

NATIONAL QUALITY FORUM

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NEUROLOGY STANDING COMMITTEE MEETING

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MONDAY

APRIL 4, 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, Will  
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:

KAREN KOLBUSZ, The Joint Commission  
COLLEEN MCKIERNAN, The Lewin Group  
LEE SCHWAMM, MGH/Harvard  
NAILA WAHID, The Lewin Group  
ANN WATT, The Joint Commission

\* present by teleconference

## A-G-E-N-D-A

Welcome. . . . .	5
Consideration of Candidate Measures	
0661: Head CT or MRI Scan Results for Acute Ischemic Stroke. . . . .	.39
Overview of e-measures . . . . .	117
Consideration of Candidate Measures (Continued)	
0434: STK-01: Venous Thromboembolism (VTE) Prophylaxis. . . . .	131
0435: STK-02: Discharged on Anti- thrombotic Therapy . . . . .	169
2832: STK-02 Discharged on Anti- thrombotic Therapy . . . . .	196
NQF Member and Public Comment. . . . .	214
0437 Thrombolytic Therapy The Joint Commission and 2834, Thrombolytic Therapy. . . . .	250
0438: STK-05: Antithrombotic Therapy by End of Hospital Day Two. . . . .	342
2935: STK-05 Antithrombotic Therapy by End of Hospital Day Two. . . . .	349
0436: STK-03: Anticoagulation Therapy for Atrial Fibrillation/Flutter. . . . .	349
0441: STK-10: Assessed for Rehabilitation. . . . .	374
2863: CSTK-06: Nimodipine Treatment. . . . .	381
Administered	
Public Comment . . . . .	402

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

2 8:41 a.m.

3 CO-CHAIR KNOWLTON: Okay. We're going  
4 to get started.

5 I'm Dave Knowlton. I'm one of the co-  
6 chairs along with Dr. Tirschwell. We'll  
7 introduce ourselves in a minute.

8 I'm going to hand it over to Peg,  
9 who's going to lead you through the original -  
10 the initial formalities. I do want to ask that  
11 you take your cards and turn them towards us  
12 until we learn your names because we'll be  
13 calling on you to speak and it would be helpful  
14 if we could see your names. That would make it a  
15 little easier for us.

16 So David, if you have anything, or  
17 I'll pass it off to Peg.

18 CO-CHAIR TIRSCHWELL: No, just welcome  
19 and thank you all for the time. I know you  
20 already put in reviewing these measures. We  
21 really appreciate your help.

22 DR. TERRY: Good morning. My name is

1 Peg Terry and I am the senior director on this  
2 project. I want to welcome everybody - I want to  
3 welcome the committee, the co-chairs, the  
4 developers, those on the phone to our two-day  
5 neurology committee meeting.

6 And I know many of you have spent some  
7 time on our work group calls and have gotten to  
8 know each other a little bit and have gotten a  
9 better look at the measures. So we'll continue  
10 from there.

11 So with that I'd like to turn it over  
12 to the staff here at NQF. Christy?

13 MS. SKIPPER: Good morning. My name  
14 is Christy Skipper and I'm the project manager  
15 for this project.

16 MS. ISIJOLA: Good morning, everyone.  
17 My name is Wunmi Isijola. I'm administrative  
18 director here at NQF looking forward to the next two  
19 days.

20 MS. OGUNGBEMI: Good morning. Alexandra  
21 Ogungbemi. Welcome.

22 MS. MUNTHALI: Good morning. Elisa

1 Munthali. I'm vice president for quality  
2 measurement. I wanted to welcome everyone and  
3 thank you so much for serving on the committee.

4 DR. TERRY: And now I'd like to turn  
5 it over to the co-chairs.

6 MS. ISIJOLA: Well, just before we get  
7 started I just wanted to acknowledge also Karen  
8 Johnson. Many of you are familiar with her but  
9 she's our chief methodologist here at NQF so  
10 Karen, do you want to introduce yourself really  
11 quickly?

12 MS. JOHNSON: Hi, I'm Karen. I  
13 remember several of your faces from the last time  
14 around when I got to sit in Peg's seat. So  
15 welcome.

16 DR. TERRY: And so with that, I'd like  
17 to turn it over to the co-chair.

18 CO-CHAIR TIRSCHWELL: Trying to figure  
19 out what's next here but I'm thinking we should  
20 go around and everybody introduce themselves  
21 really briefly. Is that okay? Or Ann, do you  
22 want to do that?

1 (Off mic comments.)

2 CO-CHAIR TIRSCHWELL: Well, we already  
3 thanked everybody. I don't have anything to add  
4 at this point.

5 DR. TERRY: Great. Okay.

6 MS. HAMMERSMITH: Hi, everyone. I'm  
7 Ann Hammersmith, NQF's general counsel. As your  
8 co-chairs just noted, I'll lead you through the  
9 disclosures of interest.

10 If any of you have been in our  
11 committees before you're used to this. I don't  
12 think my mic is working. It's glowing red.

13 MS. ISIJOLA: Just to note, we can  
14 only have no more than three mics on. So if  
15 you're not speaking please turn it off. Thanks.

16 MS. HAMMERSMITH: Okay. It's not  
17 working. Anyway, on to disclosures of interest.  
18 As I was saying, if any of you have served on our  
19 committees before you know the drill. I'll go  
20 over it quickly before we go around the table.

21 As I said, we'll combine disclosures  
22 and introductions because it's a little bit



1 quicker and we want you to be able to get on with  
2 the work we'll be doing today.

3 So if you recall, you received a  
4 disclosure of interest form that asks you a lot  
5 of information about your professional  
6 activities.

7 We review those as part of seating the  
8 committee. But we do like to do oral disclosures  
9 of interest at the first public meeting of a  
10 given committee.

11 The reason we do that is because we  
12 want the process to be open and transparent for  
13 the public and for all of you and we want you to  
14 know where each other is coming from.

15 So we are interested in your  
16 disclosure of items that are relevant to the work  
17 before the committee only if they are relevant to  
18 the work before the committee.

19 So if you invented the heart  
20 transplant that's wonderful. But it doesn't have  
21 anything to do with neurology usually so we don't  
22 really want to hear about that.

1           So please don't summarize your resume.  
2       We're particularly interested in grants,  
3       research, consulting or significant speaking  
4       engagements but only if it has to do with the  
5       work before the committee.

6           So we'll go around the table, tell us  
7       who you are, who you're with and if you have  
8       anything you want to disclose.

9           Just a quick reminder, you do serve as  
10      an individual on the committee. You don't  
11      represent your employer. You don't represent  
12      anyone who may have nominated you for service on  
13      the committee.

14          So we'll start with the co-chairs.

15          CO-CHAIR KNOWLTON: I'm Dave Knowlton.  
16      I'm retired - I just retired from being the  
17      president and chief executive officer of the New  
18      Jersey Health Care Quality Institute.

19          I've served on this committee with  
20      David before and I don't believe - I'm the one y  
21      you hardly hear from because I've been in an RV  
22      traveling around the country for the past six

1 months so learning that there aren't cell signals  
2 everywhere.

3 I don't have anything really to  
4 disclose other than the fact that I serve as the  
5 chairman of the hospital safety score --

6 CO-CHAIR TIRSCHWELL: David  
7 Tirschwell. I'm a stroke neurologist. I work at  
8 Harbor View Medical Center, which is part of the  
9 University of Washington and Seattle.

10 As far as disclosures go, I guess I  
11 represent or was nominated by Harbor View and I  
12 think also the American Stroke Association. And  
13 so I think, because I'm on an American Stroke  
14 Association committee about quality measures I'm  
15 going to be recusing myself from voting during  
16 one of the stroke association measures later.  
17 That's it.

18 MEMBER SCHMIDT: I'm Peter Schmidt  
19 from the National Parkinson Foundation. I was on  
20 this committee in 2013 for the second half of the  
21 Parkinson's measures and I have nothing to  
22 disclose.

1                   MEMBER J. SULLIVAN: My name is Jane  
2                   Sullivan. I'm a physical therapist. I'm on the  
3                   faculty at Northwestern University in Chicago and  
4                   I am working on a grant for the American Physical  
5                   Therapy Association on core set of outcome  
6                   measurement and rehabilitation. But I have  
7                   nothing to disclose.

8                   MEMBER COTTER: Good morning. I'm  
9                   Valerie Cotter. I'm an adult gerontology primary  
10                  care nurse practitioner and I'm on the faculty at  
11                  the Penn School of Nursing and I have no  
12                  disclosures.

13                 MEMBER ANDREWS: Good morning. I'm  
14                 David Andrews. I'm a patient advisor at what's  
15                 now Augusta University. Some of you probably  
16                 know it as either any one of several names. It's  
17                 changed its name several times recently - Medical  
18                 College of Georgia, Georgia Regents University,  
19                 among others.

20                 We think that we may have a name we're  
21                 keeping for a while and I have nothing to  
22                 disclose.

1                   MEMBER DICKERSON: Hi, I'm Brad  
2                   Dickerson, a neurologist working in dementia from  
3                   Massachusetts General Hospital and Harvard  
4                   Medical School.

5                   I receive grants from the NIH and am  
6                   on the board of directors in the Alzheimer's  
7                   Association and other than that have no  
8                   disclosures.

9                   MEMBER HUFF: Hello. I'm Steve Huff.  
10                  I'm an emergency - thank you - hello, I'm Steve  
11                  Huff, an emergency physician and neurologist at  
12                  the University of Virginia.

13                  I'm here at the request of the  
14                  American College of Emergency Physicians. I have  
15                  no relevant research grants or support to the  
16                  matters of this committee.

17                  Something not on my disclosure sheet -  
18                  I was on a speaker's bureau for a pharmaceutical  
19                  company - I think that's been 20 years ago.

20                  MEMBER JONES: Charlotte Jones. I'm  
21                  a pediatric neurologist - I'm Charlotte Jones.  
22                  I'm a pediatric neurologist. Okay. I'm still

1 Charlotte Jones. I'm a pediatric neurologist at  
2 Nationwide Children's Hospital and I have two  
3 disclosures that I think are important to make.

4 One of them is is that I am the  
5 pediatric representative for the AAN specialty  
6 group to the Axon Registry, which is one of -  
7 which is the registry that the AAN is identifying  
8 in a couple of measures as being used to monitor.

9 I was not involved with the measure  
10 development but I do work - I do have that role  
11 with the AAN. And I was on their urgent measure  
12 development and none of those measures are being  
13 brought forth today.

14 But those potential interactions with  
15 the AAN plus just in full disclosure one of their  
16 representatives is three doors down from me, Dr.  
17 Patel, who's here as the AAN measure developer.  
18 But we have not discussed it and he knows I'm  
19 going to say what I want to say anyway.

20 MEMBER CAMICIA: Good morning. I'm  
21 Michelle Camicia. I'm the director for Kaiser  
22 Permanente's Northern California Inpatient

1       Rehabilitation Hospital.

2               I am past president of the Association  
3       of Rehab Nurses who I'm here representing, or  
4       not. And I'm also a Ph.D. student at the  
5       University of California and doing the  
6       psychometric testing of a new instrument not  
7       related - nothing to disclose.

8               MEMBER BURKE: I'm Jim Burke. I'm a  
9       stroke neurologist at the University of Michigan  
10      and Ann Arbor no financial disclosures.

11              MEMBER KAPLITT: I'm Mike Kaplitt, a  
12      neurosurgeon at Wild Cornell Medical College in  
13      New York and I have no disclosures.

14              MEMBER HACKNEY: I'm David Hackney, a  
15      neuro radiologist at Beth Israel Deaconess  
16      Medical Center and I have no disclosures.

17              MEMBER ZAFONTE: I'm Ross Zafonte.  
18      I'm at Spalding and Mass General and my  
19      disclosures are I believe I was nominated by the  
20      American Academy of Physical Medicine and  
21      Rehabilitation and in the past I was co-PI of an  
22      R24 that looked at training young people related

1 to understanding outcomes, none of which are  
2 being evaluated today.

3 MEMBER EDWARDS: I'm Dorothy Edwards.  
4 I'm a psychologist, professor and chair of the  
5 Department of Kinesiology and I'm also a  
6 professor of medicine at the University of  
7 Wisconsin at Madison.

8 I am part of the NINDS-funded stroke  
9 net. I'm the outcomes person for actually the  
10 Georgetown group here in Washington, D.C. and I  
11 was nominated by the American Occupational  
12 Therapy Association.

13 MEMBER LINES: Hi, I'm Lisa Lines. I  
14 am at RTI International. I'm a health services  
15 researcher there. I'm also on faculty at  
16 University of Massachusetts Medical School and I  
17 have nothing to disclose.

18 MEMBER RYAN: Hello, I'm Melody Ryan.  
19 I'm on the faculty at the University of Kentucky  
20 College of Pharmacy and I also have nothing to  
21 disclose.

22 MEMBER BULSARA: I am Ketan Bulsara.



1 I'm a neuro surgeon out of the Yale New Haven  
2 system and nothing to disclose.

3 MEMBER KOENIG: Ron Koenig. I'm a  
4 neurologist in my former life. Now I'm the  
5 medical director at Anthem Blue Cross Blue Shield  
6 of Georgia -- from David and I'm actually a  
7 representative for the insurance industry working  
8 with the American Academy of Neurology to set up  
9 quality measures but have not done so and as such  
10 have nothing to disclose.

11 MEMBER BAUTISTA: I'm Jocelyn  
12 Bautista. I'm an epilepsy neurologist at the  
13 Cleveland Clinic. I've participated with the  
14 American Academy of Neurology and the American  
15 Epilepsy Society to craft clinical guidelines but  
16 nothing that pertains to the measures we're  
17 discussing.

18 MEMBER RAE-GRANT: I'm Alex Rae-Grant.  
19 I'm yet another neurologist from the Cleveland  
20 Clinic. I was recommended by the American  
21 Academy of Neurology.

22 I co-chaired a quality measures

1 committee in multiple sclerosis and none of those  
2 measures are being reviewed. I have no other  
3 conflicts.

4 MS. HAMMERSMITH: Is Kelly Sullivan on  
5 the line?

6 MEMBER K. SULLIVAN: Hi, I am. I'm  
7 Kelly Sullivan. I'm an epidemiologist at Georgia  
8 Southern University in the College of Public  
9 Health with trained specialization in neuro  
10 epidemiology and my only potential disclosure is  
11 that I'm on the American Academy of Neurology  
12 guideline development and dissemination committee  
13 and then also was a member of the dementia  
14 quality measure development group with the  
15 American Academy of Neurology.

16 MS. HAMMERSMITH: Okay. Thank you.  
17 Do any of you have any questions of me or  
18 anything you'd like to discuss with each other  
19 based on the disclosures this morning?

20 Okay. One - well, actually two more  
21 reminders before I leave. One is I just want to  
22 reinforce that you do sit as individuals because

1       you are experts.

2               So you are here to give us your  
3       opinion but you don't represent anybody else.  
4       Also want to ask you to keep in mind that the  
5       conflict of interest process can only work if  
6       everyone participates in it and is vigilant.

7               So if you're in the meeting and you  
8       think that you have a conflict or you're not sure  
9       - you think you might - or if you think a fellow  
10      committee member has a conflict or if you think  
11      someone is behaving in a very biased way we ask  
12      you to speak up during the meeting. We don't  
13      want you to sit there and then much later say  
14      well, I think I may have had a conflict. We want  
15      you to tell us now.

16              So you're always welcome to speak up  
17      openly in the meeting. If you'd rather not do  
18      that you can approach your co-chairs who will  
19      talk to NQF staff or you can go directly to NQF  
20      staff.

21              Any questions about that? Okay.

22      Thank you.

1 MS. ISIJOLA: Okay. With that being  
2 said and I believe we have one committee member  
3 who isn't here yet but once they do come we'll  
4 make sure that they disclose any potential  
5 conflicts. Thank you, Ann.

6 So before we get started - there we go  
7 - so before we get started we wanted to provide  
8 an orientation or more so an introduction of the  
9 neurology project.

10 A lot of this information we've gone  
11 over during our orientation. But before we dive  
12 into the measures we wanted to just provide an  
13 overview of our current portfolio.

14 So to date we have about 12 endorsed  
15 measures that have been reviewed in previous  
16 phases. Most of them are stroke measures and  
17 this is just a listing of those measures.

18 And when we say maintenance measures,  
19 measures that have been endorsed at some point in  
20 time.

21 Your role as committee members today  
22 is to determine whether or not these measures

1 still adhere to our evaluation criteria - whether  
2 or not they're still scientifically sound and if  
3 in fact you feel that these measures would  
4 provide a robust addition to our current  
5 portfolio.

6 So with the inclusion of those 12  
7 measures during our call for measures, which is  
8 at a point in time where we solicit new measures  
9 to be included within the project, we receive 14  
10 new measures.

11 This is kind of different just because  
12 we received many eMeasures and we'll be talking  
13 about legacy measures in later slides. But we  
14 wanted to showcase these to you because they are  
15 similar in nature to the previous measures.

16 Additionally, we have received some  
17 outcome measures as well as some hybrid measures.

18 So as your role as committee members  
19 we ask you to take ownership of the portfolio -  
20 many of the measures you're looking at today - to  
21 determine whether or not they add any value,  
22 whether or not they are repetitive or competing

1 with previous measures that are included in our  
2 portfolio.

3 But during the next two days you'll be  
4 able to determine whether or not they suffice.

5 So previously in previous projects  
6 we've still continued to see gap areas where  
7 you're looking at the treatment and assessment of  
8 different diagnoses of areas such as Parkinson's  
9 disease, multiple sclerosis, Huntington disease  
10 and the likes.

11 So as you look at these measures it's  
12 also an opportunity for you to signal to  
13 developers that we need measures that really  
14 address some of these subtopic areas.

15 So with that being said, that was a  
16 brief overview. I'll turn it over to Peg to give  
17 us more of a highlight introduction of how we  
18 will be evaluating measures over the next two  
19 days. Peg?

20 DR. TERRY: Thank you, Wunmi.

21 What I wanted to do here is really go  
22 over what's new to the process for those who have

1       been on this before - this committee before.

2               And so this year for the first time we  
3       did something called preliminary analysis and  
4       many of you have seen that. Our developers have  
5       seen that. The staff has really taken time to  
6       review it.

7               We've had two of our senior directors  
8       review all of the measures so you know. I just  
9       want to say this is really just a guidance. It  
10      is just our review. It is just that.

11              So I think it's important to  
12      understand that. The other thing that's new this  
13      year is that we have committee pre-evaluation  
14      comments and if you've been looking at the  
15      measures recently and throughout the time you can  
16      see the many comments that people have put into  
17      that part of the measure as we have it.

18              The other thing that's new is we also  
19      have pre-meeting public and member comments and  
20      that is also there for people to see.

21              And so this is to create a more  
22      transparent ability to really look at these

1 measures prior to what we're going to talk about  
2 today.

3 And the last thing is we have evidence  
4 and testing attachments which, again, for those  
5 who have been looking at the measure you have  
6 seen that.

7 So next I just want to go through  
8 something we've done before but we've done this  
9 on our Q and A calls - our quality - so and this  
10 is to just give you a sense of how NQF is looking  
11 at measures today.

12 So for new measures, and this speaks  
13 to evidence, we look at the quantity, quality and  
14 consistency and, as many of you know, we have a  
15 booklet that we at NQF use and that provides  
16 guidance on what is quantity, quality and  
17 consistency. So all staff can go through that as  
18 well as the committee.

19 We have - this really helps establish  
20 a link for process measures with outcomes and so  
21 you'll see that. This is for new measures.

22 Evidence is a must pass. This year we



1 have a little bit for maintenance measures and we  
2 will - we will be talking about a number of  
3 maintenance measures today.

4 Today there is a decreased emphasis on  
5 maintenance measures or at least on the evidence  
6 part of maintenance measure and requires that the  
7 measure developer to attest that the evidence is  
8 unchanged.

9 If the evidence is unchanged from the  
10 last evaluation, the standing committee - this  
11 evidence will be, you know, we don't need to  
12 spend a lot of time on this particular area.

13 If change is in evidence then the  
14 committee will evaluate as a new measure under  
15 evidence.

16 The second part of the importance to  
17 measure in report is gap analysis and this is  
18 really - speaks to the opportunity for  
19 improvement, variation, quality of care across  
20 providers and as well as disparities.

21 There is an increased emphasis on this  
22 and I want to mention also that gap or

1 opportunity for improvement is also a must pass.

2 Next. Okay. So under the scientific  
3 acceptability we have both reliability and  
4 validity for new measures. The measure  
5 specifications are precise with all information  
6 needed to implement the measure.

7 Under the maintenance if there's no  
8 difference required we do require an updated  
9 specification. For reliability and validity  
10 including risk adjustment, in particular  
11 reliability and validity, there is decreased  
12 emphasis.

13 So if prior testing was adequate there  
14 is really no need for additional testing at  
15 maintenance with certain exceptions including  
16 change in data source, level of analysis or  
17 setting. Must address the questions for the -  
18 what we call the SDS trial - sociodemographic  
19 trials period that we have going on right now.

20 Next. And so for feasibility - and by  
21 the way, evidence is a must pass. I mean,  
22 evidence - I mean scientific acceptability is a

1 must pass.

2           Going on to feasibility and usability,  
3 under feasibility the measure - how feasible is  
4 it using this measure including eMeasures  
5 feasibility for - that is for new measures for  
6 maintenance measures there is no difference.  
7 Implementation issues must be more prominent.  
8 Under - and this is under usability and use under  
9 new measures use - used in accountability  
10 applications and public reporting, usability  
11 impact and unintended consequences.

12           There is an increased emphasis in the  
13 area of - under maintenance measures and it's  
14 under this new process for usability.

15           Next. So we wanted to talk a little  
16 bit about companion measures because you've seen  
17 a number of companion measures this time and  
18 companion measures are what we call legacy  
19 measures that also have an electronic version and  
20 many people have looked at this.

21           Companion measures here are some of  
22 the stroke measures with an e-Measure that we

1 call companion. We have different numbers for  
2 those eMeasures but they are basically the same  
3 measure except that they are eMeasures.

4 And then I wanted to spend a few  
5 minutes talking about endorsement with reserve  
6 status and this is really important today because  
7 actually - so this speaks to whether a measure  
8 has failed in the areas of gap and remember, gap  
9 is a must pass area.

10 So if the measure has failed but has  
11 passed all the other criteria, we have the option  
12 of moving that measure to what we call inactive  
13 endorsement with reserve status.

14 This status applies only to highly  
15 credible, reliable and valid measures that have  
16 high level of performance and many of you have  
17 seen this high level performance, especially  
18 under some of the stroke measures.

19 Inactive endorsement with reserve  
20 status retains these measures in the NQF  
21 portfolio while also communicating to potential  
22 users that the measures no longer address high

1 leverage areas for accountability purposes.

2 I just want to mention this - that if  
3 the legacy measure fails on importance to  
4 measuring gap then the companion measure will not  
5 pass.

6 I think that's very important to  
7 understand as we move forward today.

8 Next. Let me just ask you, are there  
9 any questions on what I just said?

10 CO-CHAIR KNOWLTON: Yeah, I want you  
11 to repeat that last point because that's very  
12 significant. That's very important that we  
13 understand - we are going to be dealing with that  
14 today. So you may want to go through that again.

15 DR. TERRY: So let me just say it  
16 again. If the legacy measures pass - these are  
17 not the eMeasures. These are the paper measures  
18 per se. they are the existing measures. They've  
19 been endorsed before.

20 If their gap has what we call topped  
21 out possibly then the companion measure will  
22 automatically not pass. So those are the

1 eMeasures.

2 CO-CHAIR TIRSCHWELL: Can I just ask  
3 that - so there's no specific quantitative  
4 criteria for topping out? Is that sort of a  
5 gestalt that the committee decides on and how  
6 does that happen?

7 DR. TERRY: I think that at this point  
8 in time, and maybe Karen can weigh in here, we  
9 have - you know, we have looked at the number of  
10 years.

11 There's no number, if that's what  
12 you're asking - we've looked at the number of  
13 years that it is at what we consider topped out  
14 in the high 90s and basically it is - it is up to  
15 the committee to decide and, of course, if there  
16 are disparities that are mentioned that is  
17 another issue that can be taken into account.

18 Karen, anything else?

19 MS. JOHNSON: I think the only thing  
20 else that I would add is when you're looking at  
21 performance data and you see something that you  
22 think might be getting towards that topped out

1 level, be sure to look and see where the data are  
2 coming from.

3 So is that data representing most of  
4 the providers and patients that are included in  
5 the measure or is it only a small subset.  
6 Because if it's a - if it's a subset there may be  
7 something else going out there that that  
8 performance rate isn't showing it.

9 CO-CHAIR KNOWLTON: So if the  
10 committee was interesting in keeping measure or  
11 felt that the, let's say the electronic companion  
12 measure was of interest, even though they were  
13 really - felt the other one was meeting gap  
14 that's how reserve status would come into play.  
15 Am I correct? I'm incorrect?

16 DR. TERRY: No. You can't keep the -  
17 the reserve status - if the paper measure does  
18 not pass that goes into reserve status. The e-  
19 Measure is not even discussed. It cannot - yeah.

20 CO-CHAIR KNOWLTON: Does anybody have  
21 any questions on that? I'm only going on and on  
22 about it because I know we're going to be

1 discussing it and I'd rather make sure we've got  
2 a good solid picture before we move on.

3 Everybody okay?

4 MS. JOHNSON: And let me add just one  
5 more thing. Reserve status is created for  
6 previously endorsed measures.

7 So that's why we're saying if  
8 something fails on gap and does actually go into  
9 reserve status that's fine because it's a  
10 previously endorsed measure.

11 Anything new - that companion measure  
12 that's a new measure is not eligible for reserve  
13 status because it is a new measure.

14 DR. TERRY: Okay. Do you want to go  
15 ahead, Christy?

16 MS. SKIPPER: So good morning again.  
17 Before I get started, I want to welcome Dr.  
18 Ferziger to the table. So if you could please  
19 introduce yourself and share any disclosures of  
20 interest.

21 MEMBER FERZIGER: Sure. Thank you and  
22 I'm sorry to be late. It's the difficulty of



1 actually not commuting and living where my kids  
2 couldn't get to school this morning.

3 But I am a psychiatrist. I am a  
4 medical director at Merck Pharmaceutical Company  
5 in the CMS area and I have no specific  
6 disclosures. Obviously, we work on several of  
7 the areas in discussion.

8 MS. SKIPPER: Thank you. So I'm going  
9 to go over the role of the standing committee.  
10 So the role of the standing committee is to act  
11 as a proxy for the NQF membership and as such we  
12 expect and we know that you all have a multitude  
13 of experiences, values and opinions and so we're  
14 looking forward to that discussion today and that  
15 collegial interaction amongst one another and  
16 even between measure developers.

17 Standing committee members or standing  
18 committees serve two to three year terms and we  
19 will be determining that for you all on tomorrow.

20 And then also we expect that you all  
21 will work with us to achieve the goals of the  
22 neurology project by reviewing all the measures

1 that have been assigned to the portfolio and also  
2 evaluating each measure against our criteria and  
3 then indicating the extent to which those  
4 measures meet the criteria and make  
5 recommendations to NQF for endorsement.

6 And we also ask that you respond to  
7 any comments submitted during the review period  
8 and respond to any direction from CSAC. And then  
9 just in general, as we've said this morning, we  
10 expect that you all take ownership of the  
11 neurology portfolio.

12 And just a couple of ground rules for  
13 today's meeting. Probably the most important one  
14 is that we all speak into the microphone.

15 The proceedings are being recorded and  
16 we're also competing with construction right  
17 outside the window. So you may be leaning over  
18 to talk, as I am doing. But it's really  
19 important that we hear the discussion as we move  
20 on through the day.

21 And I won't read every single ground  
22 rule on the slide but if anyone goes off task I'm

1       sure we'll all bring it back to center.

2               So our process for the measure  
3       discussion today - so we do have measure  
4       developers in the room today and as their measure  
5       comes up for discussion we will be inviting them  
6       to the table.

7               There are two seats seated to my left  
8       and so they will start out by introducing the  
9       measure for two to three minutes and then the  
10      committee - or then the discussion will turn to  
11      the lead discussants for the measures.

12              And so we'll turn it to you all to  
13      begin the discussion of the measure. Inside your  
14      packet you should have a measure discussion  
15      script to help you all along in discussing the  
16      measure in the order presented there.

17              If you don't have a measure discussion  
18      script please let us know. And so the lead  
19      discussants provide a summary of any pre-meeting  
20      evaluation comments and emphasize any areas of  
21      concern or differences of opinion.

22              The developers will still be at the

1 table to answer any questions that you all may  
2 have and also if there's any misinformation that  
3 has been shared about the measure they will be  
4 able to step in and clear that up for the  
5 committee.

6 And we ask that everyone if you would  
7 like to be acknowledged to turn your place card  
8 perpendicular to the desk and we will acknowledge  
9 you.

10 And then we'll move on to voting on  
11 the measure. So voting on endorsement criteria -  
12 we'll start out with importance to measure and  
13 report and at this time - at that time we'll be  
14 taking two separate votes on the evidence and  
15 then one on gaps. Then we'll move to scientific  
16 acceptability of measure properties - again,  
17 that's two votes. One on reliability and one on  
18 validity. Those first two criteria are must  
19 pass. If the measure does not pass we will stop  
20 discussion of that measure and move to the next  
21 measure on the agenda for the morning. So,  
22 basically, if the measure fails - either of those

1 - we'll stop and move on.

2 Next, we'll move on to feasibility,  
3 take a vote on feasibility and one vote on  
4 usability and use and Alexandra will give us a  
5 more detailed overview when it does come time to  
6 vote.

7 And everyone should have a remote  
8 clicker. If you don't have one please let us  
9 know.

10 And then finally, achieving consensus,  
11 NQF guidelines state that in order for a measure  
12 to pass greater than 60 percent of members must  
13 move vote yes and a yes vote is calculated with  
14 the sum of high and moderate votes.

15 A measure does not pass or is not  
16 recommended if fewer - if there are fewer than 40  
17 percent yes votes and anything in between that 40  
18 to 60 percent. If that does happen we will  
19 address it at that time.

20 And that is all I have for now. Are  
21 there any questions about what I just shared?  
22 No? Okay. I will turn it over to Dr. Tirschwell

1 for our review of the first measure.

2 CO-CHAIR TIRSCHWELL: According to my  
3 agenda, we're a full hour ahead of schedule at  
4 this point. So try not to ruin that too badly as  
5 the day goes on.

6 So I have a little script here. I  
7 guess so the first measure that we're going to be  
8 reviewing as should be available on your agenda  
9 and I guess we'll be following along on the  
10 screen - you guys will be bringing out the  
11 documents for each measure - is 0661, head CT or  
12 MRI scan results for acute ischemic stroke or  
13 hemorrhagic stroke patients who receive head CT  
14 or MRI scan interpretation should be within 45  
15 minutes of ED arrival and the developers are CMS,  
16 Mathematica and the Lewin Group.

17 Is there someone here to introduce the  
18 measure or is it by phone?

19 MS. ISIJOLA: Operator, could you open  
20 up the line to see if we have any developers?

21 CO-CHAIR TIRSCHWELL: Yeah, go ahead.  
22 Turn your mic on though please, Steve. Not so

1 functional.

2 MEMBER HUFF: So this committee stands  
3 for a number of years. If a measure is not  
4 approved can it come back in some months for  
5 reconsideration or what is that process?

6 MS. ISIJOLA: So I can jump in and  
7 answer that. So if in fact there is additional  
8 information that you would like the developer to  
9 bring back we can work with the developer to  
10 bring that information back and during one of our  
11 post calls following this meeting we can address  
12 any concerns you have.

13 CO-CHAIR TIRSCHWELL: And potentially  
14 revote and -

15 MS. ISIJOLA: Correct.

16 CO-CHAIR TIRSCHWELL: Thank you. Any  
17 other process questions as we get started?

18 And was there a developer available  
19 for the 0661 measure that wanted to introduce it?

20 Okay. Just wait a sec.

21 MS. ISIJOLA: Operator, could you see  
22 if there are any developers from CMS or

1 Mathematica?

2 OPERATOR: We have no one from CMS and  
3 Mathematica yet.

4 MS. ISIJOLA: Okay. And I think that  
5 maybe due to the time -

6 CO-CHAIR TIRSCHWELL: Yeah, so is that  
7 fair? Should we proceed? Should we wait?

8 MS. ISIJOLA: Is anyone from the Lewin  
9 Group on the phone as well? Operator, could you  
10 check?

11 OPERATOR: No, ma'am. We don't.

12 MS. ISIJOLA: So what I would say is  
13 we could probably have the discussion and if  
14 there are information or additional information  
15 that we would like to develop or to provide we'll  
16 give them that opportunity.

17 DR. TERRY: We could possibly go to  
18 another measure and see if they get on, I mean,  
19 to the next measure - to 434. That's a  
20 possibility.

21 Would you - yeah. I'm not sure who --

22 MS. ISIJOLA: Okay. So what we'll do



1 is are there developers from the joint  
2 commission?

3 (Off mic comments.)

4 MS. JOHNSON: Can one of you guys  
5 email the other developers to see if they're  
6 waiting for the 10/15?

7 MS. ISIJOLA: Okay. So with that  
8 being said, I think we're going to do to the  
9 first joint commission measure, Measure 434.

10 And as Ann Watts mentioned, in the  
11 back if there are questions from - for the  
12 developer we ask that you hold those and give  
13 them an opportunity to address that at that time.

14 MS. JOHNSON: It might be better just  
15 to wait just a second and see if you can get a  
16 hold of the other developers via email, just in  
17 case they are planning to come on at 10:15.

18 We're running very early. So maybe we  
19 can just pause for a few minutes, go get some  
20 more coffee. We'll see if we can get in touch  
21 with them just in a couple minutes.

22 (Whereupon, the above-entitled matter

1       went off the record at 9:20 a.m. and resumed at  
2       9:32 a.m.)

3                   CO-CHAIR TIRSCHWELL: All right. Now  
4       we're really going to start. So as already  
5       mentioned, the first measure is 0661 and now we  
6       do have some developers in the room.

7                   So you guys are - you have just a few  
8       minutes to introduce the measure, appreciate - go  
9       ahead.

10                  MS. MCKIERNAN: Absolutely. So thank  
11       you for the opportunity to speak today about NQF  
12       Number 0661, which is head CT or MRI scan results  
13       for acute ischemic - is that better? Should I  
14       start over?

15                  So thank you for the opportunity to  
16       speak today about NQF Number 0661 which is head  
17       CT or MRI scan results for acute ischemic stroke  
18       or hemorrhagic stroke patients who received head  
19       CT or MRI scan interpretation within 45 minutes  
20       of ED arrival.

21                  My name is Colleen McKiernan. I'm a  
22       consultant from the wound group and am joined by

1 my colleague, Naila Wahid, also from them.

2 On behalf of CMS Mathematica Policy  
3 Research and its partner, the Lewin Group, work  
4 to maintain NQF Number 0661, a measure originally  
5 implemented in the hospital outpatient quality  
6 reporting program in 2013 and last reviewed by  
7 NQF in 2010.

8 As you all know, performing prompt  
9 brain imaging for patients suspected of acute  
10 stroke is a critical component of emergency care  
11 for accurate diagnosis and treatment.

12 Use of a head CT or MRI allows  
13 clinicians to differentiate ischemic stroke,  
14 hemorrhagic stroke, and mini-strokes. These  
15 scans can also help identify candidates for  
16 tissue plasminogen activator - or TPA - which is  
17 used to treat ischemic stroke patients and is  
18 actually contraindicated for treatment for  
19 hemorrhagic stroke.

20 The FDA has approved TPA for use  
21 within three hours of symptom onset. Thus,  
22 timely imaging following patient arrival in the

1 ED is essential for rapid identification and  
2 treatment of patients have an ischemic stroke.

3 The denominator for NQF number 0661  
4 captures ischemic - acute ischemic or hemorrhagic  
5 stroke patients who arrived in the ED within two  
6 hours following symptom onset.

7 The numerator includes patients from  
8 the denominator whose CT or MRI study was  
9 interpreted within 45 minutes.

10 Those under - those under 18, those  
11 who expired in the ED, those who left against  
12 medical advice or who elected discontinuation of  
13 treatment are excluded from the measure.

14 On behalf of CMS Mathematica and Lewin  
15 preformed a series of quantitative and  
16 qualitative efforts to assess the measure's  
17 evidence-based distribution of performance,  
18 scientific acceptability, feasibility and  
19 usability.

20 We look forward to the discussion this  
21 morning and are here to answer any questions you  
22 may have. Thanks very much.

1 CO-CHAIR TIRSCHWELL: Thank you. That  
2 was perfect. So at this point, we would turn  
3 over the floor to the discussants on the  
4 committee, Bradford and/or Stephen.

5 MEMBER DICKERSON: Good morning.  
6 Stephen and I - Dr. Huff and I have discussed  
7 this ourselves and I'll start the discussion and  
8 Dr. Huff will chime in along the way.

9 So we've heard a summary of the  
10 measure. The - this is a maintenance measure  
11 that was originally endorsed in 2011 and it's a  
12 process measure.

13 There has been new evidence presented  
14 which includes guidelines that subsume several  
15 classes of evidence.

16 So guideline one was three  
17 recommendations for patients with acute cerebral  
18 ischemic symptoms that have not yet resolved and  
19 these guidelines were based on the idea that  
20 urgent imaging is recommended to try to treat  
21 acute ischemic stroke which has a level of  
22 evidence of class 1A and then noncontrast head CT

1 or MRIs recommended to essentially rule out  
2 hemorrhagic stroke and rule in ischemic stroke,  
3 also based on strong evidence. The somewhat  
4 weaker evidence, I think, here in this guideline  
5 is related to the timing. So is 45 minutes a  
6 magic number and this is something we'll discuss  
7 further. But that has class one level of  
8 evidence C.

9 And then the other guideline, the  
10 second point of evidence that was presented is a  
11 focused update of current recommendations, again,  
12 for treatment of acute stroke and pretty similar.

13 I think that the overall consensus on  
14 the evidence is that there's broad consensus  
15 among experts that this is an important goal to  
16 be trying to attain.

17 But I think there is not great  
18 empirical research that supports the value of the  
19 particular timing, again 45 minutes.

20 So the idea is that the images should  
21 be obtained and interpreted within 45 minutes of  
22 the time the patient arrives at the emergency

1 room and I think, you know, there are questions  
2 about where that magic number came from.

3 But then overall, following the  
4 algorithm, the evidence, I think, I moderate.  
5 There's overall a high rating for opportunity for  
6 improvement. So the idea that we could - and we  
7 could talk about where this comes from as well -  
8 but the idea that we can improve on our measure I  
9 think is a strong opportunity and we can talk  
10 more about how we could potentially improve on  
11 the measure.

12 But there's no question, I think, that  
13 this - that there's a gap of care and there are  
14 opportunities for improvement that we can dig  
15 into in a little bit more detail.

16 So forgive me, I just - this is the  
17 first time I've done this and I want to make sure  
18 before getting into too much detail that I'm  
19 following the process, as you guys want it to be  
20 carried out.

21 CO-CHAIR TIRSCHWELL: I think so. So  
22 for - so we sort of have to vote in between

1 sections. So I guess the idea would sort of be  
2 to give your full presentation of information for  
3 each of the four sections. Then we'll pause to  
4 discuss and then vote, and then we'll move to the  
5 next section.

6 MEMBER DICKERSON: So I think that the  
7 first section is the preliminary ratings for  
8 opportunity improvement, which the pre-evaluation  
9 rated as high and I think - I think I would agree  
10 that that is the case. You want to say anything  
11 else about -

12 CO-CHAIR TIRSCHWELL: Steve, any other

13 -

14 MEMBER HUFF: I don't want to get too  
15 picayune here and so what, again, the overall -  
16 we're looking at reliability here at the -

17 MS. ISIJOLA: Right now we're just  
18 focusing in on the evidence. Once we have a  
19 discussion of the evidence then we will move into  
20 voting.

21 MEMBER HUFF: So I think the summary  
22 of the evidence is really that there is an



1 opportunity for improvement and that there is  
2 evidence from CMS that there are disparities and  
3 that there are opportunities for improvement in  
4 treating acute ischemic stroke and the need to  
5 better measure the obtaining of head CT or MRI in  
6 acute ischemic stroke patients seen in the  
7 emergency room.

8 CO-CHAIR TIRSCHWELL: So just to  
9 clarify a little bit, and I apologize - I wasn't  
10 quite specific enough - I guess we're not just  
11 voting in between the four sections, we're voting  
12 in between subsections?

13 MS. ISIJOLA: Yes.

14 CO-CHAIR TIRSCHWELL: So first  
15 evidence, then we vote. Then opportunities for  
16 improvement, then we vote. So any other comments  
17 or discussion about evidence?

18 MEMBER DICKERSON: Right. So I  
19 summarized the evidence which were those two  
20 guidelines and I guess we'll pause at that point.

21 MEMBER HUFF: And thank you for doing  
22 the heavy lifting on this. The - we all agree

1 the intent of this - the intent of this measure  
2 is good.

3 The question is is where does 45  
4 minutes come from. This is level C evidence.  
5 People sitting around a table much like this. We  
6 don't have any evidence that 44 minutes is good  
7 and 46 minutes is bad. We're trying to draw a  
8 line in the sands of time.

9 So there's that. The other issue is  
10 it's very surprisingly difficult - I say more  
11 difficult in the area of electronic records to  
12 determine when a patient arrives in the emergency  
13 department.

14 If you know the patient is coming in  
15 in advance, frequently an electronic record is  
16 generated and time will pass since - time will  
17 pass from when the record is generated to when  
18 the patient actually arrives.

19 Likewise, if providers - doctors,  
20 nurses, other people - are with the patient at  
21 the bedside they're not doing order entry into  
22 that electronic record.

1           If the patient runs - patient walks  
2   into the emergency room - if they come in  
3   unannounced there will not be an electronic  
4   record in existence.

5           It takes a few minutes to get that up  
6   and running. Providers are with the patient at  
7   that time. They've arrived and yet there will be  
8   no record of that, and we're left with what we  
9   have.

10          A more reliable marker might be and I  
11   believe this has been in other quality measures  
12   has been the time from first quarter of their own  
13   imaging to interpretation.

14          That would be a much more granular and  
15   a much more reliable measure.

16          CO-CHAIR TIRSCHWELL: Thanks. Peter?

17          MEMBER SCHMIDT: So I thought that the  
18   45 minutes came from the fact that they said two  
19   - that you're expecting the patient to be in the  
20   clinic within two hours and then you've got - FDA  
21   label says three hours. So I assume that they  
22   had kind of done a gross approximation which, of

1 course, has some challenges because we don't  
2 know.

3 It's too - you know, the patient is  
4 not showing up in two hours, they're showing up  
5 in some time and we're hoping it's within two  
6 hours and then they said let's give them 15  
7 minutes to administer the drug. That was where I  
8 thought that came from, not that that is a  
9 justification of it.

10 MEMBER DICKERSON: Yeah, and I think  
11 our point is that so far there's no real  
12 empirical evidence to indicate that that's been  
13 studied.

14 But if the FDA says three hours I  
15 assume that they've looked at data that says  
16 three hours. So whether or not the 45 minutes is  
17 based on that two-hour assumption I assume and,  
18 you know, I don't know how long it takes to  
19 administer TPA but -

20 MEMBER HUFF: That brings up another  
21 discussion, even though TPA is approved for  
22 administration within three hours of symptom

1 onset I would wager that every stroke neurologist  
2 here has given it outside that FDA approval -  
3 approved time based on other data, the commonly  
4 acceptable is four and a half hours. That's not  
5 really the main issue with this measure. So  
6 that's another point.

7 But if we're trying to be so granular  
8 on this and I don't know that there is really  
9 evidence to support that degree of granularity  
10 the overall intent is very good. So that's one  
11 for this discussion - I think that's probably  
12 enough.

13 CO-CHAIR TIRSCHWELL: Yes, David.

14 MEMBER HACKNEY: On that same issue,  
15 I think the - this may be because they're trying  
16 to make it fit a design that is percent of cases  
17 that meet criterion X whereas probably what you  
18 want is what's the mean time or the distribution  
19 of time from arriving at the ED given the  
20 vagueness of what that means until you have an  
21 interpreted study and then not necessarily have -  
22 picking an arbitrary number for cutoff.

1                   But that would require a different  
2                   design of how you do the measure and all the  
3                   measures are designed - presented as percent - a  
4                   numerator, denominator and a percent that meets  
5                   some criterion. But I agree it would make more  
6                   sense to say how fast is it?

7                   As for making it from the time you  
8                   order until the time you have an interpreted  
9                   study, that kind of, I think, would defeat the  
10                  goal of the measure which is that whole sequence  
11                  of events that ends when you have an answer to  
12                  what the imaging study shows.

13                  You now let everybody off the hook if  
14                  they simply aren't prompt enough about getting -  
15                  ordering the study in the first place.

16                  So while it would make it simpler and  
17                  it would be less ambiguous what the start point  
18                  was, it probably wouldn't get you to what you  
19                  actually want, which is fast as possible  
20                  turnaround.

21                  MEMBER HUFF: I think there's other  
22                  metrics that address these other issues. So we

1 all agree there's a sequence of events that takes  
2 place and this measure would seem to overreach  
3 several different steps in that sequence, and I  
4 think by overreaching our steps in the sequence  
5 there's going to be some inaccuracy interpreting  
6 that.

7 The other issue that we'll, I think,  
8 probably address later on during the discussion  
9 is, when is a stroke defined?

10 So, clinically, somebody comes in, new  
11 onset, hemiparesis, aphasia - that's a pretty  
12 clear onset. Somebody comes in with some  
13 dizziness might not be so clear if they've had a  
14 stroke or not - take some time to get that  
15 information.

16 Going further, the question becomes  
17 what biomarker are we using to define stroke. If  
18 stroke is defined by a MRI showing ischemic  
19 changes, perhaps clinically there may be few or  
20 little clinical signs to go with that.

21 And so it's a question of, you know,  
22 the interpretation or the measure here says

1 patients with acute ischemic stroke can almost  
2 become a circular reason if that - ischemic  
3 stroke is defined by MRI findings and not  
4 clinical findings you're going to have much more  
5 - a higher failure rate than if it's defined on a  
6 clinical basis and that's - I can tell you from  
7 the metrics at my institution that happens this  
8 patient. You know, what's our definition of who  
9 had a stroke. Well, they had a stroke because  
10 their MRI was positive. Clinically, it was a  
11 very ambiguous setting and yet that drops out the  
12 metric. So that's another whole discussion.

13 CO-CHAIR TIRSCHWELL: Yeah. It turns  
14 out from a practical perspective it's all based  
15 on what their ICD-9 code is at the time of  
16 discharge, which I'm sure does not conform to  
17 your much more clinically relevant issue of MRI  
18 or what not.

19 Ketan, did you have a comment?

20 MEMBER BULSARA: You know, I think  
21 when this measure was originally endorsed in 2011  
22 I think it was fantastic - fantastic in the sense



1 that it actually put a time limit in terms of  
2 when the interpretations of studies should be  
3 done.

4 But I think this measure doesn't apply  
5 to practice to date and so I'll argue more along  
6 the lines of what Steve was saying in the sense  
7 that there is new evidence.

8 There's seven randomized trials that  
9 now show that mechanical thrombectomy in a very  
10 timely fashion results in improved outcomes.

11 There are consensus guidelines by many  
12 independent societies in which I've been a part  
13 of that say patients should be - should go to  
14 mechanical thrombectomy within an hour or in 15  
15 minutes from the time of arrival in the emergency  
16 room.

17 So I think what this measure does is  
18 I think it - with the 45 minute time frame I  
19 think it sends the wrong message and potentially  
20 a dangerous message in the sense that the  
21 interpretation of the scans need to be done  
22 immediately.

1           You have a patient that comes to the  
2           emergency room who's suffering from what we feel  
3           is an ischemic stroke. The CT scan needs to be  
4           done immediately, like, within a reasonable time  
5           frame and the interpretation needs to be done  
6           immediately.

7           It creates an issue on two fronts.  
8           The first - the first one it creates an issue on  
9           is from the perspective of the patient. If you  
10          have to wait 45 minutes to get an interpretation  
11          on a CT scan before you administer, let's say,  
12          IVTPA before you activate your mechanical  
13          thrombectomy team I think you're doing the  
14          patient a disservice because it's been shown over  
15          and over and over again that the longer time it  
16          takes for recannulization the worse the outcome.

17          I think it does a disservice to the  
18          physicians and the treatment team because if you  
19          - I mean, you're very qualified. You've been  
20          doing this for years. You look at a CT scan.  
21          There's no hemorrhage or anything to that extent,  
22          in your opinion.

1                   You go ahead and administer, let's  
2                   say, IV-tPA and at the 45 minute point -- you did  
3                   this at the 15 minute point. At the 45 minute  
4                   point, the official read comes back as there's a  
5                   small hemorrhage and the patient has a  
6                   catastrophic hemorrhage to follow -- that I think  
7                   it puts the physicians and the treatment team in  
8                   a bad position.

9                   So I think this measure is absolutely  
10                  needed. I think we need a timely interpretation  
11                  of these radiographic studies. I think the 45  
12                  minutes needs to be taken out and I think it  
13                  needs to be more realistic in terms of what's  
14                  actually done in practice.

15                 CO-CHAIR TIRSCHWELL: Thank you.  
16                 David?

17                 MEMBER HACKNEY: Just to clarify, this  
18                 is not from the time the scan is done until it's  
19                 interpreted. This is the time from the patient  
20                 showing up in the ED until the time the scan is  
21                 interpreted.

22                 So as a radiologist, we often deal

1 with it was 44 minutes and 30 seconds between the  
2 time the person showed up at the ED and the time  
3 they got their CT scan. And so we've got 30  
4 seconds to read it.

5 It's not a time limit. It includes  
6 time limits of interpretation but that's not all  
7 that's in there, and I think as was previously  
8 pointed out, depending on what seems to be going  
9 on when the patient shows up, sometimes it's  
10 obvious first thing they say this is probably a  
11 stroke and at our place, they literally roll the  
12 person over to the CT scanner and say this guy's  
13 next.

14 But other times, the evaluation might  
15 take a while and that -- while deciding what to  
16 do next, before you even order a scan, is  
17 included in this measure.

18 So it is attempting to say everything  
19 that leads up to this piece of information you  
20 need before you institute therapy counts, whether  
21 it's figuring out whether they had a gunshot  
22 wound or fell down a stairs or had a stroke,

1       that's part of that time because if it's a  
2       stroke, then you need to get it quickly.

3               But it doesn't tell you what -- which  
4       elements of it are delayed. It says to the  
5       hospital. If you have delays then figure out  
6       where they are and try to address them.

7               And I don't know what you do about the  
8       fact that there are patients where the  
9       presentation is ambiguous.

10              MEMBER DICKERSON: Excuse me. I think  
11       that was part of what Steve and I were wanting us  
12       to consider is that if we -- if there's a way to  
13       improve this measure, we should make a  
14       recommendation about it and one way that we  
15       thought of was to identify when the order was  
16       submitted because if it's obvious that the person  
17       is having a stroke, then the treating team is  
18       going to make that order right away.

19              If it's ambiguous, there's going to be  
20       some time for additional work up and that would  
21       at least provide some additional information  
22       about what the prior probability clinically was

1 in the treating physician's minds about acute  
2 ischemic stroke.

3 CO-CHAIR TIRSCHWELL: David, did you  
4 have a comment?

5 MEMBER ANDREWS: I appreciate the  
6 importance of these issues that the neurologists  
7 are talking about. But, as a patient, I would  
8 like to have all the right steps done before the  
9 treatment started and I'd also like them to be  
10 done as rapidly as possible.

11 So having the evaluation that  
12 determines am I having hemorrhagic or an ischemic  
13 stroke to determine whether or not you're going  
14 to give me TPA, that's an important thing.

15 If somebody's going to be rushing to  
16 try and get it done in a time limit that's  
17 unrealistic and then putting me at risk by giving  
18 me TPA if I have a hemorrhagic stroke, then  
19 that's a concern.

20 So, you know, my question -- and I  
21 guess this is more a question than an observation  
22 -- is how much are those people who are actually

1 delivering the care thinking about oh my god,  
2 it's almost 45 minutes -- I have to get it done -  
3 - as opposed to thinking about I want to get the  
4 best possible care and I don't care if it takes  
5 too long?

6 CO-CHAIR TIRSCHWELL: From a practical  
7 perspective, I promise you that probably nobody  
8 in the emergency room is -- has got their eye on  
9 that 45 minute clock there.

10 Mostly just trying -- yes, hang on one  
11 second, Steve -- to do what's best for you, the  
12 patient, every time as quickly and as  
13 appropriately as possible.

14 Ron, Ketan and then Steve again.

15 MEMBER KOENIG: I don't think you can  
16 use when seen by the ER doctor as the criteria.  
17 I think it's something that the ER -- because my  
18 concern is that if you don't have an adequate  
19 protocol in place the persons put in the  
20 examining room and half an hour later or 45  
21 minutes later, the doctor shows up and now the  
22 clock is running.

1                   No, that's not the answer. The clock  
2 starts when the person hits the ER, unless you  
3 have a team that is going to start doing  
4 evaluations, CT, et cetera, in an ambulance with  
5 a mobile service like they have in Germany.

6                   But I think as far as practical U.S.  
7 ways when they hit the ER is when the clock  
8 starts.

9                   MEMBER BULSARA: You know, David's  
10 point is well taken in the sense that there is a  
11 lot of issues that lead to potential delays and  
12 interpretation of the CT scan.

13                   The issue I have though is that by  
14 endorsing a measure that says within 45 minutes,  
15 I think what you've done here is you've created  
16 extra time -- you've created -- you've given  
17 interpretation of a CT scan 45 minutes.

18                   So if your emergency room operation is  
19 very, very quick in the sense that your patient  
20 gets to the CT scanner within five or ten minutes  
21 of arrival or has had a mobile -- I mean, now  
22 we're moving to mobile CT scans, right, I mean,



1 we had some of units floating around. As soon as  
2 they walk into the emergency room, potentially,  
3 they have a CT scan done.

4 I think what this measure does is --  
5 I think at least the way I interpret it, in light  
6 of today's evidence, is that it gives you 45  
7 minutes to interpret the CT scan that the patient  
8 had on the mobile scanner that was done, let's  
9 say, a block away, it gives you 45 minutes.

10 And I think -- I mean, we all strive  
11 to provide the best possible care in a rapid  
12 fashion and for cerebral ischemic -- for ischemic  
13 stroke we know that you have to be rapid. I  
14 mean, if you want a reasonable outcome you have  
15 to be rapid.

16 And so I think what this measure  
17 potentially allows is allows for unnecessary  
18 delay of up to 45 minutes in the interpretation  
19 of a very crucial study.

20 And so I think that's an issue. But  
21 David's point is well taken. There are other  
22 processes that may limit it but I think you need

1 to limit the time that the radiologist has to  
2 interpret the study.

3 Has to be done at the -- while the  
4 study is done. Sure, I mean, we stand there and  
5 we look at it while the study is being done.

6 MEMBER DICKERSON: So in making a  
7 recommendation, sorry, about what to do for the  
8 next cycle, would you agree that at least one  
9 step in the right direction would be capturing  
10 the time from the order entry or the decision  
11 that a scan should be obtained to the read itself  
12 so that we can quantify that with all the other  
13 elements, still being somewhat vaguely assessed?

14 MEMBER BULSARA: I totally agree with  
15 that but I think the other more important --  
16 that's very important but I think the more  
17 important question is as the scan is being done,  
18 I think the time from this -- the time that this  
19 scan is completed to the time of interpretation  
20 is an important data element to capture because,  
21 I mean, you're making a therapeutic decision in  
22 real time based on the information that you're

1 obtaining. So I think those are -- when is the  
2 order put in, when is a scan done, and from the  
3 time that the scan is completed -- I mean, CT  
4 scan takes less than a minute to complete -- when  
5 is that CT scan read, and I think that's the time  
6 frame that I think we need to endorse or be more  
7 realistic about. I think 45 minutes is  
8 unreasonable.

9 CO-CHAIR TIRSCHWELL: Okay. Bunch of  
10 people want to make comments. Alex, Mike, Jim.

11 MEMBER RAE-GRANT: So it's nice that  
12 we have this opportunity to go around a bit  
13 before we really get going on these.

14 But my understanding about our process  
15 is that we are not developing de novo -- these  
16 measures -- that they come from an external  
17 authority and so these come from AHA/ASA  
18 guidelines for time lines for things.

19 So I don't think it's within our  
20 purview -- I'm asking -- to modify those  
21 guidelines that come to the committee where our  
22 job is to decide whether or not we adopt this and

1 at what level. Is that correct?

2 CO-CHAIR TIRSCHWELL: You would have  
3 to comment on that.

4 DR. TERRY: Basically, you're asked to  
5 review the measure as is and based on the  
6 evidence that is provided. Is that --

7 CO-CHAIR TIRSCHWELL: Yes, I mean --  
8 yes, and so there's a lot of discussion of what  
9 might be the optimal practice and the, I guess,  
10 Ketan, in some ways you're suggesting there are  
11 unintended consequences which we could discuss at  
12 a later point in evaluation of all of this about  
13 that this somehow allows people to relax and  
14 drink some coffee while they're slowly  
15 interpreting the CT scan which, of course, is --  
16 you know, I can't imagine any hospital where  
17 that's really happening.

18 You know, from my perspective this  
19 measure is more about potentially identifying  
20 systems where their percentage might be much  
21 lower than somebody else's and they would want to  
22 use that information to review their processes.

1           Maybe they're not identifying them  
2       fast enough closest to the front door. You know,  
3       I don't -- I guess I would interpret this as  
4       giving people license to slow down and I really  
5       don't think that people would be interpreting  
6       this that way at the hospital level.

7           But anyway, Mike and Jim.

8           MEMBER KAPLITT: Yes, I agree. I  
9       mean, rather than rewrite this on the fly, the  
10      way I approach this is, you know, given what  
11      they've shown us, this is supposed to be a  
12      minimal quality standard, as you said.

13           It's not -- this is not the guideline  
14      of how you should practice. It's -- this is the  
15      minimum quality standard that we feel everybody  
16      should try to achieve, right.

17           And so the way I look at it was is two  
18      hours and 45 minutes from last known well -- is  
19      the evidence there to suggest that that's -- as  
20      an outside limit a meaningful thing to achieve.  
21      Hopefully, we do better than that, right.

22           And that -- you know, while it's true

1       that the evidence specifically on that point is  
2       not provided as well, it's obviously based on the  
3       fact that you want to provide some window to  
4       treat, given that three hours is the standard  
5       for, you know, TPA therapy. There are therapies  
6       that you can do faster but that's the minimum.  
7       And I think that even though this relates to the  
8       next part, which is the performance gap, when you  
9       look at the performance gap data it's still so  
10      large, which we're about to do in a second, it  
11      suggests that while we all would like to achieve  
12      faster, the question in my mind from the evidence  
13      standpoint is on the assumption that a lot of  
14      places are still not achieving this two hour and  
15      45 minutes -- is the evidence there that at a  
16      minimum standard this amount of time is valuable  
17      for patient quality?

18               Once we reach the -- once we top out  
19      then you could make the argument are there newer  
20      standards, I think, that we should achieve.

21               But I think from the evidence  
22      standpoint, the way I look at it is, is there

1 evidence that this is of sufficient quality that  
2 this will do -- that this does something  
3 important for patients for the evidence  
4 standpoint that we should be maintaining this,  
5 you know, recognizing that that's what the last  
6 committee had already endorsed.

7           You know, and so that's the way -- I  
8 think that the fact that there's still such a  
9 large performance gap we have to say well, does  
10 that mean that's because everybody feels that the  
11 evidence is pointless or because people are still  
12 not achieving this which to me is part and parcel  
13 of the evidence in favor of doing this.

14           MEMBER BURKE: So I think one of the  
15 things that's interesting about this measure that  
16 hasn't yet been talked about is the -- this is,  
17 you know, a diagnostic test.

18           And so we're talking about sort of a  
19 step on the pathway to immediate outcome. If the  
20 outcome is giving people TPA, we're now coming up  
21 with a dozen complicated logistical problems that  
22 are conceivably avoidable if you just say measure

1       how long it takes to give someone a TPA.

2               I mean, so the -- if indeed the only  
3       causal pathway that we think rapid interpretation  
4       is relevant to is administration of TPA, then we  
5       now have to figure out is it 45 minutes, who  
6       exactly is the denominator, do you have to come  
7       up with exceptions for all these other details,  
8       when do you start the clock, a million logistics  
9       need to be figured out and if the million dollar  
10      question is did you get TPA or not or how fast  
11      did you give it, then that seems like it should  
12      be the question and this seems like it's a  
13      strange surrogate that raises a lot of  
14      complicated measurement problems that you work  
15      around by just skipping to the end point.

16              I don't know where that fits in the  
17      framework. It doesn't really. But it seems like  
18      it's relevant.

19              CO-CHAIR TIRSCHWELL: Yes, Ketan.

20              MEMBER BULSARA: You know, to  
21      Michael's point, I mean, there is great evidence  
22      in the sense that -- I mean, we need to



1       revascularize these patients as fast as possible  
2       because we know that if we revascularize them in  
3       two minutes we're going to save more of their  
4       brain than we are when we revascularize them at  
5       60 minutes.

6               The point of contention is not that  
7       this needs to be done in a rapid fashion or that  
8       this need so be done sort of -- like all  
9       institutions need to have some sort of minimum  
10      standard.

11             The point of contention is where does  
12      this 45 minutes come from. Forty-five minutes is  
13      an arbitrary number. It's not consistent with  
14      many other societies that have proposed consensus  
15      guidelines. Why have we adopted 45 minutes? Why  
16      not five minutes? Why not ten minutes? Why 45  
17      minutes? And I think if you have a time like 45  
18      minutes in there I think you have to provide  
19      evidence for it and there's no evidence for 45  
20      minutes.

21             CO-CHAIR TIRSCHWELL: Which guideline  
22      gives a different time?

1                   MEMBER BULSARA: So the Society for  
2                   NeuroInterventional Surgeons has been proposing a  
3                   lot of recommendations in terms of consensus  
4                   statements.

5                   And so there's a recent publication  
6                   that advocates that all organizations should  
7                   strive for trying to get to revascularization  
8                   within like an hour and 15 minutes or an hour and  
9                   30 minutes.

10                  CO-CHAIR TIRSCHWELL: But that doesn't  
11                  -- that's not the CT interpretation. Do they  
12                  give a different time line for CT interpretation  
13                  specifically?

14                  MEMBER BULSARA: So let's take a step  
15                  back. So if you're going to activate your  
16                  mechanical thrombectomy team and if you want them  
17                  to make growing access within an hour and 15 or  
18                  hour and 30 minutes there's a lot of steps that  
19                  occur before then and I think one of the key  
20                  steps is the interpretation of the CT scan.

21                  You have one hour to activate the  
22                  team. So most of these strokes happen, let's

1 say, at 2:00 or 3:00 in the morning. So you have  
2 to bring your whole team in. You have about 45  
3 minutes to an hour to bring your team in. And so  
4 you have to have --

5 CO-CHAIR TIRSCHWELL: I understand  
6 your point, Ketan, but I'll ask my question  
7 again. Do they recommend a different specific  
8 time frame for the interpretation of the CT?

9 MEMBER BULSARA: I'll have to go back  
10 to it. I think the recommendation is a rapid  
11 real time interpretation of the CT scan.

12 We don't specify a time.

13 CO-CHAIR TIRSCHWELL: And the other --  
14 I mean, if you start going down the endovascular  
15 route, which is a sort of a different thing,  
16 which because the evidence is new, there aren't  
17 quality metrics for that are sort of coming  
18 through NQF, it actually has to be a CTA, right,  
19 not a CT.

20 So it's really -- it's kind of a  
21 different question. If you're moving on to  
22 endovascular stuff so --

1                   MEMBER BULSARA: But data -- I mean,  
2                   some of -- I mean, just out of interest, some of  
3                   this part of the seven randomized trials, there  
4                   were some that didn't use any advanced imaging.

5                   They assumed large vessel occlusion  
6                   based on clinical criteria.

7                   CO-CHAIR TIRSCHWELL: But they all  
8                   used CTA. I don't think they -- many of them  
9                   didn't use perfusion or diffusion or things like  
10                  that. But I think virtually all of them used CT  
11                  angiogram.

12                 MEMBER BULSARA: So I guess the point  
13                 is, I mean, why -- I mean, in your clinical  
14                 practice, it's 45 minutes to an hour and we're  
15                 dealing with 45 minutes interpretation of a CT  
16                 scan, something that is reasonable.

17                 I mean, do you actually look at the CT  
18                 scans when you have a stroke patient?

19                 CO-CHAIR TIRSCHWELL: Yes. And I --  
20                 to you that this measure doesn't - it's not  
21                 looking at best practice. It's a way to quantify  
22                 our total practice in a way that might allow us

1 to find areas for improvement and I think there's  
2 a difference between those two things.

3 You know, yes, we have residents --  
4 they're in the scanner. The radiology residents  
5 in the scanner behind the CT tech and they're  
6 interpreting it way before they even write it  
7 down. They have to look at their watch so later  
8 they can say what time they actually interpreted  
9 it.

10 But, you know, obviously, the  
11 resources are quite variable at different  
12 hospitals around the country and so you do -- you  
13 know, these quality measures are about  
14 identifying some reasonable benchmark that will  
15 help you identify good practice, potentially  
16 identify variance from good practice and would  
17 give you the opportunity to focus on some cases  
18 where your variance was greatest, maybe the ones  
19 where you didn't achieve this measure, because  
20 focusing on those cases might help you identify  
21 your best targets for improving your processes of  
22 care. So there's a few more people -- Melody?

1                   MEMBER RYAN: Thanks. So I think,  
2 clearly, when this measure was originally  
3 proposed, the idea was to be able to give TPA.  
4 Okay. So that would be a three-hour window and  
5 that's still the labeling by the FDA.

6                   But what I'm wondering is there are  
7 several consensus statements now from the  
8 American Stroke Association that suggest 4.5  
9 hours is also reasonable. So do we need 45  
10 minutes or is really like within -- that they  
11 arrive within four hours and it's read within 15  
12 minutes or something?

13                  CO-CHAIR TIRSCHWELL: Okay. So you're  
14 wondering about specifications it seems like,  
15 which might be part of the later discussion.

16                  Steve and then Charlotte and Peter.

17                  MEMBER HUFF: I think we're all in  
18 agreement here and we're all in disagreement  
19 here.

20                  This is an -- you know, I guess the  
21 question is whether to view this measure as an  
22 overreaching quality measure or to look at

1 specific subtypes -- sub-measures within this.

2 No one's wanting to get emergency  
3 physicians off the hook of seeing patients  
4 acutely or whoever. There are separate metrics  
5 for that. There are separate measures for that.  
6 And yes, as an emergency physician, I'm very  
7 aware of the clock. I'm very aware that it's  
8 very difficult to hit the metrics on our stroke  
9 quality measures and sometimes, I have to cut the  
10 patient off. I cannot talk to you any longer.  
11 I have one minute here to make a decision to pull  
12 a trigger on a stroke alert and I can't have you  
13 telling me about your TIA last year that left you  
14 -- left you weak on your left side. That makes  
15 no sense. I've got a minute to make a decision  
16 here.

17 So and -- we're very aware of the  
18 metrics. We're trying to hit the metrics. We  
19 also want to give good care. So it's almost like  
20 we need to define our group. We don't have a  
21 good biomarker for this. We're talking about a  
22 patient who comes in with a himiplegia and

1       aphasia. We're talking about a patient who has  
2       resolving symptoms. We're talking about a  
3       patient who comes in with a headache and nothing  
4       else. And so, you know, the CT MRI is our  
5       biomarker for this. It's the race to get a  
6       reliable biomarker. We have that in cardiac  
7       disease with EKGs and enzymes. We don't have  
8       that in cerebral vascular diseases. So we're  
9       left with our time to the original biomarker.  
10      And I think in -- we have issues with both the  
11      numerator and the denominator for this measure.  
12      It's a real problem.

13               MEMBER JONES: I think we're all here  
14      from ivory towers. There are -- I think we're  
15      all here from ivory towers. I practiced for nine  
16      years in West Virginia.

17               There isn't somebody interpreting your  
18      CT scan. You're there doing it, and if you are  
19      trying to make decisions, if you're trying to  
20      perhaps -- there is a neurosurgeon in town who  
21      you can call in or you're deciding you have to  
22      transport that patient, these time limits, I



1 think, become destructive when what we're really  
2 trying to do is get the patient their treatment  
3 in the most -- in the quickest way and moving  
4 through.

5 And when we keep putting time levels  
6 on processes, that we're going to grade you on if  
7 you do this in a specific time -- if you do this  
8 in a specific time, not taking into consideration  
9 that the system that you work in may not have  
10 these steps, I think the comment that what we  
11 really should be focusing on and what NQF has to  
12 say is it's the outcome.

13 And so I think we have to go back to  
14 the first question of does the measure assess  
15 performance on a health outcome or PRO that  
16 impacts the patient, and do we have the evidence  
17 that the relationship between the measured health  
18 outcome and at least one health care action is  
19 identified and supported by the stated rationale.  
20 And I -- listening to everyone here, I don't  
21 think we have that for the 45 minutes and my  
22 understanding is is that's the first thing we're

1 voting on.

2 DR. TERRY: I just want to mention  
3 that this is a process measure and we do have  
4 different requirements based on outcome and  
5 process, just to clarify that point. Thank you.

6 MEMBER SCHMIDT: So one of the things  
7 that we struggled with when I was on the panel  
8 that it took a little while for us to get clear  
9 on this on the panel in 2013 was the -- we have  
10 to recognize that not every measure has to target  
11 100 percent as improvement.

12 So if we think that there are people  
13 who will be difficult to get in that window  
14 because of presentation, then you have to decide  
15 is that going to hurt my clinic because there's  
16 going to be some sort of structural bias that I'm  
17 going to get more of those than you are and so  
18 I'm going to look worse.

19 And it seems like something where  
20 we're getting -- somebody's presenting within two  
21 hours of symptom onset, it's going to be fairly  
22 randomly distributed the difficult presentations.

1 And so you don't need to institute an exclusion  
2 if the bias is going to be -- you know, if the  
3 cases are going to be showing up in a nonbiased  
4 fashion.

5 MEMBER FERZIGER: So I want to ask for  
6 some clarification about the point that we're  
7 discussing versus the feasibility question.

8 Because what I'm hearing is that the  
9 feasibility, you know, of accomplishing this  
10 measure -- I understand feasibility is really  
11 about the measure itself -- but its application  
12 in different settings will vary. I think what  
13 I'm trying to understand is is our job not to  
14 determine that there's a benchmark based on  
15 medical evidence that ought to be measured and  
16 many places may at the current time not be able  
17 to meet that benchmark. But that's information  
18 that would be very, very valuable. If the  
19 benchmark is established, then, you know, all  
20 stakeholders can decide how important it is to  
21 improve toward the gold standard at their  
22 institution. But if we don't measure it, right,

1 because feasibility of accomplishing the task is  
2 poor, you know, then we don't know what to aim  
3 for.

4 So am I understanding this part of the  
5 discussion correctly?

6 CO-CHAIR TIRSCHWELL: I guess I'm --  
7 honestly I'm not 100 percent sure how to answer  
8 that question.

9 MEMBER FERZIGER: Is the question  
10 clear or should I --

11 CO-CHAIR TIRSCHWELL: Could you  
12 rephrase it a little?

13 MEMBER FERZIGER: Sure. Well, what I  
14 was hearing is some discussion about whether -- I  
15 mean, there are two issues here, one whether the  
16 45 minutes is reasonable from a clinical point of  
17 view and two, even if it is, whether it's  
18 attainable, given all the other issues involved  
19 in care at various institutions.

20 And it seemed to me that if the second  
21 one is part of the discussion now, why would that  
22 impact, whether we choose to leave or not.

1 CO-CHAIR TIRSCHWELL: I think this  
2 discussion should be more about whether the 45  
3 minutes is an appropriate thing to do, not  
4 whether it's attainable.

5 MEMBER FERZIGER: So it would seem to  
6 me that there was some mixture of those issues.

7 CO-CHAIR TIRSCHWELL: Okay. Lots of  
8 comments. Charlotte, you have another comment  
9 and David? Sorry.

10 MEMBER JONES: Well, just to clarify.  
11 The reason I brought up the other institutions  
12 who may not be able to meet it is because I don't  
13 think that the evidence supports a time, and we  
14 have to look at the consequences of putting on a  
15 time when we may not have the evidence to support  
16 it.

17 MEMBER HACKNEY: So I agree with the  
18 comments about the limitations of this. But I'll  
19 just say that from a practical point of view this  
20 is useful, and I think I'm restating what Steve  
21 had said, that looking at your performance on  
22 this helps you identify delays in your system and

1       it doesn't -- just knowing that number doesn't  
2       tell you where the delays are.

3               But when you dig into your system you  
4       can find out where those delays are, and you can  
5       try to cut them down and that's where the quality  
6       impact of this would lie. Yes, 45 minutes is an  
7       arbitrary number.

8               It's, I think, an attempt and a guess  
9       at how long realistically does it take an ED doc  
10      to see a patient and decide that the next thing  
11      they need is a head CT scan because they might  
12      have a stroke.

13              They can't do that in one second and  
14      no, it doesn't take a long time to do or  
15      interpret the CT scan once you've gotten that  
16      far.

17              But if you're going to build in all of  
18      that, and I think there would be a disadvantage  
19      in breaking that down into a tiny bit -- bunch of  
20      steps because that lets the system off the hook.  
21      This is a system performance measure and it's --  
22      how long does it take when somebody shows up

1       until you have what we are presuming is the last  
2       piece of information you need before you're going  
3       to decide to revascularize.

4               And I think that's a useful thing to  
5       measure and I agree, I don't know that there's  
6       data that says how long that step -- this step as  
7       currently designed should take.

8               But in terms of usefulness, it helps  
9       you find out if you're slower and if you are then  
10      you try to speed up, and I think that's the value  
11      of it.

12              CO-CHAIR TIRSCHWELL:   Okay.   Michael  
13      and then Ron and Ketan and then I'm going to say  
14      unless you have something that's totally  
15      different than what's already been said -- I  
16      think we've hit the main themes here, that I  
17      would move that we go ahead and vote on this  
18      first thing, and I'll note that we are no longer  
19      ahead of time.   Michael?

20              MEMBER KAPLITT:   Yes.   So I completely  
21      agree with what you said.   I would just clarify  
22      again that there is good evidence about time.

1           There may not be good evidence about  
2   this 45 minutes but there is no question stroke  
3   is all about time and has good class one, you  
4   know, excellent evidence about time.

5           So we're just arguing right now about  
6   the 45 minute number, not about time. A. B, if  
7   we all agree around this table that time matters  
8   and there's good evidence for most therapies, you  
9   know, TPA therapy, three hours, they may have  
10   been broadening the window in recent experimental  
11   studies but it's three hours -- that's, you know,  
12   the way it is, and there may be new therapies  
13   with shorter time windows.

14          But if we agree that three hours has  
15   a good basis for it -- there's good class one  
16   evidence for three hours with TPA and there's  
17   good class one evidence that you need to image  
18   people before you provide that, then we're  
19   basically narrowing this down to somewhere in  
20   that three hours, you have to have evaluated the  
21   patient, you have to have done a scan, and that  
22   should be the standard of care, at a minimum.



1       There may be new technologies but that's the  
2       minimum.

3               So yes, you could do a study to say  
4       should it be a half an hour, should it be ten  
5       minutes, should it be 45 minutes. Then you get  
6       into feasibility questions, et cetera.

7               But I don't think that, you know,  
8       suggesting that there's no good evidence about  
9       time or there's no good evidence about imaging or  
10      whatever, you know, that's kind of the  
11      implication of some of this.

12              I know that might not be the intent,  
13      but that's the implication of some of this and  
14      there is good evidence of about three hours and  
15      there is good evidence about imaging before you  
16      provide therapy.

17              And so now we're kind of parceling it  
18      down to just this brief window that we're talking  
19      about.

20              CO-CHAIR TIRSCHWELL: And I would just  
21      add to emphasize on that, Mike, that the greater  
22      percentage you have that meets the 45 minute the

1 -- probably the shorter your average time is and  
2 that's really what we're shooting for to improve  
3 care. So I think there probably is some value.

4 Ron and then Ketan and then maybe  
5 vote.

6 MEMBER KOENIG: Just as a reference,  
7 there was -- I'm sure it's a study but comments  
8 made as to when things should be done including  
9 within 45 minutes for a scan and that came from  
10 the guidelines for early management of patients  
11 with acute ischemic stroke, the guideline for  
12 health professionals from the American Heart  
13 Association, American Stroke Association and that  
14 was in Stroke 2013 Volume 44.

15 I think we just need to have something  
16 to look at so we can let EMS know where to go to  
17 get the best service and this is, unfortunately,  
18 the only way.

19 MEMBER BULSARA: Just a really quick  
20 comment. The data that Ronald mentions is from  
21 before the seven randomized studies that showed  
22 mechanical thrombectomy as an important player in

1 terms of revascularizing these patients.

2 And you had asked about whether in the  
3 standards we had established a time and just  
4 pulling up the paper it's 15 minutes or less from  
5 the patient -- from the time that the patient  
6 hits the emergency room to getting a CT scan.

7 And so these are the ideal standards  
8 -- less than 15 minutes -- and I can circulate  
9 the article to the group if you'd like.

10 So the way it's phrased is patient --  
11 I mean, you know if a patient -- the neurology  
12 stroke team or the ER stroke team meets the  
13 patient in the emergency room. They identify  
14 high likelihood of a stroke.

15 So it's a quick check. They go  
16 straight to a CT scan and all of this is done  
17 ideally within 15 minutes and the suggestion was  
18 that this should be implemented over the course  
19 of a couple years and I can circulate the paper  
20 to the group.

21 CO-CHAIR TIRSCHWELL: It's like that's  
22 to the start of CT, not to the interpretation.

1       So it's a bit different.

2               Ron, do you mind turning off your mic?

3               MEMBER BULSARA: It's to the -- it's  
4       to interpretation. CT scan and interpretation,  
5       assuming that interpretation is done by a team  
6       that is present there with the patient.

7               CO-CHAIR TIRSCHWELL: Okay. Last  
8       comment, Steve.

9               MEMBER HUFF: I think we're in  
10       agreement this is a non-ideal surrogate marker  
11       for summing several processes and I think Jim  
12       started off this some time ago that this is a  
13       very convoluted thing to some processes.

14               We want to approve it like this --  
15       this makes sense in this discussion.

16               I would think going forward though,  
17       you know, marker would be -- which percent of  
18       TPA-eligible patients get TPA within X minutes.  
19       I mean, that's the process we're looking at here.

20               CO-CHAIR TIRSCHWELL: There is a  
21       different measure, I think, that does just that.

22               MEMBER HUFF: Then perhaps this is

1       redundant.

2                   CO-CHAIR TIRSCHWELL:   Somebody's going  
3       to explain to us a little bit about our voting,  
4       and then we'll do first -- go faster, I'm really  
5       sure --

6                   MS. OGUNGBEMI:   Good morning.  
7       Everyone should have a little blue remote  
8       control.   Please let me know if you do not have  
9       one.

10                   Once voting is open I will say voting  
11       is open and we will make our selections.   Please  
12       only use your remote control to capture your  
13       votes.   You can point your remote towards me.

14                   I will capture all of your votes  
15       telepathically.   There are either two or four  
16       options.   The two option voting slides are yes or  
17       no options, and the four voting or the four  
18       option slides are high, moderate, low and  
19       insufficient.

20                   Once you press your response, it will  
21       display in the little digital screen here.   If  
22       you press an option that's not available like

1 number five, because it will never be available,  
2 it will show just the small dash instead of an  
3 actual number.

4 If you change your vote while voting  
5 is open, only your last response will be captured  
6 to avoid multiple votes.

7 We will give sufficient time to  
8 capture votes and then I will say voting is  
9 closed and I will read the results of the votes  
10 that we've collected.

11 As Christy mentioned before, 60  
12 percent is required for consensus. So we're  
13 going to do a test vote right now.

14 Pop quiz. What does CDP stand for?  
15 Voting is open. You can point your clicker  
16 towards me and press your votes.

17 All right. Voting is closed. I hope  
18 this is not a representation of what it actually  
19 means or what you think it means. The answer is  
20 consensus development process so --

21 Exactly, yes. Because we met 60  
22 percent on a high or moderate vote, we will

1 proceed in the criteria.

2 Okay. So now we will vote seriously.

3 MS. SKIPPER: And I will be voting on  
4 behalf of Kelly Sullivan who was joining us  
5 online.

6 MS. OGUNGBEMI: Okay. We are now  
7 voting on evidence for Measure 0661. Voting is  
8 open.

9 The options are high, moderate, low  
10 and insufficient.

11 Voting is closed. The results are 5  
12 percent high, 64 percent moderate, 23 percent low  
13 and 9 percent insufficient. Measure 0661 passes  
14 on evidence.

15 CO-CHAIR TIRSCHWELL: All right. We  
16 are now moving then to the -- I think it's the  
17 gaps section. Can you guys -- are you willing to  
18 proceed?

19 MEMBER DICKERSON: Yes. We --

20 CO-CHAIR TIRSCHWELL: Take it on --  
21 let's try to keep this one a little more  
22 restrained, if we can?

1                   MEMBER DICKERSON: I think this is one  
2 place where it looks like this measure is really  
3 providing some very valuable information, which  
4 basically shows that there is tremendous gap  
5 variability in performance and the potential  
6 opportunity for improvement, and there are some  
7 initial identifications of some disparities with  
8 African Americans being less likely than white  
9 patients to meet this goal and Hispanic patients  
10 being less likely than non-Hispanic, and also  
11 female less likely than male to hit this marker.

12                   And patients treated in the facilities  
13 with fewer than 50 beds were less likely to have  
14 a head CT or MRI scan within 45 minutes of  
15 arrival.

16                   The thing that surprised me was that  
17 patients treated in major teaching facilities  
18 were also less likely, and maybe that's for some  
19 of the reasons that we've been discussing today.

20                   So I think -- I would agree that  
21 there's a high gap in care and a strong  
22 opportunity for improvement here.



1 CO-CHAIR TIRSCHWELL: Okay. Open for  
2 discussion. Seeing none, I suggest we move  
3 immediately towards voting.

4 MS. OGUNGBEMI: We are now voting on  
5 Measure 0661 on performance gap. The options are  
6 high, moderate, low, insufficient. Voting is  
7 open.

8 Voting is closed. The results are 91  
9 percent high, 9 percent moderate, zero percent  
10 low and zero percent insufficient. Measure 0661  
11 passes on performance gap.

12 CO-CHAIR TIRSCHWELL: All right. Then  
13 we're on to scientific acceptability and we start  
14 with reliability.

15 MEMBER DICKERSON: So we could spend  
16 as much time on this discussion as we did  
17 earlier, I'm sure. But the basic reliability  
18 data that have been provided here show a range of  
19 .62 to 1.0 with a median of .77 and the statement  
20 is that a value of .7 is often regarded as a  
21 minimum accepted reliability value. So we would  
22 see our measure coming in at .77.

1                   And the summary rating is moderate  
2 evidence for reliability and I think I would  
3 agree with that?

4                   CO-CHAIR TIRSCHWELL: Any comments,  
5 questions? Go ahead and vote then.

6                   MS. OGUNGBEMI: We are now voting on  
7 reliability for Measure 0661. The options are  
8 high, moderate, low and insufficient. Voting is  
9 open.

10                  Voting is closed. The results are 22  
11 percent high, 65 percent moderate, 13 percent low  
12 and zero percent insufficient.

13                  Measure 0661 passes on reliability.

14                  CO-CHAIR TIRSCHWELL: So then we're on  
15 to validity, correct?

16                  MEMBER DICKERSON: So in validity  
17 there was really -- I think this is an area of  
18 greater difficulty because, as we discussed  
19 already, you know, how do you really -- what's  
20 the gold standard, which is often challenging,  
21 and I think we could, again, debate for some time  
22 on that.

1           But the validity measure that was  
2           provided was really looking at more agreement  
3           rate between two different abstractors on 12  
4           critical data elements and so the overall kappa  
5           statistic was .52 and I think there were a number  
6           of potential threats to validity that were  
7           identified and so the summary rating again here  
8           is moderate.

9           And I personally think that we're  
10          probably down closer to low to moderate but I  
11          could accept moderate, given the challenges in  
12          identifying the gold standard here.

13          CO-CHAIR TIRSCHWELL: Any questions or  
14          comments related to validity? Yes, Alex.

15          MEMBER RAE-GRANT: Just both the  
16          reliability and the validity measures, I think -  
17          - and those of us who are new to this we need  
18          more guidance from methodologists here as to how  
19          you guys develop that, how you use it, how we  
20          should be interpreting.

21          I'm not totally clear on what our  
22          process is as we go forward on those two

1 particular parts of the measure -- does that make  
2 sense?

3 CO-CHAIR TIRSCHWELL: Karen, do you  
4 mind commenting?

5 MS. JOHNSON: Sure, let me give you  
6 just a really brief overview of testing,  
7 particularly for both reliability and validity.  
8 NQF allows data element testing or score level  
9 testing.

10 Ideally, we would see both but we  
11 don't require both. When we talk about score  
12 level testing for reliability, we often see folks  
13 do things called signal to noise methodology.

14 We have some rules of thumb that we  
15 provide sometimes. That's where that .7 comes  
16 from. It's a rule of thumb to help you think  
17 about interpreting what you see. It is only a  
18 rule of thumb.

19 It is not a threshold. So it should  
20 not be considered -- you know, if you don't see  
21 something at .7 or higher, that doesn't mean that  
22 you shouldn't consider it. Again, it is just a

1 rule of thumb and that's really what NQF does.

2 We don't specify methodologies, so we  
3 don't say you have to do this or the other. We  
4 don't specify thresholds, because particularly  
5 with reliability and to some extent with validity  
6 as well, it kind of depends on the context that  
7 you're looking at.

8 Reliability is a function of the  
9 variability that you're seeing both within and  
10 between providers, and it also is a function of  
11 the number of patients that are included.

12 So you can see that context matters  
13 and that's why it's important for you when you're  
14 interpreting testing results to look at the  
15 testing sample that was provided.

16 So, you know, is it -- it doesn't have  
17 to be statistically representative but you'd like  
18 it to be, you know, big enough to feel pretty  
19 comfortable that what you're seeing may be a good  
20 signal, if you will, as to what might be  
21 happening out in the real world.

22 For validity, we generally -- for data

1 element validity we think about comparing -- what  
2 you're looking for there is accuracy. So do you  
3 feel comfortable that what is being used in the  
4 measure is accurate?

5 A lot of times what developers will do  
6 is they will look at something -- if it's a paper  
7 measure, they might look at the extraction and  
8 then go back and actually compare it to the  
9 medical record and see what was extracted,  
10 actually what was in the record.

11 So that's what we see. Sometimes for  
12 validity testing, if you are looking at score  
13 level validity testing, as opposed to data  
14 element validity testing, what you're thinking  
15 about there is is there something else that kind  
16 of tracks with this measure.

17 So, for example, if I were looking at  
18 the percentage of patients who we got TPA within  
19 the three hours -- the limit that you were  
20 talking about and you looked later on at  
21 functional status of your patient population.

22 You would think that those two would

1 track together and that's one way of looking at  
2 validity -- at the score level. We would call it  
3 construct validity.

4 So there's a lot of different methods,  
5 a lot of different -- statistics that folks could  
6 use. That is another reason that we don't lay  
7 out what you need to do.

8 What we try to do in the PA's is tell  
9 you whether or not the methodology was an  
10 appropriate methodology. If we have rules of  
11 thumb, we try to tell you what some of those  
12 rules of thumb are.

13 But, again, you weigh that with what  
14 you feel like, you know, is it really hitting  
15 that rule of thumb. Maybe it's not quite hitting  
16 it but they used a really good sample and I feel  
17 pretty comfortable with what we found or maybe  
18 not.

19 I'm not quite sure I answered your  
20 question and let me stop there and see if you  
21 have additional questions.

22 MEMBER RAE-GRANT: That's quite a good

1 start. Thank you very much.

2 CO-CHAIR TIRSCHWELL: And I'll just  
3 add that there are also these flow charts that  
4 we've probably all seen at this point, which sort  
5 of take you through the various scenarios and the  
6 way they've done their reliability and validity  
7 testing that I sort of referred to in these green  
8 boxes in the documents here.

9 Okay. So any other comments about --  
10 or questions about validity in this case or  
11 should we move to voting? Let's go ahead and  
12 move to voting.

13 MS. OGUNGBEMI: Voting is open for  
14 validity of Measure 0661. The options are high,  
15 moderate, low and insufficient.

16 Voting is closed. The results are  
17 zero percent high, 77 percent moderate, 9 percent  
18 low and 14 percent insufficient. Measure 0661  
19 passes on validity.

20 CO-CHAIR KNOWLTON: I have a question.  
21 I'm noticing that the N is different for the  
22 voting. Are some votes not registering? The



1 previous vote was 23. The N was 23. This is 22.

2 MS. OGUNGBEMI: Right. Someone did  
3 not vote.

4 CO-CHAIR KNOWLTON: Is that it? What  
5 I'm worried is that somebody thinks they voted  
6 but it didn't register.

7 MS. OGUNGBEMI: We can revote if you  
8 would like.

9 CO-CHAIR KNOWLTON: I'm just concerned  
10 because I'm noticing that the N is different.  
11 You know, sometimes -- I want to be sure.

12 CO-CHAIR TIRSCHWELL: What is the  
13 total N, of all people? Twenty-three? So I  
14 guess especially it was a close vote.

15 CO-CHAIR KNOWLTON: I just wanted --

16 MS. OGUNGBEMI: And what we can do is  
17 let's just revote just so we are capturing  
18 everyone's vote. If you can reopen it, just for  
19 me.

20 Voting is open for 0661 on validity.  
21 The options are high, moderate, low and  
22 insufficient.

1           The results are zero percent high, 74  
2           percent moderate, 13 percent low and 13 percent  
3           insufficient. Measure 0661 passes on validity.

4           CO-CHAIR TIRSCHWELL: Feasibility?

5           MEMBER DICKERSON: So feasibility is  
6           the extent to which the specifications, including  
7           measure logic require data that are readily  
8           available or could be captured without undue  
9           burden. I just thought I would -- I don't think  
10          we've spent as much time talking about that.

11          So this is available through  
12          administrative claims, electronic clinical data,  
13          electronic health records, paper and there's  
14          actually an electronic data collection tool  
15          that's made available from vendors or facilities  
16          called the CMS extraction and reporting tool that  
17          has some of the data elements required for this  
18          measure and it's also feasible to extract from a  
19          record by someone other than the person obtaining  
20          the original information as was just discussed  
21          briefly.

22          So I think I would agree that this has

1 moderate feasibility. I think some of the  
2 feasibility concerns are related to a lot of the  
3 substance of the discussion we had before.

4 CO-CHAIR TIRSCHWELL: Questions,  
5 comments, discussion?

6 Sorry. Reuven.

7 MEMBER FERZIGER: Yes, I just wanted  
8 to ask how much variance is there across  
9 institutions for this particular issue? Is it  
10 vastly more feasible in some places than others?

11 CO-CHAIR TIRSCHWELL: Well, it's -- I  
12 think it's feasibility of obtaining the  
13 performance measure, not of achieving the  
14 performance measure.

15 MEMBER FERZIGER: Exactly what I mean.  
16 That's exactly what I mean. Is it -- there are  
17 places that have beautiful IT and quality  
18 departments and they are going to be aces at  
19 getting this. And there are places, perhaps West  
20 Virginia --

21 CO-CHAIR TIRSCHWELL: Smaller  
22 hospitals, we'll just say.

1                   MEMBER FERZIGER:  -- that will be very  
2                   challenged to do this.  So it seems like to me  
3                   like a feasibility of actually collecting the  
4                   measure might be very different at different  
5                   institutions.

6                   CO-CHAIR TIRSCHWELL:  Yes.

7                   MS. McKIERNAN:  So this is Colleen  
8                   McKiernan.  So we -- this measure is among a  
9                   suite of chart abstractive measures and so your  
10                  point is well taken.  So some facilities might  
11                  have advanced IT systems whereas others are still  
12                  using paper potentially.

13                  But because the measures are chart  
14                  extracted and there's a sample of patient -- of  
15                  cases that are abstracted for each quarter it  
16                  really levels the playing field in a way that  
17                  some of -- some meaningful use measures or other  
18                  measures that rely on EHR data can require a  
19                  standardization.

20                  The information is abstracted by a  
21                  person regardless of the location which the data  
22                  -- the information is stored.

1                   MEMBER FERZIGER: You probably  
2 addressed this, then I thought about it. It  
3 seems to me that, you know, when you have -- you  
4 have IT systems that automatically are recording  
5 times, right, you know, of diagnostic tests and  
6 treatments, right, then you have a great deal of  
7 accuracy in addition to convenience.

8                   In a place where it's abstracted  
9 afterwards, right, you really don't know the  
10 accuracy, it seems to me, you know, of the timing  
11 that was put down. That would be the lowest  
12 priority for many people.

13                  MS. McKIERNAN: So I think that one  
14 advantage of the way we have the measure  
15 specified currently is that it is not always the  
16 time that's documented in the system.

17                  So if you think about the way a  
18 radiology report ends up feeding into the system,  
19 there might be a delay between when the  
20 radiologist entered the information and if a  
21 resident entered it in and then the attending had  
22 to sign off, so the time that's documented may

1 not be representative of the actual time and the  
2 actual time would be pulled from that note.

3 So the resident would document the  
4 time at which they did the interpretation and  
5 then a person would physically have to go in and  
6 read that note and find that time.

7 So you're going to see that, whether  
8 it's a nice IT system or a paper record. But,  
9 certainly, there are pros and cons of having the  
10 EHR measure versus a chart extracted measure.

11 I think that this is kind of the way  
12 it's currently specified now is -- levels that  
13 playing field and it does require pulling that  
14 information from whatever the physician or  
15 whomever wrote down.

16 MEMBER FERZIGER: I don't want to  
17 belabor this but I'm actually concerned about  
18 this from a process point of view because when  
19 you create a measure where some institutions  
20 actually have capabilities of getting accurate  
21 data -- is very different than others and there  
22 are system incentives actually to meeting the

1 measure, you know, than it creates some issues  
2 about the commitment, you know, of all  
3 institutions, you know, to the accuracy, you  
4 know, of what they're putting there because  
5 there's some pressure on them, therefore some  
6 bias, right, to get toward a certain number.

7 So my concern would be if there is,  
8 you know, a significant feasibility variability,  
9 we should recognize that and that should be part  
10 of how we understand what's collected.

11 CO-CHAIR TIRSCHWELL: Any other  
12 comments? Let's move to voting.

13 MS. OGUNGBEMI: Voting for Measure  
14 0661 feasibility is open. The options are high,  
15 moderate, low and insufficient.

16 Voting is closed. The responses are  
17 9 percent high, 70 percent moderate, 22 percent  
18 low and zero percent insufficient. Measure 0661  
19 passes on feasibility.

20 MEMBER DICKERSON: Getting to  
21 usability and use -- so this is evaluating the  
22 extent to which various audiences use or could

1 use the results for accountability and  
2 performance improvement activities, and this  
3 publically reported through the CMS HOQR program  
4 which is a pay for data quality reporting program  
5 implemented by CMS, and the developer reports  
6 here that the median rate of head CT or MRI scan  
7 for this purpose has increased from 62 percent in  
8 2012 to 71 percent in 2014.

9           There were some unexpected findings  
10 which were -- the wide variation in facility  
11 performance doesn't seem unexpected to me but  
12 they list that in a report that the median  
13 performance is improving.

14           But they do address the fact that the  
15 validity of this measure is challenged by some  
16 differences in how facilities and the clinical  
17 data abstraction center identified the numerator.  
18

19           I would assume that would apply to the  
20 denominator as well, suggesting that clearer  
21 abstraction guidance could improve the validity  
22 of the public reported value.



1           So, you know, I think we would all  
2     like to endorse that statement, based on our  
3     discussion today if we can.

4           It's interesting, then, also that the  
5     developer states that many facilities are not  
6     meeting the minimum case count requirements for  
7     public reporting, which are more than ten cases  
8     with complete records.

9           So I think that this is reflective  
10    potentially because exclusion criteria may be  
11    being applied more variably as well.

12          And there was no potential for harm  
13    reported. So the overall usability described  
14    here was concluded to be high, which I would  
15    agree with.

16          CO-CHAIR TIRSCHWELL: Comments or  
17    discussion? Let's go ahead and vote.

18          MS. OGUNGBEMI: We are now voting on  
19    usability and use for Measure 0661. Options are  
20    high, moderate, low and insufficient. Voting is  
21    open.

22          Voting is now closed. The results are

1 65 percent high, 30 percent moderate, 4 percent  
2 low and zero percent insufficient.

3 Measure 0661 passes on usability and  
4 use.

5 CO-CHAIR TIRSCHWELL: And then --  
6 discussion of related and competing measures?  
7 There's no voting here. We just -- are we going  
8 overall? Is that what happens next?

9 DR. TERRY: Well, I was just going to  
10 say we're going to talk about related and  
11 competing tomorrow.

12 CO-CHAIR TIRSCHWELL: Okay. So next  
13 we vote on the overall suitability for  
14 endorsements. And I guess just -- I mean, it  
15 seems like it's passed all the way through and we  
16 could still say no?

17 Doesn't seem quite so algorithmic if  
18 that's the case. Right. Okay. Good. Good  
19 point. Fair enough.

20 MS. OGUNGBEMI: Okay. We are now  
21 voting for the overall suitability of endorsement  
22 for Measure 0661. The options are yes and no.

1 Voting is open.

2 Voting is closed. Measure 0661 does  
3 meet the NQF criteria for endorsement according  
4 to the committee. Thank you.

5 The responses are 83 percent yes and  
6 17 percent no.

7 CO-CHAIR TIRSCHWELL: All right.  
8 Great. Well, thank you. That was a good first  
9 measure. Thank you for tolerating being first.

10 I think we have a little break, a  
11 short break. Maybe we could reconvene -- what do  
12 you guys want to say, 11 or five before 11? 11  
13 o'clock and we'll start back in. Thank you very  
14 much, everybody.

15 (Whereupon, the above-entitled matter  
16 went off the record at 10:47 a.m. and resumed at  
17 11:00 a.m.)

18 CO-CHAIR KNOWLTON: Okay. Welcome  
19 back to the easy part of our session. We'll zip  
20 right through these measures, I'm confident.

21 We're going to be -- we're going to  
22 get an overview from Ann Phillips from the staff

1 on the issues of eMeasures -- on the criteria and  
2 the guidelines and the we will go on to some  
3 measures that we're going to measure -- that  
4 we're going to evaluate. So Ann?

5 MS. PHILLIPS: Hi everybody. I'm Ann  
6 Phillips and I review eMeasures here at the  
7 National Quality Forum.

8 Most of my work is technical  
9 evaluation and getting them ready for your  
10 review.

11 So if we go to, I guess, our  
12 introductory slide here we're going to be looking  
13 at three different types of eMeasures in the  
14 neurology project.

15 We'll be reviewing candidates for the  
16 approval for trial use program legacy measures  
17 and one de novo or new measure. That's also a  
18 hybrid measure. It's a little more complex than  
19 our regular measures.

20 Some things to keep in mind when  
21 considering these measures, especially for trial  
22 approval. Trial approval is not an endorsement.

1           Trial approval is a path to  
2 endorsement. We use the trial approval  
3 designation for new measures that are innovative  
4 that address gaps that need to get out in the  
5 field and get more testing data to come back for  
6 endorsement.

7           Hopefully, you will see those measures  
8 again while you're still on the standing  
9 committee, and you'll continue to review by  
10 evaluating the scientific acceptability.

11           Legacy measures are eMeasures with a  
12 currently endorsed claims version that's in use  
13 in a federal program, and while the  
14 electronically specified version has been  
15 implemented in the field, it's been difficult for  
16 developers to get complete data on performance  
17 right now and we'll accept synthetic testing data  
18 for these measures.

19           You'll review the legacy measures in  
20 tandem with their endorsed claims version. It  
21 keeps the discussion a little more concise  
22 because they are the same measure.

1           They just have slightly different data  
2 elements. And the hybrid measure reviewing is a  
3 new measure. It's kind of a unique measure  
4 because it's both -- uses claims data to identify  
5 the population and data from the electronic  
6 medical record to identify the patients -- who's  
7 the denominator and numerator.

8           I think we are ahead a couple of  
9 slides. Do you want to go back to the legacy  
10 measures for me? Let's talk a little bit about  
11 that. Does anybody have any question about the  
12 three types of measures, first of all, before we  
13 go on to talk about legacy a little more deeply?

14           Okay. So the legacy measure -- we're  
15 going to review this in tandem with the claims  
16 measure because it'll just keep the discussion  
17 more focused.

18           Because it makes sense to have one  
19 discussion. But keep in mind when you're voting  
20 on scientific acceptability for the legacy  
21 version of this measure, you can score this area  
22 no higher than moderate because we're using the

1       synthetic tool to support data element validity.  
2       So that's important to remember.

3               You still want to look at feasibility  
4       and usability in use and certainly the evidence  
5       performance gap, importance to measure in report.  
6       Go on to the next one please.

7               Okay. An approval for a trial use.  
8       Does anybody have any questions about the  
9       approval for trial use?

10              Do you all understand it's not  
11       endorsement? It's just -- we're just getting  
12       good measures out in the field. Testing can be  
13       really difficult to get in these -- with these  
14       new measures.

15              So when you review these, you're going  
16       to review them against the entire criteria -- the  
17       only one part of scientific acceptability and  
18       that's Section 2b1, and that that's to determine  
19       if the measure specifications are consistent with  
20       the evidence. That's a must pass.

21              So you certainly really want to  
22       consider the evidence and performance, the

1 feasibility and usability in use.

2 And we -- you know, approval for trial  
3 use measures can be supported through a synthetic  
4 data set with a testing tool like Bonnie or from  
5 a single EHR. They just don't have enough  
6 information to satisfy our two EHR minimum for  
7 electronic clinical quality measures.

8 Ideally, these measures will come back  
9 to you while you are still here and during your  
10 term on the standing committee. They have three  
11 years they can be out in the field.

12 If the measure has not changed, then  
13 you'll just talk about the measure on a call and  
14 go back and vote on scientific acceptability, and  
15 we are starting to see some of our earlier  
16 approval for trial use measures when it was still  
17 a pilot program before we made it an official  
18 program.

19 We're starting to see these come back.  
20 Some of them have come back within six months  
21 with enough testing data and the measure isn't  
22 significantly different than the measure



1 originally discussed in the project.

2 So the committee is able to go ahead  
3 and vote on the complete scientific acceptability  
4 for endorsement.

5 Does anybody have any questions about  
6 trial approval?

7 CO-CHAIR TIRSCHWELL: So I'm trying to  
8 understand the difference between these legacy  
9 measures for which there's no actual data, and  
10 approval for trial use, for which there's also no  
11 data. How do you get from one to the other?

12 MS. PHILLIPS: Legacy measures are in  
13 use in federal programs. There is a previously  
14 endorsed claims version of this measure.

15 So we can't automatically endorse the  
16 electronic version because it uses different data  
17 elements. But essentially, it's the same  
18 measure.

Approval for trial use are  
19 new measures. They aren't in use in federal  
20 programs. They generally haven't had - they're  
21 usually measures that have been conceived  
22 relatively recently where legacy measures are

1 always paired with a claims version that's been  
2 previously endorsed.

3 MS. WATT: Sorry, just a point of  
4 technicality. These are not claims-based  
5 measures. These are chart-abstracted measures.

6 MS. PHILLIPS: But we use the claims  
7 data to generally identify the population and  
8 chart abstraction to go further with the  
9 legacies. But these are the electronically  
10 specified version. Are there any other questions  
11 about approval for trial use?

12 MEMBER BAUTISTA: Will you be going  
13 over Bonnie testing?

14 MS. PHILLIPS: We'll talk about it a  
15 little bit. Do you have any specific questions  
16 regarding Bonnie?

17 MEMBER BAUTISTA: Yeah, what is it?

18 MS. PHILLIPS: I'm glad you asked.  
19 Bonnie is a tool and it's used in measure  
20 development and what it allows you to do is  
21 create a synthetic data set of patients with  
22 various conditions and run the actual measure up

1       against those patients so you can identify who is  
2       in the measure and who is out of the measure,  
3       numerator, and denominator. You have the ability  
4       to specify ages, genders, give them conditions,  
5       set up timing. So the more complex the measure  
6       logic the more the complex patients you can  
7       develop. But it's not actual patients, so we  
8       consider it synthetic.

9               MEMBER BAUTISTA: And it's not an  
10       actual medical record.

11              MS. PHILLIPS: Absolutely not. It is a  
12       synthetic test patient.

13              CO-CHAIR KNOWLTON: Are there any other  
14       questions?

15              MS. PHILLIPS: Let's go back and talk  
16       about the hybrid measure. This is a combination,  
17       this is  
18       where you are using the claims data to identify  
19       the population, but technically the medical  
20       record data. And it's a brand new measure. It's  
21       what we call a de novo measure. So the committee  
22       should really look at all the information in

1 testing attachments and feasibility assessment in  
2 reviewing scientific acceptability. But this is a  
3 measure for full endorsement. It is a new  
4 measure. So, three types of measures. You've got,  
5 a new measure, a hybrid, approval for trial use  
6 and the legacy measures. Are there any other  
7 questions about eMeasures? Nope. Okay.

8 CO-CHAIR KNOWLTON: Thank you Ann. So  
9 we are going to move on to our next candidate  
10 measures and this 434 venous thromboembolism VTE  
11 prophylaxis. And I believe the discussants are  
12 going to be Valerie and Peter. Oh, I'm sorry,  
13 Joint Commission.

14 MS. WATT: Hi, my name is Ann Watt, and  
15 I'll start. This is one of a series of measures  
16 that we include in a measure set. And, I'm going  
17 to introduce Karen Kolbusz, my colleague, who is  
18 the clinical lead for this measure, and Karen  
19 will give you a summary of the measure.

20 MS. KOLBUSZ: Thanks, Ann. This is  
21 stroke one VTE thromboprophylaxis. This is a  
22 chart-based process measure. There isn't a

1 companion electronic measure for this particular  
2 measure.

3 This measure does capture the  
4 proportion of ischemic or hemorrhagic stroke  
5 patients who received VTE prophylaxis, or who  
6 have documentation why no VTE prophylaxis was  
7 given on the day of or day after hospital  
8 admission.

9 Excluded populations from the measure  
10 include those patients who are less than 18 years  
11 of age, patients who have a length of stay less  
12 than two days, or patients who have a length of  
13 stay greater than 120 days, patients who are  
14 documented comfort measures only on the day of or  
15 day after hospital arrival, patients who are  
16 enrolled in a clinical trial related to stroke,  
17 or patients who are admitted for elective carotid  
18 intervention.

19 The measure was originally endorsed in  
20 2012. Basically, the rationale for this measure  
21 is that stroke patients are high risk for VTE  
22 prophylaxis. Prophylactic therapies are

1 recommended, since this is one of the highest at-  
2 risk hospitalized patient groups. The Class 1  
3 level of evidence A recommendation is for  
4 pharmacological prophylaxis.

5           However, a lesser recommendation, a  
6 Class B recommendation, would be for mechanical  
7 prophylaxis, in the form of sequential  
8 compression devices or intermittent pneumatic  
9 compression devices, which may be used for  
10 patients when pharmacological therapies are  
11 contraindicated.

12           The measure is widely used, last  
13 endorsed in 2012. It is currently in use for  
14 Joint Commission hospital accreditation. It's  
15 also used in the Joint Commission's Disease  
16 Specific Care Stroke Certification programs for  
17 primary stroke centers and comprehensive stroke  
18 centers. It's used and collected by hospital  
19 quality reporting programs since 2013, and is  
20 also collected by the Paul Coverdell National  
21 Acute Stroke Registry.

22           CO-CHAIR KNOWLTON: Okay, thank you.

1 Valerie and Peter, who is presenting?

2 Peter.

3 MEMBER SCHMIDT: Yes. So we agreed I  
4 would do the play by play and Valerie would  
5 provide the color.

6 So, the -- I'll start with the  
7 evidence. So, this has been discussed -- this  
8 was passed before and so we are supposed to do an  
9 -- as I understand from the introduction, we are  
10 supposed to do an abbreviated discussion of the  
11 evidence.

12 The evidence for this measure is  
13 clearly good. The only quibble I have here is  
14 that all the evidence statements discuss  
15 immobilized patients, whereas -- as does the  
16 literature, I went back and looked at some of the  
17 papers on this, everything specifies immobilized  
18 patients, patients with restricted mobility. And  
19 yet, the definition of the measure requires -- it  
20 does restrict for mobility and it's not an  
21 exclusion. And, I was wondering if you wanted to  
22 explain that decision.

1 MS. KOLBUSZ: Patients who did not have  
2 restricted mobility could be excluded from the  
3 measure, based on a reason for no VTE prophylaxis  
4 hospital admission. It would have to be clearly  
5 documented since ambulation alone would not be  
6 considered a form of VTE prophylaxis.

7 But if the documentation supported  
8 that that's all that was required for that  
9 patient, then -- actually, we would not exclude  
10 the patient, I correct myself on that one. In  
11 this case we would include the case in the  
12 numerator population for this particular measure.

13 MEMBER SCHMIDT: I just want to add, I  
14 did actually go down to our stroke center and I  
15 asked them about this, and that's what they said,  
16 they said that it's an exclusion.

17 MS. KOLBUSZ: So, we'd give you credit  
18 for it, actually.

19 CO-CHAIR KNOWLTON: Jane.

20 MEMBER J. SULLIVAN: So, these  
21 exclusions came up on several other measures, and  
22 I know that it came up on one of our calls. Can



1       you just clarify the enrollment in any stroke  
2       trial and the 120 days, what that -- what the  
3       thinking is behind those as exclusions?

4               MS. KOLBUSZ: The enrollment for 120  
5       days is based basically on a CMS regulation. It  
6       has to do with billing practices, since the  
7       billing is quarterly and the measure is also  
8       collected by hospital and patient quality  
9       reporting, we wouldn't want to double bill if the  
10      patient was in the hospital for an extended  
11      period of time. That's the reason for the 120  
12      day exclusion.

13              The clinical trial is an exclusion,  
14      not only for this measure and this measure set,  
15      but many of the core measure sets. The thinking,  
16      basically, is that if the patient is enrolled in  
17      a clinical trial the usual therapy that would be  
18      recommended may not be followed for that patient,  
19      so we exclude those cases.

20              CO-CHAIR KNOWLTON: Peter.

21              MEMBER SCHMIDT: So, I just want to add  
22      I think that the clinical trial exclusion is a

1 very good one, because there will be a biased  
2 distribution of clinical trial enrollees  
3 depending on the hospital.

4 CO-CHAIR KNOWLTON: So, your  
5 recommendation on that measure?

6 MEMBER SCHMIDT: I'm going to go with  
7 the recommendation that's in all of your  
8 worksheets, it says high. I think that's  
9 probably --

10 MEMBER J. SULLIVAN: And, I would agree  
11 with that.

12 CO-CHAIR KNOWLTON: Any questions from  
13 the Committee? And we'll vote on it.

14 MS. OGUNGBEMI: We are now voting for  
15 Measure 0434 on evidence. The options are high,  
16 moderate, low and insufficient. Voting is open.

17 (Voting.)

18 MS. OGUNGBEMI: Voting is closed. The  
19 results are 78 percent high, 22 percent moderate,  
20 0 percent low, and 0 percent insufficient.  
21 Measure 0434 passes on evidence.

22 CO-CHAIR KNOWLTON: Okay, Peter, gap.

1           MEMBER SCHMIDT: So, on the gap, we see  
2           that this had been conducted and that the  
3           national aggregate rate on this score has gone  
4           from 88 percent to 97 percent, with the mean  
5           hospital rate going from 83 to 96 percent. At  
6           the 10th percentile, it went from 60 percent to  
7           91 percent, which is a pretty dramatic increase.

8           And notably, in calendar year 2013 the  
9           number of participating hospitals was 264, and in  
10          2014 it was 1,299; so over 1,000 hospitals joined  
11          the program without a meaningful decay in the  
12          rate of performance.

13          So, even though that's 1,299 is about  
14          23 percent of all hospitals nationally, it  
15          appears that hospitals that joined the program  
16          are already conforming to the specification. So,  
17          the preliminary rating for opportunity for  
18          improvement was low.

19          CO-CHAIR KNOWLTON: Comments? Valerie.

20          MEMBER COTTER: I would just like to  
21          make a comment in that if clinically we know that  
22          there's gaps related to disparities, especially

1 around ethnic minority persons, it just seems to  
2 me that we should continue the measure based on  
3 that point.

4 If the developer does not want to  
5 present that data, which I think it would be  
6 really interesting, and I think it would be a  
7 really important piece to add to this, that  
8 that's a reason why I think we should say that we  
9 should continue with this measure, even though we  
10 have a 97 percent participation rate.

11 MS. WATT: Hi. This was a --- and  
12 thanks for the comment, and this is an issue that  
13 came up during the work group calls. And, it's  
14 not that we are not interested in disparities at  
15 the Joint Commission. It's just that this  
16 measure was really not developed for that  
17 purpose.

18 We do collect race and ethnicity, that  
19 data element. We just don't slice the data that  
20 way ordinarily, and we didn't have it then at the  
21 time of the work group. And, actually, we have  
22 just within the last 20 minutes got it. We've

1       been having -- this is true we -- I know you  
2       don't want to hear our problems, but we are  
3       moving and our data center was having a difficult  
4       time getting us numbers.

5               But, I do have information that says  
6       overall if you break down these data in the  
7       aggregate, race doesn't seem to make much of a  
8       difference.

9               However, if you look at the individual  
10      hospitals, there are a significant proportion of  
11      hospitals that do have significant gaps based on  
12      the race and ethnicity. And for this particular  
13      measure it is 2.1 percent of the hospitals  
14      reporting have what our statisticians consider to  
15      be a significant gap.

16              CO-CHAIR KNOWLTON: Any questions on  
17      gap? Thoughts? Yes, Jim?

18              MEMBER BURKE: So, just one question on  
19      the temporal trend over time. Do we know how  
20      much of this is due to people changing  
21      documentation? Are these -- are there specific  
22      data on what got you into the numerator? Did you

1 receive the drug, or did you document the  
2 contraindication? Because I think that has some  
3 implications for whether or not the persistent  
4 gap -- how meaningful that is.

5 MS. WATT: We have those data.  
6 Honestly, I don't have the results and I can't  
7 tell you what it is. I'm guessing that there's,  
8 you know, a proportion attributable to both.

9 CO-CHAIR TIRSCHWELL: And so, if I am  
10 correct, this vote right here is the one where  
11 sort of the topped out issue is in play. And, I  
12 don't know whether we need to say that out loud  
13 or not. It's, I guess, something to keep in  
14 mind, that, you know, as it will be the case with  
15 a number of other measures that are very high  
16 performing, this is probably the place to  
17 consider whether we are there or not.

18 MEMBER COTTER: And, I think because  
19 the disparities data is lacking, that that is a  
20 really good argument that this measure needs to  
21 be continued in practical use.

22 CO-CHAIR KNOWLTON: Other comments on

1 gap? Alex.

2 MEMBER RAE-GRANT: Yes. Just so to  
3 understand the process, so if we do decide this  
4 is topped out as a measure, then what's the  
5 voting strategy and then what happens to the  
6 measure? Just to understand that process.

7 DR. TERRY: If the measure does not  
8 pass under gap, this measure would be eligible to  
9 move to the reserve status, and that means it's  
10 kept in the NQF portfolio as an endorsed measure,  
11 but it's not a measure we go back and review  
12 systematically, although we could review it at  
13 some point.

14 CO-CHAIR KNOWLTON: But what would  
15 knock it out is if the vote was insufficient, is  
16 that correct?

17 DR. TERRY: Did you say low and  
18 insufficient?

19 CO-CHAIR KNOWLTON: No, I said  
20 insufficient.

21 MS. JOHNSON: So, if the majority of --  
22 a large proportion of folks feel that the

1 information is insufficient, the measure would go  
2 down, and reserve status would not be an option.  
3 Okay?

4 With TJC saying that they have  
5 additional information, if you feel that it's --  
6 what Ann has told you verbally is compelling, I  
7 think we would probably -- and we could talk  
8 about this, but I think we would probably want to  
9 continue on. But, we'd really, I think, want to  
10 see your data, Ann, and I know it's hot off the  
11 press, but we'd probably want to be able to see  
12 it.

13 If it turned out that that was enough  
14 to flip you from being topped out to not being  
15 topped out, which the disparities could do that,  
16 we would, actually, ask Ann to go back and update  
17 the submission so that goes on the record, you  
18 know, for next time around.

19 CO-CHAIR KNOWLTON: But, Karen,  
20 practically, I'm trying to understand, if we vote  
21 and we vote, what knocks it out, just  
22 insufficient or low and insufficient?



1 MS. JOHNSON: Low and insufficient  
2 together would knock it out --

3 CO-CHAIR KNOWLTON: Okay.

4 MS. JOHNSON: -- but they would have  
5 different sequelae.

6 DR. TERRY: So, for it to move to  
7 reserve, all the other criteria would have to  
8 pass.

9 CO-CHAIR KNOWLTON: So, my question  
10 goes -- well, go ahead, Peter, then I have a  
11 question for him.

12 MEMBER SCHMIDT: Well, I just want to  
13 say, and as I went through this I said that the  
14 recommendation from the primary was low. I think  
15 based on the fact that we now have some insight  
16 that there is additional data that is not on --  
17 in the record, that that should probably be  
18 insufficient, because we are aware of something  
19 but it's not included.

20 Is that right? Is that an appropriate  
21 interpretation of the intent? But does their  
22 verbal presentation of a small amount of what

1 seems like anecdotal data based on the relatively  
2 small ends reported, does that constitute  
3 evidence that we can use to adjust our  
4 assessment, or should we be basing it on -- it  
5 feels like an anecdote.

6 CO-CHAIR KNOWLTON: Karen?

7 MS. JOHNSON: Yes, and it's a difficult  
8 question, and I want to do that awful thing and  
9 pass it on to Elisa.

10 MS. MUNTHALI: So, what you're voting  
11 on is the measure as it is currently specified.  
12 But what we can do is work with the Joint  
13 Commission during the commenting period, have  
14 them update their form, during the post-comment  
15 call for the comment period; you can reconsider  
16 your vote.

17 So, that was a good question. The  
18 Joint Commission does have information, but we'd  
19 like to get more specificity on what that  
20 information is. But, just as a reminder, the  
21 measure that's in front of you.

22 CO-CHAIR TIRSCHWELL: And, there's no

1 option for tabling the vote until the next call  
2 or anything like that, so we can review this  
3 evidence?

4 MS. MUNTHALI: In essence, if you voted  
5 right now and there's a reconsideration request  
6 from the Joint Commission, you'd be revoting  
7 during that post-comment call. That's just our  
8 standard process.

9 CO-CHAIR KNOWLTON: Jocelyn.

10 MEMBER BAUTISTA: So, I thought when  
11 Peter was presenting I heard you mention that  
12 this only encompasses about 20-some percent of  
13 the hospitals nationwide, right? Some 1,200  
14 hospitals, and most of them most likely have  
15 Joint Commission stroke certification. So, they  
16 are actively trying to improve these metrics.

17 So, I think the gap then needs to be  
18 taken -- needs to take that into account. We are  
19 looking at the highest performing hospitals, and  
20 it's only 20 percent of the hospitals nationwide  
21 who could, potentially, be treating stroke  
22 patients.

1 CO-CHAIR KNOWLTON: Peter?

2 MEMBER SCHMIDT: So, the interesting  
3 point I think is that over 1,000 hospitals joined  
4 the program without significantly degrading the  
5 average results.

6 So, as the measure is expanding, we  
7 are not seeing evidence of an overall gap,  
8 although we have some suggestion that there's  
9 some -- that there's a gap in the result  
10 findings.

11 I mean, I kind of feel like if this  
12 isn't topped out, what is topped out?

13 MEMBER BAUTISTA: But, don't you still  
14 think the majority of those hospitals have Joint  
15 Commission stroke certification, and are --

16 MEMBER SCHMIDT: I take your statement  
17 that they probably do. So --

18 CO-CHAIR KNOWLTON: Ketan?

19 MEMBER BULSARA: Sorry. Something I  
20 don't understand, so just more for my  
21 understanding.

22 So, clearly, sort of this measure

1 seems to have tracked the fact that the gap has  
2 definitely decreased. So, back in 2010 it was  
3 endorsed. So, why -- again, I don't understand  
4 this process, I just want to ask it -- why would  
5 we not continue to -- even though you are right  
6 that there isn't much more gap for improvement,  
7 why would we not continue to endorse this measure  
8 with the concern that if we decide not to endorse  
9 it that we might see an attrition in terms of  
10 hospitals reverting back to what they were doing  
11 before. So, why would we not continue to endorse  
12 it?

13 CO-CHAIR TIRSCHWELL: You know, I  
14 think if you think it's still an important  
15 measure, but it's topped out, I think that's the  
16 reserve status thing where you are still  
17 endorsed, but then I don't actually know what  
18 else the difference is, quite honestly, other  
19 than we stop measuring it?

20 DR. TERRY: That is why we have  
21 endorsed status -- reserve status I mean, that if  
22 it's topped out it can go -- it is still there at

1 NQF in the portfolio, but it's not a measure that  
2 we routinely go back and look at, but we can.

3 CO-CHAIR KNOWLTON: Is that responsive  
4 to you, Ketan?

5 MEMBER BULSARA: So, if it goes into  
6 the reserve, then that means it's no longer  
7 actively endorsed, or it's --

8 MS. JOHNSON: So, it is still endorsed,  
9 and we actually have a reserve status policy that  
10 we can bring up and let you know. But, the idea  
11 would be that it's still there, the NQF still  
12 sees that it is a good measure, but the idea  
13 that, you know, if you feel that it's topped out  
14 that maybe it doesn't really still need to be  
15 used in the field, because, you know, there's  
16 opportunity costs for collecting data, et cetera.

17 So, being on reserve status signals to  
18 the field that it's still important, it still  
19 meets our criteria, but it would not be looked  
20 again through our maintenance process. So, it's  
21 just kind of there on the shelf if, in fact,  
22 performance at some point did deteriorate,

1 anybody who wants to could come back to say,  
2 let's get it off the reserve list, let's pull it  
3 back and look at it again to see if the gap  
4 actually has decreased.

5 So, that would be -- and at least --  
6 am I portraying the reserve status, I don't have  
7 it right in front of me.

8 MS. MUNTHALI: You are, and the other  
9 piece of that is as a standing committee you have  
10 oversight of the neurology portfolio. So, this  
11 is a measure that you might want to go back to as  
12 experts, knowing that performance and  
13 opportunities for improvement may be changing  
14 from the time that you last saw it now.

15 So, it's not like it goes into a  
16 closet and we never look at it again. We are  
17 just signaling, as Karen said, that this is still  
18 a good measure, but based on the information that  
19 we have and the data that we have, there are very  
20 few opportunities to improve. The performance  
21 gaps are not really there.

22 CO-CHAIR KNOWLTON: Melody.

1                   MEMBER RYAN: So, slightly related --  
2                   or pretty much related to this discussion. I'm  
3                   trying to understand like the practical  
4                   implications. Does this mean that institutions  
5                   will no longer monitor this? I would think they  
6                   would be monitoring it still for Joint  
7                   Commission.

8                   CO-CHAIR KNOWLTON: I think what this  
9                   is looking towards -- and NQF staff correct me if  
10                  I'm wrong -- but I think what happens is there is  
11                  a wide universe of measures people can measure.  
12                  So, as performance -- the question is even asked,  
13                  you know, does this warrant a national  
14                  performance measure, or have we gotten to a point  
15                  where it's pretty much adhered to and we can turn  
16                  our attention to something else where we can see  
17                  genuine improvements. That's really the issue --  
18                  -

19                  (Simultaneous speaking.)

20                  MEMBER RYAN: Sure, and I could see  
21                  institutions, like, you know, the extractors and  
22                  whatever, I mean those people cost money. So,



1       you know, if they don't have to do it or don't  
2       want to do it, they can shift to another measure.  
3       And, it's clear that having these drives  
4       performance. So, I just want to make sure --

5               CO-CHAIR TIRSCHWELL: Yes. I think,  
6       just to clear up the role, the NQF is to endorse  
7       or not, put on reserve. The decision about which  
8       measures are active or not, via the Joint  
9       Commission, is the Joint Commission's decision.

10              So, it might be a signal to them that  
11       they might want to consider refocusing efforts  
12       elsewhere, but I don't think it's a mandate to  
13       take it off the list in any way.

14              CO-CHAIR KNOWLTON: Jane?

15              MEMBER J. SULLIVAN: I guess I have a  
16       follow-up question to Melody's. If a measure is  
17       on this reserve list, is that the -- is topping  
18       out the only reason that a measure would go on  
19       the reserve list or how is it publicly  
20       communicated why it ends up there? That's one  
21       question.

22              And then my second question is, is

1 part of our concern to have a parsimonious list?  
2 I mean, is that something that we could -- we  
3 aren't going to measure everything, and that we  
4 are wanting to have a hierarchy of measuring  
5 those things for which we get the most bang for,  
6 you know, quality improvement.

7 DR. TERRY: So, it is the only reason  
8 to go into the reserve status, topping out.

9 And, yes, that's the call to have a  
10 parsimonious list of measures that are the most  
11 effective.

12 CO-CHAIR KNOWLTON: Peter?

13 MEMBER SCHMIDT: So, I just want to --  
14 based on the evidence that we've seen, we run the  
15 risk of declaring that average is exemplar. And,  
16 I think that that's -- that would be a  
17 distraction for people who are involved in  
18 quality improvement, is to think that a benchmark  
19 that we've hit is still a benchmark quality.

20 And second, you know, the panel and  
21 all of us only have so much mind share that we  
22 can put to things. And, if we focus on things

1 where we don't have evidence of a gap, it would  
2 wind up being a distraction to future  
3 measurements.

4 And third, it is a very powerful to be  
5 able to declare victory on something. If we  
6 said, this was endorsed in the past and look at  
7 the dramatic improvement, then that is a win. It  
8 is not a loss to retire a measure because we've  
9 achieved a level of success with it.

10 CO-CHAIR KNOWLTON: Valerie?

11 MEMBER COTTER: If however the  
12 developer is acknowledging a gap in the evidence,  
13 missing data related to racial and ethnic  
14 minorities. I have an issue about that. It  
15 seems like the data is there, and why is it not  
16 being presented?

17 CO-CHAIR KNOWLTON: I think those are  
18 good questions, but we don't have the answer to  
19 that, you know? So, we have to vote on what's  
20 before us. But, I agree, as this gets brought  
21 back, that's a question that we should ask.

22 It's not --- we don't have the data,

1 that was Peter's earlier point, we don't have the  
2 -- we just have anecdotal. David.

3 CO-CHAIR TIRSCHWELL: I was just going  
4 to say, using my crystal ball it sounds like we  
5 will be voting on this one again sometime in the  
6 not too distant future. So, even if it does get  
7 retired today, the new data on gaps may bring it  
8 back into the fold. So, we'll have to see.

9 CO-CHAIR KNOWLTON: Follow up, Valerie.

10 MEMBER COTTER: So, where is the push,  
11 if you will, or who makes that recommendation  
12 that we need this data to move this forward in  
13 the future?

14 CO-CHAIR KNOWLTON: The steering  
15 committee doesn't -- the steering committee  
16 doesn't develop measures, developers do, but  
17 developers are clearly listening to what the  
18 steering committee -- believe me, they listen to  
19 what you say.

20 So, my hunch is that we will hear from  
21 this again. Ketan?

22 MEMBER BULSARA: You know, like Peter

1 and Jane and Valerie pointed out, we get to look  
2 at the additional data, but in addition to that,  
3 to what Peter was saying in the sense that this  
4 is something that we are declaring a victory on.  
5 Like with any victory I think you have to  
6 understand what it is that is going to safeguard  
7 that victory.

8 So, I think if we retire a measure as  
9 important as thromboembolism prevention, I think  
10 we have to have a better understanding of what is  
11 in place -- not our policy, but what policies  
12 have been influenced that will safeguard this  
13 very, very important metric. So, I think that  
14 would be useful information.

15 CO-CHAIR KNOWLTON: Charlotte? Comment  
16 into your mic.

17 MEMBER JONES: People have talked about  
18 the fact that we have a portfolio to manage.  
19 Many of us got 48 hours to review our measures.

20 We are a limited resource. If we  
21 don't retire measures that we feel have been  
22 successfully met, and if our -- then for the next

1 two to three years, and then our colleagues  
2 following, we are going to create a situation  
3 where we -- as was previously mentioned, we can't  
4 do the work that we need to do.

5 So, I think to say that this is ready  
6 for retirement is not saying that we don't think  
7 it is valid and important, it's saying we've seen  
8 improvement. We don't see a gap right now, it's  
9 not going away if someone publishes in three  
10 months or a year that there is a bigger gap  
11 involving hospitals that don't have joint  
12 accreditation, then it's still there for us to  
13 pull it back.

14 But it means that we are not reviewing  
15 it a year from now before this meeting and  
16 spending the time on it.

17 CO-CHAIR KNOWLTON: I have a comment on  
18 this myself as well, not just to share the  
19 measure.

20 But before I retired I was a quality  
21 advocate. And, there's a lot of people going to  
22 track these measures and what happens to them.

1       What the NQF steering committee is asked to do is  
2       to set a very high, ongoing bar that people have  
3       to keep aspiring to, to get continuous  
4       improvement in quality in America, and to retire  
5       things that say we've done that one, let's move  
6       on.

7               Nobody -- I hope the advocacy  
8       community -- maybe since I've retired there  
9       aren't anymore, but hopefully, the advocacy  
10      community is going to say -- if this starts to  
11      slip, they are going to say, what's going on  
12      here? But if the measure has been identified,  
13      people are tracking it. What steering committees  
14      are asked to do is the hard test of continuing to  
15      push that envelope and that's a very important  
16      role.

17              And, you are exactly right, we need to  
18      -- and Charlotte's point -- we need to be  
19      attending to those variables, and it's a tough  
20      task.

21              So, it's easy to sit back and say,  
22      this is wonderful; we don't want to lose it. We

1 won't lose it, but that's not what we are being  
2 asked to do. We are being asked to keep pushing  
3 that bar forward, as I see it.

4 Charlotte, are you still commenting or  
5 are you done? Ketan.

6 MEMBER BULSARA: I'm in total agreement  
7 with what Charlotte said. Just, you know, I have  
8 these visions of where, you know, if declared  
9 victory everything is done, and then you go away.

10 And so, I think that you are right, we  
11 have very limited resources in terms of human  
12 hours, but I think it would be important, at  
13 least from my perspective, to understand how this  
14 has been implemented in policies that are  
15 independent of -- how the endorsement by NQF was  
16 incorporated into a policy that is being enforced  
17 independently by an organization.

18 I don't think this needs to be  
19 reviewed like annually or biannually, or how  
20 often that's done, but I do think we have to  
21 understand what is it -- what's in place that  
22 will ensure that there's not a regression or



1 attrition in this measure down the road and I'm  
2 sure there are policies out there that have  
3 always been incorporated, based on the previous  
4 endorsements, otherwise we wouldn't see such a  
5 high sort of conformity to the measure.

6 CO-CHAIR KNOWLTON: Alex?

7 MEMBER RAE-GRANT: You know, I know we  
8 are taking the time now to get the process issues  
9 behind us, so one thing is one of the issues with  
10 the potential gap is the racial-ethnic potential  
11 gap we don't know the evidence on.

12 A question for you guys is do you  
13 think about racial-ethnic makeup of your panels,  
14 as you constitute them, and should that going  
15 forward be something to be considered.

16 CO-CHAIR KNOWLTON: Well, that's a  
17 question for NQF. Go ahead.

18 CO-CHAIR TIRSCHWELL: So just -- as we  
19 move to a vote, I just want to be sure I  
20 understand this. Assuming everything else would  
21 pass, a vote of low would likely move this  
22 towards the reserve list, but a vote of

1       insufficient would drop it to unendorsed. Is  
2       that right? Or, do I have that wrong?

3               MS. JOHNSON: No, you are almost right.

4               CO-CHAIR TIRSCHWELL: That's where I  
5       usually live.

6               MS. JOHNSON: It depends. My favorite  
7       answer is it depends.

8               If you land on low, then you'll get a  
9       chance to decide if you want to do reserve. And,  
10      that will be kind of a gestalt, we won't make you  
11      vote on reserve or not, but it's where you want  
12      to go.

13              If it goes insufficient, then  
14      technically, it would not pass. Okay?

15              But, with that, we have heard the  
16      Joint Commission has additional data that we  
17      would encourage them, and I think they would be  
18      willing to bring, so that you could consider it  
19      again.

20              So, with that in mind -- with both of  
21      those things in mind, we would still need to go  
22      through the rest of the evaluation of this

1 measure, because even if it went reserve status  
2 it has to have passed everything else, right? We  
3 have to check that.

4 If it turns out that they bring  
5 something to you later, if you landed on  
6 insufficient, we don't want to spend that call  
7 doing all the measure. We could go ahead and do  
8 everything else but that, and then revisit that  
9 again at post-comment.

10 So, did that answer your question with  
11 my it depends?

12 CO-CHAIR KNOWLTON: So, if the vote was  
13 ---

14 MEMBER FERZIGER: It's actually you  
15 that I want to hear from, because I understand  
16 and actually strongly agree with the principle  
17 you espoused. So, based on that principle, how  
18 are you going to vote in this system on this  
19 question for this measure?

20 CO-CHAIR KNOWLTON: Well, let me ask  
21 my question first. I still am confused about the  
22 insufficient because I thought insufficient says

1 we would not go to reserve status. That blocks  
2 reserve status, and the vote of low leaves that  
3 open, is that correct?

4 MS. JOHNSON: You are correct. So,  
5 what we need to do is vote and see where we land  
6 --

7 CO-CHAIR KNOWLTON: So, if we vote ---  
8 if you vote for insufficient we are done, we move  
9 on.

10 MS. JOHNSON: We would --

11 CO-CHAIR KNOWLTON: That's what you  
12 waffled on, and I don't think it's -- I don't  
13 think that's --

14 MS. JOHNSON: So, what we will do is if  
15 it lands on insufficient, we will continue to  
16 discuss this measure anyway.

17 CO-CHAIR KNOWLTON: Why?

18 MS. JOHNSON: Because we know that TJC  
19 has some additional data that you haven't been  
20 able to look very closely at. So, the play off  
21 would be, we would have you do that full  
22 discussion post comment, or go ahead and do it

1 now. We have more time today than we do on a  
2 phone call later, so we would have you do  
3 everything else. It would still go out in our  
4 report. If it lands on insufficient, it would go  
5 out as not recommended for endorsement, right?  
6 But you could reconsider that at post comment.

7 I do realize this is confusing. It  
8 might be more -- it might be easier if you voted  
9 first. We'll see where you think you are in  
10 terms of is there a gap, because there might be  
11 enough information here for you guys to decide  
12 that there's not a gap. I mean, I'm not hearing  
13 that, but there might be a few here.

14 CO-CHAIR KNOWLTON: In answer to your  
15 question, I don't think there's a gap. I would  
16 vote insufficient.

17 I do believe that we should move this,  
18 and if there is new information then I would  
19 consider it then. Yes?

20 MEMBER J. SULLIVAN: I guess I'm a  
21 little confused where -- I think what we are  
22 being asked to do is vote on the definitions of

1 low, insufficient, but the conversation kind of  
2 seems like we are voting on what should happen.

3 And I think those may be two different  
4 things. The vote would dictate what would  
5 happen, but we are asked to vote based on how  
6 much of a gap there is, right?

7 MS. JOHNSON: So, looking at the  
8 information in front of you, and hearing what  
9 you've heard the Joint Commission telling you  
10 about additional information, I think you should  
11 vote first on gap.

12 Once we have your votes, then we will  
13 talk about reserve or something else. Okay?

14 CO-CHAIR KNOWLTON: Peter?

15 MEMBER SCHMIDT: I just -- can we put  
16 up the answer because as far as I understand it,  
17 the question is is there evidence of an  
18 opportunity for improvement? And there certainly  
19 is ample evidence that shows -- that seems to me  
20 to show no opportunity for improvement.

21 So, there's plenty of evidence, it's  
22 not insufficient evidence; it's insufficient

1 opportunity. And we anticipate that the future  
2 is going to bring evidence of an opportunity, but  
3 we have not seen that in a way that we can  
4 critically assess it.

5 MS. JOHNSON: This is where this  
6 becomes your decision on how you want to vote.  
7 You could take what's in front of you and land on  
8 low, given the percentages in front of you. You  
9 could also take Ann's statement that they have  
10 additional information that you haven't had a  
11 chance to see. And, you could interpret that as  
12 not having enough information to make your final  
13 decision.

14 So, it really depends on whether you  
15 think you have enough information to make that  
16 final call, and that's how you would vote.

17 CO-CHAIR KNOWLTON: Are you ready for  
18 a vote? Go ahead, Charlotte.

19 MEMBER JONES: Can you restate what we  
20 are voting on?

21 MS. MUNTHALI: I guess the measure as  
22 it's currently specified, the submission in front

1 of you.

2 CO-CHAIR KNOWLTON: Right. Anything  
3 else on discussion? Okay, we are ready for the  
4 vote.

5 MS. OGUNGBEMI: We are now voting on  
6 performance gap for measure number 0434. The  
7 options are high, moderate, low and insufficient.  
8 Voting is open.

9 (Voting.)

10 MS. OGUNGBEMI: Results are in. They  
11 are 0 percent high, 9 percent moderate, 52  
12 percent low, and 39 percent insufficient.

13 MS. JOHNSON: So, let me interpret this  
14 scenario that I hadn't thought about because --  
15 basically what we have is almost a split between  
16 low and insufficient. So, that puts us in a grey  
17 zone, quite frankly, as to what we want to do.  
18 Okay?

19 So what we will do is we will put this  
20 out in our report as consensus not reached,  
21 because we haven't completely -- and Elisa, if  
22 I'm saying this wrong tell me -- it hasn't



1 completely died, but it also hasn't completely  
2 gone towards the discussion about reserve status.

3 So, what we will do is put it out as  
4 consensus not reached. Joint Commission will  
5 have the ability to bring more in front of you at  
6 post-comment call and you will have a chance to  
7 rethink and revote.

8 In the meantime, we will go on to the  
9 next criterion, reliability. And let me stop  
10 there, see if Marcia and Elisa agree with my  
11 interpretation of our regs.

12 MS. MUNTHALI: Yes, we agree.

13 (Laughter.)

14 MEMBER SCHMIDT: So, the next section  
15 is reliability. I just want to start out by  
16 saying I bet that if you did a yes/no vote,  
17 should reserve status be available for this  
18 measure, you'd get a 90 to 100 percent yes. So,  
19 I think there is a consensus, we are just  
20 confused about how we signal that.

21 MS. JOHNSON: And we can put that in  
22 the report as well.

1                   MEMBER SCHMIDT: On reliability, this  
2 has been used extensively. We've looked at the  
3 data. I think there's a lot of face validity to  
4 the fact that this is a reliable measure.

5                   We could probably go through this  
6 pretty quickly. The preliminary rating  
7 recommendation was moderate, which probably still  
8 stands. Do we want to go into more detail about  
9 reliability?

10                  CO-CHAIR KNOWLTON: Unless there are  
11 questions. Jim?

12                  MEMBER BURKE: One quick one, which is  
13 it seems to me like the tricky part here is this  
14 documentation of did not receive, or had a reason  
15 for refusal or didn't actually -- people who are  
16 in the numerator, but did not actually receive  
17 the medication. I couldn't find specific  
18 reliability testing on that. That seems to me to  
19 be the hardest part to determine reliability.

20                  MEMBER SCHMIDT: Yes, I agree with  
21 that. It slipped my mind to mention that. I  
22 totally agree with you.

1 CO-CHAIR KNOWLTON: Does the developer  
2 have a comment on that, or question?

3 MS. KOLBUSZ: I think it's how we  
4 collect our data being that it's included in the  
5 numerator, we aren't breaking it out for  
6 reliability because we are giving credit in the  
7 numerator. We'd have to go back; we do have  
8 patient level data so we have data for the data  
9 element.

10 So, we'd have to go back and  
11 specifically look at the breakout of how many  
12 included in the numerator wound up in the  
13 numerator because of that particular data  
14 element, the reason for no VTE prophylaxis. So,  
15 I think it's possible to get it, but it's not  
16 typically how we report reliability. We look at  
17 the exclusions.

18 CO-CHAIR KNOWLTON: Any other questions  
19 or comments on reliability? We move to the vote.

20 MS. OGUNGBEMI: We are now voting on  
21 reliability for measure 0434. The options are  
22 high, moderate, low and insufficient. Voting is

1 open.

2 (Voting.)

3 MS. OGUNGBEMI: Voting is closed. The  
4 results are 26 percent high, 70 percent moderate,  
5 4 percent low, and 0 percent insufficient.  
6 Measure 0434 passes on reliability.

7 CO-CHAIR KNOWLTON: Okay, Peter.

8 MEMBER SCHMIDT: So, on validity, the  
9 validity testing has been assessed. I assume  
10 that there's a typo in the validity testing  
11 results, where the decimal point on the P value  
12 is in the wrong place, because it says .1 and I  
13 believe it's 0.001. If -- given that, I think  
14 it's a quite valid measure.

15 They include here data on frequency  
16 exclusions. I noted that I don't see patient  
17 mobilized early listed in there, so that's one  
18 that I have an interest in, but I'm interested in  
19 seeing results on that.

20 But otherwise, the -- in the  
21 preliminary call the assessment was that this was  
22 highly valid.

1 CO-CHAIR KNOWLTON: Comments or  
2 questions? Ready for a vote.

3 MS. OGUNGBEMI: We are now voting on  
4 validity for measure 0434. The options are high,  
5 moderate, low and insufficient. Voting is open.

6 (Voting.)

7 MS. OGUNGBEMI: Voting is closed. The  
8 results are 78 percent high, 22 percent moderate,  
9 0 percent low, and 0 percent insufficient.  
10 Measure 0434 passes on validity.

11 CO-CHAIR KNOWLTON: Feasibility.  
12 Peter.

13 MEMBER SCHMIDT: So again, we have  
14 quite a bit of face validity on feasibility as it  
15 is being implemented in 23 percent of U.S.  
16 hospitals. So, I don't see anything that would  
17 suggest that this is a difficult or infeasible  
18 measure.

19 The preliminary rating for feasibility  
20 was moderate. I would give it a high rating.

21 CO-CHAIR KNOWLTON: Questions?  
22 Comments? Ready for a vote.

1 MS. OGUNGBEMI: We are now voting for  
2 feasibility on measure 0434. The options are  
3 high, moderate, low and insufficient. Voting is  
4 open.

5 (Voting.)

6 MS. OGUNGBEMI: Voting is closed. The  
7 results are 74 percent high, 26 percent moderate,  
8 0 percent low and 0 percent insufficient.  
9 Measure 0434 passes on feasibility.

10 CO-CHAIR KNOWLTON: Usability?

11 MEMBER SCHMIDT: So on usability, this  
12 -- in the past year this was used 213,000 times,  
13 so it seems pretty usable. And, the  
14 recommendation was high.

15 CO-CHAIR KNOWLTON: Great. Great  
16 summary. Any comments? Questions? Let's vote.

17 MS. OGUNGBEMI: We are now voting on  
18 usability and use in measure 0434. The options  
19 are high, moderate, low and insufficient. Voting  
20 is open.

21 (Voting.)

22 MS. OGUNGBEMI: Voting is closed.

1 Results are 91 percent high, 9 percent moderate,  
2 0 percent low, 0 percent insufficient. Measure  
3 0434 passes on usability.

4 CO-CHAIR KNOWLTON: Okay. Do you want  
5 to go back to -- I hate that word, reserve  
6 status?

7 MS. JOHNSON: Let's reserve reserve  
8 status until later. You knew I was going to make  
9 you do that Dave.

10 No, what we will do, since it was  
11 consensus not reached I think we should wait to  
12 see what Joint Commission has for you.

13 Depending on what they give you, you  
14 may decide moderate, in which case the whole  
15 question about reserve status kind of goes away  
16 anyway, right? So, it kind of depends on what  
17 they give you. So, we will hold off.

18 CO-CHAIR KNOWLTON: Okay, without  
19 objection then we will be moving on to the next  
20 measure. Which is --- yes, Peggy, you're trying  
21 to get my attention.

22 DR. TERRY: I just want to let

1 everybody know, so the next measure, 0435, is  
2 really different than the measure we just looked  
3 at in that there is a companion eMeasure attached  
4 to it. Or a separate measure, but it will --  
5 whatever we vote on will affect the eMeasure.  
6 So, I just wanted to make sure you are aware that  
7 it's different than the measure we just looked  
8 at.

9 CO-CHAIR KNOWLTON: Everybody okay with  
10 that? Any questions? It's what we talked about  
11 before, if the primary measure fails then the  
12 eMeasure fails.

13 Okay, this is Dorothy and David. I  
14 don't know who is presenting. It looks like  
15 David is going for the mic.

16 MEMBER HACKNEY: I think I'm to  
17 present.

18 So, as discussed, this is the old  
19 measure on which the eMeasure is based. So, I  
20 think the plan is to go through this in a little  
21 bit of detail, and then for the eMeasure only  
22 talk about things that are eMeasure specific,



1 because most of the data comes from this measure.

2 This is 0435 Discharged on  
3 Antithrombotic Therapy. It tries to capture the  
4 portion of ischemic stroke patients who were  
5 either provided antithrombotic therapy at  
6 hospital discharge, or for whom it was documented  
7 that such treatment would be inappropriate.

8 CO-CHAIR KNOWLTON: David, before you  
9 go on, I went out of order here. I'd like to  
10 hear from the developer first, the Joint  
11 Commission wanted to comment. Excuse me for  
12 interrupting you, but I'd like to -- if you would  
13 like to comment on it, Karen.

14 MS. KOLBUSZ: Yes, thank you. This  
15 is STK-02, which is Discharge on Antithrombotic  
16 Therapy. It is a secondary prevention measure.  
17 Antithrombotic therapy is found to have benefit  
18 in preventing mortality and reducing mortality/  
19 morbidity in ischemic stroke patients.

20 As the other measures, it was endorsed  
21 last in 2012. It's widely used in the Joint  
22 Commission certification, and the Hospital

1 Inpatient Quality Reporting program, and in the  
2 Paul Coverdell National Acute Stroke Registry.

3 The exclusions for this measure are  
4 slightly different than the last measure, because  
5 it is a discharge measure. This measure also  
6 excludes patients who are less than 18 years of  
7 age, patients who have a length of stay that are  
8 greater than 120 days, patients with comfort  
9 measures only documented, patients enrolled in a  
10 clinical trial related to stroke. Also patients  
11 that would be admitted for elective carotid  
12 intervention, as well as several discharge  
13 disposition on types of the exclusions,  
14 specifically, patients discharged to another  
15 hospital or who left against medical advice, as  
16 well as those patients who expired, patients who  
17 were discharged to home for hospice care, or  
18 patients discharged to a healthcare facility for  
19 hospice care.

20 And then, in this case there is a  
21 reason data element, which allows exclusion for  
22 patients with a documented reason for not

1       prescribing antithrombotic therapy at discharge.

2               Now, during the workgroup discussions,  
3       there were several comments regarding the high  
4       percentage of patients that were reported who  
5       were discharged to home with hospice care. I  
6       don't know if the Committee would like us to  
7       address that, or if we should wait until another  
8       point for discussion.

9               CO-CHAIR TIRSCHWELL: You guys sent us  
10       data that we have in front of us, David, are you  
11       going to review that briefly when you go through  
12       things?

13              MEMBER HACKNEY: I could, but I think  
14       it would make sense for you to do it.

15              CO-CHAIR TIRSCHWELL: Me, or --

16              MEMBER HACKNEY: For the -- no, the  
17       developer, I'm sorry.

18              CO-CHAIR TIRSCHWELL: Yes, okay.

19              MS. KOLBUSZ: Okay, very good. So, the  
20       workgroup had pointed out to us that during the  
21       workgroup discussions that there were a high  
22       percentage of patients that were excluded, based

1 on that exclusion for patients discharged to home  
2 for hospice care.

3 Patients discharged to home for  
4 hospice care are excluded from several of the  
5 stroke measures. Basically, this is detected by  
6 the discharge disposition data element, which has  
7 multiple allowable values, eight in total.  
8 Allowable value number two is hospice home, and  
9 that's used to exclude those patients who are  
10 discharged to home with hospice care.

11 Looking back and reevaluating the data  
12 that was originally recorded, we found that there  
13 had been an error in loading data into the data  
14 warehouse. Therefore, other data discharge  
15 disposition values were being incorrectly  
16 counted, along with the allowable value two,  
17 which led to us reporting a very high count for  
18 this particular measure.

19 So, in the original data which was  
20 resubmitted to this workgroup for consideration,  
21 we did have an overall percentage of exclusion  
22 reported as 52.2 percent. However, when it was

1 recalculated to only focus on allowable value  
2 two, discharged to home for hospice care, the  
3 actual exclusion was 1.29 percent of patients.

4 MS. SKIPPER: And, you all do not have  
5 a copy of that in front of you, but it is  
6 available on SharePoint on our home page under  
7 General Documents. And, this information was  
8 received Friday afternoon, and we posted it this  
9 morning, TJC Response under General Documents.

10 CO-CHAIR KNOWLTON: David, do you want  
11 to pick up from here?

12 MEMBER HACKNEY: So, this is -- as we  
13 were saying, this is a measure that's been around  
14 for a while. Therefore, it's a maintenance  
15 measure.

16 There's not new evidence about the  
17 value of the underlying practice that it's  
18 attempting to address, which is discharging  
19 appropriate patients on antithrombotic therapy.  
20 There's good evidence that this -- doing that  
21 reduces subsequent stroke mortality and  
22 morbidity.

1           There are some questions about the --  
2   how should I say, how well it captures the  
3   variety of reasons that one -- a patient might be  
4   appropriately excluded. So, I will talk about  
5   that.

6           I think the major issue lies in the  
7   opportunity for improvement. There is evidence  
8   submitted in the measure that --

9           CO-CHAIR KNOWLTON: Let me interrupt  
10   you there. Let's vote on that in order. Let's  
11   deal with evidence first.

12          MEMBER HACKNEY: All right.

13          CO-CHAIR KNOWLTON: And what your  
14   committee recommendation was was high, isn't that  
15   correct?

16          MEMBER HACKNEY: Yes.

17          CO-CHAIR KNOWLTON: Comments on  
18   evidence? Okay, ready for a vote.

19          MS. OGUNGBEMI: We are now voting on  
20   evidence for measure 0435. The options are high,  
21   moderate, low and insufficient. Voting is open.

22          (Voting.)

1 MS. OGUNGBEMI: Voting is closed. The  
2 results are 91 percent high, 9 percent moderate,  
3 0 percent low, and 0 percent insufficient.  
4 Measure 0435 passes on evidence.

5 CO-CHAIR KNOWLTON: Okay, David, gap.

6 MEMBER HACKNEY: Okay. Opportunities  
7 for improvement. There was evidence in the past  
8 that the compliance with this measure was not as  
9 high as one might hope. The most recent data  
10 included in the measure was 98 percent of -- for  
11 the 10th percentile rate of compliance, so that  
12 essentially, there is a compliance approaches 100  
13 percent. There's very little room for  
14 improvement, and given the concerns about whether  
15 absolutely everyone who was marked as should have  
16 been is appropriately marked as should have been,  
17 even that 98 percent might actually be 100  
18 percent of the true group of people who should  
19 have been given the antithrombotic.

20 The other thing that's part of this is  
21 evidence of disparities. There are data --  
22 certainly, there are disparities in stroke risk.

1 There's also summarized in the measure data on  
2 the specific goal of antithrombotic therapy at  
3 discharge, but it also suggests that these  
4 disparities may have declined over time.

5 The odds ratio indicates a higher  
6 performance for some groups than others, but the  
7 overall performance is very high for all of the  
8 groups reported.

9 So, I would say there is little  
10 opportunity for improvement in overall  
11 compliance, and maybe a small amount of potential  
12 improvement. Let me rephrase that. I think  
13 there's extremely little opportunity for improved  
14 compliance overall, and there is maybe a small  
15 amount of room for improved performance when you  
16 consider this disparity data. But, at least for  
17 the groups that were considered there isn't much  
18 room for improvement there either.

19 CO-CHAIR KNOWLTON: Alex?

20 MEMBER RAE-GRANT: The only point I'd  
21 make is the several references I don't think  
22 really are germane for concern about



1 opportunities for improvement in performance.

2 They just tell us that population is different,  
3 female outcome, so I'm not sure that's data.

4 And, I think we've made enough point  
5 about racial disparities, but that data should be  
6 expected to be developed where potentially  
7 available as part of our process. Not that we  
8 have to go back each time and say, well, there  
9 may be more data, let's get it.

10 So, going forward, I think it would be  
11 reasonable higher expectation if they would  
12 provide that where available.

13 CO-CHAIR KNOWLTON: Okay. Other  
14 comments on gap?

15 Yes, sir.

16 MEMBER FERZIGER: I have a question  
17 about how we think about the disparities gap, is  
18 because, you know, if the overall use is  
19 extremely high, let's say, you know, it  
20 approaches 100 percent, at what point does the  
21 disparities gap become non-significant? In other  
22 words, do we move on, because the overall number

1 is excellent, or do we wait because even  
2 disparity needs to be addressed?

3 CO-CHAIR KNOWLTON: I think that is a  
4 point, I think that's what Alex was raising, too.

5 Valerie.

6 MEMBER COTTER: I think when you are  
7 looking at stroke, and you look at the high risk  
8 for increased incidence and prevalence among  
9 ethnic and racial minorities, that the playing  
10 field is not even. And so, while we look at data  
11 that does not include ethnic and racial  
12 minorities, we can't assume that it's equal.

13 CO-CHAIR KNOWLTON: I think the issue  
14 is that we need data. You can't hypothesize when  
15 they say 100 percent of the population are  
16 approaching us. That's assuming 100 percent are  
17 meeting the standard, if one assumes there are  
18 racial minorities in that group. So, you would  
19 assume that that's what's happening.

20 I agree, completely agree, to Alex's  
21 point that we should be affirmatively asking for  
22 this data. I agree with that point 100 percent.

1       So, I wouldn't back off that.

2                   But, I don't know that we should just  
3       say, no, there's more of a gap here, because we  
4       haven't addressed it.

5                   David.

6                   MEMBER HACKNEY: So, I just wanted to  
7       say, you know, we talked about, well, if we  
8       remove these measures will they, you know, if  
9       they expire eventually, will they -- will people  
10      stop pursuing these things.

11                   And, what we should be doing is  
12      encouraging developers to think about the next  
13      step, what is the next step in quality care, and  
14      not keep the benchmarks that we set in the past  
15      and have achieved.

16                   CO-CHAIR KNOWLTON: Other comments on  
17      gap?

18                   David, do you have your --

19                   MEMBER HACKNEY: I just wanted to  
20      mention, they do present data on gap. The  
21      reason, and maybe what I said wasn't that clear,  
22      there was evidence of gap in the past that seems

1 to be closing, the racial disparity data.

2 So, they've reported data from a  
3 publication from 2010, it doesn't directly say  
4 when the data was acquired that had the  
5 compliance for White patients at 95 percent,  
6 Black patients at 94 percent, Hispanic at 94  
7 percent, and then more recent data that had White  
8 at 98, and other race at 98. So, to the extent  
9 there existed a gap before, it looks like it's  
10 pretty much closed, but they did present the  
11 evidence. It wasn't that it wasn't there.

12 CO-CHAIR KNOWLTON: Anything else on  
13 gap? Yes.

14 MEMBER EDWARDS: Well, I just want to  
15 speak to the fact that there appears to be no gap  
16 by race in the reporting, but that doesn't mean  
17 that there's no gap in secondary prevention,  
18 that's a different issue. It's not -- it may be  
19 outside the standard.

20 MEMBER HACKNEY: Right. This doesn't  
21 tell us whether overall material is identical, it  
22 just says how the performance is on this measure.

1 CO-CHAIR KNOWLTON: Reuven?

2 MEMBER FERZIGER: One more question to  
3 understand gap. So, we are talking about  
4 absolute numbers of patients, we are not talking  
5 about institutions or zip codes, right? So, it  
6 could still be the case that disparities exist  
7 when we compare institutions, or when we compare  
8 regions, as opposed to, you know, aggregating the  
9 patients. Is that correct? It's a question to  
10 the measure developer.

11 MEMBER HACKNEY: It's certainly true  
12 that within that tiny percentage who don't need  
13 it there could be some -- that could be driven by  
14 some places who do terribly while everyone else  
15 does great. That's, certainly, possible, it  
16 could be 1.0, at all except a handful of centers  
17 that's zero, and you wouldn't know that.

18 So, if the argument is maybe that  
19 keeping it as a reserve status would be a way for  
20 them to assess themselves. That's what my  
21 suggestion would be, is reserve status.

22 CO-CHAIR KNOWLTON: Other comments on

1 gap? Nothing new? Good.

2 Ready for a vote.

3 MS. OGUNGBEMI: We are now voting on  
4 the performance gap for measure 0435. The  
5 options are high, moderate, low and insufficient.  
6 Voting is open.

7 Voting is closed. The results are 0  
8 percent high, 0 percent moderate, 78 percent low,  
9 and 22 percent insufficient. The measure passes  
10 on performance gaps.

11 The measure --

12 MS. OGUNGBEMI: Wait, no, I'm sorry,  
13 pardon me.

14 DR. TERRY: That was a trick question.

15 MS. OGUNGBEMI: The measure does not  
16 pass on performance gap. We'll move on.

17 DR. TERRY: I just want to make a  
18 statement here so it is clear where we are  
19 thinking about that, totally clear, as clear as  
20 we can make it here.

21 The measure has failed, this must pass  
22 criteria. NQF has the option of granting

1 inactive endorsement with reserve status for  
2 measures that meet all the other criteria except  
3 gap. The status applies only to highly credible  
4 as well as reliable and valid measures that have  
5 high levels of performance due to incorporations  
6 due to standardized patient care processes and  
7 quality improvement action.

8 Inactive endorsement with reserve  
9 status retains these measures in the NQF  
10 portfolio, while also communicating to potential  
11 users that the measure no longer addresses high  
12 leverage areas for accountability purposes.

13 The Consensus Standards Approval  
14 Committee, CSAC, notes that the default action  
15 should be to remove endorsement unless there is a  
16 strong justification to continue endorsement.

17 Does the Committee wish to continue  
18 evaluating the measures for possible reserve  
19 status? That's the question.

20 CO-CHAIR KNOWLTON: Well, let me weigh  
21 in here on one aspect of this. The issue is, do  
22 we, isn't one of the issues that we are

1 addressing here is keeping this alive so we can  
2 consider the eMeasure, isn't that the issue?

3 MEMBER HACKNEY: What happens if it  
4 goes to reserve, does the eMeasure just never  
5 come up?

6 CO-CHAIR KNOWLTON: That's the  
7 confusion here.

8 MEMBER HACKNEY: I would just say  
9 there's a logic to saying it doesn't come up,  
10 because all the eMeasure is intended to measure  
11 the same thing. So, if we think that compliance  
12 is so high that there isn't much weight --

13 CO-CHAIR KNOWLTON: I understand.

14 MEMBER HACKNEY: -- then I'm not sure  
15 there's a point in having much of a discussion of  
16 the eMeasure. But, I don't know what the rules  
17 are.

18 CO-CHAIR KNOWLTON: But, if you don't  
19 consider -- I agree with you, I just want to be  
20 sure the process is clear -- if we don't consider  
21 the reserve status of the eMeasure, we don't even  
22 look at it. We're done.



1           MEMBER HACKNEY: So, I guess because  
2           the eMeasure passed to reserve status, I guess  
3           we're heading to reserve.

4           MS. JOHNSON: Right, and since this is  
5           a new measure to NQF, a new measure that's never  
6           been to NQF before, it is not eligible for  
7           reserve status.

8           So, what we were thinking is that you  
9           have said that there is very little opportunity  
10          for improvement for this measure. That means  
11          that the eMeasure also would have very little  
12          opportunity for improvement, and we would stop  
13          discussion of the eMeasure, if we were talking  
14          about the eMeasure right now. We can continue  
15          talking about this measure, because it has  
16          potential for reserve status. The eMeasure does  
17          not have potential to go to reserve status.

18          MEMBER HACKNEY: So, that makes sense.  
19          The problem is, of course, people are going to  
20          switch to the eMeasure, right? I mean, if you do  
21          this at all. And so, I'm not -- we don't know  
22          what to do. Should we go ahead and treat this

1 one, even though we said that the gap is low,  
2 keep going, and then -- you know, I think if we  
3 want to vote on whether it goes on to reserve  
4 status we have to go through the rest of the  
5 criteria to make sure it passes all of those.

6 So, I guess I would propose that we do  
7 that. Then if it does go to reserve, what I'm  
8 hearing is that the eMeasure is just off the  
9 table. Okay?

10 Right. And, it seems like going  
11 forward if it's on reserve it would really be  
12 easier to measure the eMeasure. So, I think  
13 maybe there needs to be a little more discussion  
14 at the policy level at NQF as to how to think  
15 about these things. Maybe it's more of a  
16 transformation than a whole new measure.

17 CO-CHAIR KNOWLTON: Melody, go ahead.

18 MEMBER RYAN: Okay. This might be  
19 silly, but can we approve an eMeasure and then  
20 immediately put it on reserve?

21 CO-CHAIR KNOWLTON: No.

22 MEMBER RYAN: Okay, just thought I'd

1 throw it out there.

2 MEMBER HACKNEY: That beginning is  
3 going to fail on gap also. It's guaranteed to  
4 fail on gap. This is using the same data.

5 CO-CHAIR KNOWLTON: My suggestion, and  
6 I'm chairing this section, is let's go forward on  
7 the measures, on the rest of the measures. And,  
8 let's vote on them, so that that question is at  
9 least done. And then, we can decide on reserve,  
10 but we can discuss it over lunch and come back.  
11 Let's get through the criteria, David, if you  
12 don't mind.

13 MEMBER HACKNEY: Okay. So, we are up  
14 to reliability, right?

15 CO-CHAIR KNOWLTON: Right

16 MEMBER HACKNEY: So my script has a  
17 restatement of numerator/denominator, et cetera,  
18 but that was already covered.

19 There is -- the measure does produce  
20 good evidence of thorough testing and showing the  
21 measure to be reliable, that is, you get the same  
22 result when you repeat the test. So, I would

1 give it high marks for reliability.

2 CO-CHAIR KNOWLTON: Comments or  
3 questions? Okay for a vote?

4 Go for it.

5 MS. OGUNGBEMI: We are voting for  
6 measure 0435 on reliability. The options are  
7 high, moderate, low and insufficient. Voting is  
8 open.

9 Voting is closed. The results are 57  
10 percent high, 43 percent moderate, 0 percent low,  
11 and 0 percent insufficient. Measure 0435 passes  
12 on reliability.

13 CO-CHAIR KNOWLTON: Jocelyn?

14 MEMBER BAUTISTA: Just to clarify  
15 something. So, for the reliability algorithm,  
16 isn't that that if the testing is only done at  
17 the data element level, and not the measure score  
18 level, the highest rating possible is moderate?

19 MS. JOHNSON: That is correct according  
20 to our algorithm.

21 CO-CHAIR TIRSCHWELL: So, are we  
22 allowed to vote the seat of our pants outside of

1 the algorithm, or --

2 CO-CHAIR KNOWLTON: Yes.

3 MS. JOHNSON: Absolutely. I think it  
4 might be helpful if anybody is willing to share,  
5 and sorry, I was kind of thinking about something  
6 else when that went through. I see a lot of  
7 highs on there, which is a little bit outside our  
8 algorithm. So, maybe a couple people who voted  
9 high might be willing to share why they felt it  
10 was high. That would help us at least  
11 understand, as David said, voting outside the  
12 algorithm.

13 CO-CHAIR KNOWLTON: My hunch is they  
14 didn't contemplate the algorithms. Your point is  
15 well taken, though.

16 Can we move on to validity?

17 MEMBER HACKNEY: My program took  
18 advantage of that little break to crash. I had  
19 to restart. We are back now.

20 So, validity, basically, was addressed  
21 as base validity, that is, it was surveys and  
22 focus groups of the hospitals participating in

1 the pilot test, and they all agreed that it  
2 worked. They have a mechanism for ongoing  
3 feedback about the performance of the measure,  
4 and they didn't get a lot of feedback, but they  
5 got described as the specific issues that came  
6 up.

7 The primary one, I think, there were  
8 two primary issues. One was this issue that I  
9 mentioned, that is, whether the search for  
10 documentation of a reason, we are not sending  
11 someone out on any thrombotic therapy  
12 successfully identified all of the patients for  
13 whom it was appropriate not to put them on such  
14 therapy. That, the description of the process  
15 was a little worrisome, and, of course, there's  
16 no real validity possible to know whether a given  
17 case was correctly characterized.

18 And then, the other validity question  
19 that I think is more directly handled is, as the  
20 number of drugs that one might use keeps  
21 enlarging how up to date is the data that is the  
22 source table list of acceptable drugs. They say

1 they do a quarterly review, which sounds like it  
2 could be plenty, but I don't know what happens if  
3 you scored somewhat as not an inappropriate drug,  
4 but, in fact, that is now FDA approved, or it's  
5 not FDA approved, but it's accepted practice to  
6 use that drug.

7 In neither of those is there a  
8 straightforward of getting validity data for  
9 those questions. So, nonetheless, based on what  
10 they can present, that is, essentially, expert  
11 opinion, it's believed to be highly valid, but I  
12 might like to hear if there are neurologists who  
13 have an opinion, I'd like to hear those, because  
14 now we are getting into a clinical detail, on  
15 which I have only a peripheral engagement.

16 CO-CHAIR KNOWLTON: Any comments?

17 CO-CHAIR TIRSCHWELL: I'd just comment  
18 from a clinical perspective, I would say it's not  
19 that ambiguous, and it's probably pretty valid.  
20 It's so complicated.

21 MEMBER HACKNEY: In that case, I would  
22 give it a high validity. Everything else about

1 the validity is good.

2 CO-CHAIR KNOWLTON: Anything further on  
3 validity?

4 Ready for a vote?

5 MS. OGUNGBEMI: We are now voting on  
6 the validity for measure 0435. The options are  
7 high, moderate, low and insufficient. Voting is  
8 open.

9 Voting is closed. The results are 70  
10 percent high, 30 percent moderate, 0 percent low,  
11 and 0 percent insufficient. Measure 0435 passes  
12 on validity.

13 CO-CHAIR KNOWLTON: Feasibility, David?

14 MEMBER HACKNEY: So, I would give it a  
15 high. The only issue I brought up for my notes  
16 about feasibility was this question of how well  
17 does the document in the reason for not using  
18 antithrombotic therapy work, and David said he  
19 thinks this isn't going to be a problem.

20 So, that was the only thing that I had  
21 any concern about. Otherwise, and that was the  
22 one that it was unclear how you would know



1       whether that was an issue.

2               They did mention a few people that  
3       commented on it, but it's in wide use, and this  
4       small number of comments suggested to me that  
5       people weren't complaining about that. So, I  
6       think it's feasible.

7               CO-CHAIR KNOWLTON: Comments?

8               Ready for a vote.

9               MS. OGUNGBEMI: Okay. We are now  
10       voting on feasibility for measure 0435. The  
11       results are high, moderate, low and insufficient.  
12       Voting is open.

13               Voting is now closed. The results are  
14       48 percent high, 52 percent moderate, 0 percent  
15       low, and 0 percent insufficient. Measure 0435  
16       passes on feasibility.

17               CO-CHAIR KNOWLTON: Usability and use.

18               MEMBER HACKNEY: So, usability, it's  
19       being widely used by National Stroke Registry,  
20       the Joint Commission, and CMS. The data are  
21       publicly reported aggregate level, obviously, and  
22       there is, as we discussed, evidence of

1 improvement over time to the point that it may  
2 not be useful to keep checking.

3 It's unclear whether the measure -- to  
4 what extent one can attribute the improvement in  
5 performance over time to this measure was  
6 probably part of it, but, of course, there have  
7 been major efforts across the neurology world to  
8 improve compliance with guidelines. And, this is  
9 one element of that effort.

10 But, I don't know that we can isolate  
11 how much of the improvement is due to this  
12 measure. My guess would be not that much,  
13 because, as I said, this work getting with the  
14 guidelines has been such a big area over the same  
15 period of time that the improvement was  
16 documented, the quality improvement was  
17 documented.

18 But overall, I'd say it's definitely  
19 usable by all of the criteria that we were asked  
20 to address. So, I would give it a high  
21 usability.

22 CO-CHAIR KNOWLTON: Comments?

1 Questions?

2 Ready to vote on usability and use.

3 MS. OGUNGBEMI: We are now voting on  
4 usability and use for measure 0435. The options  
5 are high, moderate, low and insufficient. Voting  
6 is open.

7 Voting is closed. The results are 83  
8 percent high, 17 percent moderate, 0 percent low,  
9 and 0 percent insufficient. Measure 0435 passes  
10 on usability and use.

11 CO-CHAIR KNOWLTON: Okay. Done?

12 MEMBER HACKNEY: Yes, done.

13 CO-CHAIR KNOWLTON: So, we are not  
14 considering 2832, it's an eMeasure, and we don't  
15 consider it because the underlying measure did  
16 not pass on gap.

17 And, I spoke to staff and said we'll  
18 talk about the reserve status during our break,  
19 and we won't do anything on it now.

20 So, that leads us to --

21 MEMBER HACKNEY: Let me just interrupt  
22 for half a second.

1 CO-CHAIR KNOWLTON: Sure.

2 MEMBER HACKNEY: So, the reserve status  
3 thing, is that a vote later, or is that -- what's  
4 the process for making that decision now about  
5 reserve status?

6 MS. JOHNSON: It should be a vote, and  
7 it could happen now.

8 MEMBER HACKNEY: It could happen now?

9 MS. JOHNSON: Yes.

10 MEMBER HACKNEY: Is there a reason to  
11 delay?

12 CO-CHAIR KNOWLTON: I didn't know that  
13 the process was clear, that's why I was putting  
14 it off. If the process is clear, we can vote  
15 upon it. I was --

16 MEMBER HACKNEY: For data that we  
17 thought was going to be given to us, and it --

18 CO-CHAIR KNOWLTON: Yes.

19 MEMBER HACKNEY: -- so I think the  
20 more data thing might allow this measure to come  
21 back in and have another look at it?

22 MS. JOHNSON: That was the prior

1 amendment.

2 MEMBER HACKNEY: That's not this one.

3 MS. JOHNSON: Yes.

4 CO-CHAIR KNOWLTON: So it was only  
5 because --

6 MEMBER HACKNEY: It was only because  
7 the other one had the insufficient part, not the  
8 low part. It was inconclusive as to which of  
9 those was the right thing. I see.

10 So, this one is not coming back with  
11 evidence of gap, and the question is, should it  
12 be then reserve status. That's the only  
13 remaining question. So, I would suggest while  
14 it's fresh in our minds we go ahead and vote  
15 about it.

16 CO-CHAIR KNOWLTON: Okay.

17 CO-CHAIR TIRSCHWELL: Can I just ask  
18 what exactly does reserve status mean, when  
19 something goes on to reserve status, then what?

20 MS. JOHNSON: If you'll bear with me  
21 just a second, I'm going to pull up our policy  
22 and just read to you a little bit. I want to

1 make sure I get it right.

2 And, if you want to follow along with  
3 me, it's in our Steering Committee guidebook. I'm  
4 sorry, it's in our criteria and guidance  
5 document, which, hopefully, you have had a chance  
6 to look at.

7 "Endorsement with reserve status  
8 retains ...," let me start again, "The purpose of  
9 an inactive endorsement with reserve status is to  
10 retain endorsement of reliable and valid quality  
11 performance measures that have overall high  
12 levels of performance, with little variability,  
13 so that performance could be monitored as  
14 necessary to ensure that performance does not  
15 decline. The status would apply only to highly  
16 credible, reliable, and valid measures that have  
17 high levels of performance due to incorporation  
18 into standardized patient care processes and  
19 quality improvement actions if the issue for  
20 continued endorsement is the opportunity cost  
21 associated with continued measurement and high  
22 levels of performance, rather than focusing on

1 areas with known gaps of care. Endorsement with  
2 reserve status retains these measures in the NQF  
3 portfolio for periodic monitoring, while also  
4 communicating with potential users that the  
5 measures no longer address high-leverage areas  
6 for accountability purposes."

7 CO-CHAIR TIRSCHWELL: And, can I just  
8 comment that this issue about the trade-off being  
9 the burden of data collection sort of plays right  
10 into this whole eMeasure thing, because, in fact,  
11 if you have a good eMeasure it's all of your data  
12 is collected as part of your standard process of  
13 care. And so, that burden goes away.

14 So, I mean as the electronic medical  
15 record is emerging, and the possibility to gather  
16 these quality data become less burdensome, sort  
17 of that definition of what constitutes reserve  
18 may need to evolve to accommodate this  
19 possibility.

20 MS. JOHNSON: We definitely have these  
21 kind of conversations a lot here at NQF, so we  
22 will definitely take it back. What we are

1 hearing from you is you are uncomfortable not  
2 putting the eMeasure in reserve status as well.  
3 At least that's how I'm thinking about it.

4 I'm not going to promise that we will  
5 change our policy at this point, but I will say  
6 that we can discuss it in the future.

7 MEMBER HACKNEY: Yes, I think the other  
8 aspect of that is that this measure, whether --  
9 whatever status it's in, everyone is going to end  
10 up doing it by electronic methods. So, we may  
11 have a strange situation where we have a reserve  
12 status of a technique that no one is going to use  
13 anymore, and no approval of what everyone would,  
14 actually, use.

15 We are not going to resolve that in  
16 this Committee, but just I think that feeling  
17 might have been all the data are the same, the  
18 eMeasure is, actually, the more interesting one,  
19 because that's what's going to apply in the  
20 future, rather than in the past.

21 But, I guess we are just going to vote  
22 on reserve at this point, right?



1 MS. JOHNSON: And, I will say that the  
2 eMeasure, how it functions in terms of its  
3 reliability and validity is still unknown, right?  
4 So, we can't automatically put an unknown  
5 eMeasure into reserve status at this point. So,  
6 it's kind of a circular problem.

7 CO-CHAIR KNOWLTON: Michael.

8 MEMBER KAPLITT: Can you guys put back  
9 that voting slide with the criteria on it,  
10 because I had a question on one of the elements  
11 in there.

12 So, how important, in terms of moving  
13 to reserve status, is demonstrated improvement,  
14 because I don't know how that fits into this  
15 reserve question, because to me it doesn't show  
16 any improvement. People were doing this equally  
17 well five years ago and every year following  
18 that. It's not like it's shown improvement over  
19 time, and now it's kind of topped out. It looks  
20 like it was topped out back in 2010, if I'm  
21 understanding the data properly. So, how does  
22 that enter into this?

1                   Like I don't know what role that  
2                   plays? Does that mean that it shouldn't be  
3                   reserve status if it hasn't shown improvement,  
4                   because people have been doing this standard of  
5                   care forever, and so why bother? I don't  
6                   understand what that line item is for.

7                   MS. JOHNSON: You know, that's a really  
8                   good question. We may need to relook at that and  
9                   see what we were thinking.

10                  My understanding of this is that, you  
11                  know, generally, a measure would not have been  
12                  endorsed the last time around if there was not at  
13                  least some flavor that there was opportunity for  
14                  improvement. And now, we are looking at it  
15                  again, and we are hearing that there's not.

16                  So, just based on that, what we would  
17                  assume happens is that, in the time period from  
18                  the last endorsement to this one there has been  
19                  at least some improvement, and that would be why  
20                  that has been there.

21                  CO-CHAIR TIRSCHWELL: If you look at  
22                  the 10th percentile, Mike, I realize it's not a

1 lot of improvement, because there wasn't a huge  
2 amount of area, but, you know, the 10th  
3 percentile has gone up from 94 to 98. So, you  
4 know --

5 MEMBER HACKNEY: And, the disparities  
6 have gone down a bit.

7 CO-CHAIR KNOWLTON: Karen?

8 MS. JOHNSON: I will also tell you that  
9 a reserve status is not new. What is new,  
10 actually, is just our written policy of how we  
11 are doing this. And, I don't remember if neuro  
12 was one of the ones the last time, for some  
13 reason I was thinking it was, there was  
14 discomfort in various committees of saying, yes,  
15 this measure is topped out, and we've already  
16 talked about this measure.

17 It seems that we topped out, but yet,  
18 we feel very uncomfortable not endorsing it,  
19 right? So, what was happening is, we were --  
20 some committees were saying let's go reserve,  
21 others were saying let's not endorse, and it was  
22 kind of inconsistent.

1           So, what we tried to do is make a  
2       reserve policy, at least consistent across  
3       committees, so that, you know, that feeling of  
4       discomfort by signaling to the field that you  
5       don't think it's important anymore, we tried to  
6       take that discomfort away from you by offering  
7       potential reserve status.

8           MEMBER ANDREWS: My concern is not  
9       improvement, it's whether or not the absence of  
10      endorsement leads to decline in the use of  
11      something that we have determined is valuable.

12           So, my real question is, we talked  
13      about periodic monitoring, what does that mean?  
14      How do you monitor? How often do you monitor,  
15      because that becomes crucial in identifying  
16      whether or not there are any declines over time.

17           CO-CHAIR KNOWLTON: Peter?

18           MEMBER SCHMIDT: So, I agree with  
19      Michael that this has been topped out for five  
20      years, and I think that the issue of -- I wish  
21      that people paid so much attention to what was  
22      endorsed by this Committee that we could reach 98

1 percent of patients with a measure. But, I think  
2 that probably this is being put broadly, and we  
3 have to beware of the late woebegone phenomenon  
4 of declaring that every hospital is above  
5 average.

6 CO-CHAIR KNOWLTON: Reuven?

7 MEMBER FERZIGER: So, I use this as  
8 guidance, additional guidance, on how to think  
9 about those all season patients of the reserve  
10 status, because it's hard to separate the  
11 observer phenomenon out of this.

12 Like in Michael's point, is that in  
13 this particular case, right, we already knew, but  
14 then it's not clear why we ever needed a measure  
15 in the first place, right?

16 But, assuming that there was a use you  
17 have a measure, right?

18 You are talking about the fourth  
19 leading cause of death. So, why wouldn't we err,  
20 if we think that there's a possibility, right,  
21 but there's an observer phenomenon of rising  
22 improvements, why wouldn't we want to err on the

1 side of over measuring, or continuing to measure,  
2 until we have some information, or, let's say, we  
3 have an eMeasure that replaces it, and takes  
4 away, you know, the user opportunity cost issue.

5 It seems to me like from a policy  
6 point of view, we would want to keep measuring  
7 this.

8 MS. JOHNSON: That, actually, that  
9 argument sounds familiar to me from the last time  
10 around, and it may sound familiar to some of you  
11 who were on the panel before. I don't know that  
12 with this particular measure, but I do know some  
13 measures the last time that we were getting  
14 towards the topped out level, the Neuro Committee  
15 the last time did say, well, if there still seems  
16 to be a little bit of space, and because stroke  
17 is such a high prevalent position, even that  
18 little bit translates to a lot of people. And,  
19 that was the argument for at least one or two of  
20 the measures the last time around to go forward  
21 with it.

22 MEMBER FERZIGER: It seems to me a

1 little bit different, though. It's not just that  
2 there might be even a very small gap, but that's  
3 a significant number of people, I'm saying that  
4 if we have any information about how much, you  
5 know, the sustainability, you know, of the  
6 measure, or, you know, or of the clinical  
7 phenomenon depends on the existence of  
8 measurement.

9 CO-CHAIR KNOWLTON: Jim.

10 MEMBER BURKE: This is sort of follow-  
11 up on the criteria as well. I mean, the first  
12 one also seems like it's one that's not super  
13 obvious, about, like David, how you make that  
14 judgment. So, what we know is the number got  
15 better. But, do we know sort of the things like  
16 why it got better, is it documentation commonly  
17 exclude quality phenomena, and that seems like  
18 it's hard to get at.

19 I can imagine theoretical ways that  
20 could be measured or gotten at, but I don't know  
21 that we have any measurements here and I don't  
22 know in the future if you make any reserve

1 judgements that might be helpful to know.

2 I mean, what proportion of this -- are  
3 we seeing changes in documentation prior to the  
4 example of the phenomena? Are we seeing something  
5 else correlated here? I mean, I think with this  
6 measure it's hard to know which of those is, I  
7 hope, with accurate importance, but I don't know.

8 CO-CHAIR KNOWLTON: Charlotte?

9 MEMBER JONES: When we ask people to be  
10 accountable, when NQF says this is something we  
11 feel that you should still be accountable for and  
12 you need to measure, something else is not being  
13 measured.

14 We, certainly, understand the logic  
15 that stroke is a huge population and a huge  
16 problem, but everyone lives in a world of limited  
17 resources. And so, even if we put something on  
18 reserve, or keep it active, we are taking  
19 resources from something else.

20 CO-CHAIR KNOWLTON: Okay. Ketan.

21 MEMBER BULSARA: Just to follow up on  
22 what David and Reuven have said. There's



1       probably historical -- there's probably  
2       historical data on what happens to these measures  
3       that are either retired or not continued to be  
4       endorsed by NQF.

5               And, I think having a sense for what  
6       happens to those measures in terms of compliance  
7       once that status has been established would be  
8       very useful in helping understand whether this is  
9       something -- whether it's a transient victory or  
10      whether it's going to be a permanent victory.

11              MEMBER HACKNEY: That would depend in  
12      part on the extent to which this measure is  
13      responsible for the improvement.

14              But, as I said, you know, get with the  
15      guidelines I don't think was just one measure, it  
16      was an overall effort to get people, actually,  
17      perhaps, in accordance with this. This was part  
18      of it, but I don't know of any way we could  
19      figure out how much of it. I guess if nothing  
20      else changes this goes into reserve status,  
21      compliance goes down, then we say, ah-ha, that  
22      was the lynch pin that made the whole thing work.

1 But, there's no way to know.

2 CO-CHAIR KNOWLTON: Karen.

3 MS. JOHNSON: I'm sorry, there's a  
4 little bit more of the policy that I thought I  
5 should read to you, and I think we touched on it  
6 before, but let me just read it out.

7 "Measures assigned to the inactive  
8 endorsement status will not be reviewed in the  
9 usual endorsement maintenance review cycle.  
10 During portfolio review, the Standing Committee  
11 will periodically review measures in the reserve  
12 status for any change in evidence, evidence of  
13 deterioration in performance or unintended  
14 consequences, or any other concerns related to  
15 the measure. The Standing Committee may remove a  
16 measure from inactive endorsement status if the  
17 measure no longer meets NQF endorsement criteria.  
18 A maintenance review may occur upon request from  
19 the Standing Committee or measure steward to  
20 return the measure back from reserve."

21 CO-CHAIR KNOWLTON: Go ahead, Michael.

22 MEMBER KAPLITT: So, with all due

1       respect to the NQF people here, I personally  
2       don't feel like we are getting adequate guidance  
3       from you guys, because I don't think that any of  
4       us are, actually, disagreeing on any of the  
5       things we are talking about. We all have our own  
6       interpretation of what process we are trying to  
7       follow here, and I think that's the problem, you  
8       know, you need greater clarity in my view.

9               I think if we are here to say is this  
10       important or is this not important, I don't think  
11       any of us disagree that this is important. If we  
12       are here to say that, you know, should we  
13       continue as a group to continue to review  
14       periodically on a set schedule to set criteria  
15       this measure, and that's the difference between  
16       what we are arguing, that's a very different  
17       thing. It doesn't mean it's not important.

18              So, for example, if we put this into  
19       reserve status, JCAHO is still going to use this,  
20       right? Yes?

21              Well, you know, this is I think the  
22       problem a lot of us are having, because we don't

1 know the consequence of what we are doing right  
2 now, I think. We are all interpreting it for  
3 ourselves. I mean, maybe I'm the only one who is  
4 not sure, but the sense I get is that we all have  
5 a different idea of what's the consequence of the  
6 vote we are about to take. We don't have any  
7 disagreement on the importance of doing this in  
8 clinical practice.

9 So, I personally think we need better  
10 guidance on what the consequence of this vote is,  
11 because otherwise we've got 23 different opinions  
12 as to what we are doing.

13 CO-CHAIR KNOWLTON: Jane?

14 MEMBER J. SULLIVAN: So, piggybacking  
15 on what you said, Karen, where if the measure  
16 goes into reserve status, and the Committee at  
17 some point decides that they want to look at  
18 ongoing data, who is responsible for generating  
19 that data, because at this point the developer  
20 provides the data to the Committee. But, if  
21 there is -- is there no longer a developer if the  
22 measure goes into reserve status, and we say we

1 want to look at data, where's that data coming  
2 from?

3 MS. JOHNSON: Let's be clear that if it  
4 is in reserve status it is still endorsed, so our  
5 developers have so agreed, unless they change  
6 their mind, that they will support the measure.  
7 So, we would expect that if we asked for it the  
8 developers would give us the data.

9 CO-CHAIR KNOWLTON: I'm going to  
10 suggest we take this up after lunch. I'm going  
11 to sit with it. I would like to have a few  
12 minutes with staff to talk about this a little  
13 bit, and see if we can at least get some clarity  
14 to what we are voting on.

15 I think, Michael's point was well  
16 taken. We need to be clear on what we are voting  
17 on. We might not agree with it. We might,  
18 whatever, but let's at least be clear on what it  
19 is.

20 So, let's take some time to clarify  
21 this. We are clarifying it by questions and not  
22 by answers, so let's get some -- let's have the

1 discussion with staff during the break.

2 Let's take a public comment now, NQF  
3 member and Public Comment now, have our lunch  
4 break, see if we can clarify the waters a little  
5 bit, and bring it up right after we return.

6 So, if the operator would open the  
7 lines for member or public comment, and I would,  
8 while she's doing that, make the comment that the  
9 comments by the public, and this will include  
10 public present in our room here, that they should  
11 comment on the issues that we've had before the  
12 Committee thus far, not anything that we haven't  
13 taken up yet.

14 Operator, are there any public  
15 comments?

16 OPERATOR: If you'd like to make a  
17 public comment at this time, please press star,  
18 then the No. 1 on your telephone keypad.

19 There are no public comments.

20 CO-CHAIR KNOWLTON: Thank you. Anybody  
21 in the room?

22 Seeing none, we are going to go to

1 lunch. We will be reconvening at 1:10, 1:15.

2 (Whereupon, the above-entitled matter  
3 was recessed at 12:44 p.m., to reconvene this  
4 same day at 1:15 p.m.)

5 CO-CHAIR KNOWLTON: Okay. I believe  
6 we're all back.

7 We're going to revisit the reserve  
8 status and David gave a very good summary. Gave  
9 absolute pristine clarity to this issue.

10 CO-CHAIR TIRSCHWELL: You're setting me  
11 up for failure there.

12 All right. So, we're voting about  
13 reserve status versus not. And to be clear, not  
14 reserve status means we would be not endorsing  
15 this measure. It would no longer be endorsed by  
16 NQF and as far as interpreting how to feel about  
17 those things, if you put something on reserve  
18 status you might want to do that because, yes,  
19 we're achieving great things but we're worried  
20 that if we completely unendorse it we might lose  
21 ground and lose quality of care. So, we want to  
22 keep an eye on it. So, we're going to put it on

1       reserve status versus if we fully don't endorse  
2       it then, in fact, we're so confident that this  
3       quality is maximal and will be maintained that we  
4       just really don't need to put this limited  
5       resource for quality measuring and improvement  
6       into this particular area at this time. So,  
7       that's the vote that we're making here.

8                   CO-CHAIR KNOWLTON: Okay. So, we are  
9       considering measure 0435, discharged on  
10      antithrombotic therapy.

11                   Comments on reserve status? Nobody  
12      has a comment so everybody is ready to vote?  
13      Okay. Christy, you're handling the vote?

14                   MS. SKIPPER: Just give me one moment.

15                   CO-CHAIR KNOWLTON: Did you vote for  
16      us, Christy?

17                   CO-CHAIR TIRSCHWELL: So, the question  
18      is, does the Chair have any recommendation?  
19      Well, you know, that's a great question. I do  
20      know how -- I guess you're asking me how I'm  
21      going to vote and why. And, honestly, I am  
22      actually leaning towards more reserve status for



1       this because I do worry that if we completely  
2       take it off the radar, that we might fall back  
3       and I would like that additional information.

4               I think in the future on re-evaluation  
5       we could always remove it from endorsement later  
6       as well. Is that correct? So, that's sort of  
7       where I am.

8               MEMBER HACKNEY: The only thing I'd  
9       bring up is I think we've made the suggestion  
10      that someone needs to address this issue that the  
11      eMeasure can't resist because going forward even  
12      if this is on reserve status or even if it was  
13      still active nobody is going to do it anyway  
14      other than electronically. And if it's being  
15      done electronically then the overhead is pretty  
16      low. So, ultimately you'd like to have a measure  
17      that is usable, that's electronic, but right now  
18      we don't have a route to get there.

19              CO-CHAIR KNOWLTON: I think it's fair,  
20      David, just to highlight on that that we need to  
21      be thinking also through the implications of  
22      getting rid of an abstracted validation

1 alternative because I think as Lee was commenting  
2 during the break, how do you measure people who  
3 do not get care and how do you validate your data  
4 if you don't have access to the abstracted record  
5 to be able to do that?

6 So, it seems like the NQF part of our  
7 thoughts going back might be that NQF has to give  
8 it some thought to what the implications are  
9 because here's a measure that is clearly topped  
10 out. I mean, I don't know many measures that  
11 have got this type of compliance with it. But  
12 the reality is so it's almost as if not this one  
13 which one would you say we're done with this one?

14 On the other hand, what are the  
15 implications and that's the piece that I don't  
16 believe has been thoroughly vetted, thought  
17 through. But in this imperfect world we are  
18 called upon to vote.

19 So, anybody want to -- a burning need  
20 to make one more comment or can we vote on it?

21 Okay. Are we ready to vote? Christy?  
22 Not yet.

1 MS. OGUNGBEMI: Polling is now open.  
2 We're voting on whether or not to move 0435 to  
3 reserve status. One yes, two no.

4 Poling has closed. Eighty-seven  
5 percent, yes, thirteen percent, no. The  
6 committee has voted to move 0435 to reserve  
7 status.

8 CO-CHAIR TIRSCHWELL: Okay. So, we're  
9 finished with that. Right? We can move on to  
10 our after lunch agenda.

11 And so as we're moving into the next  
12 set of measures I would note that it's three more  
13 stroke measures from the Joint Commission and  
14 each one has a companion eMeasure and so some of  
15 these same issues which we've struggled with and  
16 mastered may come up again so we'll see how we go  
17 timing-wise and I guess maybe we could pass the  
18 baton to the Joint Commission and Dr. Lee Schwamm  
19 is here now as well representing the Joint  
20 Commission to let you guys -- why don't you just  
21 give us the overview of the first measure which  
22 are the two statin ones. We'll do it one at a

1 time so we don't have to remember too much.

2 MS. KOLBUSZ: Well, thank you for  
3 introducing Dr. Lee Schwamm. He's our physician  
4 consultant for this measure as such.

5 The next measure which is stroke 6,  
6 discharged on a statin medication, also last  
7 endorsed in 2012. This measure captures the  
8 proportion of ischemic stroke patients who are  
9 prescribed a statin medication at hospital  
10 discharge.

11 The denominator population for this  
12 measure has changed since the last endorsement  
13 period. It is now all ischemic stroke patients.  
14 It was updated to align with an update in  
15 guideline recommendations that occurred from ACC  
16 and AHA in November of 2013.

17 CO-CHAIR TIRSCHWELL: Great. So, then  
18 I think I'm on deck for talking and I just want  
19 to find my notes here. All right.

20 So, David, you're going to lead us  
21 through this. I'm going to do some of the  
22 talking. So, I'm going to start with evidence.

1 Right?

2 CO-CHAIR KNOWLTON: Right.

3 CO-CHAIR TIRSCHWELL: So, there hasn't  
4 been any new clinical trial evidence since this  
5 statin measure was first approved when we were  
6 last here. Some of the details of the numerator  
7 and the denominator have changed a little bit to  
8 come into alignment with this new guideline that  
9 was already referred to. But the fact that  
10 statins are effective and important at reducing  
11 outcomes after atherosclerotic-related ischemic  
12 stroke that's the evidence that this is based on  
13 and, you know, I don't think there's much debate  
14 about that. And so, you know, the preliminary  
15 ratings and I'm a little -- on my form there's  
16 two versions of it. Oh, it says moderate and  
17 then fast and I certainly think it's at least  
18 moderate, although maybe there's a reason why it  
19 can't be higher than moderate. Quality high,  
20 quality moderate. I'm not seeing necessarily a  
21 reason. I'm just thinking about the charts.

22 Like the other one, there was a reason

1       there wasn't something that prevented it from  
2       getting high. Is that in place here as well?

3               MS. JOHNSON: No, I think this one  
4       probably the staff landed on moderate probably  
5       because of the level B evidence. It's probably -  
6       -

7               CO-CHAIR TIRSCHWELL: Okay.

8               MS. JOHNSON: But it's not like for  
9       reliability or something where we're saying  
10      testing is a certain level so moderate is as high  
11      as you can go, it's not like that.

12              CO-CHAIR TIRSCHWELL: And high or  
13      moderate I think there's little debate that  
14      there's clear evidence to support this. So, I --  
15      that's all I've got.

16              CO-CHAIR KNOWLTON: Do we have any  
17      questions or comments?

18              Are you ready for a vote? Oh, so we  
19      don't need to vote because there's no new  
20      evidence. Okay.

21              CO-CHAIR TIRSCHWELL: I'm fine. I  
22      think we would have passed the vote anyway. So,

1       it's moot.

2                   CO-CHAIR KNOWLTON: Rather moot.

3                   CO-CHAIR TIRSCHWELL: All right. So,  
4       then we're down to our next criteria, the gap.  
5       And that same table that was in some of the  
6       earlier measures that caused consternation about  
7       whether the gap is topped -- whether there is a  
8       gap, whether we're already topped out on this  
9       measure. So, just looking at the data -- are you  
10      guys able to bring up this table? The one with  
11      the pink header line.

12                   Looking from 2010 to 2014, the 50th  
13      percentile went up from 94 percent to 99 percent.  
14      The 10th percentile went from 71 percent to 90th  
15      percentile. So, you know, clearly this one is  
16      not quite as topped out if that's a reasonable  
17      way to describe it as the anti-platelet  
18      medication was. That being said, things are  
19      looking pretty good now. The 10th percentile  
20      only takes us down to 90 percent.

21                   As far as disparities data go, it's  
22      the same thing, there wasn't -- I'm sorry? It's

1 on the other screen now. That makes it pretty  
2 much impossible to see. Sorry.

3 There was a generic reference to  
4 disparities but there actually were some more  
5 specific examples from the literature given. I'm  
6 guessing there's a possibility that we may see  
7 more data later but, again, the decision is  
8 whether the difference, you know, between the  
9 10th and 90th percentile now is 90 percent versus  
10 100 percent, whether even if there were gaps,  
11 whether that still represents a substantial  
12 enough gap to keep it fully endorsed.

13 And so I think we all understand these  
14 issues. We'll open it up to comments from the  
15 group and then we'll give the developer a chance  
16 absolutely before we vote. Is that a reasonable  
17 process?

18 CO-CHAIR KNOWLTON: Yes. Questions?  
19 Comments? Lee or Karen?

20 DR. SCHWAMM: Sure, I think it's  
21 important to note that the data you see on the  
22 performance gap is based on the prior denominator



1 exclusions where it applied only to patients who  
2 had an LDL greater than 100. The new denominator  
3 because of the subsequent evidence and the  
4 upgraded guidelines from the American Heart  
5 Association now include everybody with an LDL  
6 down to 70. So, there's a large number of  
7 patients who had moderate LDL elevations who are  
8 now eligible for the measure and we don't know  
9 the performance gap in those patients. Isn't  
10 that correct?

11 MS. KOLBUSZ: Correct.

12 CO-CHAIR TIRSCHWELL: So, we're  
13 presented with this measure where we've all  
14 agreed the evidence hasn't changed. The  
15 specifications of the measure have changed. We  
16 have no data about how the new specifications  
17 work and we're trying to decide whether there's  
18 still a gap. I don't know how we'd come to that  
19 conclusion.

20 MS. KOLBUSZ: I'd just like to clarify  
21 based on the opening of the project and the close  
22 of this project. No data had been received using

1 the new denominator population. So, there is a  
2 four month lag. The change in specifications  
3 went into effect October 1st of 2015. And those  
4 data had just been received at the Joint  
5 Commission. It would only be one quarter of  
6 data. So, it is impossible for us to provide you  
7 with data reflective of the change in the  
8 denominator population. There's just not enough  
9 time to do so. We need to reflect more.

10 DR. SCHWAMM: Okay. But it is a  
11 significant expansion of the nominator. So you'd  
12 have to hypothesize that the performance  
13 increased to the same proportion as the  
14 denominator expanded. That's the key point here.

15 Many more patients are eligible for  
16 this measure than were before.

17 CO-CHAIR TIRSCHWELL: I guess as it  
18 seems to be the case again and again we're stuck  
19 in a little bit of a policy issue about how do we  
20 evaluate this measure and the gap with the  
21 possibility that now that the specifications have  
22 been changed this older gap data which suggests

1       that it's pretty close to topped out if not  
2       already there may no longer be the case.

3               I mean, what are our options? Again,  
4       should we table this and wait for data? Should  
5       we judge it now but then potentially look at the  
6       data when you have a chance to gather some? I  
7       guess to do that like the earlier one, we would  
8       have to vote that it was insufficient which would  
9       give the Joint Commission the opportunity to come  
10      back with some data that would allow us to  
11      evaluate this particular question. Is that  
12      correct?

13             MS. ISIJOLA: So you're looking at the  
14      measure as specified today if in fact there is  
15      additional information, we can present that to  
16      you in working with the Joint Commission to  
17      review it during our post-comment call.

18             CO-CHAIR TIRSCHWELL: So, let me just  
19      backtrack a little. There must be a standard  
20      process for approving modifications to a measure.  
21      What is that process? Is it different than what  
22      we're doing right here?

1 MS. JOHNSON: I'm sorry, you caught me  
2 in mid-chew.

3 Yes, we actually do have a maintenance  
4 process. We call it the annual update. So,  
5 every year we ask our developers to update their  
6 measure. So, if they've made changes to their  
7 measure we ask them to tell us about those  
8 changes. Often those might be as was discussed  
9 earlier a new med is on the market and so they  
10 update med lists, those kinds of things.

11 We look at the updates that have been  
12 made and we decide at that point whether the  
13 change has been a big enough change that we  
14 actually have to go through what we call  
15 maintenance process. So, their change in their  
16 measure just happened to coincide with our  
17 project that's happening now. So, we're not  
18 going through an ad hoc which would be our way of  
19 looking at a change that's happened kind of  
20 outside our cycle. We're just looking at it  
21 right now.

22 So, did that answer your question,

1 David?

2 CO-CHAIR TIRSCHWELL: I guess I  
3 understand that but it seems like the timing is  
4 undermining our ability to do so in that the  
5 timing didn't allow you guys to have any data to  
6 present. We understand that. But yet we're  
7 trying to evaluate the gap. I guess I'm feeling  
8 like there is insufficient information for which  
9 me to evaluate whether there's a gap or not.

10 CO-CHAIR KNOWLTON: Valerie?

11 MEMBER COTTER: Can I just make a  
12 comment? If the guideline came out in 2010 this  
13 is six years later.

14 MS. KOLBUSZ: The new guideline was  
15 from ACC&H in November of 2013.

16 MS. ISIJOLA: 2013.

17 MS. KOLBUSZ: And that's when it was  
18 first released. And then the following, I  
19 believe, May or June 2014, the secondary  
20 prevention guidelines from the American Heart  
21 were updated that reflect the same. But during  
22 that first year period there was discussion with

1       our technical advisory panel members. They  
2       wanted to see, you know, how this was  
3       assimilated, I guess, and we didn't make the  
4       change right away. And then it does take some  
5       time once we decide to make a change because the  
6       specifications manual is actually delayed. So,  
7       this change was really decided about a year ago  
8       but didn't go into effect until October 1st of  
9       2015.

10               CO-CHAIR KNOWLTON: David?

11               DR. SCHWAMM: The only data I can give  
12       you, I mean, I can't give you exact data because  
13       I can't actually run this measure. But get with  
14       the -- I just did it right now. And get with the  
15       guidelines we have two parallel measures. We  
16       have a measure that you saw four years ago which  
17       was if you have an LDL of 100 or greater than the  
18       LDL for the measure, what's the frequency of  
19       adherence and it's basically 94 percent.

20               If you run the parallel measure which  
21       is, did you have a stroke due to atherosclerosis  
22       and get high intensity statin therapy so it's not

1 all statins. It's high intensity statins  
2 therapy. That's only about 53 percent.

3 So, in the group with the larger  
4 denominator but requiring high intensive statins,  
5 not any statin, the adherence is only about 54  
6 percent.

7 CO-CHAIR TIRSCHWELL: So, that more  
8 accurately reflects the new specifications, is  
9 that what you're suggesting?

10 DR. SCHWAMM: That reflects the new  
11 denominator. The new numerator is still statin  
12 therapy, not high intensity statin. So to be in  
13 the numerator of this other measure but it's not  
14 perfect. I'm just giving you the best that I  
15 have. It's only about 54 percent.

16 CO-CHAIR TIRSCHWELL: Okay. Peter?

17 MEMBER SCHMIDT: So, I'm a little bit  
18 confused because there's no new evidence and the  
19 numerator and denominator are definitions of  
20 change. So, we didn't review evidence but  
21 there's been a change and it's not within the  
22 measure that was approved previously.

1 CO-CHAIR TIRSCHWELL: Yes, so I  
2 struggled with this and about how much detail to  
3 go into when discussing all of this. The  
4 previous measure of specifications was sort of,  
5 you know, straight out of the one clinical trial  
6 that looked at this and, you know, I think,  
7 reasonably guidelines have assimilated a greater  
8 body of information to expand the denominator a  
9 little bit more so it really isn't -- I still  
10 think there isn't any new evidence but the  
11 guidelines have changed a little to reflect a  
12 broader evaluation of who this type of treatment  
13 is appropriate for. But I feel that tension  
14 between those two things. No new evidence so why  
15 are we changing the specification?

16 MEMBER SCHMIDT: But wouldn't that  
17 constitute like class D evidence, expert opinion,  
18 if it's a new guideline?

19 MS. KOLBUSZ: The guideline  
20 recommendations still, class 1, level of evidence  
21 A, which is what it was before. Where the change  
22 is that there wasn't a change in the level of



1 evidence. They opened up the guideline  
2 recommendation to include all ischemic stroke  
3 patients because they identified in the new  
4 guidelines four statin benefit groups. And those  
5 with clinical ASTBD are put in the first group  
6 recommending high statin therapy and your stroke  
7 and TIA patients fall into that group.

8 DR. SCHWAMM: Yes, I mean I think this  
9 is a -- this was a decision by the experts that  
10 stroke should be thought of as an atherosclerotic  
11 disease and not a spec separate carve out. Prior  
12 to that there had been no data to the benefit of  
13 statins and stroke. The SPARCL trial  
14 definitively showed that high intensity statin  
15 therapy dramatically reduced the risk of  
16 recurring stroke and of cardiac disease, coronary  
17 events and coronary revascularization.

18 So, what the new guideline did is it  
19 basically said, look, we know from the data that  
20 everybody benefits who has atherosclerosis from  
21 statin therapy and so hundred is an arbitrary  
22 number. We should get rid of that exclusion

1 because if you have an LDL of 99 you know you  
2 still benefit by reducing the LDL. There's no  
3 drop off on that curve. There's no step  
4 function.

5 So, there isn't new evidence. You're  
6 absolutely right, but the decision was to broaden  
7 the impact of statin use to anyone with evidence  
8 of atherosclerosis and so stroke due to or in the  
9 presence of athero is really reconceptualizing  
10 that patient as a patient with atherosclerotic  
11 disease and, therefore, should be on statin  
12 therapy.

13 CO-CHAIR TIRSCHWELL: And I'll just  
14 comment that in the 2014 Secondary Stroke  
15 Prevention Guidelines there are three parts to  
16 the lipid thing. I think only one of them is 1A  
17 evidence. There's a 1B and I'm not going to  
18 remember the rest accurately so I won't comment.

19 But, anyway, suffice to say the  
20 evidence is still pretty strong but the  
21 specifications have changed. And I think the  
22 changing specifications are probably more

1 important about what it says and what we don't  
2 know about the gap now then it is about whether  
3 there's evidence to still give these patients  
4 statins.

5 MS. JOHNSON: So, this is kind of an  
6 interesting conundrum that we're in and we  
7 actually have a potential way out of this. We  
8 might not like it. But what we could do, is you  
9 have the option as the steering committee to  
10 defer your consideration of this measure. And by  
11 defer, we would ask you to kind of a joint  
12 agreement with Joint Commission. When do they  
13 think they could actually have some data because  
14 what's happened is it's a change in specification  
15 that's actually made the data available not quite  
16 what you need to be able to look at.

17 So, that would be an option. So, to  
18 make it clear you could ask to defer complete  
19 discussion of this measure and Joint Commission  
20 you can decide, is it's six months or a year or  
21 whatever is a reasonable amount of time for them  
22 to be able to have data that reflect the new

1 specifications.

2 MEMBER RAE-GRANT: A couple points.

3 First of all, I don't think we need to  
4 tie ourselves in knots around this. I think it  
5 is within our purview, I'm putting this out  
6 there, that if we perceive from the evidence  
7 that's not necessarily right here that there may  
8 be a gap still within the -- we probably don't  
9 need to vote against it if we think there's more  
10 to learn. And I don't know if we need to slavish  
11 about what's written down in the preliminary  
12 document in terms of our deliberations. So,  
13 that's one thing.

14 The second is I would think about --  
15 there's different process measures and some of  
16 them are non-treatment process measures. I'm  
17 thinking of NIH stroke scale measures. I would  
18 think we should have a higher level of stringency  
19 to retain treatment-based process measures such  
20 as institutional hydro statin or whatever statin.  
21 Then we do for measures which are just measuring  
22 times to, you know, CT scan or something. And,

1       therefore, if we have that then we would want to  
2       retain a measure like this longer to insure that  
3       there's high compliance before we put it on  
4       reserve status. Does that make sense? So, we're  
5       only one year into or a couple of years into a  
6       final -- we're saying it's in compliance fully.  
7       Maybe we need to give more time to medication  
8       treatment or some other treatment process measure  
9       and that way both of those would help us not  
10      worry about this. Just vote it through and see  
11      what happens the next time we review it.

12               MEMBER FERZIGER: So, I agree with that  
13      completely. I have a question though about sort  
14      of where the state of either the treatment  
15      development or population definition is in this  
16      field, right? So, now you've made a modification  
17      to the scale. Right. What's the likelihood in  
18      two years, right, that either the population, you  
19      know, will be what we now have specified or that  
20      it would assimilate, right, be expanded because  
21      of new knowledge or that new treatment  
22      development actually would change, you know, the

1 focus from statins.

2 CO-CHAIR TIRSCHWELL: I mean, things  
3 can change. And there are processes for that.

4 MEMBER FERZIGER: So, I guess my  
5 thought would be, right. Everything is always  
6 changing and it seems that as long -- until  
7 things are stable and likely to stay that way for  
8 a long time there's no such thing as topped out  
9 because, right, because you actually have more  
10 things to measure that you haven't measured  
11 before and that are now important.

12 CO-CHAIR TIRSCHWELL: Just by the  
13 virtue of the fact that there is a change perhaps  
14 we should leave it in because --

15 MEMBER FERZIGER: Yes. If it's a  
16 substantial change, right, and that needs to be  
17 covered as well, the measurement.

18 CO-CHAIR KNOWLTON: Other comments?

19 MEMBER BULSARA: You know, I think I'm  
20 with David in the sense that we don't want to  
21 under serve this measure in the sense that we  
22 don't to vote on it one way when Lee is telling

1       us there's a lot more data so I mean just  
2       listening to this, I think the option to  
3       deferring sounds very appealing. But I don't  
4       know what the implications of that are but it  
5       does sound very appealing.

6                   CO-CHAIR KNOWLTON: David.

7                   MEMBER ANDREWS: As sort of an  
8       outsider to all this it strikes me that a lot of  
9       things change fairly quickly in modern medicine.  
10      And one of the things that NQF probably needs to  
11      grapple with is how do you have ongoing processes  
12      to deal with things that change much more rapidly  
13      than standing committees meet in order to arrive  
14      at a process that's responsive to the reality out  
15      there in the field?

16                  CO-CHAIR KNOWLTON: Other  
17      considerations? So, it seems that we've got  
18      before us either if I understand correctly,  
19      correct me if I'm wrong. We have either a vote  
20      on gap or we have a vote on deferring. Is that  
21      fair?

22                  CO-CHAIR TIRSCHWELL: Well, I think if

1 we vote on gap and you want to defer you should  
2 probably vote insufficient. Is that right or is  
3 that a different thing altogether?

4 MS. JOHNSON: Maybe let's get a gestalt  
5 first. Let's just see if anybody has, you know,  
6 we've heard one person interested in a deferral  
7 and some other folks probably not so interested  
8 in deferral. Can we just do a show of hands and  
9 see?

10 CO-CHAIR TIRSCHWELL: Well, I think --  
11 I think there are a number of options. One is,  
12 you know, as Alex was saying or actually, I'm  
13 sorry, somebody, you know, things have changed  
14 and common sense says to me that this is going to  
15 open gaps, not close them. And so I'm willing to  
16 just say that their gap is moderate and move  
17 ahead with continued endorsement. That would be  
18 one options.

19 Another option would be that I've got  
20 data in front of me and, you know, I don't -- I  
21 don't have any data about this new thing. I  
22 don't think it's going to be so low. So, I just



1 want to say that there is no gap left and it's  
2 low.

3 Or that I just don't know and I want  
4 to see those data from the first few months and  
5 that would sort of be the insufficient argument.

6 Or do you want to add a fourth one to  
7 that?

8 MS. JOHNSON: I don't want to add a  
9 fourth one but I would be curious from TJC when  
10 do you think he would have some data to be able  
11 to show because our post comment call is going to  
12 be, what? Two months from now? So, I guess the  
13 question is, will there be anything two months  
14 from now for you to look at?

15 MS. WATT: Well, our question right  
16 back at you is, how much data do you think you  
17 need? We know that we have one quarter of data  
18 now that just came in or is just coming in on  
19 April 29th and it's going to be another four  
20 months until we get the data for first quarter of  
21 2016.

22 If one quarter of data would be

1 sufficient for you we should be able to share  
2 that sometime early May.

3 DR. SCHWAMM: Just -- I don't know if  
4 it will come in in time, but I just actually sent  
5 an email out to someone at AHA who is running the  
6 measure with the guideline hospitals. And for  
7 what we have for 2016 so it may be that in 10 or  
8 15 minutes so I can give you a rough estimate of  
9 performance in the first three months of the  
10 year.

11 CO-CHAIR TIRSCHWELL: I mean, get with  
12 the guidelines, collects the newly specified  
13 measure as a conduit to data submission to the  
14 Joint Commission. Did I use all those word  
15 correctly? And get with the guidelines. You  
16 know, the numbers are staggering so three months  
17 worth of data is going to be thousands and  
18 thousands of patients undoubtedly, right? So,  
19 that would seem adequate to me. I would know a  
20 lot more then than I do now. It would  
21 potentially be a bias towards better performing  
22 hospitals so we might imagine them nationally.

1 CO-CHAIR KNOWLTON: Which may show that  
2 gap much narrower, you know, because get with the  
3 guidelines hospital are the --

4 CO-CHAIR TIRSCHWELL: Well, there's a  
5 lot of them out there. They're not all perfect.

6 CO-CHAIR KNOWLTON: So, what was your  
7 recommendation, Karen, that we do what?

8 MS. JOHNSON: Well, why don't we -- it  
9 sounds like we might have information in 15 or 20  
10 minutes. We might have it in May that would be a  
11 quarter and it sounds like that would be a lot of  
12 data, right? Why don't we -- I don't know,  
13 Elisa. Should we stop discussion of this one.  
14 Go to the next one and then come back? Or do we  
15 wait? What do you think?

16 MS. MUNTHALI: Let's stop and go to the  
17 next one.

18 MS. JOHNSON: Okay. So, we'll see what  
19 -- give us guidelines. Your analyst is back  
20 there --

21 CO-CHAIR KNOWLTON: Charlotte, let's  
22 see what Charlotte --

1 (Off mic comments.)

2 CO-CHAIR KNOWLTON: I think it's a  
3 little different. They have some data. The  
4 difference is there was an actual change in the  
5 standard and they've got data that supports that.

6 When you talked about disparities they  
7 didn't have that data yet. And they're saying,  
8 this is what we think will happen. That's  
9 different than we have data that you can look at,  
10 right?

11 MEMBER JONES: But isn't the process  
12 the same? Is it one time we're saying we don't  
13 trust the data that's being reported to us in  
14 this meeting and now we're saying we do trust the  
15 data that's being reported to us in this meeting.

16 CO-CHAIR TIRSCHWELL: Instead of saying  
17 that we don't trust it --

18 MEMBER JONES: And I'm not.

19 CO-CHAIR TIRSCHWELL: We just don't  
20 have the written data to fully review and take  
21 time to assess. But I think your point is well  
22 taken. That's even when Dr. Schwamm who adds a

1 new lightning fast data analytic element to the  
2 Joint Commission but still won't have it in front  
3 of us to evaluate completely and ponder without  
4 feeling a time pressure.

5 MEMBER JONES: I think in terms of  
6 transparency we weren't willing to accept data  
7 provided to us in a previous discussion. To do  
8 so for this raises a transparency issue. And I  
9 just think we need to be aware of that.

10 MEMBER FERZIGER: So, I just want to  
11 emphasize what you just said, right? That maybe  
12 we can project what data we will have, let's say  
13 it's beautiful data, you know, and it's very good  
14 for where it comes from. But still, you know, it  
15 leaves the gap, right, of, you know, the range of  
16 places it could come from. There's likely to be  
17 some difference. So, that means that, you know,  
18 even if we imagine the best case scenario, some  
19 of us will still think in three months that  
20 there's a gap. So, I would be prepared to vote on  
21 that basis that even if I have everything I got  
22 or I wanted I'd still think there was a gap for

1 the reason you just identified.

2 MEMBER BULSARA: Just a follow-up on  
3 what Charlotte was saying. I think in all  
4 fairness to us, I think we do have to have an  
5 opportunity to actually look at the data and in  
6 fairness I think the Joint Commission, I mean,  
7 they should -- if us deferring this doesn't  
8 result in loss of endorsement over the next  
9 couple of months, I think they should have a fair  
10 opportunity to present the best data. So, I  
11 think it works both ways and I mean if there's no  
12 penalty to deferring, I don't see why we should  
13 rush through it.

14 CO-CHAIR KNOWLTON: I agree with that.

15 CO-CHAIR TIRSCHWELL: Karen, are we  
16 back to taking your straw poll on deferring.

17 MS. JOHNSON: I think we might be.  
18 There would not be -- they would not lose  
19 endorsement. It would just be deferred.

20 MS. MUNTHALI: And I just wanted to  
21 clear up one thing about the difference between  
22 this measure and the other. On the clinical

1 practice side, guidelines changed for this  
2 measure which was very much out of the control of  
3 the Joint Commission in terms of the timing. We  
4 were trying to catch up. The deferral option that  
5 the committee has -- one of the reasons you can  
6 defer is the timing of guidelines. So, that is  
7 very much within our process. I did want to  
8 clarify that and that's why we'd rather you defer  
9 if at all possible. The measure isn't going to  
10 lose endorsement but it gives the Joint  
11 Commission enough time to catch up with practice  
12 guidelines.

13 CO-CHAIR KNOWLTON: Other comments?

14 Shall we -- what do we do a straw  
15 poll, David, you think for the --

16 CO-CHAIR TIRSCHWELL: Show of hands?

17 CO-CHAIR KNOWLTON: Show of hands? We  
18 don't have a way to electronically vote for that?

19 So, how many would be in favor or  
20 deferral of this measure now? Does anybody  
21 oppose it? Okay. So, because this is deferred  
22 we move on, is that correct?

1 CO-CHAIR TIRSCHWELL: And we'll also be  
2 deferring the eMeasure then I imagine as well.

3 CO-CHAIR KNOWLTON: Right. We'd have  
4 to.

5 CO-CHAIR TIRSCHWELL: Yes.

6 MS. WATT: Excuse me, this is Ann. I  
7 just need a little clarification.

8 So, is the one quarter of data -- will  
9 that be sufficient for you all to be able to make  
10 this determination and were we going to discuss  
11 the rest of the criteria as well as we did  
12 earlier when we -- I'm just --

13 CO-CHAIR TIRSCHWELL: When we re-review  
14 it after we have the one quarter of data we'll go  
15 through the rest of the criteria as well.

16 MS. WATT: Okay. And so one quarter of  
17 data will be sufficient?

18 CO-CHAIR TIRSCHWELL: You know, I guess  
19 there's a possibility that we would say it's not.  
20 But given the numbers, I mean, it's hard for me  
21 to believe that you wouldn't be able to  
22 demonstrate a gap if there is one there.



1                   Okay. Moving along. We're going to  
2 go to the thrombolytic therapy measures 0437 and  
3 it's e-companion 2834.

4                   Would you like to introduce the  
5 measure?

6                   MS. KOLBUSZ: This is our stroke four  
7 measure, which is our thrombolytic therapy  
8 measure, the measure that captures the proportion  
9 of acute ischemic stroke patients who arrive at  
10 this hospital within two hours of time last known  
11 well for who IV-tPA was initiated at this  
12 hospital within three hours of time last known  
13 well.

14                  The rationale is supported by an in-  
15 study. The evidence has been well established  
16 that the early administration of thrombolytic  
17 therapy to eligible ischemic stroke patients  
18 within that three hour time frame does actually  
19 improve neurological outcomes for patients. Time  
20 is considered brain so earlier administration  
21 rather than later is preferred, although more  
22 recent guidelines from the European Cooperative

1 Acute Stroke Study III did show that it can be  
2 administered safely and effectively up to four  
3 and a half hours which we acknowledge. But we  
4 still do maintain that the high bar is the three  
5 hour administration time frame.

6 CO-CHAIR TIRSCHWELL: Great and our  
7 discussants are Rubin and Mike. Who is going to  
8 take the helm?

9 MEMBER KAPLITT: Yes, I will. So,  
10 hopefully this will be less controversial than  
11 the last couple but who knows.

12 So, the evidence for this as you heard  
13 has not changed very much since the last  
14 endorsement. The numerator is basically, you  
15 know, all -- is patients who arrive within three  
16 hours or last -- who receive IV-tPA within three  
17 hours of last known well and the denominator is  
18 basically all patients who are eligible with some  
19 exclusions that we'll talk about under validity.

20 The evidence in favor of that three  
21 hour window hasn't really changed much as you  
22 just heard. I mean, there's a wealth of evidence

1       that supports that the three hour window makes  
2       sense from, you know, randomized studies, NIH  
3       studies that the FDA approval of tPA, etcetera,  
4       etcetera. So, I don't think there's new evidence  
5       that contravenes any of that to make it  
6       controversial.

7               The only issue is this European study  
8       that shows that you can in some patients extend  
9       the window to four and a half hours but I don't  
10      think that that materially changes the evidence  
11      in favor of this guideline. It really relates  
12      more to the validity question that I'll come to  
13      later. Unless, you know, people feel strongly  
14      that all patients should be treated within that  
15      four and half hour window and I don't think the  
16      one European study will support that.

17              CO-CHAIR TIRSCHWELL: Well, again, I  
18      think we're judging the measure that's before us.

19              MEMBER KAPLITT: No, what I'm saying,  
20      they'll change their measure to include that.  
21      So, I'm saying on the evidence -- so they've  
22      created a new exclusion criteria based on that

1 three to four and a half hour window of  
2 documenting patients who have -- who receive IV-  
3 tPA outside the three-hour window. That's new  
4 since the last measure. It's not part of the  
5 inclusion, it's a new, whatever data element.

6 CO-CHAIR TIRSCHWELL: Yes. Clarify  
7 that a little bit.

8 MS. KOLBUSZ: I just want to clarify.  
9 That is not new. The exclusion to exclude  
10 patients who receive tPA administration up to  
11 four and a half hours was possible with the last  
12 re-endorsement in 2012. The way we went about it  
13 though was different at that time. We relied on  
14 text documentation instructing the hospitals  
15 through abstraction guidelines that if they had a  
16 reason for not administering IV-tPA within three  
17 hours that they were allowed to select no for IV-  
18 tPA administration so that they would be able to  
19 reach the reason, data element in the algorithm.

20 In working with CMS and the data  
21 warehouses, that logic might work for humans.  
22 It's backwards computer logic and we needed to

1 correct the algorithm logic so that we would  
2 accurately categorize and capture those patients.  
3 Therefore, in working with the CMS technical work  
4 group we did the revision and added a very clear  
5 data element for exclusion of patients and we  
6 call it reason for extending the initiation of IV  
7 thrombolytic to exclude those patients who  
8 receive IV thrombolytic therapy within three to  
9 four and a half hour window when they have a  
10 valid reason for exclusion. But -- yes, they  
11 still have to come in with two hours. So, we  
12 basically recut our timing too in the algorithm  
13 making a repeat decision since the reason is  
14 often the same that we repeated it and it's all  
15 really about computer logic and computer  
16 programming, the reason for that change. It  
17 isn't a clinical change per se.

18 MEMBER KAPLITT: Yes, okay, fine. I  
19 mean there's no point in wasting a lot of time.  
20 It's not a clinical change to the extent that you  
21 always had the ability to exclude patients for  
22 some medical reason. You've just created a new

1 data element that specifies this particular  
2 reason, right? Isn't that true?

3 MS. KOLBUSZ: The new data element  
4 captures that time frame three to four a half  
5 hours.

6 MEMBER KAPLITT: Right, but people can  
7 still exclude for other medical reasons too.  
8 Somebody gets a thrombectomy, for example, within  
9 two hours, right, they're not a candidate for IV-  
10 tPA. They can be legitimately excluded from this  
11 because that's a medical reason, right? But  
12 that's not got its own data element. That's a  
13 catchall of medical reasons. I mean, I think  
14 we're arguing a semantic point here. I'm just  
15 saying that I just want to make sure I'm being  
16 accurate on what we have here, right? You have a  
17 specific data element for extended IV-tPA as an  
18 exclusion.

19 MS. KOLBUSZ: Correct. Before there  
20 one data element reason for not initiating IV-  
21 thrombolytic.

22 MEMBER KAPLITT: Right.

1 MS. KOLBUSZ: Medical patient reasons  
2 would be excluded by that data element. Now we  
3 repeat it to try to accurately capture that time  
4 frame of three to four and a half hours.

5 MEMBER KAPLITT: Okay. So, my only  
6 point is that as far as evidence is concerned the  
7 only evidence issue that's raised by the European  
8 study is whether or not one believes that the  
9 three hour time window is no longer offered and  
10 should it be a four and a half hour time window  
11 because that is the basis for this study from an  
12 evidentiary standpoint. Forget about the  
13 validity which I think it relates to validity  
14 later on.

15 And my only point is that I don't  
16 think that that one study, you know, is  
17 sufficient to fundamentally change the evidence  
18 in support of this. I believe the evidence in  
19 support of this measure is still valid for three  
20 hours. That European study notwithstanding. I  
21 don't think that one European study that is cited  
22 here more from the exclusion standpoint rather

1       than, you know, as an evidence issue. I don't  
2       think that that changes the evidence materially.  
3       That's my only point.

4                   CO-CHAIR TIRSCHWELL: Okay. Any other  
5       comments or discussion of evidence? And if not I  
6       guess if the evidence hasn't changed we don't  
7       have to vote on it again and we can just move to  
8       gap.

9                   MEMBER KAPLITT: All right. So, the  
10      gap I don't know, can you put it up here? I  
11      mean, unlike the last measures I don't think that  
12      this is really topped out by at least the  
13      standards that we've been using. You know, you  
14      can see here that we're not anywhere close to the  
15      sort of 99 percent ranges and I think that is  
16      showing clear improvement which is good but I  
17      think there is still an obvious performance gap  
18      that you can see in the numbers here.

19                   I think that from the standpoint of  
20      disparities as with all the other measures,  
21      there's no real disparity data provided. There's  
22      a lot of citations of disparities in stroke



1 outcomes among different, you know, ethnic groups  
2 and et cetera. You know, discussion of, you  
3 know, utilization and things like that. There  
4 were a few minor studies provided to suggest that  
5 the disparities were actually kind of narrowing a  
6 bit but no real data from this measure.

7 The only point that I would make is I  
8 think that, you know, the gap is still real and,  
9 you know, and needs to narrow. The only thing I  
10 would say to the developer is that given that  
11 we're not getting a whole lot of disparities data  
12 on many of these measures as this trend continues  
13 if we very soon in the next year or two start  
14 reaching into the 90 something percentile I'm  
15 just suggesting that we're going to wind up in a  
16 couple of years in the exact same situation we're  
17 winding up in the other measures and maybe we can  
18 do some preventative data collection to make sure  
19 that two years from now when this thing is  
20 reaching 95 percent, let's say, and we're arguing  
21 that there may not be as much of a gap anymore  
22 that we can actually see disparities data to see

1       whether that might represent an ongoing gap. We  
2       don't have it. I don't think we need it today  
3       because there's still an overall gap but I'm just  
4       throwing that out there.

5               CO-CHAIR TIRSCHWELL: And since we have  
6       Dr. Schwamm in the room and get with the  
7       guidelines is a big part of the data collection  
8       process, I know race and ethnicity and gender and  
9       age are all part of the massive database that is  
10      get with the guidelines and it seems to me it  
11      wouldn't be too terribly difficult to be able to  
12      break this down and look for disparities you have  
13      those data too? Okay.

14             MEMBER KAPLITT: But otherwise, I mean,  
15      so I think there is a gap. I don't know if  
16      anybody has anything to add.

17             CO-CHAIR TIRSCHWELL: Any other  
18      discussion around gap? Rubin? Yes, your card's  
19      up. No problem.

20             CO-CHAIR TIRSCHWELL: Okay. Let's move  
21      to --

22             MEMBER HUFF: Just a comment. As we

1 move toward licensing more individuals an  
2 unintended consequences are many individuals with  
3 stroke mimics are receiving thrombolysis and in  
4 most centers this ranges 20 to 30 percent is the  
5 information that I have and everybody agrees that  
6 thrombolytics clearly effective in a correctly  
7 selected patient. I think it would be  
8 interesting and probably you have the ability to  
9 gather data on thrombolytics administered to  
10 patients not with ischemic stroke but with stroke  
11 mimics.

12 CO-CHAIR TIRSCHWELL: That would be  
13 interesting data. I think if their hospital  
14 discharge diagnosis is not ischemic stroke then  
15 they're not going to be in any of these  
16 databases. So, I mean, those data are out there.  
17 I agree with your point that it's important that  
18 the high performing places have a 50 percent  
19 over-treatment rate versus, you know, 10 percent  
20 somewhere else. Then you'd maybe start worrying  
21 about it.

22 Any other comments before we go ahead

1 and vote? We bring up the vote. The screens are  
2 blank up there. Oh, here we go.

3 MS. OGUNGBEMI: One moment. We are now  
4 voting on evidence for measure 0437. Oh, pardon  
5 me.

6 We are now voting on performance gap  
7 for measure 0437. The options are high,  
8 moderate, low and insufficient. Voting is open.

9 The voting is closed. Results are 26  
10 percent high, 70 percent moderate, 4 percent low  
11 and 0 percent insufficient. Measure 0437 passes  
12 on performance gap.

13 CO-CHAIR KNOWLTON: Okay. Can we move  
14 on to --

15 MEMBER KAPLITT: So, can we move on to  
16 reliability?

17 CO-CHAIR KNOWLTON: Reliability. Yes.

18 MEMBER KAPLITT: So, reliability just  
19 to the point that someone made earlier, I will  
20 say up front that only -- testing was only done  
21 at the data element level not at the measure  
22 level. So, theoretically, we should only be

1 voting moderate as the highest score. But I  
2 leave everybody to their consciences so.

3 So, at the data element level the vast  
4 majority of the data elements showed a good  
5 inter-related reliability above, you know, 90  
6 percent for most of them. A few elements were  
7 above 80 percent but mostly in the high 80s. The  
8 only one that was a little low was time to last  
9 known well which was 80 percent in related  
10 reliability.

11 And then the only one element that was  
12 a little bit lower was the reason for not  
13 initiating IV-thrombolytic therapy which was 77  
14 percent. So, I think it's reasonably reliable.  
15 I'm assuming but obviously we don't data yet but  
16 this new element might actually help with that  
17 last one that was a little low because it  
18 clarifies for people. It's a separate element.  
19 And one of the reasons which is giving them IV-  
20 tPA late but I think that these numbers still  
21 show reasonable reliability from my standpoint.

22 CO-CHAIR KNOWLTON: Michael, if you,

1 unless somebody objects, if you don't feel it's  
2 new information we don't need to vote.

3 MEMBER KAPLITT: Yes, that's fine with  
4 me.

5 CO-CHAIR KNOWLTON: Okay.

6 MEMBER KAPLITT: I think the validity  
7 thing I do have an issue to clarify.

8 CO-CHAIR KNOWLTON: Let's stick with --  
9 then we'll move past reliability and validity.  
10 Go ahead.

11 MEMBER KAPLITT: Okay. So, I need to  
12 clarify something before I address validity with  
13 the developer.

14 So, there are two sets of data that  
15 I'm seeing in the measure. So, one is a set of  
16 data under -- sorry. There's one set of data  
17 that shows the exclusion percentages and then  
18 there's a new set of data since 2012 and they  
19 show very different numbers. Can you guys  
20 clarify what that is?

21 MEMBER KAPLITT: I can tell you the  
22 developer if you can clarify for me.

1                   So, on page, for example, on page 33  
2 of your measure under results for the potential  
3 threats to validity there's statistical analyses  
4 for exclusions and there's various percentages  
5 that are provided. But then several pages down  
6 where you're saying new since 2012 endorsement  
7 data for empirical testing there's a different  
8 set of numbers.

9                   So, are the numbers on page 33 the old  
10 numbers from the prior measure and then what's on  
11 page 35 -- I'm sorry, not page 35, page 35  
12 through 39, is that new data because those  
13 numbers are completely different and I'm trying  
14 to understand what they are.

15                  MS. KOLBUSZ: I just have a comment to  
16 make. What you are using right now is the  
17 preliminary analysis that was prepared by NQF  
18 staff.

19                  MEMBER KAPLITT: No, I'm looking at the  
20 actual measure. I'm not looking at the summary  
21 page. Well, I think I am. Maybe I'm not. I'm  
22 looking at -- yes, so 2B 3.3. There's one set of

1 data. And then there's a thing that says new  
2 since 2012 and which is a new -- essentially a  
3 new to be 3.3 and I don't know what -- I'm not  
4 understanding these numbers.

5 MS. KOLBUSZ: That is the measure  
6 worksheet. I'd like to just look at the testing  
7 form that we submitted to NQF --

8 MEMBER KAPLITT: Okay.

9 MS. KOLBUSZ: -- before I respond,  
10 please.

11 MEMBER KAPLITT: The problem is -- the  
12 reason that I'm trying to clarify this is because  
13 I don't understand what these numbers are because  
14 they're very different and they're two different  
15 sets of numbers for the same thing. So, I'm not  
16 sure where they're coming from.

17 I mean as an example, just to be clear  
18 of what we're talking about. So, it should be  
19 3.3 and I guess it's the worksheet. I didn't  
20 realize that so I apologize because I thought the  
21 worksheet was this sort of short summary thing.  
22 But under 2B 3.3 where it says that out of 39,812



1 patients it says that the patients with  
2 documented reason for not initiating IV  
3 thrombolytic was .95 percent. Then under the  
4 thing that you were just talking about in red  
5 that you guys are showing here, it's showing for  
6 206,000 patient records -- that's why I'm  
7 assuming that this is the difference between what  
8 was before and what was now but I don't know.

9 MS. KOLBUSZ: No, I think that now that  
10 I'm looking at the testing form that was  
11 submitted with the measure submission form from  
12 the Joint Commission 2B 3.2 asks, what were the  
13 statistical results from testing exclusions? And  
14 we did state that there were 2,206,379 admissions  
15 included in the initial cohort.

16 From among the 2,206,379 admissions  
17 and 13,018 hospitals, the descriptive statistics  
18 are given below and we provided exclusion data  
19 for the various data elements that result in  
20 exclusion. Clinical trials, elective carotid,  
21 time less known well was none. Time less known  
22 well to arrive in the ED greater than two hours,

1 none. And then also patients with the documents  
2 reason for not initiating IV thrombolytic and  
3 patients with a documented reason for extending  
4 the initiation of IV thrombolytic. That's one  
5 set of data.

6 On this form 2B 3.3 question. What is  
7 your interpretation of the results in terms of  
8 demonstrating that exclusions are needed to  
9 prevent unfair distortion of performance results?

10 We stated the median frequency of exclusions  
11 range from low to moderate. The distribution  
12 exclusions across hospitals is generally narrow,  
13 indicating that the occurrence is random and  
14 likely would not bias performance results,  
15 although the percentage of patients excluded may  
16 differ depending on whether the hospital was a  
17 stroke center.

18 For criterion validity it's believed  
19 that all the exclusion should be retained for the  
20 following reasons. And then we provide  
21 rationale. There's no further data in the  
22 submission we provided.

1                   MEMBER KAPLITT: So, maybe NQF can  
2     clarify for me what this other set of numbers is.  
3     I don't know who did this because the reason it  
4     matters is because if this other set of numbers  
5     was from the original thing from several years  
6     ago, it shows a massive change over time. That's  
7     why I need clarity where this other set of  
8     numbers come from.

9                   So, if you add this so-called  
10    worksheet on page 33, 2B 3.3, it says an end of  
11    39,812 patients, not two million patients, where  
12    does that come from?

13                  CO-CHAIR TIRSCHWELL: Is that from  
14    before the work group?

15                  MEMBER KAPLITT: I didn't think so but  
16    I can look it up online. I don't know.

17                  Which I would like somebody to  
18    confirm. If that's correct which I would like  
19    somebody to confirm, but if that's correct then  
20    what it shows is a big shift over time in the  
21    percentage of exclusions as, you know, even  
22    though -- even though we've seen, you know, the

1 sort of performance gap reviews we've seen a much  
2 bigger -- a big change in the percentage of  
3 exclusion. For example, if this was the original  
4 data it showed .95 percent of patients excluded  
5 for documenting a reason for not initiating IV  
6 thrombolytic therapy and now it's like 20  
7 something percent.

8 MEMBER SCHMIDT: The percentage in  
9 that section appears to be calculated  
10 incorrectly.

11 CO-CHAIR TIRSCHWELL: They used the  
12 wrong numbers. Is that right?

13 Are there two million -- there aren't,  
14 you know, there were not two million, I mean.  
15 There's a lot of records in get with the  
16 guidelines now what, two million something total  
17 or three million, four? Okay. But half of the  
18 patients in there weren't ischemic strokes that  
19 came in with two hours. So, the two million  
20 number should never have been -- that's the  
21 entire database probably at that point, right?

22 MEMBER KAPLITT: So, maybe not because

1 the carotid number says 11 percent. It says  
2 259,000 patients which is about 11 percent of the  
3 two million patients.

4 CO-CHAIR TIRSCHWELL: Right. It  
5 doesn't make sense to me.

6 DR. SCHWAMM: I think the issue is do  
7 you select as your denominator all ischemic  
8 stroke patients or do you select as your  
9 denominator all ischemic stroke patients arriving  
10 within two hours? Right, because the reason for  
11 non-treatment varies depending on whether or not  
12 you're excluded based on the --

13 CO-CHAIR TIRSCHWELL: Well, what's the  
14 measure? I mean, you should select what the  
15 measure is, right?

16 MEMBER KAPLITT: It's your denominator.

17 CO-CHAIR TIRSCHWELL: The denominator  
18 is within two hours, right?

19 MEMBER KAPLITT: If the numbers would  
20 start making sense.

21 So, this is my overall concern with  
22 validity. I have a series of numbers that I

1 spend time trying to understand and I just  
2 decided that I had to come here to get  
3 clarification because I couldn't understand these  
4 numbers.

5 MS. KOLBUSZ: One thing that I could  
6 say in regards to looking at the previous data  
7 from 2012 now that that's clear on this form to  
8 me what you were referring to. If you would look  
9 back on the total number of hospitals that  
10 collected this measure, when we came for  
11 endorsement in 2012, CMS was not collecting these  
12 data. The only hospitals collecting these data  
13 were Joint Commission certified primary stroke  
14 centers. So, it's a much smaller number of  
15 hospitals and also probably your more high  
16 achieving early adoptive type hospital. The  
17 number of hospitals has really increased as you  
18 saw with the performance gap numbers when you  
19 look especially at years 2013 and 2014. There's  
20 a significant number of hospitals. So, it jumps  
21 a lot.

22 MEMBER KAPLITT: So, they do but if

1       this 24 percent is correct and I agree that it  
2       doesn't fit. If you take 73,000 over two million  
3       that doesn't fit. So, either it's a simple math  
4       error and I'm worried about something that's not  
5       real or your denominator is different here. But  
6       this number is wrong. But if it were 24 percent  
7       exclusion whereas in that original group it was  
8       only one percent exclusion then it does represent  
9       as you broadened out, well, the gap has reduced.  
10      It's reduced in part because had a much greater  
11      level of exclusion and then the question is, does  
12      that raise the validity question.

13               But we have a more fundamental issue  
14      here that has to be clarified which is are these  
15      numbers accurate because, you know, whoever spoke  
16      earlier, I apologize I didn't see, is right.  
17      They don't make sense.

18               CO-CHAIR TIRSCHWELL: Okay. Steve then  
19      Peter. Peter?

20               MEMBER SCHMIDT: So, your last comment  
21      was a little bit worrisome that the exclusions --  
22      you seem to -- I interpret it as the exclusions

1 are used more extensively by the lower achieving  
2 hospitals and that sounds like a threat to  
3 validity to me.

4 CO-CHAIR TIRSCHWELL: So, I think there  
5 is some simple math problems here. There were  
6 some simple math problems with some of the other  
7 measures where 52 percent were being discharged  
8 home for hospice which never made any sense. And  
9 you've sent in some corrected data for that. I  
10 mean, the reality is, nobody is admitted for  
11 elective carotid intervention within two hours of  
12 their ischemic stroke. So that -- I mean, that  
13 doesn't -- it shouldn't even be part of this.

14 MEMBER SCHMIDT: I think this -- part  
15 of the challenge here and, again, I'm not  
16 familiar with the exact numbers that were  
17 submitted on this particular line. But the way  
18 the logic of the way the measure is constructed  
19 and which exclusions are applied in what order  
20 can have a big impact. So, admitted for elective  
21 carotid endarterectomy is an exclusion for all of  
22 the ischemic stroke measures because 433.10 in



1 ICD-9 is carotid stenosis or occlusion without  
2 visualized infarction. And so every carotid  
3 endarterectomy that gets admitted gets that ICD-9  
4 code assigned to it. The problem is if you have  
5 a stroke due to your carotid artery but you have  
6 a pacemaker so you can't have an MRI and the CT  
7 doesn't show an infarct, those patients also  
8 appropriately are coded 433.10. So, the Joint  
9 Commission and CMS apply the carotid elective  
10 admission for carotid endarterectomy across all  
11 these measures before any other attributes of the  
12 measure exclusions are applied. So, that's why  
13 you see carotid endarterectomy showing up here.  
14 That's just giving you a sense of how many  
15 carotid endarterectomies were performed in  
16 patients who were discharged with that diagnosis  
17 code of 433.10.

18 So, I think part of the challenge here  
19 is the sequence in which the denominator  
20 exclusions are applied and that makes it hard  
21 unless you're looking at the actual raw data from  
22 the outputs to figure out in what group does the

1 proportion of exclusions seem to make sense or  
2 does it seem a little bit strange and it has to  
3 do with who has been filtered by the previous  
4 exclusion, not all applied at the same moment. I  
5 don't know if that is helpful.

6 CO-CHAIR TIRSCHWELL: That make sense  
7 to me even if some of the more common sense  
8 things that we're seeing don't make a lot of  
9 sense. And I guess it would be -- would have  
10 been nice for those data to have been clarified  
11 with the submission.

12 So, my -- sorry, Jim.

13 MEMBER BURKE: So, that reason is  
14 documented. There's no documentation specified  
15 in this exclusion criteria so that there is a  
16 reason documented but there's no judgment about  
17 whether or not that was a good reason, is that  
18 right? Do you understand that? Because that to  
19 me seems like, if I'm understanding that right,  
20 that seems like a -- or maybe I'm not  
21 understanding it right.

22 MS. KOLBUSZ: Could you rephrase that

1 because I'm trying to read and follow and --

2 MEMBER BURKE: No, understood. So, the  
3 question is the exclusion is that there was a  
4 reason documented or contraindication. But  
5 there's no specific criteria for evaluating  
6 whether or not the reason was a good reason or a  
7 valid reason, is that right?

8 MS. KOLBUSZ: That's correct. We do  
9 not pass judgment on what's documented. The  
10 documentation is taken at face value. We're  
11 looking for linkage with thrombolytic therapy so  
12 that we know that there was consideration of  
13 thrombolytic therapy but whatever was documented  
14 as the reason we would not be casting judgment  
15 with the exception of a few stand alone reasons  
16 that are in that data element which have been  
17 identified through working with our technical  
18 advisory panel. For example, if there was a  
19 documented miss of zero on arrival to the ED we  
20 would consider that a valid stand-alone reason  
21 and we wouldn't look for further documentation or  
22 linkage.

1                   MEMBER BURKE: Okay. And that seems  
2     like it really amplifies Mike's concern if indeed  
3     these are real hospital level variations the  
4     hospitals were at 10 percentile is writing down a  
5     reason of 6 percent and the 90th percentile is  
6     writing down 54 percent whether or not we're  
7     judging how good you are at delivering tPA or how  
8     good you are at coming up with a documented  
9     exclusion, we're not going to hold those to a  
10    list. It seems like it's genuine validity  
11    concern. I'm not sure how much it changes  
12    things.

13                  CO-CHAIR TIRSCHWELL: Okay. Thank you.  
14    And I guess just an observation. What's missing  
15    from this list of exclusions or maybe it's an  
16    inclusion but the patients that presented after  
17    120 minutes, I mean, that seems like that would  
18    take a huge number out and that number is not  
19    listed here. I mean if we're taking out the ones  
20    that were electively admitted for carotid, sure.  
21    Those should, you know, they don't count but also  
22    the ones that presented later.

1 MS. KOLBUSZ: I'm sure it is a large  
2 number because when you look at the denominator  
3 population compared to other stroke measures, for  
4 example, stroke 2, you'll see that the  
5 denominator population for stroke 4 is always  
6 much smaller. It's only about a quarter percent.  
7 But that is based on a calculation. It's not  
8 based on a data element where we're reporting  
9 reliability of the validity for data elements,  
10 the calculation and the algorithm based on  
11 arrival date and time and date and time less  
12 known well.

13 CO-CHAIR TIRSCHWELL: Okay. Any other  
14 discussion on this or should we go ahead.  
15 Michael, do you have any closing comments about  
16 all that? Summarize that for us and help us --

17 MEMBER KAPLITT: Well, if you do them--  
18 I mean, if you do the math, unless the developer  
19 can, you know, show me different numbers, if you  
20 do the math, all of the other exclusions the  
21 numbers make sense actually though. That's what  
22 I was doing there. The calculations here they

1 all make sense relative to that two million two  
2 hundred thousand denominator, right.

3 The only one that doesn't is the  
4 reason for not initiating IV therapy. If you  
5 take that number against that denominator it's  
6 only three and half percent. So, if it's a  
7 simple arithmetic error then it's not a major  
8 concern going from one percent in the original  
9 group to three and half percent and now excluding  
10 I wouldn't be too worked up about it personally.  
11 But going from 1 percent to 25 percent to 24  
12 percent, you know, that's a different thing.

13 So, you know, that's the whole thing.  
14 I assume it's a simple arithmetic error in  
15 somebody's part to put those numbers here. Then  
16 fine, I don't see a major validity. All the  
17 other issues notwithstanding, clearly they're not  
18 affecting it that much. It's only gone from 1 to  
19 3-1/2 percent. But if it's gone from 1 to 24  
20 percent then all these things everybody has been  
21 raising could matter.

22 CO-CHAIR TIRSCHWELL: Yes, I mean on a

1 personal level I feel pretty confident that there  
2 is the math error and it's not nearly as big a  
3 change.

4 MEMBER KAPLITT: I do too.

5 CO-CHAIR TIRSCHWELL: Because I think  
6 the denominator probably got changed in that one  
7 but you're right. We can't be 100 percent sure  
8 about that.

9 MR. SCHMALTZ: Yes, this is Stephen  
10 Schmaltz from the Joint Commission. I do believe  
11 it is math error.

12 CO-CHAIR TIRSCHWELL: All right. So,  
13 let's go ahead and --

14 CO-CHAIR KNOWLTON: Well, I have a  
15 question.

16 CO-CHAIR TIRSCHWELL: Yes, sorry, go  
17 ahead.

18 CO-CHAIR KNOWLTON: So, what is the  
19 recommendation of your work group? I'm concerned  
20 that we're supposed to -- maybe I'm being too  
21 parochial but we're supposed to vote about what's  
22 in front of us. Now if it's a math error, it's a

1 math error, but what's in front of us and what's  
2 the recommendation.

3 MEMBER KAPLITT: Well, the original  
4 recommendation was -- I think it was like  
5 moderate or it was acceptable validity. But this  
6 issue hadn't been raised. This was something  
7 that came up when I was preparing for this where  
8 I noticed that we hadn't appreciated this and  
9 didn't discuss it. So, that's why.

10 So, the original recommendation based  
11 on everything else was that it was acceptable  
12 whatever, you know, validity. If it was a simple  
13 math error I think the gist of our call and our  
14 work group call would hold in that regard, you  
15 know. If it's not then everything changes.

16 CO-CHAIR TIRSCHWELL: Reuvin.

17 MEMBER FERZIGER: Peter's question.  
18 Did I understand that the exclusions may be  
19 different according to which kinds of hospitals  
20 they're coming from?

21 CO-CHAIR TIRSCHWELL: I mean the  
22 exclusions is kind of a safety net so that if you



1       feel like you -- you're the clinician, you feel  
2       like you have a valid reason why you're not  
3       giving tPA then this is not going to count  
4       against you that you don't give it. You just  
5       have to document that valid reason and different  
6       providers may feel that they have a different  
7       list of valid reasons. And that's all  
8       acceptable.

9               MEMBER FERZIGER: Did I understand you  
10       correctly that the rates of exclusion and the  
11       kinds of the rates were different based on the  
12       subjects that they're coming from?

13              DR. SCHWAMM: I would make two general  
14       comments. The first is that the Joint Commission  
15       -- so, I wear many different hats in this field,  
16       but at the moment I'm wearing my Joint Commission  
17       hat. But as my American Heart Association get  
18       with the guidelines measure developer, we have a  
19       slightly different approach which is we actually  
20       give a list of what we consider acceptable  
21       reasons based on the AHA guidelines, and we  
22       revise that every time that AHA changes that

1 list.

2           There is, I think, room for subjective  
3 interpretation about certain characteristics  
4 whether a patient's appropriate for treatment or  
5 not. All of the measures have reasons for non-  
6 treatment that are considered appropriate or  
7 valid. The Joint Commission standard is to  
8 require that somebody document in the record that  
9 there was a specific reason for not treating that  
10 link to the treatment. So, I didn't treat him  
11 because he was 93, and I felt his risk of  
12 hemorrhage was too high. They just collect that  
13 the reason was documented, and they actually  
14 collect reports and check off a box that says  
15 what was the reason. And they have the ability  
16 to write in a reason but if it's not on that list  
17 it doesn't.

18           I think either approach is very  
19 reasonable and valid. The more granular approach  
20 is more burdensome and onerous and so I think  
21 it's a very reasonable approach to say you must  
22 document the reason why and then rely on the

1 hospitals to review their cases and look for  
2 patterns of systematic bias or discrimination  
3 where they're not treating certain racial groups,  
4 ethnic groups, gender or just not treating  
5 anybody.

6 One thing you can do is look at the  
7 actual numbers of denominators and see if the  
8 denominator is shrinking and that's why rates are  
9 rising or if, in fact, the rate is going up  
10 because the enumerator is actually going up even  
11 as the denominator goes up. So, I think in this  
12 circumstance I do think it's very reasonable to  
13 accept a documented exclusion. and I think every  
14 measure must have that, otherwise it's like no  
15 risk adjustment. Otherwise, if you have a lot of  
16 people are inappropriate for the measure you  
17 somehow penalized, then you have a perverse  
18 incentive to treat everybody.

19 I think it is possible that some  
20 hospitals use the exclusion more frequently than  
21 others, but overall the rates of tPA use have  
22 been rising pretty dramatically across just

1 absolute rates. Used to be 3 percent; now  
2 they're closer to 8 percent. So, there has been  
3 over the last decade a continuous significant  
4 linear increase in the use of tPA.

5 MEMBER FERZIGER: It all makes sense;  
6 it just raises the spectrum of why the exclusions  
7 are being applied differently to different groups  
8 from different centers, and that would be a  
9 disparity of some concern.

10 DR. SCHWAMM: Agreed.

11 CO-CHAIR TIRSCHWELL: Okay. Let's go  
12 ahead and vote on validity.

13 MS. OGUNGBEMI: We are not voting on  
14 validity for Measure 0437. The options are high,  
15 moderate, low and insufficient. Voting is open.

16 CO-CHAIR TIRSCHWELL: Sorry, did you  
17 have another question, Valerie? I apologize.

18 MEMBER COTTER: Could you give us your  
19 advice on voting for this particular point?

20 CO-CHAIR TIRSCHWELL: Honestly, you  
21 know, I do believe this math error thing so I'm  
22 not worried about the validity here, and so I'll

1 be voting accordingly.

2 UNIDENTIFIED PERSON: Are we open?

3 MS. OGUNGBEMI: Yes, we are open.

4 Voting is closed. The results are 4  
5 percent high, 65 percent moderate, 17 percent low  
6 and 13 percent insufficient. Measure 0437 passes  
7 on validity.

8 CO-CHAIR TIRSCHWELL: Feasibility,  
9 Mike?

10 MEMBER KAPLITT: Yes, I'm just looking  
11 at my notes here. I just wrote that most of the  
12 data elements in which were generated, and I  
13 don't think there are any major feasibility  
14 issues assuming nothing new has come up since the  
15 last time.

16 CO-CHAIR TIRSCHWELL: Any discussion?  
17 Let's go ahead and move to vote on feasibility.

18 MS. OGUNGBEMI: Voting on feasibility  
19 for Measure 0437 is open. Options are high,  
20 moderate, low and insufficient.

21 Voting is closed. Results are 43  
22 percent high, 57 percent moderate, 0 percent low

1 and 0 percent insufficient. Measure 0437 passes  
2 on feasibility.

3 CO-CHAIR TIRSCHWELL: And then  
4 usability and use?

5 MEMBER KAPLITT: Usability is the same  
6 thing. I mean, I don't have a whole lot to say.  
7 It's, you know, I think that, you know, the  
8 benefits outweigh obviously I think most of the  
9 unintended consequences. Under usability, I'd  
10 put the comment that you had made earlier about  
11 this issue of, you know, physicians being able to  
12 put any measure -- you know, any medical reason  
13 that they want, but I don't think that's a major  
14 issue.

15 CO-CHAIR TIRSCHWELL: Discussion? Go  
16 ahead and move to vote then on usability and use.

17 MS. OGUNGBEMI: Usability and use is  
18 what we are now voting on for Measure 0437.  
19 Voting is open. The options are high, moderate,  
20 low and insufficient.

21 Voting is closed. Results are 52  
22 percent high, 48 percent moderate, 0 percent low

1 and 0 percent insufficient. Measure 0437 passes  
2 on Usability and Use.

3 CO-CHAIR TIRSCHWELL: So, then I think  
4 we just have the general suitability for  
5 endorsement vote. Discussion before that,  
6 Charlotte?

7 MEMBER JONES: Do we not need to  
8 discuss unintended consequences?

9 CO-CHAIR TIRSCHWELL: I think that  
10 should have been done already in the Usability  
11 and Use. So, we kind of missed that. Do you  
12 want to feel free to raise your point and we can  
13 decide whether we need to do something different?

14 MEMBER JONES: Well, I think that as  
15 Stephen pointed out with the previous one -- and  
16 it has been reported in the literature -- we know  
17 that hospitals that work on improving their time  
18 to needle increased treatment of minutes -- of  
19 stroke mimics and that's in the evidence. And I  
20 think it should be addressed. I think the fact  
21 that it wasn't even mentioned that there was a  
22 published article in a well-respected journal is

1 concerning to me and raises the question of  
2 transparency.

3 CO-CHAIR TIRSCHWELL:

4 MEMBER RAE-GRANT: This was raised at  
5 the last time. Steve raised that article and  
6 discussed that the last time. I guess we would  
7 just have discussion about that mimic issue.

8 CO-CHAIR TIRSCHWELL: That was --

9 MEMBER RAE-GRANT: It's on record as  
10 part of the discussion.

11 CO-CHAIR TIRSCHWELL: For the different  
12 measure, you mean?

13 MEMBER RAE-GRANT: Different measure,  
14 but at least we had discussed it in some way at  
15 committee. I'm pointing that out, yes.

16 MEMBER JONES: And that may have been a  
17 discussion that I wasn't part of. I was part of  
18 this one and I am, in fact, the person who sent  
19 it in into the group that it should be discussed.  
20 I think we need to discuss it as a group that at  
21 least we raised this issue as an unintended  
22 consequence of this measure.



1 CO-CHAIR TIRSCHWELL: Okay. I hear  
2 that you have raised it, and I guess I would ask:  
3 does anybody else have any comments or discussion  
4 about the unintended consequence of pushing hard  
5 for treatment leading to use of more tPA in  
6 false/positive stroke looking patients? Anybody  
7 on the committee? Dr. Schwamm?

8 DR. SCHWAMM: Yes, the only comment I  
9 would make is that it's been well demonstrated in  
10 the literature that the risk of harm to patients  
11 who have stroke demonstrated with tPA is very,  
12 very low, less than .5 percent. And it's also  
13 been demonstrated that the exponential nature of  
14 the decreasing effectiveness of the drug as time  
15 goes on, and I would argue pretty strongly the  
16 population attributable benefit to those who get  
17 treated by not waiting greatly outweighs the risk  
18 of harm to those who are treated rapidly but who  
19 turn out later on to have been a mimic. In many  
20 of those patients, it's not possible to determine  
21 their mimic status in a rapid manner. It's a  
22 judgment call. And we do lots of -- we do

1        appendectomies on patients that we think might be  
2        having appendicitis, knowing that 30 percent may  
3        not actually have had one because we know the  
4        benefits are so striking in the treated  
5        population. So, I would just argue I think that  
6        rapid treatment is still justified.

7                    CO-CHAIR TIRSCHWELL: Steve then  
8        Charlotte.

9                    MEMBER HUFF: Everybody is in favor of  
10       rapid treatment and we hope to get more accurate,  
11       more specific biomarkers in the future. I think  
12       currently with regards to appendicitis, no one  
13       has that false negative rate because everyone  
14       gets imaged for -- virtually everyone gets imaged  
15       first now.

16                   I just think that an unintended  
17       consequence of pushing is -- and it's  
18       interesting. The papers that say there's very  
19       few adverse reactions for the stroke mimics  
20       getting tPA are somewhat limited in number, and  
21       back in the days when we used to give tPA  
22       intravenously for cardiac conditions more

1 frequently, which is a much lower dose of tPA,  
2 there certainly was a recognizable complication  
3 rate so it doesn't make sense to me that we're  
4 giving more tPA and yet we seem to have no  
5 complications on a similar patient population.  
6 So, I'm just concerned about an unintended  
7 consequence, and it would be nice to monitor that  
8 in some way. I realize that may not be germane  
9 to this discussion.

10 CO-CHAIR TIRSCHWELL: Right.

11 Charlotte, go ahead.

12 MEMBER JONES: I am going to again as a  
13 pediatric neurologist, this measure goes down to  
14 the age of 18. It may very well be true that if  
15 you are talking in the 35, 40, 55 and up  
16 population that the risk of treating a mimic is  
17 reasonable on the number needed to treat. But if  
18 you were giving 18 and 19 year olds --- and I  
19 realize I don't have evidence either, but I think  
20 that their National Quality Forums should request  
21 -- and I think that even in the discussion that  
22 knowing that people are publishing the increasing

1 time to needle, increases treatments in mimics --  
2 that we have a responsibility to at least ask  
3 developers to track that. So the 18, 19 and 20  
4 year olds who are coming in with their  
5 complicated migraines or their post concussive  
6 symptoms and they're being treated because we are  
7 saying you have this period of time so you may  
8 not be able to get the history and find out that  
9 this was, in fact, a Todd's Paralysis, which is  
10 much more common in the younger population than  
11 the older population, that we have that evidence  
12 because you're going down to 18. And the  
13 risk/benefit and the positive pre-test  
14 probability are just very low in the 18 and 19  
15 year olds.

16 CO-CHAIR TIRSCHWELL: Thank you for  
17 those comments, Charlotte, and this will be  
18 absolutely noted in the reports and the summary  
19 from the committee. And I, unless somebody  
20 objects, I'd like to go ahead and suggest that we  
21 just revote on Use and Usability taking into  
22 account these new comments. Does anybody object

1 to revoting?

2 Michael, go ahead.

3 MEMBER KAPLITT: And I would simply  
4 point out that when we were questioning before  
5 about the value of the imagine measure, this is  
6 one of the values which is to reduce the  
7 unintended consequences of giving something to  
8 someone who could be harmed by it. So, you know,  
9 that's why we have the other measure to try to  
10 protect people.

11 CO-CHAIR TIRSCHWELL: Reuven?

12 MEMBER FERZIGER: Just a question to  
13 Charlotte. And that is, now I understand the  
14 risk of unintended consequences in younger  
15 patients may be significant, maybe. But how  
16 common are they, you know, as a chief complaint  
17 something that would lead to tPA in the ERs?

18 MEMBER JONES: So, what I can tell you  
19 right now is in one large children's hospital we  
20 have been asked to develop a stroke team, and we  
21 have been tracking our data, and so far we are  
22 seeing -- we've seen 12 complicated migraines

1 that were called by the ED as an acute stroke.  
2 None of them were. And we have had issues with  
3 mis-reads of MRIs in children with shunts who had  
4 Todd's Paralysis because the shunt impacts on the  
5 quick MRI that ordinarily the radiologist want to  
6 do and they've read ischemic lesions which was  
7 shunt artifact -- all of which means that as we  
8 push a younger and younger age group, there be  
9 risk benefit. It's like the adult cardiologist  
10 who says to me, well, gosh, if this was 50-year  
11 old, I'd tell you that 3-year old was having an  
12 acute MI. I have to say well, the pre-test  
13 probability of an acute MI in a 3-year old is  
14 pretty damn low.

15 MEMBER FERZIGER: So, isn't it a  
16 reasonable question to measure development to ask  
17 if this causes you to rethink the age criteria  
18 for this measure or not?

19 MS. KOLBUSZ: For the Joint Commission  
20 all of our in-patient hospital measures are for  
21 the adults in patient population, so under 18 are  
22 excluded. I think that those are all very

1 important facts, and we recognize that there is a  
2 pediatric population but the measure does not  
3 address the pediatric population whatsoever.

4 CO-CHAIR TIRSCHWELL: Yes, we realize  
5 that the 18-year olds are not the same as 70-year  
6 olds. Is that what you were going to say,  
7 Charlotte?

8 MEMBER JONES: I was going to say the  
9 American Academy of Pediatrics says they're  
10 pediatric until they're 21.

11 CO-CHAIR TIRSCHWELL: And I think  
12 Obamacare puts it up to 26. They can still be on  
13 your insurance, right?

14 UNIDENTIFIED PERSON: We will not solve  
15 the debate on when your child is no longer a  
16 child.

17 CO-CHAIR TIRSCHWELL: Any other  
18 comments or discussion before we go ahead and  
19 revote on Usability and Use? Let's go ahead  
20 then.

21 MS. OGUNGBEMI: Voting on Usability and  
22 Use for Measure 0437. This is a revote. The

1 options are high, moderate, low and insufficient.

2 Voting is open.

3 Voting is closed. The results are 30  
4 percent high, 65 percent moderate, 0 percent low  
5 and 4 percent insufficient. Usability and Use it  
6 passes Measure 0437.

7 CO-CHAIR TIRSCHWELL: Great. Now we'll  
8 go to overall. Any discussion -- further  
9 discussion before the vote on the overall  
10 measure?

11 So, we're open for Overall Suitability  
12 for Endorsement.

13 MS. OGUNGBEMI: We are now voting on  
14 Measure 0437's Overall Suitability for NQF  
15 Endorsement. Options are yes and no. Voting is  
16 open.

17 Voting is closed. Results are in.  
18 Unanimous 100 percent votes, yes. Measure 0437  
19 is suitable for NQF endorsement.

20 CO-CHAIR TIRSCHWELL: Great. So, that  
21 means that we will also be going through the  
22 eMeasure 2834. Did you guys want to add any



1        comments about the eMeasure before we go in or  
2        did you already comment about it?

3                MS. KOLBUSZ: You know as far as the  
4        evidence and all, it's the same.

5                CO-CHAIR TIRSCHWELL: Right.

6                MS. KOLBUSZ: I think you established  
7        at the beginning of the meeting that as far as  
8        the eQMs are concerned, they haven't been  
9        validated. We have used the Bonnie Tool for  
10       testing information. And I would actually turn  
11       over the discussion, I think, to our eQm nurse  
12       informatics person because she could be -- answer  
13       specifics about the eQm.

14               CO-CHAIR TIRSCHWELL: Just a brief  
15       overview is okay.

16               MS. ANDERSON: Sure.

17               CO-CHAIR TIRSCHWELL: Thanks.

18               MS. ANDERSON: Oops, sorry. I have to  
19       get my computer opened up.

20               Okay. So, as Karen said the eMeasure  
21       mimics the Chart Obstructed Measure very closely.  
22       Our description is the same description as the

1 Chart Obstructed. We are measuring for acute  
2 ischemic stroke patients who arrive at this  
3 hospital within two hours of known well and for  
4 whom tPA was initiated at this hospital within  
5 three hours of the last time well.

6 Our denominator is looking at ischemic  
7 stroke patients admitted to the emergency  
8 department whose arrival time is within two hours  
9 or less. Less than or equal to 120 minutes of  
10 the time they were known to be at their baseline  
11 state of health or time of symptom onset is less  
12 known at the time is not known.

13 Our denominator exceptions are  
14 excluding patients with comfort measures  
15 documented on the date of or date after arrival.  
16 Patients with IV or IA thrombolytic therapy prior  
17 to arrival, patients with the documentation of a  
18 NIS score of zero in the emergency department,  
19 patients with medical reasons for not initiating  
20 IV thrombolytics documents by a physician, APN,  
21 PA or pharmacist on the day of or day after  
22 arrival.

1           Patients with the following results  
2       within 180 minutes of the time they were known to  
3       be at their baseline state of health or time of  
4       symptom onset.    These include prothrombin time  
5       greater than 15 seconds, platelet count less an  
6       100,000, INR greater than 1.7, partial thrombol  
7       less time greater than 40 seconds, systolic blood  
8       pressure greater than 185, and diastolic blood  
9       pressure greater than 110 and patient refusal.

10           You can tell we get a little bit more  
11       granular in our data elements with electronic  
12       clinical quality measure than what we have on the  
13       chart obstructed measure.

14           The numerator, we are looking at acute  
15       ischemic stroke patients for whom IV-tPA was  
16       initiated at this hospital within three hours.  
17       Less than or equal to 180 minutes of when it was  
18       witnessed or reported that the patient was last  
19       known to be without the signs and symptoms of  
20       current stroke or his or her baseline state.

21           This measure has been adopted by the  
22       EHR Incentive Program and the hospital and

1 patient quality reporting program as an  
2 electronic clinical quality measure --- CMS-91.

3 The current format of this measure was  
4 first specified in December of 2012, and it has  
5 been used by hospitals attesting to meaningful  
6 use program.

7 When reporting this measure, hospitals  
8 attested to the eCQM specifications, approved by  
9 CMS for use at the time of the reporting period,  
10 thus indicating feasibility of the measure.

11 In addition to the meaningful use  
12 program, the measure of feasibility is supported  
13 by the fact that this measure was used by  
14 hospitals voluntarily submitted eQMs to the  
15 hospital and patient quality reporting program in  
16 2015.

17 In 2016, CMS is requiring  
18 organizations participating in the HIQR program  
19 to electronically submit one-quarter of data for  
20 the 28 available eQMs, and this measure is one  
21 of those measures that they can select from.  
22 However, we do not have any data currently on the

1 eMeasure.

2 CO-CHAIR TIRSCHWELL: Okay. Mike, is  
3 it you again or --

4 MEMBER KAPLITT: Yes, I guess. So, do  
5 we really need to re-review the evidence on the  
6 gap? We just did that, right?

7 CO-CHAIR TIRSCHWELL: I don't think so.

8 MEMBER KAPLITT: Right. So, we can get  
9 right to reliability I assume?

10 CO-CHAIR TIRSCHWELL: I think that's  
11 correct and acceptable so, yes.

12 MEMBER KAPLITT: Okay. So, with  
13 respect to reliability there's one major issue  
14 which is as an eMeasure, our understanding we  
15 discussed this on the work group is that NQF, you  
16 know, the NQF standards say that the eMeasure has  
17 to have been shown to be -- has to have been  
18 tested in electronic health records for more than  
19 one vendor, and there is no evidence of that  
20 here. And that's a legitimate concern because  
21 obviously we all know that for an eMeasure, the  
22 reliability is very much based on, you know, who

1 the vendor is and whether you're actually going  
2 to be able to capture what you want to capture in  
3 a reliable way.

4 CO-CHAIR TIRSCHWELL: So, it seems like  
5 there's been a shift on this issue of having  
6 already been tested in the EHR for approval. Do  
7 you guys want to comment on that? I mean,  
8 clearly if we're thinking about approving this  
9 measure and there are those -- there are no such  
10 data about the EHR then we're not requiring that  
11 to get to approval. Is that correct?

12 MS. JOHNSON: This is one of those  
13 funny measures that we're calling legacy  
14 measures.

15 CO-CHAIR TIRSCHWELL: Yes.

16 MS. JOHNSON: Correct? So, they are  
17 already in use in Federal programs, so what we at  
18 NQF have done is we're allowing use of this, I  
19 think Ann calls it simulated data, to kind of  
20 stand in for testing. We only do that for these  
21 legacy eMeasures.

22 MEMBER KAPLITT: Well, then I don't

1 know what to add. I mean, I personally disagree  
2 with that, but I don't know what to add. I mean,  
3 because I think the Bonnie Test relates to  
4 validity and that I'm fine with, but I don't  
5 think it relates to reliability. But that's fine  
6 if that's the new standard. So I don't have a  
7 whole lot to add. I don't know if anybody else  
8 wants to but I just, you know, for me I don't see  
9 how we can pass -- and I don't understand a  
10 legacy standard is different than any other  
11 standard because we're going to hold people to a  
12 standard that hasn't been tested in a sufficient  
13 number of VHRs to show that it's actually  
14 reliable and usable, I don't why it should matter  
15 whether it's a legacy measure or not. But, you  
16 know, maybe I'm in the minority.

17 CO-CHAIR TIRSCHWELL: And you said this  
18 is being used already by CMS?

19 MS. ANDERSON: Yes, it's currently in  
20 use.

21 CO-CHAIR TIRSCHWELL: Since when?

22 MS. ANDERSON: Since 2012.

1 CO-CHAIR TIRSCHWELL: Since 2012? So,  
2 how is it that we have no data?

3 DR. SCHWAMM: Reintroducing Ann Watt.

4 MS. WATT: CMS made these measures part  
5 of the meaningful use program without them ever  
6 actually having been implemented, and the  
7 requirement was that hospitals had say that, yes,  
8 we can collect the data on these measures. So,  
9 they've been in the program for that period of  
10 time. Actual data collection has not been  
11 required yet; it is just now in 2016 being  
12 required, as Lisa explained, for what the third  
13 or fourth quarter needs to be reported to CMS by  
14 the first quarter -- by February of 2017. So,  
15 that's why we have no data. These measures have  
16 been around since -- for a very long time, but  
17 data collection has not been required until just  
18 now beginning in 2016.

19 CO-CHAIR TIRSCHWELL: So, then what was  
20 the rationale for bringing it forward for  
21 approval at this point before there was the data?

22 MS. WATT: We were requested to do so,



1 and we were given the guidance that Bonnie  
2 Testing would be sufficient to attest to the  
3 reliability of the measure.

4 CO-CHAIR TIRSCHWELL: Okay. Any other  
5 -- yes, go ahead, Mike.

6 MEMBER KAPLITT: I can just tell you  
7 that just because CMS said something a few years  
8 ago, those of us who have been struggling with  
9 the meaningful use ever since that day can attest  
10 that it, you know, a lot of these EHRs have not  
11 kept up, that we've spent the last four years or  
12 whatever it is constantly trying to modify and  
13 adjust things to try to capture that because it's  
14 not always been sufficient. So, I'm not sure  
15 just because CMS said we should do it that that  
16 means that eMeasure is ready for prime time  
17 across the board. That's all.

18 CO-CHAIR TIRSCHWELL: Any other  
19 discussion before we go ahead on vote on  
20 reliability? Any other comments from the  
21 developer?

22 MS. WATT: No, my only comment be that

1 we provided the information that we were  
2 requested to provide for this measure.

3 CO-CHAIR TIRSCHWELL: Yes, Reuven, go  
4 ahead.

5 MEMBER FERZIGER: We're back on the  
6 policy domain, so I really would be quite  
7 interested given the amount of thought that Mike  
8 has given into this and the other perspective of  
9 the Chairs on advice about voting.

10 CO-CHAIR TIRSCHWELL: Well, you know,  
11 so I certainly didn't make the rule that Bonnie  
12 Testing would be adequate for demonstrating  
13 reliability. In fact, when we first talked about  
14 these measures in our working group this was --  
15 this was rated as insufficient, specifically  
16 because there was no EHR data. And then there's  
17 been a political shift to alter that perspective  
18 on the whole thing. That was done completely  
19 outside of the purview of our committee, and I  
20 don't -- you know, I don't even begin to believe  
21 that my pay grade is anywhere close to being able  
22 to comment on that.

1           Honestly, I'm a little uncomfortable  
2 with it but -- and you can vote your conscience,  
3 even if it is outside of standard algorithms.  
4 That is within the purview of this committee, if  
5 I'm correct. So, I guess I don't have much more  
6 to say about it than that.

7           MS. JOHNSON: So, let me put a little  
8 bit of context around this, and I do realize this  
9 is confusing.

10           One of the things that NQF allows is  
11 what we would call -- if a developer demonstrates  
12 data element validity, then we do not require  
13 additional reliability testing. That's been  
14 something that has been the case for many years  
15 now. So, that's one thing.

16           This measure originally came through  
17 and they had demonstrated element validity  
18 through the Bonnie Testing tool, which we also  
19 said was appropriate. What the developers had  
20 not done when you had looked at it in the work  
21 group is they had not addressed the threats to  
22 validity as things were blank. And that is why

1 we, as staff, originally selected insufficient as  
2 our rating.

3 Since then, the developer did add in  
4 some information on the threats to the validity,  
5 so that's how it has moved from insufficient to  
6 something else.

7 So, what you're looking for  
8 reliability in the case that a developer does not  
9 do separate reliability testing but relies on  
10 their data element validity testing, you have to  
11 see what you would rank or how you would rate  
12 their data element validity testing and just use  
13 that rating in reliability. And you'll see how  
14 that works in the algorithm. So, I do realize it  
15 is confusing. And I apologize for that, but  
16 that's the background of going from insufficient.

17 CO-CHAIR TIRSCHWELL: Ron?

18 MEMBER KOENIG: Would you please  
19 clarify one thing for me? In the previous state  
20 policy we had, the numerator and denominator were  
21 quite clear. The numerator were those who  
22 received, and the denominator were those who were

1 eligible. In this one, the denominator includes  
2 time of symptom onset -- the time last known at  
3 baseline rate is not known. What does that mean?

4 CO-CHAIR TIRSCHWELL: Does the  
5 developer want to comment on that?

6 MS. ANDERSON: So, your question was  
7 about why in the eCQM do we have data elements  
8 for specific time of symptom onset and baseline--

9 MEMBER KOENIG: In the first one, we  
10 had those who received and those who were  
11 eligible. On this measure, we have those who  
12 have received, but the denominator is anyone who  
13 has a stroke whether they're eligible or not so  
14 it seems by the wording.

15 CO-CHAIR TIRSCHWELL: No, I mean they  
16 still have to be within the time frame and  
17 there's a number of other exclusions.

18 MEMBER KOENIG: Well, the time of  
19 symptom onset, the time last known of baseline  
20 state is not known. So, what's the time?

21 CO-CHAIR TIRSCHWELL: If the  
22 denominator, sorry. Principal diagnosis of

1 ischemic stroke or -- yes. I think maybe the  
2 denominator details which are in the documents  
3 and I guess ischemic stroke patients within two  
4 hours -- yes. Ischemic stroke patients who  
5 present within two hours. And then there are  
6 exclusions on top of that that can --

7 MEMBER KOENIG: Does that mean if  
8 someone went to sleep and sometime during the  
9 night had a stroke and then the family brings  
10 them in late in the morning or --

11 CO-CHAIR TIRSCHWELL: No, they're out.

12 MEMBER KOENIG: Okay.

13 CO-CHAIR TIRSCHWELL: It's last known  
14 normal.

15 MEMBER KOENIG: Okay.

16 MS. ANDERSON: Right, so the baseline  
17 state and the time of symptom onset are  
18 reflective of that -- the old data element of  
19 last known well. So, in order to specify it a  
20 little bit better in the EHR, we have two data  
21 elements that when you look at the logic of the  
22 eCQM, they are worse statements, so we were

1       either looking for the baseline state or the time  
2       of symptom onset.

3                   CO-CHAIR TIRSCHWELL: Yes, it's  
4       confusing.

5                   MS. ANDERSON: It's a little bit  
6       confusing.

7                   CO-CHAIR TIRSCHWELL: The way it's  
8       worded by --

9                   MS. ANDERSON: In the way it's worded  
10      and the way it's specified.

11                  CO-CHAIR TIRSCHWELL: I think the  
12      intent makes sense.

13                  Sorry, so let's see. Where were we?  
14      So, Karen, just to summarize what you said, the  
15      change from insufficient to more acceptable was  
16      based additional information from the developers  
17      about threat to exclusion. It was never about  
18      the lack of data from EHRs. Is that an accurate  
19      statement?

20                  MS. JOHNSON: I believe I would say  
21      that is accurate. We have told developers that  
22      we will accept Bonnie Testing information. So,

1 for the testing, that is what we have. We  
2 couldn't accept not giving anything on the  
3 threats to validity. So, they did come back and  
4 tell you something about exclusions, and I  
5 believe they maybe also included some information  
6 about meaningful differences.

7 And if you would scroll down,  
8 Alexander, to the validity section, you can see  
9 that we did provide you and we red-lined it so  
10 that you would know that we went in a little bit  
11 later and made changes. So, yes, so I'm  
12 remembering correctly. They did add some  
13 information about exclusions to meaningful  
14 differences.

15 CO-CHAIR TIRSCHWELL: And the line in  
16 the policy that Mike referred to about testing in  
17 two EHRs, that line is really in there, but it  
18 refers to a new electronic measure that's not a  
19 legacy measure? Is that an accurate statement?

20 MS. JOHNSON: It refers to a non-legacy  
21 measure. I have to think about whether it's only  
22 the new ones. Depends on what you mean by new,



1 but I think it's correct to say --

2 CO-CHAIR TIRSCHWELL: Well, it's an  
3 electronic measure that's not a legacy measure.

4 MS. JOHNSON: Right.

5 CO-CHAIR TIRSCHWELL: And we don't have  
6 any of those, right?

7 MS. JOHNSON: There are some. Because  
8 electronic measures that -- what we mean by  
9 legacy is that they are being used in Federal  
10 programs such as meaningful use. So, we carved  
11 out a subset of eMeasures, and we are allowing  
12 Bonnie Testing for that subset of eMeasures. So,  
13 the one that you have in front of you now is one  
14 of these legacy eMeasures. It's being used in  
15 the meaningful use program.

16 CO-CHAIR TIRSCHWELL: But we're not --  
17 neither today nor tomorrow, are we reviewing an  
18 eMeasure that isn't a legacy eMeasure?

19 MEMBER KOENIG: I think the --

20 CO-CHAIR TIRSCHWELL: Or hybrid maybe,  
21 that's different.

22 MS. JOHNSON: The hybrid measure is one

1 of them.

2 CO-CHAIR TIRSCHWELL: That field is  
3 very different so -- and they have a lot of data.

4 MS. JOHNSON: Yes, and you also have a  
5 couple --

6 MS. MUNTHALI: Karen?

7 MS. JOHNSON: Yes.

8 MS. MUNTHALI: We're also going to look  
9 at approval for trial use --

10 MS. JOHNSON: yes.

11 MS. MUNTHALI: -- which is, I believe,  
12 hey have Bonnie for that as well.

13 CO-CHAIR TIRSCHWELL: That's different  
14 though also.

15 MS. JOHNSON: Yes. So, no, I mean  
16 other than the hybrid eMeasure, we're not. But  
17 other --

18 CO-CHAIR TIRSCHWELL: Okay.

19 MS. JOHNSON: -- other projects have.

20 CO-CHAIR TIRSCHWELL: All right.

21 So, thank you for clarifying. Any  
22 other questions? Charlotte, go ahead.

1           MEMBER JONES: So, I think this is  
2           probably the equivalent of a math error, but are  
3           you excluding patients under the age of 18 for  
4           this measure?

5           MS. ANDERSON: Correct. Our age  
6           requirement is greater than or equal to 18 years.

7           MEMBER JONES: Okay. It's not  
8           documented here.

9           MS. ANDERSON: It's in our initial  
10          patient population, so it is included. It's just  
11          not on this document.

12          MEMBER JONES: Okay. Thank you.

13          MS. ANDERSON: You're welcome.

14          CO-CHAIR TIRSCHWELL: Okay. Peter, go  
15          ahead.

16          MEMBER SCHMIDT: So, listening to the  
17          description of where we are, the reliability  
18          switched from being insufficient to being  
19          something else because of the -- because of your  
20          assessments and things like that. But I still  
21          see that the guidance from the algorithm says  
22          low.

1 MS. JOHNSON: That was our mistake.

2 MEMBER SCHMIDT: So, what would the  
3 guidance from the algorithm be now, just so that  
4 we have just a sense of what the recommendation  
5 is?

6 MS. JOHNSON: The guidance from the  
7 algorithm for validity we would say right now is  
8 moderate?

9 MEMBER SCHMIDT: For reliability?

10 MS. JOHNSON: For reliability, since  
11 they don't have other testing data for  
12 reliability, it would take on the rating that it  
13 would get for data element validity.

14 MEMBER SCHMIDT: Okay. So, but if we  
15 vote low on reliability, are we going to get to  
16 valid -- to validity?

17 MS. JOHNSON: No. It would not pass.

18 MEMBER SCHMIDT: So, validity would  
19 trump reliability, but reliability tails  
20 validity?

21 MS. JOHNSON: You know --

22 MEMBER SCHMIDT: There's a movie called

1 Catch 22, I think.

2 MS. JOHNSON: Yes. It is tricky  
3 because, you know, a reliable measure, you know,  
4 by definition needs to be valid but also valid  
5 measures we want to be reliable. So, we have to  
6 pick one.

7 MEMBER SCHMIDT: I consider myself  
8 tricked.

9 CO-CHAIR TIRSCHWELL: We should vote on  
10 validity first.

11 Okay. So, Charlotte, do you have  
12 another comment and then Alex, go ahead.

13 MEMBER RAE-GRANT: Just in terms of  
14 time management, we have four more guidelines to  
15 do in the next five minutes, just to remind us  
16 where we are.

17 CO-CHAIR TIRSCHWELL: Yes. We fell off  
18 of that one, thanks.

19 All right. Let's go ahead and vote on  
20 reliability.

21 MS. OGUNGBEMI: We are now voting for  
22 Reliability on Measure 2834. The options are

1 high, moderate, low and insufficient. Voting is  
2 open.

3 Voting is closed. Results are zero  
4 percent high, 43 percent moderate, 35 percent low  
5 and 22 percent insufficient. We are landing in a  
6 gray zone.

7 CO-CHAIR TIRSCHWELL: I mean, a gray  
8 zone suggests to me that we probably need to go  
9 through the rest of the criteria, and then at the  
10 end the overall vote will sort of deal with this  
11 gray zone here.

12 Am I running afoul of any policies at  
13 NQF in that suggestion? Does it seem okay with  
14 you guys?

15 MS. JOHNSON: I think I want Elisa and  
16 Marsha to handle that one.

17 MS. MUNTHALI: So, you would vote on  
18 overall suitability for endorsement, but we will  
19 consider the gray zone, consensus not reached  
20 issues in the first consult.

21 CO-CHAIR TIRSCHWELL: Okay. So,  
22 validity? Mike?

1           MEMBER KAPLITT: We already discussed  
2       this. They did the Bonnie Testing, the validity  
3       was good by 100 percent of the various, you know,  
4       they did like 23, I think it was, patient --  
5       synthetic patient charts so everything was  
6       covered and validity testing is not the problem  
7       here.

8           CO-CHAIR TIRSCHWELL: Discussion on  
9       validity? Sorry, did I cut you off? Anything  
10      else?

11           Let's go ahead and move to voting on  
12      validity.

13           MS. OGUNGBEMI: We're now voting on  
14      validity for Measure 2834. The options are high,  
15      moderate, low and insufficient. Voting is open.

16           Voting is closed. The results are 17  
17      percent high, 61 percent moderate, 9 percent low  
18      and 13 percent insufficient. The measure passes  
19      on validity.

20           CO-CHAIR TIRSCHWELL: Feasibility?

21           MEMBER KAPLITT: I don't know what to  
22      say. I mean, you know, I don't think that the

1 issue is any different, right, in the absence of  
2 as an eMeasure -- not as a measure. As an  
3 eMeasure, I just don't see how we can comment on  
4 feasibility without real-world data in the actual  
5 records that are used. But -- I mean, I think  
6 the measure itself, we talked about, an hour ago,  
7 we said that was feasible but I don't see how we  
8 can comment on feasibility.

9 MS. JOHNSON: I'm just curious, was  
10 there a feasibility score card filled out for  
11 this one?

12 MS. ANDERSON: No. It would be  
13 feasibility ---

14 MS. JOHNSON: We didn't have a score  
15 card; we did do a feasibility report in lieu of  
16 the score card.

17 MS. JOHNSON: Yes, the score card came  
18 before these measures or came after these  
19 measures were actually in use. So, there were no  
20 real feasibility scoring done the way that a  
21 brand new measure would be, so we did do a  
22 feasibility report which should have been



1 included in the documentation.

2 CO-CHAIR TIRSCHWELL: Reuven?

3 MEMBER FERZIGER: So, therefore, how  
4 would it be possible to vote on anything other  
5 than insufficient for feasibility, since we have  
6 neither the report nor any information about  
7 real-world feasibility?

8 CO-CHAIR TIRSCHWELL: So, I would defer  
9 that question to NQF staff. What are we voting  
10 on if we don't have any evidence of feasibility  
11 in an actual EHR? Is it just that the logic and  
12 required data are readily available without undue  
13 burden? Because they can be implemented for a  
14 performance measurement part at the end there  
15 would seem to be conjecture, I guess at this  
16 point.

17 MS. JOHNSON: Ann is going to address  
18 that. Can you turn on your mic, Ann?

19 MS. PHILLIPS: Yes, feasibility  
20 assessment was based on Bonnie performance, so it  
21 shows that the measured logic is measured logic  
22 is functional. You are correct. It does not

1 show the measured maps in the EHR. So, we would  
2 believe all the data elements are associated with  
3 value sets. All the value sets are published and  
4 the lead back and should be commonly found in the  
5 EHR.

6 CO-CHAIR TIRSCHWELL: So, is evidence  
7 that it can be implemented in a real EHR required  
8 for feasibility?

9 MS. PHILLIPS: Not for a legacy  
10 measure.

11 CO-CHAIR TIRSCHWELL: Okay, yes,  
12 Charlotte, go ahead.

13 MEMBER JONES: I just pulled up the  
14 data accuracy feasibility report, and for those  
15 people who don't have it I'll just read it. "At  
16 this time, we are unable to directly assess the  
17 accuracy of these elements in an EHR system.  
18 However, because these data elements are used  
19 across multiple measures and are harmonized with  
20 the chart instructive version of the measures  
21 with which hospitals are already familiar, they  
22 are likely to be monitored closely for

1 correctness. In addition, Data Element 14 was  
2 created based on feedback at the request of  
3 implementers to improve feasibility and is  
4 believed to be highly feasible."

5 CO-CHAIR TIRSCHWELL: Oh, sorry, go  
6 ahead, Peter.

7 MEMBER SCHMIDT: I'm wondering if this  
8 was included in meaningful use. Doesn't that  
9 mean somebody has collected information about  
10 this and we should be able to say that it was  
11 feasible or is nobody doing meaningful use?

12 MS. ANDERSON: People are reporting  
13 meaningful use, but they've been attesting that  
14 they can collect this data which is a little  
15 different than actually being able to extract the  
16 data the way that we would for an eCQM. I mean,  
17 it's a proxy, right, but --

18 CO-CHAIR TIRSCHWELL: Yes, they've  
19 said consistently that the data are not available  
20 at this time.

21 Sorry, Charlotte, are you still up  
22 there? Steve, you're thinking about it I can

1 tell.

2 MEMBER HUFF: Yes, I mean, as a non-  
3 statistician, non-IT person it's just hard for me  
4 to know, taking 31 synthetic charts and  
5 extrapolating that to tens of thousands of real  
6 charts, how real that is. So, I really depend on  
7 guidance. I have no professional opinion on  
8 this.

9 MS. WATT: Let me just give a little  
10 bit more of information about what Bonnie testing  
11 is. And speak up if I'm mis-speaking. But  
12 basically, test cases are created in the Bonnie  
13 System. That's actually what it is, is it's  
14 testing bed that reflects all of the possible  
15 answers to all the possible data elements in a  
16 measure. Those that would exclude it as well as  
17 those that would include it. And where the 31  
18 cases came up with is, that's the total number of  
19 permutations of the data element and the  
20 allowable value that would be able to say that  
21 the fair degree of confidence, yes. This measure  
22 logic computes the way we expect it to compute.

1           That actually is I think a pretty good  
2 proxy for feasibility because at least we know  
3 the measure logic works in all possible  
4 permutations of the data.

5           DR. SCHWAMM: And I think when you  
6 think about feasibility with an eMeasure, what  
7 you want to know is when you push the button, do  
8 all of the inclusions and exclusions work  
9 together in the flow of the measure construct and  
10 kick out an answer? It doesn't tell you whether  
11 the correct values were populated into the EHR,  
12 but it does show you that when you push the  
13 button you get the report. And so I think that  
14 just means that the software is valid when tested  
15 against a sample data set. It does not tell you  
16 the quality of the data entered into those value  
17 fields, but they were the correct formats. Dates  
18 were dates, times were times. Yes, no's were  
19 yes, no, etcetera.

20           CO-CHAIR TIRSCHWELL: I guess how does  
21 it -- how is it different from validity then at  
22 that point? It seems like the Bonnie testing

1 really squarely hits on the validity thing. I  
2 guess I don't -- it seems like feasibility should  
3 not be the same as validity. And --

4 DR. SCHWAMM: I'll go out on a limb and  
5 maybe be abandoned by the Joint Commission when I  
6 say this, but it seems to me the measure is valid  
7 that if in this case there's a human factor  
8 involved as well which is instead of the  
9 abstractor looking at the whole record and trying  
10 to come up with the best answer, you're relying  
11 on whoever entered that data into the EHR field  
12 at the time during the process of care that they  
13 did. And so if a medical student writes down  
14 that the time of stroke last seen well was noon,  
15 but the attending comes by later and writes down  
16 actually it was 4:00 p.m., but noon is what  
17 populated that field, then the measure construct  
18 is feasible. The construct is valid, but the  
19 data that's been entered may or may not produce  
20 an accurate report on that specific patient. I'm  
21 not sure which bucket that falls into.  
22 Reliability, I guess.

1 CO-CHAIR TIRSCHWELL: I guess what  
2 happens if we roll this out and then the reality  
3 is that it is an undue burden for these data to  
4 be collected, and they are very inconsistently  
5 completely reported then after the fact we would  
6 say, oops. I guess we were wrong about  
7 feasibility, which maybe is okay. But it seems  
8 like that's to me just the seat of my pants,  
9 that's what feasibility is about.

10 MS. WATT: I was going to that this is  
11 Ann from the Joint Commission, but we know that.

12 You know, the thing about these  
13 measures particularly is that they have been in  
14 existence for a long time. We know that a lot of  
15 EHRs, all of the EHR systems are collecting data  
16 on these measures. We know that CMS has  
17 collected data on these measures in a testing  
18 mode, and we know that the Joint Commission has  
19 had. And we also know that based on the results  
20 -- you know, this has sort of been an iterative  
21 process, and based on what we have learned  
22 changes have been made to the measure constructs

1 to make them feasible and collectible.

2 Every hospital who is reporting  
3 meaningful use has said, yes. This is a feasible  
4 measure for us to collect, and we can do it.

5 CO-CHAIR TIRSCHWELL: But what you just  
6 said is that the data have been being collected  
7 and that you've learned something from them, but  
8 you didn't share any of the data that you --

9 MS. WATT: We don't have access to CMS  
10 data and we -- the volume of data that the Joint  
11 Commission received during our test period was  
12 not sufficient to be able to do that. We have  
13 not, you know, put this measure into production  
14 on a wide scale.

15 CO-CHAIR TIRSCHWELL: Comments or  
16 questions? Yes, Reuven, go ahead.

17 MEMBER FERZIGER: So, I think that in  
18 this particular day keep running into this issue  
19 of, you know, what's policy and what's the scope  
20 of our job. And I think it may be excellent  
21 policy for this electronic measure to be deployed  
22 and for CMS to be collecting data on. And that's



1       above my capacity to judge. However, it seems  
2       that the scope of the job that we have is to  
3       judge whether feasibility has been established  
4       for this. I don't see any way in which  
5       feasibility, you know, by the definition applied  
6       anywhere else, you know, is available here. I  
7       think that it has to be insufficient. But I  
8       completely grant that despite the evaluation of  
9       insufficiency by the charge of this committee, it  
10      still may be a great idea to deploy it. I just  
11      don't see how we can say that feasibility has  
12      been established.

13               MS. OGUNGBEMI: We are now voting on  
14      feasibility for Measure 2834. The options are  
15      high, moderate, low and insufficient. Voting is  
16      open.

17               Voting is closed. The results are  
18      zero percent high, 26 percent moderate, 4 percent  
19      low and 70 percent insufficient. Measure 2834  
20      does not pass on feasibility.

21               CO-CHAIR TIRSCHWELL: And it's a must  
22      pass criteria or --

1 MS. JOHNSON: No, feasibility is not a  
2 must pass criteria. So, you will continue your  
3 discussion.

4 CO-CHAIR TIRSCHWELL: All right.  
5 Moving along.

6 Usability and Use.

7 MEMBER KAPLITT: I mean, I don't have a  
8 huge amount to talk about. I mean, assuming  
9 everything else were met, then I think that  
10 Usability is fine. I mean, because I don't think  
11 it's that much different as an eMeasure than it  
12 was -- I don't think there's any data to argue  
13 that it's any different.

14 CO-CHAIR TIRSCHWELL: Any other  
15 discussion? Reuven, are you still up there? No  
16 problem.

17 Let's go ahead and vote then.

18 MS. OGUNGBEMI: We are now voting on  
19 Usability and Use for Measure 2834. The options  
20 are high, moderate, low and insufficient. Voting  
21 is open.

22 Results are in. Voting is closed.

1 Results are 9 percent high, 48 percent moderate,  
2 17 percent low and 26 percent insufficient, and I  
3 believe we have landed in another gray zone. We  
4 landed in a gray zone.

5 CO-CHAIR TIRSCHWELL: So, we got two  
6 gray zones, one fail, and should we vote on  
7 overall endorsement? I think so. So, let's go  
8 ahead move to vote on overall endorsement.

9 And could you -- I think I'll do it  
10 this way. Could you just review the results of  
11 the -- since this has gone on for so long -- of  
12 the -- no discussion. I just want to know gray  
13 zone, pass or fail for the four criteria up until  
14 now.

15 MS. OGUNGBEMI: Yes, so for what we  
16 voted on, we have gray zone for Reliability. We  
17 have pass for Validity. Fail for Feasibility.  
18 Gray Zone, Usability and Use. So two gray zones,  
19 one pass, one fail.

20 CO-CHAIR TIRSCHWELL: Okay. So, you  
21 want some advice, Reuven? I don't know what to  
22 say. My personal feelings reflect the less than

1       overwhelming support for the different  
2       categories, and I'll be voting accordingly.

3               MS. OGUNGBEMI: We are now voting on  
4       the Overall Suitability for Endorsement on  
5       Measure 2834. Options are yes and no. Voting is  
6       open.

7               Voting is closed. The results are in  
8       and voting is closed.

9               We have 17 percent yes, 83 percent no.

10              CO-CHAIR TIRSCHWELL: I would  
11       definitely like to take a break, but I'm not sure  
12       we should.

13              So, let's see. You think we should?  
14       Okay.

15              MS. OGUNGBEMI: So, I have to say the  
16       measure is not passing on Suitability for  
17       Endorsement. So, no.

18              CO-CHAIR TIRSCHWELL: Thank you.

19              MEMBER BULSARA: Just a quick comment.

20              The developers are clear, I mean, it's  
21       not that our expectations are different from what  
22       the developers are sort of -- I mean, what their

1 expectations are, right? I mean there's a clear  
2 set of expectations in terms of what would meet  
3 criteria in terms of passing these various  
4 things, because I just want to make sure that  
5 we're not judging on different criteria, like is  
6 there any sort of variation in terms of what the  
7 expectations are from them and in terms of what  
8 we're judging them for?

9 CO-CHAIR TIRSCHWELL: Well, you know,  
10 and you guys correct me if I get this wrong.  
11 They've heard the call to put this measure  
12 forward. The Joint Commission did, and they did  
13 their best to provide as compelling data as was  
14 possible. The National Quality Forum staff, you  
15 know, put it through the regular analysis and  
16 made some preliminary recommendations but if it  
17 was just algorithmic they wouldn't need us at all  
18 I would so. And so the point of us being here  
19 today is to bring, you know, the human factor to  
20 evaluating these criteria and, you know, lay that  
21 additional level of multi-stakeholder, common  
22 sense and evaluation to what has been performed.

1       So, I don't know. Do you guys want to add  
2       anything to that, or does that make sense?

3               MS. WATT: I makes complete sense. I  
4       would just like to emphasize that up until this  
5       morning the Joint Commission was under the  
6       understanding that all of these eQOMs were NQF  
7       endorsed. That apparently now is not the case.  
8       And so we brought them forward for re-endorsement  
9       because it is the three-year cycle.

10              This endorsement came about as an  
11       artifact of the eQOM development process, you  
12       know, going back to 2010. Determination was made  
13       somewhere along the line that if the source  
14       measure was endorsed, the eQOM was endorsed.

15              We have thought that these measures  
16       were endorsed. We brought them back for re-  
17       endorsement knowing that the data are not there.  
18       These measures have not been fully implemented  
19       yet. And we prepared the submissions according  
20       to the guidance of the NQF staff. Now, in  
21       fairness to everybody, I think that it's new for  
22       all of us. We appreciate the opportunity to be

1       able to discuss it. I have to tell you though  
2       that I sort of feel as though we have been -- the  
3       Joint Commission has been -- is being penalized  
4       for guidance that we received in good faith and  
5       followed in good faith, and thank you for your  
6       consideration. That's really all I have to say.

7               CO-CHAIR TIRSCHWELL: Break?

8               MS. OGUNGBEMI: I have one.

9               CO-CHAIR TIRSCHWELL: Yes, please.

10              MS. OGUNGBEMI: If no one else. Okay.  
11       So, we are going to have the committee dinner.

12              MS. MUNTHALI: I did want to address  
13       what Ann mentioned and any apologies if there's  
14       any confusion about the status of the eCQM  
15       measures that are under review today.

16              That was probably something that  
17       happened with the legacy measures. We have since  
18       changed our eMeasure process and policy. It's  
19       been about a year or two. We've been spending  
20       the last year or two trying to socialize this  
21       with developers and committees. And as you can  
22       understand, it's been very difficult to do

1       because it's not just dependent on what we do at  
2       NQF but also what is happening with the  
3       feasibility up to the completion of the measures  
4       but also with CMS and the availability of data.  
5       And so we'll continue to work with you and other  
6       developers to make sure that, you know, everyone  
7       understands what our policy is going forward.  
8       But this discussion has been very helpful for us  
9       because this is real life implementation of the  
10      policy and process. And so we're hearing some  
11      things about how we can refine it and we probably  
12      will be having further conversations with the  
13      Joint Commission and other developers and CMS to  
14      see how globally we can all improve this.

15               MS. OGUNGBEMI: Okay. So, we are  
16      having a committee dinner/Happy Hour if you all  
17      want to join us at Georgia Brown's just down the  
18      street, about a block away between the Metro and  
19      here. So, if anyone would like to join us after  
20      the meeting is over, could you please raise your  
21      hand? It would be around 6:15.

22               (Whereupon, the above-entitled matter



1       went off the record at 3:33 p.m. and resumed at  
2       3:46 p.m.)

3                   CO-CHAIR TIRSCHWELL: All right, we're  
4       going to go ahead and jump back in with the next  
5       set of companion measures, antithrombotic therapy  
6       by end of hospital day two. I guess I would  
7       invite you guys to just introduce them both  
8       briefly. And for all of us, we've gone through a  
9       bunch of issues here. We're happy to hear new  
10      information, but we probably don't need to rehash  
11      many of the same issues that may come up again  
12      with these other measures. Thanks, Karen.

13                  MS. KOLBUSZ: Okay. The first is the  
14      chart-abstracted stroke five antithrombotic  
15      therapy by end of hospital day two. The eCQM  
16      does mimic or mirror the data elements and the  
17      construct of the chart-abstracted measure.

18                  This measure captures the proportion  
19      of ischemic stroke patients who had  
20      antithrombotic therapy administered by end of  
21      hospital day two, with day one being the arrival  
22      day or date of arrival.

1           The exclusions for this measure are  
2 similar to the others, but this is a time  
3 sensitive measure. So it's probably a little bit  
4 more similar like our VTE prophylaxis measure  
5 that was discussed first today.

6           Excluded populations include patients  
7 less than 18 years of age, patients who have a  
8 duration of stay less than two days being  
9 calculated from the arrival date, patients who  
10 have length of stay greater than 120 days,  
11 patients with comfort measures only documented on  
12 the day of or day after arrival, patients  
13 enrolled in clinical trials, patients admitted  
14 for elective carotid intervention, patients who  
15 are discharged prior to the end of hospital day  
16 two.

17           And then a new data element for this  
18 measure, we exclude patients with IV or IA  
19 thrombolytic therapy administered at this  
20 hospital or within 24 hours prior to arrival at  
21 the hospital to account for possibly the drip and  
22 ship patients that may transfer in.

1           And then there is a reason exclusion  
2 patients with documented reason for not  
3 administering antithrombotic therapy by end of  
4 hospital day two. The evidence for this, when it  
5 was last endorsed in 2012, was high.

6           There are many clinical studies that  
7 demonstrate the benefit of early antithrombotic  
8 therapy in reducing stroke mortality and stroke  
9 related morbidity.

10           The recommendation, actually, which is  
11 Class 1 level of evidence A, recommends  
12 administration of an antithrombotic, preferably  
13 aspirin within 24 to 48 hours of stroke symptom  
14 onset.

15           MS. ANDERSON: And the eCQM mimics the  
16 chart-abstracted measure as well. And this  
17 measure has been in use the same as the previous  
18 measure that we talked about for the meaningful  
19 use program at HIQR.

20           CO-CHAIR TIRSCHWELL: And when you say  
21 has been in use, meaning it's sort of on their  
22 list of things, but there are no data available

1 to you?

2 MS. ANDERSON: Correct, correct.

3 CO-CHAIR TIRSCHWELL: Okay. So over  
4 to, I don't know, Jocelyn or Steve? Who's going?

5 MEMBER BAUTISTA: I'll present.

6 CO-CHAIR TIRSCHWELL: Great, thank  
7 you.

8 MEMBER BAUTISTA: All right, so going  
9 to evidence. The developer has not submitted any  
10 new evidence since the prior endorsement. And so  
11 the evidence back then was high, multiple  
12 randomized control trials have shown the benefit  
13 of aspirin in acute ischemic stroke. So I don't  
14 know that there's anything to discuss.

15 CO-CHAIR TIRSCHWELL: I would agree  
16 and that we don't need to vote either. We can  
17 move right on to gap, unless somebody has a  
18 comment or discussion? Why don't we go with gap?

19 MEMBER BAUTISTA: So you can see from  
20 the table that we just have the same issue. The  
21 mean hospital performance is 98 percent the last  
22 three years, since 2012. And the tenth

1 percentile as well stayed 95, 96 percent the last  
2 three years.

3 So just taking that at face value,  
4 there does not appear to be much of a gap. The  
5 whole issue of disparities comes up again.  
6 There's some, perhaps, evidence from the  
7 literature that there may be some disparities in  
8 performance on this metric, but the developer  
9 doesn't submit any specific disparity data.

10 CO-CHAIR TIRSCHWELL: Discussion about  
11 gaps? Seeing none, I think we should probably  
12 vote on this. The initial recommendation was for  
13 low gaps.

14 MS. OGUNGBEMI: We are now voting for  
15 a performance gap on Measure 0438. The options  
16 are high, moderate, low, and insufficient.  
17 Voting is open.

18 Voting is closed. The results are  
19 zero percent high, 13 percent moderate, 87  
20 percent low, and zero percent insufficient.  
21 Measure 0438 does not pass on performance gap.

22 CO-CHAIR TIRSCHWELL: And so I think

1 we still need to go through the others because of  
2 the question about possibly going to reserve  
3 status versus non-endorsement. So let's proceed  
4 along to reliability.

5 MEMBER BAUTISTA: So for reliability,  
6 no new information was presented on reliability.  
7 There was previously presented, in 2012,  
8 reliability testing that showed high overall  
9 agreement rate, 97 percent, with only one data  
10 element less than 95 percent. So I don't know  
11 that we need --

12 CO-CHAIR TIRSCHWELL: So -- right. If  
13 there's no new data, do we have to vote? Or can  
14 we pass on the reliability vote also? Any  
15 discussion about this? And with there being no  
16 new data, I would say we just move on to the  
17 next, validity.

18 MEMBER BAUTISTA: There is new  
19 validity information presented, empirical  
20 validity testing on the measure score. They  
21 looked at over two million patient records, 1,300  
22 hospitals, and found high, well positive

1 correlations with six other stroke measures  
2 indicating, I guess, what you would call  
3 convergent validity.

4 They do present some information on  
5 threats to validity. They present their  
6 exclusion data which seems reasonable. And the  
7 preliminary rating for validity was high.

8 CO-CHAIR TIRSCHWELL: Any discussion  
9 or comments on validity? Okay. Well then I  
10 would move to vote since there was some new data.

11 MS. OGUNGBEMI: We are now voting on  
12 the validity for Measure 0438. Options are high,  
13 moderate, low, and insufficient. Voting is open.

14 Voting is closed. The results are 57  
15 percent high, 43 percent moderate, 0 percent low  
16 and 0 percent insufficient. Measure 0438 passes  
17 on validity.

18 CO-CHAIR TIRSCHWELL: Feasibility?

19 MEMBER BAUTISTA: So feasibility.  
20 This measure has been in use for many years. It  
21 is reliant on data abstraction, which does  
22 represent some burden. So the preliminary rating

1 for feasibility is moderate.

2 CO-CHAIR TIRSCHWELL: Discussion? Go  
3 ahead and vote. Oh, sorry. Yes, Steve.

4 MEMBER HUFF: I'll be quick. It's  
5 just -- I realize this measure's been in place a  
6 long time. It just seems like such an odd time  
7 measure. We have other measures where the  
8 granularity goes down to a minute, and this is  
9 hospital day two which, at least to this  
10 clinician, is not part of a standard timeframe.

11 It's hospital day two could be  
12 anywhere from what, 24 hours and one minute into  
13 admission up to one day, 23 hours, 59 minutes.  
14 And just an observation. It would seem to me  
15 there should be some consistency through the  
16 measures.

17 CO-CHAIR TIRSCHWELL: You know, I  
18 think that timeframe is based on some of the  
19 clinical trial data where that was the timeframe  
20 within which people were given antiplatelet  
21 agents and there was shown to be a clear benefit  
22 on outcomes. I don't know, developer? Oh,



1       sorry.

2                   DR. SCHWAMM:  Yes, so the CAST trial  
3       was the trial that demonstrated benefit if it was  
4       given within the first 48 hours.  The original  
5       implementation of the measure, many years ago,  
6       required sites to put the precise time at which  
7       the first medication was given.

8                   And the feedback at that time was it  
9       was too onerous.  And so it was changed to second  
10      hospital day which very closely, if anything,  
11      biases the measure toward earlier, rather than  
12      later treatment and was felt by hospitals to be  
13      much less onerous.  So that was the rationale for  
14      that change many years ago.

15                  CO-CHAIR TIRSCHWELL:  Any other  
16      comments or discussion?  Let's go ahead and vote  
17      on feasibility then.

18                  MS. OGUNGBEMI:  We are now voting on  
19      feasibility for Measure 0438.  Options are high,  
20      moderate, low, and insufficient.  Voting is open.

21                  Voting is closed, results are in.  
22      Twenty-two percent high, 78 percent moderate,

1 zero percent low and zero percent insufficient.

2 Measure 0438 passes on feasibility.

3 CO-CHAIR TIRSCHWELL: Great. And then  
4 finally use and usability.

5 MEMBER BAUTISTA: So the metric is  
6 used in multiple programs for public reporting,  
7 accountability, for quality improvement. So it's  
8 clearly demonstrated usability.

9 CO-CHAIR TIRSCHWELL: Any discussion?  
10 Any unintended consequences that we wanted to  
11 review? Okay, let's go ahead and vote then.

12 MS. OGUNGBEMI: We are now voting on  
13 usability and use for Measure 0438. The options  
14 are high, moderate, low, and insufficient.  
15 Voting is open.

16 Voting is closed. The results are 83  
17 percent high, 17 percent moderate, 0 percent low  
18 and 0 percent insufficient. Voting, sorry,  
19 Measure 0438 passes on usability and use.

20 CO-CHAIR TIRSCHWELL: Great. And now,  
21 so we now vote on overall endorsement. Which --  
22 no.

1                   MEMBER BAUTISTA: But it failed on  
2 gap.

3                   CO-CHAIR TIRSCHWELL: It failed on  
4 gap, right?

5                   MEMBER BAUTISTA: Yes. It failed on  
6 gap.

7                   CO-CHAIR TIRSCHWELL: So we're voting  
8 instead on reserve versus non-endorsement? Okay.  
9 So not this vote. This is not the right vote.  
10 And could you just read out all the criteria for  
11 us real quick?

12                  MS. OGUNGBEMI: Yes. We are now  
13 voting on endorsement maintenance, the potential  
14 for reserve status. If a measure is under  
15 endorsement maintenance review and did not meet  
16 importance to measure and report only due to lack  
17 of the performance gap, or the criteria 1B, does  
18 it meet criteria to create for potential reserve  
19 status?

20                           High performance is likely due to  
21 actual improvement versus an issue with measure  
22 construction. There is strong direct evidence,

1 it's proximal to the desired outcome, there are  
2 high ratings for reliability and validity,  
3 possibly moderate, it demonstrates use as well as  
4 improvement. Voting is open, options are yes or  
5 no.

6 Voting is closed. Results are 91  
7 percent yes, nine percent no. Measure 0438 does  
8 pass on the potential for reserve status.

9 CO-CHAIR TIRSCHWELL: Great. Let's  
10 move immediately to 2835, which is the companion  
11 eMeasure. And I think we could probably  
12 immediately skip over evidence.

13 DR. TERRY: But it's reserve status.

14 CO-CHAIR TIRSCHWELL: Oh, sorry.  
15 Never mind. Got it, right, because that one  
16 isn't fully endorsed, this one doesn't even get  
17 discussed. Okay. Good thing you guys are  
18 watching out for me.

19 All right, then. So then I guess  
20 we're then moving at a better pace to 0436, anti-  
21 coagulation therapy for Afib/flutter with its  
22 companion eMeasure 2833. Again, the joint

1 commission.

2 MS. KOLBUSZ: Again, basically the  
3 same on the chart based measure, stroke three,  
4 anti-coagulation therapy for atrial fibrillation  
5 flutter was last endorsed in 2012.

6 It's used in hospital and patient  
7 quality reporting, it's collected by the Paul  
8 Coverdell National Acute Stroke Registry and the  
9 Joint Commission certification programs.

10 It's used in meaningful use, all that  
11 still applies. This measure captures the  
12 proportion of ischemic stroke patients with  
13 atrial fibrillation flutter who are prescribed  
14 anti-coagulation therapy at hospital discharge.

15 The excluded populations are similar  
16 to the other discharge measures. Patients less  
17 than 18 years of age are excluded, length of stay  
18 greater than 120 days, comfort measures only  
19 documented, patients enrolled in a clinical trial  
20 related to stroke, patients admitted for elective  
21 carotid intervention, discharged to another  
22 hospital, patients who left against medical

1 advice or who expired, discharges to home for  
2 hospice care, discharges to home to another  
3 healthcare facility for hospice care.

4 And then we have a recent data element  
5 to exclude patients with a documented reason for  
6 not prescribing anti-coagulation therapy. This  
7 particular measure, since it's focusing on  
8 patients with a history or current finding of  
9 non-valvular atrial fibrillation, the  
10 recommendation is for anti-coagulation therapy at  
11 discharge, a little bit more potent than our  
12 antithrombotic measure. There's a large body of  
13 evidence to support that recommendation.

14 The original studies that we used to  
15 develop the measure were based on warfarin use.  
16 However, in recent years, novel oral anti-  
17 coagulant agents now referred to as the DOACs,  
18 the direct oral anti-coagulants, have been  
19 developed and approved by the U.S. FDA for stroke  
20 prevention and may be considered as an  
21 alternative to warfarin for select patients.

22 And those agents have all been added

1 to our list of acceptable drugs for inclusion in  
2 the numerator. That's it.

3 MS. ANDERSON: And Karen did mention  
4 that the eCQM is used for the meaningful use  
5 program and HIQR, same as the rest of our eQMs  
6 for stroke. People have been attesting to it for  
7 meaningful use but we do not have sufficient data  
8 to actually do analysis of that.

9 CO-CHAIR TIRSCHWELL: Great, thank  
10 you. And so Ketan and Alex? Okay, great.

11 MEMBER BULSARA: So in terms of  
12 evidence, I mean, this is, it's just undergoing  
13 maintenance evaluation. It's a process measure.  
14 There's no new evidence.

15 I mean, anti-coagulation does reduce  
16 the risk of stroke well established. So not much  
17 to discuss there. I just thought something to  
18 think about for future sort of renditions of this  
19 to develop some sort of data regarding the timing  
20 consensus because there seems to be variability  
21 in that. But there's nothing to really discuss  
22 in terms of new evidence. So we can move --

1           In terms of gap, you know, this is one  
2 of those measures that is very important that I  
3 think that we should definitely maintain our  
4 endorsement of. But you know, there's not much  
5 of a gap in terms of further improvement.

6           So I think we may want to consider,  
7 unless Alex feels a little bit differently in his  
8 review, that this may be something that we may  
9 want to consider reserve status for.

10           CO-CHAIR TIRSCHWELL: Any further  
11 comments on gaps? With that then, no comments,  
12 let's go ahead and move to a vote.

13           MS. OGUNGBEMI: We are now voting on  
14 performance gap for Measure 0436. Options are  
15 high, moderate, low, and insufficient. Voting is  
16 open.

17           Voting is closed. Results are zero  
18 percent high, 26 percent moderate, 74 percent  
19 low, and zero percent insufficient. Measure 0436  
20 fails on performance gap.

21           MEMBER BULSARA: In terms of  
22 reliability, as was pointed out earlier, the



1 numerator statement was ischemic stroke patients  
2 prescribed anti-coagulation therapy at discharge.  
3 Denominator was ischemic stroke patients with  
4 documented Afib and flutter.

5 And we've already gone over the  
6 exclusion criteria. Have no major issue in terms  
7 of reliability, but just out of interest, in  
8 terms of reliability testing, the numerator did  
9 change and it's been changed with the addition of  
10 new anti-coagulants. So I'm just curious as to  
11 how, what was the extent that that numerator  
12 changed?

13 CO-CHAIR TIRSCHWELL: So you're asking  
14 for data which we were not presented with?

15 MEMBER BULSARA: Just to get a sense  
16 for again, you know, so one of the criticisms in  
17 the past was not the new anti-coagulants weren't  
18 considered. Those are being considered now, but  
19 I think just out of more general interest, how  
20 did that change the numerator? And we may not  
21 have the data. And it's not pertinent to this  
22 discussion.

1 CO-CHAIR TIRSCHWELL: So you mean did  
2 performance improve with including, you know, how  
3 many people were getting the newer oral anti-  
4 coagulants initially when they weren't being  
5 counted for them?

6 MEMBER BULSARA: So my understanding  
7 is previously the patients that were being  
8 captured are the ones that were discharged on  
9 warfarin that now were added the patients with  
10 the new anti-coagulants. So how many more are we  
11 capturing?

12 CO-CHAIR TIRSCHWELL: Yes. When did  
13 the actual change in the numerator go into play?

14 DR. SCHWAMM: I think you're asking  
15 the question what was the gap in time between  
16 when the new agents have been approved for use  
17 and they show up on the form as an acceptable  
18 anti-coagulant?

19 CO-CHAIR TIRSCHWELL: Correct.

20 DR. SCHWAMM: And, you know, before  
21 Karen answers that, I'm just going to make the  
22 comment also that there are also patients who are

1 discharged on an anti-coagulant that's not  
2 approved for use for atrial fibrillation. Maybe  
3 they have a DVT and Afib.

4 They end up being excluded from the  
5 measure because it's an anti-coagulant so they're  
6 not appropriate for a different anti-coagulant.  
7 But they're not failing the measure, they just  
8 have another reason for anti-coagulation that  
9 puts them on an agent that isn't approved for use  
10 in AF.

11 CO-CHAIR TIRSCHWELL: But would the  
12 NOAC patients have been fails before the change?

13 DR. SCHWAMM: Before the change, they  
14 would have been a reason for exclusion, right, if  
15 they were on it. But it wasn't an available  
16 response option on the form. Am I saying that  
17 right?

18 MS. KOLBUSZ: It is accurate, what you  
19 said, Lee. Dabigatran was the first to be  
20 approved in 2010, it's a drug thrombotic  
21 inhibitor. And basically because the data  
22 element VTE prophylaxis was shared with other VTE

1 prophylaxis data measures in the core measures  
2 sets. For example, SCIP had two VTE measures.

3 No, I know. But basically because of  
4 that fact, in the data element VTE prophylaxis,  
5 we could not add a specific allowable value to  
6 capture dabigatran. So initially, what we did  
7 and we continue to do is we allow those patients  
8 to be captured in the reason data element, reason  
9 for no anti-coagulant, no VTE -- yes, so we allow  
10 it for the reason for anti-coagulation therapy at  
11 discharge. And they are captured, they are not  
12 excluded. They are in the numerator, I'm sorry  
13 about that.

14 Basically, they were added after 2010  
15 and we've added them with each consecutive new  
16 drug that's been approved. We have Pradaxa, we  
17 have Savaysa, we have the edoxaban, we have  
18 apixaban, and that's all the ones that are  
19 currently FDA approved.

20 DR. SCHWAMM: So I think the point to  
21 make though is that once they get approved, at  
22 the very next -- once they've been approved, at

1 the very next update to the tool, they get added.  
2 So there is a couple of six months sometimes  
3 where a new agent's approved and it's not yet in  
4 the system, but it's a pretty short gap.

5 CO-CHAIR TIRSCHWELL: So it probably  
6 hasn't had a major impact on the performance data  
7 anyway?

8 DR. SCHWAMM: No.

9 CO-CHAIR TIRSCHWELL: Okay.

10 DR. SCHWAMM: The point I was trying  
11 to make before is, like, if you have for example  
12 these are only approved for non-valvular Afib.  
13 If you had valvular Afib and you were put on one  
14 of these agents, that's not really an approved  
15 indication.

16 So that wouldn't necessarily qualify.  
17 But as soon as they have a labeled indication for  
18 atrial fibrillation, they then go into the  
19 numerator.

20 CO-CHAIR TIRSCHWELL: Okay. Any other  
21 comments or discussion on reliability? Peter,  
22 no? So let's go ahead and vote.

1 MS. OGUNGBEMI: We are now voting on  
2 reliability for Measure 0436. The options are  
3 high, moderate, low, and insufficient. Voting is  
4 open. We're just waiting on one person. Oh, got  
5 it.

6 All right, the results are 13 percent  
7 high, 87 percent moderate, zero percent low, and  
8 zero percent insufficient. Measure 0436 passes  
9 on reliability.

10 MEMBER BULSARA: For validity, I think  
11 that's the area that I had the most trouble with  
12 this measure. The numbers, like Michael had  
13 pointed out on an earlier measure, the numbers  
14 didn't add up completely.

15 And I think the one aspect that didn't  
16 add up for me is there's a significant threat to  
17 validity with 50 percent of the patients being  
18 discharged to hospice. And the other issue was  
19 why discharge to another hospital was excluded.

20 CO-CHAIR TIRSCHWELL: So those were,  
21 yes, there was a math error in those data that  
22 the Joint Commission sent. And I think the new,

1 the updated, corrected data are available on the  
2 SharePoint site. And this is Measure 436.

3 So the old data, let's see, home for  
4 hospice was 52 percent, now it's one percent. So  
5 big difference there. I'm not exactly sure where  
6 they went sideways with the math, but they've  
7 fixed it.

8 I'm trying to see if there are any  
9 other ones for 436. I don't see any.

10 MEMBER BULSARA: I think with the new  
11 data, I mean, that would be more in line with our  
12 clinical practice. I mean 50 percent and one  
13 percent, that's pretty dramatic.

14 CO-CHAIR TIRSCHWELL: I think the  
15 discharge to another hospital probably suffers  
16 from the same issue at 35 percent.

17 MEMBER BULSARA: But it does bring up  
18 an issue, though. I mean, if we're going to  
19 present numbers, if we're going to make argument  
20 with numbers, I think we have to make sure that  
21 they're accurate so we don't spend needless time  
22 sort of re-reviewing things.

1                   So I think it's imperative that the  
2 numbers accurately reflect what's actually going  
3 on. So it causes a lot of wasted time if they  
4 don't.

5                   CO-CHAIR TIRSCHWELL: Yes. Any other  
6 comments or discussion on validity? Let's go  
7 ahead and vote then on validity.

8                   MS. OGUNGBEMI: We are now voting on  
9 validity for measure 0436. The options are high,  
10 moderate, low, and insufficient. Voting is open.

11                   Voting is closed and the results are  
12 26 percent high, 74 percent moderate, zero  
13 percent low, and zero percent insufficient.  
14 Measure 0436 passes on validity.

15                   CO-CHAIR TIRSCHWELL: Feasibility?

16                   MEMBER BULSARA: No big issues on  
17 feasibility. There was a comment that sometimes  
18 data collection can be burdensome in terms of  
19 what's needed, but no issues from my perspective  
20 on feasibility.

21                   CO-CHAIR TIRSCHWELL: Discussion?  
22 Let's go ahead and vote then on feasibility.



1 MS. OGUNGBEMI: We are now voting for  
2 feasibility on measure 0436. The options are  
3 high, moderate, low, and insufficient. Voting is  
4 open.

5 Voting is closed. Results are 35  
6 percent high, 65 percent moderate, zero percent  
7 low, and zero percent insufficient. The measure  
8 passes on feasibility.

9 CO-CHAIR TIRSCHWELL: Usability?

10 MEMBER BULSARA: No issues on  
11 usability. There's seven credible organizations  
12 that are already incorporating this. So no  
13 issues on usability.

14 CO-CHAIR TIRSCHWELL: Discussion?

15 Let's go ahead and vote on usability and use.

16 MS. OGUNGBEMI: We are now voting for  
17 usability and use for Measure 0436. The options  
18 are high, moderate, low, and insufficient.  
19 Voting is open.

20 Voting is closed. Results are 74  
21 percent high, 26 percent moderate, zero percent  
22 low and zero percent insufficient. Measure 0436

1 passes on usability and use.

2 CO-CHAIR TIRSCHWELL: Okay, so that  
3 puts us, I think, in the same boat as last time  
4 where we failed on gap and so we can vote about  
5 reserve status. Getting good at this. Yes,  
6 Charlotte?

7 MEMBER JONES: If we as a committee  
8 move everything to reserve, we need to reconsider  
9 what reserve means in terms of effort, and time,  
10 and the fact that we could end up always turning  
11 every measure over to reserve status.

12 And I'm not saying which measures or  
13 not, but if everything that doesn't pass gap goes  
14 to reserve, then there's no reason to even vote.  
15 We should just set up an algorithm that if we  
16 identify no gap and we always vote to put it on  
17 reserve status, spare one vote.

18 CO-CHAIR TIRSCHWELL: Okay. Peter?

19 MEMBER SCHMIDT: So I disagree with  
20 that position. I don't think that it's up to us  
21 to keep the panel full of measures. But I do  
22 think that we should take the opportunity to

1       communicate to measure developers where we think  
2       the next challenge might be or where to go from  
3       when we've seen success with a measure, where  
4       they might want to take it.

5                   CO-CHAIR TIRSCHWELL:   Dave?

6                   CO-CHAIR KNOWLTON:   Yes, I concur with  
7       what Peter said. I think that we've got an  
8       unusual set of circumstances today with these.  
9       Part of what's keeping us in that because I  
10      certainly don't want us loading up reserve status  
11      things.

12                   But I think we've got eMeasures that  
13      are parallel with these measures right now and I  
14      think it was a difficult call for us today. So I  
15      think that's why I was seeing more reserve status  
16      on these ones, at least from where I sit.

17                   MEMBER FERZIGER:   Not to just join a  
18      chorus, but I think there's another point to  
19      think about and that is, you know, one of the  
20      things we've been challenged all day today, and I  
21      hope NQF will think about this is the issue of  
22      scope.

1           It seems like we keep coming into  
2       these policy issues that aren't really, you know,  
3       at least what I expected to be the scope of our  
4       task here. And so, you know, really the sort of  
5       scarcity issue, where the resources are and so  
6       forth, that's a policy question.

7           We shouldn't just be thinking about  
8       the neurology measures, we should be thinking  
9       about maybe we shouldn't measure neurology at all  
10      because pediatric cardiology, you know, is so  
11      important.

12          So I think your point is really  
13      important, but I just don't think it's within our  
14      purview to, you know, address the policy issue  
15      and that if it seems reasonable because the world  
16      changes to keep these things in reserve and keep  
17      looking at them, then that would be our  
18      recommendation.

19           CO-CHAIR TIRSCHWELL: Okay, any other  
20      discussion before we go ahead and vote on reserve  
21      status for this measure versus non-endorsement?

22           MS. OGUNGBEMI: We are now voting on

1 the potential for reserve status on Measure 0436.

2 The options are yes and no. Voting is open.

3 Voting is closed. Results are 96  
4 percent yes, four percent no. Measure 0436  
5 passes on its potential for reserve status.

6 CO-CHAIR TIRSCHWELL: Okay, thank you.  
7 And so that means no discussion for 2833 then.  
8 We have a break scheduled here on our agenda.

9 CO-CHAIR KNOWLTON: We already took  
10 it.

11 CO-CHAIR TIRSCHWELL: We already took  
12 that one? I thought that was a bonus break.  
13 Okay.

14 No, I just thought we added one in. I  
15 didn't think, I didn't know I was trading out my  
16 later break. Okay, well then we'll keep going.  
17 You're up, my partner.

18 CO-CHAIR KNOWLTON: We are going to  
19 start discussing 441, assessed for  
20 rehabilitation. Again, Joint Commission?

21 MS. KOLBUSZ: Okay, the chart, the  
22 base measure stroke and assess for

1 rehabilitation. It does have the eCQM companion  
2 that mirrors it. This measure captures the  
3 proportion of ischemic or hemorrhagic stroke  
4 patients assessed for who received rehabilitation  
5 services during the hospital stay.

6           The exclusions for this are very  
7 similar to the other measures. Patients less  
8 than 18 years of age, patients who have a length  
9 of stay greater than 120 days, patients with  
10 comfort measures only documented, patients  
11 enrolled in clinical trials related to stroke,  
12 patients admitted for elective carotid  
13 intervention, discharges to another hospital,  
14 discharges who left against medical advice,  
15 patients who expired, patients discharged to home  
16 for hospice care, patients discharged to  
17 healthcare facility for hospice care.

18           The basic rationale for the measure is  
19 that a large number of stroke patients who could  
20 benefit from rehabilitation services do not  
21 receive rehabilitation services. That estimate  
22 has been quite high in past studies.

1                   And so the basic premise here is that  
2                   at minimum, all patients' needs for  
3                   rehabilitation services should be assessed some  
4                   time during the hospital stay prior to discharge  
5                   from the hospital.

6                   CO-CHAIR KNOWLTON: So reviewers for  
7                   this were Michelle and Ross.

8                   MEMBER ZAFONTE: I think I'll start  
9                   and Michelle will chime in and be helpful where I  
10                  fall over the cliff. So the numerator is the  
11                  ischemic or hemorrhagic stroke patients assessed  
12                  or who received rehab services. The denominator  
13                  is sort of all individuals with ischemic or  
14                  hemorrhagic stroke.

15                  Among the exclusion criteria that we  
16                  were talking about we had some concerns with, and  
17                  we understand why, because it's combined with  
18                  other metrics.

19                  It seems to me, just as a clinician,  
20                  that you would want to know about the people at  
21                  the longer length of stay when you're considering  
22                  a rehab metric because that's the group of people

1 that would disproportionately benefit from it in  
2 preventing secondary comorbidities. But it's not  
3 within their derivation of the metric.

4 The evidence bases, this was reviewed  
5 in 2012. There doesn't seem to be that much in  
6 the way of new evidence for this. There is a  
7 series of clinical guidelines and smaller  
8 clinical trials, some outside the United States  
9 in Canada and Australia, others in other areas  
10 that suggest lower death and a lower rate of  
11 institutional care and some small studies that  
12 suggest improved functional status overall at one  
13 year.

14 So the preliminary rating of the  
15 evidence was moderate, but there hasn't been that  
16 much of a change since 2012.

17 (Off mic comments.)

18 MEMBER ZAFONTE: Do we need to vote,  
19 or --

20 CO-CHAIR KNOWLTON: There is no new  
21 evidence is there? No? Okay. No we don't.

22 MEMBER ZAFONTE: In the interest of



1 time and also sort of our Groundhog Day event,  
2 I'll go to the gap in care. Can we put that up  
3 again? Is that possible?

4 (Off microphone comments)

5 It's assessed or delivered.

6 MEMBER COTTER: How are people  
7 assessed for rehabilitation?

8 MEMBER ZAFONTE: So that comes into  
9 one of the definitional issues as we get down a  
10 little bit in this discussion. So one of the  
11 definitional issues is who contacts with them.  
12 And that has been expanded to include PAs and  
13 NPAs. And I suspect anybody contacting them from  
14 the rehabilitation team, there is a defined group  
15 of members who would define that assessment.

16 MEMBER KOENIG: I have a question  
17 first. Does a facility have to have a  
18 rehabilitation service? Is there any exclusion  
19 for, say, a small hospital does not have a  
20 rehabilitation service?

21 MEMBER ZAFONTE: I don't believe there  
22 is an exclusion there, but I turn to the metric

1 developers. I wasn't familiar that there was an  
2 exclusion.

3 MS. KOLBUSZ: If there was a small  
4 hospital that did not have a rehabilitation  
5 service, the physician, the attending physician  
6 would be considered a member of the  
7 rehabilitation team.

8 And of course, the expectation would  
9 then be that most likely, since there's no  
10 therapist there to do an assessment, that the  
11 attending would consider the rehabilitation needs  
12 of the patient before discharge.

13 MEMBER ZAFONTE: So as we turn to gap  
14 here, there's obviously been, you know,  
15 significant growth in the metric over the past  
16 five years, specifically from '13 to '14. But if  
17 we look at the 10th to 90th percentiles, you  
18 know, it's gotten pretty good.

19 It's up national aggregate rate of  
20 0.97, 50th percentile is pretty much 100 percent,  
21 and the 10th percentile is at 89th percentile.  
22 So we're at the border, I think, of the same gap

1 issue again that we've been running into on a  
2 persistent basis.

3 CO-CHAIR KNOWLTON: Comments,  
4 questions? Michelle?

5 MEMBER CAMICIA: So there is some data  
6 published on disparities and rehabilitation --

7 CO-CHAIR KNOWLTON: Is your mic on?  
8 Speak into it.

9 MEMBER CAMICIA: There are some data  
10 available on disparities for stroke patients and  
11 post-acute levels of care, though that was not  
12 submitted. And again, we share the same  
13 disparities issue that we've discussed  
14 previously.

15 MEMBER ZAFONTE: Yes. And so that  
16 data's actually pretty compelling regarding long-  
17 term outcome, access to rehabilitation services.  
18 And so that might be the place that the gap was  
19 at. And I had asked just in our break, Karen, if  
20 they had any additional data for us.

21 And there may be some inter-hospital  
22 based differences, but I'm not sure about any

1 global differences that are available.

2 CO-CHAIR KNOWLTON: Anything from the  
3 developer on that? No?

4 MS. KOLBUSZ: That's correct, it was  
5 similar to the BT prophylaxis measure. Again,  
6 when we looked at the data that we did have for  
7 disparities in our database, that there was  
8 nothing at an aggregate level that was  
9 identified.

10 However, individual hospitals, we did  
11 note disparity that was significant for some.  
12 And the disparity would be about 2.1 percent of  
13 hospitals.

14 CO-CHAIR KNOWLTON: Okay. Alex?

15 MEMBER RAE-GRANT: The preliminary  
16 rating was low. Are you proposing a different  
17 rating for this than the preliminary?

18 MEMBER ZAFONTE: No. I think from my  
19 perspective, I'm probably proposing that it winds  
20 up in the so called emeritus status, again,  
21 because I think it's something we need to check  
22 and I would like to see more data on the

1       disparities.

2                   And I understand why people have  
3       concerns with it, but I think that this  
4       disparities issue deserves to, at least, be put  
5       in that status and us take a closer look at it in  
6       the future.

7                   MEMBER RAE-GRANT:   So you would retain  
8       the low rating on the data?

9                   MEMBER ZAFONTE:   Yes.

10                  CO-CHAIR KNOWLTON:   Anybody else?  
11       Okay, let's vote on gap.

12                  MS. OGUNGBEMI:   We are now voting on  
13       performance gap for Measure 0441.   The options  
14       are high, moderate, low, and insufficient.  
15       Voting is open.

16                  Voting is closed.   The results are  
17       zero percent high, nine percent moderate, 91  
18       percent low, and zero percent insufficient.  
19       Measure 0441 fails on performance gap.

20                  CO-CHAIR KNOWLTON:   Once again, let's  
21       continue on.

22                  MEMBER ZAFONTE:   We're going to go

1 onto reliability. There has been an expansion in  
2 the definition regarding those individuals who  
3 are part of the rehabilitation team. Segue to  
4 our prior discussion a few minutes ago and the  
5 kinds of things that would be associated, i.e., a  
6 clarification of a clinical assessment.

7 There does not appear to be any major  
8 reliability issues, however this has been core  
9 crosswalked several times. And the bigger  
10 concern with this that has been pointed out  
11 several times again is that this is assessed at a  
12 data element level and not a measure score level.  
13 So it received a moderate reliability rating.

14 CO-CHAIR KNOWLTON: Questions or  
15 comments? Okay, let's vote.

16 MS. OGUNGBEMI: We are now voting on  
17 reliability for Measure 0441. Results are, or  
18 options are high, moderate, low, and  
19 insufficient. Voting is open.

20 Voting is closed. Results are nine  
21 percent high, 87 percent moderate, four percent  
22 low, and zero percent insufficient. Measure 0441

1 passes on reliability.

2 MEMBER ZAFONTE: We're going to go to  
3 validity next. The validity of this seems quite  
4 good. They did do a look with the seven other  
5 stroke metrics and tied it pretty well to the six  
6 core other stroke performance metrics supporting  
7 hypothesis that hospitals with high quality on  
8 one stroke metric tend to have relative high  
9 quality on others.

10 There are some threats to validity  
11 that I just wanted to go over again. I think  
12 Michelle and I's interest in this group of people  
13 who had the length of stay greater than 120 days,  
14 and then could we just confirm what the hospice  
15 rate was also on the re-done data on this?

16 (Off microphone comments)

17 MEMBER ZAFONTE: Yes, that's what I  
18 thought. Okay, because I have them both written  
19 down, one year, 50 percent which, of course, made  
20 no sense. Those are our only concerns with that.

21 CO-CHAIR KNOWLTON: Comments? Okay,  
22 let's vote.

1 MS. OGUNGBEMI: We are now voting on  
2 the validity for Measure 0441. The options are  
3 high, moderate, low, and insufficient. Voting is  
4 open.

5 Voting is closed. Results are 43  
6 percent high, 57 percent moderate, zero percent  
7 low, and zero percent insufficient. Measure 0441  
8 passes on validity.

9 CO-CHAIR KNOWLTON: Feasibility?

10 MEMBER ZAFONTE: Feasibility. There  
11 is some reported data collection burden for chart  
12 abstraction in this metric, but overall it was  
13 rated moderate and we happen to agree with that.

14 CO-CHAIR KNOWLTON: Questions or  
15 comments? Let's vote.

16 MS. OGUNGBEMI: We are now voting on  
17 the feasibility of Measure 0441. Voting is, or  
18 the options are high, moderate, low,  
19 insufficient. Voting is open.

20 Voting is closed. The results are  
21 nine percent high, 91 percent moderate, zero  
22 percent low and zero percent insufficient.



1 Measure 0441 passes on feasibility.

2 CO-CHAIR KNOWLTON: Usability?

3 MEMBER ZAFONTE: Usability of this is  
4 reasonably quite high. It's certainly been a  
5 metric that's been reported at a number of  
6 different organizations, I think over seven.

7 The results have been improved, with  
8 over 1,200 hospitals really obtaining a very high  
9 level of compliance with this. So the usability  
10 looks quite high.

11 CO-CHAIR KNOWLTON: Questions or  
12 comments? Vote?

13 MS. OGUNGBEMI: We are now voting on  
14 the usability and use of Measure 0441. Options  
15 are high, moderate, low, and insufficient.  
16 Voting is open.

17 Voting is closed. Results are 87  
18 percent high, 13 percent moderate, zero percent  
19 low and zero percent insufficient. Measure 0441  
20 passes on usability and use.

21 CO-CHAIR KNOWLTON: Comments on  
22 reserve status? Ross?

1                   MEMBER ZAFONTE: So I think it's  
2                   appropriate for reserve status for a number of  
3                   different reasons, one related to the changing  
4                   paradigm of care that we're all going under and  
5                   this concern with utilization of post-acute  
6                   services.

7                   And here we have some at least with  
8                   moderate evidence affecting long term outcome and  
9                   re-hospitalization, as well as  
10                  institutionalization for patients and as well as  
11                  the disparities issues that Michelle raised that  
12                  are pretty compelling in the literature, but we  
13                  need more data about.

14                 CO-CHAIR KNOWLTON: Anything further,  
15                  Michelle, to that? Any other comments or  
16                  thoughts? Peter?

17                 MEMBER SCHMIDT: So just to comment to  
18                  the measure developer, I know from my own  
19                  research and my own activities that there are  
20                  disparities in referrals. And there are, I just  
21                  did a quick PubMed search, there is literature on  
22                  this.

1           And if it had been included in the  
2       disparities section, I think you would find a lot  
3       of people very willing to -- say that there's a  
4       gap and perhaps that gap is addressing that 77  
5       percent of hospitals who are not in the set who  
6       are currently reporting.

7           You know, there's definitely outcome  
8       benefit for referral, and I feel that there's a  
9       pretty -- you could very easily make the case  
10      that those disparities were there. And I wish  
11      you had, because it would have made a difference,  
12      I think, in the outcome today.

13           CO-CHAIR KNOWLTON: Other comments?  
14      Okay, we're voting on endorsement maintenance  
15      potential for reserve status.

16           MS. OGUNGBEMI: We are now voting for  
17      the potential for reserve status on Measure 0441.  
18      The options are yes or no. Voting is open.

19           Voting is closed, results are in. We  
20      have 96 percent yes, four percent no. The  
21      potential for reserve status of Measure 0441  
22      passes.

1 CO-CHAIR KNOWLTON: We will be  
2 skipping the next measure because it is an  
3 eMeasure tied to the previous measure that did  
4 not meet gap. So we will be moving on to 2863,  
5 nimodipine treatment administered. Joint  
6 Commission again?

7 MS. KOLBUSZ: All right. The first  
8 measure that we are going to be discussing is C-  
9 stroke 6, which is comprehensive stroke 6,  
10 nimodipine treatment administered. And like the  
11 stroke measures that we've discussed all day,  
12 this is a new measure submission, the first time  
13 that it's coming to the committee for endorsement  
14 consideration.

15 This particular measure measures the  
16 proportion of subarachnoid hemorrhage patients  
17 age 18 years and older for whom nimodipine  
18 treatment was administered within 24 hours of  
19 arrival at this hospital.

20 It is an important measure to  
21 consider, the rationale for it being that  
22 nimodipine is the only calcium channel blocker

1       that's been found to be effective in the  
2       prevention of cerebral vasospasm which is a  
3       serious complication following subarachnoid  
4       hemorrhage that occurs in 30 percent to 70  
5       percent of the patients and accounts for nearly  
6       50 percent of the deaths surviving to treatment.

7               Therefore, we have included it in this  
8       particular set. The excluded populations include  
9       patients less than 18 years of age, patients who  
10      have a length of stay greater than 120 days,  
11      patients with comfort measures only documented on  
12      day of or after hospital arrival, patients  
13      enrolled in clinical trials related to stroke,  
14      and patients discharged within 24 hours of  
15      arrival at this hospital.

16             This measure was implemented effective  
17      January 1st, 2015. It was developed and is  
18      currently used by our disease specific care  
19      comprehensive stroke certification program which  
20      consists of 100 certified hospitals to date.

21             At the time that we submitted the  
22      measure, we had two quarters of data available

1 from actual implementation. Other data provided  
2 was from the pilot test of the measures. And I  
3 think that I'll just stop there and turn it over  
4 to the Chair.

5 CO-CHAIR KNOWLTON: Okay, thank you.  
6 Discussions will be Ron and Melody.

7 MEMBER RYAN: Okay, I'll take the lead  
8 and Ron will jump in when needed. Okay? So as  
9 far as evidence goes, the evidence is presented  
10 as a guideline from the American Heart  
11 Association, American Stroke Association with  
12 Level 1 Grade A recommendation for use of  
13 nimodipine for aneurysm subarachnoid hemorrhage.

14 There is also a Cochrane review, 16  
15 studies which showed good likelihood of benefit.  
16 However, if the largest trial which had 906  
17 patients in it is excluded, then the results are  
18 no longer statistically significant.

19 But that's probably just because of  
20 the numbers there. The algorithm points to high  
21 on level of evidence here. Ron, did you have  
22 anything else you wanted to add?

1 CO-CHAIR KNOWLTON: Questions or  
2 comments?

3 MEMBER KOENIG: I had a question.

4 CO-CHAIR KNOWLTON: Go ahead, Ron.

5 MEMBER KOENIG: For the developer,  
6 when you say subarachnoid hemorrhage, is it all  
7 hemorrhages or just secondary aneurysm?

8 MS. KOLBUSZ: The measure is intended  
9 for those patients that have an aneurysmal  
10 subarachnoid hemorrhage. That's provided in the  
11 rationale for the measure that we're focusing on  
12 those patients.

13 We do capture the initial patient  
14 population using the ICD 10 principal diagnosis  
15 code. There isn't a specific principal diagnosis  
16 code or any diagnosis code for that matter of  
17 non-aneurysmal subarachnoid hemorrhage.

18 Therefore, in order to really  
19 accommodate those patients, there needs to be  
20 some text documentation in the medical record  
21 that the patient was non-aneurysmal in order to  
22 address it in the measure which would be

1 addressed under the reason for not administering  
2 nimodipine treatment.

3 CO-CHAIR KNOWLTON: David?

4 CO-CHAIR TIRSCHWELL: So if the record  
5 says that this convexity subarachnoid hemorrhage  
6 was presumptively due to amyloid angiopathy, that  
7 would be enough to get you excluded from the  
8 measure?

9 MS. KOLBUSZ: We have in the reason  
10 data element for the measure, the reason for not  
11 administering nimodipine treatment, we did  
12 provide some stand alone reasons, non-aneurysmal  
13 is one. I believe the cerebral amyloid  
14 angiopathy was on there, I have to actually look  
15 it up and find it in my measures.

16 (Simultaneous speaking)

17 CO-CHAIR TIRSCHWELL: Well it  
18 specifically implies non-aneurysmal.

19 MS. KOLBUSZ: Okay, yes. Okay, so  
20 what I'm saying is though we would look for text  
21 documentation within the first 24 hours which is  
22 the timeframe for the measure because we can't



1 capture it through any other type of coded  
2 information such as an ICD 10 diagnosis code. So  
3 we would be looking for some other documentation.

4 CO-CHAIR TIRSCHWELL: Why does it have  
5 to be in the first 24 hours? Sometimes the  
6 workup can be prolonged, repeat angiograms.

7 DR. SCHWAMM: So I think the issue  
8 there is that the measure performance is was it  
9 provided within the first 24 hours.

10 CO-CHAIR TIRSCHWELL: Oh, okay. All  
11 right. That makes sense.

12 DR. SCHWAMM: So that's the issue with  
13 the notation provided. Yes, so the goal is to  
14 target aneurysm with subarachnoid hemorrhage.  
15 And there is an exclusion criteria for non-  
16 aneurysmal.

17 What Karen is saying is if there was  
18 an ICD-9 code from aneurysmal subarachnoid  
19 hemorrhage, they could to the exclusion based  
20 just on ICD-9 code because there is one they have  
21 to rely on text based description of why it's not  
22 appropriate in this case.

1 CO-CHAIR TIRSCHWELL: But we don't  
2 have to say in the chart I'm not treating this  
3 non-aneurysmal subarachnoid hemorrhage with  
4 nimodipine because it's totally inappropriate to  
5 do so?

6 DR. SCHWAMM: So you're asking do the  
7 magic words non-aneurysmal have to appear in the  
8 text? I don't know the answer to that.

9 MS. KOLBUSZ: Well, I think what  
10 you're asking is maybe twofold. A stand-alone  
11 reason we're looking for text documentation that  
12 the patient is non-aneurysmal.

13 We aren't requiring other linkage with  
14 nimodipine because we're considering it a stand-  
15 alone reason. So we're not looking for an  
16 explanation beyond non-aneurysmal. But there  
17 needs to be some documentation to identify those  
18 cases.

19 CO-CHAIR TIRSCHWELL: Okay, thank you.

20 CO-CHAIR KNOWLTON: Both of our  
21 discussants want to comment, so go ahead Melody.

22 MEMBER RYAN: So when you look at the

1 coding instructions that are given for it, the  
2 stand-alone reasons are non-aneurysmal  
3 subarachnoid hemorrhage, reversible cerebral  
4 vasoconstriction syndrome, and cerebral amyloid  
5 angiopathy. And all of the codes that are given  
6 are for non-traumatic also.

7 CO-CHAIR KNOWLTON: Ron, something  
8 further?

9 MEMBER KOENIG: Just for the Committee  
10 for review, one of the exclusions was discharge  
11 within 24 hours. And initially the information I  
12 think provided was about 60 percent. It seemed  
13 outrageously high. But when new data was  
14 presented by Christie today, it was sent out I  
15 think it comes down to one percent.

16 CO-CHAIR KNOWLTON: Anything further  
17 here? Questions, comments? Yes, sir?

18 MEMBER HUFF: The most common cause of  
19 subarachnoid hemorrhage in emergency departments  
20 is traumatic. It might just be easier to push if  
21 trauma had been entered as an exclusionary point.

22 MS. KOLBUSZ: The trauma cases would

1 not be. There are separate hemorrhagic codes for  
2 trauma and non-trauma. So they are excluded  
3 because they're not included in that group of  
4 initial hemorrhagic patients.

5 CO-CHAIR KNOWLTON: Ron, are you still  
6 up? Ketan?

7 MEMBER BULSARA: Just along what  
8 Steve's saying, do you really need to include  
9 other, I mean, I think it confuses matters if  
10 you, the more things you put into differentials  
11 because I think there's a higher likelihood  
12 you'll leave something out.

13 Why not put cavernomas in there too?  
14 Or put capillary telangiectasias and things to  
15 that extent? Why not just leave the exclusion  
16 criteria just to say aneurysmal subarachnoid  
17 hemorrhage?

18 (Off microphone comments)

19 MS. KOLBUSZ: The code is subarachnoid  
20 hemorrhage. So if you don't have a code or some  
21 other way to identify that it's aneurysmal or  
22 non-aneurysmal, the code isn't making the

1 difference either way. So we need another way to  
2 identify those cases.

3 MEMBER BULSARA: But there is a code  
4 for aneurysm and there is a code for brain  
5 aneurysm.

6 MS. KOLBUSZ: There is.

7 MEMBER BULSARA: So --

8 MS. KOLBUSZ: And it's unruptured.  
9 It's an unruptured code.

10 MEMBER BULSARA: But in order for the  
11 patients to qualify for this measure, you would  
12 have to have both ICD codes.

13 MS. KOLBUSZ: We have had feedback  
14 during the pilot test regarding the aneurysmal  
15 and non-aneurysmal patients as well as after from  
16 our comprehensive stroke centers.

17 And we've looked at a variety of ways  
18 to address their concern that because of the  
19 coding system, they're pulling in all the  
20 subarachnoid hemorrhages and how would we address  
21 these patients that are non-aneurysmal which is  
22 the largest group. I'm sure there's other

1 diagnoses that obviously nimodipine isn't  
2 appropriate for.

3 But the best way to do it in the  
4 measure construct and the way that the other  
5 measures are constructed and the way that the  
6 hospitals are familiar with abstracting was to  
7 provide in the abstraction guidelines for the  
8 reason data element guidance.

9 And we tried to make it easier and  
10 limit the burden of abstraction by making it a  
11 stand-alone reason so that they don't have to  
12 look for additional documentation.

13 CO-CHAIR KNOWLTON: Any further  
14 questions or comments? Ready for a vote. This  
15 is evidence.

16 MS. OGUNGBEMI: One moment. We are  
17 now voting on evidence for Measure 2863. The  
18 options are high, moderate, low, and  
19 insufficient. Voting is open.

20 Voting is closed. The results are 61  
21 percent high, 39 percent moderate, 0 percent low  
22 and 0 percent insufficient. Measure 2863 passes

1 on evidence.

2 CO-CHAIR KNOWLTON: Gap?

3 MEMBER RYAN: So there's also a table  
4 similar to the other ones that has been  
5 presented. For this measure, there were two  
6 different kind of phases of testing.

7 The first was the pilot testing which  
8 went on from 2010 to 2013. It had 66 sites and  
9 1,229 patients. And then when it was actually  
10 implemented in the first and second quarters of  
11 2015, the first quarter there were 39 sites and  
12 572 patients, and then 51 sites and 873 patients  
13 in the second quarter.

14 The averages were high for all of  
15 them, but when you look at that table, could you  
16 come up so everybody can see it, you do see  
17 increases from the pilot time to the time it was  
18 implemented.

19 And the range in the pilot testing  
20 went from 0 to 100. So that would indicate that  
21 there's a need there. You can see the  
22 percentiles are given for the actual

1 implementation phase. And still I think there's  
2 a pretty good need for that.

3 When we look at disparities, the  
4 information that's presented is that there's a  
5 difference in mortality and of patients based on  
6 race. Compared to white, Hispanics were least  
7 likely to have a disparity.

8 And then blacks and Asian and Pacific  
9 Islanders were most likely to have a disparity.  
10 There is also a disparity between women and men  
11 for aneurysm. But none of these data actually  
12 look at a disparity between who gets nimodipine  
13 and who doesn't get nimodipine.

14 So I think that part, the disparity  
15 part of the performance is, you know, is not  
16 there yet for this. But I do think there is a  
17 pretty big gap on performance. The preliminary  
18 rating on that I believe was moderate.

19 CO-CHAIR KNOWLTON: Questions or  
20 comments? Let's vote.

21 MS. OGUNGBEMI: We are now voting for  
22 performance gap on Measure 2863. Options are



1 high, moderate, low, insufficient. Voting is  
2 open.

3 Voting is closed. Results are 13  
4 percent high, 87 percent moderate, 0 percent low,  
5 and 0 percent insufficient. Measure 2863 passes  
6 on performance gap.

7 CO-CHAIR KNOWLTON: Reliability?

8 MEMBER RYAN: Okay. To briefly  
9 restate, the numerator is all patients for whom  
10 nimodipine treatment was administered within 24  
11 hours of arrival. The denominator is all  
12 subarachnoid hemorrhage patients.

13 Exclusions from the denominator are  
14 patients less than 18 years of age, patients who  
15 have a length of stay greater than 120 days,  
16 patients with comfort measures only, patients  
17 enrolled in clinical trials, patients discharged  
18 within 24 hours of arrival at the hospital, and  
19 those are the exclusions.

20 So as I said, looking in the coding  
21 manual you can, it actually shows you that the  
22 measures, the codes that are given are for non-

1 traumatic subarachnoid hemorrhage, and also those  
2 other ones are stand-alone reasons for not  
3 administering nimodipine treatment. So non-  
4 aneurysmal, reversible vasoconstriction, and  
5 cerebral amyloid angiopathy.

6 So that was that. The testing was  
7 tested only at the data element level which will  
8 have implications for our voting. The inter-  
9 rated reliability testing was done at 12 sites  
10 with 281 records. The agreement was very high at  
11 95 percent for everything except admitting time  
12 which was 82 percent. So all of that was  
13 actually high.

14 There were a number of hospitals but  
15 only 281 records that we used, so that does seem  
16 a little bit low. The preliminary ranking on  
17 that is moderate.

18 CO-CHAIR KNOWLTON: Questions or  
19 comments? Yes, Jim?

20 MEMBER BURKE: So I think up until  
21 this point we've mostly been talking about  
22 ischemic stroke in our ICDE codes which are

1 usually pretty well validated. Is there data  
2 particularly on the new, because it looks like  
3 under ICD-10 the subarachnoid codes change  
4 compared to before. Is there any data on the  
5 reliability of the codes as opposed to the data  
6 elements themselves?

7 MEMBER RYAN: So probably this is best  
8 discussed by the developers. But they do provide  
9 under threats to validity I think some  
10 information about crosswalking between ICD-9 and  
11 ICD-10. And I don't know what the actual name of  
12 that document is that is more involved, the one  
13 that comes after the brief summary statement.

14 CO-CHAIR KNOWLTON: Other comments or  
15 questions? Let's vote.

16 MS. OGUNGBEMI: We are now voting on  
17 reliability for Measure 2863. Options are high,  
18 moderate, low, and insufficient. Voting is open.

19 Voting is closed. Results are 9  
20 percent high, 91 percent moderate, 0 percent low  
21 and 0 percent insufficient. Measure 2863 passes  
22 on reliability.

1 CO-CHAIR KNOWLTON: Validity?

2 MEMBER RYAN: Okay, for validity this  
3 is at the measure score level. And they were  
4 tested empirically. The first hypothesis was  
5 that there would be two measures that would be  
6 highly aligned on hemorrhagic stroke.

7 So the one is this one, 06 nimodipine  
8 treatment administered. The other one is 03  
9 which is severity measurement performed for  
10 subarachnoid hemorrhage and intercerebral  
11 hemorrhage.

12 So looking at the severity in those  
13 two you would think would be highly correlated.  
14 They weren't. I don't know why, they just  
15 weren't.

16 Hypothesis two was that hospitals who  
17 do well on one stroke measure are likely to do  
18 well on the others and that one was confirmed  
19 with high correlations between those.

20 One concern we had on the workgroup  
21 phone call was that there was a high percentage  
22 of people that seemed to be discharged within 24

1 hours as previously mentioned by Ron. That  
2 actually is quite low, it's 1.42 and that was a  
3 mathematical issue that was corrected this  
4 morning.

5 Meaningful differences, there is a  
6 plan for meaningful differences. The range  
7 again, as we said, was pretty wide. So it seems  
8 like there's a possibility for good, meaningful  
9 difference there.

10 For missing data there is a plan, but  
11 we don't know how often data are actually missing  
12 for each one of those elements. And so the  
13 preliminary ranking here was moderate.

14 Some of the reason for that ranking  
15 though was because of the concern about so many  
16 people being discharged within 24 hours which we  
17 know is erroneous.

18 CO-CHAIR KNOWLTON: Questions or  
19 comments? Let's vote.

20 MS. OGUNGBEMI: We are now voting on  
21 validity for Measure 2863. Options are high,  
22 moderate, low, and insufficient. Voting is open.

1           Voting is closed. Results are 4  
2           percent high, 91 percent moderate, 4 percent low,  
3           and 0 percent insufficient. Measure 2863 passes  
4           on validity.

5           CO-CHAIR KNOWLTON: Feasibility?

6           MEMBER RYAN: The source of data here  
7           is either electronic or paper medical records.  
8           And it does involve manual chart review which  
9           would mean having to go through the charts, you  
10          know, manually. And so that could be burdensome.

11          The developer estimated that the time  
12          for the measure set was 45 minutes per record.  
13          Surprisingly I think that's a bargain at only  
14          \$3.50. But it does seem like these are data that  
15          are all available generally in the medical record  
16          and could be extracted.

17          CO-CHAIR KNOWLTON: Questions or  
18          comments? Let's vote.

19          MS. OGUNGBEMI: We are now voting for  
20          feasibility of Measure 2863. Options are high,  
21          moderate, low, and insufficient. Voting is open.

22          Voting is closed. Results are 13

1 percent high, 83 percent moderate, 4 percent low  
2 and 0 percent insufficient. Measure 2863 passes  
3 on feasibility.

4 CO-CHAIR KNOWLTON: Usability.

5 MEMBER RYAN: So the measure is  
6 currently being used for care certification for  
7 comprehensive stroke centers. In the future it  
8 is planned for public reporting and external  
9 benchmarking, but there's not a lot of detail or  
10 timeframe on that.

11 Whether or not that's desirable it's  
12 possible. I think the public might get more out  
13 of knowing that somebody is, you know, center  
14 stroke certified rather than specifically about  
15 this issue. So that was preliminarily ranked  
16 moderate.

17 CO-CHAIR KNOWLTON: Questions or  
18 comments? Let's vote.

19 MS. OGUNGBEMI: We are now voting on  
20 the usability and use of Measure 2863. Options  
21 are high, moderate, low, and insufficient.  
22 Voting is open.

1 Results are 13 percent high, 83  
2 percent moderate, 4 percent low, and 0 percent  
3 insufficient. Measure 2863 passes on usability.

4 CO-CHAIR KNOWLTON: Overall? Well,  
5 we're now going to vote on the overall  
6 acceptability of the measure. Suitability for  
7 endorsement.

8 MS. OGUNGBEMI: Yes, we are now voting  
9 for the overall suitability for endorsement of  
10 Measure 2863. The options are yes or no. Voting  
11 is open.

12 Voting is closed. Responses are 96  
13 percent yes, 4 percent no. Measure 2863 passes  
14 at suitability for endorsement.

15 CO-CHAIR KNOWLTON: I'm going to talk  
16 a bit with David and what we're going to do is  
17 we're going to defer the next issue to tomorrow  
18 because we want to have our robust discussion and  
19 then we've about zoned everybody out I think.

20 So I'm going to ask the operator to  
21 open the phone line for anybody on the phone that  
22 would like to comment, and I will also open it to



1 our guests if anybody would like to comment about  
2 issues that have been discussed today. Operator,  
3 would you open the phone line please?

4 OPERATOR: At this time if you would  
5 like to make a comment, please press star and  
6 then the number one. No comments from the phone  
7 line.

8 CO-CHAIR KNOWLTON: Anybody here?  
9 Nobody here either. Okay. So thank you for an  
10 assertive first day. We will be, those of you  
11 who are joining us, we're dining at Georgia  
12 Brown's at 6:15 I believe.

13 (Off microphone comments)

14 CO-CHAIR KNOWLTON: 6:15, correct?  
15 And we will be reconvening here tomorrow for  
16 breakfast at 8:00 a.m. Be here bright eyed and  
17 bushy tailed, we've got a lot to do tomorrow.  
18 Thank you.

19 (Whereupon, the meeting in the above-  
20 entitled matter was concluded at 5:03 p.m.)  
21  
22

A		
<b>A-G-E-N-D-A</b> 4:1		
<b>a.m</b> 1:9 5:2 42:1,2		
115:16,17 401:16		
<b>AAN</b> 14:5,7,11,15,17		
<b>abandoned</b> 326:5		
<b>abbreviated</b> 127:10		
<b>ability</b> 23:22 123:3		
161:5 229:4 253:21		
259:8 282:15		
<b>able</b> 9:1 22:4 36:4 78:3		
83:16 85:12 121:2		
136:11 147:5 156:20		
218:5 223:10 235:16		
235:22 241:10 242:1		
248:9,21 252:18		
258:11 286:11 292:8		
302:2 306:21 323:10		
323:15 324:20 328:12		
335:1		
<b>above-</b> 401:19		
<b>above-entitled</b> 41:22		
115:15 215:2 336:22		
<b>absence</b> 204:9 320:1		
<b>absolute</b> 181:4 215:9		
284:1		
<b>absolutely</b> 42:10 59:9		
123:11 175:15 189:3		
224:16 234:6 292:18		
<b>abstracted</b> 108:15,20		
109:8 217:22 218:4		
<b>abstracting</b> 390:6		
<b>abstraction</b> 112:17,21		
122:8 252:15 343:21		
376:12 390:7,10		
<b>abstractive</b> 108:9		
<b>abstractor</b> 326:9		
<b>abstractors</b> 99:3		
<b>Academy</b> 15:20 17:8,14		
17:21 18:11,15 295:9		
<b>ACC</b> 220:15		
<b>ACC&amp;H</b> 229:15		
<b>accept</b> 99:11 117:17		
245:6 283:13 311:22		
312:2		
<b>acceptability</b> 26:3,22		
36:16 44:18 97:13		
117:10 118:20 119:17		
120:14 121:3 124:2		
400:6		
<b>acceptable</b> 53:4 190:22		
280:5,11 281:8,20		
301:11 311:15 351:1		
354:17		
<b>accepted</b> 97:21 191:5		
<b>access</b> 74:17 218:4		
328:9 371:17		
<b>accommodate</b> 199:18		
383:19		
<b>accomplishing</b> 83:9		
84:1		
<b>account</b> 30:17 139:18		
292:22 338:21		
<b>accountability</b> 27:9		
29:1 112:1 183:12		
199:6 346:7		
<b>accountable</b> 208:10,11		
<b>accounts</b> 381:5		
<b>accreditation</b> 126:14		
150:12		
<b>accuracy</b> 102:2 109:7		
109:10 111:3 322:14		
322:17		
<b>accurate</b> 43:11 102:4		
110:20 208:7 254:16		
271:15 290:10 311:18		
311:21 312:19 326:20		
355:18 359:21		
<b>accurately</b> 231:8		
234:18 253:2 255:3		
360:2		
<b>aces</b> 107:18		
<b>achieve</b> 33:21 69:16,20		
70:11,20 77:19		
<b>achieved</b> 147:9 179:15		
<b>achieving</b> 37:10 70:14		
71:12 107:13 215:19		
270:16 272:1		
<b>acknowledge</b> 7:7 36:8		
250:3		
<b>acknowledged</b> 36:7		
<b>acknowledging</b> 147:12		
<b>acquired</b> 180:4		
<b>act</b> 33:10		
<b>action</b> 81:18 183:7,14		
<b>actions</b> 198:19		
<b>activate</b> 58:12 74:15,21		
<b>activator</b> 43:16		
<b>active</b> 145:8 208:18		
217:13		
<b>actively</b> 139:16 142:7		
<b>activities</b> 9:6 112:2		
378:19		
<b>actual</b> 94:3 110:1,2		
121:9 122:22 123:7		
123:10 173:3 244:4		
263:20 273:21 283:7		
304:10 320:4 321:11		
347:21 354:13 382:1		
391:22 395:11		
<b>acute</b> 4:4 38:12 42:13		
42:17 43:9 44:4 45:17		
45:21 46:12 49:4,6		
56:1 62:1 90:11		
126:21 170:2 249:9		
250:1 294:1,12,13		
298:1 299:14 340:13		
349:8		
<b>acutely</b> 79:4		
<b>ad</b> 228:18		
<b>add</b> 8:3 21:21 30:20		
32:4 89:21 104:3		
128:13 129:21 132:7		
241:6,8 258:16 267:9		
296:22 303:1,2,7		
308:3 312:12 334:1		
356:5 358:14,16		
382:22		
<b>added</b> 253:4 350:22		
354:9 356:14,15		
357:1 365:14		
<b>addition</b> 21:4 109:7		
149:2 300:11 323:1		
353:9		
<b>additional</b> 26:14 39:7		
40:14 61:20,21		
103:21 136:5 137:16		
149:2 154:16 156:19		
158:10 159:10 205:8		
217:3 227:15 307:13		
311:16 333:21 371:20		
390:12		
<b>Additionally</b> 21:16		
<b>address</b> 22:14 26:17		
28:22 37:19 39:11		
41:13 54:22 55:8 61:6		
112:14 117:4 171:7		
173:18 194:20 199:5		
217:10 262:12 295:3		
321:17 335:12 364:14		
383:22 389:18,20		
<b>addressed</b> 109:2 178:2		
179:4 189:20 287:20		
307:21 384:1		
<b>addresses</b> 183:11		
<b>addressing</b> 184:1 379:4		
<b>adds</b> 244:22		
<b>adequate</b> 26:13 63:18		
211:2 242:19 306:12		
<b>adhere</b> 21:1		
<b>adhered</b> 144:15		
<b>adherence</b> 230:19		
231:5		
<b>adjust</b> 138:3 305:13		
<b>adjustment</b> 26:10		
283:15		
<b>administer</b> 52:7,19		
58:11 59:1		
<b>administered</b> 4:20		
250:2 259:9 337:20		
338:19 380:5,10,18		
393:10 396:8		
<b>administering</b> 252:16		
339:3 384:1,11 394:3		
<b>administration</b> 52:22		
72:4 249:16,20 250:5		
252:10,18 339:12		
<b>administrative</b> 3:2 6:17		
106:12		
<b>admission</b> 125:8 128:4		
273:10 344:13		
<b>admissions</b> 265:14,16		
<b>admitted</b> 125:17 170:11		
272:10,20 273:3		
276:20 298:7 338:13		
349:20 366:12		
<b>admitting</b> 394:11		
<b>adopt</b> 67:22		
<b>adopted</b> 73:15 299:21		
<b>adoptive</b> 270:16		
<b>adult</b> 12:9 294:9		
<b>adults</b> 294:21		
<b>advance</b> 50:15		
<b>advanced</b> 1:19 76:4		
108:11		
<b>advantage</b> 109:14		
189:18		
<b>adverse</b> 290:19		
<b>advice</b> 44:12 170:15		
284:19 306:9 331:21		
350:1 366:14		
<b>advisor</b> 1:12 12:14		
<b>advisory</b> 230:1 275:18		
<b>advocacy</b> 151:7,9		
<b>advocate</b> 150:21		
<b>advocates</b> 74:6		
<b>AF</b> 355:10		
<b>Affairs</b> 2:3		
<b>affect</b> 168:5		
<b>affirmatively</b> 178:21		
<b>Afib</b> 353:4 355:3 357:12		
357:13		
<b>Afib/flutter</b> 348:21		
<b>afoul</b> 318:12		
<b>African</b> 96:8		
<b>afternoon</b> 173:8		
<b>age</b> 125:11 170:7 258:9		
291:14 294:8,17		
315:3,5 338:7 349:17		
366:8 380:17 381:9		
393:14		
<b>agenda</b> 36:21 38:3,8		
219:10 365:8		
<b>agent</b> 355:9		
<b>agent's</b> 357:3		
<b>agents</b> 344:21 350:17		
350:22 354:16 357:14		
<b>ages</b> 123:4		
<b>aggregate</b> 131:3 133:7		
193:21 370:19 372:8		
<b>aggregating</b> 181:8		
<b>ago</b> 13:19 92:12 201:17		

- 230:7,16 267:6 305:8  
320:6 345:5,14 374:4  
**AGPCNP-BC** 1:19  
**agree** 48:9 49:22 54:5  
55:1 66:8,14 69:8  
85:17 87:5,21 88:7,14  
96:20 98:3 106:22  
113:15 130:10 147:20  
155:16 161:10,12  
162:20,22 178:20,20  
178:22 184:19 204:18  
213:17 237:12 246:14  
259:17 271:1 340:15  
376:13  
**agreed** 127:3 190:1  
213:5 225:14 284:10  
**agreement** 78:18 92:10  
99:2 152:6 235:12  
342:9 394:10  
**agrees** 259:5  
**ah-ha** 209:21  
**AHA** 220:16 242:5  
281:21,22  
**AHA/ASA** 67:17  
**ahead** 32:15 38:3,21  
42:9 59:1 87:17,19  
98:5 104:11 113:17  
118:8 121:2 137:10  
153:17 155:7 156:22  
159:18 185:22 186:17  
197:14 210:21 240:17  
259:22 262:10 277:14  
279:13,17 284:12  
285:17 286:16 291:11  
292:20 293:2 295:18  
295:19 305:5,19  
306:4 314:22 315:15  
317:12,19 319:11  
322:12 323:6 328:16  
330:17 331:8 337:4  
344:3 345:16 346:11  
352:12 357:22 360:7  
360:22 361:15 364:20  
383:4 386:21  
**aim** 84:2  
**alert** 79:12  
**Alex** 17:18 67:10 99:14  
135:1 153:6 176:19  
178:4 240:12 317:12  
351:10 352:7 372:14  
**Alex's** 178:20  
**Alexander** 2:11 312:8  
**Alexandra** 3:4 6:20  
37:4  
**algorithm** 47:4 188:15  
188:20 189:1,8,12  
252:19 253:1,12  
277:10 308:14 315:21  
316:3,7 362:15  
382:20  
**algorithmic** 114:17  
333:17  
**algorithms** 189:14  
307:3  
**align** 220:14  
**aligned** 396:6  
**alignment** 221:8  
**alive** 184:1  
**allow** 76:22 196:20  
227:10 229:5 356:7,9  
**allowable** 172:7,8,16  
173:1 324:20 356:5  
**allowed** 188:22 252:17  
**allowing** 302:18 313:11  
**allows** 43:12 65:17,17  
68:13 100:8 122:20  
170:21 307:10  
**alter** 306:17  
**alternative** 218:1  
350:21  
**altogether** 240:3  
**Alzheimer's** 13:6  
**ambiguous** 54:17 56:11  
61:9,19 191:19  
**ambulance** 64:4  
**ambulation** 128:5  
**amendment** 197:1  
**America** 151:4  
**American** 11:12,13  
12:4 13:14 15:20  
16:11 17:8,14,14,20  
18:11,15 78:8 90:12  
90:13 225:4 229:20  
281:17 295:9 382:10  
382:11  
**Americans** 96:8  
**amount** 70:16 137:22  
176:11,15 203:2  
235:21 306:7 330:8  
**ample** 158:19  
**amplifies** 276:2  
**amyloid** 384:6,13 387:4  
394:5  
**analyses** 263:3  
**analysis** 23:3 25:17  
26:16 263:17 333:15  
351:8  
**analyst** 3:4,5 243:19  
**analytic** 245:1  
**and/or** 45:4  
**ANDERSON** 297:16,18  
303:19,22 309:6  
310:16 311:5,9 315:5  
315:9,13 320:12  
323:12 339:15 340:2  
351:3  
**Andrews** 1:12 12:13,14  
62:5 204:8 239:7  
**anecdotal** 138:1 148:2  
**anecdote** 138:5  
**aneurysm** 382:13 383:7  
385:14 389:4,5  
392:11  
**aneurysmal** 383:9  
385:16,18 388:16,21  
389:14 394:4  
**angiogram** 76:11  
**angiograms** 385:6  
**angiopathy** 384:6,14  
387:5 394:5  
**Ann** 3:2,5,11 7:21 8:7  
15:10 20:5 41:10  
115:22 116:4,5 124:8  
124:14,20 136:6,10  
136:16 248:6 302:19  
304:3 321:17,18  
327:11 335:13  
**Ann's** 159:9  
**annual** 228:4  
**annually** 152:19  
**answer** 36:1 39:7 44:21  
54:11 64:1 84:7 94:19  
147:18 154:7 155:10  
157:14 158:16 228:22  
297:12 325:10 326:10  
386:8  
**answered** 103:19  
**answers** 213:22 324:15  
354:21  
**Anthem** 2:10 17:5  
**anti-** 4:8,9 348:20  
350:16 354:3  
**anti-coagulant** 354:18  
355:1,5,6 356:9  
**anti-coagulants** 350:18  
353:10,17 354:10  
**anti-coagulation** 349:4  
349:14 350:6,10  
351:15 353:2 355:8  
356:10  
**anti-platelet** 223:17  
**anticipate** 159:1  
**Anticoagulation** 4:16  
**antiplatelet** 344:20  
**antithrombotic** 4:13,15  
169:3,5,15,17 171:1  
173:19 175:19 176:2  
192:18 216:10 337:5  
337:14,20 339:3,7,12  
350:12  
**anybody** 19:3 31:20  
118:11 119:8 121:5  
143:1 189:4 214:20  
218:19 240:5 247:20  
258:16 283:5 289:3,6  
292:22 303:7 369:13  
373:10 400:21 401:1  
401:8  
**anymore** 151:9 200:13  
204:5 257:21  
**anyway** 8:17 14:19 69:7  
156:16 167:16 217:13  
222:22 234:19 357:7  
**aphasia** 55:11 80:1  
**apixaban** 356:18  
**APN** 298:20  
**apologies** 335:13  
**apologize** 49:9 264:20  
271:16 284:17 308:15  
**apparently** 334:7  
**appealing** 239:3,5  
**appear** 341:4 374:7  
386:7  
**appears** 131:15 180:15  
268:9  
**appendectomies** 290:1  
**appendicitis** 290:2,12  
**application** 83:11  
**applications** 27:10  
**applied** 113:11 225:1  
272:19 273:12,20  
274:4 284:7 329:5  
**applies** 28:14 183:3  
349:11  
**apply** 57:4 112:19  
198:15 200:19 273:9  
**appreciate** 5:21 42:8  
62:5 334:22  
**appreciated** 280:8  
**approach** 19:18 69:10  
281:19 282:18,19,21  
**approaches** 175:12  
177:20  
**approaching** 178:16  
**appropriate** 85:3  
103:10 137:20 173:19  
190:13 232:13 282:4  
282:6 307:19 355:6  
378:2 385:22 390:2  
**appropriately** 63:13  
174:4 175:16 273:8  
**approval** 53:2 116:16  
116:22,22 117:1,2  
119:7,9 120:2,16  
121:6,10,18 122:11  
124:5 183:13 200:13  
251:3 302:6,11  
304:21 314:9  
**approve** 92:14 186:19  
**approved** 39:4 43:20  
52:21 53:3 191:4,5  
221:5 231:22 300:8

350:19 354:16 355:2  
 355:9,20 356:16,19  
 356:21,22 357:3,12  
 357:14  
**approving** 227:20  
 302:8  
**approximation** 51:22  
**April** 1:5 241:19  
**arbitrary** 53:22 73:13  
 86:7 233:21  
**Arbor** 15:10  
**area** 25:12 27:13 28:9  
 33:5 50:11 98:17  
 118:21 194:14 203:2  
 216:6 358:11  
**areas** 22:6,8,14 28:8  
 29:1 33:7 35:20 77:1  
 183:12 199:1,5 368:9  
**argue** 57:5 289:15  
 290:5 330:12  
**arguing** 88:5 211:16  
 254:14 257:20  
**argument** 70:19 134:20  
 181:18 206:9,19  
 241:5 359:19  
**arithmetic** 278:7,14  
**arrival** 38:15 42:20  
 43:22 57:15 64:21  
 96:15 125:15 275:19  
 277:11 298:8,15,17  
 298:22 337:21,22  
 338:9,12,20 380:19  
 381:12,15 393:11,18  
**arrive** 78:11 239:13  
 249:9 250:15 265:22  
 298:2  
**arrived** 44:5 51:7  
**arrives** 46:22 50:12,18  
**arriving** 53:19 269:9  
**artery** 273:5  
**article** 91:9 287:22  
 288:5  
**artifact** 294:7 334:11  
**Asian** 392:8  
**asked** 68:4 91:2 122:18  
 128:15 144:12 151:1  
 151:14 152:2,2  
 157:22 158:5 194:19  
 213:7 293:20 371:19  
**asking** 30:12 67:20  
 178:21 216:20 353:13  
 354:14 386:6,10  
**asks** 9:4 265:12  
**aspect** 183:21 200:8  
 358:15  
**aspirin** 339:13 340:13  
**aspiring** 151:3  
**assertive** 401:10

**assess** 44:16 81:14  
 159:4 181:20 244:21  
 322:16 365:22  
**assessed** 4:18 66:13  
 164:9 365:19 366:4  
 367:3,11 369:5,7  
 374:11  
**assessment** 22:7 124:1  
 138:4 164:21 321:20  
 369:15 370:10 374:6  
**assessments** 315:20  
**assigned** 34:1 210:7  
 273:4  
**assimilate** 237:20  
**assimilated** 230:3  
 232:7  
**Assistant** 1:13 2:16  
**Associate** 1:15,20 2:8,9  
 2:15  
**associated** 198:21  
 322:2 374:5  
**association** 11:12,14  
 11:16 12:5 13:7 15:2  
 16:12 78:8 90:13,13  
 225:5 281:17 382:11  
 382:11  
**assume** 51:21 52:15,17  
 112:19 164:9 178:12  
 178:19 202:17 278:14  
 301:9  
**assumed** 76:5  
**assumes** 178:17  
**assuming** 92:5 153:20  
 178:16 205:16 261:15  
 265:7 285:14 330:8  
**assumption** 52:17  
 70:13  
**ASTBD** 233:5  
**at-** 126:1  
**athero** 234:9  
**atherosclerosis** 230:21  
 233:20 234:8  
**atherosclerotic** 233:10  
 234:10  
**atherosclerotic-related**  
 221:11  
**atrial** 4:17 349:4,13  
 350:9 355:2 357:18  
**attached** 168:3  
**attachments** 24:4 124:1  
**attain** 46:16  
**attainable** 84:18 85:4  
**attempt** 86:8  
**attempting** 60:18  
 173:18  
**attending** 109:21  
 151:19 326:15 370:5  
 370:11

**attention** 144:16 167:21  
 204:21  
**attest** 25:7 305:2,9  
**attested** 300:8  
**attesting** 300:5 323:13  
 351:6  
**attributable** 134:8  
 289:16  
**attribute** 194:4  
**attributes** 273:11  
**attrition** 141:9 153:1  
**audiences** 111:22  
**Augusta** 12:15  
**Australia** 368:9  
**authority** 67:17  
**automatically** 29:22  
 109:4 121:15 201:4  
**availability** 336:4  
**available** 38:8 39:18  
 93:22 94:1 106:8,11  
 106:15 161:17 173:6  
 177:7,12 235:15  
 300:20 321:12 323:19  
 329:6 339:22 355:15  
 359:1 371:10 372:1  
 381:22 398:15  
**average** 90:1 140:5  
 146:15 205:5  
**averages** 391:14  
**avoid** 94:6  
**avoidable** 71:22  
**aware** 79:7,7,17 137:18  
 168:6 245:9  
**awful** 138:8  
**Axon** 14:6

---

**B**


---

**B** 88:6 126:6 222:5  
**back** 35:1 39:4,9,10  
 41:11 59:4 74:15 75:9  
 81:13 102:8 115:13  
 115:19 117:5 118:9  
 120:8,14,19,20  
 123:15 127:16 135:11  
 136:16 141:2,10  
 142:2 143:1,3,11  
 147:21 148:8 150:13  
 151:21 163:7,10  
 167:5 172:11 177:8  
 179:1 187:10 189:19  
 196:21 197:10 199:22  
 201:8,20 210:20  
 215:6 217:2 218:7  
 227:10 241:16 243:14  
 243:19 246:16 270:9  
 290:21 306:5 312:3  
 322:4 334:12,16  
 337:4 340:11

**background** 308:16  
**backtrack** 227:19  
**backwards** 252:22  
**bad** 50:7 59:8  
**badly** 38:4  
**ball** 148:4  
**bang** 146:5  
**bar** 151:2 152:3 250:4  
**bargain** 398:13  
**base** 1:15 189:21  
 365:22  
**based** 18:19 45:19 46:3  
 52:17 53:3 56:14  
 66:22 68:5 70:2 76:6  
 82:4 83:14 113:2  
 128:3 129:5 132:2  
 133:11 137:15 138:1  
 143:18 146:14 153:3  
 155:17 158:5 168:19  
 171:22 191:9 202:16  
 221:12 224:22 225:21  
 251:22 269:12 277:7  
 277:8,10 280:10  
 281:11,21 301:22  
 311:16 321:20 323:2  
 327:19,21 344:18  
 349:3 350:15 371:22  
 385:19,21 392:5  
**baseline** 298:10 299:3  
 299:20 309:3,19  
 310:16 311:1  
**baseline--** 309:8  
**bases** 368:4  
**basic** 97:17 366:18  
 367:1  
**basically** 28:2 30:14  
 36:22 68:4 88:19 96:4  
 125:20 129:5,16  
 160:15 172:5 189:20  
 230:19 233:19 250:14  
 250:18 253:12 324:12  
 349:2 355:21 356:3  
 356:14  
**basin** 138:4  
**basis** 56:6 88:15 245:21  
 255:11 371:2  
**baton** 219:18  
**Bautista** 1:13 17:11,12  
 122:12,17 123:9  
 139:10 140:13 188:14  
 340:5,8,19 342:5,18  
 343:19 346:5 347:1,5  
**bear** 197:20  
**beautiful** 107:17 245:13  
**bed** 324:14  
**beds** 96:13  
**bedside** 50:21  
**beginning** 187:2 297:7

304:18  
**behalf** 43:2 44:14 95:4  
**behaving** 19:11  
**belabor** 110:17  
**believe** 10:20 15:19  
 20:2 51:11 124:11  
 148:18 157:17 164:13  
 215:5 218:16 229:19  
 248:21 255:18 279:10  
 284:21 306:20 311:20  
 312:5 314:11 322:2  
 331:3 369:21 384:13  
 392:18 401:12  
**believed** 191:11 266:18  
 323:4  
**believes** 255:8  
**benchmark** 77:14 83:14  
 83:17,19 146:18,19  
**benchmarking** 399:9  
**benchmarks** 179:14  
**benefit** 169:17 233:4,12  
 234:2 289:16 294:9  
 339:7 340:12 344:21  
 345:3 366:20 368:1  
 379:8 382:15  
**benefits** 233:20 286:8  
 290:4  
**best** 63:4,11 65:11  
 76:21 77:21 90:17  
 231:14 245:18 246:10  
 326:10 333:13 390:3  
 395:7  
**bet** 161:16  
**Beth** 2:4 15:15  
**better** 6:9 41:14 42:13  
 49:5 69:21 149:10  
 207:15,16 212:9  
 242:21 310:20 348:20  
**beware** 205:3  
**beyond** 386:16  
**biannually** 152:19  
**bias** 82:16 83:2 111:6  
 242:21 266:14 283:2  
**biased** 19:11 130:1  
**biases** 345:11  
**big** 101:18 194:14  
 228:13 258:7 267:20  
 268:2 272:20 279:2  
 359:5 360:16 392:17  
**bigger** 150:10 268:2  
 374:9  
**bill** 129:9  
**billing** 129:6,7  
**biomarker** 55:17 79:21  
 80:5,6,9  
**biomarkers** 290:11  
**bit** 6:8 8:22 25:1 27:16  
 47:15 49:9 67:12

86:19 92:1 93:3  
 118:10 122:15 165:14  
 168:21 189:7 197:22  
 203:6 206:16,18  
 207:1 210:4 213:13  
 214:5 221:7 226:19  
 231:17 232:9 252:7  
 257:6 261:12 271:21  
 274:2 299:10 307:8  
 310:20 311:5 312:10  
 324:10 338:3 350:11  
 352:7 369:10 394:16  
 400:16  
**Black** 180:6  
**blacks** 392:8  
**blank** 260:2 307:22  
**block** 65:9 336:18  
**blocker** 380:22  
**blocks** 156:1  
**blood** 299:7,8  
**blue** 17:5,5 93:7  
**board** 13:6 305:17  
**boat** 362:3  
**body** 232:8 350:12  
**Bonnie** 120:4 122:13,16  
 122:19 297:9 303:3  
 305:1 306:11 307:18  
 311:22 313:12 314:12  
 319:2 321:20 324:10  
 324:12 325:22  
**bonus** 365:12  
**booklet** 24:15  
**border** 370:22  
**bother** 202:5  
**box** 282:14  
**boxes** 104:8  
**Brad** 13:1  
**Bradford** 1:20 45:4  
**brain** 43:9 73:4 249:20  
 389:4  
**brand** 123:20 320:21  
**break** 115:10,11 133:6  
 189:18 195:18 214:1  
 214:4 218:2 258:12  
 332:11 335:7 365:8  
 365:12,16 371:19  
**breakfast** 401:16  
**breaking** 86:19 163:5  
**breakout** 163:11  
**brief** 22:16 89:18 100:6  
 297:14 395:13  
**briefly** 7:21 106:21  
 171:11 337:8 393:8  
**bright** 401:16  
**bring** 35:1 39:9,10 75:2  
 75:3 142:10 148:7  
 154:18 155:4 159:2  
 161:5 214:5 217:9

223:10 260:1 333:19  
 359:17  
**bringing** 38:10 304:20  
**brings** 52:20 310:9  
**broad** 46:14  
**broaden** 234:6  
**broadened** 271:9  
**broadening** 88:10  
**broader** 232:12  
**broadly** 205:2  
**brought** 14:13 85:11  
 147:20 192:15 334:8  
 334:16  
**Brown's** 336:17 401:12  
**BT** 372:5  
**bucket** 326:21  
**build** 86:17  
**Bulsara** 1:15 16:22,22  
 56:20 64:9 66:14  
 72:20 74:1,14 75:9  
 76:1,12 90:19 92:3  
 140:19 142:5 148:22  
 152:6 208:21 238:19  
 246:2 332:19 351:11  
 352:21 353:15 354:6  
 358:10 359:10,17  
 360:16 361:10 388:7  
 389:3,7,10  
**bunch** 67:9 86:19 337:9  
**burden** 106:9 199:9,13  
 321:13 327:3 343:22  
 376:11 390:10  
**burdensome** 199:16  
 282:20 360:18 398:10  
**bureau** 13:18  
**Burke** 1:17 15:8,8 71:14  
 133:18 162:12 207:10  
 274:13 275:2 276:1  
 394:20  
**burning** 218:19  
**bushy** 401:17  
**button** 325:7,13

## C

**C** 46:8 50:4  
**C-** 380:8  
**calcium** 380:22  
**calculated** 37:13 268:9  
 338:9  
**calculation** 277:7,10  
**calculations** 277:22  
**calendar** 131:8  
**California** 14:22 15:5  
**call** 21:7 26:18 27:18  
 28:1,12 29:20 80:21  
 103:2 120:13 123:21  
 138:15 139:1,7 146:9  
 155:6 157:2 159:16

161:6 164:21 227:17  
 228:4,14 241:11  
 253:6 280:13,14  
 289:22 307:11 333:11  
 343:2 363:14 396:21  
**called** 23:3 100:13  
 106:16 218:18 294:1  
 316:22 372:20  
**calling** 5:13 302:13  
**calls** 6:7 24:9 39:11  
 128:22 132:13 302:19  
**Camicia** 1:17 14:20,21  
 371:5,9  
**Canada** 368:9  
**candidate** 4:3,6 124:9  
 254:9  
**candidates** 43:15  
 116:15  
**capabilities** 110:20  
**capacity** 329:1  
**capillary** 388:14  
**capture** 66:20 93:12,14  
 94:8 125:3 169:3  
 253:2 255:3 302:2,2  
 305:13 356:6 383:13  
 385:1  
**captured** 94:5 106:8  
 354:8 356:8,11  
**captures** 44:4 174:2  
 220:7 249:8 254:4  
 337:18 349:11 366:2  
**capturing** 66:9 105:17  
 354:11  
**card** 36:7 320:10,15,16  
 320:17  
**card's** 258:18  
**cardiac** 80:6 233:16  
 290:22  
**cardiologist** 294:9  
**cardiology** 364:10  
**cards** 5:11  
**care** 10:18 12:10 25:19  
 43:10 47:13 63:1,4,4  
 65:11 77:22 79:19  
 81:18 84:19 88:22  
 90:3 96:21 126:16  
 170:17,19 171:5  
 172:2,4,10 173:2  
 179:13 183:6 198:18  
 199:1,13 202:5  
 215:21 218:3 326:12  
 350:2,3 366:16,17  
 368:11 369:2 371:11  
 378:4 381:18 399:6  
**carotid** 125:17 170:11  
 265:20 269:1 272:11  
 272:21 273:1,2,5,9,10  
 273:13,15 276:20

- 338:14 349:21 366:12  
**carried** 47:20  
**carve** 233:11  
**carved** 313:10  
**case** 41:17 48:10  
 104:10 113:6 114:18  
 128:11,11 134:14  
 167:14 170:20 181:6  
 190:17 191:21 205:13  
 226:18 227:2 245:18  
 307:14 308:8 326:7  
 334:7 379:9 385:22  
**cases** 53:16 77:17,20  
 83:3 108:15 113:7  
 129:19 283:1 324:12  
 324:18 386:18 387:22  
 389:2  
**CAST** 345:2  
**casting** 275:14  
**catastrophic** 59:6  
**catch** 247:4,11 317:1  
**catchall** 254:13  
**categories** 332:2  
**categorize** 253:2  
**caught** 228:1  
**causal** 72:3  
**cause** 205:19 387:18  
**caused** 223:6  
**causes** 294:17 360:3  
**cavernomas** 388:13  
**CCM** 1:17  
**CDP** 94:14  
**cell** 11:1  
**center** 1:12,14,18 2:1,5  
 2:6,12 11:8 15:16  
 35:1 112:17 128:14  
 133:3 266:17 399:13  
**centers** 126:17,18  
 181:16 259:4 270:14  
 284:8 389:16 399:7  
**cerebral** 45:17 65:12  
 80:8 381:2 384:13  
 387:3,4 394:5  
**certain** 26:15 111:6  
 222:10 282:3 283:3  
**certainly** 110:9 119:4  
 119:21 158:18 175:22  
 181:11,15 208:14  
 221:17 291:2 306:11  
 363:10 377:4  
**certification** 126:16  
 139:15 140:15 169:22  
 349:9 381:19 399:6  
**certified** 270:13 381:20  
 399:14  
**cetera** 64:4 89:6 142:16  
 187:17 257:2  
**chair** 16:4 216:18 382:4  
**chairing** 187:6  
**chairman** 2:18 11:5  
**chairs** 5:6 306:9  
**challenge** 272:15  
 273:18 363:2  
**challenged** 108:2  
 112:15 363:20  
**challenges** 52:1 99:11  
**challenging** 98:20  
**chance** 154:9 159:11  
 161:6 198:5 224:15  
 227:6  
**change** 25:13 26:16  
 94:4 200:5 210:12  
 213:5 226:2,7 228:13  
 228:13,15,19 230:4,5  
 230:7 231:20,21  
 232:21,22 235:14  
 237:22 238:3,13,16  
 239:9,12 244:4  
 251:20 253:16,17,20  
 255:17 267:6 268:2  
 279:3 311:15 345:14  
 353:9,20 354:13  
 355:12,13 368:16  
 395:3  
**changed** 12:17 120:12  
 220:12 221:7 225:14  
 225:15 226:22 232:11  
 234:21 240:13 247:1  
 250:13,21 256:6  
 279:6 335:18 345:9  
 353:9,12  
**changes** 55:19 208:3  
 209:20 228:6,8  
 251:10 256:2 276:11  
 280:15 281:22 312:11  
 327:22 364:16  
**changing** 133:20  
 143:13 232:15 234:22  
 238:6 378:3  
**channel** 380:22  
**characteristics** 282:3  
**characterized** 190:17  
**charge** 329:9  
**Charlotte** 2:7 13:20,21  
 14:1 78:16 85:8  
 149:15 152:4,7  
 159:18 208:8 243:21  
 243:22 246:3 287:6  
 290:8 291:11 292:17  
 293:13 295:7 314:22  
 317:11 322:12 323:21  
 362:6  
**Charlotte's** 151:18  
**chart** 108:9,13 110:10  
 122:8 297:21 298:1  
 299:13 322:20 349:3  
 365:21 376:11 386:2  
 398:8  
**chart-abstracted** 122:5  
 337:14,17 339:16  
**chart-based** 124:22  
**charts** 104:3 221:21  
 319:5 324:4,6 398:9  
**check** 40:10 91:15  
 155:3 282:14 372:21  
**checking** 194:2  
**Chicago** 12:3  
**chief** 2:14 7:9 10:17  
 293:16  
**child** 295:15,16  
**children** 294:3  
**children's** 2:8 14:2  
 293:19  
**chime** 45:8 367:9  
**choose** 84:22  
**chorus** 363:18  
**Christie** 387:14  
**Christy** 3:6 6:12,14  
 32:15 94:11 216:13  
 216:16 218:21  
**circular** 56:2 201:6  
**circulate** 91:8,19  
**circumstance** 283:12  
**circumstances** 363:8  
**citations** 256:22  
**cited** 255:21  
**claims** 106:12 117:12  
 117:20 118:4,15  
 121:14 122:1,6  
 123:18  
**claims-based** 122:4  
**clarification** 83:6 248:7  
 270:3 374:6  
**clarified** 271:14 274:10  
**clarifies** 261:18  
**clarify** 49:9 59:17 82:5  
 85:10 87:21 129:1  
 188:14 213:20 214:4  
 225:20 247:8 252:6,8  
 262:7,12,20,22  
 264:12 267:2 308:19  
**clarifying** 213:21  
 314:21  
**clarity** 211:8 213:13  
 215:9 267:7  
**class** 45:22 46:7 88:3  
 88:15,17 126:2,6  
 232:17,20 339:11  
**classes** 45:15  
**clear** 36:4 55:12,13  
 82:8 84:10 99:21  
 145:3,6 179:21  
 182:18,19,19 184:20  
 196:13,14 205:14  
 213:3,16,18 215:13  
 222:14 235:18 246:21  
 253:4 256:16 264:17  
 270:7 308:21 332:20  
 333:1 344:21  
**clearer** 112:20  
**clearly** 78:2 127:13  
 128:4 140:22 148:17  
 218:9 223:15 259:6  
 278:17 302:8 346:8  
**Cleveland** 1:14 2:11  
 17:13,19  
**clicker** 37:8 94:15  
**cliff** 367:10  
**clinic** 1:14 2:12 17:13  
 17:20 51:20 82:15  
**clinical** 17:15 55:20  
 56:4,6 76:6,13 84:16  
 106:12 112:16 120:7  
 124:18 125:16 129:13  
 129:17,22 130:2  
 170:10 191:14,18  
 207:6 212:8 221:4  
 232:5 233:5 246:22  
 253:17,20 265:20  
 299:12 300:2 338:13  
 339:6 344:19 349:19  
 359:12 366:11 368:7  
 368:8 374:6 381:13  
 393:17  
**clinically** 55:10,19  
 56:10,17 61:22  
 131:21  
**clinician** 281:1 344:10  
 367:19  
**clinicians** 43:13  
**clock** 63:9,22 64:1,7  
 72:8 79:7  
**close** 105:14 225:21  
 227:1 240:15 256:14  
 306:21  
**closed** 94:9,17 95:11  
 97:8 98:10 104:16  
 111:16 113:22 115:2  
 130:18 164:3 165:7  
 166:6,22 175:1  
 180:10 182:7 188:9  
 192:9 193:13 195:7  
 219:4 260:9 285:4,21  
 286:21 296:3,17  
 318:3 319:16 329:17  
 330:22 332:7,8  
 341:18 343:14 345:21  
 346:16 348:6 352:17  
 360:11 361:5,20  
 365:3 373:16 374:20  
 376:5,20 377:17  
 379:19 390:20 393:3

395:19 398:1,22  
400:12  
**closely** 156:20 297:21  
322:22 345:10  
**closer** 99:10 284:2  
373:5  
**closest** 69:2  
**closet** 143:16  
**closing** 180:1 277:15  
**CMS** 33:5 38:15 39:22  
40:2 43:2 44:14 49:2  
106:16 112:3,5 129:5  
193:20 252:20 253:3  
270:11 273:9 300:9  
300:17 303:18 304:4  
304:13 305:7,15  
327:16 328:9,22  
336:4,13  
**CMS-91** 300:2  
**co-** 5:5  
**co-chair** 1:11,11 5:3,18  
7:17,18 8:2 10:15  
11:6 29:10 30:2 31:9  
31:20 38:2,21 39:13  
39:16 40:6 42:3 45:1  
47:21 48:12 49:8,14  
51:16 53:13 56:13  
59:15 62:3 63:6 67:9  
68:2,7 72:19 73:21  
74:10 75:5,13 76:7,19  
78:13 84:6,11 85:1,7  
87:12 89:20 91:21  
92:7,20 93:2 95:15,20  
97:1,12 98:4,14 99:13  
100:3 104:2,20 105:4  
105:9,12,15 106:4  
107:4,11,21 108:6  
111:11 113:16 114:5  
114:12 115:7,18  
121:7 123:13 124:8  
126:22 128:19 129:20  
130:4,12,22 131:19  
133:16 134:9,22  
135:14,19 136:19  
137:3,9 138:6,22  
139:9 140:1,18  
141:13 142:3 143:22  
144:8 145:5,14  
146:12 147:10,17  
148:3,9,14 149:15  
150:17 153:6,16,18  
154:4 155:12,20  
156:7,11,17 157:14  
158:14 159:17 160:2  
162:10 163:1,18  
164:7 165:1,11,21  
166:10,15 167:4,18  
168:9 169:8 171:9,15

171:18 173:10 174:9  
174:13,17 175:5  
176:19 177:13 178:3  
178:13 179:16 180:12  
181:1,22 183:20  
184:6,13,18 186:17  
186:21 187:5,15  
188:2,13,21 189:2,13  
191:16,17 192:2,13  
193:7,17 194:22  
195:11,13 196:1,12  
196:18 197:4,16,17  
199:7 201:7 202:21  
203:7 204:17 205:6  
207:9 208:8,20 210:2  
210:21 212:13 213:9  
214:20 215:5,10  
216:8,15,17 217:19  
219:8 220:17 221:2,3  
222:7,12,16,21 223:2  
223:3 224:18 225:12  
226:17 227:18 229:2  
229:10 230:10 231:7  
231:16 232:1 234:13  
238:2,12,18 239:6,16  
239:22 240:10 242:11  
243:1,4,6,21 244:2,16  
244:19 246:14,15  
247:13,16,17 248:1,3  
248:5,13,18 250:6  
251:17 252:6 256:4  
258:5,17,20 259:12  
260:13,17 261:22  
262:5,8 267:13  
268:11 269:4,13,17  
271:18 272:4 274:6  
276:13 277:13 278:22  
279:5,12,14,16,18  
280:16,21 284:11,16  
284:20 285:8,16  
286:3,15 287:3,9  
288:3,8,11 289:1  
290:7 291:10 292:16  
293:11 295:4,11,17  
296:7,20 297:5,14,17  
301:2,7,10 302:4,15  
303:17,21 304:1,19  
305:4,18 306:3,10  
308:17 309:4,15,21  
310:11,13 311:3,7,11  
312:15 313:2,5,16,20  
314:2,13,18,20  
315:14 317:9,17  
318:7,21 319:8,20  
321:2,8 322:6,11  
323:5,18 325:20  
327:1 328:5,15  
329:21 330:4,14

331:5,20 332:10,18  
333:9 335:7,9 337:3  
339:20 340:3,6,15  
341:10,22 342:12  
343:8,18 344:2,17  
345:15 346:3,9,20  
347:3,7 348:9,14  
351:9 352:10 353:13  
354:1,12,19 355:11  
357:5,9,20 358:20  
359:14 360:5,15,21  
361:9,14 362:2,18  
363:5,6 364:19 365:6  
365:9,11,18 367:6  
368:20 371:3,7 372:2  
372:14 373:10,20  
374:14 375:21 376:9  
376:14 377:2,11,21  
378:14 379:13 380:1  
382:5 383:1,4 384:3,4  
384:17 385:4,10  
386:1,19,20 387:7,16  
388:5 390:13 391:2  
392:19 393:7 394:18  
395:14 396:1 397:18  
398:5,17 399:4,17  
400:4,15 401:8,14  
**co-chaired** 17:22  
**co-chairs** 1:9 6:3 7:5  
8:8 10:14 19:18  
**co-PI** 15:21  
**coagulant** 350:17  
**coagulants** 354:4  
**coagulation** 348:21  
**Cochrane** 382:14  
**code** 56:15 273:4,17  
383:15,16,16 385:2  
385:18,20 388:19,20  
388:22 389:3,4,9  
**coded** 273:8 385:1  
**codes** 181:5 387:5  
388:1 389:12 393:22  
394:22 395:3,5  
**coding** 387:1 389:19  
393:20  
**coffee** 41:20 68:14  
**cohort** 265:15  
**coincide** 228:16  
**Collaborative** 2:1  
**colleague** 43:1 124:17  
**colleagues** 150:1  
**collect** 132:18 163:4  
282:12,14 304:8  
323:14 328:4  
**collected** 94:10 111:10  
126:18,20 129:8  
199:12 270:10 323:9  
327:4,17 328:6 349:7

**collectible** 328:1  
**collecting** 108:3 142:16  
270:11,12 327:15  
328:22  
**collection** 106:14 199:9  
257:18 258:7 304:10  
304:17 360:18 376:11  
**collects** 242:12  
**Colleen** 3:10 42:21  
108:7  
**College** 2:9,13 12:18  
13:14 15:12 16:20  
18:8  
**collegial** 33:15  
**color** 127:5  
**combination** 123:16  
**combine** 8:21  
**combined** 367:17  
**come** 20:3 31:14 37:5  
39:4 41:17 50:4 51:2  
67:16,17,21 72:6  
73:12 117:5 120:8,19  
120:20 143:1 184:5,9  
187:10 196:20 219:16  
221:8 225:18 227:9  
242:4 243:14 245:16  
251:12 253:11 267:8  
267:12 270:2 285:14  
312:3 326:10 337:11  
391:16  
**comes** 35:5 47:7 55:10  
55:12 58:1 59:4 79:22  
80:3 100:15 169:1  
245:14 326:15 341:5  
369:8 387:15 395:13  
**comfort** 125:14 170:8  
298:14 338:11 349:18  
366:10 381:11 393:16  
**comfortable** 101:19  
102:3 103:17  
**coming** 9:14 31:2 50:14  
71:20 75:17 97:22  
197:10 213:1 241:18  
264:16 276:8 280:20  
281:12 292:4 364:1  
380:13  
**comment** 4:10,22 56:19  
62:4 68:3 81:10 85:8  
90:20 92:8 131:21  
132:12 138:15 149:15  
150:17 156:22 157:6  
163:2 169:11,13  
191:17 199:8 214:2,3  
214:7,8,11,17 216:12  
218:20 229:12 234:14  
234:18 241:11 258:22  
263:15 271:20 286:10  
289:8 297:2 302:7

305:22 306:22 309:5  
 317:12 320:3,8  
 332:19 340:18 354:22  
 360:17 378:17 386:21  
 400:22 401:1,5  
**commented** 193:3  
**commenting** 100:4  
 138:13 152:4 218:1  
**comments** 8:1 23:14,16  
 23:19 34:7 35:20 41:3  
 49:16 67:10 85:8,18  
 90:7 98:4 99:14 104:9  
 107:5 111:12 113:16  
 131:19 134:22 163:19  
 165:1,22 166:16  
 171:3 174:17 177:14  
 179:16 181:22 188:2  
 191:16 193:4,7  
 194:22 214:9,15,19  
 216:11 222:17 224:14  
 224:19 238:18 244:1  
 247:13 256:5 259:22  
 277:15 281:14 289:3  
 292:17,22 295:18  
 297:1 305:20 328:15  
 343:9 345:16 352:11  
 352:11 357:21 360:6  
 368:17 369:4 371:3  
 374:15 375:16,21  
 376:15 377:12,21  
 378:15 379:13 383:2  
 387:17 388:18 390:14  
 392:20 394:19 395:14  
 397:19 398:18 399:18  
 401:6,13  
**commission** 3:9,11  
 4:12 41:2,9 124:13  
 126:14 132:15 138:13  
 138:18 139:6,15  
 140:15 144:7 145:9  
 154:16 158:9 161:4  
 167:12 169:11,22  
 193:20 219:13,18,20  
 226:5 227:9,16  
 235:12,19 242:14  
 245:2 246:6 247:3,11  
 265:12 270:13 273:9  
 279:10 281:14,16  
 282:7 294:19 326:5  
 327:11,18 328:11  
 333:12 334:5 335:3  
 336:13 349:1,9  
 358:22 365:20 380:6  
**Commission's** 126:15  
 145:9  
**commitment** 111:2  
**committee** 1:3,7 6:3,5  
 7:3 9:8,10,17,18 10:5

10:10,13,19 11:14,20  
 13:16 18:1,12 19:10  
 20:2,21 21:18 23:1,13  
 24:18 25:10,14 30:5  
 30:15 31:10 33:9,10  
 33:17 35:10 36:5 39:2  
 45:4 67:21 71:6 115:4  
 117:9 120:10 121:2  
 123:21 130:13 143:9  
 148:15,15,18 151:1  
 171:6 174:14 183:14  
 183:17 198:3 200:16  
 204:22 206:14 210:10  
 210:15,19 212:16,20  
 214:12 219:6 235:9  
 247:5 288:15 289:7  
 292:19 306:19 307:4  
 329:9 335:11 336:16  
 362:7 380:13 387:9  
**committees** 8:11,19  
 33:18 151:13 203:14  
 203:20 204:3 239:13  
 335:21  
**common** 240:14 274:7  
 292:10 293:16 333:21  
 387:18  
**commonly** 53:3 207:16  
 322:4  
**communicate** 363:1  
**communicated** 145:20  
**communicating** 28:21  
 183:10 199:4  
**community** 151:8,10  
**commuting** 33:1  
**comorbidities** 368:2  
**companion** 27:16,17,18  
 27:21 28:1 29:4,21  
 31:11 32:11 125:1  
 168:3 219:14 337:5  
 348:10,22 366:1  
**company** 2:3 13:19  
 33:4  
**compare** 102:8 181:7,7  
**compared** 277:3 392:6  
 395:4  
**comparing** 102:1  
**compelling** 136:6  
 333:13 371:16 378:12  
**competing** 21:22 34:16  
 114:6,11  
**complaining** 193:5  
**complaint** 293:16  
**complete** 67:4 113:8  
 117:16 121:3 235:18  
 334:3  
**completed** 66:19 67:3  
**completely** 87:20  
 160:21 161:1,1

178:20 215:20 217:1  
 237:13 245:3 263:13  
 306:18 327:5 329:8  
 358:14  
**completion** 336:3  
**complex** 116:18 123:5  
 123:6  
**compliance** 175:8,11  
 175:12 176:11,14  
 180:5 184:11 194:8  
 209:6,21 218:11  
 237:3,6 377:9  
**complicated** 71:21  
 72:14 191:20 292:5  
 293:22  
**complication** 291:2  
 381:3  
**complications** 291:5  
**component** 43:10  
**comprehensive** 126:17  
 380:9 381:19 389:16  
 399:7  
**compression** 126:8,9  
**compute** 324:22  
**computer** 252:22  
 253:15,15 297:19  
**computes** 324:22  
**conceivably** 71:22  
**conceived** 121:21  
**concern** 35:21 62:19  
 63:18 111:7 141:8  
 146:1 176:22 192:21  
 204:8 269:21 276:2  
 276:11 278:8 284:9  
 301:20 374:10 378:5  
 389:18 396:20 397:15  
**concerned** 105:9  
 110:17 255:6 279:19  
 291:6 297:8  
**concerning** 288:1  
**concerns** 39:12 107:2  
 175:14 210:14 367:16  
 373:3 375:20  
**concise** 117:21  
**concluded** 113:14  
 401:20  
**conclusion** 225:19  
**concur** 363:6  
**concussive** 292:5  
**conditions** 122:22  
 123:4 290:22  
**conducted** 131:2  
**conduit** 242:13  
**Conference** 1:8  
**confidence** 324:21  
**confident** 115:20 216:2  
 279:1  
**confirm** 267:18,19

375:14  
**confirmed** 396:18  
**conflict** 19:5,8,10,14  
**conflicts** 18:3 20:5  
**conform** 56:16  
**conforming** 131:16  
**conformity** 153:5  
**confused** 155:21  
 157:21 161:20 231:18  
**confuses** 388:9  
**confusing** 157:7 307:9  
 308:15 311:4,6  
**confusion** 184:7 335:14  
**conjecture** 321:15  
**cons** 110:9  
**conscience** 307:2  
**consciences** 261:2  
**consecutive** 356:15  
**consensus** 37:10 46:13  
 46:14 57:11 73:14  
 74:3 78:7 94:12,20  
 160:20 161:4,19  
 167:11 183:13 318:19  
 351:20  
**consequence** 212:1,5  
 212:10 288:22 289:4  
 290:17 291:7  
**consequences** 27:11  
 68:11 85:14 210:14  
 259:2 286:9 287:8  
 293:7,14 346:10  
**consider** 30:13 61:12  
 100:22 119:22 123:8  
 133:14 134:17 145:11  
 154:18 157:19 176:16  
 184:2,19,20 195:15  
 275:20 281:20 317:7  
 318:19 352:6,9  
 370:11 380:21  
**consideration** 4:3,6  
 81:8 172:20 235:10  
 275:12 335:6 380:14  
**considerations** 239:17  
**considered** 100:20  
 128:6 153:15 176:17  
 249:20 282:6 350:20  
 353:18,18 370:6  
**considering** 116:21  
 195:14 216:9 367:21  
 386:14  
**consistency** 24:14,17  
 344:15  
**consistent** 73:13  
 119:19 204:2  
**consistently** 323:19  
**consists** 381:20  
**constantly** 305:12  
**consternation** 223:6



**constitute** 138:2 153:14  
232:17  
**constitutes** 199:17  
**construct** 103:3 325:9  
326:17,18 337:17  
390:4  
**constructed** 272:18  
390:5  
**construction** 34:16  
347:22  
**constructs** 327:22  
**consult** 318:20  
**consultant** 42:22 220:4  
**consulting** 10:3  
**contacting** 369:13  
**contacts** 369:11  
**contemplate** 189:14  
**contention** 73:6,11  
**context** 101:6,12 307:8  
**continue** 6:9 117:9  
132:2,9 136:9 141:5,7  
141:11 156:15 183:16  
183:17 185:14 211:13  
211:13 330:2 336:5  
356:7 373:21  
**continued** 4:6 22:6  
134:21 198:20,21  
209:3 240:17  
**continues** 257:12  
**continuing** 2:12 151:14  
206:1  
**continuous** 151:3  
284:3  
**contraindicated** 43:18  
126:11  
**contraindication** 134:2  
275:4  
**contravenes** 251:5  
**control** 93:8,12 247:2  
340:12  
**controversial** 250:10  
251:6  
**conundrum** 235:6  
**convenience** 109:7  
**convergent** 343:3  
**conversation** 158:1  
**conversations** 199:21  
336:12  
**convexity** 384:5  
**convoluted** 92:13  
**Cooperative** 249:22  
**copy** 173:5  
**core** 12:5 129:15 356:1  
374:8 375:6  
**Cornell** 2:9 15:12  
**coronary** 233:16,17  
**correct** 31:15 39:15  
68:1 98:15 128:10

134:10 135:16 144:9  
156:3,4 174:15 181:9  
188:19 217:6 225:10  
225:11 227:12 239:19  
247:22 253:1 254:19  
267:18,19 271:1  
275:8 301:11 302:11  
302:16 307:5 313:1  
315:5 321:22 325:11  
325:17 333:10 340:2  
340:2 354:19 372:4  
401:14  
**corrected** 272:9 359:1  
397:3  
**correctly** 84:5 190:17  
239:18 242:15 259:6  
281:10 312:12  
**correctness** 323:1  
**correlated** 208:5  
396:13  
**correlations** 343:1  
396:19  
**cost** 144:22 198:20  
206:4  
**costs** 142:16  
**Cotter** 1:19 12:8,9  
131:20 134:18 147:11  
148:10 178:6 229:11  
284:18 369:6  
**counsel** 3:2 8:7  
**count** 113:6 172:17  
276:21 281:3 299:5  
**counted** 172:16 354:5  
**country** 10:22 77:12  
**counts** 60:20  
**couple** 14:8 34:12  
41:21 91:19 118:8  
189:8 236:2 237:5  
246:9 250:11 257:16  
314:5 357:2  
**course** 30:15 52:1  
68:15 91:18 185:19  
190:15 194:6 370:8  
375:19  
**Coverdell** 126:20 170:2  
349:8  
**covered** 187:18 238:17  
319:6  
**craft** 17:15  
**crash** 189:18  
**create** 23:21 110:19  
122:21 150:2 347:18  
**created** 32:5 64:15,16  
251:22 253:22 323:2  
324:12  
**creates** 58:7,8 111:1  
**credible** 28:15 183:3  
198:16 361:11

**credit** 128:17 163:6  
**criteria** 21:1 28:11 30:4  
34:2,4 36:11,18 63:16  
76:6 95:1 113:10  
115:3 116:1 119:16  
137:7 142:19 182:22  
183:2 186:5 187:11  
194:19 198:4 201:9  
207:11 210:17 211:14  
223:4 248:11,15  
251:22 274:15 275:5  
294:17 318:9 329:22  
330:2 331:13 333:3,5  
333:20 347:10,17,18  
353:6 367:15 385:15  
388:16  
**criterion** 53:17 54:5  
161:9 266:18  
**critical** 43:10 99:4  
**critically** 159:4  
**criticisms** 353:16  
**Cross** 17:5  
**crosswalked** 374:9  
**crosswalking** 395:10  
**CRRN** 1:17  
**crucial** 65:19 204:15  
**crystal** 148:4  
**CSAC** 34:8 183:14  
**CSTK-06** 4:19  
**CT** 4:3 38:11,13 42:12  
42:17,19 43:12 44:8  
45:22 49:5 58:3,11,20  
60:3,12 64:4,12,17,20  
64:22 65:3,7 67:3,5  
68:15 74:11,12,20  
75:8,11,19 76:10,15  
76:17 77:5 80:4,18  
86:11,15 91:6,16,22  
92:4 96:14 112:6  
236:22 273:6  
**CTA** 75:18 76:8  
**curious** 241:9 320:9  
353:10  
**current** 20:13 21:4  
46:11 83:16 299:20  
300:3 350:8  
**currently** 87:7 109:15  
110:12 117:12 126:13  
138:11 159:22 290:12  
300:22 303:19 356:19  
379:6 381:18 399:6  
**curve** 234:3  
**cut** 79:9 86:5 319:9  
**cutoff** 53:22  
**cycle** 66:8 210:9 228:20  
334:9

---

**D**


---

**D** 232:17  
**D.C** 1:8 16:10  
**dabigatran** 355:19  
356:6  
**damn** 294:14  
**dangerous** 57:20  
**dash** 94:2  
**data** 26:16 30:21 31:1,3  
52:15 53:3 66:20 70:9  
76:1 87:6 90:20 97:18  
99:4 100:8 101:22  
102:13 106:7,12,14  
106:17 108:18,21  
110:21 112:4,17  
117:5,16,17 118:1,4,5  
119:1 120:4,21 121:9  
121:11,16 122:7,21  
123:18,20 132:5,19  
132:19 133:3,6,22  
134:5,19 136:10  
137:16 138:1 142:16  
143:19 147:13,15,22  
148:7,12 149:2  
154:16 156:19 162:3  
163:4,8,8,13 164:15  
169:1 170:21 171:10  
172:6,11,13,13,14,19  
175:9,21 176:1,16  
177:3,5,9 178:10,14  
178:22 179:20 180:1  
180:2,4,7 187:4  
188:17 190:21 191:8  
193:20 196:16,20  
199:9,11,16 200:17  
201:21 209:2 212:18  
212:19,20 213:1,1,8  
218:3 223:9,21 224:7  
224:21 225:16,22  
226:4,6,7,22 227:4,6  
227:10 229:5 230:11  
230:12 233:12,19  
235:13,15,22 239:1  
240:20,21 241:4,10  
241:16,17,20,22  
242:13,17 243:12  
244:3,5,7,9,13,15,20  
245:1,6,12,13 246:5  
246:10 248:8,14,17  
252:5,19,20 253:5  
254:1,3,12,17,20  
255:2 256:21 257:6  
257:11,18,22 258:7  
258:13 259:9,13,16  
260:21 261:3,4,15  
262:14,16,16,18  
263:7,12 264:1  
265:18,19 266:5,21  
268:4 270:6,12,12

272:9 273:21 274:10 275:16 277:8,9 285:12 293:21 299:11 300:19,22 302:10,19 304:2,8,10,15,17,21 306:16 307:12 308:10 308:12 309:7 310:18 310:20 311:18 314:3 316:11,13 320:4 321:12 322:2,14,18 323:1,14,16,19 324:15,19 325:4,15 325:16 326:11,19 327:3,15,17 328:6,8 328:10,10,22 330:12 333:13 334:17 336:4 337:16 338:17 339:22 341:9 342:9,13,16 343:6,10,21 344:19 350:4 351:7,19 353:14,21 355:21 356:1,4,8 357:6 358:21 359:1,3,11 360:18 371:5,9,20 372:6,22 373:8 374:12 375:15 376:11 378:13 381:22 382:1 384:10 387:13 390:8 392:11 394:7 395:1,4 395:5 397:10,11 398:6,14 <b>data's</b> 371:16 <b>database</b> 258:9 268:21 372:7 <b>databases</b> 259:16 <b>date</b> 20:14 57:5 190:21 277:11,11 298:15,15 337:22 338:9 381:20 <b>dates</b> 325:17,18 <b>Dave</b> 5:5 10:15 167:9 363:5 <b>David</b> 1:9,9,11,11,12 2:4 5:16 10:20 11:6 12:14 15:14 17:6 53:13 59:16 62:3 85:9 148:2 168:13,15 169:8 171:10 173:10 175:5 179:5,18 187:11 189:11 192:13 192:18 207:13 208:22 215:8 217:20 220:20 229:1 230:10 238:20 239:6 247:15 384:3 400:16 <b>David's</b> 64:9 65:21 <b>day</b> 4:14,15 34:20 38:5 125:7,7,14,15 129:12 215:4 298:21,21	305:9 328:18 337:6 337:15,21,21,22 338:12,12,15 339:4 344:9,11,13 345:10 363:20 369:1 380:11 381:12 401:10 <b>days</b> 6:19 22:3,19 125:12,13 129:2,5 170:8 290:21 338:8 338:10 349:18 366:9 375:13 381:10 393:15 <b>de</b> 67:15 116:17 123:21 <b>Deaconess</b> 2:5 15:15 <b>deal</b> 59:22 109:6 174:11 239:12 318:10 <b>dealing</b> 29:13 76:15 <b>death</b> 205:19 368:10 <b>deaths</b> 381:6 <b>debate</b> 98:21 221:13 222:13 295:15 <b>decade</b> 284:3 <b>decay</b> 131:11 <b>December</b> 300:4 <b>decide</b> 30:15 67:22 82:14 83:20 86:10 87:3 135:3 141:8 154:9 157:11 167:14 187:9 225:17 228:12 230:5 235:20 287:13 <b>decided</b> 230:7 270:2 <b>decides</b> 30:5 212:17 <b>deciding</b> 60:15 80:21 <b>decimal</b> 164:11 <b>decision</b> 66:10,21 79:11,15 127:22 145:7,9 159:6,13 196:4 224:7 233:9 234:6 253:13 <b>decisions</b> 80:19 <b>deck</b> 220:18 <b>declare</b> 147:5 <b>declared</b> 152:8 <b>declaring</b> 146:15 149:4 205:4 <b>decline</b> 198:15 204:10 <b>declined</b> 176:4 <b>declines</b> 204:16 <b>decreased</b> 25:4 26:11 141:2 143:4 <b>decreasing</b> 289:14 <b>deeply</b> 118:13 <b>default</b> 183:14 <b>defeat</b> 54:9 <b>defer</b> 235:10,11,18 240:1 247:6,8 321:8 400:17 <b>deferral</b> 240:6,8 247:4 247:20	<b>deferred</b> 246:19 247:21 <b>deferring</b> 239:3,20 246:7,12,16 248:2 <b>define</b> 55:17 79:20 369:15 <b>defined</b> 55:9,18 56:3,5 369:14 <b>definitely</b> 141:2 194:18 199:20,22 332:11 352:3 379:7 <b>definition</b> 56:8 127:19 199:17 237:15 317:4 329:5 374:2 <b>definitional</b> 369:9,11 <b>definitions</b> 157:22 231:19 <b>definitively</b> 233:14 <b>degrading</b> 140:4 <b>degree</b> 53:9 324:21 <b>delay</b> 65:18 109:19 196:11 <b>delayed</b> 61:4 230:6 <b>delays</b> 61:5 64:11 85:22 86:2,4 <b>deliberations</b> 236:12 <b>delivered</b> 369:5 <b>delivering</b> 63:1 276:7 <b>dementia</b> 13:2 18:13 <b>demonstrate</b> 248:22 339:7 <b>demonstrated</b> 201:13 289:9,11,13 307:17 345:3 346:8 <b>demonstrates</b> 307:11 348:3 <b>demonstrating</b> 266:8 306:12 <b>denominator</b> 44:3,8 54:4 72:6 80:11 112:20 118:7 123:3 220:11 221:7 224:22 225:2 226:1,8,14 231:4,11,19 232:8 250:17 269:7,9,16,17 271:5 273:19 277:2,5 278:2,5 279:6 283:8 283:11 298:6,13 308:20,22 309:1,12 309:22 310:2 353:3 367:12 393:11,13 <b>denominators</b> 283:7 <b>department</b> 1:16 2:5,16 2:19 16:5 50:13 298:8 298:18 <b>departments</b> 107:18 387:19 <b>depend</b> 209:11 324:6 <b>dependent</b> 336:1	<b>depending</b> 60:8 130:3 167:13 266:16 269:11 <b>depends</b> 101:6 154:6,7 155:11 159:14 167:16 207:7 312:22 <b>deploy</b> 329:10 <b>deployed</b> 328:21 <b>derivation</b> 368:3 <b>describe</b> 223:17 <b>described</b> 113:13 190:5 <b>description</b> 190:14 297:22,22 315:17 385:21 <b>descriptive</b> 265:17 <b>deserves</b> 373:4 <b>design</b> 53:16 54:2 <b>designation</b> 117:3 <b>designed</b> 54:3 87:7 <b>desirable</b> 399:11 <b>desired</b> 348:1 <b>desk</b> 36:8 <b>despite</b> 329:8 <b>destructive</b> 81:1 <b>detail</b> 47:15,18 162:8 168:21 191:14 232:2 399:9 <b>detailed</b> 37:5 <b>details</b> 72:7 221:6 310:2 <b>detected</b> 172:5 <b>deteriorate</b> 142:22 <b>deterioration</b> 210:13 <b>determination</b> 248:10 334:12 <b>determine</b> 20:22 21:21 22:4 50:12 62:13 83:14 119:18 162:19 289:20 <b>determined</b> 204:11 <b>determines</b> 62:12 <b>determining</b> 33:19 <b>develop</b> 40:15 99:19 123:7 148:16 293:20 350:15 351:19 <b>developed</b> 132:16 177:6 350:19 381:17 <b>developer</b> 14:17 25:7 39:8,9,18 41:12 112:5 113:5 132:4 147:12 163:1 169:10 171:17 181:10 212:19,21 224:15 257:10 262:13 262:22 277:18 281:18 305:21 307:11 308:3 308:8 309:5 340:9 341:8 344:22 372:3 378:18 383:5 398:11 <b>developers</b> 6:4 22:13
---	---	--	--

23:4 33:16 35:4,22  
 38:15,20 39:22 41:1,5  
 41:16 42:6 102:5  
 117:16 148:16,17  
 179:12 213:5,8 228:5  
 292:3 307:19 311:16  
 311:21 332:20,22  
 335:21 336:6,13  
 363:1 370:1 395:8  
**developing** 67:15  
**development** 14:10,12  
 18:12,14 94:20  
 122:20 237:15,22  
 294:16 334:11  
**devices** 126:8,9  
**DHS** 2:15  
**diagnoses** 22:8 390:1  
**diagnosis** 43:11 259:14  
 273:16 309:22 383:14  
 383:15,16 385:2  
**diagnostic** 71:17 109:5  
**diastolic** 299:8  
**Dickerson** 1:20 13:1,2  
 45:5 48:6 49:18 52:10  
 61:10 66:6 95:19 96:1  
 97:15 98:16 106:5  
 111:20  
**dictate** 158:4  
**died** 161:1  
**differ** 266:16  
**difference** 26:8 27:6  
 77:2 121:8 133:8  
 141:18 211:15 224:8  
 244:4 245:17 246:21  
 265:7 359:5 379:11  
 389:1 392:5 397:9  
**differences** 35:21  
 112:16 312:6,14  
 371:22 372:1 397:5,6  
**different** 21:11 22:8  
 28:1 54:1 55:3 73:22  
 74:12 75:7,15,21  
 77:11 82:4 83:12  
 87:15 92:1,21 99:3  
 103:4,5 104:21  
 105:10 108:4,4  
 110:21 116:13 118:1  
 120:22 121:16 137:5  
 158:3 168:2,7 170:4  
 177:2 180:18 207:1  
 211:16 212:5,11  
 227:21 236:15 240:3  
 244:3,9 252:13 257:1  
 262:19 263:7,13  
 264:14,14 271:5  
 277:19 278:12 280:19  
 281:5,6,11,15,19  
 284:7,8 287:13

288:11,13 303:10  
 313:21 314:3,13  
 320:1 323:15 325:21  
 330:11,13 332:1,21  
 333:5 355:6 372:16  
 377:6 378:3 391:6  
**differentials** 388:10  
**differentiate** 43:13  
**differently** 284:7 352:7  
**difficult** 50:10,11 79:8  
 82:13,22 117:15  
 119:13 133:3 138:7  
 165:17 258:11 335:22  
 363:14  
**difficulty** 32:22 98:18  
**diffusion** 76:9  
**dig** 47:14 86:3  
**digital** 93:21  
**dining** 401:11  
**dinner** 335:11  
**dinner/Happy** 336:16  
**direct** 347:22 350:18  
**direction** 34:8 66:9  
**directly** 19:19 180:3  
 190:19 322:16  
**director** 1:15,18,21 2:1  
 2:3,7,10,11 3:2,3,6  
 6:1,18 14:21 17:5  
 33:4  
**directors** 13:6 23:7  
**disadvantage** 86:18  
**disagree** 211:11 303:1  
 362:19  
**disagreeing** 211:4  
**disagreement** 78:18  
 212:7  
**discharge** 56:16 169:6  
 169:15 170:5,12  
 171:1 172:6,14 176:3  
 220:10 259:14 349:14  
 349:16 350:11 353:2  
 356:11 358:19 359:15  
 367:4 370:12 387:10  
**discharged** 4:8,9 169:2  
 170:14,17,18 171:5  
 172:1,3,10 173:2  
 216:9 220:6 272:7  
 273:16 338:15 349:21  
 354:8 355:1 358:18  
 366:15,16 381:14  
 393:17 396:22 397:16  
**discharges** 350:1,2  
 366:13,14  
**discharging** 173:18  
**disclose** 10:8 11:4,22  
 12:7,22 15:7 16:17,21  
 17:2,10 20:4  
**disclosure** 9:4,16 13:17

14:15 18:10  
**disclosures** 8:9,17,21  
 9:8 11:10 12:12 13:8  
 14:3 15:10,13,16,19  
 18:19 32:19 33:6  
**discomfort** 203:14  
 204:4,6  
**discontinuation** 44:12  
**discrimination** 283:2  
**discuss** 18:18 46:6  
 48:4 68:11 127:14  
 156:16 187:10 200:6  
 248:10 280:9 287:8  
 288:20 335:1 340:14  
 351:17,21  
**discussants** 35:11,19  
 45:3 124:11 250:7  
 386:21  
**discussed** 14:18 31:19  
 45:6 98:18 106:20  
 121:1 127:7 168:18  
 193:22 228:8 288:6  
 288:14,19 301:15  
 319:1 338:5 348:17  
 371:13 380:11 395:8  
 401:2  
**discussing** 17:17 32:1  
 35:15 83:7 96:19  
 232:3 365:19 380:8  
**discussion** 33:7,14  
 34:19 35:3,5,10,13,14  
 35:17 36:20 40:13  
 44:20 45:7 48:19  
 49:17 52:21 53:11  
 55:8 56:12 68:8 78:15  
 84:5,14,21 85:2 92:15  
 97:2,16 107:3,5 113:3  
 113:17 114:6 117:21  
 118:16,19 127:10  
 144:2 156:22 160:3  
 161:2 171:8 184:15  
 185:13 186:13 214:1  
 229:22 235:19 243:13  
 245:7 256:5 257:2  
 258:18 277:14 285:16  
 286:15 287:5 288:7  
 288:10,17 289:3  
 291:9,21 295:18  
 296:8,9 297:11  
 305:19 319:8 330:3  
 330:15 331:12 336:8  
 340:18 341:10 342:15  
 343:8 344:2 345:16  
 346:9 353:22 357:21  
 360:6,21 361:14  
 364:20 365:7 369:10  
 374:4 400:18  
**discussions** 171:2,21

382:6  
**disease** 22:9,9 80:7  
 126:15 233:11,16  
 234:11 381:18  
**diseases** 80:8  
**Disorders** 1:21  
**disparities** 25:20 30:16  
 49:2 96:7 131:22  
 132:14 134:19 136:15  
 175:21,22 176:4  
 177:5,17,21 181:6  
 203:5 223:21 224:4  
 244:6 256:20,22  
 257:5,11,22 258:12  
 341:5,7 371:6,10,13  
 372:7 373:1,4 378:11  
 378:20 379:2,10  
 392:3  
**disparity** 176:16 178:2  
 180:1 256:21 284:9  
 341:9 372:11,12  
 392:7,9,10,12,14  
**display** 93:21  
**disposition** 170:13  
 172:6,15  
**disproportionately**  
 368:1  
**dissemination** 18:12  
**disservice** 58:14,17  
**distant** 148:6  
**distortion** 266:9  
**distraction** 146:17  
 147:2  
**distributed** 82:22  
**distribution** 44:17  
 53:18 130:2 266:11  
**dive** 20:11  
**Division** 2:7  
**dizziness** 55:13  
**DOACs** 350:17  
**doc** 86:9  
**doctor** 63:16,21  
**doctors** 50:19  
**document** 110:3 134:1  
 192:17 198:5 236:12  
 281:5 282:8,22  
 315:11 395:12  
**documentation** 125:6  
 128:7 133:21 162:14  
 190:10 207:16 208:3  
 252:14 274:14 275:10  
 275:21 298:17 321:1  
 383:20 384:21 385:3  
 386:11,17 390:12  
**documented** 109:16,22  
 125:14 128:5 169:6  
 170:9,22 194:16,17  
 265:2 266:3 274:14

274:16 275:4,9,13,19  
 276:8 282:13 283:13  
 298:15 315:8 338:11  
 339:2 349:19 350:5  
 353:4 366:10 381:11  
**documenting** 252:2  
 268:5  
**documents** 38:11 104:8  
 173:7,9 266:1 298:20  
 310:2  
**doing** 9:2 15:5 34:18  
 49:21 50:21 58:13,20  
 64:3 71:13 80:18  
 141:10 155:7 173:20  
 179:11 200:10 201:16  
 202:4 203:11 212:1,7  
 212:12 214:8 227:22  
 277:22 323:11  
**dollar** 72:9  
**domain** 306:6  
**door** 69:2  
**doors** 14:16  
**Dorothy** 2:1 16:3  
 168:13  
**dose** 291:1  
**double** 129:9  
**dozen** 71:21  
**Dr** 5:6,22 7:4,16 8:5  
 14:16 22:20 29:15  
 30:7 31:16 32:14,17  
 37:22 40:17 45:6,8  
 68:4 82:2 114:9 135:7  
 135:17 137:6 141:20  
 146:7 167:22 182:14  
 182:17 219:18 220:3  
 224:20 226:10 230:11  
 231:10 233:8 242:3  
 244:22 258:6 269:6  
 281:13 284:10 289:7  
 289:8 304:3 325:5  
 326:4 345:2 348:13  
 354:14,20 355:13  
 356:20 357:8,10  
 385:7,12 386:6  
**dramatic** 131:7 147:7  
 359:13  
**dramatically** 233:15  
 283:22  
**draw** 50:7  
**drill** 8:19  
**drink** 68:14  
**drip** 338:21  
**driven** 181:13  
**drives** 145:3  
**DrNP** 1:19  
**drop** 154:1 234:3  
**drops** 56:11  
**drug** 52:7 134:1 191:3,6

289:14 355:20 356:16  
**drugs** 190:20,22 351:1  
**due** 40:5 133:20 183:5  
 183:6 194:11 198:17  
 210:22 230:21 234:8  
 273:5 347:16,20  
 384:6  
**duration** 338:8  
**DVT** 355:3

## E

**e-** 31:18  
**e-companion** 249:3  
**e-Measure** 27:22  
**e-measures** 4:5  
**earlier** 97:17 120:15  
 148:1 223:6 227:7  
 228:9 248:12 249:20  
 260:19 271:16 286:10  
 345:11 352:22 358:13  
**early** 41:18 90:10  
 164:17 242:2 249:16  
 270:16 339:7  
**easier** 5:15 157:8  
 186:12 387:20 390:9  
**easily** 379:9  
**easy** 115:19 151:21  
**eCQM** 297:11,13 300:8  
 309:7 310:22 323:16  
 334:11,14 335:14  
 337:15 339:15 351:4  
 366:1  
**eCQMs** 297:8 300:14  
 300:20 334:6 351:5  
**ED** 38:15 42:20 44:1,5  
 44:11 53:19 59:20  
 60:2 86:9 265:22  
 275:19 294:1  
**edoxaban** 356:17  
**Education** 2:12  
**Edwards** 2:1 16:3,3  
 180:14  
**effect** 226:3 230:8  
**effective** 146:11 221:10  
 259:6 381:1,16  
**effectively** 250:2  
**effectiveness** 289:14  
**effort** 194:9 209:16  
 362:9  
**efforts** 44:16 145:11  
 194:7  
**EHR** 108:18 110:10  
 120:5,6 299:22 302:6  
 302:10 306:16 310:20  
 321:11 322:1,5,7,17  
 325:11 326:11 327:15  
**EHRs** 305:10 311:18  
 312:17 327:15

**eight** 172:7  
**Eighty-seven** 219:4  
**either** 12:16 36:22  
 93:15 169:5 176:18  
 209:3 237:14,18  
 239:18,19 271:3  
 282:18 291:19 311:1  
 340:16 389:1 398:7  
 401:9  
**EKGs** 80:7  
**elected** 44:12  
**elective** 125:17 170:11  
 265:20 272:11,20  
 273:9 338:14 349:20  
 366:12  
**electively** 276:20  
**electronic** 27:19 31:11  
 50:11,15,22 51:3  
 106:12,13,14 118:5  
 120:7 121:16 125:1  
 199:14 200:10 217:17  
 299:11 300:2 301:18  
 312:18 313:3,8  
 328:21 398:7  
**electronically** 117:14  
 122:9 217:14,15  
 247:18 300:19  
**element** 66:20 100:8  
 102:1,14 119:1  
 132:19 163:9,14  
 170:21 172:6 188:17  
 194:9 245:1 252:5,19  
 253:5 254:1,3,12,17  
 254:20 255:2 260:21  
 261:3,11,16,18  
 275:16 277:8 307:12  
 307:17 308:10,12  
 310:18 316:13 323:1  
 324:19 338:17 342:10  
 350:4 355:22 356:4,8  
 374:12 384:10 390:8  
 394:7  
**elements** 61:4 66:13  
 99:4 106:17 118:2  
 121:17 201:10 261:4  
 261:6 265:19 277:9  
 285:12 299:11 309:7  
 310:21 322:2,17,18  
 324:15 337:16 395:6  
 397:12  
**elevations** 225:7  
**eligible** 32:12 135:8  
 185:6 225:8 226:15  
 249:17 250:18 309:1  
 309:11,13  
**Elisa** 3:3 6:22 138:9  
 160:21 161:10 243:13  
 318:15

**else's** 68:21  
**email** 41:5,16 242:5  
**eMeasure** 168:3,5,12  
 168:19,21,22 184:2,4  
 184:10,16,21 185:2  
 185:11,13,14,16,20  
 186:8,12,19 195:14  
 199:10,11 200:2,18  
 201:2,5 206:3 217:11  
 219:14 248:2 296:22  
 297:1,20 301:1,14,16  
 301:21 305:16 313:18  
 313:18 314:16 320:2  
 320:3 325:6 330:11  
 335:18 348:11,22  
 380:3  
**eMeasures** 21:12 27:4  
 28:2,3 29:17 30:1  
 116:1,6,13 117:11  
 124:7 302:21 313:11  
 313:12,14 363:12  
**emergency** 2:5 13:10  
 13:11,14 43:10 46:22  
 49:7 50:12 51:2 57:15  
 58:2 63:8 64:18 65:2  
 79:2,6 91:6,13 298:7  
 298:18 387:19  
**emerging** 199:15  
**emeritus** 372:20  
**emphasis** 25:4,21  
 26:12 27:12  
**emphasize** 35:20 89:21  
 245:11 334:4  
**empirical** 46:18 52:12  
 263:7 342:19  
**empirically** 396:4  
**employer** 10:11  
**EMS** 90:16  
**encompasses** 139:12  
**encourage** 154:17  
**encouraging** 179:12  
**endarterectomies**  
 273:15  
**endarterectomy** 272:21  
 273:3,10,13  
**endorse** 67:6 113:2  
 121:15 141:7,8,11  
 145:6 203:21 216:1  
**endorsed** 20:14,19  
 29:19 32:6,10 45:11  
 56:21 71:6 117:12,20  
 121:14 122:2 125:19  
 126:13 135:10 141:3  
 141:17,21 142:7,8  
 147:6 169:20 202:12  
 204:22 209:4 213:4  
 215:15 220:7 224:12  
 334:7,14,14,16 339:5

348:16 349:5  
**endorsement** 28:5,13  
 28:19 34:5 36:11  
 114:21 115:3 116:22  
 117:2,6 119:11 121:4  
 124:3 152:15 157:5  
 183:1,8,15,16 198:7,9  
 198:10,20 199:1  
 202:18 204:10 210:8  
 210:9,16,17 217:5  
 220:12 240:17 246:8  
 246:19 247:10 250:14  
 263:6 270:11 287:5  
 296:12,15,19 318:18  
 331:7,8 332:4,17  
 334:10,17 340:10  
 346:21 347:13,15  
 352:4 379:14 380:13  
 400:7,9,14  
**endorsements** 114:14  
 153:4  
**endorsing** 64:14  
 203:18 215:14  
**endovascular** 75:14,22  
**ends** 54:11 109:18  
 138:2 145:20  
**enforced** 152:16  
**engagement** 191:15  
**engagements** 10:4  
**enlarging** 190:21  
**enrolled** 125:16 129:16  
 170:9 338:13 349:19  
 366:11 381:13 393:17  
**enrollees** 130:2  
**enrollment** 129:1,4  
**ensure** 152:22 198:14  
**enter** 201:22  
**entered** 109:20,21  
 325:16 326:11,19  
 387:21  
**entire** 119:16 268:21  
**entitled** 401:20  
**entry** 50:21 66:10  
**enumerator** 283:10  
**envelope** 151:15  
**enzymes** 80:7  
**epidemiologist** 18:7  
**epidemiology** 2:16  
 18:10  
**epilepsy** 1:14 17:12,15  
**equal** 178:12 298:9  
 299:17 315:6  
**equally** 201:16  
**Equity** 2:1  
**equivalent** 315:2  
**ER** 63:16,17 64:2,7  
 91:12  
**err** 205:19,22

**erroneous** 397:17  
**error** 172:13 271:4  
 278:7,14 279:2,11,22  
 280:1,13 284:21  
 315:2 358:21  
**ERs** 293:17  
**especially** 28:17 105:14  
 116:21 131:22 270:19  
**espoused** 155:17  
**essence** 139:4  
**essential** 44:1  
**essentially** 46:1 121:17  
 175:12 191:10 264:2  
**establish** 24:19  
**established** 83:19 91:3  
 209:7 249:15 297:6  
 329:3,12 351:16  
**estimate** 242:8 366:21  
**estimated** 398:11  
**et** 64:4 89:6 142:16  
 187:17 257:2  
**etcetera** 251:3,4 325:19  
**ethnic** 132:1 147:13  
 178:9,11 257:1 283:4  
**ethnicity** 132:18 133:12  
 258:8  
**European** 249:22 251:7  
 251:16 255:7,20,21  
**evaluate** 25:14 116:4  
 226:20 227:11 229:7  
 229:9 245:3  
**evaluated** 16:2 88:20  
**evaluating** 22:18 34:2  
 111:21 117:10 183:18  
 275:5 333:20  
**evaluation** 21:1 25:10  
 35:20 60:14 62:11  
 68:12 116:9 154:22  
 232:12 329:8 333:22  
 351:13  
**evaluations** 64:4  
**event** 369:1  
**events** 54:11 55:1  
 233:17  
**eventually** 179:9  
**everybody** 6:2 7:20 8:3  
 32:3 54:13 69:15  
 71:10 115:14 116:5  
 168:1,9 216:12 225:5  
 233:20 259:5 261:2  
 278:20 283:18 290:9  
 334:21 391:16 400:19  
**everyone's** 105:18  
**evidence** 24:3,13,22  
 25:5,7,9,11,13,15  
 26:21,22 36:14 45:13  
 45:15,22 46:3,4,8,10  
 46:14 47:4 48:18,19

48:22 49:2,15,17,19  
 50:4,6 52:12 53:9  
 57:7 65:6 68:6 69:19  
 70:1,12,15,21 71:1,3  
 71:11,13 72:21 73:19  
 73:19 75:16 81:16  
 83:15 85:13,15 87:22  
 88:1,4,8,16,17 89:8,9  
 89:14,15 95:7,14 98:2  
 119:4,20,22 126:3  
 127:7,11,12,14  
 130:15,21 138:3  
 139:3 140:7 146:14  
 147:1,12 153:11  
 158:17,19,21,22  
 159:2 173:16,20  
 174:7,11,18,20 175:4  
 175:7,21 179:22  
 180:11 187:20 193:22  
 197:11 210:12,12  
 220:22 221:4,12  
 222:5,14,20 225:3,14  
 231:18,20 232:10,14  
 232:17,20 233:1  
 234:5,7,17,20 235:3  
 236:6 249:15 250:12  
 250:20,22 251:4,10  
 251:21 255:6,7,17,18  
 256:1,2,5,6 260:4  
 287:19 291:19 292:11  
 297:4 301:5,19  
 321:10 322:6 339:4  
 339:11 340:9,10,11  
 341:6 347:22 348:12  
 350:13 351:12,14,22  
 368:4,6,15,21 378:8  
 382:9,9,21 390:15,17  
 391:1  
**evidence-based** 44:17  
**evidentiary** 255:12  
**evolve** 199:18  
**exact** 230:12 257:16  
 272:16  
**exactly** 72:6 94:21  
 107:15,16 151:17  
 197:18 359:5  
**examining** 63:20  
**example** 102:17 208:4  
 211:18 254:8 263:1  
 264:17 268:3 275:18  
 277:4 356:2 357:11  
**examples** 224:5  
**excellent** 88:4 178:1  
 328:20  
**exception** 275:15  
**exceptions** 26:15 72:7  
 298:13  
**exclude** 128:9 129:19

172:9 207:17 252:9  
 253:7,21 254:7  
 324:16 338:18 350:5  
**excluded** 44:13 125:9  
 128:2 171:22 172:4  
 174:4 254:10 255:2  
 266:15 268:4 269:12  
 294:22 338:6 349:15  
 349:17 355:4 356:12  
 358:19 381:8 382:17  
 384:7 388:2  
**excludes** 170:6  
**excluding** 278:9 298:14  
 315:3  
**exclusion** 83:1 113:10  
 127:21 128:16 129:12  
 129:13,22 170:21  
 172:1,21 173:3  
 233:22 251:22 252:9  
 253:5,10 254:18  
 255:22 262:17 265:18  
 265:20 266:19 268:3  
 271:7,8,11 272:21  
 274:4,15 275:3 276:9  
 281:10 283:13,20  
 311:17 339:1 343:6  
 353:6 355:14 367:15  
 369:18,22 370:2  
 385:15,19 388:15  
**exclusionary** 387:21  
**exclusions** 128:21  
 129:3 163:17 164:16  
 170:3,13 225:1  
 250:19 263:4 265:13  
 266:8,10,12 267:21  
 271:21,22 272:19  
 273:12,20 274:1  
 276:15 277:20 280:18  
 280:22 284:6 309:17  
 310:6 312:4,13 325:8  
 338:1 366:6 387:10  
 393:13,19  
**Excuse** 61:10 169:11  
 248:6  
**executive** 10:17  
**exemplar** 146:15  
**exist** 181:6  
**existed** 180:9  
**existence** 51:4 207:7  
 327:14  
**existing** 29:18  
**expand** 232:8  
**expanded** 226:14  
 237:20 369:12  
**expanding** 140:6  
**expansion** 226:11  
 374:1  
**expect** 33:12,20 34:10

213:7 324:22  
**expectation** 177:11  
 370:8  
**expectations** 332:21  
 333:1,2,7  
**expected** 177:6 364:3  
**expecting** 51:19  
**experiences** 33:13  
**experimental** 88:10  
**expert** 191:10 232:17  
**experts** 19:1 46:15  
 143:12 233:9  
**expire** 179:9  
**expired** 44:11 170:16  
 350:1 366:15  
**explain** 93:3 127:22  
**explained** 304:12  
**explanation** 386:16  
**exponential** 289:13  
**extend** 251:8  
**extended** 129:10  
 254:17  
**extending** 253:6 266:3  
**extensively** 162:2 272:1  
**extent** 34:3 58:21 101:5  
 106:6 111:22 180:8  
 194:4 209:12 253:20  
 353:11 388:15  
**external** 67:16 399:8  
**extra** 64:16  
**extract** 106:18 323:15  
**extracted** 102:9 108:14  
 110:10 398:16  
**extraction** 102:7 106:16  
**extractors** 144:21  
**extrapolating** 324:5  
**extremely** 176:13  
 177:19  
**eye** 63:8 215:22  
**eyed** 401:16

## F

**FAANP** 1:19  
**face** 162:3 165:14  
 275:10 341:3  
**FACEP** 2:5  
**faces** 7:13  
**facilities** 96:12,17  
 106:15 108:10 112:16  
 113:5  
**facility** 112:10 170:18  
 350:3 366:17 369:17  
**fact** 11:4 21:3 39:7  
 51:18 61:8 70:3 71:8  
 112:14 137:15 141:1  
 142:21 149:18 162:4  
 180:15 191:4 199:10  
 216:2 221:9 227:14

238:13 283:9 287:20  
 288:18 292:9 300:13  
 306:13 327:5 356:4  
 362:10  
**factor** 326:7 333:19  
**facts** 295:1  
**faculty** 12:3,10 16:15  
 16:19  
**FAHA** 1:17  
**fail** 187:3,4 331:6,13,17  
 331:19  
**failed** 28:8,10 182:21  
 347:1,3,5 362:4  
**failing** 355:7  
**fails** 29:3 32:8 36:22  
 168:11,12 352:20  
 355:12 373:19  
**failure** 56:5 215:11  
**fair** 40:7 114:19 217:19  
 239:21 246:9 324:21  
**fairly** 82:21 239:9  
**fairness** 246:4,6 334:21  
**faith** 335:4,5  
**fall** 217:2 233:7 367:10  
**falls** 326:21  
**false** 290:13  
**false/positive** 289:6  
**familiar** 7:8 206:9,10  
 272:16 322:21 370:1  
 390:6  
**family** 310:9  
**fantastic** 56:22,22  
**far** 11:10 52:11 64:6  
 86:16 158:16 214:12  
 215:16 223:21 255:6  
 293:21 297:3,7 382:9  
**fashion** 57:10 65:12  
 73:7 83:4  
**fast** 54:6,19 69:2 72:10  
 73:1 221:17 245:1  
**faster** 70:6,12 93:4  
**favor** 71:13 247:19  
 250:20 251:11 290:9  
**favorite** 154:6  
**FDA** 43:20 51:20 52:14  
 53:2 78:5 191:4,5  
 251:3 350:19 356:19  
**feasibility** 26:20 27:2,3  
 27:5 37:2,3 44:18  
 83:7,9,10 84:1 89:6  
 106:4,5 107:1,2,12  
 108:3 111:8,14,19  
 119:3 120:1 124:1  
 165:11,14,19 166:2,9  
 192:13,16 193:10,16  
 285:8,13,17,18 286:2  
 300:10,12 319:20  
 320:4,8,10,13,15,20

320:22 321:5,7,10,19  
 322:8,14 323:3 325:2  
 325:6 326:2 327:7,9  
 329:3,5,11,14,20  
 330:1 331:17 336:3  
 343:18,19 344:1  
 345:17,19 346:2  
 360:15,17,20,22  
 361:2,8 376:9,10,17  
 377:1 398:5,20 399:3  
**feasible** 27:3 106:18  
 107:10 193:6 320:7  
 323:4,11 326:18  
 328:1,3  
**February** 304:14  
**federal** 117:13 121:13  
 121:19 302:17 313:9  
**feedback** 190:3,4 323:2  
 345:8 389:13  
**feeding** 109:18  
**feel** 21:3 58:2 69:15  
 101:18 102:3 103:14  
 103:16 135:22 136:5  
 140:11 142:13 149:21  
 203:18 208:11 211:2  
 215:16 232:13 251:13  
 262:1 279:1 281:1,1,6  
 287:12 335:2 379:8  
**feeling** 200:16 204:3  
 229:7 245:4  
**feelings** 331:22  
**feels** 71:10 138:5 352:7  
**fell** 60:22 317:17  
**fellow** 19:9  
**felt** 31:11,13 189:9  
 282:11 345:12  
**female** 96:11 177:3  
**Ferziger** 2:3 32:18,21  
 83:5 84:9,13 85:5  
 107:7,15 108:1 109:1  
 110:16 155:14 177:16  
 181:2 205:7 206:22  
 237:12 238:4,15  
 245:10 280:17 281:9  
 284:5 293:12 294:15  
 306:5 321:3 328:17  
 363:17  
**fewer** 37:16,16 96:13  
**fibrillation** 349:4,13  
 350:9 355:2 357:18  
**Fibrillation/Flutter** 4:17  
**field** 108:16 110:13  
 117:5,15 119:12  
 120:11 142:15,18  
 178:10 204:4 237:16  
 239:15 281:15 314:2  
 326:11,17  
**fields** 325:17

**figure** 7:18 61:5 72:5  
 209:19 273:22  
**figured** 72:9  
**figuring** 60:21  
**filled** 320:10  
**filtered** 274:3  
**final** 159:12,16 237:6  
**finally** 37:10 346:4  
**financial** 15:10  
**find** 77:1 86:4 87:9  
 110:6 162:17 220:19  
 292:8 379:2 384:15  
**finding** 350:8  
**findings** 56:3,4 112:9  
 140:10  
**fine** 32:9 222:21 253:18  
 262:3 278:16 303:4,5  
 330:10  
**finished** 219:9  
**first** 9:9 23:2 36:18 38:1  
 38:7 41:9 42:5 47:17  
 48:7 49:14 51:12  
 54:15 58:8,8 60:10  
 81:14,22 87:18 93:4  
 115:8,9 118:12  
 155:21 157:9 158:11  
 169:10 174:11 205:15  
 207:11 219:21 221:5  
 229:18,22 233:5  
 236:3 240:5 241:4,20  
 242:9 281:14 290:15  
 300:4 304:14 306:13  
 309:9 317:10 318:20  
 337:13 338:5 345:4,7  
 355:19 369:17 380:7  
 380:12 384:21 385:5  
 385:9 391:7,10,11  
 396:4 401:10  
**fit** 53:16 271:2,3  
**fits** 72:16 201:14  
**five** 64:20 73:16 94:1  
 115:12 201:17 204:19  
 317:15 337:14 370:16  
**fixed** 359:7  
**flavor** 202:13  
**flip** 136:14  
**floating** 65:1  
**floor** 1:8 45:3  
**flow** 104:3 325:9  
**flutter** 349:5,13 353:4  
**fly** 69:9  
**focus** 77:17 146:22  
 173:1 189:22 238:1  
**focused** 46:11 118:17  
**focusing** 48:18 77:20  
 81:11 198:22 350:7  
 383:11  
**fold** 148:8

**folks** 100:12 103:5  
135:22 240:7  
**follow** 59:6 148:9 198:2  
208:21 211:7 275:1  
**follow-** 207:10  
**follow-up** 145:16 246:2  
**followed** 129:18 335:5  
**following** 38:9 39:11  
43:22 44:6 47:3,19  
150:2 201:17 229:18  
266:20 299:1 381:3  
**forever** 202:5  
**Forget** 255:12  
**forgive** 47:16  
**form** 9:4 126:7 128:6  
138:14 221:15 264:7  
265:10,11 266:6  
270:7 354:17 355:16  
**formalities** 5:10  
**format** 300:3  
**formats** 325:17  
**former** 17:4  
**forth** 14:13 364:6  
**Forty-five** 73:12  
**Forum** 1:1,8 116:7  
333:14  
**Forums** 291:20  
**forward** 6:18 29:7 33:14  
44:20 92:16 99:22  
148:12 152:3 153:15  
177:10 186:11 187:6  
206:20 217:11 304:20  
333:12 334:8 336:7  
**found** 103:17 169:17  
172:12 322:4 342:22  
381:1  
**Foundation** 1:18 2:14  
11:19  
**four** 48:3 49:11 53:4  
78:11 93:15,17,17  
226:2 230:16 233:4  
241:19 249:6 250:2  
251:9,15 252:1,11  
253:9 254:4 255:4,10  
268:17 305:11 317:14  
331:13 365:4 374:21  
379:20  
**fourth** 205:18 241:6,9  
304:13  
**frame** 57:18 58:5 67:6  
75:8 249:18 250:5  
254:4 255:4 309:16  
**framework** 72:17  
**frankly** 160:17  
**free** 287:12  
**frequency** 164:15  
230:18 266:10  
**frequently** 50:15

283:20 291:1  
**fresh** 197:14  
**Friday** 173:8  
**front** 69:2 138:21 143:7  
158:8 159:7,8,22  
161:5 171:10 173:5  
240:20 245:2 260:20  
279:22 280:1 313:13  
**Frontotemporal** 1:21  
**fronts** 58:7  
**full** 14:15 38:3 48:2  
124:3 156:21 362:21  
**fully** 216:1 224:12  
237:6 244:20 334:18  
348:16  
**function** 101:8,10 234:4  
**functional** 39:1 102:21  
321:22 368:12  
**functions** 201:2  
**fundamental** 271:13  
**fundamentally** 255:17  
**funny** 302:13  
**further** 46:7 55:16  
122:8 192:2 266:21  
275:21 296:8 336:12  
352:5,10 378:14  
387:8,16 390:13  
**future** 147:2 148:6,13  
159:1 200:6,20  
207:22 217:4 290:11  
351:18 373:6 399:7

## G

**gap** 22:6 25:17,22 28:8  
28:8 29:4,20 31:13  
32:8 47:13 70:8,9  
71:9 96:4,21 97:5,11  
119:5 130:22 131:1  
133:15,17 134:4  
135:1,8 139:17 140:7  
140:9 141:1,6 143:3  
147:1,12 150:8,10  
153:10,11 157:10,12  
157:15 158:6,11  
160:6 175:5 177:14  
177:17,21 179:3,17  
179:20,22 180:9,13  
180:15,17 181:3  
182:1,4,16 183:3  
186:1 187:3,4 195:16  
197:11 207:2 223:4,7  
223:8 224:12,22  
225:9,18 226:20,22  
229:7,9 235:2 236:8  
239:20 240:1,16  
241:1 243:2 245:15  
245:20,22 248:22  
256:8,10,17 257:8,21

258:1,3,15,18 260:6  
260:12 268:1 270:18  
271:9 301:6 340:17  
340:18 341:4,15,21  
347:2,4,6,17 352:1,5  
352:14,20 354:15  
357:4 362:4,13,16  
369:2 370:13,22  
371:18 373:11,13,19  
379:4,4 380:4 391:2  
392:17,22 393:6  
**gaps** 36:15 95:17 117:4  
131:22 133:11 143:21  
148:7 182:10 199:1  
224:10 240:15 341:11  
341:13 352:11  
**gather** 199:15 227:6  
259:9  
**gender** 258:8 283:4  
**genders** 123:4  
**general** 1:21 3:2 8:7  
13:3 15:18 34:9 173:7  
173:9 281:13 287:4  
353:19  
**generally** 101:22  
121:20 122:7 202:11  
266:12 398:15  
**generated** 50:16,17  
285:12  
**generating** 212:18  
**generic** 224:3  
**genuine** 144:17 276:10  
**Georgetown** 16:10  
**Georgia** 1:12 2:16  
12:18,18 17:6 18:7  
336:17 401:11  
**germane** 176:22 291:8  
**Germany** 64:5  
**gerontology** 12:9  
**gestalt** 30:5 154:10  
240:4  
**getting** 30:22 47:18  
54:14 82:20 91:6  
107:19 110:20 111:20  
116:9 119:11 133:4  
191:8,14 194:13  
206:13 211:2 217:22  
222:2 257:11 290:20  
354:3 362:5  
**gist** 280:13  
**give** 19:2 22:16 24:10  
37:4 40:16 41:12 48:2  
52:6 62:14 72:1,11  
74:12 77:17 78:3  
79:19 94:7 100:5  
123:4 124:19 128:17  
165:20 167:13,17  
188:1 191:22 192:14

194:20 213:8 216:14  
218:7 219:21 224:15  
227:9 230:11,12  
235:3 237:7 242:8  
243:19 281:4,20  
284:18 290:21 324:9  
**given** 9:10 53:2,19  
64:16 69:10 70:4  
84:18 99:11 125:7  
159:8 164:13 175:14  
175:19 190:16 196:17  
224:5 248:20 257:10  
265:18 305:1 306:7,8  
344:20 345:4,7 387:1  
387:5 391:22 393:22  
**gives** 65:6,9 73:22  
247:10  
**giving** 62:17 69:4 71:20  
163:6 231:14 261:19  
273:14 281:3 291:4  
291:18 293:7 312:2  
**glad** 122:18  
**global** 372:1  
**globally** 336:14  
**glowing** 8:12  
**go** 7:20 8:19,20 10:6  
11:10 19:19 20:6  
22:21 24:7,17 29:14  
32:8,14 33:9 38:21  
40:17 41:19 42:8  
55:20 57:13 59:1  
67:12 75:9 81:13  
87:17 90:16 91:15  
93:4 98:5 99:22 102:8  
104:11 110:5 113:17  
116:2,11 118:9,13  
119:6 120:14 121:2  
122:8 123:15 128:14  
130:6 135:11 136:1  
136:16 137:10 141:22  
142:2 143:11 145:18  
146:8 152:9 153:17  
154:12,21 155:7  
156:1,22 157:3,4  
159:18 161:8 162:5,8  
163:7,10 167:5  
168:20 169:9 171:11  
177:8 185:17,22  
186:4,7,17 187:6  
188:4 197:14 203:20  
206:20 210:21 214:22  
219:16 222:11 223:21  
228:14 230:8 232:3  
243:14,16 248:14  
249:2 259:22 260:2  
262:10 277:14 279:13  
279:16 284:11 285:17  
286:15 291:11 292:20

293:2 295:18,19  
 296:8 297:1 305:5,19  
 306:3 314:22 315:14  
 317:12,19 318:8  
 319:11 322:12 323:5  
 326:4 328:16 330:17  
 331:7 337:4 340:18  
 342:1 344:2 345:16  
 346:11 352:12 354:13  
 357:18,22 360:6,22  
 361:15 363:2 364:20  
 369:2 373:22 375:2  
 375:11 383:4 386:21  
 398:9  
**goal** 46:15 54:10 96:9  
 176:2 385:13  
**goals** 33:21  
**god** 63:1  
**goes** 31:18 34:22 38:5  
 136:17 137:10 142:5  
 143:15 154:13 167:15  
 184:4 186:3 197:19  
 199:13 209:20,21  
 212:16,22 283:11  
 289:15 291:13 344:8  
 362:13 382:9  
**going** 5:3,8,9 11:15  
 14:19 24:1 26:19 27:2  
 29:13 31:7,21,22 33:8  
 38:7 41:8 42:4 55:5  
 55:16 56:4 60:8 61:18  
 61:19 62:13,15 64:3  
 67:13 73:3 74:15  
 75:14 81:6 82:15,16  
 82:17,18,21 83:2,3  
 86:17 87:2,13 92:16  
 93:2 94:13 107:18  
 110:7 114:7,9,10  
 115:21,21 116:3,4,12  
 118:15 119:15 122:12  
 124:9,12,16 130:6  
 131:5 146:3 148:3  
 149:6 150:2,9,21  
 151:10,11,11 153:14  
 155:18 159:2 167:8  
 168:15 171:11 177:10  
 185:19 186:2,10  
 187:3 192:19 196:17  
 197:21 200:4,9,12,15  
 200:19,21 209:10  
 211:19 213:9,10  
 214:22 215:7,22  
 216:21 217:11,13  
 218:7 220:20,21,22  
 228:18 234:17 240:14  
 240:22 241:11,19  
 242:17 247:9 248:10  
 249:1 250:7 257:15

259:15 276:9 278:8  
 278:11 281:3 283:9  
 283:10 291:12 292:12  
 295:6,8 296:21 302:1  
 303:11 308:16 314:8  
 316:15 321:17 327:10  
 334:12 335:11 336:7  
 337:4 340:4,8 342:2  
 354:21 359:18,19  
 360:2 365:16,18  
 373:22 375:2 378:4  
 380:8 400:5,15,16,17  
 400:20  
**gold** 83:21 98:20 99:12  
**good** 5:22 6:13,16,20  
 6:22 12:8,13 14:20  
 32:2,16 45:5 50:2,6  
 53:10 77:15,16 79:19  
 79:21 87:22 88:1,3,8  
 88:15,15,17 89:8,9,14  
 89:15 93:6 101:19  
 103:16,22 114:18,18  
 115:8 119:12 127:13  
 130:1 134:20 138:17  
 142:12 143:18 147:18  
 171:19 173:20 182:1  
 187:20 192:1 199:11  
 202:8 215:8 223:19  
 245:13 256:16 261:4  
 274:17 275:6 276:7,8  
 319:3 325:1 335:4,5  
 348:17 362:5 370:18  
 375:4 382:15 392:2  
 397:8  
**gosh** 294:10  
**gotten** 6:7,8 86:15  
 144:14 207:20 370:18  
**grade** 81:6 306:21  
 382:12  
**grant** 12:4 329:8  
**granting** 182:22  
**grants** 10:2 13:5,15  
**granular** 51:14 53:7  
 282:19 299:11  
**granularity** 53:9 344:8  
**grapple** 239:11  
**gray** 318:6,7,11,19  
 331:3,4,6,12,16,18,18  
**great** 8:5 46:17 72:21  
 109:6 115:8 166:15  
 166:15 181:15 215:19  
 216:19 220:17 250:6  
 296:7,20 329:10  
 340:6 346:3,20 348:9  
 351:9,10  
**greater** 37:12 89:21  
 98:18 125:13 170:8  
 211:8 225:2 230:17

232:7 265:22 271:10  
 299:5,6,7,8,9 315:6  
 338:10 349:18 366:9  
 375:13 381:10 393:15  
**greatest** 77:18  
**greatly** 289:17  
**green** 104:7  
**grey** 160:16  
**gross** 51:22  
**ground** 34:12,21  
 215:21  
**Groundhog** 369:1  
**group** 3:10,11 6:7 14:6  
 16:10 18:14 38:16  
 40:9 42:22 43:3 79:20  
 91:9,20 132:13,21  
 175:18 178:18 211:13  
 224:15 231:3 233:5,7  
 253:4 267:14 271:7  
 273:22 278:9 279:19  
 280:14 288:19,20  
 294:8 301:15 306:14  
 307:21 367:22 369:14  
 375:12 388:3 389:22  
**groups** 126:2 176:6,8  
 176:17 189:22 233:4  
 257:1 283:3,4 284:7  
**growing** 74:17  
**growth** 370:15  
**guaranteed** 187:3  
**guess** 11:10 38:7,9  
 48:1 49:10,20 62:21  
 68:9 69:3 76:12 78:20  
 84:6 86:8 105:14  
 114:14 116:11 134:13  
 145:15 157:20 159:21  
 185:1,2 186:6 194:12  
 200:21 209:19 216:20  
 219:17 226:17 227:7  
 229:2,7 230:3 238:4  
 241:12 248:18 256:6  
 264:19 274:9 276:14  
 288:6 289:2 301:4  
 307:5 310:3 321:15  
 325:20 326:2,22  
 327:1,6 337:6 343:2  
 348:19  
**guessing** 134:7 224:6  
**guests** 401:1  
**guidance** 23:9 24:16  
 99:18 112:21 198:4  
 205:8,8 211:2 212:10  
 305:1 315:21 316:3,6  
 324:7 334:20 335:4  
 390:8  
**guidebook** 198:3  
**guideline** 18:12 45:16  
 46:4,9 69:13 73:21

90:11 220:15 221:8  
 229:12,14 232:18,19  
 233:1,18 242:6  
 251:11 382:10  
**guidelines** 17:15 37:11  
 45:14,19 49:20 57:11  
 67:18,21 73:15 90:10  
 116:2 194:8,14  
 209:15 225:4 229:20  
 230:15 232:7,11  
 233:4 234:15 242:12  
 242:15 243:3,19  
 247:1,6,12 249:22  
 252:15 258:7,10  
 268:16 281:18,21  
 317:14 368:7 390:7  
**gunshot** 60:21  
**guy's** 60:12  
**guys** 38:10 41:4 42:7  
 47:19 95:17 99:19  
 115:12 153:12 157:11  
 171:9 201:8 211:3  
 219:20 223:10 229:5  
 262:19 265:5 296:22  
 302:7 318:14 333:10  
 334:1 337:7 348:17

---

**H**


---

**Hackney** 2:4 15:14,14  
 53:14 59:17 85:17  
 168:16 171:13,16  
 173:12 174:12,16  
 175:6 179:6,19  
 180:20 181:11 184:3  
 184:8,14 185:1,18  
 187:2,13,16 189:17  
 191:21 192:14 193:18  
 195:12,21 196:2,8,10  
 196:16,19 197:2,6  
 200:7 203:5 209:11  
 217:8  
**half** 11:20 53:4 63:20  
 89:4 195:22 250:3  
 251:9,15 252:1,11  
 253:9 254:4 255:4,10  
 268:17 278:6,9  
**Hammersmith** 3:2 8:6,7  
 8:16 18:4,16  
**hand** 5:8 218:14 336:21  
**handful** 181:16  
**handle** 318:16  
**handled** 190:19  
**handling** 216:13  
**hands** 240:8 247:16,17  
**hang** 63:10  
**happen** 30:6 37:18  
 74:22 158:2,5 196:7,8  
 244:8 376:13



**happened** 228:16,19  
 235:14 335:17  
**happening** 68:17  
 101:21 178:19 203:19  
 228:17 336:2  
**happens** 56:7 114:8  
 135:5 144:10 150:22  
 184:3 191:2 202:17  
 209:2,6 237:11 327:2  
**happy** 337:9  
**Harbor** 11:8,11  
**hard** 151:14 205:10  
 207:18 208:6 248:20  
 273:20 289:4 324:3  
**hardest** 162:19  
**harm** 113:12 289:10,18  
**harmed** 293:8  
**harmonized** 322:19  
**Harvard** 2:4,19 13:3  
**hat** 281:17  
**hate** 167:5  
**hats** 281:15  
**Haven** 17:1  
**head** 4:3 38:11,13  
 42:12,16,18 43:12  
 45:22 49:5 86:11  
 96:14 112:6  
**headache** 80:3  
**header** 223:11  
**heading** 185:3  
**health** 2:1,2,6,10 3:5  
 10:18 16:14 18:9  
 81:15,17,18 90:12  
 106:13 298:11 299:3  
 301:18  
**healthcare** 170:18  
 350:3 366:17  
**hear** 9:22 10:21 34:19  
 133:2 148:20 155:15  
 169:10 191:12,13  
 289:1 337:9  
**heard** 45:9 139:11  
 154:15 158:9 240:6  
 250:12,22 333:11  
**hearing** 83:8 84:14  
 157:12 158:8 186:8  
 200:1 202:15 336:10  
**heart** 9:19 90:12 225:4  
 229:20 281:17 382:10  
**heavy** 49:22  
**hello** 13:9,10 16:18  
**helm** 250:8  
**help** 5:21 35:15 43:15  
 77:15,20 100:16  
 189:10 237:9 261:16  
 277:16  
**helpful** 5:13 189:4  
 208:1 274:5 336:8

367:9  
**helping** 209:8  
**helps** 24:19 85:22 87:8  
**hemiparesis** 55:11  
**hemorrhage** 58:21 59:5  
 59:6 282:12 380:16  
 381:4 382:13 383:6  
 383:10,17 384:5  
 385:14,19 386:3  
 387:3,19 388:17,20  
 393:12 394:1 396:10  
 396:11  
**hemorrhages** 383:7  
 389:20  
**hemorrhagic** 38:13  
 42:18 43:14,19 44:4  
 46:2 62:12,18 125:4  
 366:3 367:11,14  
 388:1,4 396:6  
**hey** 314:12  
**Hi** 7:12 8:6 13:1 16:13  
 18:6 116:5 124:14  
 132:11  
**hierarchy** 146:4  
**high** 28:16,17,22 30:14  
 37:14 47:5 48:9 91:14  
 93:18 94:22 95:9,12  
 96:21 97:6,9 98:8,11  
 104:14,17 105:21  
 106:1 111:14,17  
 113:14,20 114:1  
 125:21 130:8,15,19  
 134:15 151:2 153:5  
 160:7,11 163:22  
 164:4 165:4,8,20  
 166:3,7,14,19 167:1  
 171:3,21 172:17  
 174:14,20 175:2,9  
 176:7 177:19 178:7  
 182:5,8 183:5,11  
 184:12 188:1,7,10  
 189:9,10 191:22  
 192:7,10,15 193:11  
 193:14 194:20 195:5  
 195:8 198:11,17,21  
 206:17 221:19 222:2  
 222:10,12 230:22  
 231:1,4,12 233:6,14  
 237:3 250:4 259:18  
 260:7,10 261:7  
 270:15 282:12 284:14  
 285:5,19,22 286:19  
 286:22 296:1,4 318:1  
 318:4 319:14,17  
 329:15,18 330:20  
 331:1 339:5 340:11  
 341:16,19 342:8,22  
 343:7,12,15 345:19

345:22 346:14,17  
 347:20 348:2 352:15  
 352:18 358:3,7 360:9  
 360:12 361:3,6,18,21  
 366:22 373:14,17  
 374:18,21 375:7,8  
 376:3,6,18,21 377:4,8  
 377:10,15,18 382:20  
 387:13 390:18,21  
 391:14 393:1,4  
 394:10,13 395:17,20  
 396:19,21 397:21  
 398:2,20 399:1,21  
 400:1  
**high-leverage** 199:5  
**higher** 56:5 100:21  
 118:22 176:5 177:11  
 221:19 236:18 388:11  
**highest** 126:1 139:19  
 188:18 261:1  
**highlight** 22:17 217:20  
**highly** 28:14 164:22  
 183:3 191:11 198:15  
 323:4 396:6,13  
**highs** 189:7  
**himiplegia** 79:22  
**HIQR** 300:18 339:19  
 351:5  
**Hispanic** 96:9 180:6  
**Hispanics** 392:6  
**historical** 209:1,2  
**history** 292:8 350:8  
**hit** 64:7 79:8,18 87:16  
 96:11 146:19  
**hits** 64:2 91:6 326:1  
**hitting** 103:14,15  
**hoc** 228:18  
**hold** 41:12,16 167:17  
 276:9 280:14 303:11  
**home** 170:17 171:5  
 172:1,3,8,10 173:2,6  
 272:8 350:1,2 359:3  
 366:15  
**honestly** 84:7 134:6  
 141:18 216:21 284:20  
 307:1  
**hook** 54:13 79:3 86:20  
**hope** 94:17 151:7 175:9  
 208:7 290:10 363:21  
**hopefully** 69:21 117:7  
 151:9 198:5 250:10  
**hoping** 52:5  
**HOQR** 112:3  
**hospice** 170:17,19  
 171:5 172:2,4,8,10  
 173:2 272:8 350:2,3  
 358:18 359:4 366:16  
 366:17 375:14

**hospital** 1:22 2:8 4:14  
 4:15 11:5 13:3 14:2  
 15:1 43:5 61:5 68:16  
 69:6 125:7,15 126:14  
 126:18 128:4 129:8  
 129:10 130:3 131:5  
 169:6,22 170:15  
 205:4 220:9 243:3  
 249:10,12 259:13  
 266:16 270:16 276:3  
 293:19 294:20 298:3  
 298:4 299:16,22  
 300:15 328:2 337:6  
 337:15,21 338:15,20  
 338:21 339:4 340:21  
 344:9,11 345:10  
 349:6,14,22 358:19  
 359:15 366:5,13  
 367:4,5 369:19 370:4  
 380:19 381:12,15  
 393:18  
**hospitalized** 126:2  
**hospitals** 77:12 107:22  
 131:9,10,14,15  
 133:10,11,13 139:13  
 139:14,19,20 140:3  
 140:14 141:10 150:11  
 165:16 189:22 242:6  
 242:22 252:14 265:17  
 266:12 270:9,12,15  
 270:17,20 272:2  
 276:4 280:19 283:1  
 283:20 287:17 300:5  
 300:7,14 304:7  
 322:21 342:22 345:12  
 372:10,13 375:7  
 377:8 379:5 381:20  
 390:6 394:14 396:16  
**hot** 136:10  
**hour** 38:3 57:14 63:20  
 70:14 74:8,8,17,18,21  
 75:3 76:14 89:4  
 249:18 250:5,21  
 251:1,15 252:1 253:9  
 255:9,10 320:6  
 336:16  
**hours** 43:21 44:6 51:20  
 51:21 52:4,6,14,16,22  
 53:4 69:18 70:4 78:9  
 78:11 82:21 88:9,11  
 88:14,16,20 89:14  
 102:19 149:19 152:12  
 249:10,12 250:3,16  
 250:17 251:9 252:11  
 252:17 253:11 254:5  
 254:9 255:4,20  
 265:22 268:19 269:10  
 269:18 272:11 298:3

298:5,8 299:16 310:4  
310:5 338:20 339:13  
344:12,13 345:4  
380:18 381:14 384:21  
385:5,9 387:11  
393:11,18 397:1,16  
**Huff** 2:5 13:9,9,11 39:2  
45:6,8 48:14,21 49:21  
52:20 54:21 78:17  
92:9,22 258:22 290:9  
324:2 344:4 387:18  
**huge** 203:1 208:15,15  
276:18 330:8  
**human** 152:11 326:7  
333:19  
**humans** 252:21  
**hunch** 148:20 189:13  
**hundred** 233:21 278:2  
**Huntington** 22:9  
**hurt** 82:15  
**hybrid** 21:17 116:18  
118:2 123:16 124:5  
313:20,22 314:16  
**hydro** 236:20  
**hypothesis** 375:7 396:4  
396:16  
**hypothesize** 178:14  
226:12

## I

**I's** 375:12  
**i.e** 374:5  
**IA** 298:16 338:18  
**ICD** 383:14 385:2  
389:12  
**ICD-10** 395:3,11  
**ICD-9** 56:15 273:1,3  
385:18,20 395:10  
**ICDE** 394:22  
**idea** 45:19 46:20 47:6,8  
48:1 78:3 142:10,12  
212:5 329:10  
**ideal** 91:7  
**ideally** 91:17 100:10  
120:8  
**identical** 180:21  
**identification** 44:1  
**identifications** 96:7  
**identified** 81:19 99:7  
112:17 151:12 190:12  
233:3 246:1 275:17  
372:9  
**identify** 43:15 61:15  
77:15,16,20 85:22  
91:13 118:4,6 122:7  
123:1,18 362:16  
386:17 388:21 389:2  
**identifying** 14:7 68:19

69:1 77:14 99:12  
204:15  
**III** 250:1  
**image** 88:17  
**imaged** 290:14,14  
**images** 46:20  
**imagine** 68:16 207:19  
242:22 245:18 248:2  
293:5  
**imaging** 43:9,22 45:20  
51:13 54:12 76:4 89:9  
89:15  
**immediate** 71:19  
**immediately** 57:22 58:4  
58:6 97:3 186:20  
348:10,12  
**immobilized** 127:15,17  
**impact** 27:11 84:22  
86:6 234:7 272:20  
357:6  
**impacts** 81:16 294:4  
**imperative** 360:1  
**imperfect** 218:17  
**implement** 26:6  
**implementation** 27:7  
336:9 345:5 382:1  
392:1  
**implemented** 43:5  
91:18 112:5 117:15  
152:14 165:15 304:6  
321:13 322:7 334:18  
381:16 391:10,18  
**implementers** 323:3  
**implication** 89:11,13  
**implications** 134:3  
144:4 217:21 218:8  
218:15 239:4 394:8  
**implies** 384:18  
**importance** 25:16 29:3  
36:12 62:6 119:5  
208:7 212:7 347:16  
**important** 14:3 23:11  
28:6 29:6,12 34:13,19  
46:15 62:14 66:15,16  
66:17,20 71:3 83:20  
90:22 101:13 119:2  
132:7 141:14 142:18  
149:9,13 150:7  
151:15 152:12 201:12  
204:5 211:10,10,11  
211:17 221:10 224:21  
235:1 238:11 259:17  
295:1 352:2 364:11  
364:13 380:20  
**impossible** 224:2 226:6  
**improve** 47:8,10 61:13  
83:21 90:2 112:21  
139:16 143:20 194:8

249:19 323:3 336:14  
354:2  
**improved** 57:10 176:13  
176:15 368:12 377:7  
**improvement** 1:14  
25:19 26:1 47:6,14  
48:8 49:1,3,16 77:1  
82:11 96:6,22 112:2  
131:18 141:6 143:13  
146:6,18 147:7 150:8  
151:4 158:18,20  
174:7 175:7,14  
176:10,12,18 177:1  
183:7 185:10,12  
194:1,4,11,15,16  
198:19 201:13,16,18  
202:3,14,19 203:1  
204:9 209:13 216:5  
256:16 346:7 347:21  
348:4 352:5  
**improvements** 144:17  
205:22  
**improving** 77:21  
112:13 287:17  
**in-** 249:14  
**in-patient** 294:20  
**inaccuracy** 55:5  
**inactive** 28:12,19 183:1  
183:8 198:9 210:7,16  
**inappropriate** 169:7  
191:3 283:16 386:4  
**incentive** 283:18  
299:22  
**incentives** 110:22  
**incidence** 178:8  
**include** 124:16 125:10  
128:11 164:15 178:11  
214:9 225:5 233:2  
251:20 299:4 324:17  
338:6 369:12 381:8  
388:8  
**included** 21:9 22:1 31:4  
60:17 101:11 137:19  
163:4,12 175:10  
265:15 312:5 315:10  
321:1 323:8 379:1  
381:7 388:3  
**includes** 44:7 45:14  
60:5 309:1  
**including** 26:10,15 27:4  
90:8 106:6 354:2  
**inclusion** 21:6 252:5  
276:16 351:1  
**inclusions** 325:8  
**inconclusive** 197:8  
**inconsistent** 203:22  
**inconsistently** 327:4  
**incorporated** 152:16

153:3  
**incorporating** 361:12  
**incorporation** 198:17  
**incorporations** 183:5  
**incorrect** 31:15  
**incorrectly** 172:15  
268:10  
**increase** 131:7 284:4  
**increased** 25:21 27:12  
112:7 178:8 226:13  
270:17 287:18  
**increases** 292:1 391:17  
**increasing** 291:22  
**independent** 57:12  
152:15  
**independently** 152:17  
**indicate** 52:12 391:20  
**indicates** 176:5  
**indicating** 34:3 266:13  
300:10 343:2  
**indication** 357:15,17  
**individual** 10:10 133:9  
372:10  
**individuals** 18:22 259:1  
259:2 367:13 374:2  
**industry** 17:7  
**infarct** 273:7  
**infarction** 273:2  
**infeasible** 165:17  
**influenced** 149:12  
**informatics** 297:12  
**information** 3:5 9:5  
20:10 26:5 39:8,10  
40:14,14 48:2 55:15  
60:19 61:21 66:22  
68:22 83:17 87:2 96:3  
106:20 108:20,22  
109:20 110:14 120:6  
123:22 133:5 136:1,5  
138:18,20 143:18  
149:14 157:11,18  
158:8,10 159:10,12  
159:15 173:7 206:2  
207:4 217:3 227:15  
229:8 232:8 243:9  
259:5 262:2 297:10  
306:1 308:4 311:16  
311:22 312:5,13  
321:6 323:9 324:10  
337:10 342:6,19  
343:4 385:2 387:11  
392:4 395:10  
**inhibitor** 355:21  
**initial** 5:10 96:7 265:15  
315:9 341:12 383:13  
388:4  
**initially** 354:4 356:6  
387:11

<b>initiated</b> 249:11 298:4 299:16	376:22 377:15,19 390:19,22 393:1,5 395:18,21 397:22 398:3,21 399:2,21 400:3	<b>intravenously</b> 290:22	353:6 358:18 359:16 359:18 363:21 364:5 364:14 371:1,13 373:4 385:7,12 397:3 399:15 400:17
<b>initiating</b> 254:20 261:13 265:2 266:2 268:5 278:4 298:19	<b>insurance</b> 17:7 295:13	<b>introduce</b> 5:7 7:10,20 32:19 38:17 39:19 42:8 124:17 249:4 337:7	<b>issues</b> 27:7 54:22 62:6 64:11 80:10 84:15,18 85:6 111:1 116:1 153:8,9 183:22 190:5 190:8 214:11 219:15 224:14 278:17 285:14 294:2 318:20 337:9 337:11 360:16,19 361:10,13 364:2 369:9,11 374:8 378:11 401:2
<b>initiation</b> 253:6 266:4	<b>insure</b> 237:2	<b>introducing</b> 35:8 220:3	<b>it'll</b> 118:16
<b>innovative</b> 117:3	<b>intended</b> 184:10 383:8	<b>introduction</b> 20:8 22:17 127:9	<b>item</b> 202:6
<b>Inpatient</b> 14:22 170:1	<b>intensity</b> 230:22 231:1 231:12 233:14	<b>introductions</b> 8:22	<b>items</b> 9:16
<b>INR</b> 299:6	<b>intensive</b> 231:4	<b>introductory</b> 116:12	<b>iterative</b> 327:20
<b>Inside</b> 35:13	<b>intent</b> 50:1,1 53:10 89:12 137:21 311:12	<b>invented</b> 9:19	<b>IV</b> 253:6,8 265:2 266:2 266:4 268:5 278:4 298:16,20 338:18
<b>insight</b> 137:15	<b>inter-</b> 394:8	<b>invite</b> 337:7	<b>IV-</b> 252:2,17 254:9,20 261:19
<b>institute</b> 1:14 10:18 60:20 83:1	<b>inter-hospital</b> 371:21	<b>inviting</b> 35:5	<b>IV-thrombolytic</b> 261:13
<b>institution</b> 56:7 83:22	<b>inter-related</b> 261:5	<b>involve</b> 398:8	<b>IV-tPA</b> 59:2 249:11 250:16 252:16 254:17 299:15
<b>institutional</b> 236:20 368:11	<b>interaction</b> 33:15	<b>involved</b> 14:9 84:18 146:17 326:8 395:12	<b>ivory</b> 80:14,15
<b>institutionalization</b> 378:10	<b>interactions</b> 14:14	<b>involving</b> 150:11	<b>IVTPA</b> 58:12
<b>institutions</b> 73:9 84:19 85:11 107:9 108:5 110:19 111:3 144:4 144:21 181:5,7	<b>intercerebral</b> 396:10	<b>ion</b> 333:2	
<b>instructing</b> 252:14	<b>interest</b> 8:9,17 9:4,9 19:5 31:12 32:20 76:2 164:18 353:7,19 368:22 375:12	<b>ischemic</b> 4:4 38:12 42:13,17 43:13,17 44:2,4,4 45:18,21 46:2 49:4,6 55:18 56:1,2 58:3 62:2,12 65:12,12 90:11 125:4 169:4,19 220:8,13 221:11 233:2 249:9 249:17 259:10,14 268:18 269:7,9 272:12,22 294:6 298:2,6 299:15 310:1 310:3,4 337:19 340:13 349:12 353:1 353:3 366:3 367:11 367:13 394:22	<b>J</b>
<b>instructions</b> 387:1	<b>interested</b> 9:15 10:2 132:14 164:18 240:6 240:7 306:7	<b>Isijola</b> 3:2 6:16,17 7:6 8:13 20:1 38:19 39:6 39:15,21 40:4,8,12,22 41:7 48:17 49:13 227:13 229:16	<b>J</b> 12:1 128:20 130:10 145:15 157:20 212:14
<b>instructive</b> 322:20	<b>interesting</b> 31:10 71:15 113:4 132:6 140:2 200:18 235:6 259:8 259:13 290:18	<b>Islanders</b> 392:9	<b>JAMES</b> 1:17
<b>instrument</b> 15:6	<b>intermittent</b> 126:8	<b>isolate</b> 194:10	<b>Jane</b> 2:15 12:1 128:19 145:14 149:1 212:13
<b>insufficiency</b> 329:9	<b>International</b> 2:11 16:14	<b>Israel</b> 2:4 15:15	<b>January</b> 381:17
<b>insufficient</b> 93:19 95:10 95:13 97:6,10 98:8,12 104:15,18 105:22 106:3 111:15,18 113:20 114:2 130:16 130:20 135:15,18,20 136:1,22,22 137:1,18 154:1,13 155:6,22,22 156:8,15 157:4,16 158:1,22,22 160:7,12 160:16 163:22 164:5 165:5,9 166:3,8,19 167:2 174:21 175:3 182:5,9 188:7,11 192:7,11 193:11,15 195:5,9 197:7 227:8 229:8 240:2 241:5 260:8,11 284:15 285:6,20 286:1,20 287:1 296:1,5 306:15 308:1,5,16 311:15 315:18 318:1,5 319:15,18 321:5 329:7,15,19 330:20 331:2 341:16,20 343:13,16 345:20 346:1,14,18 352:15 352:19 358:3,8 360:10,13 361:3,7,18 361:22 373:14,18 374:19,22 376:3,7,19	<b>interpret</b> 65:5,7 66:2 69:3 86:15 159:11 160:13 271:22	<b>issue</b> 30:17 50:9 53:5 53:14 55:7 56:17 58:7 58:8 64:13 65:20 107:9 132:12 134:11 144:17 147:14 174:6 178:13 180:18 183:21 184:2 190:8 192:15 193:1 198:19 199:8 204:20 206:4 215:9 217:10 226:19 245:8 251:7 255:7 256:1 262:7 269:6 271:13 280:6 286:11,14 288:7,21 301:13 302:5 320:1 328:18 340:20 341:5 347:21	<b>Jersey</b> 10:18
	<b>interpretation</b> 38:14 42:19 51:13 55:22 57:21 58:5,10 59:10 60:6 64:12,17 65:18 66:19 72:3 74:11,12 74:20 75:8,11 76:15 91:22 92:4,4,5 110:4 137:21 161:11 211:6 266:7 282:3		<b>Jim</b> 15:8 67:10 69:7 92:11 133:17 162:11 207:9 274:12 394:19
	<b>interpretations</b> 57:2		<b>job</b> 67:22 83:13 328:20 329:2
	<b>interpreted</b> 44:9 46:21 53:21 54:8 59:19,21 77:8		<b>Jocelyn</b> 1:13 17:11 139:9 188:13 340:4
	<b>interpreting</b> 55:5 68:15 69:5 77:6 80:17 99:20 100:17 101:14 212:2 215:16		<b>Johnson</b> 3:3 7:8,12 30:19 32:4 41:4,14 100:5 135:21 137:1,4 138:7 142:8 154:3,6 156:4,10,14,18 158:7 159:5 160:13 161:21 167:7 185:4 188:19 189:3 196:6,9,22 197:3,20 199:20 201:1 202:7 203:8
	<b>interrupt</b> 174:9 195:21		
	<b>interrupting</b> 169:12		
	<b>intervention</b> 125:18 170:12 272:11 338:14 349:21 366:13		

206:8 210:3 213:3  
 222:3,8 228:1 235:5  
 240:4 241:8 243:8,18  
 246:17 302:12,16  
 307:7 311:20 312:20  
 313:4,7,22 314:4,7,10  
 314:15,19 316:1,6,10  
 316:17,21 317:2  
 318:15 320:9,14,17  
 321:17 330:1  
**join** 336:17,19 363:17  
**joined** 42:22 131:10,15  
 140:3  
**joining** 95:4 401:11  
**joint** 3:9,11 4:12 41:1,9  
 124:13 126:14,15  
 132:15 138:12,18  
 139:6,15 140:14  
 144:6 145:8,9 150:11  
 154:16 158:9 161:4  
 167:12 169:10,21  
 193:20 219:13,18,19  
 226:4 227:9,16  
 235:11,12,19 242:14  
 245:2 246:6 247:3,10  
 265:12 270:13 273:8  
 279:10 281:14,16  
 282:7 294:19 326:5  
 327:11,18 328:10  
 333:12 334:5 335:3  
 336:13 348:22 349:9  
 358:22 365:20 380:5  
**Jones** 2:7 13:20,20,21  
 14:1 80:13 85:10  
 149:17 159:19 208:9  
 244:11,18 245:5  
 287:7,14 288:16  
 291:12 293:18 295:8  
 315:1,7,12 322:13  
 362:7  
**journal** 287:22  
**judge** 227:5 329:1,3  
**judgements** 208:1  
**judging** 251:18 276:7  
 333:5,8  
**judgment** 207:14  
 274:16 275:9,14  
 289:22  
**jump** 39:6 337:4 382:8  
**jumps** 270:20  
**June** 229:19  
**justification** 52:9  
 183:16  
**justified** 290:6

---

**K**

---

**K** 18:6  
**Kaiser** 1:18 14:21

**Kaplitt** 2:8 15:11,11  
 69:8 87:20 201:8  
 210:22 250:9 251:19  
 253:18 254:6,22  
 255:5 256:9 258:14  
 260:15,18 262:3,6,11  
 262:21 263:19 264:8  
 264:11 267:1,15  
 268:22 269:16,19  
 270:22 277:17 279:4  
 280:3 285:10 286:5  
 293:3 301:4,8,12  
 302:22 305:6 319:1  
 319:21 330:7  
**kappa** 99:4  
**Karen** 3:3,9 7:7,10,12  
 30:8,18 100:3 124:17  
 124:18 136:19 138:6  
 143:17 169:13 203:7  
 210:2 212:15 224:19  
 243:7 246:15 297:20  
 311:14 314:6 337:12  
 351:3 354:21 371:19  
 385:17  
**keep** 19:4 31:16 81:5  
 95:21 116:20 118:16  
 118:19 134:13 151:3  
 152:2 179:14 186:2  
 194:2 206:6 208:18  
 215:22 224:12 328:18  
 362:21 364:1,16,16  
 365:16  
**keeping** 12:21 31:10  
 181:19 184:1 363:9  
**keeps** 117:21 190:20  
**Kelly** 2:16 18:4,7 95:4  
**Kentucky** 2:13 16:19  
**kept** 135:10 305:11  
**Ketan** 1:15 16:22 56:19  
 63:14 68:10 72:19  
 75:6 87:13 90:4  
 140:18 142:4 148:21  
 152:5 208:20 351:10  
 388:6  
**key** 74:19 226:14  
**keypad** 214:18  
**kick** 325:10  
**kids** 33:1  
**kind** 21:11 51:22 54:9  
 75:20 89:10,17 101:6  
 102:15 110:11 118:3  
 140:11 142:21 154:10  
 158:1 167:15,16  
 189:5 199:21 201:6  
 201:19 203:22 228:19  
 235:5,11 257:5  
 280:22 287:11 302:19  
 391:6

**kinds** 228:10 280:19  
 281:11 374:5  
**Kinesiology** 16:5  
**knew** 167:8 205:13  
**knock** 135:15 137:2  
**knocks** 136:21  
**knots** 236:4  
**know** 5:19 6:6,8 8:19  
 9:14 12:16 23:8 24:14  
 25:11 30:9 31:22  
 33:12 35:18 37:9 43:8  
 47:1 50:14 52:2,3,18  
 52:18 53:8 55:21 56:8  
 56:20 61:7 62:20 64:9  
 65:13 68:16,18 69:2  
 69:10,22 70:5 71:5,7  
 71:17 72:16,20 73:2  
 77:3,10,13 78:20 80:4  
 83:2,9,19 84:2,2 87:5  
 88:4,9,11 89:7,10,12  
 90:16 91:11 92:17  
 93:8 98:19 100:20  
 101:16,18 103:14  
 105:11 109:3,5,9,10  
 111:1,2,3,4,8 113:1  
 120:2 128:22 131:21  
 133:1,19 134:8,12,14  
 136:10,18 141:13,17  
 142:10,13,15 144:13  
 144:21 145:1 146:6  
 146:20 147:19 148:22  
 152:7,8 153:7,7,11  
 156:18 168:1,14  
 171:6 177:18,19  
 179:2,7,8 181:8,17  
 184:16 185:21 186:2  
 190:16 191:2 192:22  
 194:10 196:12 201:14  
 202:1,7,11 203:2,4  
 204:3 206:4,11,12  
 207:5,5,6,14,15,20,22  
 208:1,6,7 209:14,18  
 210:1 211:8,12,21  
 212:1 216:19,20  
 218:10 221:13,14  
 223:15 224:8 225:8  
 225:18 230:2 232:5,6  
 233:19 234:1 235:2  
 236:10,22 237:19,22  
 238:19 239:4 240:5  
 240:12,13,20 241:3  
 241:17 242:3,16,19  
 243:2,12 245:13,14  
 245:15,17 248:18  
 250:15 251:2,13  
 255:16 256:1,10,13  
 257:1,2,3,8,9 258:8  
 258:15 259:19 261:5

264:3 265:8 267:3,16  
 267:21,22 268:14  
 271:15 274:5 275:12  
 276:21 277:19 278:12  
 278:13 280:12,15  
 284:21 286:7,7,11,12  
 287:16 290:3 293:8  
 293:16 297:3 301:16  
 301:21,22 303:1,2,7,8  
 303:16 305:10 306:10  
 306:20 312:10 316:21  
 317:3,3 319:3,21,22  
 324:4 325:2,7 327:11  
 327:12,14,16,18,19  
 327:20 328:13,19  
 329:5,6 331:12,21  
 333:9,15,19,20 334:1  
 334:12 336:6 340:4  
 340:14 342:10 344:17  
 344:22 352:1,4  
 353:16 354:2,20  
 356:3 363:19 364:2,4  
 364:10,14 365:15  
 367:20 370:14,18  
 378:18 379:7 386:8  
 392:15 395:11 396:14  
 397:11,17 398:10  
 399:13  
**knowing** 86:1 143:12  
 290:2 291:22 334:17  
 399:13  
**knowledge** 237:21  
**Knowlton** 1:9,11 5:3,5  
 10:15,15 29:10 31:9  
 31:20 104:20 105:4,9  
 105:15 115:18 123:13  
 124:8 126:22 128:19  
 129:20 130:4,12,22  
 131:19 133:16 134:22  
 135:14,19 136:19  
 137:3,9 138:6 139:9  
 140:1,18 142:3  
 143:22 144:8 145:14  
 146:12 147:10,17  
 148:9,14 149:15  
 150:17 153:6,16  
 155:12,20 156:7,11  
 156:17 157:14 158:14  
 159:17 160:2 162:10  
 163:1,18 164:7 165:1  
 165:11,21 166:10,15  
 167:4,18 168:9 169:8  
 173:10 174:9,13,17  
 175:5 176:19 177:13  
 178:3,13 179:16  
 180:12 181:1,22  
 183:20 184:6,13,18  
 186:17,21 187:5,15

188:2,13 189:2,13 191:16 192:2,13 193:7,17 194:22 195:11,13 196:1,12 196:18 197:4,16 201:7 203:7 204:17 205:6 207:9 208:8,20 210:2,21 212:13 213:9 214:20 215:5 216:8,15 217:19 221:2 222:16 223:2 224:18 229:10 230:10 238:18 239:6,16 243:1,6,21 244:2 246:14 247:13,17 248:3 260:13,17 261:22 262:5,8 279:14,18 363:6 365:9,18 367:6 368:20 371:3,7 372:2 372:14 373:10,20 374:14 375:21 376:9 376:14 377:2,11,21 378:14 379:13 380:1 382:5 383:1,4 384:3 386:20 387:7,16 388:5 390:13 391:2 392:19 393:7 394:18 395:14 396:1 397:18 398:5,17 399:4,17 400:4,15 401:8,14 <b>known</b> 69:18 199:1 249:10,12 250:17 261:9 265:21,21 277:12 298:3,10,12 298:12 299:2,19 309:2,3,19,20 310:13 310:19 <b>knows</b> 14:18 250:11 <b>Koenig</b> 2:10 17:3,3 63:15 90:6 308:18 309:9,18 310:7,12,15 313:19 369:16 383:3 383:5 387:9 <b>Kolbusz</b> 3:9 124:17,20 128:1,17 129:4 163:3 169:14 171:19 220:2 225:11,20 229:14,17 232:19 249:6 252:8 254:3,19 255:1 263:15 264:5,9 265:9 270:5 274:22 275:8 277:1 294:19 297:3,6 337:13 349:2 355:18 365:21 370:3 372:4 380:7 383:8 384:9,19 386:9 387:22 388:19 389:6,8,13	<b>L</b> <b>label</b> 51:21 <b>labeled</b> 357:17 <b>labeling</b> 78:5 <b>lack</b> 311:18 347:16 <b>lacking</b> 134:19 <b>lag</b> 226:2 <b>land</b> 154:8 156:5 159:7 <b>landed</b> 155:5 222:4 331:3,4 <b>landing</b> 318:5 <b>lands</b> 156:15 157:4 <b>large</b> 70:10 71:9 76:5 135:22 225:6 277:1 293:19 350:12 366:19 <b>larger</b> 231:3 <b>largest</b> 382:16 389:22 <b>late</b> 32:22 205:3 261:20 310:10 <b>Laughter</b> 161:13 <b>lay</b> 103:6 333:20 <b>LDL</b> 225:2,5,7 230:17 230:18 234:1,2 <b>lead</b> 5:9 8:8 35:11,18 64:11 124:18 220:20 293:17 322:4 382:7 <b>leading</b> 205:19 289:5 <b>leads</b> 60:19 195:20 204:10 <b>leaning</b> 34:17 216:22 <b>learn</b> 5:12 236:10 <b>learned</b> 327:21 328:7 <b>learning</b> 11:1 <b>leave</b> 18:21 84:22 238:14 261:2 388:12 388:15 <b>leaves</b> 156:2 245:15 <b>Lecturer</b> 1:19 <b>led</b> 172:17 <b>Lee</b> 3:10 218:1 219:18 220:3 224:19 238:22 355:19 <b>left</b> 35:7 44:11 51:8 79:13,14,14 80:9 170:15 241:1 349:22 366:14 <b>legacies</b> 122:9 <b>legacy</b> 21:13 27:18 29:3 29:16 116:16 117:11 117:19 118:9,13,14 118:20 121:8,12,22 124:6 302:13,21 303:10,15 312:19 313:3,9,14,18 322:9 335:17 <b>legitimate</b> 301:20 <b>legitimately</b> 254:10 <b>length</b> 125:11,12 170:7	338:10 349:17 366:8 367:21 375:13 381:10 393:15 <b>lesions</b> 294:6 <b>lesser</b> 126:5 <b>let's</b> 31:11 52:6 58:11 59:1 65:8 74:14,22 95:21 104:11 105:17 111:12 113:17 118:10 123:15 143:2,2 151:5 166:16 167:7 174:10 174:10 177:9,19 187:6,8,11 203:20,21 206:2 213:3,18,20,22 213:22 214:2 240:4,5 243:16,21 245:12 257:20 258:20 262:8 279:13 284:11 285:17 295:19 311:13 317:19 319:11 330:17 331:7 332:13 342:3 345:16 346:11 348:9 352:12 357:22 359:3 360:6 360:22 361:15 373:11 373:20 374:15 375:22 376:15 392:20 395:15 397:19 398:18 399:18 <b>level</b> 26:16 28:16,17 31:1 45:21 46:7 50:4 68:1 69:6 100:8,12 102:13 103:2 126:3 147:9 163:8 186:14 188:17,18 193:21 206:14 222:5,10 232:20,22 236:18 260:21,22 261:3 271:11 276:3 279:1 333:21 339:11 372:8 374:12,12 377:9 382:12,21 394:7 396:3 <b>levels</b> 81:5 108:16 110:12 183:5 198:12 198:17,22 371:11 <b>leverage</b> 29:1 183:12 <b>Lewin</b> 3:10,11 38:16 40:8 43:3 44:14 <b>license</b> 69:4 <b>licensing</b> 259:1 <b>lie</b> 86:6 <b>lies</b> 174:6 <b>lieu</b> 320:15 <b>life</b> 17:4 336:9 <b>lifting</b> 49:22 <b>light</b> 65:5 <b>lightning</b> 245:1 <b>likelihood</b> 91:14 237:17 382:15 388:11	<b>likes</b> 22:10 <b>Likewise</b> 50:19 <b>limb</b> 326:4 <b>limit</b> 57:1 60:5 62:16 65:22 66:1 69:20 102:19 390:10 <b>limitations</b> 85:18 <b>limited</b> 149:20 152:11 208:16 216:4 290:20 <b>limits</b> 60:6 80:22 <b>line</b> 18:5 38:20 50:8 74:12 202:6 223:11 272:17 312:15,17 334:13 359:11 400:21 401:3,7 <b>linear</b> 284:4 <b>lines</b> 2:10 16:13,13 57:6 67:18 214:7 <b>link</b> 24:20 282:10 <b>linkage</b> 275:11,22 386:13 <b>lipid</b> 234:16 <b>Lisa</b> 2:10 16:13 304:12 <b>list</b> 112:12 143:2 145:13 145:17,19 146:1,10 153:22 190:22 276:10 276:15 281:7,20 282:1,16 339:22 351:1 <b>listed</b> 164:17 276:19 <b>listen</b> 148:18 <b>listening</b> 81:20 148:17 239:2 315:16 <b>listing</b> 20:17 <b>lists</b> 228:10 <b>literally</b> 60:11 <b>literature</b> 127:16 224:5 287:16 289:10 341:7 378:12,21 <b>little</b> 5:15 6:8 8:22 25:1 27:15 38:6 47:15 49:9 55:20 82:8 84:12 93:3 93:7,21 95:21 115:10 116:18 117:21 118:10 118:13 122:15 157:21 168:20 175:13 176:9 176:13 185:9,11 186:13 189:7,18 190:15 197:22 198:12 206:16,18 207:1 210:4 213:12 214:4 221:7,15 222:13 226:19 227:19 231:17 232:9,11 244:3 248:7 252:7 261:8,12,17 271:21 274:2 299:10 307:1,7 310:20 311:5 312:10 323:14 324:9
--	---	--	--

338:3 350:11 352:7  
369:10 394:16  
**live** 154:5  
**lives** 208:16  
**living** 33:1  
**loading** 172:13 363:10  
**location** 108:21  
**logic** 106:7 123:6 184:9  
208:14 252:21,22  
253:1,15 272:18  
310:21 321:11,21,21  
324:22 325:3  
**logistical** 71:21  
**logistics** 72:8  
**long** 52:18 63:5 72:1  
86:9,14,22 87:6 238:6  
238:8 304:16 327:14  
331:11 344:6 378:8  
**long-** 371:16  
**longer** 28:22 58:15  
79:10 87:18 142:6  
144:5 183:11 199:5  
210:17 212:21 215:15  
227:2 237:2 255:9  
295:15 367:21 382:18  
**look** 6:9 22:11 23:22  
24:13 31:1 44:20  
58:20 66:5 69:17 70:9  
70:22 76:17 77:7  
78:22 82:18 85:14  
90:16 101:14 102:6,7  
119:3 123:22 133:9  
142:2 143:3,16 147:6  
149:1 156:20 163:11  
163:16 178:7,10  
184:22 196:21 198:6  
202:21 212:17 213:1  
227:5 228:11 233:19  
235:16 241:14 244:9  
246:5 258:12 264:6  
267:16 270:8,19  
275:21 277:2 283:1,6  
310:21 314:8 370:17  
373:5 375:4 384:14  
384:20 386:22 390:12  
391:15 392:3,12  
**looked** 15:22 27:20  
30:9,12 52:15 102:20  
127:16 142:19 162:2  
168:2,7 232:6 307:20  
342:21 372:6 389:17  
**looking** 6:18 21:20 22:7  
23:14 24:5,10 30:20  
33:14 48:16 76:21  
85:21 92:19 99:2  
101:7 102:2,12,17  
103:1 116:12 139:19  
144:9 158:7 172:11

178:7 202:14 223:9  
223:12,19 227:13  
228:19,20 263:19,20  
263:22 265:10 270:6  
273:21 275:11 285:10  
289:6 298:6 299:14  
308:7 311:1 326:9  
364:17 385:3 386:11  
386:15 393:20 396:12  
**looks** 96:2 168:14  
180:9 201:19 377:10  
395:2  
**lose** 151:22 152:1  
215:20,21 246:18  
247:10  
**loss** 147:8 246:8  
**lot** 9:4 20:10 25:12  
64:11 68:8 70:13  
72:13 74:3,18 102:5  
103:4,5 107:2 150:21  
162:3 189:6 190:4  
199:21 203:1 206:18  
211:22 239:1,8  
242:20 243:5,11  
253:19 256:22 257:11  
268:15 270:21 274:8  
283:15 286:6 303:7  
305:10 314:3 327:14  
360:3 379:2 399:9  
401:17  
**lots** 85:7 289:22  
**loud** 134:12  
**low** 93:18 95:9,12 97:6  
97:10 98:8,11 99:10  
104:15,18 105:21  
106:2 111:15,18  
113:20 114:2 130:16  
130:20 131:18 135:17  
136:22 137:1,14  
153:21 154:8 156:2  
158:1 159:8 160:7,12  
160:16 163:22 164:5  
165:5,9 166:3,8,19  
167:2 174:21 175:3  
182:5,8 186:1 188:7  
188:10 192:7,10  
193:11,15 195:5,8  
197:8 217:16 240:22  
241:2 260:8,10 261:8  
261:17 266:11 284:15  
285:5,20,22 286:20  
286:22 289:12 292:14  
294:14 296:1,4  
315:22 316:15 318:1  
318:4 319:15,17  
329:15,19 330:20  
331:2 341:13,16,20  
343:13,15 345:20

346:1,14,17 352:15  
352:19 358:3,7  
360:10,13 361:3,7,18  
361:22 372:16 373:8  
373:14,18 374:18,22  
376:3,7,18,22 377:15  
377:19 390:18,21  
393:1,4 394:16  
395:18,20 397:2,22  
398:2,21 399:1,21  
400:2  
**lower** 68:21 261:12  
272:1 291:1 368:10  
368:10  
**lowest** 109:11  
**lunch** 187:10 213:10  
214:3 215:1 219:10  
**lynch** 209:22

---

**M**

---

**MA** 1:11  
**ma'am** 40:11  
**Madison** 2:2 16:7  
**magic** 46:6 47:2 386:7  
**main** 53:5 87:16  
**maintain** 43:4 250:4  
352:3  
**maintained** 216:3  
**maintaining** 71:4  
**maintenance** 20:18  
25:1,3,5,6 26:7,15  
27:6,13 45:10 142:20  
173:14 210:9,18  
228:3,15 347:13,15  
351:13 379:14  
**major** 96:17 174:6  
194:7 278:7,16  
285:13 286:13 301:13  
353:6 357:6 374:7  
**majority** 135:21 140:14  
261:4  
**makeup** 153:13  
**making** 54:7 66:6,21  
196:4 216:7 253:13  
269:20 388:22 390:10  
**male** 96:11  
**manage** 149:18  
**management** 90:10  
317:14  
**manager** 3:6 6:14  
**mandate** 145:12  
**manner** 289:21  
**manual** 230:6 393:21  
398:8  
**manually** 398:10  
**maps** 322:1  
**Marcia** 3:7 161:10  
**MARGARET** 3:6

**marked** 175:15,16  
**marker** 51:10 92:10,17  
96:11  
**market** 228:9  
**marks** 188:1  
**Marsha** 318:16  
**Mass** 15:18  
**Massachusetts** 1:21  
13:3 16:16  
**massive** 258:9 267:6  
**mastered** 219:16  
**material** 180:21  
**materially** 251:10 256:2  
**math** 271:3 272:5,6  
277:18,20 279:2,11  
279:22 280:1,13  
284:21 315:2 358:21  
359:6  
**Mathematica** 38:16  
40:1,3 43:2 44:14  
**mathematical** 397:3  
**matter** 41:22 115:15  
215:2 278:21 303:14  
336:22 383:16 401:20  
**matters** 13:16 88:7  
101:12 267:4 388:9  
**maximal** 216:3  
**McKiernan** 3:10 42:10  
42:21 108:7,8 109:13  
**MD** 1:11,13,15,17,20  
2:3,4,5,7,8,10,11  
**mean** 26:21,22 40:18  
53:18 58:19 64:21,22  
65:10,14 66:4,21 67:3  
68:7 69:9 71:10 72:2  
72:21,22 75:14 76:1,2  
76:13,13,17 84:15  
91:11 92:19 100:21  
107:15,16 114:14  
131:4 140:11 141:21  
144:4,22 146:2  
157:12 180:16 185:20  
197:18 199:14 202:2  
204:13 207:11 208:2  
208:5 211:17 212:3  
218:10 227:3 230:12  
233:8 238:2 239:1  
242:11 246:6,11  
248:20 250:22 253:19  
254:13 256:11 258:14  
259:16 264:17 268:14  
269:14 272:10,12  
276:17,19 277:18  
278:22 280:21 286:6  
288:12 302:7 303:1,2  
309:3,15 310:7  
312:22 313:8 314:15  
318:7 319:22 320:5

323:9,16 324:2 330:7  
 330:8,10 332:20,22  
 333:1 340:21 351:12  
 351:15 354:1 359:11  
 359:12,18 388:9  
 398:9  
**meaning** 339:21  
**meaningful** 69:20  
 108:17 131:11 134:4  
 300:5,11 304:5 305:9  
 312:6,13 313:10,15  
 323:8,11,13 328:3  
 339:18 349:10 351:4  
 351:7 397:5,6,8  
**means** 53:20 94:19,19  
 135:9 142:6 150:14  
 185:10 215:14 245:17  
 294:7 296:21 305:16  
 325:14 362:9 365:7  
**measure** 14:9,11,17  
 18:14 23:17 24:5 25:6  
 25:7,14,17 26:4,6  
 27:3,4 28:3,7,10,12  
 29:3,4,21 31:5,10,12  
 31:17,19 32:10,11,12  
 32:13 33:16 34:2 35:2  
 35:3,4,9,13,14,16,17  
 36:3,11,12,16,19,20  
 36:21,22 37:11,15  
 38:1,7,11,18 39:3,19  
 40:18,19 41:9,9 42:5  
 42:8 43:4 44:13 45:10  
 45:10,12 47:8,11 49:5  
 50:1 51:15 53:5 54:2  
 54:10 55:2,22 56:21  
 57:4,17 59:9 60:17  
 61:13 64:14 65:4,16  
 68:5,19 71:15,22  
 76:20 77:19 78:2,21  
 78:22 80:11 81:14  
 82:3,10 83:10,11,22  
 86:21 87:5 92:21 95:7  
 95:13 96:2 97:5,10,22  
 98:7,13 99:1 100:1  
 102:4,7,16 104:14,18  
 106:3,7,18 107:13,14  
 108:4,8 109:14  
 110:10,10,19 111:1  
 111:13,18 112:15  
 113:19 114:3,22  
 115:2,9 116:3,17,18  
 117:22 118:2,3,3,14  
 118:16,21 119:5,19  
 120:12,13,21,22  
 121:14,18 122:19,22  
 123:2,2,5,16,20,21  
 124:3,4,5,16,18,19,22  
 125:1,2,3,9,19,20

126:12 127:12,19  
 128:3,12 129:7,14,14  
 129:15 130:5,15,21  
 132:2,9,16 133:13  
 134:20 135:4,6,7,8,10  
 135:11 136:1 138:11  
 138:21 140:6,22  
 141:7,15 142:1,12  
 143:11,18 144:11,14  
 145:2,16,18 146:3  
 147:8 149:8 150:19  
 151:12 153:1,5 155:1  
 155:7,19 156:16  
 159:21 160:6 161:18  
 162:4 163:21 164:6  
 164:14 165:4,10,18  
 166:2,9,18 167:2,20  
 168:1,2,4,7,11,19  
 169:1,16 170:3,4,5,5  
 172:18 173:13,15  
 174:8,20 175:4,8,10  
 176:1 180:22 181:10  
 182:4,9,11,15,21  
 183:11 184:10 185:5  
 185:5,10,15 186:12  
 186:16 187:19,21  
 188:6,11,17 190:3  
 192:6,11 193:10,15  
 194:3,5,12 195:4,9,15  
 196:20 200:8 202:11  
 203:15,16 205:1,14  
 205:17 206:1,12  
 207:6 208:6,12  
 209:12,15 210:15,16  
 210:17,19,20 211:15  
 212:15,22 213:6  
 215:15 216:9 217:16  
 218:2,9 219:21 220:4  
 220:5,7,12 221:5  
 223:9 225:8,13,15  
 226:16,20 227:14,20  
 228:6,7,16 230:13,16  
 230:18,20 231:13,22  
 232:4 235:10,19  
 237:2,8 238:10,21  
 242:6,13 246:22  
 247:2,9,20 249:5,7,8  
 249:8 251:18,20  
 252:4 255:19 257:6  
 260:4,7,11,21 262:15  
 263:2,10,20 264:5  
 265:11 269:14,15  
 270:10 272:18 273:12  
 281:18 283:14,16  
 284:14 285:6,19  
 286:1,12,18 287:1  
 288:12,13,22 291:13  
 293:5,9 294:16,18

295:2,22 296:6,10,14  
 296:18 297:21 299:12  
 299:13,21 300:2,3,7  
 300:10,12,13,20  
 302:9 303:15 305:3  
 306:2 307:16 309:11  
 312:18,19,21 313:3,3  
 313:22 315:4 317:3  
 317:22 319:14,18  
 320:2,6,21 322:10  
 324:16,21 325:3,9  
 326:6,17 327:22  
 328:4,13,21 329:14  
 329:19 330:19 332:5  
 332:16 333:11 334:14  
 337:17,18 338:1,3,4  
 338:18 339:16,17,18  
 341:15,21 342:20  
 343:12,16,20 344:7  
 345:5,11,19 346:2,13  
 346:19 347:14,16,21  
 348:7 349:3,11 350:7  
 350:12,15 351:13  
 352:14,19 355:5,7  
 358:2,8,12,13 359:2  
 360:9,14 361:2,7,17  
 361:22 362:11 363:1  
 363:3 364:9,21 365:1  
 365:4,22 366:2,18  
 372:5 373:13,19  
 374:12,17,22 376:2,7  
 376:17 377:1,14,19  
 378:18 379:17,21  
 380:2,3,8,12,15,20  
 381:16,22 383:8,11  
 383:22 384:8,10,22  
 385:8 389:11 390:4  
 390:17,22 391:5  
 392:22 393:5 395:17  
 395:21 396:3,17  
 397:21 398:3,12,20  
 399:2,5,20 400:3,6,10  
 400:13  
**measure's** 44:16 344:5  
**measured** 81:17 83:15  
 207:20 208:13 238:10  
 321:21,21 322:1  
**measurement** 3:4,7 7:2  
 12:6 72:14 198:21  
 207:8 238:17 321:14  
 396:9  
**measurements** 147:3  
 207:21  
**measures** 4:3,6 5:20  
 6:9 11:14,16,21 14:8  
 14:12 17:9,16,22 18:2  
 20:12,15,16,17,18,19  
 20:22 21:3,7,7,8,10

21:13,15,17,17,20  
 22:1,11,13,18 23:8,15  
 24:1,11,12,20,21 25:1  
 25:3,5 26:4 27:5,6,9  
 27:13,16,17,18,19,21  
 27:22 28:15,18,20,22  
 29:16,17,18 32:6  
 33:22 34:4 35:11  
 51:11 54:3 67:16  
 77:13 79:5,9 99:16  
 108:9,13,17,18 114:6  
 115:20 116:3,16,19  
 116:21 117:3,7,11,18  
 117:19 118:10,12  
 119:12,14 120:3,7,8  
 120:16 121:9,12,19  
 121:21,22 122:5,5  
 124:4,6,10,15 125:14  
 128:21 134:15 144:11  
 145:8 146:10 148:16  
 149:19,21 150:22  
 169:20 170:9 172:5  
 179:8 183:2,4,9,18  
 187:7,7 198:11,16  
 199:2,5 206:13,20  
 209:2,6 210:7,11  
 218:10 219:12,13  
 223:6 230:15 236:15  
 236:16,17,19,21  
 249:2 256:11,20  
 257:12,17 272:7,22  
 273:11 277:3 282:5  
 294:20 298:14 300:21  
 302:13,14 304:4,8,15  
 306:14 313:8 317:5  
 320:18,19 322:19,20  
 327:13,16,17 334:15  
 334:18 335:15,17  
 336:3 337:5,12  
 338:11 343:1 344:7  
 344:16 349:16,18  
 352:2 356:1,1,2  
 362:12,21 363:13  
 364:8 366:7,10  
 380:11,15 381:11  
 382:2 384:15 390:5  
 393:16,22 396:5  
**measuring** 29:4 141:19  
 146:4 206:1,6 216:5  
 236:21 298:1  
**mechanical** 57:9,14  
 58:12 74:16 90:22  
 126:6  
**mechanism** 190:2  
**med** 228:9,10  
**median** 97:19 112:6,12  
 266:10  
**medical** 1:12 2:3,4,5,9

- 2:10,20 11:8 12:17  
13:4 15:12,16 16:16  
17:5 33:4 44:12 83:15  
102:9 118:6 123:10  
123:19 170:15 199:14  
253:22 254:7,11,13  
255:1 286:12 298:19  
326:13 349:22 366:14  
383:20 398:7,15  
**medication** 162:17  
220:6,9 223:18 237:7  
345:7  
**medicine** 2:2,6 15:20  
16:6 239:9  
**meet** 34:4 53:17 83:17  
85:12 96:9 115:3  
183:2 239:13 333:2  
347:15,18 380:4  
**meeting** 1:3 6:5 9:9  
19:7,12,17 31:13  
34:13 39:11 110:22  
113:6 150:15 178:17  
244:14,15 297:7  
336:20 401:19  
**meets** 54:4 89:22 91:12  
142:19 210:17  
**Melody** 2:12 16:18  
77:22 143:22 186:17  
382:6 386:21  
**Melody's** 145:16  
**member** 4:10 11:18  
12:1,8,13 13:1,9,20  
14:20 15:8,11,14,17  
16:3,13,18,22 17:3,11  
17:18 18:6,13 19:10  
20:2 23:19 32:21 39:2  
45:5 48:6,14,21 49:18  
49:21 51:17 52:10,20  
53:14 54:21 56:20  
59:17 61:10 62:5  
63:15 64:9 66:6,14  
67:11 69:8 71:14  
72:20 74:1,14 75:9  
76:1,12 78:1,17 80:13  
82:6 83:5 84:9,13  
85:5,10,17 87:20 90:6  
90:19 92:3,9,22 95:19  
96:1 97:15 98:16  
99:15 103:22 106:5  
107:7,15 108:1 109:1  
110:16 111:20 122:12  
122:17 123:9 127:3  
128:13,20 129:21  
130:6,10 131:1,20  
133:18 134:18 135:2  
137:12 139:10 140:2  
140:13,16,19 142:5  
144:1,20 145:15  
146:13 147:11 148:10  
148:22 149:17 152:6  
153:7 155:14 157:20  
158:15 159:19 161:14  
162:1,12,20 164:8  
165:13 166:11 168:16  
171:13,16 173:12  
174:12,16 175:6  
176:20 177:16 178:6  
179:6,19 180:14,20  
181:2,11 184:3,8,14  
185:1,18 186:18,22  
187:2,13,16 188:14  
189:17 191:21 192:14  
193:18 195:12,21  
196:2,8,10,16,19  
197:2,6 200:7 201:8  
203:5 204:8,18 205:7  
206:22 207:10 208:9  
208:21 209:11 210:22  
212:14 214:3,7 217:8  
229:11 231:17 232:16  
236:2 237:12 238:4  
238:15,19 239:7  
244:11,18 245:5,10  
246:2 250:9 251:19  
253:18 254:6,22  
255:5 256:9 258:14  
258:22 260:15,18  
262:3,6,11,21 263:19  
264:8,11 267:1,15  
268:8,22 269:16,19  
270:22 271:20 272:14  
274:13 275:2 276:1  
277:17 279:4 280:3  
280:17 281:9 284:5  
284:18 285:10 286:5  
287:7,14 288:4,9,13  
288:16 290:9 291:12  
293:3,12,18 294:15  
295:8 301:4,8,12  
302:22 305:6 306:5  
308:18 309:9,18  
310:7,12,15 313:19  
315:1,7,12,16 316:2,9  
316:14,18,22 317:7  
317:13 319:1,21  
321:3 322:13 323:7  
324:2 328:17 330:7  
332:19 340:5,8,19  
342:5,18 343:19  
344:4 346:5 347:1,5  
351:11 352:21 353:15  
354:6 358:10 359:10  
359:17 360:16 361:10  
362:7,19 363:17  
367:8 368:18,22  
369:6,8,16,21 370:6  
370:13 371:5,9,15  
372:15,18 373:7,9,22  
375:2,17 376:10  
377:3 378:1,17 382:7  
383:3,5 386:22 387:9  
387:18 388:7 389:3,7  
389:10 391:3 393:8  
394:20 395:7 396:2  
398:6 399:5  
**members** 20:21 21:18  
33:17 37:12 230:1  
369:15  
**membership** 33:11  
**men** 392:10  
**mention** 25:22 29:2  
82:2 139:11 162:21  
179:20 193:2 351:3  
**mentioned** 30:16 41:10  
42:5 94:11 150:3  
190:9 287:21 335:13  
397:1  
**mentions** 90:20  
**Merck** 2:3 33:4  
**message** 57:19,20  
**met** 1:7 94:21 149:22  
330:9  
**methodologies** 101:2  
**methodologist** 7:9  
**methodologists** 99:18  
**methodology** 100:13  
103:9,10  
**methods** 103:4 200:10  
**metric** 56:12 149:13  
341:8 346:5 367:22  
368:3 369:22 370:15  
375:8 376:12 377:5  
**metrics** 54:22 56:7  
75:17 79:4,8,18,18  
139:16 367:18 375:5  
375:6  
**Metro** 336:18  
**MGH/Harvard** 3:10  
**MI** 294:12,13  
**mic** 8:1,12 38:22 41:3  
92:2 149:16 168:15  
244:1 321:18 368:17  
371:7  
**Michael** 2:8 87:12,19  
201:7 204:19 210:21  
261:22 277:15 293:2  
358:12  
**Michael's** 72:21 205:12  
213:15  
**Michelle** 1:17 14:21  
367:7,9 371:4 375:12  
378:11,15  
**Michigan** 1:17 15:9  
**microphone** 34:14  
369:4 375:16 388:18  
401:13  
**mics** 8:14  
**mid-chew** 228:2  
**migraines** 292:5 293:22  
**Mike** 15:11 67:10 69:7  
89:21 202:22 250:7  
285:9 301:2 305:5  
306:7 312:16 318:22  
**Mike's** 276:2  
**million** 72:8,9 267:11  
268:13,14,16,17,19  
269:3 271:2 278:1  
342:21  
**mimic** 288:7 289:19,21  
291:16 337:16  
**mimics** 259:3,11  
287:19 290:19 292:1  
297:21 339:15  
**mind** 19:4 70:12 92:2  
100:4 116:20 118:19  
134:14 146:21 154:20  
154:21 162:21 187:12  
213:6 348:15  
**minds** 62:1 197:14  
**mini-strokes** 43:14  
**minimal** 69:12  
**minimum** 69:15 70:6,16  
73:9 88:22 89:2 97:21  
113:6 120:6 367:2  
**minor** 257:4  
**minorities** 147:14 178:9  
178:12,18  
**minority** 132:1 303:16  
**minute** 5:7 57:18 59:2,3  
59:3 63:9 67:4 79:11  
79:15 88:6 89:22  
344:8,12  
**minutes** 28:5 35:9  
38:15 41:19,21 42:8  
42:19 44:9 46:5,19,21  
50:4,6,7 51:5,18 52:7  
52:16 57:15 58:10  
59:12 60:1 63:2,21  
64:14,17,20 65:7,9,18  
67:7 69:18 70:15 72:5  
73:3,5,12,12,15,16,16  
73:17,18,20 74:8,9,18  
75:3 76:14,15 78:10  
78:12 81:21 84:16  
85:3 86:6 88:2 89:5,5  
90:9 91:4,8,17 92:18  
96:14 132:22 213:12  
242:8 243:10 276:17  
287:18 298:9 299:2  
299:17 317:15 344:13  
374:4 398:12  
**mirror** 337:16



**mirrors** 366:2  
**mis-reads** 294:3  
**mis-speaking** 324:11  
**misinformation** 36:2  
**missed** 287:11  
**missing** 147:13 276:14  
 397:10,11  
**Mission** 2:14  
**mistake** 316:1  
**mixture** 85:6  
**MMSC** 1:20  
**mobile** 64:5,21,22 65:8  
**mobility** 127:18,20  
 128:2  
**mobilized** 164:17  
**mode** 327:18  
**moderate** 37:14 47:4  
 93:18 94:22 95:9,12  
 97:6,9 98:1,8,11 99:8  
 99:10,11 104:15,17  
 105:21 106:2 107:1  
 111:15,17 113:20  
 114:1 118:22 130:16  
 130:19 160:7,11  
 162:7 163:22 164:4  
 165:5,8,20 166:3,7,19  
 167:1,14 174:21  
 175:2 182:5,8 188:7  
 188:10,18 192:7,10  
 193:11,14 195:5,8  
 221:16,18,19,20  
 222:4,10,13 225:7  
 240:16 260:8,10  
 261:1 266:11 280:5  
 284:15 285:5,20,22  
 286:19,22 296:1,4  
 316:8 318:1,4 319:15  
 319:17 329:15,18  
 330:20 331:1 341:16  
 341:19 343:13,15  
 344:1 345:20,22  
 346:14,17 348:3  
 352:15,18 358:3,7  
 360:10,12 361:3,6,18  
 361:21 368:15 373:14  
 373:17 374:13,18,21  
 376:3,6,13,18,21  
 377:15,18 378:8  
 390:18,21 392:18  
 393:1,4 394:17  
 395:18,20 397:13,22  
 398:2,21 399:1,16,21  
 400:2  
**modern** 239:9  
**modification** 237:16  
**modifications** 227:20  
**modify** 67:20 305:12  
**moment** 216:14 260:3

274:4 281:16 390:16  
**MONDAY** 1:5  
**money** 144:22  
**monitor** 14:8 144:5  
 204:14,14 291:7  
**monitored** 198:13  
 322:22  
**monitoring** 144:6 199:3  
 204:13  
**month** 226:2  
**months** 11:1 39:4  
 120:20 150:10 235:20  
 241:4,12,13,20 242:9  
 242:16 245:19 246:9  
 357:2  
**moot** 223:1,2  
**morbidity** 169:19  
 173:22 339:9  
**morning** 5:22 6:13,16  
 6:20,22 12:8,13 14:20  
 18:19 32:16 33:2 34:9  
 36:21 44:21 45:5 75:1  
 93:6 173:9 310:10  
 334:5 397:4  
**mortality** 169:18 173:21  
 339:8 392:5  
**mortality/** 169:18  
**move** 29:7 32:2 34:19  
 36:10,15,20 37:1,2,13  
 48:4,19 87:17 97:2  
 104:11,12 111:12  
 124:9 135:9 137:6  
 148:12 151:5 153:19  
 153:21 156:8 157:17  
 163:19 177:22 182:16  
 189:16 219:2,6,9  
 240:16 247:22 256:7  
 258:20 259:1 260:13  
 260:15 262:9 285:17  
 286:16 319:11 331:8  
 340:17 342:16 343:10  
 348:10 351:22 352:12  
 362:8  
**moved** 308:5  
**movie** 316:22  
**moving** 28:12 64:22  
 75:21 81:3 95:16  
 133:3 167:19 201:12  
 219:11 249:1 330:5  
 348:20 380:4  
**MPH** 2:10,12  
**MRI** 4:3 38:12,14 42:12  
 42:17,19 43:12 44:8  
 49:5 55:18 56:3,10,17  
 80:4 96:14 112:6  
 273:6 294:5  
**MRIs** 46:1 294:3  
**MSc** 1:11

**MSN** 1:17  
**MSPH** 2:7  
**multi-stakeholder**  
 333:21  
**multiple** 18:1 22:9 94:6  
 172:7 322:19 340:11  
 346:6  
**multitude** 33:12  
**Munthali** 3:3 6:22 7:1  
 138:10 139:4 143:8  
 159:21 161:12 243:16  
 246:20 314:6,8,11  
 318:17 335:12

---

## N

---

**N** 104:21 105:1,10,13  
**N.W** 1:8  
**Naila** 3:11 43:1  
**name** 5:22 6:13,17 12:1  
 12:17,20 42:21  
 124:14 395:11  
**names** 5:12,14 12:16  
**narrow** 257:9 266:12  
**narrower** 243:2  
**narrowing** 88:19 257:5  
**national** 1:1,8 2:14  
 11:19 116:7 126:20  
 131:3 144:13 170:2  
 193:19 291:20 333:14  
 349:8 370:19  
**nationally** 131:14  
 242:22  
**nationwide** 2:8 14:2  
 139:13,20  
**nature** 21:15 289:13  
**nearly** 279:2 381:5  
**necessarily** 53:21  
 221:20 236:7 357:16  
**necessary** 198:14  
**need** 22:13 25:11 26:14  
 49:4 57:21 59:10  
 60:20 61:2 65:22 67:6  
 72:9,22 73:8,9 78:9  
 79:20 83:1 86:11 87:2  
 88:17 90:15 99:17  
 103:7 117:4 134:12  
 142:14 148:12 150:4  
 151:17,18 154:21  
 156:5 178:14 181:12  
 199:18 202:8 208:12  
 211:8 212:9 213:16  
 216:4 217:20 218:19  
 222:19 226:9 235:16  
 236:3,9,10 237:7  
 241:17 245:9 248:7  
 258:2 262:2,11 267:7  
 287:7,13 288:20  
 301:5 318:8 333:17

337:10 340:16 342:1  
 342:11 362:8 368:18  
 372:21 378:13 388:8  
 389:1 391:21 392:2  
**needed** 26:6 59:10  
 205:14 252:22 266:8  
 291:17 360:19 382:8  
**needle** 287:18 292:1  
**needless** 359:21  
**needs** 58:3,5 59:12,13  
 73:7 134:20 139:17  
 139:18 152:18 178:2  
 186:13 217:10 238:16  
 239:10 257:9 304:13  
 317:4 367:2 370:11  
 383:19 386:17  
**negative** 290:13  
**neither** 191:7 313:17  
 321:6  
**net** 16:9 280:22  
**neuro** 15:15 17:1 18:9  
 203:11 206:14  
**Neuroendovascular**  
 1:15  
**NeuroInterventional**  
 74:2  
**neurological** 1:14  
 249:19  
**neurologist** 11:7 13:2  
 13:11,21,22 14:1 15:9  
 17:4,12,19 53:1  
 291:13  
**neurologists** 62:6  
 191:12  
**neurology** 1:3,7,13,21  
 2:7 6:5 9:21 17:8,14  
 17:21 18:11,15 20:9  
 33:22 34:11 91:11  
 116:14 143:10 194:7  
 364:8,9  
**neurosurgeon** 15:12  
 80:20  
**Neurosurgery** 1:16  
**Neurovascular** 1:16  
**never** 94:1 143:16  
 184:4 185:5 268:20  
 272:8 311:17 348:15  
**new** 10:17 15:6,13 17:1  
 21:8,10 22:22 23:12  
 23:18 24:12,21 25:14  
 26:4 27:5,9,14 32:11  
 32:12,13 45:13 55:10  
 57:7 75:16 88:12 89:1  
 99:17 116:17 117:3  
 118:3 119:14 121:19  
 123:20 124:3,5 148:7  
 157:18 173:16 182:1  
 185:5,5 186:16 203:9

203:9 221:4,8 222:19  
 225:2,16 226:1 228:9  
 229:14 231:8,10,11  
 231:18 232:10,14,18  
 233:3,18 234:5  
 235:22 237:21,21  
 240:21 245:1 251:4  
 251:22 252:3,5,9  
 253:22 254:3 261:16  
 262:2,18 263:6,12  
 264:1,2,3 285:14  
 292:22 303:6 312:18  
 312:22,22 320:21  
 334:21 337:9 338:17  
 340:10 342:6,13,16  
 342:18 343:10 351:14  
 351:22 353:10,17  
 354:10,16 356:15  
 357:3 358:22 359:10  
 368:6,20 380:12  
 387:13 395:2  
**newer** 70:19 354:3  
**newly** 242:12  
**nice** 67:11 110:8 274:10  
 291:7  
**night** 310:9  
**NIH** 13:5 236:17 251:2  
**nimodipine** 4:19 380:5  
 380:10,17,22 382:13  
 384:2,11 386:4,14  
 390:1 392:12,13  
 393:10 394:3 396:7  
**NINDS-funded** 16:8  
**nine** 80:15 348:7  
 373:17 374:20 376:21  
**NIS** 298:18  
**no's** 325:18  
**NOAC** 355:12  
**noise** 100:13  
**nominated** 10:12 11:11  
 15:19 16:11  
**nominator** 226:11  
**non-** 282:5 324:2  
 385:15 393:22 394:3  
**non-aneurysmal**  
 383:17,21 384:12,18  
 386:3,7,12,16 387:2  
 388:22 389:15,21  
**non-endorsement**  
 342:3 347:8 364:21  
**non-Hispanic** 96:10  
**non-ideal** 92:10  
**non-IT** 324:3  
**non-legacy** 312:20  
**non-significant** 177:21  
**non-trauma** 388:2  
**non-traumatic** 387:6  
**non-treatment** 236:16

269:11  
**non-valvular** 350:9  
 357:12  
**nonbiased** 83:3  
**noncontrast** 45:22  
**noon** 326:14,16  
**Nope** 124:7  
**normal** 310:14  
**Northern** 14:22  
**Northwestern** 2:15 12:3  
**notably** 131:8  
**notation** 385:13  
**note** 8:13 87:18 110:2,6  
 219:12 224:21 372:11  
**noted** 8:8 164:16  
 292:18  
**notes** 183:14 192:15  
 220:19 285:11  
**noticed** 280:8  
**noticing** 104:21 105:10  
**notwithstanding**  
 255:20 278:17  
**novel** 350:16  
**November** 220:16  
 229:15  
**novo** 67:15 116:17  
 123:21  
**NPAs** 369:13  
**NQF** 3:1 4:10 6:12,18  
 7:9 19:19,19 24:10,15  
 28:20 33:11 34:5  
 37:11 42:11,16 43:4,7  
 44:3 75:18 81:11  
 100:8 101:1 115:3  
 135:10 142:1,11  
 144:9 145:6 151:1  
 152:15 153:17 182:22  
 183:9 185:5,6 186:14  
 199:2,21 208:10  
 209:4 210:17 211:1  
 214:2 215:16 218:6,7  
 239:10 263:17 264:7  
 267:1 296:14,19  
 301:15,16 302:18  
 307:10 318:13 321:9  
 334:6,20 336:2  
 363:21  
**NQF's** 8:7  
**number** 25:2 27:17 30:9  
 30:11,12 39:3 42:12  
 42:16 43:4 44:3 46:6  
 47:2 53:22 73:13 86:1  
 86:7 88:6 94:1,3 99:5  
 101:11 111:6 131:9  
 134:15 160:6 172:8  
 177:22 190:20 193:4  
 207:3,14 225:6  
 233:22 240:11 268:20

269:1 270:9,14,17,20  
 271:6 276:18,18  
 277:2 278:5 290:20  
 291:17 303:13 309:17  
 324:18 366:19 377:5  
 378:2 394:14 401:6  
**numbers** 28:1 133:4  
 181:4 242:16 248:20  
 256:18 261:20 262:19  
 263:8,9,10,13 264:4  
 264:13,15 267:2,4,8  
 268:12 269:19,22  
 270:4,18 271:15  
 272:16 277:19,21  
 278:15 283:7 358:12  
 358:13 359:19,20  
 360:2 382:20  
**numerator** 44:7 54:4  
 80:11 112:17 118:7  
 123:3 128:12 133:22  
 162:16 163:5,7,12,13  
 221:6 231:11,13,19  
 250:14 299:14 308:20  
 308:21 351:2 353:1,8  
 353:11,20 354:13  
 356:12 357:19 367:10  
 393:9  
**numerator/denomina...**  
 187:17  
**nurse** 12:10 297:11  
**nurses** 15:3 50:20  
**Nursing** 1:20 12:11

## O

**o'clock** 115:13  
**Obamacare** 295:12  
**object** 292:22  
**objection** 167:19  
**objects** 262:1 292:20  
**observation** 62:21  
 276:14 344:14  
**observer** 205:11,21  
**obstructed** 297:21  
 298:1 299:13  
**obtained** 46:21 66:11  
**obtaining** 49:5 67:1  
 106:19 107:12 377:8  
**obvious** 60:10 61:16  
 207:13 256:17  
**obviously** 33:6 70:2  
 77:10 193:21 261:15  
 286:8 301:21 370:14  
 390:1  
**occlusion** 76:5 273:1  
**Occupational** 16:11  
**occur** 74:19 210:18  
**occurred** 220:15  
**occurrence** 266:13

**occurs** 381:4  
**October** 226:3 230:8  
**odd** 344:6  
**odds** 176:5  
**offered** 255:9  
**offering** 204:6  
**officer** 1:14 2:14 10:17  
**official** 59:4 120:17  
**Ogungbemi** 3:4 6:20,21  
 93:6 95:6 97:4 98:6  
 104:13 105:2,7,16  
 111:13 113:18 114:20  
 130:14,18 160:5,10  
 163:20 164:3 165:3,7  
 166:1,6,17,22 174:19  
 175:1 182:3,12,15  
 188:5 192:5 193:9  
 195:3 219:1 260:3  
 284:13 285:3,18  
 286:17 295:21 296:13  
 317:21 319:13 329:13  
 330:18 331:15 332:3  
 332:15 335:8,10  
 336:15 341:14 343:11  
 345:18 346:12 347:12  
 352:13 358:1 360:8  
 361:1,16 364:22  
 373:12 374:16 376:1  
 376:16 377:13 379:16  
 390:16 392:21 395:16  
 397:20 398:19 399:19  
 400:8  
**oh** 63:1 124:12 221:16  
 222:18 260:2,4 323:5  
 344:3,22 348:14  
 358:4 385:10  
**okay** 5:3 7:21 8:5,16  
 13:22 18:16,20 19:21  
 20:1 26:2 32:3,14  
 37:22 39:20 40:4,22  
 41:7 67:9 78:4,13  
 85:7 87:12 92:7 95:2  
 95:6 97:1 104:9  
 114:12,18,20 115:18  
 118:14 119:7 124:7  
 126:22 130:22 136:3  
 137:3 154:14 158:13  
 160:3,18 164:7 167:4  
 167:18 168:9,13  
 171:18,19 174:18  
 175:5,6 177:13 186:9  
 186:18,22 187:13  
 188:3 193:9 195:11  
 197:16 208:20 215:5  
 216:8,13 218:21  
 219:8 222:7,20  
 226:10 231:16 243:18  
 247:21 248:16 249:1

253:18 255:5 256:4  
 258:13,20 260:13  
 262:5,11 264:8  
 268:17 271:18 276:1  
 276:13 277:13 284:11  
 289:1 297:15,20  
 301:2,12 305:4  
 310:12,15 314:18  
 315:7,12,14 316:14  
 317:11 318:13,21  
 322:11 327:7 331:20  
 332:14 335:10 336:15  
 337:13 340:3 343:9  
 346:11 347:8 348:17  
 351:10 357:9,20  
 362:2,18 364:19  
 365:6,13,16,21  
 368:21 372:14 373:11  
 374:15 375:18,21  
 379:14 382:5,7,8  
 384:19,19 385:10  
 386:19 393:8 396:2  
 401:9  
**old** 168:18 263:9  
 294:11,11,13 310:18  
 359:3  
**older** 226:22 292:11  
 380:17  
**olds** 291:18 292:4,15  
 295:5,6  
**once** 20:3 48:18 70:18  
 70:18 86:15 93:10,20  
 158:12 209:7 230:5  
 356:21,22 373:20  
**one's** 79:2  
**one-quarter** 300:19  
**onerous** 282:20 345:9  
 345:13  
**ones** 77:18 203:12  
 219:22 276:19,22  
 312:22 354:8 356:18  
 359:9 363:16 391:4  
 394:2  
**ongoing** 151:2 190:2  
 212:18 239:11 258:1  
**online** 95:5 267:16  
**onset** 43:21 44:6 53:1  
 55:11,12 82:21  
 298:11 299:4 309:2,8  
 309:19 310:17 311:2  
 339:14  
**oops** 297:18 327:6  
**open** 9:12 38:19 93:10  
 93:11 94:5,15 95:8  
 97:1,7 98:9 104:13  
 105:20 111:14 113:21  
 115:1 130:16 156:3  
 160:8 164:1 165:5

166:4,20 174:21  
 182:6 188:8 192:8  
 193:12 195:6 214:6  
 219:1 224:14 240:15  
 260:8 284:15 285:2,3  
 285:19 286:19 296:2  
 296:11,16 318:2  
 319:15 329:16 330:21  
 332:6 341:17 343:13  
 345:20 346:15 348:4  
 352:16 358:4 360:10  
 361:4,19 365:2  
 373:15 374:19 376:4  
 376:19 377:16 379:18  
 390:19 393:2 395:18  
 397:22 398:21 399:22  
 400:11,21,22 401:3  
**opened** 233:1 297:19  
**opening** 225:21  
**openly** 19:17  
**operation** 64:18  
**Operations** 1:18  
**operator** 38:19 39:21  
 40:2,9,11 214:6,14,16  
 400:20 401:2,4  
**opinion** 19:3 35:21  
 58:22 191:11,13  
 232:17 324:7  
**opinions** 33:13 212:11  
**opportunities** 47:14  
 49:3,15 143:13,20  
 175:6 177:1  
**opportunity** 22:12  
 25:18 26:1 40:16  
 41:13 42:11,15 47:5,9  
 48:8 49:1 67:12 77:17  
 96:6,22 131:17  
 142:16 158:18,20  
 159:1,2 174:7 176:10  
 176:13 185:9,12  
 198:20 202:13 206:4  
 227:9 246:5,10  
 334:22 362:22  
**oppose** 247:21  
**opposed** 63:3 102:13  
 181:8 395:5  
**optimal** 68:9  
**option** 28:11 93:16,18  
 93:22 136:2 139:1  
 182:22 235:9,17  
 239:2 240:19 247:4  
 355:16  
**options** 93:16,17 95:9  
 97:5 98:7 104:14  
 105:21 111:14 113:19  
 114:22 130:15 160:7  
 163:21 165:4 166:2  
 166:18 174:20 182:5

188:6 192:6 195:4  
 227:3 240:11,18  
 260:7 284:14 285:19  
 286:19 296:1,15  
 317:22 319:14 329:14  
 330:19 332:5 341:15  
 343:12 345:19 346:13  
 348:4 352:14 358:2  
 360:9 361:2,17 365:2  
 373:13 374:18 376:2  
 376:18 377:14 379:18  
 390:18 392:22 395:17  
 397:21 398:20 399:20  
 400:10  
**oral** 9:8 350:16,18  
 354:3  
**order** 35:16 37:11 50:21  
 54:8 60:16 61:15,18  
 66:10 67:2 169:9  
 174:10 239:13 272:19  
 310:19 383:18,21  
 389:10  
**ordering** 54:15  
**ordinarily** 132:20 294:5  
**organization** 152:17  
**organizations** 74:6  
 300:18 361:11 377:6  
**orientation** 20:8,11  
**original** 5:9 80:9 106:20  
 172:19 267:5 268:3  
 271:7 278:8 280:3,10  
 345:4 350:14  
**originally** 43:4 45:11  
 56:21 78:2 121:1  
 125:19 172:12 307:16  
 308:1  
**ought** 83:15  
**outcome** 12:5 21:17  
 58:16 65:14 71:19,20  
 81:12,15,18 82:4  
 177:3 348:1 371:17  
 378:8 379:7,12  
**outcomes** 16:1,9 24:20  
 57:10 221:11 249:19  
 257:1 344:22  
**outpatient** 43:5  
**outputs** 273:22  
**outrageously** 387:13  
**outside** 34:17 53:2  
 69:20 180:19 188:22  
 189:7,11 228:20  
 252:3 306:19 307:3  
 368:8  
**outsider** 239:8  
**outweigh** 286:8  
**outweighs** 289:17  
**over-treatment** 259:19  
**overall** 46:13 47:3,5

48:15 53:10 99:4  
 113:13 114:8,13,21  
 133:6 140:7 172:21  
 176:7,10,14 177:18  
 177:22 180:21 194:18  
 198:11 209:16 258:3  
 269:21 283:21 296:8  
 296:9,11,14 318:10  
 318:18 331:7,8 332:4  
 342:8 346:21 368:12  
 376:12 400:4,5,9  
**overhead** 217:15  
**overreach** 55:2  
**overreaching** 55:4  
 78:22  
**oversight** 143:10  
**overview** 4:5 20:13  
 22:16 37:5 100:6  
 115:22 219:21 297:15  
**overwhelming** 332:1  
**ownership** 21:19 34:10

---

**P**

---

**P** 164:11  
**P-R-O-C-E-E-D-I-N-G-S**  
 5:1  
**p.m** 215:3,4 326:16  
 337:1,2 401:20  
**PA** 298:21  
**PA's** 103:8  
**pace** 348:20  
**pacemaker** 273:6  
**Pacific** 392:8  
**packet** 35:14  
**page** 173:6 263:1,1,9  
 263:11,11,11,21  
 267:10  
**pages** 263:5  
**paid** 204:21  
**paired** 122:1  
**panel** 82:7,9 146:20  
 206:11 230:1 275:18  
 362:21  
**panels** 153:13  
**pants** 188:22 327:8  
**paper** 29:17 31:17 91:4  
 91:19 102:6 106:13  
 108:12 110:8 398:7  
**papers** 127:17 290:18  
**paradigm** 378:4  
**parallel** 230:15,20  
 363:13  
**Paralysis** 292:9 294:4  
**parcel** 71:12  
**parceling** 89:17  
**pardon** 182:13 260:4  
**Parkinson** 2:14 11:19  
**Parkinson's** 11:21 22:8

**parochial** 279:21  
**parsimonious** 146:1,10  
**part** 9:7 11:8 16:8 23:17  
 25:6,16 57:12 61:1,11  
 70:8 71:12 76:3 78:15  
 84:4,21 111:9 115:19  
 119:17 146:1 162:13  
 162:19 175:20 177:7  
 194:6 197:7,8 199:12  
 209:12,17 218:6  
 252:4 258:7,9 271:10  
 272:13,14 273:18  
 278:15 288:10,17,17  
 304:4 321:14 344:10  
 363:9 374:3 392:14  
 392:15  
**partial** 299:6  
**participated** 17:13  
**participates** 19:6  
**participating** 131:9  
 189:22 300:18  
**participation** 132:10  
**particular** 25:12 26:10  
 46:19 100:1 107:9  
 125:1 128:12 133:12  
 163:13 172:18 205:13  
 206:12 216:6 227:11  
 254:1 272:17 284:19  
 328:18 350:7 380:15  
 381:8  
**particularly** 10:2 100:7  
 101:4 327:13 395:2  
**partner** 43:3 365:17  
**parts** 100:1 234:15  
**PAs** 369:12  
**pass** 5:17 24:22 26:1,21  
 27:1 28:9 29:5,16,22  
 31:18 36:19,19 37:12  
 37:15 50:16,17  
 119:20 135:8 137:8  
 138:9 153:21 154:14  
 182:16,21 195:16  
 219:17 275:9 303:9  
 316:17 329:20,22  
 330:2 331:13,17,19  
 341:21 342:14 348:8  
 362:13  
**passed** 28:11 114:15  
 127:8 155:2 185:2  
 222:22  
**passes** 95:13 97:11  
 98:13 104:19 106:3  
 111:19 114:3 130:21  
 164:6 165:10 166:9  
 167:3 175:4 182:9  
 186:5 188:11 192:11  
 193:16 195:9 260:11  
 285:6 286:1 287:1

296:6 319:18 343:16  
 346:2,19 358:8  
 360:14 361:8 362:1  
 365:5 375:1 376:8  
 377:1,20 379:22  
 390:22 393:5 395:21  
 398:3 399:2 400:3,13  
**passing** 332:16 333:3  
**Patel** 14:17  
**path** 117:1  
**pathway** 71:19 72:3  
**patient** 1:12 12:14  
 43:22 46:22 50:12,14  
 50:18,20 51:1,1,6,19  
 52:3 56:8 58:1,9,14  
 59:5,19 60:9 62:7  
 63:12 64:19 65:7  
 70:17 76:18 79:10,22  
 80:1,3,22 81:2,16  
 86:10 88:21 91:5,5,10  
 91:11,13 92:6 102:21  
 108:14 123:12 126:2  
 128:9,10 129:8,10,16  
 129:18 163:8 164:16  
 174:3 183:6 198:18  
 234:10,10 255:1  
 259:7 265:6 291:5  
 294:21 299:9,18  
 300:1,15 315:10  
 319:4,5 326:20  
 342:21 349:6 370:12  
 383:13,21 386:12  
**patient's** 282:4  
**patients** 31:4 38:13  
 42:18 43:9,17 44:2,5  
 44:7 45:17 49:6 56:1  
 57:13 61:8 71:3 73:1  
 79:3 90:10 91:1 92:18  
 96:9,9,12,17 101:11  
 102:18 118:6 122:21  
 123:1,6,7 125:5,10,11  
 125:12,13,15,17,21  
 126:10 127:15,18,18  
 128:1 139:22 169:4  
 169:19 170:6,7,8,9,10  
 170:14,16,16,18,22  
 171:4,22 172:1,3,9  
 173:3,19 180:5,6  
 181:4,9 190:12 205:1  
 205:9 220:8,13 225:1  
 225:7,9 226:15 233:3  
 233:7 235:3 242:18  
 249:9,17,19 250:15  
 250:18 251:8,14  
 252:2,10 253:2,5,7,21  
 259:10 265:1,1 266:1  
 266:3,15 267:11,11  
 268:4,18 269:2,3,8,9

273:7,16 276:16  
 289:6,10,20 290:1  
 293:15 298:2,7,14,16  
 298:17,19 299:1,15  
 310:3,4 315:3 337:19  
 338:6,7,9,11,12,13,14  
 338:18,22 339:2  
 349:12,16,19,20,22  
 350:5,8,21 353:1,3  
 354:7,9,22 355:12  
 356:7 358:17 366:4,7  
 366:8,9,10,12,15,15  
 366:16,19 367:11  
 371:10 378:10 380:16  
 381:5,9,9,11,12,14  
 382:17 383:9,12,19  
 388:4 389:11,15,21  
 391:9,12,12 392:5  
 393:9,12,14,14,16,16  
 393:17  
**patients'** 367:2  
**patterns** 283:2  
**Paul** 126:20 170:2  
 349:7  
**pause** 41:19 48:3 49:20  
**pay** 112:4 306:21  
**pediatric** 2:7 13:21,22  
 14:1,5 291:13 295:2,3  
 295:10 364:10  
**Pediatrics** 295:9  
**Peg** 5:8,17 6:1 22:16,19  
**Peg's** 7:14  
**Peggy** 167:20  
**penalized** 283:17 335:3  
**penalty** 246:12  
**Penn** 12:11  
**Pennsylvania** 1:19  
**people** 15:22 23:16,20  
 27:20 50:5,20 62:22  
 67:10 68:13 69:4,5  
 71:11,20 77:22 82:12  
 88:18 105:13 109:12  
 133:20 144:11,22  
 146:17 149:17 150:21  
 151:2,13 162:15  
 175:18 179:9 185:19  
 189:8 193:2,5 201:16  
 202:4 204:21 206:18  
 207:3 208:9 209:16  
 211:1 218:2 251:13  
 254:6 261:18 283:16  
 291:22 293:10 303:11  
 322:15 323:12 344:20  
 351:6 354:3 367:20  
 367:22 369:6 373:2  
 375:12 379:3 396:22  
 397:16  
**perceive** 236:6

**percent** 37:12,17,18  
 53:16 54:3,4 82:11  
 84:7 92:17 94:12,22  
 95:12,12,12,13 97:9,9  
 97:9,10 98:11,11,11  
 98:12 104:17,17,17  
 104:18 106:1,2,2,2  
 111:17,17,17,18  
 112:7,8 114:1,1,1,2  
 115:5,6 130:19,19,20  
 130:20 131:4,4,5,6,7  
 131:14 132:10 133:13  
 139:12,20 160:11,11  
 160:12,12 161:18  
 164:4,4,5,5 165:8,8,9  
 165:9,15 166:7,7,8,8  
 167:1,1,2,2 172:22  
 173:3 175:2,2,3,3,10  
 175:13,17,18 177:20  
 178:15,16,22 180:5,6  
 180:7 182:8,8,8,9  
 188:10,10,10,11  
 192:10,10,10,11  
 193:14,14,14,15  
 195:8,8,8,9 205:1  
 219:5,5 223:13,13,14  
 223:20 224:9,10  
 230:19 231:2,6,15  
 256:15 257:20 259:4  
 259:18,19 260:10,10  
 260:10,11 261:6,7,9  
 261:14 265:3 268:4,7  
 269:1,2 271:1,6,8  
 272:7 276:5,6 277:6  
 278:6,8,9,11,11,12,19  
 278:20 279:7 284:1,2  
 285:5,5,5,6,22,22,22  
 286:1,22,22,22 287:1  
 289:12 290:2 296:4,4  
 296:4,5,18 318:4,4,4  
 318:5 319:3,17,17,17  
 319:18 329:18,18,18  
 329:19 331:1,1,2,2  
 332:9,9 340:21 341:1  
 341:19,19,20,20  
 342:9,10 343:15,15  
 343:15,16 345:22,22  
 346:1,1,17,17,17,18  
 348:7,7 352:18,18,18  
 352:19 358:6,7,7,8,17  
 359:4,4,12,13,16  
 360:12,12,13,13  
 361:6,6,6,7,21,21,21  
 361:22 365:4,4  
 370:20 372:12 373:17  
 373:17,18,18 374:21  
 374:21,21,22 375:19  
 376:6,6,6,7,21,21,22

376:22 377:18,18,18 377:19 379:5,20,20 381:4,5,6 387:12,15 390:21,21,21,22 393:4,4,4,5 394:11,12 395:20,20,20,21 398:2,2,2,3 399:1,1,1 399:2 400:1,2,2,2,13 400:13 <b>percentage</b> 68:20 89:22 102:18 171:4,22 172:21 181:12 266:15 267:21 268:2,8 396:21 <b>percentages</b> 159:8 262:17 263:4 <b>percentile</b> 131:6 175:11 202:22 203:3 223:13 223:14,15,19 224:9 257:14 276:4,5 341:1 370:20,21,21 <b>percentiles</b> 370:17 391:22 <b>perfect</b> 45:2 231:14 243:5 <b>performance</b> 28:16,17 30:21 31:8 44:17 70:8 70:9 71:9 81:15 85:21 86:21 96:5 97:5,11 107:13,14 112:2,11 112:13 117:16 119:5 119:22 131:12 142:22 143:12,20 144:12,14 145:4 160:6 176:6,7 176:15 177:1 180:22 182:4,10,16 183:5 190:3 194:5 198:11 198:12,13,14,17,22 210:13 224:22 225:9 226:12 242:9 256:17 260:6,12 266:9,14 268:1 270:18 321:14 321:20 340:21 341:8 341:15,21 347:17,20 352:14,20 354:2 357:6 373:13,19 375:6 385:8 392:15 392:17,22 393:6 <b>performed</b> 273:15 333:22 396:9 <b>performing</b> 43:8 134:16 139:19 242:21 259:18 <b>period</b> 26:19 34:7 129:11 138:13,15 194:15 202:17 220:13 229:22 292:7 300:9 304:9 328:11 <b>periodic</b> 199:3 204:13	<b>periodically</b> 210:11 211:14 <b>peripheral</b> 191:15 <b>permanent</b> 209:10 <b>Permanente's</b> 14:22 <b>permutations</b> 324:19 325:4 <b>perpendicular</b> 36:8 <b>persistent</b> 134:3 371:2 <b>person</b> 16:9 60:2,12 61:16 64:2 106:19 108:21 110:5 240:6 285:2 288:18 295:14 297:12 324:3 358:4 <b>personal</b> 279:1 331:22 <b>personally</b> 99:9 211:1 212:9 278:10 303:1 <b>persons</b> 63:19 132:1 <b>perspective</b> 56:14 58:9 63:7 68:18 152:13 191:18 306:8,17 360:19 372:19 <b>pertains</b> 17:16 <b>pertinent</b> 353:21 <b>perverse</b> 283:17 <b>Peter</b> 2:13 11:18 51:16 78:16 124:12 127:1,2 129:20 130:22 137:10 139:11 140:1 146:12 148:22 149:3 158:14 164:7 165:12 204:17 231:16 271:19,19 315:14 323:6 357:21 362:18 363:7 378:16 <b>Peter's</b> 148:1 280:17 <b>Ph.D</b> 15:4 <b>pharmaceutical</b> 13:18 33:4 <b>pharmacist</b> 298:21 <b>pharmacological</b> 126:4 126:10 <b>Pharmacy</b> 2:13 16:20 <b>PharmD</b> 2:12 <b>phase</b> 392:1 <b>phases</b> 20:16 391:6 <b>PhD</b> 2:1,7,8,10,13,16 <b>phenomena</b> 207:17 208:4 <b>phenomenon</b> 205:3,11 205:21 207:7 <b>Phillips</b> 3:5 115:22 116:5,6 121:12 122:6 122:14,18 123:11,15 321:19 322:9 <b>PHN</b> 1:17 <b>phone</b> 6:4 38:18 40:9 157:2 396:21 400:21 400:21 401:3,6	<b>phrased</b> 91:10 <b>physical</b> 2:19 12:2,4 15:20 <b>physically</b> 110:5 <b>physician</b> 1:13 13:11 79:6 110:14 220:3 298:20 370:5,5 <b>physician's</b> 62:1 <b>physicians</b> 13:14 58:18 59:7 79:3 286:11 <b>picayune</b> 48:15 <b>pick</b> 173:11 317:6 <b>picking</b> 53:22 <b>picture</b> 32:2 <b>piece</b> 60:19 87:2 132:7 143:9 218:15 <b>piggybacking</b> 212:14 <b>pilot</b> 120:17 190:1 382:2 389:14 391:7 391:17,19 <b>pin</b> 209:22 <b>pink</b> 223:11 <b>place</b> 36:7 54:15 55:2 60:11 63:19 96:2 109:8 134:16 149:11 152:21 164:12 205:15 222:2 344:5 371:18 <b>places</b> 70:14 83:16 107:10,17,19 181:14 245:16 259:18 <b>plan</b> 168:20 397:6,10 <b>planned</b> 399:8 <b>planning</b> 41:17 <b>plasminogen</b> 43:16 <b>platelet</b> 299:5 <b>play</b> 31:14 127:4,4 134:11 156:20 354:13 <b>player</b> 90:22 <b>playing</b> 108:16 110:13 178:9 <b>plays</b> 199:9 202:2 <b>please</b> 8:15 10:1 32:18 35:18 37:8 38:22 93:8 93:11 119:6 214:17 264:10 308:18 335:9 336:20 401:3,5 <b>plenty</b> 158:21 191:2 <b>plus</b> 14:15 <b>pneumatic</b> 126:8 <b>point</b> 8:4 20:19 21:8 29:11 30:7 38:4 45:2 46:10 49:20 52:11 53:6 54:17 59:2,3,4 64:10 65:21 68:12 70:1 72:15,21 73:6,11 75:6 76:12 82:5 83:6 84:16 85:19 93:13 94:15 104:4 108:10	110:18 114:19 122:3 132:3 135:13 140:3 142:22 144:14 148:1 151:18 164:11 171:8 176:20 177:4,20 178:4,21,22 184:15 189:14 194:1 200:5 200:22 201:5 205:12 206:6 212:17,19 213:15 226:14 228:12 244:21 253:19 254:14 255:6,15 256:3 257:7 259:17 260:19 268:21 284:19 287:12 293:4 304:21 321:16 325:22 333:18 356:20 357:10 363:18 364:12 387:21 394:21 <b>pointed</b> 60:8 149:1 171:20 287:15 352:22 358:13 374:10 <b>pointing</b> 288:15 <b>pointless</b> 71:11 <b>points</b> 236:2 382:20 <b>policies</b> 149:11 152:14 153:2 318:12 <b>policy</b> 43:2 142:9 149:11 152:16 186:14 197:21 200:5 203:10 204:2 206:5 210:4 226:19 306:6 308:20 312:16 328:19,21 335:18 336:7,10 364:2,6,14 <b>Poling</b> 219:4 <b>political</b> 306:17 <b>poll</b> 246:16 247:15 <b>Polling</b> 219:1 <b>ponder</b> 245:3 <b>poor</b> 84:2 <b>Pop</b> 94:14 <b>populated</b> 325:11 326:17 <b>population</b> 102:21 118:5 122:7 123:19 128:12 177:2 178:15 208:15 220:11 226:1 226:8 237:15,18 277:3,5 289:16 290:5 291:5,16 292:10,11 294:21 295:2,3 315:10 383:14 <b>populations</b> 125:9 338:6 349:15 381:8 <b>portfolio</b> 20:13 21:5,19 22:2 28:21 34:1,11 135:10 142:1 143:10 149:18 183:10 199:3
--	---	---	---

210:10  
**portion** 169:4  
**portraying** 143:6  
**position** 59:8 206:17  
 362:20  
**positive** 56:10 292:13  
 342:22  
**possibility** 40:20  
 199:15,19 205:20  
 224:6 226:21 248:19  
 397:8  
**possible** 54:19 62:10  
 63:4,13 65:11 73:1  
 163:15 181:15 183:18  
 188:18 190:16 247:9  
 252:11 283:19 289:20  
 321:4 324:14,15  
 325:3 333:14 369:3  
 399:12  
**possibly** 29:21 40:17  
 338:21 342:2 348:3  
**post** 39:11 156:22  
 157:6 241:11 292:5  
**post-acute** 371:11  
 378:5  
**post-comment** 138:14  
 139:7 155:9 161:6  
 227:17  
**posted** 173:8  
**potent** 350:11  
**potential** 14:14 18:10  
 20:4 28:21 64:11 96:5  
 99:6 113:12 153:10  
 153:10 176:11 183:10  
 185:16,17 199:4  
 204:7 235:7 263:2  
 347:13,18 348:8  
 365:1,5 379:15,17,21  
**potentially** 39:13 47:10  
 57:19 65:2,17 68:19  
 77:15 108:12 113:10  
 139:21 177:6 227:5  
 242:21  
**powerful** 147:4  
**practical** 56:14 63:6  
 64:6 85:19 134:21  
 144:3  
**practically** 136:20  
**practice** 57:5 59:14  
 68:9 69:14 76:14,21  
 76:22 77:15,16  
 173:17 191:5 212:8  
 247:1,11 359:12  
**practiced** 80:15  
**practices** 129:6  
**practitioner** 12:10  
**Pradaxa** 356:16  
**pre-evaluation** 23:13

48:8  
**pre-meeting** 23:19  
 35:19  
**pre-test** 292:13 294:12  
**precise** 26:5 345:6  
**preferably** 339:12  
**preferred** 249:21  
**performed** 44:15  
**preliminarily** 399:15  
**preliminary** 23:3 48:7  
 131:17 162:6 164:21  
 165:19 221:14 236:11  
 263:17 333:16 343:7  
 343:22 368:14 372:15  
 372:17 392:17 394:16  
 397:13  
**premise** 367:1  
**prepared** 245:20  
 263:17 334:19  
**preparing** 280:7  
**prescribed** 220:9  
 349:13 353:2  
**prescribing** 171:1  
 350:6  
**presence** 234:9  
**present** 1:10 3:1,8,15  
 92:6 132:5 168:17  
 179:20 180:10 191:10  
 214:10 227:15 229:6  
 246:10 310:5 340:5  
 343:4,5 359:19  
**presentation** 48:2 61:9  
 82:14 137:22  
**presentations** 82:22  
**presented** 35:16 45:13  
 46:10 54:3 147:16  
 225:13 276:16,22  
 342:6,7,19 353:14  
 382:9 387:14 391:5  
 392:4  
**presenting** 82:20 127:1  
 139:11 168:14  
**president** 2:13 3:3,7 7:1  
 10:17 15:2  
**presiding** 1:9  
**press** 93:20,22 94:16  
 136:11 214:17 401:5  
**pressure** 111:5 245:4  
 299:8,9  
**presuming** 87:1  
**presumptively** 384:6  
**pretty** 46:12 55:11  
 101:18 103:17 131:7  
 144:2,15 162:6  
 166:13 180:10 191:19  
 217:15 223:19 224:1  
 227:1 234:20 279:1  
 283:22 289:15 294:14

325:1 357:4 359:13  
 370:18,20 371:16  
 375:5 378:12 379:9  
 392:2,17 395:1 397:7  
**prevalence** 178:8  
**prevalent** 206:17  
**prevent** 266:9  
**preventative** 257:18  
**prevented** 222:1  
**preventing** 169:18  
 368:2  
**prevention** 149:9  
 169:16 180:17 229:20  
 234:15 350:20 381:2  
**previous** 20:15 21:15  
 22:1,5 105:1 153:3  
 232:4 245:7 270:6  
 274:3 287:15 308:19  
 339:17 380:3  
**previously** 22:5 32:6,10  
 60:7 121:13 122:2  
 150:3 231:22 342:7  
 354:7 371:14 397:1  
**primary** 12:9 126:17  
 137:14 168:11 190:7  
 190:8 270:13  
**prime** 305:16  
**principal** 309:22 383:14  
 383:15  
**principle** 155:16,17  
**prior** 24:1 26:13 61:22  
 196:22 208:3 224:22  
 233:11 263:10 298:16  
 338:15,20 340:10  
 367:4 374:4  
**priority** 109:12  
**pristine** 215:9  
**PRO** 81:15  
**probability** 61:22  
 292:14 294:13  
**probably** 12:15 34:13  
 40:13 53:11,17 54:18  
 55:8 60:10 63:7 90:1  
 90:3 99:10 104:4  
 109:1 130:9 134:16  
 136:7,8,11 137:17  
 140:17 162:5,7  
 191:19 194:6 205:2  
 209:1,1 222:4,4,5  
 234:22 236:8 239:10  
 240:2,7 259:8 268:21  
 270:15 279:6 315:2  
 318:8 335:16 336:11  
 337:10 338:3 341:11  
 348:11 357:5 359:15  
 372:19 382:19 395:7  
**problem** 80:12 185:19  
 192:19 201:6 208:16

211:7,22 258:19  
 264:11 273:4 319:6  
 330:16  
**problems** 71:21 72:14  
 133:2 272:5,6  
**proceed** 40:7 95:1,18  
 342:3  
**proceedings** 34:15  
**process** 9:12 19:5  
 22:22 24:20 27:14  
 35:2 39:5,17 45:12  
 47:19 67:14 82:3,5  
 92:19 94:20 99:22  
 110:18 124:22 135:3  
 135:6 139:8 141:4  
 142:20 153:8 177:7  
 184:20 190:14 196:4  
 196:13,14 199:12  
 211:6 224:17 227:20  
 227:21 228:4,15  
 236:15,16,19 237:8  
 239:14 244:11 247:7  
 258:8 326:12 327:21  
 334:11 335:18 336:10  
 351:13  
**processes** 65:22 68:22  
 77:21 81:6 92:11,13  
 183:6 198:18 238:3  
 239:11  
**produce** 187:19 326:19  
**production** 328:13  
**professional** 9:5 324:7  
**professionals** 90:12  
**professor** 1:13,15,20  
 2:4,8,9,12,15,16,18  
 16:4,6  
**profusion** 76:9  
**program** 43:6 112:3,4  
 116:16 117:13 120:17  
 120:18 131:11,15  
 140:4 170:1 189:17  
 299:22 300:1,6,12,15  
 300:18 304:5,9  
 313:15 339:19 351:5  
 381:19  
**programming** 253:16  
**programs** 1:16 121:13  
 121:20 126:16,19  
 302:17 313:10 346:6  
 349:9  
**project** 3:4,5,6 6:2,14  
 6:15 20:9 21:9 33:22  
 116:14 121:1 225:21  
 225:22 228:17 245:12  
**projects** 22:5 314:19  
**prolonged** 385:6  
**prominent** 27:7  
**promise** 63:7 200:4

**prompt** 43:8 54:14  
**properly** 201:21  
**properties** 36:16  
**Prophylactic** 125:22  
**prophylaxis** 4:7 124:11  
 125:5,6,22 126:4,7  
 128:3,6 163:14 338:4  
 355:22 356:1,4 372:5  
**proportion** 125:4  
 133:10 134:8 135:22  
 208:2 220:8 226:13  
 249:8 274:1 337:18  
 349:12 366:3 380:16  
**propose** 186:6  
**proposed** 73:14 78:3  
**proposing** 74:2 372:16  
 372:19  
**pros** 110:9  
**protect** 293:10  
**prothrombin** 299:4  
**protocol** 63:19  
**provide** 20:7,12 21:4  
 35:19 40:15 61:21  
 65:11 70:3 73:18  
 88:18 89:16 100:15  
 127:5 177:12 226:6  
 266:20 306:2 312:9  
 333:13 384:12 390:7  
 395:8  
**provided** 68:6 70:2  
 97:18 99:2 101:15  
 169:5 245:7 256:21  
 257:4 263:5 265:18  
 266:22 306:1 382:1  
 383:10 385:9,13  
 387:12  
**providers** 25:20 31:4  
 50:19 51:6 101:10  
 281:6  
**provides** 24:15 212:20  
**providing** 96:3  
**proximal** 348:1  
**proxy** 33:11 323:17  
 325:2  
**psychiatrist** 33:3  
**psychologist** 16:4  
**psychometric** 15:6  
**PT** 2:15  
**public** 2:2 4:10,22 9:9  
 9:13 18:8 23:19 27:10  
 112:22 113:7 214:2,3  
 214:7,9,10,14,17,19  
 346:6 399:8,12  
**publically** 112:3  
**publication** 74:5 180:3  
**publicly** 145:19 193:21  
**published** 287:22 322:3  
 371:6

**publishes** 150:9  
**publishing** 291:22  
**PubMed** 378:21  
**pull** 79:11 143:2 150:13  
 197:21  
**pulled** 110:2 322:13  
**pulling** 91:4 110:13  
 389:19  
**purpose** 112:7 132:17  
 198:8  
**purposes** 29:1 183:12  
 199:6  
**pursuing** 179:10  
**purview** 67:20 236:5  
 306:19 307:4 364:14  
**push** 148:10 151:15  
 294:8 325:7,12  
 387:20  
**pushing** 152:2 289:4  
 290:17  
**put** 5:20 23:16 57:1  
 63:19 67:2 109:11  
 145:7 146:22 158:15  
 160:19 161:3,21  
 186:20 190:13 201:4  
 201:8 205:2 208:17  
 211:18 215:17,22  
 216:4 233:5 237:3  
 256:10 278:15 286:10  
 286:12 307:7 328:13  
 333:11,15 345:6  
 357:13 362:16 369:2  
 373:4 388:10,13,14  
**puts** 59:7 160:16  
 295:12 355:9 362:3  
**putting** 62:17 81:5  
 85:14 111:4 196:13  
 200:2 236:5

## Q

**qualified** 58:19  
**qualify** 357:16 389:11  
**qualitative** 44:16  
**quality** 1:1,8,13 2:7 3:3  
 3:7 7:1 10:18 11:14  
 17:9,22 18:14 24:9,13  
 24:16 25:19 43:5  
 51:11 69:12,15 70:17  
 71:1 75:17 77:13  
 78:22 79:9 86:5  
 107:17 112:4 116:7  
 120:7 126:19 129:8  
 146:6,18,19 150:20  
 151:4 170:1 179:13  
 183:7 194:16 198:10  
 198:19 199:16 207:17  
 215:21 216:3,5  
 221:19,20 291:20

299:12 300:1,2,15  
 325:16 333:14 346:7  
 349:7 375:7,9  
**quantify** 66:12 76:21  
**quantitative** 30:3 44:15  
**quantity** 24:13,16  
**quarter** 51:12 108:15  
 226:5 241:17,20,22  
 243:11 248:8,14,16  
 277:6 304:13,14  
 391:11,13  
**quarterly** 129:7 191:1  
**quarters** 381:22 391:10  
**question** 47:12 50:3  
 55:16,21 62:20,21  
 66:17 70:12 72:10,12  
 75:6,21 78:21 81:14  
 83:7 84:8,9 88:2  
 103:20 104:20 118:11  
 133:18 137:9,11  
 138:8,17 144:12  
 145:16,21,22 147:21  
 153:12,17 155:10,19  
 155:21 157:15 158:17  
 163:2 167:15 177:16  
 181:2,9 182:14  
 183:19 187:8 190:18  
 192:16 197:11,13  
 201:10,15 202:8  
 204:12 216:17,19  
 227:11 228:22 237:13  
 241:13,15 251:12  
 266:6 271:11,12  
 275:3 279:15 280:17  
 284:17 288:1 293:12  
 294:16 309:6 321:9  
 342:2 354:15 364:6  
 369:16 383:3  
**questioning** 293:4  
**questions** 18:17 19:21  
 26:17 29:9 31:21 36:1  
 37:21 39:17 41:11  
 44:21 47:1 89:6 98:5  
 99:13 103:21 104:10  
 107:4 119:8 121:5  
 122:10,15 123:14  
 124:7 130:12 133:16  
 147:18 162:11 163:18  
 165:2,21 166:16  
 168:10 174:1 188:3  
 191:9 195:1 213:21  
 222:17 224:18 314:22  
 328:16 371:4 374:14  
 376:14 377:11 383:1  
 387:17 390:14 392:19  
 394:18 395:15 397:18  
 398:17 399:17  
**quibble** 127:13

**quick** 10:9 64:19 90:19  
 91:15 162:12 294:5  
 332:19 344:4 347:11  
 378:21  
**quicker** 9:1  
**quickest** 81:3  
**quickly** 7:11 8:20 61:2  
 63:12 162:6 239:9  
**quite** 49:10 77:11  
 103:15,19,22 114:17  
 141:18 160:17 164:14  
 165:14 223:16 235:15  
 306:6 308:21 366:22  
 375:3 377:4,10 397:2  
**quiz** 94:14

## R

**R24** 15:22  
**race** 80:5 132:18 133:7  
 133:12 180:8,16  
 258:8 392:6  
**racial** 147:13 177:5  
 178:9,11,18 180:1  
 283:3  
**racial-ethnic** 153:10,13  
**radar** 217:2  
**radiographic** 59:11  
**radiologist** 15:15 59:22  
 66:1 109:20 294:5  
**radiology** 2:4 77:4  
 109:18  
**Rae-Grant** 2:11 17:18  
 17:18 67:11 99:15  
 103:22 135:2 153:7  
 176:20 236:2 288:4,9  
 288:13 317:13 372:15  
 373:7  
**raise** 271:12 287:12  
 336:20  
**raised** 255:7 280:6  
 288:4,5,21 289:2  
 378:11  
**raises** 72:13 245:8  
 284:6 288:1  
**raising** 178:4 278:21  
**random** 266:13  
**randomized** 57:8 76:3  
 90:21 251:2 340:12  
**randomly** 82:22  
**range** 97:18 245:15  
 266:11 391:19 397:6  
**ranges** 256:15 259:4  
**rank** 308:11  
**ranked** 399:15  
**ranking** 394:16 397:13  
 397:14  
**rapid** 44:1 65:11,13,15  
 72:3 73:7 75:10

289:21 290:6,10  
**rapidly** 62:10 239:12  
 289:18  
**rate** 31:8 56:5 99:3  
 112:6 131:3,5,12  
 132:10 175:11 259:19  
 283:9 290:13 291:3  
 308:11 309:3 342:9  
 368:10 370:19 375:15  
**rated** 48:9 306:15  
 376:13 394:9  
**rates** 281:10,11 283:8  
 283:21 284:1  
**rating** 47:5 98:1 99:7  
 131:17 162:6 165:19  
 165:20 188:18 308:2  
 308:13 316:12 343:7  
 343:22 368:14 372:16  
 372:17 373:8 374:13  
 392:18  
**ratings** 48:7 221:15  
 348:2  
**ratio** 176:5  
**rationale** 81:19 125:20  
 249:14 266:21 304:20  
 345:13 366:18 380:21  
 383:11  
**raw** 273:21  
**re-** 334:16  
**re-done** 375:15  
**re-endorsement** 252:12  
 334:8  
**re-evaluation** 217:4  
**re-hospitalization**  
 378:9  
**re-review** 248:13 301:5  
**re-reviewing** 359:22  
**reach** 70:18 204:22  
 252:19  
**reached** 160:20 161:4  
 167:11 318:19  
**reaching** 257:14,20  
**reactions** 290:19  
**read** 34:21 59:4 60:4  
 66:11 67:5 78:11 94:9  
 110:6 197:22 210:5,6  
 275:1 294:6 322:15  
 347:10  
**readily** 106:7 321:12  
**ready** 116:9 150:5  
 159:17 160:3 165:2  
 165:22 174:18 182:2  
 192:4 193:8 195:2  
 216:12 218:21 222:18  
 305:16 390:14  
**real** 52:11 66:22 75:11  
 80:12 101:21 190:16  
 204:12 256:21 257:6

257:8 271:5 276:3  
 320:20 322:7 324:5,6  
 336:9 347:11  
**real-world** 320:4 321:7  
**realistic** 59:13 67:7  
**realistically** 86:9  
**reality** 218:12 239:14  
 272:10 327:2  
**realize** 157:7 202:22  
 264:20 291:8,19  
 295:4 307:8 308:14  
 344:5  
**really** 5:21 7:10,21 9:22  
 11:3 22:13,21 23:5,9  
 23:22 24:19 25:18  
 26:14 28:6 31:13  
 34:18 42:4 48:22 53:5  
 53:8 67:13 68:17 69:4  
 72:17 75:20 78:10  
 81:1,11 83:10 90:2,19  
 93:4 96:2 98:17,19  
 99:2 100:6 101:1  
 103:14,16 108:16  
 109:9 119:13,21  
 123:22 132:6,7,16  
 134:20 136:9 142:14  
 143:21 144:17 159:14  
 168:2 176:22 186:11  
 202:7 216:4 230:7  
 232:9 234:9 250:21  
 251:11 253:15 256:12  
 270:17 276:2 301:5  
 306:6 312:17 324:6  
 326:1 335:6 351:21  
 357:14 364:2,4,12  
 377:8 383:18 388:8  
**reason** 9:11 56:2 85:11  
 103:6 128:3 129:11  
 132:8 145:18 146:7  
 162:14 163:14 170:21  
 170:22 179:21 190:10  
 192:17 196:10 203:13  
 221:18,21,22 246:1  
 252:16,19 253:6,10  
 253:13,16,22 254:2  
 254:11,20 261:12  
 264:12 265:2 266:2,3  
 267:3 268:5 269:10  
 274:13,16,17 275:4,6  
 275:6,7,14,20 276:5  
 278:4 281:2,5 282:9  
 282:13,15,16,22  
 286:12 339:1,2 350:5  
 355:8,14 356:8,8,10  
 362:14 384:1,9,10  
 386:11,15 390:8,11  
 397:14  
**reasonable** 58:4 65:14

76:16 77:14 78:9  
 84:16 177:11 223:16  
 224:16 235:21 261:21  
 282:19,21 283:12  
 291:17 294:16 343:6  
 364:15  
**reasonably** 232:7  
 261:14 377:4  
**reasons** 96:19 174:3  
 247:5 254:7,13 255:1  
 261:19 266:20 275:15  
 281:7,21 282:5  
 298:19 378:3 384:12  
 387:2 394:2  
**recalculated** 173:1  
**recall** 9:3  
**recannulization** 58:16  
**receive** 13:5 21:9 38:13  
 134:1 162:14,16  
 250:16 252:2,10  
 253:8 366:21  
**received** 9:3 21:12,16  
 42:18 125:5 173:8  
 225:22 226:4 308:22  
 309:10,12 328:11  
 335:4 366:4 367:12  
 374:13  
**receiving** 259:3  
**recessed** 215:3  
**recognizable** 291:2  
**recognize** 82:10 111:9  
 295:1  
**recognizing** 71:5  
**recommend** 75:7  
**recommendation** 61:14  
 66:7 75:10 126:3,5,6  
 130:5,7 137:14  
 148:11 162:7 166:14  
 174:14 216:18 233:2  
 243:7 279:19 280:2,4  
 280:10 316:4 339:10  
 341:12 350:10,13  
 364:18 382:12  
**recommendations** 34:5  
 45:17 46:11 74:3  
 220:15 232:20 333:16  
**recommended** 17:20  
 37:16 45:20 46:1  
 126:1 129:18 157:5  
**recommending** 233:6  
**recommends** 339:11  
**reconceptualizing**  
 234:9  
**reconsider** 138:15  
 157:6 362:8  
**reconsideration** 39:5  
 139:5  
**reconvene** 115:11

215:3  
**reconvening** 215:1  
 401:15  
**record** 42:1 50:15,17,22  
 51:4,8 102:9,10  
 106:19 110:8 115:16  
 118:6 123:10,20  
 136:17 137:17 199:15  
 218:4 282:8 288:9  
 326:9 337:1 383:20  
 384:4 398:12,15  
**recorded** 34:15 172:12  
**recording** 109:4  
**records** 50:11 106:13  
 113:8 265:6 268:15  
 301:18 320:5 342:21  
 394:10,15 398:7  
**recurring** 233:16  
**recusing** 11:15  
**recut** 253:12  
**red** 8:12 265:4  
**red-lined** 312:9  
**reduce** 293:6 351:15  
**reduced** 233:15 271:9  
 271:10  
**reduces** 173:21  
**reducing** 169:18 221:10  
 234:2 339:8  
**redundant** 93:1  
**reevaluating** 172:11  
**reference** 90:6 224:3  
**references** 176:21  
**referral** 379:8  
**referrals** 378:20  
**referred** 104:7 221:9  
 312:16 350:17  
**referring** 270:8  
**refers** 312:18,20  
**refine** 336:11  
**reflect** 226:9 229:21  
 232:11 235:22 331:22  
 360:2  
**reflective** 113:9 226:7  
 310:18  
**reflects** 231:8,10  
 324:14  
**refocusing** 145:11  
**refusal** 162:15 299:9  
**regard** 280:14  
**regarded** 97:20  
**regarding** 122:16 171:3  
 351:19 371:16 374:2  
 389:14  
**regardless** 108:21  
**regards** 270:6 290:12  
**Regents** 1:12 12:18  
**regions** 181:8  
**register** 105:6



**registering** 104:22  
**registry** 14:6,7 126:21  
 170:2 193:19 349:8  
**regression** 152:22  
**regs** 161:11  
**regular** 116:19 333:15  
**regulation** 129:5  
**rehab** 2:19 15:3 367:12  
 367:22  
**rehabilitation** 1:18 4:18  
 12:6 15:1,21 365:20  
 366:1,4,20,21 367:3  
 369:7,14,18,20 370:4  
 370:7,11 371:6,17  
 374:3  
**rehash** 337:10  
**reinforce** 18:22  
**Reintroducing** 304:3  
**related** 15:7,22 46:5  
 99:14 107:2 114:6,10  
 125:16 131:22 144:1  
 144:2 147:13 170:10  
 210:14 261:9 339:9  
 349:20 366:11 378:3  
 381:13  
**relates** 70:7 251:11  
 255:13 303:3,5  
**relationship** 81:17  
**relative** 278:1 375:8  
**relatively** 121:22 138:1  
**relax** 68:13  
**released** 229:18  
**relevant** 9:16,17 13:15  
 56:17 72:4,18  
**reliability** 26:3,9,11  
 36:17 48:16 97:14,17  
 97:21 98:2,7,13 99:16  
 100:7,12 101:5,8  
 104:6 161:9,15 162:1  
 162:9,18,19 163:6,16  
 163:19,21 164:6  
 187:14 188:1,6,12,15  
 201:3 222:9 260:16  
 260:17,18 261:5,10  
 261:21 262:9 277:9  
 301:9,13,22 303:5  
 305:3,20 306:13  
 307:13 308:8,9,13  
 315:17 316:9,10,12  
 316:15,19,19 317:20  
 317:22 326:22 331:16  
 342:4,5,6,8,14 348:2  
 352:22 353:7,8  
 357:21 358:2,9 374:1  
 374:8,13,17 375:1  
 393:7 394:9 395:5,17  
 395:22  
**reliable** 28:15 51:10,15

80:6 162:4 183:4  
 187:21 198:10,16  
 261:14 302:3 303:14  
 317:3,5  
**reliant** 343:21  
**relied** 252:13  
**relies** 308:9  
**relook** 202:8  
**rely** 108:18 282:22  
 385:21  
**relying** 326:10  
**remaining** 197:13  
**remember** 7:13 28:8  
 119:2 203:11 220:1  
 234:18  
**remembering** 312:12  
**remind** 317:15  
**reminder** 10:9 138:20  
**reminders** 18:21  
**remote** 37:7 93:7,12,13  
**remove** 179:8 183:15  
 210:15 217:5  
**renditions** 351:18  
**reopen** 105:18  
**repeat** 29:11 187:22  
 253:13 255:3 385:6  
**repeated** 253:14  
**repetitive** 21:22  
**rephrase** 84:12 176:12  
 274:22  
**replaces** 206:3  
**report** 25:17 36:13  
 109:18 112:12 119:5  
 157:4 160:20 161:22  
 163:16 320:15,22  
 321:6 322:14 325:13  
 326:20 347:16  
**reported** 112:3,22  
 113:13 138:2 171:4  
 172:22 176:8 180:2  
 193:21 244:13,15  
 287:16 299:18 304:13  
 327:5 376:11 377:5  
**reporting** 27:10 43:6  
 106:16 112:4 113:7  
 126:19 129:9 133:14  
 170:1 172:17 180:16  
 277:8 300:1,7,9,15  
 323:12 328:2 346:6  
 349:7 379:6 399:8  
**reports** 112:5 282:14  
 292:18  
**represent** 10:11,11  
 11:11 19:3 258:1  
 271:8 343:22  
**representation** 94:18  
**representative** 14:5  
 17:7 101:17 110:1

**representatives** 14:16  
**representing** 15:3 31:3  
 219:19  
**represents** 224:11  
**request** 13:13 139:5  
 210:18 291:20 323:2  
**requested** 304:22 306:2  
**require** 26:8 54:1  
 100:11 106:7 108:18  
 110:13 282:8 307:12  
**required** 26:8 94:12  
 106:17 128:8 304:11  
 304:12,17 321:12  
 322:7 345:6  
**requirement** 304:7  
 315:6  
**requirements** 82:4  
 113:6  
**requires** 25:6 127:19  
**requiring** 231:4 300:17  
 302:10 386:13  
**research** 10:3 13:15  
 43:3 46:18 378:19  
**researcher** 2:10 16:15  
**reserve** 28:5,13,19  
 31:14,17,18 32:5,9,12  
 135:9 136:2 137:7  
 141:16,21 142:6,9,17  
 143:2,6 145:7,17,19  
 146:8 153:22 154:9  
 154:11 155:1 156:1,2  
 158:13 161:2,17  
 167:5,7,7,15 181:19  
 181:21 183:1,8,18  
 184:4,21 185:2,3,7,16  
 185:17 186:3,7,11,20  
 187:9 195:18 196:2,5  
 197:12,18,19 198:7,9  
 199:2,17 200:2,11,22  
 201:5,13,15 202:3  
 203:9,20 204:2,7  
 205:9 207:22 208:18  
 209:20 210:11,20  
 211:19 212:16,22  
 213:4 215:7,13,14,17  
 216:1,11,22 217:12  
 219:3,6 237:4 342:2  
 347:8,14,18 348:8,13  
 352:9 362:5,8,9,11,14  
 362:17 363:10,15  
 364:16,20 365:1,5  
 377:22 378:2 379:15  
 379:17,21  
**resident** 109:21 110:3  
**residents** 77:3,4  
**resist** 217:11  
**resolve** 200:15  
**resolved** 45:18

**resolving** 80:2  
**resource** 149:20 216:5  
**resources** 77:11 152:11  
 208:17,19 364:5  
**respect** 211:1 301:13  
**respond** 34:6,8 264:9  
**response** 93:20 94:5  
 173:9 355:16  
**responses** 111:16  
 115:5 400:12  
**responsibility** 292:2  
**responsible** 209:13  
 212:18  
**responsive** 142:3  
 239:14  
**rest** 154:22 186:4 187:7  
 234:18 248:11,15  
 318:9 351:5  
**restart** 189:19  
**restate** 159:19 393:9  
**restatement** 187:17  
**restating** 85:20  
**restrained** 95:22  
**restrict** 127:20  
**restricted** 127:18 128:2  
**resubmitted** 172:20  
**result** 140:9 187:22  
 246:8 265:19  
**results** 4:3 38:12 42:12  
 42:17 57:10 94:9  
 95:11 97:8 98:10  
 101:14 104:16 106:1  
 112:1 113:22 130:19  
 134:6 140:5 160:10  
 164:4,11,19 165:8  
 166:7 167:1 175:2  
 182:7 188:9 192:9  
 193:11,13 195:7  
 260:9 263:2 265:13  
 266:7,9,14 285:4,21  
 286:21 296:3,17  
 299:1 318:3 319:16  
 327:19 329:17 330:22  
 331:1,10 332:7  
 341:18 343:14 345:21  
 346:16 348:6 352:17  
 358:6 360:11 361:5  
 361:20 365:3 373:16  
 374:17,20 376:5,20  
 377:7,17 379:19  
 382:17 390:20 393:3  
 395:19 398:1,22  
 400:1  
**resume** 10:1  
**resumed** 42:1 115:16  
 337:1  
**retain** 198:10 236:19  
 237:2 373:7

**retained** 266:19  
**retains** 28:20 183:9  
 198:8 199:2  
**rethink** 161:7 294:17  
**retire** 147:8 149:8,21  
 151:4  
**retired** 10:16,16 148:7  
 150:20 151:8 209:3  
**retirement** 150:6  
**return** 210:20 214:5  
**Reuven** 2:3 107:6 181:1  
 205:6 208:22 293:11  
 306:3 321:2 328:16  
 330:15 331:21  
**Reuvin** 280:16  
**revascularization** 74:7  
**revascularize** 73:1,2,4  
 87:3  
**revascularizing** 91:1  
**revascularization** 233:17  
**reversible** 387:3 394:4  
**reverting** 141:10  
**review** 9:7 23:6,8,10  
 34:7 38:1 68:5,22  
 116:6,10 117:9,19  
 118:15 119:15,16  
 135:11,12 139:2  
 149:19 171:11 191:1  
 210:9,10,11,18  
 211:13 227:17 231:20  
 237:11 244:20 283:1  
 331:10 335:15 346:11  
 347:15 352:8 382:14  
 387:10 398:8  
**reviewed** 18:2 20:15  
 43:6 152:19 210:8  
 368:4  
**reviewers** 367:6  
**reviewing** 5:20 33:22  
 38:8 116:15 118:2  
 124:2 150:14 313:17  
**reviews** 268:1  
**revise** 281:22  
**revision** 253:4  
**revisit** 155:8 215:7  
**revote** 39:14 105:7,17  
 161:7 292:21 295:19  
 295:22  
**revoting** 139:6 293:1  
**rewrite** 69:9  
**rid** 217:22 233:22  
**right** 26:19 34:16 42:3  
 48:17 49:18 61:18  
 62:8 64:22 66:9 69:16  
 69:21 75:18 83:22  
 88:5 94:13,17 95:15  
 97:12 105:2 109:5,6,9  
 111:6 114:18 115:7

115:20 117:17 134:10  
 137:20 139:5,13  
 141:5 143:7 150:8  
 151:17 152:10 154:2  
 154:3 155:2 157:5  
 158:6 160:2 167:16  
 174:12 180:20 181:5  
 185:4,14,20 186:10  
 187:14,15 197:9  
 198:1 199:9 200:22  
 201:3 203:19 205:13  
 205:15,17,20 211:20  
 212:1 214:5 215:12  
 217:17 219:9 220:19  
 221:1,2 223:3 227:22  
 228:21 230:4,14  
 234:6 236:7 237:16  
 237:17,18,20 238:5,9  
 238:16 240:2 241:15  
 242:18 243:12 244:10  
 245:11,15 248:3  
 254:2,6,9,11,16,22  
 256:9 263:16 268:12  
 268:21 269:4,10,15  
 269:18 271:16 274:18  
 274:19,21 275:7  
 278:2 279:7,12  
 291:10 293:19 295:13  
 297:5 301:6,8,9  
 310:16 313:4,6  
 314:20 316:7 317:19  
 320:1 323:17 330:4  
 333:1 337:3 340:8,17  
 342:12 347:4,9  
 348:15,19 355:14,17  
 358:6 363:13 380:7  
 385:11  
**rising** 205:21 283:9,22  
**risk** 26:10 62:17 125:21  
 126:2 146:15 175:22  
 178:7 233:15 282:11  
 283:15 289:10,17  
 291:16 293:14 294:9  
 351:16  
**risk/benefit** 292:13  
**RN** 1:17  
**road** 153:1  
**robust** 21:4 400:18  
**role** 14:10 20:21 21:18  
 33:9,10 145:6 151:16  
 202:1  
**roll** 60:11 327:2  
**Ron** 17:3 63:14 87:13  
 90:4 92:2 308:17  
 382:6,8,21 383:4  
 387:7 388:5 397:1  
**Ronald** 2:10 90:20  
**room** 1:8 35:4 42:6 47:1

49:7 51:2 57:16 58:2  
 63:8,20 64:18 65:2  
 91:6,13 175:13  
 176:15,18 214:10,21  
 258:6 282:2  
**Ross** 2:18 15:17 367:7  
 377:22  
**rough** 242:8  
**route** 75:15 217:18  
**routinely** 142:2  
**RTI** 2:11 16:14  
**Rubin** 250:7 258:18  
**ruin** 38:4  
**rule** 34:22 46:1,2  
 100:16,18 101:1  
 103:15 306:11  
**rules** 34:12 100:14  
 103:10,12 184:16  
**run** 122:22 146:14  
 230:13,20  
**running** 41:18 51:6  
 63:22 242:5 318:12  
 328:18 371:1  
**runs** 51:1  
**rush** 246:13  
**rushing** 62:15  
**RV** 10:21  
**Ryan** 2:12 16:18,18  
 78:1 144:1,20 186:18  
 186:22 382:7 386:22  
 391:3 393:8 395:7  
 396:2 398:6 399:5

---

**S**

---

**safeguard** 149:6,12  
**safely** 250:2  
**safety** 11:5 280:22  
**sample** 101:15 103:16  
 108:14 325:15  
**sands** 50:8  
**satisfy** 120:6  
**Savaysa** 356:17  
**save** 73:3  
**saw** 143:14 230:16  
 270:18  
**saying** 8:18 32:7 57:6  
 136:4 149:3 150:6,7  
 160:22 161:16 173:13  
 184:9 203:14,20,21  
 207:3 222:9 237:6  
 240:12 244:7,12,14  
 244:16 246:3 251:19  
 251:21 254:15 263:6  
 292:7 355:16 362:12  
 384:20 385:17 388:8  
**says** 51:21 52:14,15  
 55:22 61:4 64:14 87:6  
 130:8 133:5 155:22

164:12 180:22 208:10  
 221:16 235:1 240:14  
 264:1,22 265:1  
 267:10 269:1,1  
 282:14 294:10 295:9  
 315:21 384:5  
**scale** 236:17 237:17  
 328:14  
**scan** 4:3 38:12,14 42:12  
 42:17,19 58:3,11,20  
 59:18,20 60:3,16  
 64:12,17 65:3,7 66:11  
 66:17,19 67:2,3,4,5  
 68:15 74:20 75:11  
 76:16 80:18 86:11,15  
 88:21 90:9 91:6,16  
 92:4 96:14 112:6  
 236:22  
**scanner** 60:12 64:20  
 65:8 77:4,5  
**scans** 43:15 57:21  
 64:22 76:18  
**scarcity** 364:5  
**scenario** 160:14 245:18  
**scenarios** 104:5  
**schedule** 38:3 211:14  
**scheduled** 365:8  
**Schmaltz** 279:9,10  
**Schmidt** 2:13 11:18,18  
 51:17 82:6 127:3  
 128:13 129:21 130:6  
 131:1 137:12 140:2  
 140:16 146:13 158:15  
 161:14 162:1,20  
 164:8 165:13 166:11  
 204:18 231:17 232:16  
 268:8 271:20 272:14  
 315:16 316:2,9,14,18  
 316:22 317:7 323:7  
 362:19 378:17  
**school** 1:20 2:2,4,20  
 12:11 13:4 16:16 33:2  
**Schwamm** 3:10 219:18  
 220:3 224:20 226:10  
 230:11 231:10 233:8  
 242:3 244:22 258:6  
 269:6 281:13 284:10  
 289:7,8 304:3 325:5  
 326:4 345:2 354:14  
 354:20 355:13 356:20  
 357:8,10 385:7,12  
 386:6  
**Sciences** 2:6  
**scientific** 26:2,22 36:15  
 44:18 97:13 117:10  
 118:20 119:17 120:14  
 121:3 124:2  
**scientifically** 21:2

**SCIP** 356:2  
**sclerosis** 18:1 22:9  
**scope** 328:19 329:2  
 363:22 364:3  
**score** 11:5 100:8,11  
 102:12 103:2 118:21  
 131:3 188:17 261:1  
 298:18 320:10,14,16  
 320:17 342:20 374:12  
 396:3  
**scored** 191:3  
**scoring** 320:20  
**screen** 38:10 93:21  
 224:1  
**screens** 260:1  
**script** 35:15,18 38:6  
 187:16  
**scroll** 312:7  
**SDS** 26:18  
**se** 29:18 253:17  
**search** 190:9 378:21  
**season** 205:9  
**seat** 7:14 188:22 327:8  
**seated** 35:7  
**seating** 9:7  
**seats** 35:7  
**Seattle** 11:9  
**sec** 39:20  
**second** 11:20 25:16  
 41:15 46:10 63:11  
 70:10 84:20 86:13  
 145:22 146:20 195:22  
 197:21 236:14 345:9  
 391:10,13  
**secondary** 169:16  
 180:17 229:19 234:14  
 368:2 383:7  
**seconds** 60:1,4 299:5,7  
**section** 1:16 48:5,7  
 95:17 119:18 161:14  
 187:6 268:9 312:8  
 379:2  
**sections** 48:1,3 49:11  
**see** 5:14 22:6 23:16,20  
 24:21 30:21 31:1  
 38:20 39:21 40:18  
 41:5,15,20 86:10  
 97:22 100:10,12,17  
 100:20 101:12 102:9  
 102:11 103:20 110:7  
 117:7 120:15,19  
 131:1 136:10,11  
 141:9 143:3 144:16  
 144:20 148:8 150:8  
 152:3 153:4 156:5  
 157:9 159:11 161:10  
 164:16 165:16 167:12  
 189:6 197:9 202:9

213:13 214:4 219:16  
 224:2,6,21 230:2  
 237:10 240:5,9 241:4  
 243:18,22 246:12  
 256:14,18 257:22,22  
 271:16 273:13 277:4  
 278:16 283:7 303:8  
 308:11,13 311:13  
 312:8 315:21 320:3,7  
 329:4,11 332:13  
 336:14 340:19 359:3  
 359:8,9 372:22  
 391:16,16,21  
**seeing** 79:3 97:2 101:9  
 101:19 140:7 164:19  
 208:3,4 214:22  
 221:20 262:15 274:8  
 293:22 341:11 363:15  
**seen** 23:4,5 24:6 27:16  
 28:17 49:6 63:16  
 104:4 146:14 150:7  
 159:3 267:22 268:1  
 293:22 326:14 363:3  
**sees** 142:12  
**Segue** 374:3  
**select** 252:17 269:7,8  
 269:14 300:21 350:21  
**selected** 259:7 308:1  
**selections** 93:11  
**semantic** 254:14  
**sending** 190:10  
**sends** 57:19  
**senior** 1:19 2:13 3:3,6,7  
 6:1 23:7  
**sense** 24:10 54:6 56:22  
 57:6,20 64:10,19  
 72:22 79:15 92:15  
 100:2 118:18 149:3  
 171:14 185:18 209:5  
 212:4 237:4 238:20  
 238:21 240:14 251:2  
 269:5,20 271:17  
 272:8 273:14 274:1,6  
 274:7,9 277:21 278:1  
 284:5 291:3 311:12  
 316:4 333:22 334:2,3  
 353:15 375:20 385:11  
**sensitive** 338:3  
**sent** 171:9 242:4 272:9  
 288:18 358:22 387:14  
**separate** 36:14 79:4,5  
 168:4 205:10 233:11  
 261:18 308:9 388:1  
**sequelae** 137:5  
**sequence** 54:10 55:1,3  
 55:4 273:19  
**sequential** 126:7  
**series** 44:15 124:15

269:22 368:7  
**serious** 381:3  
**seriously** 95:2  
**serve** 10:9 11:4 33:18  
 238:21  
**served** 8:18 10:19  
**service** 10:12 64:5  
 90:17 369:18,20  
 370:5  
**services** 2:10 16:14  
 366:5,20,21 367:3,12  
 371:17 378:6  
**serving** 7:3  
**session** 115:19  
**set** 12:5 17:8 120:4  
 122:21 123:5 124:16  
 129:14 151:2 179:14  
 211:14,14 219:12  
 262:15,16,18 263:8  
 263:22 266:5 267:2,4  
 267:7 325:15 333:2  
 337:5 362:15 363:8  
 379:5 381:8 398:12  
**sets** 129:15 262:14  
 264:15 322:3,3 356:2  
**setting** 26:17 56:11  
 215:10  
**settings** 83:12  
**seven** 57:8 76:3 90:21  
 361:11 375:4 377:6  
**severity** 396:9,12  
**share** 32:19 146:21  
 150:18 189:4,9 242:1  
 328:8 371:12  
**shared** 36:3 37:21  
 355:22  
**SharePoint** 173:6 359:2  
**sheet** 13:17  
**shelf** 142:21  
**Shield** 17:5  
**shift** 145:2 267:20  
 302:5 306:17  
**ship** 338:22  
**shooting** 90:2  
**short** 115:11 264:21  
 357:4  
**shorter** 88:13 90:1  
**show** 57:9 94:2 97:18  
 158:20 201:15 240:8  
 241:11 243:1 247:16  
 247:17 250:1 261:21  
 262:19 273:7 277:19  
 303:13 322:1 325:12  
 354:17  
**showcase** 21:14  
**showed** 60:2 90:21  
 233:14 261:4 268:4  
 342:8 382:15

**showing** 31:8 52:4,4  
 55:18 59:20 83:3  
 187:20 256:16 265:5  
 265:5 273:13  
**shown** 58:14 69:11  
 201:18 202:3 301:17  
 340:12 344:21  
**shows** 54:12 60:9 63:21  
 86:22 96:4 158:19  
 251:8 262:17 267:6  
 267:20 321:21 393:21  
**shrinking** 283:8  
**shunt** 294:4,7  
**shunts** 294:3  
**side** 79:14 206:1 247:1  
**sideways** 359:6  
**sign** 109:22  
**signal** 22:12 100:13  
 101:20 145:10 161:20  
**signaling** 143:17 204:4  
**signals** 11:1 142:17  
**significant** 10:3 29:12  
 111:8 133:10,11,15  
 207:3 226:11 270:20  
 284:3 293:15 358:16  
 370:15 372:11 382:18  
**significantly** 120:22  
 140:4  
**signs** 55:20 299:19  
**silly** 186:19  
**similar** 21:15 46:12  
 291:5 338:2,4 349:15  
 366:7 372:5 391:4  
**simple** 271:3 272:5,6  
 278:7,14 280:12  
**simpler** 54:16  
**simply** 54:14 293:3  
**simulated** 302:19  
**Simultaneous** 144:19  
 384:16  
**single** 34:21 120:5  
**sir** 177:15 387:17  
**sit** 7:14 18:22 19:13  
 151:21 213:11 363:16  
**site** 359:2  
**sites** 345:6 391:8,11,12  
 394:9  
**sitting** 50:5  
**situation** 150:2 200:11  
 257:16  
**six** 10:22 120:20 229:13  
 235:20 343:1 357:2  
 375:5  
**skip** 348:12  
**Skipper** 3:6 6:13,14  
 32:16 33:8 95:3 173:4  
 216:14  
**skipping** 72:15 380:2

<b>Skull</b> 1:15	199:16 207:10,15	<b>specifies</b> 127:17 254:1	259:20 269:20 365:19
<b>slavish</b> 236:10	217:6 232:4 237:13	<b>specify</b> 75:12 101:2,4	367:8
<b>sleep</b> 310:8	239:7 241:5 256:15	123:4 310:19	<b>started</b> 5:4 7:7 20:6,7
<b>slice</b> 132:19	264:21 268:1 318:10	<b>spectrum</b> 284:6	32:17 39:17 62:9
<b>slide</b> 34:22 116:12	327:20 332:22 333:6	<b>speed</b> 87:10	92:12
201:9	335:2 339:21 351:18	<b>spend</b> 25:12 28:4 97:15	<b>starting</b> 120:15,19
<b>slides</b> 21:13 93:16,18	351:19 359:22 364:4	155:6 270:1 359:21	<b>starts</b> 64:2,8 151:10
118:9	367:13 369:1	<b>spending</b> 150:16	<b>state</b> 37:11 237:14
<b>slightly</b> 118:1 144:1	<b>sound</b> 21:2 206:10	335:19	265:14 298:11 299:3
170:4 281:19	239:5	<b>spent</b> 6:6 106:10	299:20 308:19 309:20
<b>slip</b> 151:11	<b>sounds</b> 148:4 191:1	305:11	310:17 311:1
<b>slipped</b> 162:21	206:9 239:3 243:9,11	<b>split</b> 160:15	<b>stated</b> 81:19 266:10
<b>slow</b> 69:4	272:2	<b>spoke</b> 195:17 271:15	<b>statement</b> 97:19 113:2
<b>slower</b> 87:9	<b>source</b> 26:16 190:22	<b>squarely</b> 326:1	140:16 159:9 182:18
<b>slowly</b> 68:14	334:13 398:6	<b>stable</b> 238:7	311:19 312:19 353:1
<b>small</b> 31:5 59:5 94:2	<b>Southern</b> 2:16 18:8	<b>staff</b> 1:13 3:1 6:12	395:13
137:22 138:2 176:11	<b>space</b> 206:16	19:19,20 23:5 24:17	<b>statements</b> 74:4 78:7
176:14 193:4 207:2	<b>Spalding</b> 15:18	115:22 144:9 195:17	127:14 310:22
368:11 369:19 370:3	<b>SPARCL</b> 233:13	213:12 214:1 222:4	<b>states</b> 113:5 368:8
<b>smaller</b> 107:21 270:14	<b>spare</b> 362:17	263:18 308:1 321:9	<b>statin</b> 219:22 220:6,9
277:6 368:7	<b>speak</b> 5:13 19:12,16	333:14 334:20	221:5 230:22 231:5
<b>so-called</b> 267:9	34:14 42:11,16	<b>staggering</b> 242:16	231:11,12 233:4,6,14
<b>socialize</b> 335:20	180:15 324:11 371:8	<b>stairs</b> 60:22	233:21 234:7,11
<b>societies</b> 57:12 73:14	<b>speaker's</b> 13:18	<b>stakeholders</b> 83:20	236:20,20
<b>Society</b> 17:15 74:1	<b>speaking</b> 8:15 10:3	<b>stand</b> 66:4 94:14	<b>statins</b> 221:10 231:1,1
<b>sociodemographic</b>	144:19 384:16	275:15 302:20 384:12	231:4 233:13 235:4
26:18	<b>speaks</b> 24:12 25:18	<b>stand-</b> 386:14	238:1
<b>software</b> 325:14	28:7	<b>stand-alone</b> 275:20	<b>statistic</b> 99:5
<b>solicit</b> 21:8	<b>spec</b> 233:11	386:10 387:2 390:11	<b>statistical</b> 263:3 265:13
<b>solid</b> 32:2	<b>specialization</b> 18:9	394:2	<b>statistically</b> 101:17
<b>solve</b> 295:14	<b>specialty</b> 14:5	<b>standard</b> 69:12,15 70:4	382:18
<b>somebody</b> 55:10,12	<b>specific</b> 30:3 33:5	70:16 73:10 83:21	<b>statistician</b> 324:3
68:21 80:17 86:22	49:10 75:7 79:1 81:7	88:22 98:20 99:12	<b>statisticians</b> 133:14
105:5 240:13 254:8	81:8 122:15 126:16	139:8 178:17 180:19	<b>statistics</b> 103:5 265:17
262:1 267:17,19	133:21 162:17 168:22	199:12 202:4 227:19	<b>status</b> 28:6,13,14,20
282:8 292:19 323:9	176:2 190:5 224:5	244:5 282:7 303:6,10	31:14,17,18 32:5,9,13
340:17 399:13	254:17 275:5 282:9	303:11,12 307:3	102:21 135:9 136:2
<b>somebody's</b> 62:15	290:11 309:8 326:20	344:10	141:16,21,21 142:9
82:20 93:2 278:15	341:9 356:5 381:18	<b>standardization</b> 108:19	142:17 143:6 146:8
<b>somewhat</b> 46:3 66:13	383:15	<b>standardized</b> 183:6	155:1 156:1,2 161:2
191:3 290:20	<b>specifically</b> 70:1 74:13	198:18	161:17 167:6,8,15
<b>soon</b> 65:1 257:13	163:11 170:14 306:15	<b>standards</b> 70:20 91:3,7	181:19,21 183:1,3,9
357:17	370:16 384:18 399:14	183:13 256:13 301:16	183:19 184:21 185:2
<b>sorry</b> 32:22 66:7 85:9	<b>specification</b> 26:9	<b>standing</b> 1:3,7 25:10	185:7,16,17 186:4
107:6 122:3 124:12	131:16 232:15 235:14	33:9,10,17,17 117:8	195:18 196:2,5
140:19 171:17 182:12	<b>specifications</b> 26:5	120:10 143:9 210:10	197:12,18,19 198:7,9
189:5 198:4 210:3	78:14 106:6 119:19	210:15,19 239:13	198:15 199:2 200:2,9
223:22 224:2 228:1	225:15,16 226:2,21	<b>standpoint</b> 70:13,22	200:12 201:5,13
240:13 262:16 263:11	230:6 231:8 232:4	71:4 255:12,22	202:3 203:9 204:7
274:12 279:16 284:16	234:21,22 236:1	256:19 261:21	205:10 209:7,20
297:18 309:22 311:13	300:8	<b>stands</b> 39:2 162:8	210:8,12,16 211:19
319:9 323:5,21 344:3	<b>specificity</b> 138:19	<b>star</b> 214:17 401:5	212:16,22 213:4
345:1 346:18 348:14	<b>specifics</b> 297:13	<b>start</b> 10:14 35:8 36:12	215:8,13,14,18 216:1
356:12	<b>specified</b> 109:15	42:4,14 45:7 54:17	216:11,22 217:12
<b>sort</b> 30:4 47:22 48:1	110:12 117:14 122:10	64:3 72:8 75:14 91:22	219:3,7 237:4 289:21
71:18 73:8,9 75:15,17	138:11 159:22 227:14	97:13 104:1 115:13	335:14 342:3 347:14
82:16 104:4,7 134:11	237:19 242:12 274:14	124:15 127:6 161:15	347:19 348:8,13
140:22 153:5 199:9	300:4 311:10	198:8 220:22 257:13	352:9 362:5,11,17

363:10,15 364:21  
 365:1,5 368:12  
 372:20 373:5 377:22  
 378:2 379:15,17,21  
**stay** 125:11,13 170:7  
 238:7 338:8,10  
 349:17 366:5,9 367:4  
 367:21 375:13 381:10  
 393:15  
**stayed** 341:1  
**steering** 148:14,15,18  
 151:1,13 198:3 235:9  
**stenosis** 273:1  
**step** 36:4 66:9 71:19  
 74:14 87:6,6 179:13  
 179:13 234:3  
**Stephen** 2:5 45:4,6  
 279:9 287:15  
**steps** 55:3,4 62:8 74:18  
 74:20 81:10 86:20  
**Steve** 13:9,10 38:22  
 48:12 57:6 61:11  
 63:11,14 78:16 85:20  
 92:8 271:18 288:5  
 290:7 323:22 340:4  
 344:3  
**Steve's** 388:8  
**steward** 210:19  
**stick** 262:8  
**STK-01** 4:7  
**STK-02** 4:8,9 169:15  
**STK-03** 4:16  
**STK-05** 4:13,15  
**STK-10** 4:18  
**stop** 36:19 37:1 103:20  
 141:19 161:9 179:10  
 185:12 243:13,16  
 382:3  
**stored** 108:22  
**straight** 91:16 232:5  
**straightforward** 191:8  
**strange** 72:13 200:11  
 274:2  
**strategy** 135:5  
**straw** 246:16 247:14  
**street** 1:8 336:18  
**strikes** 239:8  
**striking** 290:4  
**stringency** 236:18  
**strive** 65:10 74:7  
**stroke** 4:4 11:7,12,13  
 11:16 15:9 16:8 20:16  
 27:22 28:18 38:12,13  
 42:17,18 43:10,13,14  
 43:17,19 44:2,5 45:21  
 46:2,2,12 49:4,6 53:1  
 55:9,14,17,18 56:1,3  
 56:9,9 58:3 60:11,22

61:2,17 62:2,13,18  
 65:13 76:18 78:8 79:8  
 79:12 86:12 88:2  
 90:11,13,14 91:12,12  
 91:14 124:21 125:4  
 125:16,21 126:16,17  
 126:17,21 128:14  
 129:1 139:15,21  
 140:15 169:4,19  
 170:2,10 172:5  
 173:21 175:22 178:7  
 193:19 206:16 208:15  
 219:13 220:5,8,13  
 221:12 230:21 233:2  
 233:6,10,13,16 234:8  
 234:14 236:17 249:6  
 249:9,17 250:1  
 256:22 259:3,10,10  
 259:14 266:17 269:8  
 269:9 270:13 272:12  
 272:22 273:5 277:3,4  
 277:5 287:19 289:6  
 289:11 290:19 293:20  
 294:1 298:2,7 299:15  
 299:20 309:13 310:1  
 310:3,4,9 326:14  
 337:14,19 339:8,8,13  
 340:13 343:1 349:3,8  
 349:12,20 350:19  
 351:6,16 353:1,3  
 365:22 366:3,11,19  
 367:11,14 371:10  
 375:5,6,8 380:9,9,11  
 381:13,19 382:11  
 389:16 394:22 396:6  
 396:17 399:7,14  
**strokes** 74:22 268:18  
**strong** 46:3 47:9 96:21  
 183:16 234:20 347:22  
**strongly** 155:16 251:13  
 289:15  
**structural** 82:16  
**struggled** 82:7 219:15  
 232:2  
**struggling** 305:8  
**stuck** 226:18  
**student** 15:4 326:13  
**studied** 52:13  
**studies** 57:2 59:11  
 88:11 90:21 251:2,3  
 257:4 339:6 350:14  
 366:22 368:11 382:15  
**study** 44:8 53:21 54:9  
 54:12,15 65:19 66:2,4  
 66:5 89:3 90:7 249:15  
 250:1 251:7,16 255:8  
 255:11,16,20,21  
**stuff** 75:22

**sub-measures** 79:1  
**subarachnoid** 380:16  
 381:3 382:13 383:6  
 383:10,17 384:5  
 385:14,18 386:3  
 387:3,19 388:16,19  
 389:20 393:12 394:1  
 395:3 396:10  
**subjective** 282:2  
**subjects** 281:12  
**submission** 136:17  
 159:22 242:13 265:11  
 266:22 274:11 380:12  
**submissions** 334:19  
**submit** 300:19 341:9  
**submitted** 34:7 61:16  
 174:8 264:7 265:11  
 272:17 300:14 340:9  
 371:12 381:21  
**subsections** 49:12  
**subsequent** 173:21  
 225:3  
**subset** 31:5,6 313:11  
 313:12  
**substance** 107:3  
**substantial** 224:11  
 238:16  
**subsume** 45:14  
**subtopic** 22:14  
**subtypes** 79:1  
**success** 147:9 363:3  
**successfully** 149:22  
 190:12  
**suffering** 58:2  
**suffers** 359:15  
**suffice** 22:4 234:19  
**sufficient** 71:1 94:7  
 242:1 248:9,17  
 255:17 303:12 305:2  
 305:14 328:12 351:7  
**suggest** 69:19 78:8  
 97:2 165:17 197:13  
 213:10 257:4 292:20  
 368:10,12  
**suggested** 193:4  
**suggesting** 68:10 89:8  
 112:20 231:9 257:15  
**suggestion** 91:17 140:8  
 181:21 187:5 217:9  
 318:13  
**suggests** 70:11 176:3  
 226:22 318:8  
**suitability** 114:13,21  
 287:4 296:11,14  
 318:18 332:4,16  
 400:6,9,14  
**suitable** 296:19  
**suite** 108:9

**Sullivan** 2:15,16 12:1,2  
 18:4,6,7 95:4 128:20  
 130:10 145:15 157:20  
 212:14  
**sum** 37:14  
**summarize** 10:1 277:16  
 311:14  
**summarized** 49:19  
 176:1  
**summary** 35:19 45:9  
 48:21 98:1 99:7  
 124:19 166:16 215:8  
 263:20 264:21 292:18  
 395:13  
**summing** 92:11  
**super** 207:12  
**support** 13:15 53:9  
 85:15 119:1 213:6  
 222:14 251:16 255:18  
 255:19 332:1 350:13  
**supported** 81:19 120:3  
 128:7 249:14 300:12  
**supporting** 375:6  
**supports** 46:18 85:13  
 244:5 251:1  
**supposed** 69:11 127:8  
 127:10 279:20,21  
**sure** 19:8 20:4 31:1  
 32:1,21 35:1 40:21  
 47:17 56:16 66:4 84:7  
 84:13 90:7 93:5 97:17  
 100:5 103:19 105:11  
 144:20 145:4 153:2  
 153:19 168:6 177:3  
 184:14,20 186:5  
 196:1 198:1 212:4  
 224:20 254:15 257:18  
 264:16 276:11,20  
 277:1 279:7 297:16  
 305:14 326:21 332:11  
 333:4 336:6 359:5,20  
 371:22 389:22  
**surgeon** 17:1  
**Surgeons** 74:2  
**Surgery** 1:15  
**surprised** 96:16  
**surprisingly** 50:10  
 398:13  
**surrogate** 72:13 92:10  
**surveys** 189:21  
**surviving** 381:6  
**suspect** 369:13  
**suspected** 43:9  
**sustainability** 207:5  
**switch** 185:20  
**switched** 315:18  
**symptom** 43:21 44:6  
 52:22 82:21 298:11

299:4 309:2,8,19  
 310:17 311:2 339:13  
**symptoms** 45:18 80:2  
 292:6 299:19  
**syndrome** 387:4  
**synthetic** 117:17 119:1  
 120:3 122:21 123:8  
 123:12 319:5 324:4  
**system** 17:2 81:9 85:22  
 86:3,20,21 109:16,18  
 110:8,22 155:18  
 322:17 324:13 357:4  
 389:19  
**systematic** 283:2  
**systematically** 135:12  
**systems** 68:20 108:11  
 109:4 327:15  
**systolic** 299:7

# T

**table** 8:20 10:6 32:18  
 35:6 36:1 50:5 88:7  
 186:9 190:22 223:5  
 223:10 227:4 340:20  
 391:3,15  
**tabling** 139:1  
**tailed** 401:17  
**tails** 316:19  
**take** 5:11 21:19 34:10  
 37:3 55:14 60:15  
 74:14 86:9,14,22 87:7  
 95:20 104:5 139:18  
 140:16 145:13 159:7  
 159:9 199:22 204:6  
 212:6 213:10,20  
 214:2 217:2 230:4  
 244:20 250:8 271:2  
 276:18 278:5 316:12  
 332:11 362:22 363:4  
 373:5 382:7  
**taken** 23:5 30:17 59:12  
 64:10 65:21 108:10  
 139:18 189:15 213:16  
 214:13 244:22 275:10  
**takes** 51:5 52:18 55:1  
 58:16 63:4 67:4 72:1  
 206:3 223:20  
**talk** 19:19 24:1 27:15  
 34:18 47:7,9 79:10  
 100:11 114:10 118:10  
 118:13 120:13 122:14  
 123:15 136:7 158:13  
 168:22 174:4 195:18  
 213:12 250:19 330:8  
 400:15  
**talked** 71:16 149:17  
 168:10 179:7 203:16  
 204:12 244:6 306:13

320:6 339:18  
**talking** 21:12 25:2 28:5  
 62:7 71:18 79:21 80:1  
 80:2 89:18 102:20  
 106:10 181:3,4  
 185:13,15 205:18  
 211:5 220:18,22  
 264:18 265:4 291:15  
 367:16 394:21  
**tandem** 117:20 118:15  
**target** 82:10 385:14  
**targets** 77:21  
**task** 34:22 84:1 151:20  
 364:4  
**teaching** 96:17  
**team** 58:13,18 59:7  
 61:17 64:3 74:16,22  
 75:2,3 91:12,12 92:5  
 293:20 369:14 370:7  
 374:3  
**tech** 77:5  
**technical** 116:8 230:1  
 253:3 275:17  
**technicality** 122:4  
**technically** 123:19  
 154:14  
**technique** 200:12  
**technologies** 89:1  
**Technology** 3:5  
**telangiectasias** 388:14  
**teleconference** 3:15  
**telepathically** 93:15  
**telephone** 214:18  
**tell** 10:6 19:15 56:6 61:3  
 86:2 103:8,11 134:7  
 160:22 177:2 180:21  
 203:8 228:7 262:21  
 293:18 294:11 299:10  
 305:6 312:4 324:1  
 325:10,15 335:1  
**telling** 79:13 158:9  
 238:22  
**temporal** 133:19  
**ten** 64:20 73:16 89:4  
 113:7  
**tend** 375:8  
**tens** 324:5  
**tension** 232:13  
**tenth** 340:22  
**tenure** 2:9  
**term** 120:10 371:17  
 378:8  
**terms** 33:18 57:1 59:13  
 74:3 87:8 91:1 141:9  
 152:11 157:10 201:2  
 201:12 209:6 236:12  
 245:5 247:3 266:7  
 317:13 333:2,3,6,7

351:11,22 352:1,5,21  
 353:6,8 360:18 362:9  
**terribly** 181:14 258:11  
**Terry** 3:6 5:22 6:1 7:4  
 7:16 8:5 22:20 29:15  
 30:7 31:16 32:14  
 40:17 68:4 82:2 114:9  
 135:7,17 137:6  
 141:20 146:7 167:22  
 182:14,17 348:13  
**test** 71:17 94:13 123:12  
 151:14 187:22 190:1  
 303:3 324:12 328:11  
 382:2 389:14  
**tested** 301:18 302:6  
 303:12 325:14 394:7  
 396:4  
**testing** 15:6 24:4 26:13  
 26:14 100:6,8,9,12  
 101:14,15 102:12,13  
 102:14 104:7 117:5  
 117:17 119:12 120:4  
 120:21 122:13 124:1  
 162:18 164:9,10  
 187:20 188:16 222:10  
 260:20 263:7 264:6  
 265:10,13 297:10  
 302:20 305:2 306:12  
 307:13,18 308:9,10  
 308:12 311:22 312:1  
 312:16 313:12 316:11  
 319:2,6 324:10,14  
 325:22 327:17 342:8  
 342:20 353:8 391:6,7  
 391:19 394:6,9  
**tests** 109:5  
**text** 252:14 383:20  
 384:20 385:21 386:8  
 386:11  
**thank** 5:19 7:3 13:10  
 18:16 19:22 20:5  
 22:20 32:21 33:8  
 39:16 42:10,15 45:1  
 49:21 59:15 82:5  
 104:1 115:4,8,9,13  
 124:8 126:22 169:14  
 214:20 220:2 276:13  
 292:16 314:21 315:12  
 332:18 335:5 340:6  
 351:9 365:6 382:5  
 386:19 401:9,18  
**thanked** 8:3  
**thanks** 8:15 44:22  
 51:16 78:1 124:20  
 132:12 297:17 317:18  
 337:12  
**them--** 277:17  
**themes** 87:16

**theoretical** 207:19  
**theoretically** 260:22  
**therapeutic** 66:21  
**therapies** 70:5 88:8,12  
 125:22 126:10  
**therapist** 12:2 370:10  
**therapy** 4:8,9,11,12,13  
 4:15,16 12:5 16:12  
 60:20 70:5 88:9 89:16  
 129:17 169:3,5,16,17  
 171:1 173:19 176:2  
 190:11,14 192:18  
 216:10 230:22 231:2  
 231:12 233:6,15,21  
 234:12 249:2,7,17  
 253:8 261:13 268:6  
 275:11,13 278:4  
 298:16 337:5,15,20  
 338:19 339:3,8  
 348:21 349:4,14  
 350:6,10 353:2  
 356:10  
**thing** 23:12,18 24:3  
 30:19 32:5 60:10  
 62:14 69:20 75:15  
 81:22 85:3 86:10 87:4  
 87:18 92:13 96:16  
 138:8 141:16 153:9  
 175:20 184:11 192:20  
 196:3,20 197:9  
 199:10 209:22 211:17  
 217:8 223:22 234:16  
 236:13 238:8 240:3  
 240:21 246:21 257:9  
 257:19 262:7 264:1  
 264:15,21 265:4  
 267:5 270:5 278:12  
 278:13 283:6 284:21  
 286:6 306:18 307:15  
 308:19 326:1 327:12  
 348:17  
**things** 67:18 71:15 76:9  
 77:2 82:6 90:8 100:13  
 116:20 146:5,22,22  
 151:5 154:21 158:4  
 168:22 171:12 179:10  
 186:15 207:15 211:5  
 215:17,19 223:18  
 228:10 232:14 238:2  
 238:7,10 239:9,10,12  
 240:13 257:3 274:8  
 276:12 278:20 305:13  
 307:10,22 315:20  
 333:4 336:11 339:22  
 359:22 363:11,20  
 364:16 374:5 388:10  
 388:14  
**think** 8:12 11:12,13

12:20 13:19 14:3 19:8  
 19:9,9,10,14 23:11  
 29:6 30:7,19,22 40:4  
 41:8 46:4,13,17 47:1  
 47:4,9,12,21 48:6,9,9  
 48:21 52:10 53:11,15  
 54:9,21 55:4,7 56:20  
 56:22 57:4,17,18,19  
 58:13,17 59:6,9,10,11  
 59:12 60:7 61:10  
 63:15,17 64:6,15 65:4  
 65:5,10,16,20,22  
 66:15,16,18 67:1,5,6  
 67:7,19 69:5 70:7,20  
 70:21 71:8,14 72:3  
 73:17,18 74:19 75:10  
 76:8,10 77:1 78:1,17  
 80:10,13,14 81:1,10  
 81:13,21 82:12 83:12  
 85:1,13,20 86:8,18  
 87:4,10,16 89:7 90:3  
 90:15 92:9,11,16,21  
 94:19 95:16 96:1,20  
 98:2,17,21 99:5,9,16  
 100:16 102:1,22  
 106:9,22 107:1,12  
 109:13,17 110:11  
 113:1,9 115:10 118:8  
 129:22 130:8 132:5,6  
 132:8 134:2,18 136:7  
 136:8,9 137:14  
 139:17 140:3,14  
 141:14,14,15 144:5,8  
 144:10 145:5,12  
 146:16,18 147:17  
 149:5,8,9,13 150:5,6  
 152:10,12,18,20  
 153:13 154:17 156:12  
 156:13 157:9,15,21  
 158:3,10 159:15  
 161:19 162:3 163:3  
 163:15 164:13 167:11  
 168:16,20 171:13  
 174:6 176:12,21  
 177:4,10,17 178:3,4,6  
 178:13 179:12 184:11  
 186:2,12,14 189:3  
 190:7,19 193:6  
 196:19 200:7,16  
 204:5,20 205:1,8,20  
 208:5 209:5,15 210:5  
 211:3,7,9,10,21 212:2  
 212:9 213:15 217:4,9  
 217:19 218:1 220:18  
 221:13,17 222:3,13  
 222:22 224:13,20  
 232:6,10 233:8  
 234:16,21 235:13

236:3,4,9,14,18  
 238:19 239:2,22  
 240:10,11,22 241:10  
 241:16 243:15 244:2  
 244:8,21 245:5,9,19  
 245:22 246:3,4,6,9,11  
 246:17 247:15 251:4  
 251:10,15,18 254:13  
 255:13,16,21 256:2  
 256:11,15,17,19  
 257:8 258:2,15 259:7  
 259:13 261:14,20  
 262:6 263:21 265:9  
 267:15 269:6 272:4  
 272:14 273:18 279:5  
 280:4,13 282:2,18,20  
 283:11,12,13,19  
 285:13 286:7,8,13  
 287:3,9,14,20,20  
 288:20 290:1,5,11,16  
 291:19,21 294:22  
 295:11 297:6,11  
 301:7,10 302:19  
 303:3,5 310:1 311:11  
 312:21 313:1,19  
 315:1 317:1 318:15  
 319:4,22 320:5 325:1  
 325:5,6,13 328:17,20  
 329:7 330:9,10,12  
 331:7,9 332:13  
 334:21 341:11,22  
 344:18 348:11 351:18  
 352:3,6 353:19  
 354:14 356:20 358:10  
 358:15,22 359:10,14  
 359:20 360:1 362:3  
 362:20,22 363:1,7,12  
 363:14,15,18,19,21  
 364:12,13 365:15  
 367:8 370:22 372:18  
 372:21 373:3 375:11  
 377:6 378:1 379:2,12  
 382:3 385:7 386:9  
 387:12,15 388:9,11  
 392:1,14,16 394:20  
 395:9 396:13 398:13  
 399:12 400:19  
**thinking** 7:19 63:1,3  
 102:14 129:3,15  
 182:19 185:8 189:5  
 200:3 202:9 203:13  
 217:21 221:21 236:17  
 302:8 323:22 364:7,8  
**thinks** 105:5 192:19  
**third** 147:4 304:12  
**thirteen** 219:5  
**thorough** 187:20  
**thoroughly** 218:16

**thought** 51:17 52:8  
 61:15 106:9 109:2  
 139:10 155:22 160:14  
 186:22 196:17 210:4  
 218:8,16 233:10  
 238:5 264:20 306:7  
 334:15 351:17 365:12  
 365:14 375:18  
**thoughts** 133:17 218:7  
 378:16  
**thousand** 278:2  
**thousands** 242:17,18  
 324:5  
**threat** 272:2 311:17  
 358:16  
**threats** 99:6 263:3  
 307:21 308:4 312:3  
 343:5 375:10 395:9  
**three** 8:14 14:16 33:18  
 35:9 43:21 45:16  
 51:21 52:14,16,22  
 70:4 88:9,11,14,16,20  
 89:14 102:19 116:13  
 118:12 120:10 124:4  
 150:1,9 219:12  
 234:15 242:9,16  
 245:19 249:12,18  
 250:4,15,16,20 251:1  
 252:1,16 253:8 254:4  
 255:4,9,19 268:17  
 278:6,9 298:5 299:16  
 340:22 341:2 349:3  
**three-hour** 78:4 252:3  
**three-year** 334:9  
**threshold** 100:19  
**thresholds** 101:4  
**thrombectomy** 57:9,14  
 58:13 74:16 90:22  
 254:8  
**thromboembolism** 4:7  
 124:10 149:9  
**thrombol** 299:6  
**thrombolysis** 259:3  
**thrombolytic** 4:11,12  
 249:2,7,16 253:7,8  
 254:21 265:3 266:2,4  
 268:6 275:11,13  
 298:16 338:19  
**thrombolytics** 259:6,9  
 298:20  
**thromboprophylaxis**  
 124:21  
**thrombotic** 4:8,9  
 190:11 355:20  
**throw** 187:1  
**throwing** 258:4  
**thumb** 100:14,16,18  
 101:1 103:11,12,15

**TIA** 79:13 233:7  
**tie** 236:4  
**tied** 375:5 380:3  
**time** 5:19 6:7 7:13  
 20:20 21:8 23:2,5,15  
 25:12 27:17 30:8  
 36:13,13 37:5,19 40:5  
 41:13 46:22 47:17  
 50:8,16,16 51:7,12  
 52:5 53:3,18,19 54:7  
 54:8 55:14 56:15 57:1  
 57:15,18 58:4,15  
 59:18,19,20 60:2,2,5  
 60:6 61:1,20 62:16  
 63:12 64:16 66:1,10  
 66:18,18,19,22 67:3,5  
 67:18 70:16 73:17,22  
 74:12 75:8,11,12 77:8  
 80:9,22 81:5,7,8  
 83:16 85:13,15 86:14  
 87:19,22 88:3,4,6,7  
 88:13 89:9 90:1 91:3  
 91:5 92:12 94:7 97:16  
 98:21 106:10 109:16  
 109:22 110:1,2,4,6  
 129:11 132:21 133:4  
 133:19 136:18 143:14  
 150:16 153:8 157:1  
 176:4 177:8 194:1,5  
 194:15 201:19 202:12  
 202:17 203:12 204:16  
 206:9,13,15,20  
 213:20 214:17 216:6  
 220:1 226:9 230:5  
 235:21 237:7,11  
 238:8 242:4 244:12  
 244:21 245:4 247:11  
 249:10,12,18,19  
 250:5 252:13 253:19  
 254:4 255:3,9,10  
 261:8 265:21,21  
 267:6,20 270:1  
 277:11,11 281:22  
 285:15 287:17 288:5  
 288:6 289:14 292:1,7  
 298:5,8,10,11,12  
 299:2,3,4,7 300:9  
 304:10,16 305:16  
 309:2,2,8,16,18,19,20  
 310:17 311:1 317:14  
 322:16 323:20 326:12  
 326:14 327:14 338:2  
 344:6,6 345:6,8  
 354:15 359:21 360:3  
 362:3,9 367:4 369:1  
 380:12 381:21 391:17  
 391:17 394:11 398:11  
 401:4

**timeframe** 344:10,18,19  
384:22 399:10  
**timely** 43:22 57:10  
59:10  
**times** 12:17 60:14  
102:5 109:5 166:12  
236:22 325:18,18  
374:9,11  
**timing** 46:5,19 109:10  
123:5 229:3,5 247:3,6  
253:12 351:19  
**timing-wise** 219:17  
**tiny** 86:19 181:12  
**Tirschwell** 1:9,11 5:6  
5:18 7:18 8:2 11:6,7  
30:2 37:22 38:2,21  
39:13,16 40:6 42:3  
45:1 47:21 48:12 49:8  
49:14 51:16 53:13  
56:13 59:15 62:3 63:6  
67:9 68:2,7 72:19  
73:21 74:10 75:5,13  
76:7,19 78:13 84:6,11  
85:1,7 87:12 89:20  
91:21 92:7,20 93:2  
95:15,20 97:1,12 98:4  
98:14 99:13 100:3  
104:2 105:12 106:4  
107:4,11,21 108:6  
111:11 113:16 114:5  
114:12 115:7 121:7  
134:9 138:22 141:13  
145:5 148:3 153:18  
154:4 171:9,15,18  
188:21 191:17 197:17  
199:7 202:21 215:10  
216:17 219:8 220:17  
221:3 222:7,12,21  
223:3 225:12 226:17  
227:18 229:2 231:7  
231:16 232:1 234:13  
238:2,12 239:22  
240:10 242:11 243:4  
244:16,19 246:15  
247:16 248:1,5,13,18  
250:6 251:17 252:6  
256:4 258:5,17,20  
259:12 267:13 268:11  
269:4,13,17 271:18  
272:4 274:6 276:13  
277:13 278:22 279:5  
279:12,16 280:16,21  
284:11,16,20 285:8  
285:16 286:3,15  
287:3,9 288:3,8,11  
289:1 290:7 291:10  
292:16 293:11 295:4  
295:11,17 296:7,20

297:5,14,17 301:2,7  
301:10 302:4,15  
303:17,21 304:1,19  
305:4,18 306:3,10  
308:17 309:4,15,21  
310:11,13 311:3,7,11  
312:15 313:2,5,16,20  
314:2,13,18,20  
315:14 317:9,17  
318:7,21 319:8,20  
321:2,8 322:6,11  
323:5,18 325:20  
327:1 328:5,15  
329:21 330:4,14  
331:5,20 332:10,18  
333:9 335:7,9 337:3  
339:20 340:3,6,15  
341:10,22 342:12  
343:8,18 344:2,17  
345:15 346:3,9,20  
347:3,7 348:9,14  
351:9 352:10 353:13  
354:1,12,19 355:11  
357:5,9,20 358:20  
359:14 360:5,15,21  
361:9,14 362:2,18  
363:5 364:19 365:6  
365:11 384:4,17  
385:4,10 386:1,19  
**tissue** 43:16  
**TJC** 136:4 156:18 173:9  
241:9  
**today** 9:2 14:13 16:2  
20:21 21:20 24:2,11  
25:3,4 28:6 29:7,14  
33:14 35:3,4 42:11,16  
96:19 113:3 148:7  
157:1 227:14 258:2  
313:17 333:19 335:15  
338:5 363:8,14,20  
379:12 387:14 401:2  
**today's** 34:13 65:6  
**Todd's** 292:9 294:4  
**told** 136:6 311:21  
**tolerating** 115:9  
**tomorrow** 33:19 114:11  
313:17 400:17 401:15  
401:17  
**tool** 106:14,16 119:1  
120:4 122:19 297:9  
307:18 357:1  
**top** 70:18 310:6  
**topped** 29:20 30:13,22  
134:11 135:4 136:14  
136:15 140:12,12  
141:15,22 142:13  
201:19,20 203:15,17  
204:19 206:14 218:9

223:7,8,16 227:1  
238:8 256:12  
**topping** 30:4 145:17  
146:8  
**total** 76:22 105:13  
152:6 172:7 268:16  
270:9 324:18  
**totally** 66:14 87:14  
99:21 162:22 182:19  
386:4  
**touch** 41:20  
**touched** 210:5  
**tough** 151:19  
**towers** 80:14,15  
**town** 80:20  
**tPA** 43:16,20 52:19,21  
62:14,18 70:5 71:20  
72:1,4,10 78:3 88:9  
88:16 92:18 102:18  
251:3 252:3,10,18  
254:10 261:20 276:7  
281:3 283:21 284:4  
289:5,11 290:20,21  
291:1,4 293:17 298:4  
**TPA-eligible** 92:18  
**track** 103:1 150:22  
292:3  
**tracked** 141:1  
**tracking** 151:13 293:21  
**tracks** 102:16  
**trade-off** 199:8  
**trading** 365:15  
**trained** 18:9  
**training** 15:22  
**transfer** 338:22  
**transformation** 186:16  
**transient** 209:9  
**translates** 206:18  
**transparency** 245:6,8  
288:2  
**transparent** 9:12 23:22  
**transplant** 9:20  
**transport** 80:22  
**trauma** 387:21,22 388:2  
**traumatic** 387:20 394:1  
**traveling** 10:22  
**treat** 43:17 45:20 70:4  
185:22 282:10 283:18  
291:17  
**treated** 96:12,17 251:14  
289:17,18 290:4  
292:6  
**treating** 49:4 61:17 62:1  
139:21 282:9 283:3,4  
291:16 386:2  
**treatment** 4:19 22:7  
43:11,18 44:2,13  
46:12 58:18 59:7 62:9

81:2 169:7 232:12  
237:8,8,14,21 282:4,6  
282:10 287:18 289:5  
290:6,10 345:12  
380:5,10,18 381:6  
384:2,11 393:10  
394:3 396:8  
**treatment-based**  
236:19  
**treatments** 109:6 292:1  
**tremendous** 96:4  
**trend** 133:19 257:12  
**trial** 26:18 116:16,21,22  
117:1,2 119:7,9 120:2  
120:16 121:6,10,18  
122:11 124:5 125:16  
129:2,13,17,22 130:2  
170:10 221:4 232:5  
233:13 314:9 344:19  
345:2,3 349:19  
382:16  
**trials** 26:19 57:8 76:3  
265:20 338:13 340:12  
366:11 368:8 381:13  
393:17  
**trick** 182:14  
**tricked** 317:8  
**tricky** 162:13 317:2  
**tried** 204:1,5 390:9  
**tries** 169:3  
**trigger** 79:12  
**trouble** 358:11  
**true** 69:22 133:1 175:18  
181:11 254:2 291:14  
**trump** 316:19  
**trust** 244:13,14,17  
**try** 38:4 45:20 61:6  
62:16 69:16 86:5  
87:10 95:21 103:8,11  
255:3 293:9 305:13  
**trying** 7:18 46:16 50:7  
53:7,15 63:10 74:7  
79:18 80:19,19 81:2  
83:13 121:7 136:20  
139:16 144:3 167:20  
211:6 225:17 229:7  
247:4 263:13 264:12  
270:1 275:1 305:12  
326:9 335:20 357:10  
359:8  
**turn** 5:11 6:11 7:4,17  
8:15 22:16 35:10,12  
36:7 37:22 38:22 45:2  
144:15 289:19 297:10  
321:18 369:22 370:13  
382:3  
**turnaround** 54:20  
**turned** 136:13



**turning** 92:2 362:10  
**turns** 56:13 155:4  
**Twenty-three** 105:13  
**Twenty-two** 345:22  
**two** 4:14,15 6:18 14:2  
 18:20 22:3,18 23:7  
 33:18 35:7,9 36:14,17  
 36:18 44:5 49:19  
 51:18,20 52:4,5 58:7  
 69:17 70:14 73:3 77:2  
 82:20 84:15,17 93:15  
 93:16 99:3,22 102:22  
 120:6 125:12 150:1  
 158:3 172:8,16 173:2  
 190:8 206:19 219:3  
 219:22 221:16 230:15  
 232:14 237:18 241:12  
 241:13 249:10 253:11  
 254:9 257:13,19  
 262:14 264:14 265:22  
 267:11 268:13,14,16  
 268:19,19 269:3,10  
 269:18 271:2 272:11  
 278:1,1 281:13 298:3  
 298:8 310:3,5,20  
 312:17 331:5,18  
 335:19,20 337:6,15  
 337:21 338:8,16  
 339:4 342:21 344:9  
 344:11 356:2 381:22  
 391:5 396:5,13,16  
**two-day** 6:4  
**two-hour** 52:17  
**twofold** 386:10  
**type** 218:11 232:12  
 270:16 385:1  
**types** 116:13 118:12  
 124:4 170:13  
**typically** 163:16  
**typo** 164:10

---

**U**


---

**U.S** 64:6 165:15 350:19  
**ultimately** 217:16  
**unable** 322:16  
**Unanimous** 296:18  
**unannounced** 51:3  
**unchanged** 25:8,9  
**unclear** 192:22 194:3  
**uncomfortable** 200:1  
 203:18 307:1  
**undergoing** 351:12  
**underlying** 173:17  
 195:15  
**undermining** 229:4  
**understand** 23:12 29:7  
 29:13 75:5 83:10,13  
 111:10 119:10 121:8

127:9 135:3,6 136:20  
 140:20 141:3 144:3  
 149:6 152:13,21  
 153:20 155:15 158:16  
 181:3 184:13 189:11  
 202:6 208:14 209:8  
 224:13 229:3,6  
 239:18 263:14 264:13  
 270:1,3 274:18  
 280:18 281:9 293:13  
 303:9 335:22 367:17  
 373:2  
**understanding** 16:1  
 67:14 81:22 84:4  
 140:21 149:10 201:21  
 202:10 264:4 274:19  
 274:21 301:14 334:6  
 354:6  
**understands** 336:7  
**understood** 275:2  
**undoubtedly** 242:18  
**undue** 106:8 321:12  
 327:3  
**unendorse** 215:20  
**unendorsed** 154:1  
**unexpected** 112:9,11  
**unfair** 266:9  
**unfortunately** 90:17  
**UNIDENTIFIED** 285:2  
 295:14  
**unintended** 27:11  
 68:11 210:13 259:2  
 286:9 287:8 288:21  
 289:4 290:16 291:6  
 293:7,14 346:10  
**unique** 118:3  
**Unit** 1:21  
**United** 368:8  
**units** 65:1  
**universe** 144:11  
**University** 1:17,19 2:1  
 2:6,12,15,17 11:9  
 12:3,15,18 13:12 15:5  
 15:9 16:6,16,19 18:8  
**unknown** 201:3,4  
**unnecessary** 65:17  
**unrealistic** 62:17  
**unreasonable** 67:8  
**unruptured** 389:8,9  
**unusual** 363:8  
**update** 46:11 136:16  
 138:14 220:14 228:4  
 228:5,10 357:1  
**updated** 26:8 220:14  
 229:21 359:1  
**updates** 228:11  
**upgraded** 225:4  
**urgent** 14:11 45:20

**usability** 27:2,8,10,14  
 37:4 44:19 111:21  
 113:13,19 114:3  
 119:4 120:1 166:10  
 166:11,18 167:3  
 193:17,18 194:21  
 195:2,4,10 286:4,5,9  
 286:16,17 287:2,10  
 292:21 295:19,21  
 296:5 330:6,10,19  
 331:18 346:4,8,13,19  
 361:9,11,13,15,17  
 362:1 377:2,3,9,14,20  
 399:4,20 400:3  
**usable** 166:13 194:19  
 217:17 303:14  
**use** 24:15 27:8,9 37:4  
 43:12,20 63:16 68:22  
 76:4,9 93:12 99:19  
 103:6 108:17 111:21  
 111:22 112:1 113:19  
 114:4 116:16 117:2  
 117:12 119:4,7,9  
 120:1,3,16 121:10,13  
 121:18,19 122:6,11  
 124:5 126:13 134:21  
 138:3 166:18 177:18  
 190:20 191:6 193:3  
 193:17 195:2,4,10  
 200:12,14 204:10  
 205:7,16 211:19  
 234:7 242:14 283:20  
 283:21 284:4 286:4  
 286:16,17 287:2,11  
 289:5 292:21 295:19  
 295:22 296:5 300:6,9  
 300:11 302:17,18  
 303:20 304:5 305:9  
 308:12 313:10,15  
 314:9 320:19 323:8  
 323:11,13 328:3  
 330:6,19 331:18  
 339:17,19,21 343:20  
 346:4,13,19 348:3  
 349:10 350:15 351:4  
 351:7 354:16 355:2,9  
 361:15,17 362:1  
 377:14,20 382:12  
 399:20  
**useful** 85:20 87:4  
 149:14 194:2 209:8  
**usefulness** 87:8  
**user** 206:4  
**users** 28:22 183:11  
 199:4  
**uses** 118:4 121:16  
**usual** 129:17 210:9  
**usually** 9:21 121:21

154:5 395:1  
**utilization** 257:3 378:5

---

**V**


---

**vaguely** 66:13  
**vagueness** 53:20  
**Valerie** 1:19 12:9  
 124:12 127:1,4  
 131:19 147:10 148:9  
 149:1 178:5 229:10  
 284:17  
**valid** 28:15 150:7  
 164:14,22 183:4  
 191:11,19 198:10,16  
 253:10 255:19 275:7  
 275:20 281:2,5,7  
 282:7,19 316:16  
 317:4,4 325:14 326:6  
 326:18  
**validate** 218:3  
**validated** 297:9 395:1  
**validation** 217:22  
**validity** 26:4,9,11 36:18  
 98:15,16 99:1,6,14,16  
 100:7 101:5,22 102:1  
 102:12,13,14 103:2,3  
 104:6,10,14,19  
 105:20 106:3 112:15  
 112:21 119:1 162:3  
 164:8,9,10 165:4,10  
 165:14 189:16,20,21  
 190:16,18 191:8,22  
 192:1,3,6,12 201:3  
 250:19 251:12 255:13  
 255:13 262:6,9,12  
 263:3 266:18 269:22  
 271:12 272:3 276:10  
 277:9 278:16 280:5  
 280:12 284:12,14,22  
 285:7 303:4 307:12  
 307:17,22 308:4,10  
 308:12 312:3,8 316:7  
 316:13,16,18,20  
 317:10 318:22 319:2  
 319:6,9,12,14,19  
 325:21 326:1,3  
 331:17 342:17,19,20  
 343:3,5,7,9,12,17  
 348:2 358:10,17  
 360:6,7,9,14 375:3,3  
 375:10 376:2,8 395:9  
 396:1,2 397:21 398:4  
**valuable** 70:16 83:18  
 96:3 204:11  
**value** 21:21 46:18 87:10  
 90:3 97:20,21 112:22  
 164:11 172:8,16  
 173:1,17 275:10

293:5 322:3,3 324:20  
 325:16 341:3 356:5  
**values** 33:13 172:7,15  
 293:6 325:11  
**valvular** 357:13  
**variability** 96:5 101:9  
 111:8 198:12 351:20  
**variable** 77:11  
**variables** 151:19  
**variably** 113:11  
**variance** 77:16,18  
 107:8  
**variation** 25:19 112:10  
 333:6  
**variations** 276:3  
**varies** 269:11  
**variety** 174:3 389:17  
**various** 84:19 104:5  
 111:22 122:22 203:14  
 263:4 265:19 319:3  
 333:3  
**vary** 83:12  
**vascular** 80:8  
**vasoconstriction** 387:4  
 394:4  
**vasospasm** 381:2  
**vast** 261:3  
**vastly** 107:10  
**vendor** 301:19 302:1  
**vendors** 106:15  
**venous** 4:7 124:10  
**verbal** 137:22  
**verbally** 136:6  
**version** 27:19 117:12  
 117:14,20 118:21  
 121:14,16 122:1,10  
 322:20  
**versions** 221:16  
**versus** 83:7 110:10  
 215:13 216:1 224:9  
 259:19 342:3 347:8  
 347:21 364:21  
**vessel** 76:5  
**vetted** 218:16  
**VHRs** 303:13  
**vice** 2:13 3:3,7 7:1  
**victory** 147:5 149:4,5,7  
 152:9 209:9,10  
**view** 11:8,11 78:21  
 84:17 85:19 110:18  
 206:6 211:8  
**vigilant** 19:6  
**Virginia** 2:6 13:12 80:16  
 107:20  
**virtually** 76:10 290:14  
**virtue** 238:13  
**visions** 152:8  
**visualized** 273:2

**volume** 90:14 328:10  
**voluntarily** 300:14  
**vote** 37:3,3,6,13,13  
 47:22 48:4 49:15,16  
 87:17 90:5 94:4,13,22  
 95:2 98:5 105:1,3,14  
 105:18 113:17 114:13  
 120:14 121:3 130:13  
 134:10 135:15 136:20  
 136:21 138:16 139:1  
 147:19 153:19,21,22  
 154:11 155:12,18  
 156:2,5,7,8 157:16,22  
 158:4,5,11 159:6,16  
 159:18 160:4 161:16  
 163:19 165:2,22  
 166:16 168:5 174:10  
 174:18 182:2 186:3  
 187:8 188:3,22 192:4  
 193:8 195:2 196:3,6  
 196:14 197:14 200:21  
 212:6,10 216:7,12,13  
 216:15,21 218:18,20  
 218:21 222:18,19,22  
 224:16 227:8 236:9  
 237:10 238:22 239:19  
 239:20 240:1,2  
 245:20 247:18 256:7  
 260:1,1 262:2 279:21  
 284:12 285:17 286:16  
 287:5 296:9 305:19  
 307:2 316:15 317:9  
 317:19 318:10,17  
 321:4 330:17 331:6,8  
 340:16 341:12 342:13  
 342:14 343:10 344:3  
 345:16 346:11,21  
 347:9,9 352:12  
 357:22 360:7,22  
 361:15 362:4,14,16  
 362:17 364:20 368:18  
 373:11 374:15 375:22  
 376:15 377:12 390:14  
 392:20 395:15 397:19  
 398:18 399:18 400:5  
**voted** 105:5 139:4  
 157:8 189:8 219:6  
 331:16  
**votes** 36:14,17 37:14  
 37:17 93:13,14 94:6,8  
 94:9,16 104:22  
 158:12 296:18  
**voting** 11:15 36:10,11  
 48:20 49:11,11 82:1  
 93:3,10,10,16,17 94:4  
 94:8,15,17 95:3,7,7  
 95:11 97:3,4,6,8 98:6  
 98:8,10 104:11,12,13

104:16,22 105:20  
 111:12,13,16 113:18  
 113:20,22 114:7,21  
 115:1,2 118:19  
 130:14,16,17,18  
 135:5 138:10 148:5  
 158:2 159:20 160:5,8  
 160:9 163:20,22  
 164:2,3 165:3,5,6,7  
 166:1,3,5,6,17,19,21  
 166:22 174:19,21,22  
 175:1 182:3,6,7 188:5  
 188:7,9 189:11 192:5  
 192:7,9 193:10,12,13  
 195:3,5,7 201:9  
 213:14,16 215:12  
 219:2 260:4,6,8,9  
 261:1 284:13,15,19  
 285:1,4,18,21 286:18  
 286:19,21 295:21  
 296:2,3,13,15,17  
 306:9 317:21 318:1,3  
 319:11,13,15,16  
 321:9 329:13,15,17  
 330:18,20,22 332:2,3  
 332:5,7,8 341:14,17  
 341:18 343:11,13,14  
 345:18,20,21 346:12  
 346:15,16,18 347:7  
 347:13 348:4,6  
 352:13,15,17 358:1,3  
 360:8,10,11 361:1,3,5  
 361:16,19,20 364:22  
 365:2,3 373:12,15,16  
 374:16,19,20 376:1,3  
 376:5,16,17,19,20  
 377:13,16,17 379:14  
 379:16,18,19 390:17  
 390:19,20 392:21  
 393:1,3 394:8 395:16  
 395:18,19 397:20,22  
 398:1,19,21,22  
 399:19,22 400:8,10  
 400:12  
**VTE** 4:7 124:10,21  
 125:5,6,21 128:3,6  
 163:14 338:4 355:22  
 355:22 356:2,4,9

## W

**waffled** 156:12  
**wager** 53:1  
**Wahid** 3:11 43:1  
**wait** 39:20 40:7 41:15  
 58:10 167:11 171:7  
 178:1 182:12 227:4  
 243:15  
**waiting** 41:6 289:17

358:4  
**walk** 65:2  
**walks** 51:1  
**want** 5:10 6:2,2 7:10,22  
 9:1,12,13,22 10:8  
 14:19 18:21 19:4,13  
 19:14 23:9 24:7 25:22  
 29:2,10,14 32:14,17  
 47:17,19 48:10,14  
 53:18 54:19 63:3  
 65:14 67:10 68:21  
 70:3 74:16 79:19 82:2  
 83:5 92:14 105:11  
 110:16 115:12 118:9  
 119:3,21 128:13  
 129:9,21 132:4 133:2  
 136:8,9,11 137:12  
 138:8 141:4 143:11  
 145:2,4,11 146:13  
 151:22 153:19 154:9  
 154:11 155:6,15  
 159:6 160:17 161:15  
 162:8 167:4,22  
 173:10 180:14 182:17  
 184:19 186:3 197:22  
 198:2 205:22 206:6  
 212:17 213:1 215:18  
 215:21 218:19 220:18  
 237:1 238:20 240:1  
 241:1,3,6,8 245:10  
 247:7 252:8 254:15  
 286:13 287:12 294:5  
 296:22 302:2,7 309:5  
 317:5 318:15 325:7  
 331:12,21 333:4  
 334:1 335:12 336:17  
 352:6,9 363:4,10  
 367:20 386:21 400:18  
**wanted** 7:2,7 20:7,12  
 21:14 22:21 27:15  
 28:4 39:19 105:15  
 107:7 127:21 168:6  
 169:11 179:6,19  
 230:2 245:22 246:20  
 346:10 375:11 382:22  
**wanting** 61:11 79:2  
 146:4  
**wants** 143:1 303:8  
**warehouse** 172:14  
**warehouses** 252:21  
**warfarin** 350:15,21  
 354:9  
**warrant** 144:13  
**Washington** 1:8 11:9  
 16:10  
**wasn't** 49:9 179:21  
 180:11,11 203:1  
 222:1 223:22 232:22

287:21 288:17 355:15  
370:1  
**wasted** 360:3  
**wasting** 253:19  
**watch** 77:7  
**watching** 348:18  
**waters** 214:4  
**Watt** 3:11 122:3 124:14  
124:14 132:11 134:5  
241:15 248:6,16  
304:3,4,22 305:22  
324:9 327:10 328:9  
334:3  
**Watts** 41:10  
**way** 19:11 26:21 45:8  
61:12,14 65:5 69:6,10  
69:17 70:22 71:7  
76:21,22 77:6 81:3  
88:12 90:18 91:10  
103:1 104:6 108:16  
109:14,17 110:11  
114:15 132:20 145:13  
159:3 181:19 209:18  
210:1 223:17 228:18  
235:7 237:9 238:7,22  
247:18 252:12 272:17  
272:18 288:14 291:8  
302:3 311:7,9,10  
320:20 323:16 324:22  
329:4 331:10 368:6  
388:21 389:1,1 390:3  
390:4,5  
**ways** 64:7 68:10 207:19  
246:11 389:17  
**we'll** 5:6,12 6:9 8:21 9:2  
10:6,14 20:3 21:12  
35:1,12 36:10,12,13  
36:15 37:1,2 38:9  
40:15,22 41:20 46:6  
48:3,4 49:20 55:7  
93:4 107:22 115:13  
115:19 116:15 117:17  
122:14 130:13 148:8  
157:9 182:16 195:17  
219:16,22 224:14,15  
243:18 248:1,14  
250:19 262:9 296:7  
336:5 365:16  
**we're** 5:3 10:2 12:20  
17:16 24:1 31:22 32:7  
33:13 34:16 38:3,7  
41:8,18 42:4 48:16,17  
49:10,11 50:7 51:8  
52:5 53:7 64:22 70:10  
71:18,20 73:3 76:14  
78:17,18 79:17,18,21  
80:1,2,8,13,14 81:1,6  
81:22 82:20 83:6 88:5

88:18 89:17,18 90:2  
92:9,19 94:12 97:13  
98:14 99:9 114:10  
115:21,21 116:3,4,12  
118:14,22 119:11  
120:19 184:22 185:3  
215:6,7,12,19,19,22  
216:2,7 218:13 219:2  
219:8,11 222:9 223:4  
223:8 225:12,17  
226:18 227:22 228:17  
228:20 229:6 235:6  
237:4,6 244:12,14  
249:1 251:18 254:14  
256:14 257:11,15,16  
257:20 264:18 274:8  
275:10 276:6,9,19  
277:8 279:20,21  
291:3 296:11 302:8  
302:10,13,18 303:11  
306:5 313:16 314:8  
314:16 319:13 333:5  
333:8 336:10 337:3,9  
347:7 348:20 358:4  
359:18,19 370:22  
373:22 375:2 378:4  
379:14 383:11 386:11  
386:14,15 400:5,16  
400:17 401:11  
**we've** 20:10 22:6 23:7  
24:8,8 30:12 32:1  
34:9 45:9 60:3 87:16  
94:10 96:19 104:4  
106:10 132:22 146:14  
146:19 147:8 150:7  
151:5 162:2 177:4  
203:15 212:11 214:11  
217:9 219:15 225:13  
239:17 240:6 256:13  
267:22 268:1 293:22  
305:11 335:19 337:8  
353:5 356:15 363:3,7  
363:12,20 371:1,13  
380:11 389:17 394:21  
400:19 401:17  
**weak** 79:14  
**weaker** 46:4  
**wealth** 250:22  
**wear** 281:15  
**wearing** 281:16  
**weigh** 30:8 103:13  
183:20  
**weight** 184:12  
**welcome** 4:2 5:18 6:2,3  
6:21 7:2,15 19:16  
32:17 115:18 315:13  
**well-respected** 287:22  
**went** 42:1 115:16

127:16 131:6 137:13  
155:1 169:9 189:6  
223:13,14 226:3  
252:12 310:8 312:10  
337:1 359:6 391:8,20  
**weren't** 193:5 245:6  
268:18 353:17 354:4  
396:14,15  
**West** 80:16 107:19  
**whatsoever** 295:3  
**white** 96:8 180:5,7  
392:6  
**wide** 112:10 144:11  
193:3 328:14 397:7  
**widely** 126:12 169:21  
193:19  
**Wild** 15:12  
**willing** 95:17 154:18  
189:4,9 240:15 245:6  
379:3  
**WILSON** 3:7  
**win** 147:7  
**wind** 147:2 257:15  
**winding** 257:17  
**window** 34:17 70:3  
78:4 82:13 88:10  
89:18 250:21 251:1,9  
251:15 252:1,3 253:9  
255:9,10  
**windows** 88:13  
**winds** 372:19  
**Wisconsin** 2:2 16:7  
**wish** 183:17 204:20  
379:10  
**witnessed** 299:18  
**woebegone** 205:3  
**women** 392:10  
**wonderful** 9:20 151:22  
**wondering** 78:6,14  
127:21 323:7  
**word** 167:5 242:14  
**worded** 311:8,9  
**wording** 309:14  
**words** 177:22 386:7  
**work** 6:7 9:2,16,18 10:5  
11:7 14:10 19:5 33:6  
33:21 39:9 43:3 61:20  
72:14 81:9 116:8  
132:13,21 138:12  
150:4 192:18 194:13  
209:22 225:17 252:21  
253:3 267:14 279:19  
280:14 287:17 301:15  
307:20 325:8 336:5  
**worked** 190:2 278:10  
**workgroup** 171:2,20,21  
172:20 396:20  
**working** 8:12,17 12:4

13:2 17:7 227:16  
252:20 253:3 275:17  
306:14  
**works** 246:11 308:14  
325:3  
**worksheet** 264:6,19,21  
267:10  
**worksheets** 130:8  
**workup** 385:6  
**world** 101:21 194:7  
208:16 218:17 364:15  
**worried** 105:5 215:19  
271:4 284:22  
**worrisome** 190:15  
271:21  
**worry** 217:1 237:10  
**worrying** 259:20  
**worse** 58:16 82:18  
310:22  
**worth** 242:17  
**wouldn't** 54:18 129:9  
153:4 179:1 181:17  
205:19,22 232:16  
248:21 258:11 275:21  
278:10 333:17 357:16  
**wound** 42:22 60:22  
163:12  
**write** 77:6 282:16  
**writes** 326:13,15  
**writing** 276:4,6  
**written** 203:10 236:11  
244:20 375:18  
**wrong** 57:19 144:10  
154:2 160:22 164:12  
239:19 268:12 271:6  
327:6 333:10  
**wrote** 110:15 285:11  
**Wunmi** 3:2 6:17 22:20

---

**X**


---

**X** 53:17 92:18

---

**Y**


---

**y** 10:20  
**Yale** 1:16 17:1  
**yeah** 29:10 31:19 38:21  
40:6,21 52:10 56:13  
122:17  
**year** 23:2,13 24:22  
33:18 79:13 131:8  
150:10,15 166:12  
201:17 228:5 229:22  
230:7 235:20 237:5  
242:10 257:13 291:18  
292:4,15 335:19,20  
368:13 375:19  
**years** 13:19 30:10,13  
39:3 58:20 80:16

91:19 120:11 125:10  
 150:1 170:6 201:17  
 204:20 229:13 230:16  
 237:5,18 257:16,19  
 267:5 270:19 305:7  
 305:11 307:14 315:6  
 338:7 340:22 341:2  
 343:20 345:5,14  
 349:17 350:16 366:8  
 370:16 380:17 381:9  
 393:14  
**yes/no** 161:16  
**YETUNDE** 3:4  
**York** 15:13  
**young** 15:22  
**younger** 292:10 293:14  
 294:8,8

---

**Z**


---

**Zafonte** 2:18 15:17,17  
 367:8 368:18,22  
 369:8,21 370:13  
 371:15 372:18 373:9  
 373:22 375:2,17  
 376:10 377:3 378:1  
**zero** 97:9,10 98:12  
 104:17 106:1 111:18  
 114:2 181:17 275:19  
 298:18 318:3 329:18  
 341:19,20 346:1,1  
 352:17,19 358:7,8  
 360:12,13 361:6,7,21  
 361:22 373:17,18  
 374:22 376:6,7,21,22  
 377:18,19  
**zip** 115:19 181:5  
**zone** 160:17 318:6,8,11  
 318:19 331:3,4,13,16  
 331:18  
**zoned** 400:19  
**zones** 331:6,18

---

**0**


---

**0** 130:20,20 160:11  
 164:5 165:9,9 166:8,8  
 167:2,2 175:3,3 182:7  
 182:8 188:10,11  
 192:10,11 193:14,15  
 195:8,9 260:11  
 285:22 286:1,22  
 287:1 296:4 343:15  
 343:16 346:17,18  
 390:21,22 391:20  
 393:4,5 395:20,21  
 398:3 399:2 400:2  
**0.001** 164:13  
**0.97** 370:20  
**03** 396:8

**0434** 4:7 130:15,21  
 160:6 163:21 164:6  
 165:4,10 166:2,9,18  
 167:3  
**0435** 4:8 168:1 169:2  
 174:20 175:4 182:4  
 188:6,11 192:6,11  
 193:10,15 195:4,9  
 216:9 219:2,6  
**0436** 4:16 348:20  
 352:14,19 358:2,8  
 360:9,14 361:2,17,22  
 365:1,4  
**0437** 4:11 249:2 260:4,7  
 260:11 284:14 285:6  
 285:19 286:1,18  
 287:1 295:22 296:6  
 296:18  
**0437's** 296:14  
**0438** 4:13 341:15,21  
 343:12,16 345:19  
 346:2,13,19 348:7  
**0441** 4:18 373:13,19  
 374:17,22 376:2,7,17  
 377:1,14,19 379:17  
 379:21  
**06** 396:7  
**0661** 4:3 38:11 39:19  
 42:5,12,16 43:4 44:3  
 95:7,13 97:5,10 98:7  
 98:13 104:14,18  
 105:20 106:3 111:14  
 111:18 113:19 114:3  
 114:22 115:2

---

**1**


---

**1** 126:2 164:12 214:18  
 232:20 278:11,18,19  
 339:11 382:12  
**1,000** 131:10 140:3  
**1,200** 139:13 377:8  
**1,229** 391:9  
**1,299** 131:10,13  
**1,300** 342:21  
**1.0** 97:19 181:16  
**1.29** 173:3  
**1.42** 397:2  
**1.7** 299:6  
**1:10** 215:1  
**1:15** 215:1,4  
**10** 242:7 259:19 276:4  
 383:14 385:2  
**10/15** 41:6  
**10:15** 41:17  
**10:47** 115:16  
**100** 82:11 84:7 161:18  
 175:12,17 177:20  
 178:15,16,22 224:10

225:2 230:17 279:7  
 296:18 319:3 370:20  
 381:20 391:20  
**100,000** 299:6  
**1030** 1:8  
**10th** 131:6 175:11  
 202:22 203:2 223:14  
 223:19 224:9 370:17  
 370:21  
**11** 115:12,12,12 269:1,2  
**11:00** 115:17  
**110** 299:9  
**117** 4:5  
**12** 20:14 21:6 99:3  
 293:22 394:9  
**12:44** 215:3  
**120** 125:13 129:2,4,11  
 170:8 276:17 298:9  
 338:10 349:18 366:9  
 375:13 381:10 393:15  
**13** 98:11 106:2,2 285:6  
 319:18 341:19 358:6  
 370:16 377:18 393:3  
 398:22 400:1  
**13,018** 265:17  
**131** 4:7  
**14** 21:9 104:18 323:1  
 370:16  
**15** 52:6 57:14 59:3 74:8  
 74:17 78:11 91:4,8,17  
 242:8 243:9 299:5  
**15th** 1:8  
**16** 382:14  
**169** 4:8  
**17** 115:6 195:8 285:5  
 319:16 331:2 332:9  
 346:17  
**18** 44:10 125:10 170:6  
 291:14,18 292:3,12  
 292:14 294:21 315:3  
 315:6 338:7 349:17  
 366:8 380:17 381:9  
 393:14  
**18-year** 295:5  
**180** 299:2,17  
**185** 299:8  
**19** 291:18 292:3,14  
**196** 4:9  
**1A** 45:22 234:16  
**1B** 234:17 347:17  
**1st** 226:3 230:8 381:17

---

**2**


---

**2** 277:4  
**2,206,379** 265:14,16  
**2.1** 133:13 372:12  
**2:00** 75:1  
**20** 13:19 132:22 139:20

243:9 259:4 268:6  
 292:3  
**20-some** 139:12  
**2010** 43:7 141:2 180:3  
 201:20 223:12 229:12  
 334:12 355:20 356:14  
 391:8  
**2011** 45:11 56:21  
**2012** 112:8 125:20  
 126:13 169:21 220:7  
 252:12 262:18 263:6  
 264:2 270:7,11 300:4  
 303:22 304:1 339:5  
 340:22 342:7 349:5  
 368:5,16  
**2013** 11:20 43:6 82:9  
 90:14 126:19 131:8  
 220:16 229:15,16  
 270:19 391:8  
**2014** 112:8 131:10  
 223:12 229:19 234:14  
 270:19  
**2015** 226:3 230:9  
 300:16 381:17 391:11  
**2016** 1:5 241:21 242:7  
 300:17 304:11,18  
**2017** 304:14  
**206,000** 265:6  
**21** 295:10  
**213,000** 166:12  
**214** 4:10  
**22** 98:10 105:1 111:17  
 130:19 165:8 182:9  
 317:1 318:5  
**23** 95:12 105:1,1 131:14  
 165:15 212:11 319:4  
 344:13  
**24** 271:1,6 278:11,19  
 338:20 339:13 344:12  
 380:18 381:14 384:21  
 385:5,9 387:11  
 393:10,18 396:22  
 397:16  
**25** 278:11  
**250** 4:12  
**259,000** 269:2  
**26** 164:4 166:7 260:9  
 295:12 329:18 331:2  
 352:18 360:12 361:21  
**264** 131:9  
**28** 300:20  
**281** 394:10,15  
**2832** 4:9 195:14  
**2833** 348:22 365:7  
**2834** 4:12 249:3 296:22  
 317:22 319:14 329:14  
 329:19 330:19 332:5  
**2835** 348:10

**2863** 4:19 380:4 390:17  
390:22 392:22 393:5  
395:17,21 397:21  
398:3,20 399:2,20  
400:3,10,13

**2935** 4:15

**29th** 241:19

**2B** 263:22 264:22

265:12 266:6 267:10

**2b1** 119:18

### 3

**3** 284:1

**3-1/2** 278:19

**3-year** 294:11,13

**3.2** 265:12

**3.3** 263:22 264:3,19,22

266:6 267:10

**3.50** 398:14

**3:00** 75:1

**3:33** 337:1

**3:46** 337:2

**30** 60:1,3 74:9,18 114:1

192:10 259:4 290:2

296:3 381:4

**31** 324:4,17

**33** 263:1,9 267:10

**342** 4:14

**349** 4:15,17

**35** 263:11,11,11 291:15

318:4 359:16 361:5

**374** 4:18

**381** 4:19

**39** 4:4 160:12 263:12

390:21 391:11

**39,812** 264:22 267:11

### 4

**4** 1:5 114:1 164:5

260:10 277:5 285:4

296:5 329:18 398:1,2

399:1 400:2,13

**4.5** 78:8

**4:00** 326:16

**40** 37:16,17 291:15

299:7

**402** 4:22

**43** 188:10 285:21 318:4

343:15 376:5

**433.10** 272:22 273:8,17

**434** 40:19 41:9 124:10

**436** 359:2,9

**44** 50:6 60:1 90:14

**441** 365:19

**45** 38:14 42:19 44:9

46:5,19,21 50:3 51:18

52:16 57:18 58:10

59:2,3,11 63:2,9,20

64:14,17 65:6,9,18

67:7 69:18 70:15 72:5

73:12,15,16,17,19

75:2 76:14,15 78:9

81:21 84:16 85:2 86:6

88:2,6 89:5,22 90:9

96:14 398:12

**46** 50:7

**48** 149:19 193:14

286:22 331:1 339:13

345:4

### 5

**5** 4:2 95:11 289:12

**5:03** 401:20

**50** 96:13 259:18 358:17

359:12 375:19 381:6

**50-year** 294:10

**50th** 223:12 370:20

**51** 391:12

**52** 99:5 160:11 193:14

272:7 286:21 359:4

**52.2** 172:22

**53** 231:2

**54** 231:5,15 276:6

**55** 291:15

**57** 188:9 285:22 343:14

376:6

**572** 391:12

**59** 344:13

### 6

**6** 220:5 276:5 380:9,9

**6:15** 336:21 401:12,14

**60** 37:12,18 73:5 94:11

94:21 131:6 387:12

**61** 319:17 390:20

**62** 97:19 112:7

**64** 95:12

**65** 98:11 114:1 285:5

296:4 361:6

**66** 391:8

### 7

**7** 97:20 100:15,21

**70** 111:17 164:4 192:9

225:6 260:10 329:19

381:4

**70-year** 295:5

**71** 112:8 223:14

**73,000** 271:2

**74** 106:1 166:7 352:18

360:12 361:20

**77** 97:19,22 104:17

261:13 379:4

**78** 130:19 165:8 182:8

345:22

### 8

**8** 284:2

**8:00** 401:16

**8:30** 1:9

**8:41** 5:2

**80** 261:7,9

**80s** 261:7

**82** 394:12

**83** 115:5 131:5 195:7

332:9 346:16 399:1

400:1

**87** 341:19 358:7 374:21

377:17 393:4

**873** 391:12

**88** 131:4

**89th** 370:21

### 9

**9** 95:13 97:9 104:17

111:17 160:11 167:1

175:2 319:17 331:1

395:19

**9:20** 42:1

**9:32** 42:2

**90** 161:18 223:20 224:9

257:14 261:5

**906** 382:16

**90s** 30:14

**90th** 223:14 224:9

276:5 370:17

**91** 97:8 131:7 167:1

175:2 348:6 373:17

376:21 395:20 398:2

**93** 282:11

**94** 180:6,6 203:3 223:13

230:19

**95** 180:5 257:20 265:3

268:4 341:1 342:10

394:11

**96** 131:5 341:1 365:3

379:20 400:12

**97** 131:4 132:10 342:9

**98** 175:10,17 180:8,8

203:3 204:22 340:21

**99** 223:13 234:1 256:15

**9th** 1:8

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