 20:4 41:16
teleconference 3:22
telephone 197:7 244:22
tell 26:3 125:4 141:16
 142:14 150:11 191:14
 208:5
telling 35:21
TEMPLE 2:18 24:21
 46:4
temporary 258:16
ten 74:13 86:6 178:15
 195:8
tend 60:6 257:17
tercile 194:20,21,22
 235:18,21 239:9
terciles 202:6
term 216:3 231:2
 233:18 249:13,13
terms 15:18 16:17
 21:18 31:17 40:16
 42:12 43:9 46:16
 52:21 53:1,3 70:20
 85:19 89:5 151:4
 167:10 184:1 191:10
 198:18 199:6 214:8,9
 214:14 259:10
terrible 11:5
territory 252:14
tertile 155:9
tertiles 155:1
test 223:10,16 262:6
tested 149:9
testing 7:8 108:1,2,5,9
 108:20 154:20,21
 156:20
Tetralogy 55:12
Texas 127:14
text 89:9 92:2
thank 6:14 7:20,22

55:19 91:1 93:12
 110:5 115:20 127:22
 130:21 143:10 147:19
 149:2 172:3 182:20
 197:10 209:22 233:20
 233:20 241:4 266:14
 267:21 269:14
thanks 26:13 38:7,21
 40:5 45:2 48:3 49:7
 86:20 98:15 100:17
 120:4 152:21 189:16
 189:22 193:18 224:1
 270:7
theater 121:16
theme 198:2
theoretically 140:1
therapy 249:21
they'd 186:20 258:5
thing 7:18 12:7 18:5
 20:14,16 22:22 28:2
 29:17 36:14 41:16
 42:3 50:13 59:12 64:8
 73:7 76:1 79:5 91:16
 103:21 113:1 115:13
 117:15 118:1 134:15
 145:3 161:15,19
 171:12 206:11 211:5
 215:11 221:19 236:20
 250:18 254:5,7
 262:18
things 6:15 8:3 10:4
 15:11 16:4,8,19 17:13
 26:17,18 27:22 28:9
 36:21 40:18 44:4
 83:18 115:3 119:10
 123:7 156:5 169:20
 187:15 206:14 211:12
 212:4 218:20 220:15
 223:13 254:6 256:2
 258:7 259:10
think 5:3,8,13 7:16 8:16
 10:11,15 11:10,14
 12:7,11 13:11,16
 15:11,20 16:1 17:5,8
 17:9,16,20 19:16
 20:10 22:20 23:1 24:4
 24:11,22 25:6,9,12
 26:6,8,8,10,18 27:3,5
 27:6,9 28:13 29:11,17
 30:6,18,21 31:5,13,19
 31:21 32:6,15 33:19
 34:15,19 35:7,12
 36:20 37:4,5,15,20
 38:4 40:12,18,20 41:7
 42:11,15 43:4,7,12,17
 44:15,21 45:7,16 47:3
 50:13,16 56:9 57:16
 57:18 58:1 64:6,9,21

65:5 66:13 70:12,17
 71:4,11,12,22 72:7,15
 73:2,20 74:5,18 75:9
 75:14 76:16 77:3,7,12
 77:15 78:2,6,16 79:1
 79:12,21 80:3 81:15
 81:17 82:16 83:2 85:1
 86:3,18 87:10,21
 89:12,21 93:6 97:11
 97:16 98:1,5,13 100:4
 101:16,20,22 104:11
 104:12 108:16 109:16
 110:18 111:21 112:4
 115:4,5,15 116:1
 117:18,22 119:15
 120:2,10,21 123:10
 125:15 127:5 128:7
 128:11 130:12 131:7
 136:16 138:2,13
 139:4 141:7,11
 142:12 144:5,20
 146:20 147:3 149:13
 149:18,20 151:11,14
 152:4 153:6,10
 154:10,17 157:3,8
 160:6 161:12 162:7
 162:10,12,13,21
 163:12 164:2,3,11
 167:10,18 168:20
 169:3,4 171:18 174:3
 174:4,20 175:3,4,20
 176:2,22 177:17
 178:4,18,20,22 179:8
 180:12,15 181:1,7,19
 182:14,16 183:5,16
 184:9,17 185:7,14,17
 186:13 187:5,10,15
 188:1 189:1,18 190:5
 190:6 191:1,4,5,6,13
 193:2,12 194:16
 196:1 198:4,5 199:15
 199:19 201:18 203:5
 203:12 206:2,3,8
 207:16,21 211:3,19
 212:22 213:18 214:21
 215:1 216:3 217:1,4
 217:15,18 218:9,18
 219:5 221:5,22 223:7
 231:1 232:7,14
 237:14 238:4 239:22
 245:15 250:17,20
 251:4,19 253:2,20
 254:4,8,19 257:11,14
 258:12 260:11,19
 261:12,19 263:10
 266:21 268:1,4 269:3
thinking 6:22 30:4
 33:20 76:17 171:3

179:8 191:5,9,11
thinks 89:20
third 96:22 212:2
 249:10
Thirty-six 200:2
THOMASON 2:20 32:11
 90:18 233:12 242:16
 242:18
thoracic 1:19 3:10,11
 3:13,16 39:16 243:20
thorough 267:2
thought 13:9 16:5 21:1
 28:9 40:7,15 62:10
 73:22 74:21 85:7
 110:2 144:11 170:11
 236:15 257:7
thoughtful 45:4
thoughtfully 46:10
thoughts 7:7 16:9 38:8
 153:8
thousand 87:9 159:19
 219:11
three 14:11 25:8 49:13
 88:16 104:16,22
 136:7 139:22 148:19
 168:16 171:20 211:19
 219:13 235:19 243:2
 246:13 250:9,11
 251:22 256:14 257:5
 258:20,21 261:18,19
 262:1
throw 227:6
ties 115:19
time 5:4 12:13 13:3
 17:13 25:3 29:6 31:15
 37:6 38:1 44:1 46:13
 59:5 61:12 66:7 67:4
 90:20 98:22 100:19
 101:4 103:12 106:19
 111:16 112:21,22
 114:5,14 115:7
 117:19 118:15 119:5
 137:14,17,18,20,21
 141:10,12,14,16
 143:6 145:5 155:5
 158:6 169:5,18,19
 179:14 193:4 197:5,9
 204:17 213:1,3,10,21
 215:18,22 216:17
 217:11 221:16 226:17
 226:18,19,21 227:1
 228:12 234:8 236:5
 239:10,10 243:13
 246:8,10 253:11
 261:21 263:12 266:9
 266:13 267:5
time-saving 202:20
timely 269:17

times 10:9 23:22 33:5,6
 34:13 44:12 107:17
 159:21 220:4
tip 191:19
today 6:9,15 8:7,10
 19:22 29:6 30:7 34:8
 41:20 46:13 86:5
 109:3 113:7 134:1
 236:17 244:1 249:4,5
 249:22 265:18 267:1
today's 5:11
told 15:12 35:11 36:2
 39:3
tone 30:15
tongues 191:19
Tony 214:4
tool 64:16 121:1 202:20
 215:8
tools 38:18
toothpaste 155:19
top 21:20 39:4 91:11
 118:22 238:20 240:1
topic 10:16 28:14 53:11
 92:19 161:22 268:15
 268:16
topics 5:17
topped 21:21 79:19
 141:21 162:21 171:6
 174:7 176:21 177:6
total 14:21,22 27:22
 163:5 178:5,9,11
totally 35:2 110:17
 111:8
touch 267:8
toughest 5:9
track 60:18 67:22 68:22
 68:22 115:3,4 213:3
tracked 106:16
tracking 67:7,12
tract 55:15
traction 179:17
traditionally 66:10
 205:20
train 170:10
trained 82:9
transfer 13:14
transfers 13:19
transformed 65:9
transitioning 197:17
transplant 55:21
trauma 261:9
travel 76:7,9
travels 270:8
treated 23:10 24:13
 57:6
treatment 57:14 182:22
treatments 56:13
tremendous 7:21 51:2

163:6,7,9
trend 257:22
trial 192:11
trials 189:15
trick 111:2
tried 207:8
true 13:3 47:20 148:14
 148:22 189:19 218:18
 218:18 252:22
trust 256:5
try 8:18 15:14 46:21
 47:11 66:22 113:18
 130:13 136:13 219:1
 219:21 222:17 224:3
trying 11:3 20:4,5,6
 36:22 63:1 64:13
 110:8 163:1,2 189:6
 220:16 223:6,19,22
 236:19 239:4
tube 155:19
Tuesday 92:18
turn 35:5 172:2
turning 117:2
turns 175:11 256:20
tutelage 270:4
tweak 27:4,5
two 6:6 14:4 59:10
 60:10 84:13 88:16
 97:12 104:15,21
 108:6 113:18 137:10
 142:15 148:19 149:1
 159:18 160:6 161:14
 161:20 162:3,20
 163:11 166:17 177:18
 185:15 187:15 199:9
 219:13 224:18,20
 226:12 227:1,5 231:3
 231:6,12 236:5 246:8
 246:11 248:20 249:21
 250:8,10 258:20
 261:1
tying 59:13
type 16:2 52:19 248:14
 252:5
types 51:1 57:15
 212:11
typically 155:10 202:4

U

U 18:17
UCLA 2:3,15
ultimate 143:21
ultimately 24:22 41:1
 132:22 212:8,8
unanimous 45:8 100:5
 120:1 123:16 150:3
 158:20 161:9 166:9
 182:18 201:2 204:13
 226:10 230:12 234:12
 235:9 238:13 245:14
 247:5 248:6 265:17
unclear 59:8 83:22
uncomfortable 80:16
 153:20
uncommon 56:20
underestimate 257:18
undergo 231:15
undergoing 121:9
 132:8 159:4 225:13
underlying 29:22 30:10
understand 16:18,19
 21:5 50:12 238:18
understandable 78:3
understanding 26:20
 38:19 108:5,22 188:7
understood 89:10
 154:14
undue 156:7
uniformly 69:10,18
unintended 10:5 12:8
 16:14 25:17 27:14
 44:8 64:10 71:18 88:3
 96:7,17 172:20
 253:12,21 254:2,8,20
unique 128:17
United 49:18 58:11,15
 75:15 76:2
unity 256:17
universe 106:9
University 1:12,20 2:10
 2:21 125:1
unnecessarily 97:10,18
unrelated 111:8 189:19
unusual 61:16 113:10
 114:22
up-front 202:8
update 193:4,5
upheld 41:1
usability 46:19 47:4
 78:11 87:16,21 93:13
 93:16 117:9 119:13
 119:17 131:17 136:15
 157:7,21 158:7,13
 165:20 166:1 181:19
 182:2 191:10 195:13
 196:6 200:20 204:10
 230:7 235:6 242:12
 247:22 265:11
usage 260:13
use 35:9,17 43:20 44:7
 54:16 58:13 91:8 93:4
 93:17 103:19 119:18
 129:15 139:13 148:6
 158:7,14 172:12,13
 185:3 191:11 214:16
 216:7 222:1 223:21

227:10 249:11 261:19
useful 73:17 74:10,16
 74:19 79:10 125:13
 163:20 206:4 221:10
usefulness 44:7
user 135:7
users 172:9
uses 121:1 135:13
 163:17
usual 186:1
usually 114:21 205:12
utilized 7:4

V

VA 218:17
VADs 258:13,14,15,16
valid 83:10 145:20
 146:11 155:12 179:12
 181:14 264:18
validating 85:19
validation 151:4
validity 82:4,5,7,10,12
 82:15,16 83:12,13
 87:1,3 112:12,14,20
 115:20 116:13,16
 125:20 128:6,8 131:5
 149:14 153:15,21
 154:8,10,18,20
 155:13 156:17,18
 157:6 165:8,13,15,18
 181:7,12,18 191:2,6
 195:17,18,22 196:4
 200:10,11,14,17
 204:1,3,7 211:21
 219:4 229:9,12,13,19
 229:21 230:4 234:20
 234:21 239:19 242:3
 242:4,6,9 247:13,14
 247:16,19 263:21
 264:3,6
valuable 35:17 65:8
 115:13 119:10
value 2:8 18:8 23:4,9,14
 63:2,8 70:13 101:21
 117:19,20 119:7
 125:12 216:6 221:13
 262:21
value-based 15:7 21:18
valued 81:18
values 25:3 146:21
 259:18
valve 50:17,17 55:14
 101:8 132:12 134:11
 134:12 196:17 197:15
 197:19,20,20,21
 201:9 224:12,17,18
 224:20 225:12,14
 230:21,21 231:16,21

232:16 233:16 235:12
 235:19 236:6,9,9
 237:15,19,19,22
 243:16,17,19 244:2,2
 244:7,8
valve-specific 225:3
valves 244:7
variability 22:6 80:11
 80:13 81:5 108:21
 169:6 199:17,20
 201:20 226:20
variable 211:14
variables 122:2
variance 168:9
variation 30:11 79:3,8
 98:11 100:19 129:5,7
 130:7,7 136:18
 142:13 143:14 148:2
 148:8,14,22 151:19
 151:20 226:22 229:2
 241:17 260:2,16
variations 25:18
varies 68:6 100:12
variety 57:22 122:4
 124:11 127:15 134:8
 192:18 237:2
various 99:12
vary 29:19,20
vascular 185:4
vehicle 211:22
Vener 127:13
ventilation 249:6
ventilation/intubation
 251:1
ventilator 122:9
ventricular 55:14
venture 252:14
versus 14:2 26:4 47:18
 130:7 151:15 155:17
 162:2 167:14,14
 168:7 194:21 195:1
 231:4 235:21 239:10
 264:16
Veterans 1:14
vetted 145:2,9 146:11
 216:6 266:1
vetting 205:18
Vice 2:4 3:2
victim 220:7,8
Vidant 2:20
video 92:9
view 37:17,18 179:3
 189:18 218:9
vigorous 116:3
vigorously 31:6 65:11
visible 30:16
visits 50:3
voice 90:19 98:18

volume 49:10 50:8
 52:14,22 59:7,12,13
 59:18 60:1,6,8,10,14
 62:15 66:8,11,16,17
 67:8,21 68:1,2,5
 72:19,22 73:1,9,13,14
 73:17 74:22 75:7,10
 75:12 77:19,22 79:9
 80:14 83:22 84:7,10
 84:15,16,17,21,21
 85:2 88:16,21 101:8
 105:14,18 106:5,6
 116:20 164:16
volumes 85:22
volunteers 216:15
vote 47:2,5 56:7 65:3
 66:4 69:19,21 73:3
 78:19 80:7,7,17,20,22
 81:22,22 82:15 83:13
 83:14,14 86:22 87:14
 93:13,21 100:3,4
 101:5 106:13 107:6
 112:3,6 116:13 117:1
 117:2,3,6 119:12,14
 119:21 123:13,15,15
 126:6,6 128:2 131:2
 131:11,14,16,19
 138:6 142:6 143:12
 147:21 149:5 150:3,6
 150:10,17 151:11
 153:7,10,17,21
 154:11 156:16 157:10
 157:10,11,16,22
 158:3,7,17 160:10
 161:7 162:14,15
 164:18 165:5,13
 166:2 167:19 169:10
 169:11,12,13 175:13
 178:16 179:19 180:3
 180:8 181:4,7 182:4,4
 182:14 188:9 189:2
 191:4 193:12,17
 195:5,15,16,22 196:9
 199:1,22 200:8,14,21
 201:1 202:21 203:7
 203:21 204:3,11
 226:7,9 228:22
 229:18 230:10,11
 234:3,7,14 235:2,7
 238:11 241:16 242:5
 242:14 247:4,7,7,15
 248:3 251:11 260:22
 262:6,7 263:2,16
 264:1,20 265:7,15,16
voted 85:5 147:6
 173:16 245:12
votes 70:1 82:17 84:4
 94:2 131:18 149:22

153:1,11,21 157:12
 165:15 166:1,15
 195:12 196:5 200:20
 204:9 229:8 230:6
 234:19 235:5 242:11
 247:21 265:11
voting 8:9 46:22 69:22
 77:8 80:17,19 81:2
 82:13 87:1 112:9
 117:5 138:8 143:13
 149:6 152:5 156:17
 156:18 157:8 160:21
 164:9 166:5,8 167:21
 179:10 181:11,13
 182:8,10 193:14,19
 195:6 203:8 226:8
 229:1,20 234:8,15
 242:2,6 246:21 247:3
 247:13,16 248:4
 263:17 264:2,21

W

wait 147:14 266:2
waiting 143:17
walk 5:15 14:11 259:6
wand 80:19
want 5:20 6:10 7:19 8:5
 9:5,7,10 17:11 19:15
 20:16 21:15 22:18
 26:11 29:10 32:18,19
 33:15 35:22 37:8,8
 40:19 49:7 52:11
 63:10,11 65:3 68:9
 70:8 78:14 82:17
 83:14 89:15 90:19
 91:3 94:6 95:21 99:15
 110:10 117:1 126:13
 137:11 140:9 142:3
 147:13 150:15 159:22
 160:12 168:18 169:1
 173:10,12 174:14
 177:12 178:17 181:7
 183:3 189:20 205:9
 206:22 207:18 210:19
 212:14 214:6 215:20
 217:7 218:20 219:7
 220:8,11,19,21
 223:17 231:17 237:7
 252:10 254:5,10
 258:8 266:16 269:14
 269:15
wanted 5:18 6:11,14
 7:22 10:4 12:13 17:7
 29:15 30:14 31:12
 33:16 34:11 64:2
 87:17 102:5 106:2
 112:15 138:4 177:14
 204:16 228:18 230:15

233:15 242:18 256:2
269:22
wanting 96:17
wants 33:9 188:5,12,15
190:3 217:1 266:4,7
warranted 257:2
Warsaw 58:17
Washington 1:8 42:20
42:21
wasn't 86:21 115:9
164:8 247:2
watching 114:8
waving 80:18
way 5:7 9:14 18:7,10,11
19:1,3,9,13 21:16
23:16,17,19 24:17
25:9 27:4,5 31:19
32:4 37:16 39:19
44:22 46:16 66:18
72:12 74:5 76:3 89:22
104:11 108:14 114:11
130:5 134:6 139:7
146:18 148:3 155:19
161:17 162:6 171:2,6
187:5 190:20 198:6
199:18 216:4 218:4
218:10 224:14 235:17
237:16 240:15 246:16
250:7 259:16 261:20
ways 11:19 16:5 32:3
41:19,22 45:14 76:18
85:3 99:15 140:22
176:6 260:6
we'll 45:22 47:22 53:11
67:11 82:3 83:11,13
87:4 95:8 100:3,6
101:5 107:9 112:12
116:13,17 117:8
119:21 120:17 125:13
125:19 126:10 131:6
132:1,2 133:21
138:16 143:4,7
147:11,15,18 148:4
149:4 150:3 153:20
154:11 157:9,21
158:4,21 165:2,7,22
166:2,10,14 168:3
171:14,19 180:9,10
181:3,6,7,20 182:3,21
188:8 189:1,2 195:5
195:15,16,22 199:4
200:7,9,21 203:4,20
203:22 204:9 217:5
224:4 226:11 230:14
234:13,14,18 238:13
242:3,5,11 247:12,15
248:1 251:11,16
261:1 263:6,21 265:5

265:10 267:3,8,17
268:4,5,21 269:1
we're 17:11 46:6 53:7
64:11 77:3 79:12 81:4
83:6,18 84:19 86:22
92:4,20 94:2,16 95:7
97:5,6 98:4 106:22
107:3 109:2 117:5,21
121:21 123:2 124:16
124:20,21 125:3
127:16,19 128:5
132:5 138:21 139:7
143:17 149:6 153:6
156:16 163:2,13
165:3 166:5 174:6
182:8 185:6,14 186:7
186:9,10 187:5,6
190:14 193:19 197:13
197:16 202:9 208:12
217:7 221:3,8,20
223:6 224:9,13,15
231:19 232:17,21
234:8 235:10 237:6
239:4,18 240:4
243:15 245:4,15
246:21 248:12,13
250:7 252:12 254:6
255:8 257:13 263:17
264:2,10
we've 5:13 31:13 38:17
70:3 77:7 79:15 89:12
91:18,20 95:12
106:18 120:22 121:1
123:21 124:16 126:11
131:8 149:15 157:3
176:2 180:12 182:14
203:13,16 204:18
205:21 213:13 221:11
222:18 236:16 242:19
244:1 245:17 251:6
255:4,7 266:22
weaker 72:10,16,17
webinar 266:20
webinars 244:22
website 52:10 74:3,4
75:3 89:7,8,10 91:12
92:7 123:1 135:7
140:8,8
week 53:15 267:9
269:18
weeks 43:14 56:17
103:22
weigh 28:11 40:21
117:19
weight 259:15 260:3,18
260:19
weighted 259:11,11,13
259:16

weighting 262:17
weights 259:17,20
Welcome 4:2
well-adjusted 35:8
well-appreciated 46:9
went 5:4 28:18 42:7
66:14,19 67:3 71:13
103:21 120:6 139:6
176:15 179:9 224:7
233:14
weren't 24:3 208:13
210:11 211:11
wide 246:13
widely 29:19,20
wider 24:8,10 119:11
William 1:9,13
willing 45:6 57:3 90:12
213:19 219:18,19
WILSON 3:2 175:6
wind 101:17
window 29:1 102:13,13
102:20 103:2,9,11
windows 54:1,2
wisely 5:14
withdrawing 71:16
withdrawn 114:22
Woebegone 104:7
women 237:15,17
wondered 25:12
wondering 177:8 205:6
206:20
word 9:4 71:22,22
239:22 240:2
words 5:21 35:13
145:21 171:10
wordsmith 92:2
work 16:22 28:2 31:8
33:22 45:9,21,22 46:1
49:1,3 58:13 65:13
114:11 204:21 205:9
206:1,6 211:16 214:1
255:8 265:19
worked 65:12 128:12
214:2 218:16
working 4:12 7:16
27:21 32:21 38:17
49:6 65:13 92:14,20
106:19 124:22 198:6
224:4,14 245:4 270:4
works 90:1 134:6
250:16
worksheet 202:14
world 35:19 65:6
107:17 124:1 163:1
163:10 174:21 223:21
236:6
world-class 106:20
worst 239:13,14

worth 267:4
worthy 164:7
wouldn't 170:21 212:14
wound 159:1,6 161:2
161:16,22 162:4
164:6 249:4
wrap 207:4
write 62:1 185:5 212:10
writing 267:9
written 10:22 13:5,11
60:4 68:15,18 100:11
wrong 31:9,10 71:21
wrote 89:7

X

Y

Yap 3:16 49:5
Yates 2:21 14:17 21:12
21:13 24:11 36:1,5
39:1 113:5 115:9
116:1 117:10 155:13
156:3,15 162:18
186:7 209:4,17 246:2
246:7,22 250:22
251:4 256:4
yeah 186:6 191:17
193:7 210:8 232:7
238:3 240:22 243:1
year 38:14 50:3 53:21
53:21 55:12 90:15
101:10,12 102:12,12
102:13,17,20 103:1,8
103:11 104:4 135:21
139:16 155:10,10
159:20 177:4,12
205:3,3,5,5 210:6
217:10,13 241:7
243:13 244:4,17
245:6,10 246:18
255:14 257:7,8,20
262:1
year-old 192:3
years 7:4 30:22 41:13
74:14,15 139:17
142:15 159:4 171:20
198:11 207:6,22
208:13 212:13 218:19
219:13 225:13 253:18
255:9 256:14 257:6
258:15,19,20,20
261:18,20 270:3
yesterday 6:3 7:7 9:14
12:4 17:18 18:6 33:12
62:14 66:13 85:4
101:19 105:14 163:17
205:18 221:20
YETUNDE 3:6

York 10:9 33:5,6 34:13
44:12

Z

zero 18:14 56:22 58:4
70:4 81:12 82:1,2
87:2,15,15 93:15
101:15 107:8 112:11
115:7 116:15 117:8
119:16 128:4,4 147:8
147:8 154:3,3 157:5,5
157:18 158:11,11
164:21 165:17,17
168:1,1 181:17 195:9
196:3,3 199:15 200:3
200:3,16,16 204:5,5
229:5,5 230:3,3
234:17,17 235:4,4
240:20 241:20,20
242:8,8 247:9,9,18,18
255:13 262:10,10
263:4,4 264:5,5 265:3
265:3

0

0.2 159:18
0.38 101:1
0.55 130:17
0.69 130:20
0.75 101:1
0.88 130:18
0115 4:5 132:2
0116 4:8 166:12
0118 4:8 182:21
0121 4:9 224:10
0122 4:15 235:12
0123 4:9 201:5
0130 4:5 158:22
0696 4:18 248:10
0732 4:3 52:14
0733 4:4 94:22,22 95:8
98:16

1

1 4:2 22:9 51:12,19,20
100:22
1.1 159:19
1.4 143:2
1.68 201:17
1:00 203:11 224:4
1:51 270:10
10 50:2 81:11 87:2
93:15 94:4
10:29 120:6
10:45 120:4
10:48 120:7
100 101:10 120:1 201:2
232:15 233:2

100-plus 51:17
1030 1:8
11 133:5,9 195:2 248:16
250:3
11.1 239:17
11.5 226:22
11.9 239:1 240:16
12 125:22 139:17
199:19 207:22 239:1
250:10 251:21
12-month 137:10
12.5 103:4,5 104:16
105:1,1,2 251:21
12.7 226:20
12.75 101:3
12:15 196:20
12:40 224:7
12:59 224:8
120 4:4 49:19
125 49:17 51:1
13 246:10
132 4:5
14 116:15 128:4 178:7
179:21 207:22 246:17
15 111:3 208:13
150 74:16
1501 4:16 231:18,20
1502 4:17 245:19
158 4:5
15th 1:8
16 194:1 263:3
166 4:8
18 54:21 55:9 74:8,12
132:8 158:10 159:3
166:21 184:5,11,20
186:22 187:3,10,19
188:18 190:3 191:5
192:2,2 198:10 204:5
225:13
18.8 101:2
182 4:8
19 112:10 185:11 195:9
19-year-old 184:13
19,000 229:15
190 189:11
197 4:10
1998 53:17
1D 262:14

2

2 22:12 29:1 51:12
67:17
2.3 235:21
2.7 226:19
2:30 266:1
20 1:5 51:21 70:4
114:18 117:7 118:17
157:4 191:5 208:13

20-year 184:5
20.6 235:20
200 101:11 102:16
130:18
2006 48:17
2007 133:5 198:9
2008 226:13,14
2009 225:5
201 4:9
2010 243:11 250:14
2011 52:18 100:2
198:10 225:10 226:14
226:15
2012 139:6,15,18
2014 48:17 53:17
226:15
2015 1:5 91:18 139:18
20th 168:5
21 82:1 184:4,11,21
186:5 187:3 188:6,10
188:14,18 189:9,10
192:2,2 235:20 265:2
21-year 190:3
21-year-old 187:1
21-year-olds 187:20
2100 101:10
22 11:17 55:13 126:1
224 4:9
23 162:16
232 4:16
235 4:15
24 200:15
245 4:17
248 4:18
25 30:22 119:16 136:12
26 263:19
265 4:20
2683 4:4 94:17 95:1
120:18
27 157:18 235:3
27th 266:20
28 239:18
29 87:14 154:3 234:16

3

3 51:12 67:17
3-day 29:1
3-minute 48:9
3.4 100:18 101:12
30 11:7 13:7,9 71:14
87:1 88:2 96:2,6,9
97:13 99:1,2 136:12
159:6 198:16 202:4
225:16,18
30-day 10:6,20 11:4,9
11:17 12:2 13:4 14:9
14:19 19:17 20:7,8,21
20:22 28:19 42:4

3000 113:19
31 96:5 97:15
32 117:17 118:1,11
193:22
33 165:16 167:22
35 70:4 181:16 230:2
36 240:5
37 242:7 264:4
38 131:4 164:20

4

4 51:12
4-year 54:1,2
4,000 191:20
4.19 201:15
4.81 201:15
40 39:10 81:11 189:10
41 196:2
42 247:17
43 126:8 147:8 241:19
44 262:9
45 45:4 70:3
450 210:22
47 193:22
48 203:16,17 229:4

5

5 4:2 51:13,21 53:21
64:5,7 70:14 71:9
93:15 105:2 107:8
112:10 116:15 117:7
119:16 121:6,8
203:17 250:10
5.26 226:17,21
5.85 226:16
50 57:1 71:14 81:10
129:11 240:19 241:1
50/50 233:4
52 4:3 229:4
53 107:7 247:8
57 147:7 164:21 241:19

6

6 5:8
6:00 216:16
60 61:13 87:1 95:16
176:19 181:16
62 131:3
63 264:4
64 200:2
65 230:2
67 167:22
680 119:3

7

7.7 238:21 240:14
70 61:13 119:15
71 87:14 154:2 195:8

234:16
73 235:3
74 263:19
75 103:6 104:15 105:1
117:7 189:10 250:9
76 112:10
77 179:21
77,000 51:15
79 82:1 265:2

8

8 256:20 261:14
8.51 201:17
8.6 239:17
8:30 1:8 5:2
80 50:19,22
800 130:19 209:5
800-plus 213:9
80s 218:15
81 116:14
85 93:14
86 125:21
89 194:22

9

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In the matter of: Surgery Standing Committee

Before: NQF

Date: 03-20-15

Place: Washington, DC

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