

NATIONAL QUALITY FORUM

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NEUROLOGY STANDING COMMITTEE MEETING

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TUESDAY
APRIL 5, 2016

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The Neurology Standing Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:30 a.m., David Knowlton and David Tirschwell, Co-Chairs, presiding.

PRESENT:

DAVID KNOWLTON, MA, Co-Chair

DAVID TIRSCHWELL, MD, MSc, Co-Chair

DAVID ANDREWS, Patient Advisor, Georgia Regents Medical Center

JOCELYN BAUTISTA, MD, Assistant Professor, Neurology Staff Physician, Quality Improvement Officer, Cleveland Clinic Neurological Institute Epilepsy Center

KETAN BULSARA, MD, Associate Professor, Director of Neuroendovascular and Skull Base Surgery Programs, Neurovascular Section, Yale Department of Neurosurgery

JAMES BURKE, MD, University of Michigan

MICHELLE CAMICIA, MSN, RN, PHN, CRRN, CCM, FAHA, Director of Operations, Kaiser Foundation Rehabilitation Center

VALERIE COTTER, DrNP, AGPCNP-BC, FAANP, Advanced Senior Lecturer, University of Pennsylvania School of Nursing

BRADFORD DICKERSON, MD, MMSC, Associate Professor of Neurology, Director of the Frontotemporal Disorders Unit, Massachusetts General Hospital

**DOROTHY EDWARDS, PhD, Director, Collaborative
Center for Health Equity, University of
Wisconsin Madison School of Medicine and
Public Health**

**REUVEN FERZIGER, MD, Director, US Medical
Affairs, Merck and Company***

**DAVID HACKNEY, MD, Professor of Radiology,
Harvard Medical School, Beth Israel
Deaconess Medical Center**

**STEPHEN HUFF, MD, FACEP, Department of Emergency
Medicine, University of Virginia Health
Sciences Center**

**CHARLOTTE JONES, MD, PhD, MSPH, Director of
Quality, Division of Pediatric Neurology,
Nationwide Children's Hospital**

**MICHAEL KAPLITT, MD, PhD, Associate Professor,
Associate Professor with tenure, Weill
Cornell Medical College***

**RONALD KOENIG, MD, Medical Director, Anthem,
Inc.**

**LISA LINES, PhD, MPH, Health Services
Researcher, RTI International**

**ALEXANDER RAE-GRANT, MD, Director, Cleveland
Clinic Center for Continuing Education**

**MELODY RYAN, PharmD, MPH, Professor, University
of Kentucky College of Pharmacy**

**PETER SCHMIDT, PhD, Senior Vice President and
Chief Mission Officer, National Parkinson
Foundation**

**JANE SULLIVAN, PT, DHS, MS, Associate Professor,
Northwestern University**

**KELLY SULLIVAN, PhD, Assistant Professor,
Department of Epidemiology, Georgia
Southern University***

**ROSS ZAFONTE, DO, Professor and Chairman,

Department of Physical and Rehab, Harvard
Medical School**

NQF STAFF PRESENT:

ANN HAMMERSMITH, General Counsel
WUNMI ISIJOLA, Administrative Director
KAREN JOHNSON, Senior Director
ELISA MUNTHALI, Vice President, Quality
Measurement
YETUNDE ALEXANDRA OGUNGBEMI, Project Analyst
ANN PHILLIPS, Project Analyst, Health Information
Technology
CHRISTY SKIPPER, Project Manager
MARGARET TERRY, Senior Director
MARCIA WILSON, Senior Vice President, Quality
Measurement

ALSO PRESENT:

AMY BENNETT, American Academy of Neurology
SUSANNAH BERNHEIM, Yale-CORE
SOO BORSON, University of Washington *
JUDY BURLESON, American College of Radiology
KRISTEN BUTTERFIELD, Pharmacy Quality Alliance
KAREN DORSEY, Yale-New Haven Health System
WOODY EISENBERG, PQA
DIEDRA GRAY, PCPI
KAREN KOLBUSZ, The Joint Commission
JULIE KUHLE, PQA
ANUP PATEL, American Academy of Neurology
STEPHEN SCHMALTZ, The Joint Commission
LEE SCHWAMM, MGH/Harvard
DAVID SEIDENWURM, American College of Radiology
SAMANTHA TIERNEY, PCPI Foundation
ANN WATT, The Joint Commission

*** present by teleconference**

C-O-N-T-E-N-T-S

Welcome.	
Recap of Day 1	5
Consideration of Candidate Measures	
2864: CSTK-01: National Institutes of Health Stroke Scale (NIHSS) Score Performed for Ischemic Stroke Patients	
2865: CSTK-02: Modified Rankin Score (mRS) at 90 days	.52
2866: CSTK-03: Severity Measurement Performed for Subarachnoid Hemorrhage (SAH) and Intracerebral Hemorrhage Patients.	.89
2876: Hospital 30-day, all cause RSMR.	106
2877: Hybrid hospital RSMR	190
1952: Time to Intravenous Thrombolytic Therapy.	213
1814: Counseling for Women of Childbearing Potential with Epilepsy.	244
0507: Diagnostic Imaging: Stenosis Measurement in CAR	279
2111: Antipsychotic Use in Persons with Dementia	296
2872: Dementia - Cognitive Assessment.	296
Public Comment	351
Next Steps	251

Adjourn

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

2 8:32 a.m.

3 CO-CHAIR KNOWLTON: Welcome back. I'm
4 going to promise you a rapid day. People have
5 schedules to keep, and we promise you a day
6 without controversy today.

7 I was assured by Christy that all the
8 controversial measures were yesterday, so we
9 should just -- yes. You will be very shortly
10 issued a rubber stamp.

11 So David's going to give us a recap of
12 what happened yesterday, and then we're going to
13 pick up where we left off which is 2864, National
14 Institutes of Health Stroke Scale.

15 CO-CHAIR TIRSCHWELL: All right, so
16 just to briefly review from yesterday kind of in
17 order, and actually one of them I'm not exactly
18 sure that I have the right notes down.

19 But 0661 Head CT or MRI path, though
20 there was lots of debate about the 45-minute
21 rule. STK-01 venous thromboembolism, there was
22 low gap there. So I actually don't remember.

1 Did that one go to reserve? 0434. Oh, that was
2 the no consensus one.

3 MS. KOLBUSZ: It's the one we have a
4 question about, David, because ---

5 CO-CHAIR TIRSCHWELL: Yes.

6 MS. KOLBUSZ: -- it was before the
7 reserved status was resolved. And since all the
8 others went through the reserved status process
9 and you seem to have that under hand now, do you
10 want to revisit the STK-01 VTE Prophylaxis?

11 CO-CHAIR TIRSCHWELL: Is that where we
12 left it was that the gap was low and then we kind
13 of tabled it after that? It's a little different
14 because --

15 MS. JOHNSON: That was the one where
16 the gap wasn't as -- the performance rates were
17 not nearly as high. So I think there was --

18 PARTICIPANT: -- I recall it. It
19 seemed that there wasn't consensus about how to
20 handle the reserve status. It was more
21 calculated --

22 MS. JOHNSON: No, I think it was more

1 consensus of is there a gap or not --

2 CO-CHAIR TIRSCHWELL: Right.

3 MS. JOHNSON: -- and you guys had the
4 disparities data, but you were going to bring
5 that back potentially at post-comment call.

6 CO-CHAIR TIRSCHWELL: Yes, for the
7 other ones we were all in agreement that there
8 was no gap and so they went onto reserve. This
9 one, I think it was kind of split between maybe
10 there is a little gap and maybe there isn't. And
11 so that's --

12 MS. KOLBUSZ: We did give the
13 disparities, though, data yesterday.

14 CO-CHAIR TIRSCHWELL: The data that,
15 right, the verbal data we want to give you guys a
16 chance to present your data in full and have the
17 chance to review it. So --

18 MS. WATT: Is that true for all of
19 them? Are we looking for disparities data?
20 We're just trying to --

21 CO-CHAIR TIRSCHWELL: No, the other,
22 just that one. The other ones have been moved to

1 reserve.

2 MS. WATT: Okay. And so the
3 determination about that then is determined by
4 the disparities, right?

5 CO-CHAIR TIRSCHWELL: For STK-01?

6 MS. WATT: The first one, 0434. Yes.

7 CO-CHAIR TIRSCHWELL: Yes.

8 MS. WATT: Okay, thank you.

9 CO-CHAIR TIRSCHWELL: Okay, great.
10 Thanks for clarifying that.

11 0435, discharged on antithrombotic
12 failed on the low gap but was put on reserve, I
13 believe, and 2832 was thus, the eMeasure was not
14 discussed.

15 0439 discharged on statins were both
16 deferred again for data issues. They changed the
17 denominator. We were going to try to get the
18 first quarter of data or so, so we'll look
19 forward to hearing more about that one.

20 STK-04 0437, thrombolytic therapy
21 failed, and that was -- was that on gap as well?
22 Sorry, the eMeasure failed. 0437 passed, 2834

1 failed for insufficient feasibility.

2 0438, which is STK-05 antithrombotic
3 therapy, that one failed because there was no gap
4 so it went into reserve status. The eMeasure,
5 2835 was not reviewed.

6 0436, anticoagulation after AFib, no
7 gap again so it was put on reserve. The eMeasure
8 was not discussed. 0441, STK 10, assessed for
9 rehab, again no gap, put on reserve, eMeasure not
10 discussed.

11 2863, CSTK-06, Nimodipine
12 administered, that passed and that's where we
13 are. And so today we're starting with 2864,
14 CSTK-01, NIH Stroke Scale score performed for
15 ischemic stroke patients.

16 Does the Joint Commission want to
17 introduce the measure?

18 MS. KOLBUSZ: Yes, good morning
19 everyone. This is CSTK-01, National Institutes
20 of Health Stroke Scale score performed for
21 ischemic stroke patients.

22 This is looking for ischemic stroke

1 patients for whom an initial NIHSS score is
2 performed prior to any acute recanalization
3 therapy such as IV thrombolytic, t-PA, therapy,
4 or IA t-PA, or mechanical endovascular
5 reperfusion therapy in patients undergoing
6 recanalization therapy and documented in the
7 medical record, or documented within 12 hours of
8 arrival at the hospital emergency department for
9 patients who do not undergo recanalization
10 therapy.

11 The rationale for the measure is that
12 it's thought that all ischemic stroke patients
13 should have a rapid neurological examination when
14 presenting to the hospital department with
15 warning signs or symptoms of stroke to determine
16 the priority for treatment with t-PA.

17 The use of a standardized stroke scale
18 for scoring should be used. And the NIHSS is a
19 scale that has been recommended by the American
20 Heart Association, the American Stroke
21 Association, it is recommended in the guidelines
22 and it is widely accepted. Therefore that score

1 has been decided upon as the tool to be used for
2 this particular measure.

3 The denominator population for the
4 measure are ischemic stroke patients who arrive
5 at the hospital emergency department. The
6 numerator is ischemic stroke patients for whom a
7 NIHSS score is performed prior to any acute
8 recanalization therapy in patients undergoing
9 recanalization therapy and documented in the
10 medical record, or documented within 12 hours of
11 hospital arrival for patients who do not undergo
12 recanalization therapy.

13 Excluded populations include patients
14 less than 18 years of age, patients who have a
15 length of stay greater than 120 days, patients
16 with Comfort Measures only documented on the day
17 of or day after hospital arrival, patients
18 admitted for a Elective Carotid Intervention, or
19 patients who do not undergo recanalization
20 therapy and are discharged within 12 hours of
21 arrival at the hospital.

22 CO-CHAIR TIRSCHWELL: Great, any other

1 comments?

2 DR. SCHWAMM: Yes, I just want to make
3 three brief points, and we can talk about them
4 again at the end of the discussion. The first is
5 just in terms of understanding why it's important
6 to have this as an NQF-endorsed measure.

7 It is now guideline recommended by the
8 American Heart Association that the NIH Stroke
9 Scale Score be performed in all ischemic stroke
10 patients.

11 Studies have shown that centers that
12 routinely perform the NIH Stroke Scale Score give
13 t-PA to a greater percentage of eligible
14 patients, so it clearly is part of a system, a
15 sort of systematic approach to assessing patients
16 with stroke.

17 And I think most importantly and only
18 released after these submissions, there is a new
19 AHA guideline related to thrombectomy, so
20 endovascular clot removal, which recommends that
21 the procedure be considered for patients with an
22 NIH Stroke Scale score of 6 or higher. So the

1 collection of the score now is predicated on the
2 appropriate triage of patients to comprehensive
3 centers.

4 So I think for all of those reasons
5 there's a strong connection between the score,
6 which isn't just for severity and risk
7 adjustment. It actually now is being used to
8 guide treatment decisions.

9 CO-CHAIR TIRSCHWELL: Okay, thank you.
10 So the discussants are Michelle, Mike, and Lisa.
11 Who's going to take the lead?

12 MEMBER LINES: I've been nominated.

13 CO-CHAIR TIRSCHWELL: All right.

14 MEMBER LINES: I assume Michelle will
15 jump in with any corrections to my work.

16 So this is a new measure. It's a
17 process measure to talk about the evidence. The
18 developer has talked about what they've laid out
19 in terms of the evidence.

20 And they say that presenting, that the
21 NIHSS assessment for ischemic stroke patients
22 increases early detection and diagnosis,

1 increases the identification of patients eligible
2 for treatment and helps predict outcomes.

3 They did not present any systematic
4 review or QQC, but they did present the
5 guidelines. The guidelines support neurological
6 testing, but there's no evidence on the 12-hour
7 time frame, and that was something that came up
8 during the workgroup discussion.

9 So using an algorithm, you know, the
10 initial recommendation was that the evidence was
11 moderate. I would say moderate to low, because
12 evidence certainly exists that neuro testing is
13 important, but I wrote this somewhere in the
14 workgroup call as well, the NIHSS is an older
15 instrument.

16 There's a newer instrument available,
17 the modified NIHSS which, I mean, from a
18 measurement perspective it seems to me that it
19 would be a good idea to at least allow for some
20 innovation and allow the measure to be specified
21 both with either the NIHSS or the mNIHSS.

22 The mNIHSS is more reliable, it's

1 more, it's shorter, it's also something that can
2 be estimated from the claims. So it has some
3 advantages.

4 And the other thing about that is that
5 the evidence exists but it's not necessarily any
6 evidence about that 12-hour time frame.

7 CO-CHAIR TIRSCHWELL: Discussion from
8 the group related to evidence? Ketan?

9 MEMBER BULSARA: You know what. Just
10 because Lisa brings it up, to the developers why
11 not use the modified NIHSS?

12 DR. SCHWAMM: And there have been
13 several efforts to create alternative versions of
14 the NIH Stroke Scale score. There's also the
15 Canadian Stroke Scale score. There are other
16 measures of stroke severity.

17 The reality is I think that to a
18 certain extent these are arbitrary ways to try to
19 create a metric of stroke severity which would
20 just acknowledge that there's nothing magical
21 about the NIH Stroke Scale score.

22 In an area though, where things are

1 somewhat arbitrary, standardizing around a single
2 instrument has proven to be extremely important.
3 All the major societies endorse the use of the
4 full NIH Stroke Scale score not the modified NIH
5 Stroke Scale score.

6 Not really because there's any lack of
7 evidence to support its equivalence, but more
8 that there are training materials, standardized
9 approaches, people have a sense of what a 5, an
10 8, a 12 means on the standard score.

11 So I would argue that the data
12 supporting the use of just that alternative scale
13 would have been weaker, but certainly were this
14 measure to be approved it would be reasonable for
15 the next measure submission to think about
16 allowing alternative constructs for stroke
17 severity to be allowed.

18 CO-CHAIR TIRSCHWELL: Mike, you're on
19 the phone. Would you like to make a comment?
20 Mike Kaplitt. Can you open his phone line,
21 please?

22 OPERATOR: His line is open.

1 MEMBER KAPLITT: Can you hear me?

2 Sorry, can you hear me?

3 CO-CHAIR TIRSCHWELL: Yes. Yes.

4 MEMBER KAPLITT: Okay, I apologize.

5 So yes, sorry I can't be there, but thank you.

6 So I, you know, I have no problem with the use of
7 the NIH Stroke Scale because I think there is
8 adequate evidence provided and there's a lot of
9 guidelines, et cetera.

10 And while there are newer measures, I
11 agree, there's a limit I think to how much we
12 can, you know, I think there's a limit to how
13 much we can sort of actively move with the
14 changing world when it comes to these types of
15 guidelines because they obviously do lag a bit.

16 And I think that the evidence is good
17 enough that there is value in the NIH Stroke
18 Scale as the developer said at the beginning and
19 as was in the evidence.

20 My problem is that as was said
21 earlier, the 12-hour thing, I see just no
22 evidence for that and I really need somebody to

1 explain to me what the basis is for that.

2 What the evidence is that doing an NIH
3 Stroke Scale on someone who's not recanalized
4 within 12 hours of arrival, 12 hours of arrival
5 not 12 hours of last known well, which still has
6 no basis.

7 So someone comes in, let's say, six or
8 eight hours after the onset of symptoms could
9 wind up getting an NIH Stroke Scale essentially
10 20 hours or 18 hours after the last known well,
11 and somebody's got to tell me what the value is
12 of that other than voyeurism.

13 So what are we using it for to justify
14 the effort? And if there is no evidence to
15 support that then my problem is that as we've
16 said over and over again, we have to evaluate the
17 measure before us not the measure we would want.

18 And I have absolutely no problem with
19 this measure without that 12-hour thing, just my
20 personal view. But once that 12-hour thing is
21 part of the measure and an absolute part of the
22 numerator, if there's no evidence, to me there's

1 not, if the evidence is low for that then the
2 evidence is low for the measure, period.

3 CO-CHAIR TIRSCHWELL: Does the
4 developer want to respond to that?

5 DR. SCHWAMM: So it's a very
6 reasonable concern. I think the measure
7 construct was designed to be a compromise between
8 what would be too onerous and what would be
9 important in terms of understanding the processes
10 of care that occur in the emergency department
11 where the opportunities for intervention are
12 occurring in those first few hours after
13 emergency room arrival.

14 And were you to allow, let's say, 24
15 hours for measurement, if the patient came in and
16 then deteriorated in the first 24 hours and then
17 you measure the NIH Stroke Scale score at the
18 end, your risk adjusted outcome for that patient
19 is deceptively better. Clearly, you need to
20 measure it before you do any intervention, acute
21 intervention, t-PA, thrombectomy, et cetera.

22 And I think the major supporting claim

1 for this is that it helps you communicate the
2 degree of severity and the expected course of
3 that patient. Do they need an ICU? Are they
4 likely to be discharged home?

5 So clearly, you need to collect it
6 acutely in patients in whom you're going to do
7 acute interventions. Twelve hours is enough time
8 so that patients who arrive during the work day
9 can have it assessed during the work day.

10 Patients who arrive overnight or early
11 in the morning can have it assessed in the
12 morning, so that it gives flexibility if an
13 emergency physician performs it at one
14 institution but it's only the neurologist at
15 another institution.

16 It provides some room for flexible
17 assessment with the idea that for many patients
18 those first 12 hours, it will be a reasonable
19 surrogate of their initial presentation.

20 But I would agree it's not a perfect
21 number and there's no study that looked at --

22 MEMBER KAPLITT: I'd like to know

1 again, we're supposed to be judging evidence
2 here. That's the section we're on. So the
3 first, you know, the first part of it which is
4 that there's evidence that you should do the NIH
5 Stroke Scale before any intervention or on a
6 patient who's a candidate for intervention within
7 the time window of that intervention, I don't
8 think there's a huge disagreement here.

9 I mean, people may argue as we heard
10 earlier about whether it's the best instrument
11 now, but I don't think anybody would argue about
12 the importance of an instrument.

13 But most of what you just said, you
14 know, again you're not giving us to my knowledge
15 any evidence for anything you've just said. It's
16 just an opinion, unless I'm missing something.

17 CO-CHAIR TIRSCHWELL: Any further
18 comments? Yes, Peter.

19 MEMBER SCHMIDT: Are we focusing on
20 the 12 hours when we should be focusing on the
21 before any intervention? What percentage of the
22 population is not, you know, would not fall into

1 the first part of the definition?

2 CO-CHAIR TIRSCHWELL: The majority of
3 the population.

4 MEMBER SCHMIDT: The majority would
5 fall into the first part?

6 CO-CHAIR TIRSCHWELL: No.

7 MEMBER SCHMIDT: No, would not. Okay.

8 CO-CHAIR TIRSCHWELL: Only a minority
9 become eligible for these treatments
10 unfortunately.

11 And I just want to add one other
12 comment about the full version of the NIH Stroke
13 Scale. I realize there are some statistical
14 issues to suggest maybe the modified is a little
15 bit better, but there's a face validity issue
16 here where the NIH Stroke Scale is designed to
17 try to replicate a fairly comprehensive
18 neurologic exam.

19 And I realize that some of the
20 elements are a little bit less reliable, but that
21 probably just reflects reality in the way
22 neurological exams are done.

1 And I think the full version has
2 better face validity for sort of a more
3 comprehensive neurologic exam, and you then start
4 peeling stuff off just on the basis of numbers I
5 feel like you undermine it.

6 And I would agree with the comment
7 that there is so much inertia and really global
8 acceptance of the full version of the scale that
9 to kind of change wholesale would really, I think
10 it would lead to a massive cost and reduplication
11 of efforts for training and other stuff. And I
12 don't think it's justified.

13 MEMBER EDWARDS: I'd like to speak to
14 the rehabilitation value of the 12-hour
15 assessment with the full scale. Lengths of stay
16 for acute stroke are very short, and the entire
17 team uses these scores and these scales,
18 particularly the scale items.

19 So, on an acute stroke service there's
20 usually an OT/PT speech pathologist and often
21 maybe a psychologist who look at the scores, and
22 the rehabilitation decisions are made very, very

1 early in the process given the short length of
2 stay.

3 And so this is a very, very important
4 part of treatment that actually isn't listed in
5 the measure development that I think should be
6 noted.

7 CO-CHAIR TIRSCHWELL: Great. Thank
8 you. Steve?

9 MEMBER HUFF: Point of clarification,
10 this is a marker for stroke center certification
11 and not for individual physician performance. Is
12 that correct?

13 MS. KOLBUSZ: That's correct. It's
14 for comprehensive stroke centers.

15 MEMBER HUFF: Just note that
16 anecdotally frequently my institution the CT scan
17 is ready, we're trying to get this patient to the
18 CT scanner and there's a hold-up while someone on
19 the team is performing a stroke scale.

20 So this is an unintended consequence.
21 You know, we're under a 45-minute timeline from
22 time of arrival to get CT to do this, so I would

1 just not think this should trickle down to
2 individual physician performance in the acute
3 setting.

4 You know, the Stroke Scale is used to
5 guide treatment when it's convenient. When the
6 person has disabling symptoms, and aphasia's the
7 best example, often treatment is given regardless
8 of what the Stroke Scale is.

9 So it's just another marker. You
10 know, NINDS used significant and enduring as the
11 symptom to get t-PA treatment, and through the
12 years efforts to assign specific numbers for
13 treatment for the Stroke Scale have been revised.
14 They've been revised through the years. So as a
15 center performance I think this is fine.

16 CO-CHAIR TIRSCHWELL: Thanks.

17 Dorothy, do you have another comment?

18 MEMBER EDWARDS: Just that I remember
19 that in the early days of t-PA administration
20 people with scores of greater, you know, people
21 with mild stroke were excluded from t-PA
22 treatment.

1 And one of the advantages of going
2 down to a score of 6 is that there are people who
3 are actually benefitting from treatment who are
4 not seen as having symptoms severe enough to
5 warrant the risk.

6 MEMBER HUFF: Certainly the treatment
7 of individual patients is in flux and no absolute
8 number has been created and there's different
9 subscales within the larger scale.

10 So it's a number that gets used when
11 it fits. When it doesn't get used often
12 treatment happens anyway. So it's not really a
13 line in the sand.

14 CO-CHAIR TIRSCHWELL: It's not a hard
15 line in the sand, I would agree with that. And
16 there are trials going on to look at whether
17 there really should be any specific limit.

18 Okay, any other comments or discussion
19 related to evidence?

20 MS. KOLBUSZ: I think the measure
21 developer has one comment to make.

22 CO-CHAIR TIRSCHWELL: Please.

1 MS. KOLBUSZ: And this was raised
2 after the workgroup call when the evidence was
3 questioned, because it was mentioned on the call
4 that there wasn't a systematic review that was
5 supplied for this particular measure and that is
6 not exactly correct.

7 Under the section of the measure
8 submission form, 1a.6.1, we did provide the
9 citation from Teale EA and Forster A, which was a
10 systematic review of case-mix adjustment models
11 for stroke.

12 There were other models also mentioned
13 in that review, but it was not mentioned as
14 evidence and I think that it should be
15 represented.

16 CO-CHAIR TIRSCHWELL: Okay. And the
17 upshot was that the review suggested using the
18 NIH Stroke Scale in case-mix adjustment was
19 appropriate?

20 MS. KOLBUSZ: It did support the use
21 of the NIH Stroke Scale for ischemic stroke
22 patients.

1 CO-CHAIR TIRSCHWELL: For case-mix
2 adjustment?

3 MS. KOLBUSZ: Yes.

4 CO-CHAIR TIRSCHWELL: Okay. All
5 right, any other comments? I say we move to vote
6 then on evidence, working on getting that up.

7 MS. SKIPPER: Good morning. We are
8 now voting on evidence for Measure 2864. One
9 high, two moderate, three low, four insufficient.
10 Voting is open.

11 CO-CHAIR TIRSCHWELL: Everybody make
12 sure you click your clicker.

13 MS. SKIPPER: And aim this way. We're
14 waiting on two more, three more. Two more, one
15 person out and we're voting on behalf of two
16 others on the phone.

17 CO-CHAIR TIRSCHWELL: One more time.

18 MS. SKIPPER: One more.

19 CO-CHAIR TIRSCHWELL: That's it.

20 MS. SKIPPER: Okay, regarding Measure
21 2864 evidence, zero percent high, 76 percent
22 moderate, 24 percent low, zero percent

1 insufficient. The measure passes on evidence.

2 CO-CHAIR TIRSCHWELL: Gaps?

3 MEMBER LINES: Okay. So according to
4 data from 2015, the mean performance rate at 38
5 to 50 hospitals sampled was 84 to 85 percent and
6 the national aggregate rate was 83 percent, so
7 certainly a gap.

8 The developers presented also some
9 evidence on disparities, a retrospective chart
10 review, 574 patients, 25 percent of them were
11 African American. They were admitted to five
12 different certified primary stroke centers.

13 They found that 40 percent of whites
14 and 29 percent or 30 percent of blacks had a
15 documented NIHSS score and that was a p-value of
16 0.03. But after they adjusted for the greater
17 number of late arrivals in African Americans
18 there was no longer a racial disparity for this
19 variable.

20 So it was p was 0.054. That was the
21 evidence presented on disparities, so certainly a
22 gap, limited evidence of any disparities at this

1 point.

2 CO-CHAIR TIRSCHWELL: So a gap in that
3 there's an overall opportunity for improvement
4 but no clear disparity data presented. Any
5 comments or discussion from the committee?
6 Developer?

7 DR. SCHWAMM: Yes, I do want to point
8 out that starting in October of this year there
9 will be a new data element available in ICD-10 to
10 capture the NIH Stroke Scale score, and you'll
11 hear later today about CMS risk-adjusted
12 mortality and readmission measures that will hope
13 to leverage that NIH Stroke Scale score
14 documented in claims data.

15 CO-CHAIR TIRSCHWELL: Right. Yes,
16 Michelle.

17 MEMBER CAMICIA: A question for the
18 developer. On the prior measures you had more
19 representative sample of sites, and could you
20 explain why we have limited sites for this
21 measure?

22 MS. KOLBUSZ: Yes. I don't know if

1 our biostatistician is on the line, Stephen
2 Schmaltz, or if it can be opened for him.

3 CO-CHAIR TIRSCHWELL: Part of the
4 lower number is that this is just comprehensive
5 stroke center, so it's a much smaller number of
6 hospitals. Is that what you were worried about?
7 Okay.

8 MEMBER CAMICIA: Yes.

9 DR. SCHWAMM: We have a lot of data
10 collected and get with the guidelines with rates
11 of completion that were originally around 40
12 percent when we started recommending collection
13 of this element and get with the guidelines,
14 which is almost 2,000 hospitals nationwide now.

15 Initially, rates were higher in
16 patients receiving t-PA compared to patients who
17 did not, but rates overall now are close to 80
18 percent.

19 So we still have a big performance
20 gap. It doesn't get with the guidelines, which
21 is a very nationally represented sample but it is
22 feasible. People have been collecting it more

1 and more systematically, and so I think there is
2 a broader sample of use available. It's not just
3 being done in comprehensive centers.

4 CO-CHAIR TIRSCHWELL: And is the rate,
5 just off the top of your head, higher in the
6 comprehensive stroke centers where it's required
7 as opposed to the primary stroke centers?

8 DR. SCHWAMM: Yes.

9 MEMBER CAMICIA: Thank you, important
10 information to have. It really does speak to the
11 measure.

12 CO-CHAIR TIRSCHWELL: Any other
13 comments or discussion on gaps or opportunities
14 for improvement? If not, let's go ahead and
15 vote.

16 MS. SKIPPER: We're now voting on gap
17 for 2864. One moderate -- one high, excuse me --
18 two moderate, three low, four insufficient.

19 CO-CHAIR TIRSCHWELL: Fast, I saw it.
20 It went really quick. It was all high and
21 moderate. It did go by really quick.

22 MS. SKIPPER: So Measure 2864 on gap,

1 27 percent high, 73 percent moderate, zero
2 percent low, zero percent insufficient. This
3 measure passes on gap.

4 CO-CHAIR TIRSCHWELL: Lisa,
5 reliability?

6 MEMBER LINES: So my script tells me
7 to go through the numerator and denominator and
8 exclusions but we did that already, so I think we
9 can skip that.

10 The data source that was specified and
11 tested is medical record abstraction, paper or
12 electronic. I don't have any concerns or issues
13 with the specifications, definitions or coding.

14 In terms of reliability testing, they
15 tested at the data element level. They did
16 interrater reliability testing. They tested the
17 14 data elements that are involved at 12 sites,
18 281 total records from 2013.

19 The calculated percent agreement for
20 the 14 data elements, and they range from 71.5
21 percent to 99.3 percent, they calculated a kappa
22 score for the initial NIHSS score performed, the

1 ED patient, the elective carotid intervention.

2 The kappas on the first two were
3 great. The elective carotid intervention, the
4 kappa was quite low. They suggested that is
5 because of the low prevalence of patients with
6 elective carotid intervention in the testing
7 sample, so they relied on the percentage
8 agreement value in their interpretation of the
9 reliability.

10 I would say caution. That if
11 testing's only done at the data element level
12 then the highest possible rating is moderate, but
13 I would say it's probably moderate is fine.

14 CO-CHAIR TIRSCHWELL: Comments or
15 discussion about reliability? Let's go ahead and
16 vote then. Don't vote yet.

17 MS. SKIPPER: We are now voting on
18 reliability for Measure 2864. One high, two
19 moderate, three low, four insufficient.

20 Measure 2864 on reliability, nine
21 percent high, 91 percent moderate, zero percent
22 low, zero percent insufficient. The measure does

1 pass on reliability.

2 CO-CHAIR TIRSCHWELL: Validity?

3 MEMBER LINES: Okay. So the question
4 is whether this classification's in line with the
5 evidence. As we've already discussed, they did
6 not provide evidence to support the 12-hour time
7 frame.

8 They tested validity at the measure
9 score level. Face validity of the elements was
10 reported, but they did not address face validity
11 of the measure score as a representation of
12 quality as required for the criterion.

13 Data element validity was assessed for
14 accuracy and clarity by hospitals, but the data
15 element validity criterion requires comparison to
16 a gold standard and that was not done.

17 We discussed on the workgroup call the
18 issues about missing data, and they then
19 provided, there was a very high percent that
20 were, one of them was off. It was not actually
21 accurate data that was presented on missings, so
22 they presented us with revised data and those are

1 fine.

2 Using the algorithm I would say the
3 validity seems moderate to low.

4 CO-CHAIR TIRSCHWELL: Discussion?
5 Comment from the developer?

6 DR. SCHWAMM: I think part of the
7 challenge is there is no referenced standard
8 against which to measure the score so, really,
9 you need to rely on interrater reliability or
10 intraclass correlation coefficients.

11 And the NIH Stroke Scale score has
12 been studied extensively in that regard. There's
13 a very large body of literature looking at
14 comparing two independent raters and more
15 recently comparing ratings over telemedicine to
16 ratings in person, and the vast majority of the
17 elements perform in the excellent or good
18 category in interrater reliability with only one
19 or two elements performing below that.

20 So I think the measure itself, unless
21 I'm misunderstanding the validity question, has
22 been thoroughly evaluated for validity.

1 CO-CHAIR TIRSCHWELL: I think some of
2 those things you referred to are probably more
3 reliability than validity, the interrater
4 comparison. The validity, and I agree that there
5 is no better stroke severity measure gold
6 standard to compare it to, but if you look at
7 predictive validity for example, and looking at
8 its association with mortality and outcomes, like
9 a more evidence that you could ever want to read
10 in your lifetime to suggest that it is a valid
11 measure of stroke severity, but whether it's a
12 valid measure of quality is a slightly different
13 question, I guess.

14 Any other comments? Discussion?

15 MR. SCHMALTZ: This is Steve Schmaltz
16 from the Joint Commission. At 5 Validity we also
17 looked at the correlation of the measure score
18 with other measures in the CSTK set and they were
19 positive and significant.

20 CO-CHAIR TIRSCHWELL: So yes, you're
21 referring to the correlation with CSTK-02, so
22 it's just the fact that it was done there was a

1 positive correlation between success in this
2 quality measure and success in another quality
3 measure, right?

4 MR. SCHMALTZ: Correct.

5 CO-CHAIR TIRSCHWELL: Okay, thank you.
6 Okay, let's go ahead and vote then, validity.

7 MS. SKIPPER: We are now voting on
8 validity for Measure 2864. One high, two
9 moderate, three low, four insufficient.

10 Just one more. Polling has closed.
11 High five percent, 68 percent moderate, 27
12 percent low. This measure does pass on validity.

13 CO-CHAIR TIRSCHWELL: Thank you.

14 Feasibility, Lisa?

15 MEMBER LINES: Okay. The medical
16 record review to abstract all data elements
17 required for this measure set averaged 45 minutes
18 per record.

19 As Melody mentioned yesterday, the
20 developer estimated that the cost per case for
21 abstracting this measure is approximately \$3.50,
22 which seems very odd.

1 CO-CHAIR TIRSCHWELL: Can I just
2 interrupt for a second, because that 45 minutes,
3 3.50 thing is in a whole bunch of measures.
4 There must be, can you give us some clarification
5 on that?

6 MS. KOLBUSZ: Yes. I will give some
7 clarification --

8 CO-CHAIR TIRSCHWELL: Thank you.

9 MS. KOLBUSZ: -- since we've been
10 referenced so many times in regards to the \$3.50.

11 This was a pilot test. During the
12 pilot test we try to get a handle on the burden
13 of abstraction and the time and the resources
14 that will be set forth to collect the measure
15 set.

16 During the pilot test of the measures,
17 which may not have been totally clear in the
18 submission, there were 13 measures collected. So
19 basically what we did when we went to our 12
20 pilot sites is we determined the level of
21 personnel who collected the data.

22 There were nurses collecting data,

1 data abstractors, administrative staff. We used
2 2012 labor statistics using the national rate,
3 taking an average, taking a 45-minute of that
4 average and dividing it by the 13 measures in the
5 pilot test.

6 CO-CHAIR TIRSCHWELL: So the 45
7 minutes is for all of them?

8 MS. KOLBUSZ: And so it's for a total
9 chart, correct, for all the measures.

10 CO-CHAIR TIRSCHWELL: Yes. That
11 wasn't, I was really not clear and so that makes
12 a lot more sense.

13 Lisa, go ahead.

14 MEMBER LINES: That was all I had for
15 feasibility.

16 CO-CHAIR TIRSCHWELL: Okay. So we
17 don't have quality reviewer slave camps anywhere
18 in the United States as far as we could tell,
19 which is good. It's very reassuring. Let's go
20 ahead and vote on feasibility.

21 Oh, I'm sorry. Michelle, please.

22 MEMBER CAMICIA: So that was the

1 average of across all measures, so this measure
2 might actually carry some of the greater burden
3 of that 45 minutes.

4 DR. SCHWAMM: This is a very
5 straightforward measure to abstract. The person
6 conducting the evaluation documents, either the
7 14 subelements and the total or just the total,
8 it's usually in the first few pages of the
9 medical record.

10 I would estimate that this, just
11 speaking as a person who looks at charts for
12 these kind of things, it's one of the easiest
13 elements to abstract because you don't have to
14 make any judgments, you just have to find the
15 score and write it down. So it's quite
16 straightforward. That's the abstraction.

17 The performance of the score in a
18 patient who has a mild deficit can take a matter
19 of, you know, two to three minutes. In a patient
20 with complex deficits could take four to five
21 minutes. But this is a very brief screening
22 evaluation. It's not an in-depth neurologic

1 exam.

2 CO-CHAIR TIRSCHWELL: Thank you,
3 anything else? Let's go ahead and vote on
4 feasibility then, please.

5 MS. SKIPPER: We're voting on
6 feasibility for Measure 2864. One high, two
7 moderate, three low, four insufficient. Waiting
8 on one more so, everyone, if you can just point
9 in my direction.

10 The voting has closed on feasibility
11 for Measure 2864, 41 percent high, 50 percent
12 moderate, nine percent low, zero percent
13 insufficient. The measure does pass on
14 feasibility.

15 CO-CHAIR TIRSCHWELL: All right,
16 great. Usability and use.

17 MEMBER LINES: Okay. So it's used for
18 Joint Commission stroke center certification, so
19 thus far it's limited to about 50 hospitals not
20 currently reported to the public.

21 In the pilot data it was about 72
22 percent and improved to 83 percent or so in the

1 second quarter of 2015. I, at this point, should
2 ask the committee members whether they have any
3 personal experience using this measure. I don't
4 personally have any experience.

5 CO-CHAIR TIRSCHWELL: I have personal
6 experience. It was okay. You know, honestly,
7 again if you take care of stroke patients
8 clinically, this is, you know, this is just part
9 of everyday activities. It's totally routine.
10 It only takes a few minutes.

11 And I think once you get used to it,
12 it's quite reliable and can convey quite a bit of
13 information in a very efficient fashion, so
14 tremendously widely used and accepted in the
15 clinical world.

16 DR. SCHWAMM: The only other comment I
17 would make is that I think it's a very important
18 tool for interprofessional communication, and so
19 it's a tool that increasingly is used by nurses
20 when they sign patients out to each other.

21 As was mentioned before, physical
22 therapists, occupational therapists, Dr. Zafonte,

1 you talked about its role in rehabilitation
2 medicine, but it is the currency of how we think
3 about stroke severity and has, I think it has
4 profound benefit as a communication tool over and
5 above the severity measurement itself.

6 CO-CHAIR TIRSCHWELL: With no further
7 -- yes, Ross.

8 MEMBER ZAFONTE: Let me just agree
9 with Lee on this one. We in the post-acute world
10 as Dorothy has said, use it in very much the way
11 nowadays in that in spinal cord the ASIA scale is
12 utilized.

13 So it's metric for tracking and an
14 important communication tool, and so I think it
15 has an existential long term value as well.

16 CO-CHAIR TIRSCHWELL: Let's go ahead
17 and vote on usability and use, please.

18 MS. SKIPPER: We're now voting on
19 usability and use for Measure 2864. One high,
20 two moderate, three low, four insufficient.

21 On usability and use, Measure 2864, 68
22 percent high, 32 percent moderate, zero percent

1 low, zero percent insufficient. The measure does
2 pass on usability and use.

3 CO-CHAIR TIRSCHWELL: So then we'll
4 just go on and vote on overall suitability for
5 endorsement.

6 MS. SKIPPER: Polling is open for
7 overall suitability for endorsement in Measure
8 2864, one yes, two no.

9 MEMBER KAPLITT: Can I say something
10 before we vote? This is Mike. Can you guys hear
11 me?

12 CO-CHAIR TIRSCHWELL: Go ahead, Mike.

13 MEMBER KAPLITT: Hello?

14 CO-CHAIR TIRSCHWELL: Go ahead.

15 MEMBER KAPLITT: You know, before we
16 vote I just want to make one final comment and
17 then we can all vote.

18 While I understand that the vast
19 majority voted moderate on the evidence, I just
20 want to remind everybody that as we vote on this
21 final measure if we approve it we will be
22 approving a measure for which not a single person

1 in this room or on the phone has disputed the
2 fact that there is zero evidence in support of a
3 critical component of the primary measure of the
4 numerator, and that component for which there is
5 no evidence will wind up applying to the vast
6 majority of patients for which this will be used.

7 So I just wanted to make that comment,
8 and if anybody wants to dispute that that's fine.
9 But if it's not in dispute, I just want everybody
10 to keep that in mind as we vote.

11 CO-CHAIR TIRSCHWELL: Why don't you
12 ask him?

13 CO-CHAIR KNOWLTON: Mike, this is
14 David. I'm not following what the evidence piece
15 you're referencing. Maybe I've lost the
16 antecedent in what you're saying.

17 MEMBER KAPLITT: Okay. So, once again
18 as we discussed in the evidence part, and I
19 understand that everybody voted and decided that
20 it wasn't that important.

21 But I'm just reminding everybody that
22 the developer has stated that the numerator,

1 meaning the patients that will be included are
2 those that receive an NIH Stroke Scale prior to
3 undergoing therapy, or documented within 12 hours
4 of arrival who do not undergo recanalization
5 therapy. Okay.

6 And as we've said that second part of
7 the numerator will apply to the majority of
8 patients because the majority will probably not
9 undergo recanalization therapy, and I have not
10 heard one word of evidence to support the
11 rationale for requiring 12-hour documentation of
12 the NIH Stroke Scale for patients who do not
13 undergo recanalization therapy.

14 And now we have this discussion and I
15 understand that we voted, I'm just reminding
16 everybody that despite the fact that everybody,
17 that the majority of people voted that there was
18 moderate evidence, this is, this part, this
19 documented within 12 hours of arrival if they
20 don't undergo recanalization therapy is the
21 developer's own essential component of this
22 measure.

1 It's the essential component of the
2 numerator, and that's the part, that unjustified
3 part that has no evidence. No one has argued for
4 evidence that there is evidence for a 12-hour NIH
5 Stroke Scale for anybody who's not undergoing
6 recanalization therapy. That will apply to the
7 majority of patients for whom this measure is
8 going to be used, so I'm just reminding everybody
9 of that.

10 CO-CHAIR TIRSCHWELL: Yes. This is
11 David Tirschwell. I'll just defend the measure
12 briefly and say that the time window thing is a
13 little bothersome, but at the end of the day you
14 do end up having to put some line in the sand.
15 Often it's a random line in the sand.

16 And I think we've heard from multiple
17 members of the committee about the value of
18 having this Stroke Scale score available on all
19 of the ischemic stroke patients, regardless of
20 whether they get intervention, as a means of
21 communication to optimize patient care and
22 outcomes.

1 So, you know, I agree with you the 12-
2 hour thing is not supported by very specific
3 evidence, but I think there are bigger issues.

4 MEMBER KAPLITT: I know what you're
5 saying, but then we're just substituting our
6 opinion. I mean, you know, then we're not using
7 evidence, we're substituting our opinions for
8 what we'd like to do.

9 And that's fine, I mean we're all here
10 to vote our conscience and we're experts and
11 that's fine. But we're not basing it on
12 evidence. It's a randomly chosen number, you
13 know, I mean that we're ratifying here for the
14 entire country, which is okay if that's what we
15 want to do.

16 CO-CHAIR TIRSCHWELL: Okay. We've got
17 some more comments in the room. Ketan?

18 MEMBER BULSARA: You know, I hear what
19 Mike is saying, and I do agree with your line of
20 argument too. And, you know, as somebody like
21 many folks here that's actively involved in
22 dealing with these patients in the acute setting

1 and within sort of the 12 to 24 hours, I think
2 one of the biggest sort of atrocities we have in
3 the field is we don't have a way to standardize
4 reporting among different institutions.

5 And it brings back, as Mike well
6 knows, the example of the Glasgow Coma Scale
7 where, I mean, people were rating folks with
8 different severity. Everyone's sort of opinion
9 varied on how somebody was doing.

10 And I think though the 12 hours is not
11 ideal, it is a point. I think we do need a point
12 we do need some standardization, and because of
13 the overall good that I feel that measure would
14 provide I'm willing to support it.

15 MEMBER BAUTISTA: Yes, I totally
16 understand Mike's concerns. But I think, you
17 know, the essence is that we need an initial NIH
18 Stroke Scale, an initial at some point after
19 arrival, soon after arrival, and the 12 hours is
20 just our operational way of saying that.

21 CO-CHAIR TIRSCHWELL: Okay, let's go
22 ahead. Did the developer want to say anything

1 else? Okay, let's go ahead and vote then on
2 overall suitability for endorsement.

3 I don't know what, that's some ancient
4 results there we will ignore.

5 MS. SKIPPER: Just a moment, please.

6 Voting is open for overall suitability
7 for endorsement in Measure 2864, one yes, two no.
8 Measure 2864 regarding overall suitability for
9 endorsement, 86 percent yes, 14 percent no.

10 CO-CHAIR TIRSCHWELL: So it passes?

11 MS. SKIPPER: So this measure has been
12 recommended for endorsement.

13 CO-CHAIR TIRSCHWELL: Okay, thank you,
14 everybody. Good conversation.

15 The next measure, we're actually on to
16 today's real schedule, CSTK-02, modified Rankin
17 Score at 90 days, Number 2865. We invite the
18 Joint Commission to introduce the measure.

19 MS. KOLBUSZ: Okay. The next measure
20 is CSTK-02 which is the modified Rankin Score at
21 90 days. It's also used for a comprehensive
22 stroke certification program.

1 This measure captures the percentage
2 of ischemic stroke patients treated with
3 intravenous, IV, or intra-arterial, IA,
4 thrombolytic, t-PA, therapy, or who undergo
5 mechanical endovascular reperfusion therapy for
6 whom a 90 day, giving a range of greater than or
7 equal to 75 days and less than or equal to 105
8 days, modified Rankin Score is obtained via
9 telephone or in person.

10 The rationale for the measure is that
11 the modified Rankin Score is an accepted standard
12 for assessing recovering post stroke. At this
13 time it's the most widely used outcome clinical
14 outcome measure for stroke in clinical trials.

15 It may be conducted in person or over
16 the phone. It's been recommended in American
17 guideline recommendations from the American Heart
18 Association and American Stroke Association that
19 the interviews should be obtained and conducted
20 for acute stroke patients treated with IV or IA
21 t-PA or mechanical endovascular reperfusion
22 therapy within three months or 30 days post-

1 discharge, although recovery may continue well
2 beyond the three-month period for ischemic stroke
3 patients.

4 The denominator for the pet population
5 are only the ischemic stroke patients treated
6 with IV or IA t-PA therapy or who undergo
7 mechanical endovascular reperfusion therapy.

8 The numerator are those ischemic
9 stroke patients for whom a 90-day modified Rankin
10 is obtained via telephone or in person. And the
11 exclusions for the measure are patients less than
12 18 years of age, patients who have a length of
13 stay greater than 120 days, patients admitted for
14 elective carotid intervention, or patients who
15 expired during the hospital stay.

16 DR. SCHWAMM: So I just, I want to
17 make a comment about this measure. I think for
18 us so many of our measures are process measures,
19 and to try to start introducing outcome measures
20 that will look at the outcomes of these therapies
21 and help to hold our centers who perform
22 reperfusion therapy, albeit in a small number of

1 patients so it's not an overly burdensome request
2 in terms of the number of patients any center
3 will experience, but to hold them accountable to
4 measuring outcomes in those patients
5 systematically and routinely is an incredibly
6 important step in making sure that these
7 therapies are used appropriately, that the
8 appropriate type of patients are being treated,
9 and that we can then look at outcomes across
10 centers adjusting for baseline severity and risk
11 and have a single standardized outcome measure at
12 a standardized time point in the clinical world
13 that can be compared effectively to the data we
14 have from all the clinical trials which use the
15 90-day modified Rankin as the gold standard for
16 measuring outcome of the effectiveness of these
17 interventions.

18 CO-CHAIR TIRSCHWELL: Discussants are
19 Jim and Peter. Who's going to lead off?

20 MEMBER SCHMIDT: So I'm going to lead
21 off and Jim is going to jump in where he sees
22 opportunities.

1 CO-CHAIR TIRSCHWELL: Evidence.

2 MEMBER SCHMIDT: So evidence, so I
3 want to start out by saying that I would love to,
4 I love outcome measures being included. I would
5 love to see an outcome measure, but I think that
6 this needs some work and, but review it again.

7 I'm jumping ahead, but this measure
8 cites expert, there really is no evidence
9 submitted for this measure. It cites expert
10 opinion from an article on telemedicine which
11 mentions 90 days.

12 In the submission I saw expert -- I'm
13 sorry you're shaking your head, but in the
14 submission I saw, the article cited was expert
15 opinion on an article about a telemedicine
16 measure where it acknowledged that a 90-day
17 follow-up was performed, but it didn't say that
18 90-day follow-up was important in any way, and
19 I'd love to see something that included that.

20 The 90 days, you've mentioned that
21 it's a standard, but I've not seen anything that
22 says -- so with the 12-hour window I was

1 comfortable because it was anywhere from zero to
2 12. This specifies a specific interval.

3 If we were comparing outcomes that
4 would be very valuable, but I'd love to see one,
5 you know, it didn't have the, you didn't say 60
6 days is wrong and 90 days is right. There's no
7 evidence for the time frame.

8 So it really is just based on expert
9 opinion. And based on the algorithm the rating
10 for evidence was recommended to be insufficient,
11 and I think that that was our finding in the
12 workgroup.

13 CO-CHAIR TIRSCHWELL: Jim, do you want
14 to add anything to that?

15 MEMBER BURKE: I mean, I think the
16 trick here is just that there's, it's hard to
17 articulate the causal pathway through which
18 measuring this number changes things.

19 I mean, this is the thing we struggled
20 with in NIH Stroke Scale was a bunch of different
21 arguments going out there. None of it seemed
22 super decisive, but I think on balance people

1 come on the whole decisive.

2 Here, you have this trick of when I
3 measure a number that per se does nothing for a
4 patient. That's not quality in the slightest.
5 The question is can that number be used to
6 improve quality over time and if so, how, and is
7 there evidence that can or it will be done?

8 And I think that this is where I agree
9 with Peter is there's not a lot of evidence here
10 that we can do that and that there's sort of, if
11 we'd get there, statistical problems once you do,
12 because you're talking about a small number of
13 cases.

14 We're fixing the denominator on people
15 treated with IV or IA, and now we're going to
16 measure a five-state outcome and try and make
17 comparisons across institutions with a lot of
18 moving parts.

19 It seems to me that even if we do,
20 even if we got past the evidence, which I agree I
21 don't see a whole lot here to support it, I think
22 we're going to get into other problems

1 measurement wise downstream.

2 CO-CHAIR TIRSCHWELL: And so, and just
3 to clarify, although the modified Rankin Scale is
4 a measure of functional status we're not
5 measuring, this measure isn't the modified Rankin
6 Scale score, it's whether you measured the
7 modified. So it's actually a process measure not
8 an outcome measure, just to be clear about that.

9 Jocelyn. And then back to you, Peter.

10 MEMBER BAUTISTA: So I think the issue
11 is that if we don't require the measurement of
12 the outcome measure we'll never get to the
13 outcome, and I think that's the tricky part of
14 this. So you're never going to get a randomized
15 control trial of measuring the modified Rankin,
16 so where's the evidence going to ever come from?

17 MEMBER BURKE: I mean, I think you're
18 right. I totally agree. This is sort of like
19 the boot strapping problem, right. Like the
20 theoretical thing that we're going to argue about
21 when we get to adjusted mortality is we really
22 want adjusted function, and that if you don't

1 have this how are you ever going to get there?

2 But that's not what we're -- I think
3 this is where we're stuck. The measure in front
4 of us, whether or not you report a modified
5 Rankin on these people it's not obviously going
6 to do anything in outcomes other than through
7 this other next measure where it might be able to
8 do it.

9 CO-CHAIR TIRSCHWELL: One rebuttal and
10 then Peter.

11 MEMBER BAUTISTA: Well, there is this
12 pathway, right, to the exception, insufficient
13 evidence with exception that we could go down if
14 we wanted to.

15 CO-CHAIR TIRSCHWELL: Can we just have
16 NQF review that criteria exception for evidence?

17 MS. JOHNSON: Sure. So the idea
18 behind our exception to evidence is exactly this.
19 In some cases there probably never will be, you
20 know, hard empirical evidence to show, you know,
21 one thing or another. It happens a lot with care
22 coordination kinds of measures, those kinds of

1 things.

2 So NQF does recognize that and we
3 offer a pathway if you find that there is
4 insufficient evidence to support a particular
5 measure then you can consider whether you want to
6 go ahead and pass the measure using the
7 exception.

8 That is the bottom portion of the
9 evidence algorithm there, and it actually asks
10 you a few questions to think about, and I think
11 they're there on the questions for the committee,
12 maybe if you go down just a little bit, Christy,
13 or Alexandra.

14 Are there or could there be
15 performance measures of health outcome or
16 evidence based intermediate clinical outcomes,
17 intervention or treatment? That's part of the
18 algorithm on that bottom piece there.

19 So let me be very clear. When we get
20 to the voting section you have to decide whether
21 or not you believe that there's insufficient
22 evidence. If we have a majority of folks who

1 believe that there is insufficient evidence, then
2 we could go ahead and consider whether or not we
3 would want to do an exception through this
4 measure.

5 CO-CHAIR TIRSCHWELL: Charlotte, go
6 ahead.

7 MEMBER JONES: Procedural question.
8 If we vote the exception to the evidence, if we
9 were to get to that point, do we then at the end
10 when we're talking about usability discuss the
11 burden that we are asking -- this comes back to
12 my previous comment about resources is every time
13 we ask someone to do something they're not doing
14 something else.

15 CO-CHAIR TIRSCHWELL: The burden will
16 be considered if we proceed through just like in
17 every other case.

18 MEMBER JONES: Okay.

19 CO-CHAIR TIRSCHWELL: Peter, go ahead.

20 MEMBER SCHMIDT: So I just want to add
21 that one other allowable value for the measuring
22 numerator is a modified Rankin Scale not

1 performed or unable to determine, which means
2 that people will be, I mean this goes to
3 reliability.

4 This is not, there's no evidence that
5 collecting, if we say that there's evidence that
6 collecting the modified Rankin Scale, or if we
7 say that there should be an exception that
8 collecting this information is valuable, not
9 collecting the information also goes into the
10 numerator.

11 MS. KOLBUSZ: And they fail. They
12 fail. They fail. It's the only way you fail the
13 measure is that you didn't do it. This measure
14 started out as an outcome measure and we scaled
15 it back during the pilot test, but we left all
16 the values for the modified Rankin hoping that at
17 some day it can be converted.

18 So we collect the data elements for
19 the modified Rankin now. But there had to be
20 additional allowable values for situations where
21 the institution tried to obtain a modified Rankin
22 were unable to do so.

1 For whatever reason the patients lost
2 a follow-up, moved out of state or whatever, or
3 they just didn't do it, which would be value 7
4 and 8. But the only way you fail is you just
5 don't do it.

6 CO-CHAIR TIRSCHWELL: Okay. Yes. Any
7 other comments before we go back to the -- go
8 ahead, Lee.

9 DR. SCHWAMM: I think the issue here
10 is, you know, why three months, which is again a
11 very reasonable question. There's no evidence
12 provided to support that that was better than two
13 months, better than six months, better than one
14 year.

15 There is some data from the rehab
16 literature about the slope of the recovery curve
17 and its inflection point at three months. But
18 the reason why three months is it was chosen as
19 the standard in the NINDS-TPA trial in 1996.

20 And every trial in stroke reperfusion
21 therapy has used that outcome to establish the
22 efficacy or the lack of efficacy, and it's an FDA

1 requirement that trials that are conducted in
2 this way include that functional assessment at
3 three months.

4 So I think it is a de facto standard.
5 And so when sites want to look at the results
6 they are achieving and compare them to the
7 available literature, that is the time period at
8 which there is a community of consensus that
9 there's a, that provides the comparator.

10 So I think the question about evidence
11 here really ought to be, is there evidence that
12 this time frame is an appropriate time frame for
13 which a comparator is available?

14 CO-CHAIR TIRSCHWELL: And I'll just
15 comment. As far as the possible criteria for the
16 exception from evidence, sort of the last one
17 there perhaps rings true for me at least.

18 Does the steering committee agree that
19 it's acceptable or beneficial to hold providers
20 accountable for this process of care even if
21 there's not evidence that just measuring it
22 affects the outcome?

1 And I think it's that lead to the next
2 step that these are the outcomes and that we'll
3 be comparing outcomes that makes me want to do it
4 even without the evidence linking it directly to
5 outcomes.

6 Go ahead, Jane.

7 MEMBER J. SULLIVAN: So just a
8 procedural question. Does the evidence get
9 ranked first before, and then if the evidence
10 ranks low then there's this question about
11 whether this applies or qualifies for the
12 exception to the evidence. Okay, thank you.

13 CO-CHAIR TIRSCHWELL: First we have to
14 vote it majority insufficient, then we can go to
15 the exception question.

16 All right, comments or discussion
17 related to evidence? Let's go ahead and vote
18 then, please.

19 MS. SKIPPER: We're now voting on
20 evidence for measure 2865. One high, two
21 moderate, three low, four insufficient.

22 Voting has closed. Measure 2865 on

1 evidence, zero percent high, nine percent
2 moderate, 14 percent low, 77 percent
3 insufficient. So we would move to voting on
4 taking exception to the evidence.

5 So measure 2865, we're voting on
6 potential exception to empirical evidence, one
7 insufficient evidence with exception, two no
8 exception.

9 So on potential exception to empirical
10 evidence for measure 2865, 59 percent
11 insufficient evidence with exception, 41 percent
12 no exception.

13 CO-CHAIR TIRSCHWELL: Huh.

14 MS. JOHNSON: So we are in a very iffy
15 place, and I don't know if I should have said
16 this beforehand or not. This is an exception to
17 how we do our voting counts.

18 As you know, to pass a must-pass
19 criterion we say you have to have greater than 60
20 percent, right. That's our limit. And in some
21 cases we allow this gray zone and we continue on.

22 The exception to the evidence piece is

1 one where we do not have a gray zone. So
2 basically what we are saying with this one is you
3 need more than 50 percent for this to go forward.
4 Sorry, more than 60 percent for this to go
5 forward.

6 So with that, and I realize I did not
7 tell you that before you voted, so if you would
8 like to re-vote we can certainly do that now that
9 you have that extra information.

10 CO-CHAIR TIRSCHWELL: Sorry. Jocelyn,
11 go ahead.

12 MEMBER BAUTISTA: Yes, and I do wonder
13 if everybody really understood what we were
14 doing. I mean it's different than anything we've
15 done.

16 CO-CHAIR TIRSCHWELL: Okay. And Ross,
17 did you want to say something?

18 MEMBER ZAFONTE: Can you restate that?

19 MS. JOHNSON: Sure. This is one of
20 the criteria where we do not have a gray zone.
21 So in order to actually go forward with the
22 exception we need you to have a more than 60

1 percent vote. That's where it needs to land,
2 more than 60 percent.

3 CO-CHAIR TIRSCHWELL: Sixty percent or
4 more, or more than 60 --

5 MS. JOHNSON: More than 60. We've had
6 conversations about this, more than 60.

7 CO-CHAIR TIRSCHWELL: Thank you.

8 MS. JOHNSON: Yes.

9 CO-CHAIR TIRSCHWELL: And Michael,
10 you're on the line. Do you have a comment?

11 MEMBER KAPLITT: Yes, I just want to
12 say that, I mean if we're going to re-vote I
13 just, you know, because I haven't, you know, been
14 able to break in before, but if we're going to
15 re-vote on this I just wanted to make the comment
16 that unlike the last thing where I had, you know,
17 issues with the evidence, at least that wasn't a
18 major burden. You know, I didn't hear, maybe
19 somebody raised this. But, you know, this is a
20 significant burden that we're putting on people.

21 And so if we're going to vote,
22 because, you know, for making sure that you can

1 contact patients again at 90 days, of course that
2 would be nice. We all hope we can do it, but you
3 can't guarantee it. It's not like when they're
4 in the hospital and you just have to go and
5 examine them.

6 So that's a major burden we're placing
7 on people in terms of --

8 CO-CHAIR TIRSCHWELL: So this vote here
9 is not about burden. That's part of the later
10 assessment and probably should not be included in
11 your interpretation of this particular issue
12 here. Alex?

13 MEMBER KAPLITT: Algorithm -- no. If
14 you look at the algorithm for the exception,
15 Number 12, it says, does the steering committee
16 agree that it's, to hold providers accountable
17 for empirical evidence in the absence of
18 empirical evidence to benefit patients.

19 And then in parentheses it says
20 consider potential detriments to endorsing the
21 measure. Example --

22 CO-CHAIR TIRSCHWELL: Sorry, I'm not

1 seeing that part in front of me right now, that
2 you have the more complete listing there, so I
3 apologize, Mike.

4 MEMBER KAPLITT: And that if we're
5 going to be doing this based on rating the
6 evidence as insufficient with exception that
7 criteria should be considered, which as it says
8 that if we're going to be doing it with exception
9 we should be considering the other impacts of the
10 consequence of this.

11 CO-CHAIR TIRSCHWELL: Sorry, did
12 somebody else have a comment? Alex, did you want
13 to say something?

14 MEMBER RAE-GRANT: Just that we're
15 kind of up to lobbying time here.

16 CO-CHAIR TIRSCHWELL: Yes.

17 MEMBER RAE-GRANT: You know we need to
18 have measures or move toward outcome measures. I
19 think that's a critical element. This is a well-
20 defined outcome measure. There's never going to
21 be the kind of evidence you have for a treatment
22 trial.

1 And this pushes us as a field towards
2 measuring what we do institutionally, and I think
3 that's the only way we're going to move forward
4 on this kind of issue.

5 I don't know why we're going on and on
6 about this. It's not a big deal. It's a
7 standard measure. And I think we should just
8 move forward, and whatever way we can to allow it
9 to continue I would recommend we do that. That's
10 my lobbying.

11 CO-CHAIR TIRSCHWELL: And just to
12 comment on the burden thing. This is probably
13 even in the best centers only about ten to
14 fifteen percent of all ischemic stroke patients
15 that you have to collect it on.

16 Peter?

17 MEMBER SCHMIDT: This was submitted as
18 a process measure not as an outcome measure.

19 MEMBER RAE-GRANT: It's a weigh
20 station to outcome measures, and if you don't
21 even get this far you'll never get to the outcome
22 measures. That's the point that you guys are

1 making.

2 DR. SCHWAMM: I just wanted to clarify
3 the, to be in the numerator for this measure you
4 either have to have collected the value or
5 demonstrate that you made multiple attempts to
6 reach the patient and were unsuccessful.

7 So it's not, it doesn't penalize
8 centers who have patients who are lost to follow-
9 up, arbitrarily. There is guidance in the coding
10 instructions around how many times you have to
11 try and what you have to document, but I think it
12 really is a very reasonable approach to what
13 center's making a good faith effort to collect
14 the data.

15 MEMBER SCHMIDT: Just, I was not going
16 to bring it up again. I had accepted your
17 response ever since.

18 CO-CHAIR TIRSCHWELL: So in front of
19 us on the screen, although not nationally
20 broadcast, or yes nationally broadcast? Just in
21 the room is the more detailed bit about the
22 exception, and I'm just going to read through it

1 so that we're clear about it.

2 Are there or could there be
3 performance measures of a related health outcome
4 or evidence based clinical outcome process?

5 Thank you.

6 I'm struggling with trying to figure
7 out whether that fits for this becoming an
8 outcome measure. Performance measure, related
9 health outcome or evidence based -- for example,
10 proposed measure where the BP is assessed each
11 visit instead of BP control or the use of
12 effective treatment.

13 So I mean if the -- yes, Jocelyn. Do
14 you want to comment on this?

15 MEMBER BAUTISTA: Never get to the
16 measurement of the outcome you'll never get to
17 the outcome. So I think we have to say, I mean,
18 I think no would be a reasonable response to that
19 question.

20 CO-CHAIR TIRSCHWELL: Okay. That the
21 benefits -- so is there evidence from a systemic
22 review, I think, or a systemic assessment of

1 expert opinion that benefits of what is being
2 measured outweigh the potential harms, I think
3 there is expert opinion.

4 And does the steering committee agree
5 that it is okay or beneficial to hold the
6 providers accountable in the absence of empirical
7 evidence?

8 And here's the thing that Michael was
9 referring to, consider potential detriments to
10 endorsing EG. Focus attention away from more
11 impactful practices, more costly without
12 certainty of benefit, divert resources from
13 developing more impactful measures.

14 And I think we've heard some
15 arguments. Some people have worried about
16 resources. Okay, I can see we're going to have
17 some more discussion. And others have thought
18 that this assessment in the small proportion of
19 patients is an important vital step in moving to
20 the true outcome measure and so is worthy of the
21 burden.

22 Charlotte, Michelle, James.

1 MEMBER JONES: Hi. I understand that
2 people feel that this is an important next step,
3 but as the steering committee from the National
4 Quality Forum, we carry a much higher reputation
5 for being evidence based.

6 Local committees, other guideline
7 writers don't carry a, "We are going to use the
8 evidence to base our opinions," that we do. If
9 we go to an exception, we should recognize not
10 only are we utilizing resources but we are saying
11 that we are backing away from evidence.

12 It's an exception for good reasons,
13 but I think it has ramifications beyond this one
14 measure. And people are talking about lobbying.
15 I think this is a slippery slope.

16 CO-CHAIR TIRSCHWELL: Michelle?

17 MEMBER CAMICIA: Since we're not
18 talking about feasibility yet but we sort of are,
19 I think it's relevant to provide the information
20 on the uniform assessment and functional measures
21 for post-acute care that will be measured on all
22 patients who utilize post-acute care. That will

1 provide outcome data related to function.

2 CO-CHAIR TIRSCHWELL: Jim, did you
3 retract your statement?

4 Okay, Dave.

5 CO-CHAIR KNOWLTON: I get a little
6 confused here because I'm at least one of the
7 non-clinicians here so I don't fully understand
8 this perhaps, but I was a stroke patient.

9 And I'm trying to understand from a
10 patient perspective what the implications of this
11 are and it's not clear to me. Usually these
12 things are clear, but this isn't clear to me.

13 I agree that we want to get to outcome
14 measures. Does this block, because it's the one
15 that gets accepted use without evidence, I go to
16 Charlotte's point. Does this block the
17 development of a more robust measure? I think
18 that's asked in the evidence assessment. Up on
19 the screen it's Number 12.

20 You know, absent empirical evidence do
21 we consider this? Does it then become a
22 roadblock towards development of other measures

1 that might be more robust and more helpful to
2 patients?

3 So I'm looking at this from a patient
4 perspective and I'm asking those of you who are
5 clinicians maybe you have a judgment that this is
6 important anyway that it will not create a block
7 to an impetus to a more robust measure, because
8 follow-up with stroke patients in my experience
9 was important and was not done very well.

10 And so I wonder, clinically, what are
11 the implications. I felt we voted quickly
12 without fully understanding what the implications
13 are.

14 If we're going to get a more robust
15 measure and this is a weigh station as it's been
16 called on the way I'm done with that. But if
17 not, then I don't want it to block.

18 CO-CHAIR TIRSCHWELL: I would say just
19 the opposite that it doesn't block. This is a
20 stepping stone and facilitates the development of
21 a better outcome measure.

22 Jim?

1 MEMBER BURKE: I mean, I think this
2 seems like a place where we've like fallen
3 through the process cracks, right. I mean what
4 we're hearing here is sort of two different
5 perspectives.

6 One perspective says that there's
7 substantial support for the idea that this could
8 be a very useful outcome measure in the future,
9 and then there's a separate framework here which
10 says, but should you measure it today as this
11 measure. And it seems like people are pulling
12 apart on those two things.

13 It almost seems like an NQF process
14 where we could say something different rather
15 than this measure need exist as a weigh station
16 that the broad target to which their aiming makes
17 sense, and it doesn't seem like we have, that's
18 not what this vote is.

19 I mean, this vote is different than
20 that. This vote is, you know, we're going to get
21 stuck on the third box, I think. And, you know,
22 right now it's a question of, and we've got those

1 two sort of operative or divergent perspectives
2 here, and I'm not sure how to reconcile that when
3 we vote.

4 CO-CHAIR TIRSCHWELL: I think we're
5 going to have to vote and we'll get the through
6 the third box by a vote because I don't think
7 there's any other way to move forward.

8 I think we've clarified the issues
9 that are on the table and I'd like to go ahead
10 and suggest that we re-vote on the question of
11 exception to the evidence criteria.

12 MS. SKIPPER: We're voting on Measure
13 2865 potential exception to empirical evidence,
14 one insufficient evidence with exception, two, no
15 exception.

16 Okay. Polling has closed for
17 exception to empirical evidence for Measure 2865.
18 Fifty percent insufficient evidence with
19 exception, fifty percent no exception.

20 CO-CHAIR TIRSCHWELL: So if I'm
21 interpreting the rules correctly, this measure
22 does not pass and we move to the next measure.

1 Okay, the next measure is CSTK-03,
2 severity measurement for hemorrhage types of
3 strokes.

4 MS. KOLBUSZ: This is also collected
5 for the comprehensive stroke program and it's a
6 severity measurement for the hemorrhagic stroke
7 patients.

8 The description for the measure is
9 that it captures the percentage of subarachnoid
10 hemorrhage patients and intracerebral hemorrhage
11 patients for whom a severity measurement, a Hunt
12 and Hess Scale performed for the subarachnoid
13 hemorrhage patients, or an ICH score performed
14 for the ICH hemorrhage patients, is performed
15 prior to surgical intervention, specifically
16 treatments for aneurysm such as clipping,
17 coiling, however any surgical intervention it
18 would be expected to be performed before in
19 patients who are undergoing a surgical
20 intervention and documented in the medical
21 record, or if the patient does not undergo a
22 surgical intervention then the expectation is

1 that it would be done and documented within six
2 hours of arrival at the hospital emergency
3 department.

4 The denominator for this particular
5 measure, it is a stratified measure so it is an
6 overall rate. We do have several subcomponents.
7 The denominator is the subarachnoid in
8 intracerebral hemorrhage stroke patients who
9 arrive at the hospital emergency department.

10 However, the numerator is actually
11 stratified into three components. There is the
12 overall rate numerator which is combining the
13 number of SAH and ICH stroke patients for whom a
14 severity measurement is performed as I just had
15 described.

16 The 03 measure looks only at the
17 subarachnoid patients and assesses whether or not
18 they had the appropriate severity measure of Hunt
19 and Hess Scale performed.

20 And the 03b measure looks at only the
21 intracerebral stroke patients to determine if
22 they had the appropriate measurement of an ICH

1 score performed within the time frame specified
2 for the measure.

3 For the exclusions for this particular
4 measure similar to our other measure STK-01,
5 CSTK-01, excuse me, it's the patients less than
6 18 years of age, the patients who have a length
7 of stay greater than 120 days, patients with
8 comfort measures only documented on the day of or
9 day after hospital arrival, nonsurgical patients
10 who are discharged within six hours of arrival at
11 the hospital, and then there's also an exclusion
12 for patients with an admitting diagnosis of
13 traumatic brain injury, unruptured arterial
14 venous malformation, nontraumatic subdural
15 hematoma as specified by co-Table 8.2F, so that
16 we do not mix in trauma cases and what not into
17 the mix. That's it.

18 CO-CHAIR TIRSCHWELL: Great. Thank
19 you very much. So our discussants are Jane and
20 Kelly, the Sullivans.

21 MEMBER J. SULLIVAN: So this is the
22 Sullivan's measure. Kelly and I talked about

1 this last night. I'm going to lead this off and
2 she is going to weigh in when she sees
3 performance gaps in what I'm saying.

4 So to the evidence the developer
5 offers the support of three clinical practice
6 guideline recommendations from American Heart, or
7 American Stroke with Class I levels A and B
8 evidence, a systematic review and three
9 randomized control trials that support the
10 measure that support the usefulness of a severity
11 measure based on the fact of the rapid evolution
12 of the condition and that the score can be useful
13 in providing prognostic information.

14 The workgroup committee agreed with
15 the preliminary assessment of NQF that the
16 evidence was moderate.

17 CO-CHAIR TIRSCHWELL: Any discussion
18 for the evidence issue? Ketan?

19 MEMBER BULSARA: You know we have the
20 same issue regarding the timing for six hours.
21 And so I guess the question is, I mean, if you
22 have a patient that comes in with a, yes,

1 subarachnoid hemorrhage, so let's just focus on
2 subarachnoid hemorrhage.

3 I would think that all of those
4 patients would need an initial Hunt/Hess score or
5 some sort of grading in terms of the severity,
6 and so why the six hours?

7 And then sort of the alternative of
8 that is many times when these patients come in
9 they're admitted. They're admitted to the neuro
10 intensive care unit because they have an aneurysm
11 that's likely to rehemorrhage. The highest rate
12 is within the first 24 hours.

13 These patients are sedated so you
14 really don't have much of an exam. And probably
15 the only exam you have is, is that you're doing
16 pupil checks.

17 And so the question of the exam
18 immediately before like the microsurgical
19 clipping or intravascular treatment at the
20 aneurysm, I'm not sure that that is a reliable
21 exam.

22 So again, which -- I think the couple

1 as we, what time frame should we use? I don't
2 think the six hours is a reasonable time frame.
3 I don't think immediately before the procedure is
4 a good time frame, because again the current
5 practice is we keep these patients sedated, we
6 don't have an exam.

7 So I would have trouble with the six-
8 hour point.

9 CO-CHAIR TIRSCHWELL: Any other
10 comments or discussion? I mean, I wonder if just
11 like the 12 hours wasn't particularly evidence
12 based, this six hours doesn't have exact evidence
13 but we have to make some assessment.

14 In fact as you argued, I think the NIH
15 Stroke Scale score and as hemorrhages are more
16 severe in general and perhaps a little bit more
17 urgently treated, I think they decided on a
18 slightly tighter time window as it relates to so
19 when to measure it.

20 But Steve, do you have a comment?

21 MEMBER HUFF: It just occurs to me it
22 would read simpler if it just said arrival at the

1 hospital, period. Many of these patients are
2 interfacility transfers and won't be seen in the
3 emergency department of the institution where the
4 coiling or clipping might occur.

5 So just curious that this is, you
6 know, hospital arrival would be simpler. It
7 would also capture patients that are transferred
8 in to tertiary centers.

9 MEMBER BULSARA: You know, I totally
10 agree with Steve. I mean, I think that's more
11 reflective of current practice. I think the wait
12 probably should be phrased as soon as the
13 patients get to the emergency room they have a
14 Hunt/Hess score that's documented.

15 MEMBER HUFF: I didn't say that at
16 all, okay. I'm just saying it's interesting how
17 this measure, which will probably be performed by
18 specialists, by neurosurgeons or stroke
19 neurologists, it has an emergency department
20 marker in it.

21 And many of these patients, practice
22 pattern at least in my region is, are transferred

1 directly to a Neuro ICU. And so they'll be seen
2 at a small regional hospital, maybe even a
3 limited access hospital, and then will go to an
4 ICU.

5 MEMBER BULSARA: I stand corrected. I
6 disagree with Steve. And the reason I disagree
7 is that the best exam that you're going to get on
8 these patients are when they first come to the
9 emergency room.

10 I think you need to document that
11 exam, and then I do think it's important to
12 document an exam before the patient is taken for
13 any sort of either interventional or
14 microsurgical procedure, but I don't think that
15 exam is very accurate.

16 MEMBER SCHMIDT: So whenever you have
17 something that needs to be done as soon as
18 possible and where you know that earlier is
19 better, it's often good to design a measure where
20 you choose a threshold where you say about
21 between 40 and 60 percent.

22 The average is going to fall somewhere

1 between 40 and 60 percent so that we can push
2 people into that window. There isn't going to be
3 evidence for that kind of thing because you
4 design your measure so that it's optimal for
5 improvement, and then as things improve you can
6 say, well, now we're going to say five hours
7 because we want it to be as soon as possible and
8 we're going to push our threshold up.

9 So this is one of the places where
10 measure development and evidence often don't have
11 parallels.

12 DR. SCHWAMM: I just wanted to clarify
13 that according to the Joint Commission direct
14 admissions are also captured in this measure, so
15 it's not just ED based arrivals.

16 MEMBER HUFF: Perhaps that should be
17 amended to reflect that in the measure.

18 MS. KOLBUSZ: It is actually a data
19 element in the algorithm. It's direct admission.
20 After we pilot tested we had set this measure up
21 to kind of mimic the thrombolytic therapy where
22 you came through the ED.

1 But in the comprehensive stroke
2 centers we were losing too many patients to
3 direct admission, so we added the data element
4 direct admission which is reflected in the
5 algorithm.

6 CO-CHAIR TIRSCHWELL: Yes.

7 MEMBER BULSARA: Let me just quick put
8 the Hunt test score in perspective. I mean, this
9 is a test that takes less than a minute to do.
10 There's no reason that any patient that presents
11 at the emergency room or that presents in a neuro
12 intensive care unit shouldn't have that done
13 within a very short time of their arrival, and
14 this test takes less than a minute to do.

15 CO-CHAIR TIRSCHWELL: I think the hard
16 part may be getting your neurosurgeon to document
17 it in a timely fashion. Light humor.

18 All right, discussion on evidence.
19 Yes, go ahead. Okay. Let's go ahead and vote
20 then.

21 MS. SKIPPER: We are now voting on
22 evidence for Measure Number 2866. Voting is

1 open. One high, two moderate, three low, four
2 insufficient.

3 Results are zero percent high, 17
4 percent moderate, or 17 people voted moderate,
5 four people low, one person insufficient. This
6 measure does pass on evidence.

7 CO-CHAIR TIRSCHWELL: Now we'll have
8 to fix that. It does pass clear majority,
9 greater than 60 percent. Let's talk about gap
10 and opportunities, Jane.

11 MEMBER J. SULLIVAN: So the developer
12 provided some information about performance gap
13 from earlier pilot data which indicated a very
14 large, up to an 80 percent performance gap based
15 on 66 sites and 2,471 cases, as well as data from
16 the first two quarters of 2015 which indicated a
17 smaller but still substantial performance gap.
18 And we were not provided with any data on
19 disparities.

20 CO-CHAIR TIRSCHWELL: Discussion
21 related to gap or opportunities for improvement?
22 If no -- yes.

1 MEMBER BULSARA: Just a comment.

2 Usually it's the initial providers that are
3 documenting at least at many institutions that
4 I've been to that are documenting these scores.

5 So I mean, even though the test takes
6 less than a minute to do, it may be a lack of
7 education for the initial staff that's seeing the
8 patients or the neurology team or the
9 neurosurgery team in terms of not documenting
10 them rapidly.

11 CO-CHAIR TIRSCHWELL: Suggesting
12 there's an educational opportunity here as well
13 perhaps.

14 MEMBER BULSARA: Plenty of educational
15 opportunity.

16 CO-CHAIR TIRSCHWELL: Okay. Let's go
17 ahead and vote then on gaps and opportunities for
18 improvement.

19 MS. SKIPPER: We are now voting on gap
20 for Measure 2866. One high, two moderate, three
21 low, four insufficient.

22 CO-CHAIR TIRSCHWELL: Charlotte's not

1 here right now, so --

2 MS. SKIPPER: Results are 18 high, 3
3 moderate, zero low, zero insufficient. This
4 measure does pass on gap.

5 CO-CHAIR TIRSCHWELL: Great.

6 Reliability?

7 MEMBER J. SULLIVAN: So reliability
8 testing was done at the data element level. We
9 were provided with data about pilot reliability
10 testing at 12 sites done in 2013 with 281
11 records.

12 The percent agreement across the
13 elements for the abstractors ranged from 71 to 99
14 percent and the kappas were in the 90s. So the
15 workgroup committee agreed that the reliability
16 was moderate to high.

17 CO-CHAIR TIRSCHWELL: Comments or
18 discussion about reliability? Let's move to vote
19 on reliability then.

20 MS. SKIPPER: We are now voting on
21 reliability for measure 2866. One high, two
22 moderate, three low, four insufficient.

1 Results are five high, 16 moderate.
2 This measure does pass on reliability.

3 CO-CHAIR TIRSCHWELL: Validity?

4 MEMBER J. SULLIVAN: So the developer
5 provided information on face validity which was
6 assessed with surveys and focus groups as well as
7 some convergent validity data on other measures
8 within the set for hemorrhagic stroke.

9 When Kelly and I talked about this we
10 had some -- and there were some data provided
11 about threats to validity. Some of the comments
12 that were provided about under use and usability
13 during the six-month pilot testing phase, we
14 wondered if they might also be threats to
15 validity in terms of difficulty with
16 abbreviations and alternative terms for the test
17 and issues with how to calculate the ICH score.

18 So I guess that's a question is
19 whether those factors impact the validity of the
20 data.

21 MS. KOLBUSZ: Those are findings
22 during the pilot test, so before finalizing the

1 measure set and ruling it out for implementation
2 we did take the feedback from the pilot sites and
3 we did make modifications to the abstraction
4 guidelines and put the actual score in the data
5 element definition so people that didn't really
6 fully understand the scoring or how the total
7 score of six would be obtained like for ICH, they
8 could see the components and the ratings.

9 CO-CHAIR TIRSCHWELL: Any other
10 discussion related to validity? Let's move to
11 vote for validity, please.

12 MS. SKIPPER: We are now voting on
13 validity for measure 2866. One high, two
14 moderate, three low, four insufficient.

15 CO-CHAIR TIRSCHWELL: Charlotte's back
16 so it should be 22.

17 MS. SKIPPER: We're waiting on one
18 more. Could everyone aim toward me?

19 CO-CHAIR TIRSCHWELL: Alright.

20 MS. SKIPPER: Results are 32 percent
21 high, 64 percent moderate, five percent low, zero
22 percent insufficient. The measure does pass on

1 validity.

2 CO-CHAIR TIRSCHWELL: And so then
3 feasibility.

4 MEMBER J. SULLIVAN: So the measure's-
5 - part of this measure set for the comprehensive
6 stroke certification that were implemented in
7 January of 2015. It's in the public domain.

8 The data's captured through the EMR or
9 a paper medical record abstraction, and the
10 workgroup felt that the feasibility seemed
11 moderate to high.

12 CO-CHAIR TIRSCHWELL: Discussion on
13 feasibility? Let's move to vote then on
14 feasibility.

15 MS. SKIPPER: We are now voting on
16 feasibility for measure 2866. One high, two
17 moderate, three low, four insufficient.

18 MS. SKIPPER: Results are 41 percent
19 high, 59 percent moderate, zero percent low, zero
20 percent insufficient. The measure does pass on
21 feasibility.

22 CO-CHAIR TIRSCHWELL: Usability and

1 use.

2 MEMBER J. SULLIVAN: So the issues
3 that I talked about earlier have been addressed
4 by the developer. The measure is currently in
5 use in an accountability program in the disease-
6 specific care certification for comprehensive
7 stroke centers.

8 And there was no one on our workgroup
9 committee who has experience using the measure,
10 so we wanted to ask if there were people who
11 could comment from that perspective.

12 CO-CHAIR TIRSCHWELL: I have
13 experience using the measures, and as Ketan said
14 the Hunt and Hess Scale is extremely brief. The
15 ICH score's a little bit more complicated because
16 you do have to compute a volume for your
17 intracerebral hemorrhage.

18 The other variables are pretty simple
19 after that. It is a skill to develop, it's not
20 that hard, and I think it's feasible. We use it.
21 It's a good learning tool for intracerebral
22 hemorrhage patients.

1 And all the other arguments about
2 communicating severity in a facile fashion like
3 we discussed for the NIH Stroke Scale score, I
4 think also can apply to both the Hunt and Hess
5 and the ICH score.

6 Although Hunt and Hess probably
7 already has similar status amongst neurosurgeons,
8 the ICH score is sort of gaining momentum in
9 those same areas.

10 Michael, do you have a comment? Can
11 we open up Dr. Kaplitt's phone line?

12 MEMBER KAPLITT: Sorry. No, no, it's
13 me. Sorry. I had muted it so you wouldn't
14 whatever, I wouldn't bother you with my coughing.

15 So the -- I'd be curious on Ketan's
16 opinion on this as well. I agree, the Hunt and
17 Hess is trivial and we all do it. You know,
18 right, if somebody's rushing to the operating
19 room they may not have time to put it in the
20 chart, but everybody does it and they'll document
21 it retrospectively or, you know, retroactively or
22 whatever.

1 But the ICH score, I agree with
2 everything you said, but if the ICH score also
3 applies to patients that has to be done prior to
4 going to the OR.

5 So if you have somebody with a clot
6 that's actually going to be removed or someone
7 that's going to get a hemicraniectomy, let's say,
8 because they're young and you can't remove the
9 clot but you're doing something for them or
10 whatever, or even if someone's getting a
11 ventriculostomy which is a surgical procedure
12 even though we act as if it's sort of a minor
13 procedure, but it still is, I guess I'm
14 wondering, you know, it's certainly not part of
15 our standard practice --

16 CO-CHAIR TIRSCHWELL: Mike, I think
17 you just had a feedback explosion there or
18 something. Are you still there?

19 MEMBER KAPLITT: Yes, I don't know.
20 Yes, something happened, whatever.

21 CO-CHAIR TIRSCHWELL: Okay.

22 MEMBER KAPLITT: Yes, so I was going

1 to say it's certainly part of our standard
2 practice, you know, to do that prior to operating
3 especially when it's an urgent operation.

4 It's actually calculated volumes and
5 stuff. I just, I don't know how usable it is,
6 frankly, for a patient who's going for emergency,
7 you know, clot evacuation.

8 CO-CHAIR TIRSCHWELL: Yes.

9 DR. SCHWAMM: And the only comment I
10 would make is that the only element of the score
11 that changes is the Glasgow Coma score, right.
12 The score is made up of the Glasgow Coma score,
13 age, this question about whether the volume of
14 blood in the brain is greater than 30 mls,
15 whether there's blood in the ventricular system
16 as well, and whether the bleeding is above or
17 below the tentorium.

18 So everything in there is available to
19 you at any point in time to retroactively
20 calculate the score. The only thing that needs
21 to be calculated on arrival is the Glasgow Coma
22 score, which is routinely calculated in patients

1 who present with brain hemorrhage and alterations
2 of consciousness.

3 So I think it's a very reasonable
4 point that you would ideally want to make this
5 assessment based on information available to you
6 when the patient arrives, but your point is also
7 well taken.

8 It is not, the ICH score is not what
9 you use to decide whether you clip the aneurysm
10 or whether you go to the operating room. The
11 Hunt and Hess score in some cases if it's very,
12 very high may deter you from going to the
13 operating room, but basically the decision is
14 made on the patient's clinical appearance.

15 These scores are really ways of
16 assessing the severity of the initial injury and
17 are very useful in algorithms that look at the
18 likelihood of survival.

19 MEMBER KAPLITT: I mean I just worry a
20 bit about the usability in the population of
21 patients that are going for clot evacuation. I
22 mean, you know, Hunt and Hess pretty much

1 everybody's doing instinctively on an aneurysm
2 patient, you know, as you said, and if it's
3 really bad it does influence what we're doing.

4 But measuring clot volume prior to
5 actually going to the OR in somebody who's
6 declining and herniating, if you see that the
7 clot is amenable to evacuation and the patient's
8 herniating, I just don't know how easy it's going
9 to be to use this to say, wait a minute, you've
10 got to, you know, document that it's more than X,
11 you know, volume.

12 DR. SCHWAMM: But the CT scan is
13 available. You don't have to stop and measure it
14 before you go to the operating room. The data
15 that you need is available to you.

16 So you're really asking the question
17 of when do you construct the score not when do
18 you measure the components that are used in
19 creating the score.

20 MEMBER KAPLITT: Maybe I'm misreading
21 it. It says --

22 CO-CHAIR TIRSCHWELL: So then it would

1 be okay in the chart? Would I get a pass if at
2 24 hours I said, you know, based on the initial
3 CT scan, initial Glasgow Coma score, the
4 patient's ICH score at presentation was 3?

5 MS. KOLBUSZ: If in the body of the
6 note you documented that it was at presentation
7 we would give you a pass on it and use the time
8 documented in the note over a stamped time or a
9 file time on the actual written note.

10 If you don't indicate that though in
11 the note, you're going to fail.

12 CO-CHAIR TIRSCHWELL: Mike, does that
13 make sense to you?

14 MEMBER KAPLITT: No. Well, it makes
15 sense to me in terms of what she said. It
16 doesn't make sense to me in terms of what it's
17 doing, you know, but that's fine. You know, I
18 mean this is supposed to be a quality measure.

19 And if the purpose of performing this
20 prior to surgical intervention is to determine
21 whether we're achieving a certain standard of
22 quality, doing it retrospectively I'm just not

1 sure what that does in terms of quality. Because
2 you've already made your decision based on other
3 -- if you don't actually do the ICH score prior
4 to the evacuation then you're doing the
5 evacuation based on other means.

6 And then if you retroactively go back
7 just to satisfy the measure that's fine, but I
8 just then don't understand the purpose.

9 DR. SCHWAMM: Yes, just if I can
10 clarify one thing. You're not required to report
11 the number of ccs of hemorrhage on the scan as
12 part of the score.

13 You just have to measure whether it is
14 greater than 30 ccs, which most people who
15 practice in this field can rapidly estimate
16 simply by reviewing the scan which is done by
17 everybody who's going to make a decision about
18 going to the operating room.

19 And so in the super tentorium, above
20 the tentorium in the hemispheres no one ever goes
21 to the operating room for a hemorrhage that's
22 smaller than 30 ccs because it's not enough mass

1 effect to cause an indication for surgery. In
2 the posterior fossa it definitely can.

3 And so I think, really, what we're
4 talking about is the rare individual where the
5 volume of hemorrhage by visual inspection is
6 close to that cut point and would require you to
7 estimate, which --

8 MEMBER KAPLITT: But again, so does
9 ventriculostomy count as a surgical procedure?
10 So let's say someone has a small bleed --

11 DR. SCHWAMM: Yes.

12 MEMBER KAPLITT: -- you know, and they
13 need a ventric -- you have to do this prior to
14 placing the ventriculostomy.

15 DR. SCHWAMM: I think the answer would
16 be yes, because I think ventriculostomy would
17 certainly be coded as a surgical procedure.

18 CO-CHAIR TIRSCHWELL: All right, any
19 other --

20 MEMBER KAPLITT: So somebody has a
21 small post fos bleed and you want to put a
22 ventric and in the ER you have to have like

1 calculated this out? I don't know. I mean, I
2 agree with you that it's not necessarily a hard
3 thing to do when we do it, I just, since we're
4 into usability I'm just, there are situations
5 where I think it might be tough. That's all.

6 CO-CHAIR TIRSCHWELL: And I think it's
7 pretty clear that you wouldn't delay your
8 procedure to write this down in the chart. That
9 could easily be done later.

10 And in many cases, you know, as we
11 talked about communication amongst providers to
12 optimize patient care and outcomes is again, just
13 like for the other severity scores is relevant
14 here. So let's go ahead and vote on use and
15 usability.

16 MS. SKIPPER: We are now voting on
17 usability and use for Measure 2866. One high,
18 two moderate, three low, four insufficient.

19 Results are five percent high, 86
20 percent moderate, five percent low, five percent
21 insufficient. The measure does pass on usability
22 and use.

1 CO-CHAIR TIRSCHWELL: So let's move
2 then to vote about overall appropriateness for
3 endorsement. Suitability, excuse me.

4 MS. SKIPPER: We are now voting on
5 overall suitability for endorsement for Measure
6 2866. One yes, two no.

7 Results are 95 percent yes, five
8 percent no. Measure 2866 has been recommended
9 for overall suitability for endorsement.

10 CO-CHAIR TIRSCHWELL: Great. So,
11 thanks. I guess I'm wondering do people want to
12 take an early break or do you want to take a
13 delayed break? Why don't we take a ten-minute
14 early break and reconvene at 10:35 promptly.

15 (Whereupon, the above-entitled matter
16 went off the record at 10:24 a.m. and resumed at
17 10:36 a.m.)

18 CO-CHAIR TIRSCHWELL: All right.
19 Well, I'd like to get started again. The next
20 measure that we're reviewing is 2876, which is
21 similar to 2877, which will be next.

22 This first one is hospital 30-day,

1 all-cause, risk-standardized mortality rate
2 following acute ischemic stroke hospitalization,
3 claims-based risk adjustment for severity score
4 from CMS and Yale. Let me ask -- sorry one --

5 (Off microphone comment.)

6 CO-CHAIR TIRSCHWELL: I'm not saying
7 CMS out. Before we start, for the NQF folks,
8 these two measures are totally independent. So
9 regardless of what happens with the first one,
10 we'll be looking at the second one. Okay, good.
11 Thank you for that clarity.

12 Why don't you guys introduce yourself
13 and then introduce your measure?

14 MS. BERNHEIM: Hi, this is Susannah
15 Bernheim. I am the quality measurement program
16 director at Yale CORE, we're the measure
17 developers for this -- doing this under CMS'
18 stewardship. I think you know my partner-in-
19 crime, who has been sitting on his seat all day.

20 DR. SCHWAMM: And actually for this,
21 I'm also an expert for this measure developer,
22 and I actually was a consultant along with

1 several other experts on the development of the
2 measure.

3 MS. BERNHEIM: Okay. So I'm going to
4 try to keep this quite brief. I will orient you
5 to this measure. This is an outcomes measure.
6 It takes ischemic stroke patients and assesses
7 mortality within 30 days.

8 This is a really important measure in
9 that it is a update to a measure that CMS
10 currently uses in their inpatient quality
11 reporting program, that is a claims-based measure
12 of 30-day mortality after ischemic stroke.

13 That measure, when we brought it
14 forward some years ago, the single biggest
15 concern from the committee evaluating at that
16 time was that we did not have a means of
17 evaluating stroke severity when a patient came
18 into the hospital.

19 So this measure takes an essentially
20 identical cohort, an outcome definition and a
21 similar modeling strategy, but we reselected
22 variables and included the NIH Stroke Scale as a

1 risk adjustment variable for the measure. The
2 reason we're able to bring this forward at this
3 point, as you all are probably aware, is there's
4 much more evidence for the use of the NIH Stroke
5 Scale consistently. There's much broader uptake
6 within the -- with the guideline hospitals, it's
7 well over 80 percent at this point.

8 And as of today, you're recommending
9 that it be endorsed as a quality measure, the
10 collection of this, and there's been work to
11 incorporate the NIH Stroke Scale into claims
12 data. So as of October this year, there will be
13 codes that coders can use that identify what the
14 NIH Stroke Scale is.

15 As Lee spoke to earlier, once that
16 information is in the medical record as a number,
17 it's a pretty straightforward thing for a coder
18 to take that number and translate it to an ICD-10
19 code. So we're very optimistic about the
20 translation into the codes.

21 I think the other important thing to
22 reflect is that the way that we were able to

1 develop this measure is that we linked claims
2 data to Get With the Guidelines data. So we were
3 able to look at this measure in about 1,500
4 hospitals, but they're all Get With The
5 Guidelines hospitals that way we had for each of
6 the patients full Medicare claims data as well as
7 an NIH Stroke Scale that came from the registry
8 data. The registry data in this case was just
9 being used as a surrogate for the claims data
10 that we'll have going forward. So that's how we
11 were able to develop the risk model.

12 The only other key point I'll make is
13 that we heard some very early concerns about
14 whether mortality is even an appropriate measure
15 in stroke. So I just want to reiterate the
16 evidence that's out there around mortality being
17 linked to a number of processes of care,
18 prevention of complications, use of stroke
19 centers and stroke units, timeliness of being
20 seen by the right caretakers.

21 We have a number of studies that we
22 can reference, but I think that there's pretty

1 substantial evidence that high quality care will
2 reduce mortality, and that if you're accounting
3 for stroke severity you can fairly assess
4 relative performance of hospitals. Thank you.

5 CO-CHAIR TIRSCHWELL: Thank you. Did
6 you want to -- any additional comments?

7 DR. SCHWAMM: Yeah. I just wanted to,
8 for those who aren't familiar with it, first of
9 all I wanted to applaud the Yale group and CMS
10 for taking the feedback from this steering
11 committee several years ago to heart, and really
12 paving the way for doing a validation study,
13 where we partnered registry data with claims
14 data.

15 But also for figuring out a way to
16 actually collect and utilize the NIH Stroke Scale
17 score in all hospitals in the United States, not
18 just those who are participating in a voluntary
19 quality improvement program. So I think it has
20 very broad-reaching implications.

21 In work that we've done in Get With
22 the Guidelines, the NIH Stroke Scale score

1 contributes over 90 percent of the discriminating
2 value in the c statistics for the predictive
3 power of the model. The model has a c statistic
4 for about .86, .82 is carried by the NIH Stroke
5 Scale score, two digit score alone.

6 So it's a -- unlike some other
7 diseases, it really is one of the most important
8 measures in predicting outcome as relates to
9 mortality after ischemic stroke. So I think
10 adding it to this measure makes it a more robust
11 measure.

12 CO-CHAIR TIRSCHWELL: Great. Our
13 reviewers are Jim and Lisa. Who's leading off?

14 MEMBER BURKE: So I'm going to lead
15 off and Lisa's going to jump in. So I guess
16 before -- I think there's probably a quick prior
17 here, which is the bulk of the thing that we
18 spent talking on the workgroup bears -- bodes on
19 the evidence question as well as on the validity
20 question.

21 It was a thing that was alluded to,
22 which is this question of is the mortality the

1 right measure sort of philosophically, and this
2 sort of bears on both of these. And so sort of
3 what came up on the workgroup call and was talked
4 about a lot, and there was -- lots of people said
5 this in sort of various ways, but everyone was
6 getting around the same idea here, was that
7 mortality is not what we measure for stroke
8 trials.

9 There's a bunch of reasons for that.
10 A big one is that mortality is not, obviously,
11 the right patient-centered outcome. But we know
12 that in the real world, a lot of patients will
13 have a bad stroke and then die, and that is not
14 necessarily the bad outcome once they've had a
15 bad stroke.

16 If you ask older Americans about their
17 preferences, about surviving with a severe stroke
18 disability or dying, a large proportion of them
19 will tell you they would rather die than live
20 with a severe disability from stroke. The trick
21 here becomes -- that's not true after the fact.

22 Most people who survive after a severe

1 stroke are happy that they did, but this becomes
2 sort of the preference-sensitive question here
3 that gets tricky. It's doubly-tricky because
4 there's a lot of care factors that can lead to a
5 transition between death and survival with severe
6 mortality.

7 So if we take everybody and we put in
8 PEG tubes or we don't put in PEG tubes, that has
9 a major influence on mortality, but it may be
10 highly orthogonal to quality.

11 That sort of broad philosophic
12 perspective, about making sure that patients'
13 preferences are adequately accounted for, was
14 sort of the big thing that sort of fell out in
15 the conversation. It came up sort of time and
16 time again when we talked about it, and it bears
17 on both the evidence question and the validity
18 question.

19 So in terms of the evidence question,
20 what the developers cited were several
21 observational studies that were of reasonable
22 quality, all of them somewhat limited though,

1 about whether or not doing something that looks
2 like it's probably good care is associated with
3 mortality.

4 So if you're in the Get With the
5 Guidelines registry, you have slightly lower
6 mortality than if you don't -- not in the
7 registry, the idea being that participating in
8 the quality improvement registry might reduce
9 mortality. Patients who come in on weekends have
10 slightly lower mortality than patients who come
11 in during weekdays, maybe because of quality of
12 care.

13 There was a complication paper and it
14 was at least one more where there were some
15 process measures correlating with mortality. All
16 of them, you know, require a bit of a leap of
17 faith to assume that quality was the key mediator
18 that led to that.

19 It's not a clearly unreasonable
20 conclusion, but it's also far from a given that
21 that was the key mediator. There's unmeasured,
22 confounding in all of these and a whole lot of

1 different factors that any one of these you could
2 pick at and pull it apart.

3 The other evidence problem is that the
4 evidence provided with this was not necessarily
5 completely systematic. I think that there's
6 other data that suggests that things that should
7 be hospital quality don't necessarily correlate
8 with mortality.

9 The big one here is I think volume
10 outcome relationships. So an ischemic stroke,
11 you know, we in general high volume should mean
12 lots of experience, lots of resources and you're
13 good at it, and there's a modest association
14 there with mortality.

15 The other one that I think is -- and
16 full disclosure, this is work that I participated
17 in -- was that when you look at hospital-level
18 variation in the proportion of people with early
19 DNR orders, which is not easy to interpret but
20 might mean something about patient preferences,
21 that that is very strongly correlated with
22 mortality, and again not necessarily obviously a

1 quality factor.

2 When you look at though, the NQF
3 algorithm for this, the evidence bar appears to
4 be really low. So if you look at the algorithm
5 for outcome measures, which is different than the
6 algorithm for everything else, the language seems
7 to suggest that almost anything would get you
8 over the bar.

9 So all you need to do is have an
10 association between some quality factor and an
11 outcome, and I wondered if that was -- you know,
12 that's how it got put out in the preliminary
13 statement. If that's the case, there's probably
14 nothing to talk about here.

15 It's a totally obvious pass, but that
16 seems like it's a really, really remarkably low
17 bar.

18 MS. JOHNSON: And just to answer your
19 question, we do have a different bar, if you
20 will, for outcome measures and part of that idea
21 is that, you know, outcomes are the ones that are
22 important to patients.

1 We could discuss whether this one for
2 stroke is, but we do have a different bar. We do
3 not require, you know, the studies, the quantity-
4 quality consistency, that sort of thing that we
5 do require for processed intermediate outcomes.

6 So to answer your question yes, what
7 we require is a rationale and that basically
8 supports the relationship between something that
9 you can do and that outcome. So that's what we
10 ask for.

11 MEMBER BURKE: So it seems like the
12 question here is I mean, you know, there's
13 clearly an association between something you can
14 do that looks like quality of an outcome. The
15 question is do you have to have some sort of
16 burden of the evidence, because this is the part
17 that seems like it's much trickier, right?

18 Is it a question of are the factors
19 that lead to mortality on the whole quality or on
20 the whole something else seems like it's the open
21 question. I guess that was -- I think if I was
22 going to summarize the workgroup conversation,

1 that's where the concern was.

2 The concern was that quality might be
3 -- or is likely one of the factors driving that,
4 but it might not be the predominant one and it
5 might be pretty small, and we don't really know
6 what part of the fraction that is. Is there any
7 guidance on how to judge in that situation?

8 MS. JOHNSON: I don't think we have
9 specific guidance in there, but I think you have
10 to ask as you're thinking about this, is there
11 actually something that providers can do to
12 mediate this outcome, and that's basically the
13 question that we're asking you.

14 CO-CHAIR TIRSCHWELL: Peter.

15 MEMBER SCHMIDT: So my understanding,
16 the reason why there's the lower bar for evidence
17 for an outcome measure is that there is no target
18 for the measure specified in the definition, that
19 we are -- it is important to measure outcomes,
20 but it is not necessarily -- by the fact that
21 you're measuring the outcome, it doesn't mean
22 that you're saying that zero is the target for

1 death at 30 days. You're just saying that we're
2 going to measure what that outcome is.

3 MS. JOHNSON: I think you're correct.
4 I don't -- I wouldn't say that that's why we have
5 a different evidence bar. I think it probably
6 goes back more to QI practices in general, you
7 know. If your outcome is not what you would like
8 it to be in your own shop it might be one thing;
9 in somebody else's it might be something else.

10 And there may be many things -- there
11 probably are many things that you could do to
12 affect your outcomes, but it would be way too
13 onerous to expect developers to figure out every
14 possible thing and go do lit searches for all of
15 those things.

16 So again, the idea is the QI piece of
17 it. You are correct that most outcome measures,
18 we generally don't expect a zero or 100 percent.

19 MEMBER SCHMIDT: They just fall -- we
20 measure falls in Parkinson's disease. But if you
21 put everyone in a wheelchair, no one would fall.
22 So we do not consider zero falls to be our

1 target.

2 CO-CHAIR TIRSCHWELL: Yeah, go ahead.

3 MS. BERNHEIM: Just a sort of big
4 picture perspective on this question as an
5 outcomes measure developer, because we think
6 about this all the time, right.

7 So when we start to develop a measure,
8 we ask ourselves two crucial questions. One, do
9 we think the outcome we're assessing has a
10 relationship with quality of care, that higher
11 quality of care is likely to influence this
12 outcome?

13 Two, and I think this gets to your
14 earlier point is can we adequately risk adjust,
15 because the issue is are there too many other
16 things that are clouding the picture for us to
17 sort of tease out the quality? So certainly
18 there are lots of things that affect stroke
19 mortality rates.

20 What we think is that if we do an
21 adequate job of accounting for the severity of
22 the patients who are coming in and their other

1 risk factors, then as we start to see differences
2 across institutions, having done a good job of
3 accounting for differences among their patients,
4 what we're seeing is reflecting something about
5 relative quality of those institutions.

6 It's not perfect and this is not the
7 perfect outcome for stroke patients. As you all
8 have discussed earlier, the perfect outcome is
9 hard to measure.

10 But I think the important question is
11 does this tell us something if we've done
12 adequate risk adjustment about what's happening
13 at these institutions? Do we have evidence that
14 institutions that do a better job at DVT
15 prevention, early intervention, using the
16 appropriate care providers, getting MRIs in a
17 timely fashion, using PPA when it's appropriate,
18 having stroke units, are likely to have lower
19 risk-adjusted mortality rates?

20 That's really what we're -- that's
21 really how we think about it, and we think that
22 the evidence reasonable in that version. It is

1 true, there is no gold standard for total
2 quality. Process measures are much simpler to
3 handle, because they're sort of yes-no, but the
4 outcome measures reflect an enormous range of
5 processes that are going on in a hospital and
6 it's very hard to hold it against a gold
7 standard.

8 So the way we tend to think about it
9 is, is there reasonable evidence that quality
10 influences this and can we adequately risk-adjust
11 for the other factors? That's what we -- how we
12 think about it when we bring this measure
13 forward.

14 CO-CHAIR TIRSCHWELL: Any other
15 discussion related to evidence? If not, I
16 suggest we vote on evidence.

17 MS. SKIPPER: We are now voting on
18 Evidence on Measure 2876. 1 yes, 2 no if the
19 rationale supports the relationship of the health
20 outcome to at least one health care structure,
21 process, intervention or service.

22 (Voting.)

1 MS. SKIPPER: Results are 100 percent
2 yes.

3 CO-CHAIR TIRSCHWELL: I think it
4 wasn't enough votes.

5 MS. SKIPPER: I thought there were 22.

6 MS. OGUNGBEMI: It did say 22.

7 CO-CHAIR TIRSCHWELL: It did?

8 MS. OGUNGBEMI: Yeah.

9 CO-CHAIR TIRSCHWELL: Okay. I thought
10 it's the bottom left. Is that what you meant?

11 PARTICIPANT: There's separate little
12 bar.

13 CO-CHAIR TIRSCHWELL: Oh okay. Yeah,
14 I can't see that one.

15 MS. SKIPPER: We're going to revote.

16 CO-CHAIR TIRSCHWELL: Okay.

17 MS. SKIPPER: We're now voting on
18 evidence for measure 2876, 1 yes, 2 no.

19 CO-CHAIR TIRSCHWELL: Yeah. I need
20 better glasses. On the bottom left it used to
21 count up as well. I don't know why it's not
22 doing that anymore.

1 (Voting.)

2 MS. SKIPPER: So results are 100
3 percent yes, zero percent no. The measure does
4 pass on evidence.

5 CO-CHAIR TIRSCHWELL: So next we're on
6 to gaps in care or opportunities for improvement.
7 Jim.

8 MEMBER BURKE: So on gaps, we've got
9 data on -- let me take a quick aside to introduce
10 the data source because we're going to come back
11 to it a couple of times. This is what Susannah
12 alluded to.

13 Basically, what they did was they took
14 Get With the Guidelines hospitals, where you have
15 a voluntary quality improvement registry, where
16 patients -- where in the most recent years, a
17 large proportion -- a large majority of the
18 patients have a stroke scale entered.

19 They linked that to Medicare claims
20 and then they created a data set of what they
21 think the world will look like when NIH Stroke
22 Scale is reported via ICD-10 codes. They built

1 their model on that data set, and what they found
2 was that there is considerable variation in the
3 hospital level 25th -- or the lowest quartile, or
4 it's the 20th percentile at 13 percent mortality,
5 highest at 15-16 percent mortality, and a range
6 of 10.8 to 19 percent mortality, with a median of
7 about 14.5.

8 So on this measure, there is
9 variation. That is also true with CMS' current
10 measure, although one suggesting for NIH Stroke
11 Scale but it looks like the range and
12 interquartile range are substantially reduced
13 compared to what was there previously. So it is
14 clear variation exists. Whether or not one looks
15 at those numbers and sees that as large variation
16 I think is really hard to figure out.

17 They also did present disparities
18 data, looking at three sort of separate
19 subpopulations at the hospital level. The short
20 answer is there's no big differences here, which
21 is to say if anything, mortality looks like it's
22 probably a little bit lower than hospitals that

1 take care of a high proportion of African-
2 Americans. No big difference on socioeconomic
3 status and no big difference on dual eligibles.
4 I think that's the data.

5 CO-CHAIR TIRSCHWELL: So any
6 discussion about gaps in care, disparities,
7 opportunities for improvement?

8 (No response.)

9 CO-CHAIR TIRSCHWELL: Okay. Seeing
10 none, I move to suggest we vote.

11 MS. SKIPPER: We are now voting on gap
12 for measure 2876, 1 high, 2 moderate, 3 low, 4
13 insufficient. Waiting on one more vote.

14 (Voting.)

15 MS. SKIPPER: The results are 32
16 percent high, 55 percent moderate, 14 percent
17 low, 0 percent insufficient. The measure does
18 pass on gap.

19 CO-CHAIR TIRSCHWELL: So then
20 reliability Jim.

21 MEMBER BURKE: So --

22 CO-CHAIR TIRSCHWELL: And actually

1 before you start, Karen, do you make -- mind
2 making the one comment about reliability that we
3 discussed?

4 MS. JOHNSON: Sure. Remember
5 yesterday we talked about does NQF set thresholds
6 for reliability and that sort of thing? The
7 answer was no, we don't set thresholds. What we
8 try to do when we can is provide rules of thumb.
9 We have a rule of thumb that we often apply to
10 reliability estimates, that 0.7 and there's some
11 concern and we actually talked to our -- one of
12 our statistical consultants over the weekend
13 about this one.

14 She actually cautioned us for this
15 particular measure to back away a little bit from
16 that rule of thumb for this measure, and part of
17 the reason for that is because reliability
18 actually is contextual. We mentioned this again
19 yesterday. It has to do with variation between,
20 within and sample size, and also to some extent
21 maybe how, you know, the methodology that people
22 used. There's different methods to look at

1 reliability.

2 So for this particular one, we would
3 like you to consider the other rule of thumb that
4 was mentioned both by the developer as well as in
5 our PAs. There is a classification system for
6 ICCs and for dis correlations specifically. It's
7 the Landis and Koch classification and maybe use
8 that as your rule of thumb when you're thinking
9 about this measure.

10 Probably even more compelling might be
11 some information that Susannah could bring
12 forward. They actually did an additional
13 literature search. I don't think that was in
14 your submission, but they have some other studies
15 where they did something similar and have
16 correlation magnitudes that may help you put what
17 they found into a better context. Any questions?

18 (No response.)

19 CO-CHAIR TIRSCHWELL: Jim.

20 MEMBER BURKE: So the, you know,
21 reliability here there's sort of element
22 reliability and then overall scale reliability.

1 Element reliability here for most of these are
2 really easy, right. So for claims-based
3 measures, reliability's kind of a given so that's
4 not going to be a problem at all.

5 The element where there's a
6 reliability question is NIH Stroke Scale. We
7 know that it's highly reliable when measured in
8 the context of a clinical -- or we should say
9 reasonably reliable when measured in the context
10 of a clinical trial, or in a limited context. We
11 don't know nearly as much though about what it
12 looks like in the real world, and the worry here
13 is going to be what is NIH Stroke Scale
14 reliability look like when it goes across all
15 Medicare hospitals? This is I think for right
16 now something we just don't know.

17 Reliability is a question of the
18 context in which it's measured, and we just have
19 never measured it in that context. There's a
20 reference in here that it will get tested and
21 measured at some point in time, some place in the
22 developer's documentation.

1 I didn't know if we know what the plan
2 is there or how that data was going to be used or
3 modify things. If we find out the reliability
4 looks bad, what do we do?

5 CO-CHAIR TIRSCHWELL: Sure, go ahead.

6 MS. BERNHEIM: Yes. So we noted, we
7 expect in October that there will begin to be
8 collection and that will give us an opportunity
9 -- and I don't want to speak for CMS, but my
10 expectation is that CMS would wait until we did
11 some additional testing.

12 Again, we'll have the advantage of
13 having Get With The Guidelines data as well, and
14 we can do some comparisons of what we're seeing
15 from the claims data and the registry data to
16 ensure that there's a clean transition to the
17 claims NIH Stroke Scale, but I will say I think
18 it's critical that we test the measure in the
19 final data set that it would be used in before it
20 gets implemented. But sort of harkening to
21 something that Lee said earlier, I think the key
22 is the reliability of the clinician getting the

1 information into the chart.

2 I'm not at all concerned that once
3 there's a number and a chart that it will be
4 accurately translated to the claims. Do you want
5 to add anything to that?

6 DR. SCHWAMM: The only additional data
7 I could offer is we did a data validation audit
8 in Get With The Guidelines. It was published in
9 the American Heart Journal back in -- sorry, 2011
10 and looked, actually had charts sent in and
11 specifically NIH Stroke Scale score accuracy.

12 On reabstraction, it was 93.6 percent
13 accurate. So I think, you know, many fine
14 academic teaching hospitals are Get With The
15 Guidelines hospitals, but there are hundreds and
16 hundreds of smaller community hospitals that are
17 in Get With The Guidelines.

18 So we don't have data on the entirety
19 of Medicare hospitals and you're absolutely
20 right. Seeing the extent to which they can
21 reliably perform an NIH Stroke Scale score is
22 something that will need to be assessed as part

1 of the implementation of the measure.

2 MEMBER BURKE: So correct me if I'm
3 wrong, but that Get With The Guidelines
4 reference, that's a question of when essentially
5 two different people abstracted the chart, but
6 they fail to pull out the same number. I mean I
7 think the reliability concern here -- more than
8 the one you alluded to before -- is going to be
9 who's doing the stroke scale and putting it in
10 the chart.

11 DR. SCHWAMM: Right.

12 (Simultaneous speaking.)

13 MEMBER BURKE: -- the reliability
14 problem, that's probably where it would -- I
15 mean, I would agree with you entirely. Once
16 there's a number in the chart, people are going
17 to be able to find it reliably.

18 DR. SCHWAMM: Now there is a VA study
19 that was done many years ago with the National
20 Stroke Project data that I think that Judy
21 Lichtman was involved in, where they looked
22 actually at reabstraction from the source

1 neurological exam, and showed that actually
2 reabstraction rates correlated well with the --
3 you know, or retrospective NIH correlated very
4 well with the actually prospectively obtained NIH
5 Stroke Scale score.

6 But there's no data source that I'm
7 aware of that we can look to, short of
8 implementing this measure and getting those sites
9 to start collecting it to address that question.

10 CO-CHAIR TIRSCHWELL: Is that all you
11 have on reliability?

12 MEMBER BURKE: There's more, but I
13 think Lisa had a question.

14 CO-CHAIR TIRSCHWELL: Oh, okay. Yeah,
15 sorry, go ahead.

16 MEMBER LINES: Well, I'm not sure if
17 you're going to talk about this next and stop me
18 if I'm -- but we're asked to talk about the --
19 you know, to talk about the issues or concerns
20 that we have with the specifications, definitions
21 or coding. Other members of the committee know
22 that I have a problem with the NIS because there

1 is a better instrument out there.

2 I have an issue with hardwiring an
3 outcome measure to a flawed -- possibly flawed
4 instrument, especially rolling it out across the
5 entire country. So I'm just going to state that
6 again, especially when you're going to be doing
7 multiple imputation of NIS scores for the risk
8 adjustment process. That seems crazy to me.

9 Also, you know, one of the things
10 that's not excluded here is patients with comfort
11 measures only, and almost all of the other
12 measures that we've looked at they're excluding
13 those patients, but not this one.

14 MEMBER BURKE: I think we can probably
15 get to that one on validity. I'm not sure that's
16 quite a reliability thing, but I think that will
17 come back up there. There's a couple of points
18 we need to talk about there.

19 The other big reliability point here
20 is the -- so does the element reliability, and I
21 think the stroke scale's the conceivable worry
22 there. We don't know what the real world numbers

1 are going to look like. What they also did was
2 they did sort of an overall reliability of the
3 measure itself, and this is what we're getting to
4 with the what is the right ICC cutoff point?

5 What they did was they took this big
6 linked sample, they split it in half over three
7 years, and they sort of estimated the measure for
8 -- in one half of the sample and estimated the
9 measure in one other half of the sample, and they
10 came up with an ICC of .055, which I think means
11 that -- what's that?

12 (Off microphone comment.)

13 MEMBER BURKE: I think it got
14 mistranslated. It was 55 yeah. It got written
15 as 51 a bunch of times, but in their number was
16 55.

17 Actually, one quick point. I couldn't
18 tell from your documentation. That was adjusted
19 -- that was sort of Spearman-Brown adjusted to
20 the three years or was that the actual measured
21 one?

22 (Off microphone comment.)

1 MEMBER BURKE: So that was a -- okay.
2 So the .055 then is to say how much does -- when
3 you come up with these two different numbers, how
4 much does hospital -- what proportion of the
5 variance in those numbers does hospital predict?
6 Is that a correct assessment?

7 MS. BERNHEIM: So I'm going to check
8 first to see if my statistician is on the call,
9 because he will do a better job of answering
10 these questions than me. But I'll do my best if
11 he's not. Jeph, are you on the call? If Jeph
12 Herrin's on the call?

13 DR. HERRIN: Yes. I am here. Okay.

14 MS. BERNHEIM: Oh great, great. So
15 I'm going to let you take these questions if it's
16 comfortable from the phone okay.

17 DR. HERRIN: Okay. Yeah, that's fine.
18 So I think that there's -- you know, the ICC is a
19 statistic which can be calculated a number of
20 different ways and it has applied in a lot of
21 different situations. It's very tempting to try
22 and come up with a single very simple

1 interpretation such as percent variance
2 explained.

3 Some people have tried to do that.
4 Some people have said this actually is the same
5 as a kappa or an alpha -- I'll come back to
6 alpha. We think of it as just the, you know,
7 it's an inter-rater reliability statistic, and
8 we're looking at whether when two people measure
9 -- or two measurements are made on the same
10 hospital, if -- not only are those consistent
11 with each other but also if the differences
12 between the hospitals are consistent.

13 So it's a very sort of conservative
14 measure. We're really trying to do more than
15 look at the correlation or just do sort of a one-
16 way, you know, traditional ICC is where you just
17 look at the variance between divided by the total
18 variance, and it's not exactly that.

19 So that's sort of the long answer to
20 your question. Some people would say that, you
21 know, would like to interpret it is 55 percent of
22 the variance is explained by the hospitals, but

1 I'm not sure that's exactly true.

2 MEMBER BURKE: So let me ask two
3 questions to clarify, because I think it has some
4 relevance -- because I think particularly when it
5 comes to making a judgment about this number,
6 there's a couple of things we need to figure out.

7 One is what was the number before it
8 was adjusted? So basically the problem here was
9 that when this measure gets implemented in the
10 real world -- we didn't talk about this and we
11 probably should -- it's going to be off of three
12 years of data. And this was a -- in the
13 validation sample or in their validation
14 reliability testing they sort of did three years
15 and then split it in half for the reliability.

16 So it was kind of like one and a half
17 years. That Spearman-Brown adjustment sort of
18 assumes the reliability is the same over that
19 time, isn't that right?

20 DR. HERRIN: Correct.

21 MEMBER BURKE: Okay. So that seems to
22 be saying it's an assumption, and if we just did

1 it over the one and a half years what was it, I
2 mean because it probably went up a lot, right?

3 MS. BERNHEIM: It doesn't go up a lot,
4 but I'm going to look for you right now.

5 MEMBER BURKE: Oh okay, okay.

6 MS. BERNHEIM: I don't have it in
7 front of me, but we've got it in the --

8 MEMBER BURKE: Maybe that was the .51.
9 All right. But it doesn't go that much. Then
10 the other question would be the -- the other
11 questions about this reliability are again what
12 would the score reliability look like in the real
13 world and might it look different here, you know?

14 The element reliability can feed into
15 that. If people in the real world are not
16 measuring those elements well, that's a problem.
17 Two would be whether or not this sample
18 generalizes as well as it could to the real
19 world. So it's 1,500 hospitals as opposed to
20 more than 3,000.

21 So if people who are participating --
22 obviously a very, very large sample and it's a

1 heterogeneous sample, but whether or not it
2 represents the rest of the world is not entirely
3 clear. In general, the more heterogeneous sample
4 that you measure across, your reliability is
5 going to fall. So my guess is it would come down
6 somewhat in the real world, but whether or not --
7 or how much it would come down seems like it's
8 not entirely clear.

9 Then the last question is sort of the
10 value judgment about what ICC's good enough, and
11 this was something where when we talked about
12 this in the workgroup call, people had very
13 different perspectives. Some people said 0.55
14 sounds like a pretty good number, and some people
15 said wait, we're only explaining just over half
16 the variance. That sounds terrible.

17 I don't know if there's -- as we got
18 here, no clear guidance on what's low and what's
19 moderate here in terms of that, and what we
20 really want to know is what would it be when we
21 do it in the real world, which we don't quite
22 know yet?

1 DR. HERRIN: So in terms of
2 generalizing it to a larger scale hospital, I
3 don't think it's -- it's not clear to me that the
4 ICC would go one way or the other. I think it's
5 mostly affected by the volume of the hospital,
6 and unless we think that the hospitals that are
7 being admitted are much smaller on average than
8 the 1,500 we've measured I wouldn't expect the
9 ICC to go down.

10 But you know, smaller hospitals are
11 less reliably measured because we know less about
12 them. So --

13 MEMBER BURKE: I mean I think the
14 problem with the generalizing -- I obviously
15 don't know what happens. The problem is that
16 you're just going to pick up heterogeneity in
17 hospital type, heterogeneity in practices,
18 heterogeneity in patients. But there's some type
19 of homogeneity that says look, I'm going to
20 participate in Get With The Guidelines.

21 It's an assumption. I don't know that
22 it's true, and I don't know that it's -- how

1 important it would be. But if I had to guess, I
2 guess this is smaller in the real world. This is
3 just generally when you take a measure at it in a
4 couple of people and then you look at it in a lot
5 more people, the reliability usually goes down.

6 CO-CHAIR TIRSCHWELL: And I just have
7 a question for the developers. I think on the
8 call, I had suggested this. I don't know whether
9 you've had a chance to look at it. But one of
10 the -- you know, the way the current measure is
11 out there in the world, it's you see your
12 numbers, but then you just sort of get a expected
13 -- within the expected range, above the expected
14 range, below the expected range.

15 A really simple question that I have
16 is when you look at the test and this retest for
17 the same hospitals, how many hospitals end up
18 being reclassified into a different territory --
19 into a different category?

20 DR. SCHWAMM: By what maneuver, when
21 you're saying --

22 CO-CHAIR TIRSCHWELL: By the first

1 data set -- you know, with the split sample. So
2 you know, you've got two ratings for each
3 hospital.

4 DR. SCHWAMM: You're asking what the
5 net reclassification?

6 CO-CHAIR TIRSCHWELL: Which you guys
7 did when you put the NIH Stroke Scale score in to
8 justify the fact that you needed it. So I
9 thought that would be an interesting way to
10 assess whether we're worried about this
11 reliability or not.

12 MS. BERNHEIM: So a couple of quick
13 things. I'm trying to look quickly to see if I
14 can get back to the reliability of the current
15 national measure, because that will answer some
16 of your questions about whether this changes a
17 lot when you have a broader sample.

18 So if my team is on the phone, if
19 people could look back in our prior NQF
20 application to help us find that reliability
21 number for the current measure, that would be
22 really helpful. I'm thinking on too many threads

1 at once. No, not at all.

2 So there's a couple of things I think
3 are worth saying. So I want to remind this group
4 that maybe to our own discredit we have taken an
5 extraordinarily conservative approach. We don't
6 want to overplay. So what we do is we pretend
7 that half the patients walked into the hospital
8 and we assess the quality, which is this latent
9 thing that we're trying to assess. We're not,
10 you know, test-retesting whether somebody thought
11 there was heart failure in a patient, right?

12 It's the quality of the hospital, and
13 then we have the other half of the patients walk
14 into the hospital and we assess the quality. So
15 we do not expect extraordinarily high numbers,
16 although I will say when we have large sample
17 sizes, we do get higher numbers. We tend to see
18 this ICC track somewhat with the numbers of
19 patients that come in a hospital.

20 There are a number of other things we
21 do with this measure in use to protect us from
22 misclassifying hospitals. So really small

1 hospitals are left out during reporting.

2 Hospitals with fewer than 25 cases aren't
3 reported on at all, and then when hospitals are
4 classified, we have a number for them which is
5 ICC is looking at but we then create an interval
6 estimate.

7 So we have much more confidence in the
8 higher than or lower than number, because we've
9 taken the RSMR, which is the Risk-Standardized
10 Mortality Rate, which is what the ICC is checking
11 -- how reliable that is, and then we've put a
12 confidence interval around it.

13 So we're doing lots of things to
14 ensure that we're not mischaracterizing hospitals
15 that I think help protect against this low
16 reliability rate. I think it's also, you know
17 this is -- by the sources that we use, this is
18 moderate. It's not terrible, it's not terrific.
19 It is comparable to many similar measures and
20 many similar studies.

21 I'm going to check, if anybody on my
22 team has a quick number on me for the current

1 measure? I know I didn't give you much time but
2 -- Karen are you there?

3 MS. DORSEY: I'm here. I'm trying to
4 figure out if I'm looking at the right form, but
5 it looks like we reported .4 for this measure.

6 MS. BERNHEIM: So this is before we
7 used the Spearman-Brown and in a national level?

8 MS. DORSEY: Correct, correct.

9 MS. BERNHEIM: So a slightly lower
10 number for a national sample still meeting the
11 moderate number. Thank you.

12 MS. DORSEY: That's right.

13 CO-CHAIR TIRSCHWELL: Reclassification
14 thing. Any comment on that?

15 MS. BERNHEIM: So we have not done
16 that. We have not classified hospitals based --
17 I mean the ICC is getting at the same concept,
18 right? But we have not run hospitals with half
19 their volume and then run them with the other
20 half the volume and seen whether or not they're
21 reclassified. It's just not something we've
22 done.

1 DR. HERRIN: And part of the reason
2 is that we used bootstrapping and it's very time
3 intensive. So you know --

4 CO-CHAIR TIRSCHWELL: We can't hear
5 you.

6 DR. HERRIN: I'm sorry. We used
7 bootstrapping to construct confidence intervals.
8 As you may know it takes a very long time to do,
9 there is a lot of intensive calculations. So we
10 haven't necessarily done that for the split
11 samples.

12 I wanted to make a couple of other
13 comments too, you know, regarding the .7 cutoff
14 or convention. My understanding is that that's
15 going to be used from a paper of Nunnally and
16 Bernstein, I think. We're talking about inter-
17 item reliability for survey instrument like for
18 metric tools. They're talking about if you have
19 a number of items on an instrument and you want
20 to look at -- calculate the alpha.

21 You know, what's the minimum
22 acceptable value, and they proposed .7 and I

1 would tend to concur with them, if I was looking
2 at inter-item reliability on an instrument. I
3 think .7 is pretty minimal, but I think that it's
4 a bit of a -- it's not clear to me and I don't
5 know anyone else who has generally applied that
6 same value to things like inter-rater
7 reliability, kappas or ICCs.

8 We have taken the position, I think,
9 that you know, in addition to looking at other
10 measures, the other way to calibrate what this
11 should be is to look at other contexts where we
12 have a feel for what's going on.

13 So you know, as I think Karen or
14 someone mentioned earlier, we did the literature
15 search and looked for ICCs that were calculated
16 in familiar contexts, contexts like chart
17 abstraction, stroke assessment even. We found a
18 study where someone -- pairs of clinicians
19 assessed patients for stroke and on risk factors
20 they found ICCs in the range of like .47 up to
21 .6-something.

22 We find that looking at situations

1 where we have a feel for what should be
2 happening, that we get a better sense of what's a
3 meaningful ICC and it seems like --

4 MEMBER BURKE: How does this ICC
5 compare to the other CMS mortality measures? How
6 does this compare to MI, pneumonia and heart
7 failure?

8 MS. BERNHEIM: So it's quite similar
9 to MI in part because we have similar volumes.
10 Pneumonia has a much larger volume, so we get a
11 much higher ICC, hospital-wide has a higher one
12 and the other ones are sort in the midst. So
13 this is among the lower but it's in the range of
14 the other measures.

15 CO-CHAIR TIRSCHWELL: How high does it
16 get in the higher volume hospitals?

17 MS. BERNHEIM: So hospital-wide, well
18 we do remember we're talking about eight million
19 patients. We get up to .8. Nothing else comes
20 close.

21 CO-CHAIR TIRSCHWELL: Sorry. I didn't
22 understand that answer.

1 MS. BERNHEIM: In the higher volume
2 hospitals -- I'm sorry. I'm talking about higher
3 volume conditions. I don't think we've looked at
4 this in hospitals.

5 CO-CHAIR TIRSCHWELL: Yeah. I'm
6 talking about higher volume hospitals. You said
7 the ICC sort of --

8 MS. BERNHEIM: I meant higher volume
9 conditions. Sorry.

10 MEMBER BURKE: The prevalent
11 conditions.

12 MS. BERNHEIM: Right. The measures
13 for which hospitals tend to have higher volumes
14 overall, we tend to see higher ICCs, which is why
15 the hospital-wide measure, where every hospital
16 has a pretty high volume because we're capturing
17 90 percent of their measured visits.

18 CO-CHAIR TIRSCHWELL: So here, there
19 are stroke hospitals that have higher volumes.
20 Do they -- if you look at that subset, do they
21 have higher ICCs?

22 MS. BERNHEIM: That's a great

1 question. That's not something we've done.

2 CO-CHAIR TIRSCHWELL: Okay.

3 MEMBER BURKE: So I think there's one
4 more small reliability point, which is by
5 necessity this is Medicare fee-for-service, and
6 we don't know how -- I haven't seen a lot of data
7 on how that biases at the hospital level.

8 Which is to say if you have Medicare
9 Advantage patients or that happens to be a large
10 proportion of your patient population, and if
11 they have any difference in outcomes at all, then
12 we're going to have conceivable reliability
13 problems there as well.

14 I haven't seen stroke-specific data on
15 differences in mortality in Medicare fee-for-
16 service and Medicare Part C. I don't have a
17 strong prior that one would expect, but if it
18 does, that's going to be another reliability
19 problem.

20 MS. BERNHEIM: We have not done this
21 in stroke, but we have looked at this in a couple
22 of different ways. We have one paper out that

1 just assesses whether or not the amount of
2 Medicare Advantage penetration in an area
3 influences how hospitals do on a number of our
4 other measures, earlier measures. There doesn't
5 seem to be any relationship.

6 We've done some work looking at
7 whether hospitals, when we use an all-payor data
8 set, 18 and older, looks similar as they do if
9 we're just looking at the over 65 and again have
10 pretty, pretty good correlations.

11 CO-CHAIR TIRSCHWELL: Okay. Any
12 further discussion on reliability?

13 (No response.)

14 CO-CHAIR TIRSCHWELL: I suggest we
15 move to vote on reliability. It's not up on the
16 screen. Okay, thanks.

17 MS. SKIPPER: We are now voting on
18 reliability for measure 2876, 1 high, 2 moderate,
19 3 low, 4 insufficient.

20 CO-CHAIR TIRSCHWELL: 20. Has
21 everybody voted?

22 (Voting.)

1 MS. SKIPPER: Results are five percent
2 high, 77 percent moderate, five percent low, 14
3 percent insufficient. The measure passes on
4 reliability.

5 CO-CHAIR TIRSCHWELL: All right then,
6 validity. Jim.

7 MEMBER BURKE: All right. So
8 validity, there's a couple of points of evidence
9 offered, one of which is a face validity argument
10 as well as some expert opinion supporting this
11 concept, and also went through a public comment
12 period, where they've gotten feedback on this.
13 The majority of that feedback was saying NIH
14 Stroke Scale is important and thus including it
15 helps the validity argument considerably.

16 The other piece of data they offer
17 tentatively importance of validity is that these
18 are relative predictive models. They've got c
19 statistics around .08. Then they offer some
20 empiric validity testing, which I think has
21 problems for part of the reason that Dr. Schwamm
22 alluded to earlier.

1 So I have to make sure I fully
2 understand what happened here, but what I think
3 they did validity testing-wise is that they sort
4 of looked at two adjusted mortality measures at
5 the hospital level. One is the measure we just
6 talked about, which was claims and the stroke
7 scale pulled from Get With The Guidelines. The
8 separate measure that they came up with was a
9 pure registry-based measure, and this said I took
10 stroke scale and age and blood pressure and where
11 you came from and all the things that get
12 measured in the quality registry, and then
13 separately predicted at the hospital level what
14 mortality was.

15 The trick is is that across those two
16 measures, that was using the exact same stroke
17 scale element, right? So the stroke scale
18 element that was entered in the registry was part
19 of both models, and given that that is the
20 dominant variable in predicting mortality, you
21 know, and then age is the second most important
22 one, and I assume that gets measured very, very

1 similarly.

2 The fact that those two correlate
3 pretty well seems to me like it's not a whole lot
4 of support that would have been overwhelmingly
5 what we guessed. This is not two separate
6 measures. These are overlapping measures that
7 came up with that.

8 MS. BERNHEIM: Right. So we put that
9 in there because there's often historically been
10 concerns about the claims data as a source of
11 risk adjustment variables. So when we've had the
12 opportunity, we do this with all of their
13 measures.

14 If there is a data source where we can
15 compare, where we take the same patients in the
16 same hospitals with the same approach to risk
17 modeling, but we've put forward the measure that
18 has the claims elements in it and then for those
19 same patients, we build a model that has clinical
20 elements that come out of the chart, and it's
21 really validation of whether the claims-based
22 risk adjustment is adequate.

1 Because we then look at how we profile
2 hospitals and assess whether or not if we had all
3 of the data elements that are in say the registry
4 or a chart-abstracted model, would we learn the
5 same thing about hospitals as we do if we have a
6 purely claims-based measure.

7 So we followed that in this case.
8 You're absolutely right. There is an inherent
9 assumption in everything we're doing that when
10 we're pulling the Get With The Guidelines, NIH
11 Stroke Scale into the claims model, it is
12 mimicking what we will find in claims. We've
13 discussed earlier that that will need to be
14 checked. There wasn't really another way to do
15 this.

16 We have done something similar with
17 the purely claims-based measure that is available
18 right now in the IQR program without the NIH
19 Stroke Scale, but that's not the measure that
20 we're putting forward. So it offers some
21 reassurance that if we had -- you know, that the
22 other comorbidities in this model are adequately

1 capturing the severity of illness and with the
2 NIH Stroke Scale now in claims, we don't need to
3 wait until we can pull things from clinical
4 records.

5 We can get a good claims-only based
6 model, which is really our goal here. But you're
7 right. There's no way to get around the fact
8 that we only have currently one data source.

9 MEMBER BURKE: I mean one thing we saw
10 a bunch yesterday was it was correlation between
11 process measures getting at this latent construct
12 of quality concept. Something like that seems
13 like it would be external validity support or
14 construct validity support that we don't have
15 here.

16 I mean so I think this becomes very
17 important, because on the NQF algorithm, if you
18 don't give that a lot of credit, then there's no
19 empiric validity data here. There's an argument
20 for it, but that doesn't seem like it should get
21 much weight, and if that doesn't get much weight
22 that's going to be a problem on the algorithm.

1 MS. BERNHEIM: So on the issue of sort
2 of trying to line up process measures against
3 outcome measures, as people probably know this
4 literature, there are so many things that are
5 different between both the groups that are
6 captured in the process measures and the small
7 amount of how much they contribute to the
8 outcomes that we can measure, given the process
9 measures we can measure, that it's been very hard
10 to use that model as construct validity in our
11 measures.

12 We've tinkered around with it, but it
13 hasn't been easy. It's a real challenge with
14 these outcome measures, right? I mean if you --
15 we often rely on the face validity and the
16 strength of the model. This is a model that
17 performs incredibly well. I think you'll get to
18 that as well. We have a very strong c statistic
19 and good predictive ability.

20 So the combination of the known
21 importance of the NIH Stroke Scale as a risk
22 adjuster, the relationship between quality and

1 outcomes and the strength of this model combined
2 is what, you know, sort of gives us the face
3 validity and we do rely on that to some extent.

4 MEMBER BURKE: So in terms of the
5 other validity issues then, there are not a lot
6 of exclusions. Exclusions are small in number
7 and depending on your perspective, this is good
8 news or bad news. So it's good that they're not
9 losing people, but then this gets to the
10 preference concept.

11 Like yesterday we saw on these
12 measures that account for comfort care only, they
13 were losing 10-15 percent of the population for
14 that. Here, we're not losing these people. So
15 this was again the big workgroup conversation on
16 validity, was if we do not have accounting for
17 preferences, are we actually measuring quality?
18 That was probably again the thing that we talked
19 about the most.

20 The other elements of the model, one
21 is how the risk adjustment algorithm works. We
22 didn't go into that at great detail. It's

1 spelled out in extraordinary length and very
2 completely in the number of accompanying
3 documents and they're following fairly standard
4 procedures there. They came up with a high
5 predictive model. So I don't know that that's
6 necessarily the thing we need to belabor a whole
7 lot.

8 The other major threat to validity
9 problem is this missing data problem, which again
10 gets into something that we're kind of making a
11 big guess about, what's going to happen in the
12 real world.

13 So in Get With The Guidelines, you
14 know, where in -- this is in this quality
15 registry where people participate voluntarily.
16 In the most recent years, I think it was 83-ish
17 percent had reported NIH Stroke Scale. So you
18 had relatively small -- missing this huge
19 improvement over time but not 100 percent, and
20 that leaves a question of how do you estimate the
21 model when you have 17 percent of the most
22 important variable missing?

1 What they did here was that -- and
2 what they -- it sounds like would be the intent
3 to do in the real world if there is meaningful
4 missingness is to use multiple imputation, to
5 sort of plug in statistically what that variable
6 would look like in the real world and come up
7 with credible variance estimates at the hospital
8 level with that.

9 The trick to this is several things,
10 one of which is we don't know what missingness is
11 going to look like in the real world, and we kind
12 of get back to this big problem. Not only don't
13 we know how we can't measure NIH Stroke Scale,
14 when we do how often is it going to be missing?
15 Is that going to vary at the hospital level?

16 The other I think bigger problem is
17 multiple imputations approach it assumes the data
18 is missing at random, and you know, I don't know
19 of any data to support that's the case. But if I
20 had to use my intuition, I would say it's very,
21 very unlikely the data is missing at random.
22 It's going to be mild patients or patients

1 admitted directly to the hospital or places where
2 -- or patients who have early withdrawal, all
3 kinds of over the place is going to be -- missing
4 this is very unlikely to be at random, and that
5 to me seems like it's a major assumption here.

6 MEMBER LINES: I also think it sets
7 up the measure for gaming.

8 CO-CHAIR TIRSCHWELL: The missingness
9 issue and the imputation --

10 MEMBER BURKE: The gaming would be
11 never write down. Always leave your zeroes and
12 ones missing, and then get imputed upwards.

13 CO-CHAIR TIRSCHWELL: And yeah, one
14 second. And I guess I'd also like to hear a
15 comment about how you would -- I think you could
16 probably figure out, you guys not me, that if
17 there was an unusually high percentage of comfort
18 measure patients out of hospital, what impact
19 that would have on a hospital's rating.

20 DR. SCHWAMM: I just want to make one
21 comment about -- and I don't know -- I'm not sure
22 I know what to do with this information, but

1 we've looked a lot at this question of trying to
2 adjust for comfort measures only.

3 And the problem is if you look at
4 studies of mortality in the inpatient setting,
5 the number of patients who die despite the team's
6 best efforts to keep them alive is remarkably
7 low. Almost everyone who has a stroke and dies
8 in the hospital dies because of a transition in
9 life sustaining treatment and preferences.

10 So how do we tell the difference
11 between you come in 40 years old with an NIH of
12 14 in the first hour of your stroke and I don't
13 give you TPA, or I give it very slowly, or I give
14 it badly because your scan says I shouldn't give
15 it and you have a hemorrhage?

16 Now I say I'm so sorry to your wife,
17 you know. This is terrible. He's never going to
18 have a good quality of life. We should
19 transition to CMO. He does and he dies.

20 CO-CHAIR TIRSCHWELL: I guess just
21 like you do with all the other measures for the
22 Joint Commission, which is that you only remove

1 the people who had early comfort measure removal.

2 So obviously a lot of thought went
3 into this, and it's already being included in a
4 lot of quality measures. So I mean -- and this
5 potentially might be the most important one of
6 all and we're not including it.

7 MEMBER BURKE: And I think the comfort
8 measure only gets at sort of part of the problem,
9 right. Still, it's a much bigger and broader
10 problem than that, which is people come to the
11 hospital, they have a serious swallowing deficit.
12 They say no, I don't want a PEG tube; I want to
13 go home and try to eat, and then they aspirate
14 and then they die, right?

15 That doesn't seem like it should be on
16 the hospital. I mean it's broadly this
17 accounting for preferences is really important,
18 and I completely agree. It's extraordinarily
19 hard to do. I think you're 100 percent right.
20 Every approach you'd have for it, other than
21 measuring preferences previously in the entire
22 Medicare population, adjusting for that is going

1 to have this as a problem.

2 It's just a question of how big of a
3 problem is it, and for me the worry is, and this
4 is the part where I would love to have some sort
5 of empiric data, I mean your last observation --
6 your first observation is the one that worries
7 me, which is I can point to and think of very few
8 patients who died, but for this transition.

9 Which makes me think that if indeed
10 there's major variation at the hospital level in
11 terms of how that happens, either because your
12 patients have different preferences, or in the
13 absence of those patient preferences you pick up
14 the facility preferences, that means that that
15 might be how we're measuring here. We might be
16 measuring in aggregate what are patient
17 preferences or, in the absence of that, what are
18 facility preferences more than we're measuring
19 quality. I think that kind of gets to be for me
20 the big rub here.

21 MS. BERNHEIM: So there's a lot in
22 there and I'm going to try to cover it. So this

1 is really important. It affects a relatively
2 small number of patients.

3 If I could assess the decision to make
4 somebody comfort care within the first X number
5 of hours, you guys can fight with me about what
6 number of hours it is and take those patients
7 out, we would. We don't have that. So we do
8 everything we can to try to make sure that we're
9 not invalidating the measure without that data
10 element.

11 So first, just a reminder that
12 patients who just are enrolled in hospice in the
13 first day are excluded. If they're in hospice
14 leading up to the hospitalization or on the first
15 day of hospitalization, they are excluded from
16 this measure.

17 That's about .08 percent of the
18 patients, and the comfort measure numbers are on
19 the order of three percent. So probably in the
20 guidelines data, right? So the same data source.
21 So we think we're capturing a portion of those
22 patients with our hospice enrollment. Not

1 perfect, but an important exclusion.

2 The next question is sort of what's
3 the likelihood that the percentage of patients
4 that this applies to differs across hospitals,
5 because if they're in all of the hospitals, then
6 we're still able to assess hospitals equally. It
7 certainly differs, right?

8 I mean there's differences in patient
9 mixes, differences in inpatient practices at
10 hospital. So there's no question it differs
11 some, and then the question is how strongly does
12 the looking at the NIH Stroke Scale help us with
13 this issue, right. So although it's not true for
14 every patient and I am not an neurologist, so Lee
15 can back me up.

16 But there's a strong, strong
17 relationship between your NIH Stroke Scale and
18 the likelihood that you're going to end up making
19 -- your NIH Stroke Scale on admission and the
20 likelihood that aside from quality issues that go
21 in the wrong direction, you're going to be making
22 early decisions about end of life care.

1 So by bringing this NIH Stroke Scale
2 in, we think we're handling another piece of
3 that. It isn't perfect, but I think when you get
4 down to the remaining patients, we're not likely
5 to sort of, you know, drastically mischaracterize
6 hospitals.

7 The second threat is are we likely to
8 create incentives that people don't like and I
9 worry about that. I will just say that we've
10 sort of had a philosophy of sort of we're not
11 going to avoid important quality measures on the
12 concern that, you know, people are really going
13 to do the wrong thing by their patients.

14 I mean it does happen, but in general
15 people are motivated to be doing the right thing
16 by their patients, and we've looked in some of
17 our other mortality measures for evidence that,
18 you know, people are keeping people alive to day
19 31. We don't see, right. We see the -- you
20 know.

21 So are there going to -- is this
22 measure going to really cause people to avoid

1 conversations and keep people alive for a couple
2 of extra days so they have one fewer mortality?
3 I really hope not, but I don't think it's worth
4 throwing the whole measure out for the concern
5 that occasionally people are going to do that.

6 So anyway, it's not perfect, but I
7 think that there are enough things within this
8 measure with the NIH Stroke Scale in there that
9 it's unlikely that it's going to have huge
10 ramifications for how we compare hospitals.

11 CO-CHAIR TIRSCHWELL: Let me just
12 bring up one other point real quick, and I guess
13 I'm not actually sure. Jim, I'm sure you
14 remember where this was exactly. There was some
15 analysis where being African American was
16 associated with a .62 odds ratio, highly
17 statistically significant of course, of
18 mortality.

19 So if we believe that this measure is
20 in an accurate measure of quality, we would have
21 to then believe that African American patients
22 are getting substantially higher quality stroke

1 care than whatever the reference is. Am I
2 misinterpreting that Jim?

3 MEMBER BURKE: I don't think so. Well
4 I mean I think that if you want to make the
5 empiric -- now we get down to this -- this is
6 sort of the argument I was sort of prefacing at
7 the beginning, and I'm not sure how to resolve it
8 but it's tricky, right.

9 It says that when you look at
10 mortality, how much of it might be this, how much
11 of it might be preferences and how much of it
12 might be quality? And if we're convinced that
13 it's a lot of quality and a little bit of
14 preferences, then it's easy to go with this.

15 But I think David's point's a good one
16 and I'm worried that's not the case. Because we
17 control -- most of the mortality happens through
18 our decision-making, there's these empiric
19 slivers of evidence that make me worry that it's
20 a lot more preferences.

21 So the race one is I think one.
22 Again, I don't know what this means, but it's

1 worrisome that we know that African-Americans
2 generally have preferences for more aggressive
3 care, are much less likely to have withdrawal of
4 care and generally speaking have more aggressive
5 preferences for life-sustaining treatment.

6 Then we see really a lot lower
7 mortality by race, which goes against a lot of
8 priors here if it was about quality. Then two is
9 the early DNR thing here, which is the question
10 of how much does this vary at the hospital level?
11 That varies a ton at the hospital level, and it's
12 a question of -- I mean low, the lowest quintile
13 of hospitals in terms of early DNR rates have
14 zero.

15 So nobody's an early DNR, where the
16 highest quintile, it's a third of patients. When
17 you put that in a mortality model, it is -- it's
18 a more important predictor than age. So it's a
19 really, really big predictor of what happens
20 there, and this is the part where I'm
21 uncomfortable with a leap of faith, that it's
22 more about quality than it is about preferences.

1 DR. SCHWAMM: I want to make a
2 comment. I'll let Susannah comment, reply to
3 your last comment. The issue about the
4 relationship between race and in-hospital
5 mortality, we've seen this since the mother
6 analyses, and what we don't have in the registry
7 and it's not in the claims data is stroke
8 subtype.

9 But we do know that African-Americans
10 and Hispanics have a much higher frequency of
11 small vessel occlusion, so lacunar strokes which
12 at the same NIH --

13 CO-CHAIR TIRSCHWELL: But you're
14 testing for stroke severity.

15 DR. SCHWAMM: Yeah, but at the same
16 stroke initial stroke severity have substantially
17 lower mortality. So I think the -- I don't know,
18 because we don't have the data to be able to
19 probe that question. But I do think that part of
20 that, and we've looked at this.

21 You can see a similar paradox in a
22 paper we just published about smoking, where

1 smokers have lower in-hospital mortality, which
2 right, makes no sense.

3 But it's confounded by age and the
4 fact that smokers tend to have these more minor
5 small vessel strokes first, which even when you
6 try to adjust for stroke severity you can't --
7 you can't quite diminish or eliminate that
8 effect. That was my only comment about that.

9 MS. BERNHEIM: And I'm just -- I am
10 just going to go back to sort of the construction
11 of the models and the incorporation of the stroke
12 severity, right?

13 So these are real concerns, if you
14 didn't have any way of accounting for a hospital
15 that has more such patients. But there's going
16 to be a strong relationship between the severity
17 of the patients that you care for and the
18 likelihood that they're going to make preferences
19 for not going through life-sustaining treatments.

20 So we think that the inclusion of the
21 NIH Stroke Scale in here helps to garner against
22 the concerns you're having.

1 DR. SCHWAMM: Just so we want to make
2 one last comment, which is this measure is an
3 attempt to improve on a measure that is currently
4 in use by CMS.

5 So I would agree, it's not perfect.
6 The question is what do you prefer, because the
7 measure that's currently in use has no adjustment
8 for an NIH Stroke Scale score and we're going to
9 have NIH Stroke Scale score available in the
10 claims data set. So that's sort of Issue No. 1.

11 Issue No. 2 I completely agree.
12 Wouldn't it be great to have a functional outcome
13 measure for how patients do after stroke, like
14 the modified Rankin?

15 CO-CHAIR TIRSCHWELL: Not just whether
16 we measure the modified Rankin. So okay, and
17 clearly we're not voting on whether we prefer
18 this to the one that's out there already, just to
19 clarify. That's not what this vote is about.
20 Any other comments on validity? Oh sorry, yes.
21 Charlotte and then Michelle.

22 MEMBER JONES: I just want to make the

1 point that you've raised about hospitals. I've
2 worked in two hospitals, one of which I was told
3 by an ER physician no patient dies in my ER. So
4 I transported the patient to the Neuro ICU to
5 die, and I worked at a hospital where no child
6 does not receive nutrition.

7 So I think we need to consider our
8 hospitals and maybe the numbers are tiny, but I
9 think hospitals are different and it's something
10 we need to think about.

11 MS. BERNHEIM: We've previously
12 discussed the issue of one day versus two days.
13 So this one day can mean one minute or 23
14 minutes, 59 seconds, and certainly decisions
15 might not be made within that period of time.
16 That may reflect quality and helping people
17 decide on a different path.

18 CO-CHAIR TIRSCHWELL: Alright, yeah.
19 Ketan.

20 MEMBER BULSARA: I mean just along
21 with what Michelle was saying, I mean as we know
22 oftentimes these patients are coming with an

1 ischemic stroke. They go through this period of
2 peak swelling.

3 They look worse than when they
4 actually come in, and then the decisions
5 regarding hospice and things to that extent are
6 made like almost a week down the road.

7 I think we just have to make sure that
8 there is appropriate risk adjustment and
9 adjudication for these patients, and hospitals
10 aren't being penalized for leading patients down
11 the path of hospice when after peak swelling
12 there's no chance of a reasonable functional
13 outcome.

14 CO-CHAIR TIRSCHWELL: Okay. So that's
15 -- we're starting to circle back on similar
16 issues again and again. So I would say unless
17 there are new substantially different comments,
18 Jim did you want to have the final word?

19 MEMBER BURKE: Yeah. I mean I think
20 that -- I mean I think validity is the problem
21 here, right. So there's the missing data problem
22 and I think that the validity problem here is

1 that, you know, when you don't include something
2 in the model, that can mean hey, we get people a
3 little bit off here one way or the other. We
4 misclassified. We called you actually ten point
5 mortality and you should be 10.5.

6 Those types of imperfections are
7 things we can live with. This is place where we
8 might get it backwards, right. I mean so you can
9 theorize a hospital that is doing absolutely the
10 right thing, that has a patient population, that
11 just does not opt for aggressive care, and that
12 we're now going to call that a low-performing
13 hospital when they might be delivering optimal
14 preference-sensitive care?

15 The question here becomes I think
16 ultimately one of burden of proof. It's the I
17 don't know that that's not what this measure's
18 going to do in the real world, and that's my big
19 worry about it, is that if the burden of proof is
20 on somebody to show that that's not the case,
21 then I think that it's, you know, we're there.

22 But I think that the burden of proof

1 probably has to be on the measure, to make sure
2 that it's really measuring quality as opposed to
3 something else, and that's the bar that I just
4 haven't been able to get over.

5 CO-CHAIR TIRSCHWELL: Thank you. Go
6 ahead.

7 MS. BERNHEIM: Just briefly, I do want
8 to clarify. CMS has not decided how they would
9 address the missing data. They have concerns
10 about imputation and they have other mechanisms
11 that they use in other measures when there's
12 missing data.

13 I think this measure would only be in
14 use if there was a very high -- I think they will
15 work very hard with the societies and others to
16 get to a very high rate of NIH Stroke Scale. I
17 would not support its use if we were imputing
18 large numbers.

19 So just to reassure people that, you
20 know again, I can't speak for CMS. But as the
21 measure developer, to the extent that we have
22 influence and understanding of the plan, I don't

1 think this measure would get used with high rates
2 of imputation of NIH Stroke Scale. I don't think
3 that's consistent with CMS policy. So just to
4 reassure people about that.

5 The second is just the one other point
6 I will make that's relevant to what Lee said
7 earlier, is that although you are not comparing
8 this measure to the measure that's currently in
9 use, we do have a lot of experience with that
10 measure, right.

11 I mean CMS has been reporting on
12 hospitals 30-day mortality using a claims-based
13 measure for a couple of years now, and you're not
14 -- you know, I'm sure there are hospitals that
15 quibble with how they're doing. But this general
16 concern that we're going to somehow vastly
17 mischaracterize hospitals---this measure will be
18 a big improvement to that. But there is
19 experience with a measure that does a less good
20 job of accounting for the likelihood that you're
21 going to have patients that are having more
22 severe strokes and more comfort care.

1 So to the extent that that helps
2 committee members be comfortable that this
3 measure is going to do a reasonable job of
4 characterizing hospitals, I think it's worth
5 taking into account.

6 CO-CHAIR TIRSCHWELL: Well what is the
7 experience? What has been the outcome? Has
8 quality improved? Have mortality rates gone
9 down? What's been the impact of reporting that
10 publicly?

11 MS. BERNHEIM: So Karen, I should have
12 this on my fingertips, but I don't. I think, or
13 maybe even it's our chart book team. I think we
14 are seeing small declines in stroke mortality.
15 Now can I say that this measure has took credit
16 for that as opposed to lots of other things over
17 time among hospitals on the current measure?

18 CO-CHAIR TIRSCHWELL: Okay. Let's go
19 ahead then and vote on validity.

20 MS. SKIPPER: We are now voting on
21 Validity for Measure 2876, 1 high, 2 moderate, 3
22 low, 4 insufficient.

1 (Voting.)

2 MS. SKIPPER: Voting has closed.

3 Results are 0 percent high, 59 percent moderate,
4 36 percent low, 5 percent insufficient. We have
5 reached a gray zone on this measure, on this
6 criteria for this measure.

7 CO-CHAIR TIRSCHWELL: I believe gray
8 zone on this one means we proceed through the
9 other parts and then vote overall? Okay. Let's
10 continue along. After Validity is Feasibility.

11 MEMBER BURKE: So mercifully it gets
12 quick now. So feasibility is pretty easy. It's
13 just a question of feasibility of NIH Stroke
14 Scale. You know already -- this measure already
15 exists. It's already rolled out.

16 It's all off of claims, it's all
17 really easy but for one element, and being that
18 we've already endorsed everyone should do that,
19 that doesn't seem like it's much of a marginal
20 ask at this point in time. So Feasibility
21 doesn't seem like it's a big problem.

22 CO-CHAIR TIRSCHWELL: Excellent

1 summary. Let's move to vote on feasibility.

2 MS. SKIPPER: Just a moment. We're
3 now voting on feasibility for Measure 2876, 1
4 high, 2 moderate, 3 low, 4 insufficient.

5 (Voting.)

6 MS. SKIPPER: Results are 36 percent
7 high, 50 percent moderate, 9 percent low, 5
8 percent insufficient. The measure passes on
9 Feasibility.

10 CO-CHAIR TIRSCHWELL: And then finally
11 Use and Usability.

12 MEMBER BURKE: I think this gets at
13 the question that David raised earlier, which is
14 one is what's actually happened with this in the
15 real world to the extent it's been there so far.
16 There's no evidence one way or the other on that.
17 There's concerns about unintended consequences.
18 I don't know that they're going to be the case.

19 You know, I think there's an
20 opportunity for gaming here in the real world
21 with missing data as a possible tool to that and
22 other approaches as well with the coding

1 differences. Those are all concerns.

2 For me I think the substantive
3 question here is what do you do with this
4 information? This is much less obvious to me,
5 right. So when I've got a hospital that's got a
6 performance measure and it says look, I'm not
7 giving people DVT prophylaxis, you go why not?
8 You look at those cases and you figure out and
9 you get it right.

10 If you turn out to be a hospital that
11 says I have high mortality, and then you look and
12 you say oh, but we're giving everybody aspirin,
13 we're doing DVT prophylaxis and we're doing all
14 of those things, what do you do with that? It
15 seems like much less obvious about how you
16 operationalize that and how you're going to use
17 that to improve quality.

18 I can imagine that it's useful. I
19 imagine you might be able to do something with
20 it. But it seems much trickier to me than, for
21 example, with a process measure you're going to
22 be able to look at this and go aha, here's the

1 thing we fix.

2 It's going to be "aha this happened"
3 and maybe it's our patient preferences, maybe
4 it's our doctor's preferences or maybe it
5 actually is a genuine quality problem.

6 CO-CHAIR TIRSCHWELL: Comments from
7 the Committee on that, Use and Usability?
8 Developers?

9 DR. SCHWAMM: The only point I would
10 make, I mean I think it's an interesting
11 conceptual question when you look at your door to
12 treatment time for TPA, and you see oh, I'm not
13 -- I'm not treating patients as fast as I'd like
14 to.

15 You still have to go back and look at
16 the intermediate process steps that make up that
17 outcome, to figure out am I not scanning quickly
18 enough, am I not recognizing quickly enough?

19 So I would say I got the report back
20 and I had excess mortality, first thing I would
21 do is pull the cases that died, start reviewing
22 the charts, you know, start looking at where are

1 my -- where do I appear to be deviating from best
2 practices.

3 It might be that I look at everything
4 and I decide no, I just am taking, you know,
5 maybe my approach to assessing patient
6 preferences different from my peers. But there's
7 nothing I see here that I would want to do
8 differently.

9 I don't think the outcome measure has
10 to tell you what to do. It just has to tell you
11 what you should be paying attention to.

12 MEMBER BURKE: I mean I don't want to
13 belabor this, but I mean I think this concept of
14 using outcome measure when you already have
15 evidence-based process measures, like what is the
16 marginal value add of that? I could imagine one
17 exists; I just don't know what it is, right.

18 But I think you're right. I would go
19 back and I'd say look, did I fail to do the
20 things that, you know, did I miss TPA cases?
21 Sure, but that should already be getting pulled
22 up in those process measures, right.

1 Did I have a long time to treatment?
2 That should be getting pulled up in those process
3 measures. If it's not, what is the difference
4 here, particularly when I don't know all the
5 things that lead to mortality.

6 DR. SCHWAMM: Well, many of the
7 measures that we include in our process measure
8 set for stroke are not about reducing mortality.
9 They're actually about improving functional
10 outcome and reducing recurrent stroke, and their
11 time horizons are way beyond 30 days.

12 So I think things that contribute to
13 early mortality are going to be DVT/PE, sepsis,
14 hypotension, you know, things that -- acute MI,
15 things that are under the -- some of which are
16 under the control of the hospital, some of which
17 are based on the patient characteristics.

18 CO-CHAIR TIRSCHWELL: Peter.

19 MEMBER SCHMIDT: So yesterday we
20 talked about a number of measures where we said
21 well, I feel like the time frame is arbitrary.
22 These things should be done as soon as possible.

1 People could pass on within the time frame, but
2 people who do it sooner within the time frame
3 might have better outcomes, and that would be
4 worth identifying.

5 CO-CHAIR TIRSCHWELL: Any other
6 comments, discussion?

7 (No response.)

8 CO-CHAIR TIRSCHWELL: I say we move to
9 vote on Use and Usability.

10 MS. OGUNGBEMI: Voting is now open for
11 Usability and Use on Measure 2876. The options
12 are high, moderate, low and insufficient. Voting
13 is open.

14 (Voting.)

15 MS. OGUNGBEMI: Voting is closed. The
16 results are zero percent high, 82 percent
17 moderate, 14 percent low and 5 percent
18 insufficient. Usability and Use passes for
19 Measure 2876.

20 CO-CHAIR TIRSCHWELL: So now we'll
21 move to vote on overall suitability for
22 endorsement and just to recall, all of the

1 categories passed. Validity was a gray vote with
2 just less than 60 percent moderate or high.

3 MS. OGUNGBEMI: We are now voting on
4 the overall suitability for endorsement on
5 Measure 2876. The options are yes and no.
6 Voting is open.

7 CO-CHAIR TIRSCHWELL: Rogue voter.

8 (Voting.)

9 MS. OGUNGBEMI: We're going to revote.

10 CO-CHAIR TIRSCHWELL: Did you guys get
11 some clickers or --

12 PARTICIPANT: There's an app on my
13 phone.

14 PARTICIPANT: I almost endorsed that.

15 (Laughter.)

16 (Voting.)

17 MS. OGUNGBEMI: Okay. This is revote
18 for the overall suitability for endorsement on
19 Measure 2876. Options are yes and no. Voting is
20 open.

21 (Voting.)

22 MS. OGUNGBEMI: Voting is closed. The

1 results are 77 percent yes, 23 percent no.

2 Measure 2876 is suitable for endorsement.

3 CO-CHAIR TIRSCHWELL: Okay, great.

4 Thank you all for that important conversation and
5 discussion. So now we're going to move on to the
6 next measure. You all have to stop me when it's
7 like time to pick up our lunch and come
8 immediately back to the table to continue
9 working.

10 Similar and I'm hoping that because
11 the issues are somewhat redundant, that we won't
12 have to talk about all of them in quite as great
13 length again, 2877 and we invite the developers
14 to introduce the measure.

15 MS. BERNHEIM: So this measure is
16 extremely similar to the prior measure. It is
17 the same cohort of patients. It's the same
18 outcome. It's the same basic approach to risk
19 adjustment.

20 What we've done in this case is that
21 we are interested in the move towards the use of
22 electronic health records to support quality

1 measurement, especially as there's been interest
2 in the use of clinical data elements that can be
3 pulled from the record.

4 So we had done some prior work to
5 establish a set of about 21 or 22 variables that
6 can be feasibly pulled from electronic health
7 records under any system, and there's lots of
8 detail if you want it about sort of how we
9 established that these were feasibly pulled.

10 But essentially they're mostly labs
11 and vitals within the first two hours for the
12 vitals and 24 hours for the labs. I probably
13 have those numbers wrong.

14 So we -- for this risk model, we used
15 as candidate risk adjustment variables a set of
16 clinical variables that were feasible to pull,
17 part of our what we call core clinical data
18 elements as well as the claims-based, and then we
19 used a modeling strategy that was sort of
20 repeated step-wise to decide which of those
21 variables came into the model.

22 So the difference in this model and

1 the one you just heard about is that in addition
2 to the NIH Stroke Scale, we have three clinical
3 variables, blood glucose, a blood pressure
4 measure -- I should have these right in front of
5 me and of course I don't.

6 Here, I'm going to tell you the actual
7 ones. Heart rate, diastolic blood pressure and
8 glucose, and the NIH Stroke Scale and a slightly
9 smaller number of claims-based risk factors as
10 well.

11 So the way that this would get
12 implemented is that CMS would get the EHR data
13 elements submitted from hospitals, link it with
14 the claims and so it would be a combination of
15 claims and EHR data elements.

16 I will just mention as an aside we
17 have a similar measure for AMI mortality that is
18 NQF-endorsed. CMS has not yet proposed its use
19 but has signaled future intention to move towards
20 these measures. So this would be partnered and
21 there's a strategy underway for collecting these
22 data elements that CMS is signaling in their

1 rulemaking process.

2 Otherwise, the measure is the same.
3 It has a slightly higher C statistic, this
4 approach than the other one, but it's hard to
5 argue that it's meaningful. It's really just
6 part of a progression towards the use of EHR data
7 elements in outcomes measures.

8 There's a modification of this measure
9 also in the application that gets rid of the
10 claims element. That's sort of the next version
11 that they could use, where you -- once you can
12 get all of the information from the EHRs or if
13 you have a health system or a state that's really
14 advanced and wanted to use it, there's a sort of
15 a modification of the measure that's all EHR-
16 based.

17 But the measure that's really in front
18 of you is one that's what we call a hybrid
19 measure. Somebody has a question.

20 DR. SCHWAMM: And the only other thing
21 I would -- you might wonder well why did you add
22 like blood pressure and heart rate and things

1 like that? The feedback to NQF -- from NQF to
2 CMS at the last review where the prior measures
3 were discussed was to incorporate measures of
4 clinical severity.

5 So one of the available data sets for
6 CMS was some of this EHR data, and the question
7 was asked and actually tested, what if we just
8 use those and don't get into the quagmire of
9 trying to make a new code for NIH and collect
10 NIH? It just -- it adds, you know, like a little
11 tiny piece of gravy on the top of the NIH Stroke
12 Scale score.

13 So again, if it's available and
14 there's no cost to collecting it, why not put it
15 in the model? But again, that's why those other
16 elements ended up in this model in the first
17 place. But the addition of the NIH Stroke Scale
18 score is such a powerful addition to the model
19 that that's really still the dominate model.

20 So the differences between this and
21 the previous one are really more one of source
22 rather than scope.

1 CO-CHAIR TIRSCHWELL: Okay. So our
2 discussants are Ketan and Charlotte. Charlotte,
3 are you going to start or --

4 MEMBER JONES: No. Before we start I
5 have a methodologic question. We have just
6 accepted the measure without these three
7 additional criteria. So when we're voting,
8 previously we said they're already doing this,
9 but it's not before you so we're not really
10 comparing them.

11 Now it really is a comparison between
12 this measure and the one we just voted on.

13 CO-CHAIR TIRSCHWELL: No. I don't --
14 I think they're independent. We should think of
15 it as this is the only one that we're reviewing
16 right now.

17 MEMBER JONES: But the logic of if we
18 voted this one down, it would only be because of
19 those three elements.

20 CO-CHAIR TIRSCHWELL: I'm sorry, which
21 three elements are you referring to?

22 MS. BERNHEIM: The additional three

1 clinical risk factors that are in here. The
2 claims measure, the claims-based risk adjusters
3 are slightly different for this measure, again
4 because we used a process to select measures.
5 But the main difference is that there are some
6 clinical data elements included.

7 CO-CHAIR TIRSCHWELL: Yeah. I guess
8 if you think those are enough to fail this one,
9 then yes, you should fail it. But --

10 MEMBER JONES: So NQF, we could end up
11 having both of these measures on our portfolio,
12 we would be a responsible for?

13 (Off microphone comment.)

14 CO-CHAIR TIRSCHWELL: I think
15 eventually the likelihood is that in the future,
16 we would -- we'd be migrating to these measures
17 that come out of the electronic health care
18 records, as there's, you know, little or no
19 burden hopefully in the future to collect them
20 because they're part of your standard processes
21 of care. So yes, we could have both of them.

22 MEMBER JONES: Okay. Yeah, go ahead.

1 MEMBER BULSARA: So as was pointed out
2 earlier, I mean this measure is almost identical
3 to the previous one, and Jim did a fantastic job
4 in terms of the discussion. So I think this will
5 probably move a little bit faster, because we've
6 already discussed sort of the salient points in
7 the previous one.

8 So we'll go straight to evidence, and
9 I mean there is evidence in the sense that, as
10 was pointed out earlier, CMS is already using a
11 version to sort of risk adjudicate.

12 There's a lot of data that says that
13 we can improve things such as communication
14 between providers, prevention of and response to
15 complications, etcetera. So I think there's a
16 lot of evidence that we do need to -- we do need
17 to risk adjust.

18 CO-CHAIR TIRSCHWELL: So let's go
19 ahead and vote on Evidence.

20 MS. OGUNGBEMI: We are now voting for
21 Evidence for Measure 2877. The options are yes
22 or no. Voting is open.

1 CO-CHAIR TIRSCHWELL: Thank you. I
2 like the stopwatch at the bottom. I can read it
3 now. I don't know why it's not working.

4 (Voting.)

5 MS. OGUNGBEMI: Voting is closed. The
6 results are 95 percent yes, 5 percent no.
7 Evidence passes for Measure 2877.

8 CO-CHAIR TIRSCHWELL: Gap in
9 care/opportunity for improvement.

10 MEMBER BULSARA: You know, the
11 discussion for that is identical to the previous
12 one. So I think we shed no new data.

13 CO-CHAIR TIRSCHWELL: Let's move to
14 then vote on gap in care and opportunity for
15 improvement.

16 MS. OGUNGBEMI: We are now voting on
17 performance gap for Measure 2877. The options
18 are high, moderate, low and insufficient. Voting
19 is open.

20 (Voting.)

21 MS. OGUNGBEMI: Voting is closed. The
22 results are 36 percent high, 64 percent moderate,

1 0 percent low and 0 percent insufficient.

2 Measure 2877 passes on performance gap.

3 CO-CHAIR TIRSCHWELL: So then
4 Reliability.

5 MEMBER BULSARA: The only, and I don't
6 think this should deter it from necessarily
7 moving forward, but the only issue I come up with
8 for reliability, something that was brought up
9 yesterday, is that we don't have one standardized
10 electronic health care record across the country.
11 So just I guess we need to assess for some way as
12 to whether they'll be consistency across the
13 measures.

14 The other, the other issue that came
15 up that Karen addressed was, you know, we -- the
16 ICC reliability was like .7, which is the minimal
17 acceptable reliability value. But we're told
18 that we should go with the Landis-Koch
19 classification, where that will be a -- 56
20 percent is moderate agreement.

21 So again, I don't fully understand the
22 statistical reasons behind that, but if we're

1 accepting the Landis-Koch classification, then
2 this passes on reliability.

3 CO-CHAIR TIRSCHWELL: Any other --
4 yes, Charlotte. Go ahead.

5 MEMBER JONES: And again, people have
6 the option of considering in their voting that we
7 are again using the Get With the Guidelines data
8 that we -- for the national population. So you
9 have the same however you voted before, but
10 that's a reliability issue.

11 CO-CHAIR TIRSCHWELL: So that they
12 might not be representative? Is that what you're
13 saying?

14 MEMBER JONES: They might not be
15 representative.

16 CO-CHAIR TIRSCHWELL: Okay, thanks.
17 Any other comments from the Committee on
18 reliability?

19 DR. SCHWAMM: I would point the
20 Committee members to a paper published by Reeves
21 and our colleagues, demonstrating that the
22 population of patients in the fee for service

1 Medicare population compared to the Get With the
2 Guidelines population, that they were quite
3 similar and felt to be representative.

4 CO-CHAIR TIRSCHWELL: If there are no
5 more -- maybe there's one comment.

6 MEMBER BAUTISTA: Just to clarify. So
7 did they actually test within different
8 electronic medical records?

9 DR. SCHWAMM: Not that I gathered, no.

10 CO-CHAIR TIRSCHWELL: Yeah, okay. Can
11 you clarify Susannah?

12 MS. BERNHEIM: Yes. So this is the
13 art of developing measures when you don't have a
14 perfect data source, so it's a little bit
15 complicated. But I want to make sure that the
16 Committee understands. So to build the model, we
17 were using data elements from the registry as
18 surrogates for the EHR data.

19 However, those data elements are part
20 of our broader work to develop a core, set of
21 core clinical data elements, and those core
22 clinical data elements we have done a lot of

1 feasibility and reliability, validity testing.

2 We've done a couple of things where
3 we've surveyed hospitals about whether they can
4 adequately pull an initial -- remember, this is
5 initial vital signs and lab values.

6 They're sort of the easiest things to
7 get out of EHRs, and then we've done in a couple
8 of hospital health systems what is considered
9 data element validity for EHR data elements,
10 where you use our electronic specifications for
11 pulling them out, and then you have a nurse
12 abstracter also pull the same data elements and
13 you check to see if they're the same.

14 Extremely high at one hospital, one
15 health system. Not quite done adequately at the
16 other, but once we figured out where the problem
17 was with the abstraction, pulling the wrong
18 numbers, also good match. I mean so we've shown
19 successfully in a number of different EHRs that
20 you can pull these out and get accurate values.

21 CO-CHAIR TIRSCHWELL: Great, thanks.

22 Jim.

1 MEMBER BURKE: Do we have those data?
2 Are those data here? We have anything on the
3 element reliability.

4 MS. BERNHEIM: So I think that they
5 were attached as a separate report with our --

6 CO-CHAIR TIRSCHWELL: In the technical
7 report?

8 MS. BERNHEIM: Karen Dorsey, are you
9 still on the line, because you know exactly where
10 to find all of our hybrid data testing.

11 MS. DORSEY: Yes. In our initial
12 report, we included the validity, the data
13 element validity testing, but we didn't include
14 the reliability testing for the second site. You
15 know, you're technically right. Because we did
16 validity testing twice, we sort of left it out of
17 the first submission.

18 But we later spoke with NQF and
19 provided them the reliability as a separate
20 submission prior to this meeting, prior to the
21 working group meeting.

22 MS. BERNHEIM: And is it in this

1 measure worksheet Karen? I'm seeing on -- go
2 ahead.

3 MS. DORSEY: I didn't see it in that
4 measure worksheet, so I don't know how it might
5 have gotten in front of a Committee.

6 MS. BERNHEIM: So I have a table in
7 the measure worksheet that I'm looking at on page
8 68. I don't know if everybody has the same thing
9 that I have, that is about data element validity
10 and it shows the two sites and it shows the
11 percent agreement between the data set where the
12 records matched.

13 In the first site, it's 94 to 96
14 percent. In the second site, you'll see two of
15 the data elements were lower, and again Karen
16 does a better job than I do of explaining. I
17 think that had to do with which one they pulled,
18 right?

19 MS. DORSEY: Right. Yeah, they had
20 made a slight error in the execution of the
21 query. So it was a little bit lower in the
22 second site, and then we do have data on two

1 health systems looking just at the rate of
2 capture. So just discussing the feasibility of
3 the data elements.

4 MS. BERNHEIM: And the rate of capture
5 was what?

6 MS. DORSEY: Over 90 percent for all
7 the elements, both sites.

8 CO-CHAIR TIRSCHWELL: Okay. Any other
9 --

10 MS. DORSEY: Sorry, one caveat. It
11 was over 70 percent for the raw value because it
12 included the full scope of patients, not just
13 patients admitted for medical conditions. So it
14 was also surgical patients.

15 CO-CHAIR TIRSCHWELL: Any other
16 comments? Jim, yeah sure.

17 MEMBER BURKE: I guess so there's a
18 question were those using different EMRs, and
19 then for NQF, would this -- we had the concept
20 yesterday for the eMeasure or validity and
21 reliability testing that we had to see this for
22 multiple EMRs, and that had algorithmic

1 consequences. So for a hybrid measure, how do
2 those consequences work out?

3 MS. BERNHEIM: Just to clarify, these
4 are two separate or three. Go ahead Karen.

5 MS. DORSEY: Sorry. I was going to
6 say yes we tested. The testing was done in -- on
7 Epic system, and the feasibility testing was one
8 in Epic and certain validity testing was done in
9 the Kiefer system. So we've done multiple
10 systems.

11 In terms of merging the data, that
12 happens after the hospital submits the data. So
13 that's not anything that adds burdens to the
14 hospital or is involved at the hospital level.
15 They just report the data elements and then they
16 are linked.

17 CO-CHAIR TIRSCHWELL: Karen, did you
18 want to comment on the criteria thing?

19 MS. JOHNSON: Well I think -- yeah. I
20 think Karen did say that some of the work was
21 done in at least two systems. So you've got
22 that. I think the other thing to think about and

1 the way that I think about it is they're pulling
2 data from the registry and the data from the
3 registry comes from a lot more EHRs I'm assuming
4 than just a couple, right, a couple of sites?

5 CO-CHAIR TIRSCHWELL: But it's hand-
6 abstracted mostly so --

7 MS. JOHNSON: Okay, okay. So that's
8 the piece that I wasn't sure about. But I think
9 there's those two.

10 CO-CHAIR TIRSCHWELL: Okay. Any other
11 comments before we vote on reliability? Let's go
12 ahead and vote then.

13 MS. OGUNGBEMI: We are now voting on
14 Reliability for Measure 2877. The options are
15 high, moderate, low and insufficient. Voting is
16 open.

17 (Voting.)

18 MS. OGUNGBEMI: Voting is closed. The
19 results are 9 percent high, 82 percent moderate,
20 5 percent low and 5 percent insufficient.
21 Measure 2877 passes on Reliability.

22 CO-CHAIR TIRSCHWELL: Feasibility.

1 PARTICIPANT: Validity.

2 CO-CHAIR TIRSCHWELL: Oh, I'm sorry.

3 Yes please.

4 MEMBER BULSARA: So for the same
5 reasons that Jim pointed out in the previous
6 discussion, I think this measure continues to
7 have validity issues, and I mean I do think that
8 hospitals, I mean the patients that go into
9 hospice may adversely affect the perceived
10 quality of a given hospital.

11 I think the way the measures or like
12 the risk factors are sort of adjudicated, there's
13 a correlation coefficient that's assigned to each
14 that's used in the overall calculation.

15 So I think that's sort of a
16 preference-based coefficient and I think it could
17 vary depending on one's socioeconomic backgrounds
18 and things to that extent. So same validity
19 issues that Jim had mentioned earlier.

20 CO-CHAIR TIRSCHWELL: Okay. Anybody -
21 - no further discussion on validity?

22 (No response.)

1 CO-CHAIR TIRSCHWELL: Move to vote on
2 validity then.

3 MS. OGUNGBEMI: We're now voting on
4 Validity for Measure 2877. The options are high,
5 moderate, low and insufficient. Voting is open.

6 (Voting.)

7 MS. OGUNGBEMI: Voting is closed. The
8 results are 0 percent high, 73 percent moderate,
9 27 percent low and 0 percent insufficient.
10 Measure 2877 passes on validity.

11 CO-CHAIR TIRSCHWELL: Now Feasibility.

12 MEMBER BULSARA: So the measure is a
13 hybrid. It relies on the NIH Stroke core and
14 electronic record and ICD-10 coding. I think,
15 you know, I'm not sure how much -- I think we're
16 just going to have to see how accurate or
17 reliable the data's going to be sort of long-term
18 in terms of acquisition. I don't know if
19 Charlotte has anything else to add to that.

20 MEMBER JONES: I think again we're
21 left with looking at data that we don't have, and
22 then they looked at the SES factors and decided

1 that they didn't add additional value, so did
2 not include it in their final measures.

3 CO-CHAIR TIRSCHWELL: Yeah. That was,
4 I think, more of a validity issue. Any other
5 comments on Feasibility? Let's go ahead and vote
6 on Feasibility then.

7 MS. OGUNGBEMI: We're now voting on
8 Feasibility for Measure 2877. The options are
9 high, moderate, low and insufficient. Voting is
10 open.

11 (Voting.)

12 MS. OGUNGBEMI: Voting is closed. The
13 results are 14 percent high, 73 percent moderate,
14 9 percent low and 5 percent insufficient.
15 Measure 2877 passes on Feasibility.

16 CO-CHAIR TIRSCHWELL: Usability and
17 Use.

18 MEMBER BULSARA: Usability, the only
19 issues with electronic, sort of the variations in
20 terms of electronic health care systems that are
21 out there, and which I pointed out earlier in the
22 sense that we'll have this data. We'll risk

1 adjudicate. I mean what do we really do with it
2 after that.

3 CO-CHAIR TIRSCHWELL: Any further
4 comments or discussion?

5 (No response.)

6 CO-CHAIR TIRSCHWELL: Let's go ahead
7 and vote then on Usability and Use.

8 MS. OGUNGBEMI: We are now voting on
9 Usability and Use for Measure 2877. The options
10 are high, moderate, low and insufficient. Voting
11 is open.

12 (Voting.)

13 MS. OGUNGBEMI: Voting is closed. The
14 results are 9 percent high, 73 percent moderate,
15 14 percent low and 5 percent insufficient.
16 Measure 2877 passes on Usability and Use.

17 CO-CHAIR TIRSCHWELL: And then I think
18 we'll move directly to vote on overall
19 suitability.

20 MS. OGUNGBEMI: We are now voting for
21 Measure 2877's overall suitability for
22 endorsement. Options are yes or no. Voting is

1 open.

2 (Voting.)

3 MS. OGUNGBEMI: Voting is closed.

4 Results are 90 percent yes, 10 percent no.

5 Measure 2877 passes on its suitability for
6 endorsement.

7 CO-CHAIR TIRSCHWELL: Great. Thank
8 you everybody for moving through that one, and I
9 just want to make one comment and this is me the
10 neurologist taking care of sick patients, not as
11 the chair. Susannah, you said that if I could
12 identify the patients that had comfort measures
13 on the first day, I would take them out.

14 Well, in the hybrid measure, it seems
15 like there's a real possibility for that.
16 Fantastic. That's what I was hoping you would
17 say. Thank you.

18 (Off microphone comments.)

19 CO-CHAIR TIRSCHWELL: Well then I
20 don't know what the right answer is, because I
21 can imagine a very imperfect world where there's
22 a perverse incentive then to make people comfort

1 care if they're sick, because they're going to
2 have a bad outcome and then they get excluded
3 from your measure and not counted against you.

4 So I think we need to research it at
5 the very least and see what different things to
6 -- thank you very much. All right. Are we
7 moving straight in? Are we breaking for lunch?
8 No lunch. You're going to have to earn your
9 lunch.

10 All right. We're going straight to
11 the one that -- and David's going to be --
12 David's going to be in charge now right, 1952.

13 CO-CHAIR KNOWLTON: Okay. I didn't
14 realize that. Okay. We're going to 1952. Time
15 to Intravenous Thrombolytic Therapy, Heart
16 Association, Stroke Association. Ron and Alex
17 are the discussants. You folks are representing
18 the developer.

19 CO-CHAIR TIRSCHWELL: And I am -- just
20 to note, I am, because I'm on the Committee, I'm
21 recusing myself. I'm not participating in this
22 one.

1 MS. TIERNEY: Yes hi. I'm Sam
2 Tierney, and I'm with the PCPI Foundation, and
3 we're supporting the American Heart Association
4 in their submission of this measure. We're going
5 to let Dr. Schwamm actually introduce the measure
6 to you all.

7 MS. GRAY: Hi. I'm Diedra Gray, also
8 with the PCPI Foundation.

9 DR. SCHWAMM: So now I'm speaking on
10 behalf of the American Heart Association. So
11 this measure is Time to Intravenous Thrombolytic
12 Therapy. The measure was submitted for
13 endorsement maintenance, which was because it was
14 originally endorsed in 2012.

15 It's used in -- it's already in use in
16 a variety of AHA/ASA programs, including most
17 prominently the Get With the Guidelines stroke
18 registry, the recognition program of the registry
19 and the target stroke quality improvement
20 initiative, which is based on trying to shorten
21 time to treatment among those patients in whom
22 treatment has -- the decision has been made to

1 treat.

2 So this is not a measure that is
3 trying to increase the total number of eligible
4 patients being treated, but rather focusing on
5 rapid treatment among those in whom treatment is
6 indicated.

7 The intent of the measure is to
8 increase the proportion of patients who receive
9 treatment within 60 minutes of hospital arrival.
10 I will point out parenthetically that the
11 European registry equivalent of Get With the
12 Guidelines called the SITS registry, which is a
13 mandatory registry for all patients treated on
14 label with thrombolysis in Europe.

15 It has now moved to a 45 minute target
16 for their equivalent, 40 minute target, excuse
17 me, for their equivalent of this initiative. So
18 despite some concerns that were voiced initially
19 at this hearing and in other quarters, that this
20 measure would promote an inappropriate rush to
21 treatment and treatment of inappropriate
22 patients, in fact there has been no increased

1 risk and harm.

2 In a paper that was published in 2014,
3 Drs. Fonarow, Mozaffarian and colleagues,
4 including myself in JAMA demonstrated that with
5 the increased rate of treatment, there was not
6 only lower rates of symptomatic intra-cranial
7 hemorrhage but more patients discharged home and
8 actually a reduction in overall mortality.

9 So it's the first study to demonstrate
10 a reduction in mortality associated with TPA use.
11 I'm not going to belabor the evidence. Let me
12 shift to the actual measure inclusion statement.
13 So the numerator includes all patients age 18 and
14 older receiving intravenous TPA during the
15 hospital stay, and receiving it at that hospital,
16 by the way, not another hospital in transit, and
17 having a time from hospital arrival to initiation
18 of thrombolytic therapy of 60 minutes or less in
19 the denominator.

20 Included are all ischemic stroke
21 patients who received thrombolytic therapy during
22 their hospital stay and exclusions are age less

1 than 18, a stroke that occurred while in
2 hospital, patients received in transfer, patients
3 that received TPA greater than 4.5 hours after
4 they were last known well, so outside of the on
5 label indication, and patients enrolled in an
6 experimental clinical trial as an alternative to
7 thrombolytic therapy.

8 Patients with a documented eligibility
9 or medical reason for a delay in treatment are
10 also exceptions from the denominator when
11 documented explicitly by a provider as the reason
12 for delay, and those include social, religious,
13 initial refusal, hypertension that required
14 aggressive control with intravenous medication
15 and therefore still permitted treatment but
16 delayed treatment beyond 60 minutes, inability to
17 confirm patient eligibility.

18 So lack of an appropriate witness to
19 provide medical history and time of onset of
20 patients who are aphasic, or further diagnostic
21 evaluation that needs to confirm stroke for
22 patients which hypoglycemia, which is a blood

1 glucose less than 50, seizures or other major
2 metabolic disorders.

3 This gets to the point that Dr. Huff
4 made earlier about making sure that stroke mimics
5 are not being treated with this measure. It
6 incorporates the ability to exclude patients in
7 whom further rapid diagnostic testing is
8 indicated, or the management of emergent acute
9 conditions such as cardiopulmonary and
10 respiratory failure requiring intubation, or
11 again as we said before, an investigational or
12 experimental protocol. So I'll stop there.

13 CO-CHAIR KNOWLTON: And our
14 discussants are Charlotte and Jocelyn. Who's --
15 oh, I'm sorry. I'm on the wrong one. Ron and
16 Alex.

17 MEMBER RAE-GRANT: Yeah Ron has ceded
18 -- Ron ceded to me, but I'm sure he'll jump in if
19 I'm wallowing badly. So under Evidence, there's
20 evidence prior to the 2012 review and then
21 subsequent evidence.

22 A number of guidelines that require

1 this measure, and then basically data from
2 multiple patients, multiple studies showing
3 earlier time to treatment with TPA improves
4 outcome.

5 The newer data updates are the AHA/ASA
6 2013 guideline which includes this measure, door-
7 to-needle time within 60 minutes from hospital
8 arrival, and then two additional studies.

9 There's one that's an observational study looking
10 at time to needle and showing better outcomes and
11 shorter time-to-needle, and then a large meta-
12 analysis showing again improvements in outcome
13 the shorter the time is to the needle.

14 So the points about time-based were
15 made. This was a decision to use 60 minutes but
16 maybe it will change at some point to meet the
17 European criteria. So that's the new data and
18 that does rate as high evidence. That's all I'm
19 saying on Evidence.

20 CO-CHAIR KNOWLTON: Questions,
21 comments. Valerie.

22 MEMBER COTTER: Can I just ask a point

1 of clarification in the exclusion criteria? It's
2 unclear to me why patient stroke occurred while
3 in hospital is an exclusion. Isn't that why the
4 patient is in the hospital, because they're
5 having stroke?

6 CO-CHAIR KNOWLTON: Go ahead.

7 DR. SCHWAMM: Excellent point. The
8 patients are always treated in the emergency
9 department when they present with symptoms of
10 stroke. This is to exclude patients who are in
11 the hospital for cardiac surgery and have a
12 stroke while they're in the hospital.

13 And so in those patients, there is no
14 defined arrival time that would make sense to
15 apply to this measure. About ten percent of
16 strokes occur in hospital, and there are separate
17 quality improvement initiatives going on to try
18 to improve the timeliness of care for those
19 patients.

20 But many of those patients are
21 disqualified on medical reasons, because they
22 have just had a procedure that puts them at

1 increased risk of bleeding.

2 CO-CHAIR KNOWLTON: Thank you. Other
3 questions? Yeah, Jim.

4 MEMBER BURKE: So we get dinged on one
5 of these like every month or two, where somebody
6 comes in and they came in and then normalized and
7 were not treated and then they get worse again.

8 I mean if it's door-to-treatment
9 criteria then that's something you're going to
10 lose on. Is that right? Is there an exclusion
11 for that or is there -- can you reset the clock
12 if somebody gets back to normal? It doesn't look
13 like it on this.

14 DR. SCHWAMM: It's a very complicated
15 clinical issue, and people -- experts will
16 disagree as to whether or not you should reset
17 the clock. I think if patients get completely
18 back to normal, have another scan that
19 demonstrates no evidence of infarction and then
20 worsen again, many would reset that clock and
21 then would say that actually that was an in-
22 hospital stroke.

1 So if you come in with stroke symptoms
2 but fully resolved in the emergency department,
3 you haven't had a stroke. You had a TIA. You
4 are at that point in the hospital, and then if
5 you subsequently have another event, even if it's
6 in the next 15, 20 minutes or hour, you could be
7 considered then to have an in-hospital stroke.

8 This is actually how Get With the
9 Guidelines deals with this issue of patients who
10 completely return to normal and then recur while
11 in the emergency department. I think it's an
12 artifact of measurement, because again the point
13 here is to really look at processes of care, and
14 I would say that the experience you're
15 describing, we can all think of a few cases.

16 But they're in general the exception
17 rather than the rule. So I would say that in
18 those patients, those patients will at times fall
19 into this measure and remain in the denominator,
20 which is why 100 percent is, you know, is not the
21 goal.

22 CO-CHAIR KNOWLTON: Other comments,

1 questions on Evidence?

2 (No response.)

3 CO-CHAIR KNOWLTON: Okay. Let's go to
4 vote.

5 MS. OGUNGBEMI: We are now voting on
6 Evidence for Measure 1952. The options are high,
7 moderate, low and insufficient. Voting is open.

8 CO-CHAIR KNOWLTON: You'll be down
9 one. David's not voting.

10 (Voting.)

11 MS. OGUNGBEMI: Voting is closed. The
12 results are 86 percent high, 14 percent moderate,
13 0 percent low and 0 percent insufficient.
14 Measure 1952 passes on Evidence.

15 CO-CHAIR KNOWLTON: Alex, gap.

16 MEMBER RAE-GRANT: So under gaps, a
17 recent study from Fonarow and another study,
18 Mozaffarian, indicating 30 percent of patients
19 receiving TPA within the guideline recommended 60
20 minutes toward a needle time, indicating a
21 substantial gap.

22 There was also Get With the Guidelines

1 registry data and some improvement, but still 70
2 percent of -- only 70 percent meeting this
3 criteria as of 2015.

4 There was some disparities data
5 showing that certain populations, older patients,
6 black patients, those with less severe stroke or
7 arriving in off hours, those patients were less
8 likely to receive timely care. So this did
9 indicate a high gap in care.

10 CO-CHAIR KNOWLTON: Questions or
11 comments? Let's go to a vote.

12 MS. OGUNGBEMI: We are now voting on
13 performance gap for Measure 1952. Options are
14 high, moderate, low and insufficient. Voting is
15 open.

16 (Off microphone comments.)

17 MS. OGUNGBEMI: We know who's voting.
18 We just need the vote to come in.

19 (Voting.)

20 MS. OGUNGBEMI: Okay, voting is
21 closed. Results are 71 percent high, 29 percent
22 moderate, 0 percent low and 0 percent

1 insufficient. Measure 1952 passes on performance
2 gap.

3 CO-CHAIR KNOWLTON: Okay. Ron,
4 Reliability then.

5 MEMBER RAE-GRANT: Alright. So
6 Reliability, specifications from a clinical
7 registry, Get With the Guidelines at the hospital
8 facility level, and I'm not going to go through
9 the numerator/denominator again. We've gone
10 through that.

11 Reliability testing, there was empiric
12 validity testing using a signal noise analysis,
13 and this was used in Get With the Guidelines
14 stroke registry data from 800 some-odd hospitals,
15 and that had an inter-rater reliability of .72,
16 which was -- indicated substantial agreement.

17 Updated results were done and
18 reliability seemed to be higher if all hospitals
19 had a higher reporting event rate of 23.9 versus
20 10, and 20 percent of the hospitals in the
21 registry had fewer than ten reporting events that
22 were not included. So that would be a

1 preliminary rating of moderate for Reliability.

2 CO-CHAIR KNOWLTON: Questions and
3 comments? Charlotte.

4 MEMBER JONES: Previously the Joint
5 Commission had excluded hospitals from these
6 measures who had ten or fewer events, and in a
7 previous discussion they had specifically
8 mentioned that children's hospitals were
9 excluded, that potentially could be seeing
10 patients between 18 and 21. Is this -- can the
11 developers address this?

12 DR. SCHWAMM: So the measure, as with
13 all the measure sets, is for adults aged 18 and
14 older. I think the answer is yes, some children
15 -- well, children's hospitals don't -- I guess I
16 don't know the answer. That's a good question.
17 I think the answer is if they failed to treat
18 more than ten subjects a year, they would not
19 have their data reported in this measure.

20 They could still participate in the
21 registry and collect this data and analyze their
22 performance, but when the number of treated

1 patients is so low, you know, complying, meeting
2 a rate of 60 percent, of 50 percent of patients
3 is hard to interpret.

4 MS. TIERNEY: Yeah. I was just going
5 to add that the sample is based on those
6 hospitals participating in Get With the
7 Guidelines.

8 So it doesn't necessarily exclude
9 children's hospitals, if they're hospitals that
10 participate in the program. But it does have
11 that ten event minimum, so that may impact that,
12 as Dr. Schwamm said.

13 CO-CHAIR KNOWLTON: Anybody else?

14 (No response.)

15 CO-CHAIR KNOWLTON: Okay. Let's go to
16 the vote.

17 MS. OGUNGBEMI: We are now voting on
18 Reliability for Measure 1952. Options are high,
19 moderate, low and insufficient. Voting is open.

20 (Voting.)

21 MS. OGUNGBEMI: Voting is closed. The
22 results are 5 percent high, 95 percent moderate,

1 0 percent low and 0 percent insufficient.

2 Measure 1952 passes on Reliability.

3 CO-CHAIR KNOWLTON: Validity?

4 MEMBER RAE-GRANT: So under Validity,
5 it's primarily older work that was done. Data
6 element testing show agreement using kappa
7 statistics and Get With the Guideline stroke
8 program data. The newer data is from 20 experts
9 from the AHA Council on Stroke 2015-2016
10 Leadership Committee looking at face validity of
11 the measure, and that indicated good validity.

12 Let's go to the next page. 85 percent
13 of respondents agreed or strongly agreed the
14 measure could actually distinguish good and poor
15 quality. So that would probably indicate
16 moderate validity.

17 Threats to validity. I think we
18 primarily reviewed these exception issues and
19 overall, the numbers that were given for 672
20 hospitals with minimum ten reporting events.

21 There was a 10.8 percent overall
22 exclusion rate on one measure and then on another

1 measure 18.2 percent. I don't know if people
2 want to comment on the threats to validity. I
3 don't think we thought there was a major issue,
4 Ron.

5 CO-CHAIR KNOWLTON: Comments or
6 questions on validity? Charlotte.

7 MEMBER JONES: I'm confused. So Get
8 With the Guidelines excluded patients with less
9 than ten patients, but the measure before us does
10 not exclude hospitals with fewer than ten events
11 or does it?

12 MS. TIERNEY: The sample used for
13 testing the measure's reliability excluded
14 hospitals that had less than ten events. The
15 measure in and of itself technically does not do
16 that.

17 MEMBER JONES: So I address this in
18 Usability? Dave?

19 MEMBER RAE-GRANT: So do you want to
20 come back to this in Usability?

21 MEMBER JONES: Yeah.

22 MEMBER RAE-GRANT: Okay.

1 MEMBER JONES: I'm just trying to
2 figure out where we discussed it.

3 CO-CHAIR KNOWLTON: Yeah. Why don't
4 you bring it up in Usability if that's all right.

5 MEMBER JONES: Okay, thank you.

6 CO-CHAIR KNOWLTON: Other comments on
7 Validity?

8 (No response.)

9 CO-CHAIR KNOWLTON: Okay. Let's go to
10 a vote on it.

11 MS. OGUNGBEMI: We are now voting on
12 Validity for Measure 1952. Options are high,
13 moderate, low and insufficient. Voting is open.

14 (Voting.)

15 MS. OGUNGBEMI: Voting is closed. The
16 results are 5 percent high, 90 percent moderate,
17 5 percent low and 0 percent insufficient.
18 Measure 1952 passes on Validity.

19 CO-CHAIR KNOWLTON: Feasibility.

20 MEMBER RAE-GRANT: Under Feasibility,
21 again the data is collected through the Get With
22 the Guidelines registry. The developer states

1 there was no issue with data collection and
2 relatively standard data elements, and it's
3 extracted from the record by someone other than
4 the person obtaining original information. So
5 this was preliminarily rated for Feasibility as
6 moderate.

7 CO-CHAIR KNOWLTON: Okay. Charlotte,
8 did you want to comment here? No. Oh, on
9 Usability. Okay. Further comments or questions
10 on usability?

11 PARTICIPANT: Feasibility.

12 CO-CHAIR KNOWLTON: Feasibility. I'm
13 going to get this right, trust me.

14 (No response.)

15 CO-CHAIR KNOWLTON: Okay.
16 Feasibility. We're ready to vote.

17 MS. OGUNGBEMI: We are now voting on
18 Feasibility for Measure 1952. Options are high,
19 moderate, low and insufficient. Voting is open.

20 (Voting.)

21 MS. OGUNGBEMI: Voting is closed. The
22 results are 10 percent high, 90 percent moderate,

1 0 percent low and 0 percent insufficient.

2 Measure 1952 passes on Feasibility.

3 CO-CHAIR KNOWLTON: Usability.

4 MEMBER RAE-GRANT: So in the
5 Usability, this is currently used as an
6 accountability program. There are a number of
7 benchmarking and achievement award measures which
8 relate to this, and recognition of professional
9 certification and stroke hospital recognition
10 programs. And again, the developer presented
11 data demonstrating a mean performance improvement
12 from 2012 of 53 percent to 2015, 70 percent.

13 So again, this would be rated
14 preliminarily as high Usability end use.

15 CO-CHAIR KNOWLTON: Charlotte.

16 MEMBER JONES: So the Get With the
17 Guidelines program was used to develop the
18 measure. They excluded hospitals that had less
19 than ten. But we're going to put this out as a
20 measure that hospitals that include children's
21 hospitals and limited access and other programs
22 that may have less than ten are going to get

1 dinged if they don't.

2 DR. SCHWAMM: Can I clarify?

3 CO-CHAIR KNOWLTON: Lee go ahead.

4 DR. SCHWAMM: So for the data provided
5 for demonstrating reliability and preparing the
6 measure specifications and the measure supporting
7 materials, we did not include hospitals treating
8 less than ten patients in the analysis. The
9 measure does not exclude hospitals that put in
10 less than ten patients.

11 Recognize that the reliability of
12 those estimates of percentages will be lower in
13 hospitals that include fewer than ten patients.
14 But it doesn't prevent those hospitals from
15 running that measure and hospitals currently run
16 that measure, even if they are small hospitals
17 and see fewer than ten patients.

18 So it doesn't prevent the hospitals
19 from participating, but in terms of presenting
20 you with data around the reliability and
21 validity, that cutoff was chosen.

22 MEMBER JONES: Okay. So then we are

1 going to be putting forth a measure endorsed by
2 NQF, and we are going to say hospitals that we
3 don't have reliability and validity should be --
4 should be held accountable for this measure, when
5 we don't have data to say it's reliable and
6 valid.

7 I would say it is going to create a
8 significant burden on those hospitals if this
9 measure is accepted as it currently is, that any
10 hospital who sees a patient over 18 needs to get
11 them TPA within 60 minutes.

12 CO-CHAIR KNOWLTON: Dr. Schwamm, if
13 you want to comment.

14 MS. GRAY: Yeah hi. So just to
15 clarify. As Dr. Schwamm said, the measure
16 doesn't exclude the hospitals that see fewer than
17 ten patients. The minimum of ten observations is
18 applied to the reliability testing as a
19 statistical kind of a rule in signal to noise
20 ratio analysis.

21 So the minimum of ten is really set
22 there to minimize bias amongst the hospitals

1 included in the sample that we're going to
2 analyze. That doesn't speak to any exclusion for
3 the measure.

4 DR. SCHWAMM: So I guess in response
5 to your question about the responsibility of
6 hospitals that receive patients in the first few
7 hours after the sudden onset of neurological
8 symptoms that could be consistent with stroke, I
9 think the answer is in many jurisdictions, those
10 patients are not necessarily taken by ambulance
11 to a primarily children's hospital.

12 It does happen, but many of those
13 patients are taken to an adult general hospital.
14 But if you are a children's hospital and you
15 receive a patient in that time period, I think
16 the same standards should apply, which is that
17 patients who have evidence of an acute ischemic
18 stroke need to have a rapid evaluation and
19 treatment as quickly as possible.

20 It may be that in this population it's
21 very difficult to determine age of patient
22 eligibility. It may be that the perception is

1 that stroke is not leading the diagnosis. It
2 doesn't mean that those patients shouldn't be
3 rapidly and carefully evaluated just as they
4 should be everywhere else.

5 So children's hospitals are not
6 unfamiliar with ischemic stroke. It's actually
7 fairly common in neonates and young children. So
8 it's not like it's -- as I'm sure you know, it's
9 not like it's an unheard-of event.

10 So this is a challenge that I think is
11 unique to children's hospital, but is an
12 important one, which is that they not assume that
13 young adults in the 18 to 21 year-old range who
14 present with symptoms, not to dismiss stroke as a
15 possibility.

16 So I think the risk here of harm and
17 the burden is remarkably low when you think about
18 the benefit to the population of patients who are
19 arriving with true ischemic stroke. So I guess
20 I'm -- this is not -- this measure is not -- I
21 don't think that creates an undue burden.

22 MEMBER JONES: So I am going to

1 disagree as the pediatric neurologist on this
2 committee. The likelihood of -- we have in our
3 jurisdiction we are going to get four acute
4 ischemic events a year, based on our case load
5 and based on the fact that we are a stroke
6 center.

7 That's not necessarily in the 18 to 21
8 year-olds. The burden of creating a stroke
9 service, the burden of having the people to
10 respond to get TPA in an hour, that's a
11 significant burden for a very rare event. I
12 think saying that a children's hospital that does
13 not decide to invest in that, you're right. For
14 that patient who has had a stroke that may be.

15 But in a world of limited resources,
16 and we all live in that world, trying for the one
17 in 10,000 I think is the numbers that our stroke
18 people quote, is not a good use of resources.
19 You probably have the Get With the data -- the
20 Get With the Guidelines data would tell you how
21 many 18 to 21 year-olds you have.

22 I have real problems about you did

1 your reliability and validity testing excluding
2 hospitals with less than ten, and now you're
3 saying hospitals that get less than ten are going
4 to be held to the same standard when we don't
5 have reliability and validity testing.

6 CO-CHAIR KNOWLTON: Ron.

7 MEMBER KOENIG: Charlotte, would you
8 then say that we shouldn't be doing this at all
9 in the adult population? I mean I'm sort of --

10 MEMBER JONES: So I don't think that's
11 fair, but I would say this measure in front of
12 us, the way the developers chose to write it and
13 not exclude -- they could have easily said
14 patients under the age of 21, recognizing that
15 the majority of children's hospitals try not to
16 --

17 And yes, if a patient comes in and we
18 quickly recognize that 22 year-old or that 40
19 year-old or I have a stroke in the hospital, my
20 children's hospital is going to do everything
21 within their power to get me out of there and to
22 get me to the local adult hospital where I will

1 get TPA, which is what I want them to do.

2 But when the 18-1/2 year-old with a
3 long history of migraines, who has been treated
4 at my hospital for years and years shows up,
5 there's probably going to be a delay that I think
6 in terms of resource utilization is perfect and
7 appropriate based on needs.

8 I get that you all want to pass this,
9 because for the general group it is good. But if
10 we are voting on this measure as it was put forth
11 by these developers, I have a problem with
12 patients -- that they chose to include patients
13 down to the age of 18.

14 CO-CHAIR KNOWLTON: Valerie.

15 MEMBER COTTER: I'd just like to make
16 a point as a clinician and as a parent. Are we
17 putting the, you know, that parents should know
18 where to take their child if they think their
19 child is having a stroke? I mean from the
20 consumer point of view, as a parent point of
21 view, it's not up to us to decide what hospital
22 is best to take my kid that's having a stroke.

1 It's up to the hospital. The burden
2 should be on the hospital to make that diagnosis
3 and move forward with care and treatment.

4 CO-CHAIR KNOWLTON: Peter.

5 MEMBER SCHMIDT: So many of these
6 comments could have been applied to many previous
7 measures, and you know, would apply equally to
8 many prior measures and were not. There's no
9 exclusion for less than ten in the head CT
10 measure, for example. So and then the next
11 question that comes up to me is what outcome
12 would you want out of this should there be some
13 --

14 Because if you're not at a good place
15 to get stroke care, is it bad for us to identify
16 that you're not a good place to get stroke care?

17 CO-CHAIR KNOWLTON: Alex, did you have
18 your card up?

19 DR. SCHWAMM: The only point I was
20 going to make is I mean you're pointing out an
21 incredibly important systems issue in care. In
22 Canada, what they've developed is a stroke

1 network, so that there's a centralized group of
2 sick kids in Toronto.

3 So they get calls all the time about
4 strokes in smaller centers and help them work
5 their way through, and they have the coordinated
6 care and registry. So perhaps something like
7 this would push more of a coordinated approach to
8 pediatric stroke, including the 18 to 21 year-old
9 range. But I'm not sure that's within the
10 purview of what we're doing, and again I think we
11 should --

12 You made the point. I think it's on
13 record and unless there's other changes to the
14 discussion, we maybe should move on.

15 CO-CHAIR KNOWLTON: Anything further
16 on this?

17 (No response.)

18 CO-CHAIR KNOWLTON: Ron and Charlotte
19 and Peter, put your cards down if you don't want
20 me to call them. Okay. Let's vote on this
21 Usability and Use.

22 MS. OGUNGBEMI: We are now voting on

1 Usability and Use for Measure 1952. Options are
2 high, moderate, low and insufficient. Voting is
3 open.

4 (Voting.)

5 MS. OGUNGBEMI: Voting is closed. The
6 results are 19 percent high, 71 percent moderate,
7 10 percent low and 0 percent insufficient.
8 Measure 1952 passes on Usability and Use.

9 CO-CHAIR KNOWLTON: So now on overall
10 then?

11 MS. OGUNGBEMI: We are now voting on
12 the overall suitability for endorsement of
13 Measure 1952. Your options are yes and no.
14 Voting is open.

15 (Voting.)

16 MS. OGUNGBEMI: Voting is closed. A
17 unanimous 100 percent for yes, the Measure 1952
18 is suitable for endorsement.

19 PARTICIPANT: I know you'll continue
20 without me, but I am leaving.

21 CO-CHAIR TIRSCHWELL: Thanks. So we
22 are going to have a working lunch today. We're

1 going to take ten minutes to move efficiently
2 through the lunch line. Bring your food back to
3 the table, and we'll dig right in. Oh, sorry.

4 While you're doing that, we're going
5 to open the phones up for public comment. Is
6 that okay? So can the operator open the phones
7 for public comment please?

8 OPERATOR: Yes. At this time, if you
9 want to make a comment, please press star then
10 the number one.

11 CO-CHAIR TIRSCHWELL: Turn the volume
12 up. Is that possible?

13 (No response.)

14 OPERATOR: There are no public
15 comments at this time.

16 CO-CHAIR TIRSCHWELL: Thank you. Any
17 comments from the audience in the back? Sorry,
18 we did not mean to ignore you guys.

19 (No response.)

20 CO-CHAIR TIRSCHWELL: Alright, thank
21 you.

22 (Whereupon, the above-entitled matter

1 went off the record at 12:51 p.m. and resumed at
2 1:03 p.m.)

3 CO-CHAIR KNOWLTON: Okay let's get
4 going. Just so we're clear, we've got a little
5 bit of a quorum challenge if we lose more people,
6 so we're really trying to be respectful of
7 people's need to get to transportation and get
8 through as many of these as we can. So this is--
9 we're starting consideration of Measure 1814, the
10 counseling of women of childbearing potential
11 with epilepsy. I was told we were doing this
12 one.

13 PARTICIPANT: We skipped 1814.

14 CO-CHAIR KNOWLTON: We skipped 1814.

15 PARTICIPANT: Correct.

16 CO-CHAIR KNOWLTON: Okay. Do we have
17 a developer here on this issue?

18 PARTICIPANT: Is the American Academy
19 of Neurology here to introduce -- yes. Sorry.

20 CO-CHAIR KNOWLTON: Sorry to be
21 misleading here. Would you like to introduce
22 yourselves and your measure?

1 MS. BENNETT: Hello, I'm Amy Bennett,
2 Manager of Quality Improvement for the American
3 Academy of Neurology. On behalf of the American
4 Academy of Neurology, thank you in advance or
5 considering our measure. We --

6 CO-CHAIR KNOWLTON: Pull your mic a
7 little bit closer. They've got to pick you up.

8 MS. BENNETT: We affectionately know
9 this measure as the Women with Epilepsy measure,
10 so. This is a process measure addressing the
11 percentage of all female patients age 12 to 14 of
12 child-bearing potential, diagnosed with epilepsy.
13 Would it be possible to display the measure
14 specifications of this measure at this time?
15 Sorry, with epilepsy who are counseled at least
16 once a year about how epilepsy and its treatment
17 may affect contraception or pregnancy. This
18 measure is intended to help women with epilepsy
19 understand pregnancy risks and mitigate these
20 risk factors, which may in turn prevent unplanned
21 pregnancies, fetal malformations and improve
22 patients' quality of life.

1 The measure has been implemented in
2 the CMS PQRS program, and is being implemented in
3 the AAN's Axon Registry. The Axon Registry is
4 currently in a pilot phase, so data is
5 unavailable at this time on performance. The
6 Women with Epilepsy measure was initially
7 endorsed as a time-limited endorsement, and then
8 during the 2014 annual review, testing data was
9 provided. During that review, the group granted
10 full endorsement, but recommended exception
11 concerns noted during the testing be addressed.
12 So later in 2014, the AAN seated a workgroup and
13 updated the measure and further clarified
14 exceptions to the measure in response to the
15 testing data. So that is my brief introduction
16 to the measure.

17 CO-CHAIR KNOWLTON: Has this been
18 fully endorsed by NQF?

19 MS. BENNETT: Yes.

20 MS. JOHNSON: That particular measure
21 was what we called at the time, time limited, and
22 it had special circumstances underneath it, and

1 what happened is with time limited measures--
2 which we don't do any more, by the way--the
3 developer brings that to our CSAC group, and the
4 CSAC looks at the testing data and makes the
5 decision.

6 CO-CHAIR KNOWLTON: Jocelyn and
7 Charlotte, are you presenting?

8 MEMBER BAUTISTA: Uh huh.

9 CO-CHAIR KNOWLTON: This is Jocelyn and
10 Charlotte. Go ahead.

11 MEMBER BAUTISTA: Okay, so we'll go
12 directly into the evidence. The developer did
13 provide updated evidence for this measure. So
14 when it was initially approved for time limited
15 use, we invoked the exception to the evidence.
16 There was insufficient evidence--the group
17 thought at the time--there was insufficient
18 evidence, but felt it was an important enough
19 measure to proceed. So the updated evidence is
20 basically clinical guidelines published in 2014
21 that rated level 3 evidence for the importance of
22 counseling on contraception, et cetera. So I

1 think we're still left with the issue that
2 there's no direct evidence that counseling on
3 these issues leads to improved outcomes in women
4 with epilepsy, but I don't think there ever will
5 be. I don't think there ever will be a
6 randomized, controlled trial; I mean I could be
7 wrong, but I don't envision that there ever will
8 be randomized, controlled trials that look at
9 counseling versus no counseling on these issues.
10 So I think we're in this issue.

11 CO-CHAIR KNOWLTON: Charlotte, what
12 did you want to add?

13 MEMBER JONES: I agree that there will
14 never be a trial looking at whether counseling or
15 no counseling is beneficial, but I do think there
16 could certainly be trials looking at what forms
17 of counseling are appropriate; there could be
18 trials looking at who provides counseling, and
19 there could also be trials looking at are some--
20 are there times in people's lives when they are
21 more willing to be counseled and more likely to
22 take counseling to heart. So I think saying

1 nobody's ever going to stop counseling women,
2 therefore we should use the evidence exception is
3 inappropriate.

4 CO-CHAIR KNOWLTON: Valerie.

5 MEMBER COTTER: Can we make the point
6 is the only outcome about, you know, having a
7 healthy baby or is the outcome also about making
8 informed decision and choice about moving forward
9 and having a pregnancy? I mean, I think it's
10 really important that women are fully informed to
11 participate in that decision about whether they
12 want to get pregnant or not.

13 MEMBER BAUTISTA: I do think that's
14 important, but the outcomes that the developer
15 put forward, I don't believe that was one of
16 their outcomes.

17 MEMBER COTTER: Unplanned pregnancy is
18 listed as a potential outcome, and that--

19 CO-CHAIR KNOWLTON: Better to speak
20 close to your mics. People are eating, and it's
21 hard to hear, so speak close to your mics, so
22 everybody can hear. And we're taping this too,

1 so that's important.

2 MR. PATEL: So counseling then,
3 unwanted pregnancies is definitely part of this
4 measure and it was listed in there, and the data
5 used to justify it was also part of the measure.
6 So it's very important, and we consider it to be
7 crucially part of the measure. And you know,
8 that does address perhaps there could be some
9 ways that you could counsel, like Dr. Jones has
10 recommended or certain aspects of it, but one
11 thing I would point out is, you know, this
12 measure isn't specifically about those things,
13 it's just the overall goal is to provide that
14 counseling, and that's the first step, and what
15 hopes to be better outcomes develop because of
16 the counseling that's provided.

17 CO-CHAIR KNOWLTON: Other comments or
18 questions or thoughts? David?

19 MEMBER ANDREWS: Maybe I'm revealing
20 my ignorance, but why is this a different issue
21 for women with epilepsy than women in general?

22 MR. PATEL: A lot of the anti-

1 epileptics that we use to treat women can have
2 effects on their contraceptive choices, effects
3 to the child, the unborn child, as far as neural
4 tube defects, so that's a big issue there. Data
5 has shown that women with epilepsy have a harder
6 time achieving fertility and other outcomes that
7 way, and so therefore, it tends to be more--a
8 little bit bigger of an issue as it relates to
9 women who have epilepsy.

10 MEMBER ANDREWS: How big a little bit?

11 MR. PATEL: Sir?

12 MEMBER ANDREWS: How big a little bit?

13 You said there's a little--sorry.

14 MS. BENNETT: So approximately 90
15 percent of women who have pregnancies with
16 epilepsy do not have complications, but for 10
17 percent, there is potential complications with
18 their pregnancy, which could potentially be
19 seizure dis-control or birth defects. And then
20 there's also the concern about unplanned
21 pregnancy, the fact that the impact of the anti-
22 seizure medication reduces the efficacy of the

1 birth control, so it leads to unplanned
2 pregnancies.

3 CO-CHAIR KNOWLTON: Anybody else?
4 Lisa.

5 MEMBER LINES: So that's interesting,
6 but do we have comparable data in terms of rate
7 of unplanned pregnancies in women without
8 epilepsy versus women with; do they have rates of
9 complications for women with epilepsy versus
10 women without? I'm not hearing that.

11 CO-CHAIR TIRSCHWELL: So I'll just say
12 from a clinical perspective the risk of a
13 complication of pregnancy in women who have
14 epilepsy who are taking anti-epileptics and sort
15 of are cognizant of what's going on, that they're
16 pregnant early is substantially higher. So
17 there's a huge potential impact here; there's no
18 arguing that. I guess the argument is whether
19 this measure is going to impact that, but it
20 seems like last time we were so compelled by the
21 fact that at the very least, we should try to
22 tell these women about this potentially huge

1 health issue. That carried the day, carried them
2 over the finish line without any evidence.

3 CO-CHAIR KNOWLTON: Peter.

4 MEMBER SCHMIDT: I just think that
5 there might be a technical error in the
6 preliminary rating because my understanding is
7 that low would mean that there is a discrepancy,
8 or that the evidence is conflicting about whether
9 or not we should do this. My sense is that there
10 is high face validity to this measure. We've had
11 agreement that you--that it would be unethical to
12 test this in a randomized way. So the issue is,
13 is it insufficient, or do we think that the issue
14 in front of us has evidence for it?

15 CO-CHAIR KNOWLTON: Jocelyn.

16 MEMBER BAUTISTA: I think the rating
17 of low, the preliminary rating for low on the
18 evidence is the fact that there is evidence that
19 certain anti-epileptic medications have effects
20 on--you know, it's all of the related evidence
21 that there are important issues that need to be
22 discussed about women's epilepsy, but there's no

1 direct evidence that the counseling will impact
2 the ultimate outcomes. I think that's why it got
3 the low rating.

4 MEMBER SCHMIDT: But not counseling
5 would certainly--not counseling would clearly be
6 worse. Face validity but not counseling means
7 that that information is not conveyed.

8 MEMBER BAUTISTA: We argued the
9 original time it was presented.

10 CO-CHAIR KNOWLTON: Steve?

11 MEMBER HUFF: This would seem to be a
12 mom and apple pie thing. I mean, at face value,
13 how could this be a bad thing?

14 PARTICIPANT: Do you want to quantify
15 that? Just kidding.

16 MEMBER HUFF: Yes, I mean the only
17 good question is, is what would you do with this
18 measure and how would you use this to--how would
19 this be used to alter providers' behaviors?

20 CO-CHAIR KNOWLTON: I think I'm
21 wondering whether--I'm trying to channel you
22 here, Peter--if we're going for the exception to

1 the evidence rule again, it would probably have
2 to go to insufficient, not to low. Low will
3 fail; insufficient means that we can go to the
4 exception again. I don't know. Yes. I learned
5 that yesterday.

6 MS. JOHNSON: And just a little bit of
7 NQF trivia, the last time around we didn't have
8 the algorithms. So you guys, we still had an
9 exception back then, but our algorithms are new
10 since the last time. How we landed on low really
11 had to do with the nice guidelines being graded
12 and graded with a level C. So, and that's why we
13 landed on low rather than insufficient.

14 CO-CHAIR KNOWLTON: David.

15 MEMBER HACKNEY: I'm just unclear on
16 what kind of evidence we would say we would want
17 if we were to come up with insufficient. You
18 know, if we had evidence that said this 50
19 percent of women got counseled, this 50 percent
20 didn't, these people had less unintended
21 pregnancies and less birth defects, then we would
22 have good evidence that counseling--so that would

1 be the gold standard. We could it--it would be
2 less gold if it was observational data, which
3 seems feasible, but that--

4 MEMBER DICKERSON: I think that's the
5 evidence that we're looking for that we don't
6 have. That raises the question of why, if we're
7 here again addressing this question, why hasn't
8 the measure been used or why haven't
9 encouragements been made or incentives been made
10 to use the measure to collect this kind of data?

11 MS. BENNETT: So the measure has been
12 utilized in the CMS PQRS Program, but the
13 performance rates under that have not been
14 released by CMS. And additionally, the AAN is in
15 the process of developing a performance
16 improvement registry, but that hasn't been
17 launched at this date. So it has been released
18 and studied in practice, and we know that there
19 is a gap in care based on published data, but we
20 haven't had a tracking system for the data yet.

21 CO-CHAIR KNOWLTON: Peter.

22 MR. PATEL: I would like that there

1 are case reports on other data that have since
2 come out since the original measure was proposed
3 and endorsed by NQF on that continued gap. You
4 know, we still are seeing greater than 50 percent
5 of women not getting this counseling and
6 therefore, we have not seen the rates decrease in
7 what we would hope to see. Now as further
8 implementation occurs, and it gets improved and
9 hopefully continued endorsement occurs from this
10 group that will lead to that, then we're
11 hopefully going to be tracking those outcomes and
12 then be able to present that as well.

13 CO-CHAIR KNOWLTON: Peter.

14 MEMBER SCHMIDT: So I just want to say
15 that to the point of does counseling affect
16 pregnancy rates, I think we've seen a natural
17 experiment going on across schools since
18 curriculums are adapted that it does in fact
19 affect pregnancy rates.

20 CO-CHAIR KNOWLTON: Anything further
21 on evidence?

22 MEMBER JONES: I think I just have to

1 put in counseling has a minimal impact on
2 pregnancy rate. What really impacts pregnancy
3 rate is access to contraception on demand. That
4 is what really makes the difference.

5 CO-CHAIR KNOWLTON: So we--are we
6 ready to vote on evidence? Are people
7 comfortable with what we--

8 CO-CHAIR TIRSCHWELL: Can we clarify
9 when we put it up that if you think it should
10 fail on evidence, you can vote low; if you think
11 it should pass, it's high or moderate; if you
12 think we should invoke the exception again, then
13 you probably need to be in the insufficient
14 category. Did I do all that right?

15 CO-CHAIR KNOWLTON: Okay, ready to
16 vote? Let's go.

17 MS. OGUNGBEMI: We are now voting for
18 Measure 1814 on evidence; the options are high,
19 moderate, low and insufficient. Voting is open.
20 Voting is closed. Results are zero percent high,
21 10 percent moderate, 15 percent low and 75
22 percent insufficient. Measure 1814 does not pass

1 on evidence.

2 CO-CHAIR KNOWLTON: Okay, so we move
3 on to whether we wish to make an exception here;
4 we do that by a vote. Any comment on it before
5 we move to a vote?

6 CO-CHAIR TIRSCHWELL: There's no gray
7 zone here, right? 60 or bust.

8 PARTICIPANT: Greater than 60.

9 CO-CHAIR TIRSCHWELL: Greater than 60.

10 CO-CHAIR KNOWLTON: Greater than 60.

11 All right, let's go.

12 MS. OGUNGBEMI: We are now voting on
13 evidence and the potential exception to empirical
14 evidence for measure 1818. Your options are
15 insufficient evidence with exception or no
16 exception. Voting is open. Voting is closed.
17 Okay then we will re-vote.

18 PARTICIPANT: We've got to start the
19 two days over again.

20 MS. OGUNGBEMI: We are now re-voting
21 on the evidence, potential exception to empirical
22 evidence for Measure 1814. Your options are

1 insufficient evidence with exception and no
2 exception. Voting is open. Voting is closed.
3 The results are 90 percent insufficient evidence
4 with exception and 10 percent no exception.
5 Measure 1814 passes on its insufficient evidence
6 with exception.

7 CO-CHAIR KNOWLTON: A gap? Jocelyn.

8 MEMBER BAUTISTA: So in the
9 performance data submitted by the developer,
10 there is a clear gap in care. Less than 40
11 percent of women receive counseling about
12 epilepsy and its treatment. So I don't think--
13 and that's supported by the literature. I don't
14 think there's any question that there's a gap.

15 CO-CHAIR KNOWLTON: Comments or
16 questions now, then let's move to vote.

17 MS. OGUNGBEMI: We are now voting on
18 performance gap for Measure 1814. The options are
19 high, moderate, low and insufficient. Voting is
20 open. Can everyone try to vote, please? Voting
21 is closed; results are 85 percent high, 10 percent
22 moderate, five percent low, and zero percent

1 insufficient. Measure 1814 passes on performance
2 gap.

3 CO-CHAIR KNOWLTON: Reliability.

4 MEMBER BAUTISTA: So reliability
5 testing consisted of data element validity
6 testing, which does satisfy NQF requirements. So
7 the way they did this, they recruited 3 neurology
8 practices in Minnesota and asked them to submit
9 their data, retrospective data, and they had sort
10 of a chart review to evaluate the validity of the
11 data elements. Two of the three practices did
12 well; one of practices had to resubmit data, which
13 I think raises some questions. So the preliminary
14 rating for reliability was low.

15 MS. BENNETT: So in follow up, the
16 practice was asked to submit additional records,
17 and the concern was that the cognitive impairment
18 exception had been invoked, and then there was a
19 failure to document mild mental retardation in the
20 chart, which led to the request for additional
21 data.

22 MEMBER BAUTISTA: So there are number

1 of exceptions to this measure, and I think that's
2 where the validity may become an issue. So they
3 have exclusions for patients with intellectual
4 disability, and physicians interpret that term in
5 different ways, and they document it in different
6 ways, and I think that speaks to the problem of
7 extracting that particular data element.

8 MS. BENNETT: So in response to this
9 data testing, we further refined exceptions so
10 that it is very clear which developmental
11 disabilities and neurological disorders,
12 neurodevelopmental disorders meet the exception
13 criteria. In the original version of this
14 measure, it had just stated severe developmental
15 disability, so it wasn't clear what met that
16 exclusion. So we hope that by further refining
17 exclusions, it is now clear which patients would
18 meet the exclusion criteria.

19 PARTICIPANT: So what does it say?

20 MS. BENNETT: It now states what is
21 listed on--sorry--on 699, it states the
22 exclusions; the exception for neurodevelopmental

1 disorder, encephalopathy, hydrocephalus, brain
2 injury, cerebral palsy, or a diagnosis of severe
3 cognitive impairment or severe intellectual
4 disability, whereas before it had just stated
5 severe medical reason for severe disability.

6 CO-CHAIR KNOWLTON: Charlotte.

7 MEMBER JONES: Question for the
8 developers. What was the definition of counseling
9 that was used in the chart review? When I went
10 through the literature, I didn't--because you have
11 a number of things you want patients counseled
12 on. You want them counseled on breast-feeding,
13 you want them counseled on contraception, you want
14 them counseled on birth defects, you want them
15 counseled on folic acid. So when you are
16 identifying that counseling has occurred, it seems
17 to me that there are at least four or five
18 different factors that constitute counseling. How
19 are you distinguishing those?

20 MS. BENNETT: We've defined counseling
21 to include--counseling should include a discussion
22 about folic acid supplementation, contraception,

1 potential anti-seizure medication effects on
2 pregnancy, safe pregnancies and breast-feeding.

3 MEMBER JONES: So you are asking them
4 to counsel on all five of these things to--

5 MS. BENNETT: Once a year, yes.

6 MEMBER JONES: --to--once a year?

7 MS. BENNETT: Yes.

8 MEMBER JONES: On all five of these
9 things?

10 MS. BENNETT: Yes.

11 MEMBER JONES: Okay.

12 MEMBER DICKERSON: So they couldn't
13 claim that they did it without doing all five?

14 MS. BENNETT: I think that if there was
15 documentation that they didn't counsel on one
16 particular aspect of the--it wouldn't meet the
17 measure criteria. But we have developed an e-
18 measure, the ability to pull this data through our
19 registry without additional burden on doing a
20 chart review. So we have the data elements to
21 find to pull from EHR.

22 MEMBER JONES: How are you pulling that

1 from the EHR?

2 MS. BENNETT: An elaborate data
3 dictionary so that each individual component,
4 there are a multitude of words that we've worked
5 through with our registry committee members to
6 identify all the different variations of words
7 that could be used rather than breast-feeding or
8 other items. So each one of these has an
9 elaborate data dictionary that's included with it.
10 Yes, you can extract it from a medical record
11 without doing a chart review.

12 CO-CHAIR KNOWLTON: This is an
13 electronic measure, let's--this is interesting,
14 but it's off of the point of what we're proving
15 here. Yes, it does, and that's a valid concern
16 and you can raise it Charlotte, but whether
17 there's a data dictionary and we're using it in
18 the EHR at some point is not before us at the
19 moment. Jim?

20 MEMBER BURKE: So are three practices
21 enough to tell us anything about reliability?

22 CO-CHAIR KNOWLTON: On the mic, please.

1 MEMBER BURKE: Are three practices
2 enough to tell us anything about reliability? I
3 mean, we had a gripe earlier today about whether
4 or not 1,500 hospitals is enough to tell us about
5 3,000. Three seems awfully thin for reliability.

6 CO-CHAIR KNOWLTON: Other comments,
7 questions?

8 MEMBER KAPLITT: Yes, this is Mike
9 Kaplitt, I had put my electronic hand thing up,
10 but I guess nobody saw it. I just have a--on the
11 same point, whether three is enough or not, on its
12 face the developer said that they changed the--I
13 guess it was the exclusion criteria or the data
14 elements or something, based on the fact that they
15 learned from that one out of three practices that
16 had problems, they learned that they needed to
17 improve it. So I'm wondering why has this come
18 forward now, rather than retesting this with,
19 let's say, even if three is sufficient, why wasn't
20 it retested in three new practices to make sure
21 that that solved the problem? Because using your
22 own words, you said you hoped that this will solve

1 the problem, but we have no data to say that it
2 did. So whether it's enough or not, you felt that
3 there was enough of an issue to change this, and
4 now we have no new data to say that it solved the
5 problem.

6 MS. BENNETT: So during the update
7 process, we had an extensive discussion with the
8 workgroup about should there be exclusions at all.
9 There was a lot of argument that there shouldn't
10 be any exclusions, that even those with severe
11 developmental disabilities are at risk for abuse
12 and violence that could result in an unplanned
13 pregnancy through rape. But there was a workgroup
14 consensus that these are the exceptions to be
15 utilized, so a committee of 30--25 individuals
16 agreed that these are appropriate exclusions for
17 the measure. Testing a measure takes
18 approximately 18 months; we released this
19 measurement set in 2015; this project was
20 announced and we haven't had enough time to
21 conduct additional validity testing through the
22 use and the registry, but that is our intent that

1 there will be ongoing assessment of the measure
2 through data gathered from our registry.

3 MR. PATEL: And I'd like to clarify
4 that the definitions of exclusions were not based
5 on the feedback we got from the practice; it was
6 on workgroup consensus. And again, like Amy had
7 said, we spent a lot of time to make sure we had
8 the proper definitions and they were more tightly
9 aligned so it would be easier to capture in
10 measures.

11 MEMBER KAPLITT: Okay, because my
12 recollection of the discussion, and I assume we
13 have transcripts, is that when the reliability was
14 presented, it was presented as that one of the
15 three groups had an issue, and then they were
16 asked to resubmit data, and then whoever responded
17 from the developer said that, you know, as a
18 result of that, you guys made your changes. Now
19 I'm sure it was the workgroup that made the
20 change, but either the three groups provided
21 useful data or they didn't, right? I mean, if you
22 didn't do anything based on it, then what's the

1 relevance of those three groups? There just seems
2 to be--there seems to be an issue with both the
3 logic of how this process is done, and the timing.
4 Is there some time pressure that forced this to be
5 done now rather than 18 months from now, when you
6 had more--I mean I don't know why it would take 18
7 months to get data from three practices, but even
8 if that were true, is there some time pressure
9 that we have to do this now?

10 MS. BENNETT: It's up for maintenance
11 review now.

12 MEMBER KAPLITT: Okay.

13 MEMBER SCHMIDT: So I feel like there
14 should be more data available because it's up for
15 maintenance review. It's been used and it had a
16 provisional endorsement; isn't there data from the
17 prior period where--that could inform our decision
18 on this?

19 MS. BENNETT: The AAN did not generate
20 data; we didn't have a source for gathering data
21 in the interim, so any data that has been used in
22 practice has been private data. So we're reliant

1 upon what's been published as well as the fact
2 that CMS hasn't released the performance rates
3 under PQRS. So the AAN doesn't have access to
4 other people's information on use of the
5 performance in practice.

6 MR. PATEL: That will be corrected with
7 the registry, but again, the registry is just
8 getting started.

9 CO-CHAIR KNOWLTON: Anything further on
10 this? I hear that people have concerns, but
11 anything new? Any additional issues? Okay, we
12 are voting on reliability.

13 MS. OGUNGBEMI: We are now voting on
14 reliability for Measure 1814. Options are high,
15 moderate, low, and insufficient. Voting is open.
16 Voting is closed. Results are zero percent high,
17 40 percent moderate, 30 percent low, and 30
18 percent insufficient. We are in a gray zone.

19 MS. JOHNSON: We're between 40 and 60
20 inclusive if you add high and moderate. So if
21 that 40 had been 39, it would have failed. You're
22 in a gray zone.

1 CO-CHAIR KNOWLTON: Correct. We proceed
2 then?

3 MS. JOHNSON: Yes.

4 CO-CHAIR KNOWLTON: Okay. And Jocelyn
5 had the lead, so Charlotte, it's on you.
6 Microphone, please.

7 MEMBER JONES: So in terms of validity,
8 the group used an 8/30 process where they reviewed
9 eight charts to determine if the records were
10 compliant. If eight were greater than 90 percent
11 I believe, they then stopped assuming that all
12 charts were compliant. If not, they went to 30,
13 and that was where they found that they needed to
14 address the issue of date of birth because they
15 were missing a year's worth of patients, and then
16 they also had a group that--where the patients who
17 were surgically sterile or intellectual
18 disability, they resubmitted that data with
19 corrections. So the validation process identified
20 errors, they went back and improved on that, they
21 had problems with the intellectual disability,
22 which was modified as previously discussed. They

1 had statistics for the rate of contraceptive
2 counseling and the rate of contraceptive and
3 pregnancy counseling; I don't know where breast-
4 feeding fell in to that, so I'm wondering if they
5 have additional data on that, but that was not
6 provided to us, and they certainly showed--and
7 this was one of their ways for gaps. So the
8 validity in terms of was the information in the
9 chart retrievable seemed moderate to low; based on
10 the analysis, one is left with the question, as
11 one often is left with chart reviews, is what is
12 checked or entered the correct information, but
13 that's the reality that we have to deal with. So
14 when it comes to validity testing, I believe based
15 on the algorithm, and I don't have--we have the
16 problem of the small number of clinics, and the
17 generalized ability for the validity. And I
18 apologize, Jocelyn and I had discussed how we were
19 going to do this, but she had to leave because of
20 time constraints.

21 MS. BENNETT: They contracted with
22 Minnesota Community Measurement, who utilized a

1 process developed by the NCQA, and ultimately
2 their finding was there was no significant flaws
3 or errors with the data. Minnesota Community
4 Measurement was confident that the rate
5 calculation and any additional data analysis can
6 be completed using validated and reliable data.
7 So that's what the AAN was informed based on our
8 contracted assessment of this reliability.

9 CO-CHAIR KNOWLTON: Comments or
10 questions? Okay, we're voting on validity.

11 MS. OGUNGBEMI: We are now voting on
12 validity for Measure 1814. Options are high,
13 moderate, low and insufficient. Voting is open.
14 Voting is closed. Results are zero percent high,
15 68 percent moderate, 11 percent low and 21 percent
16 insufficient. Measure 1814 passes on validity.

17 CO-CHAIR KNOWLTON: Okay, feasibility.

18 MEMBER JONES: Feasibility, the
19 information is generated and used by health care
20 personnel during the provision of care. We have
21 heard that it is possible to--all date elements
22 are in defined fields and a combination of

1 electronic sources, and there was information that
2 one of the clinics reported difficulty in doing
3 the work. We also have the feasibility that these
4 were three groups that volunteered to participate,
5 which will not necessarily be true if this is a
6 endorsed measure, but the same thing is true as we
7 certainly used the Get With the Guidelines
8 programs, and those are also volunteer. So I
9 don't know that that in and of itself is a threat
10 to feasibility. We haven't raised it with the
11 stroke data. Usability--

12 CO-CHAIR KNOWLTON: Don't go into
13 usability yet. Stay on feasibility.

14 MEMBER JONES: Stay on feasibility.

15 CO-CHAIR KNOWLTON: Because we have to
16 vote on it. Any comments on feasibility? Okay,
17 let's vote on feasibility.

18 MS. OGUNGBEMI: We are now voting on
19 feasibility for Measure 1814. The options are
20 high, moderate, low and insufficient. Voting is
21 open. Voting is closed. Results are zero percent
22 high, 89 percent moderate, five percent low and

1 five percent insufficient. Measure 1814 passes on
2 feasibility.

3 CO-CHAIR KNOWLTON: Feasibility and
4 use? Charlotte.

5 MEMBER JONES: So the American Academy
6 of Neurology makes a significant--and this is
7 where I am a member of the American Academy of
8 Neurology AXON registries. I am an advisor to the
9 group, and I'm honestly feeling a bit of a
10 conflict of interest here because it was not my
11 understanding that all of these measures were
12 definitely to be incorporated. I am hearing from
13 the AAN that it is going to be incorporated, so I
14 feel--and I feel really bad because this was a
15 measure I was assigned to. I almost feel like I
16 have to recuse myself because I was unaware that
17 it had been accepted into the AXON registry. I
18 wasn't part of the development of it. But the
19 AXON registry is a registry that is a voluntary
20 registry that is at this point, not used for bench
21 marking, and--

22 CO-CHAIR KNOWLTON: Charlotte, if you

1 have a conflict, then you should stop discussing
2 and you should not vote.

3 MS. BENNETT: Dr. Patel is here to
4 provide expertise on his use of the measure in the
5 field, if you would like to hear his--

6 CO-CHAIR KNOWLTON: He can speak as to
7 development, but to that point and then we'll move
8 back to our committee. Go ahead.

9 MR. PATEL: Yes, so at our institution
10 we actually have created though our EHR quick
11 buttons that take less than 30 seconds to
12 complete, that you're compliant with the different
13 components of this measure. It was very easy to
14 implement, and it's being rolled out. We also
15 created other best practice alerts which would
16 be--would flag you if you had a patient that would
17 meet criteria for this measure, and again you
18 would then follow the prompts and be able to
19 collect that data. They're discrete elements, so
20 they're easy to collect, and we're going to be now
21 reporting on that and looking at those outcomes
22 that we talked about earlier. So from a usability

1 standpoint, it can easily be placed into anyone's
2 EHR. And again with the AXON registry, we're
3 going to have those data dictionary elements,
4 they're going to be able to be pulled out, which
5 means that the individual user of--that's going to
6 do this measure will not have additional work or
7 any obstructions to that.

8 CO-CHAIR KNOWLTON: Okay, thank you
9 Doctor. Are there other thoughts from the
10 committee? Okay, well let's move forward on a
11 vote here.

12 MS. OGUNGBEMI: We are now voting on
13 usability and use for Measure 1814. Options are
14 high, moderate, low and insufficient. Voting is
15 open. Results are 11 percent high, 89 percent
16 moderate, zero percent low and zero percent
17 insufficient. Measure 1814 passes on usability
18 and use.

19 CO-CHAIR KNOWLTON: We're going to have
20 to return and re-vote on the other issues, because
21 Charlotte recused herself. So we've got to go
22 back to evidence. I don't know if we need to

1 discuss it, but we --

2 CO-CHAIR TIRSCHWELL: So it doesn't
3 matter which one we take out, it won't change the
4 results.

5 CO-CHAIR KNOWLTON: Right.

6 CO-CHAIR TIRSCHWELL: I would propose
7 that we don't -- for evidence, and then the next
8 one on the exception as well, same thing, and then
9 the next one was--I think it's just gap, no issue
10 there, vast majority. This one is the one that we
11 probably have to re-vote on.

12 CO-CHAIR KNOWLTON: Okay so the issue
13 then is reliability. Any comments? Are we
14 logistically settled on what we're doing? Yes?

15 CO-CHAIR TIRSCHWELL: So we're just re-
16 voting on--

17 CO-CHAIR KNOWLTON: We're just re-
18 voting on reliability.

19 CO-CHAIR TIRSCHWELL: Well, and then
20 we'll see what the other results are.

21 CO-CHAIR KNOWLTON: Yes, that's right.

22 MS. OGUNGBEMI: We are now re-voting on

1 reliability for Measure 1814. Options are high,
2 moderate, low and insufficient. Voting is open.
3 For reliability, the results are zero percent
4 high, 56 percent moderate, 17 percent low and 28
5 percent insufficient, so we are still in a gray
6 zone.

7 CO-CHAIR KNOWLTON: That's okay.

8 MS. OGUNGBEMI: We are not voting on
9 the overall suitability for endorsement of Measure
10 1814. Options are yes or no. Voting is open.
11 Voting is closed. Results are 67 percent yes, 33
12 percent no. Measure 1814 is suitable for
13 endorsement.

14 MR. PATEL: Thank you everybody.

15 CO-CHAIR KNOWLTON: Okay. Moving on,
16 0507, Diagnostic Imaging Stenosis Measurement
17 and Carotid Imaging Reports. Hello. You want to
18 introduce yourself and your measure? Turn your
19 microphone on, please.

20 MS. BURLESON: Hi, I'm Judy Burleson
21 with the American College of Radiology, and I
22 believe we have Dr. David Seidenwurm on the phone

1 if we can open that up to him as well. I'll
2 introduce the measure, 0507, Stenosis Measurement
3 in Carotid Imaging Reports. This measure was
4 originally endorsed in 2008 and was reviewed again
5 and maintained for endorsement in 2013. It has
6 been in the PQS program since 2007 and is
7 currently contained in the ACRS Clinical Quality
8 data registry for PQS reporting purposes. Is Dr.
9 Seidenwurm on the phone?

10 DR. SEIDENWURM: Yes.

11 MS. BURLESON: Hi.

12 DR. SEIDENWURM: Hello. Hi.

13 MS. BURLESON: Hi. The measure
14 denominator is final imaging reports for carotid
15 imaging studies to include neck MRA, CTA and neck
16 duplex ultrasound and carotid angiogram. The
17 numerator is of those reports, those that have
18 documented the method used for stenosis
19 calculation in a way that includes direct or
20 indirect reference to measurements of distal
21 internal carotid diameter as the denominator for
22 stenosis measurement. And this would include a

1 direct angiographic stenosis calculation based on
2 the distal lumen as the denominator for stenosis
3 measurement, or an equivalent validated method
4 referenced to that type of calculation. So for
5 duplex ultrasound studies, velocity parameters
6 that correlate with the anatomic measurements that
7 use a distal internal carotid lumen as the
8 denominator.

9 Where the improvement focus is for this
10 measure is on the wide variation and the
11 classification, documentation and reporting of
12 methods for stenosis calculation, which may also
13 lead to variation in the appropriateness of
14 carotid intervention. Different methods of
15 stenosis calculation yield different results, so
16 the degree of stenosis is an important element of
17 the decision for carotid intervention and thus the
18 characterization of the degree of stenosis needs
19 to be standardized in order to provide reliable
20 info for treatment decisions. As described in the
21 denominator, the measure is applicable to CTNMR
22 imaging techniques and geography as well as duplex

1 ultrasound, and reference standards for these
2 techniques allow interpretation that coordinate
3 with methods such as the NASCET methodology. Dr.
4 Seidenwurm, do you have any comments?

5 DR. SEIDENWURM: No, I think you did a
6 very good job summarizing. Thank you.

7 CO-CHAIR KNOWLTON: Our discussants
8 are, let me see, Brad and David.

9 MEMBER HACKNEY: I'm going to start
10 Brad and I discussing.

11 CO-CHAIR KNOWLTON: Okay.

12 MEMBER HACKNEY: So this is a measure
13 that has been previously approved; it's--there's
14 one issue about it that I'm going to raise once,
15 but it comes up in a lot of the evaluations, and
16 that is the denominator. The value of this is
17 that there's excellent evidence that in
18 symptomatic adults, in adults with brain ischemic
19 symptoms ipsilateral to a carotid stenosis, that
20 the severity of that stenosis helps predict
21 whether they would benefit from mechanical
22 intervention, surgery or carotid stenting. And so

1 if the group were confined to that, the evidence
2 would be great, and a lot of the other issues
3 would be great. The problem is because the
4 denominator includes everybody who gets vascular
5 imaging of the neck, it includes a large number of
6 people, maybe the vast majority for whom there is
7 no data that it matters at all what the diameter
8 of the carotid is or how you measure it.

9 So for the people for whom it matters,
10 the good thing about the NASCET measure is that it
11 has been empirically proven to be a good predictor
12 of response to surgery versus medical management,
13 and nobody does this anymore but there have been
14 studies in the past that demonstrated that some of
15 the alternate measures--methods of calculating the
16 stenosis severity were not as reproducible as the
17 NASCET measure. So as applied to the target
18 population, it's great; as applied to everyone,
19 that people who don't have atherosclerotic
20 disease, for example, the people who don't have
21 symptoms, children who might have symptoms but
22 don't have symptoms because of atherosclerotic

1 disease, and even if they did, there are no data
2 on what you do with that number in a child. Now
3 you have a measure in which potentially the
4 majority of the instances, this number doesn't
5 mean anything. And so as I said, this will come
6 up repeatedly through the evaluation, but that's
7 the basic concern that I have, and it's really the
8 only concern that I have.

9 So should we start with--I think I
10 addressed evidence. There is good evidence that
11 it matters in some people, and no evidence that it
12 matters in others. They also--there's an issue
13 about how the measure is constructed, and I just
14 want clarity on. It is in some people not
15 possible to actually do the measurement,
16 particularly when the stenosis is tight for
17 technical reasons or the way the UGIB works. In
18 the evidence document, they mention that in that
19 case, you do a qualitative estimate rather than a
20 quantitative measurement, and that's what
21 everybody does who uses this. The only thing I'm
22 concerned about is it doesn't actually say that in

1 the measure, it just says it in the evidence, so
2 is that included by reference or is it considered
3 okay officially by the measure to do that, and I
4 don't know if the developer has an answer or David
5 has an answer for that.

6 DR. SEIDENWURM: Are you asking the
7 question now, David?

8 MEMBER HACKNEY: Yes, I'm asking that
9 question just--

10 DR. SEIDENWURM: Sure. The way we've
11 interpreted that aspect of things is that there
12 are published crosswalks between all of the
13 different modalities and angiographic data, which
14 were the original basis for the methodology. So
15 for example, the velocities and velocity ratios,
16 speckle patterns and so forth in duplex
17 ultrasound, the patterns of signal dropout with
18 different MRA techniques and then direct
19 measurement methodologies for CTA. So I think
20 that with direct or indirect reference to
21 measurements, and I think is how we've kind of
22 elided that point.

1 MEMBER HACKNEY: Okay, I was asking a
2 fairly narrow question that may not be that
3 important. That is, is it okay--the evidence
4 document says you can use a qualitative estimate
5 when you can't do a measurement, so and I guess
6 that's the question is, is that statement in the
7 evidence document, therefore part of the
8 definition in the measure, and it's fine to use
9 that, or does the measure say you have to measure,
10 although the evidence document says qualitative is
11 okay? Do you understand my question?

12 DR. SEIDENWURM: Well, maybe. I
13 thought I did before, but I think now I think I
14 understand it differently. I think what you're
15 getting at is the fact that the interpretation of
16 some these studies leads to some gray zones. For
17 example, the near total occlusion pattern in
18 angiography, which is the gold standard for this.
19 The signal drop out spectral patterns, so some of
20 those are necessarily somewhat qualitative, and I
21 think that's why we were allowing that. One
22 always has to make a judgment with respect to

1 measurements and cross-sectional imaging with
2 partial volume phenomena and pixel sizes and so
3 forth. So I think we were just allowing for
4 professional judgment at the gray zones.

5 MEMBER HACKNEY: Okay, so if people can
6 use qualitative when they can't measure, then
7 that's not a problem. So the evidence as I would
8 say, we've got two answers. For the narrow group
9 that I mentioned, the evidence is great; for the
10 broad group, there's no evidence. So I don't know
11 what to--how to resolve that in terms of a one
12 score for evidence.

13 CO-CHAIR KNOWLTON: David.

14 CO-CHAIR TIRSCHWELL: So I have two
15 comments or questions, and one may be easy.
16 Ultrasound is generally not reported with a
17 specific stenosis measurement, it's more often a
18 range. Is that still okay with this?

19 DR. SEIDENWURM: If that question is
20 asked of the developer, yes it is, as long as the
21 ranges are validated against the reference
22 measured.

1 CO-CHAIR TIRSCHWELL: So the individual
2 hospital has to do their own correlation at one
3 point?

4 MEMBER HACKNEY: There are published
5 criteria.

6 CO-CHAIR TIRSCHWELL: So as long as
7 they're using published criteria to estimate the
8 range of stenosis, then they're good?

9 MEMBER HACKNEY: Right, because you
10 can't do this measure directly with ultrasound in
11 any case, but there are published criteria, and
12 the measure--

13 CO-CHAIR TIRSCHWELL: So they're not
14 really using the NASCET method in the carotid
15 ultrasound?

16 MEMBER HACKNEY: Well, they're saying
17 use a method that has been validated against
18 NASCET measurements.

19 CO-CHAIR TIRSCHWELL: Okay, fine. So
20 that was the easy one. The second one is, is that
21 it's not entirely true that there's no evidence
22 for intervention in asymptomatic patients; in

1 fact, if you look at the most recent guidelines,
2 I agree, I'm not sure I believe them anymore, but
3 as it stands right now, guidelines for carotid
4 interventions include the possibility, especially
5 in older adults with atherosclerosis, that
6 asymptomatic patients with greater than 60 percent
7 stenosis are potentially candidates for an
8 appropriate intervention, and in fact, 75 percent
9 of carotid interventions in this country are done
10 in asymptomatic patients. So I don't think you
11 can really go with the if they're asymptomatic
12 it's never appropriate to have the stenosis
13 measurement.

14 MEMBER DICKERSON: I think the concern
15 was more that for MRA in particular, there's often
16 a low prior probability of carotid concerns, and
17 it's just the catch all in many emergency room
18 evaluations, and so do we want to force the poor
19 radiologist to have to quantify every one of
20 those.

21 MEMBER HACKNEY: Actually, my concern
22 isn't so much the force to quantify, because

1 coming up with a number isn't that hard. But what
2 I'm worried about is precisely that issue that
3 David raised, that the vast majority of carotid
4 interventions are done in asymptomatic patients,
5 but they shouldn't be. And so I'm afraid that
6 this is encouraging--

7 CO-CHAIR TIRSCHWELL: I mean, that's
8 not true though. There's a randomized trial going
9 on now, because there's clinical equipoise about
10 whether they should or should not be done, and the
11 guidelines as they stand still endorse
12 intervention for asymptomatic patients, although
13 a lot of clinical practice has moved away from
14 that.

15 MEMBER DICKERSON: And in this case, it
16 would provide some data from a broader catchment
17 to address that potentially.

18 CO-CHAIR KNOWLTON: Peter.

19 MEMBER SCHMIDT: I'm just going to
20 point out that we just voted as insufficient a
21 recommendation based on clinical practice
22 guidelines and gave it the exception with the

1 counseling measure.

2 CO-CHAIR TIRSCHWELL: Those clinical
3 practice guidelines are based on randomized
4 trials.

5 CO-CHAIR KNOWLTON: Are there comments
6 on this evidence for this measure? Are we ready
7 to vote on it? Okay

8 MS. OGUNGBEMI: We are now voting on
9 evidence for Measure 0507; the options are high,
10 moderate, low and insufficient. Voting is open.

11 MEMBER HACKNEY: I'll just mention,
12 which I didn't--neglected to do, the preliminary
13 rating was moderate.

14 MS. OGUNGBEMI: Voting is closed.
15 Results are five percent high, 84 percent
16 moderate, five percent low and five percent
17 insufficient. Measure 0507 passes on evidence.

18 CO-CHAIR KNOWLTON: Gap?

19 MEMBER HACKNEY: So there is excellent
20 demonstration of a gap that has changed
21 dramatically in the last few years, but there's
22 still a substantial share of studies that are not

1 reported this way. So I think there's good, high
2 evidence of a gap.

3 CO-CHAIR KNOWLTON: Questions or
4 comments on gap? Let's vote on it.

5 MS. OGUNGBEMI: We are now voting on
6 performance gap for Measure 0507. Options are
7 high, moderate, low and insufficient. Voting is
8 open. Voting is closed. Results are 47 percent
9 high and 53 percent moderate, zero percent low,
10 zero percent insufficient. Measure 0507 passes on
11 performance gap.

12 CO-CHAIR KNOWLTON: Reliability?

13 MEMBER HACKNEY: There is--the evidence
14 document includes excellent evidence of
15 reliability. They did a calculation that got
16 about .86 for reliability, and it's well
17 documented. It's very straightforward and
18 reliable to tell whether somebody has complied
19 with this.

20 CO-CHAIR KNOWLTON: Any questions or
21 comments? Let's vote.

22 MS. OGUNGBEMI: We are now voting on

1 reliability for Measure 0507. Options are high,
2 moderate, low and insufficient. Voting is open.
3 We're just missing one single vote. Oh, got it.
4 Voting is closed. Results are 79 percent high, 21
5 percent moderate, zero percent low and zero
6 percent insufficient. Measure 0507 passes on
7 reliability.

8 CO-CHAIR KNOWLTON: Validity?

9 MEMBER HACKNEY: This was reviewed by
10 an expert panel, and then a second expert panel
11 did another review in February 2015. So there was
12 an initial expert panel review as it was being
13 developed, then one after it was in existence, and
14 then another one in February 2015, and all of them
15 agreed that this passes face validity and fairly
16 strongly endorsed the validity of the measure. So
17 I'd say aye.

18 CO-CHAIR KNOWLTON: Questions or
19 comments? Let's vote on validity.

20 MS. OGUNGBEMI: We are now voting on
21 validity for Measure 0507. Options are high,
22 moderate, low and insufficient. Voting is open.

1 Voting is closed. Results are 58 percent high, 42
2 percent moderate, zero percent low and zero
3 percent insufficient. Measure 0507 passes on
4 validity.

5 CO-CHAIR KNOWLTON: Feasibility?

6 MEMBER HACKNEY: Feasibility is high.
7 This is already in use, it is widely used, it uses
8 only information that's already routinely
9 generated for clinical care, and the data elements
10 are in the fields in electronic sources. So high
11 feasibility.

12 CO-CHAIR KNOWLTON: Questions or
13 comments? Let's vote on the feasibility.

14 MS. OGUNGBEMI: We are now voting on
15 feasibility for Measure 0507. Options are high,
16 moderate, low and insufficient. Voting is open.
17 Voting is closed. Results are 95 percent high,
18 five percent moderate, zero percent low, and zero
19 percent insufficient. Measure 0507 passes on
20 feasibility.

21 CO-CHAIR KNOWLTON: Usability and use.

22 MEMBER HACKNEY: This is widely used.

1 It's used by CMS in their PQRS, it's used by the
2 American College of Radiology in their clinical
3 data registry. It's not being publicly reported
4 now, but there is an anticipation from the
5 developer that it will be, so it's entirely
6 usable. Unintended consequences, I discussed my
7 concern about that, but otherwise I'd say that
8 it's very usable, and I'd give it a high.

9 CO-CHAIR KNOWLTON: Questions or
10 comments? Okay, let's vote on usability and use.

11 MS. OGUNGBEMI: We are now voting on
12 usability and use for Measure 0507. Options are
13 high, moderate, low and insufficient. Voting is
14 open. Voting is closed. Results are 79 percent
15 high, 29 percent moderate, zero percent low and
16 zero percent insufficient. Measure 0507 passes on
17 usability and use.

18 CO-CHAIR KNOWLTON: So look at the
19 overall suitability for endorsement.

20 MS. OGUNGBEMI: We are now voting on
21 the overall suitability for endorsement for
22 Measure 0507. Options are yes or no. Voting is

1 open. Voting is closed. The overall suitability
2 for endorsement result is 100 percent yes, zero
3 percent no. Measure 0507 passes on its
4 suitability for endorsement.

5 MS. TIERNEY: So--

6 DR. SEIDENWURM: Thank you.

7 CO-CHAIR TIRSCHWELL: Thank you. You
8 win. It's a good day for you.

9 CO-CHAIR KNOWLTON: Okay, we're moving
10 on. Since we've already had our lunch, we're
11 moving on to 2111. So we're going out of order,
12 so we're doing 2872 and then 2870? Okay, we're
13 starting with 2872, Dementia and Cognitive
14 Assessment, Physician Consortium for Performance
15 Improvement. Is there a developer here?

16 CO-CHAIR TIRSCHWELL: We have currently
17 just 17 members now? Are we at the quorum number?

18 PARTICIPANT: Yes, we do. We still
19 have a quorum.

20 CO-CHAIR TIRSCHWELL: We're at 17, so
21 does anybody else have to leave very soon?
22 Dorothy, when do you need to leave? Okay, and

1 your measure is --

2 (Off microphone comments.)

3 CO-CHAIR KNOWLTON: Okay.

4 MS. TIERNEY: So should we just take up
5 the 2872?

6 CO-CHAIR KNOWLTON: We are proceeding
7 with 2872.

8 MS. TIERNEY: Okay, so we have a
9 clinical expert on the phone, Dr. Soo Borson, who
10 is going to present the measure for us. Dr.
11 Borson, are you on the line, or can you make sure
12 she has an open line?

13 OPERATOR: Her line is open.

14 MS. TIERNEY: Thank you. Dr. Borson?

15 DR. BORSON: Yes, can you hear me?

16 MS. TIERNEY: Yes, we can.

17 DR. BORSON: Okay, great. Good
18 afternoon everybody. Yes, this is annual
19 measurement of cognition in people with a
20 diagnosis of dementia. Why this matters is as
21 follows: the measure is intended to encourage
22 initial and ongoing assessment of cognition in

1 patients who are diagnosed with dementia. It
2 qualifies as a patient engagement measure, which
3 is a recognized national priority. The measure
4 requires annual assessment regardless of care
5 setting, and applies to all care settings. Repeat
6 cognitive assessment at its heart is a core
7 element of dementia staging; cognitive function
8 itself is most tightly linked, beyond functional
9 status and other measures, to a patient's ability
10 to make medical decisions and to participate in
11 their own care planning. Repeat measurement of
12 cognition can help identify otherwise silent
13 causes of reversible excess decline, for example,
14 medications and certain medical conditions that
15 are otherwise not easy to detect.

16 Cognitive decline is also associated
17 with important patient care factors and outcomes,
18 including the following: impaired ability to
19 understand and manage one's own personal health
20 condition, greater risk for elder self-neglect,
21 higher levels of every day disability and
22 functional impairment, need for greater care giver

1 involvement in managing every day affairs and
2 health care, need for medical decisional proxy,
3 higher risk of medical and surgical complications
4 of dementia, earlier institutionalization and
5 timely initiation of comfort care near the end of
6 life. It's important to note that this measure
7 applies to patients with any type of dementia,
8 regardless of ideologic subtype. Subtype is not
9 a basis for criticism of this measure. This
10 measure follows a similar construction to many in
11 which membership in a broad diagnostic category
12 determines patients' eligibility.

13 The measure is intended to be flexible.
14 It's left to the physician's discretion as to
15 which tool or technique is to be used to measure
16 cognitive impairment, provided the approach uses
17 an objective measure. A physician should use the
18 tool or technique that is most useful based on the
19 patient's needs. The measure also applies to
20 multiple care settings from ambulatory care in the
21 office or urgent care settings, inpatient medical,
22 surgical, behavioral health and psychiatric

1 facilities, skilled nursing facilities,
2 occupational therapy services, domiciliary rest
3 home and custodial care services.

4 Just as a reminder, NQF had previously
5 convened a committee to look at gaps in
6 Alzheimer's and dementia care, and they did
7 identify cognitive assessments as a gap area.
8 Somewhere between 40 and 50 percent of individuals
9 with diagnosed dementia have an annual cognitive
10 assessment, and some would say that's probably
11 even a higher percentage than is generally true.
12 There are medical exceptions that can be valid,
13 and there may be a few patient exceptions--

14 CO-CHAIR TIRSCHWELL: Sue, I'm going to
15 interrupt you. This is David Tirschwell, I'm co-
16 chairing this committee. We really just needed a
17 one-minute overview; we're going to go through all
18 the criteria, so you're not obligated to do that.

19 DR. BORSON: Okay, that's fine.

20 CO-CHAIR TIRSCHWELL: Thank you.

21 DR. BORSON: So--well thank you.

22 CO-CHAIR TIRSCHWELL: And Karen, this

1 is a measure that's up for trial use, is that
2 right?

3 MS. JOHNSON: That is correct.

4 CO-CHAIR TIRSCHWELL: Can you give us
5 the 10-second cliff notes on how that changes our
6 evaluation process?

7 MS. JOHNSON: I can. It'll shorten it
8 I think. It is a trial use measure, so you'll be
9 considering evidence, you'll be considering gap,
10 you will not be considering much in the way of
11 scientific acceptability, except whether or not it
12 conforms to the evidence. So that's what you need
13 to look at. So there's not testing for these data
14 for this measure, and that's fine. And then
15 you'll talk about feasibility and usability and
16 use. The difference is in the scientific
17 acceptability reliability validity stuff.

18 CO-CHAIR TIRSCHWELL: Great. Thank
19 you. And David Andrews and Jane Sullivan are our
20 discussants.

21 MEMBER ANDREWS: Just to be clear at
22 the outset, in your proposal this says it's

1 reviewed every 12 months. That really means
2 repeated, is that correct?

3 MS. JOHNSON: Yes, it does.

4 MEMBER ANDREWS: Okay. As you've
5 heard, this is up for trial approval, so the
6 developers have presented several studies that
7 indicate that cognitive decline contributes to
8 poor self-care, which can lead to inappropriate,
9 undesirable medical outcomes. So in that sense,
10 the evidence that this is something worth
11 assessing is fairly clear, but in my mind as the
12 consumer side of this world is a concern is that,
13 okay, we assess it, does anybody do anything with
14 that assessment? Does it actually contribute to
15 making decisions about educating the patient
16 further, moving them to more residential care, or
17 whatever. That's not really our concern now, but
18 I think it is an issue that needs to be addressed
19 actually with a lot of measures, not just this
20 one. So I think that's sufficient for now.

21 CO-CHAIR TIRSCHWELL: Any other
22 comments or discussion from the committee on

1 evidence? Valerie, go ahead.

2 MEMBER COTTER: I'm just going to make
3 the point that I'm all in favor of this, but we
4 already have this in place with annual Medicare
5 wellness visits, and clinicians should be
6 assessing cognitive function in any new members to
7 Medicare, and then on an annual basis. I think
8 the reason it's not being implemented across the
9 country is because it doesn't specify a measure to
10 evaluate the cognitive function, so you just ask
11 a patient how's your memory and thinking, and if
12 a patient says yes, you can just drop it. In some
13 ways, I wish this measure had dictated what that
14 measure might be or give a subset of measures that
15 might be possible for a clinician to use. It
16 might be even more helpful than the Medicare
17 wellness visit.

18 MEMBER ANDREWS: Just to be clear, in
19 some of the evidence they present, it suggests
20 that the real issue is executive function and not
21 memory function that contributes to these problems
22 over time. You have a number of tests that are

1 identified, which gets to the next reliability
2 section, some of which have both memory and
3 executive items within the tests. So whether over
4 time as your trialing this, you discover that some
5 of these are more effective than others in
6 identifying the needs -- is an important issue to
7 keep in mind going forward.

8 CO-CHAIR TIRSCHWELL: Brad.

9 MEMBER DICKERSON: I was a little
10 confused when I was first reading this, too, and
11 what I think I understand is that this is really
12 meant for patients with diagnosed dementia so that
13 you can stage their illness and help educate them
14 and their families along the way, not for
15 screening for cognitive impairment as the annual
16 wellness visit generally intends to try to
17 implement. So whether primary care physicians are
18 doing this in their annual wellness visit for
19 their patients with dementia, I don't know, but I
20 think there's been tremendous tension around
21 trying to prescribe a particular instrument, and
22 I think we should avoid doing that, but I think we

1 should mandate that people don't just get put into
2 a facility or get diagnosed as having dementia and
3 no one re-address where they are in the process.

4 CO-CHAIR TIRSCHWELL: Dorothy.

5 MEMBER EDWARDS: Well the problem is I
6 absolutely agree with you, but these measures
7 won't stage dementia. These are not any of the
8 dementia staging tools like the CDR or any of the
9 other tools used to stage dementia, and so this is
10 just a repeat of basically the screening measures.
11 Not that I don't think that that would be better
12 than nothing, but that's not--these aren't staging
13 tools.

14 MEMBER DICKERSON: I completely agree
15 with you, and that was another thing I wanted to
16 bring up at some point, and I guess the time is
17 right now. So you know, when a person can no
18 longer perform the mini mental or you know, even
19 the severe impairment battery, that's when you
20 really need more effort to try to stage their
21 progression, and I think these are clinician-based
22 judgments that various tools that you mentioned

1 and others are helpful for, and I think the
2 emphasis on cognitive test performance is really,
3 you know, only part of the story, and obviously
4 that's part of the story at the mild to moderate
5 stages, but once you get into the moderate to
6 severe stages, you can't rely on cognitive tests
7 any more. So I was a little concerned that that
8 would make it difficult to stage the stages of
9 dementia where you really need to be doing this
10 kind of care planning.

11 CO-CHAIR TIRSCHWELL: So I think as
12 we'll see, if there's still gap with this measure,
13 then there's likely to be even more gap with any
14 of those more perhaps comprehensive evaluations,
15 so in some ways I'm seeing that as a vote for.
16 Any other comments on evidence before we vote?
17 Let's go ahead and vote on evidence.

18 MS. OGUNGBEMI: We are now voting on
19 evidence for Measure 2872. The options are high,
20 moderate, low and insufficient. Voting is open.

21 CO-CHAIR TIRSCHWELL: Is our goal 18?
22 Push that button one more time. Push it really

1 hard.

2 MS. OGUNGBEMI: Results are 33 percent
3 high, 61 percent moderate, zero percent low and
4 six percent insufficient. Measure 2872 passes on
5 evidence.

6 CO-CHAIR TIRSCHWELL: Yes, Lisa?

7 MEMBER LINES: Don't the guidelines say
8 that we can't rate it as high if a QQC is not
9 presented, and there is no QQC on this one?

10 CO-CHAIR TIRSCHWELL: So they say that
11 there was a QQC, and I haven't read it close
12 enough to argue with it, but in reality, those
13 algorithms are strong guidance, but we end up, I
14 think, being able to vote as we see fit. No
15 problem. So next, gap and opportunities for
16 improvement.

17 MEMBER ANDREWS: Okay, in terms of gap,
18 they identify that in 2015, there was a
19 performance rate of 63.93, which suggests a fairly
20 strong gap in performance here. So I think
21 there's no question about what this is, something
22 that has a performance gap that's appropriate.

1 CO-CHAIR TIRSCHWELL: Was there
2 anything about disparities?

3 MEMBER ANDREWS: Oh, the disparities,
4 this is more or less the same thing we've heard
5 with lots of other things. There undoubtedly are
6 disparities people talk about, but they're not
7 identified here, which is again one of the things
8 that I think as this gets used in its trial would
9 be very appropriate for data collection.

10 CO-CHAIR TIRSCHWELL: Great. Any
11 discussion? Dorothy.

12 MEMBER EDWARDS: They're very, very
13 documented, there's a rich literature on the
14 disparities in diagnosis and actually treatment of
15 dementia in communities of color and other
16 medically underserved groups. They're just not
17 cited in this application.

18 MEMBER ANDREWS: Right, and the issue
19 of whether there are disparities in the
20 assessment, I'm not sure if they're data, I don't
21 know the data that well.

22 MEMBER EDWARDS: Yes, there are.

1 Substantial.

2 CO-CHAIR TIRSCHWELL: Great, any other
3 discussion? If not, we'll move to voting on
4 performance gap and opportunities for improvement.

5 MS. OGUNGBEMI: We are now voting on
6 performance gap for Measure 2872. The options are
7 high, moderate, low and insufficient. Voting is
8 open.

9 CO-CHAIR TIRSCHWELL: Everybody's
10 voted? All right, there we go.

11 MS. OGUNGBEMI: Voting is closed.
12 Results are 78 percent high, 22 percent moderate,
13 zero percent low and zero percent insufficient.
14 Measure 2872 passes on performance gap.

15 CO-CHAIR TIRSCHWELL: So do we talk
16 about reliability but then not vote on it? Karen?

17 MS. JOHNSON: I'm sorry?

18 CO-CHAIR TIRSCHWELL: Do we talk about
19 reliability but then not vote on it, or--

20 MS. JOHNSON: You talk about
21 reliability only in how it -- the specs go with
22 the evidence, so basically that's the only thing

1 you have to make sure of, is that the specs --

2 CO-CHAIR TIRSCHWELL: I mean, do we
3 vote? Do we take a different vote?

4 MS. JOHNSON: Yes, you do take a vote.
5 You take a vote. So it's a -- yes, on
6 reliability.

7 CO-CHAIR TIRSCHWELL: We just vote
8 whether it goes with the specs?

9 MS. JOHNSON: Yes, and there should be
10 a special slide for trial use, scientific
11 acceptability. If you look at that, there should
12 be an extra slide.

13 CO-CHAIR TIRSCHWELL: So David, can you
14 tell us about reliability as relates to the
15 evidence?

16 MEMBER ANDREWS: Yes, I misunderstood
17 because I didn't think we did vote on this, but be
18 that as it may, I accept your authority. In this
19 case then, with reliability and validity, they did
20 a Bonnie test, and I think I almost understand
21 what Bonnie tests are and how they work now.
22 Almost. And the evidence from the Bonnie tests

1 were very positive that these were both going to
2 be reliable and valid measures.

3 CO-CHAIR TIRSCHWELL: Jane, and then
4 Dorothy.

5 MEMBER J. SULLIVAN: I have a question,
6 because as I'm looking on the measure worksheet,
7 it says "reliability for this measure will not be
8 considered; the committee will not be asked to
9 vote on reliability."

10 MS. JOHNSON: My mistake; we should be
11 voting on scientific acceptability, and what
12 you're asked to vote on is do the specifications,
13 are they consistent with the evidence. So that
14 was my mistake for saying you should vote on
15 reliability for -- this is a trial use measure, so
16 even though they did do Bonnie testing, you'll
17 look at that to think about how the feasibility
18 basically is what you'll look at there. They're
19 not putting this forward as being a tested
20 measure.

21 CO-CHAIR TIRSCHWELL: So we're going to
22 pass through reliability after that great summary,

1 David, and -- sorry? Well, but you just said the
2 scientific acceptability that we have to comment
3 on is whether the specifications are in line with
4 the evidence, and that's under validity, so that's
5 all I meant by that. So you can give a yes/no
6 answer to that.

7 MEMBER ANDREWS: Yes.

8 CO-CHAIR TIRSCHWELL: Okay. Let's
9 vote. Yes, go ahead Jane.

10 MEMBER J. SULLIVAN: So I have a
11 question just about the language in -- maybe it's
12 semantics, but the way that this is written, it
13 says that the numerator statement is patients for
14 whom an assessment of cognition is performed and
15 the results reviewed. Are those two separate
16 things?

17 CO-CHAIR TIRSCHWELL: Where are you
18 exactly?

19 MEMBER J. SULLIVAN: Now I'm on the
20 numerator statement. Well that's -- I don't --
21 but do you have to have documentation of it being
22 done, and that somebody reviewed -- it just is

1 weird that it's written that way to me.

2 PARTICIPANT: So thanks for that
3 question. The assessment needs to be performed;
4 the intent is that the physician also reviews the
5 results as they see the patient and treat the
6 patient. But at the end of the day when we're
7 figuring out what actually needs the measure to
8 count, we're looking at whether or not it was
9 performed, especially given that this is an e-
10 measure.

11 CO-CHAIR TIRSCHWELL: Thank you. So e-
12 measure approval for trial use, measure
13 specifications, specifications consistent with
14 evidence, must pass.

15 MS. OGUNGBEMI: We are now voting on
16 the e-measures approval for trial use. The
17 options are high, moderate, low and insufficient.
18 Voting is open.

19 CO-CHAIR TIRSCHWELL: Whoa, that can't
20 be right. 20 votes? Somebody left. Move that
21 blue sticker away from you. Thank you. It should
22 be like 17 or something or other, right? We're

1 down to--

2 MS. OGUNGBEMI: So we are going to re-
3 vote on Measure 2872, the e-measure approval for
4 trial use. The options are high, moderate, low an
5 insufficient. Voting is open. Voting is closed.
6 Results are 35 percent high, 65 percent moderate,
7 zero percent low and zero percent insufficient.
8 The e-measure approval for trial use for Measure
9 2872 passes.

10 CO-CHAIR TIRSCHWELL: So now we move on
11 to feasibility, David.

12 MEMBER ANDREWS: So the feasibility was
13 tested with two entities, one electronic health
14 record vendor and also a national network of 30
15 post-acute care facilities, and the reports from
16 both of those activities were that this was highly
17 feasible. The data are entered and readily
18 available.

19 CO-CHAIR TIRSCHWELL: So any
20 discussion? If not, move to--oh Valerie, go
21 ahead.

22 MEMBER COTTER: Just brief, but if it

1 was tested in long term care and subacute care,
2 will it be as feasible in acute care environments
3 and in primary care practices?

4 MS. GRAY: So I can speak to that.
5 The assumption is yes, and that's because the two
6 EHR vendors that were included in the feasibility
7 assessment both allow for their products to be
8 implemented in ambulatory care settings, so urgent
9 care, physician offices, even independent living,
10 things like that, and they both have cloud-based
11 platforms that will allow for data sharing and
12 things like that. So the same data that can be
13 captured by the post-acute care network will be
14 able to be captured in ambulatory care settings.

15 CO-CHAIR TIRSCHWELL: Anything else on
16 feasibility? If not, let's vote.

17 MS. OGUNGBEMI: We are now voting on
18 the feasibility of Measure 2872. Options are
19 high, moderate, low and insufficient. Voting is
20 open. Voting is closed. Results are 47 percent
21 high, 47 percent moderate, six percent low and
22 zero percent insufficient. Measure 2872 passes on

1 feasibility.

2 CO-CHAIR TIRSCHWELL: Usability and
3 use.

4 MEMBER ANDREWS: This is currently in
5 accountability programs, it's in PQRS and also
6 meaningful use two, so it would be regarded as
7 very usable as rated by the algorithm as moderate.
8 I'd lean toward a little higher than that.

9 CO-CHAIR TIRSCHWELL: Any discussion?
10 If not, let's proceed to vote on use and
11 usability.

12 MS. OGUNGBEMI: We are now voting on
13 usability and use for Measure 2872. The options
14 are high, moderate, low and insufficient. Voting
15 is open. Voting is closed. Results are 59
16 percent high, 41 percent moderate, zero percent
17 low and zero percent insufficient. Measure 2872
18 passes on usability and use.

19 CO-CHAIR TIRSCHWELL: And so is that
20 it? Are we done, because we don't do overall
21 suitability because it's trial use? Okay. Please
22 give her a microphone.

1 DR. TERRY: I just want everybody to
2 know that at this point in time, we hope to have
3 one more--we have two more measures to go. We
4 hope to get to one, but we may not be able to
5 based on timing and a quorum. So at this point,
6 we're planning to move to 2111, and so we'll have
7 to evaluate that as we're going along, whether we
8 can get to both measures at this point. There's
9 a question.

10 CO-CHAIR TIRSCHWELL: Sounds great. So
11 let's go to 2111, are you guys PQA?

12 MS. TIERNEY: No, it's not us, but I
13 just have a quick process question. I do--we have
14 had other measures approved for trial use, and
15 they usually do take an overall vote for approval
16 for trial use. That was the vote, the vote on
17 usability? I don't believe so.

18 CO-CHAIR TIRSCHWELL: That was the
19 scientific acceptability that --

20 MS. TIERNEY: Yes, I don't want to
21 delay getting on to the next measure, but I just
22 think that that has been part of the process.

1 CO-CHAIR TIRSCHWELL: Sounds like we
2 are supposed to do it. So--

3 MS. OGUNGBEMI: So really quickly,
4 we're just going to do an overall vote just for
5 process, for approval for trial use. We are now
6 voting on Measure 2872's overall suitability for
7 the e-measure approval for trial use. Voting is
8 open. Options are yes or no. Results are
9 unanimous. The voting is closed, it's 100 percent
10 yes, zero percent no. The e-measure is suitable
11 for trial use.

12 CO-CHAIR TIRSCHWELL: Okay great. So
13 now we're going to change to Measure 2111, Anti-
14 Psychotic Use in Persons with Dementia, the
15 developer PQA please introduce yourself and then
16 briefly introduce your measure.

17 DR. EISENBERG: Thank you. I'm Woody
18 Eisenberg with PQA, and I'm joined today by my
19 colleague, Julie Kuhle. We're also joined by
20 another colleague by phone, Kristen Butterfield,
21 who would love to be here, but she's sharing the
22 worst case of laryngitis in the world with her

1 children, and I've advised her to only croak in
2 response to your questions as needed. But let me
3 just check-- Kristen are you on the line?

4 MS. BUTTERFIELD: Yes, I'm here Woody.
5 Thank you.

6 DR. EISENBERG: Thank you. Okay. So
7 we're here to re-endorse a measure initially
8 endorsed in 2012, and by way of introduction,
9 there are serious safety concerns related to the
10 use of anti-psychotic medications in the elderly
11 patients with dementia, including cardiovascular
12 complications and death. This measure includes
13 that particular very vulnerable population and
14 also includes consequences of high resource use,
15 as well as poor quality of care. This measure is
16 specified for patients 65 years or older, it
17 identifies the population of patients with
18 dementia who are at high risk of these adverse
19 events from anti-psychotic medications and
20 importantly, who do not have a documented
21 diagnosis for which an anti-psychotic agent is
22 clearly indicated.

1 Now there are some exclusions, and the
2 exclusions to the measure are the same three
3 diagnoses that are currently being used in a
4 nursing home compare measure for which the benefit
5 of anti-psychotic medications apparently outweighs
6 the potential risk. These three exclusions are
7 schizophrenia, Tourette's, and Huntington's. But
8 in developing the measure, our clinicians also
9 thought that bipolar disease should be a fourth
10 diagnosis to exclude from the measure. So the
11 measure identifies the proportion of patients at
12 high risk of anti-psychotic associated adverse
13 events in patients who do not have a diagnosis
14 code to indicate that an anti-psychotic would be
15 beneficial.

16 And while there can be appropriate use
17 of anti-psychotic drugs in persons with dementia,
18 when they're a threat to others or to themselves,
19 this should be consistent across plans, and this
20 is a measure that's intended to be used at the
21 plan level. It is not for individual providers.
22 We are not expecting zero to be the goal of this

1 measure. There will be certain members included.
2 It's a population-based measure to assess
3 utilization across Medicare plans, it is specified
4 for the data that are available at the plan level,
5 and that is medical claims and diagnoses and drug
6 claims data. The measure uses diagnostic codes or
7 medication codes to identify patients with
8 dementia because dementia is under reported.
9 Currently, this measure is being used by CMS Part
10 D for quality improvement purposes this year,
11 2016, for the first time, sending patient safety
12 reports to health plans, and they plan to start
13 using this 2016 data for display measures for the
14 Part D plan starting in 2018. So this is our
15 first use of this measure.

16 We've done some testing, pilot testing
17 by two large Medicare advantage plans using 2011
18 data showed room for improvement in performance.
19 Data across the two plans found a rate of 13.7 to
20 15.9 percent of patients--okay, okay. Then let me
21 just add that reliability testing was performed
22 because that's something that was requested during

1 the phone conference, and the testing was carried
2 out across 720 CMS Part D contracts, including
3 over 35 million beneficiaries, and the contract
4 reliability mean score was 0.76 and the median
5 0.87, which are acceptable for reliability.

6 DR. TERRY: I just have to make one
7 more statement. I just want to actually thank all
8 of the developers who have traveled here today to
9 be with us and to present their information, and
10 I wanted to say that we are aware that we will
11 probably have to move a measure at this point.
12 We'll have to see how it goes. We'll see how it
13 goes, but move a measure to a call, which we will
14 set up as soon as we can. So I just wanted to
15 thank everybody, and we wanted all the developers
16 to actually have an opportunity to at least
17 discuss one measure here that they could. So
18 thank you.

19 CO-CHAIR TIRSCHWELL: So are we
20 continuing? Okay, sorry. So Valerie, Dorothy,
21 Kelly, start with evidence.

22 MEMBER COTTER: Okay, so we'll start

1 with evidence. The only thing that we could find
2 in the literature that's been updated that was not
3 submitted is that the American Geriatric Society
4 has updated their BEERS criteria list of
5 potentially inappropriate drug use for older
6 adults, and that was just published in 2015, with
7 similar strong recommendations against anti-
8 psychotic drug use. Other than that, we were not
9 able to find any additional evidence. I think
10 this will come up further in the discussion, but
11 in our workgroup, one of the major issues for us
12 was the denominator in that it included not just
13 patients with a diagnosis of dementia, but it
14 could be a patient that did not have a diagnosis
15 of dementia but was prescribed two or more
16 prescription drugs, you know, the cholinesterase
17 inhibitors and the NMDA antagonist drug. And in
18 our mind, that is a big issue in this guideline.
19 I think we all recognize that dementia is not well
20 diagnosed as we would like it to be, but it seems
21 like we should be able to manage without that
22 proxy for a diagnosis, in this case to be able to

1 demonstrate anti-psychotic drug use in dementia
2 patients.

3 CO-CHAIR TIRSCHWELL: Any further
4 comments from the committee? Peter.

5 MEMBER SCHMIDT: So a week ago, there
6 is an FDA hearing, and I was here in the city at
7 that meeting for Pimavanserin, a anti-psychotic
8 drug that was being approved for psychosis in
9 Parkinson's patients. So there's been a body of
10 literature about that drug that has been released,
11 it was reviewed at the FDA hearing, and I will be
12 presenting in June in Berlin research on the
13 impact of quality of life for patients with
14 psychosis who go untreated with Parkinson's
15 disease. So in 2013 when we first discussed this,
16 John Duda and I both brought up Parkinson's
17 disease; we were comfortable because there was no
18 FDA indication for Parkinson's disease on an anti-
19 psychotic; that situation has now changed. There
20 is--the FDA has not yet accepted the
21 recommendations of the panel, but it was voted
22 that this drug, that Pimavanserin should be

1 approved with an indication for Parkinson's
2 disease psychosis. I'm not sure how we can leave
3 off Parkinson's psychosis from this.

4 CO-CHAIR TIRSCHWELL: Well then they
5 would also have to have a diagnosis of dementia,
6 which is not all Parkinson's disease patients
7 either, right?

8 MEMBER SCHMIDT: Well the patients in
9 the study all had at least MCI. It's a psychosis
10 requiring treatment with an anti-psychotic. It's
11 typically in more advanced Parkinson's patients.

12 MEMBER COTTER: And I'll just bring up
13 I think that is another issue here around what is
14 the diagnosis in that we're seeing more and more
15 patients with cognitive impairment or more
16 specifically, mild cognitive impairment that is
17 not dementia, being prescribed especially the
18 cholinesterase inhibitors, maybe not the NMDA
19 antagonists, but the cholinesterase inhibitors.

20 CO-CHAIR TIRSCHWELL: And so are you--
21 is the use of anti-psychotics more appropriate in
22 those patients or equally as inappropriate?

1 MEMBER COTTER: I don't know if that's
2 the right question here. I think the question is
3 should all those patients be included in the
4 denominator? And I think--

5 CO-CHAIR TIRSCHWELL: I guess that was
6 my worry about including them depends on whether
7 you think it's equally inappropriate or it's not
8 as inappropriate.

9 MEMBER COTTER: Well I don't think
10 that's the issue here because an anti-psychotic
11 could be prescribed for a patient with cognitive
12 impairment that also has depression, psychotic
13 depression, and that's inappropriate treatment.
14 Our point is that it seems like it's sort of a
15 basket in all--you know, like dementia and
16 cognitive impairment, mild cognitive impairment,
17 Parkinson's disease, lots of diagnoses that--some
18 diagnoses that may not be dementia at all that
19 could be included here.

20 MEMBER SCHMIDT: So I just want to add
21 to my comment that there are quite a few
22 Parkinson's patients who are prescribed

1 contraindicated anti-psychotics when really they
2 are incorrectly medicated. So there's a balance
3 between help and harm.

4 CO-CHAIR TIRSCHWELL: Melody, and then
5 Dorothy.

6 MEMBER EDWARDS: So dementia is a
7 generic term, not a specific diagnosis. It's a
8 generic term for cognitive impairment. I think
9 this is the challenge of this particular measure,
10 is that the black box warning is there for a
11 reason, and it's very, very important to monitor
12 the off label use, particularly the inappropriate
13 use, but getting to the denominator to figure out
14 the reliability of the measure or the validity of
15 the measure is a real challenge because we know
16 that the best attempts to create a composite
17 measure, either the ICD-9 or ICD-10 code, or the
18 prescription data actually confounded. They're
19 confounded by people with mild cognitive
20 impairment, they're confounded by individuals who
21 actually are never diagnosed and never medicated
22 with either of those drugs who are very, very

1 demented who are actually at greater risk for the
2 use of the--particularly the atypical anti-
3 psychotics. So the issue of diagnostic precision
4 is really, really important for this measure. And
5 I'm unfortunately going to have to go, but I want
6 to thank you for letting me say that.

7 MEMBER RYAN: So I'm not sure just
8 because someone has Parkinson's and dementia there
9 should be an exclusion for that person. I'm not
10 understanding that logic, because the original
11 studies were that the FDA looked at this for the
12 black box warning included all the people with
13 dementia regardless of extra diagnoses or not --
14 they were in clinical trials.

15 CO-CHAIR TIRSCHWELL: Yes, I guess
16 there's only this one medication with the
17 evidence, and maybe the black box is going to look
18 different. I don't really know. It seems like
19 they'll have to deal with that. Yes Brad, go
20 ahead.

21 MEMBER DICKERSON: But I mean if a
22 person had Parkinson's and dementia diagnoses,

1 they wouldn't be excluded, would they? It's just
2 that if they only have a diagnosis of Parkinson's
3 with psychosis, they wouldn't be included, right?

4 MEMBER RYAN: Right.

5 MEMBER DICKERSON: Yes, so if they have
6 Parkinson's with dementia, we're going to capture
7 that.

8 MEMBER RYAN: I'm just--I think Peter
9 was advocating for just Parkinson's as an
10 exclusion criteria.

11 MEMBER DICKINSON: As an inclusion,
12 right? You wanted them to be included?

13 MEMBER SCHMIDT: The question is should
14 they be in the same group with Huntington's. So
15 if you look at the ends, there probably are as
16 many people with Parkinson's and psychosis as
17 there are with Huntington's.

18 MEMBER DICKERSON: But I mean that does
19 get back to the question that Dorothy was trying
20 to ask, which is why would the developers want to
21 make this or criteria with cholinesterase
22 inhibitors? I mean I think maybe patients don't

1 have dementia in their diagnosis, and you were
2 hoping to capture more of them, but cholinesterase
3 inhibitors are being used in traumatic brain
4 injury, multiple sclerosis, a variety of
5 conditions besides just mild cognitive impairment,
6 and so I agree with Dorothy's point that that's
7 really going to pollute your ability to monitor
8 their efficacy and adverse events in the dementia
9 population.

10 MS. KUHLE: A couple of things. As
11 evidence changes, we have a systematic process
12 that we look every year at our measures to see
13 what is out there, what changes as far as
14 medications, evidence, et cetera. So we would
15 look at this new medication once it's FDA approved
16 and there's some information there. To the idea
17 of including medications, and remember this is
18 non-approved use, and medications are used as
19 diagnostic markers often. In this case, all four
20 medications are only FDA approved for dementia
21 related to Alzheimer's. We know that there is
22 some off-label use. Remember, this measure is

1 only 65 years old and older. We did do a study
2 after the last committee meeting to look at
3 traumatic brain injury, and I think it was less
4 than one percent that actually had that diagnosis,
5 and some of those also had dementia.

6 So it is complicated. It's a
7 population-based measure. And I'm going to just
8 reiterate it's not perfect, and we don't intend
9 the numerator to be zero. We don't want this
10 measure to be zero. There will be some use of
11 anti-psychotics that's appropriate, similar to
12 other measures.

13 CO-CHAIR TIRSCHWELL: I've got a
14 question, then Valerie we'll go to you. I mean if
15 it's at a population level and you're looking for
16 plans that are outliers, I guess if you're pulling
17 in the right additional people into the
18 denominator, it seems like it would still be the
19 same plans that are the outliers, whereas if
20 you're pulling--and so you're not actually getting
21 any more information, and if you're pulling in the
22 wrong people into the denominator, you may start

1 actually mis-classifying plans. So I'm not--I
2 mean I get that you're trying to increase your
3 sensitivity, but I think there's no gain, I can't
4 figure out how there's any gain in actual
5 information, and I think there's a real chance for
6 sort of misclassification.

7 DR. EISENBERG: Well, we didn't want to
8 develop a measure that would further discourage
9 clinicians from using diagnoses of dementia. If
10 we are measuring only--if we have a measure that's
11 including only those patients with the diagnosis
12 of dementia from our testing, we're probably going
13 to catch about 50 percent of the people that we
14 will catch if we use the drugs as well, and we
15 were concerned that leaving out the drugs would
16 really miss a lot and perhaps discourage further
17 diagnoses.

18 CO-CHAIR TIRSCHWELL: Because you think
19 there would then be a perverse incentive not to
20 diagnose this, because then we won't be looking at
21 what they're doing--

22 DR EISENBERG: Yes.

1 CO-CHAIR TIRSCHWELL: --over there. Is
2 there any evidence for that actually occurring?

3 DR. EISENBERG: Well, we know right now
4 that there is tremendous under reporting of
5 dementia, so that's the only evidence.

6 MEMBER COTTER: It doesn't make sense
7 to me though. As a provider, why wouldn't you
8 make the diagnosis? I mean, you're not trying to
9 hide it from the patient or from the family. I
10 mean, they ask you why you're prescribing this
11 medication; they want to know what the purpose of
12 the medication is, so--and I just wanted to make
13 another point that it's my understanding that the
14 cholinesterase inhibitors are not only FDA
15 approved for AD, but also for vascular dementia,
16 so it's broader than just Alzheimer's disease.

17 DR. EISENBERG: Yes, the measure
18 doesn't specify Alzheimer's disease. It's for
19 dementia, and to my knowledge, the studies that
20 show increased morbidity and mortality also didn't
21 specify Alzheimer's disease, it was dementia.

22 MEMBER COTTER: But when I look at the

1 list of all the diagnoses that potentially could
2 be included, the inclusive--the list, it's not
3 just dementia. It's a long list of dementia
4 otherwise specified, Alzheimer's disease, vascular
5 dementia. It's a long list of the diagnoses that
6 could be included.

7 CO-CHAIR TIRSCHWELL: Any other comments? Dorothy
8 was commenting from -- after her exit I guess.

9 All right, so I feel like we ventured a little bit
10 off of the evidence, although if we thought the
11 evidence wasn't applicable because the denominator
12 issue was a relevant conversation, but we do need
13 to vote on the evidence issue first.

14 MEMBER COTTER: Can I just make a point
15 on -- the evidence that I think we're voting on is
16 none of these patients should -- or most should
17 not be prescribed anti-psychotic drug use, but the
18 evidence I don't think that is being demonstrated
19 is how under reported dementia is.

20 CO-CHAIR TIRSCHWELL: Okay.

21 MEMBER DICKERSON: Yes, I guess can we
22 just clarify exactly what we are voting on,

1 because you know I think there is perfect -- as
2 you guys said, there is appropriate use of anti-
3 psychotic medications, and there is efficacy data
4 for them even though -- in dementia, even though
5 there's adverse event data as well. So you know,
6 I think we should be very clear about what we're
7 really voting on here.

8 CO-CHAIR TIRSCHWELL: I think what
9 we're voting on in its simplest terms, and I think
10 we'll come back to the specifications later in the
11 validity issue, but this vote is I think more
12 about whether we think there's good evidence that
13 measuring at the plan level overuse of anti-
14 psychotics might help promote interventions that
15 can lead to improved quality of care. That's how
16 I see it.

17 Do you guys -- okay with that, or you
18 want to -- that's bad, that means I'm starting to
19 talk like NQF or something. I've lost my English.
20 You know, that there's evidence I think that
21 measuring this could be part of a quality
22 improvement process based on the potential for

1 overuse.

2 (Off microphone comment.)

3 CO-CHAIR TIRSCHWELL: Yes. Sure. I'm
4 going to read a comment briefly by Dr. Ferziger.

5 In addition to schizophrenia and
6 Tourette's as mentioned, APs, anti-psychotics have
7 indications for depression, bipolar,
8 schizoaffective and autism behavior. They should
9 all be considered for exclusions to the measure.
10 It's concerning to me the measure developer was
11 not aware or did not cite diagnoses for which some
12 anti-psychotics have FDA indications, including I
13 guess Parkinson's disease as well. This is more
14 complex issue than may be apparent. Of course.

15 MS. KUHLE: So as was stated, there is
16 a measure that's being used in Nursing Home
17 Quality Compare, looking at anti-psychotic use,
18 and they only exclude three diagnoses:
19 schizophrenia, Huntington's and Tourette's.

20 And we were trying to be as compatible
21 with that measure as possible, although we did --
22 the workgroup of experts did think that bipolar

1 was also important. So we strayed from the
2 Nursing Home Compare measure by adding bipolar, we
3 did consider these other diagnoses. We know that
4 anti-psychotics can be used for them, it's the
5 risk benefit of -- and alternatives, you know,
6 similar to other medications.

7 CO-CHAIR TIRSCHWELL: Right, and as you
8 said, the goal isn't zero, it's just to identify
9 outliers on the high end where you might be able
10 to make an intervention and improve quality of
11 care. So any -- Valerie, do you want to make
12 another comment? Okay, well then put your card
13 down.

14 All right, let's vote on the evidence.

15 MS. OGUNGBEMI: We are now voting on
16 evidence for measure 2111; the options are high,
17 moderate, low and insufficient. Voting is open.

18 (Voting.)

19 MS. OGUNGBEMI: Voting is closed.
20 Results are 31 percent high, 63 percent moderate,
21 six percent low and zero percent insufficient.
22 Measure 2111 passes on evidence.

1 CO-CHAIR TIRSCHWELL: So let's move on
2 to gap.

3 MEMBER COTTER: Using the CMS Part D
4 contract data, the developer submitted that the
5 performance gap was 12.8 percent, with a range of
6 7.7 to 10 percent -- or to 19.4 percent. Sorry.
7 So there is a wide gap, a wide performance gap
8 here that I think is significant.

9 They also submitted some disparities
10 data. Let's see, again, those residents residing
11 in a nursing home facility and showed that those
12 who resided there longer than 100 days had a mean
13 rate of 10.8 percent -- I'm sorry, the nursing
14 home had a rate of 23.9 percent. So the
15 preliminary rating is for moderate, opportunity
16 for improvement.

17 CO-CHAIR TIRSCHWELL: Any discussion
18 from the group? Further comments from the
19 developer? Let's go ahead then and vote on
20 importance -- excuse me -- performance gap.

21 MS. OGUNGBEMI: We are now voting on
22 performance gap for measure 2111; the options are

1 high, moderate, low and insufficient. Voting is
2 open.

3 (Voting.)

4 MS. OGUNGBEMI: Voting is closed.
5 Results are 13 percent high, 88 percent moderate,
6 zero percent low and zero percent insufficient.
7 Measure 2111 passes on performance gap.

8 CO-CHAIR TIRSCHWELL: Let's move on to
9 reliability.

10 MEMBER COTTER: The developer submitted
11 updated testing, again from CMS Part D contract
12 data, and the testing was done at the measure
13 score level. I think you actually presented that
14 at your beginning of the presentation, wasn't it?
15 So I don't know that we need to hear that again,
16 or that I need to present it again.

17 CO-CHAIR TIRSCHWELL: Maybe just recap
18 it real quick.

19 MEMBER COTTER: So I think what's been
20 presented is that the updated reliability data is
21 sufficient. It was originally preliminarily rated
22 as insufficient, but we would say it is sufficient

1 probably at the moderate level.

2 CO-CHAIR TIRSCHWELL: Okay. Anybody
3 have any questions or comments about that? Seeing
4 none, we'll proceed to voting.

5 MS. OGUNGBEMI: We are now voting on
6 reliability for measure 2111; options are high,
7 moderate, low or insufficient. Voting is open.

8 (Voting.)

9 MS. OGUNGBEMI: Voting is closed.
10 Results are zero percent high, 100 percent
11 moderate, zero percent low and zero percent
12 insufficient. Measure 2111 passes on reliability.

13 CO-CHAIR TIRSCHWELL: Validity.

14 MEMBER COTTER: So the developer
15 presented on face validity that was reviewed by an
16 expert panel, and it was a vote of 67 percent in
17 favor of the endorsement. So it looks like all we
18 have is the face validity I believe.

19 I think the threats to validity in this
20 particular measure are not insignificant, and I
21 think we discussed those at the beginning. In
22 such a large, broad denominator that you're going

1 to be capturing some patients that do not have
2 dementia and are prescribed these cholinesterase
3 inhibitors and NMDA antagonists and an anti-
4 psychotic, and I think that is a significant
5 validity threat. Now the preliminary rating for
6 validity is moderate.

7 CO-CHAIR TIRSCHWELL: Does anybody have
8 any comments? So the whole discussion about the
9 denominator I think is what is a little bit more
10 about what we're voting for than it was earlier in
11 the evidence. Jim, go ahead.

12 MEMBER BURKE: I think this is kind of
13 like the hospital care compare question from
14 earlier is ultimately, do we know how these data
15 are going to be reported? Because I think a lot
16 of these distinctions about who should exactly be
17 in the denominator are worrisome if it's called
18 we're going to make subtle distinctions and report
19 lots of difference as opposed to culling out
20 outliers that are two standard deviations above
21 the mean. Do we know once these data exist, how
22 they're going to be used?

1 MS. KUHLE: I can respond to that.
2 We've had discussions with CMS, they are reporting
3 it to plans in their patient safety reports for
4 quality improvement only. So you know, I think
5 when we develop measures, our members go right to
6 this measure is going to be used in the star
7 rating program, and there is no indication.

8 In fact, there's indication from CMS
9 that they will not ever move this to a
10 performance-based measure for payment. Rather, it
11 is quality improvement, it is virtually patient
12 safety and quality improvement for the plans to
13 react to.

14 CO-CHAIR TIRSCHWELL: Thank you. Any
15 other comments or questions before we vote on
16 validity? Seeing none, I say we vote.

17 MS. OGUNGBEMI: We are now voting on
18 validity for measure 2111; options are high,
19 moderate, low and insufficient. Voting is open.

20 (Voting.)

21 MS. OGUNGBEMI: Voting is closed.
22 Results are zero percent high, 81 percent

1 moderate, 19 percent low and zero percent
2 insufficient. Measure 2111 passes on validity.

3 CO-CHAIR TIRSCHWELL: All right then,
4 feasibility.

5 MEMBER COTTER: This seems to have high
6 feasibility, it's -- the data is easily collected
7 in the electronic claims. So we didn't have an
8 issue about the feasibility, and the preliminary
9 rating is high.

10 CO-CHAIR TIRSCHWELL: Any discussion?
11 If not, let's move to vote.

12 MS. OGUNGBEMI: We are now voting on
13 the feasibility of measure 2111; options are high,
14 moderate, low and insufficient. Voting is open.

15 (Voting.)

16 MS. OGUNGBEMI: Voting is closed.
17 Results are 69 percent high, 31 percent moderate,
18 zero percent low and zero percent insufficient.
19 Measure 2111 passes on feasibility.

20 CO-CHAIR TIRSCHWELL: Usability and
21 use.

22 MEMBER COTTER: So at this point, it's

1 not publicly reported or in any accountability
2 program. As was said, there's planned use.

3 I guess there's one question here about
4 if current programs are not adopting the measure
5 since its initial endorsement, and there's no data
6 to demonstrate improvement, why isn't it being
7 used? I mean that -- is it a usability issue why
8 programs are not adopting the measure?

9 MS. KUHLE: Sure. So, good question.
10 This measure is really suited to CMS Part D, I
11 mean that's basically where it was developed for.
12 We also developed an MDS measure that's very
13 similar, and there was a lot of interest by
14 Nursing Home Compare.

15 So they did some testing with RTI, they
16 were very interested in the measure. Part D was
17 waiting for Nursing Home Compare, the nursing home
18 side of CMS to decide whether they were going to
19 use that measure; that one wasn't endorsed. This
20 is all to say that there was just a gap; one part
21 was waiting for the other hand of CMS to decide
22 what to do with the measure. The Nursing Home

1 Compare measure didn't go forward, so CMS decided
2 really in 2015 to start using this. They haven't
3 noticed -- they have to give notice to plans, so
4 there's a time lag even once they decide to use a
5 measure before it actually is used.

6 MEMBER COTTER: Thank you.

7 MS. KUHLE: Sure.

8 MEMBER SCHMIDT: So I just want to
9 bring up again under the category of unintended
10 consequences that we are on the edge of approving
11 a measure that would recommend against on-label
12 use of medication, which seems like a conflict
13 that I wouldn't want to be involved in.

14 CO-CHAIR TIRSCHWELL: And by that, you
15 mean in the -- some of the potential better
16 denominator exclusions groups, if we were to add
17 some more exclusions, they might get roped in and
18 so there's some appropriate use might get bungled
19 in with some of these numbers?

20 MEMBER SCHMIDT: Well, it sounds like
21 Michael also has some items that could be included
22 in this, too. It would be interesting to review

1 the label for anti-psychotic medications and make
2 sure that we are addressing on label use of
3 medications so that we don't adopt a measure where
4 if I have a choice between using chemical
5 restraints on a difficult patient and treating
6 troublesome hallucinations in another, that given
7 that choice, that I'm not biased -- you know, I
8 don't make my choice based on what is more
9 convenient for the center, but what is on-label
10 use and what has evidence.

11 CO-CHAIR TIRSCHWELL: Yes, do you want
12 to respond?

13 MS. KUHLE: I will respond to that. I
14 think this is one of the reasons that CMS only
15 wants to use it for quality improvement. We don't
16 -- so there are some unintended consequences even
17 with the high-risk medications in the elderly, and
18 CMS has now taken that from a star rating
19 performance measure where there's a big push by
20 plans to decrease that rate, and have moved it now
21 just to a display measure -- just to a displayed
22 measure where they're just reporting it. And I

1 think part of that is this notion that not to move
2 towards zero -- too close to zero. Maybe that
3 addresses your point.

4 DR. EISENBERG: And again as was raised
5 earlier, all of our measures are reviewed every
6 year by our measure update panel, and new
7 indications or perhaps existing indications that
8 were not -- did not receive adequate attention can
9 be addressed.

10 CO-CHAIR TIRSCHWELL: Great. Melody?

11 MEMBER RYAN: So the way I understand
12 that the new likely candidate that would be
13 approved is it would be for psychosis only related
14 to Parkinson's. So these patients wouldn't
15 necessarily be demented, right? I mean, we don't
16 have any reason to think that you know, that
17 treating with this drug in dementia is necessarily
18 appropriate?

19 MEMBER SCHMIDT: So the psych -- about
20 a third of patients with Parkinson's disease will
21 develop psychosis during the course of their
22 disease; it works out to maybe 300,000 people.

1 Psychosis that is -- that occurs early in the
2 disease is typically due to incorrect medication;
3 psychosis that occurs late in the disease is
4 commonly comorbid with dementia and requires
5 treatment with an anti-psychotic.

6 MEMBER RYAN: So again, I would say
7 that the dementia studies didn't exclude
8 Parkinson's patients in the anti-psychotic use for
9 the agents we have now. I don't know that we can
10 say for an agent we don't have now yet that we can
11 base our conversation on it.

12 CO-CHAIR TIRSCHWELL: And I just heard
13 the developer say that they are committed to being
14 nimble and responding to changes in the market,
15 so.

16 MEMBER SCHMIDT: But the evidence is
17 there, I mean this is not -- quetiapine, Clozaril
18 have all been tested and there is evidence for
19 Clozaril ambiguous with clozapine, quetiapine for
20 -- in Parkinson's disease, but this is not
21 something without evidence.

22 MEMBER JONES: So there's lots of data

1 going in, this is a population I would say the
2 number of patients who are over 65 whose
3 Tourette's is being treated with anti-psychotics
4 is probably minuscule. Somebody raised autism,
5 although the autism population is large, in the
6 over 65, they are tiny.

7 So if you're going to re-evaluate this
8 on a regular basis, some of these populations can
9 go in and out. Right now, I think you've got a
10 lot of the major populations that you need and in
11 large enough numbers, a lot of these smaller
12 groups that we're talking about -- perhaps not the
13 Parkinson's population, but a lot of these other
14 ones are going to be a wash.

15 CO-CHAIR TIRSCHWELL: I'm going to --
16 is David going to be back? Okay, well I'm just
17 hearing the same arguments going around, and more
18 and more people are getting ready to leave, so I'm
19 going to suggest, unless somebody has a different
20 comment, that we go ahead and vote on usability
21 and use.

22 MS. OGUNGBEMI: We are voting on

1 usability and use for measure 2111; options are
2 high, moderate, low and insufficient. Voting is
3 open.

4 (Voting.)

5 MS. OGUNGBEMI: Voting is closed.
6 Results are 19 percent high, 75 percent moderate,
7 six percent low and zero percent insufficient.

8 CO-CHAIR TIRSCHWELL: And then one
9 final vote --

10 MS. OGUNGBEMI: Usability and use
11 passes for measure 2111, and now we are going to
12 vote on the suitability for endorsement for
13 measure 2111. Voting is open.

14 CO-CHAIR TIRSCHWELL: Thank you.

15 (Voting.)

16 MS. OGUNGBEMI: Voting is closed. We
17 have a unanimous 100 percent overall suitability
18 for endorsement for measure 2111. Thank you.

19 CO-CHAIR TIRSCHWELL: Thank you very
20 much. Thank you, and I apologize Woody for
21 cutting you off at the beginning. We might not
22 have made it.

1 Yes, we're going to open the
2 microphone. Operator, if you could open the mic
3 for public comment.

4 OPERATOR: And at this time, if you
5 would like to make a public comment, please press
6 star, then the number one on your telephone
7 keypad.

8 (Pause.)

9 OPERATOR: And we have no public
10 comments at this time.

11 CO-CHAIR TIRSCHWELL: Anybody else?
12 Any comments back there? Okay, thank you. All
13 right, now we only have about an hour more of
14 agenda items. Do -- I don't know, Christy, do you
15 want to take us through the next steps?

16 MS. SKIPPER: Yes, so first of all,
17 thank you all for hanging in there with us as we
18 sort of pressed up to the hour, but just a couple
19 of next steps for activities on this project.

20 So we will be having a post-meeting
21 call on April 22 from 1:00 to 3:00 p.m. Eastern
22 Time, where we will need to have a vote for the

1 measure that we did not get to today. And then
2 between now and the end of the month, our team
3 will be working to draft a report documenting the
4 proceedings of this meeting, and then it will be
5 posted for a month beginning on May 6 for public
6 and NQF member comment.

7 On June 23, I will have a standing
8 committee call to review and respond to comments
9 that were made based on the report of this
10 meeting, and then we'll incorporate your comments
11 and then also draft another report for NQF member
12 vote on July 6, and they'll have from July 6 to
13 July 20. And then recommendations will go to CSAC
14 for review and approval on August 9, and then to
15 the Board September 15 for endorsement.

16 And then appeals will open April 19th
17 -- or I'm sorry, August 19 and run for a month
18 through September 19. And just -- and then also
19 we will need to -- for those of you that are here,
20 we need to assign term limits as standing
21 committee members, so we'll quickly have everyone
22 draw a number from our magic bowl down here and

1 whatever number you pull will be your term
2 assignment.

3 And then also you may elect yourself to
4 one other term following this term, and that term
5 is three years. And if there is a problem with
6 any term number that you pull, just please let us
7 know. And then we'll have you announce your
8 number out loud for the group so that we can
9 record what your term is.

10 PARTICIPANT: Can you explain that
11 second statement?

12 MS. SKIPPER: So ---

13 PARTICIPANT: I understand the number
14 --

15 MEMBER SCHMIDT: Peter Schmidt, two.

16 MS. SKIPPER: Was that it? Did that
17 answer your question? So you may elect yourself
18 or nominate yourself to serve another term
19 following this term that you will be randomly
20 choosing today.

21 (Off microphone comment.)

22 DR. TERRY: I just wanted to thank

1 everybody, in particular our co-chairs, for really
2 a wonderful meeting, and thank you everybody and
3 thank you for hanging in there. It's really been
4 very good. So thank you.

5 MS. SKIPPER: Yes, for those of you on
6 the phone, we will have NQF draw a number on your
7 behalf. So to Kelly and Michael, we will be
8 pulling for you.

9 MEMBER COTTER: Valerie Cotter, number
10 two.

11 MEMBER ANDREWS: David Andrews, three.

12 MEMBER HUFF: Steve Huff, two, subject
13 to the American College of Emergency Physicians.

14 MEMBER JONES: Charlotte Jones, three.

15 MEMBER BURKE: Jim Burke, two.

16 MEMBER JONES: Because it's going to
17 take me three years to learn how to use the mic.

18 MEMBER LINES: Lisa Lines, three.

19 MEMBER RYAN: Melody Ryan, two.

20 CO-CHAIR KNOWLTON: Dave Knowlton,
21 three.

22 MS. SKIPPER: Jocelyn Bautista, two.

1 Michelle Camicia, three. Dorothy Edwards, two.
2 Reuven Ferziger, three. David Hackney, two.
3 Michael Kaplitt, three. Ronald Koenig, two. Alex
4 Rae-Grant, three. Jane Sullivan, two. Kelly
5 Sullivan, two. And --

6 MS. ISIJOLA: Well thank you again,
7 everyone. We appreciate your hard work and
8 flexibility with keeping with us until after
9 three. We have a ton of next steps, and we'll
10 definitely send out details of that.

11 A lot of the information today will be
12 compiled in a report for public commenting, and
13 many of the discussion that we have had and the
14 gray zone will be discussed during that public
15 commenting post-call. So please look out for
16 emails and have a safe travel back home.

17 (Whereupon, the above-entitled matter
18 was concluded at 3:24 p.m.)
19
20
21
22

A			
a--on 266:10	accountable 54:3 64:20	addressing 245:10	257:19
a.m 1:9 5:2 106:16,17	69:16 74:6 234:4	256:7 346:2	affectionately 245:8
AAN 246:12 256:14	accounted 114:13	adds 194:10 206:13	AFib 9:6
269:19 270:3 273:7	accounting 111:2	adequate 17:8 121:21	afraid 290:5
275:13	121:21 122:3 160:16	122:12 156:22 347:8	African 29:11,17
AAN's 246:3	165:17 174:14 180:20	adequately 114:13	170:15,21
abbreviations 93:16	accuracy 35:14 132:11	121:14 123:10 157:22	African- 127:1
ability 159:19 218:6	accurate 35:21 87:15	202:4,15	African-Americans
264:18 272:17 298:9	132:13 170:20 202:20	Adjourn 4:22	172:1 173:9
298:18 330:7	209:16	adjudicate 197:11	afternoon 297:18
able 59:7 68:14 109:2	accurately 132:4	211:1	age 11:14 53:12 82:6
109:22 110:3,11	achievement 232:7	adjudicated 208:12	99:13 155:10,21
133:17 168:6 173:18	achieving 64:6 102:21	adjudication 177:9	172:18 174:3 216:13
179:4 184:19,22	251:6	adjust 121:14 164:2	216:22 235:21 238:14
257:12 276:18 277:4	acid 263:15,22	174:6 197:17	239:13 245:11
307:14 315:14 317:4	acknowledge 15:20	adjusted 19:18 29:16	aged 226:13
323:9,21,22 337:9	acknowledged 55:16	58:21,22 136:18,19	agenda 351:14
above-entitled 106:15	acquisition 209:18	139:8 155:4	agent 319:21 348:10
243:22 355:17	ACRS 280:7	adjuster 159:22	agents 348:9
absence 69:17 74:6	act 98:12	adjusters 196:2	aggregate 29:6 166:16
166:13,17	actively 17:13 49:21	adjusting 54:10 165:22	aggressive 172:2,4
absent 76:20	activities 43:9 314:16	adjustment 13:7 27:10	178:11 217:14
absolute 18:21 26:7	351:19	27:18 28:2 107:3	ago 108:14 111:11
absolutely 18:18	actual 94:4 102:9	109:1 122:12 135:8	133:19 324:5
132:19 157:8 178:9	136:20 192:6 216:12	139:17 156:11,22	AGPCNP-BC 1:19
305:6	332:4	160:21 175:7 177:8	agree 17:11 20:20 23:6
abstract 38:16 41:5,13	acute 10:2 11:7 19:20	190:19 191:15	26:15 37:4 44:8 49:1
abstracted 133:5 207:6	20:7 23:16,19 25:2	administered 9:12	49:19 57:8,20 58:18
abstracter 202:12	49:22 52:20 107:2	administration 25:19	64:18 69:16 74:4
abstracting 38:21	187:14 218:8 235:17	administrative 3:2 40:1	76:13 86:10 97:16
abstraction 33:11	237:3 315:2	admission 88:19 89:3,4	98:1 105:2 133:15
39:13 41:16 94:3 95:9	acutely 20:6	168:19	165:18 175:5,11
149:17 202:17	AD 333:15	admissions 88:14	248:13 289:2 305:6
abstractors 40:1 92:13	adapted 257:18	admitted 11:18 29:11	305:14 330:6
abuse 267:11	add 22:11 56:14 61:20	53:13 84:9,9 142:7	agreed 83:14 92:15
academic 132:14	132:5 186:16 193:21	163:1 205:13	228:13,13 267:16
Academy 3:10,15	209:19 210:1 227:5	admitting 82:12	293:15
244:18 245:3,4 275:5	248:12 270:20 321:21	adopt 346:3	agreement 7:7 33:19
275:7	326:20 345:16	adopting 344:4,8	34:8 92:12 199:20
accept 310:18	added 89:3	adult 235:13 238:9,22	204:11 225:16 228:6
acceptability 301:11,17	adding 112:10 337:2	adults 226:13 236:13	253:11
310:11 311:11 312:2	addition 149:9 192:1	282:18,18 289:5	aha 12:19 184:22 185:2
317:19	194:17,18 336:5	323:6	228:9
acceptable 64:19	additional 62:20 111:6	advance 245:4	AHA/ASA 214:16 219:5
148:22 199:17 322:5	129:12 131:11 132:6	advanced 1:19 193:14	ahead 32:14 34:15 38:6
acceptance 23:8	195:7,22 210:1 219:8	325:11	40:13,20 42:3 44:16
accepted 10:22 43:14	261:16,20 264:19	advantage 131:12	45:12,14 50:22 51:1
52:11 72:16 76:15	267:21 270:11 272:5	152:9 153:2 321:17	55:7 60:6 61:2,6,19
195:6 234:9 275:17	273:5 277:6 323:9	advantages 15:3 26:1	63:8 65:6,17 67:11
324:20	331:17	adverse 319:18 320:12	79:9 89:19,19 91:17
accepting 200:1	additionally 256:14	330:8 335:5	105:14 121:2 131:5
access 87:3 232:21	address 35:10 134:9	adversely 208:9	134:15 179:6 181:19
258:3 270:3	179:9 226:11 229:17	advised 319:1	196:22 197:19 200:4
accompanying 161:2	250:8 271:14 290:17	advisor 1:12 275:8	204:2 206:4 207:12
account 160:12 181:5	addressed 96:3 199:15	advocating 329:9	210:5 211:6 220:6
accountability 96:5	246:11 284:10 302:18	affairs 2:3 299:1	233:3 247:10 276:8
232:6 316:5 344:1	347:9	affect 120:12 121:18	303:1 306:17 312:9
	addresses 347:3	208:9 245:17 257:15	314:21 328:20 338:19

341:11 349:20	170:21 214:3,10	325:10 326:10 334:17	177:8 217:18 239:7
aim 28:13 94:18	244:18 245:2,3 275:5	336:17 346:1 348:5,8	248:17 267:16 289:8
aiming 78:16	275:7 279:21 295:2	anti-psychotics 325:21	289:12 307:22 308:9
albeit 53:22	323:3 354:13	327:1 331:11 336:6	320:16 325:21 331:11
alerts 276:15	Americans 29:17	336:12 337:4 349:3	335:2 345:18 347:18
Alex 69:12 70:12	113:16 127:2	anti-seizure 264:1	appropriately 54:7
213:16 218:16 223:15	AMI 192:17	anticipation 295:4	appropriateness 106:2
240:17 355:3	amount 153:1 159:7	anticoagulation 9:6	281:13
ALEXANDER 2:12	Amy 3:10 245:1 268:6	Antipsychotic 4:16	approval 302:5 313:12
Alexandra 3:4 60:13	analyses 173:6	antithrombotic 8:11 9:2	313:16 314:3,8
algorithm 14:9 36:2	analysis 170:15 219:12	ANUP 3:15	317:15 318:5,7
56:9 60:9,18 69:13,14	225:12 233:8 234:20	anybody 21:11 46:8	352:14
88:19 89:5 117:3,4,6	272:10 273:5	48:5 146:21 208:20	approve 45:21
158:17,22 160:21	Analyst 3:4,5	227:13 252:3 296:21	approved 16:14 247:14
272:15 316:7	analyze 226:21 235:2	302:13 340:2 341:7	282:13 317:14 324:8
algorithmic 205:22	anatomic 281:6	351:11	325:1 330:15,20
algorithms 100:17	ancient 51:3	anymore 124:22 283:13	333:15 347:13
255:8,9 307:13	and-- 275:21	289:2	approving 45:22
aligned 268:9	Andrews 1:12 250:19	anyone's 277:1	345:10
alive 164:6 169:18	251:10,12 301:19,21	anyway 26:12 77:6	approximately 38:21
170:1	302:4 303:18 307:17	170:6	251:14 267:18
all--you 326:15	308:3,18 310:16	apart 78:12 116:2	April 1:5 351:21 352:16
all-cause 107:1	312:7 314:12 316:4	aphasia's 25:6	APs 336:6
all-payor 153:7	354:11,11	aphasic 217:20	arbitrarily 72:9
Alliance 3:12	anecdotally 24:16	apologize 17:4 70:3	arbitrary 15:18 16:1
allow 14:19,20 19:14	aneurysm 80:16 84:10	272:18 350:20	187:21
66:21 71:8 282:2	84:20 100:9 101:1	app 189:12	area 15:22 153:2 300:7
315:7,11	angiogram 280:16	apparent 336:14	areas 97:9
allowable 61:21 62:20	angiographic 281:1	apparently 320:5	argue 16:11 21:9,11
allowed 16:17	285:13	appeals 352:16	58:20 193:5 307:12
allowing 16:16 286:21	angiography 286:18	appear 186:1	argued 48:3 85:14
287:3	ANN 3:2,5,17	appearance 100:14	254:8
alluded 112:21 125:12	announce 353:7	appears 117:3	arguing 252:18
133:8 154:22	announced 267:20	applaud 111:9	argument 49:20 154:9
alpha 138:5,6 148:20	annual 246:8 297:18	apple 254:12	154:15 158:19 171:6
Alright 94:19 176:18	298:4 300:9 303:4,7	applicable 281:21	252:18 267:9
225:5 243:20	304:15,18	334:11	arguments 56:21 74:15
also--there's 284:12	answer 104:15 117:18	application 144:20	97:1 349:17
alter 254:19	118:6 126:20 128:7	193:9 308:17	arrival 10:8 11:11,17,21
alterations 100:1	138:19 144:15 150:22	applied 137:20 149:5	18:4,4 19:13 24:22
alternate 283:15	212:20 226:14,16,17	234:18 240:6 283:17	47:4,19 50:19,19 81:2
alternative 15:13 16:12	235:9 285:4,5 312:6	283:18	82:9,10 85:22 86:6
16:16 84:7 93:16	353:17	applies 65:11 98:3	89:13 99:21 215:9
217:6	answering 137:9	168:4 298:5 299:7,19	216:17 219:8 220:14
alternatives 337:5	answers 287:8	apply 47:7 48:6 97:4	arrivals 29:17 88:15
Alzheimer's 300:6	antagonist 323:17	128:9 220:15 235:16	arrive 11:4 20:8,10 81:9
330:21 333:16,18,21	antagonists 325:19	240:7	arrives 100:6
334:4	341:3	applying 46:5	arriving 224:7 236:19
ambiguous 348:19	antecedent 46:16	appreciate 355:7	art 201:13
ambulance 235:10	Anthem 2:10	approach 12:15 72:12	arterial 82:13
ambulatory 299:20	anti- 250:22 251:21	145:5 156:16 162:17	article 55:10,14,15
315:8,14	318:13 323:7 324:18	165:20 186:5 190:18	articulate 56:17
amenable 101:7	328:2 335:2,13 341:3	193:4 241:7 299:16	artifact 222:12
amended 88:17	anti-epileptic 253:19	approaches 16:9	ASIA 44:11
American 3:10,11,15	anti-epileptics 252:14	183:22	aside 125:9 168:20
3:16 10:19,20 12:8	anti-psychotic 319:10	appropriate 13:2 27:19	192:16
29:11 52:16,17,18	319:19,21 320:5,12	54:8 64:12 81:18,22	asked 76:18 134:18
83:6,7 132:9 170:15	320:14,17 324:1,7	110:14 122:16,17	194:7 261:8,16

268:16 287:20 311:8
311:12
asking 61:11 77:4
101:16 119:13 144:4
264:3 285:6,8 286:1
asks 60:9
aspect 264:16 285:11
aspects 250:10
aspirate 165:13
aspirin 184:12
assess 111:3 144:10
145:8,9,14 157:2
167:3 168:6 199:11
302:13 321:2
assessed 9:8 20:9,11
35:13 73:10 93:6
132:22 149:19
assesses 81:17 108:6
153:1
assessing 12:15 52:12
100:16 121:9 186:5
302:11 303:6
assessment 4:18 13:21
20:17 23:15 64:2
69:10 73:22 74:18
75:20 76:18 83:15
85:13 100:5 137:6
149:17 268:1 273:8
296:14 297:22 298:4
298:6 300:10 302:14
308:20 312:14 313:3
315:7
assessments 300:7
assign 25:12 352:20
assigned 208:13
275:15
assignment 353:2
Assistant 1:13 2:16
Associate 1:15,20 2:8,9
2:15
associated 115:2
170:16 216:10 298:16
320:12
association 10:20,21
12:8 37:8 52:18,18
116:13 117:10 118:13
213:16,16 214:3,10
assume 13:14 115:17
155:22 236:12 268:12
assumes 139:18
162:17
assuming 207:3 271:11
assumption 139:22
142:21 157:9 163:5
315:5
assured 5:7
asymptomatic 288:22
289:6,10,11 290:4,12

atherosclerosis 289:5
atherosclerotic 283:19
283:22
atrocities 50:2
attached 203:5
attempt 175:3
attempts 72:5 327:16
attention 74:10 186:11
347:8
atypical 328:2
audience 243:17
audit 132:7
August 352:14,17
authority 310:18
autism 336:8 349:4,5
available 14:16 30:9
32:2 48:18 64:7,13
99:18 100:5 101:13
101:15 157:17 175:9
194:5,13 269:14
314:18 321:4
average 40:3,4 41:1
87:22 142:7
averaged 38:17
avoid 169:11,22 304:22
award 232:7
aware 109:3 134:7
322:10 336:11
awfully 266:5
Axon 246:3,3 275:8,17
275:19 277:2
aye 293:17

B

B 83:7
baby 249:7
back 5:3 7:5 50:5 58:9
61:11 62:15 63:7
94:15 103:6 120:6
125:10 128:15 132:9
135:17 138:5 144:14
144:19 162:12 168:15
174:10 177:15 185:15
185:19 186:19 190:8
221:12,18 229:20
243:2,17 255:9
271:20 276:8 277:22
329:19 335:10 349:16
351:12 355:16
backgrounds 208:17
backing 75:11
backwards 178:8
bad 101:3 113:13,14,15
131:4 160:8 213:2
240:15 254:13 275:14
335:18
badly 164:14 218:19
balance 56:22 327:2

bar 117:3,8,17,19 118:2
119:16 120:5 124:12
179:3
base 1:15 75:8 348:11
based 56:8,9 60:16
70:5 73:4,9 75:5
83:11 85:12 88:15
90:14 100:5 102:2
103:2,5 147:16 158:5
187:17 193:16 214:20
227:5 237:4,5 239:7
256:19 266:14 268:4
268:22 272:9,14
273:7 281:1 290:21
291:3 299:18 317:5
335:22 346:8 352:9
baseline 54:10
basic 190:18 284:7
basically 39:19 67:2
100:13 118:7 119:12
125:13 139:8 219:1
247:20 305:10 309:22
311:18 344:11
basing 49:11
basis 18:1,6 23:4
285:14 299:9 303:7
349:8
basket 326:15
battery 305:19
Bautista 1:13 50:15
58:10 59:11 67:12
73:15 201:6 247:8,11
249:13 253:16 254:8
260:8 261:4,22
354:22
be--there 269:2
be--would 276:16
bears 112:18 113:2
114:16
becoming 73:7
BEERS 323:4
beginning 17:18 171:7
339:14 340:21 350:21
352:5
behalf 28:15 214:10
245:3 354:7
behavior 336:8
behavioral 299:22
behaviors 254:19
belabor 161:6 186:13
216:11
believe 8:13 60:21 61:1
170:19,21 182:7
249:15 271:11 272:14
279:22 289:2 317:17
340:18
bench 275:20
benchmarking 232:7

beneficial 64:19 74:5
248:15 320:15
beneficiaries 322:3
benefit 44:4 69:18
74:12 236:18 282:21
320:4 337:5
benefits 73:21 74:1
benefitting 26:3
Bennett 3:10 245:1,1,8
246:19 251:14 256:11
261:15 262:8,20
263:20 264:5,7,10,14
265:2 267:6 269:10
269:19 272:21 276:3
Berlin 324:12
Bernheim 3:10 107:14
107:15 108:3 121:3
131:6 137:7,14 140:3
140:6 144:12 147:6,9
147:15 150:8,17
151:1,8,12,22 152:20
156:8 159:1 166:21
174:9 176:11 179:7
181:11 190:15 195:22
201:12 203:4,8,22
204:6 205:4 206:3
Bernstein 148:16
best 21:10 25:7 71:13
87:7 137:10 164:6
186:1 239:22 276:15
327:16
Beth 2:4
better 19:19 22:15 23:2
37:5 63:12,13,13
77:21 87:19 122:14
124:20 129:17 135:1
137:9 150:2 188:3
204:16 219:10 249:19
250:15 305:11 345:15
beyond 53:2 75:13
187:11 217:16 298:8
bias 234:22
biased 346:7
biases 152:7
big 31:19 71:6 113:10
114:14 116:9 121:3
126:20 127:2,3
135:19 136:5 160:15
161:11 162:12 166:2
166:20 172:19 178:18
180:18 182:21 251:4
251:10,12 323:18
346:19
bigger 49:3 162:16
165:9 251:8
biggest 50:2 108:14
biostatistician 31:1
bipolar 320:9 336:7,22

337:2
birth 251:19 252:1
 255:21 263:14 271:14
bit 17:15 22:15,20
 43:12 60:12 72:21
 85:16 96:15 100:20
 115:16 126:22 128:15
 149:4 171:13 178:3
 197:5 201:14 204:21
 244:5 245:7 251:8,10
 251:12 255:6 275:9
 334:9 341:9
black 224:6 327:10
 328:12,17
blacks 29:14
bleed 104:10,21
bleeding 99:16 221:1
block 76:14,16 77:6,17
 77:19
blood 99:14,15 155:10
 192:3,3,7 193:22
 217:22
blue 313:21
Board 352:15
bodes 112:18
body 36:13 102:5 324:9
Bonnie 310:20,21,22
 311:16
book 181:13
boot 58:19
bootstrapping 148:2,7
Borson 3:11 297:9,11
 297:14,15,17 300:19
 300:21
bother 97:14
bothersome 48:13
bottom 60:8,18 124:10
 124:20 198:2
bowl 352:22
box 78:21 79:6 327:10
 328:12,17
BP 73:10,11
Brad 282:8,10 304:8
 328:19
BRADFORD 1:20
brain 82:13 99:14 100:1
 263:1 282:18 330:3
 331:3
break 68:14 106:12,13
 106:14
breaking 213:7
breast- 272:3
breast-feeding 263:12
 264:2 265:7
brief 12:3 41:21 96:14
 108:4 246:15 314:22
briefly 5:16 48:12 179:7
 318:16 336:4

bring 7:4 72:16 109:2
 123:12 129:11 170:12
 230:4 243:2 305:16
 325:12 345:9
bringing 169:1
brings 15:10 50:5 247:3
broad 78:16 114:11
 287:10 299:11 340:22
broad-reaching 111:20
broadcast 72:20,20
broader 32:2 109:5
 144:17 165:9 201:20
 290:16 333:16
broadly 165:16
brought 108:13 199:8
 324:16
build 156:19 201:16
built 125:22
bulk 112:17
BULSARA 1:15 15:9
 49:18 83:19 86:9 87:5
 89:7 91:1,14 176:20
 197:1 198:10 199:5
 208:4 209:12 210:18
bunch 39:3 56:20 113:9
 136:15 158:10
bungled 345:18
burden 39:12 41:2
 61:11,15 68:18,20
 69:6,9 71:12 74:21
 118:16 178:16,19,22
 196:19 234:8 236:17
 236:21 237:8,9,11
 240:1 264:19
burdens 206:13
burdensome 54:1
Burke 1:17 56:15 58:17
 78:1 112:14 118:11
 125:8 127:21 129:20
 133:2,13 134:12
 135:14 136:13 137:1
 139:2,21 140:5,8
 142:13 150:4 151:10
 152:3 154:7 158:9
 160:4 163:10 165:7
 171:3 177:19 182:11
 183:12 186:12 203:1
 205:17 221:4 265:20
 266:1 341:12 354:15
 354:15
Burleson 3:11 279:20
 279:20 280:11,13
bust 259:7
Butterfield 3:12 318:20
 319:4
button 306:22
buttons 276:11

C

c 112:2,3 152:16 154:18
 159:18 193:3 255:12
C-O-N-T-E-N-T-S 4:1
calculate 93:17 99:20
 148:20
calculated 6:21 33:19
 33:21 99:4,21,22
 105:1 137:19 149:15
calculating 283:15
calculation 208:14
 273:5 280:19 281:1,4
 281:12,15 292:15
calculations 148:9
calibrate 149:10
call 7:5 14:14 27:2,3
 35:17 113:3 137:8,11
 137:12 141:12 143:8
 178:12 191:17 193:18
 241:20 322:13 351:21
 352:8
called 77:16 178:4
 215:12 246:21 341:17
calls 241:3
Camicia 1:17 30:17
 31:8 32:9 40:22 75:17
 355:1
camps 40:17
Canada 240:22
Canadian 15:15
candidate 4:4 21:6
 191:15 347:12
candidates 289:7
capture 30:10 86:7
 205:2,4 268:9 329:6
 330:2
captured 88:14 95:8
 159:6 315:13,14
captures 52:1 80:9
capturing 151:16 158:1
 167:21 341:1
CAR 4:15
card 240:18 337:12
cardiac 220:11
cardiopulmonary 218:9
cardiovascular 319:11
cards 241:19
care 19:10 43:7 48:21
 59:21 64:20 75:21,22
 84:10 89:12 96:6
 105:12 110:17 111:1
 114:4 115:2,12
 121:10,11 122:16
 123:20 125:6 127:1,6
 160:12 167:4 168:22
 171:1 172:3,4 174:17
 178:11,14 180:22
 196:17,21 198:14

199:10 210:20 212:10
 213:1 220:18 222:13
 224:8,9 240:3,15,16
 240:21 241:6 256:19
 260:10 273:19,20
 294:9 298:4,5,11,17
 298:22 299:2,5,20,20
 299:21 300:3,6
 302:16 304:17 306:10
 314:15 315:1,1,2,3,8
 315:9,13,14 319:15
 335:15 337:11 341:13
care/opportunity 198:9
carefully 236:3
caretakers 110:20
carotid 11:18 34:1,3,6
 53:14 279:17 280:3
 280:14,16,21 281:7
 281:14,17 282:19,22
 283:8 288:14 289:3,9
 289:16 290:3
carried 112:4 253:1,1
 322:1
carry 41:2 75:4,7
case 38:20 61:17 110:8
 117:13 157:7 162:19
 171:16 178:20 183:18
 190:20 237:4 257:1
 284:19 288:11 290:15
 310:19 318:22 323:22
 330:19
case-mix 27:10,18 28:1
cases 57:13 59:19
 66:21 82:16 90:15
 100:11 105:10 146:2
 184:8 185:21 186:20
 222:15
catch 289:17 332:13,14
catchment 290:16
categories 189:1
category 36:18 143:19
 258:14 299:11 345:9
causal 56:17
cause 4:10 104:1
 169:22
causes 298:13
caution 34:10
cautioned 128:14
caveat 205:10
CCM 1:17
ccs 103:11,14,22
CDR 305:8
ceded 218:17,18
center 1:12,14,18 2:1,5
 2:6,12 24:10 25:15
 31:5 42:18 54:2 237:6
 346:9
center's 72:13

centers 12:11 13:3
 24:14 29:12 32:3,6,7
 53:21 54:10 71:13
 72:8 86:8 89:2 96:7
 110:19 241:4
centralized 241:1
cerebral 263:2
certain 15:18 102:21
 206:8 224:5 250:10
 253:19 298:14 321:1
certainly 14:12 16:13
 26:6 29:7,21 67:8
 98:14 99:1 104:17
 121:17 168:7 176:14
 248:16 272:6 274:7
certainly--not 254:5
certainty 74:12
certification 24:10
 42:18 51:22 95:6 96:6
 232:9
certified 29:12
cetera 17:9 19:21
 247:22 330:14
chair 212:11
chairing 300:16
Chairman 2:18
challenge 36:7 159:13
 236:10 244:5 327:9
 327:15
chance 7:16,17 143:9
 177:12 332:5
change 23:9 219:16
 267:3 268:20 278:3
 318:13
changed 8:16 266:12
 291:20 324:19
changes 56:18 99:11
 144:16 241:13 268:18
 301:5 330:11,13
 348:14
changing 17:14
channel 254:21
characteristics 187:17
characterization
 281:18
characterizing 181:4
charge 213:12
Charlotte 2:7 61:5
 74:22 175:21 195:2,2
 200:4 209:19 218:14
 226:3 229:6 231:7
 232:15 238:7 241:18
 247:7,10 248:11
 263:6 265:16 271:5
 275:4,22 277:21
 354:14
Charlotte's 76:16 91:22
 94:15

chart 29:9 40:9 97:20
 102:1 105:8 132:1,3
 133:5,10,16 149:16
 156:20 181:13 261:10
 261:20 263:9 264:20
 265:11 272:9,11
chart-abstracted 157:4
charts 41:11 132:10
 185:22 271:9,12
check 137:7 146:21
 202:13
check-- 319:3
checked 157:14 272:12
checking 146:10
checks 84:16
chemical 346:4
Chief 2:14
child 176:5 239:18,19
 251:3,3 284:2
child-bearing 245:12
childbearing 4:13
 244:10
children 226:14 236:7
 283:21 319:1
children's 2:8 226:8,15
 227:9 232:20 235:11
 235:14 236:5,11
 237:12 238:15,20
choice 249:8 346:4,7,8
choices 251:2
cholinesterase 323:16
 325:18,19 329:21
 330:2 333:14 341:2
choose 87:20
choosing 353:20
chose 238:12 239:12
chosen 49:12 63:18
 233:21
Christy 3:6 5:7 60:12
 351:14
circle 177:15
circumstances 246:22
citation 27:9
cite 336:11
cited 55:14 114:20
 308:17
cites 55:8,9
city 324:6
claim 19:22 264:13
claims 15:2 30:14
 109:11 110:1,6,9
 111:13 125:19 131:15
 131:17 132:4 155:6
 156:10,18 157:11,12
 158:2 173:7 175:10
 182:16 192:14,15
 193:10 196:2 321:5,6
 343:7

claims-based 107:3
 108:11 130:2 156:21
 157:6,17 180:12
 191:18 192:9 196:2
claims-only 158:5
clarification 24:9 39:4,7
 220:1
clarified 79:8 246:13
clarify 58:3 72:2 88:12
 103:10 139:3 175:19
 179:8 201:6,11 206:3
 233:2 234:15 258:8
 268:3 334:22
clarifying 8:10
clarity 35:14 107:11
 284:14
Class 83:7
classification 129:5,7
 199:19 200:1 281:11
classification's 35:4
classified 146:4 147:16
clean 131:16
clear 30:4 39:17 40:11
 58:8 60:19 73:1 76:11
 76:12,12 90:8 105:7
 126:14 141:3,8,18
 142:3 149:4 244:4
 260:10 262:10,15,17
 301:21 302:11 303:18
 335:6
clearly 12:14 19:19
 20:5 115:19 118:13
 175:17 254:5 319:22
Cleveland 1:14 2:12
click 28:12
clicker 28:12
clickers 189:11
cliff 301:5
Clinic 1:14 2:12
clinical 43:15 52:13,14
 54:12,14 60:16 73:4
 83:5 100:14 130:8,10
 156:19 158:3 191:2
 191:16,17 192:2
 194:4 196:1,6 201:21
 201:22 217:6 221:15
 225:6 247:20 252:12
 280:7 290:9,13,21
 291:2 294:9 295:2
 297:9 328:14
clinically 43:8 77:10
clinician 131:22 239:16
 303:15
clinician-based 305:21
clinicians 77:5 149:18
 303:5 320:8 332:9
clinics 272:16 274:2
clip 100:9

clipping 80:16 84:19
 86:4
clock 221:11,17,20
close 31:17 104:6
 150:20 249:20,21
 307:11 347:2
closed 38:10 42:10
 65:22 79:16 182:2
 188:15 189:22 198:5
 198:21 207:18 209:7
 210:12 211:13 212:3
 223:11 224:21 227:21
 230:15 231:21 242:5
 242:16 258:20 259:16
 260:2,21 270:16
 273:14 274:21 279:11
 291:14 292:8 293:4
 294:1,17 295:14
 296:1 309:11 314:5
 315:20 316:15 318:9
 337:19 339:4 340:9
 342:21 343:16 350:5
 350:16
closer 245:7
clot 12:20 98:5,9 99:7
 100:21 101:4,7
cloud-based 315:10
clouding 121:16
clozapine 348:19
Clozaril 348:17,19
CMO 164:19
CMS 30:11 107:4,7
 108:9 111:9 131:9,10
 150:5 175:4 179:8,20
 180:3,11 192:12,18
 192:22 194:2,6
 197:10 246:2 256:12
 256:14 270:2 295:1
 321:9 322:2 338:3
 339:11 342:2,8
 344:10,18,21 345:1
 346:14,18
CMS' 107:17 126:9
co- 300:15
Co-Chair 1:11,11 5:3,15
 6:5,11 7:2,6,14,21 8:5
 8:7,9 11:22 13:9,13
 15:7 16:18 17:3 19:3
 21:17 22:2,6,8 24:7
 25:16 26:14,22 27:16
 28:1,4,11,17,19 29:2
 30:2,15 31:3 32:4,12
 32:19 33:4 34:14 35:2
 36:4 37:1,20 38:5,13
 39:1,8 40:6,10,16
 42:2,15 43:5 44:6,16
 45:3,12,14 46:11,13
 48:10 49:16 50:21

51:10,13 54:18 55:1
 56:13 58:2 59:9,15
 61:5,15,19 63:6 64:14
 65:13 66:13 67:10,16
 68:3,7,9 69:8,22
 70:11,16 71:11 72:18
 73:20 75:16 76:2,5
 77:18 79:4,20 82:18
 83:17 85:9 89:6,15
 90:7,20 91:11,16,22
 92:5,17 93:3 94:9,15
 94:19 95:2,12,22
 96:12 98:16,21 99:8
 101:22 102:12 104:18
 105:6 106:1,10,18
 107:6 111:5 112:12
 119:14 121:2 123:14
 124:3,7,9,13,16,19
 125:5 127:5,9,19,22
 129:19 131:5 134:10
 134:14 143:6,22
 144:6 147:13 148:4
 150:15,21 151:5,18
 152:2 153:11,14,20
 154:5 163:8,13
 164:20 170:11 173:13
 175:15 176:18 177:14
 179:5 181:6,18 182:7
 182:22 183:10 185:6
 187:18 188:5,8,20
 189:7,10 190:3 195:1
 195:13,20 196:7,14
 197:18 198:1,8,13
 199:3 200:3,11,16
 201:4,10 202:21
 203:6 205:8,15
 206:17 207:5,10,22
 208:2,20 209:1,11
 210:3,16 211:3,6,17
 212:7,19 213:13,19
 218:13 219:20 220:6
 221:2 222:22 223:3,8
 223:15 224:10 225:3
 226:2 227:13,15
 228:3 229:5 230:3,6,9
 230:19 231:7,12,15
 232:3,15 233:3
 234:12 238:6 239:14
 240:4,17 241:15,18
 242:9,21 243:11,16
 243:20 244:3,14,16
 244:20 245:6 246:17
 247:6,9 248:11 249:4
 249:19 250:17 252:3
 252:11 253:3,15
 254:10,20 255:14
 256:21 257:13,20
 258:5,8,15 259:2,6,9

259:10 260:7,15
 261:3 263:6 265:12
 265:22 266:6 270:9
 271:1,4 273:9,17
 274:12,15 275:3,22
 276:6 277:8,19 278:2
 278:5,6,12,15,17,19
 278:21 279:7,15
 282:7,11 287:13,14
 288:1,6,13,19 290:7
 290:18 291:2,5,18
 292:3,12,20 293:8,18
 294:5,12,21 295:9,18
 296:7,9,16,20 297:3,6
 300:14,20,22 301:4
 301:18 302:21 304:8
 305:4 306:11,21
 307:6,10 308:1,10
 309:2,9,15,18 310:2,7
 310:13 311:3,21
 312:8,17 313:11,19
 314:10,19 315:15
 316:2,9,19 317:10,18
 318:1,12 322:19
 324:3 325:4,20 326:5
 327:4 328:15 331:13
 332:18 333:1 334:7
 334:20 335:8 336:3
 337:7 338:1,17 339:8
 339:17 340:2,13
 341:7 342:14 343:3
 343:10,20 345:14
 346:11 347:10 348:12
 349:15 350:8,14,19
 351:11 354:20
co-chairs 1:9 354:1
co-Table 82:15
code 109:19 194:9
 320:14 327:17
coded 104:17
coder 109:17
coders 109:13
codes 109:13,20
 125:22 321:6,7
coding 33:13 72:9
 134:21 183:22 209:14
coefficient 208:13,16
coefficients 36:10
cognition 297:19,22
 298:12 312:14
cognitive 4:18 261:17
 263:3 296:13 298:6,7
 298:16 299:16 300:7
 300:9 302:7 303:6,10
 304:15 306:2,6
 325:15,16 326:11,16
 326:16 327:8,19
 330:5

cognizant 252:15
cohort 108:20 190:17
coiling 80:17 86:4
Collaborative 2:1
colleague 318:19,20
colleagues 200:21
 216:3
collect 20:5 39:14
 62:18 71:15 72:13
 111:16 194:9 196:19
 226:21 256:10 276:19
 276:20
collected 31:10 39:18
 39:21 72:4 80:4
 230:21 343:6
collecting 31:22 39:22
 62:5,6,8,9 134:9
 192:21 194:14
collection 13:1 31:12
 109:10 131:8 231:1
 308:9
College 2:9,13 3:11,16
 279:21 295:2 354:13
color 308:15
Coma 50:6 99:11,12,21
 102:3
combination 159:20
 192:14 273:22
combined 160:1
combining 81:12
come 57:1 58:16 84:8
 87:8 115:9,10 125:10
 135:17 137:3,22
 138:5 141:5,7 145:19
 156:20 162:6 164:11
 165:10 177:4 190:7
 196:17 199:7 222:1
 224:18 229:20 255:17
 257:2 266:17 284:5
 323:10 335:10
comes 17:14 18:7
 61:11 83:22 139:5
 150:19 207:3 221:6
 238:17 240:11 272:14
 282:15
comfort 11:16 82:8
 135:10 160:12 163:17
 164:2 165:1,7 167:4
 167:18 180:22 212:12
 212:22 299:5
comfortable 56:1
 137:16 181:2 258:7
 324:17
coming 121:22 176:22
 290:1
comment 4:19 16:19
 22:12 23:6 25:17
 26:21 36:5 43:16

45:16 46:7 53:17
 61:12 64:15 68:10,15
 70:12 71:12 73:14
 85:20 91:1 96:11
 97:10 99:9 107:5
 128:2 136:12,22
 147:14 154:11 163:15
 163:21 173:2,2,3
 174:8 175:2 196:13
 201:5 206:18 212:9
 229:2 231:8 234:13
 243:5,7,9 259:4 312:2
 326:21 336:2,4
 337:12 349:20 351:3
 351:5 352:6 353:21
commenting 334:8
 355:12,15
comments 12:1 21:18
 26:18 28:5 30:5 32:13
 34:14 37:14 49:17
 63:7 65:16 85:10
 92:17 93:11 111:6
 148:13 175:20 177:17
 185:6 188:6 200:17
 205:16 207:11 210:5
 211:4 212:18 219:21
 222:22 224:11,16
 226:3 229:5 230:6
 231:9 240:6 243:15
 243:17 250:17 260:15
 266:6 273:9 274:16
 278:13 282:4 287:15
 291:5 292:4,21
 293:19 294:13 295:10
 297:2 302:22 306:16
 324:4 334:7 338:18
 340:3 341:8 342:15
 351:10,12 352:8,10
Commission 3:14,15
 3:17 9:16 37:16 42:18
 51:18 88:13 164:22
 226:5
committed 348:13
committee 1:3,7 30:5
 43:2 48:17 60:11
 64:18 69:15 74:4 75:3
 83:14 92:15 96:9
 108:15 111:11 134:21
 181:2 185:7 200:17
 200:20 201:16 204:5
 213:20 228:10 237:2
 265:5 267:15 276:8
 277:10 300:5,16
 302:22 311:8 324:4
 331:2 352:8,21
committees 75:6
common 236:7
commonly 348:4

communicate 20:1	89:1 95:5 96:6 306:14	206:1,2 295:6 319:14	273:8
communicating 97:2	compromise 19:7	345:10 346:16	contracts 322:2
communication 43:18	compute 96:16	conservative 138:13	contraindicated 327:1
44:4,14 48:21 105:11	conceivable 135:21	145:5	contribute 159:7
197:13	152:12	consider 60:5 61:2	187:12 302:14
communities 308:15	concept 147:17 154:11	69:20 74:9 76:21	contributes 112:1
community 64:8 132:16	158:12 160:10 186:13	120:22 129:3 176:7	302:7 303:21
272:22 273:3	205:19	250:6 337:3	control 58:15 73:11
comorbid 348:4	conceptual 185:11	considerable 126:2	83:9 171:17 187:16
comorbidities 157:22	concern 19:6 108:15	considerably 154:15	217:14 252:1
Company 2:3	119:1,2 128:11 133:7	consideration 4:4	controlled 248:6,8
comparable 146:19	169:12 170:4 180:16	244:9	controversial 5:8
252:6	251:20 261:17 265:15	considered 12:21 61:16	controversy 5:6
comparator 64:9,13	284:7,8 289:14,21	70:7 202:8 222:7	convened 300:5
compare 37:6 64:6	295:7 302:12,17	285:2 311:8 336:9	convenient 25:5 346:9
150:5,6 156:15	concerned 132:2	considering 70:9 200:6	convention 148:14
170:10 320:4 336:17	284:22 306:7 332:15	245:5 301:9,9,10	convergent 93:7
337:2 341:13 344:14	concerning 336:10	consisted 261:5	conversation 51:14
344:17 345:1	concerns 33:12 50:16	consistency 118:4	114:15 118:22 160:15
compared 31:16 54:13	110:13 134:19 156:10	199:12	190:4 334:12 348:11
126:13 201:1	174:13,22 179:9	consistent 138:10,12	conversations 68:6
comparing 36:14,15	183:17 184:1 215:18	180:3 235:8 311:13	170:1
56:3 65:3 180:7	246:11 270:10 289:16	313:13 320:19	converted 62:17
195:10	319:9	consistently 109:5	convey 43:12
comparison 35:15 37:4	concluded 355:18	Consortium 296:14	conveyed 254:7
195:11	conclusion 115:20	constitute 263:18	convinced 171:12
comparisons 57:17	concur 149:1	constraints 272:20	coordinate 282:2
131:14	condition 83:12 298:20	construed 19:7 101:17	coordinated 241:5,7
compatible 336:20	conditions 151:3,9,11	148:7 158:11,14	coordination 59:22
compelled 252:20	205:13 218:9 298:14	159:10	cord 44:11
compelling 129:10	330:5	constructed 284:13	core 107:16 191:17
compiled 355:12	conduct 267:21	construction 174:10	201:20,21,21 209:13
complete 70:2 276:12	conducted 52:15,19	299:10	298:6
completed 273:6	64:1	constructs 16:16	Cornell 2:9
completely 116:5 161:2	conducting 41:6	consultant 107:22	correct 24:12,13 27:6
165:18 175:11 221:17	conference 1:8 322:1	consultants 128:12	38:4 40:9 120:3,17
222:10 305:14	confidence 146:7,12	consumer 239:20	133:2 137:6 139:20
completion 31:11	148:7	302:12	147:8,8 244:15 271:1
complex 41:20 336:14	confident 273:4	contact 69:1	272:12 301:3 302:2
compliant 271:10,12	confined 283:1	contained 280:7	corrected 87:5 270:6
276:12	confirm 217:17,21	context 129:17 130:8,9	corrections 13:15
complicated 96:15	conflict 275:10 276:1	130:10,18,19	271:19
201:15 221:14 331:6	345:12	contexts 149:11,16,16	correctly 79:21
complication 115:13	conflicting 253:8	contextual 128:18	correlate 116:7 156:2
252:13	conforms 301:12	continue 53:1 66:21	281:6
complications 110:18	confounded 174:3	71:9 182:10 190:8	correlated 116:21
197:15 251:16,17	327:18,19,20	242:19	134:2,3
252:9 299:3 319:12	confounding 115:22	continued 257:3,9	correlating 115:15
complied 292:18	confused 76:6 229:7	continues 208:6	correlation 36:10 37:17
complying 227:1	304:10	continuing 2:12 322:20	37:21 38:1 129:16
component 46:3,4	connection 13:5	contraception 245:17	138:15 158:10 208:13
47:21 48:1 265:3	conscience 49:10	247:22 258:3 263:13	288:2
components 81:11	consciousness 100:2	263:22	correlations 153:10
94:8 101:18 276:13	consensus 6:2,19 7:1	contraceptive 251:2	cost 23:10 38:20
composite 327:16	64:8 267:14 268:6	272:1,2	194:14
comprehensive 13:2	consequence 24:20	contract 322:3 338:4	costly 74:11
22:17 23:3 24:14 31:4	70:10	339:11	Cotter 1:19 219:22
32:3,6 51:21 80:5	consequences 183:17	contracted 272:21	239:15 249:5,17

303:2 314:22 322:22
 325:12 326:1,9 333:6
 333:22 334:14 338:3
 339:10,19 340:14
 343:5,22 345:6 354:9
 354:9
coughing 97:14
Council 228:9
counsel 3:2 250:9
 264:4,15
counseled 245:15
 248:21 255:19 263:11
 263:12,13,14,15
counseling 4:13 244:10
 247:22 248:2,9,9,14
 248:15,17,18,22
 249:1 250:2,14,16
 254:1,4,5,6 257:5,15
 258:1 260:11 263:8
 263:16,18,20 272:2,3
 291:1
counseling--so 255:22
count 104:9 124:21
 313:8
counted 213:3
country 49:14 135:5
 199:10 289:9 303:9
counts 66:17
couple 84:22 125:11
 135:17 139:6 143:4
 144:12 145:2 148:12
 152:21 154:8 170:1
 180:13 202:2,7 207:4
 207:4 330:10 351:18
course 20:2 69:1
 170:17 192:5 336:14
 347:21
cover 166:22
cracks 78:3
crazy 135:8
create 15:13,19 77:6
 146:5 169:8 234:7
 327:16
created 26:8 125:20
 276:10,15
creates 236:21
creating 101:19 237:8
credible 162:7
credit 158:18 181:15
crime 107:19
criteria 59:16 64:15
 67:20 70:7 79:11
 182:6 195:7 206:18
 219:17 220:1 221:9
 224:3 262:13,18
 264:17 266:13 276:17
 288:5,7,11 300:18
 323:4 329:10,21

criterion 35:12,15
 66:19
critical 46:3 70:19
 131:18
criticism 299:9
croak 319:1
cross-sectional 287:1
crosswalks 285:12
CRRN 1:17
crucial 121:8
crucially 250:7
CSAC 247:3,4 352:13
CSTK 37:18
CSTK-01 4:4 9:14,19
 82:5
CSTK-02 4:6 37:21
 51:16,20
CSTK-03 4:8 80:1
CSTK-06 9:11
CT 5:19 24:16,18,22
 101:12 102:3 240:9
CTA 280:15 285:19
CTNMR 281:21
culling 341:19
curious 86:5 97:15
currency 44:2
current 85:4 86:11
 126:9 143:10 144:14
 144:21 146:22 181:17
 344:4
currently 42:20 96:4
 108:10 158:8 175:3,7
 180:8 232:5 233:15
 234:9 246:4 280:7
 296:16 316:4 320:3
 321:9
curriculums 257:18
curve 63:16
custodial 300:3
cut 104:6
cutoff 136:4 148:13
 233:21
cutting 350:21

D

D 321:10,14 322:2
 338:3 339:11 344:10
 344:16
D.C 1:8
data 7:4,13,14,15,16,19
 8:16,18 16:11 29:4
 30:4,9,14 31:9 33:10
 33:15,17,20 34:11
 35:13,14,18,21,22
 38:16 39:21,22 40:1
 42:21 54:13 62:18
 63:15 72:14 76:1
 88:18 89:3 90:13,15

90:18 92:8,9 93:7,10
 93:20 94:4 101:14
 109:12 110:2,2,6,8,8
 110:9 111:13,14
 116:6 125:9,10,20
 126:1,18 127:4 131:2
 131:13,15,15,19
 132:6,7,18 133:20
 134:6 139:12 144:1
 152:6,14 153:7
 154:16 156:10,14
 157:3 158:8,19 161:9
 162:17,19,21 166:5
 167:9,20,20 173:7,18
 175:10 177:21 179:9
 179:12 183:21 191:2
 191:17 192:12,15,22
 193:6 194:5,6 196:6
 197:12 198:12 200:7
 201:14,17,18,19,21
 201:22 202:9,9,12
 203:1,2,10,12 204:9
 204:11,15,22 205:3
 206:11,12,15 207:2,2
 209:21 210:22 219:1
 219:5,17 224:1,4
 225:14 226:19,21
 228:5,8,8 230:21
 231:1,2 232:11 233:4
 233:20 234:5 237:19
 237:20 246:4,8,15
 247:4 250:4 251:4
 252:6 256:2,10,19,20
 257:1 260:9 261:5,9,9
 261:11,12,21 262:7,9
 264:18,20 265:2,9,17
 266:13 267:1,4 268:2
 268:16,21 269:7,14
 269:16,20,20,21,22
 271:18 272:5 273:3,5
 273:6 274:11 276:19
 277:3 280:8 283:7
 284:1 285:13 290:16
 294:9 295:3 301:13
 308:9,20,21 314:17
 315:11,12 321:4,6,13
 321:18,19 327:18
 335:3,5 338:4,10
 339:12,20 341:14,21
 343:6 344:5 348:22
data's 95:8 209:17
date 256:17 271:14
 273:21
Dave 76:4 229:18
 354:20
David 1:9,9,11,11,12
 2:4 3:16 6:4 46:14
 48:11 183:13 250:18

255:14 279:22 282:8
 285:4,7 287:13 290:3
 300:15 301:19 310:13
 312:1 314:11 349:16
 354:11 355:2
David's 5:11 171:15
 213:11,12 223:9
day 4:3 5:4,5 11:16,17
 20:8,9 48:13 52:6
 62:17 82:8,9 107:19
 167:13,15 169:18
 176:12,13 212:13
 253:1 296:8 298:21
 299:1 313:6
days 4:7 11:15 25:19
 51:17,21 52:7,8,22
 53:13 55:11,20 56:6,6
 69:1 82:7 108:7 120:1
 170:2 176:12 187:11
 259:19 338:12
de 64:4
Deaconess 2:5
deal 71:6 272:13 328:19
dealing 49:22
deals 222:9
death 114:5 120:1
 319:12
debate 5:20
deceptively 19:19
decide 60:20 100:9
 176:17 186:4 191:20
 237:13 239:21 344:18
 344:21 345:4
decided 11:1 46:19
 85:17 179:8 209:22
 345:1
decision 100:13 103:2
 103:17 167:3 214:22
 219:15 247:5 249:8
 249:11 269:17 281:17
decision-making
 171:18
decisional 299:2
decisions 13:8 23:22
 168:22 176:14 177:4
 281:20 298:10 302:15
decisive 56:22 57:1
decline 298:13,16
 302:7
declines 181:14
declining 101:6
decrease 257:6 346:20
defects 251:4,19
 255:21 263:14
defend 48:11
deferred 8:16
deficit 41:18 165:11
deficits 41:20

defined 70:20 220:14
263:20 273:22
definitely 104:2 250:3
275:12 355:10
definition 22:1 94:5
108:20 119:18 263:8
286:8
definitions 33:13
134:20 268:4,8
degree 20:2 281:16,18
delay 105:7 217:9,12
239:5 317:21
delayed 106:13 217:16
delivering 178:13
demand 258:3
demented 328:1 347:15
dementia 4:17,18
296:13 297:20 298:1
298:7 299:4,7 300:6,9
304:12,19 305:2,7,8,9
306:9 308:15 318:14
319:11,18 320:17
321:8,8 323:13,15,19
324:1 325:5,17
326:15,18 327:6
328:8,13,22 329:6
330:1,8,20 331:5
332:9,12 333:5,15,19
333:21 334:3,3,5,19
335:4 341:2 347:17
348:4,7
demonstrate 72:5
216:9 324:1 344:6
demonstrated 216:4
283:14 334:18
demonstrates 221:19
demonstrating 200:21
232:11 233:5
demonstration 291:20
denominator 8:17 11:3
33:7 53:4 57:14 81:4
81:7 216:19 217:10
222:19 280:14,21
281:2,8,21 282:16
283:4 323:12 326:4
327:13 331:18,22
334:11 340:22 341:9
341:17 345:16
department 1:16 2:5,17
2:19 10:8,14 11:5
19:10 81:3,9 86:3,19
220:9 222:2,11
depending 160:7
208:17
depends 326:6
depression 326:12,13
336:7
described 81:15 281:20

describing 222:15
description 80:8
design 87:19 88:4
designed 19:7 22:16
despite 47:16 164:5
215:18
detail 160:22 191:8
detailed 72:21
details 355:10
detect 298:15
detection 13:22
deter 100:12 199:6
deteriorated 19:16
determination 8:3
determine 10:15 62:1
81:21 102:20 235:21
271:9
determined 8:3 39:20
determines 299:12
detriments 69:20 74:9
develop 96:19 110:1,11
121:7 201:20 232:17
250:15 332:8 342:5
347:21
developed 240:22
264:17 273:1 293:13
344:11,12
developer 13:18 17:18
19:4 26:21 30:6,18
36:5 38:20 46:22
50:22 83:4 90:11 93:4
96:4 107:21 121:5
129:4 179:21 213:18
230:22 232:10 244:17
247:3,12 249:14
260:9 266:12 268:17
285:4 287:20 295:5
296:15 318:15 336:10
338:4,19 339:10
340:14 348:13
developer's 47:21
130:22
developers 15:10 29:8
107:17 114:20 120:13
143:7 185:8 190:13
226:11 238:12 239:11
263:8 302:6 322:8,15
329:20
developing 74:13
201:13 256:15 320:8
development 24:5
76:17,22 77:20 88:10
108:1 275:18 276:7
developmental 262:10
262:14 267:11
deviating 186:1
deviations 341:20
DHS 2:15

diagnose 332:20
diagnosed 245:12
298:1 300:9 304:12
305:2 323:20 327:21
diagnoses 320:3 321:5
326:17,18 328:13,22
332:9,17 334:1,5
336:11,18 337:3
diagnosis 13:22 82:12
236:1 240:2 263:2
297:20 308:14 319:21
320:10,13 323:13,14
323:22 325:5,14
327:7 329:2 330:1
331:4 332:11 333:8
diagnostic 4:15 217:20
218:7 279:16 299:11
321:6 328:3 330:19
diameter 280:21 283:7
diastolic 192:7
DICKERSON 1:20
256:4 264:12 289:14
290:15 304:9 305:14
328:21 329:5,18
334:21
DICKINSON 329:11
dictated 303:13
dictionary 265:3,9,17
277:3
didn't--because 263:10
didn't--neglected
291:12
die 113:13,19 164:5
165:14 176:5
died 166:8 185:21
Diedra 3:13 214:7
dies 164:7,8,19 176:3
difference 127:2,3
152:11 164:10 187:3
191:22 196:5 258:4
301:16 341:19
differences 122:1,3
126:20 138:11 152:15
168:8,9 184:1 194:20
different 6:13 26:8
29:12 37:12 50:4,8
56:20 67:14 78:4,14
78:19 116:1 117:5,19
118:2 120:5 128:22
133:5 137:3,20,21
140:13 141:13 143:18
143:19 152:22 159:5
166:12 176:9,17
177:17 186:6 196:3
201:7 202:19 205:18
213:5 250:20 262:5,5
263:18 265:6 276:12
281:14,15 285:13,18

310:3 328:18 349:19
differently 186:8
286:14
differs 168:4,7,10
difficult 235:21 306:8
346:5
difficulty 93:15 274:2
dig 243:3
digit 112:5
diminish 174:7
dinged 221:4 233:1
direct 88:13,19 89:3,4
248:2 254:1 280:19
281:1 285:18,20
direction 42:9 168:21
directly 65:4 87:1 163:1
211:18 247:12 288:10
director 1:15,18,21 2:1
2:3,7,10,12 3:2,3,6
107:16
dis-control 251:19
disabilities 262:11
267:11
disability 113:18,20
262:4,15 263:4,5
271:18,21 298:21
disabling 25:6
disagree 87:6,6 221:16
237:1
disagreement 21:8
discharge 53:1
discharged 8:11,15
11:20 20:4 82:10
216:7
disclosure 116:16
discorrelations 129:6
discourage 332:8,16
discover 304:4
discredit 145:4
discrepancy 253:7
discrete 276:19
discretion 299:14
discriminating 112:1
discuss 61:10 118:1
278:1 322:17
discussants 13:10
54:18 82:19 195:2
213:17 218:14 282:7
301:20
discussed 8:14 9:8,10
35:5,17 46:18 97:3
122:8 128:3 157:13
176:12 194:3 197:6
230:2 253:22 271:22
272:18 295:6 324:15
340:21 355:14
discussing 205:2 276:1
282:10

discussion 12:4 14:8
15:7 26:18 30:5 32:13
34:15 36:4 37:14
47:14 65:16 74:17
83:17 85:10 89:18
90:20 92:18 94:10
95:12 123:15 127:6
153:12 188:6 190:5
197:4 198:11 208:6
208:21 211:4 226:7
241:14 263:21 267:7
268:12 302:22 308:11
309:3 314:20 316:9
323:10 338:17 341:8
343:10 355:13
discussions 342:2
disease 120:20 283:20
284:1 320:9 324:15
324:17,18 325:2,6
326:17 333:16,18,21
334:4 336:13 347:20
347:22 348:2,3,20
disease- 96:5
diseases 112:7
dismiss 236:14
disorder 263:1
disorders 1:21 218:2
262:11,12
disparities 7:4,13,19
8:4 29:9,21,22 90:19
126:17 127:6 224:4
308:2,3,6,14,19 338:9
disparity 29:18 30:4
display 245:13 321:13
346:21
displayed 346:21
dispute 46:8,9
disputed 46:1
disqualified 220:21
distal 280:20 281:2,7
distinctions 341:16,18
distinguish 228:14
distinguishing 263:19
divergent 79:1
divert 74:12
divided 138:17
dividing 40:4
Division 2:7
DNR 116:19 172:9,13
172:15
do--we 317:13
Doctor 277:9
doctor's 185:4
document 72:11 87:10
87:12 89:16 97:20
101:10 261:19 262:5
284:18 286:4,7,10
292:14

documentation 47:11
130:22 136:18 264:15
281:11 312:21
documented 10:6,7
11:9,10,16 29:15
30:14 47:3,19 80:20
81:1 82:8 86:14 102:6
102:8 217:8,11
280:18 292:17 308:13
319:20
documenting 91:3,4,9
352:3
documents 41:6 161:3
doing 18:2 50:9 61:13
67:14 70:5,8 84:15
98:9 101:1,3 102:17
102:22 103:4 107:17
111:12 115:1 124:22
133:9 135:6 146:13
157:9 169:15 178:9
180:15 184:13,13
195:8 238:8 241:10
243:4 244:11 264:13
264:19 265:11 274:2
278:14 296:12 304:18
304:22 306:9
doing-- 332:21
domain 95:7
domiciliary 300:2
dominant 155:20
dominate 194:19
door 185:11
door- 219:6
door-to-treatment
221:8
Dorothy 2:1 25:17
44:10 296:22 305:4
308:11 311:4 322:20
327:5 329:19 334:7
355:1
Dorothy's 330:6
Dorsey 3:12 147:3,8,12
203:8,11 204:3,19
205:6,10 206:5
doubly-tricky 114:3
downstream 58:1
Dr 12:2 15:12 19:5 30:7
31:9 32:8 36:6 41:4
43:16,22 53:16 63:9
72:2 88:12 97:11 99:9
101:12 103:9 104:11
104:15 107:20 111:7
132:6 133:11,18
137:13,17 139:20
142:1 143:20 144:4
148:1,6 154:21
163:20 173:1,15
175:1 185:9 187:6

193:20 200:19 201:9
214:5,9 218:3 220:7
221:14 226:12 227:12
233:2,4 234:12,15
235:4 240:19 250:9
276:3 279:22 280:8
280:10,12 282:3,5
285:6,10 286:12
287:19 296:6 297:9
297:10,14,15,17
300:19,21 317:1
318:17 319:6 322:6
332:7,22 333:3,17
336:4 347:4 353:22
draft 352:3,11
dramatically 291:21
drastically 169:5
draw 352:22 354:6
driving 119:3
DrNP 1:19
drop 286:19 303:12
dropout 285:17
Drs 216:3
drug 321:5 323:5,8,17
324:1,8,10,22 334:17
347:17
drugs 320:17 323:16
327:22 332:14,15
dual 127:3
Duda 324:16
due 348:2
duplex 280:16 281:5,22
285:16
DVT 122:14 184:7,13
DVT/PE 187:13
dying 113:18

E

e- 264:17 313:9,11
e-measure 314:3,8
318:7,10
e-measures 313:16
EA 27:9
earlier 17:21 21:10
87:18 90:13 96:3
109:15 121:14 122:8
131:21 149:14 153:4
154:22 157:13 180:7
183:13 197:2,10
208:19 210:21 218:4
219:3 266:3 276:22
299:4 341:10,14
347:5
early 13:22 20:10 24:1
25:19 106:12,14
110:13 116:18 122:15
163:2 165:1 168:22
172:9,13,15 187:13

252:16 348:1
earn 213:8
easier 268:9
easiest 41:12 202:6
easily 105:9 238:13
277:1 343:6
Eastern 351:21
easy 101:8 116:19
130:2 159:13 171:14
182:12,17 276:13,20
287:15 288:20 298:15
eat 165:13
eating 249:20
ED 34:1 88:15,22
edge 345:10
educate 304:13
educating 302:15
education 2:12 91:7
educational 91:12,14
Edwards 2:1 23:13
25:18 305:5 308:12
308:22 327:6 355:1
effect 104:1 174:8
effective 73:12 304:5
effectively 54:13
effectiveness 54:16
effects 251:2,2 253:19
264:1
efficacy 63:22,22
251:22 330:8 335:3
efficient 43:13
efficiently 243:1
effort 18:14 72:13
305:20
efforts 15:13 23:11
25:12 164:6
EHR 192:12,15 193:6
194:6 201:18 202:9
264:21 265:1,18
276:10 277:2 315:6
EHR- 193:15
EHRs 193:12 202:7,19
207:3
eight 18:8 150:18 271:9
271:10
Eisenberg 3:13 318:17
318:18 319:6 332:7
332:22 333:3,17
347:4
either 14:21 41:6 72:4
87:13 166:11 268:20
325:7 327:17,22
elaborate 265:2,9
elder 298:20
elderly 319:10 346:17
elect 353:3,17
elective 11:18 34:1,3,6
53:14

electronic 33:12 190:22 191:6 196:17 199:10 201:8 202:10 209:14 210:19,20 265:13 266:9 274:1 294:10 314:13 343:7	EMRs 205:18,22 encephalopathy 263:1 encourage 297:21 encouragements 256:9 encouraging-- 290:6 ended 194:16 endorse 16:3 290:11 endorsed 109:9 182:18 189:14 214:14 234:1 246:7,18 257:3 274:6 280:4 293:16 319:8 344:19	equivalent 215:11,16 215:17 281:3 ER 104:22 176:3,3 error 204:20 253:5 errors 271:20 273:3 especially 99:3 135:4,6 191:1 289:4 313:9 325:17 essence 50:17 essential 47:21 48:1 essentially 18:9 108:19 133:4 191:10 establish 63:21 191:5 established 191:9 estimate 41:10 103:15 104:7 146:6 161:20 284:19 286:4 288:7 estimated 15:2 38:20 136:7,8 estimates 128:10 162:7 233:12 et 17:9 19:21 247:22 330:14 etcetera 197:15 Europe 215:14 European 215:11 219:17 evacuation 99:7 100:21 101:7 103:4,5 evaluate 18:16 261:10 303:10 317:7 evaluated 36:22 236:3 evaluating 108:15,17 evaluation 41:6,22 217:21 235:18 284:6 301:6 evaluations 282:15 289:18 306:14 event 222:5 225:19 227:11 236:9 237:11 335:5 events 225:21 226:6 228:20 229:10,14 237:4 319:19 320:13 330:8 eventually 196:15 everybody 28:11 45:20 46:9,19,21 47:16,16 48:8 51:14 67:13 97:20 103:17 114:7 153:21 184:12 204:8 212:8 249:22 279:14 283:4 284:21 297:18 317:1 322:15 354:1,2 everybody's 101:1 309:9 Everyday 43:9 Everyone's 50:8	evidence 13:17,19 14:6 14:10,12 15:5,6,8 16:7 17:8,16,19,22 18:2,14,22 19:1,2 21:1,4,15 26:19 27:2 27:14 28:6,8,21 29:1 29:9,21,22 35:5,6 37:9 45:19 46:2,5,14 46:18 47:10,18 48:3,4 48:4 49:3,7,12 55:1,2 55:8 56:7,10 57:7,9 57:20 58:16 59:13,16 59:18,20 60:4,9,16,22 61:1,8 62:4,5 63:11 64:10,11,16,21 65:4,8 65:9,12,17,20 66:1,4 66:6,7,10,11,22 68:17 69:17,18 70:6,21 73:4 73:9,21 74:7 75:5,8 75:11 76:15,18,20 79:11,13,14,17,18 83:4,8,16,18 85:11,12 88:3,10 89:18,22 90:6 109:4 110:16 111:1 112:19 114:17,19 116:3,4 117:3 118:16 119:16 120:5 122:13 122:22 123:9,15,16 123:18 124:18 125:4 154:8 169:17 171:19 183:16 197:8,9,16,19 197:21 198:7 216:11 218:19,20,21 219:18 219:19 221:19 223:1 223:6,14 235:17 247:12,13,15,18,19 247:21 248:2 249:2 253:2,8,14,18,18,20 254:1 255:1,16,18,22 256:5 257:21 258:6 258:10,18 259:1,13 259:14,15,21,22 260:1,3,5 277:22 278:7 282:17 283:1 284:10,10,11,18 285:1 286:3,7,10 287:7,9,10,12 288:21 291:6,9,17 292:2,13 292:14 301:9,12 302:10 303:1,19 306:16,17,19 307:5 309:22 310:15,22 311:13 312:4 313:14 322:21 323:1,9 328:17 330:11,14 333:2,5 334:10,11,13 334:15,18 335:12,20 337:14,16,22 341:11
--	--	--	---

346:10 348:16,18,21
evidence--the 247:16
evidence-based 186:15
evolution 83:11
exact 85:12 155:16
exactly 5:17 27:6 59:18
 138:18 139:1 170:14
 203:9 312:18 334:22
 341:16
exam 22:18 23:3 42:1
 84:14,15,17,21 85:6
 87:7,11,12,15 134:1
examination 10:13
examine 69:5
example 25:7 37:7 50:6
 69:21 73:9 184:21
 240:10 283:20 285:15
 286:17 298:13
exams 22:22
excellent 36:17 182:22
 220:7 282:17 291:19
 292:14
exception 59:12,13,16
 59:18 60:7 61:3,8
 62:7 64:16 65:12,15
 66:4,6,7,8,9,11,12,16
 66:22 67:22 69:14
 70:6,8 72:22 75:9,12
 79:11,13,14,15,17,19
 79:19 222:16 228:18
 246:10 247:15 249:2
 254:22 255:4,9
 258:12 259:3,13,15
 259:16,21 260:1,2,4,4
 260:6 261:18 262:12
 262:22 278:8 290:22
exceptions 217:10
 246:14 262:1,9
 267:14 300:12
exceptions-- 300:13
excess 185:20 298:13
exclude 218:6 220:10
 227:8 229:10 233:9
 234:16 238:13 320:10
 336:18 348:7
excluded 11:13 25:21
 135:10 167:13,15
 213:2 226:5,9 229:8
 229:13 232:18 329:1
excluding 135:12 238:1
exclusion 82:11 168:1
 220:1,3 221:10
 228:22 235:2 240:9
 262:16,18 266:13
 328:9 329:10
exclusions 33:8 53:11
 82:3 160:6,6 216:22
 262:3,17,22 267:8,10

267:16 268:4 320:1,2
 320:6 336:9 345:16
 345:17
excuse 32:17 82:5
 106:3 215:16 338:20
execution 204:20
executive 303:20 304:3
exist 78:15 341:21
existence 293:13
existential 44:15
existing 347:7
exists 14:12 15:5
 126:14 182:15 186:17
exit 334:8
expect 120:13,18 131:7
 142:8 145:15 152:17
expectation 80:22
 131:10
expected 20:2 80:18
 143:12,13,13,14
expecting 320:22
experience 43:3,4,6
 54:3 77:8 96:9,13
 116:12 180:9,19
 181:7 222:14
experiment 257:17
experimental 217:6
 218:12
expert 55:8,9,12,14
 56:8 74:1,3 107:21
 154:10 293:10,10,12
 297:9 340:16
expertise 276:4
experts 49:10 108:1
 221:15 228:8 336:22
expired 53:15
explain 18:1 30:20
 353:10
explained 138:2,22
explaining 141:15
 204:16
explicitly 217:11
explosion 98:17
extensive 267:7
extensively 36:12
extent 15:18 128:20
 132:20 160:3 177:5
 179:21 181:1 183:15
 208:18
external 158:13
extra 67:9 170:2 310:12
 328:13
extract 265:10
extracted 231:3
extracting 262:7
extraordinarily 145:5
 145:15 165:18
extraordinary 161:1

extremely 16:2 96:14
 190:16 202:14

F

FAANP 1:19
face 22:15 23:2 35:9,10
 93:5 154:9 159:15
 160:2 228:10 253:10
 254:6,12 266:12
 293:15 340:15,18
FACEP 2:5
facile 97:2
facilitates 77:20
facilities 300:1,1
 314:15
facility 166:14,18 225:8
 305:2 338:11
fact 37:22 46:2 47:16
 83:11 85:14 113:21
 119:20 144:8 156:2
 158:7 174:4 215:22
 237:5 251:21 252:21
 253:18 257:18 266:14
 270:1 286:15 289:1,8
 342:8
facto 64:4
factor 117:1,10
factors 93:19 114:4
 116:1 118:18 119:3
 122:1 123:11 149:19
 192:9 196:1 208:12
 209:22 245:20 263:18
 298:17
FAHA 1:17
fail 62:11,12,12,12 63:4
 102:11 133:6 186:19
 196:8,9 255:3 258:10
failed 8:12,21,22 9:1,3
 226:17 270:21
failure 145:11 150:7
 218:10 261:19
fair 238:11
fairly 22:17 111:3 161:3
 236:7 286:2 293:15
 302:11 307:19
faith 72:13 115:17
 172:21
fall 21:22 22:5 87:22
 120:19,21 141:5
 222:18
fallen 78:2
falls 120:20,22
familiar 111:8 149:16
families 304:14
family 333:9
fantastic 197:3 212:16
far 40:18 42:19 64:15
 71:21 115:20 183:15

251:3 330:13
fashion 43:13 89:17
 97:2 122:17
fast 32:19 185:13
faster 197:5
favor 303:3 340:17
FDA 63:22 324:6,11,18
 324:20 328:11 330:15
 330:20 333:14 336:12
feasibility 9:1 38:14
 40:15,20 42:4,6,10,14
 75:18 95:3,10,13,14
 95:16,21 182:10,12
 182:13,20 183:1,3,9
 202:1 205:2 206:7
 207:22 209:11 210:5
 210:6,8,15 230:19,20
 231:5,11,12,16,18
 232:2 273:17,18
 274:3,10,13,14,16,17
 274:19 275:2,3 294:5
 294:6,11,13,15,20
 301:15 311:17 314:11
 314:12 315:6,16,18
 316:1 343:4,6,8,13,19
feasible 31:22 96:20
 191:16 256:3 314:17
 315:2
feasibly 191:6,9
February 293:11,14
fee 200:22
fee-for- 152:15
fee-for-service 152:5
feed 140:14
feedback 94:2 98:17
 111:10 154:12,13
 194:1 268:5
feeding 272:4
feel 23:5 50:13 75:2
 149:12 150:1 187:21
 269:13 275:14,15
 334:9
feel--and 275:14
feeling 275:9
fell 114:14 272:4
felt 77:11 95:10 201:3
 247:18 267:2
female 245:11
fertility 251:6
Ferziger 2:3 336:4
 355:2
fetal 245:21
fewer 146:2 170:2
 225:21 226:6 229:10
 233:13,17 234:16
field 50:3 71:1 103:15
 276:5
fields 273:22 294:10

fifteen 71:14
fifty 79:18,19
fight 167:5
figure 73:6 120:13
 126:16 139:6 147:4
 163:16 184:8 185:17
 230:2 327:13 332:4
figured 202:16
figuring 111:15 313:7
file 102:9
final 45:16,21 131:19
 177:18 210:2 280:14
 350:9
finalizing 93:22
finally 183:10
find 41:14 60:3 131:3
 133:17 144:20 149:22
 157:12 203:10 264:21
 323:1,9
finding 56:11 273:2
findings 93:21
fine 25:15 34:13 36:1
 46:8 49:9,11 102:17
 103:7 132:13 137:17
 286:8 288:19 300:19
 301:14
fingertips 181:12
finish 253:2
first 8:6,18 12:4 19:12
 19:16 20:18 21:3,3
 22:1,5 34:2 41:8 65:9
 65:13 84:12 87:8
 90:16 106:22 107:9
 111:8 137:8 143:22
 164:12 166:6 167:4
 167:11,13,14 174:5
 185:20 191:11 194:16
 203:17 204:13 212:13
 216:9 235:6 250:14
 304:10 321:11,15
 324:15 334:13 351:16
fit 307:14
fits 26:11 73:7
five 29:11 38:11 41:20
 88:6 93:1 94:21
 105:19,20,20 106:7
 154:1,2 260:22
 263:17 264:4,8,13
 274:22 275:1 291:15
 291:16,16 294:18
five-state 57:16
fix 90:8 185:1
fixing 57:14
flag 276:16
flawed 135:3,3
flaws 273:2
flexibility 20:12 355:8
flexible 20:16 299:13

Floor 1:8
flux 26:7
focus 74:10 84:1 93:6
 281:9
focusing 21:19,20
 215:4
folic 263:15,22
folks 49:21 50:7 60:22
 107:7 213:17
follow 261:15 276:18
follow- 72:8
follow-up 55:17,18 63:2
 77:8
followed 157:7
following 46:14 107:2
 161:3 298:18 353:4
 353:19
follows 297:21 299:10
Fonarow 216:3 223:17
food 243:2
force 289:18,22
forced 269:4
form 27:8 147:4
forms 248:16
Forster 27:9
forth 39:14 234:1
 239:10 285:16 287:3
Forum 1:1,8 75:4
forward 8:19 67:3,5,21
 71:3,8 79:7 108:14
 109:2 110:10 123:13
 129:12 156:17 157:20
 199:7 240:3 249:8,15
 266:18 277:10 304:7
 311:19 345:1
fos 104:21
fossa 104:2
found 29:13 126:1
 129:17 149:17,20
 271:13 321:19
Foundation 1:18 2:15
 3:17 214:2,8
four 28:9 32:18 34:19
 38:9 41:20 42:7 44:20
 65:21 90:1,5 91:21
 92:22 94:14 95:17
 105:18 237:3 263:17
 330:19
fourth 320:9
fraction 119:6
frame 14:7 15:6 35:7
 56:7 64:12,12 82:1
 85:1,2,4 187:21 188:1
 188:2
framework 78:9
frankly 99:6
frequency 173:10
frequently 24:16

front 59:3 70:1 72:18
 140:7 192:4 193:17
 204:5 238:11 253:14
Frontotemporal 1:21
full 7:16 16:4 22:12
 23:1,8,15 110:6
 116:16 205:12 246:10
fully 76:7 77:12 94:6
 155:1 199:21 222:2
 246:18 249:10
function 58:22 76:1
 298:7 303:6,10,20,21
functional 58:4 64:2
 75:20 175:12 177:12
 187:9 298:8,22
further 21:17 44:6
 153:12 208:21 211:3
 217:20 218:7 231:9
 241:15 246:13 257:7
 257:20 262:9,16
 270:9 302:16 323:10
 324:3 332:8,16
 338:18
future 78:8 192:19
 196:15,19

G

gain 332:3,4
gaining 97:8
gaming 163:7,10
 183:20
gap 5:22 6:12,16 7:1,8
 7:10 8:12,21 9:3,7,9
 29:7,22 30:2 31:20
 32:16,22 33:3 90:9,12
 90:14,17,21 91:19
 92:4 127:11,18 198:8
 198:14,17 199:2
 223:15,21 224:9,13
 225:2 256:19 257:3
 260:7,10,14,18 261:2
 278:9 291:18,20
 292:2,4,6,11 300:7
 301:9 306:12,13
 307:15,17,20,22
 309:4,6,14 338:2,5,7
 338:7,20,22 339:7
 344:20
gaps 29:2 32:13 83:3
 91:17 125:6,8 127:6
 223:16 272:7 300:5
garner 174:21
gathered 201:9 268:2
gathering 269:20
general 1:22 3:2 85:16
 116:11 120:6 141:3
 169:14 180:15 222:16
 235:13 239:9 250:21

generalized 272:17
generalizes 140:18
generalizing 142:2,14
generally 120:18 143:3
 149:5 172:2,4 287:16
 300:11 304:16
generate 269:19
generated 273:19 294:9
generic 327:7,8
genuine 185:5
geography 281:22
Georgia 1:12 2:17
Geriatric 323:3
getting 18:9 28:6 89:16
 98:10 113:6 122:16
 131:22 134:8 136:3
 147:17 158:11 170:22
 186:21 187:2 257:5
 270:8 286:15 317:21
 327:13 331:20 349:18
give 5:11 7:12,15 12:12
 39:4,6 102:7 131:8
 147:1 158:18 164:13
 164:13,13,14 295:8
 301:4 303:14 312:5
 316:22 345:3
given 24:1 25:7 115:20
 130:3 155:19 159:8
 208:10 228:19 313:9
 346:6
giver 298:22
gives 20:12 160:2
giving 21:14 52:6 184:7
 184:12
Glasgow 50:6 99:11,12
 99:21 102:3
glasses 124:20
global 23:7
glucose 192:3,8 218:1
go 6:1 32:14,21 33:7
 34:15 38:6 40:13,19
 42:3 44:16 45:4,12,14
 50:21 51:1 59:13 60:6
 60:12 61:2,5,19 63:7
 63:7 65:6,14,17 67:3
 67:4,11,21 69:4 75:9
 76:15 79:9 87:3 89:19
 89:19 91:16 100:10
 101:14 103:6 105:14
 120:14 121:2 131:5
 134:15 140:3,9 142:4
 142:9 160:22 165:13
 168:20 171:14 174:10
 177:1 179:5 181:18
 184:7,22 185:15
 186:18 196:22 197:8
 197:18 199:18 200:4
 204:1 206:4 207:11

208:8 210:5 211:6	232:19,22 234:1,2,7	greater 11:15 12:13	Hackney 2:4 255:15
220:6 223:3 224:11	235:1 236:22 237:3	25:20 29:16 41:2 52:6	282:9,12 285:8 286:1
225:8 227:15 228:12	238:3,20 239:5	53:13 66:19 82:7 90:9	287:5 288:4,9,16
230:9 233:3 247:10	240:20 242:22 243:1	99:14 103:14 217:3	289:21 291:11,19
247:11 255:2,3	243:4 244:4 249:1	257:4 259:8,9,10	292:13 293:9 294:6
258:16 259:11 274:12	252:15,19 254:22	271:10 289:6 298:20	294:22 355:2
276:8 277:21 289:11	257:11,17 272:19	298:22 328:1	half 136:6,8,9 139:15
300:17 303:1 306:17	275:13 276:20 277:3	gripe 266:3	139:16 140:1 141:15
309:10,21 312:9	277:4,5,19 282:9,14	group 15:8 111:9 145:3	145:7,13 147:18,20
314:20 317:3,11	290:8,19 296:11	203:21 239:9 241:1	hallucinations 346:6
324:14 328:5,19	297:10 300:14,17	246:9 247:3,16	HAMMERSMITH 3:2
331:14 338:19 341:11	303:2 304:7 311:1,21	257:10 271:8,16	hand 6:9 266:9 344:21
342:5 345:1 349:9,20	314:2 317:7 318:4,13	275:9 283:1 287:8,10	hand- 207:5
352:13	328:5,17 329:6 330:7	329:14 338:18 353:8	handle 6:20 39:12
goal 158:6 222:21	331:7 332:12 336:4	groups 93:6 159:5	123:3
250:13 306:21 320:22	340:22 341:15,18,22	268:15,20 269:1	handling 169:2
337:8	342:6 344:18 349:1,7	274:4 308:16 345:16	hanging 351:17 354:3
goes 62:2,9 103:20	349:14,15,16,17,19	349:12	happen 161:11 169:14
120:6 130:14 143:5	350:11 351:1 354:16	guarantee 69:3	235:12
172:7 310:8 322:12	gold 35:16 37:5 54:15	guess 37:13 83:21	happened 5:12 98:20
322:13	123:1,6 256:1,2	93:18 98:13 106:11	155:2 183:14 185:2
going 5:4,11,12 7:4	286:18	112:15 118:21 141:5	247:1
8:17 13:11 20:6 26:1	good 9:18 14:19 17:16	143:1,2 161:11	happening 122:12
26:16 48:8 54:19,20	28:7 36:17 40:19	163:14 164:20 170:12	150:2
54:21 56:21 57:15,22	50:13 51:14 72:13	196:7 199:11 205:17	happens 26:12 59:21
58:14,16,20 59:1,5	75:12 85:4 87:19	226:15 235:4 236:19	107:9 142:15 152:9
68:12,14,21 70:5,8,20	96:21 107:10 115:2	252:18 266:10,13	166:11 171:17 172:19
71:3,5 72:15,22 74:16	116:13 122:2 141:10	286:5 305:16 326:5	206:12
75:7 77:14 78:20 79:5	141:14 153:10 158:5	328:15 331:16 334:8	happy 114:1
83:1,2 87:7,22 88:2,6	159:19 160:7,8	334:21 336:13 344:3	hard 26:14 56:16 59:20
88:8 98:4,6,7,22 99:6	164:18 171:15 180:19	guessed 156:5	89:15 96:20 105:2
100:12,21 101:5,8	202:18 226:16 228:11	guidance 72:9 119:7,9	122:9 123:6 126:16
102:11 103:17,18	228:14 237:18 239:9	141:18 307:13	159:9 165:19 179:15
108:3 110:10 112:14	240:14,16 254:17	guide 13:8 25:5	193:4 227:3 249:21
112:15 118:22 120:2	255:22 282:6 283:10	guideline 12:7,19 52:17	290:1 307:1 355:7
123:5 124:15 125:10	283:11 284:10 288:8	75:6 83:6 109:6 219:6	harder 251:5
130:4,13 131:2 133:8	292:1 296:8 297:17	223:19 228:7 323:18	hardwiring 135:2
133:16 134:17 135:5	335:12 344:9 354:4	guidelines 10:21 14:5,5	harkening 131:20
135:6 136:1 137:7,15	gotten 154:12 204:5	17:9,15 31:10,13,20	harm 216:1 236:16
139:11 140:4 141:5	graded 255:11,12	94:4 110:2,5 111:22	327:3
142:16,19 146:21	grading 84:5	115:5 125:14 131:13	harms 74:2
148:15 149:12 152:12	granted 246:9	132:8,15,17 133:3	Harvard 2:4,19
152:18 158:22 161:11	gravy 194:11	142:20 155:7 157:10	have--we 272:15
162:11,14,15,22	gray 3:13 66:21 67:1,20	161:13 167:20 200:7	Haven 3:12
163:3 164:17 165:22	182:5,7 189:1 214:7,7	201:2 214:17 215:12	he'll 218:18
166:22 168:18,21	234:14 259:6 270:18	218:22 222:9 223:22	head 5:19 32:5 55:13
169:11,12,21,22	270:22 279:5 286:16	225:7,13 227:7 229:8	240:9
170:5,9 174:10,15,18	287:4 315:4 355:14	230:22 232:17 237:20	health 2:1,2,6,11 3:5,12
174:19 175:8 178:12	great 8:9 11:22 24:7	247:20 255:11 274:7	4:5 5:14 9:20 60:15
178:18 180:16,21	34:3 42:16 82:18 92:5	289:1,3 290:11,22	73:3,9 123:19,20
181:3 183:18 184:16	106:10 112:12 137:14	291:3 307:7	190:22 191:6 193:13
184:21 185:2 187:13	137:14 151:22 160:22	guys 7:3,15 45:10	196:17 199:10 202:8
189:9 190:5 192:6	175:12 190:3,12	71:22 107:12 144:6	202:15 205:1 210:20
195:3 206:5 209:16	202:21 212:7 283:2,3	163:16 167:5 189:10	253:1 273:19 298:19
209:17 213:1,8,10,11	283:18 287:9 297:17	243:18 255:8 268:18	299:2,22 314:13
213:12,14 214:4	301:18 308:10 309:2	317:11 335:2,17	321:12
216:11 220:17 221:9	311:22 317:10 318:12		healthy 249:7
225:8 227:4 231:13	347:10		hear 17:1,2 30:11 45:10

H

49:18 68:18 148:4
163:14 249:21,22
270:10 276:5 297:15
339:15
heard 21:9 47:10 48:16
74:14 110:13 192:1
273:21 302:5 308:4
348:12
hearing 8:19 78:4
215:19 252:10 275:12
324:6,11 349:17
heart 10:20 12:8 52:17
83:6 111:11 132:9
145:11 150:6 192:7
193:22 213:15 214:3
214:10 248:22 298:6
held 234:4 238:4
Hello 45:13 245:1
279:17 280:12
help 53:21 129:16
144:20 146:15 168:12
241:4 245:18 298:12
304:13 327:3 335:14
helpful 77:1 144:22
303:16 306:1
helping 176:16
helps 14:2 20:1 154:15
174:21 181:1 282:20
hematoma 82:15
hemicraniectomy 98:7
hemispheres 103:20
hemorrhage 4:8,9 80:2
80:10,10,13,14 81:8
84:1,2 96:17,22 100:1
103:11,21 104:5
164:15 216:7
hemorrhages 85:15
hemorrhagic 80:6 93:8
herniating 101:6,8
HERRIN 137:13,17
139:20 142:1 148:1,6
Herrin's 137:12
Hess 80:12 81:19 96:14
97:4,6,17 100:11,22
heterogeneity 142:16
142:17,18
heterogeneous 141:1,3
hey 178:2
hi 75:1 107:14 214:1,7
234:14 279:20 280:11
280:12,13
hide 333:9
high 6:17 28:9,21 32:17
32:20 33:1 34:18,21
35:19 38:8,11 42:6,11
44:19,22 65:20 66:1
90:1,3 91:20 92:2,16
92:21 93:1 94:13,21

95:11,16,19 100:12
105:17,19 111:1
116:11 127:1,12,16
145:15 150:15 151:16
153:18 154:2 161:4
163:17 179:14,16
180:1 181:21 182:3
183:4,7 184:11
188:12,16 189:2
198:18,22 202:14
207:15,19 209:4,8
210:9,13 211:10,14
219:18 223:6,12
224:9,14,21 227:18
227:22 230:12,16
231:18,22 232:14
242:2,6 253:10
258:11,18,20 260:19
260:21 270:14,16,20
273:12,14 274:20,22
277:14,15 279:1,4
291:9,15 292:1,7,9
293:1,4,21 294:1,6,10
294:15,17 295:8,13
295:15 306:19 307:3
307:8 309:7,12
313:17 314:4,6
315:19,21 316:14,16
319:14,18 320:12
337:9,16,20 339:1,5
340:6,10 342:18,22
343:5,9,13,17 350:2,6
high-risk 346:17
higher 12:22 31:15 32:5
75:4 121:10 145:17
146:8 150:11,11,16
151:1,2,6,8,13,14,19
151:21 170:22 173:10
193:3 225:18,19
252:16 298:21 299:3
300:11 316:8
highest 34:12 84:11
126:5 172:16
highly 114:10 130:7
170:16 314:16
his-- 276:5
Hispanics 173:10
historically 156:9
history 217:19 239:3
hold 53:21 54:3 64:19
69:16 74:5 123:6
hold-up 24:18
home 20:4 165:13
216:7 300:3 320:4
336:16 337:2 338:11
338:14 344:14,17,17
344:22 355:16
homogeneity 142:19

honestly 43:6 275:9
hope 30:12 69:2 170:3
257:7 262:16 317:2,4
hoped 266:22
hopefully 196:19 257:9
257:11
hopes 250:15
hoping 62:16 190:10
212:16 330:2
horizons 187:11
hospice 167:12,13,22
177:5,11 208:9
hospital 1:22 2:8 4:10
4:11 10:8,14 11:5,11
11:17,21 53:15 69:4
81:2,9 82:9,11 86:1,6
87:2,3 106:22 108:18
116:7 123:5 126:3,19
137:4,5 138:10 142:2
142:5,17 144:3 145:7
145:12,14,19 151:15
152:7 155:5,13 162:7
162:15 163:1,18
164:8 165:11,16
166:10 168:10 172:10
172:11 174:14 176:5
178:9,13 184:5,10
187:16 202:8,14
206:12,14,14 208:10
215:9 216:15,15,16
216:17,22 217:2
219:7 220:3,4,11,12
220:16 221:22 222:4
225:7 232:9 234:10
235:11,13,14 236:11
237:12 238:19,20,22
239:4,21 240:1,2
288:2 341:13
hospital's 163:19
hospital-level 116:17
hospital-wide 150:11
150:17 151:15
hospitalization 107:2
167:14,15
hospitals 29:5 31:6,14
35:14 42:19 109:6
110:4,5 111:4,17
125:14 126:22 130:15
132:14,15,16,19
138:12,22 140:19
142:6,10 143:17,17
145:22 146:1,2,3,14
147:16,18 150:16
151:2,4,6,13,19 153:3
153:7 156:16 157:2,5
168:4,5,6 169:6
170:10 172:13 176:1
176:2,8,9 177:9

180:12,14 181:4,17
192:13 202:3 208:8
225:14,18,20 226:5,8
226:15 227:6,9,9
228:20 229:10,14
232:18,20,21 233:7,9
233:13,14,15,16,18
234:2,8,16,22 235:6
236:5 238:2,3,15
266:4
hospitals---this 180:17
hour 49:2 85:8 164:12
222:6 237:10 351:13
351:18
hours 10:7 11:10,20
18:4,4,5,8,10,10
19:12,15,16 20:7,18
21:20 47:3,19 50:1,10
50:19 81:2 82:10
83:20 84:6,12 85:2,11
85:12 88:6 102:2
167:5,6 191:11,12
217:3 224:7 235:7
how's 303:11
Huff 2:5 24:9,15 26:6
85:21 86:15 88:16
218:3 254:11,16
354:12,12
huge 21:8 161:18 170:9
252:17,22
huh 66:13 247:8
humor 89:17
hundreds 132:15,16
Hunt 80:11 81:18 89:8
96:14 97:4,6,16
100:11,22
Hunt/Hess 84:4 86:14
Huntington's 320:7
329:14,17 336:19
hybrid 4:11 193:18
203:10 206:1 209:13
212:14
hydrocephalus 263:1
hypertension 217:13
hypoglycemia 217:22
hypotension 187:14

I

IA 10:4 52:3,20 53:6
57:15
ICC 136:4,10 137:18
138:16 142:4,9
145:18 146:5,10
147:17 150:3,4,11
151:7 199:16
ICC's 141:10
ICCs 129:6 149:7,15,20
151:14,21

ICD-10 30:9 109:18 125:22 209:14 327:17	implemented 95:6 131:20 139:9 192:12 246:1,2 303:8 315:8	inability 217:16 inappropriate 215:20 215:21 249:3 302:8 323:5 325:22 326:7,8 326:13 327:12	indicating 223:18,20 indication 104:1 217:5 324:18 325:1 342:7,8
ICD-9 327:17	implementing 134:8	incentive 212:22 332:19	indications 336:7,12 347:7,7
ICH 80:13,14 81:13,22 93:17 94:7 96:15 97:5 97:8 98:1,2 100:8 102:4 103:3	implications 76:10 77:11,12 111:20	incentives 169:8 256:9	indirect 280:20 285:20
ICU 20:3 87:1,4 176:4	importance 21:12 154:17 159:21 247:21 338:20	include 11:13 64:2 178:1 187:7 203:13 210:2 217:12 232:20 233:7,13 239:12 263:21 280:15,22 289:4	individual 24:11 25:2 26:7 104:4 265:3 277:5 288:1 320:21
idea 14:19 20:17 59:17 78:7 113:6 115:7 117:20 120:16 330:16	important 12:5 14:13 16:2 19:9 24:3 32:9 43:17 44:14 46:20 54:6 55:18 74:19 75:2 77:6,9 87:11 108:8 109:21 112:7 117:22 119:19 122:10 143:1 154:14 155:21 158:17 161:22 165:5,17 167:1 168:1 169:11 172:18 190:4 236:12 240:21 247:18 249:10 249:14 250:1,6 253:21 281:16 286:3 298:17 299:6 304:6 327:11 328:4 337:1	includes 216:13 219:6 280:19 283:4,5 292:14 319:12,14	influences 267:15 300:8 327:20
ideal 50:11	improve 57:6 88:5 175:3 184:17 197:13 220:18 245:21 266:17 337:10	including 154:14 165:6 214:16 216:4 241:8 298:18 319:11 322:2 326:6 330:17 332:11 336:12	inertia 23:7
ideally 100:4	improved 42:22 181:8 248:3 257:8 271:20 335:15	inclusion 174:20 216:12 329:11	infarction 221:19
identical 108:20 197:2 198:11	improvement 1:14 30:3 32:14 88:5 90:21 91:18 111:19 115:8 125:6,15 127:7 161:19 180:18 198:9 198:15 214:19 220:17 224:1 232:11 245:2 256:16 281:9 296:15 307:16 309:4 321:10 321:18 335:22 338:16 342:4,11,12 344:6 346:15	incorporate 109:11 194:3 352:10	inflection 63:17
identification 14:1	improvements 219:12	incorporated 275:12,13	influence 101:3 114:9 121:11 179:22
identified 271:19 304:1 308:7	improves 219:3	incorporates 218:6	influences 123:10 153:3
identifies 319:17 320:11	improving 187:9	incorporation 174:11	info 281:20
identify 109:13 212:12 240:15 265:6 298:12 300:7 307:18 321:7 337:8	imputation 135:7 162:4 163:9 179:10 180:2	incorrect 348:2	inform 269:17
identifying 188:4 263:16 304:6	imputations 162:17	incorrectly 327:2	information 3:5 32:10 43:13 62:8,9 67:9 75:19 83:13 90:12 93:5 100:5 109:16 129:11 132:1 163:22 184:4 193:12 231:4 254:7 270:4 272:8,12 273:19 274:1 294:8 322:9 330:16 331:21 332:5 355:11
ideologic 299:8	imputed 163:12	increase 215:3,8 332:2 increased 215:22 216:5 221:1 333:20	informed 249:8,10 273:7
iffy 66:14	imputing 179:17	increases 13:22 14:1	inherent 157:8
ignore 250:20	in- 221:21	increasingly 43:19	inhibitors 323:17 325:18,19 329:22 330:3 333:14 341:3
ignore 51:4 243:18	in-depth 41:22	incredibly 54:5 159:17 240:21	initial 10:1 14:10 20:19 33:22 50:17,18 84:4 91:2,7 100:16 102:2,3 173:16 202:4,5 203:11 217:13 293:12 297:22 344:5
illness 158:1 304:13	in-hospital 173:4 174:1 222:7	independent 36:14 107:8 195:14 315:9	initially 31:15 215:18 246:6 247:14 319:7
imagine 184:18,19 186:16 212:21		indicate 102:10 224:9 228:15 302:7 320:14	initiation 216:17 299:5
imaging 4:15 279:17 280:3,14,15 281:22 283:5 287:1		indicated 90:13,16 215:6 218:8 225:16 228:11 319:22	initiative 214:20 215:17
Imagining 279:16			initiatives 220:17
immediately 84:18 85:3 190:8			injury 82:13 100:16 263:2 330:4 331:3
impact 93:19 163:18 181:9 227:11 251:21 252:17,19 254:1 258:1 324:13			innovation 14:20
impactful 74:11,13			inpatient 108:10 164:4 168:9 299:21
impacts 70:9 258:2			insignificant 340:20
impaired 298:18			inspection 104:5
impairment 261:17 263:3 298:22 299:16 304:15 305:19 325:15 325:16 326:12,16,16 327:8,20 330:5			instances 284:4
imperfect 212:21			instinctively 101:1
imperfections 178:6			Institute 1:14
impetus 77:7			Institutes 4:4 5:14 9:19
implement 276:14 304:17			
implementation 94:1 133:1 257:8			

institution 20:14,15
 24:16 62:21 86:3
 276:9
institutionalization
 299:4
institutionally 71:2
institutions 50:4 57:17
 91:3 122:2,5,13,14
instructions 72:10
instrument 14:15,16
 16:2 21:10,12 135:1,4
 148:17,19 149:2
 304:21
insufficient 9:1 28:9
 29:1 32:18 33:2 34:19
 34:22 38:9 42:7,13
 44:20 45:1 56:10
 59:12 60:4,21 61:1
 65:14,21 66:3,7,11
 70:6 79:14,18 90:2,5
 91:21 92:3,22 94:14
 94:22 95:17,20
 105:18,21 127:13,17
 153:19 154:3 181:22
 182:4 183:4,8 188:12
 188:18 198:18 199:1
 207:15,20 209:5,9
 210:9,14 211:10,15
 223:7,13 224:14
 225:1 227:19 228:1
 230:13,17 231:19
 232:1 242:2,7 247:16
 247:17 253:13 255:2
 255:3,13,17 258:13
 258:19,22 259:15
 260:1,3,5,19 261:1
 270:15,18 273:13,16
 274:20 275:1 277:14
 277:17 279:2,5
 290:20 291:10,17
 292:7,10 293:2,6,22
 294:3,16,19 295:13
 295:16 306:20 307:4
 309:7,13 313:17
 314:5,7 315:19,22
 316:14,17 337:17,21
 339:1,6,22 340:7,12
 342:19 343:2,14,18
 350:2,7
intellectual 262:3 263:3
 271:17,21
intend 331:8
intended 245:18 297:21
 299:13 320:20
intends 304:16
intensive 84:10 89:12
 148:3,9
intent 162:2 215:7

267:22 313:4
intention 192:19
inter- 148:16
inter-item 149:2
inter-rater 138:7 149:6
 225:15
interest 191:1 275:10
 344:13
interested 190:21
 344:16
interesting 86:16 144:9
 185:10 252:5 265:13
 345:22
interfacility 86:2
interim 269:21
intermediate 60:16
 118:5 185:16
internal 280:21 281:7
International 2:11
interpret 116:19 138:21
 227:3 262:4
interpretation 34:8
 69:11 138:1 282:2
 286:15
interpreted 285:11
interpreting 79:21
interprofessional 43:18
interquartile 126:12
interrater 33:16 36:9,18
 37:3
interrupt 39:2 300:15
interval 56:2 146:5,12
intervals 148:7
intervention 11:18
 19:11,20,21 21:5,6,7
 21:21 34:1,3,6 48:20
 53:14 60:17 80:15,17
 80:20,22 102:20
 122:15 123:21 281:14
 281:17 282:22 288:22
 289:8 290:12 337:10
interventional 87:13
interventions 20:7
 54:17 289:4,9 290:4
 335:14
interviews 52:19
intra-arterial 52:3
intra-cranial 216:6
intracerebral 4:9 80:10
 81:8,21 96:17,21
intraclass 36:10
intravascular 84:19
intravenous 4:12 52:3
 213:15 214:11 216:14
 217:14
introduce 9:17 51:18
 107:12,13 125:9
 190:14 214:5 244:19

244:21 279:18 280:2
 318:15,16
introducing 53:19
introduction 246:15
 319:8
intubation 218:10
intuition 162:20
invalidating 167:9
invest 237:13
investigational 218:11
invite 51:17 190:13
invoke 258:12
invoked 247:15 261:18
involved 33:17 49:21
 133:21 206:14 345:13
involvement 299:1
ipsilateral 282:19
IQR 157:18
is-- 244:8
is--the 292:13 324:20
ischemic 4:5 9:15,21
 9:22 10:12 11:4,6
 12:9 13:21 27:21
 48:19 52:2 53:2,5,8
 71:14 107:2 108:6,12
 112:9 116:10 177:1
 216:20 235:17 236:6
 236:19 237:4 282:18
ISIJOLA 3:2 355:6
Israel 2:4
issue 22:15 58:10 63:9
 69:11 71:4 83:18,20
 121:15 135:2 159:1
 163:9 168:13 173:3
 175:10,11 176:12
 199:7,14 200:10
 210:4 221:15 222:9
 229:3 231:1 240:21
 244:17 248:1,10
 250:20 251:4,8 253:1
 253:12,13 262:2
 267:3 268:15 269:2
 271:14 278:9,12
 282:14 284:12 290:2
 302:18 303:20 304:6
 308:18 323:18 325:13
 326:10 328:3 334:12
 334:13 335:11 336:14
 343:8 344:7
issued 5:10
issues 8:16 22:14 33:12
 35:18 49:3 68:17 79:8
 93:17 96:2 134:19
 160:5 168:20 177:16
 190:11 208:7,19
 210:19 228:18 248:3
 248:9 253:21 270:11
 277:20 283:2 323:11

It'll 301:7
it's--there's 282:13
it--it 256:1
item 148:17
items 23:18 148:19
 265:8 304:3 345:21
 351:14
IV 10:3 52:3,20 53:6
 57:15

J
J 65:7 82:21 90:11 92:7
 93:4 95:4 96:2 311:5
 312:10,19
JAMA 216:4
James 1:17 74:22
Jane 2:15 65:6 82:19
 90:10 301:19 311:3
 312:9 355:4
January 95:7
Jeph 137:11,11
Jim 54:19,21 56:13 76:2
 77:22 112:13 125:7
 127:20 129:19 154:6
 170:13 171:2 177:18
 197:3 202:22 205:16
 208:5,19 221:3
 265:19 341:11 354:15
job 121:21 122:2,14
 137:9 180:20 181:3
 197:3 204:16 282:6
Jocelyn 1:13 58:9
 67:10 73:13 218:14
 247:6,9 253:15 260:7
 271:4 272:18 354:22
John 324:16
JOHNSON 3:3 6:15,22
 7:3 59:17 66:14 67:19
 68:5,8 117:18 119:8
 120:3 128:4 206:19
 207:7 246:20 255:6
 270:19 271:3 301:3,7
 302:3 309:17,20
 310:4,9 311:10
joined 318:18,19
Joint 3:14,15,17 9:16
 37:16 42:18 51:18
 88:13 164:22 226:4
Jones 2:7 61:7,18 75:1
 175:22 195:4,17
 196:10,22 200:5,14
 209:20 226:4 229:7
 229:17,21 230:1,5
 232:16 233:22 236:22
 238:10 248:13 250:9
 257:22 263:7 264:3,6
 264:8,11,22 271:7
 273:18 274:14 275:5

348:22 354:14,14,16
Journal 132:9
judge 119:7
judging 21:1
judgment 77:5 139:5
 141:10 286:22 287:4
judgments 41:14
 305:22
Judy 3:11 133:20
 279:20
Julie 3:14 318:19
July 352:12,12,13
jump 13:15 54:21
 112:15 218:18
jumping 55:7
June 324:12 352:7
jurisdiction 237:3
jurisdictions 235:9
just-- 285:9
just--I 329:8
justified 23:12
justify 18:13 144:8
 250:5

K

Kaiser 1:18
Kaplitt 2:8 16:20 17:1,4
 20:22 45:9,13,15
 46:17 49:4 68:11
 69:13 70:4 97:12
 98:19,22 100:19
 101:20 102:14 104:8
 104:12,20 266:8,9
 268:11 269:12 355:3
Kaplitt's 97:11
kappa 33:21 34:4 138:5
 228:6
kappas 34:2 92:14
 149:7
Karen 3:3,12,14 128:1
 147:2 149:13 181:11
 199:15 203:8 204:1
 204:15 206:4,17,20
 300:22 309:16
keep 5:5 46:10 85:5
 108:4 164:6 170:1
 304:7
keeping 169:18 355:8
Kelly 2:16 82:20,22
 93:9 322:21 354:7
 355:4
Kentucky 2:13
Ketan 1:15 15:8 49:17
 83:18 96:13 176:19
 195:2
Ketan's 97:15
key 110:12 115:17,21
 131:21

keypad 351:7
kid 239:22
kidding 254:15
kids 241:2
Kiefer 206:9
kind 5:16 6:12 7:9 23:9
 41:12 70:15,21 71:4
 88:3,21 130:3 139:16
 161:10 162:11 166:19
 234:19 255:16 256:10
 285:21 306:10 341:12
kinds 59:22,22 163:3
know 14:9 15:9 17:6,12
 20:22 21:3,14,22
 24:21 25:4,10,20
 30:22 41:19 43:6,8
 45:15 49:1,4,6,13,18
 49:20 50:17 51:3 56:5
 59:20,20 63:10 66:15
 66:18 68:13,13,16,18
 68:19,22 70:17 71:5
 76:20 78:20,21 83:19
 86:6,9 87:18 97:17,21
 98:14,19 99:2,5,7
 100:22 101:2,8,10,11
 102:2,17,17 104:12
 105:1,10 107:18
 113:11 115:16 116:11
 117:11,21 118:3,12
 119:5 120:7 124:21
 128:21 129:20 130:7
 130:11,16 131:1,1
 132:13 134:3,19,21
 135:9,22 137:18
 138:6,16,21 140:13
 141:17,20,22 142:10
 142:11,15,21,22
 143:8,10 144:1,2
 145:10 146:16 147:1
 148:3,8,13,21 149:5,9
 149:13 152:6 155:21
 157:21 159:3 160:2
 161:5,14 162:10,13
 162:18,18 163:21,22
 164:17 169:5,12,18
 169:20 171:22 172:1
 173:9,17 176:21
 178:1,17,21 179:20
 180:14 182:14 183:18
 183:19 185:22 186:4
 186:17,20 187:4,14
 194:10 196:18 198:3
 198:10 199:15 203:9
 203:15 204:4,8
 209:15,18 212:20
 222:20 224:17 226:16
 227:1 229:1 236:8
 239:17,17 240:7

242:19 245:8 249:6
 250:7,11 253:20
 255:4,18 256:18
 257:4 268:17 269:6
 272:3 274:9 277:22
 285:4 287:10 304:19
 305:17,18 306:3
 308:21 317:2 323:16
 326:1,15 327:15
 328:18 330:21 333:3
 333:11 335:1,5,20
 337:3,5 339:15
 341:14,21 342:4
 346:7 347:16 348:9
 351:14 353:7
knowledge 21:14
 333:19
Knowlton 1:9,11 5:3
 46:13 76:5 213:13
 218:13 219:20 220:6
 221:2 222:22 223:3,8
 223:15 224:10 225:3
 226:2 227:13,15
 228:3 229:5 230:3,6,9
 230:19 231:7,12,15
 232:3,15 233:3
 234:12 238:6 239:14
 240:4,17 241:15,18
 242:9 244:3,14,16,20
 245:6 246:17 247:6,9
 248:11 249:4,19
 250:17 252:3 253:3
 253:15 254:10,20
 255:14 256:21 257:13
 257:20 258:5,15
 259:2,10 260:7,15
 261:3 263:6 265:12
 265:22 266:6 270:9
 271:1,4 273:9,17
 274:12,15 275:3,22
 276:6 277:8,19 278:5
 278:12,17,21 279:7
 279:15 282:7,11
 287:13 290:18 291:5
 291:18 292:3,12,20
 293:8,18 294:5,12,21
 295:9,18 296:9 297:3
 297:6 354:20,20
known 18:5,10 159:20
 217:4
knows 50:6
Koch 129:7
Koenig 2:10 238:7
 355:3
KOLBUSZ 3:14 6:3,6
 7:12 9:18 24:13 26:20
 27:1,20 28:3 30:22
 39:6,9 40:8 51:19

62:11 80:4 88:18
 93:21 102:5
Kristen 3:12 318:20
 319:3
Kuhle 3:14 318:19
 330:10 336:15 342:1
 344:9 345:7 346:13

L

lab 202:5
label 215:14 217:5
 327:12 346:1,2
labor 40:2
labs 191:10,12
lack 16:6 63:22 91:6
 217:18
lacunar 173:11
lag 17:15 345:4
laid 13:18
land 68:1
landed 255:10,13
Landis 129:7
Landis-Koch 199:18
 200:1
language 117:6 312:11
large 36:13 90:14
 113:18 125:17,17
 126:15 140:22 145:16
 152:9 179:18 219:11
 283:5 321:17 340:22
 349:5,11
larger 26:9 142:2
 150:10
laryngitis 318:22
late 29:17 348:3
latent 145:8 158:11
Laughter 189:15
launched 256:17
lead 13:11 23:10 54:19
 54:20 65:1 83:1
 112:14 114:4 118:19
 187:5 257:10 271:5
 281:13 302:8 335:15
Leadership 228:10
leading 112:13 167:14
 177:10 236:1
leads 248:3 252:1
 286:16
lean 316:8
leap 115:16 172:21
learn 157:4 354:17
learned 255:4 266:15
 266:16
learning 96:21
leave 163:11 272:19
 296:21,22 325:2
 349:18
leaves 161:20

leaving 242:20 332:15	42:19 87:3 114:22	334:3,5	250:22 267:9 268:7
Lecturer 1:19	130:10 232:21 237:15	long-term 209:17	282:15 283:2 290:13
led 115:18 261:20	246:21 247:1,14	longer 29:18 305:18	302:19 332:16 341:15
Lee 3:16 44:9 63:8	limits 352:20	338:12	344:13 349:10,11,13
109:15 131:21 168:14	line 16:20,22 26:13,15	look 8:18 23:21 26:16	355:11
180:6 233:3	31:1 35:4 48:14,15	37:6 53:20 54:9 64:5	lots 5:20 113:4 116:12
left 5:13 6:12 62:15	49:19 68:10 97:11	69:14 100:17 110:3	116:12 121:18 146:13
124:10,20 146:1	159:2 203:9 243:2	116:17 117:2,4	181:16 191:7 308:5
203:16 209:21 248:1	253:2 297:11,12,13	125:21 128:22 130:14	326:17 341:19 348:22
272:10,11 299:14	312:3 319:3	134:7 136:1 138:15	loud 353:8
313:20	Lines 2:11 13:12,14	138:17 140:4,12,13	love 55:3,4,5,19 56:4
length 11:15 24:1 53:12	29:3 33:6 35:3 38:15	142:19 143:4,9,16	166:4 318:21
82:6 161:1 190:13	40:14 42:17 134:16	144:13,19 148:20	low 5:22 6:12 8:12
Lengths 23:15	163:6 252:5 307:7	149:11 151:20 157:1	14:11 19:1,2 28:9,22
let's 18:7 19:14 32:14	354:18,18	162:6,11 164:3 171:9	32:18 33:2 34:4,5,19
34:15 38:6 40:19 42:3	link 192:13	177:3 184:6,8,11,22	34:22 36:3 38:9,12
44:16 50:21 51:1	linked 110:1,17 125:19	185:11,15 186:3,19	42:7,12 44:20 45:1
65:17 84:1 89:19 90:9	136:6 206:16 298:8	221:12 222:13 248:8	65:10,21 66:2 90:1,5
91:16 92:18 94:10	linking 65:4	289:1 295:18 300:5	91:21 92:3,22 94:14
95:13 98:7 104:10	Lisa 2:11 13:10 15:10	301:13 310:11 311:17	94:21 95:17,19
105:14 106:1 181:18	33:4 38:14 40:13	311:18 328:17 329:15	105:18,20 117:4,16
182:9 183:1 197:18	112:13 134:13 252:4	330:12,15 331:2	127:12,17 141:18
198:13 207:11 210:5	307:6 354:18	333:22 355:15	146:15 153:19 154:2
211:6 223:3 224:11	Lisa's 112:15	looked 20:21 37:17	164:7 172:12 181:22
227:15 228:12 230:9	list 323:4 334:1,2,3,5	132:10 133:21 135:12	182:4 183:4,7 188:12
241:20 244:3 258:16	listed 24:4 249:18	149:15 151:3 152:21	188:17 198:18 199:1
259:11 260:16 266:19	250:4 262:21	155:4 164:1 169:16	207:15,20 209:5,9
274:17 277:10 292:4	listing 70:2	173:20 209:22 328:11	210:9,14 211:10,15
292:21 293:19 294:13	lit 120:14	looking 7:19 9:22 36:13	223:7,13 224:14,22
295:10 306:17 312:8	literature 36:13 63:16	37:7 77:3 107:10	227:1,19 228:1
315:16 316:10 317:11	64:7 129:13 149:14	126:18 138:8 146:5	230:13,17 231:19
337:14 338:1,10,19	159:4 260:13 263:10	147:4 149:1,9,22	232:1 236:17 242:2,7
339:8 343:11	308:13 323:2 324:10	153:6,9 168:12	253:7,17,17 254:3
let's--this 265:13	little 6:13 7:10 22:14,20	185:22 204:7 205:1	255:2,2,10,13 258:10
letting 328:6	48:13 60:12 76:5	209:21 219:9 228:10	258:19,21 260:19,22
level 33:15 34:11 35:9	85:16 96:15 124:11	248:14,16,18,19	261:14 270:15,17
39:20 92:8 126:3,19	126:22 128:15 171:13	256:5 276:21 311:6	272:9 273:13,15
147:7 152:7 155:5,13	178:3 194:10 196:18	313:8 331:15 332:20	274:20,22 277:14,16
162:8,15 166:10	197:5 201:14 204:21	336:17	279:2,4 289:16
172:10,11 206:14	244:4 245:7 251:8,10	looks 41:11 81:16,20	291:10,16 292:7,9
225:8 247:21 255:12	251:12 255:6 304:9	115:1 118:14 126:11	293:2,5,22 294:2,16
320:21 321:4 331:15	306:7 316:8 334:9	126:14,21 130:12	294:18 295:13,15
335:13 339:13 340:1	341:9	131:4 147:5 153:8	306:20 307:3 309:7
levels 83:7 298:21	little--sorry 251:13	247:4 340:17	309:13 313:17 314:4
leverage 30:13	live 113:19 178:7	lose 221:10 244:5	314:7 315:19,21
Lichtman 133:21	237:16	losing 89:2 160:9,13,14	316:14,17 337:17,21
life 164:9,18 168:22	lives 248:20	lost 46:15 63:1 72:8	339:1,6 340:7,11
245:22 299:6 324:13	living 315:9	335:19	342:19 343:1,14,18
life-sustaining 172:5	load 237:4	lot 17:8 31:9 40:12 57:9	350:2,7
174:19	lobbying 70:15 71:10	57:17,21 59:21 113:4	low-performing 178:12
lifetime 37:10	75:14	113:12 114:4 115:22	lower 31:4 115:5,10
Light 89:17	local 75:6 238:22	137:20 140:2,3 143:4	119:16 122:18 126:22
likelihood 100:18 168:3	logic 195:17 269:3	144:17 148:9 152:6	146:8 147:9 150:13
168:18,20 174:18	328:10	156:3 158:18 160:5	172:6 173:17 174:1
180:20 196:15 237:2	logistically 278:14	161:7 164:1 165:2,4	204:15,21 216:6
limit 17:11,12 26:17	long 44:15 138:19	166:21 171:13,20	233:12
66:20	148:8 187:1 239:3	172:6,7 180:9 197:12	lowest 126:3 172:12
limited 29:22 30:20	287:20 288:6 315:1	197:16 201:22 207:3	lumen 281:2,7

lunch 190:7 213:7,8,9
242:22 243:2 296:10

M

MA 1:11
Madison 2:2
magic 352:22
magical 15:20
magnitudes 129:16
main 196:5
maintained 280:5
maintenance 214:13
269:10,15
major 16:3 19:22 68:18
69:6 114:9 161:8
163:5 166:10 218:1
229:3 323:11 349:10
majority 22:2,4 36:16
45:19 46:6 47:7,8,17
48:7 60:22 65:14 90:8
125:17 154:13 238:15
278:10 283:6 284:4
290:3
making 54:6 68:22 72:1
72:13 114:12 128:2
139:5 161:10 168:18
168:21 218:4 249:7
302:15
malformation 82:14
malformations 245:21
manage 298:19 323:21
management 218:8
283:12
Manager 3:6 245:2
managing 299:1
mandate 305:1
mandatory 215:13
maneuver 143:20
MARCIA 3:7
MARGARET 3:6
marginal 182:19 186:16
marker 24:10 25:9
86:20
markers 330:19
market 348:14
marking 275:21
mass 103:22
Massachusetts 1:22
massive 23:10
match 202:18
matched 204:12
materials 16:8 233:7
matter 41:18 106:15
243:22 278:3 355:17
matters 283:7,9 284:11
284:12 297:20
MCI 325:9
MD 1:11,13,15,17,20

2:3,4,5,7,8,10,12
MDS 344:12
mean 14:17 21:9 29:4
49:6,9,13 50:7 56:15
56:19 58:17 62:2
67:14 68:12 73:13,17
78:1,3,19 83:21 85:10
86:10 89:8 91:5
100:19,22 102:18
105:1 116:11,20
118:12 119:21 133:6
133:15 140:2 142:13
147:17 158:9,16
159:14 165:4,16
166:5 168:8 169:14
171:4 172:12 176:13
176:20,21 177:19,20
178:2,8 180:11
185:10 186:12,13
197:2,9 202:18 208:7
208:8 211:1 221:8
232:11 236:2 238:9
239:19 240:20 243:18
248:6 249:9 253:7
254:12,16 266:3
268:21 269:6 284:5
290:7 310:2 322:4
328:21 329:18,22
331:14 332:2 333:8
333:10 338:12 341:21
344:7,11 345:15
347:15 348:17
meaning 47:1
meaningful 150:3 162:3
193:5 316:6
means 16:10 48:20
62:1 103:5 108:16
136:10 166:14 171:22
182:8 254:6 255:3
277:5 302:1 335:18
meant 124:10 151:8
304:12 312:5
measure 9:17 10:11
11:2,4 12:6 13:16,17
14:20 16:14,15 18:17
18:17,19,21 19:2,6,17
19:20 24:5 26:20 27:5
27:7 28:8,20 29:1
30:21 32:11,22 33:3
34:18,20,22 35:8,11
36:8,20 37:5,11,12,17
38:2,3,8,12,17,21
39:14 41:1,5 42:6,11
42:13 43:3 44:19,21
45:1,7,21,22 46:3
47:22 48:7,11 50:13
51:7,8,11,15,18,19
52:1,10,14 53:11,17

54:11 55:5,7,9,16
57:3,16 58:4,5,7,8,12
59:3,7 60:5,6 61:4
62:13,13,14 65:20,22
66:5,10 69:21 70:20
71:7,18,18 72:3 73:8
73:8,10 74:20 75:14
76:17 77:7,15,21 78:8
78:10,11,15 79:12,17
79:21,22 80:1,8 81:5
81:5,16,18,20 82:2,4
82:4,22 83:10,11
85:19 86:17 87:19
88:4,10,14,17,20
89:22 90:6 91:20 92:4
92:21 93:2 94:1,13,22
95:5,16,20 96:4,9
101:13,18 102:18
103:7,13 105:17,21
106:5,8,20 107:13,16
107:21 108:2,5,5,8,9
108:11,13,19 109:1,9
110:1,3,14 112:10,11
113:1,7 119:17,18,19
120:2,20 121:5,7
122:9 123:12,18
124:18 125:3 126:8
126:10 127:12,17
128:15,16 129:9
131:18 133:1 134:8
135:3 136:3,7,9 138:8
138:14 139:9 141:4
143:3,10 144:15,21
145:21 147:1,5
151:15 153:18 154:3
155:5,8,9 156:17
157:6,17,19 159:8,9
162:13 163:7,18
165:1,8 167:9,16,18
169:22 170:4,8,19,20
175:2,3,7,13,16 179:1
179:13,21 180:1,8,8
180:10,13,17,19
181:3,15,17,21 182:5
182:6,14 183:3,8
184:6,21 186:9,14
187:7 188:11,19
189:5,19 190:2,6,14
190:15,16 192:4,17
193:2,8,15,17,19
195:6,12 196:2,3
197:2,21 198:7,17
199:2 204:1,4,7 206:1
207:14,21 208:6
209:4,10,12 210:8,15
211:9,16,21 212:5,14
213:3 214:4,5,11,12
215:2,7,20 216:12

218:5 219:1,6 220:15
222:19 223:6,14
224:13 225:1 226:12
226:13,19 227:18
228:2,11,14,22 229:1
229:9,15 230:12,18
231:18 232:2,18,20
233:6,6,9,15,16 234:1
234:4,9,15 235:3
236:20 238:11 239:10
240:10 242:1,8,13,17
244:9,22 245:5,9,9,10
245:13,14,18 246:1,6
246:13,14,16,20
247:13,19 250:4,5,7
250:12 252:19 253:10
254:18 256:8,10,11
257:2 258:18,22
259:14,22 260:5,18
261:1 262:1,14
264:17,18 265:13
267:17,17 268:1
270:14 273:12,16
274:6,19 275:1,15
276:4,13,17 277:6,13
277:17 279:1,9,12,18
280:2,3,13 281:10,21
282:12 283:8,10,17
284:3,13 285:1,3
286:8,9,9 287:6
288:10 291:1,6,9,17
292:6,10 293:1,6,16
293:21 294:3,15,19
295:12,16,22 296:3
297:1,10,21 298:2,3
299:6,9,10,13,15,17
299:19 301:1,8,14
303:9,13,14 306:12
306:19 307:4 309:6
309:14 311:6,7,15,20
313:7,10,12,12 314:3
314:8 315:18,22
316:13,17 317:21
318:6,13,16 319:7,12
319:15 320:2,4,8,10
320:11,20 321:1,2,6,9
321:15 322:11,13,17
327:9,14,15,17 328:4
330:22 331:7,10
332:8,10 333:17
336:9,10,16,21 337:2
337:16,22 338:22
339:7,12 340:6,12,20
342:6,10,18 343:2,13
343:19 344:4,8,10,12
344:16,19,22 345:1,5
345:11 346:3,19,21
346:22 347:6 350:1

350:11,13,18 352:1
measure's 178:17
 229:13
measure's- 95:4
measure-- 288:12
measured 58:6 74:2
 75:21 130:7,9,18,19
 130:21 136:20 142:8
 142:11 151:17 155:12
 155:22 287:22
measurement 3:4,7 4:8
 4:15 14:18 19:15 44:5
 58:1,11 73:16 80:2,6
 80:11 81:14,22
 107:15 191:1 222:12
 267:19 272:22 273:4
 279:16 280:2,22
 281:3 284:15,20
 285:19 286:5 287:17
 289:13 297:19 298:11
measurements 138:9
 280:20 281:6 285:21
 287:1 288:18
measures 4:4 5:8 11:16
 15:16 17:10 30:12,18
 37:18 39:3,16,18 40:4
 40:9 41:1 53:18,18,19
 55:4 59:22 60:15
 70:18,18 71:20,22
 73:3 74:13 75:20
 76:14,22 82:8 93:7
 96:13 107:8 112:8
 115:15 117:5,20
 120:17 123:2,4 130:3
 135:11,12 146:19
 149:10 150:5,14
 151:12 153:4,4 155:4
 155:16 156:6,6,13
 158:11 159:2,3,6,9,11
 159:14 160:12 164:2
 164:21 165:4 169:11
 169:17 179:11 186:15
 186:22 187:3,7,20
 192:20 193:7 194:2,3
 196:4,11,16 199:13
 201:13 208:11 210:2
 212:12 226:6 232:7
 240:7,8 268:10
 275:11 298:9 302:19
 303:14 305:6,10
 311:2 317:3,8,14
 321:13 330:12 331:12
 342:5 347:5
measures-- 247:1
measures--methods
 283:15
measuring 54:4,16
 56:18 58:5,15 61:21

64:21 71:2 101:4
 119:21 140:16 160:17
 165:21 166:15,16,18
 179:2 332:10 335:13
 335:21
mechanical 10:4 52:5
 52:21 53:7 282:21
mechanisms 179:10
median 126:6 322:4
mediate 119:12
mediator 115:17,21
medical 1:12 2:3,4,5,9
 2:10,20 10:7 11:10
 33:11 38:15 41:9
 80:20 95:9 109:16
 201:8 205:13 217:9
 217:19 220:21 263:5
 265:10 283:12 298:10
 298:14 299:2,3,21
 300:12 302:9 321:5
medically 308:16
Medicare 110:6 125:19
 130:15 132:19 152:5
 152:8,15,16 153:2
 165:22 201:1 303:4,7
 303:16 321:3,17
medicated 327:2,21
medication 217:14
 251:22 264:1 321:7
 328:16 330:15 333:11
 333:12 345:12 348:2
medications 253:19
 298:14 319:10,19
 320:5 330:14,17,18
 330:20 335:3 337:6
 346:1,3,17
medicine 2:2,6 44:2
meet 219:16 262:12,18
 264:16 276:17
meeting 1:3 147:10
 203:20,21 224:2
 227:1 324:7 331:2
 352:4,10 354:2
Melody 2:13 38:19
 327:4 347:10 354:19
member 13:12,14 15:9
 17:1,4 20:22 21:19
 22:4,7 23:13 24:9,15
 25:18 26:6 29:3 30:17
 31:8 32:9 33:6 35:3
 38:15 40:14,22 42:17
 44:8 45:9,13,15 46:17
 49:4,18 50:15 54:20
 55:2 56:15 58:10,17
 59:11 61:7,18,20 65:7
 67:12,18 68:11 69:13
 70:4,14,17 71:17,19
 72:15 73:15 75:1,17

78:1 82:21 83:19
 85:21 86:9,15 87:5,16
 88:16 89:7 90:11 91:1
 91:14 92:7 93:4 95:4
 96:2 97:12 98:19,22
 100:19 101:20 102:14
 104:8,12,20 112:14
 118:11 119:15 120:19
 125:8 127:21 129:20
 133:2,13 134:12,16
 135:14 136:13 137:1
 139:2,21 140:5,8
 142:13 150:4 151:10
 152:3 154:7 158:9
 160:4 163:6,10 165:7
 171:3 175:22 176:20
 177:19 182:11 183:12
 186:12 187:19 195:4
 195:17 196:10,22
 197:1 198:10 199:5
 200:5,14 201:6 203:1
 205:17 208:4 209:12
 209:20 210:18 218:17
 219:22 221:4 223:16
 225:5 226:4 228:4
 229:7,17,19,21,22
 230:1,5,20 232:4,16
 233:22 236:22 238:7
 238:10 239:15 240:5
 247:8,11 248:13
 249:5,13,17 250:19
 251:10,12 252:5
 253:4,16 254:4,8,11
 254:16 255:15 256:4
 257:14,22 260:8
 261:4,22 263:7 264:3
 264:6,8,11,12,22
 265:20 266:1,8
 268:11 269:12,13
 271:7 273:18 274:14
 275:5,7 282:9,12
 285:8 286:1 287:5
 288:4,9,16 289:14,21
 290:15,19 291:11,19
 292:13 293:9 294:6
 294:22 301:21 302:4
 303:2,18 304:9 305:5
 305:14 307:7,17
 308:3,12,18,22
 310:16 311:5 312:7
 312:10,19 314:12,22
 316:4 322:22 324:5
 325:8,12 326:1,9,20
 327:6 328:7,21 329:4
 329:5,8,11,13,18
 333:6,22 334:14,21
 338:3 339:10,19
 340:14 341:12 343:5

343:22 345:6,8,20
 347:11,19 348:6,16
 348:22 352:6,11
 353:15 354:9,11,12
 354:14,15,16,18,19
members 43:2 48:17
 134:21 181:2 200:20
 265:5 296:17 303:6
 321:1 342:5 352:21
membership 299:11
memory 303:11,21
 304:2
mental 261:19 305:18
mention 192:16 284:18
 291:11
mentioned 27:3,12,13
 38:19 43:21 55:20
 128:18 129:4 149:14
 208:19 226:8 287:9
 305:22 336:6
mentions 55:11
mercifully 182:11
Merck 2:3
merging 206:11
met 1:7 262:15
meta- 219:11
metabolic 218:2
method 280:18 281:3
 288:14,17
methodologic 195:5
methodologies 285:19
methodology 128:21
 282:3 285:14
methods 128:22 281:12
 281:14 282:3
metric 15:19 44:13
 148:18
MGH/Harvard 3:16
MI 150:6,9 187:14
mic 245:6 265:22 351:2
 354:17
Michael 2:8 68:9 74:8
 97:10 345:21 354:7
 355:3
Michelle 1:17 13:10,14
 30:16 40:21 74:22
 75:16 175:21 176:21
 355:1
Michigan 1:17
microphone 107:5
 136:12,22 196:13
 212:18 224:16 271:6
 279:19 297:2 316:22
 336:2 351:2 353:21
microsurgical 84:18
 87:14
mics 249:20,21
midst 150:12

migraines 239:3	mistake 311:10,14	340:7,11 341:6	314:10,20 317:6
migrating 196:16	mistranslated 136:14	342:19 343:1,14,17	322:11,13 338:1
Mike 13:10 16:18,20	misunderstanding	350:2,6	339:8 342:9 343:11
45:10,12 46:13 49:19	36:21	modest 116:13	347:1
50:5 70:3 98:16	misunderstood 310:16	modification 193:8,15	moved 7:22 63:2
102:12 266:8	mitigate 245:19	modifications 94:3	215:15 290:13 346:20
Mike's 50:16	mix 82:16,17	modified 4:6 14:17	moving 57:18 74:19
mild 25:21 41:18	mixes 168:9	15:11 16:4 22:14	199:7 212:8 213:7
162:22 261:19 306:4	mls 99:14	51:16,20 52:8,11 53:9	249:8 279:15 296:9
325:16 326:16 327:19	MMSC 1:20	54:15 58:3,5,7,15	296:11 302:16
330:5	mNIHSS 14:21,22	59:4 61:22 62:6,16,19	Mozaffarian 216:3
million 150:18 322:3	modalities 285:13	62:21 175:14,16	223:18
mimic 88:21	model 110:11 112:3,3	271:22	MPH 2:11,13
mimicking 157:12	126:1 156:19 157:4	modify 131:3	MRA 280:15 285:18
mimics 218:4	157:11,22 158:6	mom 254:12	289:15
mind 46:10 128:1	159:10,16,16 160:1	moment 51:5 183:2	MRI 5:19
302:11 304:7 323:18	160:20 161:5,21	265:19	MRIs 122:16
mini 305:18	172:17 178:2 191:14	momentum 97:8	MSc 1:11
minimal 149:3 199:16	191:21,22 194:15,16	monitor 327:11 330:7	MSN 1:17
258:1	194:18,19 201:16	month 221:5 352:2,5,17	MSPH 2:7
minimize 234:22	modeling 108:21	months 52:22 63:10,13	multiple 48:16 72:5
minimum 148:21	156:17 191:19	63:13,17,18 64:3	135:7 162:4,17
227:11 228:20 234:17	models 27:10,12	267:18 269:5,7 302:1	205:22 206:9 219:2,2
234:21	154:18 155:19 174:11	morbidity 333:20	299:20 330:4
Minnesota 261:8	moderate 14:11,11 28:9	more--a 251:7	multitude 265:4
272:22 273:3	28:22 32:17,18,21	more--I 269:6	MUNTHALI 3:3
minor 98:12 174:4	33:1 34:12,13,19,21	more--we 317:3	must-pass 66:18
minority 22:8	36:3 38:9,11 42:7,12	morning 9:18 20:11,12	muted 97:13
minuscule 349:4	44:20,22 45:19 47:18	28:7	
minute 89:9,14 91:6	65:21 66:2 83:16 90:1	mortality 30:12 37:8	N
101:9 176:13 215:15	90:4,4 91:20 92:3,16	58:21 107:1 108:7,12	N.W 1:8
215:16	92:22 93:1 94:14,21	110:14,16 111:2	narrow 286:2 287:8
minutes 38:17 39:2	95:11,17,19 105:18	112:9,22 113:7,10	NASCET 282:3 283:10
40:7 41:3,19,21 43:10	105:20 127:12,16	114:6,9 115:3,6,9,10	283:17 288:14,18
176:14 215:9 216:18	141:19 146:18 147:11	115:15 116:8,14,22	national 1:1,8 2:14 4:4
217:16 219:7,15	153:18 154:2 181:21	118:19 121:19 122:19	5:13 9:19 29:6 40:2
222:6 223:20 234:11	182:3 183:4,7 188:12	126:4,5,6,21 146:10	75:3 133:19 144:15
243:1	188:17 189:2 198:18	150:5 152:15 155:4	147:7,10 200:8 298:3
mis-classifying 332:1	198:22 199:20 207:15	155:14,20 164:4	314:14
mischaracterize 169:5	207:19 209:5,8 210:9	169:17 170:2,18	nationally 31:21 72:19
180:17	210:13 211:10,14	171:10,17 172:7,17	72:20
mischaracterizing	223:7,12 224:14,22	173:5,17 174:1 178:5	nationwide 2:8 31:14
146:14	226:1 227:19,22	180:12 181:8,14	natural 257:16
misclassification 332:6	228:16 230:13,16	184:11 185:20 187:5	NCQA 273:1
misclassified 178:4	231:6,19,22 242:2,6	187:8,13 192:17	near 286:17 299:5
misclassifying 145:22	258:11,19,21 260:19	216:8,10 333:20	nearly 6:17 130:11
misinterpreting 171:2	260:22 270:15,17,20	mother 173:5	necessarily 15:5 105:2
misleading 244:21	272:9 273:13,15	motivated 169:15	113:14 116:4,7,22
misreading 101:20	274:20,22 277:14,16	move 17:13 28:5 66:3	119:20 148:10 161:6
missing 21:16 35:18	279:2,4 291:10,13,16	70:18 71:3,8 79:7,22	199:6 227:8 235:10
161:9,18,22 162:14	292:7,9 293:2,5,22	92:18 94:10 95:13	237:7 274:5 286:20
162:18,21 163:3,12	294:2,16,18 295:13	106:1 127:10 153:15	347:15,17
177:21 179:9,12	295:15 306:4,5,20	183:1 188:8,21 190:5	necessity 152:5
183:21 271:15 293:3	307:3 309:7,12	190:21 192:19 197:5	neck 280:15,15 283:5
missingness 162:4,10	313:17 314:4,6	198:13 209:1 211:18	need 17:22 19:19 20:3
163:8	315:19,21 316:7,14	240:3 241:14 243:1	20:5 36:9 50:11,12,17
missings 35:21	316:16 337:17,20	259:2,5 260:16 276:7	67:3,22 70:17 78:15
Mission 2:14	338:15 339:1,5 340:1	277:10 309:3 313:20	84:4 87:10 101:15

104:13 117:9 124:19
 132:22 135:18 139:6
 157:13 158:2 161:6
 176:7,10 197:16,16
 199:11 213:4 224:18
 235:18 244:7 253:21
 258:13 277:22 296:22
 298:22 299:2 301:12
 305:20 306:9 334:12
 339:15,16 349:10
 351:22 352:19,20
needed 144:8 266:16
 271:13 300:16 319:2
needle 219:10,13
 223:20
needs 55:6 68:1 87:17
 99:20 217:21 234:10
 239:7 281:18 299:19
 302:18 304:6 313:3,7
neonates 236:7
net 144:5
network 241:1 314:14
 315:13
neural 251:3
neuro 14:12 84:9 87:1
 89:11 176:4
neurodevelopmental
 262:12,22
Neuroendovascular
 1:15
neurologic 22:18 23:3
 41:22
neurological 1:14
 10:13 14:5 22:22
 134:1 235:7 262:11
neurologist 20:14
 168:14 212:10 237:1
neurologists 86:19
neurology 1:3,7,13,21
 2:7 3:10,15 91:8
 244:19 245:3,4 261:7
 275:6,8
neurosurgeon 89:16
neurosurgeons 86:18
 97:7
neurosurgery 1:16 91:9
Neurovascular 1:16
never 58:12,14 59:19
 70:20 71:21 73:15,16
 130:19 163:11 164:17
 248:14 289:12 327:21
 327:21
new 12:18 13:16 30:9
 177:17 194:9 198:12
 219:17 255:9 266:20
 267:4 270:11 303:6
 330:15 347:6,12
newer 14:16 17:10

219:5 228:8
news 160:8,8
nice 69:2 255:11
night 83:1
NIH 9:14 12:8,12,22
 15:14,21 16:4,4 17:7
 17:17 18:2,9 19:17
 21:4 22:12,16 27:18
 27:21 30:10,13 36:11
 47:2,12 48:4 50:17
 56:20 85:14 97:3
 108:22 109:4,11,14
 110:7 111:16,22
 112:4 125:21 126:10
 130:6,13 131:17
 132:11,21 134:3,4
 144:7 154:13 157:10
 157:18 158:2 159:21
 161:17 162:13 164:11
 168:12,17,19 169:1
 170:8 173:12 174:21
 175:8,9 179:16 180:2
 182:13 192:2,8 194:9
 194:10,11,17 209:13
NIHSS 4:5 10:1,18 11:7
 13:21 14:14,17,21
 15:11 29:15 33:22
nimble 348:14
Nimodipine 9:11
NINDS 25:10
NINDS-TPA 63:19
nine 34:20 42:12 66:1
NIS 134:22 135:7
NMDA 323:17 325:18
 341:3
nobody's 172:15 249:1
noise 225:12 234:19
nominate 353:18
nominated 13:12
non-approved 330:18
non-clinicians 76:7
nonsurgical 82:9
nontraumatic 82:14
normal 221:12,18
 222:10
normalized 221:6
Northwestern 2:16
not--I 332:1
not--these 305:12
note 24:15 102:6,8,9,11
 213:20 299:6
noted 24:6 131:6
 246:11
notes 5:18 301:5
notice 345:3
noticed 345:3
notion 347:1
nowadays 44:11

NQF 3:1 59:16 60:2
 78:13 83:15 107:7
 117:2 128:5 144:19
 158:17 194:1,1
 196:10 203:18 205:19
 234:2 246:18 255:7
 257:3 261:6 300:4
 335:19 352:6,11
 354:6
NQF-endorsed 12:6
 192:18
number 20:21 26:8,10
 29:17 31:4,5 49:12
 51:17 53:22 54:2
 56:18 57:3,5,12 69:15
 76:19 81:13 89:22
 103:11 109:16,18
 110:17,21 132:3
 133:6,16 136:15
 137:19 139:5,7
 141:14 144:21 145:20
 146:4,8,22 147:10,11
 148:19 153:3 160:6
 161:2 164:5 167:2,4,6
 187:20 192:9 202:19
 215:3 218:22 226:22
 232:6 243:10 261:22
 263:11 272:16 283:5
 284:2,4 290:1 296:17
 303:22 349:2 351:6
 352:22 353:1,6,8,13
 354:6,9
numbers 23:4 25:12
 126:15 135:22 137:3
 137:5 143:12 145:15
 145:17,18 167:18
 176:8 179:18 191:13
 202:18 228:19 237:17
 345:19 349:11
numerator 11:6 18:22
 33:7 46:4,22 47:7
 48:2 53:8 61:22 62:10
 72:3 81:10,12 216:13
 280:17 312:13,20
 331:9
numerator/denomina...
 225:9
Nunnally 148:15
nurse 202:11
nurses 39:22 43:19
nursing 1:20 300:1
 320:4 336:16 337:2
 338:11,13 344:14,17
 344:17,22
nutrition 176:6

O

objective 299:17

obligated 300:18
observation 166:5,6
observational 114:21
 219:9 256:2
observations 234:17
obstructions 277:7
obtain 62:21
obtained 52:8,19 53:10
 94:7 134:4
obtaining 231:4
obvious 117:15 184:4
 184:15
obviously 17:15 59:5
 113:10 116:22 140:22
 142:14 165:2 306:3
occasionally 170:5
occlusion 173:11
 286:17
occupational 43:22
 300:2
occur 19:10 86:4
 220:16
occurred 217:1 220:2
 263:16
occurring 19:12 333:2
occurs 85:21 257:8,9
 348:1,3
October 30:8 109:12
 131:7
odd 38:22
odds 170:16
of--that's 277:5
off-label 330:22
offer 60:3 132:7 154:16
 154:19
offered 154:9
offers 83:5 157:20
office 299:21
Officer 1:14 2:14
offices 315:9
officially 285:3
oftentimes 176:22
OGUNGBEMI 3:4 124:6
 124:8 188:10,15
 189:3,9,17,22 197:20
 198:5,16,21 207:13
 207:18 209:3,7 210:7
 210:12 211:8,13,20
 212:3 223:5,11
 224:12,17,20 227:17
 227:21 230:11,15
 231:17,21 241:22
 242:5,11,16 258:17
 259:12,20 260:17
 270:13 273:11 274:18
 277:12 278:22 279:8
 291:8,14 292:5,22
 293:20 294:14 295:11

295:20 306:18 307:2 309:5,11 313:15 314:2 315:17 316:12 318:3 337:15,19 338:21 339:4 340:5,9 342:17,21 343:12,16 349:22 350:5,10,16 oh 6:1 40:21 124:13 134:14 137:14 140:5 175:20 184:12 185:12 208:2 218:15 231:8 243:3 293:3 308:3 okay 8:2,8,9 13:9 17:4 22:7 26:18 27:16 28:4 28:20 29:3 31:7 35:3 38:5,6,15 40:16 42:17 43:6 46:17 47:5 49:14 49:16 50:21 51:1,13 51:19 61:18 63:6 65:12 67:16 73:20 74:5,16 76:4 79:16 80:1 86:16 89:19 91:16 98:21 102:1 107:10 108:3 124:9 124:13,16 127:9 134:14 137:1,13,16 137:17 139:21 140:5 140:5 152:2 153:11 153:16 175:16 177:14 181:18 182:9 189:17 190:3 195:1 196:22 200:16 201:10 205:8 207:7,7,10 208:20 213:13,14 223:3 224:20 225:3 227:15 229:22 230:5,9 231:7 231:9,15 233:22 241:20 243:6 244:3 244:16 247:11 258:15 259:2,17 264:11 268:11 269:12 270:11 271:4 273:10,17 274:16 277:8,10 278:12 279:7,15 282:11 285:3 286:1 286:11 287:5,18 288:19 291:7 295:10 296:9,12,22 297:3,8 297:17 300:19 302:4 302:13 307:17 312:8 316:21 318:12 319:6 321:20 322:20,22 334:20 335:17 337:12 340:2 349:16 351:12 okay--the 286:3 old 164:11 331:1 older 14:14 113:16 153:8 216:14 224:5	226:14 228:5 289:5 319:16 323:5 331:1 on-- 278:16 on--sorry--on 262:21 on--you 253:20 on-label 345:11 346:9 once 18:20 43:11 46:17 57:11 109:15 113:14 132:2 133:15 145:1 193:11 202:16 245:16 264:5 282:14 306:5 330:15 341:21 345:4 one's 208:17 298:19 one- 138:15 one-minute 300:17 onerous 19:8 120:13 ones 7:7,22 117:21 150:12 163:12 192:7 349:14 ongoing 268:1 297:22 only--if 332:10 onset 18:8 217:19 235:7 open 16:20,22 28:10 45:6 51:6 90:1 97:11 118:20 188:10,13 189:6,20 197:22 198:19 207:16 209:5 210:10 211:11 212:1 223:7 224:15 227:19 230:13 231:19 242:3 242:14 243:5,6 258:19 259:16 260:2 260:20 270:15 273:13 274:21 277:15 279:2 279:10 280:1 291:10 292:8 293:2,22 294:16 295:14 296:1 297:12,13 306:20 309:8 313:18 314:5 315:20 316:15 318:8 337:17 339:2 340:7 342:19 343:14 350:3 350:13 351:1,2 352:16 opened 31:2 operating 97:18 99:2 100:10,13 101:14 103:18,21 operation 99:3 operational 50:20 operationalize 184:16 Operations 1:18 operative 79:1 operator 16:22 243:6,8 243:14 297:13 351:2 351:4,9 opinion 21:16 49:6 50:8	55:10,15 56:9 74:1,3 97:16 154:10 opinions 49:7 75:8 opportunities 19:11 32:13 54:22 90:10,21 91:17 125:6 127:7 307:15 309:4 opportunity 30:3 91:12 91:15 131:8 156:12 183:20 198:14 322:16 338:15 opposed 32:7 140:19 179:2 181:16 341:19 opposite 77:19 opt 178:11 optimal 88:4 178:13 optimistic 109:19 optimize 48:21 105:12 option 200:6 options 188:11 189:5 189:19 197:21 198:17 207:14 209:4 210:8 211:9,22 223:6 224:13 227:18 230:12 231:18 242:1,13 258:18 259:14,22 260:18 270:14 273:12 274:19 277:13 279:1 279:10 291:9 292:6 293:1,21 294:15 295:12,22 306:19 309:6 313:17 314:4 315:18 316:13 318:8 337:16 338:22 340:6 342:18 343:13 350:1 or-- 309:19 order 5:17 67:21 167:19 281:19 296:11 orders 116:19 orient 108:4 original 231:4 254:9 257:2 262:13 285:14 328:10 originally 31:11 214:14 280:4 339:21 orthogonal 114:10 OT/PT 23:20 ought 64:11 outcome 19:18 52:13 52:14 53:19 54:11,16 55:4,5 57:16 58:8,12 58:13 60:15 62:14 63:21 64:22 70:18,20 71:18,20,21 73:3,4,8 73:9,16,17 74:20 76:1 76:13 77:21 78:8 108:20 112:8 113:11 113:14 116:10 117:5	117:11,20 118:9,14 119:12,17,21 120:2,7 120:17 121:9,12 122:7,8 123:4,20 135:3 159:3,14 175:12 177:13 181:7 185:17 186:9,14 187:10 190:18 213:2 219:4,12 240:11 249:6,7,18 outcomes 14:2 37:8 48:22 53:20 54:4,9 56:3 59:6 60:16 65:2 65:3,5 105:12 108:5 117:21 118:5 119:19 120:12 121:5 152:11 159:8 160:1 188:3 193:7 219:10 248:3 249:14,16 250:15 251:6 254:2 257:11 276:21 298:17 302:9 outliers 331:16,19 337:9 341:20 outset 301:22 outside 217:4 outweigh 74:2 outweighs 320:5 overall 30:3 31:17 45:4 45:7 50:13 51:2,6,8 81:6,12 106:2,5,9 129:22 136:2 151:14 182:9 188:21 189:4 189:18 208:14 211:18 211:21 216:8 228:19 228:21 242:9,12 250:13 279:9 295:19 295:21 296:1 316:20 317:15 318:4,6 350:17 overlapping 156:6 overly 54:1 overnight 20:10 overplay 145:6 overuse 335:13 336:1 overview 300:17 overwhelmingly 156:4
P			
p 29:20			
P-R-O-C-E-E-D-I-N-G-S			
5:1			
p-value 29:15			
p.m 244:1,2 351:21			
355:18			
page 204:7 228:12			
pages 41:8			
pairs 149:18			
palsy 263:2			

panel 293:10,10,12
324:21 340:16 347:6
paper 33:11 95:9
115:13 148:15 152:22
173:22 200:20 216:2
paradox 173:21
parallels 88:11
parameters 281:5
parent 239:16,20
parentheses 69:19
parenthetically 215:10
parents 239:17
Parkinson 2:14
Parkinson's 120:20
324:9,14,16,18 325:1
325:3,6,11 326:17,22
328:8,22 329:2,6,9,16
336:13 347:14,20
348:8,20 349:13
part 12:14 18:21,21
21:3 22:1,5 24:4 31:3
36:6 43:8 46:18 47:6
47:18 48:2,3 58:13
60:17 69:9 70:1 89:16
95:5 98:14 99:1
103:12 117:20 118:16
119:6 128:16 132:22
148:1 150:9 152:16
154:21 155:18 165:8
166:4 172:20 173:19
191:17 193:6 196:20
201:19 250:3,5,7
275:18 286:7 306:3,4
317:22 321:9,14
322:2 335:21 338:3
339:11 344:10,16,20
347:1
partial 287:2
PARTICIPANT 6:18
124:11 189:12,14
208:1 231:11 242:19
244:13,15,18 254:14
259:8,18 262:19
296:18 313:2 353:10
353:13
participate 142:20
161:15 226:20 227:10
249:11 274:4 298:10
participated 116:16
participating 111:18
115:7 140:21 213:21
227:6 233:19
particular 11:2 27:5
60:4 69:11 81:4 82:3
128:15 129:2 246:20
262:7 264:16 289:15
304:21 319:13 327:9
340:20 354:1

particularly 23:18
85:11 139:4 187:4
284:16 327:12
partner-in- 107:18
partnered 111:13
192:20
parts 57:18 182:9
PAs 129:5
pass 35:1 38:12 42:13
45:2 60:6 66:18 79:22
90:6,8 92:4 93:2
94:22 95:20 102:1,7
105:21 117:15 125:4
127:18 188:1 239:8
258:11,22 311:22
313:14
passed 8:22 9:12 189:1
passes 29:1 33:3 51:10
154:3 183:8 188:18
198:7 199:2 200:2
207:21 209:10 210:15
211:16 212:5 223:14
225:1 228:2 230:18
232:2 242:8 260:5
261:1 273:16 275:1
277:17 291:17 292:10
293:6,15 294:3,19
295:16 296:3 307:4
309:14 314:9 315:22
316:18 337:22 339:7
340:12 343:2,19
350:11
Patel 3:15 250:2,22
251:11 256:22 268:3
270:6 276:3,9 279:14
path 5:19 176:17
177:11
pathologist 23:20
pathway 56:17 59:12
60:3
patient 1:12 19:15,18
20:3 21:6 24:17 34:1
41:18,19 48:21 57:4
72:6 76:8,10 77:3
80:21 83:22 87:12
89:10 99:6 100:6
101:2 105:12 108:17
116:20 145:11 152:10
166:13,16 168:8,14
176:3,4 178:10 185:3
186:5 187:17 217:17
220:2,4 234:10
235:15,21 237:14
238:17 276:16 298:2
298:17 300:13 302:15
303:11,12 313:5,6
321:11 323:14 326:11
333:9 342:3,11 346:5

patient's 100:14 101:7
102:4 298:9 299:19
patient-centered
113:11
patients 4:5,9 9:15,21
10:1,5,9,12 11:4,6,8
11:11,13,14,15,17,19
12:10,14,15,21 13:2
13:21 14:1 20:6,8,10
20:17 26:7 27:22
29:10 31:16,16 34:5
43:7,20 46:6 47:1,8
47:12 48:7,19 49:22
52:2,20 53:3,5,9,11
53:12,13,14 54:1,2,4
54:8 63:1 69:1,18
71:14 72:8 74:19
75:22 77:2,8 80:7,10
80:11,13,14,19 81:8
81:13,17,21 82:5,6,7
82:9,12 84:4,8,13
85:5 86:1,7,13,21
87:8 89:2 91:8 96:22
98:3 99:22 100:21
108:6 110:6 113:12
115:9,10 117:22
121:22 122:3,7
125:16,18 135:10,13
142:18 145:7,13,19
149:19 150:19 152:9
156:15,19 162:22,22
163:2,18 164:5 166:8
166:12 167:2,6,12,18
167:22 168:3 169:4
169:13,16 170:21
172:16 174:15,17
175:13 176:22 177:9
177:10 180:21 185:13
190:17 200:22 205:12
205:13,14 208:8
212:10,12 214:21
215:4,8,13,22 216:7
216:13,21 217:2,2,5,8
217:20,22 218:6
219:2 220:8,10,13,19
220:20 221:17 222:9
222:18,18 223:18
224:5,6,7 226:10
227:1,2 229:8,9 233:8
233:10,13,17 234:17
235:6,10,13,17 236:2
236:18 238:14 239:12
239:12 245:11 262:3
262:17 263:11 271:15
271:16 288:22 289:6
289:10 290:4,12
298:1 299:7 304:12
304:19 312:13 319:11

319:16,17 320:11,13
321:7 323:13 324:2,9
324:13 325:6,8,11,15
325:22 326:3,22
329:22 332:11 334:16
341:1 347:14,20
348:8 349:2
patients' 114:12 245:22
299:12
patients--okay 321:20
pattern 86:22 286:17
patterns 285:16,17
286:19
Pause 351:8
paving 111:12
paying 186:11
payment 342:10
PCPI 3:13,17 214:2,8
peak 177:2,11
pediatric 2:7 237:1
241:8
peeling 23:4
peers 186:6
PEG 114:8,8 165:12
penalize 72:7
penalized 177:10
penetration 153:2
Pennsylvania 1:20
people 5:4 16:9 21:9
25:20,20 26:2 31:22
47:17 50:7 56:22
57:14 59:5 62:2 68:20
69:7 74:15 75:2,14
78:11 88:2 90:4,5
94:5 96:10 103:14
106:11 113:4,22
116:18 128:21 133:5
133:16 138:3,4,8,20
140:15,21 141:12,13
141:14 143:4,5
144:19 159:3 160:9
160:14 161:15 165:1
165:10 169:8,12,15
169:18,18,22 170:1,5
176:16 178:2 179:19
180:4 184:7 188:1,2
200:5 212:22 221:15
229:1 237:9,18 244:5
249:20 255:20 258:6
270:10 283:6,9,19,20
284:11,14 287:5
297:19 305:1 308:6
327:19 328:12 329:16
331:17,22 332:13
347:22 349:18
people's 244:7 248:20
270:4
perceived 208:9

percent 28:21,21,22,22
29:5,6,10,13,14,14
31:12,18 33:1,1,2,2
33:19,21,21 34:21,21
34:21,22 35:19 38:11
38:11,12 42:11,11,12
42:12,22,22 44:22,22
44:22 45:1 51:9,9
66:1,1,2,2,10,11,20
67:3,4 68:1,2,3 71:14
79:18,19 87:21 88:1
90:3,4,9,14 92:12,14
94:20,21,21,22 95:18
95:19,19,20 105:19
105:20,20,20 106:7,8
109:7 112:1 120:18
124:1 125:3,3 126:4,5
126:6 127:16,16,16
127:17 132:12 138:1
138:21 151:17 154:1
154:2,2,3 160:13
161:17,19,21 165:19
167:17,19 182:3,3,4,4
183:6,7,7,8 188:16,16
188:17,17 189:2
190:1,1 198:6,6,22,22
199:1,1,20 204:11,14
205:6,11 207:19,9
207:20,20 209:8,9,9
210:13,13,14,14
211:14,14,15,15
212:4,4 220:15
222:20 223:12,12,13
223:13,18 224:2,2,21
224:21,22,22 225:20
227:2,2,22,22 228:1,1
228:12,21 229:1
230:16,16,17,17
231:22,22 232:1,1,12
232:12 242:6,6,7,7,17
251:15,17 255:19,19
257:4 258:20,21,21
258:22 260:3,4,11,21
260:21,22,22 270:16
270:17,17,18 271:10
273:14,15,15,15
274:21,22,22 275:1
277:15,15,16,16
279:3,4,4,5,11,12
289:6,8 291:15,15,16
291:16 292:8,9,9,10
293:4,5,5,6 294:1,2,2
294:3,17,18,18,19
295:14,15,15,16
296:2,3 300:8 307:2,3
307:3,4 309:12,12,13
309:13 314:6,6,7,7
315:20,21,21,22

316:16,16,16,17
318:9,10 321:20
331:4 332:13 337:20
337:20,21,21 338:5,6
338:6,13,14 339:5,5,6
339:6 340:10,10,11
340:11,16 342:22,22
343:1,1,17,17,18,18
350:6,6,7,7,17
percentage 12:13 21:21
34:7 52:1 80:9 163:17
168:3 245:11 300:11
percentages 233:12
percentile 126:4
perception 235:22
perfect 20:20 122:6,7,8
168:1 169:3 170:6
175:5 201:14 239:6
331:8 335:1
perform 12:12 36:17
53:21 132:21 305:18
performance 6:16
24:11 25:2,15 29:4
31:19 41:17 60:15
73:3,8 83:3 90:12,14
90:17 111:4 184:6
198:17 199:2 224:13
225:1 226:22 232:11
246:5 256:13,15
260:9,18 261:1 270:2
270:5 292:6,11
296:14 306:2 307:19
307:20,22 309:4,6,14
321:18 338:5,7,20,22
339:7 346:19
performance-based
342:10
performed 4:5,8 9:14
9:20 10:2 11:7 12:9
33:22 55:17 62:1
80:12,13,14,18 81:14
81:19 82:1 86:17
312:14 313:3,9
321:21
performing 24:19 36:19
102:19
performs 20:13 159:17
period 19:2 53:2 64:7
86:1 154:12 176:15
177:1 235:15 269:17
permitted 217:15
person 25:6 28:15
36:16 41:5,11 45:22
52:9,15 53:10 90:5
231:4 305:17 328:9
328:22
personal 18:20 43:3,5
298:19

personally 43:4
personnel 39:21 273:20
persons 4:16 318:14
320:17
perspective 14:18
76:10 77:4 78:6 89:8
96:11 114:12 121:4
160:7 252:12
perspectives 78:5 79:1
141:13
perverse 212:22 332:19
pet 53:4
Peter 2:14 21:18 54:19
57:9 58:9 59:10 61:19
71:16 119:14 187:18
240:4 241:19 253:3
256:21 257:13 290:18
324:4 329:8 353:15
Peter--if 254:22
Pharmacy 2:13 3:12
PharmD 2:13
phase 93:13 246:4
PhD 2:1,7,8,11,14,16
phenomena 287:2
PHILLIPS 3:5
philosophic 114:11
philosophically 113:1
philosophy 169:10
PHN 1:17
phone 16:19,20 28:16
46:1 52:16 97:11
137:16 144:18 189:13
279:22 280:9 297:9
318:20 322:1 354:6
phones 243:5,6
phrased 86:12
physical 2:19 43:21
physician 1:13 20:13
24:11 25:2 176:3
296:14 299:17 313:4
315:9
physician's 299:14
physicians 262:4
304:17 354:13
pick 5:13 116:2 142:16
166:13 190:7 245:7
picture 121:4,16
pie 254:12
piece 46:14 60:18 66:22
120:16 154:16 169:2
194:11 207:8
pilot 39:11,12,16,20
40:5 42:21 62:15
88:20 90:13 92:9
93:13,22 94:2 246:4
321:16
Pimavanserin 324:7,22
pixel 287:2

place 66:15 78:2 130:21
163:3 178:7 194:17
240:14,16 303:4
placed 277:1
places 88:9 163:1
placing 69:6 104:14
plan 131:1 179:22
320:21 321:4,12,14
335:13
planned 344:2
planning 298:11 306:10
317:6
plans 320:19 321:3,12
321:17,19 331:16,19
332:1 342:3,12 345:3
346:20
platforms 315:11
please 16:21 26:22
40:21 42:4 44:17 51:5
65:18 94:11 208:3
243:7,9 260:20
265:22 271:6 279:19
316:21 318:15 351:5
353:6 355:15
Plenty 91:14
plug 162:5
pneumonia 150:6,10
point 24:9 30:1,7 42:8
43:1 50:11,11,18
54:12 61:9 63:17
71:22 76:16 85:8
99:19 100:4,6 104:6
109:3,7 110:12
121:14 130:21 135:19
136:4,17 152:4 166:7
170:12 176:1 178:4
180:5 182:20 185:9
200:19 215:10 218:3
219:16,22 220:7
222:4,12 239:16,20
239:20 240:19 241:12
249:5 250:11 257:15
265:14,18 266:11
275:20 276:7 285:22
288:3 290:20 303:3
305:16 317:2,5,8
322:11 326:14 330:6
333:13 334:14 343:22
347:3
point's 171:15
pointed 197:1,10 208:5
210:21
pointing 240:20
points 12:3 135:17
154:8 197:6 219:14
policy 180:3
Polling 38:10 45:6
79:16

pollute 330:7	268:5 269:22 270:5	327:18	37:2 47:8 59:19 69:10
poor 228:14 289:18	276:15 290:13,21	present 1:10 3:1,9,20	71:12 84:14 86:12,17
302:8 319:15	291:3	7:16 14:3,4 100:1	97:6 109:3 112:16
population 11:3 21:22	practices 74:11 120:6	126:17 220:9 236:14	115:2 117:13 120:5
22:3 53:4 100:20	142:17 168:9 186:2	257:12 297:10 303:19	120:11 126:22 129:10
152:10 160:13 165:22	261:8,11,12 265:20	322:9 339:16	133:14 135:14 139:11
178:10 200:8,22	266:1,15,20 269:7	presentation 20:19	140:2 159:3 160:18
201:1,2 235:20	315:3	102:4,6 339:14	163:16 167:19 179:1
236:18 238:9 283:18	precisely 290:2	presented 29:8,21 30:4	191:12 197:5 228:15
319:13,17 330:9	precision 328:3	35:21,22 232:10	237:19 239:5 255:1
331:15 349:1,5,13	predicated 13:1	254:9 268:14,14	258:13 278:11 300:10
population-based	predict 14:2 137:5	302:6 307:9 339:13	322:11 329:15 332:12
321:2 331:7	282:20	339:20 340:15	340:1 349:4
populations 11:13	predicted 155:13	presenting 10:14 13:20	probe 173:19
224:5 349:8,10	predicting 112:8	233:19 247:7 324:12	problem 17:6,20 18:15
portfolio 196:11	155:20	presents 89:10,11	18:18 58:19 116:3
portion 60:8 167:21	predictive 37:7 112:2	President 2:14 3:3,7	130:4 133:14 134:22
position 149:8	154:18 159:19 161:5	presiding 1:9	139:8 140:16 142:14
positive 37:19 38:1	predictor 172:18,19	press 243:9 351:5	142:15 152:19 158:22
311:1	283:11	pressed 351:18	161:9,9 162:12,16
possibility 212:15	predominant 119:4	pressure 155:10 192:3	164:3 165:8,10 166:1
236:15 289:4	prefacing 171:6	192:7 193:22 269:4,8	166:3 177:20,21,22
possible 34:12 64:15	prefer 175:6,17	pretend 145:6	182:21 185:5 202:16
87:18 88:7 120:14	preference 160:10	pretty 96:18 100:22	239:11 262:6 266:21
183:21 187:22 235:19	preference-based	105:7 109:17 110:22	267:1,5 272:16 283:3
243:12 245:13 273:21	208:16	119:5 141:14 149:3	287:7 305:5 307:15
284:15 303:15 336:21	preference-sensitive	151:16 153:10,10	353:5
possibly 135:3	114:2 178:14	156:3 182:12	problems 57:11,22
post 52:12 104:21	preferences 113:17	prevalence 34:5	152:13 154:21 237:22
post- 52:22	114:13 116:20 160:17	prevalent 151:10	266:16 271:21 303:21
post-acute 44:9 75:21	164:9 165:17,21	prevent 233:14,18	procedural 61:7 65:8
75:22 314:15 315:13	166:12,13,14,17,18	245:20	procedure 12:21 85:3
post-call 355:15	171:11,14,20 172:2,5	prevention 110:18	87:14 98:11,13 104:9
post-comment 7:5	172:22 174:18 185:3	122:15 197:14	104:17 105:8 220:22
post-meeting 351:20	185:4 186:6	previous 61:12 194:21	procedures 161:4
posted 352:5	pregnancies 245:21	197:3,7 198:11 208:5	proceed 61:16 182:8
posterior 104:2	250:3 251:15 252:2,7	226:7 240:6	247:19 271:1 316:10
potential 4:14 66:6,9	255:21 264:2	previously 126:13	340:4
69:20 74:2,9 79:13	pregnancy 245:17,19	165:21 176:11 195:8	proceeding 297:6
244:10 245:12 249:18	249:9,17 251:18,21	226:4 271:22 282:13	proceedings 352:4
251:17 252:17 259:13	252:13 257:16,19	300:4	process 6:8 13:17 24:1
259:21 264:1 320:6	258:2,2 264:2 267:13	primarily 228:5,18	53:18 58:7 64:20
335:22 345:15	272:3	235:11	71:18 73:4 78:3,13
potentially 7:5 165:5	pregnant 249:12	primary 29:12 32:7 46:3	115:15 123:2,21
226:9 251:18 252:22	252:16	304:17 315:3	135:8 158:11 159:2,6
284:3 289:7 290:17	preliminarily 231:5	prior 10:2 11:7 30:18	159:8 184:21 185:16
323:5 334:1	232:14 339:21	47:2 80:15 98:3 99:2	186:15,22 187:2,7
power 112:3 238:21	preliminary 83:15	101:4 102:20 103:3	193:1 196:4 245:10
powerful 194:18	117:12 226:1 253:6	104:13 112:16 144:19	256:15 267:7 269:3
PPA 122:17	253:17 261:13 291:12	152:17 190:16 191:4	271:8,19 273:1 301:6
PQA 3:13,14 317:11	338:15 341:5 343:8	194:2 203:20,20	305:3 317:13,22
318:15,18	preparing 233:5	218:20 240:8 269:17	318:5 330:11 335:22
PQRS 246:2 256:12	prescribe 304:21	289:16	processed 118:5
270:3 295:1 316:5	prescribed 323:15	priority 10:16 298:3	processes 19:9 110:17
PQS 280:6,8	325:17 326:11,22	priors 172:8	123:5 196:20 222:13
practice 83:5 85:5	334:17 341:2	private 269:22	products 315:7
86:11,21 98:15 99:2	prescribing 333:10	probability 289:16	professional 232:8
103:15 256:18 261:16	prescription 323:16	probably 22:21 34:13	287:4

Professor 1:13,15,21
2:4,8,9,13,15,16,18
profile 157:1
profound 44:4
prognostic 83:13
program 51:22 80:5
96:5 107:15 108:11
111:19 157:18 214:18
227:10 228:8 232:6
232:17 246:2 256:12
280:6 342:7 344:2
programs 1:16 214:16
232:10,21 274:8
316:5 344:4,8
progression 193:6
305:21
project 3:4,5,6 133:20
267:19 351:19
prominently 214:17
promise 5:4,5
promote 215:20 335:14
promptly 106:14
prompts 276:18
proof 178:16,19,22
proper 268:8
prophylaxis 6:10 184:7
184:13
proportion 74:18
113:18 116:18 125:17
127:1 137:4 152:10
215:8 320:11
proposal 301:22
propose 278:6
proposed 73:10 148:22
192:18 257:2
prospectively 134:4
protect 145:21 146:15
protocol 218:12
proven 16:2 283:11
provide 27:8 35:6 50:14
75:19 76:1 128:8
217:19 247:13 250:13
276:4 281:19 290:16
provided 17:8 35:19
63:12 90:12,18 92:9
93:5,10,12 116:4
203:19 233:4 246:9
250:16 268:20 272:6
299:16
provider 217:11 333:7
providers 64:19 69:16
74:6 91:2 105:11
119:11 122:16 197:14
320:21
providers' 254:19
provides 20:16 64:9
248:18
providing 83:13

proving 265:14
provision 273:20
provisional 269:16
proxy 299:2 323:22
psych 347:19
psychiatric 299:22
psychologist 23:21
psychosis 324:8,14
325:2,3,9 329:3,16
347:13,21 348:1,3
psychotic 318:14 323:8
324:19 326:12 335:3
341:4
psychotics 328:3
335:14
PT 2:15
public 2:2 4:19 42:20
95:7 154:11 243:5,7
243:14 351:3,5,9
352:5 355:12,14
publicly 181:10 295:3
344:1
published 132:8 173:22
200:20 216:2 247:20
256:19 270:1 285:12
288:4,7,11 323:6
pull 116:2 133:6 158:3
185:21 191:16 202:4
202:12,20 245:6
264:18,21 353:1,6
pulled 155:7 186:21
187:2 191:3,6,9
204:17 277:4
pulling 78:11 157:10
202:11,17 207:1
264:22 331:16,21
354:8
pulling--and 331:20
pupil 84:16
pure 155:9
purely 157:6,17
purpose 102:19 103:8
333:11
purposes 280:8 321:10
purview 241:10
push 88:1,8 241:7
306:22,22 346:19
pushes 71:1
put 8:12 9:7,9 48:14
89:7 94:4 97:19
104:21 114:7,8
117:12 120:21 129:16
144:7 146:11 156:8
156:17 172:17 194:14
232:19 233:9 239:10
241:19 249:15 258:1
258:9 266:9 305:1
337:12

puts 220:22
putting 68:20 133:9
157:20 234:1 239:17
311:19

Q

QI 120:6,16
QQC 14:4 307:8,9,11
quagmire 194:8
qualifies 65:11 298:2
qualitative 284:19
286:4,10,20 287:6
quality 1:1,8,13 2:7 3:3
3:7,12 35:12 37:12
38:2,2 40:17 57:4,6
75:4 102:18,22 103:1
107:15 108:10 109:9
111:1,19 114:10,22
115:8,11,17 116:7
117:1,10 118:4,14,19
119:2 121:10,11,17
122:5 123:2,9 125:15
145:8,12,14 155:12
158:12 159:22 160:17
161:14 164:18 165:4
166:19 168:20 169:11
170:20,22 171:12,13
172:8,22 176:16
179:2 181:8 184:17
185:5 190:22 208:10
214:19 220:17 228:15
245:2,22 280:7
319:15 321:10 324:13
335:15,21 336:17
337:10 342:4,11,12
346:15
quantify 254:14 289:19
289:22
quantitative 284:20
quantity- 118:3
quarter 8:18 43:1
quarters 90:16 215:19
quartile 126:3
query 204:21
question 6:4 30:17 35:3
36:21 37:13 57:5 61:7
63:11 64:10 65:8,10
65:15 73:19 78:22
79:10 83:21 84:17
93:18 99:13 101:16
112:19,20,22 114:2
114:17,18,19 117:19
118:6,12,15,18,21
119:13 121:4 122:10
130:6,17 133:4 134:9
134:13 138:20 140:10
141:9 143:7,15 152:1
161:20 164:1 166:2

168:2,10,11 172:9,12
173:19 175:6 178:15
182:13 183:13 184:3
185:11 193:19 194:6
195:5 205:18 226:16
235:5 240:11 254:17
256:6,7 260:14 263:7
272:10 285:7,9 286:2
286:6,11 287:19
307:21 311:5 312:11
313:3 317:9,13 326:2
326:2 329:13,19
331:14 341:13 344:3
344:9 353:17

questioned 27:3

questions 60:10,11
121:8 129:17 137:10
137:15 139:3 140:11
144:16 219:20 221:3
223:1 224:10 226:2
229:6 231:9 250:18
260:16 261:13 266:7
273:10 287:15 292:3
292:20 293:18 294:12
295:9 319:2 340:3
342:15

quetiapine 348:17,19
quibble 180:15
quick 32:20,21 89:7
112:16 125:9 136:17
144:12 146:22 170:12
182:12 276:10 317:13
339:18
quickly 77:11 144:13
185:17,18 235:19
238:18 318:3 352:21
quintile 172:12,16
quite 34:4 41:15 43:12
43:12 108:4 135:16
141:21 150:8 174:7
190:12 201:2 202:15
326:21
quorum 244:5 296:17
296:19 317:5
quote 237:18

R

race 171:21 172:7
173:4
racial 29:18
radiologist 289:19
Radiology 2:4 3:11,16
279:21 295:2
Rae-Grant 2:12 70:14
70:17 71:19 218:17
223:16 225:5 228:4
229:19,22 230:20
232:4 355:4

raise 265:16 282:14	144:2	211:1 222:13 234:21	52:17 83:6 323:7
raised 27:1 68:19 176:1	ratio 170:16 234:20	244:6 249:10 255:10	324:21 352:13
183:13 274:10 290:3	rational 10:11 47:11	258:2,4 275:14 284:7	recommended 10:19
347:4 349:4	52:10 118:7 123:19	288:14 289:11 300:16	10:21 12:7 51:12
raises 256:6 261:13	ratios 285:15	302:1,17 304:11	52:16 56:10 106:8
ramifications 75:13	raw 205:11	305:20 306:2,9,22	223:19 246:10 250:10
170:10	re- 278:15,17 314:2	318:3 327:1 328:4,4	recommending 31:12
random 48:15 162:18	re-address 305:3	328:18 330:7 332:16	109:8
162:21 163:4	re-endorse 319:7	335:7 344:10 345:2	recommends 12:20
randomized 58:14 83:9	re-evaluate 349:7	354:1,3	reconcile 79:2
248:6,8 253:12 290:8	re-vote 67:8 68:12,15	reason 63:1,18 87:6	reconvene 106:14
291:3	79:10 259:17 277:20	89:10 109:2 119:16	record 10:7 11:10 33:11
randomly 49:12 353:19	278:11	128:17 148:1 154:21	38:16,18 41:9 80:21
range 33:20 52:6 123:4	re-voting 259:20	217:9,11 263:5 303:8	95:9 106:16 109:16
126:5,11,12 143:13	278:22	327:11 347:16	191:3 199:10 209:14
143:14,14 149:20	reabstraction 132:12	reasonable 16:14 19:6	231:3 241:13 244:1
150:13 236:13 241:9	133:22 134:2	20:18 63:11 72:12	265:10 314:14 353:9
287:18 288:8 338:5	reach 72:6	73:18 85:2 100:3	records 33:18 92:11
ranged 92:13	reached 182:5	114:21 122:22 123:9	158:4 190:22 191:7
ranges 287:21	react 342:13	177:12 181:3	196:18 201:8 204:12
ranked 65:9	read 37:9 72:22 85:22	reasonably 130:9	261:16 271:9
Rankin 4:6 51:16,20	198:2 307:11 336:4	reasons 13:4 75:12	recovering 52:12
52:8,11 53:9 54:15	readily 314:17	113:9 199:22 208:5	recovery 53:1 63:16
58:3,5,15 59:5 61:22	reading 304:10	220:21 284:17 346:14	recruited 261:7
62:6,16,19,21 175:14	readmission 30:12	reassurance 157:21	recur 222:10
175:16	ready 24:17 231:16	reassure 179:19 180:4	recurrent 187:10
ranks 65:10	258:6,15 291:6	reassuring 40:19	recuse 275:16
rape 267:13	349:18	rebuttal 59:9	recused 277:21
rapid 5:4 10:13 83:11	real 51:16 113:12	recall 6:18 188:22	recusing 213:21
215:5 218:7 235:18	130:12 135:22 139:10	recanalization 10:2,6,9	reduce 111:2 115:8
rapidly 91:10 103:15	140:12,15,18 141:6	11:8,9,12,19 47:4,9	reduced 126:12
236:3	141:21 143:2 159:13	47:13,20 48:6	reduces 251:22
rare 104:4 237:11	161:12 162:3,6,11	recanalized 18:3	reducing 187:8,10
rate 29:4,6 32:4 40:2	170:12 174:13 178:18	recap 4:3 5:11 339:17	reduction 216:8,10
81:6,12 84:11 107:1	183:15,20 212:15	receive 47:2 176:6	redundant 190:11
146:10,16 179:16	237:22 303:20 327:15	215:8 224:8 235:6,15	reduplication 23:10
192:7 193:22 205:1,4	332:5 339:18	260:11 347:8	Reeves 200:20
216:5 219:18 225:19	reality 15:17 22:21	received 216:21 217:2	reference 110:22
227:2 228:22 252:6	272:13 307:12	217:3	130:20 133:4 171:1
258:2,3 272:1,2 273:4	realize 22:13,19 67:6	receiving 31:16 216:14	280:20 282:1 285:2
307:8,19 321:19	213:14	216:15 223:19	285:20 287:21
338:13,14 346:20	really 16:6 17:22 23:7,9	reclassification 144:5	referenced 36:7 39:10
rated 231:5 232:13	26:12,17 32:10,20,21	147:13	281:4
247:21 316:7 339:21	36:8 40:11 55:8 56:8	reclassified 143:18	referencing 46:15
raters 36:14	58:21 64:11 67:13	147:21	referred 37:2
rates 6:16 31:10,15,17	72:12 84:14 94:5	recognition 214:18	referring 37:21 74:9
121:19 122:19 134:2	100:15 101:3,16	232:8,9	195:21
172:13 180:1 181:8	104:3 108:8 111:11	recognize 60:2 75:9	refined 262:9
216:6 252:8 256:13	112:7 117:4,16,16	233:11 238:18 323:19	refining 262:16
257:6,16,19 270:2	119:5 122:20,21	recognized 298:3	reflect 88:17 109:22
ratifying 49:13	126:16 130:2 138:14	recognizing 185:18	123:4 176:16
rating 34:12 50:7 56:9	141:20 143:15 144:22	238:14	reflected 89:4
70:5 163:19 226:1	145:22 156:21 157:14	recollection 268:12	reflecting 122:4
253:6,16,17 254:3	158:6 165:17 167:1	recommend 71:9	reflective 86:11
261:14 291:13 338:15	169:12,22 170:3	345:11	reflects 22:21
341:5 342:7 343:9	172:6,19,19 179:2	recommendation 14:10	refusal 217:13
346:18	182:17 193:5,13,17	290:21	regard 36:12
ratings 36:15,16 94:8	194:19,21 195:9,11	recommendations	regarded 316:6

regarding 28:20 51:8 83:20 148:13 177:5 regardless 25:7 48:19 107:9 298:4 299:8 328:13 regards 39:10 Regents 1:12 region 86:22 regional 87:2 registries 275:8 registry 110:7,8 111:13 115:5,7,8 125:15 131:15 155:12,18 157:3 161:15 173:6 201:17 207:2,3 214:18,18 215:11,12 215:13 224:1 225:7 225:14,21 226:21 230:22 241:6 246:3,3 256:16 264:19 265:5 267:22 268:2 270:7,7 275:17,19,19,20 277:2 280:8 295:3 registry-based 155:9 regular 349:8 rehab 2:19 9:9 63:15 rehabilitation 1:18 23:14,22 44:1 rehemorrhage 84:11 reiterate 110:15 331:8 relate 232:8 related 12:19 15:8 26:19 65:17 73:3,8 76:1 90:21 94:10 123:15 253:20 319:9 330:21 347:13 relates 85:18 112:8 251:8 310:14 relationship 118:8 121:10 123:19 153:5 159:22 168:17 173:4 174:16 relationships 116:10 relative 111:4 122:5 154:18 relatively 161:18 167:1 231:2 released 12:18 256:14 256:17 267:18 270:2 324:10 relevance 139:4 269:1 relevant 75:19 105:13 180:6 334:12 reliability 33:5,14,16 34:9,15,18,20 35:1 36:9,18 37:3 62:3 92:6,7,9,15,18,19,21 93:2 127:20 128:2,6	128:10,17 129:1,21 129:22,22 130:1,6,14 130:17 131:3,22 133:7,13 134:11 135:16,19,20 136:2 138:7 139:14,15,18 140:11,12,14 141:4 143:5 144:11,14,20 146:16 148:17 149:2 149:7 152:4,12,18 153:12,15,18 154:4 199:4,8,16,17 200:2 200:10,18 202:1 203:3,14,19 205:21 207:11,14,21 225:4,6 225:11,15,18 226:1 227:18 228:2 229:13 233:5,11,20 234:3,18 238:1,5 261:3,4,14 265:21 266:2,5 268:13 270:12,14 273:8 278:13,18 279:1,3 292:12,15,16 293:1,7 301:17 304:1 309:16,19,21 310:6 310:14,19 311:7,9,15 311:22 321:21 322:4 322:5 327:14 339:9 339:20 340:6,12 reliability's 130:3 reliable 14:22 22:20 43:12 84:20 130:7,9 146:11 209:17 234:5 273:6 281:19 292:18 311:2 reliably 132:21 133:17 142:11 reliant 269:22 relied 34:7 relies 209:13 religious 217:12 rely 36:9 159:15 160:3 306:6 remain 222:19 remaining 169:4 remarkably 117:16 164:6 236:17 remember 5:22 25:18 128:4 150:18 170:14 202:4 330:17,22 remind 45:20 145:3 reminder 167:11 300:4 reminding 46:21 47:15 48:8 removal 12:20 165:1 remove 98:8 164:22 removed 98:6 repeat 298:5,11 305:10	repeated 191:20 302:2 repeatedly 284:6 reperfusion 10:5 52:5 52:21 53:7,22 63:20 replicate 22:17 reply 173:2 report 59:4 103:10 185:19 203:5,7,12 206:15 341:18 352:3 352:9,11 355:12 reported 35:10 42:20 125:22 146:3 147:5 161:17 226:19 274:2 287:16 292:1 295:3 321:8 334:19 341:15 344:1 reporting 50:4 108:11 146:1 180:11 181:9 225:19,21 228:20 276:21 280:8 281:11 333:4 342:2 346:22 reports 257:1 279:17 280:3,14,17 314:15 321:12 342:3 representation 35:11 representative 30:19 200:12,15 201:3 represented 27:15 31:21 representing 213:17 represents 141:2 reproducible 283:16 reputation 75:4 request 54:1 261:20 requested 321:22 require 58:11 104:6 115:16 118:3,5,7 218:22 required 32:6 35:12 38:17 103:10 217:13 requirement 64:1 requirements 261:6 requires 35:15 298:4 348:4 requiring 47:11 218:10 325:10 research 213:4 324:12 Researcher 2:11 reselected 108:21 reserve 6:1,20 7:8 8:1 8:12 9:4,7,9 reserved 6:7,8 reset 221:11,16,20 resided 338:12 residential 302:16 residents 338:10 residing 338:10 resolve 171:7 287:11	resolved 6:7 222:2 resource 239:6 319:14 resources 39:13 61:12 74:12,16 75:10 116:12 237:15,18 respect 286:22 respectful 244:6 respiratory 218:10 respond 19:4 237:10 342:1 346:12,13 352:8 responded 268:16 respondents 228:13 responding 348:14 response 72:17 73:18 127:8 129:18 153:13 188:7 197:14 208:22 211:5 223:2 227:14 230:8 231:14 235:4 241:17 243:13,19 246:14 262:8 283:12 319:2 responsibility 235:5 responsible 196:12 rest 141:2 300:2 restate 67:18 restraints 346:5 resubmit 261:12 268:16 resubmitted 271:18 result 267:12 268:18 296:2 results 51:4 64:5 90:3 92:2 93:1 94:20 95:18 105:19 106:7 124:1 125:2 127:15 154:1 182:3 183:6 188:16 190:1 198:6,22 207:19 209:8 210:13 211:14 212:4 223:12 224:21 225:17 227:22 230:16 231:22 242:6 258:20 260:3,21 270:16 273:14 274:21 277:15 278:4,20 279:3,11 281:15 291:15 292:8 293:4 294:1,17 295:14 307:2 309:12 312:15 313:5 314:6 315:20 316:15 318:8 337:20 339:5 340:10 342:22 343:17 350:6 resumed 106:16 244:1 retardation 261:19 retest 143:16 retested 266:20 retesting 266:18 retract 76:3
--	--	---	---

retrievable 272:9
retroactively 97:21
 99:19 103:6
retrospective 29:9
 134:3 261:9
retrospectively 97:21
 102:22
return 222:10 277:20
Reuven 2:3 355:2
revealing 250:19
reversible 298:13
review 5:16 7:17 14:4
 27:4,10,13,17 29:10
 38:16 55:6 59:16
 73:22 83:8 194:2
 218:20 246:8,9
 261:10 263:9 264:20
 265:11 269:11,15
 293:11,12 345:22
 352:8,14
reviewed 9:5 228:18
 271:8 280:4 293:9
 302:1 312:15,22
 324:11 340:15 347:5
reviewer 40:17
reviewers 112:13
reviewing 103:16
 106:20 185:21 195:15
reviews 272:11 313:4
revised 25:13,14 35:22
revisit 6:10
revote 124:15 189:9,17
rich 308:13
rid 193:9
right 5:15,18 7:2,15 8:4
 13:13 28:5 30:15 38:3
 42:15 56:6 58:18,19
 59:12 65:16 66:20
 70:1 78:3,22 89:18
 92:1 97:18 99:11
 104:18 106:18 110:20
 113:1,11 118:17
 121:6 130:2,15
 132:20 133:11 136:4
 139:19 140:2,4,9
 145:11 147:4,12,18
 151:12 154:5,7
 155:17 156:8 157:8
 157:18 158:7 159:14
 165:9,14,19 167:20
 168:7,13 169:15,19
 171:8 174:2,12
 177:21 178:8,10
 180:10 184:5,9
 186:17,18,22 192:4
 195:16 203:15 204:18
 204:19 207:4 212:20
 213:6,10,12 221:10

230:4 231:13 237:13
 243:3 258:14 259:7
 259:11 268:21 278:5
 278:21 288:9 289:3
 301:2 305:17 308:18
 309:10 313:20,22
 325:7 326:2 329:3,4
 329:12 331:17 333:3
 334:9 337:7,14 342:5
 343:3 347:15 349:9
 351:13
rings 64:17
risk 13:6 19:18 26:5
 54:10 107:3 109:1
 110:11 121:14 122:1
 122:12 135:7 149:19
 156:11,16,22 159:21
 160:21 177:8 190:18
 191:14,15 192:9
 196:1,2 197:11,17
 208:12 210:22 216:1
 221:1 236:16 245:20
 252:12 267:11 298:20
 299:3 319:18 320:6
 320:12 328:1 337:5
risk-adjust 123:10
risk-adjusted 30:11
 122:19
risk-standardized
 107:1 146:9
risks 245:19
RN 1:17
road 177:6
roadblock 76:22
robust 76:17 77:1,7,14
 112:10
Rogue 189:7
role 44:1
rolled 182:15 276:14
rolling 135:4
Ron 213:16 218:15,17
 218:18 225:3 229:4
 238:6 241:18
Ronald 2:10 355:3
room 1:8 19:13 20:16
 46:1 49:17 72:21
 86:13 87:9 89:11
 97:19 100:10,13
 101:14 103:18,21
 289:17 321:18
roped 345:17
Ross 2:18 44:7 67:16
routine 43:9
routinely 12:12 54:5
 99:22 294:8
RSMR 4:10,11 146:9
RTI 2:11 344:15
rub 166:20

rubber 5:10
rule 5:21 128:9,16
 129:3,8 222:17
 234:19 255:1
rulemaking 193:1
rules 79:21 128:8
ruling 94:1
run 147:18,19 233:15
 352:17
running 233:15
rush 215:20
rushing 97:18
Ryan 2:13 328:7 329:4
 329:8 347:11 348:6
 354:19,19

S

safe 264:2 355:16
safety 319:9 321:11
 342:3,12
SAH 4:8 81:13
salient 197:6
Sam 214:1
SAMANTHA 3:17
sample 30:19 31:21
 32:2 34:7 128:20
 136:6,8,9 139:13
 140:17,22 141:1,3
 144:1,17 145:16
 147:10 227:5 229:12
 235:1
sampled 29:5
samples 148:11
sand 26:13,15 48:14,15
satisfy 103:7 261:6
saw 32:19 55:12,14
 158:9 160:11 266:10
saying 46:16 49:5,19
 50:20 55:3 67:2 75:10
 83:3 86:16 107:6
 119:22 120:1 139:22
 143:21 145:3 154:13
 176:21 200:13 219:19
 237:12 238:3 248:22
 288:16 311:14
says 55:22 69:15,19
 70:7 78:6,10 101:21
 142:19 164:14 171:9
 184:6,11 197:12
 285:1 286:4,10
 301:22 303:12 311:7
 312:13
scale 4:5 5:14 9:14,20
 10:17,19 12:9,12,22
 15:14,15,21 16:4,5,12
 17:7,18 18:3,9 19:17
 21:5 22:13,16 23:8,15
 23:18 24:19 25:4,8,13

26:9 27:18,21 30:10
 30:13 36:11 44:11
 47:2,12 48:5,18 50:6
 50:18 56:20 58:3,6
 61:22 62:6 80:12
 81:19 85:15 96:14
 97:3 108:22 109:5,11
 109:14 110:7 111:16
 111:22 112:5 125:18
 125:22 126:11 129:22
 130:6,13 131:17
 132:11,21 133:9
 134:5 142:2 144:7
 154:14 155:7,10,17
 155:17 157:11,19
 158:2 159:21 161:17
 162:13 168:12,17,19
 169:1 170:8 174:21
 175:8,9 179:16 180:2
 182:14 192:2,8
 194:12,17
scale's 135:21
scaled 62:14
scales 23:17
scan 24:16 101:12
 102:3 103:11,16
 164:14 221:18
scanner 24:18
scanning 185:17
schedule 51:16
schedules 5:5
schizoaffective 336:8
schizophrenia 320:7
 336:5,19
Schmaltz 3:15 31:2
 37:15,15 38:4
Schmidt 2:14 21:19
 22:4,7 54:20 55:2
 61:20 71:17 72:15
 87:16 119:15 120:19
 187:19 240:5 253:4
 254:4 257:14 269:13
 290:19 324:5 325:8
 326:20 329:13 345:8
 345:20 347:19 348:16
 353:15,15
School 1:20 2:2,4,20
schools 257:17
Schwamm 3:16 12:2
 15:12 19:5 30:7 31:9
 32:8 36:6 41:4 43:16
 53:16 63:9 72:2 88:12
 99:9 101:12 103:9
 104:11,15 107:20
 111:7 132:6 133:11
 133:18 143:20 144:4
 154:21 163:20 173:1
 173:15 175:1 185:9

187:6 193:20 200:19
 201:9 214:5,9 220:7
 221:14 226:12 227:12
 233:2,4 234:12,15
 235:4 240:19
Sciences 2:6
scientific 301:11,16
 310:10 311:11 312:2
 317:19
sclerosis 330:4
scope 194:22 205:12
score 4:5,6 9:14,20
 10:1,22 11:7 12:9,12
 12:22 13:1,5 15:14,15
 15:21 16:4,5,10 19:17
 26:2 29:15 30:10,13
 33:22,22 35:9,11 36:8
 36:11 37:17 41:15,17
 48:18 51:17,20 52:8
 52:11 58:6 80:13 82:1
 83:12 84:4 85:15
 86:14 89:8 93:17 94:4
 94:7 97:3,5,8 98:1,2
 99:10,11,12,12,20,22
 100:8,11 101:17,19
 102:3,4 103:3,12
 107:3 111:17,22
 112:5,5 132:11,21
 134:5 140:12 144:7
 175:8,9 194:12,18
 287:12 322:4 339:13
score's 96:15
scores 23:17,21 25:20
 91:4 100:15 105:13
 135:7
scoring 10:18 94:6
screen 72:19 76:19
 153:16
screening 41:21 304:15
 305:10
script 33:6
se 57:3
search 129:13 149:15
searches 120:14
seat 107:19
seated 246:12
second 39:2 43:1 47:6
 107:10 155:21 163:14
 169:7 180:5 203:14
 204:14,22 288:20
 293:10 353:11
seconds 176:14 276:11
section 1:16 21:2 27:7
 60:20 304:2
sedated 84:13 85:5
see 17:21 55:5,19 56:4
 57:21 74:16 94:8
 101:6 122:1 124:14

137:8 143:11 144:13
 145:17 151:14 169:19
 169:19 172:6 173:21
 185:12 186:7 202:13
 204:3,14 205:21
 209:16 213:5 233:17
 234:16 257:7 278:20
 282:8 306:12 307:14
 313:5 322:12,12
 330:12 335:16 338:10
seeing 70:1 91:7 122:4
 127:9 131:14 132:20
 181:14 204:1 226:9
 257:4 306:15 325:14
 340:3 342:16
seen 26:4 55:21 86:2
 87:1 110:20 147:20
 152:6,14 173:5 257:6
 257:16
sees 54:21 83:2 126:15
 234:10
Seidenwurm 3:16
 279:22 280:9,10,12
 282:4,5 285:6,10
 286:12 287:19 296:6
seizure 251:19,22
seizures 218:1
select 196:4
self-care 302:8
self-neglect 298:20
semantics 312:12
send 355:10
sending 321:11
Senior 1:19 2:14 3:3,6,7
sense 16:9 40:12 78:17
 102:13,15,16 150:2
 174:2 197:9 210:22
 220:14 253:9 302:9
 333:6
sensitivity 332:3
sent 132:10
separate 78:9 124:11
 126:18 155:8 156:5
 203:5,19 206:4
 220:16 312:15
separately 155:13
sepsis 187:13
September 352:15,18
serious 165:11 319:9
serve 353:18
service 23:19 123:21
 152:16 200:22 237:9
services 2:11 300:2,3
SES 209:22
set 37:18 38:17 39:14
 39:15 88:20 93:8 94:1
 95:5 125:20 126:1
 128:5,7 131:19 144:1

153:8 175:10 187:8
 191:5,15 201:20
 204:11 234:21 267:19
 322:14
sets 163:6 194:5 226:13
setting 25:3 49:22
 164:4 298:5
settings 298:5 299:20
 299:21 315:8,14
settled 278:14
severe 26:4 85:16
 113:17,20,22 114:5
 180:22 224:6 262:14
 263:2,3,5,5 267:10
 305:19 306:6
severity 4:8 13:6 15:16
 15:19 16:17 20:2 37:5
 37:11 44:3,5 50:8
 54:10 80:2,6,11 81:14
 81:18 83:10 84:5 97:2
 100:16 105:13 107:3
 108:17 111:3 121:21
 158:1 173:14,16
 174:6,12,16 194:4
 282:20 283:16
shaking 55:13
share 291:22
sharing 315:11 318:21
shed 198:12
shift 216:12
shop 120:8
short 23:16 24:1 89:13
 126:19 134:7
shorten 214:20 301:7
shorter 15:1 219:11,13
shortly 5:9
show 59:20 178:20
 228:6 333:20
showed 134:1 321:18
 338:11
showed--and 272:6
showing 219:2,10,12
 224:5
shown 12:11 202:18
 251:5
shows 204:10,10 239:4
sick 212:10 213:1 241:2
side 302:12 344:18
sign 43:20
signal 225:12 234:19
 285:17 286:19
signaled 192:19
signaling 192:22
significant 25:10 37:19
 68:20 170:17 234:8
 237:11 273:2 338:8
 341:4
significant--and 275:6

signs 10:15 202:5
silent 298:12
similar 82:4 97:7
 106:21 108:21 129:15
 146:19,20 150:8,9
 153:8 157:16 173:21
 177:15 190:10,16
 192:17 201:3 299:10
 323:7 331:11 337:6
 344:13
similarly 156:1
simple 96:18 137:22
 143:15
simpler 85:22 86:6
 123:2
simplest 335:9
simply 103:16
Simultaneous 133:12
single 16:1 45:22 54:11
 108:14 137:22 293:3
Sir 251:11
site 203:14 204:13,14
 204:22
sites 30:19,20 33:17
 39:20 64:5 90:15
 92:10 94:2 134:8
 204:10 205:7 207:4
SITS 215:12
sitting 107:19
situation 119:7 324:19
situations 62:20 105:4
 137:21 149:22
six 18:7 63:13 81:1
 82:10 83:20 84:6 85:2
 85:12 94:7 307:4
 315:21 337:21 350:7
six- 85:7
six-month 93:13
Sixty 68:3
size 128:20
sizes 145:17 287:2
skill 96:19
skilled 300:1
skip 33:9
skipped 244:13,14
SKIPPER 3:6 28:7,13
 28:18,20 32:16,22
 34:17 38:7 42:5 44:18
 45:6 51:5,11 65:19
 79:12 89:21 91:19
 92:2,20 94:12,17,20
 95:15,18 105:16
 106:4 123:17 124:1,5
 124:15,17 125:2
 127:11,15 153:17
 154:1 181:20 182:2
 183:2,6 351:16
 353:12,16 354:5,22

Skull 1:15	150:21 151:2,9	134:20 202:10 225:6	321:14 335:18
slave 40:17	164:16 175:20 195:20	233:6 245:14 311:12	state 63:2 135:5 193:13
slide 310:10,12	205:10 206:5 208:2	312:3 313:13,13	stated 46:22 262:14
slight 204:20	218:15 243:3,17	335:10	263:4 336:15
slightest 57:4	244:19,20 245:15	specified 14:20 33:10	statement 76:3 117:13
slightly 37:12 85:18	309:17 312:1 322:20	82:1,15 119:18	216:12 286:6 312:13
115:5,10 147:9 192:8	338:6,13 352:17	319:16 321:3 334:4	312:20 322:7 353:11
193:3 196:3	sort 12:15 17:13 23:2	specifies 56:2	states 40:18 111:17
slippery 75:15	50:1,2,8 57:10 58:18	specify 303:9 333:18	230:22 262:20,21
slivers 171:19	64:16 75:18 78:4 79:1	333:21	statins 8:15
slope 63:16 75:15	84:5,7 87:13 97:8	speckle 285:16	station 71:20 77:15
slowly 164:13	98:12 113:1,2,2,5	specs 309:21 310:1,8	78:15
small 53:22 57:12 74:18	114:2,11,14,14,15	spectral 286:19	statistic 112:3 137:19
87:2 104:10,21 119:5	118:4,15 121:3,17	speech 23:20	138:7 159:18 193:3
145:22 152:4 159:6	123:3 126:18 128:6	spelled 161:1	statistical 22:13 57:11
160:6 161:18 167:2	129:21 131:20 136:2	spent 112:18 268:7	128:12 199:22 234:19
173:11 174:5 181:14	136:7,19 138:13,15	spinal 44:11	statistically 162:5
233:16 272:16	138:19 139:14,17	split 7:9 136:6 139:15	170:17
smaller 31:5 90:17	141:9 143:12 150:12	144:1 148:10	statistician 137:8
103:22 132:16 142:7	151:7 155:3 159:1	spoke 109:15 203:18	statistics 40:2 112:2
142:10 143:2 192:9	160:2 162:5 165:8	staff 1:13 3:1 40:1 91:7	154:19 228:7 272:1
241:4 349:11	166:4 168:2 169:5,10	stage 304:13 305:7,9	status 6:7,8,20 9:4 58:4
smokers 174:1,4	169:10 171:6,6	305:20 306:8	97:7 127:3 298:9
smoking 173:22	174:10 175:10 191:8	stages 306:5,6,8	stay 11:15 23:15 24:2
So-- 296:5 318:2	191:19 193:10,14	staging 298:7 305:8,12	53:13,15 82:7 216:15
so--and 333:12	197:6,11 202:6	stamp 5:10	216:22 274:13,14
So--well 300:21	203:16 208:12,15	stamped 102:8	steering 64:18 69:15
social 217:12	209:17 210:19 238:9	stand 87:5 290:11	74:4 75:3 111:10
societies 16:3 179:15	252:14 261:9 326:14	standard 16:10 35:16	stenosis 4:15 279:16
Society 323:3	332:6 351:18	36:7 37:6 52:11 54:15	280:2,18,22 281:1,2
socioeconomic 127:2	sounds 141:14,16	55:21 63:19 64:4 71:7	281:12,15,16,18
208:17	162:2 317:10 318:1	98:15 99:1 102:21	282:19,20 283:16
solve 266:22	345:20	123:1,7 161:3 196:20	284:16 287:17 288:8
solved 266:21 267:4	source 33:10 125:10	231:2 238:4 256:1	289:7,12
some-- 248:19	133:22 134:6 156:10	286:18 341:20	stenting 282:22
some-odd 225:14	156:14 158:8 167:20	standardization 50:12	step 54:6 65:2 74:19
somebody 17:22 49:20	194:21 201:14 269:20	standardize 50:3	75:2 250:14
50:9 68:19 70:12 98:5	sources 146:17 274:1	standardized 10:17	step-wise 191:20
101:5 104:20 120:9	294:10	16:8 54:11,12 199:9	Stephen 2:5 3:15 31:1
145:10 167:4 178:20	Southern 2:17	281:19	stepping 77:20
193:19 221:5,12	speak 23:13 32:10	standardizing 16:1	steps 4:20 185:16
292:18 312:22 313:20	131:9 179:20 235:2	standards 235:16 282:1	351:15,19 355:9
349:4,19	249:19,21 276:6	standing 1:3,7 352:7,20	sterile 271:17
somebody's 18:11	315:4	standpoint 277:1	Steve 24:8 37:15 85:20
97:18	speaking 41:11 133:12	stands 289:3	86:10 87:6 254:10
someone's 98:10	172:4 214:9	star 243:9 342:6 346:18	354:12
somewhat 16:1 114:22	speaks 262:6	351:6	stewardship 107:18
141:6 145:18 190:11	Spearman-Brown	start 23:3 53:19 55:3	sticker 313:21
286:20	136:19 139:17 147:7	107:7 121:7 122:1	STK 9:8
Soo 3:11 297:9	special 246:22 310:10	128:1 134:9 185:21	STK-01 5:21 6:10 8:5
soon 50:19 86:12 87:17	specialists 86:18	185:22 195:3,4	82:4
88:7 187:22 296:21	specific 25:12 26:17	259:18 282:9 284:9	STK-04 8:20
322:14	49:2 56:2 96:6 119:9	321:12 322:21,22	STK-05 9:2
sooner 188:2	287:17 327:7	331:22 345:2	stone 77:20
sorry 8:22 17:2,5 40:21	specifically 80:15	started 31:12 62:14	stop 101:13 134:17
55:13 67:4,10 69:22	129:6 132:11 226:7	106:19 270:8	190:6 218:12 249:1
70:11 97:12,13 107:4	250:12 325:16	starting 9:13 30:8	276:1
132:9 134:15 148:6	specifications 33:13	177:15 244:9 296:13	stopped 271:11

stopwatch 198:2	216:20 217:1,21	subset 151:20 303:14	supporting 16:12 19:22
story 306:3,4	218:4 220:2,5,10,12	substantial 78:7 90:17	154:10 214:3 233:6
straight 197:8 213:7,10	221:22 222:1,3,7	111:1 223:21 225:16	supports 118:8 123:19
straightforward 41:5	224:6 225:14 228:7,9	291:22 309:1	supposed 21:1 102:18
41:16 109:17 292:17	232:9 235:8,18 236:1	substantially 126:12	318:2
strapping 58:19	236:6,14,19 237:5,8	170:22 173:16 177:17	sure 5:18 28:12 54:6
strategy 108:21 191:19	237:14,17 238:19	252:16	59:17 67:19 68:22
192:21	239:19,22 240:15,16	substantive 184:2	79:2 84:20 103:1
stratified 81:5,11	240:22 241:8 274:11	substituting 49:5,7	114:12 128:4 131:5
strayed 337:1	stroke-specific 152:14	subtle 341:18	134:16 135:15 139:1
Street 1:8	strokes 80:3 173:11	subtype 173:8 299:8,8	155:1 163:21 167:8
strength 159:16 160:1	174:5 180:22 220:16	success 38:1,2	170:13,13 171:7
stroke 4:5,5 5:14 9:14	241:4	successfully 202:19	177:7 179:1 180:14
9:15,20,21,22 10:12	strong 13:5 152:17	sudden 235:7	186:21 201:15 205:16
10:15,17,20 11:4,6	159:18 168:16,16	Sue 300:14	207:8 209:15 218:4
12:8,9,12,16,22 13:21	174:16 307:13,20	sufficient 266:19	218:18 236:8 241:9
15:14,15,16,19,21	323:7	302:20 339:21,22	266:20 268:7,19
16:4,5,16 17:7,17	strongly 116:21 168:11	suggest 22:14 37:10	285:10 289:2 297:11
18:3,9 19:17 21:5	228:13 293:16	79:10 117:7 123:16	308:20 310:1 325:2
22:12,16 23:16,19	structure 123:20	127:10 153:14 349:19	328:7 336:3 344:9
24:10,14,19 25:4,8,13	struggled 56:19	suggested 27:17 34:4	345:7 346:2
25:21 27:11,18,21,21	struggling 73:6	143:8	surgery 1:16 104:1
29:12 30:10,13 31:5	stuck 59:3 78:21	suggesting 91:11	220:11 282:22 283:12
32:6,7 36:11 37:5,11	studied 36:12 256:18	126:10	surgical 80:15,17,19,22
42:18 43:7 44:3 47:2	studies 12:11 110:21	suggests 116:6 303:19	98:11 102:20 104:9
47:12 48:5,18,19	114:21 118:3 129:14	307:19	104:17 205:14 299:3
50:18 51:22 52:2,12	146:20 164:4 219:2,8	suitability 45:4,7 51:2,6	299:22
52:14,18,20 53:2,5,9	280:15 281:5 283:14	51:8 106:3,5,9 188:21	surgically 271:17
56:20 63:20 71:14	286:16 291:22 302:6	189:4,18 211:19,21	surrogate 20:19 110:9
76:8 77:8 80:5,6 81:8	328:11 333:19 348:7	212:5 242:12 279:9	surrogates 201:18
81:13,21 83:7 85:15	study 20:21 111:12	295:19,21 296:1,4	survey 148:17
86:18 89:1 93:8 95:6	133:18 149:18 216:9	316:21 318:6 350:12	surveyed 202:3
96:7 97:3 107:2 108:6	219:9 223:17,17	350:17	surveys 93:6
108:12,17,22 109:4	325:9 331:1	suitable 190:2 242:18	survival 100:18 114:5
109:11,14 110:7,15	stuff 23:4,11 99:5	279:12 318:10	survive 113:22
110:18,19 111:3,16	301:17	suited 344:10	surviving 113:17
111:22 112:4,9 113:7	subacute 315:1	Sullivan 2:15,16 65:7	Susannah 3:10 107:14
113:13,15,17,20	subarachnoid 4:8 80:9	82:21 90:11 92:7 93:4	125:11 129:11 173:2
114:1 116:10 118:2	80:12 81:7,17 84:1,2	95:4 96:2 301:19	201:11 212:11
121:18 122:7,18	subcomponents 81:6	311:5 312:10,19	sustaining 164:9
125:18,21 126:10	subdural 82:14	355:4,5	swallowing 165:11
130:6,13 131:17	subelements 41:7	Sullivan's 82:22	swelling 177:2,11
132:11,21 133:9,20	subject 354:12	Sullivans 82:20	symptom 25:11
134:5 135:21 144:7	subjects 226:18	summarize 118:22	symptomatic 216:6
149:17,19 151:19	submission 16:15 27:8	summarizing 282:6	282:18
152:21 154:14 155:6	39:18 55:12,14	summary 183:1 311:22	symptoms 10:15 18:8
155:10,16,17 157:11	129:14 203:17,20	super 56:22 103:19	25:6 26:4 220:9 222:1
157:19 158:2 159:21	214:4	supplementation	235:8 236:14 282:19
161:17 162:13 164:7	submissions 12:18	263:22	283:21,21,22
164:12 168:12,17,19	submit 261:8,16	supplied 27:5	system 3:12 12:14
169:1 170:8,22 173:7	submits 206:12	support 14:5 16:7	99:15 129:5 191:7
173:14,16,16 174:6	submitted 55:9 71:17	18:15 27:20 35:6 46:2	193:13 202:15 206:7
174:11,21 175:8,9,13	192:13 214:12 260:9	47:10 50:14 57:21	206:9 256:20
177:1 179:16 180:2	323:3 338:4,9 339:10	60:4 63:12 78:7 83:5	systematic 12:15 14:3
181:14 182:13 187:8	subpopulations 126:19	83:9,10 156:4 158:13	27:4,10 83:8 116:5
187:10 192:2,8	subscales 26:9	158:14 162:19 179:17	330:11
194:11,17 209:13	subsequent 218:21	190:22	systematically 32:1
213:16 214:17,19	subsequently 222:5	supported 49:2 260:13	54:5

systemic 73:21,22
systems 202:8 205:1
 206:10,21 210:20
 240:21

T

t-PA 10:3,4,16 12:13
 19:21 25:11,19,21
 31:16 52:4,21 53:6
table 79:9 190:8 204:6
 243:3
tabled 6:13
take 13:11 41:18,20
 43:7 94:2 106:12,12
 106:13 109:18 114:7
 125:9 127:1 137:15
 143:3 156:15 167:6
 212:13 239:18,22
 243:1 248:22 269:6
 276:11 278:3 297:4
 310:3,4,5 317:15
 351:15 354:17
taken 87:12 100:7
 145:4 146:9 149:8
 235:10,13 346:18
takes 43:10 89:9,14
 91:5 108:6,19 148:8
 267:17
talk 12:3 13:17 90:9
 117:14 134:17,18,19
 135:18 139:10 190:12
 301:15 308:6 309:15
 309:18,20 335:19
talked 13:18 44:1 82:22
 93:9 96:3 105:11
 113:3 114:16 128:5
 128:11 141:11 155:6
 160:18 187:20 276:22
talking 57:12 61:10
 75:14,18 104:4
 112:18 148:16,18
 150:18 151:2,6
 349:12
taping 249:22
target 78:16 119:17,22
 121:1 214:19 215:15
 215:16 283:17
teaching 132:14
Teale 27:9
team 23:17 24:19 91:8
 91:9 144:18 146:22
 181:13 352:2
team's 164:5
tease 121:17
technical 203:6 253:5
 284:17
technically 203:15
 229:15

technique 299:15,18
techniques 281:22
 282:2 285:18
Technology 3:5
teleconference 3:20
telemedicine 36:15
 55:10,15
telephone 52:9 53:10
 351:6
tell 18:11 40:18 67:7
 113:19 122:11 136:18
 164:10 186:10,10
 192:6 237:20 252:22
 265:21 266:2,4
 292:18 310:14
tells 33:6
tempting 137:21
ten 71:13 178:4 220:15
 225:21 226:6,18
 227:11 228:20 229:9
 229:10,14 232:19,22
 233:8,10,13,17
 234:17,17,21 238:2,3
 240:9 243:1
ten-minute 106:13
tend 123:8 145:17
 149:1 151:13,14
 174:4
tends 251:7
tension 304:20
tentatively 154:17
tentorium 99:17 103:19
 103:20
tenure 2:9
term 44:15 262:4 315:1
 327:7,8 352:20 353:1
 353:4,4,4,6,9,18,19
terms 12:5 13:19 19:9
 33:14 54:2 69:7 84:5
 91:9 93:15,16 102:15
 102:16 103:1 114:19
 141:19 142:1 160:4
 166:11 172:13 197:4
 206:11 209:18 210:20
 233:19 239:6 252:6
 271:7 272:8 287:11
 307:17 335:9
terrible 141:16 146:18
 164:17
terrific 146:18
territory 143:18
TERRY 3:6 317:1 322:6
 353:22
tertiary 86:8
test 39:11,12,16 40:5
 62:15 89:8,9,14 91:5
 93:16,22 131:18
 143:16 201:7 253:12

306:2 310:20
test-retesting 145:10
tested 33:11,15,16 35:8
 88:20 130:20 194:7
 206:6 311:19 314:13
 315:1 348:18
testing 14:6,12 33:14
 33:16 34:6 92:8,10
 93:13 131:11 139:14
 154:20 173:14 202:1
 203:10,13,14,16
 205:21 206:6,7,8
 218:7 225:11,12
 228:6 229:13 234:18
 238:1,5 246:8,11,15
 247:4 261:5,6 262:9
 267:17,21 272:14
 301:13 311:16 321:16
 321:16,21 322:1
 332:12 339:11,12
 344:15
testing's 34:11
testing-wise 155:3
tests 303:22 304:3
 306:6 310:21,22
thank 8:8 13:9 17:5
 24:7 32:9 38:5,13
 39:8 42:2 51:13 65:12
 68:7 73:5 82:18
 107:11 111:4,5
 147:11 179:5 190:4
 198:1 212:7,17 213:6
 221:2 230:5 243:16
 243:20 245:4 277:8
 279:14 282:6 296:6,7
 297:14 300:20,21
 301:18 313:11,21
 318:17 319:5,6 322:7
 322:15,18 328:6
 342:14 345:6 350:14
 350:18,19,20 351:12
 351:17 353:22 354:2
 354:3,4 355:6
thanks 8:10 25:16
 106:11 153:16 200:16
 202:21 242:21 313:2
that-- 249:18 256:3
that--some 326:17
that--where 271:16
the--I 266:12
the--it 264:16
the--particularly 328:2
theoretical 58:20
theorize 178:9
therapies 53:20 54:7
therapists 43:22,22
therapy 4:12 8:20 9:3
 10:3,3,5,6,10 11:8,9

11:12,20 47:3,5,9,13
 47:20 48:6 52:4,5,22
 53:6,7,22 63:21 88:21
 213:15 214:12 216:18
 216:21 217:7 300:2
thin 266:5
thing 15:4 17:21 18:19
 18:20 39:3 48:12 49:2
 56:19 58:20 59:21
 68:16 71:12 74:8 88:3
 99:20 103:10 105:3
 109:17,21 112:17,21
 114:14 118:4 120:8
 120:14 128:6 135:16
 145:9 147:14 157:5
 158:9 160:18 161:6
 169:13,15 172:9
 178:10 185:1,20
 193:20 204:8 206:18
 206:22 250:11 254:12
 254:13 266:9 274:6
 278:8 283:10 284:21
 305:15 308:4 309:22
 323:1
things 15:22 37:2 41:12
 56:18 60:1 76:12
 78:12 88:5 116:6
 120:10,11,15 121:16
 121:18 131:3 135:9
 139:6 144:13 145:2
 145:20 146:13 149:6
 155:11 158:3 159:4
 162:9 170:7 177:5
 178:7 181:16 184:14
 186:20 187:5,12,14
 187:15,22 193:22
 197:13 202:2,6
 208:18 213:5 250:12
 263:11 264:4,9
 285:11 308:5,7
 312:16 315:10,12
 330:10
think 6:17,22 7:9 12:17
 13:4 15:17 16:15 17:7
 17:11,12,16 19:6,22
 21:8,11 23:1,9,12
 24:5 25:1,15 26:20
 27:14 32:1 33:8 36:6
 36:20 37:1 43:11,17
 44:2,3,14 48:16 49:3
 50:1,10,11,16 53:17
 55:5 56:11,15,22 57:8
 57:21 58:10,13,17
 59:2 60:10,10 63:9
 64:4,10 65:1 70:19
 71:2,7 72:11 73:17,18
 73:22 74:2,14 75:13
 75:15,19 76:17 78:1

78:21 79:4,6,8 84:3
 84:22 85:2,3,14,17
 86:10,11 87:10,11,14
 89:15 96:20 97:4
 98:16 100:3 104:3,15
 104:16 105:5,6
 107:18 109:21 110:22
 111:19 112:9,16
 116:5,9,15 118:21
 119:8,9 120:3,5 121:5
 121:9,13,20 122:10
 122:21,21 123:8,12
 124:3 125:21 126:16
 127:4 129:13 130:15
 131:17,21 132:13
 133:7,20 134:13
 135:14,16,21 136:10
 136:13 137:18 138:6
 139:3,4 142:3,4,6,13
 143:7 145:2 146:15
 146:16 148:16 149:3
 149:3,8,13 151:3
 152:3 154:20 155:2
 158:16 159:17 161:16
 162:16 163:6,15
 165:7,19 166:7,9,19
 167:21 169:2,3 170:3
 170:7 171:3,4,15,21
 173:17,19 174:20
 176:7,9,10 177:7,19
 177:20,22 178:15,21
 178:22 179:13,14
 180:1,2 181:4,12,13
 183:12,19 184:2
 185:10 186:9,13,18
 187:12 195:14,14
 196:8,14 197:4,15
 198:12 199:6 203:4
 204:17 206:19,20,22
 206:22 207:1,8 208:6
 208:7,11,15,16
 209:14,15,20 210:4
 211:17 213:4 221:17
 222:11,15 226:14,17
 228:17 229:3 235:9
 235:15 236:10,16,17
 236:21 237:12,17
 238:10 239:5,18
 241:10,12 248:1,4,5
 248:10,15,22 249:9
 249:13 253:4,13,16
 254:2,20 256:4
 257:16,22 258:9,10
 258:12 260:14 261:13
 262:1,6 264:14 278:9
 282:5 284:9 285:19
 285:21 286:13,13,14
 286:21 287:3 289:10

289:14 292:1 301:8
 302:18,20 303:7
 304:11,20,22,22
 305:11,21 306:1,11
 307:14,20 308:8
 310:17,20 311:17
 317:22 323:9,19
 325:13 326:2,7,9
 327:8 329:8,22 331:3
 332:3,5,18 334:15,18
 335:1,6,8,9,11,12,20
 336:22 338:8 339:13
 339:19 340:19,21
 341:4,9,12,15 342:4
 346:14 347:1,16
 349:9
think-- 260:12 326:4
thinking 119:10 129:8
 144:22 303:11
third 78:21 79:6 172:16
 347:20
thoroughly 36:22
thought 10:12 74:17
 124:5,9 144:9 145:10
 165:2 229:3 247:17
 286:13 320:9 334:10
thoughts 250:18 277:9
threads 144:22
threat 161:8 169:7
 274:9 320:18 341:5
threats 93:11,14 228:17
 229:2 340:19
three 12:3 28:9,14
 32:18 34:19 38:9
 41:19 42:7 44:20
 52:22 63:10,17,18
 64:3 65:21 81:11 83:5
 83:8 90:1 91:20 92:22
 94:14 95:17 105:18
 126:18 136:6,20
 139:11,14 167:19
 192:2 195:6,19,21,22
 206:4 261:11 265:20
 266:1,5,11,15,19,20
 268:15,20 269:1,7
 274:4 320:2,6 336:18
 353:5 354:11,14,17
 354:18,21 355:1,2,3,4
 355:9
three-month 53:2
threshold 87:20 88:8
thresholds 128:5,7
thrombectomy 12:19
 19:21
thromboembolism
 5:21
thrombolysis 215:14
thrombolytic 8:20 10:3

52:4 88:21 213:15
 214:11 216:18,21
 217:7
Thromboyltic 4:12
throwing 170:4
thumb 128:8,9,16 129:3
 129:8
TIA 222:3
Tierney 3:17 214:1,2
 227:4 229:12 296:5
 297:4,8,14,16 317:12
 317:20
tight 284:16
tighter 85:18
tightly 268:8 298:8
time 4:12 14:7 15:6
 20:7 21:7 24:22 28:17
 35:6 39:13 48:12
 52:13 54:12 56:7 57:6
 61:12 64:7,12,12
 70:15 82:1 85:1,2,4
 85:18 89:13 97:19
 99:19 102:7,8,9
 108:16 114:15,16
 121:6 130:21 139:19
 147:1 148:2,8 161:19
 176:15 181:17 182:20
 185:12 187:1,11,21
 188:1,2 190:7 213:14
 214:11,21 216:17
 217:19 219:3,7,10,13
 220:14 223:20 235:15
 241:3 243:8,15
 245:14 246:5,21,21
 247:1,14 251:6
 252:20 254:9 255:7
 255:10 267:20 268:7
 269:4,8 272:20
 303:22 304:4 305:16
 306:22 317:2 321:11
 345:4 351:4,10,22
time--there 247:17
time-based 219:14
time-limited 246:7
time-to-needle 219:11
timeline 24:21
timeliness 110:19
 220:18
timely 89:17 122:17
 224:8 299:5
times 39:10 72:10 84:8
 125:11 136:15 222:18
 248:20
timing 83:20 269:3
 317:5
tinkered 159:12
tiny 176:8 194:11 349:6
Tirschwell 1:9,11 5:15

6:5,11 7:2,6,14,21 8:5
 8:7,9 11:22 13:9,13
 15:7 16:18 17:3 19:3
 21:17 22:2,6,8 24:7
 25:16 26:14,22 27:16
 28:1,4,11,17,19 29:2
 30:2,15 31:3 32:4,12
 32:19 33:4 34:14 35:2
 36:4 37:1,20 38:5,13
 39:1,8 40:6,10,16
 42:2,15 43:5 44:6,16
 45:3,12,14 46:11
 48:10,11 49:16 50:21
 51:10,13 54:18 55:1
 56:13 58:2 59:9,15
 61:5,15,19 63:6 64:14
 65:13 66:13 67:10,16
 68:3,7,9 69:8,22
 70:11,16 71:11 72:18
 73:20 75:16 76:2
 77:18 79:4,20 82:18
 83:17 85:9 89:6,15
 90:7,20 91:11,16,22
 92:5,17 93:3 94:9,15
 94:19 95:2,12,22
 96:12 98:16,21 99:8
 101:22 102:12 104:18
 105:6 106:1,10,18
 107:6 111:5 112:12
 119:14 121:2 123:14
 124:3,7,9,13,16,19
 125:5 127:5,9,19,22
 129:19 131:5 134:10
 134:14 143:6,22
 144:6 147:13 148:4
 150:15,21 151:5,18
 152:2 153:11,14,20
 154:5 163:8,13
 164:20 170:11 173:13
 175:15 176:18 177:14
 179:5 181:6,18 182:7
 182:22 183:10 185:6
 187:18 188:5,8,20
 189:7,10 190:3 195:1
 195:13,20 196:7,14
 197:18 198:1,8,13
 199:3 200:3,11,16
 201:4,10 202:21
 203:6 205:8,15
 206:17 207:5,10,22
 208:2,20 209:1,11
 210:3,16 211:3,6,17
 212:7,19 213:19
 242:21 243:11,16,20
 252:11 258:8 259:6,9
 278:2,6,15,19 287:14
 288:1,6,13,19 290:7
 291:2 296:7,16,20

300:14,15,20,22	traditional 138:16	328:14	323:15 341:20 353:15
301:4,18 302:21	training 16:8 23:11	trick 56:16 57:2 113:20	354:10,12,15,19,22
304:8 305:4 306:11	transcripts 268:13	155:15 162:9	355:1,2,3,4,5
306:21 307:6,10	transfer 217:2	trickier 118:17 184:20	type 54:8 142:17,18
308:1,10 309:2,9,15	transferred 86:7,22	trickle 25:1	281:4 299:7
309:18 310:2,7,13	transfers 86:2	tricky 58:13 114:3	types 17:14 80:2 178:6
311:3,21 312:8,17	transit 216:16	171:8	typically 325:11 348:2
313:11,19 314:10,19	transition 114:5 131:16	tried 62:21 138:3	
315:15 316:2,9,19	164:8,19 166:8	trivia 255:7	U
317:10,18 318:1,12	translate 109:18	trivial 97:17	UGIB 284:17
322:19 324:3 325:4	translated 132:4	trouble 85:7	Uh 247:8
325:20 326:5 327:4	translation 109:20	troublesome 346:6	ultimate 254:2
328:15 331:13 332:18	transportation 244:7	true 7:18 64:17 74:20	ultimately 178:16 273:1
333:1 334:7,20 335:8	transported 176:4	113:21 123:1 126:9	341:14
336:3 337:7 338:1,17	trauma 82:16	139:1 142:22 168:13	ultrasound 280:16
339:8,17 340:2,13	traumatic 82:13 330:3	236:19 269:8 274:5,6	281:5 282:1 285:17
341:7 342:14 343:3	331:3	288:21 290:8 300:11	287:16 288:10,15
343:10,20 345:14	travel 355:16	trust 231:13	unable 62:1,22
346:11 347:10 348:12	traveled 322:8	try 8:17 15:18 22:17	unanimous 242:17
349:15 350:8,14,19	treat 215:1 226:17	39:12 53:19 57:16	318:9 350:17
351:11	251:1 313:5	72:11 108:4 128:8	unavailable 246:5
to-- 264:4 314:1	treated 52:2,20 53:5	137:21 165:13 166:22	unaware 275:16
to--all 273:21	54:8 57:15 85:17	167:8 174:6 220:17	unborn 251:3
to--how 254:18 287:11	215:4,13 218:5 220:8	238:15 252:21 260:20	unclear 220:2 255:15
to--oh 314:20	221:7 226:22 239:3	304:16 305:20	uncomfortable 172:21
to--once 264:6	349:3	trying 7:20 24:17 73:6	undergo 10:9 11:11,19
to-needle 219:7	treating 185:13 233:7	76:9 138:14 144:13	47:4,9,13,20 52:4
today 5:6 9:13 30:11	346:5 347:17	145:9 147:3 159:2	53:6 80:21
78:10 109:8 242:22	treatment 10:16 13:8	164:1 194:9 214:20	undergoing 10:5 11:8
266:3 318:18 322:8	14:2 24:4 25:5,7,11	215:3 230:1 237:16	47:3 48:5 80:19
352:1 353:20 355:11	25:13,22 26:3,6,12	244:6 254:21 304:21	undermine 23:5
today's 51:16	60:17 70:21 73:12	329:19 332:2 333:8	underneath 246:22
told 176:2 199:17	84:19 164:9 172:5	336:20	underserved 308:16
244:11	185:12 187:1 214:21	tube 165:12 251:4	understand 45:18
ton 172:11 355:9	214:22 215:5,9,21	tubes 114:8,8	46:19 47:15 50:16
tool 11:1 43:18,19 44:4	215:21 216:5 217:9	TUESDAY 1:5	75:1 76:7,9 94:6
44:14 96:21 183:21	217:15,16 219:3	turn 184:10 243:11	103:8 150:22 155:2
299:15,18	235:19 240:3 245:16	245:20 279:18	199:21 245:19 286:11
tools 148:18 305:8,9,13	260:12 281:20 308:14	Twelve 20:7	286:14 298:19 304:11
305:22	325:10 326:13 348:5	twice 203:16	310:20 347:11 353:13
top 32:5 194:11	treatments 22:9 80:16	two 28:9,14,14,15 32:18	understanding 12:5
Toronto 241:2	174:19	34:2,18 36:14,19 38:8	19:9 77:12 119:15
total 33:18 40:8 41:7,7	tremendous 304:20	41:19 42:6 44:20 45:8	148:14 179:22 253:6
94:6 123:1 138:17	333:4	51:7 63:12 65:20 66:7	275:11 328:10 333:13
215:3 286:17	tremendously 43:14	78:4,12 79:1,14 90:1	understands 201:16
totally 39:17 43:9 50:15	triage 13:2	90:16 91:20 92:21	understood 67:13
58:18 86:9 107:8	trial 58:15 63:19,20	94:13 95:16 105:18	underway 192:21
117:15	70:22 130:10 217:6	106:6 107:8 112:5	undesirable 302:9
tough 105:5	248:6,14 290:8 301:1	121:8,13 133:5 137:3	undoubtedly 308:5
Tourette's 320:7 336:6	301:8 302:5 308:8	138:8,9 139:2 140:17	undue 236:21
336:19 349:3	310:10 311:15 313:12	144:2 155:4,15 156:2	unethical 253:11
TPA 164:13 185:12	313:16 314:4,8	156:5 172:8 176:2,12	unfamiliar 236:6
186:20 216:10,14	316:21 317:14,16	191:11 204:10,14,22	unfortunately 22:10
217:3 219:3 223:19	318:5,7,11	206:4,21 207:9 219:8	328:5
234:11 237:10 239:1	trialing 304:4	221:5 259:19 261:11	unheard-of 236:9
track 145:18	trials 26:16 52:14 54:14	287:8,14 312:15	uniform 75:20
tracking 44:13 256:20	64:1 83:9 113:8 248:8	314:13 315:5 316:6	unintended 24:20
257:11	248:16,18,19 291:4	317:3 321:17,19	183:17 255:20 295:6

345:9 346:16
unique 236:11
unit 1:21 84:10 89:12
United 40:18 111:17
units 110:19 122:18
University 1:17,19 2:1
 2:6,13,16,17 3:11
unjustified 48:2
unmeasured 115:21
unplanned 245:20
 249:17 251:20 252:1
 252:7 267:12
unreasonable 115:19
unruptured 82:13
unsuccessful 72:6
untreated 324:14
unusually 163:17
unwanted 250:3
update 108:9 267:6
 347:6
updated 225:17 246:13
 247:13,19 323:2,4
 339:11,20
updates 219:5
upshot 27:17
uptake 109:5
upwards 163:12
urgent 99:3 299:21
 315:8
urgently 85:17
usability 42:16 44:17
 44:19,21 45:2 61:10
 93:12 95:22 100:20
 105:4,15,17,21
 183:11 185:7 188:9
 188:11,18 210:16,18
 211:7,9,16 229:18,20
 230:4 231:9,10 232:3
 232:5,14 241:21
 242:1,8 274:13
 276:22 277:13,17
 294:21 295:10,12,17
 301:15 316:2,11,13
 316:18 317:17 343:20
 344:7 349:20 350:1
 350:10
Usability-- 274:11
usable 99:5 295:6,8
 316:7
use 4:16 10:17 15:11
 16:3,12 17:6 27:20
 32:2 42:16 44:10,17
 44:19,21 45:2 54:14
 73:11 75:7 76:15 85:1
 93:12 96:1,5,20 100:9
 101:9 102:7 105:14
 105:17,22 109:4,13
 110:18 129:7 145:21

146:17 153:7 159:10
 162:4,20 175:4,7
 179:11,14,17 180:9
 183:11 184:16 185:7
 188:9,11,18 190:21
 191:2 192:18 193:6
 193:11,14 194:8
 202:10 210:17 211:7
 211:9,16 214:15
 216:10 219:15 232:14
 237:18 241:21 242:1
 242:8 247:15 249:2
 251:1 254:18 256:10
 267:22 270:4 275:4
 276:4 277:13,18
 281:7 286:4,8 287:6
 288:17 294:7,21
 295:10,12,17 299:17
 301:1,8,16 303:15
 310:10 311:15 313:12
 313:16 314:4,8 316:3
 316:6,10,13,18,21
 317:14,16 318:5,7,11
 318:14 319:10,14
 320:16 321:15 323:5
 323:8 324:1 325:21
 327:12,13 328:2
 330:18,22 331:10
 332:14 334:17 335:2
 336:17 343:21 344:2
 344:19 345:4,12,18
 346:2,10,15 348:8
 349:21 350:1,10
 354:17
useful 78:8 83:12
 100:17 184:18 268:21
 299:18
usefulness 83:10
user 277:5
uses 23:17 108:10
 284:21 294:7 299:16
 321:6
usually 23:20 41:8
 76:11 91:2 143:5
 317:15
utilization 239:6 321:3
utilize 75:22 111:16
utilized 44:12 256:12
 267:15 272:22
utilizing 75:10

V

VA 133:18
Valerie 1:19 219:21
 239:14 249:4 303:1
 314:20 322:20 331:14
 337:11 354:9
valid 37:10,12 234:6

265:15 300:12 311:2
validated 273:6 281:3
 287:21 288:17
validation 111:12 132:7
 139:13,13 156:21
 271:19
validity 22:15 23:2 35:2
 35:8,9,10,13,15 36:3
 36:21,22 37:3,4,7,16
 38:6,8,12 93:3,5,7,11
 93:15,19 94:10,11,13
 95:1 112:19 114:17
 135:15 154:6,8,9,15
 154:17,20 155:3
 158:13,14,19 159:10
 159:15 160:3,5,16
 161:8 175:20 177:20
 177:22 181:19,21
 182:10 189:1 202:1,9
 203:12,13,16 204:9
 205:20 206:8 208:1,7
 208:18,21 209:2,4,10
 210:4 225:12 228:3,4
 228:10,11,16,17
 229:2,6 230:7,12,18
 233:21 234:3 238:1,5
 253:10 254:6 261:5
 261:10 262:2 267:21
 271:7 272:8,14,17
 273:10,12,16 293:8
 293:15,16,19,21
 294:4 301:17 310:19
 312:4 327:14 335:11
 340:13,15,18,19
 341:5,6 342:16,18
 343:2
valuable 56:4 62:8
value 17:17 18:11 23:14
 34:8 44:15 48:17
 61:21 63:3 72:4 112:2
 141:10 148:22 149:6
 186:16 199:17 205:11
 210:1 254:12 282:16
values 62:16,20 202:5
 202:20
variable 29:19 109:1
 155:20 161:22 162:5
variables 96:18 108:22
 156:11 191:5,15,16
 191:21 192:3
variance 137:5 138:1
 138:17,18,22 141:16
 162:7
variation 116:18 126:2
 126:9,14,15 128:19
 166:10 281:10,13
variations 210:19 265:6
varied 50:9

varies 172:11
variety 214:16 330:4
various 113:5 305:22
vary 162:15 172:10
 208:17
vascular 283:4 333:15
 334:4
vast 36:16 45:18 46:5
 278:10 283:6 290:3
vastly 180:16
velocities 285:15
velocity 281:5 285:15
vendor 314:14
vendors 315:6
venous 5:21 82:14
ventric 104:13,22
ventricular 99:15
ventriculostomy 98:11
 104:9,14,16
ventured 334:9
verbal 7:15
version 22:12 23:1,8
 122:22 193:10 197:11
 262:13
versions 15:13
versus 176:12 225:19
 248:9 252:8,9 283:12
vessel 173:11 174:5
Vice 2:14 3:3,7
view 18:20 239:20,21
violence 267:12
Virginia 2:6
virtually 342:11
visit 73:11 303:17
 304:16,18
visits 151:17 303:5
visual 104:5
vital 74:19 202:5
vitals 191:11,12
voiced 215:18
volume 96:16 99:13
 101:4,11 104:5 116:9
 116:11 142:5 147:19
 147:20 150:10,16
 151:1,3,6,8,16 243:11
 287:2
volumes 99:4 150:9
 151:13,19
voluntarily 161:15
voluntary 111:18
 125:15 275:19
volunteer 274:8
volunteered 274:4
vote 28:5 32:15 34:16
 34:16 38:6 40:20 42:3
 44:17 45:4,10,16,17
 45:20 46:10 49:10
 51:1 61:8 65:14,17

68:1,21 69:8 78:18,19
 78:20 79:3,5,6 89:19
 91:17 92:18 94:11
 95:13 105:14 106:2
 123:16 127:10,13
 153:15 175:19 181:19
 182:9 183:1 188:9,21
 189:1 197:19 198:14
 207:11,12 209:1
 210:5 211:7,18 223:4
 224:11,18 227:16
 230:10 231:16 241:20
 258:6,10,16 259:4,5
 260:16,20 274:16,17
 276:2 277:11 291:7
 292:4,21 293:3,19
 294:13 295:10 306:15
 306:16,17 307:14
 309:16,19 310:3,3,4,5
 310:7,17 311:9,12,14
 312:9 314:3 315:16
 316:10 317:15,16,16
 318:4 334:13 335:11
 337:14 338:19 340:16
 342:15,16 343:11
 349:20 350:9,12
 351:22 352:12
voted 45:19 46:19
 47:15,17 67:7 77:11
 90:4 153:21 195:12
 195:18 200:9 290:20
 309:10 324:21
voter 189:7
votes 124:4 313:20
voting 28:8,10,15 32:16
 34:17 38:7 42:5,10
 44:18 51:6 60:20
 65:19,22 66:3,5,17
 79:12 89:21,22 91:19
 92:20 94:12 95:15
 105:16 106:4 123:17
 123:22 124:17 125:1
 127:11,14 153:17,22
 175:17 181:20 182:1
 182:2 183:3,5 188:10
 188:12,14,15 189:3,6
 189:8,16,19,21,22
 195:7 197:20,22
 198:4,5,16,18,20,21
 200:6 207:13,15,17
 207:18 209:3,5,6,7
 210:7,9,11,12 211:8
 211:10,12,13,20,22
 212:2,3 223:5,7,9,10
 223:11 224:12,14,17
 224:19,20 227:17,19
 227:20,21 230:11,13
 230:14,15 231:17,19

231:20,21 239:10
 241:22 242:2,4,5,11
 242:14,15,16 258:17
 258:19,20 259:12,16
 259:16 260:2,2,17,19
 260:20 270:12,13,15
 270:16 273:10,11,13
 273:14 274:18,20,21
 277:12,14 278:16,18
 279:2,8,10,11 291:8
 291:10,14 292:5,7,8
 292:22 293:2,4,20,22
 294:1,14,16,17
 295:11,13,14,20,22
 296:1 306:18,20
 309:3,5,7,11 311:11
 313:15,18 314:5,5
 315:17,19,20 316:12
 316:14,15 318:6,7,9
 334:15,22 335:7,9
 337:15,17,18,19
 338:21 339:1,3,4
 340:4,5,7,8,9 341:10
 342:17,19,20,21
 343:12,14,15,16
 349:22 350:2,4,5,13
 350:15,16

voyeurism 18:12

VTE 6:10

vulnerable 319:13

W

wait 86:11 101:9 131:10
 141:15 158:3
waiting 28:14 42:7
 94:17 127:13 344:17
 344:21
walk 145:13
walked 145:7
wallowing 218:19
want 6:10 7:15 9:16
 12:2 18:17 19:4 22:11
 30:7 37:9 45:16,20
 46:9 49:15 50:22
 53:16 55:3 56:13
 58:22 60:5 61:3,20
 64:5 65:3 67:17 68:11
 70:12 73:14 76:13
 77:17 88:7 100:4
 104:21 106:11,12
 110:15 111:6 131:9
 132:4 141:20 145:3,6
 148:19 163:20 165:12
 165:12 171:4 173:1
 175:1,22 177:18
 179:7 186:7,12 191:8
 201:15 206:18 212:9
 229:2,19 231:8

234:13 239:1,8
 240:12 241:19 243:9
 248:12 249:12 254:14
 255:16 257:14 263:12
 263:13,13,14 279:17
 284:14 289:18 317:1
 317:20 322:7 326:20
 328:5 329:20 331:9
 332:7 333:11 335:18
 337:11 345:8,13
 346:11 351:15
wanted 46:7 59:14
 68:15 72:2 88:12
 96:10 111:7,9 148:12
 193:14 305:15 322:10
 322:14,15 329:12
 333:12 353:22
wants 46:8 263:11
 346:15
warning 10:15 327:10
 328:12
warrant 26:5
was--I 278:9
wash 349:14
Washington 1:8 3:11
wasn't 6:16,19 27:4
 40:11 46:20 68:17
 85:11 124:4 157:14
 207:8 262:15 266:19
 275:18 334:11 339:14
 344:19
WATT 3:17 7:18 8:2,6,8
way 22:21 28:13 44:10
 50:3,20 55:18 62:12
 63:4 64:2 71:3,8
 77:16 79:7 109:22
 110:5 111:12,15
 120:12 123:8 138:16
 142:4 143:10 144:9
 149:10 157:14 158:7
 174:14 178:3 183:16
 187:11 192:11 199:11
 207:1 208:11 216:16
 238:12 241:5 251:7
 253:12 261:7 280:19
 284:17 285:10 292:1
 301:10 304:14 312:12
 313:1 319:8 347:11
way--the 247:2
ways 15:18 100:15
 113:5 137:20 152:22
 250:9 262:5,6 272:7
 303:13 306:15
we'll 8:18 45:3 58:12
 65:2 79:5 90:7 107:10
 110:10 131:12 188:20
 197:8 210:22,22
 211:18 243:3 247:11

276:7 278:20 306:12
 309:3 317:6 322:12
 322:12,22 331:14
 335:10 340:4 352:10
 352:21 353:7 355:9
we're 5:12 7:20 9:13
 21:1,2 24:17,21 28:13
 28:15 32:16 42:5
 44:18 49:5,6,7,9,10
 49:11,13 51:15 57:14
 57:15,22 58:4,20 59:2
 59:3 61:10 65:19 66:5
 68:12,14,20,21 69:6
 70:4,8,14 71:3,5 73:1
 74:16 75:17 77:14
 78:4,20 79:4,12 88:6
 88:8 94:17 101:3
 102:21 104:3 105:3
 106:20 107:16 109:2
 109:19 119:13 120:1
 121:9 122:4,20
 124:15,17 125:5,10
 131:14 134:18 136:3
 138:8,14 141:15
 144:10 145:9,9
 146:13,14 148:16
 150:18 151:16 152:12
 153:9 157:9,10,20
 160:14 161:10 165:6
 166:15,18 167:8,21
 168:6 169:2,4,10
 171:12 175:8,17
 177:15 178:12,21
 180:16 183:2 184:12
 184:13,13 189:9
 190:5 195:7,9,15
 199:17,22 209:3,15
 209:20 210:7 213:10
 213:14 214:3,4
 231:16 232:19 235:1
 241:10 242:22 243:4
 244:4,6,9 248:1,10
 249:22 254:22 256:5
 256:6 257:10 265:14
 265:17 269:22 270:19
 273:10 276:20 277:2
 277:19 278:14,15,17
 293:3 296:9,10,11,12
 296:12,20 300:17
 311:21 313:6,8,22
 317:6,7 318:4,13,19
 319:7 325:14 329:6
 332:12 334:15 335:6
 335:9 341:10,18
 349:12 351:1
we've 18:15 35:5 39:9
 47:6 48:16 49:16
 67:14 68:5 74:14 78:2

78:22 79:8 111:21
 122:11 125:8 135:12
 140:7 142:8 146:8,11
 147:21 151:3 152:1
 153:6 156:11,17
 157:12 159:12 164:1
 169:9,16 173:5,20
 176:11 182:18 190:20
 197:5 202:2,3,7,18
 206:9 225:9 244:4
 253:10 257:16 259:18
 263:20 265:4 277:21
 285:10,21 287:8
 296:10 308:4 321:16
 342:2
we-- 258:7
we--are 258:5
weaker 16:13
week 177:6 324:5
weekdays 115:11
weekend 128:12
weekends 115:9
weigh 71:19 77:15
 78:15 83:2
weight 158:21,21
Weill 2:9
weird 313:1
Welcome 4:2 5:3
well- 70:19
wellness 303:5,17
 304:16,18
went 6:8 7:8 9:4 32:20
 39:19 106:16 140:2
 154:11 165:2 244:1
 263:9 271:12,20
wheelchair 120:21
where--that 269:17
whether--I'm 254:21
whites 29:13
Whoa 313:19
wholesale 23:9
wide 281:10 338:7,7
widely 10:22 43:14
 52:13 294:7,22
wife 164:16
willing 50:14 248:21
WILSON 3:7
win 296:8
wind 18:9 46:5
window 21:7 48:12
 55:22 85:18 88:2
Wisconsin 2:2
wise 58:1
wish 259:3 303:13
with--I 284:9
withdrawal 163:2 172:3
witness 217:18
women 4:13 244:10

245:9,18 246:6 248:3
 249:1,10 250:21,21
 251:1,5,9,15 252:7,8
 252:9,10,13,22
 255:19 257:5 260:11
women's 253:22
wonder 67:12 77:10
 85:10 193:21
wondered 93:14 117:11
wonderful 354:2
wondering 98:14
 106:11 254:21 266:17
 272:4
Woody 3:13 318:17
 319:4 350:20
word 47:10 177:18
words 265:4,6 266:22
work 13:15 20:8,9 55:6
 109:10 111:21 116:16
 153:6 179:15 191:4
 201:20 206:2,20
 228:5 241:4 274:3
 277:6 310:21 355:7
worked 176:2,5 265:4
workgroup 14:8,14
 27:2 35:17 56:12
 83:14 92:15 95:10
 96:8 112:18 113:3
 118:22 141:12 160:15
 246:12 267:8,13
 268:6,19 323:11
 336:22
working 28:6 190:9
 198:3 203:21 242:22
 352:3
works 160:21 284:17
 347:22
worksheet 204:1,4,7
 311:6
world 17:14 43:15 44:9
 54:12 113:12 125:21
 130:12 135:22 139:10
 140:13,15,19 141:2,6
 141:21 143:2,11
 161:12 162:3,6,11
 178:18 183:15,20
 212:21 237:15,16
 302:12 318:22
worried 31:6 74:15
 144:10 171:16 290:2
worries 166:6
worrisome 172:1
 341:17
worry 100:19 130:12
 135:21 166:3 169:9
 171:19 178:19 326:6
worse 177:3 221:7
 254:6

worsen 221:20
worst 318:22
worth 145:3 170:3
 181:4 188:4 271:15
 302:10
worthy 74:20
wouldn't 97:13,14
 105:7 120:4 142:8
 175:12 264:16 329:1
 329:3 333:7 345:13
 347:14
write 41:15 105:8
 163:11 238:12
writers 75:7
written 102:9 136:14
 312:12 313:1
wrong 56:6 133:3
 168:21 169:13 191:13
 202:17 218:15 248:7
 331:22
wrote 14:13
WUNMI 3:2

X

X 101:10 167:4

Y

Yale 1:16 107:4,16
 111:9
Yale-CORE 3:10
Yale-New 3:12
yeah 111:7 121:2 124:8
 124:13,19 134:14
 136:14 137:17 151:5
 163:13 173:15 176:18
 177:19 196:7,22
 201:10 204:19 205:16
 206:19 210:3 218:17
 221:3 227:4 229:21
 230:3 234:14
year 30:8 63:14 109:12
 226:18 237:4 245:16
 264:5,6 321:10
 330:12 347:6
year's 271:15
year-old 236:13 238:18
 238:19 239:2 241:8
year-olds 237:8,21
years 11:14 25:12,14
 53:12 82:6 108:14
 111:11 125:16 133:19
 136:7,20 139:12,14
 139:17 140:1 161:16
 164:11 180:13 239:4
 239:4 291:21 319:16
 331:1 353:5 354:17
yes-no 123:3
yes/no 312:5

yesterday 5:8,12,16
 7:13 38:19 128:5,19
 158:10 160:11 187:19
 199:9 205:20 255:5
YETUNDE 3:4
yield 281:15
you-- 325:20
you--that 253:11
young 98:8 236:7,13

Z

Zafonte 2:18 43:22 44:8
 67:18
zero 28:21,22 33:1,2
 34:21,22 42:12 44:22
 45:1 46:2 56:1 66:1
 90:3 92:3,3 94:21
 95:19,19 119:22
 120:18,22 125:3
 172:14 188:16 258:20
 260:22 270:16 273:14
 274:21 277:16,16
 279:3 292:9,10 293:5
 293:5 294:2,2,18,18
 295:15,16 296:2
 307:3 309:13,13
 314:7,7 315:22
 316:16,17 318:10
 320:22 331:9,10
 337:8,21 339:6,6
 340:10,11,11 342:22
 343:1,18,18 347:2,2
 350:7
zeroes 163:11
zone 66:21 67:1,20
 182:5,8 259:7 270:18
 270:22 279:6 355:14
zones 286:16 287:4

O

O 127:17 182:3 199:1,1
 209:8,9 223:13,13
 224:22,22 228:1,1
 230:17 232:1,1 242:7
0.03 29:16
0.054 29:20
0.55 141:13
0.7 128:10
0.76 322:4
0.87 322:5
03 81:16
03b 81:20
0434 6:1 8:6
0435 8:11
0436 9:6
0437 8:20,22
0438 9:2
0439 8:15

0441 9:8
0507 4:15 279:16 280:2
 291:9,17 292:6,10
 293:1,6,21 294:3,15
 294:19 295:12,16,22
 296:3
055 136:10 137:2
0661 5:19
08 154:19 167:17

1

1 4:3 123:18 124:18
 127:12 153:18 175:10
 181:21 183:3
1,500 110:3 140:19
 142:8 266:4
1:00 351:21
1:03 244:2
10 9:8 212:4 225:20
 231:22 242:7 251:16
 258:21 260:4,21
 338:6
10-15 160:13
10-second 301:5
10,000 237:17
10.5 178:5
10.8 126:6 228:21
 338:13
10:24 106:16
10:35 106:14
10:36 106:17
100 120:18 124:1 125:2
 161:19 165:19 222:20
 242:17 296:2 318:9
 338:12 340:10 350:17
1030 1:8
105 52:7
106 4:10
11 273:15 277:15
12 10:7 11:10,20 16:10
 18:4,4,5 20:18 21:20
 33:17 39:19 47:3,19
 50:1,10,19 56:2 69:15
 76:19 85:11 92:10
 245:11 302:1
12- 49:1
12-hour 14:6 15:6 17:21
 18:19,20 23:14 35:6
 47:11 48:4 55:22
12.8 338:5
12:51 244:1
120 11:15 53:13 82:7
13 39:18 40:4 126:4
 339:5
13.7 321:19
14 33:17,20 41:7 51:9
 66:2 127:16 154:2
 164:12 188:17 210:13

211:15 223:12 245:11
14.5 126:7
15 222:6 258:21 352:15
15-16 126:5
15.9 321:20
15th 1:8
16 93:1
17 90:3,4 161:21 279:4
 296:17,20 313:22
18 11:14 18:10 53:12
 82:6 92:2 153:8
 216:13 217:1 226:10
 226:13 234:10 236:13
 237:7,21 239:13
 241:8 267:18 269:5,6
 306:21
18-1/2 239:2
18.2 229:1
1814 4:13 244:9,13,14
 258:18,22 259:22
 260:5,18 261:1
 270:14 273:12,16
 274:19 275:1 277:13
 277:17 279:1,10,12
1818 259:14
19 126:6 242:6 343:1
 350:6 352:17,18
19.4 338:6
190 4:11
1952 4:12 213:12,14
 223:6,14 224:13
 225:1 227:18 228:2
 230:12,18 231:18
 232:2 242:1,8,13,17
1996 63:19
19th 352:16
1a.6.1 27:8

2

2 123:18 124:18 127:12
 153:18 175:11 181:21
 183:4
2,000 31:14
2,471 90:15
20 18:10 153:20 222:6
 225:20 228:8 313:20
 352:13
2007 280:6
2008 280:4
2011 132:9 321:17
2012 40:2 214:14
 218:20 232:12 319:8
2013 33:18 92:10 219:6
 280:5 324:15
2014 216:2 246:8,12
 247:20
2015 29:4 43:1 90:16
 95:7 224:3 232:12

267:19 293:11,14
 307:18 323:6 345:2
2015-2016 228:9
2016 1:5 321:11,13
2018 321:14
20th 126:4
21 191:5 226:10 236:13
 237:7,21 238:14
 241:8 273:15 293:4
2111 4:16 296:11 317:6
 317:11 318:13 337:16
 337:22 338:22 339:7
 340:6,12 342:18
 343:2,13,19 350:1,11
 350:13,18
213 4:12
22 94:16 124:5,6 191:5
 238:18 309:12 351:21
23 176:13 190:1 352:7
23.9 225:19 338:14
24 19:14,16 28:22 50:1
 84:12 102:2 191:12
244 4:14
25 29:10 146:2
251 4:20
25th 126:3
27 33:1 38:11 209:9
279 4:15
28 279:4
281 33:18 92:10
2832 8:13
2834 8:22
2835 9:5
2863 9:11
2864 4:4 5:13 9:13 28:8
 28:21 32:17,22 34:18
 34:20 38:8 42:6,11
 44:19,21 45:8 51:7,8
2865 4:6 51:17 65:20,22
 66:5,10 79:13,17
2866 4:8 89:22 91:20
 92:21 94:13 95:16
 105:17 106:6,8
2870 296:12
2872 4:18 296:12,13
 297:5,7 306:19 307:4
 309:6,14 314:3,9
 315:18,22 316:13,17
2872's 318:6
2876 4:10 106:20
 123:18 124:18 127:12
 153:18 181:21 183:3
 188:11,19 189:5,19
 190:2
2877 4:11 106:21
 190:13 197:21 198:7
 198:17 199:2 207:14
 207:21 209:4,10

210:8,15 211:9,16
 212:5
2877's 211:21
29 29:14 224:21 295:15
296 4:17,18

3

3 92:2 102:4 127:12
 153:19 181:21 183:4
 247:21 261:7
3,000 140:20 266:5
3.50 38:21 39:3,10
3:00 351:21
3:24 355:18
30 29:14 52:22 99:14
 103:14,22 108:7
 120:1 187:11 223:18
 270:17,17 271:12
 276:11 314:14
30--25 267:15
30-day 4:10 106:22
 108:12 180:12
300,000 347:22
31 169:19 337:20
 343:17
32 44:22 94:20 127:15
33 279:11 307:2
35 314:6 322:3
351 4:19
36 182:4 183:6 198:22
38 29:4
39 270:21

4

4 127:12 147:5 153:19
 181:22 183:4
4.5 217:3
40 29:13 31:11 87:21
 88:1 164:11 215:16
 238:18 260:10 270:17
 270:19,21 300:8
41 42:11 66:11 95:18
 316:16
42 294:1
45 38:17 39:2 40:6 41:3
 215:15
45-minute 5:20 24:21
 40:3
47 149:20 292:8 315:20
 315:21

5

5 1:5 4:3 16:9 37:16
 182:4 183:7 188:17
 198:6 207:20,20
 210:14 211:15 227:22
 230:16,17
50 29:5 42:11,19 67:3

183:7 218:1 227:2
 255:18,19 257:4
 300:8 332:13
51 136:15 140:8
52 4:7
53 232:12 292:9
55 127:16 136:14,16
 138:21
56 199:19 279:4
574 29:10
58 294:1
59 66:10 95:19 176:14
 182:3 316:15

6

6 12:22 26:2 352:5,12
 352:12
6-something 149:21
60 56:5 66:19 67:4,22
 68:2,4,5,6 87:21 88:1
 90:9 189:2 215:9
 216:18 217:16 219:7
 219:15 223:19 227:2
 234:11 259:7,8,9,10
 270:19 289:6
61 307:3
62 170:16
63 337:20
63.93 307:19
64 94:21 198:22
65 153:9 314:6 319:16
 331:1 349:2,6
66 90:15
67 279:11 340:16
672 228:19
68 38:11 44:21 204:8
 273:15
69 343:17
699 262:21

7

7 63:3 148:13,22 149:3
 199:16
7.7 338:6
70 205:11 224:1,2
 232:12
71 92:13 224:21 242:6
71.5 33:20
72 42:21 225:15
720 322:2
73 33:1 209:8 210:13
 211:14
75 52:7 258:21 289:8
 350:6
76 28:21
77 66:2 154:2 190:1
78 309:12
79 293:4 295:14

8

8 16:10 63:4 150:19
8.2F 82:15
8/30 271:8
8:30 1:9
8:32 5:2
80 31:17 90:14 109:7
800 225:14
81 342:22
82 112:4 188:16 207:19
83 29:6 42:22
83-ish 161:16
84 29:5 291:15
85 29:5 228:12 260:21
86 51:9 105:19 112:4
 223:12 292:16
88 339:5
89 4:9 274:22 277:15

9

9 183:7 207:19 210:14
 211:14 352:14
90 4:7 51:17,21 52:6
 55:11,20 56:6 69:1
 112:1 151:17 205:6
 212:4 230:16 231:22
 251:14 260:3 271:10
90-day 53:9 54:15
 55:16,18
90s 92:14
91 34:21
93.6 132:12
94 204:13
95 106:7 198:6 227:22
 294:17
96 204:13
99 92:13
99.3 33:21
9th 1:8

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