

NATIONAL QUALITY FORUM  
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CARDIOVASCULAR ENDORSEMENT  
MAINTENANCE STEERING COMMITTEE

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TUESDAY,  
FEBRUARY 15, 2011

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The Cardiovascular Endorsement  
Maintenance Steering Committee met at the  
Conference Center of the American Immigration  
Lawyers Association, 1331 G Street, N.W.,  
Washington, D.C., at 9:00 a.m., Mary George  
and Raymond Gibbons, Co-Chairs, presiding.

PRESENT:

MARY GEORGE, Co-Chair, MD, MSPH Centers for  
Disease Control and Prevention  
RAYMOND GIBBONS, Co-Chair, MD Mayo Clinic  
CAROL ALLRED, RN, National Coalition for Women

of Heart Disease  
ROCHELLE AYALA, MD, FACP, Memorial Healthcare  
System  
SUNG HEE LESLIE CHO, MD, Cleveland Clinic  
ANN DE VELASCO, RN, National Coalition for  
Women of Heart Disease  
DIANNE JEWELL, PT, DPT, PhD, CCS, American

Physical Therapy Association  
DANA KING, MD, MPH, Medical University of  
South Carolina  
BRUCE KOPLAN, MD, MPH, Brigham and Woman's  
Hospital  
THOMAS KOTTKE, MD, MSPH, Health Partners  
DAVID MAGID, MD, MPH, Colorado Permanente

Medical Group

GEORGE J. PHILIPPIDES, MD, FACC, Boston  
Medical Center  
JON RASMUSSEN, PharmD, Kaiser Permanente -  
Colorado  
DEVORAH RICH, PhD, Greater Detroit Area Health  
Council  
ANDREA RUSSO, MD, Cooper University Hospital  
MARK SANZ, MD, The International Heart  
Institute of Montana  
SIDNEY C. SMITH, JR., MD, University of North  
Carolina at Chapel Hill  
ROGER SNOW, MD, Commonwealth of Massachusetts  
CHRISTINE STEARNS, MA, JD, New Jersey Business  
and Industry Association  
KATHLEEN SZUMANSKI, RN, Emergency Nurses  
Association  
SUMA THOMAS, MD, FACC, Lahey Clinic Medical  
Center

NQF STAFF:

HEIDI BOSSLEY, MSN, MBA  
HELEN BURSTIN, MD, MPH  
ANN HAMMERSMITH  
ASHLEY MORSELL  
KAREN PACE

KATHRYN STREETER  
REVA WINKLER, MD, MPH

ALSO PRESENT:

DALE BRATZLER, DO, MPH, Oklahoma Foundation  
for Medical Quality, Inc.\*  
JOSEPH P. DROZDA, JR., MD, American College of  
Cardiology\*  
REBECCA JONES, MSN, RN\*  
FREDERICK MASOUDI, MD, MSPH, American College  
of Cardiology  
COLLETTE PITZEN, RN, BSN, CPHQ, Minnesota  
Community Measurement\*

ANNE SNOWDEN, MPH, CPHQ, Minnesota Community  
Measurement\*

JOHN A. SPERTUS, MD, MPH, University of  
Washington School of Public Health\*

SAMANTHA TIERNEY, MPH, American Medical  
Association

MANASI TIRODKAR, PhD, MS, National Committee  
for Quality Assurance

\*Present via telephone

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

Page

Welcome.....	5
Disclosure of Interest.....	6
Project Introduction and Overview of Evaluation Process.....	19
Consideration of Candidate Measures....	
Coronary Artery Disease - Secondary Prevention.....	40
Measure 0073.....	56
Measure 1486.....	92
Measure 0068.....	113
Measure 0067.....	132
Measure 0075.....	151
Measure 0074.....	162
Public Comment.....	178
Measure 0066.....	192
Measure 0070.....	211
Measure 0071.....	237
Measure 0065.....	256
Measure 0076.....	282
AMI - Emergency Department	
Measure 0289.....	316
Measure 0132.....	365
Measure 0286.....	370
Measure 0163.....	386
Measure 0164.....	394
Measure 0288.....	414
Adjournment.....	418

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

9:02 a.m.

Welcome and Introductions

DR. WINKLER: Good morning. We do expect a few more folks to join us, and we'll let them join in as they arrive. I'm Reva Winkler. I'm the Senior Director for Performance Measures at the National Quality Forum, and along with my project managers, Ashley Morsell and Kathryn Streeter, we're the project team for this effort on cardiovascular endorsement maintenance for NQF.

So several other folks from NQF will be joining us. Helen Burstin, who's our Senior Vice President for Performance Measures will be joining us, as well as Karen Pace, who is our in-house methodologic expert will.

Also, I'd like to introduce Ann Hammersmith, who is our general counsel, and she will be helping us with introductions in a few minutes. So to get started, I'd be very happy to introduce the Chairs for this

1 Committee and turn the meeting over to them.  
2 Dr. Ray Gibbons and Dr. Mary George.

3 CO-CHAIR GIBBONS: Good morning.  
4 Thank you for taking time out of your busy  
5 lives to help us with this project. I think  
6 many of you I've known for a long time.

7 Some I'm meeting for the first  
8 time, and we're going to all try to figure out  
9 who everybody is by introducing ourselves and  
10 going around the table, and basically it's  
11 who, where and why you're here. Okay.

12 Disclosure of Interest

13 MS. HAMMERSMITH: Good morning,  
14 everyone. As you already know, I'm Ann  
15 Hammersmith. I'm NQF's general counsel. The  
16 reason I am here is to go through the conflict  
17 of interest disclosure portion of today's  
18 program.

19 If you recall, you each filled out  
20 a disclosure of interest form that we  
21 provided, and what we ask you to do is to go  
22 around the table, as you're introducing

1 yourself, and telling us who you're with, and  
2 disclose anything that you believe is relevant  
3 to your service here today.

4 We go through the disclosures  
5 carefully. We do our best to eliminate people  
6 who we believe have an actual conflict of  
7 interest. But in the spirit of openness and  
8 transparency, we like to do an oral disclosure  
9 at the beginning of each panel. So I'm going  
10 to start with Dr. Gibbons.

11 CO-CHAIR GIBBONS: So just to  
12 remind you who, where, why you're here and the  
13 disclosures. So in that spirit, although I've  
14 done research on measures and certainly  
15 participated in guidelines, I have no specific  
16 disclosures for this project.

17 CO-CHAIR GEORGE: I'm Mary George  
18 from the Centers for Disease Control and  
19 Prevention, and I just want to also welcome  
20 all of you here and remind you to be very  
21 considerate of our tight time schedule today.  
22 I have been involved in measure development

1 for stroke, not for cardiovascular disease,  
2 and I oversee a quality improvement stroke  
3 program at CDC, and I have no other  
4 disclosures.

5 DR. PHILIPPIDES: My name is  
6 George Philippides. I work at Boston Medical  
7 Center. I've been involved in some ACCHA  
8 guidelines, one of which is getting ready for  
9 publication, that has to do with anti-platelet  
10 medications. I don't know if that's an  
11 important disclosure, but I thought that I'd  
12 mention it.

13 MS. HAMMERSMITH: Thank you.

14 DR. MAGID: I'm David Magid from  
15 Kaiser of Colorado and the University of  
16 Colorado, and don't have any disclosures.

17 DR. STEARNS: I am Christine  
18 Stearns. I'm with the New Jersey Business and  
19 Industry Association, and I don't have any  
20 disclosures.

21 DR. KOTTKE: Tom Kottke from  
22 Health Partners and the University of



1 Minnesota. No disclosures.

2 DR. RASMUSSEN: Jon Rasmussen from  
3 Kaiser Permanente Colorado and the University  
4 of Colorado. No disclosures.

5 DR. AYALA: Rochelle Ayala from  
6 Memorial Health Care System in South Florida.  
7 I also represent the National Association of  
8 Public Hospitals, and I don't have any  
9 disclosures.

10 MS. RICH: Devorah Rich from the  
11 Greater Detroit Area Health Council, and I  
12 don't have any disclosures.

13 DR. RUSSO: Andrea Russo from  
14 Robert Wood Johnson Medical School, Cooper  
15 University, representing the American College  
16 of Cardiology. I'm also an  
17 electrophysiologist to work with, although  
18 maybe not a direct disclosure, would be  
19 working with some quality initiatives with  
20 both the American College of Cardiology and  
21 Heart Rhythm Society.

22 MR. SANZ: Mark Sanz. I'm an

1        interventional cardiologist in Missoula,  
2        Montana, private practice, here representing  
3        ACC. No real disclosures.

4                    DR. SMITH: I'm Sid Smith from the  
5        University of North Carolina. I'm also a  
6        cardiologist. I've been involved in guideline  
7        development, both with the ACC and AHA, and  
8        now with NIH. I don't have any disclosures  
9        related to this.

10                   DR. KING: Hi. My name is Dana  
11        King. I'm at the Medical University of South  
12        Carolina, and I'm here representing the  
13        American Academy of Family Physicians, and I  
14        don't have any relevant disclosures.

15                   DR. SNOW: Hello. I'm Roger Snow.  
16        I'm the Deputy Managing Director for Mass  
17        Health, which is the Massachusetts Medicaid  
18        agency, and I'm here as a purchaser. I have  
19        no disclosures.

20                   MS. THOMAS: Hi, I'm Suma Thomas.  
21        I'm a general cardiologist at Lahey Clinic in  
22        Burlington, and I have no disclosures.

1 DR. JEWELL: Good morning. My  
2 name is Dianne Jewell. I'm a board-certified  
3 cardiovascular and pulmonary physical  
4 therapist. I'm on faculty at Virginia  
5 Commonwealth University just down the road,  
6 but I'm here for the American Physical Therapy  
7 Association.

8 I am a member of AACBPR, one of  
9 the measure developers. It's on our agenda,  
10 but I've had no involvement in the measures  
11 that are being presented or the program  
12 certification from which they collect their  
13 data.

14 MS. ALLRED: Hi. I'm Carol  
15 Allred. I'm Chairman of the Board of Women  
16 Heart, the National Coalition for Women with  
17 Heart Disease. I live in Texas and I  
18 appreciate the cold weather you're offering up  
19 for us this morning, and I guess my only  
20 disclosure is I am a patient.

21 DR. CHO: Hi. My name is Leslie  
22 Cho. I'm an interventional cardiologist from

1 Cleveland Clinic. I head the section of  
2 Preventive Cardiology and Rehabilitation. I  
3 have no disclosures.

4 DR. KOPLAN: Hello, I'm Bruce  
5 Koplan. I'm from Boston, Massachusetts at the  
6 Brigham and Women's Hospital, where I'm a  
7 cardiologist and cardiac electrophysiologist.  
8 I'm also here representing the Heart Rhythm  
9 Society, and I've been involved in helping,  
10 with a group helping to develop quality  
11 measures, and I don't believe I have any  
12 disclosures.

13 MS. De VELASCO: Good morning.  
14 I'm Annie de Velasco. I represent Women  
15 Heart. I'm on the board of directors. I'm a  
16 cardiac rehabilitation nurse and a heart  
17 disease survivor. I have no disclosures.

18 MS. SZUMANSKI: I am Kathy  
19 Szumanski. I am from the Chicago area from  
20 the Emergency Nurses Association. The rest of  
21 my team is in Portland, so I get to spend the  
22 week here in Washington. I have no

1 disclosures.

2 MS. HAMMERSMITH: Thank you. Are  
3 any committee members on the phone? No, okay.  
4 Yes.

5 DR. MAGID: I'm sorry. I'm also  
6 representing the American College of Emergency  
7 Physicians.

8 MS. HAMMERSMITH: Thank you for  
9 giving me the perfect segue into my next  
10 comment. A number of you have said that you  
11 are here representing a particular  
12 organization.

13 I'd like to take this opportunity  
14 to alert all of you that you sit as  
15 individuals on this Committee. We appreciate  
16 your disclosing any relationship that you have  
17 with a particular organization, but you do sit  
18 as individuals, even if you were nominated by  
19 a particular organization. Does anyone have  
20 any questions about that?

21 (No response.)

22 MS. HAMMERSMITH: Do you have any

1 questions of each other regarding the  
2 disclosures?

3 (No response.)

4 MS. HAMMERSMITH: Okay. Thank  
5 you. Have a good meeting.

6 DR. WINKLER: Just, I'd like to  
7 take the opportunity to introduce Dr. Helen  
8 Burstin, who's the Senior Vice President for  
9 Performance Measures. Want to say hello to  
10 the group?

11 DR. BURSTIN: Hi, everybody.  
12 Helen Burstin. Pleasure to be here with you.  
13 You guys are our inaugural endorsement  
14 maintenance committee.

15 So thank you for helping us do  
16 heart stuff. We'll talk more about that. But  
17 for first time, most of the measures in the  
18 portfolio that are existing and new will be  
19 compared head to head.

20 So you've got a big task ahead of  
21 you, and we'll be here trying to help you out  
22 any way we can. And George was my senior

1 resident, oh, I don't know, 25 years ago. So  
2 it's just kind of strange seeing him in this  
3 context.

4 DR. WINKLER: Do we want to  
5 introduce the audience?

6 CO-CHAIR GIBBONS: Why don't we do  
7 that --

8 DR. WINKLER: I do want to  
9 introduce Dr. Karen Pace, who is another  
10 senior vice president, or senior director at  
11 NQF. Karen, you can do better than I can.

12 MS. PACE: Hi. I'm Karen Pace,  
13 and I'm one of the senior program directors at  
14 NQF, but I also work closely with our CSAC and  
15 staff and board on our evaluation criteria and  
16 measurement methodologies. So I'm here as a  
17 resource to you all about our evaluation  
18 criteria.

19 CO-CHAIR GIBBONS: So we have a  
20 number of measure developers' representatives  
21 in the room, and I'll ask them to introduce  
22 themselves as we get to their remarks, rather

1 than introducing everybody at this time.

2           So a few comments at the  
3 beginning. Obviously, we have a group of  
4 individuals with varied expertise from all  
5 over the country and from different  
6 backgrounds, and as we proceed through this  
7 process, we also have some people who have  
8 been on other NQF committees and others who  
9 have not.

10           I would encourage everybody to ask  
11 questions. There are no stupid questions for  
12 this exercise because we need input and the  
13 reason why you're all here is to get as varied  
14 perspectives as possible. Obviously, I think  
15 we want to make certain that we proceed from  
16 a kind of attitude of mutual respect.

17           There are people in the room who  
18 have published extensively on some of the  
19 issues we're going to address, and I would  
20 urge them to offer their expertise, but to  
21 recognize that many others might not  
22 necessarily share the depth of their expertise



1 on all of the fine points here.

2 We do have a challenge with  
3 respect to time limits. For each measure, we  
4 for the most part have about 15 minutes, and  
5 at the end of that 15 minutes, we have to take  
6 a series of votes, which may take as much as  
7 five minutes. So I'm very concerned about our  
8 ability to keep on schedule.

9 So those of you who are designated  
10 to be the primary reviewer on any measure will  
11 need to summarize your thoughts about the  
12 measure in five minutes, to allow us five  
13 minutes for discussion and then five minutes  
14 for voting, if we are going to keep on time.

15 Obviously, that will not allow you  
16 to go through every detail of the measure, or  
17 every detail of the submission, but rather  
18 focus on issues of potential concern and  
19 potential sort of weakness in the application.

20 I would remind our measure  
21 developers that they were told three to five  
22 minutes for their comments. At five minutes,

1 a giant hook comes out of the ceiling, and  
2 lifts you off your location. So we are going  
3 to have to stick to that time limit.

4 Several of you have already  
5 recognized and asked questions by email about  
6 the issue of harmonization. That is a  
7 tremendous challenge for us as this process  
8 goes forward for many of these measures. As  
9 the primary reviewer gives his or her  
10 presentation, I would ask them specifically to  
11 mention any issues of harmonization.

12 If somebody has an instant,  
13 wonderful, grand solution, please offer it.  
14 But I for one didn't see any instant,  
15 wonderful, grand solutions for most of these,  
16 and I think it's going to therefore take  
17 further discussion.

18 We did allocate some time  
19 yesterday for that, but I would anticipate  
20 we're probably going to have to do some  
21 additional discussion by subsequent conference  
22 call. Once we've identified a significant

1 issue for harmonization, we're not going to  
2 take a final vote for approval of that  
3 measure, but defer that vote until that issue  
4 is addressed.

5 Are there questions about any of  
6 the comments I've made thus far?

7 (No response.)

8 DR. WINKLER: My turn?

9 CO-CHAIR GIBBONS: Yes, your turn.

10 Project Introduction/Overview

11 DR. WINKLER: Okay. What I'd like  
12 to do is review sort of the general overview  
13 of this project and the expectations for the  
14 work of this Committee.

15 First and foremost, I'd like to  
16 remind everybody to, when you're speaking,  
17 please use the microphones. This, all the  
18 discussion is being recorded and a transcript  
19 will be made. Both the recording and the  
20 transcript will be posted on NQF's website.  
21 So the discussions in this room are on the  
22 record.

1                   Just other housekeeping issues.  
2           The restrooms are through either of the doors,  
3           out where we have refreshments and to your  
4           left. Feel free to come and go as you need.  
5           We will be taking breaks, both mid-morning,  
6           mid-afternoon. We will have opportunity for  
7           public comment, for both those in the room and  
8           from the phone at the end of each half-day.

9                   All right. So do the next one.  
10          The purpose of this project is very  
11          straightforward. It is the first of NQF's  
12          sort of new way of doing things going forward.  
13          Over the last 11 years, NQF has endorsed a  
14          large number of measures in a large number of  
15          topic areas. Our portfolio numbers over 600  
16          measures at this point in time.

17                 It is certainly time for us to  
18          look at the measures in the portfolio from a  
19          timeliness, a usefulness perspective. So  
20          going forward, we are bringing all of the  
21          measures that have been endorsed through  
22          perhaps a variety of different projects, that

1 are often setting-specific or procedure-  
2 specific perhaps, and looking at them in a  
3 topic-specific manner.

4           And this is the first one. We're  
5 looking at cardiovascular measures. So we  
6 have a large number of cardiovascular measures  
7 in the portfolio. Due to that large number,  
8 we've had to split them into Phase 1 and Phase  
9 2, and today we'll be looking at Phase 1  
10 measures around coronary artery disease and  
11 myocardial infarction.

12           So just some basics about NQF-  
13 endorsed measures. NQF endorses measures for  
14 public reporting as well as quality  
15 improvement. We use our formal consensus  
16 development process, which we've described to  
17 the members of the Committee. You are an  
18 important part of that process.

19           Once a measure is endorsed, it's  
20 known as a voluntary consensus standard, so  
21 you may hear that terminology used to refer to  
22 our measures, and our endorsed measures are

1 widely used for public reporting by CMS,  
2 states, health plans, insurers and others.

3 So what we are doing is refining  
4 that portfolio to match the evolution in the  
5 quality measurement enterprise that's occurred  
6 very rapidly, actually, over the last decade.

7 Next. As I mentioned, Phase 1,  
8 we'll be looking at ten -- I believe it's  
9 just, I think it's now nine newly submitted  
10 measures, and 25 maintenance measures. But we  
11 will be looking at them equally. They are all  
12 to be evaluated against the evaluation  
13 criteria, and make the determination if they  
14 should continue in endorsement.

15 Next one. We also are organizing  
16 the measures around the patient-focused  
17 episode of care model that has been developed  
18 by other activities within NQF, the idea being  
19 that, from a patient's perspective, they go  
20 through a variety of stages in their episode  
21 of care.

22 They don't see their experience in

1 the silos of just in the hospital or just in  
2 the doctor's office or just in the rehab  
3 facility, but they actually travel all  
4 throughout all of those settings.

5 We are striving to reach a  
6 portfolio of measures that helps describe and  
7 evaluate that process. The patient-focused  
8 episode of care model follows the natural  
9 trajectory over time. It emphasizes care  
10 coordination, particularly transitions and  
11 trade-offs.

12 We are looking for measures that  
13 promote the shared accountability of  
14 individuals, teams and systems, looking at  
15 patient preferences as they make this journey,  
16 as well as looking at the opportunities for  
17 payment reform.

18 So this is an approach that's been  
19 adopted and widely embraced by the NQF  
20 membership. So this project actually works  
21 very nicely, in that we do have measures that  
22 address all of the aspects of the episode of

1 care for this particular condition.

2 Over the last decade of the  
3 quality measurement enterprise, we've seen a  
4 lot of evolution. What we're hearing from the  
5 field, from NQF members, from the folks who  
6 use measures out there is their needs are  
7 changing.

8 So measures that we may have  
9 endorsed eight years ago may not be suitable  
10 today. They may have outlived their  
11 usefulness or there are better measures in  
12 existence.

13 So the need for ongoing  
14 maintenance of portfolio is crystal clear. So  
15 we're looking to find measures that drive  
16 higher performance. We are looking for  
17 measures that bring together important aspects  
18 into composites. We are looking for measures  
19 that look at disparities, how can we address  
20 the disparities that we know exist.

21 Harmonization. Huge effort; huge,  
22 huge issue. We're certainly seeing that in



1 conversations we're having with the funders of  
2 this project, which happens to be the  
3 Department of Health and Human Services. We  
4 also want to look at measures that measure the  
5 largest possible group supported by the  
6 evidence.

7 This particularly comes up with  
8 age limitations. It comes up with narrowly  
9 focused groups in identifying a denominator  
10 when perhaps a broader population would be --  
11 it would apply to.

12 We want to promote the shared  
13 accountability and measure across those  
14 patient-focused episodes of care, with a focus  
15 on outcome measures, appropriate measures,  
16 cost resource measures coupled with quality  
17 measures to embrace the idea of inefficiency.

18 So we're looking for the measures  
19 that are pushing things, and so I think that  
20 as we look through the measures that are on  
21 our agenda today, we will be dealing with many  
22 of these issues and continuing to have to ask

1 ourselves how well is this measure able to  
2 meet these goals, and meet the needs of folks  
3 out in the world who are using the measures to  
4 drive quality improvement.

5 Your role as a steering committee  
6 is to act as a proxy for NQF's multi-  
7 stakeholder membership. That is why around  
8 this table we have clinicians, we have  
9 researchers, but we also have patients, we  
10 have consumers, we have purchasers, we have  
11 people that represent communities.

12 So that we're bringing that multi-  
13 stakeholder perspective to the table, so that  
14 everyone has an opportunity to participate in  
15 this process. The Steering Committee works  
16 with the staff to reach the goals of the  
17 project. The biggest effort we're asking from  
18 you is this measure evaluation and your final  
19 recommendation to the NQF membership.

20 We will come back to you at  
21 various points, but the largest effort is in  
22 this initial evaluation phase.

1                   Next one. Just pictorially, the  
2                   consensus development process. You are the  
3                   yellow box, and a very pivotal box in that you  
4                   help us make sure this whole process works.

5                   Now measures have been submitted  
6                   to us in response to a call for measures, as  
7                   well as to our advising the measure developers  
8                   that their measures are due for maintenance.  
9                   The measures have been submitted by the  
10                  measure developers through -- we have an  
11                  online submission process.

12                  One of the roles of staff is to  
13                  look at the conditions for the submission  
14                  before we even bring it to you. One is a  
15                  measure steward agreement that addresses the  
16                  agreement for use of their intellectual  
17                  property and this applies to all measures that  
18                  are owned by non-governmental agencies.

19                  The fact that the measure  
20                  developer agrees to maintain and update at  
21                  least every three years, so that the measure  
22                  maintains its currency. But the measure is

1 intended for public reporting, as well as for  
2 quality improvement, one of NQF's major goals,  
3 and that the information should be generally  
4 complete and answer the questions asked.

5 Next. The endorsement criteria,  
6 as we've reviewed with you in more detail,  
7 just to briefly review the four major criteria  
8 are importance to measure and report. There  
9 are three subcriteria. This is a threshold  
10 criteria.

11 As we go through the discussions  
12 today, we'll ask you to discuss the  
13 subcriteria around importance. Then we will  
14 stop and actually vote the importance. If the  
15 measure does not pass the importance criteria,  
16 we will move on to the next measure. If it  
17 does pass the importance criteria, we will  
18 move on and discuss scientific acceptability.

19 The second criteria is Scientific  
20 Acceptability of the measure properties. The  
21 third is Usability, and the fourth is  
22 Feasibility. After all the measures are

1 evaluated individually, we will then begin  
2 addressing issues of competing measures and  
3 harmonization, which are going to be  
4 significant issues in this particular project.

5 Next slide. So when we look at  
6 the evaluation criteria, it's not a black and  
7 white, simple assessment, and steering  
8 committees often will feel challenged by this  
9 exercise. So, you know, the subcriteria are  
10 meant to help you understand how to evaluate  
11 the main criteria.

12 Most of them, however, are a  
13 matter of degree rather than all or nothing.  
14 So we're asking you to use your expertise,  
15 your experience and your best judgment to  
16 evaluate the measures using the criteria.

17 Next. The rating scale we'll use,  
18 with the exception for the threshold criteria  
19 of importance, which will be a yes/no vote,  
20 for the others we're going to ask you to rate  
21 it to what degree does this measure and its  
22 characteristics meet the criteria as laid out

1 in NQF's measure evaluation criteria?

2 And your choices will be  
3 completely, partially, minimally or not at  
4 all. Again, there's a value judgment involved  
5 here. It's not an absolute. We'll describe  
6 how we're going to do the voting so we can see  
7 how the Committee votes on each of them.

8 The next one. Importance. Just  
9 to remind you, threshold criteria. So this  
10 will be one of the important elements to focus  
11 in on. It comprises three subcriteria of  
12 impact, opportunity performance or the gap,  
13 and then the evidence that supports the  
14 measures. We are looking for measures that  
15 are strongly and solidly evidence-based.

16 Next. Scientific acceptability of  
17 the measure properties looks at the  
18 specificity and the precision of  
19 specifications.

20 We're looking at what we know  
21 about the reliability of the measure, the  
22 validity of the measure, the justification for

1 exclusions, risk adjustment if it's  
2 applicable, how well the results give you  
3 information that is meaningful and useful in  
4 discriminating performance, looking at  
5 comparable results from multiple data sources,  
6 and then looking at how the measure can  
7 address disparities.

8           Usability is the extent to which  
9 the audiences of the results of these measures  
10 can use the information. Can they understand  
11 it? Is it harmonized and does it add value in  
12 comparison to the other measures being used.

13           Next one. Feasibility. The  
14 extent to which the required data are readily  
15 available, retrievable with undue burden and  
16 can be implemented for performance  
17 measurement. Clearly, measures that are  
18 currently being used can provide their own  
19 information on their track record.

20           So as Dr. Gibbons has already  
21 mentioned, the issue of harmonization as well  
22 as competing measures, measures that are so

1 very similar, the question is do we need both  
2 measures, is going to be a prominent issue for  
3 us. So to deal with that in an efficient  
4 manner, we're going to go through the  
5 evaluation step-wise.

6 The first one is today, primarily  
7 our focus will be on evaluating each of the  
8 individual measures against those four  
9 criteria. We will ask you, not so much to  
10 recommend a measure at this point, but does  
11 the measure meet the criteria for endorsement.  
12 That will be Step 1.

13 Subsequent to this, we will be  
14 evaluating harmonization among related  
15 measures. We'll be preparing side by side the  
16 measure specifications. We will be taking  
17 them to the measure developers and asking them  
18 to reconcile the differences to achieve  
19 harmonization.

20 You will then, the Steering  
21 Committee will then be asked to evaluate the  
22 results of that discussion, and whether the



1 degree of harmonization that has been achieved  
2 is sufficient to meet the criteria. Also, the  
3 Steering Committee will be asked to select the  
4 best in class measure from among competing  
5 measures.

6 Then after all of these steps have  
7 been completed, we will arrive at the final  
8 recommendations from this Committee, that will  
9 go forward to recommendations to the NQF  
10 membership and the public at large, and we  
11 will be soliciting public comment on them.

12 Then those comments we'll bring  
13 back to you for the next opportunity to  
14 discuss. So that's the process we'll be using  
15 for evaluating these measures.

16 Next one. Just -- we're going to  
17 give the measure developers an opportunity to  
18 introduce themselves, as well as opportunity  
19 for comment from people on the phone or in the  
20 room. All right.

21 One of the things, each of you was  
22 handed a gizmo to come in. I don't know what

1 else to call it. It's a thing. I had a lot  
2 of these black little gizmos in my life. If  
3 you look on the back, where it says ADD and  
4 then there's a number. I'm holding Dr.  
5 Gibbons. He's number 15.

6 Please record this number, and we  
7 want you to use the same gizmo tomorrow. So  
8 be sure you have the same number tomorrow,  
9 okay. Real important.

10 So we're going to go through an  
11 exercise of voting as a demonstration. This  
12 actually allows us to capture the votes  
13 electronically and record them electronically.  
14 But we'll be able to display them for you to  
15 see the results rather instantaneously, and  
16 sort of avoid the hand-raising, counting  
17 process. Hopefully, this will make our voting  
18 a little bit easier.

19 The keypads are numbered 0 to 9,  
20 but if you notice, on the right-hand screen is  
21 where you'll have a voting slide, and we've  
22 got a demo, okay. We're going to ask you to

1 actually practice here. So your options are  
2 yes, you had difficulties traveling, or no,  
3 you did not. So 1 or 2 on your gizmo, and one  
4 of the important things is it will not record  
5 until Ashley has triggered that little thing  
6 in the bottom.

7 So I'm going to give everybody a  
8 chance. Pick up your gizmo. Ashley, go ahead  
9 and start it. Everybody pick your answer, and  
10 the push the send button to finalize your  
11 vote.

12 Did everybody do it? Okay. What  
13 do the results look like? Okay, okay. So  
14 that's what we're going to be doing. We'll  
15 try one more. Let's try it one more time  
16 where you've got more than one answer. So  
17 remember. The slide will show you which  
18 number relates to which of your responses.

19 So this one's a little bit harder  
20 than two choices, so Ashley, go ahead and  
21 start it. Everybody vote. Select your, and  
22 then -- did you hit send? What happened?

1 Ashley's got that wide-eyed look. Okay. I  
2 was going to say, did we get answers?

3 Okay. We're going to do it again.  
4 We'll just redo it. All right. Try this one  
5 again. Everybody vote and hit send.

6 Now do we have answers? There we  
7 go. Okay. Good deal. All right. So this is  
8 what we're going to be doing throughout the  
9 day.

10 DR. BURSTIN: And just one tip we  
11 learned from Karen's last committee, is when  
12 people started to get impatient and people  
13 really wanted the question to be called, there  
14 become this sort of universal symbol of people  
15 twirling their gizmos to end discussion and  
16 vote. So hopefully, Mary and Ray will be able  
17 to see that.

18 DR. WINKLER: Okay. So we are  
19 getting ready -- we are just about ready to  
20 get started. We're first going to have an  
21 introduction of the three measure developers  
22 for those measures that address secondary

1 prevention for coronary artery disease or  
2 ischemic vascular disease.

3           When we begin discussing  
4 individual measures, I'd ask the person who  
5 was assigned as the lead discussant to begin  
6 by announcing the number, the title and the  
7 description, and then address your comments to  
8 the importance criteria.

9           We'll then ask the rest of the  
10 Committee to add anything they'd like to on  
11 the discussion of importance criteria, and  
12 then the Committee will vote, just as you've  
13 done here, and then we'll do the same thing  
14 for Scientific Acceptability.

15           We'll discuss those criteria,  
16 vote. We'll discuss Usability, vote,  
17 Feasibility, vote, and then whether it met,  
18 and go on down the road. Does anybody on the  
19 Committee have any questions about doing that?  
20 You're all going to have an opportunity to  
21 lead a discussion.

22           DR. SNOW: Point of clarification

1 about the importance issue. Importance is  
2 about the intent of the measure, not its  
3 achievements, right? It's what the measure  
4 seeks to do. Okay.

5 DR. WINKLER: And we use the  
6 terminology the measure focus, what it is  
7 you're measuring.

8 CO-CHAIR GIBBONS: I have a  
9 question, because I think it's important to  
10 clarify. So some people have already asked  
11 about details of the measures that they don't  
12 like. So for the maintenance project, I  
13 presume that we are in the same mode as for  
14 the new approval, which is if there's a fatal  
15 flaw, then the measure will be --

16 The only way to deal with that is  
17 to disapprove the measure, and the measure  
18 developer will have some time frame in which  
19 they could potentially address the fatal flaw.  
20 Is that correct?

21 DR. BURSTIN: It all depends how  
22 one defines fatal flaw, of course. So I think

1 you do have an opportunity as a steering  
2 committee, that there may be some small  
3 modifications, for example, to a measure, that  
4 you think would significantly approve it.

5 You can conditionally recommend  
6 the measure, as you just experienced, with the  
7 condition that the measure developer respond  
8 back to you, a series of questions.

9 They don't have to be, you know,  
10 you actually have to meet them. They  
11 oftentimes will respond and you'll go  
12 actually, that's a very good point. Okay.  
13 But a fatal flaw is something obviously a  
14 little different. You can't rewrite measures.  
15 You can't have measure developers rewriting  
16 measures on the fly.

17 But if there are some issues or  
18 exclusions or things like that, those are  
19 where I think your input's really important.

20 CO-CHAIR GIBBONS: All right. Any  
21 other questions from the Committee?

22 (No response.)

1 DR. WINKLER: All right. It's  
2 time to hear from -- a brief introduction on  
3 the measures for secondary prevention from our  
4 measure developers, and we have three of them.

5 So I think we'll let NCQA go  
6 first. Bob, is that going to be you or who?  
7 Okay. If you'd just introduce yourself and  
8 give us your three to five minute summary.

9 CAD - Secondary Prevention

10 MS. TIRODKAR: Good morning. My  
11 name is Manasi Tirodkar, and I'm a research  
12 scientist at NCQA, and I've been maintaining  
13 the cardiovascular measures for a couple of  
14 years. Okay. Can you hear? Okay.

15 So in my three to five minutes, I  
16 am going to cover a couple of points related  
17 to the rationale for this measure set, the  
18 approach to measure development and testing in  
19 general, and a couple of lessons learned,  
20 which are the three major things we were asked  
21 to talk about.

22 Just to explain a little bit about



1 the ischemic vascular disease patient target  
2 population, this is the broadest category that  
3 we can cover, and it captures a full spectrum  
4 of patients for whom the risk factor  
5 recommendations apply, related to blood  
6 pressure and cholesterol.

7 Ischemic vascular disease is very  
8 common, and has a very well defined set of  
9 risk factors and treatments. Our expert and  
10 coding panels have removed diagnostic  
11 categories for CAD and PDD, which are not  
12 related to risk factors, particularly blood  
13 pressure and cholesterol.

14 We, in developing measures, our  
15 measure development process usually takes at  
16 least a year, and we utilize a Measurement  
17 Advisory Panel or MAP, as we call it, and we  
18 keep going back to them over the course of  
19 this year. They help us generate measure  
20 concept. Staff will often draft measures and  
21 then bring them back to the Measure Advisory  
22 Panel, and we get continued input from them,

1 even when we reevaluate measures.

2 Three times a year, we have an  
3 oversight committee called the Committee on  
4 Performance Measurement, that approves both  
5 draft specifications as well as final  
6 specifications, and has a final approval  
7 before publication in HEDIS.

8 Through the course of this measure  
9 development process, we do have a field  
10 testing process that's appropriate either for  
11 health plan or physician level, depending on  
12 the level of the specification, and we do have  
13 both health plan and physician-level  
14 specifications over here.

15 We have a public comment process  
16 as well for 30 days during the course of  
17 measure development, and as well there's an  
18 ongoing process for ongoing opportunities  
19 throughout the year for people to provide  
20 comments and suggestions, or issues that they  
21 have with the measures through our policy  
22 clarification system. This is the ongoing

1 measure maintenance that we provide throughout  
2 the year.

3 As well, every three years, we do  
4 regularly reevaluate measures, unless we're  
5 aware of some evidence or new guidelines that  
6 come up in the middle of that three-year  
7 reevaluation cycle, in which case we will  
8 change the three years and do a reevaluation  
9 immediately.

10 One of the issues that we've had  
11 actually with this is aligning the update of  
12 the measures with updates of guidelines. So  
13 for example, a couple of these measures we  
14 started reevaluating in 2009, and put it on  
15 hold because the JNC-8 and ATP-4  
16 recommendations didn't come out. I believe  
17 they were supposed to come out in 2010 and now  
18 they're going to maybe come out this year.

19 So moving forward, it would be  
20 great to see some alignment with guideline  
21 developers as well, to provide reevaluations  
22 for the measures and maintain them.

1           The other issue is, excuse me,  
2           surrounding harmonization, which we're very  
3           open to and we know that a couple of the other  
4           measures relate to CAD and ours relate to IVD.  
5           We have talked about harmonization with a  
6           couple of other measure developers in the  
7           past, but because their measure development  
8           processes have been so different, nothing has  
9           actually panned out.

10           But moving forward, we're very  
11           open to this, and if anybody has any grand  
12           solutions, we're definitely open to hearing  
13           those. Are there any questions? That's all  
14           I have.

15           CO-CHAIR GIBBONS: Thank you very  
16           much. And now we're hoping, I think --

17           DR. WINKLER: Is anybody from PCPI  
18           here? Dr. Masoudi? Oh.

19           DR. MASOUDI: I'm not from PCPI  
20           per se, but I'm here to represent those  
21           measures. I'm Fred Masoudi from the  
22           University of Colorado-Denver. I'm a member

1 of the -- I'm actually the recent past chair  
2 of the ACC-AHA Performance Measures Task  
3 Force, which in conjunction with PCPI  
4 developed the measures for coronary artery  
5 disease that you'll be reviewing today.

6 I'm also a member of the NQF and  
7 represent the Task Force at the NQF. I'm  
8 almost tempted to take six minutes, just to  
9 see if the hook descends, but I won't, Ray, I  
10 promise.

11 So just again to be brief, and  
12 Manasi did a nice job going over much of this.  
13 But these measures represent the joint efforts  
14 of the PCPI, the ACC and the AHA in developing  
15 performance measures for coronary artery  
16 disease. The ones that you'll be discussing  
17 today include, I believe, six measures, of  
18 which two are new measures and three are being  
19 reviewed for maintenance.

20 These include the blood pressure  
21 control measure, which is new; a lipid control  
22 measure which is for maintenance; a symptom

1 management measure, which is new; anti-  
2 platelet therapy, a maintenance measure; beta  
3 blockers for patients with myocardial  
4 infarction or systolic dysfunction, also a  
5 maintenance measure; and ACE inhibitors for  
6 diabetes for a left ventricular systolic  
7 dysfunction, which is also a maintenance  
8 measure.

9           This measure set was originally  
10 developed in 2003 and was revised in 2005.  
11 Many of the 2005 measures were actually  
12 endorsed by NQF and have been used in public  
13 fora, including CMS' PQRS program, in Phase 1  
14 of Meaningful Use.

15           This particular set of measures  
16 includes updates to the coronary disease  
17 measures from 2005, reflecting the latest  
18 guideline evidence and address areas most in  
19 need of performance improvement. I won't, I  
20 think it's clear to everyone the importance of  
21 coronary artery disease, so I won't address in  
22 great detail the fact that this is an issue

1 that afflicts millions and millions of  
2 Americans, and is responsible for nearly \$200  
3 billion in health care costs, and is still the  
4 leading cause of death, especially in women.

5 These measures, just to address  
6 some of the issues around measure development,  
7 there's a multi-disciplinary work group which  
8 is convened by PCPI, ACC and ACCF but is not  
9 just a group of cardiologists. These include  
10 cardiologists but also specialists in internal  
11 medicine, family medicine and hospital  
12 medicine, advanced practice nursing, as well  
13 as individuals with expertise in performance  
14 measure development.

15 These measures are entirely  
16 guideline-based, although many of the  
17 guidelines that are relevant to this effort  
18 are those that emanate from the ACC-AHA.  
19 Other guidelines, including those from the  
20 NHLBI and the Public Health Service were used  
21 in developing these measures. The measures  
22 are harmonized to the extent possible with

1 other measures within the ACC-AHA-PCPI measure  
2 sets.

3 In terms of the process, after the  
4 measures are developed by the work group, they  
5 are submitted for public comment and peer  
6 review. This is a fairly extensive process  
7 whereby dozens of individuals are committed  
8 from other organizations to perform peer  
9 review, and the measures are also put forward  
10 for public comment.

11 The writing groups do almost as  
12 much work as they do in actually developing  
13 the individual measures and responding to the  
14 public comment and peer review. And so again,  
15 you have these five measures.

16 There is some overlap, of course,  
17 with the NCQA measures. This issue of  
18 harmonization will come up, but we very much  
19 appreciate your willingness to evaluate these.

20 I also have on the phone with me  
21 Dr. Joe Drozda and John Spertus. I don't know  
22 if they have other comments. They're both



1 chairs of the Writing Committee.

2 DR. SPERTUS: How could one say it  
3 better than you, Fred?

4 CO-CHAIR GIBBONS: Joe, do you  
5 want to identify yourself? It was Joe, wasn't  
6 it?

7 DR. MASOUDI: No, that's John  
8 Spertus.

9 CO-CHAIR GIBBONS: Okay, John.  
10 Could you better identify yourself for the  
11 Committee?

12 DR. SPERTUS: My name's John  
13 Spertus, and I'm a cardiologist in Kansas City  
14 and was involved in actually both the  
15 original, the modification and the recent  
16 version of the performance measures.

17 The ACC and AHA have a detailed  
18 methodology by which we develop performance  
19 measures. It's been published and we adhered  
20 strictly to those criteria.

21 CO-CHAIR GIBBONS: Thank you.

22 DR. WINKLER: Is someone on the

1 line from Minnesota Community Measurement?

2 Collette, are you there? Okay. Is somebody  
3 on the line from Minnesota Community  
4 Measurement?

5 MS. SNOWDEN: This is Anne  
6 Snowden. Can you hear me?

7 DR. WINKLER: Yes, Anne, we can  
8 hear you. Thank you.

9 MS. SNOWDEN: Okay. I'm the  
10 Director of Performance Measurement and  
11 Reporting for Minnesota Community  
12 Measurements, and we're seeking re-endorsement  
13 for our optimal vascular care measure. I'll  
14 just give a brief background and I have three  
15 points to make.

16 Minnesota Community Measurement's  
17 optimal vascular care measure has been  
18 reported for eight years. It was first  
19 reported by Health Partners back in 2004, and  
20 that is when it was originally endorsed,  
21 through Health Partners.

22 Health Partners -- we have moved

1 the stewardship to Minnesota Community  
2 Measurement, because we're the measure  
3 collaborative in our region. Results for this  
4 measure were first reported by Community  
5 Measurement in 2007, and initially it was a  
6 clinically-enhanced measure that was built on  
7 administrative claims. But now we use data  
8 submitted directly from medical groups, and  
9 have been doing so for about five years.

10 The first point I wanted to make  
11 that kind of sets this measure apart from  
12 others is that it's an all or none composite  
13 measure with four components. We're able to  
14 score and publicly report each component  
15 separately, as well as the optimal care score.

16 We believe the composite measure  
17 sends a message that multiple factors need to  
18 be attended to when providing optimal care for  
19 people with IVD, and the rationale is that  
20 it's better outcomes for the patient to be  
21 well-managed on many physiological parameters  
22 than only focusing on one factor.

1                   For consumers, having an optimal  
2                   care score defined for them and rolled up is  
3                   much more understandable than having to  
4                   compare many measure scores across many  
5                   providers of care.

6                   The other point I wanted to make  
7                   is -- that wasn't in our application clearly -  
8                   - is that medical groups in our state are  
9                   really engaged in using our measure for  
10                  quality improvement. We have seen results  
11                  improve. That's the point that I wanted to  
12                  most make.

13                  Although you saw in the  
14                  application that the state-wide rate has  
15                  remained steady over the last three years,  
16                  this is due in part to the fact that more and  
17                  more new clinics are submitting data to us  
18                  each year, and we have found that clinics that  
19                  submit for the first time tend to have lower  
20                  rates than practices that submit data over  
21                  time.

22                  So in 2010, we analyzed the rates

1 for only those clinics that submitted for both  
2 2009 and 2010, and found actually that the  
3 average rate for them increased from 33  
4 percent to 36 percent, which was a nice three  
5 percentage point improvement in one year.

6 The other key point I wanted to  
7 make is that we recently changed the blood  
8 pressure component to reflect current evidence  
9 that was found in the Accord study. So now  
10 patients with a comorbidity of diabetes have  
11 a different blood pressure target of less than  
12 140 over 90.

13 We do have a routine process in  
14 place annually to review our measures, and  
15 last year we had an advisory committee review  
16 the evidence on blood pressure targets for the  
17 diabetics, and they made a decision that for  
18 this measure to incorporate two blood pressure  
19 targets, less than 140 over 90 for the IVD  
20 patients with diabetes, and less than 130 over  
21 80 for the IVD patients without diabetes.

22 Our Measurement Reporting

1 Committee reviewed and approved these changes  
2 and concluded that there was not yet enough  
3 evidence to change the blood pressure target  
4 to less than 140 over 90 for all IVD patients  
5 in this measure. But we will be reviewing the  
6 evidence, you know, from the JNC-8 that's  
7 expected this fall.

8 Then the last thing I wanted to  
9 mention in terms of lessons learned is that we  
10 have an established patient criteria of having  
11 two visits in two years with the appropriate  
12 diagnosis code to establish a patient at a  
13 practice site.

14 Unlike diabetics, where there's a  
15 diagnosis code linked to the billable charge,  
16 and there's more frequent visits, there isn't  
17 necessarily a routine lab or test for IVD, and  
18 as a result, we've seen that using this  
19 criteria method for an established patient can  
20 and does limit the number of IVD patients  
21 included who have IVD.

22 So we recognize this limitation

1 and we need to balance it with the need for  
2 established patient criteria, and we continue  
3 to review this. So with that, I will  
4 conclude.

5 CO-CHAIR GIBBONS: Thank you very  
6 much. Now your measure isn't slated to come  
7 up for discussion until early afternoon. Are  
8 you going to be able to join us at that time?

9 MS. SNOWDEN: Yes.

10 CO-CHAIR GIBBONS: All right, that  
11 would be great. We're currently targeting one  
12 o'clock for you. All right. I think we've  
13 heard from all the measure developers and for  
14 this particular session of measures, which  
15 takes us from now until two o'clock this  
16 afternoon.

17 So now we want to proceed with the  
18 individual measures, and the first one is 0073  
19 on blood pressure measurement, and Dana King  
20 was the primary reviewer. Dana, the floor is  
21 yours.

22 Measure 0073

1 DR. KING: Thank you. Okay. This  
2 is NQF Review No. 0073. Please turn there in  
3 your various reviews.

4 This is ischemic vascular disease  
5 review for blood pressure management, and a  
6 brief description is, basically, this is the  
7 percentage of patients, adults 18 years of age  
8 or older, who are discharged alive with either  
9 having had an acute myocardial infarction,  
10 coronary artery bypass or angioplasty, who  
11 have -- or a diagnosis of ischemic vascular  
12 disease who have their blood pressure reported  
13 as under control by the end of the following  
14 year.

15 So it's basically an outcome  
16 measure. The first criteria that we need to  
17 think about, of course, is importance, and I  
18 think that's actually been covered fairly well  
19 by our submitters. There are a few that doubt  
20 that coronary artery disease is a problem, and  
21 even fewer still that would doubt that blood  
22 pressure management is important.



1                   So there are -- obviously the  
2                   number one cause of death and 70 million  
3                   people with hypertension is a pretty good  
4                   criteria for the importance of measuring it,  
5                   and that would just be in the general  
6                   population alone. But consider the importance  
7                   being even greater among those who already  
8                   have the disease, the consequence, and we're  
9                   aiming towards secondary prevention.

10                   So I would probably want to move  
11                   quickly to Step 1, Question 1.

12                   CO-CHAIR GIBBONS: Thank you very  
13                   much. So are there any questions for Dana  
14                   before we vote on importance?

15                   (No response.)

16                   CO-CHAIR GIBBONS: Anybody want to  
17                   add anything?

18                   (No response.)

19                   CO-CHAIR GIBBONS: Okay. So we  
20                   will move to vote on importance, and this is  
21                   now no longer a test. This actually counts.  
22                   So we're going to see if we get the same

1 numbers of people pressing the buttons as on  
2 the first test.

3 DR. SMITH: I have a question,  
4 Ray. Ray, I have a question, if I may.

5 CO-CHAIR GIBBONS: Yes.

6 DR. SMITH: If we have a concern  
7 about inclusion criteria for a particular  
8 measure, that should not come up here?

9 CO-CHAIR GIBBONS: Correct.

10 DR. SMITH: If you think  
11 hypertension's important.

12 CO-CHAIR GIBBONS: Correct.

13 MS. PACE: Just to explain that,  
14 our importance criterion has the three  
15 subcriteria. One is about the impact of the  
16 condition or the procedure that the measure is  
17 focusing on.

18 The second one is there  
19 opportunity for improvement, and this is where  
20 especially for a measure that's already been  
21 endorsed in the past, we want to look at  
22 what's the current performance. Is it, quote,

1 a "topped out" kind of measure, where  
2 everyone's doing it and we don't really have  
3 that much more opportunity.

4 The third is, is it evidence-  
5 based? So whatever the focus of measurement  
6 is, is there a solid evidence base to say that  
7 this should be a performance measure? So the  
8 specifics about how it's specified,  
9 reliability and validity come under the next  
10 criterion, Scientific Acceptability of measure  
11 properties.

12 CO-CHAIR GIBBONS: All right.  
13 We're going to get back to the voting at this  
14 point. So Ashley started the clock.

15 DR. SANZ: Ray?

16 CO-CHAIR GIBBONS: Mark.

17 DR. SANZ: While people are  
18 voting, could people -- could you tell us  
19 where these measures are in the packets we've  
20 received, because they've been spread among  
21 four groups, two primary batches plus an  
22 additional batch. So that would be helpful.

1 CO-CHAIR GIBBONS: I agree.

2 That's a challenge. Ashley, can you assist us  
3 with that? Looks like we've completed the  
4 vote. I don't think we took a minute. This  
5 is good.

6 DR. SANZ: This is Batch 4 -- or  
7 Group 4, Batch 1 of the first thing. So  
8 people who are trying to find it.

9 MS. MORSELL: We have thumb drives  
10 actually with the materials based on the day.  
11 So if you don't have a thumb drive, raise your  
12 hand and I'll give you one, if it makes it  
13 easier to navigate.

14 CO-CHAIR GIBBONS: Okay. We're  
15 going to move on now. Dana, you're back on.  
16 Scientific acceptability, Criteria 2.

17 DR. KING: Okay. Scientific  
18 Acceptability. We're measuring the blood  
19 pressure. The numerator is the number of  
20 patients whose blood pressure is adequately  
21 controlled. Blood pressure must meet the  
22 desired threshold. The first one is 140 over

1 90. There's an additional one of 130 over 80  
2 for certain patients.

3 The denominator is basically  
4 people with these conditions who have had  
5 their blood pressure measured during the  
6 previous year, either in a health plan or  
7 outside of a health plan.

8 It's the last -- they go by the  
9 last measurement. So it's a single blood  
10 pressure measurement, the last or the most --  
11 the one toward the end of the year. There  
12 have not been any adjustments or risk  
13 adjustments, and there has not been  
14 stratification reported in this measure by  
15 age, race, gender.

16 The data comes from paper as well  
17 as electronic medical records. As you may or  
18 may not know, only approximately half of the  
19 medical offices have electronic medical  
20 records for this kind of data. So they, of  
21 necessity, have to collect data from paper  
22 survey, electronic claims data as well as

1 electronic medical records, because everyone  
2 doesn't have one. So that's the state of the  
3 art at the current time. Any questions?

4 CO-CHAIR GIBBONS: So your  
5 feelings about Scientific Acceptability?

6 DR. KING: There was a concern by  
7 a couple of the reviewers about the 140 over  
8 90 threshold versus the 130 over 80, the  
9 concern being although there's some evidence,  
10 evidence in this particular population to make  
11 a stricter standard is probably lacking, and  
12 140 over 90 is probably -- even that, in this  
13 exact population, doesn't have a lot of  
14 evidence.

15 But making it stricter has little  
16 or no evidence, and so there was some concern  
17 about that. Otherwise, most of the comments  
18 were more about the feasibility rather than  
19 about the scientific validity of this measure.

20 CO-CHAIR GIBBONS: Are there other  
21 comments or concerns about the Scientific  
22 Acceptability? Sid?

1 DR. SMITH: Yes. I have a concern  
2 about the elderly. First of all, let me  
3 state that I believe the treatment of  
4 hypertension is of huge and fundamental  
5 importance to preventing both new and  
6 recurrent events in cardiovascular disease.  
7 So I fully support the notion that we should  
8 get some idea about how well hypertension's  
9 being treated.

10 What concerns me are the numbers,  
11 and specifically in the elderly. There have  
12 been ten trials now -- and I can show you the  
13 data -- performed in the elderly. Of those  
14 ten trials, only one has a treatment benefit  
15 of taking a systolic blood pressure of less  
16 than 140. That trial showed no benefit.

17 The trials that show benefit have  
18 ended up with systolic pressures that range  
19 from around 145 to 155. So I have a concern  
20 with stating in, let's say in an 85 year-old,  
21 that we have scientific evidence that there is  
22 benefit to taking their blood pressure

1       systolic to less than 140. So I would just  
2       like to see the paper that supports that.

3               The other thing is the initiation  
4       of therapy. In all ten, well in eight of the  
5       ten trials, the treatment was initiated at  
6       systolic blood pressure greater than 160,  
7       which would be Stage 2 hypertension, 140 to  
8       160 being Stage 1.

9               So the idea that initiating  
10       treatment for hypertension in the elderly,  
11       let's say a blood pressure of 148 systolic,  
12       and taking it below 140, it would help me to  
13       see a trial that supports that.

14              My concern is that we have the  
15       evidence base which would support indicating  
16       the validity of doing this, and the inference  
17       that those who were managing elderly patients  
18       were unable to get a systolic blood pressure  
19       under 140, suggesting that was somehow  
20       inadequate therapy. I'm think we need to be  
21       careful about this.

22              CO-CHAIR GIBBONS: Are there other



1        comments or concerns?    Mark.

2                    DR. SANZ:    I just have a quick  
3        question.    We talked here about 130 over 80,  
4        140 over 90.    When I look at 2A.1, I don't see  
5        130 over 80 anywhere.    It says 140 over 80,  
6        blood pressure threshold 1; 140 over 90, blood  
7        pressure threshold 2, and then in 2A.3,  
8        there's five different detailed numerators  
9        you're supposed to take.

10                    It seems very complicated, and I  
11        don't see where you get benefit from measuring  
12        140 over 80 versus 140 over 90.    It's also,  
13        for those who do blood pressures, very  
14        difficult to separate those two out on repeat  
15        measurements.    The difference can be pretty  
16        slim.    I don't know if the measure developers  
17        want to comment on that.

18                    CO-CHAIR GIBBONS:    David, did you  
19        have a comment or question?

20                    DR. MAGID:    Yes.    One of the  
21        things that wasn't stated was whether or not  
22        home blood pressure measurements would be

1       accepted, and I think this has been, at least  
2       with regard to NCQA, in the past they have not  
3       accepted that.

4               But I think that the evidence base  
5       is so powerful at this point to show that home  
6       blood pressure monitoring leads to better  
7       blood pressure control.

8               It's both more acceptable and  
9       satisfactory to patients as well as providers.  
10       So the absence of that is a real problem, and  
11       I don't know if you can speak to that, but  
12       it's not stated in here clearly.

13               MS. TIRODKAR: Yes. Currently, we  
14       are not accepting home blood pressure  
15       measurements, and during our last panel  
16       meeting, we talked extensively about that.  
17       One of the concerns was for standardization of  
18       equipment or calibration of equipment. You  
19       know, is a blood pressure monitor bought at  
20       Walgreen's the same as one that's provided by  
21       a physician's office?

22               And until we could test the

1 feasibility of getting accurate measurements  
2 from home blood pressure monitors we did not  
3 want to include that in the specification. We  
4 have received that question a lot, even  
5 through our policy clarification system.

6 It's something that we'd like to  
7 consider definitely moving forward, and we  
8 have considered it in the past.

9 DR. MAGID: It takes about ten  
10 minutes or less to validate a blood pressure  
11 cup. I think that argument has, with the  
12 tremendous evidence base that we have now, I  
13 think you're hiding behind something that's  
14 really unnecessary at this point. I don't  
15 know if we can provide feedback.

16 CO-CHAIR GIBBONS: Well, you have.  
17 It's on the public record.

18 MS. TIRODKAR: Yes, absolutely.

19 CO-CHAIR GIBBONS: Next question.

20 DR. JEWELL: Thank you, and this  
21 is really more a question regarding our  
22 overall process. I'm struggling a bit with

1 the absence of reliability and validity data  
2 in a number of these measures, or the level of  
3 incompleteness of such evidence, and how to  
4 weigh that against importance.

5 Because I worry a bit about  
6 creating measures that while they may be  
7 important, don't do what they say they're  
8 doing. So I need a little guidance from  
9 either the group that reviewed this measure,  
10 or just in general. How hard-nosed should I  
11 be?

12 MS. PACE: I'll make a couple of  
13 comments for you. One of the things that, you  
14 know, your discussion about the evidence is  
15 good discussion, and for the future measures,  
16 we'd like you to discuss that under  
17 Importance, because that's really where we  
18 want the evidence to be reviewed under the  
19 importance criterion.

20 So our subcriteria under  
21 Scientific Acceptability of measure properties  
22 is really about the reliability and validity.

1 You're right, that the evidence base really  
2 provides the foundation for having a valid  
3 quality indicator.

4 But if there's really not solid  
5 evidence to support the measure focus as they  
6 are intending, then that's something that  
7 should be considered in your vote on  
8 importance.

9 The observation about reliability  
10 and validity. I think, you know, that's the  
11 core of what we're looking for in scientific  
12 acceptability. So it may be a good idea to  
13 measure, but how the measure is constructed  
14 may not demonstrate that it's a reliable or  
15 valid measure.

16 If there's no information about  
17 reliability and validity, then that's  
18 something that you need to weigh pretty  
19 heavily.

20 We don't tell you that you can't  
21 move forward with a measure, but you know, we  
22 have really gone into the period where we're

1 -- untested measures are things that we really  
2 don't want to consider for endorsement, unless  
3 there's really justification for that.

4           So some of the data for this  
5 particular measure, some of the information  
6 that was provided under reliability gave  
7 descriptive statistics for the whole group of  
8 patients. But it didn't really give  
9 reliability information about either the data  
10 elements or at the physician score level.

11           So it's things that you need to  
12 weigh. Also your knowledge of these data and  
13 the topics weighs into your consideration of  
14 all of these things. So there's not a hard-  
15 line black and white, but it is certainly  
16 something for your consideration.

17           CO-CHAIR GIBBONS: Sid.

18           DR. SMITH: Just to go back to the  
19 evidence base which I have, and the people  
20 that proposed this measure may have more  
21 evidence, which I think would help me to see,  
22 there's no doubt that initiating therapy in

1 elderly patients for the treatment of  
2 hypertension has value. So of the ten trials  
3 that I have, eight of them show benefit.

4 In none of the trials where the  
5 criteria for initiating therapy, a systolic  
6 less than 160. So in all of the ten trials,  
7 the criteria for treating was not Stage 1  
8 hypertension; it's Stage 2. Of those trials,  
9 eight of them, and I can show you a slide at  
10 break or whenever we have a chance, all of  
11 them show benefit. Eight of the ten show  
12 benefit.

13 None of them, of those eight, took  
14 the systolic blood pressure to less than 140.  
15 That's what I'm struggling with, in terms of  
16 putting this out as a measure. Only one of  
17 them went to less than 140, and it showed no  
18 benefit.

19 So I'm trying to -- it's extremely  
20 important to understand the data support the  
21 treatment of hypertension in the elderly. The  
22 issue is what are we going to measure, and

1 it's putting people on the line for not  
2 achieving a certain target, if it could  
3 potentially be dangerous and we don't have the  
4 evidence.

5 CO-CHAIR GIBBONS: Okay. We're  
6 going to have to move ahead, or else we'll  
7 never get through the agenda.

8 So I would just sort of offer the  
9 comment that this is the kind of thing, per  
10 the comments that Helen made earlier, that  
11 could potentially be addressed -- potentially  
12 be addressed -- with a response to the  
13 developer saying we'd like to see an exclusion  
14 for X, or a different criteria for X age.  
15 Karen?

16 MS. PACE: Just one other thing,  
17 just to orient people. In your, on your thumb  
18 drive, if you go to this measure, and I don't  
19 know if Kate can put it up.

20 CO-CHAIR GIBBONS: We're not going  
21 to have time.

22 MS. PACE: Right. But I'm just



1 saying when people have a question about what  
2 evidence was submitted in support of a  
3 measure, it should be in that measure  
4 submission form. So that's where it would be.

5 CO-CHAIR GIBBONS: Mary?

6 CO-CHAIR GEORGE: The only comment  
7 I would like to add is in the scientific  
8 evidence that was submitted for this, it said  
9 it was important to exclude ESRD patients from  
10 this measure, but they are not listed as an  
11 exclusion in the measure specification. I  
12 think that's an important consideration.

13 CO-CHAIR GIBBONS: I think we have  
14 to call the question and vote on the  
15 Scientific Acceptability of the measure.

16 DR. SANZ: Ray, while people are  
17 voting, will this then, no matter what  
18 happens, does the measure developer get a  
19 chance to take into account all these things,  
20 and then bring it back at some later date, or  
21 is this a final up/no, or yes/no?

22 CO-CHAIR GIBBONS: Well, they have

1 a right of appeal for certain in the process,  
2 and they also have a right to come back with  
3 modifications or with, in their opinion,  
4 answers to the questions that were raised.  
5 This is all on the public record, but they  
6 will receive a sort of summary from us.

7 MS. PACE: Has everyone voted or  
8 think that they've voted?

9 CO-CHAIR GIBBONS: All right.  
10 Moving on to Usability, Criteria 3. Dana.

11 DR. KING: Okay. The NQF criteria  
12 for Usability; it seemed to be evident that  
13 blood pressure has been measured, is used.

14 There's data that the submitter  
15 provided on blood pressures on literally  
16 thousands of people. The range of blood  
17 pressure control, from 10th to 90th  
18 percentile, was from 68 to 91 percent, with  
19 the mean being around 75 percent of the people  
20 achieving control at that 140 over 90 level.

21 We mentioned also this other  
22 criterion, which of course is somewhat

1 confusing, since on the submission it was 140  
2 over 80, but in the data that was submitted  
3 for reliability results, it was 130 over 80.

4 In that, the 10th percentile was  
5 28 and the 90th was 62. Nevertheless, it  
6 seems to be -- and there was an N of over  
7 2,300 measures, that this is a usable, doable  
8 criteria, and it also documents a gap. In  
9 other words, we're not achieving what we would  
10 hope would be a reasonable -- although 100  
11 percent would be unreasonable, surely 80 to 90  
12 would be reachable in this population, who is  
13 under pretty high surveillance. We've only  
14 reached 75 at the 140 over 90 level. So it  
15 seems to be a usable measure.

16 DR. RASMUSSEN: If I could make a  
17 comment.

18 CO-CHAIR GIBBONS: Certainly.

19 DR. RASMUSSEN: In the parlance of  
20 NCQA and HEDIS, it seems to be an  
21 administrative measure, meaning once the data  
22 is queried there's no necessarily manual

1 review of the data. I'm wondering if this  
2 measure would benefit from being a hybrid  
3 measure, which would mean someone could  
4 manually review it.

5 I think we could get to Dr.  
6 Smith's comments, in that if we have a cohort  
7 of patients that we don't feel should be  
8 treated to a more aggressive goal, this would  
9 allow us an opportunity to exclude that  
10 patient clinically appropriately, but keep the  
11 measure intact.

12 MS. TIRODKAR: This is a hybrid  
13 specification actually.

14 DR. RASMUSSEN: This is hybrid?

15 MS. TIRODKAR: Yes. This is a  
16 physician-level measure.

17 DR. RASMUSSEN: So there already  
18 is an opportunity, then, for a clinician to go  
19 in and exclude a patient?

20 CO-CHAIR GIBBONS: I'm sorry. Do  
21 you have your mic on back there?

22 MS. TIRODKAR: Yes, I do. Yes.

1 CO-CHAIR GIBBONS: Could you talk  
2 closer to it, because we're having trouble at  
3 the front of the room hearing you.

4 MS. TIRODKAR: Okay. Yes, this is  
5 a hybrid specification, because it's a  
6 physician-level measure. There is a step-wise  
7 process for identifying patients in medical  
8 records.

9 CO-CHAIR GIBBONS: Okay. Dana,  
10 can I ask you specifically comment on 3B? Is  
11 there a need for harmonization?

12 DR. KING: In the application,  
13 they said this measure is different from  
14 controlling high blood pressure in other  
15 populations. So I don't know that it needs to  
16 be necessarily harmonized, if it's just blood  
17 pressure in a different population --

18 CO-CHAIR GIBBONS: Yes. I think  
19 our concern has to be that there are other  
20 measures addressing hypertension, and  
21 therefore in terms of specifications, for  
22 example exclusions or even targets, there's

1 another measure with a different target, then  
2 we ought to harmonize. So I think we're going  
3 to end up having to delay a final vote,  
4 pending the harmonization issue.

5 But in the meantime, I'm going to  
6 suggest that we now vote on number three,  
7 Usability.

8 I'd just point out that we're  
9 slowing down in part because we are not  
10 getting 21 votes in. So if everybody would  
11 make sure when they're voting that they press  
12 send, and I would ask you even if you're not  
13 comfortable, vote some way, because that will  
14 speed things up. Otherwise, we're going to  
15 take an extra minute for every one of these.

16 All right. Let's move on to  
17 number four, Feasibility. Dana?

18 DR. KING: Does the measure meet  
19 the criteria for Feasibility? It's very  
20 feasible. In fact, we just went over the data  
21 a moment ago that's been collected. It's  
22 actually been an ongoing collection in this

1 population. It's from a variety of sources,  
2 and they do not have any exclusions mentioned.

3 The costs are -- the costs in here  
4 were mentioned as not applicable, because this  
5 data's already been collected for various and  
6 sundry reasons.

7 CO-CHAIR GIBBONS: Okay. Are  
8 there comments or questions about Feasibility?  
9 If not --

10 DR. SNOW: Quickly, we heard  
11 earlier that this was a hybrid measure because  
12 it was physician related, but it also says all  
13 the data are available electronically.  
14 There's a little disconnect there as a  
15 practical measure, because still at least half  
16 the physicians' offices are not EHRs. Two  
17 years from now, if high tech survives, that  
18 will be different.

19 But it may technically be hybrid  
20 or electronic, but it's not -- you don't have  
21 to go to records if you've got an academic  
22 medical center.

1 DR. RICH: For purposes of public  
2 reporting, I think that it is difficult if you  
3 only have half the records that are usable.  
4 So it would be very -- I think it would be a  
5 burden for public reporting purposes to have  
6 it as a hybrid measure.

7 CO-CHAIR GIBBONS: And, if I  
8 understood correctly earlier, it's being  
9 proposed as a hybrid measure; is that correct?

10 MS. TIRODKAR: The hybrid  
11 specification is optional. So it may be used  
12 if the electronic -- if data is not available  
13 entirely electronically here. So I'm looking  
14 at my spec here, and it says the hybrid method  
15 and medical record method may be used for this  
16 measure. So I'm not sure if that answers the  
17 question.

18 CO-CHAIR GIBBONS: Mark.

19 DR. SANZ: We don't understand the  
20 differentiation. As clinicians, what are we  
21 talking about, hybrid versus administrative?  
22 Can you explain that in 30 seconds?



1 CO-CHAIR GIBBONS: That's the  
2 question to the developer? Thirty seconds to  
3 explain that distinction?

4 MS. TIRODKAR: Sure. Electronic  
5 would be claims-based, or sorry,  
6 administrative would be a claims-based  
7 measure, and hybrid would be a medical record  
8 review measure, whether it's an EHR or a paper  
9 record.

10 So you could use -- you could pull  
11 data from either an electronic or paper chart,  
12 to identify your numerator or denominator  
13 population, as opposed to just administrative  
14 claims.

15 DR. RASMUSSEN: On a practical  
16 level, what it does is just give the clinician  
17 an opportunity to manually review a chart and  
18 to add to the numerator. So hybrid is always  
19 already an administrative measure. The hybrid  
20 designation just gives the clinician an extra  
21 opportunity to review the chart and include or  
22 exclude patients based on other criteria.

1 DR. SNOW: Or in some instances,  
2 for some measures it may be necessary to do  
3 that. So that the hybrid measure is a  
4 combination of chart review, onerous chart  
5 review and the more convenient electronic  
6 computer stuff. If it's referred to as  
7 administrative, then the computer can do the  
8 whole thing and you don't need to go to the  
9 chart.

10 CO-CHAIR GIBBONS: Okay. I think  
11 we need to vote on number four, Feasibility.

12 MS. PACE: Has everybody voted?  
13 Has everybody voted?

14 CO-CHAIR GEORGE: Reva, Reva.  
15 Does the system not show you which clickers  
16 have logged in? Because it should -- you can  
17 let us know which number didn't come through,  
18 and then we can try again.

19 CO-CHAIR GIBBONS: I think we'll  
20 need to review that and figure out which one  
21 is not working. Somebody is not being counted  
22 here. They have a hanging chad.

1 MS. PACE: Don't blame Florida.

2 CO-CHAIR GIBBONS: Sorry. Okay, I  
3 think what we're going to do is defer this  
4 final vote on endorsement, pending the  
5 harmonization resolution.

6 DR. WINKLER: Yes. What we'd like  
7 to do, though, is get a sense from your  
8 discussion of whether prior to discussion of  
9 harmonization, does this measure from the  
10 evaluation you've done at this point in time  
11 meet the criteria for endorsement.

12 MS. PACE: It doesn't mean that  
13 you're recommending this one at this time.  
14 That will be pending the comparison for  
15 harmonization or competing measures. So the  
16 idea is if this measure, standing alone, does  
17 it meet the criteria.

18 DR. AYALA: I have a question.  
19 Going back to your comments about whether or  
20 not we may recommend exclusions and some  
21 modification of the measure, when we look at  
22 the overall endorsement question, how do we

1 incorporate that?

2 How do we -- if we do, if we would  
3 recommend it with exclusions, would we then  
4 say no, we don't recommend it, or would we say  
5 yes, we recommend it and how would we say "but  
6 with exclusions"?

7 DR. WINKLER: Right. First thing,  
8 we're asking for your assessment on the  
9 measure, as submitted.

10 If you would like to in addition  
11 then say, you know, we would have a  
12 conditional recommendation, that can be a  
13 subsequent vote. But right now, we do want to  
14 know your assessment of the measure, as  
15 submitted, with the information that's put  
16 here.

17 CO-CHAIR GIBBONS: So we're going  
18 to vote on the measure, as submitted.

19 All right. We can do that, but  
20 I'd just point out if we get into any vote  
21 where there's a one-vote margin, it then  
22 becomes moot and it will have to be revoted

1 later on.

2 MS. PACE: We'll vote it by hand.

3 CO-CHAIR GIBBONS: Okay. So we  
4 have a clicker that's not working. We will  
5 get to that. All right. You want to try a  
6 second vote right now on the exclusion?

7 DR. WINKLER: Given that the vote  
8 was against the measure as submitted, would  
9 the Committee like to offer some conditions  
10 where they might feel more favorable about the  
11 measure, in which the measure developer could  
12 consider and then come back to you?

13 CO-CHAIR GIBBONS: This has got to  
14 be quick and easy.

15 DR. KING: Yes. I would suggest  
16 from what I heard from the Committee that we  
17 make -- throw out the 130 over 80, 140 over  
18 80. Leave it 140 over 90 and either exclude  
19 people over age 65 or have a criterion of 160  
20 over 90 for patients over age 65.

21 I'm seeing some nods, so that --  
22 doesn't fix everything, but I think that would

1 be one of the conditions that perhaps was  
2 making some people say no.

3 DR. AYALA: I would add to that  
4 that in the exclusions allowed for the  
5 clinician to make comments regarding the  
6 patient's ability to tolerate a lower blood  
7 pressure, because I don't think that just an  
8 age cut-off is going to be all that we need  
9 there.

10 DR. RICH: The concern that I  
11 would have again is that only half of the  
12 information would be captured electronically,  
13 and so it would be a burdensome measure.

14 DR. PHILIPPIDES: Any measure that  
15 has relevant clinical information is going to  
16 be like that. If we limit ourselves to  
17 administrative measures, then you know, we're  
18 not going to be doing patients justice.

19 DR. RASMUSSEN: And from a  
20 standpoint of 50 percent having access to  
21 electronic medical records, does that  
22 represent the population?

1                   So there may be 50 percent of  
2                   medical groups that have electronic medical  
3                   records, but is 75 percent of the population  
4                   covered by an organization that has electronic  
5                   medical records? I don't have an answer to  
6                   that. It's more of a question for the group.

7                   DR. SNOW: Yes. Well, I agree  
8                   with your speculation, because it's the bigger  
9                   practices that are more likely to have medical  
10                  records, although it tends to even out,  
11                  because there are so many smaller one- and  
12                  two-physician practices.

13                  However, going forward, as the  
14                  high tech and meaningful use and all that  
15                  takes place, and that is moving and the  
16                  money's being spent, then higher and higher  
17                  percentages of practices will be. So this is  
18                  a problem that should largely resolve over the  
19                  next three or four years.

20                  DR. MAGID: I'd also just say that  
21                  -- sorry, that we're not talking about digging  
22                  through lots of records. We're going to the

1 last visit. Every visit should have blood  
2 pressure measured, and it should be at the  
3 very top of the visit.

4 So I mean there may be some cases  
5 where it really is hard to find some  
6 information, but not for this measure.

7 CO-CHAIR GIBBONS: Okay, yes,  
8 Helen.

9 DR. BURSTIN: Just one point.  
10 This measure was retooled for program this  
11 year. It's been specified for EHRs. One  
12 question that's indicated would be it actually  
13 is specified for 140 over 90.

14 So I think probably rather than  
15 getting into the specifics of saying "change  
16 this, change that," it sounds like the  
17 Committee would like clarification about the  
18 level of blood pressure measurement overall.

19 CO-CHAIR GIBBONS: Well, the  
20 Committee has a major concern about applying  
21 that standard to the elderly.

22 DR. BURSTIN: Yes, right, and I



1 think that's a reasonable question. But also  
2 it sounds like the measure doesn't exactly  
3 match what's been retooled for EHRs either.

4 CO-CHAIR GIBBONS: Sid.

5 DR. SMITH: I kind of want to say  
6 how important I believe the treatment of  
7 hypertension is, and we do have eight out of  
8 ten trials showing that initiation of therapy  
9 among elderly patients, whose blood pressure  
10 systolic is greater than 160, has benefit. It  
11 reduces cardiovascular events, the major one  
12 being stroke.

13 The problem is that of those  
14 trials, the majority, eight to nine of them  
15 only got the systolic blood pressure down to  
16 the range of 145, 148, and in one case 150.

17 So the issue is how we go about  
18 being sure that our elderly patients are being  
19 treated appropriately for hypertension, and  
20 the measure that we have here of getting it  
21 below 140 is not supported by evidence of  
22 which I am aware.

1                   So I don't know if there's a way  
2                   we -- I mean, the other way to approach this  
3                   is all patients with blood pressure of 160  
4                   over a systolic range should be treated or  
5                   something. There's got to be a way through  
6                   this. I'm just concerned about the measure  
7                   and what --

8                   CO-CHAIR GIBBONS: All right.  
9                   Fred in the back.

10                  DR. MASOUDI: Just very briefly.

11                  MS. PACE: Microphone.

12                  DR. MASOUDI: From the measure  
13                  developer's perspective, you know, we're  
14                  somewhat hostage, of course, to the  
15                  guidelines. So whatever the guidelines say is  
16                  what we would adhere to.

17                  I'm not completely sure that the  
18                  secondary prevention guidelines specifically  
19                  suggest that patients above a certain age  
20                  threshold should be held to a different blood  
21                  pressure threshold, which makes it somewhat  
22                  challenging.

1 I'm not sure the extent to which  
2 the trials that you refer to were necessarily  
3 secondary prevention trials versus overall  
4 blood pressure trials, because these are all  
5 secondary prevention measures. So just  
6 something to consider.

7 In the PCPI measure, the one thing  
8 I will note is that rather than having a stern  
9 threshold there's also this issue about the  
10 use of two medications, which is an attempt to  
11 try to get around that.

12 CO-CHAIR GIBBONS: Okay. I think  
13 I've heard enough, that I would suggest that  
14 we've given plenty of feedback to the measure  
15 developer. Leave it to them to come back with  
16 a crisper proposal with clarification, as  
17 Helen has pointed out, and also with  
18 consideration of the data in the elderly.

19 Because in the interest of time,  
20 we must move on. So we're going to move on to  
21 the next measure, and the next measure is a  
22 little bit confusing. It has a little bit of

1 a checkered history compared to everything  
2 else, and so I want to just describe that to  
3 everybody, so it's clear.

4 Measure 1486

5 It is Measure 1489. I'm sorry,  
6 1486. I keep getting that number transposed.  
7 1486, which was blood pressure measurement in  
8 patients with coronary disease, submitted by  
9 PCPI.

10 Now it appeared that we weren't  
11 going to have any data, so the staff sent out  
12 a note saying that this should be considered  
13 last, I think it was. It dropped to the  
14 bottom of our list, and it was pulled from the  
15 roster of possibles for the voting, for the  
16 ratings.

17 So I was the primary reviewer and  
18 discovered there was no way for me to rate it,  
19 because it was no longer listed as an option  
20 in the ratings. Therefore, as far as I know,  
21 we're not going to have it anywhere on the  
22 Excel spreadsheet, and so you're going to

1 listen to the primary reviewer.

2 This was in Batch 2 for Group 1,  
3 for those who want to make sure that they're  
4 looking at it, and so I will try to lead us  
5 through this, recognizing that there's no  
6 voting track record on this one.

7 So this is about blood pressure  
8 control in patients with coronary artery  
9 disease. We've already had a discussion about  
10 the importance of blood pressure control, and  
11 I would argue that it's pretty clear this is  
12 important. We ought to proceed to a vote on  
13 Importance.

14 MS. PACE: Has everybody voted?  
15 Are people up?

16 CO-CHAIR GIBBONS: People are up  
17 now.

18 MS. PACE: Okay.

19 CO-CHAIR GIBBONS: Okay. So we  
20 obviously feel it's important, and I'm now  
21 going to move on to Criteria No. 2, which is  
22 Scientific Acceptability. The numerator is

1 clearly defined.

2 It's patients with a blood  
3 pressure of less than 140 over 90, or a blood  
4 pressure equal to 140 over 90, and who have  
5 been prescribed two or more anti-hypertensive  
6 medications during the most recent office  
7 visit.

8 So I think I felt that the measure  
9 was well-specified. The only problem in terms  
10 of Section No. 2 was the absence, at the time  
11 I was reviewing it, of any data with respect  
12 to reliability under Section 2B, and that data  
13 was apparently submitted last night at 5:30.

14 So we now have such data, and we  
15 have something, and I will presume that the  
16 data is going to turn out to be reasonable on  
17 staff review. So I did not really have any  
18 concerns about that. There is no risk  
19 adjustment, and I really felt that pending  
20 receipt of the PCPI data on reliability, that  
21 this was a well-specified measure.

22 DR. RASMUSSEN: Could you comment

1 on the evidence regarding a patient who has  
2 blood pressure greater than 140 but is on two  
3 medications? Clinically, it seems sound, but  
4 what's the evidence behind that?

5 CO-CHAIR GIBBONS: It's actually  
6 not greater than, it's very clearly specified,  
7 equal to. So you only make it into the  
8 numerator if you're equal to 140 over 90. Dr.  
9 Masoudi, do you want to comment on that issue?

10 DR. SPERTUS: This is Dr. Spertus.  
11 That got a typo. It's greater than or equal  
12 to 140 over 90.

13 DR. MASOUDI: Right. So the point  
14 of it is either control, as defined by the  
15 guidelines, or being on at least two  
16 medications, is how it's specified.

17 DR. RASMUSSEN: So clinically,  
18 that makes a lot of sense. What's the  
19 evidence base for that recommendation as a  
20 positive hit in the numerator?

21 DR. MASOUDI: Yes. I don't know  
22 that there's, you know, I don't know that

1 there's a specific clinical trial or a  
2 guideline recommendation that you could point  
3 to to support that.

4 But this is really an issue that  
5 helps for the clinical application measures,  
6 as you point out, the idea that you don't  
7 necessarily want someone to be on six or seven  
8 medications.

9 So it's really more along the  
10 lines of clinical applicability, not the  
11 specific evidence base per se.

12 DR. SPERTUS: This is John  
13 Spertus. The other consideration was that we  
14 didn't want to create an incentive for  
15 physicians not to take care of patients who  
16 had difficult to control blood pressure.

17 So we felt we could be  
18 exacerbating disparities by creating a  
19 performance standard that disincentivized a  
20 doctor from taking care of somebody whose  
21 blood pressure was just frankly very difficult  
22 to control.



1                   So by requiring two or more  
2                   medications, you are, you know, getting clear  
3                   evidence that a significant attempt with  
4                   pharmacotherapy is being pursued, to try and  
5                   control the blood pressure. But there are  
6                   some patients you just can't get too low, and  
7                   we thought doctors should get credit for that.

8                   CO-CHAIR GIBBONS: David?

9                   DR. MAGID: So I'd say two things.  
10                  One is that a fair number of patients are  
11                  going to require more than two medications.  
12                  So that seems rather arbitrary. The second  
13                  thing is that for hypertension control, you  
14                  know, it's monitoring, it's intensification.

15                  But it's also adherence, and  
16                  physicians need to be addressing that. So,  
17                  you know, just because you prescribe two  
18                  medications, if the patient's not taking it,  
19                  that needs to be addressed. That could be  
20                  part of the problem. So it seems rather  
21                  arbitrary and not particularly evidence-based.

22                  DR. MASOUDI: Yes. Again, it's an

1 attempt to find a clinical balance here, where  
2 you're not necessarily -- again, I think one  
3 of the issues with measures that we were  
4 cognizant of is this issue of unintended  
5 consequences.

6 One of the unintended consequences  
7 of saying it's control or nothing, is that you  
8 take those patients who are non-adherent,  
9 whose blood pressure is difficult to control,  
10 and you incentivize the physician not to take  
11 care of them.

12 DR. DROZDA: This is Joe Drozda.  
13 Can you hear me?

14 CO-CHAIR GIBBONS: Yes Joe, we  
15 can.

16 DR. DROZDA: Yes, I just want to  
17 address the issue of adherence, because it is  
18 an important one, and I would agree with the  
19 comment, that physicians need to address  
20 adherence.

21 It was discussed at some length by  
22 the writing committee who developed these

1 measures, and I think the final conclusion was  
2 that adherence is a very complex outcome to  
3 really measure, with impacts from multiple  
4 areas.

5           Probably the most significant  
6 impact coming from outside the physician's  
7 locus of control, primarily related to  
8 prescription coverage, prescription drug  
9 coverage, co-pays, et cetera, and a lot of  
10 social things that are really beyond the  
11 physician's locus of control.

12           So I think we felt that it was, we  
13 were addressing something very important that  
14 the physician was identifying, that the  
15 patient had difficulty controlling blood  
16 pressure, and was at least prescribing two  
17 medications to bring it under control.

18           We think that's an important step,  
19 you know. Adherence, I think, is something  
20 that needs to be addressed, you know, and  
21 maybe at a different level of measurement than  
22 the individual physician. But I think that

1 would be the next step in the evolution of  
2 these measures.

3 CO-CHAIR GIBBONS: So I want to  
4 just clarify. John Spertus has indicated that  
5 the equals to 140 is a typo. I want to make  
6 certain that the other representatives agree  
7 with that. That typo appears at least three  
8 times in the submission.

9 I've just been paging through it,  
10 at least three times, and I would point out  
11 then, that as I understand it, if it's greater  
12 than 140, somebody who's 220 over 120 on two  
13 medications is in the numerator?

14 DR. MASOUDI: Just first of all,  
15 our apologies for the errors in the  
16 submission. It is patients who have blood  
17 pressures above the target, but who are on at  
18 least two medications.

19 So the idea would be that again,  
20 either the patient has their blood pressure  
21 under control, or the physician caregiver is  
22 making a good faith effort to get under

1 control with being on at least two  
2 medications, acknowledging that indeed there  
3 may be other patients who (a) remain out of  
4 control, or (b) require more medications for  
5 control.

6 CO-CHAIR GIBBONS: Okay. So I  
7 would then suggest that for additional  
8 discussion, we're not going to consider it as  
9 submitted, but with that change from equal  
10 to/greater than throughout the submission.  
11 That would include the title, the header of  
12 Section 2A and the body of 2A.

13 DR. DROZDA: I would concur that  
14 that is definitely a typo. It is greater than  
15 or equal to 140 over 90.

16 CO-CHAIR GIBBONS: All right.  
17 Thank you, Joe. Yes.

18 DR. DROZDA: And by the way, we  
19 were concerned actually about people on the  
20 lower end of that spectrum, you know, with  
21 someone trying to get a blood pressure of 140  
22 over 92 under the target by adding on three

1 and four medications, putting the patient at  
2 some jeopardy.

3 So we were more concerned about  
4 patient safety on the other end of the  
5 spectrum.

6 DR. JEWELL: So on our thumb drive  
7 is a document that appears to have been added  
8 yesterday evening around five-ish. So I think  
9 that's the document to which you were  
10 referring, and in it there's a thorough  
11 description of the analytic approach to  
12 assessing reliability, but there are no data.

13 So we're still in the same boat we  
14 were in without that information a while ago.  
15 Just FYI.

16 CO-CHAIR GIBBONS: Thank you for  
17 looking into that. So in fact then we have no  
18 reliability data yet at this point. Okay, I  
19 think we've had enough discussion. Can we  
20 vote on Criteria No. 2, Scientific  
21 Acceptability?

22 Well, the Chair is happy to report

1 that we again have 21 working devices. So  
2 whoever banged their gizmo on the table, in an  
3 attempt to make certain it was working, it  
4 undoubtedly fixed it. Don't do it again.

5 MS. PACE: And just one other  
6 comment. Remember that it won't -- you have  
7 to wait until the timer starts. So you may  
8 have thought you voted, but if you voted too  
9 quickly, it won't register. Just one other  
10 comment. I'm not sure where things are going  
11 to stand for that untested measure. Will we  
12 have any others t that come up for a vote of  
13 untested? Okay. So on Scientific  
14 Acceptability, when there's no reliability or  
15 validity, really minimal is the highest rating  
16 something could under that criterion. So just  
17 going forward, to keep that in mind.

18 CO-CHAIR GIBBONS: So under  
19 Usability, as indicated in the application  
20 under Section 3A, testing was not yet  
21 completed, and I think the hope was that there  
22 were going to be data shortly, and as we've

1 just heard, the submission last night  
2 apparently does not have any data on this  
3 point.

4 So I think given that, I felt that  
5 we had minimal information. There's a clear  
6 need for harmonization, because we have  
7 multiple other measures that involve blood  
8 pressure, and per our earlier discussion about  
9 the earlier blood pressure measurement. So I  
10 had no further comments.

11 Obviously, this would have added  
12 value, because we're not currently doing this,  
13 and that's why they don't have any data yet.  
14 Comments or questions about the issue of  
15 Usability? All right. If not -- Fred.

16 DR. MASOUDI: Can we send to you a  
17 paper that's noted under -- in this report  
18 that was just sent in for your review, in  
19 terms of its value --

20 CO-CHAIR GIBBONS: Sure, sure.  
21 Yes. So the paper is noted in the submission  
22 last night?



1 DR. MASOUDI: It is.

2 CO-CHAIR GIBBONS: Okay.

3 DR. DROZDA: This is Joe Drozda.

4 Can I make a comment about harmonization?

5 CO-CHAIR GIBBONS: Yes.

6 DR. DROZDA: You know, we did make  
7 significant efforts along the lines of  
8 harmonization.

9 We did have representation, for  
10 instance, from NCQA and the Joint Commission  
11 on the writing group, in order to try to  
12 coordinate and harmonize. Of course, all of  
13 the measures have been harmonized with other  
14 ACC, AHA, PCPI performance measures. So the  
15 issue has been addressed.

16 CO-CHAIR GIBBONS: Okay. So I  
17 guess one concern I have is when JNC-8 is  
18 released, if that has a different number, what  
19 happens?

20 DR. DROZDA: The measure will be  
21 revised to track the guideline.

22 CO-CHAIR GIBBONS: Okay, and but

1 Joe, at least I didn't see that mentioned  
2 anywhere in the submission.

3 DR. DROZDA: Well, I'm sorry it  
4 wasn't mentioned in there, but there is a --  
5 we already have a process in place for doing  
6 it. We had representation on the committee  
7 that did this from JNC-8 and CEP and the ACC-  
8 AHA guidelines update that's currently  
9 undergoing revision.

10 So we had people on board to try  
11 to keep us on track, and we decided to go with  
12 measures where we thought there would be the  
13 least chance of a significant change in the  
14 guideline. But we covered ourselves by  
15 putting in that process, to revise the measure  
16 based on the new guidelines as they come out.

17 CO-CHAIR GIBBONS: Okay. Well,  
18 that's very helpful. Now let me just point  
19 out for clarity, that from the standpoint of  
20 this process, we have to look for  
21 harmonization with all the other submissions,  
22 and there's another submission that we'll be

1       considering at one o'clock that involves blood  
2       pressure, that uses different standards.

3               So this measure has a  
4       harmonization issue, presuming that we  
5       consider that measure acceptable. So although  
6       you tried to cover all the waterfront, the  
7       waterfront didn't include all the other groups  
8       that actually submitted to this group today.

9               DR. DROZDA: I understand.

10              CO-CHAIR GIBBONS: All right.

11       It's perhaps a technical nuance but an  
12       important one for this committee. The  
13       Minnesota Community Measurement Project  
14       submission has a different number.

15              DR. DROZDA: Yes. It is a  
16       significant challenge for measure developers,  
17       but we realize its importance.

18              CO-CHAIR GIBBONS: Yes, and it's  
19       not to say anybody did anything wrong. I  
20       don't want to give the implication of that.  
21       It's just that as we looked at the measures,  
22       if we come out with two different measures

1 with different numbers, the people that are  
2 going to be in the cross hairs are the NQF,  
3 for why you didn't sort this out in some way.  
4 So that's why.

5 All right. So any other comments  
6 about number three before we vote on that?

7 (No response.)

8 CO-CHAIR GIBBONS: Okay. Let's go  
9 ahead with the vote.

10 Oh good, we're still working, or  
11 all 21 are still working. So for those on the  
12 phone, I think I'll at least give a summary.  
13 There were 2 complete, 5 partial, 12 minimal  
14 and 2 not at all, and the measure developer  
15 will get a summary of all of this.

16 Okay. So moving onto number four,  
17 which is Usability, I'm sorry Feasibility,  
18 sorry, I felt that all of these data elements  
19 are collected as the by product of care  
20 processes, as defined. I thought it was  
21 usable and feasible. I keep using the wrong  
22 one, feasible. I didn't see any concerns from

1 that standpoint. Other comments? Yes.

2 DR. PHILIPPIDES: Is there an  
3 issue with unintended consequences with this  
4 measure as written?

5 CO-CHAIR GIBBONS: George, you  
6 want to comment further?

7 DR. PHILIPPIDES: Just as far as  
8 the goals as outlined, let me see what I made  
9 a note here.

10 CO-CHAIR GIBBONS: I suppose the  
11 same concern that Sid raised earlier about the  
12 elderly would conceivably also apply here.  
13 That's a good point.

14 DR. DROZDA: This is Joe Drozda.  
15 Can I address that?

16 CO-CHAIR GIBBONS: Sure, Joe.

17 DR. DROZDA: This measure, as  
18 described, contains the opportunity for  
19 denominator exceptions, which can be medical,  
20 patient or system reasons, according to PCPI  
21 methodology. As you may know, our measures  
22 allow for those sorts of exceptions.

1           But we don't necessarily have all  
2 three categories in each measure. But this  
3 category does have all three categories of  
4 exceptions, and the reason for that is because  
5 of a great deal of complexity around the  
6 treatment of hypertension.

7           We've already heard about the  
8 elderly. We've heard about ESRD. We've  
9 heard, you know, there are other issues with  
10 respect to patient factors that enter into  
11 treatment decisions, and we wanted to allow  
12 for all of that through the exception process,  
13 in order to avoid the unintended consequences  
14 to which you refer.

15           So we feel comfortable that we've  
16 built in a methodology to minimize those sorts  
17 of unintended consequences.

18           CO-CHAIR GIBBONS: Okay, that's  
19 helpful, and I think in fairness we should  
20 point out that compared to the earlier measure  
21 where Sid raised this issue, this one has less  
22 of an issue, because if someone is on two

1 drugs and still hypertensive, they'd be  
2 included in the numerator.

3 DR. DROZDA: They would?

4 CO-CHAIR GIBBONS: There wouldn't  
5 be the same drive to lower their blood  
6 pressure. All right. Other comments about  
7 number four before we vote?

8 (No response.)

9 CO-CHAIR GIBBONS: All right.  
10 Let's go ahead and vote on Criteria 4,  
11 Usability.

12 Feasibility. I seem to have a  
13 mental block.

14 MS. PACE: Did everybody vote?  
15 Everybody vote?

16 (Off record comments.)

17 CO-CHAIR GIBBONS: We're going to  
18 get that at the break.

19 (Off record comments.)

20 CO-CHAIR GIBBONS: All right. For  
21 those on the phone, completely was 11,  
22 partially was 9 and not at all was 1. So I

1 think at this point, given what we have in  
2 hand, we should get to the endorsement  
3 question. Does the measure meet all the NQF  
4 criteria for endorsement? Yes or no.  
5 Discussion or comments before we vote on that?

6 (No response.)

7 CO-CHAIR GIBBONS: Okay, and I  
8 think we should go ahead and vote on the  
9 endorsement question.

10 (Off record comments.)

11 CO-CHAIR GIBBONS: Okay. So there  
12 were 8 yeses and 12 noes for those on the  
13 phone. The Chair shares everybody's  
14 frustration with the dilemma with the voting.  
15 We're going to try to address that at the  
16 break. Personally, I always have these  
17 technical problems, and I attribute them to my  
18 age and lack of technical geekness.

19 So it's always good to see  
20 somebody else have problems. In any case,  
21 we're going to try to solve this as the break,  
22 and we're going to take a break right now and



1 point out that we want everybody back in 15  
2 minutes, please, which would be 11:15.

3 (Whereupon, the above-entitled  
4 matter went off the record at 10:59 a.m. and  
5 resumed at 11:17 a.m.)

6 CO-CHAIR GIBBONS: Okay. We're  
7 going to move on now to the next measure. If  
8 everybody could be seated. Despite this  
9 wonderful side conversation, our next measure  
10 is 0068 on the use of aspirin or  
11 antithrombotics, and Bruce Koplan is going to  
12 be the primary reviewer. Bruce?  
13 Measure 0068

14 DR. KOPLAN: Thank you. So this  
15 is Measure No. 0068. The title is "Ischemic  
16 Vascular Disease, Use of Aspirin or other  
17 Antithrombotics."

18 A brief description of the measure  
19 is that it's looking at the percentage of  
20 patients with ischemic vascular disease who  
21 currently report taking aspirin, and the  
22 percentage of patients with ischemic vascular

1 disease who are counseled about the risks and  
2 benefits of aspirin.

3 It's a process measure, looking at  
4 effectiveness, and in terms of under number  
5 one, the importance of the measure, it's noted  
6 by the developer that the use of anti-platelet  
7 agents in patients with ischemic vascular  
8 disease is supported by large clinical trials,  
9 guidelines, et cetera, and that with so many  
10 people involved, it's not surprising that  
11 significant gaps exist in its use.

12 So this does seem to be a measure  
13 of importance and a measure where improvement  
14 is, could be made. I don't think I have a lot  
15 more to say about that.

16 CO-CHAIR GIBBONS: All right. Any  
17 other discussion or comments about importance?

18 (No response.)

19 CO-CHAIR GIBBONS: Hearing none,  
20 we'll move ahead to the first vote. Ashley.  
21 So this is a yes or no vote, but we'll wait  
22 for Ashley to get it opened. Don't vote too

1 early; you'll be missed.

2 DR. SMITH: Ray, do we have data  
3 on the gap right now? I've been in one  
4 meeting where people said you're wasting your  
5 time to measure aspirin, because 95 percent of  
6 the patients are getting it. So I just want  
7 to be sure we do have data.

8 CO-CHAIR GIBBONS: Bruce, did the  
9 developer provide any data?

10 DR. KOPLAN: They're in the back  
11 here, so I believe there is some data.

12 CO-CHAIR GIBBONS: I mean it's  
13 hugely important. I just don't know whether -  
14 - I was accosted by one person in another  
15 committee meeting who said geez, everybody's  
16 doing that. You're wasting your time measuring  
17 it.

18 MS. PACE: In the submission form  
19 under 1B, there is a summary of data from the  
20 physical application to the Heart Stroke  
21 Recognition Program that NCQA sponsors, going  
22 from year 2005 through 2009, and the average

1 rate in 2005 was 86.95; 2006, it was 91; 2007  
2 it was 89 percent; 2008, it was 88 percent,  
3 and 2009, it was 92.06 percent.

4 CO-CHAIR GIBBONS: But most  
5 important is the 26th percentile range from 80  
6 to 88. So the 25th percentile has not broken  
7 90.

8 DR. KOPLAN: But I would also  
9 wonder if something of this magnitude with so  
10 many people involved, like a smaller gap. Is  
11 a smaller gap more relevant when you're  
12 talking about something like aspirin? If you  
13 can go from 90 to 94 percent, isn't that  
14 important?

15 And here, you're quoting numbers  
16 that are even lower than 90 percent, so I  
17 would think that a gap is relevant.

18 DR. SMITH: I think so. It's also  
19 cost effective. I mean it's really -- you  
20 know, I think we ought to keep measuring.

21 CO-CHAIR GIBBONS: We're going to  
22 go ahead and get the vote on importance.

1 All right, that's pretty clear.

2 Bruce, number two, Scientific Acceptability.

3 DR. KOPLAN: Okay. So for  
4 Scientific Acceptability, it appears as if the  
5 numerator is the number of members in the  
6 denominator who are -- who take aspirin or  
7 anti-platelet therapy during a 12-month  
8 development period.

9 The denominator is people over the  
10 age of 18 who could be on a health -- either  
11 on a health plan or not on a health plan, that  
12 have some degree of lack of interruption.  
13 There's some demonstration of lack of  
14 interruption in their care, and at least one  
15 inpatient/outpatient visit with an ischemic  
16 vascular disease diagnosis.

17 It appears to be a fairly clearly  
18 stated numerator and denominator. In terms of  
19 all of the ICD-9 diagnosis codes. If the, you  
20 know, expert panel recommendation is different  
21 but it seems to be a pretty clearly stated  
22 numerator and denominator.

1                   There's no significant exclusions,  
2                   and the score is based on proportion with a  
3                   higher number of being better, which seems to  
4                   make sense. In terms of reliability and  
5                   validity, there is supplemental documentation  
6                   provided by the developer in a separate file.

7                   CO-CHAIR GIBBONS: Questions or  
8                   comments about Scientific Acceptability?

9                   (No response.)

10                  CO-CHAIR GIBBONS: Okay. We'll go  
11                  ahead and vote on that one.

12                  MS. PACE: Does everybody think  
13                  they voted?

14                  CO-CHAIR GIBBONS: All right.  
15                  Number three, Usability.

16                  DR. KOPLAN: So moving on to  
17                  Usability, the developer does note that public  
18                  reporting initiatives are currently in use  
19                  through organizations, including their own, I  
20                  believe, and in terms of harmonization issues,  
21                  I gather from the beginning discussion today  
22                  that that's something that's going to be

1 deferred.

2 But just as a mention, there are  
3 certainly a number of measures that deal with  
4 aspirin and anti-platelet drugs, and  
5 harmonization is a big issue here. As you  
6 said with another measure, there doesn't seem  
7 to be any fault of the developer.

8 This, as an aside, this measure  
9 does seem to be one of the perhaps more broad  
10 measures related to anti-platelet therapy, and  
11 in terms of harmonization, that may come into  
12 play in the future. But in a general sense,  
13 these results seem to -- would be expected to  
14 be pretty easily understood and useable.

15 CO-CHAIR GIBBONS: Okay. Other  
16 comments, questions about number three,  
17 Usability? The harmonization thing looms on  
18 almost all of these. Dana?

19 DR. KING: Does this, is this the  
20 place where exclusions are to be talked about?  
21 Because obviously people that have had a GI  
22 bleed, complications, aspirin, allergy, et

1       cetera, need to be specifically and  
2       categorically excluded, and there may also be  
3       people who have blood pressure uncontrolled or  
4       are chronically non-adherent.

5               I certainly have some ne'er-do-  
6       wells in my practice who I'm -- and whom I'm  
7       afraid to give the aspirin, even if on a good  
8       day their blood pressure is under control, I  
9       know from their history that it may not in the  
10      future.

11              I think there needs to be some  
12      accommodation, some exclusion for clinical  
13      reasons, and that's why we're never going to  
14      get to 100 percent, you know, aspirin  
15      prescription rate, unless we have a proper  
16      exclusion. So I just want to mention that.

17              DR. KOPLAN: There doesn't appear,  
18      there don't appear to be any exclusions in the  
19      measure. As one other -- that leads to  
20      another question that relates to yours. I  
21      think in the initial description, the measure  
22      talks about either it's been prescribed or



1 there's documentation of counseling.

2           So one would think that perhaps  
3 counseling, if counseling is documented, that  
4 could cover perhaps someone who's had  
5 bleeding. But I'm not sure for meeting the  
6 rest of the measure, how the documentation of  
7 counseling is accounted for. That wasn't  
8 really clear to me.

9           DR. KING: I think it's reasonable  
10 to request clarification, and not any  
11 assumptions or presumptions about that mere  
12 word "counseling," and that they specifically  
13 exclude the categories I suggested earlier.

14           CO-CHAIR GIBBONS: Can we have the  
15 measure developers here to comment on this  
16 issue?

17           MS. TIRODKAR: As relates to the  
18 exclusion issue, the reason we do not have  
19 exclusion for clinical reasons is because the  
20 -- we include it, we have exclusions if the  
21 percent of the population that those reasons  
22 would affect is greater than five percent. If

1 it is less than five percent, then we do not  
2 add an exclusion.

3 And because the exclusions for  
4 clinical reasons would thought to have been  
5 less than five percent, that is the reason  
6 that there isn't an exclusion for any clinical  
7 reasons.

8 DR. RUSSO: I would just comment  
9 also the same thing. I think you'd have to at  
10 least have exclusions for certainly allergies,  
11 and we don't know the exact population. You  
12 know, there may be GI bleeding recently and  
13 the other thing too is there's nothing in the  
14 numerator to say anything about counseling.

15 So it's not an "and" for the  
16 description of the measure. I mean it's  
17 really just use of aspirin, not counseling for  
18 risks and benefits. So either, you know,  
19 that's not the real description or it should  
20 be included.

21 CO-CHAIR GIBBONS: So I might  
22 point out, without preempting a lot, that this

1 issue is discussed in detail in 0076 from the  
2 Minnesota Community Measurement Project, and  
3 that's one of the sort of fundamentals of this  
4 harmonization kind of concern, because  
5 virtually all the points that have been raised  
6 are covered in that measure.

7 DR. JEWELL: So the points that  
8 you're all raising actually fall under Section  
9 2. So that makes me wonder if people have  
10 different thoughts on what they voted on  
11 Section 2 or if it's material at this point.

12 CO-CHAIR GIBBONS: We can  
13 certainly revote Section 2. I mean I think  
14 that's an excellent point. Do we have a  
15 sense? I see some nods. I think there's  
16 enough nodding going on that we'll revote  
17 Section 2, Scientific Acceptability. Thank  
18 you, Ashley. All right. So let's revote  
19 Section 2.

20 Well, I think that's an example of  
21 constructive input from the Committee,  
22 changing things quite a bit. Okay. So let's

1 go back to the Usability question. We were on  
2 that when we moved back to number two.

3 Other than harmonization, you  
4 thought it was pretty usable, right Bruce?

5 DR. KOPLAN: Yes.

6 CO-CHAIR GIBBONS: Okay. Other  
7 comments about Usability?

8 (No response.)

9 CO-CHAIR GIBBONS: All right. If  
10 not, I think we'll go ahead and vote on  
11 Usability.

12 All right. Now we'll go move on  
13 to Item 4, Feasibility. The Chair has finally  
14 got that right on the fourth try.

15 DR. KOPLAN: So in terms of  
16 Feasibility, the data, the developer reports  
17 that the data will be generated as a  
18 byproduct of the care process during health  
19 care delivery, and one would expect it to be  
20 feasible to do so.

21 It's also going to be collected,  
22 or data will be collected electronically, and

1 it appears to be the type of data that could  
2 be collected electronically. There are some  
3 issues, there's a section on relevant  
4 exclusions in the Feasibility section too, and  
5 so we touched on perhaps there should be some  
6 exclusions that aren't mentioned.

7 The other issue I might just bring  
8 up has to do with the developer states that  
9 there are -- there don't appear to be any  
10 unintended consequences, and I would wonder if  
11 there's also the potential for unintended  
12 consequences from either undercounting or  
13 over-counting, if these measures are going to  
14 be used.

15 So I'm not, I might ask if there  
16 could perhaps be something in there about the  
17 potential for unintended consequences. But  
18 overall, it seems to be feasible.

19 CO-CHAIR GIBBONS: Comments or  
20 questions? Yes, Helen.

21 DR. BURSTIN: This measure was  
22 also retooled for meaningful use. So it's

1 already been retooled for EHRS as well.

2 CO-CHAIR GIBBONS: Okay. I think  
3 we ought to vote now on Criteria 4,  
4 Feasibility.

5 Okay. So now we're up to the  
6 final question, and it's basically does it  
7 meet criteria for endorsement, again pending  
8 the harmonization issues that we've mentioned.  
9 Comments or questions before we vote on this?

10 DR. RASMUSSEN: The only comment  
11 I'd have about this is, and we'll see this on  
12 a few measures, performance is extremely good.  
13 When you look at the 90th percentile and it's  
14 100 percent, that means if you miss one  
15 patient, you already drop down to the 75th  
16 percentile.

17 It's very clinically sound, and  
18 I'm impressed by the level of documentation,  
19 because aspirin is a non-prescription  
20 medication. So the fact that people are  
21 documenting it appropriately is very  
22 impressive.

1                   But my main concern is the juice  
2                   worth the squeeze on this measure, when we've  
3                   already got some very high-performing  
4                   organizations.

5                   DR. KOTTKE:   Ray, if I could make  
6                   a comment.

7                   CO-CHAIR GIBBONS:   Sure, Tom.

8                   DR. KOTTKE:   They stuck it in a  
9                   spreadsheet where we can calculate the impact  
10                  relative to other things.  If we could erase  
11                  the deficit in aspirin from 92 to 100, it  
12                  would be twice the impact of giving everybody  
13                  immediate angioplasty for STEMIs.  I'll  
14                  retract my comments.

15                  (Laughter.)

16                  CO-CHAIR GIBBONS:   All right.  
17                  Well, we answered that one.

18                  PARTICIPANT:   That's quite a  
19                  statement, coming from an interventional  
20                  cardiologist.  You'd better come up with some  
21                  data, not just throw that out there.

22                  (Laughter.)

1 DR. AYALA: You know, about this  
2 gap issue. I just wanted to bring up a very  
3 like logistical, operational-type point on  
4 this, and that is that when we see these high  
5 compliance rates, you have to think about what  
6 went into getting those rates.

7 It's not always that the doctor  
8 did the right thing, you know, every time. A  
9 lot of times it's a whole team of people that  
10 are administratively supported, groups of  
11 nurses, pharmacists, a lot of people pulling  
12 everything, nudging the doctor to do the right  
13 thing, sometimes prescribing these things  
14 themselves.

15 So I would be very cautious about  
16 taking something off, just because it's  
17 reaching a high level of compliance, because  
18 it's not always what you think it is at the  
19 operational level, and the administrators who  
20 may not be clinical take these types of  
21 indicators and their performance level on a --  
22 very seriously, and they support this type of



1 group and team effect, to get to the right, to  
2 get the right outcomes.

3 CO-CHAIR GIBBONS: David.

4 DR. MAGID: I just, and maybe this  
5 is more for the folks from NQF. Have you  
6 taken off measures for high performance, and  
7 can you give us an example of something that  
8 you did?

9 MS. PACE: We have, for the  
10 smoking cessation. Right. So yes. I mean  
11 part of it is there's not, that's not a hard  
12 and fast. Okay, if there's high performance,  
13 take it off. The example we have is with  
14 smoking cessation measures. Those were not  
15 re-endorsed. They were extremely high  
16 performance, right.

17 But when you look at those  
18 measures, that high performance was probably  
19 more due to measure construction and how the  
20 measure was implemented and how the  
21 documentation went for it, versus that  
22 everyone's really doing well with smoking

1 cessation counseling.

2 So that speaks to say that that  
3 measure is really not helping us, but not that  
4 we don't need a measure on smoking cessation.  
5 In terms of, you know, how much performance  
6 gap is the right amount of gap, I think as  
7 some of you have already mentioned, it really  
8 is contextual.

9 What's the impact, you know, as  
10 you've had some discussions already. So  
11 there's no hard and fast, you know, you have  
12 to have a certain performance gap in order to  
13 make it a valid measure.

14 If it's something that will help  
15 us improve overall health of our population,  
16 and moving another few percentage points  
17 represents a very large part of the  
18 population, then that's important.

19 So and that's why we have you as  
20 the experts around the table, to really be  
21 able to look at that information and make  
22 those decisions.

1 CO-CHAIR GIBBONS: Helen.

2 DR. BURSTIN: Just one more point  
3 of clarification. If you actually look at the  
4 Opportunity for Improvement on the form, that  
5 data comes from physician applications to the  
6 Heart and Stroke Recognition Program, which is  
7 a little bit different than the general  
8 population.

9 So it's already a fairly self-  
10 selected group going "I'm good, look at my  
11 application." So it's going to have a higher  
12 number, I suspect, than the general population  
13 of docs who don't seek that recognition.

14 CO-CHAIR GIBBONS: Point taken.  
15 Can we now go ahead and vote on -- sure.

16 CO-CHAIR GEORGE: Just a quick  
17 comment of perhaps some unintended  
18 consequences for not endorsing measures,  
19 particularly something like this which is so  
20 important in public health, that it could send  
21 the wrong message as well.

22 CO-CHAIR GIBBONS: That's

1 definitely a point well-taken. All right. I  
2 think we're going to vote on endorsement now.

3 Okay. So Bruce, congratulations.  
4 You got us through that in 19 minutes and 45  
5 seconds. Now we're not quite -- I would point  
6 out to the Committee, we're not quite at the  
7 15 minute standard, and the way we're going,  
8 you're not going to get to eat any lunch.

9 No. I think we're making  
10 progress, and we're getting better at this as  
11 we learn what the issues are, right. Helen  
12 assures me the first one's always long, but  
13 the other rule is the Chair is always worried.

14 So we're going to move on to the  
15 next measure, which is 0067, CAD Anti-Platelet  
16 Therapy, and we pressed George into action  
17 with not too much notice. So George, now  
18 you've got to see if you can meet Bruce's  
19 standard.

20 Measure 0067

21 DR. PHILIPPIDES: Well, since he  
22 did all the heavy lifting, and these are

1 similar measures, we're going to get to lunch.

2 CO-CHAIR GIBBONS: And mine voted  
3 twice on them.

4 DR. PHILIPPIDES: This is 0067,  
5 percentage of patients aged 18 years and  
6 older. Group 3. That's 3. Patients aged 18  
7 years and older with a diagnosis of coronary  
8 artery disease, seen within a 12 month period,  
9 who are prescribed aspirin or clopidogrel.

10 Just to jump in very quickly, the  
11 feeling was that this is a high impact patient  
12 population. It was an effective measure of  
13 proven intervention. So I think it got high  
14 grades as far as the initial scientific merit.

15 CO-CHAIR GIBBONS: So questions  
16 about the Importance question before we vote  
17 on that?

18 (No response.)

19 CO-CHAIR GIBBONS: All right. Can  
20 we go ahead and vote on Importance?

21 All right. Move on to number two,  
22 Scientific Acceptability.

1 DR. PHILIPPIDES: So the measure  
2 is well-defined and specified. The numerator  
3 is obviously patients who were prescribed one  
4 of those two anti-platelet agents within a 12  
5 month period.

6 It can include prescription given  
7 to the patient for aspirin or clopidogrel at  
8 one or more visits during the period, or a  
9 patient who is already on that, going into  
10 that one-year period during those visits.

11 The denominator is basically all  
12 patients 18 years or older with CAD seen  
13 within the last 12 months. So fairly clear on  
14 both fronts. Unlike the prior measure, this  
15 one has sort of well-specified or fairly well-  
16 specified exclusions, getting to your point,  
17 including allergies to either of the  
18 medications, bleeding coagulation disorders,  
19 concomitant warfarin therapy, and then it has  
20 here "other medical reasons."

21 So these need to be documented.  
22 So there might be some discussion as to what

1 other medical reasons might be, whether that's  
2 sort of a large alley to exclude, or whether  
3 that will lead to unintended consequences.  
4 But the exclusions as stated are clear for the  
5 most part. So there might be some questions  
6 there.

7 DR. RASMUSSEN: So I do have a  
8 question about exclusions. As I've read  
9 through them, I'm trying to identify a patient  
10 who would not meet this measure, because if  
11 you have patient who declines, they can be  
12 excluded.

13 If there's lack of drug  
14 availability, they could be excluded. I'm  
15 just having a difficult time even thinking of  
16 a patient that wouldn't meet this measure,  
17 that we couldn't exclude.

18 CO-CHAIR GIBBONS: Do the measure  
19 developers want to comment on this issue? Do  
20 we have people on the phone? Joe.

21 DR. DROZDA: This is Joe Drozda.  
22 Actually, it would be the patient for whom the

1 medication has not been prescribed, you know,  
2 without those, you know, without a specific  
3 reason for not doing it. So I think there is  
4 a clear population who would not meet this.

5 Again, the PCPI methodology on  
6 exceptions, and the reason there is an "other"  
7 under medical is that it allows the physician  
8 to choose a medical reason for not  
9 prescribing.

10 What you've listed as the  
11 exceptions are actually examples, and not an  
12 all-inclusive list. That's just kind of the  
13 generic methodology that PCPI follows in its,  
14 you know, in the exceptions.

15 Again, we allowed for both -- for  
16 medical patient and system reasons in this  
17 particular measure.

18 DR. RASMUSSEN: Your point is very  
19 well taken about having an "other" option. In  
20 fact, I think a lot of the measures that we're  
21 going to review today would benefit from  
22 having that option.



1 I think it would be important to  
2 monitor that "other" exclusion, to make sure  
3 that it doesn't get gamed, that we don't see  
4 an increasing percentage over time. But your  
5 point is well-taken.

6 DR. DROZDA: And I think that's a  
7 very important point. That's actually been  
8 empirically looked at in the PCPI, by PCPI,  
9 and we found actually that the exceptions in  
10 general are not used very much. They're a  
11 fairly infrequent occurrence.

12 So to this point, we haven't found  
13 any evidence of quote-unquote "gaming." If  
14 you sat up and think about it, you'd have to  
15 think about the patient requiring anti-  
16 platelet therapy, and then you'd have to make  
17 up an excuse for not doing it. At least we  
18 made you think about it, even if you were  
19 trying to game.

20 But I can't, that's not the kind  
21 of thing that people usually would game, you  
22 know, or it would be very difficult.

1 CO-CHAIR GIBBONS: That's a very  
2 good point, Joe. Other questions?

3 (No response.)

4 CO-CHAIR GIBBONS: Okay. I think  
5 we should go ahead and vote on Scientific  
6 Acceptability.

7 So for Joe and anybody else on the  
8 phone, completely 16, partially 5. Okay.  
9 Next, Usability.

10 DR. PHILIPPIDES: So moving on to  
11 Usability, the measure does appear to be  
12 meaningful and easily understandable to  
13 providers and consumers. The harmonization  
14 issue, I believe, is vexing, because there are  
15 several that are similar. We'll probably just  
16 shelve that for now, I would hope. Thank you.

17 As regards to other measure sets  
18 that are out there, this seems to be valid on  
19 that front as well. So overall, the feeling  
20 was it was a fairly usable method.

21 CO-CHAIR GIBBONS: Other comments  
22 or questions about this? Mark?

1 DR. SANZ: I don't think you can  
2 shelve harmonization. I just feel like if I'm  
3 an abstractor in my institution, and someone  
4 comes to me as a physician and says how do I  
5 deal with this, you know? You've got this  
6 patient on aspirin and they match the measure  
7 68, I think that we just did.

8 But your "other" reason doesn't  
9 fit 67. Now what do I do? This is just a  
10 nightmare.

11 CO-CHAIR GIBBONS: You know, I  
12 think Mark, you've sort of put your finger on  
13 the real problem, which is for actual  
14 clinicians, be they nurse practitioners,  
15 physician assistants positions or nurse  
16 abstractors and quality programs in hospitals,  
17 they quickly perceive on the ground some of  
18 the difficulties of adequate documentation and  
19 dealing with all the subtleties of the  
20 differences in the measures.

21 All our task is to try, as much as  
22 possible, to align things to at least reduce

1 that. We probably can't make it zero, but I  
2 think we can at least reduce it.

3 So if you look at this measure,  
4 for example, with the exclusions and things  
5 like being on warfarin, I think they're pretty  
6 important, and to the degree that other  
7 measures in this area don't capture them,  
8 maybe we have to suggest that they have to.

9 DR. SANZ: Yes. Number one, I'm  
10 not -- I agree with the importance of the  
11 measure. Number two, I agree with the  
12 importance of the other measures. But number  
13 three, these should not be allowed to go  
14 forward in total. We're being asked to vote  
15 absent the knowledge of the future, which is  
16 having all of these together.

17 CO-CHAIR GIBBONS: So you're being  
18 asked to vote sort of pending resolution of  
19 the harmonization issue. We will try to spend  
20 some time on that tomorrow. It's likely going  
21 to take a conference call in the future, where  
22 we're going to try as much as possible to, you

1 know, assert consistency in the various  
2 definitions. Does that help Mark?

3 DR. DROZDA: This is Joe Drozda.  
4 Can I comment on the harmonization issue?

5 CO-CHAIR GIBBONS: Yes. Sure,  
6 Joe.

7 DR. DROZDA: And I understand, and  
8 I'm very sympathetic with this need to  
9 harmonize. You know, I think Mark has just  
10 nailed it as to the reason why. But here's a  
11 thought. The measure you're looking at right  
12 now from ACC, AHA, PCPI, is actually a  
13 maintenance measure.

14 In other words, it already is in  
15 existence. It's already being used. It's  
16 been, we've been, we've spent considerable  
17 time in testing it, and we found the measure  
18 to be useful. Now we're coming to a  
19 maintenance phase, and there may be others  
20 that have come up with new measures that are  
21 similar to it.

22 So in that context, you know, as

1 sort of being the first out there, and having  
2 the experience with it, how should that  
3 harmonization be addressed with new measures  
4 coming on?

5 I guess that's a rhetorical  
6 question right now, but I find it difficult  
7 for us, you know, at this stage, for this  
8 measure developer, to go back and modify the  
9 measure to meet, you know, to make it look  
10 like someone else's measure.

11 (No response.)

12 CO-CHAIR GIBBONS: Helen.

13 DR. BURSTIN: Hi Joe, it's Helen  
14 Burstin. I just want to point out that  
15 actually almost all of the measures that  
16 you're being compared against are existing  
17 measures for maintenance. It's just that  
18 we're actually trying to harmonize them this  
19 round.

20 There is an expectation that  
21 probably a good number of the measures will  
22 need to change and potentially even compete

1       against each other, and pick best in class.

2                   It's just the reality of where we  
3       are now. We can't have, you know, dozens of  
4       measures on the same topic. We've been  
5       explicitly asked to make harmonization a major  
6       focus of our work going forward. So it is the  
7       reality of where we are.

8                   DR. DROZDA: Yes, and I didn't  
9       mean to argue that, because I agree with your  
10      need to do that. But I was just pointing out  
11      that, you know, maybe some of the things that  
12      need to be looked at as you look at  
13      harmonization, and if we're competing against  
14      other measures that have been in existence,  
15      well you know, how they work.

16                   I mean you have some really good  
17      comparisons that you can now use in your  
18      efforts to harmonize. So just a --

19                   CO-CHAIR GIBBONS: You can't see  
20      all the heads nodding, but a lot of heads are  
21      nodding in agreement with that point, Joe.  
22      There's somebody down here. Tom?

1 DR. KOTTKE: Yes. In fact, this  
2 probably isn't an issue for the abstractor,  
3 because the abstractor only has to write down  
4 did the patient take aspirin, did they not  
5 take aspirin? Is there a recorded reason for  
6 not being prescribed aspirin?

7 It is, I do acknowledge it's  
8 probably the end user that, you know. But  
9 it's sort of like measuring blood pressure in  
10 the left arm and the right arm. I mean one's  
11 different than the other, and so it depends on  
12 -- obviously it depends on the criteria. It  
13 depends on where you're measuring it.

14 The goal of harmonization is great  
15 where there's an outright conflict. But this  
16 is going to be, there's always going to be a  
17 little disconnect between measures, and it's  
18 not going to be solved with a conference call.  
19 But I think we can push forward.

20 Unless there's an out and out  
21 conflict between, you know, one measure says  
22 "give aspirin when you're on coumadin and you



1       have atrial fib or something," and the other  
2       says do not, then we have to decide that way.  
3       But otherwise I think absolute harmonization  
4       is an illusive goal.

5                   CO-CHAIR GIBBONS:  Other comments  
6       before --

7                   DR. SMITH:  Just I want to be sure  
8       that I understand.  We've decided that  
9       harmonization will take place, and that if  
10      this is approved and there is a similar  
11      recommendation, that they will be harmonized?

12                  CO-CHAIR GIBBONS:  Well, as Helen,  
13      I think, elucidated, we will try to harmonize  
14      them.  If we can't harmonize them, we will  
15      decide do we really want these two measures on  
16      similar areas to both go forward, or is there  
17      a best in class that wins.

18                  DR. SMITH:  Fine, and that will  
19      come back to the Committee, right?

20                  CO-CHAIR GIBBONS:  Correct.  So  
21      but I agree with Tom.  This is an enormous  
22      task, but I would just point out that a

1 conference call might actually settle it to  
2 some degree, if you say this measure is best  
3 in class, this one wins, and the other one is  
4 not continued. Karen?

5 MS. PACE: So I just want to say  
6 what you're voting on right now is this  
7 individual measure, if it were the only  
8 measure you were -- had before you. So it  
9 definitely is just provisional, pending  
10 further comparison.

11 CO-CHAIR GIBBONS: Okay. We've  
12 got to move ahead and vote.

13 DR. SANZ: Ray, I'd just like to  
14 make one point. Why do we have to do the  
15 harmonizing? If there are seven different  
16 aspirin measures, why can't we just say to the  
17 developers you go do the harmonizing and come  
18 back to us?

19 MS. PITZEN: That's actually what  
20 we're going to do.

21 DR. BURSTIN: The measure  
22 developers will be asked to harmonize. But at

1 the end of the day, it's this Committee that's  
2 going to have to make the decisions, that's  
3 all.

4 CO-CHAIR GIBBONS: Okay. We need  
5 to vote on the Usability.

6 Okay. For Joe and anybody else on  
7 the call, completely 16 and partially 5.  
8 Moving on now to Feasibility, George.

9 DR. PHILIPPIDES: In regards to  
10 Feasibility, it appears that the data elements  
11 are readily available and retrievable, with  
12 the routine generation of the concurrent data.  
13 Similarly, the exclusions for the most part  
14 are available just with the routine evaluation  
15 of the data that exists.

16 There are electronic records that  
17 carry this data to date, and there are plans  
18 in many large institutions to sort of move  
19 towards that in a greater fashion.

20 In regards to collection  
21 strategies, there was some rudimentary  
22 evaluation of things from the DOQ project,

1 looking to see when there were numerator or  
2 denominator issues, and the percentages of  
3 error or difficulty were small.

4 So it seemed reasonable, the data  
5 collected was good and not too difficult to  
6 collect. So overall, it felt like the  
7 Feasibility was reasonable.

8 CO-CHAIR GIBBONS: All right.

9 Other comments on Feasibility?

10 (No response.)

11 CO-CHAIR GIBBONS: Okay. If not,  
12 we're going to go ahead and vote on  
13 Feasibility.

14 19 completely, 2 partially for  
15 those on the telephone. Okay. So now the  
16 final vote, does the measure meet NQF criteria  
17 for endorsement. If it was the single  
18 measure, as Karen has nicely outlined. Maybe  
19 we should change the wording on the question  
20 for the maintenance measures for that reason.

21 Well in any case, they're our  
22 guinea pigs. Thank you very much. That makes

1 me feel just wonderful. Learning guinea pigs.

2 I feel better already. Comments or --

3 DR. RUSSO: Just a general  
4 question. To get back to the harmonization,  
5 when we're looking at two, if one is, turns  
6 out to be much more rigorous, much more all-  
7 inclusive looking, shouldn't it be at this  
8 point if we see that one might perform or one  
9 looks better than the other, do we really --

10 Do we go back and say they're both  
11 okay, or do we -- how does that work, or  
12 should there be something up front? Because  
13 if we're reviewing everything every three  
14 years, I guess we'll see performance or how  
15 does that work?

16 DR. WINKLER: Well, a couple of  
17 things. What we're asking you to do is look  
18 at these independently. The next step, as I  
19 described earlier, is we will put them side by  
20 side, and you will start to resolve those  
21 questions.

22 Our agenda's ambitious enough on

1 what we're trying to do today. So we're  
2 trying to take this in a stepwise fashion, and  
3 you know, deal with them in manageable bits  
4 and pieces. So that's the way we've organized  
5 the evaluation. So you're just doing kind of  
6 Step 1 today. We'll get there. It will  
7 happen.

8 CO-CHAIR GIBBONS: Okay. If there  
9 are no other further comments or questions,  
10 we're going to go ahead and vote.

11 Well, that vote set a record in  
12 several ways. It was fast and it was  
13 unanimous for those on the phone, supporting  
14 endorsement of this measure. All right. Well  
15 done, George. You didn't quite best Bruce,  
16 though.

17 Okay. We're going to move on to  
18 the next one, which is 0075, one of two  
19 measures dealing with lipid control, and my  
20 co-chair, Mary George, is the primary  
21 discussant.  
22 Measure 0075

1 CO-CHAIR GEORGE: So this is  
2 number 0075. It was in Group 4. The measure  
3 description is the percentage of members 18 to  
4 75, discharged alive for MI, CABG, PTCA from  
5 January 1 through November 1 of the year prior  
6 to the measurement year, or who had a  
7 diagnosis of ischemic vascular disease during  
8 the measurement year and the year prior to the  
9 measurement year, who had a complete lipid  
10 profile and an LDL less than 100.

11 The measure stewards presented a  
12 great deal of evidence based on guidelines and  
13 some clinical trials, to support the impact of  
14 this measure, as well as the cost data from  
15 the burden of disease. They have demonstrated  
16 some opportunity for improvement as well, and  
17 it is supported by the current ATP-3  
18 guidelines.

19 CO-CHAIR GIBBONS: You want to  
20 call the question?

21 CO-CHAIR GEORGE: So any questions  
22 on this?

1 DR. PHILIPPIDES: I have a very  
2 basic question, pardon me. Why not just take  
3 out the first three lines and have it be  
4 patients with ischemic vascular disease. The  
5 addition of MI and CABG has that help it.

6 CO-CHAIR GEORGE: Right. I think  
7 it gets into and also that gets into a little  
8 later question on the complexity of  
9 constructing this denominator group. But --

10 DR. PHILIPPIDES: It seems that  
11 IVD is all-inclusive.

12 CO-CHAIR GEORGE: Right.

13 DR. PHILIPPIDES: But the other  
14 descriptors are not really necessary there.

15 DR. KOPLAN: Would you think that  
16 IVD would include more patients than what are  
17 described in the description?

18 DR. PHILIPPIDES: Look at the  
19 other way. I don't think that CABG or bypass  
20 adds anything to IVD. I think IVD might be a  
21 broader classification. Sorry.

22 DR. KING: True, but not everybody



1 writes down every diagnosis when someone comes  
2 in for follow-up, and so if they just got out  
3 and they had a heart attack, I write down  
4 post-MI. I don't necessarily also write down  
5 "oh yes. I'm also following them for coronary  
6 artery disease," because like that's fairly  
7 obvious.

8           So it depends on how you coded it  
9 in the visits or in the follow-up or in the  
10 next hospitalization they had. Was that  
11 really a flare-up of their whatever. So in  
12 other words, they're trying to be all-  
13 inclusive. I don't think they're trying to  
14 make it complex. It's they're just adding in  
15 the codes would be my interpretation of that.

16           DR. SNOW: And that often at the  
17 coding level is going to be important for  
18 inclusion. They want these people to be  
19 included, and really just supporting what Dana  
20 said, because getting the people to actually  
21 put down, as we will see later on, what they  
22 are supposed to be for the measure, is itself

1 a challenge.

2 DR. PHILIPPIDES: Not to belabor  
3 this, but to extend that thought. Then should  
4 we put down peripheral vascular disease, in  
5 the chance that somebody coded that and not  
6 any of these other ones? The other way to do  
7 this, as my friend here said, is just list the  
8 ICD-9 codes that should be included in some  
9 fashion.

10 CO-CHAIR GEORGE: In the  
11 denominator specifications, they have a  
12 variety of ICD-9 codes, and ICD-9 procedure  
13 codes, CPT codes, et cetera, to try and  
14 identify the patient population.

15 DR. RUSSO: And isn't the lipid  
16 control an outcome also? It's a combined  
17 process plus outcome or you're measuring lipid  
18 control?

19 CO-CHAIR GIBBONS: No. I think  
20 most people would not define that as an  
21 outcome. It's a process.

22 (Off record comments.)

1 CO-CHAIR GIBBONS: Well, we're  
2 getting into the nuances of terminology. Most  
3 would call that an intermediate outcome. It's  
4 not a clinical outcome in terms of, you know,  
5 what the public typically sees as outcomes.

6 Okay. I think we should go ahead  
7 and vote on importance.

8 CO-CHAIR GIBBONS: Okay. We'll  
9 move on to Scientific Acceptability, and some  
10 of the questions actually have already been on  
11 that issue.

12 CO-CHAIR GEORGE: All right. So  
13 moving on, I would just like to note under the  
14 numerator statement, I think there may be a  
15 typo. It says, in defining the numerator,  
16 that the member is non-compliant if the  
17 automated result for the most recent LDL test  
18 equals 100. I think that should be greater  
19 than or equal to 100.

20 In terms of exclusions, they say  
21 to exclude patient's self-report or self-  
22 monitoring, to exclude LDL to HDL ratio and

1 findings reported on progress notes or other  
2 non-laboratory documentation.

3 Reliability testing is not  
4 available. It is in process. There's no risk  
5 adjustment, and no comparability and no  
6 disparities noted.

7 CO-CHAIR GIBBONS: Comments.

8 DR. WINKLER: I have a question.  
9 I see under the specifications that in the  
10 target population age, it's listed 18 to 75  
11 years. However, under the denominator  
12 details, it says "18 years or older as of  
13 December 31st."

14 CO-CHAIR GEORGE: All right, and I  
15 think what I'm looking at under 2A.4, Target  
16 Population Age Range, it says 18 to 75.

17 DR. JEWELL: And again, on our  
18 jump drives, they're -- in the folder there  
19 is an additional document about reliability  
20 measures, I think, for all the NCQA measures  
21 perhaps?

22 CO-CHAIR GEORGE: Right.

1 DR. JEWELL: And again for this  
2 one, it was the reliability, if I'm  
3 understanding the chart correctly, at .69.

4 CO-CHAIR GEORGE: That is correct.

5 DR. RASMUSSEN: To comment on the  
6 potential typo, this is an existing measure,  
7 and my understanding is that an LDL of 100  
8 would not be in the numerator. It must be  
9 less than.

10 CO-CHAIR GEORGE: I believe that's  
11 what they intended. I was just pointing out  
12 the typo in the documentation.

13 DR. WINKLER: I had another  
14 question for clarification. The results on  
15 the reliability testing indicate two values  
16 for a complete lipid profile, and then LDL  
17 less than 100. I'm not clear in the  
18 submission for the specifications. Are we  
19 looking at the profile screening being  
20 performed and the less than 100? Both. Okay.

21 (Off record comments.)

22 CO-CHAIR GIBBONS: Other

1 questions?

2 DR. THOMAS: I just have a  
3 question about exclusions for patients who,  
4 for example, can't tolerate a statin. Would  
5 that be in exclusions, or you know, it's  
6 oftentimes hard to get under 100 if they can't  
7 tolerate a statin due to muscle myalgia, et  
8 cetera. Wouldn't that make it an exclusion?  
9 Maybe I'm misunderstanding.

10 DR. SMITH: Well, the measure is  
11 LDL less than 100. But there are those who  
12 say that we really ought to be saying they're  
13 on statin therapy. But the current mantra,  
14 the guideline now refers to LDL. So that  
15 another type of lipid lowering therapy would  
16 be recommended, if they got myopathy on the  
17 statin.

18 DR. THOMAS: Right. But I don't  
19 know. Clinically speaking, it seems very  
20 typical when they are -- I mean if we've got  
21 really high LDLs, it's oftentimes hard to get  
22 them below 100, when they can't tolerate

1       statin. That was just my thought.

2                   DR. WINKLER: And you might hold  
3       that thought for the next lipid measure, where  
4       that is addressed.

5                   DR. THOMAS: Okay.

6                   DR. SANZ: Is diabetes a part of  
7       this? Because -- very high risk. I mean  
8       let's face it. Should it be?

9                   DR. WINKLER: Actually, NQF has an  
10       endorsed measure for diabetes with an LDL  
11       control of less than 100.

12                   DR. SANZ: So that's coming up  
13       later or something?

14                   DR. WINKLER: You aren't going to  
15       see it. It's already happened in another  
16       group.

17                   DR. SANZ: With a diabetes group?

18                   DR. WINKLER: For diabetes.

19                   CO-CHAIR GIBBONS: Other questions  
20       about Scientific Acceptability?

21                   (No response.)

22                   CO-CHAIR GIBBONS: If not, I

1 suggest we vote on this.

2 (Pause.)

3 CO-CHAIR GIBBONS: Moving on to  
4 usability.

5 CO-CHAIR GEORGE: So in terms of  
6 usability, this is already in use as part of  
7 the HEDIS measures, as well as others, and  
8 clearly this would need to be harmonized with  
9 other lipid measures, and that's all the  
10 documentation that they have provided, and  
11 those others that reviewed the measure didn't  
12 see any significant problems with this in  
13 terms of usability.

14 CO-CHAIR GIBBONS: Comments or  
15 questions?

16 (No response.)

17 CO-CHAIR GIBBONS: If not, let's  
18 go ahead and vote on usability.

19 (Pause.)

20 CO-CHAIR GIBBONS: All right, and  
21 once again let's move to feasibility.

22 CO-CHAIR GEORGE: So they've



1 documented that this data is generated as a  
2 byproduct of care processes during delivery.  
3 It's available as electronic data. Their  
4 exclusions pose no problems, and they did not  
5 identify any susceptibility to inaccuracies or  
6 errors. Any questions on that?

7 (No response.)

8 CO-CHAIR GIBBONS: I think we  
9 should go ahead and vote on feasibility for  
10 this measure.

11 (Pause.)

12 CO-CHAIR GIBBONS: Okay, and now  
13 the final question, does the measure meet  
14 criteria for endorsement, considered alone?  
15 Questions or comments.

16 (No response.)

17 CO-CHAIR GIBBONS: All right. I  
18 think we should go ahead and vote on this one.

19 (Pause.)

20 CO-CHAIR GIBBONS: Okay. Another  
21 unanimous vote, and I'd like to congratulate  
22 the Committee. We completed that one in 14

1 minutes and 45 seconds.

2 So we're now going to move on to  
3 Measure 0074, and Mary, we expect you to  
4 duplicate this effort.

5 Measure 0074

6 CO-CHAIR GEORGE: All right.

7 Well, we'll give it a try. 0074, again, was  
8 in Group 4. A brief description. This is the  
9 percentage of patients aged 18 and older with  
10 a diagnosis of coronary artery disease seen  
11 within a 12 month period, who have an LDL less  
12 than 100, or who have an LDL greater than or  
13 equal to 100, and a documented care plan to  
14 achieve an LDL less than 100, including at a  
15 minimum the prescription of a statin.

16 Again, they present considerable  
17 evidence, as did the other one, in terms of  
18 opportunity for improvement and impact, and  
19 evidence according to the guidelines.

20 CO-CHAIR GIBBONS: Yes.

21 DR. WINKLER: I just want to  
22 inform the Committee that this is indeed a

1 maintenance measure, but there have been  
2 significant revisions to this measure since it  
3 was original endorsed.

4 The original form was use of  
5 statins in patients with CAD. So it didn't  
6 involve the LDL level. So this really had  
7 significant revisions.

8 CO-CHAIR GIBBONS: Okay. I think  
9 we should go ahead and vote on importance for  
10 this measure.

11 (Pause.)

12 CO-CHAIR GIBBONS: Okay. We're  
13 going to move on now to scientific  
14 acceptability.

15 CO-CHAIR GEORGE: And again, under  
16 Section 2A.3, I think there's probably another  
17 typo with the -- missing the greater than or  
18 equal to sign in the numerator statement.  
19 What's written here is patients who have LDL  
20 equal to 100, and have a documented care plan,  
21 and I think that's supposed to be greater than  
22 or equal.

1 DR. DROZDA: This is Joe Drozda.

2 I would confirm that as a typo.

3 CO-CHAIR GEORGE: Okay, thank you.

4 Target population age 18 and older. In terms  
5 of denominator exclusions, there are  
6 exclusions in this measure for documentation  
7 of patient reasons for not prescribing a  
8 statin, such as patient declined or other  
9 patient reasons, and also documentation of  
10 reasons for not prescribing due to financial  
11 reasons, other system reasons.

12 So no risk adjustment was used in  
13 this. It is a rate of proportion. Data  
14 source is electronic claims data or electronic  
15 medical records data. Some of the testing  
16 that was done on this in terms of reliability  
17 showed some difference between different  
18 organizations that were doing the testing.  
19 But they did say that all the PCPI measures  
20 were assessed for content validity, and they  
21 have done reliability testing.

22 I think in terms of the group that

1 reviewed this, you'll probably see on the  
2 spreadsheet there was some difference of  
3 opinion in terms of comparability of multiple  
4 data sources that was noted.

5 DR. JEWELL: So in, under measure  
6 specifications, under 2A.1 under definitions,  
7 it says "Prescribed may include prescription  
8 given to the patient for statin at one or more  
9 visits in the measurement period, or patient  
10 already taking a statin, as documented in  
11 current medication list."

12 So it seems to me that I'm not  
13 clear where the situation comes up where the  
14 patient's not, is already on the statin but  
15 still is achieving the target. Where do they  
16 go in this? Maybe I'm not making sense, but  
17 if they already come on a statin to your  
18 office, you're getting credit for that because  
19 you didn't take them off of it?

20 I'm just trying to understand how  
21 the measure would work, not that you're not  
22 doing what you're supposed to be doing. But

1 I just don't understand how it works under  
2 that context.

3 DR. DROZDA: This is Joe Drozda.

4 CO-CHAIR GIBBONS: Joe, go ahead.

5 DR. DROZDA: I want to take a  
6 crack at it. There may be others who are  
7 better, but from a technical standpoint,  
8 especially as we get into implementing  
9 meaningful use, we found that prescription  
10 measures really come off the medication list,  
11 as much as they do, you know, a written or  
12 electronic prescription.

13 If somebody's on the medication,  
14 you're following people longitudinally, you  
15 know, and you don't give a prescription that  
16 particular year, but the patient continues on  
17 the medicine. That's really what we're  
18 interested in.

19 So it's two different ways of  
20 identifying the fact that, you know, this  
21 patient has been prescribed a statin.

22 DR. JEWELL: Okay. So that makes

1 sense to me. I guess I just wonder how many  
2 times you would -- it's not clear to me how  
3 the measure relates to the subsequent clinical  
4 decisions you would make, if in fact after a  
5 few rounds of that, they're not responding the  
6 way you would want.

7 But perhaps that's out of scope of  
8 the measure, but it just seems, from a  
9 usability standpoint, that as a consumer, that  
10 seems misleading to me.

11 DR. DROZDA: I guess I'm not  
12 understanding the question perfectly. But if  
13 you have someone who's got coronary disease  
14 with an LDLC of greater than or equal to 100  
15 during that year, you have to put a plan on  
16 there about how you're going to get to a less  
17 than 100, and that has to include the  
18 prescription of the statin.

19 But it does mean you're going to  
20 have to have some other, you know, you're  
21 going to have to address the issue formally.

22 DR. JEWELL: Okay.

1 CO-CHAIR GIBBONS: Sure, George?

2 DR. PHILIPPIDES: What's the  
3 experience of NQF with patient refusal as an  
4 exclusion criteria? Is there any concern that  
5 that can just be documented as a surrogate for  
6 I didn't do it, and it would lead to sort of  
7 false exclusions? I don't know what the track  
8 record is on that.

9 CO-CHAIR GEORGE: Well, I don't  
10 think we have any data on that per se. The  
11 evaluation criteria, though, specifically  
12 addressed that patient exclusion or for  
13 patient preference type of exclusions should  
14 be -- if they're going to be included in a  
15 measure, should be specified, so that the  
16 effect of those are transparent.

17 Because just for the reason you're  
18 saying. I mean is the performance level  
19 related to -- actually, in these type of  
20 measures, is the performance level really  
21 related to patients getting to target, or what  
22 portion of those are above target but have



1 some plan that nobody knows how good the plan  
2 is or that the patient, you know, preference,  
3 checkbox.

4 So questions have come up about  
5 measures that are specified this way, but we  
6 don't have a hard and fast rule about it. But  
7 that's the guidance from the CSAC about  
8 patient preference.

9 CO-CHAIR GIBBONS: Comment from  
10 the developer?

11 DR. DROZDA: Yes. You know, I  
12 hear the concern, and it's one that's been  
13 voiced, you know, frequently over time. I  
14 think in some of the testing that we've done  
15 through PCPI, we found that, and not only for  
16 this measure but for others, that patient  
17 refusal is a vanishingly small number of, you  
18 know, of the reasons used for exceptions, that  
19 the vast majority of exceptions fall under  
20 medical.

21 We felt, though, that we had to  
22 have a -- had to allow patients the

1 independence and give them the respect they're  
2 due, in terms of being able to decline any  
3 medication. We were sort of thinking about it  
4 at the other end of the spectrum as we honor  
5 patient autonomy.

6 DR. MASOUDI: There's information  
7 in the packages as well, in terms of some of  
8 the data in testing. Exceptions are used  
9 relatively rarely. I think this one about  
10 patient refusal, I would have to look through  
11 this in more detail. But the exceptions are  
12 generally used fairly rarely, in general.  
13 We're talking less than five percent.

14 CO-CHAIR GIBBONS: And it does get  
15 back to the point that Fred made earlier. In  
16 order to do that, somebody has to think of it  
17 and then record patient refusals. So it's a  
18 two-step process and the first step is pretty  
19 important, that they're actually thinking  
20 about the issue.

21 Other questions before we vote on  
22 scientific acceptability? All right. Let's

1 go ahead and vote.

2 DR. KING: Yes, I have a comment.

3 CO-CHAIR GIBBONS: Sorry, Dave.

4 DR. KING: I don't know. My  
5 summary thought about this, the mish-mosh of  
6 reasons, the documentation, what the  
7 extractors would do, in my mind, questions the  
8 reliability and validity of this. It's almost  
9 like you're mixing your metaphors. Are we  
10 trying to get below 100 or did we just mean  
11 to?

12 The amalgamated measure at the end  
13 was well 99 percent of the time, we either did  
14 or we meant to. I would say well, how would  
15 we use that? So the scientific acceptability,  
16 the reliability, validity and the usefulness  
17 of that information is getting towards zero to  
18 me right now.

19 So I don't -- but I would  
20 certainly want to hear other people's thoughts  
21 about it.

22 DR. DROZDA: One of the, and I

1 hear what you're saying. One of the concerns  
2 if we would, say, go for a measure of LDL less  
3 than 100, is that the evidence unfortunately  
4 is showing that the end doesn't necessarily  
5 justify the means.

6 There are medications that might  
7 help you get to less than 100 that might not  
8 give you the ultimate in terms of the kind of  
9 clinical outcomes you're looking for.

10 So if we stuck just with an LDL  
11 target, which is maybe the alternative, of  
12 less than 100, I think we might be, you know,  
13 there's some risk for some adverse outcomes  
14 that are completely independent. So we  
15 decided that we needed to, you know, if you're  
16 less than 100, that's fine.

17 But if you're over 100, you're --  
18 we wanted to make certain we were specifying  
19 that you're on a statin and have an approach  
20 to get to less than 100. Again, you know, if  
21 we start excluding too many people at a  
22 physician level, we start getting to

1 vanishingly small numbers, and it's very  
2 difficult to assess performance that way.

3 DR. RUSSO: I'd like to just  
4 comment too. I mean that's, you know, if  
5 you're seeing someone just in reality of one  
6 or two points in time, and you're working it,  
7 that's how medicine is. So you're not going  
8 to be 100 percent on that first visit or  
9 second visit, showing --

10 So I think it's a valid way to  
11 look at this. It's not perfect. Otherwise,  
12 certainly if you only pick the number, maybe  
13 then no one will achieve, you know, we're  
14 never going to get close to 90 or 100 percent,  
15 but then you have to kind of lower that  
16 threshold of where you want to be.

17 But I think it's a reasonable way  
18 to look at things in reality and how we  
19 practice.

20 DR. PHILIPPIDES: There is one  
21 strange wrinkle here. It seems that if you,  
22 with an LDL of 101 and you're on a statin,

1 then you've made the measure; is that correct?  
2 But if you're at 99 and off a statin, you've  
3 made it as well.

4 I would argue I'd rather be at a  
5 101 and on a statin, then at 99 and off a  
6 statin if I'm post-MI. So it's not just  
7 enough to be between 70 and 100. That  
8 actually shows that even in those lower LDL  
9 ranges, you might want to be on a statin.

10 There's a little quirk here. I  
11 don't think it's going to be clinically  
12 important. I don't think people will stop  
13 using statins because of that. But it is a  
14 strange aspect of the way that this is  
15 written.

16 DR. MASOUDI: But so this is a  
17 problem with any of the threshold measures,  
18 right? The hypertension measure, the statin  
19 measure, it's all the same in many respects.

20 I think the issue with this  
21 measure is by focusing on statins, again, from  
22 our lessons with ezetimibe, fibrates and so

1 on, it doesn't provide the incentive to go  
2 ahead and just throw those medications on with  
3 the hopes that you somehow are achieving this  
4 goal, which is basically a numerical goal.

5 It's not an outcomes goal, when  
6 the primacy of the data, I mean the  
7 substantial weight of the data is with the  
8 statins. The only reason that the threshold  
9 is in there, and I personally on a clinical  
10 level put every patient with coronary disease  
11 on a statin, is because we do have to  
12 acknowledge the existence of the guideline  
13 recommendation. We can't go beyond that in  
14 specifying the performance measure.

15 DR. DROZDA: I concur on that, and  
16 we'll be tracking the guidelines on this  
17 point.

18 CO-CHAIR GEORGE: I was just going  
19 to say I guess it also raises a question of  
20 whether this will come up against anything in  
21 ATP-4 guidelines, that will need to be  
22 addressed.

1 DR. DROZDA: We will be monitoring  
2 those guidelines. We're aware of them, and  
3 you know, we're willing to modify based on any  
4 changes and recommendations.

5 CO-CHAIR GIBBONS: Okay. I think  
6 we need to go ahead and vote on scientific  
7 acceptability.

8 (Pause.)

9 CO-CHAIR GIBBONS: 9 completely, 8  
10 partially, 4 minimally. All right. We need  
11 to go to next item, usability.

12 CO-CHAIR GEORGE: In terms of  
13 usability, this is not currently being used  
14 for public reporting, but it is being used  
15 with the guidelines, outpatient program.  
16 Other issues, harmonization was not addressed,  
17 and I think it does need to be harmonized with  
18 other lipid measures. The additive value was  
19 not addressed as well.

20 CO-CHAIR GIBBONS: Comments or  
21 questions?

22 (No response.)



1 CO-CHAIR GIBBONS: All right.

2 Let's go ahead and vote on usability.

3 (Pause.)

4 CO-CHAIR GIBBONS: Okay. 6  
5 completely, 11 partially and 4 minimally. And  
6 now the final criteria, feasibility.

7 CO-CHAIR GEORGE: Excuse me. The  
8 data can be extracted electronically.  
9 Developers saw no problems with the exclusions  
10 that they have listed. Costs have not been  
11 calculated for implementing this, and there  
12 was -- right. And that was one of the  
13 concerns of one of the reviewers. That was  
14 all that was addressed.

15 CO-CHAIR GIBBONS: Comments or  
16 questions from the other members of the group  
17 or anybody else?

18 (No response.)

19 CO-CHAIR GIBBONS: If not, I think  
20 we should go ahead and vote on feasibility.

21 (Pause.)

22 CO-CHAIR GIBBONS: 8 completely,

1 11 partially, 1 minimally. We're now going to  
2 move to the final question of endorsement.  
3 Comments or discussion about this before we  
4 vote? Seeing none, we will go ahead and vote  
5 now please.

6 (Pause.)

7 CO-CHAIR GIBBONS: 17 yes, 4 no.

8 So at this point, we're going to be -- we'll  
9 pause for a moment to allow for comments from  
10 other NQF or from NQF members and the public,  
11 either people who are in the room or on the  
12 phone. Are there comments? Dr. Masoudi.

13 Public Comment

14 DR. MASOUDI: Yes. Just with  
15 respect to the issue of harmonization, I think  
16 it would be useful for the group to discuss,  
17 I suppose.

18 Not at this time; I don't know  
19 when it would be best. But the aspects, you  
20 know, the specific aspects of the measures  
21 that are more favorable for one and less  
22 favorable for the other.

1                   For instance, the presence or  
2                   absence of exclusions. Is that a plus or a  
3                   minus? Focus on statins versus not. Is that  
4                   a plus or a minus? Because that, I think,  
5                   would be helpful from the developer's  
6                   perspective, in terms of understanding where  
7                   to go with harmonization, sort of what  
8                   specific aspects of the measure was it,  
9                   clearly, when there's discordance in the  
10                  perception of the measure as to where to go  
11                  with it.

12                  CO-CHAIR GIBBONS: Thank you. I  
13                  think that, as you mentioned, there will need  
14                  to be a side to side comparison and those  
15                  factors will obviously be key. Dana?

16                  DR. KING: Yes, I have a comment,  
17                  and I need to get this clarified in my own  
18                  mind, about the use of the NQF standards in  
19                  the future. In other words, if you want  
20                  people's blood pressure to be below 140 over  
21                  90, or their LDL to be below 100, I mean we  
22                  sort of all want that.

1                   If it's going to be used for  
2                   future pay for performance or evaluation of  
3                   practices and how hard they're trying, then we  
4                   probably need to pay attention to the  
5                   exclusions, the allergies, the "I gave them  
6                   everything but they refused it," and the more  
7                   difficult, you know, chart extraction reasons,  
8                   or "I gave them the lifestyle, I gave them the  
9                   medicine, and they threw it in the trash on  
10                  the way out."

11                  But I think that's an important  
12                  perspective for us to have, because even in my  
13                  own mind, you know, I'm saying the standard  
14                  should be, you know, everyone should have a  
15                  blood pressure and cholesterol, et cetera, and  
16                  everyone should be on aspirin.

17                  But I mean practices, on the other  
18                  hand, shouldn't be -- I know that we should  
19                  put it in the positive, pay for performance,  
20                  but on the other hand punished monetarily when  
21                  reasonable things, you know, intercede. So  
22                  can you give us some insight into kind of

1 which way to lean and how mushy we should be?

2 DR. WINKLER: Essentially, NQF's  
3 stated goals have always been a priority for  
4 measure suitable for public reporting. That  
5 is a fairly high bar, the expectations that  
6 the measures do reflect a valid assessment of  
7 performance.

8 That is clearly the use of NQF  
9 measures by a wide variety of organizations,  
10 have used them in a wide variety of ways, and  
11 some people have characterized those as sort  
12 of high stakes uses, if you will.

13 So I think from that perspective,  
14 we are not looking at measures that are, that  
15 might be used in local situations for quality  
16 improvement kind of thing, but really are for  
17 sharing with others outside of yourself,  
18 public reporting, if you will, or some of the  
19 other uses, to really provide a valid  
20 assessment of your performance.

21 That's what we're really at.

22 That's what the criteria are aiming, to help

1 you look at the characteristics of the measure  
2 and judge them against those criteria, to be  
3 able to meet that standard.

4 DR. RUSSO: And just a general  
5 question. You know, I was originally reading  
6 through the measures and I'm not sure. So on  
7 the same line, in terms of unintended  
8 consequences and we have patients who are  
9 maybe not compliant or not willing to take  
10 medicines. That may be in certain areas, and  
11 we don't want to have disincentives to take  
12 care of these patients.

13 So as we look at them, or should  
14 we be considering more risk adjustment in all  
15 the measures, or is that in the plans, or do  
16 we add more mushy things into the measure  
17 itself? It's not really clear to me how to --

18 DR. WINKLER: Well, I think one of  
19 the benefits of a lot of these measures being  
20 maintenance measures is clearly there should  
21 be a track record. We should have some  
22 experience. We should know the answers to

1 some of these questions, if they've truly been  
2 used.

3 If they've not been used, we have  
4 to ask the question why have they not been  
5 used, and what have or we haven't learned from  
6 them? So I think that's a very important  
7 aspect of the evaluation, particularly for the  
8 maintenance measures.

9 We're in a little bit different  
10 situation for some of the new measures, that  
11 they really don't have much of a track record.  
12 They may have been tested in a limited way,  
13 but not perhaps widely used that we can answer  
14 those questions as thoroughly as you would  
15 like.

16 But nonetheless, I think they are  
17 valid questions to consider and ask the  
18 developers how they plan on addressing  
19 potential issues. But for the maintenance  
20 measures, I think we really want to look at  
21 our experience and our track record for the  
22 use of the measures.

1 CO-CHAIR GIBBONS: Karen?

2 MS. PACE: Just to go back to  
3 Dana's question, I think this gets at, you  
4 know, as Reva was saying, we want measures,  
5 we're endorsing measures that are useful for  
6 both public reporting and quality improvement.

7 So the question that you're posing  
8 that has arisen before, when you have a  
9 measure that kind of mixes the target with the  
10 plan, is if you have two providers with the  
11 exact same score, but one is actually  
12 achieving those target levels more, it's  
13 invisible.

14 So you don't really have that  
15 information to look at comparisons. So that  
16 has been a question that's been raised about  
17 those types of measures.

18 The other thing about intermediate  
19 clinical outcome measures such as the target  
20 level is that you don't really expect 100  
21 percent, because of some of these issues that  
22 we've talked about. The question is whether



1 you do need risk adjustment for -- certainly  
2 for health outcome measures we do.

3 Perhaps at some, for some of these  
4 intermediate clinical outcome measures, there  
5 should be some discussion of that or at least  
6 thought about that, whether that's relevant or  
7 not.

8 Typically, we have a lot of  
9 intermediate clinical outcome measures without  
10 risk adjustment. But then the question is,  
11 you know, is there really a variation across  
12 practices of these people that should not get,  
13 reach that level.

14 Because if it's fairly consistent  
15 or random across practices, then it's not  
16 really disadvantaging any one practice for  
17 performance measurement. So it's a lot of  
18 intricate things to consider and, you know, we  
19 don't have one right way. You know, we  
20 appreciate you grappling with these kinds of  
21 questions and issues.

22 CO-CHAIR GIBBONS: Are there

1 people on the phone who want to comment from  
2 the public? The phone line's open, I believe.  
3 Is there anyone else at the back of the room,  
4 other than Committee members, who want to  
5 comment further?

6 DR. JEWELL: So the issue of  
7 adherence has permeated every conversation  
8 I've been involved with in NQF, having now  
9 served on a number of panels, and I vacillate  
10 between having a blanket statement in the  
11 exclusion criteria of every single measure  
12 that comes along, that says those patients who  
13 don't cooperate aren't counted.

14 The point that you made, which is  
15 that it's potentially an easy out. I can't  
16 remember either, Helen. Has the CSAC given  
17 any guidance on this? I can't remember, and  
18 I just -- because it is something we wrestle  
19 with relative to attribution, and I know it's  
20 not a solvable problem completely.

21 But I just, I want to acknowledge  
22 that it pretty much hits us everywhere we go

1 with this, with measure development and  
2 application.

3 MS. PACE: I think it's something  
4 that they do question, and as I said, the most  
5 guidance we have is the footnotes in the  
6 evaluation criteria about patient preference  
7 really should be included in measures  
8 judiciously, and hopefully in a way that their  
9 impact is transparent.

10 The other side of adherence is  
11 that adherence is influenced by the health  
12 care provider. So, you know, where do you  
13 draw the line, you know? If some providers  
14 are more effective in communicating; I don't  
15 know. But that's hard to, you know.

16 So to say that they should  
17 definitely be excluded, I mean those are the  
18 trade-offs and the balances that have been  
19 discussed. But I can't say that there's been  
20 one directive up to this point. We may see  
21 that in the future, but --

22 DR. AYALA: I have a question

1 about that. Is this something that NQF could  
2 maybe take up, and that is to get a better  
3 definition of non-compliance on the part of  
4 the patient?

5 Because it's almost like risk  
6 adjustment in the hospital setting is very  
7 well-defined, but in the outpatient setting,  
8 where a lot of these measures are going to be  
9 used, there is that risk to the physician  
10 being graded on their performance if they have  
11 a significant part of their population that  
12 are either transient or have other  
13 socioeconomic situations that interfere with  
14 their adherence.

15 So if there could be some specific  
16 definition of non-compliance or non-adherence,  
17 where the provider shows that they have done  
18 X, Y and Z, and the patient still is not  
19 complying, that that might help to balance out  
20 that concern that, you know, if you just say  
21 the patient didn't take it the first time and  
22 that's it; the patient just said they didn't

1 want it, that you're being too easy on the  
2 provider.

3 DR. BURSTIN: One thing I'll  
4 mention is that's part of our medication  
5 management project. A couple of years ago,  
6 our committee spent a lot of time looking at  
7 pharmacy data, relevant measures of adherence,  
8 and actually did come up with what I thought  
9 were some pretty good ways of describing it.

10 It's more from the pharmacy data  
11 perspective, but this issue of, you know,  
12 patients' ability to get their medicines  
13 always comes up.

14 If somebody's always practiced in  
15 the safety net, it's always one of those ones  
16 that makes me very uncomfortable, because I  
17 feel like I can try and do my best, and I feel  
18 badly when I feel like we're held to a  
19 different standard. But obviously that's  
20 something to keep that in mind.

21 CO-CHAIR GIBBONS: I would just  
22 point out that the science in this area is

1 certainly in evolution, because there's now a  
2 variety of efforts at patient education tools,  
3 which on the surface to most physicians look  
4 sort of like Mickey Mouse revisited. They're  
5 trying to remember when they've seen anything  
6 so primitive, but now actually have been  
7 demonstrated to work in improving compliance.

8           There's an enormous track record  
9 of fairly simple things. So and boy, it's  
10 moving before us forward right now at warp  
11 speed in a variety of ways, the sort of shared  
12 decision-making concept among others. But in  
13 pure medicine compliance, there are a bunch of  
14 things that have now been shown to clearly  
15 work.

16           DR. KING: Not just educational  
17 interventions, but ones that reduce the  
18 barriers to refills. So simple reminders or,  
19 you know, letting patients have their  
20 medications mailed to them as opposed to  
21 coming to the pharmacy. These are actually  
22 very effective, make sense.

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CO-CHAIR GIBBONS: Okay. So I think we'd better break for lunch. We are a little bit behind, so I'd ask everybody if they could to try to shorten lunch to 20 minutes, so we start at five after one please.

(Whereupon, at 12:45 p.m., a lunch recess was taken.)

1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 1:06 p.m.

3 CO-CHAIR GIBBONS: So our next  
4 measure is 0066, ACE and ARB therapy, and Jon  
5 Rasmussen will be the primary reviewer. Jon?  
6 Measure 0066

7 DR. RASMUSSEN: The brief  
8 description of this measure is the percentage  
9 of patients, aged 18 and older, with a  
10 diagnosis of CAD, that are seen by a provider  
11 in the last 12 months, who also have either  
12 diabetes or an ejection fraction of less than  
13 40 percent.

14 Impact is very high. We've talked  
15 a lot about the impact of coronary artery  
16 disease, and the evidence is quite strong on  
17 this measure. Any comments?

18 CO-CHAIR GIBBONS: So comments or  
19 questions about importance?

20 (No response.)

21 CO-CHAIR GIBBONS: If not, let's  
22 go ahead and vote on importance in between



1 mouthfuls of food.

2 (Pause.)

3 CO-CHAIR GIBBONS: Okay. So we  
4 have 18 yeses and no no votes. We have a few  
5 people who aren't yet back. So we'll move on  
6 to scientific acceptability. Jon?

7 DR. RASMUSSEN: In terms of  
8 scientific acceptability, the data is quite  
9 strong for using an ACE as a first-line agent  
10 or an ARB as a second-line agent, in those  
11 patients who have CAD and CAD with diabetes or  
12 CAD with ejection fraction less than 40  
13 percent.

14 The recommendation is that they  
15 should be started and continued indefinitely  
16 in all of these patients. One point of  
17 consideration for the group may be that there  
18 are two other cohorts that could potentially  
19 be included in this group, and those are  
20 patients with CAD and hypertension, and  
21 patients with CAD and chronic kidney disease.

22 The group that submitted this

1 measure did some work through the PCPI, and  
2 they talk about reliability and validity, and  
3 they've looked at different medical groups to  
4 assess some of those, with no outstanding  
5 issues.

6 With respect to exclusions in this  
7 population, they have very similar exclusion  
8 criteria that they've described in the past,  
9 and actually why don't we get -- I'll get into  
10 that a little bit more in the second  
11 categorization.

12 As far as meaningful differences,  
13 also in the addendum that they presented with  
14 the PCPI data, they show that there are some  
15 differences between groups. Not hugely  
16 significant; however, enough that focusing on  
17 this measure could show some improvement.

18 Disparities, they did not note  
19 any. This is a measure that is not currently  
20 used widely, so they had limited data on that.

21 CO-CHAIR GIBBONS: Questions or  
22 issues with scientific acceptability?

1 DR. JEWELL: I just have a  
2 question.

3 CO-CHAIR GIBBONS: Yes.

4 DR. JEWELL: And I'm realizing  
5 this was similar on the measure before lunch.  
6 For the patients who were counted as coming in  
7 already on the medication, if the physician  
8 makes a decision to discontinue the use of  
9 that medication for whatever reason, is that  
10 patient counted as positive in the numerator  
11 because they showed up on the statin at the  
12 beginning of the visit, or are they put into  
13 an exclusion category because they were pulled  
14 off the statin at the end of the visit?

15 DR. RASMUSSEN: So the way that  
16 the measure is written, a single fill of an  
17 ACE or ARB would count them in the numerator.

18 DR. JEWELL: Okay.

19 DR. RASMUSSEN: That said, if  
20 there's an identifiable reason that the  
21 patient should not be taking the medication,  
22 this measure, as written, would catch them in

1 the exclusion criteria. So it could go --  
2 frankly, it could go either way.

3 CO-CHAIR GIBBONS: Bruce.

4 DR. KOPLAN: Just one -- I should  
5 have asked this question when you were  
6 discussing number one. But so if I understand  
7 this correctly, this measure is for ACE  
8 inhibitors or ARBs in people with coronary  
9 disease, and either diabetes or left  
10 ventricular dysfunction, is that correct?

11 DR. RASMUSSEN: Correct. They  
12 must have CAD and then one or the other.

13 DR. KOPLAN: So I know we talked  
14 about harmonizing, not splitting. But  
15 sometimes the implications of ACE inhibitors  
16 or the settings of ACE inhibitors or how you  
17 measure who's on, or how you think about  
18 putting people on these things is for me a  
19 little different.

20 It's like sometimes a different  
21 situation if somebody's diabetic, versus doing  
22 it for left ventricular dysfunction. Is this

1 something -- you hate to divide a measure into  
2 two or something. But it just seems like  
3 there's a little bit of lumping going on here  
4 that might create some, putting some people  
5 together that are little different.

6 DR. RASMUSSEN: The way the  
7 recommendations are written, there are four  
8 potential disease states in those who have  
9 CAD, that could benefit from ACE and ARB  
10 therapy.

11 Now we'll talk about another  
12 measure later that they actually specified the  
13 exact type of beta blocker that someone with  
14 a certain disease may have. So it's not the  
15 whole, every beta blocker under the sun. It's  
16 a specific amount.

17 As written, it seems that if  
18 there's a patient, a patient with diabetes,  
19 for example, that clinically shouldn't be  
20 taking it or may have a different threshold,  
21 they could be excluded in the exclusion  
22 criteria. I'm not, I don't have a good sense

1 of how we could exclude them immediately in  
2 the denominator.

3 CO-CHAIR GIBBONS: Sid?

4 DR. SMITH: This may be a little  
5 bit of wordsmithing, but I'm wondering if it  
6 would be more accurate to say "most recent  
7 left ventricular ejection fraction, rather  
8 than prior. You've got a patient that comes  
9 in, they may have had an injection fraction.  
10 Someone's looking at the records if they grab  
11 from 18 months ago, that was low.

12 But after whatever it was,  
13 infarct, whatever treatment, they now have an  
14 ejection fraction of 48 percent that was done  
15 three months before their current visit, are  
16 we saying that it's not the same patient as --  
17 I'm just wondering if most recent ejection  
18 fraction is more accurate than prior.

19 Prior could be any one of a number  
20 of ejection fractions along the way, and might  
21 not reflect the true state of left ventricular  
22 function, particularly in recovery from a

1       STEMI, although we do say with a STEMI they  
2       should all be on ACE inhibitors if they have--

3                   CO-CHAIR GIBBONS: Did the measure  
4       developers want to comment on that issue?

5                   DR. DROZDA: Joe Drozda. Can you  
6       hear me?

7                   CO-CHAIR GIBBONS: Yes, Joe.  
8       We're having difficulties.

9                   DR. DROZDA: Yes. Here's what I  
10      would say to that. Again, we're not creating  
11      a guideline here; we're trying to track the  
12      guidelines. Again, the guideline, you know,  
13      states that when patients who have an ejection  
14      fraction of less than or equal to 40 percent,  
15      you know, should be placed on an ACE inhibitor  
16      indefinitely.

17                   So there's nothing in the  
18      guideline of which I'm aware of, and I'm going  
19      to have to go back and look at it again. But  
20      I'm not aware of that, that the guideline  
21      states that if the ejection fraction then  
22      comes back up over 40 percent, it can be

1 discontinued.

2 But so we're kind of looking at it  
3 from that standpoint, and the situation where  
4 someone comes in with a 48 percent. It's the  
5 first time you've seen them. They're not on  
6 ACE. They had a 40 percent two years ago. I  
7 can't, you know, I hear what's being said, but  
8 I can't believe that that's a very common  
9 situation.

10 DR. AYALA: I have a question.  
11 The definition prescribed, it says that it  
12 could include just that the patient was given  
13 a prescription, not necessarily that it had  
14 been filled, and this is only required one  
15 time in the 12 month period.

16 So for me, the validity of this  
17 measure, in trying to capture, you know, get  
18 to an outcome that requires more persistent  
19 use of an ACE inhibitor or ARB makes me  
20 concerned, and I have the similar concern with  
21 the measure I'm going to look at for heart  
22 failure, beta blockers for heart failure. So



1 just if we could clarify that definition.

2 DR. RASMUSSEN: This actually may  
3 be a good opportunity, because I think we'll  
4 come across this issue again and again when  
5 we're talking about adherence measures. I  
6 think in the next category is where we'll  
7 probably vote on it, with inclusion and  
8 exclusion criteria.

9 But this is a -- this particular  
10 measure is a single point estimate of  
11 adherence. One time in that time frame that  
12 they pick up a medication. That is not a  
13 particularly, in my eyes, a great way to  
14 measure adherence.

15 We've got some examples of another  
16 HEDIS measure, beta blocker post-MI, where  
17 they set a time frame of 180 days, and expect  
18 a medication possession ratio of at least 75  
19 percent.

20 To me, that's a more accurate  
21 representation of appropriate clinical care  
22 than a single medication fill.

1 DR. SPERTUS: The challenge is  
2 that one will fall down on its feasibility.  
3 I mean it's going to be exceedingly difficult  
4 to calculate that in a large number of  
5 settings. While it may be feasible in some  
6 health plan's perspectives, in lots of others  
7 it won't be.

8 DR. DROZDA: This is Joe Drozda.  
9 Again, I want to be clear about the measure.  
10 This is not a patient adherence measure.  
11 We're not putting it forth as that. This is  
12 a provider adherence measure, that the  
13 provider understands that ACE/ARB are  
14 indicated in this situation and prescribes it.

15 So that's really what we're  
16 measuring. Adherence is important to measure.  
17 I think we still have a lot of issues around  
18 it, including something that Dr. Spertus just  
19 said, and that is the feasibility, especially  
20 at a physician level.

21 Right now, I'm personally involved  
22 in some work, trying to get information back

1 from pharmacies through the e-Prescription  
2 mechanism, about fills and refills, so the  
3 physician even knows what the refill data are.

4 I think we're seeing some  
5 challenges even to PBM data, with the \$4  
6 prescriptions that are being floated out,  
7 prescriptions without going through the  
8 insurance benefit. So it's becoming more and  
9 more difficult, even with PBM, Pharmacy  
10 Benefit Manager data, to really fully  
11 understand adherence.

12 So there's a lot of challenges in  
13 measuring adherence, let alone the other  
14 issues I mentioned earlier about attributing  
15 it to physicians, when actually probably a  
16 system level or a plan level or employer level  
17 measure may actually be more useful in terms  
18 of it helping us with adherence.

19 CO-CHAIR GIBBONS: Other comments  
20 or questions about scientific acceptability?

21 (No response.)

22 CO-CHAIR GIBBONS: If not, I think

1 we should go ahead and vote.

2 (Pause.)

3 CO-CHAIR GIBBONS: Okay. So we  
4 have 12 completely, 8 partially and 1  
5 minimally. Can we move on the third  
6 criterion, usability? Microphone, Jon.

7 DR. RASMUSSEN: I keep turning it  
8 off to keep it from squealing, and neglect to  
9 turn it back on. For the Usability data, this  
10 measure is not yet publicly reported.  
11 However, it does have a significant amount of  
12 value if the measure were approved as it  
13 relates to clinical care.

14 Adding values to existing  
15 measures, now we're back to the harmonization  
16 question again. There's another measure that  
17 I'll be presenting that's looking at a very  
18 similar outcome, but immediately post-  
19 discharge from hospital.

20 CO-CHAIR GIBBONS: Okay. Questions  
21 or issues regarding Usability?

22 (No response.)

1 CO-CHAIR GIBBONS: Okay. I don't  
2 see any lights on, so let's go ahead and vote  
3 on Usability, please.

4 12 completely, 9 partially. Let's  
5 move on to Feasibility.

6 DR. RASMUSSEN: Similar to other  
7 medication-related measures, the information  
8 could be extractable. The information  
9 regarding ICD-9 codes also should be  
10 extractable without too much difficulty. One  
11 comment that I would make, and this is looking  
12 at it from the stance of an abstractor, is the  
13 exclusion criteria, very similar to other ones  
14 that have been reported in the past. So it's  
15 not a lot of difference there.

16 I wonder if the Committee would  
17 consider if it's reasonable to have some  
18 explicit exclusion criteria. So for an ACE  
19 inhibitor, for example, angioedema or renal  
20 artery stenosis, so that the abstractor can  
21 eliminate those administratively --

22 (Telephonic interruption.)

1 DR. RASMUSSEN: So I'm wondering  
2 if the --

3 DR. BURSTIN: If the folks on the  
4 call could just please go on mute while you're  
5 not speaking? Thank you.

6 DR. RASMUSSEN: So I wonder if  
7 there's some advantage in spelling out some  
8 specific exclusion criteria that would make it  
9 easier for the abstractor to take patients out  
10 of the denominator if they felt that was  
11 important.

12 The converse of that and the  
13 authors discussed this, is that some of these  
14 may relative contraindications. So if you  
15 have a patient who has hypotension, it's not  
16 unreasonable to rechallenge, perhaps, with  
17 another agent.

18 So the balance is do you make it  
19 easier to eliminate patients from the  
20 denominator, mostly appropriately, or do you  
21 leave it more to a manual review, to determine  
22 whether or not the patient should be taking

1 the medication?

2 CO-CHAIR GIBBONS: Dr. Masoudi.

3 DR. MASOUDI: Yes. We've  
4 struggled with this at the ACC-AHA in the  
5 development of all of our measures, is this  
6 issue of whether or not to have a very clear,  
7 explicit list of contraindications, versus  
8 those, you know, versus a more permissive  
9 list, that allows for absolute  
10 contraindications.

11 I think what we found from an  
12 acceptability perspective is that having a  
13 very prescriptive list does two things. One  
14 is that it increases the abstraction burden,  
15 in terms of having to look for specific issues  
16 throughout the chart, rather than looking more  
17 broadly for just saying an ACE inhibitor's not  
18 indicated for this reason or that.

19 The other issue is from a clinical  
20 acceptability situation. I've worked a lot  
21 with the CMS measures and we'll talk about  
22 those later too, is the -- you know, because

1 of this issue of the nuances of clinical care  
2 and the vast, you know, different types of  
3 exclusions that are possible, it's really hard  
4 to come up with sort of an acceptable and  
5 reasonably exhaustive list of  
6 contraindications, and draw bright lines about  
7 say what's the right reason for withholding an  
8 ACE inhibitor for hyperkalemia or for  
9 hypotension, like you say.

10 CO-CHAIR GIBBONS: I'm just a  
11 little concerned, because the mic in the room  
12 is a little soft. Joe and John, could you  
13 hear Fred's answer?

14 DR. SPERTUS: Yes. To just add to  
15 what he said, in terms of the kind of  
16 experience that we've seen with these measures  
17 in some of the testing we've done, it's  
18 actually kind of to what was said earlier.  
19 There are patients that apparently had some of  
20 these examples of denominator exceptions like  
21 for ACEs and ARBs, but who nevertheless were  
22 on the ACEs and ARBs, and for just the reasons



1 that were said.

2 These are relative sort of  
3 contraindications. The patient may have had  
4 a problem, was rechallenged. Anyway, the  
5 physician decided it was in the best interest  
6 to be back on the medicine. We found that,  
7 you know, we want to include those patients in  
8 both numerator and denominator.

9 So I think we're finding in what  
10 we're seeing so far that physicians are using  
11 these exceptions in a clinically appropriate  
12 way, as they manage patients over time.

13 DR. DROZDA: I would just agree  
14 with that. I think it's really, the issue  
15 about relative contraindications is an  
16 important one, and we wanted to give credit to  
17 those physicians where they chose to go ahead  
18 with the therapy, and it would be in the  
19 numerator and the patient would be counted.

20 Those who couldn't tolerate the  
21 therapy, for whatever reason, they were then  
22 excluded, and so that's what the exclusions

1 are used for.

2 CO-CHAIR GIBBONS: Okay. I think  
3 it's important to point out that I for one can  
4 hear the two of you better from wherever you  
5 are, than I can hear Fred from the other end  
6 of the room. Your voices are coming like God  
7 out of the ceiling. So --

8 DR. MASOUDI: And what would mine  
9 be coming out like?

10 (Laughter.)

11 DR. SPERTUS: By the way, he's  
12 right here with me.

13 (Laughter.)

14 DR. MASOUDI: So there, Dr.  
15 Gibbons.

16 CO-CHAIR GIBBONS: All right. I  
17 think we're ready for a vote on Feasibility.

18 Okay. 13 completely, 8 partially.  
19 All right. I think we're going to now move on  
20 to the final key question, does the measure  
21 meet NQF criteria for endorsement. Comments  
22 or questions before we vote?

1 (No response.)

2 CO-CHAIR GIBBONS: It looks like  
3 we're ready for a vote, if you could open that  
4 up.

5 It would appear we had a technical  
6 glitch there, so I think we're probably going  
7 to have to revote in a second.

8 (Pause.)

9 CO-CHAIR GIBBONS: Oh, we are?  
10 Have we opened it? All right. We're going  
11 to open for revoting.

12 Okay. Another unanimous yes vote.  
13 All right. We're now going to move to the  
14 next measure, which is on 0070, beta blockers  
15 in patients with prior MI, and Rochelle is our  
16 primary reviewer.

17 Measure 0070

18 DR. AYALA: Yes, and I'm glad we  
19 had that discussion before, because now that  
20 I'm focusing on this measure from the  
21 perspective of physicians' compliance, as  
22 opposed to adherence, that might change some

1 of my comments from what I submitted in the  
2 spreadsheet.

3 So this is -- the measure title is  
4 "Chronic Stable Coronary Artery Disease, Beta  
5 Blocker Therapy, Prior MI or Left Ventricular  
6 Systolic Dysfunction, Ejection Fraction Less  
7 Than 40 Percent."

8 The description is percentage of  
9 patients, aged 18 years or older, with a  
10 diagnosis of coronary artery disease, seen  
11 within a 12 month period, who also have a  
12 prior MI or current or prior left ventricular,  
13 ejection fraction of less than 40 percent, who  
14 were prescribed beta blocker therapy.

15 Again, this is whether the  
16 physician gave the prescription or if the  
17 patient filled it at the time that it was  
18 tested during that 12 month period. The  
19 importance to measure, lots of data here for  
20 this measure and the other one that I'm going  
21 to review next, that gives the clinical  
22 importance of treating patients with acute MI

1 or with prior QMI and left ventricular  
2 ejection fraction less than 40 percent, with  
3 beta blockers.

4 This indicator actually takes into  
5 account the exact type of beta blocker for the  
6 patients with the ejection fraction less than  
7 40 percent, and that's different from the  
8 other one. For those, it should be the  
9 bisoprolol, carbetalol, or sustained release  
10 metoprolol.

11 Are there any questions regarding  
12 the, or anyone take exception with the fact  
13 that it's important to measure, based on the  
14 data?

15 (No response.)

16 DR. AYALA: No. Then can we --

17 CO-CHAIR GIBBONS: Let's vote on  
18 Importance.

19 DR. SANZ: I have a question.

20 CO-CHAIR GIBBONS: Sure, go.

21 DR. SANZ: Too late

22 DR. AYALA: No, that's all right.

1 Go ahead.

2 DR. SANZ: I've never seen a  
3 measure yet this morning where we have to  
4 actually use a specific medication, and I have  
5 a problem with this, because basically I send  
6 all my patients home on BID metoprolol. That  
7 wouldn't be allowed under this. I don't think  
8 that's appropriate.

9 CO-CHAIR GIBBONS: Maybe the  
10 measure developers. Fred, you want to  
11 comment.

12 DR. MASOUDI: Well, this is an  
13 outpatient measure. The beta blockers  
14 specified are those specifically mentioned in  
15 the guidelines for patients with left  
16 ventricular systolic dysfunction, namely  
17 carbetalol or long-acting metoprolol. The  
18 other beta blockers are not specified in the  
19 guidelines as efficacious in patients with  
20 systolic dysfunction.

21 CO-CHAIR GIBBONS: Sid.

22 DR. SMITH: The data on beta

1 blocker therapy with normal LV function, more  
2 than three years after a myocardial infarction  
3 I'd like to see. There are data saying that  
4 patients with myocardial infarction benefit  
5 from beta blockers, and generally they're  
6 followed about two to three years.

7 But there are no data that I've  
8 seen, taking patients with myocardial  
9 infarction more than three or four years ago,  
10 placing them on a beta blocker, showing that  
11 they benefit. We've gotten into this in the  
12 current guidelines. So it's just a matter of  
13 the people who put this together, coming up  
14 with an evidence-based study showing that that  
15 happened.

16 CO-CHAIR GIBBONS: Okay. So we're  
17 sort of moved into Scientific Acceptability.  
18 We've already voted on Importance.

19 DR. SMITH: So I'm disclosing. I  
20 voted for this. I have a little trouble, and  
21 if I don't think the science is exactly right,  
22 do I vote? Yes. All the other stuff is

1 pretty good.

2 CO-CHAIR GIBBONS: That's the way  
3 it's supposed to be.

4 DR. AYALA: The only other comment  
5 in that regard too is so although we have  
6 studies showing certain beta blockers are  
7 beneficial, the absence of studies showing  
8 that other ones aren't is what? I would  
9 suggest considering maybe --

10 DR. MASOUDI: The issue is that  
11 it's responsive to the guidelines. There is  
12 specific guidance in the guidelines with  
13 respect to the beta blockers that should be  
14 used in patients with systolic dysfunction.  
15 So this is responsive to explicit  
16 recommendation in the guidelines.

17 I agree with you, that it's true  
18 that propranolol has not been studied in  
19 patients with systolic dysfunction. But  
20 again, to the extent that the Performance  
21 measures need to follow the guidelines, we're  
22 following that recommendation.



1                   With respect to the issue of  
2           longer treatment after MI, the current ACC-AHA  
3           secondary prevention guidelines suggest  
4           indefinite therapy in patients with MI. So  
5           again, it's really more following the  
6           guidelines and some of these admittedly  
7           important nuances in the interpretation of the  
8           existing data.

9                   DR. KING: Those guidelines are  
10          being revised. I'm looking up the women's  
11          guidelines, because I think they may have --  
12          we may have it already, the ones that came out  
13          yesterday. I know the secondary prevention  
14          ones have --

15                  CO-CHAIR GIBBONS: Anybody on the  
16          phone want to weigh in on this.

17                  DR. DROZDA: Yes, this is Joe  
18          Drozda. Again, we have to go with what we  
19          have, and right now the guidelines are what  
20          they are. Again, we will, if we need to  
21          modify it based on new guideline  
22          recommendations, we will do that, and we have

1 a plan for accomplishing it.

2 DR. SNOW: But this goes to what  
3 may be a core and fundamental problem. The  
4 measure developer has to go with the  
5 guidelines. The guidelines want to be  
6 "evidence-based." Where does the evidence  
7 come from?

8 Drugs that the pharmaceutical  
9 industry will pull out a sweet little  
10 randomized control trial for, but nobody's  
11 studying atenolol or propranolol or the other  
12 beta blockers because they're generic. So  
13 this thing that is kind of in the room, not  
14 what we want to be driving the discussion, has  
15 a major impact on it, and I don't know how to  
16 solve that problem.

17 CO-CHAIR GIBBONS: Well, at least  
18 for this one let me reiterate what Fred said,  
19 and just qualify it. In patients with  
20 symptomatic systolic heart failure, these are  
21 the three drugs that have been studied and  
22 been efficacious.

1 Other beta blockers have been  
2 studied. Bucindolol was studied, was not  
3 efficacious. Metoprolol tartrate, ordinary  
4 metoprolol, was studied, was not efficacious.  
5 So that's why these three are singled out,  
6 because in randomized trials in symptomatic  
7 heart failure.

8 Now these patients would not  
9 require symptomatic heart failure. They're  
10 officially Stage B heart failure by the  
11 guidelines, and beta blockers are recommended  
12 on the basis of expert opinion, and basically  
13 chose to extrapolate from the symptomatic data  
14 with respect to the drugs.

15 Does that help? I mean other  
16 drugs have been studied and didn't work.  
17 That's why the differentiation here.

18 DR. SNOW: Yes, I appreciate that.

19 DR. AYALA: Okay. Back to the  
20 Scientific Acceptability. The numerator we  
21 already discussed. The denominator, all  
22 patients aged 18 years and older with a

1 diagnosis of coronary artery disease, seen  
2 within a 12 month period, who also have prior  
3 MI or current or prior EF less than 40  
4 percent.

5 They also list a good summary of  
6 exclusions, including medical reasons. For  
7 example, allergy intolerant, bradycardia, so  
8 on and so forth, and documentation of patient  
9 reasons for not taking, for example, that the  
10 patient declined or other patient reasons.

11 Then also for documentation of system reasons  
12 for not prescribing the beta blocker therapy,  
13 and they also have an "other" category there.

14 DR. RUSSO: Can I just ask one  
15 question?

16 DR. AYALA: Go ahead.

17 DR. RUSSO: Is it supposed to be  
18 symptomatic heart failure, because at least  
19 the way it's described, it's coronary disease?

20 CO-CHAIR GIBBONS: No, no. But  
21 the science, that's what I was trying to  
22 establish, where the scientific evidence for

1 the drugs comes from. It's from trials in  
2 symptomatic heart failure.

3 DR. RUSSO: But can we extrapolate  
4 --

5 CO-CHAIR GIBBONS: The guidelines  
6 have. The guideline process has.

7 DR. RUSSO: Because that, I think  
8 we would not even question that. But if it  
9 were a heart failure measure, at least I  
10 wouldn't think twice, because we all put them  
11 on carvedilol. But if it's -- I understand,  
12 that we have to be consistent with the  
13 guidelines.

14 But it's a little harder, because  
15 I guess we could see how it works. I have a  
16 little problem, because it's not in the heart  
17 failure group.

18 CO-CHAIR GIBBONS: Well, I don't  
19 want to sort of delve too much into the  
20 process, but you can see the problem from a  
21 guideline developer's standpoint, if what  
22 you're suggesting means the moment the patient

1 develops symptomatic heart failure on  
2 metoprolol tartrate, then the clinician is  
3 supposed to change the drug. The chances of  
4 that happening are --

5 DR. AYALA: Zero. That makes  
6 sense.

7 DR. RASMUSSEN: Can I ask a  
8 question about systems issues. What does that  
9 mean exactly?

10 DR. AYALA: Developer?

11 DR. SPERTUS: Yes, systems issues  
12 deal with factors outside of the locus of  
13 control of the patient or the physician, that  
14 have an impact on whether or not, you know,  
15 therapy can be prescribed. For instance,  
16 insurance and medication availability, et  
17 cetera, et cetera.

18 DR. DROZDA: Another good example  
19 would be cardiac rehabilitation, when there  
20 just is no local cardiac rehabilitation  
21 program.

22 DR. MASOUDI: And the extent to

1 which these exclusions are relevant to any one  
2 of the measures, there is -- so this is,  
3 relatively speaking, boilerplate in terms of  
4 the ACC-AHA-PCPI put together their  
5 exclusions. But certainly these systems  
6 reasons are vanishingly irrelevant or close to  
7 irrelevant for something like the prescription  
8 of medication, are highly relevant to  
9 something like the provision of cardiac  
10 rehabilitation, or the provision of say  
11 primary PCI, where that's not available.

12 So this is just -- this is a  
13 boilerplate exclusion language that's used for  
14 all of the measures.

15 DR. DROZDA: And quite frankly, we  
16 don't see this cited, these sorts of things  
17 cited very often. It's just extremely rare  
18 for almost any measure.

19 CO-CHAIR GIBBONS: And somebody  
20 else can help me out, but this actually did  
21 occur for this one a few years ago, when both  
22 generic manufacturers for extended release

1 metoprolol were on FDA sanction, and there was  
2 this great tendency in Pharmacy Benefit  
3 Programs to switch all the patients to  
4 tartrate. If this measure had been done  
5 during that six month time frame, there would  
6 have been big problems.

7 DR. MASOUDI: Although that would  
8 have been a system --

9 CO-CHAIR GIBBONS: That's what I  
10 mean. It would have been a --

11 DR. DROZDA: A great example, yes.

12 CO-CHAIR GIBBONS: That would have  
13 been a system issue that nobody had any  
14 control over, that would have needed to be  
15 factored into the measure.

16 DR. AYALA: Okay.

17 CO-CHAIR GIBBONS: Okay. I think  
18 we need to vote on Scientific Acceptability.

19 DR. SMITH: We can go ahead and  
20 vote. I just want to be sure that it's  
21 understood that this beta blocker thing will  
22 be revised, because although they may not have



1 had it when they wrote it, it is a fact now  
2 and this Committee has to deal with the fact  
3 that the existing guideline is not consistent  
4 with this. I'm working, I'm trying to bring  
5 it up right now. It was published yesterday.

6 DR. MASOUDI: Right. So the  
7 women's guideline does in fact specify a one-  
8 year time frame.

9 DR. SMITH: Exactly. That's what  
10 I'm saying.

11 DR. MASOUDI: So right.

12 DR. SMITH: You're in touch with  
13 reality.

14 DR. MASOUDI: I try to be. What  
15 are those green things? So that's right. But  
16 so the in fairness, the measure was written  
17 before the release of the women's guideline,  
18 which just came out last week or something  
19 like that, and we have -- the ACC-AHA-PCPI  
20 have in place a mechanism whereby we can be  
21 responsive and are responsive in relatively  
22 short time frames to changes in the

1 guidelines.

2 Of course, the timeliness in which  
3 that can occur depends on the nature of the  
4 change. But it seems to me that this  
5 exclusion would be something that would  
6 relatively easy to work into the measure, as  
7 you know, MI within a year or whatever the new  
8 guideline ends up specifying.

9 DR. DROZDA: And I would agree,  
10 and that's because we were aware that things  
11 were in development, and we already had gone  
12 through the process of saying yes, we'll  
13 change if there are changes in the  
14 recommendations.

15 DR. SMITH: I'm not being critical  
16 of the people who wrote this. I'm trying to  
17 be sure that the Committee approves something  
18 that's consistent with what's going to be out  
19 there.

20 CO-CHAIR GIBBONS: Okay. Well, I  
21 think we understand the importance of that,  
22 and Joe has reflected and Fred has reflected

1 the PCPI process taking that into account. So  
2 this vote was 4 completely, 9 partially, 2  
3 minimally. We need to move on now to  
4 Usability.

5 DR. AYALA: Yes. I might need  
6 some help from the developers on this one,  
7 because it says it's currently in use, but  
8 then it says this measure is not yet used in  
9 a public reporting initiative. Is that  
10 because you're referring to the pilot groups  
11 that you're using in there?

12 MS. TIERNEY: Sorry about. Sam  
13 with the AMA PCPI. The reason we have that  
14 distinction is yes, the measures are in use  
15 in a number of programs like PQRS and  
16 meaningful use and things like that. However  
17 they have not at this point been used to  
18 report public physician data, make available  
19 performance data.

20 So we kind of draw a distinction  
21 between public reporting and just the use of  
22 the measures in implementation programs or

1 things like that. Hopefully that --

2 DR. DROZDA: So they are being  
3 used in accountability sort of programs,  
4 without going to the extent of public  
5 reporting.

6 DR. SPERTUS: This is John  
7 Spertus. Sid, I'm not sure that the beta  
8 blocker recommendations can be inconsistent  
9 with the stable ischemic heart disease  
10 guidelines, that would be quite relevant to  
11 this particular performance measurement set.

12 DR. SMITH: Yes, I'll take a look.  
13 My guess is it will be. The argument has been  
14 triggered, does everybody with coronary  
15 disease need to be on a beta blocker? That's  
16 where it starts. People start rummaging  
17 around, saying you know, we really don't have  
18 the evidence that people with normal left  
19 ventricular function and coronary disease  
20 should be on a beta blocker, and they don't  
21 have hypertension.

22 So then well where did this

1 evidence comes from? Oh, it's the Miami  
2 trials. So going back into these trials with  
3 acute myocardial infarction, where it was  
4 clear that patients started on beta blockers  
5 benefitted. The benefit seemed to occur early  
6 on, within the first year, and the trials went  
7 out for about three years.

8 And frequently, the benefits were  
9 associated with arrhythmic deaths. So that's  
10 led to a, what's going to be a revision, what  
11 is a revision that now being reviewed and one  
12 guideline's out, that beta blocker -- all  
13 patients with coronary disease do not need to  
14 be on beta blockers, that the subset of  
15 patients where they are a proven value are  
16 those who have congestive heart failure or  
17 systolic dysfunction, and those who have had  
18 a recent acute coronary syndrome.

19 So if you get somebody into your  
20 office who had an MI six years ago, who has  
21 normal LV function, no hypertension, the  
22 evidence to start a beta blocker right there

1 is not strong.

2 If you take somebody into the cath  
3 lab and do an angioplasty for an 80, 90  
4 percent left anterior descending lesion, they  
5 have normal LV function and no hypertension,  
6 have not had a recent infarct, the evidence  
7 that they need to be on a beta blocker is not  
8 strong.

9 So if we've tried to focus in on  
10 where is the evidence that patients with  
11 coronary disease will really benefit from beta  
12 blockers, and the evidence is really strong  
13 for heart failure and for acute coronary  
14 syndromes.

15 Now that's why they've written in  
16 this thing, beta blockers should be used for  
17 up to 12 months, or up to three years. The  
18 level of evidence A, is for 12 months for  
19 three years, B, and all women after MI or  
20 acute coronary syndrome with normal LV  
21 function unless contraindicated.

22 It doesn't say anything about

1 extending them beyond that if they have normal  
2 LV function.

3 DR. DROZDA: So the statements,  
4 updated statements from the heart disease  
5 guidelines may change, but it's currently  
6 written for the post-ACS MI group, and those  
7 with LV dysfunction. It's explicitly said  
8 indefinitely, and then, you know, it's a much  
9 lower recommendation for all other patients  
10 with coronary disease. So it may change a  
11 lot.

12 DR. SMITH: I have a coop coming  
13 up on that, so I need to -- that the lipids  
14 that we're discussing. It will be harmonized,  
15 and I think Fred, I mean as long as it's made  
16 consistent with what's out there, that's the  
17 important thing.

18 DR. DROZDA: We definitely have  
19 that mechanism in place, to update these very  
20 promptly when evidence changes.

21 DR. SMITH: But the origin of it,  
22 of you know, the whole thing has been should

1 we be putting everybody on beta blockade that  
2 has coronary disease, if they have normal LV  
3 function, normal LV gram and haven't had a  
4 recent acute event. That's where the --

5 DR. DROZDA: Right.

6 DR. SMITH: And trying to see what  
7 the evidence, and the evidence is not strong  
8 there. I don't know how existent it is  
9 really. But I don't -- I think this is a good  
10 measure, and if as Fred says and as you say,  
11 Joe, it can be revised to be consistent, then  
12 it's a reasonable thing to look at.

13 DR. DROZDA: Yes.

14 CO-CHAIR GIBBONS: Okay. I think  
15 we need to vote on Usability.

16 9 completely, 10 partially, 2  
17 minimally. Now on to Feasibility.

18 DR. AYALA: The data is generated  
19 as a byproduct of the care processes, and is  
20 also electronically collected. In terms of  
21 susceptibility to inaccuracies, there was one  
22 question I had regarding the supplement that



1 was provided with this, and it talks about the  
2 CMS PCQRI 2008 claims data.

3 It says that for the beta blocker  
4 therapy indicator, 63.67 percent of the  
5 submissions were rejected due to an inaccurate  
6 diagnosis code. I was hoping the developers  
7 could talk about that.

8 MS. TIERNEY: Yes. So in that  
9 instance, some --

10 CO-CHAIR GIBBONS: Is your mic on?

11 MS. TIERNEY: Sorry. Is it on?  
12 Okay. In that instance, someone or several  
13 people, obviously 63.67 percent of people  
14 submitted a CPT-2 code saying they prescribed  
15 a beta blocker, but there was no diagnosis to  
16 correctly identify patients with CAD. So they  
17 submitted a CPT-2 code that seemed like they  
18 were reporting on this measure, but then they  
19 didn't have the diagnosis data that matched  
20 with that.

21 It's kind of a nuance of the PQRI  
22 program and probably related to some of the

1 challenges with that, because this is some of  
2 the data from the early implementation of the  
3 PQRI program, before maybe they worked out  
4 some of these challenges. Does that make  
5 sense?

6 DR. AYALA: So are the challenges  
7 worked out, because that's a big part of the  
8 population that we'd be testing?

9 MS. TIERNEY: Right. So well part  
10 of the problem is with the PQRI program. But  
11 yes, I do believe they've tried to clarify  
12 some of that in terms of reporting  
13 instructions for people who are going to be  
14 using the PQRI program and trying to report  
15 data for PQRI. But I think that's part of the  
16 problem.

17 DR. MASOUDI: Right. So the issue  
18 is not with the measure itself; it's really  
19 with the program that is trying to use these  
20 specifications to drive a measure in their  
21 way.

22 It turns out that the way it was

1 being, you know, for a group of people that  
2 were initially reporting in this program that  
3 was just being begun, there were a proportion  
4 of patients that didn't belong in there,  
5 because they actually didn't have the  
6 underlying diagnosis to support their  
7 inclusion in the measure.

8 DR. AYALA: So it sounds like  
9 you're confident that that's fixed now?

10 DR. MASOUDI: I think we have to  
11 turn to CMS to ask them whether or not they've  
12 fixed -- you know, again, it's not -- it's not  
13 so much an issue with the measure per se, as  
14 the implementation by one program of the  
15 measure. So I would have to let them speak to  
16 that.

17 DR. DROZDA: So what PQRI was a  
18 self-reported system. So it depended on  
19 physicians putting down codes on claim forms,  
20 and you know, anybody who's done a, filled out  
21 a claim before knows how that -- there can be  
22 issues with respect to the accuracy of the

1 reporter.

2 So you know, I think this is  
3 something that would be generic to any self-  
4 reported measure. We'll hopefully over time  
5 be extracting these things out of the medical  
6 record with, you know, I said the electronic  
7 medical record, without user involvement, so  
8 that we wouldn't have those sorts of issues.

9 CO-CHAIR GIBBONS: Okay. Are  
10 there other questions or concerns about  
11 Feasibility?

12 (No response.)

13 CO-CHAIR GIBBONS: Okay. Let's go  
14 ahead and vote.

15 So we have 9 completely, 8  
16 partially and 2 minimally. All right. Let's  
17 move on now to the final, important question,  
18 does the measure meet NQF criteria for  
19 endorsement. Discussion or comments or  
20 questions before we vote?

21 (No response.)

22 CO-CHAIR GIBBONS: If not, let's

1 go ahead and vote.

2 17 yeses, 4 no's. So thank you.

3 We're going to move on to the next measure,  
4 0071, on persistence of beta blocker therapy.

5 Many of the comments we've made on the  
6 previous measure probably apply here, and  
7 Rochelle, you're still on.

8 Measure 0071

9 DR. AYALA: Okay. This one is  
10 more of an adherence, because it's  
11 persistence, 75 percent of the time in the 180  
12 degree period after discharge, that the  
13 patient was on a beta blocker.

14 Just for your information, our  
15 group voted very strongly for this one, and  
16 it's acute myocardial infarction, persistence  
17 of beta blocker treatment after a heart  
18 attack, and it's the percentage of patients 35  
19 years and older during the measurement year,  
20 who were hospitalized and discharged alive  
21 July 1st of the year prior to the measurement  
22 year through June 3rd of the measurement year,

1 with a diagnosis of acute MI and who received  
2 persistent beta blocker treatment for six  
3 months after discharge.

4 Again, the same discussion that we  
5 had before about persistence of beta blocker  
6 therapy apply here. So we can probably go to  
7 that Importance to Measure vote.

8 CO-CHAIR GIBBONS: Thank you. I  
9 agree. Let's go ahead and vote on Importance.

10 Okay, unanimous, 21 to 0. Let's  
11 go to Scientific Acceptance.

12 DR. AYALA: Okay. So the  
13 numerator statement is 180 day course of  
14 treatment with beta blockers. Identify all  
15 members in the denominator population whose  
16 dispense days supply is 135 days in the 180  
17 day period following discharge, which will  
18 give you at least 75 percent of the day supply  
19 filled. So it's filled.

20 The numerator, I'm sorry, and the  
21 denominator is patients age 18 years and older  
22 as of December the 31st of the measurement

1 year, and the discharge date, the continuous  
2 enrollment is discharge date through the 180  
3 day after discharge.

4 They had to be discharged alive  
5 from an acute inpatient setting, with an AMI  
6 from July 1st of the year prior to the  
7 measurement year, through June 30th of the  
8 measurement year.

9 If the member has more than one  
10 episode of acute MI from July 1st of the year  
11 prior to the measurement year through June  
12 30th of the measurement year, the organization  
13 should only include the first discharge and  
14 must use the codes listed in the table, and  
15 there are lots of codes listed.

16 In the exclusions, you have to  
17 look back as far as possible in patients with  
18 the history, through either administrative  
19 data or medical record review, and they list  
20 the codes for that. There's no risk  
21 adjustment necessary.

22 CO-CHAIR GIBBONS: Questions or

1 issues about Scientific Acceptability?

2 DR. RASMUSSEN: So this measure  
3 actually provides actually provides a good  
4 contrast between some of the other medication  
5 measurements that we looked at. In terms of  
6 exclusion criteria, there's very specific  
7 codes in which patients can be excluded from  
8 the denominator.

9 Also, there's a lack of a  
10 clinician option to exclude patients from this  
11 denominator. So to make this one more robust,  
12 I would like to see at least a clinician  
13 option to exclude patients.

14 The one that jumps to mind is  
15 fatigue. That's not a listed accepted  
16 contraindication. But it's not uncommon for  
17 a patient to try rechallenge on a beta  
18 blocker, and not be able to take it.

19 Also another contrast is that this  
20 is truly an adherence measure post-MI,  
21 measuring a possession ratio for a patient.  
22 So I'd be curious to hear the authors'



1 explanation as to, you know, hearing the other  
2 explanation about being a provider measure,  
3 and this one is more of a patient measure, if  
4 you will, looking at adherence long term, 180  
5 days long term.

6 Sorry, I put a lot in there. So  
7 the first part was just a statement about  
8 opening up to exclusion. The second is we've  
9 heard about some other medication measures.  
10 This one truly measures adherence, 180 days  
11 post-MI.

12 Why did you choose -- hearing the  
13 comments about the other measure being more of  
14 a physician, we want to make sure the  
15 physicians are doing the right job, versus  
16 patients doing the right job. What was the  
17 decision that went into that in designing this  
18 measure?

19 MS. TIRODKAR: Unfortunately, I  
20 cannot answer that question, because I was not  
21 --this was developed before I started working  
22 in NCQA. But I can get back to you on the

1 rationale for the 180 days definitely. But  
2 right now --

3 DR. RASMUSSEN: But it's not so  
4 much the 180 days. I think that's a  
5 reasonable surrogate for adherence. So maybe  
6 I'd reformat my question a little bit. Has  
7 this -- this measure's been public for a few  
8 years now. Have people been able to abstract  
9 the medication data successfully across a wide  
10 range of health care organizations?

11 MS. TIRODKAR: Yes, they have, and  
12 we have this measure both at the health plan  
13 level as well as the physician level, and we  
14 have not had, at least recently heard any  
15 issues with feasibility for extracting the  
16 prescription data.

17 DR. RUSSO: Just a general  
18 question. So the other side of having all the  
19 specific exclusions listed are that they may  
20 have been a transient type of thing. So if  
21 we're say transient second degree block with  
22 an inferior infarct or something like that,

1 but you want to put them on a beta blocker.

2 So if you're listed as an  
3 exclusion and you're on a beta blocker, we  
4 still count that as not an exclusion? Just a  
5 logistically, how is that counted? So you  
6 might want -- or even asthma. It may be mild  
7 asthma or a history of asthma.

8 So are we excluding that patient  
9 totally, or do we still include them if  
10 they're on the beta blocker? So do we -- are  
11 we overly-excluding patients that shouldn't be  
12 excluded is the question.

13 DR. KOTTKE: Yes. I don't know  
14 the answer to your specific question, but it  
15 came up in one of the measures that I'm going  
16 to talk about, which is aspirin use, and in  
17 that case, they counted the patient in both  
18 the numerator and denominator, if they were  
19 receiving it, even if they met criteria for  
20 exclusion.

21 They felt that there were too many  
22 people being excluded. So I think that's sort

1 of -- that's how they chose to do it in the  
2 aspirin measure, which seems like a very  
3 reasonable approach to me.

4 DR. RUSSO: You wouldn't want to  
5 exclude them --

6 DR. KOTTKE: Give them credit  
7 where you can, but give them -- let them off  
8 the hook as well.

9 DR. RASMUSSEN: I don't know that  
10 this would necessarily fall into the  
11 harmonization discussion, because we're  
12 looking at different medications.

13 But the discussion around strict  
14 exclusion criteria or more open exclusion  
15 criteria. I think arguments can be made on  
16 both sides, and I wonder if we would benefit  
17 from taking a stance either way.

18 If we're going to have strict  
19 exclusion criteria for one measure, should we  
20 do it for all, or if we're going to keep them  
21 more open, should we do it for all as well?

22 DR. RUSSO: It just seems to me if

1 you're going to -- that we would want to say  
2 excluded because of asthma. And then but if  
3 you have, if you exclude all these patients  
4 just by the code. So that whoever's going  
5 through the charts would be excluding all  
6 those patients that shouldn't be excluded  
7 perhaps.

8 CO-CHAIR GEORGE: I have one  
9 comment for the developers in the measure  
10 description. It says this applies to ages 35  
11 and older, and your denominator says it  
12 applies to age 18 and older. Can you clarify  
13 that?

14 MS. TIRODKAR: Yes. That is a  
15 mistake. It should be 18 and older.

16 DR. AYALA: Ready to vote?

17 DR. KING: I have a question. Is  
18 there any thought to, on this one, specific  
19 beta blockers, like we said before, because  
20 there are beta blockers that are less specific  
21 for the lungs, and one of the exclusions here  
22 is asthma and COPD.

1                   There are, of course, different  
2 beta blockers affect the lungs to a different  
3 degree. Did the developers consider being  
4 more specific about lung-sparing beta  
5 blockers, or was that not an issue?

6                   MS. TIRODKAR: Again, I don't know  
7 the exact answer to that question, but that's  
8 definitely something I can bring back as an  
9 issue, to perhaps deal with the issue of the  
10 exclusion for asthma.

11                  CO-CHAIR GIBBONS: Okay. I think  
12 we want to go ahead and vote on Scientific  
13 Acceptability.

14                  DR. KOTTKE: Ray, while people are  
15 voting, in a fairly large cohort, the addition  
16 or subtraction of one over one to a fraction  
17 would be decimal-best, and so I don't think  
18 that it's a particularly bothersome question.

19                  CO-CHAIR GIBBONS: That's a very  
20 good point. Okay. The vote is 8 completely,  
21 11 partially, 2 minimally. Do we still have  
22 anybody on the phone?

1 DR. DROZDA: Yes, but not with  
2 regard to this measure.

3 CO-CHAIR GIBBONS: That's fine.  
4 I'm just making sure I'm not sort of speaking  
5 into the wilderness with my recording of the  
6 votes.

7 DR. AYALA: Okay, so now  
8 Usability. It's in use. It's a HEDIS  
9 measure, and our developer said that they're  
10 not having any issues with the reporting on  
11 that.

12 CO-CHAIR GIBBONS: Any comments or  
13 questions about the Usability?

14 (No response.)

15 CO-CHAIR GIBBONS: If not, let's  
16 go ahead and vote on this.

17 17 completely, 2 minimally and 1  
18 not at all. Let's move on now to Feasibility.

19 DR. AYALA: Okay. The data's  
20 generated as a byproduct of care processes  
21 during care delivery, and the data elements  
22 are all collected electronically, and they did

1 not list any difficulties with Feasibility.

2 DR. RASMUSSEN: I had a thought,  
3 and this falls into susceptibility to  
4 inaccuracies, regarding a patient who meets  
5 one of the exclusion criteria that is actually  
6 on the medication. Depending upon how the  
7 abstractor pulls the data, once you define  
8 your denominator, if the first pass is are  
9 these patients on medication, you should catch  
10 them.

11 Then in the hierarchy, if the last  
12 thing you do is exclusion, you should be able  
13 to count them in the numerator and not lose  
14 them in the measure.

15 CO-CHAIR GIBBONS: Mark.

16 DR. SANZ: I have a question about  
17 how one would gather this data if you don't  
18 have an electronic source for -- even if you  
19 do have an electronic medical record. So an  
20 MI patient goes home.

21 He's seen maybe, he or she at one  
22 month. They're doing okay. So maybe I see



1       them at three months, and then after that,  
2       it's eight months to a year and yearly  
3       thereafter. How do I get this 135 days out of  
4       180 day information?

5                   DR. RASMUSSEN: So in my  
6       experience, one of the ways that you can get  
7       that is if a patient is going to a pharmacy,  
8       and that claim is adjudicated through their  
9       insurance company, they will have a record of  
10      that refill.

11                   Not an inconsequential point  
12      though, even more so and Roger alluded to it,  
13      is an increasing number of organizations that  
14      are offering \$4 prescriptions.

15                   Those claims are not adjudicated.  
16      So they essentially never hit the electronic  
17      record, and those patients are increasingly  
18      being lost in measures like this, because  
19      there is truly no record of that prescription  
20      ever being filled. If it is adjudicated,  
21      however, that data would be able to be  
22      abstracted.

1 DR. SANZ: We need to look at the  
2 universe of patients outside of those who have  
3 insurance, which increasingly is larger and  
4 larger, given the environment. In my world,  
5 a third of the patients or higher don't have  
6 insurance. So let's not assume that as the  
7 source for data collection.

8 DR. SNOW: In Massachusetts, 98  
9 percent of the patients have insurance. Well,  
10 maybe it's time. It's interesting. The  
11 people who are offering \$4 prescriptions are  
12 large corporations that have those data.  
13 They're just not sharing them, and I think  
14 that it is worthwhile for somebody to say come  
15 on guys, 'fess up.

16 DR. KOTTKE: I have a question  
17 about feasibility for the doc who has paper  
18 and cardboard records. I mean I have a hard  
19 enough time in EPIC trying to figure out what,  
20 you know.

21 (Laughter.)

22 DR. KOTTKE: Yes. I mean, you

1 know, I still have practice in some places  
2 with those records, and I have really no idea  
3 what my patients are taking from the record.  
4 I'm sure that's true. My paper records I  
5 couldn't read anyway. But in the Medicaid  
6 world, Medicaid patients don't pay co-pays.

7           They don't pay \$4. They use the  
8 benefit, and the point that was being made as  
9 that where the pharmacies are involved, they  
10 do have real time documentation of the use of  
11 the prescription. So you can, fairly  
12 reliably, much of the time, get adherence data  
13 with some of the limitations that we've  
14 discussed.

15           DR. SNOW: So are doctor's offices  
16 that use paper records expected to call  
17 pharmacies and ask? Is that what the  
18 implication is?

19           DR. RASMUSSEN: Maybe the author  
20 could describe that. This is an NCQA measure,  
21 which is generally looking at health  
22 maintenance organizations. So patients who

1 have, have coverage. So it does self-select  
2 the population. But I guess I'm not certain  
3 how they, to your question, who chases down  
4 that data.

5 MS. TIRODKAR: Okay. Physician  
6 level, for the physician level specification,  
7 and it's sort of in the guidelines to the  
8 HEDIS volume, the requirement is to submit  
9 data on 30 consecutive patients. So you have  
10 to pull 30 charts, okay. It's not --

11 DR. KOTTKE: So I have a  
12 medication list in there, and that's either  
13 what I've prescribed, or it's what the nurse  
14 got from the patient when she did the  
15 medication reconciliation.

16 But I have really no idea what the  
17 bills were, and I think one thing that's  
18 important is HEDIS is for managed care  
19 organizations, right? And so -- or health  
20 plans, health plans.

21 And so the feasibility of this for  
22 a doctor with a cardboard record is

1       questionable.

2                   DR. BURSTIN:   Just one comment.  
3       Much of this is based on pharmacy claims data,  
4       I would assume.   So again, you're not -- it's  
5       fill rates, correct me if I'm wrong.   But it's  
6       based on supply fill rates.

7                   You wouldn't know that even in  
8       your paper record or your EPIC.   Right.   So  
9       that's why it's outside the purview of -- I  
10      think, correct me if I'm wrong.   This is  
11      really mainly based on pharmacy claims.

12                  DR. DROZDA:   This is Joe Drozda.  
13      Can I make a comment?   I'm bringing it back to  
14      something I said earlier about, you know,  
15      physician level adherence measures, in terms  
16      of patient adherence, are really something  
17      we're going to have to evolve to.

18                  You're just getting into what  
19      we're struggling with, and by "we," I mean in  
20      my own work here at Sisters of Mercy Health  
21      System.   We're trying to get our fill data  
22      from -- directly from the pharmacy back

1 through the same type that we prescribe  
2 through.

3 That is technically possible, but  
4 where a provider of the prescription services  
5 is saying they don't have a business model  
6 yet, which means they're trying to figure out  
7 how to make money out of the return  
8 information. All we're asking for is every  
9 time any prescription gets filled, that the  
10 attending or the prescribing physician get a  
11 ping back.

12 That can be done, and the reason  
13 I'm bringing it up is I would like to have  
14 other people on my side, as we start pushing  
15 to have this sort of information flow.

16 CO-CHAIR GIBBONS: Well, I think  
17 one of the practicalities that's been  
18 mentioned is the increasing use of the  
19 multiple available mass retailer quarterly  
20 programs for \$10 a generic prescription or  
21 thereabouts.

22 I know I see an increasing number

1 of patients who are availing themselves of  
2 that, when they realize that that's cheaper  
3 than their co-pay, under whatever insurance  
4 they have.

5 Those records, as mentioned, are  
6 not available. In principle they could be  
7 made available, but given the competitive  
8 nature of that retail world, I think our  
9 chances of seeing that any time soon are  
10 small. Yes. I think we want to vote on  
11 Feasibility.

12 Okay. 4 completely, 11 partially,  
13 5 minimally and 1 not at all. All right. Now  
14 to the critical question, does the measure  
15 meet all the NQF criteria for endorsement, yes  
16 or no.

17 Sorry, start again. Vote again,  
18 please.

19 (Laughter.)

20 CO-CHAIR GIBBONS: We have two  
21 very fast fingers here. That's very obvious.  
22 Very fast fingers. Okay. We're going to

1 start again.

2 (Laughter.)

3 This is sort of like an early exit  
4 poll in New Hampshire, in the presidential  
5 elections. Okay. 13 yes, 8 no. We will move  
6 on to 0065, which is Symptoms and Assessment  
7 in CAD, and this is Christine's.

8 Measure 0065

9 DR. STEARNS: Thank you. This  
10 measure would look at medical records to  
11 determine if the patient had been evaluated  
12 for their level of activity, and also for the  
13 presence or absence of angina symptoms and if  
14 that's in their medical record.

15 The developers indicated that the  
16 measure is important to reduce mortality, and  
17 also to reduce symptoms, and that it is a  
18 patient-centered measure. This had been put,  
19 I think, down to the bottom of the list,  
20 because unfortunately we don't have  
21 reliability or validity data submitted.

22 So I don't know if that has come



1 in, but I think as of, and someone can help me  
2 if there's anything that has been submitted.  
3 So I think that that makes our evaluation  
4 process a little bit more challenging.

5 DR. DROZDA: These data have been  
6 published on this, and you know, I think PCPI  
7 really got caught unawares on the reliability  
8 and validity data requirement. But there are  
9 published results from the Pinnacle on the  
10 fact that this was assessable in about 89  
11 percent of records. That's on 14,000  
12 patients.

13 DR. WINKLER: We received  
14 information from PCPI last night, and the  
15 testing information, similar to the ones  
16 earlier, describes the process, but provides  
17 no actual data on the reliability of the  
18 measurements, either at the data element level  
19 or at the level of the measure score.

20 The only data that was submitted  
21 is a single result, and for reliability  
22 testing, we are looking for something more

1 data-driven.

2 DR. DROZDA: And could you just  
3 expand on that? What would qualify as good  
4 reliability data, the feasibility or ability  
5 to collect the data, or the fact that it was  
6 independently adjudicated by another source  
7 and was collected accurately?

8 DR. STEARNS: Yes. In this case,  
9 we're talking about reliability and not  
10 feasibility data, and reliability at the  
11 measure score will depend on how the data is  
12 collected.

13 If it's an abstraction, this is  
14 your classic inter-rater reliability type  
15 situation. For other types of data  
16 abstraction, there are other ways of  
17 evaluating the reliability of that data, so  
18 that you know that the information you're  
19 getting is accurate.

20 There are also reliability  
21 assessments that can be done at the level of  
22 the measure score, such as signal to noise and

1 other similar techniques. So we're looking  
2 for something in those realms, to give us a  
3 sense that is the information you're  
4 collecting reliable.

5 DR. MAGID: Hey John? Just a  
6 question. So I guess people should know that  
7 you developed the SAQ, the Seattle Angina  
8 Questionnaire. So can you tell us what --so  
9 we often use the Seattle Angina Questionnaire  
10 in outcomes studies. But what is the evidence  
11 to support using it in the performance  
12 measure?

13 DR. DROZDA: So the domain that --  
14 this is, unlike everything else we've  
15 essentially talked about, which is either a  
16 process measure or a surrogate outcome  
17 measure, this is a directly relevant patient  
18 outcome measure in that this describes the  
19 health status, the symptoms, function and  
20 quality of life of patients.

21 It has been used in all of our, in  
22 207 general practitioner clinics in Australia,

1 to look at potential under-use of treatment in  
2 patients with coronary disease, by documenting  
3 extraordinary variability in the patients  
4 having weekly angina or greater. I know that  
5 appropriateness is something that this group  
6 at NQF is very interested in understanding.

7 In the application of the pool of  
8 patients with chronic coronary disease, it  
9 would really be an opportunity to look at the  
10 quality of symptom control of patients with a  
11 symptomatic disease, and an indicator of  
12 potential under-use.

13 There were clinics in Australia  
14 where none of the patients had weekly angina,  
15 and there were another ten percent -- about 20  
16 percent of clinics where over half the  
17 patients had weekly angina, and about ten  
18 percent where all the patients had weekly  
19 angina.

20 That would indicate a great  
21 variability in the control of patients'  
22 angina, and there was sort of a remarkable

1 sense by the doctors that the patients were  
2 optimally managed. So it is a direct patient  
3 assessment of the quality of their symptomatic  
4 control. I don't know if that's sort of what  
5 you're getting at, or you want to understand  
6 the reliability, reproducibility or the  
7 sensitivity of the instrument itself.

8 DR. MAGID: No. I think the  
9 qualities of the instrument are well-  
10 developed. But I think it's one thing to say  
11 that we're going to measure anginal symptoms  
12 and report that as an outcome, which is kind  
13 of what you were alluding to in your response.

14 But in fact that's not what this  
15 is at all. This is just saying that it's  
16 documented and done, and that there's nothing  
17 that says that it's acted or that it's really  
18 being truly used as an outcome. So --

19 DR. DROZDA: So we had that. Yes,  
20 it's a great point. So we had a second  
21 measure that looks at the control of angina.  
22 So the first step is, you know, is it even

1 reproducibly assessed. This emerged in the  
2 very first set of performance measures,  
3 because of the absence of documentation.

4 A lot of times what would be  
5 documented in the record was just stable  
6 coronary disease, or angina-stable. Another  
7 doctor picking up that chart would have no  
8 idea if they talked to the patient and they're  
9 having angina climbing a flight of stairs,  
10 whether that's a worsening or an exacerbation  
11 or not.

12 So the measure was first  
13 introduced as a means to make sure that there  
14 was explicit documentation of the system  
15 burden and the activity that precipitated  
16 those symptoms.

17 We are now getting more  
18 comfortable, and now in the next measure,  
19 you'll be discussing in a few minutes, looking  
20 at management, similar to the way we did with  
21 blood pressure, that it was, you know, either  
22 asymptomatic, which is the therapeutical, or

1 you know, there was a plan of action or at  
2 least two anti-angina medicines prescribed, to  
3 try and maximally control the angina.

4 So you know, the first step before  
5 you can look at it as an outcome is to make  
6 sure it's being reproducibly collected in each  
7 visit and each clinic where patients with  
8 coronary disease are treated.

9 DR. MASOUDI: And I would just add  
10 that actually the symptom management measure,  
11 which was submitted for approval, has actually  
12 been removed from the agenda because there is  
13 no testing data, and the reason there's no  
14 testing data is because symptom assessments  
15 are not routinely present in a lot of clinical  
16 documentation.

17 So this would certainly be the  
18 first step to getting towards a measure that  
19 would actually assess an action plan to  
20 address symptom status. Without this, it's  
21 hard to imagine how you could meaningfully  
22 test a measure that is really what we want to

1 get at, which is the optimal outcomes for  
2 patients.

3 DR. DROZDA: Yes. I didn't  
4 realize that was removed. That's unfortunate.

5 DR. SPERTUS: Yes. We really  
6 wanted these two measures to be used as paired  
7 measures for obvious reasons, and John's just  
8 gone through them. We're getting at the  
9 nubbin of what you do when you take care of a  
10 patient with coronary disease.

11 You're looking number one, to  
12 prevent mortality and extend life. But number  
13 two, and maybe it should be number one, you're  
14 looking at optimizing management of their  
15 anginal symptoms.

16 So actually number three, the  
17 symptom assessment and level of activity  
18 assessment, is indeed a very patient-centered  
19 outcome measure. Again, I find it frustrating  
20 not to be able to use it and the measure on  
21 management, because this is really getting to  
22 what patients are looking for.



1 DR. WINKLER: Just I'll clarify  
2 what has transpired vis-a-vis these measures.  
3 These two measures on symptom management,  
4 assessment and management, as well as the new  
5 blood pressure control measures, on their  
6 initial submissions, I think most of you have  
7 read that they checked the box saying the  
8 measures haven't been tested.

9 We questioned that, because that  
10 just is not one of the conditions we're  
11 accepting in this evaluation process. So we  
12 went back to PCPI and said really, we got  
13 nothing?

14 So they basically told us that,  
15 you know, for the blood pressure control and  
16 the symptom assessment, they had some, you  
17 know, some information, which is what we saw  
18 come in very late last night.

19 But for the management, they out  
20 and out said there's nothing. So that was the  
21 communication that transpired, to put us in  
22 the position we are in terms of evaluating

1 those measures.

2 DR. DROZDA: And it does create a  
3 leap of faith in this group, but you know, we  
4 have documented in the past, when we had a  
5 hypertension measure, our plan for control,  
6 the ability to capture that in one of the very  
7 early PCPI initiatives.

8 I think the cardio-hit project  
9 demonstrated that, and now you're taking the  
10 extrapolation that you will take the results  
11 from the symptom assessment and the physical  
12 activity assessment, and then be able to also  
13 marry to it the capacity to collect, that  
14 they're either on two anti-anginal meds or  
15 that they're --

16 You know, you're taking those  
17 results and then interpreting them and  
18 collecting the other additional data. While  
19 we haven't tested that, there's a certain  
20 cycle here where if NQF were to approve it, it  
21 would create much more support for collecting  
22 and generating that data, and you've gotten

1 rid of that sort of provisional acceptance, so  
2 that we could have that.

3 But you know, and I guess we've  
4 now removed that measure. But the hope was  
5 that you would find these to be very patient-  
6 centered oriented measures that resonated with  
7 your goals, to look at meaningful outcomes and  
8 to lay the foundations for looking at  
9 appropriateness and efficiency, and that you  
10 would take on, you know, faith that we'd be  
11 able to collect data and that we've collected  
12 in other performance measures in other  
13 settings.

14 Then with that, we would be able  
15 to generate more data as this moves forward.  
16 We've just proposed these measures; they were  
17 just approved, and we just haven't had the  
18 time to generate all of that data for you.

19 DR. RUSSO: Just a quick question.  
20 Is it possible to create a composite measure  
21 of the two, if part of it's been tested and  
22 part hasn't? Would that be a way that -- is

1       there any history for doing something like  
2       that?

3                   DR. WINKLER:   Well as yet, we  
4       haven't received any appropriate really  
5       testing data about either measure.   So that's  
6       still an open question, in terms of the  
7       reliability of even the measure that's being  
8       discussed right now.

9                   DR. AYALA:   I'm sorry, did I miss  
10      it?  Is there a gap?  Did we say that there is  
11      an identified gap in this, that physicians  
12      taking care of patients with coronary artery  
13      disease are not asking questions about  
14      symptoms?

15                  DR. MASOUDI:  Well, they're  
16      certainly not documenting it.  I mean this is  
17      -- talk about a place where there's an  
18      enormous gap.  Again, one of the reasons why  
19      it's been so difficult to try and test a  
20      measure looking at say, symptom relief, be  
21      that in heart failure or be that in coronary  
22      disease, it's so sparsely documented that it's

1       difficult to even test that.

2                       So whether or not physicians are  
3 asking about it is hard to say. I think some  
4 of them are, and they're saying, "well how are  
5 you? I'm well," to "when did you get angina"  
6 and putting down a CCS class or at least  
7 thinking about it, to a more sophisticated  
8 approach, like using a more detailed  
9 instrument.

10                      But in terms of documentation,  
11 it's not known or my suspicion is there's a  
12 huge gap just in terms of really asking  
13 patients in any sort of meaningful way how  
14 they're doing. That's -- you know, if you  
15 take the documentation as any guide to that,  
16 it would suggest that there's an enormous gap  
17 here.

18                      DR. SMITH: You have to look -- I  
19 mean you may want to -- I think there are  
20 physicians, Fred, that when they see the  
21 patient with coronary disease, ask if they've  
22 had angina, that's included in the dictated

1 report, electronic medical record. They then  
2 ask what, how much physical activity do you  
3 get? Do you get it daily, do you get a half  
4 an hour every day a week?

5 So there are people that are  
6 interested in this, and it may vary, depending  
7 upon where it's a primary care visit, where  
8 the physician has multiple issues on the  
9 table, and doesn't pursue each one of the  
10 diagnoses.

11 But it is important, and so I  
12 suppose anything that would enhance that  
13 activity among physicians and make it closer  
14 to 100 percent would be a good thing.

15 CO-CHAIR GEORGE: Have there been  
16 other efforts, in terms of physician  
17 education, prior to going straight to a  
18 measure?

19 DR. SMITH: Are there other  
20 efforts?

21 DR. MASOUDI: I don't know, and I  
22 don't know that that's a standard we would

1 hold any other measure to as well. I mean I  
2 think the -- I mean historically, that hasn't  
3 been the approach that has been used, in terms  
4 of determining whether or not a measure is  
5 reasonable.

6 You know, you demonstrate a gap in  
7 care. This is something that's meaningful to  
8 patients. It satisfies all these other  
9 criteria. But again, I'm not off the top of  
10 my head aware of specific interventions to try  
11 and improve this particular aspect of care.  
12 I don't know if anyone else is aware of them  
13 out there, but --

14 DR. DROZDA: I think it's a, you  
15 know, I mean it's an enormous gap. We've done  
16 a lot of research in this area. I mean, you  
17 know, many of the people on the panel are  
18 cardiologists. Go pull ten random charts and  
19 see how well it's documented. I mean it's not  
20 even documented at the time of angioplasty in  
21 over half the cases.

22 So you know, I just -- there's a

1       tension here between having exhaustive data on  
2       something that has just not been measured, and  
3       the desire of this organization and the entire  
4       U.S. health care system to try and start  
5       getting to patient-centered outcomes that are  
6       meaningful to patients and to society.

7               And, you know, the symptoms is the  
8       number one goal that most of our interventions  
9       are directed for in the management of stable  
10       ischemic heart disease.

11               DR. SPERTUS:   So, this is Joe.  
12       We're going to ultimately have to work our way  
13       to the point where we can say, in a risk-  
14       adjusted way, what percent of our patients  
15       have optimal control of their symptoms.  We're  
16       not going to be able to get there unless we're  
17       actually measuring it.

18               In other words, that we're  
19       measuring that we're asking, and we're  
20       measuring that we're looking at not only  
21       symptoms but the level of activity, so that we  
22       can come up with that ultimate outcome measure



1       that I'm sure everyone's looking for. I don't  
2       know how you get there without this.

3                       CO-CHAIR GIBBONS: Helen.

4                       DR. BURSTIN: Hi, it's Helen  
5       Burstin. I just want to point out again, it's  
6       really just been an evolution over the last  
7       couple of years that's gotten to the point  
8       where very clearly the appetite for untested  
9       measures has really reduced significantly.

10                      There's a lot of concern about  
11       untested measures being out there. The Board  
12       of Directors has given us clear direction to  
13       move towards tested measures, unless there are  
14       three criteria. Unless there's an obvious gap  
15       in the portfolio, or there's a legislative  
16       mandate for that measure, or the measure is  
17       not complex. All those are "ands."

18                      So this one doesn't really qualify  
19       in a way. But I guess the question I would  
20       have for John and Joe is on the submission  
21       form, you talk about the ACCF Registry  
22       Pinnacle having data from 47 practices. Is

1       there no way to use the data already in hand,  
2       collected electronically, to test these  
3       measures?

4                   DR. DROZDA: Well, we do know that  
5       the symptom activity was recorded in those  
6       practices about 89 percent of the time. What  
7       those results are, which is the symptom  
8       management measure, are not known, and the  
9       sort of re-abstraction or the interrelated  
10      reliability, you know, was not available and  
11      not conducted as part of that.

12                   But we know that it was reported  
13      on the vast majority of patients. So it's  
14      feasible to collect, you know. There is a  
15      tremendous challenge. You know, there are  
16      lots of articles in the clinical trials arena  
17      that show that two different doctors assessing  
18      the same patients have much less agreement in  
19      the same patient over time using the Seattle  
20      Angina Questionnaire.

21                   So you know, the accuracy of the  
22      Canadian Cardiovascular Society

1 classification, I just think it's very, you  
2 know, that's a very tall bar for us, and  
3 you're not going to see 100 percent  
4 concordance. You're not going to know what's  
5 right.

6 So it's a very challenging bar for  
7 this kind of measure, to try and provide some  
8 of the reliability data you're demanding.

9 MS. ALLRED: I would like to add  
10 something, just from a patient point of view  
11 on quality. If I'm having symptoms, I don't  
12 really care whether my physician is actually  
13 asking me at a visit whether the symptoms are  
14 there or not. I care whether when I tell him  
15 that I'm having symptoms, he's doing something  
16 to help me alleviate it. That's quality in my  
17 book.

18 DR. MASOUDI: Absolutely.

19 DR. DROZDA: And that's a  
20 management measure.

21 DR. MASOUDI: I absolutely agree,  
22 and that was what the other measure was all

1 about, was the management of symptoms, this  
2 paired measure of symptom assessment and  
3 symptom management. I agree completely.

4 DR. DROZDA: And what this current  
5 measure is looking at is did the doctor then  
6 record it in a way that is sufficiently  
7 descriptive, that if a doctor had to fill in  
8 for him while he was on vacation, he would  
9 know how you were doing when you last saw him.

10 So this is the first step of  
11 ultimately the control measure that you're  
12 advocating for, that we too are advocating  
13 for.

14 DR. SANZ: It just seems like this  
15 should have some data. Before we mandate this  
16 nationwide to every doctor, we need some data  
17 that either the patient will be more  
18 satisfied, the outcomes will be better, there  
19 will be less angioplasty or more angioplasty  
20 or less MIs.

21 There has to be something to  
22 justify adding to the routine of a physician

1 and patient during the visit, before we  
2 mandate it to everybody nationwide. It's a  
3 good research theory.

4 DR. JEWELL: Well, but there's  
5 even a more fundamental issue here. We're  
6 talking about using a patient level measure.  
7 This is the world where physical therapy  
8 struggles in measure development.

9 We have lots of outcome measures  
10 that are well validated at the patient level,  
11 but have been never tested at the provider or  
12 organizational level, as a way to successfully  
13 distinguish quality among providers.

14 That's the data we're really  
15 looking for, not even whether it -- I mean  
16 yes, we want to know if it means something in  
17 real life too. But even more fundamentally,  
18 we have to understand whether any of the  
19 measures we consider are successful at  
20 distinguishing quality among the providers,  
21 because otherwise we have all those unintended  
22 consequences all over again.

1                   That's really the data that we're  
2                   looking for here I believe, not whether in  
3                   fact it will rock anybody's world, in terms of  
4                   patient management, although we hope it will  
5                   and we want to see that too. But first and  
6                   foremost, we need reliability and validity  
7                   data that we can distinguish quality at the  
8                   physician level with this measure, and we  
9                   don't have it.

10                   DR. DROZDA: Well first of all,  
11                   this is part and parcel of quality, right. I  
12                   mean, if you think that a good quality  
13                   physician is doing a better job controlling a  
14                   patient's symptoms, then this is a relevant  
15                   outcome. It's like saying is mortality a good  
16                   measure of quality? I don't know. I mean it  
17                   depends, you know. But I think that that's  
18                   one important point we're trying to make.

19                   There is a terrific report in the  
20                   Archives of Internal Medicine by John  
21                   Beltrame, B-E-L-T-R-A-M-E, that shows  
22                   extraordinary variability from, you know,

1 across a random sample of population-weighted  
2 GP clinics in Australia.

3 And you can look, you know, to  
4 that data to show there's enormous  
5 variability. Now that was generated with the  
6 Seattle Angina Questionnaire, not the Canadian  
7 Cardiovascular Study classification, which  
8 also qualifies in this measure. But I think  
9 that merely measuring this and documenting  
10 that variability will show marked differences  
11 in the ability of different providers to  
12 control their patients' angina.

13 Of those patients who, you know,  
14 if all of the patients at a practitioner's  
15 clinic are having weekly angina, how many of  
16 them are seeing a cardiologist or getting  
17 reevaluated for different treatment options?

18 You know, this is the foundation  
19 upon which great quality improvement could  
20 occur if the goal is to minimize patient  
21 symptoms and burden of coronary disease.

22 DR. PHILIPPIDES: Just one brief

1 note in your defense, John, wherever you are.  
2 I think that we, as physicians, do a terrible  
3 job of assessing activity. We give a lot of  
4 lip service about the obesity epidemic and the  
5 diabetes epidemic, and how 90 percent of the  
6 diabetes is all about lifestyle and moving.

7 Yet I'll bet you if I went into my  
8 own medical record, and it's electronic, I  
9 wouldn't have any idea as to who's active and  
10 who's not, and how active they are. You know,  
11 I don't think I even ask most of the time. So  
12 I think it is actually a big deficiency in the  
13 health care system.

14 I don't know if this is the best  
15 tool to get at it, but anything that gets at  
16 it is probably a good start. So I think we  
17 should look at it in that light as well.

18 CO-CHAIR GIBBONS: Okay. I think  
19 we have to call the question, and we're going  
20 to vote on whether the measure meets criteria  
21 for Importance, yes or no.

22 So the vote 8 yes, 13 no. So we



1 have finished our consideration of this  
2 measure.

3 DR. WINKLER: Right.

4 DR. DROZDA: Thirteen people said  
5 angina was not important, symptoms and  
6 activity level are not important? I just  
7 don't understand that.

8 DR. WINKLER: That's not the  
9 question. The question is according to our  
10 criteria, was there a demonstrated performance  
11 gap, evidence of effectiveness of the  
12 particular measure focus. Those were the key  
13 issues of our criteria under importance, not  
14 that angina is not important.

15 I mean I think everyone here in  
16 the room is agreeing that topic's important,  
17 that in practice people should be assessing  
18 these things. We're just talking about the  
19 measure, as specified in meeting our criteria.

20 CO-CHAIR GIBBONS: Okay. We're  
21 going to now move on to 0076, which is optimal  
22 vascular care, and hope that Anne from the

1 Minnesota Community Measurement Project has  
2 given us a lot of flexibility in the original  
3 one o'clock estimate that is now 2:40. Anne,  
4 are you by any chance out there?

5 Measure 0076

6 MS. SNOWDEN: Yes, I am.

7 CO-CHAIR GIBBONS: There's a lot  
8 of support here in the room, recognizing that  
9 you were very patient with us. Okay. So I'm  
10 the primary discussant on this one, and I just  
11 have to get my folder open to the right place.

12 So this measure, 0076, is the  
13 percentage of adult patients ages 18 to 75 who  
14 have ischemic vascular disease, and per the  
15 previous discussion, that's defined broadly in  
16 terms of coronary disease, renal artery  
17 disease, carotid disease, peripheral vascular  
18 disease, with optimally managed modifiable  
19 risk factors.

20 Those are LDL, blood pressure,  
21 tobacco-free status and daily aspirin use.  
22 It's an all or none performance measure. For

1 those who recall the IOM report on performance  
2 measures a while back, the IOM report  
3 advocated for composite measures, rather than  
4 individual measures, the strategy basically  
5 being if you're being taken care of and your  
6 LDL was good and you weren't smoking and you  
7 were on aspirin but your blood pressure was  
8 220 over 120, maybe you weren't really getting  
9 good care.

10 So this has been in existence in  
11 the state of Minnesota, and been publicly  
12 reported for a number of years. So as far as  
13 Importance goes, I think we'll all agree that  
14 taken care of blood pressure, cholesterol,  
15 smoking and aspirin use in patients with  
16 established coronary disease or vascular  
17 disease is important. So I didn't have any  
18 concerns whatsoever about Importance. Are  
19 there questions about Importance?

20 (No response.)

21 CO-CHAIR GIBBONS: If not, we'll  
22 proceed to the vote. Is this important to

1 measure?

2 DR. WINKLER: Somebody on the  
3 phone, we're getting a lot of your background  
4 noise. If you're not speaking, please put  
5 yourself on mute.

6 CO-CHAIR GIBBONS: Okay, we have  
7 20 yeses. So we're going to move on now to  
8 Scientific Acceptability. So the numerator is  
9 important to understand. Some of the  
10 provisions are pretty straightforward.  
11 Aspirin or contraindications to aspirin,  
12 tobacco-free, and an LDL of less than 100. I  
13 think those are pretty straightforward.

14 The one that's not straightforward  
15 is blood pressure. Now this measure is based  
16 on the state-wide organization responsible for  
17 guidelines in the state of Minnesota, ICSI,  
18 and I should declare my conflict, in that I  
19 have served on ICSI committees, and was part  
20 of the ICSI process pretty heavily for a  
21 number of years.

22 So ICSI is responsible for

1 reviewing the scientific evidence, and defines  
2 basically standards for the state of  
3 Minnesota, and has a long history of doing so.  
4 The history of the blood pressure measurement  
5 is complex.

6 At one point in time, as part of  
7 this measure, it was less than 140 over 90  
8 unless you had diabetes, in which case it was  
9 less than 130 over 80, reflecting JNC 7.  
10 Subsequently, ICSI changed that for  
11 consistency to be less than 130 over 80 in  
12 everyone.

13 That was largely on the basis of  
14 the epidemiologic evidence and the one paper  
15 from the Heart Association about coronary  
16 disease and blood pressure control. That was  
17 not patient data, but epidemiologic data.  
18 Then Accord came out. So now ICSI has  
19 revisited that, and now the standard is less  
20 than 140 over 90, if you have diabetes, and  
21 less than 130 over 80 for everyone else.

22 So it is the flip of JNC 7, and I

1 personally think that that's going to be an  
2 issue from the standpoint of the scientific  
3 acceptability of this measure. The rest of  
4 the specifications are very well done.

5 I would urge those of you who have  
6 raised a bunch of questions to look at them.  
7 They've been time-tested over a long time,  
8 help me, ten years? Anne on the phone can  
9 help me. Quite a while in the state of  
10 Minnesota. So the specifications, as far as  
11 ICD-9 codes, exclusions, particularly vis-a-  
12 vis the issues we discussed earlier on  
13 aspirin, they are very carefully detailed in  
14 here.

15 But I was concerned about the  
16 scientific acceptability of the blood pressure  
17 measurement. Anne, would you like to comment?

18 MS. SNOWDEN: Sure. I guess we  
19 ran this by our Measurement and Reporting  
20 Committee, and they believed that it was  
21 important for the measure to follow the  
22 guidelines, not for the measure to drive the

1 guidelines.

2           So we felt it was important to  
3 wait until the JNC 8 weighed in on a blood  
4 pressure control for all IVD patients, before  
5 changing it and assuming that we should move  
6 everybody to 140 over 90 -- less than 140 over  
7 90.

8           CO-CHAIR GIBBONS: So if I  
9 understand that correctly, you are going to  
10 change the specifications once JNC 8 is  
11 released?

12           MS. SNOWDEN: Correct.

13           CO-CHAIR GIBBONS: Sid, I know you  
14 can't share any inside information, but do we  
15 have a potential target for when that release  
16 will occur?

17           DR. SMITH: Yes. We're hoping  
18 that they'll be released in January of 2012,  
19 with a preliminary report at AHA in November.  
20 The other evidence that I mentioned from the  
21 European guidelines, if you look at randomized  
22 trials quoted by them for coronary disease,

1       there are eight.

2                   Only two of them showed a benefit  
3       for lowering blood pressure with a goal of  
4       130. One of them had actually reached 123,  
5       with a control at 133. The other reached 135.  
6       Four of the trials showed actually no benefit  
7       and two showed partial benefit.

8                   So the evidence for lowering blood  
9       pressure to less than 130 in coronary disease  
10      is questionable right now. So I think  
11      Minnesota should be complimented on their  
12      decision to stay with 140 over 90, and  
13      hopefully -- I mean, the JNC and ATP-4 are  
14      just challenging all of these targets.

15                   CO-CHAIR GIBBONS: It's important  
16      to us they haven't. It's 130 over 80, except  
17      if you have diabetes. That's when it's 140  
18      over 90.

19                   DR. SMITH: I thought I heard the  
20      report from Minnesota on the phone say that  
21      they decided to stay with 140 over 90.

22                   CO-CHAIR GIBBONS: They're still



1       there.  Anne, clarify that.  As I read this,  
2       you're staying with the existing Minnesota  
3       guideline, which is 130 over 80 unless you  
4       have diabetes?

5                   MS. SNOWDEN:  Correct.

6                   DR. SMITH:  I think that's  
7       potentially a problem, unless there's  
8       evidence, I mean, to support it.  That would  
9       be -- but it's an opportunity for Minnesota to  
10      actually split it up and look at whether  
11      patients at 130, less than 130 over 80  
12      actually do better than those held at 140 over  
13      90, and report back on this.

14                   But in the absence of evidence,  
15      one thing that's good is that they've got a  
16      cut point of 75.  So they're not applying this  
17      to really older patients.  I think that's  
18      good.  But I would have concern about holding  
19      folks' feet to the fire.

20                   You know, to get less than 130 as  
21      opposed to 140 may mean additional medicine  
22      with more side effects.  It may mean higher

1 cost. So I think there's some considerations  
2 about --

3 CO-CHAIR GIBBONS: So NQF staff,  
4 we need some guidance here. The measure  
5 developer is expressing a willingness to  
6 change to JNC-8 when available, but that won't  
7 likely be before January 2012. At this point,  
8 we should look at the measure as submitted.  
9 Is this correct?

10 DR. BURSTIN: Yes. Look at the  
11 measure as submitted, and look at the current  
12 evidence and guidelines, I'm afraid.

13 DR. SMITH: But I think the  
14 current AHA guidelines don't recommend 130  
15 either. We don't have -- I think it's --

16 CO-CHAIR GIBBONS: We have one  
17 paper that I have to admit is a bit of an  
18 embarrassment, because it actually came  
19 through the AHA system while I was a member of  
20 the leadership group, and I couldn't read the  
21 thousands of pages coming through my email at  
22 that point in time, so I missed it.

1                   That paper was on coronary  
2                   disease, and actually favored a goal of less  
3                   than 130 over 80.

4                   DR. SMITH: But it was a  
5                   scientific statement, and it did not make it  
6                   in -- the guideline committees did not act on  
7                   that.

8                   DR. KOTTKE: So Sid, what's the  
9                   current position of AHA on blood pressure  
10                  targeted?

11                  DR. SMITH: 140, as stated most  
12                  recently today in the women's guidelines.  
13                  They were just released.

14                  CO-CHAIR GIBBONS: 140 over 90.  
15                  Okay. So with that discussion, Karen, did you  
16                  want to comment?

17                  MS. PACE: Yes. I'm just saying  
18                  all of this, it sounds like, is a lot of  
19                  concern about the evidence of the target  
20                  that's specified, and if that's a concern, we  
21                  probably need to go back and vote on  
22                  Importance, which is where we talk about the

1 clinical evidence that supports a measure.

2 CO-CHAIR GIBBONS: I would  
3 respectfully suggest that we move forward,  
4 because if we move forward and this is the  
5 only issue, the measure developer then has an  
6 opportunity to change. Whereas if we  
7 downgrade it on the basis of Importance, it's  
8 going to be much more difficult. So that's  
9 why I put it this way.

10 So this is under Scientific  
11 Acceptability. Any other questions before we  
12 vote?

13 (No response.)

14 CO-CHAIR GIBBONS: Please vote.

15 So 1 completely, 13 partially, 5  
16 minimally and 2 not at all. So now we're  
17 going to move on to Feasibility.

18 PARTICIPANT: Usability.

19 CO-CHAIR GIBBONS: I'm sorry.  
20 Made the error again. It's a clear indication  
21 that we need a break, when the Chair starts to  
22 get those out of order again.

1           So the measure is clearly in use.  
2           It's in use in the state of Minnesota,  
3           reported by a large number of practices, and  
4           a large number of patients. There's data in  
5           the submission that goes over, you know, vast  
6           numbers; 2010, 96,000 patients, that kind of  
7           thing.

8           So there's plenty of data on use.  
9           But it's important to point out that that use  
10          reflects a commitment that's occurred  
11          gradually over time.

12          As Anne stated earlier, in the  
13          introduction and her comments, this started  
14          out as administrative data and then it evolved  
15          to be clinical data, and I think the groups  
16          who have undertaken this have generally done  
17          a very good job, and there's a large number,  
18          large penetration in the state.

19          I think there is a concern, from  
20          my standpoint, from the standpoint of that  
21          use, will others be as adept at doing it?  
22          Obviously, there's issues of harmonization

1 vis-a-vis some of the standards that are set  
2 in here, some of the definitions, for example,  
3 for aspirin, which I've alluded to, and the  
4 contraindications to aspirin, that overlap  
5 heavily with some of our other measures.  
6 Likewise, some of the issues regarding LDL.

7 But certainly in the state of  
8 Minnesota, this is alive and well and very  
9 much usable. Yes?

10 DR. MAGID: So we were just  
11 talking about the fact that we generally like  
12 this, because it's saying these are all things  
13 that need to be addressed for the same group  
14 of patients. So that's good. So if we like -  
15 - and, as George pointed out, there's lots of  
16 room for improvement, because not that many  
17 people are doing everything.

18 So all those things are really  
19 good. So if we have just -- if we're picking  
20 at this one issue, like you know, maybe the  
21 blood pressure target, how do you -- we may  
22 not say that we think we want to endorse this,

1 but we want to give feedback that we like this  
2 a lot, and if you just change one or two  
3 things, we would really like it a lot. How do  
4 we do that? What's the -- Karen, what's the  
5 way to give that message?

6 MS. PACE: Okay. A couple of  
7 things. Number one, you've given the message  
8 by stating so. But we can make it be even a  
9 little bit more. If indeed you don't feel you  
10 can support the measure as is and you would  
11 vote against it under its current state, you  
12 could potentially offer the condition that if  
13 the, you know, blood pressure target value was  
14 changed to X, then you would support the  
15 measure.

16 That sends a very powerful  
17 message, then puts it in the developer's hand  
18 to either act, respond or not, and they can  
19 tell you what they think and you've made it  
20 real clear what you will accept and what you  
21 won't.

22 CO-CHAIR GIBBONS: Yes.

1 DR. RUSSO: One other comment. I  
2 think this is one of the measures that are  
3 probably to have some. They do talk about  
4 risk adjustment, but I could see if this has  
5 been tested in a certain area, that really I  
6 could think of certain areas that may be very  
7 difficult to achieve all of those goals in  
8 certain patient groups or socioeconomic  
9 status.

10 They do comment about that. But I  
11 think this might be an important one to look  
12 at risk adjustment down the line.

13 CO-CHAIR GIBBONS: Well, there is  
14 data in the submission on risk adjustment,  
15 because that has been a concern in the state,  
16 and the bottom line is that the risk  
17 adjustment model, after it was carefully  
18 established and applied, created fairly modest  
19 changes in the data.

20 So they do provide the risk-  
21 adjusted data to the physicians. I think I  
22 have that right, but the publicly reported



1 data is unadjusted. Is that right, Anne?

2 MS. SNOWDEN: That's correct.

3 CO-CHAIR GIBBONS: Now by the way,  
4 Minnesota is not as lily white as everybody  
5 thinks. I know it was popular during the  
6 health care reform debate for that frequently  
7 to be stated.

8 I would like to point out that the  
9 latest census data is not out. But as of the  
10 previous census, in terms of percent Caucasian  
11 population, Minnesota did not rank in the top  
12 quintile of the country. It was actually  
13 number 13, and it was more diverse than  
14 Kentucky, which most people don't realize. We  
15 are becoming more diverse. So I'm quite happy  
16 in telling you we'll be lower than 13 on that  
17 ranking.

18 And contrary to what people on the  
19 Hill said, we do have poor people, and Tom can  
20 attest to that, as well, being from the Twin  
21 Cities area.

22 DR. SMITH: I like this measure,

1       though.  You know, I think health care systems  
2       that achieve this type of control and  
3       prevention should be recognized.  So my only  
4       concern is just with the discriminatory  
5       factors, the goals.

6                   MS. PITZEN:  This is Collette from  
7       Minnesota Community Measurement.  May I add a  
8       comment?

9                   CO-CHAIR GIBBONS:  Certainly.

10                   MS. PITZEN:  I just wanted to  
11       reassure the group.  We went through something  
12       similar with our diabetes composite.  When  
13       that measure was being presented at NQF, the  
14       Accord study on blood pressure came out two  
15       days earlier.  We did work through our  
16       processes.  The ICSI guideline were changed,  
17       and we turned that around really rapidly.

18                   So as soon as we had the support  
19       to do that, we went forward and did that.  So  
20       I would imagine this measure would be the  
21       same.

22                   DR. SMITH:  It would be

1 interesting to look at the data for those that  
2 did have control of less than 130 over 80, as  
3 opposed to those that were 140 under 90. I  
4 mean it's not randomized, but there might be  
5 some interesting findings here, whether the  
6 outcomes are different.

7 MS. SNOWDEN: Yes, we can do that.

8 DR. KOTTKE: Yes, it is. I think  
9 it -- this is Tom Kottke. Don't you report on  
10 your website both levels, 130 over 80 and 140  
11 over 90, optimal vascular care?

12 MS. SNOWDEN: No. Actually,  
13 optimal vascular care measure only includes  
14 the one blood pressure currently. But what  
15 you may be referring to is the HEDIS measure,  
16 which is controlling high blood pressure of  
17 less than 140 over 90 for people who are  
18 hypertensive.

19 DR. KOTTKE: Okay. Health  
20 Partners used the report.

21 MS. SNOWDEN: We do have the  
22 actual individual values of all the patients.

1 So we could do some analysis on 140 over 90  
2 versus 130 over 80.

3 CO-CHAIR GIBBONS: That's a small  
4 sample size at 90,000.

5 DR. SMITH: I think there's a  
6 paper there, yes.

7 CO-CHAIR GIBBONS: Okay. I think  
8 we've had enough discussion. Usability.

9 14 completely, 7 partially.  
10 Finally, Feasibility. All of this information  
11 is generated from the process of care, and  
12 simply needs to be extracted. It is amenable  
13 to EMRs. There are very few exclusions,  
14 because the contraindications have been rolled  
15 into the definitions, as I mentioned, for  
16 aspirin, for example, and as far as  
17 inaccuracies and errors and unintended  
18 consequences, there's quite a long description  
19 in here where basically the data's been  
20 carefully audited.

21 Groups have to have a 90 percent  
22 accuracy rate, and they get re-reviewed if

1 they haven't. So it's a well-established,  
2 well-oiled process, which I think has learned  
3 a lot over the course of time as to revisions  
4 in the definitions and the data abstraction.

5 I think it should be pointed out  
6 again that this has a long history. It  
7 started out as administrative data, then  
8 became clinical data, and it's not entirely  
9 clear to me from the standpoint of the  
10 national rollout, just how many groups would  
11 be able to take up that challenge right off  
12 the bat. So any other questions or comments  
13 about Feasibility?

14 (No response.)

15 CO-CHAIR GIBBONS: Okay. If not,  
16 let's vote.

17 18 completely, 3 partially. Okay.  
18 So, finally, we get to the issue does the  
19 measure meet all the NQF criteria, and I think  
20 in light of the previous discussion, it's with  
21 -- as submitted with the current blood  
22 pressure targets, which I think multiple

1 Committee members are already expressing  
2 support for the measure in general, but  
3 concern about that specific item, and the  
4 potential for let's say a rollout prior to JNC  
5 8, which would have a different target  
6 included in it.

7 So let's vote on this final  
8 question at this point.

9 DR. KOTTKE: Ray, while you're  
10 voting, in 2006, which is the last reported  
11 year with both, the higher blood pressure --  
12 the optimal CAD care measure with 140 over 90,  
13 with 73.5 percent of patients who are members  
14 of Health Partners. With the more stringent,  
15 it was 55 percent. So it's almost -- that's  
16 an 18 percent difference, 18 percentage points  
17 difference in people meeting the optimal.

18 CO-CHAIR GIBBONS: That's very  
19 helpful, Tom. So the measure is approved,  
20 with a vote of 13 to 7.

21 DR. WINKLER: I need to clarify,  
22 because you've just approved this measure with

1 a blood pressure target of 130 over 80. Yes,  
2 that's what you just did. So that's why I  
3 want to be sure we're all on the same page.

4 CO-CHAIR GIBBONS: Maybe we should  
5 vote again.

6 DR. RICH: I thought that we were  
7 approving it with that modification?

8 DR. WINKLER: That was the first  
9 vote.

10 CO-CHAIR GIBBONS: Oh, I'm sorry.  
11 Then the Chair takes full responsibility for  
12 that, if that wasn't clear. We have to vote  
13 on the measure as submitted, and as submitted  
14 is 130 over 80, unless you have diabetes, and  
15 then it's 140 over 90. We can send them a  
16 message, but they have to then come back into  
17 the system.

18 DR. RICH: Could we revote on  
19 that?

20 DR. WINKLER: We could do two  
21 votes.

22 CO-CHAIR GIBBONS: We could do two

1 votes. Well, that's a good idea. David,  
2 that's a good point, and we can do that. So  
3 let's vote first on the measure as submitted,  
4 yes or no.

5 So now, and there's been quite a  
6 shift. We have 5 yeses and 16 no's, based on  
7 the measure as submitted. So now, I think in  
8 light of David's question, I think we --  
9 right, we have the prerogative to do this. So  
10 David, what blood pressure would you like to  
11 see?

12 DR. MAGID: 140.

13 CO-CHAIR GIBBONS: 140 over 90,  
14 for everyone.

15 MS. PITZEN: Can I ask for  
16 clarification? Do you mean less than 140 over  
17 90?

18 CO-CHAIR GIBBONS: Sid or somebody  
19 else help us? How exactly is it worded in the  
20 current guidelines?

21 DR. SMITH: I'll check. I believe  
22 it's less than 140 over 90.



1 CO-CHAIR GIBBONS: Okay. So less  
2 than 140 over 90 for everyone, regardless of  
3 diabetes. Is that right, David?

4 DR. MAGID: Yes.

5 CO-CHAIR GIBBONS: Are there any  
6 comments or discussion about that  
7 modification?

8 (No response.)

9 CO-CHAIR GIBBONS: Now I would  
10 point out, just so we're clear, that existing  
11 AHA guidelines are in line with JNC 7, so that  
12 they still have a stricter target of less than  
13 130 over 80 for -- help me Sid, diabetics --

14 DR. SMITH: CKD.

15 CO-CHAIR GIBBONS: CKD.

16 DR. SMITH: The secondary  
17 prevention ones that you and I are working on  
18 are probably still being reviewed.

19 CO-CHAIR GIBBONS: I wasn't going  
20 to go there, Sid. So, okay. So with that  
21 modification, any questions or suggestions or  
22 comments? We're now going to revote, to send

1 this message to the measure developer. Can we  
2 put up the last question?

3 DR. WINKLER: Just revote it.

4 CO-CHAIR GIBBONS: Okay. So we're  
5 now going to revote with that change.

6 All right. So the vote with that  
7 modification, which obviously Minnesota  
8 Community Measurement would have to accept, is  
9 19 yeses and 1 no. So Anne, is there any  
10 other information we can provide you besides  
11 that feedback?

12 MS. SNOWDEN: It would just be  
13 helpful to get the actual evidence that you're  
14 referring to, to justify that change, and we  
15 would be happy to change the measure  
16 accordingly.

17 CO-CHAIR GIBBONS: Sure.

18 DR. SMITH: Yes. The best place  
19 to look would be the 2009 European  
20 Hypertension Update. If you send me an email  
21 or if you give me your email address, or maybe  
22 I can get it from staff --

1 CO-CHAIR GIBBONS: We'll get it to  
2 you from staff, Anne.

3 DR. SMITH: I've sent that to Ray  
4 today, so it's in there.

5 CO-CHAIR GIBBONS: All right. I  
6 think at this point the -- yes, anybody else  
7 on the phone?

8 MS. SNOWDEN: I was just saying  
9 thank you for that.

10 CO-CHAIR GIBBONS: Okay. At this  
11 point, we're going to take a break. Let's  
12 see. We'll need everybody back. We'll take  
13 a 15 minute break. So we'll need everybody  
14 back at 3:25.

15 (Whereupon, the above-entitled  
16 matter went off the record at 3:12 p.m., and  
17 resumed at 3:32 p.m.)

18 CO-CHAIR GIBBONS: I've been  
19 assured that the ventilation system is  
20 working. Okay. I want to assure people, I've  
21 been assured that the ventilation system is  
22 working. All I can tell you, it could be

1 worse.

2           There was a famous meeting of the  
3 AHA Program Committee in Dallas, Texas. The  
4 outside temperature was 108 degrees, I kid you  
5 not, and the air conditioning in the building  
6 failed.

7           So by the end of that meeting,  
8 there were people who were down to the bare  
9 essentials, in terms of clothes. So we are --  
10 we're not going to get there, I'm told.

11           We're going to be fine, but we've  
12 got to move now to Key Myocardial Infarction  
13 Measures in the Emergency Department, and I  
14 believe these are all CMS measures. So we're  
15 going to allow somebody, hopefully  
16 representing CMS, somewhere in the back there,  
17 to comment for three to five minutes, to open  
18 up this section.

19           DR. WINKLER: Probably not here,  
20 but on the phone. Is somebody from either CMS  
21 or Oklahoma on the phone to introduce your  
22 measures?

1 DR. BRATZLER: Yes. This is Dale  
2 Bratzler. I'm here.

3 DR. WINKLER: Hi Dale, thank you.  
4 Go right ahead.

5 CO-CHAIR GIBBONS: Thanks for  
6 being with us. We are, as you can see, are a  
7 little bit behind the planned two o'clock  
8 start on these, but we appreciate you  
9 introducing them.

10 DR. BRATZLER: Okay. So I'm going  
11 to give very, very brief introductory  
12 comments. I apologize, I'm driving. I have  
13 a flight to catch. So very briefly, the  
14 Emergency Department AMI measures that were  
15 initially developed, there are two different  
16 sets of measures.

17 One set are those measures that  
18 were initially developed for hospital  
19 inpatients. Those patients are identified by  
20 a principal diagnosis of acute myocardial  
21 infarction. The second group of measures were  
22 developed as part of a process related to

1 rural-sensitive measures.

2 In other words, there was an  
3 entire separate round of measure development  
4 that was looking at measures that primarily  
5 applied to hospitals that typically did not  
6 admit acute myocardial infarction patients, so  
7 they were considered rural-sensitive measures.

8 I'm sorry. Can you guys hear me okay?

9 CO-CHAIR GIBBONS: You are loud  
10 and clear.

11 DR. BRATZLER: Okay, very good.  
12 I'm getting a lot of feedback, so I can't  
13 tell. So you're going to see that there's  
14 some overlap of the measures. I talked  
15 briefly with NQF about this.

16 There for instance is a measure on  
17 a use of aspirin for acute myocardial  
18 infarctions, and there's a long-standing ACC-  
19 supported measure that Dr. Fred Masoudi can  
20 talk about, that focuses on patients who are  
21 admitted to the hospital with an acute MI.

22 But since most small hospitals

1 don't admit patients with acute MI, they  
2 transfer them. There is a similar measure  
3 that focuses on patients with acute MI or  
4 chest pains, who are then subsequently  
5 transferred to another facility for ongoing  
6 acute cardiac care.

7 So that just gives you a brief  
8 background on the development of the measures.  
9 The measures, there is some overlap. Dr.  
10 Masoudi really is the champion for the  
11 inpatient measures and can speak to those  
12 better than I.

13 The outpatient or the Emergency  
14 Department measures that focus on small  
15 hospitals were developed initially as a part  
16 of our program, looking at rural-sensitive  
17 measures, and then subsequently when the Tax  
18 Relief Act was passed and CMS had to develop  
19 performance metrics for hospital outpatient  
20 departments, it made sense to include some of  
21 these rural-sensitive measures to evaluate  
22 care that was given in hospital emergency

1 departments for patients who are then  
2 subsequently not admitted to the hospital but  
3 transferred somewhere else for care.

4 I'll be happy to answer questions  
5 about the individual measures as we go.

6 CO-CHAIR GIBBONS: Thank you very  
7 much. We're going to go --

8 MS. ALLRED: Can I just ask a  
9 question?

10 CO-CHAIR GIBBONS: Sure. Go  
11 ahead.

12 MS. ALLRED: So is it Dale, is  
13 that right? Dale, that's really interesting  
14 background, and it makes sense for some  
15 measures. I'm specifically talking about the  
16 issue of rural hospitals and transfers. So a  
17 measure that looked at how quickly you  
18 transfer a patient for, say, primary PCI, if  
19 you're a non-PCI capable hospital. That makes  
20 a lot of sense.

21 But some of these measures are  
22 really intended to apply to the broad spectrum



1 of Emergency Department patients, and not  
2 specifically this situation where you're  
3 transferring the patient. They're measures  
4 where you broaden the population beyond MI, to  
5 a broader class of patients.

6 So can you explain the thinking on  
7 that, because it's a little different from --  
8 the way it's going to be applied is a little  
9 different from what you presented?

10 DR. BRATZLER: Yes. So I think I  
11 can explain, and so we've had this  
12 conversation. I'm going to use the aspirin  
13 measure as the example. Since there are two  
14 separate aspirin measures, one that applies to  
15 inpatients who are admitted with acute  
16 myocardial infarction.

17 That measure has actually been in  
18 use by CMS for many, many years. It was  
19 initially developed literally years ago under  
20 the Cooperative Cardiovascular Project, and  
21 has been used for the inpatient population of  
22 acute MI patients ever since.

1           It's one of the measures that  
2 hospitals submit as a part of the hospital  
3 reporting system for the annual payment  
4 updates, and the cases are identified based on  
5 a principle discharge diagnosis of acute  
6 myocardial infarction. So we never see a case  
7 if they don't an acute MI discharge diagnosis.

8           The other measure on aspirin was  
9 developed, again, when we started the rural-  
10 sensitive project, and we were looking for  
11 performance metrics that would apply to  
12 hospitals, to rural hospitals that we knew  
13 were not routinely admitting MIs.

14           So rural hospitals never had  
15 patients eligible for the aspirin measure  
16 before, because it only looked at inpatients.  
17 So we were looking for measures that applied  
18 in the outpatient setting.

19           And then, as I mentioned, the Tax  
20 Relief Act required the identification of new  
21 measures that focused on hospital outpatient  
22 departments, and so those rural-sensitive

1 measures made a lot of sense for rural  
2 hospitals that were transferring.

3 So the denominator population  
4 that's identified for the aspirin measure in  
5 rural hospitals includes patients who come in  
6 with suspected chest pain or acute MI that's  
7 felt to be cardiac in origin. So chest pain  
8 that's cardiac in origin or acute MI.

9 So the denominator population is  
10 different, and we identify the cases through  
11 different mechanisms. Since there is no  
12 inpatient admission, we don't have any  
13 discharge diagnosis claims by which to  
14 identify the cases.

15 So I guess you could argue that  
16 that aspirin measure should be expanded in the  
17 inpatient setting, to look at a patient that  
18 came into a large hospital that does admit  
19 MIs. But that's how the measures were  
20 developed over time.

21 It's important because of  
22 legislation, different legislative

1 requirements for measures that focus on  
2 different settings of care, and in part based  
3 on a different track for development of the  
4 two different measures. I hope I've explained  
5 it.

6 DR. MAGID: Oh, we'll talk more  
7 about it later. Thanks.

8 CO-CHAIR GIBBONS: Okay. We're  
9 going to then start down the list of the  
10 Emergency Department measures. 289, Median to  
11 ECG, and this is Carol.

12 DR. WINKLER: Microphone.

13 CO-CHAIR GIBBONS: Mic.

14 Measure 0289

15 MS. ALLRED: Okay. Can you hear  
16 me now? The title of the measure is Median  
17 Time to ECG. The description is median time  
18 from emergency department arrival to ECG,  
19 performed in the ED prior to transfer, for  
20 acute myocardial infarction, AMI, or chest  
21 pain patients with probably cardiac chest  
22 pains.

1                   That seems to be fairly self-  
2                   explanatory. Of course, it's important. It's  
3                   a definite step in the process, and it's a  
4                   diagnostic tool and it impacts a large number  
5                   of people. There is a gap in performance that  
6                   is identified, and part of that has to do with  
7                   getting everybody to ECG. Part of it has to  
8                   do with the median time of performance. So  
9                   there is some room for improvement. With  
10                  that, I think the rest of it's pretty self-  
11                  explanatory, and I will be happy to ask  
12                  questions, answer questions.

13                   CO-CHAIR GIBBONS: Okay.  
14                  Questions about Importance?

15                   DR. KING: Excuse me. What did  
16                  you cite as the gap, where there was a need  
17                  for improvement?

18                   MS. ALLRED: Well, they cite the  
19                  gap in the people being seen and identified  
20                  early on. So the improvement in quality.

21                   But I also was looking at the  
22                  summary of the median time to ECG, and if you

1 look at the difference between the maximum and  
2 the median, the maximum is like 540 minutes  
3 and that's capped. So there's obviously a big  
4 disparity in performance in emergency  
5 departments until time of ECG.

6 DR. KING: I think it's a little  
7 misleading. I don't have that -- I meant to  
8 bring that sheet. I printed it out. But if  
9 you actually look at the difference by  
10 quartiles or quintiles, there isn't huge  
11 differences. They're on the order of one to  
12 two minutes between them, and --

13 MS. ALLRED: Actually, even with  
14 the quintiles, there's a difference for the  
15 most part between, you know, if you go to the  
16 middle of it, of course it's pretty close.  
17 But the rest of them, there is a disparity  
18 there, a gap in the time.

19 DR. WINKLER: What page are you  
20 on?

21 MS. ALLRED: I'm on page three.

22 DR. WINKLER: It's 1B.2.

1 DR. MAGID: There are going to be  
2 some measurement issues for which this becomes  
3 a real issue, but I don't think that's what we  
4 talk about at this point.

5 MS. ALLRED: Right.

6 CO-CHAIR GIBBONS: So the 25th  
7 percentile, for example, is 14 minutes and the  
8 75th percentile is five.

9 MS. ALLRED: Right.

10 PARTICIPANT: So that's a little  
11 more than three minutes.

12 CO-CHAIR GIBBONS: Yes. So I  
13 think there's opportunity for improvement.  
14 Other questions on this?

15 DR. WINKLER: Yes, I have one  
16 question. Really two questions to the group.  
17 This applies to patients who are going to be  
18 transferred. Is this the kind of measure that  
19 applies to anyone who comes into an emergency  
20 room with chest pain or whatever?

21 I mean I don't understand the  
22 limitation for this particular measure, as

1 perhaps a measure of performance in the  
2 emergency room around time. Then my second  
3 question is, is using the measure of median  
4 time useful and meaningful to people, compared  
5 to perhaps a percent of patients within a  
6 certain, you know, what the appropriate time  
7 frame is? Is that a readily understood kind  
8 of concept for understanding the performance  
9 of an emergency room?

10 CO-CHAIR GIBBONS: Dale, do you  
11 want to comment on how this one got going? It  
12 looks to me like maybe it had to do with the  
13 origin of this.

14 DR. BRATZLER: Yes, I will. So  
15 the conversation about median time versus  
16 proportion has been discussed many times  
17 before, and I think, you know, from a consumer  
18 perspective, proportion may be a better  
19 measure.

20 But I think where we came down on  
21 this particular measure was sooner was better  
22 than later. We weren't sure that there was an



1 exact number within which we should set a  
2 proportion limit, so we went with median  
3 measure as a measure of performance  
4 improvement.

5 You know, I can't argue the point  
6 that a measure could be applied to any  
7 emergency department setting. I certainly  
8 can't argue that.

9 I simply highlight that measure  
10 was developed as a part of a process of  
11 developing performance measures for real  
12 hospitals and then subsequently hospital  
13 outpatient departments, and you could make the  
14 case to expand the denominator population to  
15 patients who are subsequently admitted to the  
16 hospital also.

17 DR. MAGID: Well, I mean, for the  
18 purposes of NQF, this would not be limited to  
19 transfer patients alone. We're being asked to  
20 consider this for all comers to the emergency  
21 department.

22 DR. WINKLER: Well, one problem is

1       how it's specified.  If the specifications  
2       include those limits, then it is limited.

3                 DR. MAGID:  Is that how it's  
4       specified?

5                 DR. BRATZLER:  Yes, and that --

6                 MS. ALLRED:  It is specified.

7       Patients who were transferred.

8                 DR. BRATZLER:  Yes, that is  
9       correct.

10                DR. KOTTKE:  But isn't that  
11       because the patients who are transferred  
12       aren't admitted?

13                DR. SNOW:  Yes.  This is a measure  
14       that can be applied to people who are going to  
15       be transferred, as distinguished from all  
16       those other things for people who are going to  
17       go upstairs, and those measures are timed to  
18       initial insertion of catheter.

19                That kind of stuff applies to  
20       people who are staying, but they don't apply  
21       to rural, small hospitals, whose job is to get  
22       the people out of there and to do that, you

1 need an EKG. How quickly can you get the EKG?  
2 That's the concept here. But how quickly can  
3 you get the EKG and the big hospital is  
4 equally true. It's just that we're not  
5 looking at this that way.

6 DR. AYALA: But can I mention that  
7 in the hospital, they're also timed for how  
8 fast they're going to get to PCI or  
9 thrombolytics. So that EKG is sort of rolled  
10 up into the operationalization of the process,  
11 to get to that end point.

12 So for the inpatients, I think  
13 it's less important to separate this part of  
14 the process out, as opposed to the ones that  
15 are going to be transferred, because the  
16 hospitals that are transferring the patient  
17 aren't under the gun for the time to PCI time,  
18 for example.

19 DR. SNOW: Exactly. But the PCI  
20 patients will have had an EKG done. It's just  
21 we don't document it, because we're doing the  
22 other. But for the guys who are going

1 elsewhere, this is the measure.

2 DR. SMITH: I'm not sure I  
3 understand. It seems to me, first of all, we  
4 are looking at rural hospitals, is that right?

5 CO-CHAIR GIBBONS: Well, we're  
6 just looking at hospitals at transfer.

7 DR. SNOW: Transferring hospitals,  
8 not specifically rural.

9 DR. SMITH: Doing the EKG, whether  
10 they're going to be transferred or not, seems  
11 to me is important, and a timely EKG, and that  
12 reflects quality. In fact, the decision about  
13 transferring right now is dependent upon some  
14 EKG findings, our latest update on the PCI  
15 guidelines, which I chaired.

16 So criteria are diffuse, ST  
17 segment elevation from two studies and early  
18 congestive heart failure, they should go soon  
19 after fibrolysis. But is the idea that we're  
20 only looking at patients that we think -- part  
21 of knowing that a patient's going to need to  
22 be transferred is having the EKG.

1                   So I don't know how we limit the  
2                   population to only those that we're going to  
3                   transfer, before we know we're going to  
4                   transfer them.

5                   DR. KOPLAN: Well, if it's going  
6                   to be a measure, it will be patients who were  
7                   transferred, and then they'll go back and look  
8                   at it, right? It's not going to be  
9                   prospective. It will be after the fact.

10                  DR. RUSSO: I would agree too.  
11                  Why not expand it? I think it's fine this  
12                  way, but it might be useful for each center,  
13                  you know, the time to thrombolytic therapy, to  
14                  PCI, to be able to look back and say where  
15                  their time delay was. So why not expand it,  
16                  or is there a reason?

17                  DR. KOPLAN: And also maybe on a  
18                  small level, the patients who had a big delay  
19                  might be less likely to get transferred,  
20                  because they might not be candidates anymore  
21                  or something like that. So there might be a  
22                  selection bias issue.

1 MS. ALLRED: The guidelines that  
2 they quote in here state that the EKGs should  
3 be done within ten minutes and seen by a  
4 qualified emergency physician.

5 DR. SMITH: You're absolutely  
6 right, and the level of evidence for those  
7 guidelines is C, opinion. We don't have any  
8 randomized trials comparing 12 to 8 to 15 to  
9 20.

10 But you're absolutely right. The  
11 guidelines recommend doing the EKG within ten  
12 minutes, and in many -- and we actually are  
13 doing them in the field, when EMS arrives and  
14 getting them transmitted.

15 So I think being sure that our  
16 hospitals that are seeing patients with  
17 myocardial infarction do EKG quickly is  
18 something we ought to be very certain about.  
19 How we get from that down into a group that  
20 they suspect may need to be transferred,  
21 without looking at the EKG, I'm uncertain  
22 about.

1 DR. SNOW: No, their cart's before  
2 the horse.

3 DR. BRATZLER: Again, I just want  
4 to highlight, that the denominator population  
5 here is limited to patients who are  
6 transferred. So I hear the argument. I  
7 understand the discussion, but you could make  
8 the case to apply it to any patient that  
9 showed up in any ED with chest pains. But for  
10 the purposes of this group of measures,  
11 they're looking at patients who are  
12 transferred for cardiac therapy.

13 DR. SNOW: And looking  
14 retrospectively at how long it took to get  
15 that EKG.

16 DR. SMITH: What about the  
17 patients that weren't transferred and died in  
18 the hospital who didn't get an EKG in time and  
19 might have benefitted from being transferred?

20 DR. BRATZLER: Yes. That group is  
21 missed, clearly. I will tell you, without  
22 question, that when we first rolled out this

1       measure, there were a number of hospitals that  
2       still had to call somebody in to do an EKG.  
3       They actually did not have staff trained in  
4       the hospital to do an EKG.

5                 DR. RUSSO:   And how would you take  
6       -- you bring up we're doing EKGs in the field,  
7       so is that time zero to the ER?  Because they  
8       might not get it in the ER; they'll get it --  
9       do we count that EKG?

10                DR. SMITH:   It would be repeated  
11       right when they arrive.  They should again.  
12       But by that time --

13                DR. BRATZLER:  If it's done in the  
14       field --

15                DR. MAGID:   If it's a STEMI, you'd  
16       just go right to the cath lab.

17                DR. SMITH:   Well, we activate the  
18       lab, but then -- I guess about cath, that  
19       they're coming into Siler City or a hospital  
20       that doesn't have a cath lab, they alert us  
21       about transfer having that information.  So  
22       it's very helpful to get the EKG promptly.



1 DR. JEWELL: So if I could ask the  
2 measure developer, the data that you have  
3 about the gaps, where you have the  
4 percentiles, that was looking only at patients  
5 as defined in the denominator?

6 So the 41,000 eligible cases that  
7 you used, those were only patients who were  
8 transferred, or those were just the population  
9 of patients in the ED with chest pain? Can  
10 you hear me?

11 CO-CHAIR GIBBONS: Are you still  
12 there, Dale? I think we lost him.

13 DR. JEWELL: Well, so the reason I  
14 asked the question was that if in fact that  
15 data is not just patients who were  
16 transferred, then that's a further argument to  
17 expand the measure.

18 DR. MASOUDI: These data are based  
19 on the measure, as specified.

20 DR. JEWELL: Okay. That's what I  
21 wanted to know. Okay, thank you.

22 MS. JONES: This is Rebecca from

1 the Oklahoma Foundation for Medical Quality,  
2 and I would comment that it is based on the  
3 population of patients who are transferred.

4 DR. JEWELL: Thank you.

5 DR. MAGID: And that makes sense,  
6 in the sense that, I mean I've seen the Action  
7 data on time to ECG and it doesn't have this  
8 kind of distribution.

9 CO-CHAIR GIBBONS: I would just  
10 point out that for a hospital receiving  
11 STEMIs, although it's important obviously to  
12 do an ECG, the measure is rolled into time to  
13 thrombolysis or time to PCI.

14 So it's irrelevant. I mean what  
15 you want is the end product, and anybody  
16 looking at the end product is going to look at  
17 the components and figure out where the  
18 problems are.

19 So to have two measures out there,  
20 for example, and your time to ECG is great,  
21 but your time to PCI or time to thrombolysis  
22 is poor, well, that's doesn't make any sense,

1 because the measure that really matters is the  
2 time to reperfusion.

3 So I really don't know that we  
4 want to expand this to STEMI-receiving  
5 hospitals, because I really think it's  
6 irrelevant.

7 DR. MAGID: The other thing that's  
8 a little bit confusing, and it's a shame that  
9 Dale's not on the phone, but when he describes  
10 -- he says it's the patients who are being  
11 transferred.

12 Well, the patients who are being  
13 transferred are patients with STEMI. Yet the  
14 denominator is this much broader  
15 classifications with chest pains. So it  
16 doesn't make sense why it's not --

17 CO-CHAIR GIBBONS: At least in our  
18 region, it's not just patients with STEMI  
19 being transferred. I don't know. Others can  
20 comment, but it's a broader group of patients  
21 being transferred, where they get an initial  
22 ECG and say "Whoops, this looks like a problem

1 with their heart. Out of here."

2 DR. BRATZLER: Yes, this is Dale.  
3 I'm back on. I'm sorry. I'm in transit.  
4 Rebecca, I know you're on the call. I am  
5 correct, that this measure only applies to  
6 patients who are actually transferred?

7 MS. JONES: Right. Now the chest  
8 pain and the ECG measures will apply to any  
9 patient that is seen in the ED and discharged  
10 and transferred to another facility.

11 The only one that is track-  
12 specific or specifically for patients who are  
13 transferred for PCI is the timing measure for  
14 transfers for acute coronary syndrome, or  
15 acute coronary intervention.

16 DR. BRATZLER: So the point is is  
17 that if a patient came in with severe heart  
18 failure and chest pain and were transferred,  
19 they would be in this measure.

20 DR. SNOW: Chest pain patients  
21 with probable cardiac chest pains. So it  
22 could be from any potential cardiac source.

1 Congestive heart failure would count.

2 DR. MAGID: Dale, another  
3 question. Could someone else -- another  
4 question for you. Since I reviewed some  
5 measures that have this denominator of  
6 patients with probable cardiac chest pain, you  
7 know, they always refer back to Appendix A,  
8 Table 1.0, and I could never find that in any  
9 of the documents we had.

10 So you know, I think when you've  
11 got, you know, when you've got patients being  
12 admitted to the hospital for MI or for ACS or  
13 for angina, that all makes sense. But there's  
14 this broader class of codes of just chest  
15 pain, and you could have trauma and have a  
16 primary diagnosis of chest pain.

17 So I found it very hard to  
18 understand really what the validity of that  
19 denominator was, since we weren't really  
20 provided that data.

21 The only information that I did  
22 find was in this report that was sent from a

1 Health Services Advisory Group, and in that  
2 report, it said that for all the data measures  
3 that we're about to talk about, and all the  
4 data elements that were in it, it said the  
5 highest mismatched data element on an  
6 individual measure was probable cardiac chest  
7 pain.

8 So it was identified as the least  
9 valid of all of the things in this larger set.  
10 Can you speak to that?

11 DR. BRATZLER: Yes. So the  
12 appendix I think that you're referring to is  
13 just a list of possible ICD-9 codes that  
14 reflect chest pain codes. But we then have a  
15 data element, a chart of extracted data  
16 element, to see whether or not there are terms  
17 in the chart that would exclude the case.

18 So the example of trauma. If we  
19 find somebody where the physician documented  
20 trauma to the chest or chest wall pain, other  
21 things that suggest that it wasn't cardiac of  
22 origin, the hospital is expected to answer no

1 on that data element and exclude that case  
2 from this particular measure.

3 So it is a chart-abstracted  
4 measure, and you know, with all of our chart-  
5 abstracted measures, we have some degree of  
6 mismatch between the abstractors and secondary  
7 review, and that's why we continuously update  
8 the data dictionary, to try to address those  
9 issues.

10 But there is no ICD-9 code that is  
11 strict enough that we can rule out, you know,  
12 the non-cardiac chest pains. So we have the  
13 data element.

14 DR. MAGID: So that's very  
15 helpful. But this report is dated January  
16 2011, the one that says that the highest  
17 mismatched data element was probable cardiac  
18 chest pain.

19 DR. BRATZLER: Did it mention --

20 DR. MAGID: It was a mismatch 20  
21 percent of the time.

22 DR. BRATZLER: I honestly didn't

1 think it was mismatched that frequently, but  
2 again, we -- and in fact within the past few  
3 weeks, have made some additional updates to  
4 the data element, to try to address some of  
5 these discrepancies in chart review.

6 MS. JONES: Right, and this is  
7 Rebecca. I would point out that that report  
8 is one on initial validation of measures, and  
9 consequently, since then we've provided  
10 numerous educational conference calls to  
11 providers, and we've got our Q and A system  
12 that's up and running.

13 So we've definitely seen a  
14 significant decrease in the number of  
15 questions related to that measure. So we  
16 really expect the trends, as the newer monthly  
17 reports come out, trending down on that.

18 DR. MAGID: Okay. The report's  
19 dated last month.

20 MS. JONES: Right, and that was  
21 the first time that they had compiled the data  
22 for the entire measure set, and these measures



1 have been implemented for three years.

2 DR. PHILIPPIDES: Basic question.  
3 I'm assuming patients who die in the first  
4 emergency room, who are not transferred out,  
5 would not count in this measure? You could  
6 argue that that's a failure of therapy,  
7 especially if there's a delayed EKG. But that  
8 would actually not count against the initial  
9 hospital.

10 DR. BRATZLER: Well, I guess you  
11 could make that point, and you know, what  
12 we've done is identified a sample of patients  
13 that are transferred, and you know, that  
14 population of patients simply isn't in the  
15 denominator, because we'd have to figure out  
16 a way to identify all of the patients that  
17 might have been seen in a ED.

18 DR. MAGID: Can I ask a question  
19 just slightly out of order, but I think it's  
20 related. You know, when you think of  
21 something like the arrival time at the  
22 hospital, that's pretty standardized. There's

1 someone who always records it in a specific  
2 way. The same thing with the time when you  
3 leave the emergency department.

4 There's no one who ever records --  
5 or I shouldn't say no one ever, but typically  
6 we're relying on the time stamp of the ECG, as  
7 opposed to a time that's recorded by the  
8 technician who takes the ECG. Right. So yes.  
9 So we have four ECGs in my ED, and I actually  
10 went and looked at them.

11 I put them all next to each other,  
12 and two of the four actually read the same  
13 time, the other two were off by, one by a  
14 minute and the other by three minutes. So I'm  
15 just wondering what kind of standardization,  
16 and this is, you know, maybe it's a high  
17 volume center that has four ECG machines.

18 But the point is that obviously  
19 they weren't all reading the same time, and  
20 they couldn't possibly all be reading the  
21 correct time. So I'm just wondering what kind  
22 of standardization and validation that you've

1 done of that specific data element, since it's  
2 so key to this measure?

3 DR. BRATZLER: Rebecca, do you  
4 want to speak to the specifications about how  
5 the hospital has to abstract this data?

6 MS. JONES: Right, and that was  
7 one of the ones that also was a higher  
8 mismatch rate on the data element. But on  
9 that, we specifically provide instructions and  
10 guidance on scenarios, such as if they have  
11 multiple times for an ECG. We actually have  
12 them default to the time on the ECG strip,  
13 unless there's clear documentation that it was  
14 an error.

15 We also provide instructions on if  
16 there are multiple ECGs done, which one to  
17 take first. Likewise, we also include the  
18 timing as we accept pre-arrival ECG in the  
19 field.

20 That was something that we saw  
21 questions on, is that their times were off or  
22 that they knew that they were off, and once

1 again, we just provided guidance in the  
2 specifications on which time to select, and  
3 encouraged them to try to make that a routine  
4 part of their operations and their ED.

5 If they had four ECG machines, you  
6 know, put that in part of maybe a checklist of  
7 when they do their crash cart checks, to go by  
8 and make sure all the ECG machines are timed  
9 together.

10 DR. AYALA: You know, we worked on  
11 this at the institution where I'm from, and  
12 it's about synchronizing the clocks at every  
13 step of the way, from door to balloon, for  
14 example. We actually ended up getting atomic  
15 clocks, because you really cannot -- you  
16 cannot rely on what you're recommending here,  
17 to default to a particular machine time.

18 You really have to have the clock  
19 synchronized, and I didn't think of that in  
20 this situation. But that's really critical.

21 MS. ALLRED: You should be able to  
22 calibrate each of those machines and know that

1 they're fairly accurate. I would expect that  
2 that would be a requirement, that they were  
3 done frequently.

4 DR. AYALA: But it's not just the  
5 machine itself. It's how the machines are  
6 timed compared to the timing of the entrance  
7 of the patient into the ED. It's the  
8 synchronization of the clocks along the whole  
9 process.

10 MS. ALLRED: The other thing that  
11 jumped out at me when I was going through  
12 this, it talks about the time to ECG, but it  
13 does not mention in the measure the ECG time  
14 to when it's read. You know, it's going to  
15 have to be read by somebody for it to go into  
16 effect.

17 MS. JONES: Right, and I think the  
18 reason why we don't have that is it's a lot  
19 more difficult to capture the time of  
20 interpretation by a physician, and we, I  
21 think, had the presumption that at least if we  
22 were tracking the time to the test, and could

1 encourage facilities to get as close to that  
2 zero time as possible, the report was there,  
3 ready for someone to interpret it, and  
4 therefore use it in the diagnosis and plan of  
5 care and treatment for the transfer.

6 CO-CHAIR GIBBONS: So I would just  
7 point out in light of this discussion that  
8 Table 2, which I'm looking at in one of the  
9 reports we were sent, from Quarter 2 of 2009  
10 to Quarter 1 of 2010, said that the top-ranked  
11 mismatched data element was the documented  
12 date and time of the earliest ECG.

13 That was wrong 23.4 percent of the  
14 time, and the earliest documented time the  
15 patient arrived at the emergency department  
16 was number two, in terms of mismatched  
17 elements, and that was wrong 19 percent of the  
18 time.

19 MS. JONES: Right, and I think  
20 that part of the --

21 (Simultaneous speaking.)

22 CO-CHAIR GIBBONS: So if I

1 understand correctly, were you hoping that's  
2 better?

3 MS. JONES: -- new measures that  
4 have rolled out with, you know, new data  
5 elements. These hospitals have never been  
6 required before to track and to trace, and so  
7 getting them to consistently get their  
8 practitioners and providers to, you know,  
9 document this has been a challenge.

10 But I think once again that we've  
11 provided, you know, instructions on what's  
12 acceptable to meet the criteria, and you could  
13 see hospitals indicating the things that  
14 they're doing to try to change practices or  
15 change documentation to become more consistent  
16 in their practice.

17 DR. BRATZLER: This is Dale. I  
18 apologize, I'm going to go through airport  
19 security and then I'll call back in.

20 CO-CHAIR GIBBONS: All right,  
21 thank you Dale. We're all smiling, because  
22 we've all been there.

1 DR. BRATZLER: Yes.

2 DR. MAGID: I wonder if, you know,  
3 to summarize a couple of the issues that have  
4 come up. One is is that the evidences for  
5 time to reperfusion, not time to ECG, and that  
6 we've got major problems with many aspects of  
7 this measure, both the time of arrival, the  
8 time of ECG and the denominator of patients  
9 with probable cardiac chest pains. So it  
10 seems like there are a lot of problems with  
11 this measure.

12 DR. AYALA: I just want to add to  
13 that, and I think what we really want from  
14 this -- I think what they're trying to get at  
15 this measure is how fast does the patient get  
16 out of that ED? How fast is he transferred?  
17 So it's almost like they really want to check  
18 not time to EKG, but time to transfer, which  
19 is really getting closer to that intervention.

20 DR. SNOW: But in defense of the  
21 measure, that's not the goal of this measure.  
22 If you're talking about care, it's time to



1 reperfusion. That's not a question. But  
2 that's not what this is looking at, because  
3 the small hospital is not going to be doing  
4 the reperfusion and they don't control it.

5 This is a measure for small  
6 hospitals and how soon they can process that  
7 patient, and yes, it's really time to get him  
8 back in the other ambulance. But they're not  
9 measuring that. They're measuring something  
10 before that, and perhaps they can be  
11 criticized if you think from the care  
12 perspective.

13 But, gee, these are cardiac  
14 measurements, and this is the one that they  
15 can get, and it's one that yes, indeed, there  
16 are problems with the accuracy of the timing  
17 and all this and this.

18 But those are things that can be  
19 fixed, and they can make it a reliable measure  
20 of one point in the care spectrum. That's  
21 what the goal is here, I think, of the  
22 developers.

1 DR. AYALA: But I would argue with  
2 that, because like when you look at time to  
3 PCI, for example, time to EKG is really  
4 important. I mean you really can't make your  
5 90 minutes if you don't get that first EKG  
6 within ten minutes, or about that. You can  
7 make up for it later.

8 But the point there is that the  
9 outcome you're looking for is the  
10 intervention. In this same case, you will  
11 push these hospitals to get that EKG really  
12 quickly, if you tell them you have this many  
13 minutes to get the patient out of your ED.

14 It's the same thing. You're  
15 getting them closer to the intervention, and  
16 they will, by default, have to get that EKG  
17 done really quickly. But you want to make  
18 sure that you're going after the right end  
19 point.

20 DR. MAGID: And Roger, there is a  
21 measure. I'm sorry. There is a measure  
22 coming up, specifically looking at the time to

1 transfer. So to the extent that this is a  
2 process along the way to that --

3 DR. SNOW: You're saying it's  
4 redundant?

5 DR. MAGID: I think so, yes.

6 DR. SANZ: You know, I come from  
7 Montana. Much of this discussion here -- and  
8 maybe I'm the hick in this -- is irrelevant.  
9 I mean we are talking about critical access  
10 hospitals that have perhaps eight beds that  
11 are inpatient on a given day, and they fudge  
12 it because they have another eight that are at  
13 their nursing home.

14 So they move them back and forth  
15 in order to obtain the minimal or the maximum  
16 Medicare benefit. They have one EKG machine  
17 in the hospital. They have no emergency room  
18 physician. They have a PA most of the time  
19 that they contract with.

20 If they can get them out of there,  
21 it's all because of what the main hospital  
22 that is sending the transport can do based on

1 weather this time of the year. I mean, you  
2 don't have -- you're not understanding what  
3 this is aimed at. This is not the inner-city  
4 hospital that has the Mecca, and there's a lot  
5 of people around this room that come from  
6 Meccas, that are getting transports from 20  
7 minutes away.

8           These are three and four hours  
9 away, with major winter storms in between,  
10 where the patient may or may not frankly be  
11 better transferred. If they have a small  
12 inferoposterior MI, they may have a higher  
13 risk of dying on the road than coming to the  
14 hospital.

15           You've got to be careful. I think  
16 this is a great place to start. If you can  
17 get some of these hospitals to get an EKG  
18 machine that first of all has 12 leads, has a  
19 timer that prints out, because the EKGs I get  
20 don't all have timers.

21           I mean you are not talking about a  
22 group that I deal with, and let them start

1 with something simple. You cannot make them  
2 start talking about time to reperfusion when  
3 they're in a different age.

4           They don't have a lot of money,  
5 you know. They get Medicare plus, I don't  
6 know. Somebody around here probably knows.  
7 Medicare plus five percent, somewhere in that  
8 range. So they're living on a thread, and  
9 what they can do is not the same as what  
10 you're used to. That's all I'll say.

11           DR. AYALA: Thank you. I'm from  
12 Florida, so we don't have the snowstorms, and  
13 I appreciate your comments on that.

14           CO-CHAIR GIBBONS: Well, I do  
15 think it's worth pointing out, since Mark has  
16 spoken so eloquently on this point, that we  
17 tend to lose track of the fact that 25 percent  
18 of Americans live in areas that are "rural" as  
19 defined in various ways by access to a  
20 hospital that in fact does PCI.

21           There are papers on that, and it's  
22 a pretty astonishing percentage of the

1 population that we tend to forget about. So  
2 thank you, Mark, for your insights from rural  
3 America. We appreciate them. I think we're  
4 going to have to start taking some votes.  
5 We're going to start to take some votes.  
6 First, Importance.

7 17 to 4; yes 17, no 4 for those on  
8 the phone. Next, Scientific Acceptability.

9 MS. ALLRED: Okay. Scientific  
10 Acceptability, I think we've touched a lot of  
11 the different areas already. The one thing  
12 that I would like to go back to and point out  
13 is there's a lot of disparity information in  
14 this, and I know we haven't talked about  
15 disparities anyplace.

16 But I would love to see the  
17 numerator and denominator include some  
18 information about sex, gender, ethnicity,  
19 because it's all there, and it might explain  
20 some of the gaps in timing for some of it. So  
21 I thought that was an important issue that was  
22 just not addressed.

1           In terms of exclusions, I mean we  
2           already heard the exclusions. If you die, you  
3           probably don't get in the measure. So I would  
4           say we could vote on that, based on what we've  
5           been through.

6           DR. PHILIPPIDES: Not to beat the  
7           inclusion population to death, but I can  
8           understand the scientific data behind getting  
9           STEMIs, getting EKGs quickly there.

10           But the other group of possible or  
11           probable cardiac chest pain that are  
12           transferred out, is there data supporting that  
13           there's an urgency in getting those guys in  
14           EKG?

15           I guess I'm asking, why don't they  
16           just say that it's an acute coronary syndrome,  
17           and make that the sort of backdrop for getting  
18           a rapid-fire EKG?

19           CO-CHAIR GIBBONS: Dale or anybody  
20           else from CMS on the phone, do you want to  
21           answer that?

22           DR. PHILIPPIDES: I think that

1       there's some data in getting a rapid EKG.  But  
2       probable cardiac chest pain -- if somebody  
3       happens to decide needs to be transferred out,  
4       I'm not sure there's data supporting it.

5                 DR. BRATZLER:  So here's my  
6       pushback there.  I think when a patient hits  
7       the door of an emergency room with chest pain,  
8       and there's not an obvious non-cardiac cause,  
9       it makes sense to do an electrocardiogram.  So  
10      that's why we've never limited to what would  
11      be seen as the diagnosis after the evaluation.

12                What we're asking is if somebody  
13      when the patient hits the door, the patient  
14      was complaining of chest pain, and there are  
15      none of the exclusions noted with an EKG done  
16      and how quickly, that's what we look at.

17                DR. PHILIPPIDES:  So I agree with  
18      that, and I think that's a different measure.  
19      Now you're basically saying how fast when  
20      somebody comes in with the same -- if they  
21      have chest pain as their primary complaint,  
22      will they get an EKG?  Also a valid measure.



1 I think it's a slightly different thing than  
2 what I thought you were getting at here with  
3 this measure.

4 DR. BRATZLER: Well, I think we  
5 get at the same thing. The problem is that,  
6 I mean if there's a problem, it's because we -  
7 - currently, because of the construct of the  
8 measure, we're limited to the denominator  
9 population of those patients that had either  
10 chest pain or AMI and were transferred.

11 But we've been reluctant to limit  
12 the denominator population to just ACS or AMI,  
13 because we're looking at did they complain of  
14 chest pain when they hit the door, and did  
15 somebody not say that it obviously was not  
16 cardiac? If they thought it was cardiac chest  
17 pain, they ought to do an EKG.

18 DR. PHILIPPIDES: And the reason  
19 for requiring that they be cardiac -- probable  
20 cardiac chest pain with transfer, is it  
21 connotes that someone took this chest pain  
22 more seriously?

1 DR. BRATZLER: If you look at all  
2 five of the EDAs in my measures, they are  
3 limited to patients who are transferred. It's  
4 a population of patients that's usually  
5 identified through the claims process.

6 So the measures that we're looking  
7 at today are transfer measures, again  
8 developed initially out of the rural-sensitive  
9 group, which focused mainly on performance  
10 measures for patients transferred from one  
11 emergency department to another hospital.

12 DR. MAGID: Thank you. Dale, do  
13 you think that you can improve significantly  
14 on the problems with documentation? So 32  
15 percent of the time, the ECG date and time was  
16 found to be invalid. Twenty-five percent of  
17 the time the arrival time was felt to be  
18 invalid, and as I mentioned before, just short  
19 of 20 percent of the time, the denominator of  
20 patients was felt to be invalid.

21 DR. BRATZLER: So I would bet --  
22 I'd have to look at the data. But I will bet

1 that the vast majority of time discrepancies  
2 are a matter of minutes, if that much.

3 So you know, for arrival time, we  
4 see the exact same thing for the current  
5 inpatient ACC measures, because there are  
6 different times recorded in the chart, and it  
7 depends on who looks at the chart and when  
8 they look at it.

9 So I'm betting that the majority  
10 of those time discrepancies are very, very  
11 small discrepancies. But absolutely. We're  
12 constantly making updates to all of the  
13 performance measures for documentation, to  
14 improve documentation.

15 You know, this has taken on even  
16 greater significance as we convert to e-  
17 specifications for measures where, you know,  
18 we have to depend on one of the times that's  
19 entered into the electronic medical record,  
20 which may or may not be valid. But it's  
21 what's going to end up being in the  
22 performance measure.

1 DR. RUSSO: I thought this was  
2 like the simplest measure of them all, but I  
3 guess not. You know, I would love to see, and  
4 I don't know if you -- I think it's fine the  
5 way it is.

6 But is there a way, could we  
7 request, the disparities, I think you hit  
8 upon, is I really wonder if there would be  
9 some real gender differences or other  
10 differences. I think that would be  
11 fascinating to look at. I don't know if we  
12 could request that.

13 DR. WINKLER: We can ask.

14 MS. JONES: And this is Rebecca.  
15 I can check on that. I think we may have been  
16 requested to run some sort of disparity  
17 report, but I'm going to look through my files  
18 real quickly here and see if -- what those  
19 disparities were.

20 MS. ALLRED: Yes. In the measure,  
21 we don't have any disparity data, in the  
22 measure we looked at.

1 CO-CHAIR GIBBONS: Okay. I think  
2 we're going to have to vote on Scientific  
3 Acceptability. For those who have nine  
4 o'clock dinner reservations, we want to get  
5 them out on time.

6 MS. JONES: This is Rebecca again.  
7 I did find data on gender and racial  
8 disparities for these measures. So if CMS  
9 would approve, we could get those sent on.

10 CO-CHAIR GIBBONS: That would be  
11 much appreciated. Thank you. We're still  
12 waiting on the vote here. 7 completely, 10  
13 partially, 4 minimally. Moving on to  
14 Usability.

15 MS. ALLRED: Okay, Usability. I  
16 think it is usable. It's being currently used  
17 in outpatient data, quality data programs. It  
18 does not have any harmonization. I suspect  
19 that this is a measure that could possibly at  
20 some point in time be put into a group.

21 DR. SMITH: So I just want to be  
22 sure I understand. We're going to be looking

1 at EKGs only on those people that are  
2 transferred, and what might come out of this  
3 is if you want to transfer a patient, you  
4 should do the EKG sooner. You've got to do a  
5 better job of that, get new machines, get new  
6 people, whatever.

7 We're not going to learn anything  
8 about the people they didn't want to transfer.  
9 Maybe they should have transferred them if  
10 they had gotten the EKG sooner. Maybe there's  
11 a real problem there. It's a very --

12 DR. BRATZLER: Okay, but I would  
13 argue how often when the patient hits the  
14 door, in that first ten minutes, do you know  
15 you're going to transfer the patient? I would  
16 argue that you usually don't know.

17 DR. SMITH: Yes, and the EKG is  
18 what helps me make up my mind. So from my  
19 standpoint, if I had responsibility in one of  
20 those hospitals, I would want an EKG on all  
21 patients admitted with a suspicion of STEMI,  
22 so that I could quickly identify those that

1 would do best for transfer. So that's where  
2 I'm having, I'm still having trouble working  
3 my way through. I'm hoping that --

4 DR. BRATZLER: Well again, I think  
5 that's what the hospitals are doing. They are  
6 setting in place programs to ensure timely  
7 electrocardiograms in patients who present  
8 with chest pain that may be cardiac, and then  
9 we happen to sample a subpopulation of that  
10 group that subsequently gets transferred to  
11 another institution.

12 DR. KOTTKE: I may be sort of  
13 dense here, but isn't the issue that these  
14 patients are not actually admitted to the  
15 hospital, so they don't show up as a hospital  
16 discharge. So you have to look for them, you  
17 have to look for them as a transfer, and  
18 that's the only way you can find them.

19 DR. BRATZLER: Yes.

20 DR. SMITH: Well, that's  
21 interesting. So you are getting data on that  
22 other group of patients? I mean, you're not

1 discriminating against them because they  
2 didn't get transferred, are you? I hope that  
3 wouldn't be the case.

4 DR. BRATZLER: No. We do not see  
5 those patients.

6 DR. KOTTKE: One corollary  
7 condition. If you're looking at mortality,  
8 you can't just look at inpatient mortality and  
9 out of patient mortality. You also have to  
10 look at emergency room mortality, because  
11 that's a third distinct class here. Your  
12 numbers would be wacko unless you do that.

13 CO-CHAIR GIBBONS: I think we need  
14 to keep moving. We need to vote on Usability.

15 7 completely, 12 partially, 2  
16 minimally. Now we're going to move to  
17 Feasibility.

18 MS. ALLRED: Okay. I think  
19 Feasibility, the data's readily available.  
20 It's also a byproduct of care, so there should  
21 be no problem with Feasibility.

22 CO-CHAIR GIBBONS: Discussion



1 about feasibility?

2 (No response.)

3 CO-CHAIR GIBBONS: All right.

4 We're now going to vote on Feasibility.

5 11 completely, 8 partially, 2  
6 minimally. Now we're going to move to the  
7 final key vote, does the measurement meet all  
8 the NQF criteria for endorsement? Is there  
9 any additional discussion? Sid.

10 DR. SMITH: One quick question,  
11 because I think Tom has helped me, that there  
12 -- do I understand correctly now that there  
13 are a group of patients that are being  
14 transferred, that are falling out of the  
15 system, that we don't have data on?

16 That we have data on people that  
17 stay at that hospital, and we have it on  
18 people they get to the hospital, to major  
19 hospitals. But there's a group that are being  
20 transferred where we don't have information on  
21 how they're managed.

22 That doesn't come out -- in our

1 system, I think we get that from the  
2 transferring hospital, but it's because  
3 they're part of the RACE program and it's a  
4 bigger state.

5 But around the country, there are  
6 hospitals where they get transferred and  
7 nobody's made to look at or looking at the  
8 data on how those patients are managed. In  
9 that case, it seems like a very important  
10 measure.

11 DR. KOTTKE: Yes, that's correct,  
12 because the receiving hospital like us or  
13 Ray's, you know what you're doing. But if you  
14 would look at the transferring hospital for  
15 discharges, you would not see that, because  
16 they're just discharged --

17 DR. SMITH: Yes. But in our  
18 situation, we know because we work together  
19 with those hospitals. There's a state-wide  
20 initiative, where we work with hospitals that  
21 don't have, and everybody's part of the team.  
22 We discuss outcomes. But that should -- I

1 think that's just a model, you know, one small  
2 program.

3 DR. MAGID: There are actually two  
4 other measures in the packet, one that we'll  
5 discuss today and one tomorrow that do focus  
6 on that population. So there's a measure that  
7 looks at, for those people being transferred,  
8 the time from their arrival to when they're  
9 transferred, and this is just a subset of that  
10 larger time interval.

11 Then there's, for those being  
12 transferred for PCI, there's time from arrival  
13 to the first hospital to balloon inflation.  
14 So there are two other measures for that  
15 group.

16 DR. SMITH: While you're focusing  
17 on this, this is an important thing, if this  
18 happening and it's not being looked at in  
19 other systems.

20 DR. KOTTKE: Yes.

21 MS. De VELASCO: I'd like to say  
22 something as both a nurse and a consumer.

1 Having gone to many seminars where we listen  
2 to basically horror stories of women who have  
3 gone to emergency rooms and not been rapidly  
4 diagnosed, from a consumer point of view I  
5 think this sends a loud message, that we are  
6 trying to develop things that are to them, at  
7 their level of understanding, means better  
8 access to care.

9 So if they actually realize that  
10 there are guidelines now of when they can have  
11 an EKG, and then may need to be transferred,  
12 because a lot of our people do come from rural  
13 areas, I think this sends a loud message to  
14 patients, that there is a commitment on our  
15 part to get them diagnosed early and to get  
16 them to proper treatment.

17 CO-CHAIR GIBBONS: Thank you.  
18 Let's go ahead and vote.

19 The Chair is concerned someone's  
20 fallen asleep.

21 MS. PACE: If everybody thinks  
22 they voted? Okay, go ahead and do it.

1 CO-CHAIR GIBBONS: The vote is 17  
2 yes, 2 no. We're now going to move on to  
3 aspirin, and the first is 0132, Aspirin at  
4 Arrival for AMI. David.  
5 Measure 0132

6 DR. MAGID: Okay. So in terms of  
7 impact, early aspirin in the first 24 hours  
8 has the same -- some feedback -- the same --  
9 Carol, could you flip yours off. Carol?  
10 There's the same benefit from early aspirin as  
11 you get from reperfusion therapy. So I think  
12 clearly strong impact, and there's very strong  
13 evidence for this, and that's cited.

14 There's not a large performance  
15 gap, but I think this is, as talked to a  
16 couple of people, important enough that even  
17 in the absence of a large performance gap, I  
18 would recommend that we vote yes for this.

19 CO-CHAIR GIBBONS: Other  
20 discussion about Importance?

21 (No response.)

22 CO-CHAIR GIBBONS: We will vote on

1 Importance.

2 The group is pulling together as  
3 the day moves along. All right. Scientific  
4 Acceptability.

5 DR. MAGID: I think it is well-  
6 specified and there's excellent data on  
7 reliability and validity. The exclusions are  
8 reasonable. There's no risk adjustment, and  
9 you can gather this data either electronically  
10 or through chart review. There is not any  
11 significant disparities. I would recommend  
12 this as -- that we move forward, score this  
13 well.

14 CO-CHAIR GIBBONS: Any questions  
15 or comments?

16 DR. KING: Is this one of those --  
17 I mean, don't 90 or 105 percent of the people  
18 get aspirin?

19 DR. MAGID: Yes.

20 CO-CHAIR GIBBONS: 98.5.

21 DR. MAGID: There's no question  
22 that there's not a great deal of variability.

1 I talked about that in the first -- it was an  
2 issue at the first level. But I think it's an  
3 important enough, the impact is high enough  
4 that it's worth continuing, despite the lack  
5 of variability.

6 DR. SNOW: Whenever I'm in a  
7 meeting such as this, and I'm the only  
8 physician and somebody gets chest pain, of  
9 course, I always go down, and I assign  
10 somebody to go get some aspirin. The guy  
11 always says the same thing. He says, "I took  
12 one this morning." I tell him you're going to  
13 take another one, and he does.

14 Then of course, the EMTs come and  
15 they throw me away and they take over. Then  
16 he gets to the hospital. Does he get a third  
17 one?

18 DR. MAGID: No.

19 DR. SNOW: If you interrogate him  
20 and he says he just got one --

21 DR. MAGID: I wouldn't give him  
22 another one, no.

1 DR. SNOW: I've never asked that  
2 before.

3 CO-CHAIR GIBBONS: All right.  
4 We're going to go ahead and vote on the  
5 Scientific Acceptability.

6 19 to 2. Okay. We're going to  
7 move on to Usability.

8 DR. MAGID: I think it's  
9 meaningful and useful for public reporting.  
10 It is an existing measure, so it doesn't have  
11 to add value.

12 CO-CHAIR GIBBONS: Other comments?

13 (No response.)

14 CO-CHAIR GIBBONS: David, you are  
15 going for a record here. You are going for  
16 the record, clearly. We're now going to vote  
17 on Usability.

18 18 completely, 2 partially, 1  
19 minimally. Now Feasibility.

20 DR. MAGID: So this is data that  
21 is generated in care. The time from arrival  
22 is there, the time when aspirin is



1 administered is there. It could be obtained  
2 from either electronic sources or from chart  
3 review.

4 The exclusions don't require any  
5 additional data sources. I don't think it's  
6 susceptible to significant inaccuracies or  
7 unintended consequences, and I think that the  
8 data collection can be readily implemented.

9 CO-CHAIR GIBBONS: Are there any  
10 additional comments?

11 (No response.)

12 CO-CHAIR GIBBONS: All right.  
13 We're going to vote on Feasibility.

14 19 completely, 1 partially. Okay.  
15 Now the final question, does the measure meet  
16 all the NQF criteria for endorsement?

17 DR. MAGID: And I recommend that  
18 it does.

19 CO-CHAIR GIBBONS: All right.  
20 We'll go ahead and call the question and vote  
21 on this one.

22 18 yes, 1 no for those on the

1 phone. All right. We did indeed set a new  
2 record on that one.

3 DR. SMITH: One question, Ray.  
4 The thing that sort of lingers, it bothers me  
5 a little bit, we're saying aspirin should be  
6 given within 24 hours of presenting with a  
7 STEMI? We have guidelines that say it should  
8 be chewed in the field. Did I read that  
9 correctly?

10 PARTICIPANT: I think it says  
11 before, before or at arrival.

12 DR. SMITH: Before? At arrival,  
13 okay.

14 CO-CHAIR GIBBONS: Okay. So we're  
15 going to move on to 0286, Aspirin at Arrival.  
16 David.

17 Measure 0286

18 DR. MAGID: So I didn't quite  
19 understand this until Dale explained it to us,  
20 but I assume, Dale, this is the same thing,  
21 where we're looking at these critical access  
22 hospitals that transfer patients, and that

1 this is looking at aspirin being delivered in  
2 the emergency department before transfer, in  
3 patients who are transferred? Is that  
4 correct?

5 DR. BRATZLER: That is correct.  
6 So the denominator population again is -- I  
7 would point out on the last measure that the  
8 denominator population is only those patients  
9 who are discharged from the hospital, that  
10 ended up with a principle diagnosis of acute  
11 myocardial infarction.

12 This measure looks at patients  
13 with either cardiac chest pain or acute  
14 myocardial infarction, and asks whether or not  
15 they received aspirin either prior to arrival  
16 or in the emergency department prior to the  
17 transfer.

18 DR. MAGID: Okay. So I would say  
19 that there is strong evidence in support of  
20 aspirin in the setting of acute MI, that this  
21 patient population is a little bit larger than  
22 that, and there's not necessarily strong

1 evidence in support of aspirin in the entire  
2 population, but clearly those who have MI.

3 We don't really know what  
4 proportion of these people end up getting  
5 aspirin anyhow, and whether the difference  
6 between getting it in the ED versus getting  
7 it, you know, a few hours later. We don't  
8 know. We don't have good evidence to say what  
9 the incremental benefit.

10 But there's reason to think that  
11 it might be beneficial, and there is some data  
12 on the performance gap that's quite a bit  
13 larger than what we saw for aspirin within 24  
14 hours. So I would say that it probably meets  
15 the importance of a measure to report.

16 CO-CHAIR GIBBONS: Okay.

17 Additional comments or questions?

18 DR. SANZ: My only question is do  
19 we need both? If you believe this one's  
20 important, then why do the other one? If you  
21 don't believe that probable chest pain needs  
22 immediate aspirin, then you don't need this

1 one, because the AMI part's the same, right?

2 DR. MAGID: So I think the only  
3 reason, you know, I'm on the fence on this  
4 one, to be clear. So I think -- so first of  
5 all, I don't think there's clear evidence to  
6 say that people outside of those having an MI  
7 benefit. So that, we just don't know one way  
8 or the other. I think the issue is that these  
9 patients -- I mean this came up in the sort of  
10 time to ECG discussion too.

11 These patients are likely to fall  
12 out of the -- so when you've got these  
13 receiving hospitals getting these transfer  
14 patients, Mark, they will fall out of the  
15 denominator for those patients. So they won't  
16 be counted in the quality metrics of those  
17 hospitals, because they didn't show up  
18 initially at that hospital.

19 So that's the only potential  
20 reason, is that they kind of fall out. But  
21 the strength of evidence and strength of  
22 impact is not what it is for the other

1 measurement.

2 DR. BRATZLER: So this is Dale. A  
3 couple of points. One is that in a lot of  
4 these small hospitals, the differentiation of  
5 non-STEMI, where I think there is good  
6 evidence of aspirin benefit, is not that easy.  
7 I mean so we all agree that if you have ST  
8 segment elevation MI, you ought to get an  
9 aspirin, and those are usually reasonably easy  
10 to identify.

11 But I think one of the issues that  
12 came up was that in a lot of the small  
13 hospitals that may not have access to rapid  
14 testing for troponin or other things, they're  
15 making a decision based on whether the patient  
16 presents with something that looks like  
17 probable cardiac chest pain, and should you  
18 give an aspirin to that population.

19 I would argue that that's what we  
20 have emergency -- we have a lot of ambulance  
21 services all over the country doing, is  
22 delivering aspirin to chest pain patients if

1 there's no obvious contraindications before  
2 diagnosis was made.

3 DR. MAGID: No, I think that's  
4 reasonable.

5 CO-CHAIR GIBBONS: Okay. I think  
6 we should vote on Importance.

7 18 yes, 3 no. Let's move on to  
8 Scientific Acceptability.

9 DR. MAGID: So I think that the  
10 specifications are clear, and the reliability  
11 is reasonable. Oops, can you go back to that?

12 The validity suffers from some of  
13 the same issues that we discussed about with  
14 the time to ECG, and just recalling that about  
15 20 percent or 19.5 percent of those patients  
16 who were initially deemed to meet criteria  
17 were then found to be invalid.

18 So there are some issues about  
19 validity. They're not any major issues around  
20 exclusions. Risk adjustment is not an issue.  
21 There were some meaningful differences across  
22 sites. It is, I think, the comparability

1 around just data sources is not an issue, and  
2 we don't have any data on disparities.

3 CO-CHAIR GIBBONS: Maybe I can ask  
4 this question of Dale, and probably should  
5 have asked it on the Median to ECG measure as  
6 well. Dale, as I looked at this, it didn't  
7 look to me like there was any low-end cutoff  
8 for very low volumes. Is there?

9 DR. BRATZLER: So there is for  
10 reporting on Hospital Compare. I don't have  
11 that information. I mean for the inpatient  
12 measures, it's 25 cases per year. Rebecca, do  
13 you know what the lower limit is?

14 MS. JONES: It's five cases.

15 DR. BRATZLER: Five cases what,  
16 per quarter?

17 MS. JONES: I believe it's per  
18 quarter.

19 DR. BRATZLER: So a hospital can  
20 submit their data, regardless of their volume.  
21 But there's a cutoff that CMS uses for public  
22 display.



1 MS. JONES: And that's if they do  
2 not have more than five cases that make it  
3 into the denominator.

4 CO-CHAIR GIBBONS: That seems  
5 pretty sparse to me. I don't know what others  
6 think, but that seems awfully low to -- in  
7 other words, if a hospital has 21 cases a  
8 year, they're going to report this measure?  
9 I'm going back to Mark's six bed place.

10 CO-CHAIR GEORGE: I'd say for  
11 meaningful use, there is absolutely no lower  
12 number. If you have even zero cases, you  
13 report with meaningful use for the hospital  
14 measures.

15 DR. BRATZLER: You know, to a  
16 certain extent, I think we're highlighting one  
17 of the issues that we have around measuring  
18 performance in small and rural hospitals,  
19 where volume is always an issue, and I think  
20 this is part of the attempt to get smaller  
21 rural hospitals participating in quality  
22 measurement and reporting.

1                   But you know, I can argue about  
2                   the thresholds that are reported, that are  
3                   published in the value-based purchasing rule,  
4                   about a lower limit. I think any number is  
5                   going to be somewhat arbitrary.

6                   DR. JEWELL: So on the measure  
7                   submission form, it says under reliability and  
8                   validity that the measure is undergoing  
9                   validation through the CMS Clinical Data  
10                  Abstraction Center?

11                  DR. WINKLER: We sent you the  
12                  results.

13                  DR. JEWELL: Did you? I don't  
14                  have it.

15                  DR. MAGID: That's what I've been  
16                  quoting you guys.

17                  DR. JEWELL: So okay. I  
18                  apologize. I didn't see it.

19                  DR. RUSSO: Wait. Can you just  
20                  clarify? So if you have -- so whatever number  
21                  of patients, they're not -- if you have a  
22                  large number of patients, you're not sampling

1 patients. Shouldn't you just report all the  
2 patients you have that meet, or how is that  
3 working? We're not allowing  
4 --

5 DR. MAGID: I thought it said that  
6 if there were less than 80 patients, you  
7 reported all your patients, and then if it was  
8 greater than 80, you could sample. That was  
9 what I recall, at least.

10 DR. RUSSO: I worry more about the  
11 sampling kind of thing or how that's done, in  
12 terms of gaming the system, than the lower, I  
13 guess there should be a minimum number.

14 DR. MAGID: Yes. Dale, do you --  
15 I don't know how many of them have more than  
16 80. But can you comment on the sampling  
17 approach?

18 DR. BRATZLER: Yes. The sampling  
19 approach is supposed to be random sampling.  
20 That's actually developed by the Iowa -- or  
21 the Florida QI. I think it's the Florida QI  
22 who actually runs that contract. But I don't

1 know if Rebecca has that in front of her. But  
2 they do have the sampling scheme. It's  
3 supposed to be random.

4 MS. JONES: It does, and if  
5 there's less than 80 cases per quarter, that  
6 they're required to sample 100 percent of  
7 their cases. So once it rises to greater than  
8 80, it starts leveling off.

9 DR. SMITH: Ray, could you or  
10 someone clarify for me. Does this mean that  
11 a patient that comes in with a STEMI and gets  
12 transferred, and took low-dose aspirin 24  
13 hours before they came to the emergency room  
14 and got transferred. Let's say they're there  
15 and, geez, I realize it's a baby dose low-dose  
16 aspirin's good probably, because I'm having  
17 this chest pain.

18 They come to the emergency room  
19 and do not get 325 adult dose, do not get that  
20 and are transferred away. They are -- under  
21 the way I read this, they've gotten acceptable  
22 therapy. It still bothers me. I don't know

1 of any evidence that supports low-dose aspirin  
2 24 hours before arriving at a hospital with  
3 symptoms of STEMI is efficacious.

4 In most of the studies I've seen,  
5 it's been adult dose aspirin given at the time  
6 of STEMI.

7 DR. BRATZLER: No, I think you're  
8 correct about the evidence. The question is,  
9 did those studies include patients that took  
10 daily aspirin?

11 DR. SMITH: No, we don't know. Do  
12 we know whether they were taking it  
13 chronically, or whether they just took one?

14 DR. MAGID: I think that there's  
15 another issue related to that, which is that  
16 you're going to find out that the  
17 documentation in the chart will say, you know,  
18 aspirin taken prior to arrival. It's not  
19 going to give you that time stamp about how  
20 long ago it was.

21 So that's kind of why you probably  
22 just need to give them credit, because you

1 won't be able to sort that out in that level  
2 of detail.

3 CO-CHAIR GIBBONS: Are there other  
4 questions?

5 DR. BRATZLER: No, I would just  
6 highlight that, you know, this is something  
7 that certainly can be discussed and the  
8 measure specifications can be changed, if we  
9 think the evidence requires that they be  
10 redosed if they just take it chronically. So  
11 I have no problem with reevaluating that.

12 CO-CHAIR GIBBONS: Okay. Let's go  
13 ahead and vote on Scientific Acceptability.

14 We have 7 completely, 11  
15 partially, 3 minimally. Now we can go to  
16 Usability.

17 DR. MAGID: So I think it does  
18 meet the criteria for meaningful and useful  
19 public reporting, and because it will focus on  
20 these hospitals that are not otherwise  
21 captured in the existing measure, it would  
22 meet the criteria for adding some value to our

1 existing measure.

2 CO-CHAIR GIBBONS: Are there other  
3 questions about Usability?

4 (No response.)

5 CO-CHAIR GIBBONS: Okay. I  
6 propose we vote on Usability.

7 14 completely, 4 partially, 1  
8 minimally. Okay. We're going to move on now  
9 to Feasibility.

10 DR. MAGID: So the data elements  
11 that you need, the time of arrival and whether  
12 aspirin was given by the emergency department  
13 I think will be easily generated as part of  
14 routine care. You can either use electronic  
15 data sources or chart review.

16 The exclusions are, I think,  
17 appropriately specified, and there's good  
18 data, at least, from the prior aspirin measure  
19 to say that they're not deployed that often.  
20 I don't think they'll be -- I talked to you  
21 already about some of the susceptibility to  
22 inaccuracies that's already been reported, and

1 that data collection can be implemented.

2 CO-CHAIR GIBBONS: Questions or  
3 comments?

4 (No response.)

5 CO-CHAIR GIBBONS: Okay. I think  
6 we'll go ahead and vote on Feasibility,  
7 please.

8 16 completely, 4 partially. And  
9 then finally does the measure meet NQF  
10 criteria for endorsement? Any additional  
11 discussion?

12 (No response.)

13 CO-CHAIR GIBBONS: Okay. Let's go  
14 ahead and vote on this.

15 19 yes, 1 no. Okay. So we are  
16 approaching five o'clock. We are well behind  
17 schedule, so I need to get a sense of  
18 everybody. At this point in time there are in  
19 fact eight measures that we were scheduled to  
20 get through today.

21 That's conservatively two hours'  
22 work. So I propose that we at least try to do



1 a few more today, if that's acceptable to  
2 everybody, especially since several of these  
3 fall within the same framework of acute  
4 therapy. So if -- I would suggest that we try  
5 to see if we can do 163, 164 and 288,  
6 depending on the length of discussion.

7 I guess there's no way to vote on  
8 this, other than to ask whether that seems  
9 acceptable to people. Probably take us to  
10 5:30 or a little bit beyond, as opposed to  
11 delaying two hours' worth of work into  
12 tomorrow.

13 In which case, we'd all just start  
14 at 6:00 a.m. I'm glad everybody's still  
15 paying attention. This is good. You laugh at  
16 my jokes, too. That's even better. All  
17 right, good.

18 DR. SMITH: Carpe diem, push on.

19 CO-CHAIR GIBBONS: All right. So  
20 we'll do 163, Primary PCI Within 90 Minutes of  
21 Arrival.

22 Measure 0163

1 DR. PHILIPPIDES: And that's a  
2 good description of this project. There's  
3 some key elements. That's 90 minutes. That's  
4 no transfers. They have to arrive there  
5 first. But I think we can discuss that in  
6 Part 2.

7 Overall high impact area of health  
8 care, very good data that early PCI is very  
9 important. I think we should support it on a  
10 scientific basis.

11 CO-CHAIR GIBBONS: Questions or  
12 comments?

13 (No response.)

14 CO-CHAIR GIBBONS: All right.  
15 Let's go ahead and vote on Importance.

16 Oh, everybody's awake. That's  
17 good. Unanimous vote. All right. Scientific  
18 Acceptability.

19 DR. PHILIPPIDES: So I think the  
20 measure, as outlined, we can discuss the 90  
21 minutes, is precise and specified. The  
22 reliability testing, there's not much there,

1 but what is offered as far as CDAC comparison  
2 to hospital data, it seems like there's  
3 reasonable reliability, and it's valid as far  
4 as the measure goes.

5 One of the other people that  
6 reviewed this on my group had a question as to  
7 90 minutes versus 60 minutes. I think what  
8 they're getting at here, and I might be off on  
9 this, those who do primary intervention can  
10 chime in.

11 I think if somebody goes to an  
12 outside hospital and they're being transferred  
13 in, you want to get them through this in about  
14 90 minutes. Meaning 30 minutes travel,  
15 roughly, 60 minutes to now your a new door to  
16 balloon time. The theory is that as they're  
17 sending them in, your team is getting up and  
18 running.

19 This, I think, is a different  
20 animal. I see you shaking your head. I know.  
21 Here they're saying they show up at your place  
22 without having been at another institution.

1                   What should the clock be? There's  
2 a big issue here. They're saying 90 minutes.  
3 There's some who think it should be 60. So  
4 I'll leave that as the open discussion now.

5                   DR. MASOUDI: Well again, this is  
6 responsive to the guideline. I mean I think  
7 ideally, it would be five minutes or ten  
8 minutes.

9                   DR. PHILIPPIDES: The guidelines  
10 say 90.

11                  DR. MASOUDI: Yes.

12                  DR. BRATZLER: And this is Dale.  
13 I'll also just point out that the measure  
14 currently excludes patients transferred from  
15 another facility.

16                  DR. PHILIPPIDES: Yes, that's  
17 correct. That's exactly the point I was  
18 trying to make. Right. Okay. Other issues,  
19 the exclusions. One thing to mention, they  
20 added an exclusion which I think is very  
21 important, that if somebody was so unstable  
22 but they had to be stabilized before going to

1 PCI, that was a reasonable exclusion.

2 So somebody comes in and they're  
3 in shock, and they have to get pressure  
4 started and the balloon pumped. That's okay.  
5 Somebody might have had a stroke  
6 concomitantly. They can get that dealt with.  
7 So that was added on.

8 There was a concern that this  
9 might lead to false exclusions, but so far  
10 from preliminary data, that seems to be a low  
11 percentage. So those of you who know the data  
12 better than I do, please confirm that that's  
13 the case, and therefore, I don't think that  
14 that's a deal-breaker.

15 I think the exclusions as changed  
16 to the present duration are reasonable and  
17 better than before. There are disparities,  
18 which I think are important and we should talk  
19 about. There was roughly a seven percent  
20 difference in rates for Caucasians, going for  
21 a PCI in a timely fashion, compared to  
22 African-Americans, and there was a gradation

1 with other groups within that.

2 It was not further stratified in  
3 any way. We can't say anything more about  
4 those populations. But as Carol and Anne and  
5 others have said, I think that moving forward,  
6 it would be great if we could have a  
7 particular focus on these disparities going  
8 forward, to see what we can learn from that.  
9 I think it's an important issue.

10 Those are sort of the main issues  
11 as far as the scientific evidence goes.

12 DR. SMITH: I'm assuming that in  
13 exclusions, we also include the usual end of  
14 life issues, someone that may have severe  
15 Alzheimer's disease or has indicated a  
16 preference that no further invasive  
17 procedures. I mean, that's sort of standard.  
18 I just --

19 DR. MASOUDI: The measure only  
20 applies to those patients who actually get  
21 primary PCI. So if you're going to -- the  
22 presumption is if you're going to perform PCI,

1 you should do it in a timely manner. But if  
2 you're not doing it, for instance, in someone  
3 who has -- in other words, and it doesn't  
4 apply, and they don't get PCI, they're  
5 actually not in the measure at all.

6 DR. SMITH: That's what I would --  
7 yes, that's an exclusion criteria.

8 CO-CHAIR GIBBONS: Okay. I think  
9 we should vote on Scientific Acceptability.

10 Okay, 19 completely, 2 partially.  
11 Moving on to Usability.

12 DR. PHILIPPIDES: The information  
13 produced is meaningful and understandable.  
14 It's been used in different registries in the  
15 past. I think that there's added value  
16 clearly of knowing what the door to balloon  
17 time is in patients being treated with a  
18 STEMI.

19 So I don't have any major  
20 problems, and even for harmonization, it seems  
21 like this is a different measure that fits in  
22 nicely with some of the other ones we've

1 described going into the acute MI realm. So  
2 overall, I think it's usable and reasonable.

3 CO-CHAIR GIBBONS: Comments?

4 (No response.)

5 CO-CHAIR GIBBONS: Okay. I think  
6 we go ahead and vote on Usability.

7 Unanimous. All right,  
8 Feasibility.

9 DR. PHILIPPIDES: The clinical  
10 measures to date are obtainable through  
11 routine care processes. As the electronic  
12 records become more widespread, that will  
13 become even easier.

14 In regards to the exclusions, I  
15 think they're also reasonable, and again, they  
16 are mostly derived from the usual care  
17 processes documentation. So I don't think  
18 those represent an undue burden.

19 There is a susceptibility to  
20 inaccuracies, and there can be some gaming.  
21 If too much is made of that one out card, that  
22 a physician or nurse can document a non-system



1 reason for delay.

2 But again, to date, there's no  
3 reason to believe that that's going to be a  
4 significant issue. So what else? Yes. So I  
5 think that it's feasible and it's worked well  
6 in the past.

7 CO-CHAIR GIBBONS: Okay. We're  
8 going to go ahead and vote on Feasibility.

9 Another unanimous vote. All  
10 right. So we're moving on. Does the measure  
11 meet the NQF criteria for endorsement? Keep  
12 your eyes out. I'm going to throw in a dummy  
13 question here, just to make sure people aren't  
14 just voting yes on everything.

15 All right. I think it's a virtual  
16 tie between you and David. Well done. All  
17 right. Unanimous, 21 to 0 for endorsement.  
18 All right. Now we're going to move to the  
19 Fibrinolytic Therapy Measures, 0164, within 30  
20 minutes, and then it's pair right after that,  
21 which is 0288, and Andrea.  
22 Measure 0164

1 DR. RUSSO: Yes. Both of those  
2 are relatively, are pretty similar. But  
3 basically, the measure is receiving, you know,  
4 fibrinolytic therapy within 30 minutes of  
5 hospital arrival in the 0164 measure, and  
6 described as the percentage of acute MI  
7 patients with ST elevation or left bundle on  
8 the ECG closest to arrival time, receiving  
9 thrombolytic therapy during the hospital stay  
10 and having a time from arrival to the hospital  
11 to fibrinolysis by 30 minutes or less. This  
12 is backed up by lots of literature.

13 Although we're doing, you know,  
14 there's more PCI being done, so there are  
15 probably less patients, at least in urban  
16 areas or around areas that have access to PCI.  
17 There's less of it going on, but it doesn't  
18 diminish the significance of delivering  
19 fibrinolytic therapy within a good period of  
20 time.

21 So I think it has a high level of  
22 evidence in terms of lots of randomized

1 studies, and would certainly not question the  
2 importance of this measure.

3 CO-CHAIR GIBBONS: Questions or  
4 comments? Yes.

5 DR. SNOW: Thank you. New left  
6 bundle branch block on ECG closest to arrival  
7 time, or do you really need a bracket on that?  
8 Could it have been an old left bundle branch  
9 block?

10 DR. RUSSO: The new isn't listed  
11 under the description, but under the --

12 DR. MASOUDI: In the  
13 specification, in the detailed specifications  
14 of these measures, it's left bundle branch  
15 block that's either new or not known to be  
16 old. That's the way it's specified, if you  
17 look. The new are presumably newer.

18 DR. SNOW: That is, you don't have  
19 a year-old EKG that has to go on there. You  
20 don't have that; correct. So it's new  
21 presumably, new or presumed new.

22 CO-CHAIR GEORGE: This measure

1 seems very interested, because it has a huge  
2 disparities analysis with it.

3 DR. RUSSO: Yes. I didn't mention  
4 that for this section, but I agree. And  
5 actually, the performance was actually not,  
6 it's only in the 50 -- it's really not as good  
7 as you would expect, I guess because the time  
8 period's relatively short.

9 You may take 30 minutes to get  
10 your EKG, I guess, in some places. But the  
11 disparities are very interesting. So I think  
12 it's important.

13 The Caucasians, I think, came out  
14 way above, although some of the N's in the  
15 denominator are relatively small in some of  
16 the other groups. Caucasians met this more  
17 than non-Caucasians.

18 CO-CHAIR GIBBONS: Importance to  
19 measure. I suggest we vote.

20 All right. A lot of agreement  
21 here late in the day. Scientific  
22 Acceptability.

1 DR. RUSSO: So we started talking  
2 a little bit about some of the measurement  
3 specifications in the numerator, patients  
4 whose time from hospital arrival to  
5 fibrinolysis is 30 minutes or less. And then,  
6 you know, the denominator, all the different  
7 denominators are in 2A.4. Greater than 18  
8 years, male or female.

9 The only thing -- and there must  
10 be some basis to this but I'm not aware -- but  
11 the only thing in terms of exclusions, is  
12 patients who have had a length of stay greater  
13 than 120 days. It didn't seem to be relevant,  
14 but I wasn't sure why that's in there  
15 particularly.

16 DR. MASOUDI: It has to do with  
17 some nuances around sort of when the data is  
18 available and collected, based on lengths of  
19 stays. I don't even totally understand it.  
20 But it just have to do with the ease of  
21 collecting data on these patients who have  
22 extraordinarily long lengths of stay in a

1 hospital, and how it overlaps quarters. So  
2 Dale, maybe you can speak to that.

3 CO-CHAIR GIBBONS: Dale?

4 DR. BRATZLER: Yes, you're  
5 absolutely correct. That's correct. So if  
6 the patient has a very, very long length of  
7 stay, it's possible that they're -- these data  
8 are submitted quarterly to CMS.

9 So if it's more, if they're in the  
10 hospital for more than a quarter, it's unclear  
11 where you attribute that stay. So those  
12 patients are excluded from all the measures.

13 DR. MASOUDI: It's fortunately a  
14 vanishingly small proportion of patients.

15 DR. RUSSO: Yes, and we talked  
16 already a bit about the disparities that were  
17 also well-described.

18 DR. AYALA: Can I ask a question  
19 about the comments that were made about  
20 measuring disparities? We've talked about the  
21 time to ECG, the time to PCI and now this one.  
22 What happens with those comments that we make,

1 where we request the stratification of the  
2 patients by race, ethnicity, gender going  
3 forward?

4 DR. WINKLER: A couple of things.  
5 I mean first, we'll pose the question and your  
6 comments to the measure developers for their  
7 response. But also as part of the  
8 recommendations that accompanies the  
9 endorsement of the measure, you can also  
10 recommend that the measure be stratified when  
11 it's implemented.

12 DR. SANZ: Is there a size cutoff,  
13 either sample size or institution size?  
14 Because I can tell you, some of these critical  
15 access hospitals, in fact I doubt any of them  
16 have a pharmacist on hand to make up the TPA  
17 or whatever they're going to use, TNK.

18 And that's going to be where a lot  
19 of disparities are. You ought to be looking  
20 at true rural versus large inner city hospital  
21 without a PCI capability.

22 DR. BRATZLER: So I'll make a

1 point, and I'm going to have to go soon.  
2 They're going to close the door on my plane.  
3 But this measure only applies to patients who  
4 are admitted and have a discharge diagnosis of  
5 acute myocardial infarction.

6 So most of those small hospitals,  
7 even if they gave a fibrinolytic therapy, are  
8 transferring the patients anyway. So this  
9 really is a large hospital or a medium to  
10 large hospital measure.

11 CO-CHAIR GIBBONS: But Dale, is  
12 there a low-end cutoff, because I'm actually  
13 thinking of the reverse? That is, hospitals  
14 that are set up to be primary PCI hospitals,  
15 and give fibrinolytic therapy very, very  
16 infrequently, as in single digits per year.  
17 Are they still reported?

18 DR. BRATZLER: Only if they have  
19 25 cases per year that are eligible. But yes,  
20 it would be Fred, because I think yes, because  
21 it's 25 AMI cases a year. So if they had one  
22 case that was eligible for fibrinolytic



1 therapy and they gave it, then the case would  
2 then -- the case would be reported.

3 DR. MASOUDI: So it's a minimum  
4 case volume, but it's total AMIs. It's sort  
5 of irrespective of the family of measures. So  
6 if there are 25 or more cases per year  
7 reported, they do get reported one way or  
8 another. There's going to be variability in  
9 the patients who qualify for each of the  
10 measures within those 25.

11 CO-CHAIR GIBBONS: Okay. I think  
12 we should vote on scientific acceptability.

13 (Pause.)

14 CO-CHAIR GIBBONS: 19 completely,  
15 1 partially. Let's move on now to usability.

16 DR. RUSSO: This, I think, is  
17 important and meaningful for public reporting.  
18 There is the next measure that's on there, you  
19 know, I guess harmonization or duplication  
20 even. I'm not sure how we deal with that.  
21 But I think this would be a positive response  
22 in my mind.

1 CO-CHAIR GIBBONS: Other comments?

2 (No response.)

3 CO-CHAIR GIBBONS: All right. I  
4 suggest we vote now on usability.

5 (Pause.)

6 CO-CHAIR GIBBONS: 19 complete, 2  
7 partial. And now moving on to feasibility.

8 DR. RUSSO: Feasibility, the data  
9 can be collected either from electronic health  
10 records or review of -- chart review. The  
11 report is here. Actually, there's a really  
12 nice section on looking at susceptibility to  
13 inaccuracies, errors or unintended  
14 consequences on this particular measure.

15 Just to outline some of those, in  
16 terms of false inclusions, they revised the  
17 measure to exclude cases where fibrinolytic  
18 therapy was given during PCI, because  
19 obviously that's not what you're looking at,  
20 or given after PCI. This is just as initial  
21 therapy.

22 They also looked at -- you had to

1 previously, I guess, document that if the  
2 patient had a cardiac arrest or some other  
3 explanation, why you didn't give fibrinolytic  
4 therapy within a 30 minute period of time.  
5 You had to document.

6           They had cardiogenic shock now.  
7 You can just -- you don't need to write that  
8 in the chart. It can be implicit, that if  
9 they had shock or they had balloon pumps, you  
10 could extract that as the reason.

11           Then there was, I think, even a  
12 comment about false exclusions, the type of  
13 reason for delay in giving therapy. They made  
14 some comments of how discharge is no longer  
15 counted toward such reasons. I mean they went  
16 through a really nice discussion on how they  
17 revised and the reasons for revising that. So  
18 I think they did a nice job with this.

19           CO-CHAIR GIBBONS: All right.  
20 We're going to vote on feasibility.

21           (Pause.)

22           CO-CHAIR GIBBONS: 20 completely,

1 1 partially. And then finally the key  
2 question, does the measure meet the NQF  
3 criteria for endorsement. Any comments before  
4 we vote?

5 (No response.)

6 CO-CHAIR GIBBONS: All right.  
7 Let's go ahead and vote on that.

8 (Pause.)

9 MS. PACE: Has everybody clicked  
10 in? Go ahead.

11 CO-CHAIR GIBBONS: 20 yes and 0  
12 no, and one clicker that didn't work, I think.  
13 All right. So we're going to move on to the  
14 related measure, 288, Fibrinolytic Therapy  
15 Within 30 Minutes of ED Arrival.  
16 Measure 288

17 DR. RUSSO: So this is really, you  
18 know, pretty much the same, a lot less  
19 description in there. But basically,  
20 fibrinolytic therapy, and they used emergency  
21 room. So I guess the question is can you  
22 arrive anywhere else other than the emergency

1 room? Would you arrive, if you're not a  
2 transfer, you wouldn't arrive directly to a  
3 unit. So I don't know if that's a relevant  
4 distinguishing characteristic there.

5 But again, receiving fibrinolysis  
6 with time to arrival from the ED, to  
7 fibrinolysis of 30 minutes or less. Again,  
8 you know, important. It's guideline-based or  
9 based on multiple trials. So I think it  
10 certainly meets the importance to measure like  
11 the last one. But it's really -- I don't know  
12 how we deal with duplication.

13 (Off record comments.)

14 CO-CHAIR GIBBONS: Microphone.

15 DR. MAGID: Just the difference  
16 between the percentage versus the median time?  
17 Is that what we're looking at?

18 DR. RUSSO: It says "time of 30  
19 minutes or less," but then the spec.

20 DR. MASOUDI: So 164 and I believe  
21 287 are sort of the same measure. One is a  
22 proportion and one is the median time. So

1 it's sort of the same, it's almost the same  
2 measure. Well, it is the same measure, but  
3 it's just a different reporting mechanism.

4 I believe that middle one is the  
5 critical access hospital measure. So that's  
6 sort of out of that separate set. So that's  
7 why there are three of them.

8 DR. RUSSO: Do we need all three?

9 DR. WINKLER: These last three  
10 measures, 288, 287 and 290 are all part of  
11 measures that apply to that group of patients  
12 that are transferred for therapy. This is  
13 more those small rural hospitals, if you will,  
14 or so they aren't going to be capturing the  
15 same patients that were captured in the  
16 hospital measure, who were admitted to the  
17 same hospital and discharged with a diagnosis  
18 of AMI.

19 DR. RUSSO: Is there a way to  
20 write it so that you would capture all of them  
21 in one measure?

22 DR. MASOUDI: Well I mean to be

1 honest, the proportion within 30 minutes and  
2 the median time are essentially exactly the  
3 same measure, with the exception of the fact  
4 that they report it somewhat differently.

5 DR. MAGID: But so do you guys  
6 have a preferred one versus the other?

7 DR. MASOUDI: Well, I think that  
8 there's been an appeal to both sides of it.  
9 So and that's why it's reported. This is how  
10 it's been reported publicly in Hospital  
11 Compare for quite some time.

12 DR. MAGID: Okay.

13 DR. MASOUDI: So to me, it's sort  
14 of -- it's almost like a distinction without  
15 a difference with respect to those two  
16 measures. The third one, and again that's a  
17 group that I'm not as familiar with, but  
18 that's the group that applies more to the  
19 critical access hospitals, and that's why it's  
20 a separate measure.

21 DR. MASOUDI: And are the critical  
22 access hospitals transferring people for

1       fibrinolysis, because that doesn't make a  
2       whole lot of sense, does it?

3               DR. MASOUDI: Not transferring  
4       patients, but giving fibrinolysis and then  
5       typically transferring them. So it's  
6       something that you can measure, the care  
7       provided there.

8               DR. MAGID: Well, wouldn't they be  
9       captured in the regular. In other words, is  
10      it because they're not admitted to that  
11      hospital that they're not captured --

12              DR. MASOUDI: Right. So it's the  
13      same factor that Dale was talking about  
14      before. Because they're not admissions, they  
15      don't get counted. You don't measure them.  
16      They fall through the cracks.

17              DR. MAGID: And is there a  
18      measurement of percentage or a median?

19              DR. MASOUDI: It looks as if it's  
20      a proportion, and I'm not sure why. I can't  
21      speak to why they didn't do both.

22              DR. MAGID: Right, but I wonder if



1 we could just -- I mean what do we do first,  
2 the median or the proportion? I'm confused  
3 now. What did we do already just now?

4 DR. WINKLER: What we were just  
5 talking about was --

6 DR. MASOUDI: Proportion.

7 DR. MAGID: The proportion. So it  
8 seems like maybe we should do the critical  
9 access proportion.

10 DR. WINKLER: That's what's next.

11 DR. MAGID: Okay, and then is  
12 there any reason not to vote the exact same  
13 way as we did? In other words, we've got our  
14 votes recorded. I would propose that we just  
15 do the exact same votes.

16 (Simultaneous speaking.)

17 DR. MAGID: I think we want to  
18 have dinner before nine o'clock. All right,  
19 all in favor, click one.

20 DR. KOPLAN: But these are clearly  
21 going to be harmonized later, right?

22 DR. WINKLER: These were created

1 by the same developer. To the degree that  
2 they're harmonized right now, we can -- if you  
3 can identify elements that require additional  
4 harmonization, please do.

5 DR. MASOUDI: The  
6 numerator/denominator times, everything are  
7 identical for the first and the third measure.  
8 So they're entirely harmonized, with the  
9 exception of the fact that one reports the  
10 proportion of patients who get it within 30  
11 minutes, and the other reports a median time.

12 DR. KOPLAN: How many patients --  
13 let's say that all of the patients who  
14 potentially could fall into this measure fall  
15 into the measure, like 100 percent capture  
16 across the United States for both of them.

17 DR. MASOUDI: Yes, yes.

18 DR. KOPLAN: How many patients  
19 would be in both?

20 DR. MASOUDI: The same number.

21 DR. RUSSO: All. It's the same  
22 group.

1 DR. MASOUDI: It's exactly the  
2 same group.

3 (Simultaneous speaking.)

4 CO-CHAIR GIBBONS: There's two  
5 issues. So wait, wait, wait, stop. I think -  
6 - let's stick on just 164 and 288. I think  
7 we're getting confused by branching out to  
8 287. So let's just stick right now on 164 and  
9 288. We just voted on 164, and now 288 is the  
10 patients being transferred.

11 So they would not be captured in  
12 164. They would not be, and it gets back to  
13 the point David asked earlier, because one  
14 group is admitted to the hospital and treated  
15 there, and their numbers do not include  
16 patients who are transferred in. The other  
17 group are patients who are treated there and  
18 transferred out.

19 DR. MAGID: Right. But it's the  
20 same measure; it's just to a different  
21 population. So I'm sort of suggesting that  
22 since all the other things are the same, it's

1 just two different populations. If we liked  
2 it in the first group, we should like it just  
3 as much in the second group.

4 So I'm just saying that we don't  
5 need to go -- we should be able to apply our  
6 voting results to this second population.  
7 Same measure, just a different population,  
8 because the reason why they're not in the  
9 first one is because they don't get admitted  
10 to that initial hospital. So that's what I'm  
11 proposing.

12 DR. SANZ: All I can say is just  
13 looking at the document, you would never get  
14 that. 2A never talks about a patient who is  
15 not admitted. It just says that any time  
16 discharged or transferred to a --

17 DR. MAGID: Well, that was true of  
18 every one of the measures that Dale gave us,  
19 because we were all assigned -- several of us  
20 were assigned to them, and we could not --  
21 until he gave us the preamble, we didn't know  
22 that. But as soon as he gave us the preamble,

1       then we--

2                       (Simultaneous speaking.)

3               DR. SANZ:  But there's no way --

4               DR. RUSSO:  You can't tell, you  
5       can't tell.

6               DR. SANZ:  I agree with what  
7       you're saying.  I don't disagree with what  
8       you're saying.  You can't tell that from here.

9                       (Simultaneous speaking.)

10              DR. RUSSO:  It needs to be included  
11       in the measure.  Somehow they need to write  
12       that in.

13              DR. MAGID:  Right.  Well, that  
14       would be true of every one of his measures  
15       then.  That's true of every one of his  
16       measures.  It isn't clear.

17              DR. SANZ:  It should say "patient  
18       transferred out of the emergency room without  
19       admission."

20              DR. MAGID:  Yes.

21              DR. RUSSO:  Right.

22              DR. MAGID:  The time to ECG, the

1 aspirin, none of that was in the document,  
2 yes.

3 DR. RUSSO: Right, exactly.

4 DR. JEWELL: And that information  
5 isn't included in the measure specifications.  
6 In the overall manual that's produced, that  
7 vendors and hospitals use to track this data,  
8 it's made clear that it applies to their OPP  
9 as providers in emergency departments and  
10 patients that are not admitted.

11 We can certainly go through and  
12 make those recommendations to update, but I  
13 think that that might be something that NQF  
14 would recommend for every single measure that  
15 they approve, because I know that CMS does  
16 have multiple measures, but the measure  
17 specifications themselves don't specifically  
18 delineate that information, although it's  
19 given in the overall manual that provides all  
20 of the specifications.

21 DR. RUSSO: I think that would be  
22 worthwhile including in each measure, so other

1 groups don't go through this again.

2 CO-CHAIR GIBBONS: Okay. So David  
3 has suggested we should vote the same way on  
4 this one, as on the last one, in essence  
5 without revoting.

6 Does anyone object to that? Is  
7 anyone going to vote any differently than they  
8 just did on the other measure on this one, now  
9 that they understand this nuance, which was  
10 not readily apparent from reading these?

11 (No response.)

12 CO-CHAIR GIBBONS: Everybody's  
13 nodding yes. So can I have anybody who's  
14 objecting to David's plan raise their hand?  
15 If not, we will assume that we're just going  
16 to record the votes as the same on this one as  
17 on the other one, and avoid voting, given the  
18 hour of the day.

19 I think we're all tired. So we  
20 are going to quit at this point. But when we  
21 come back tomorrow, I would point out that the  
22 first thing we're going to do is address

1 Measure 287, which is the median time to  
2 fibrinolysis, which is the companion to 164,  
3 which is the proportion of people treated  
4 within 30 minutes.

5 We are going to have to decide  
6 whether we want to report both of those out or  
7 how we're going to deal with that. It's a  
8 sort of very basic duplication, just a slight  
9 difference in the way they're reported out.  
10 What's the start time?

11 DR. WINKLER: Yes. In terms of  
12 starting tomorrow, the agenda calls for eight  
13 o'clock. We have access to this room shortly  
14 after 7:30. So we'll need a little time to  
15 set up. But if everybody could be here before  
16 eight o'clock, so that if you could grab your  
17 coffee and something to eat, sit down at eight  
18 o'clock, we go. All right. If we can get  
19 agreement for that, that would be helpful.

20 CO-CHAIR GIBBONS: Everybody think  
21 they manage to swing in here at 7:45, grab  
22 some coffee or thereabouts and get plunked



1 down so we can start work? All right. Well,  
2 I thank everybody for their perseverance  
3 through a long day.

4 DR. WINKLER: Thank you.

5 CO-CHAIR GIBBONS: And I think we  
6 accomplished a lot. It's a difficult process,  
7 and we knew from the outset looking at this,  
8 that this would be a challenge to get through  
9 everything. I think we've had good discussion  
10 and probably, as you know, had a longer  
11 discussion on those things that we turned  
12 down, than the things that we accepted.

13 But I think that was important to  
14 be fair to the measure developers.

15 DR. WINKLER: A couple of  
16 logistical things. Your voting gizmo, please  
17 leave. We'll get them back to you tomorrow.  
18 The flash drives you may take with you and  
19 load them onto your computers as you wish.  
20 We'll ask for them back tomorrow. Any other  
21 questions on sort of logistics?

22 CO-CHAIR GIBBONS: Do we have to

1 open anything for public comment right now?

2 DR. WINKLER: That would be a good  
3 idea.

4 CO-CHAIR GIBBONS: Any members of  
5 the public in the back wish to comment, or  
6 anybody on the phone?

7 (No response.)

8 CO-CHAIR GIBBONS: I think our  
9 diligence has exceeded the public diligence.  
10 All right. I think we're adjourned.

11 (Whereupon, at 5:32 p.m., the  
12 above-entitled matter went off the record.)

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<b>A</b>				
<b>AACBPR</b> 11:8	<b>accept</b> 295:20 306:8 339:18	<b>accomplishing</b> 218:1	263:1,19 330:6	<b>address</b> 16:19 23:22 24:19 31:7
<b>ability</b> 17:8 86:6 189:12 258:4 266:6 279:11	<b>acceptability</b> 28:18 28:20 30:16 37:14 59:10 60:16,18 62:5,22 68:21 69:12 73:15 93:22 102:21 103:14 117:2,4 118:8 123:17 133:22 138:6 155:9 159:20 163:14 170:22 171:15 176:7 193:6,8 194:22 203:20 207:12,20 215:17 219:20 224:18 240:1 246:13 284:8 286:3,16 292:11 350:8,10 357:3 366:4 368:5 375:8 382:13 386:18 391:9 396:22 401:12	<b>accord</b> 53:9 285:18 298:14 <b>accosted</b> 115:14 <b>account</b> 73:19 213:5 227:1 <b>accountability</b> 23:13 25:13 228:3 <b>accounted</b> 121:7 <b>accuracy</b> 235:22 274:21 300:22 345:16 <b>accurate</b> 67:1 198:6,18 201:20 258:19 341:1 <b>accurately</b> 258:7 <b>ACC-AHA</b> 45:2 47:18 207:4 217:2 <b>ACC-AHA-PCPI</b> 48:1 223:4 225:19 <b>ACE</b> 46:5 192:4 193:9 195:17 196:7,15,16 197:9 199:2,15 200:6,19 205:18 207:17 208:8 <b>ACEs</b> 208:21,22 <b>ACE/ARB</b> 202:13 <b>achieve</b> 32:18 162:14 173:13 296:7 298:2 <b>achieved</b> 33:1 <b>achievements</b> 38:3 <b>achieving</b> 72:2 74:20 75:9 165:15 175:3 184:12 <b>acknowledge</b> 144:7 175:12 186:21 <b>acknowledging</b> 101:2 <b>ACS</b> 333:12 353:12 <b>act</b> 26:6 291:6 295:18 311:18 314:20 <b>acted</b> 261:17 <b>action</b> 132:16	262:15 264:17 266:12 270:2,13 272:21 274:5 280:3 281:6 <b>actual</b> 7:6 139:13 257:17 299:22 306:13 <b>acute</b> 56:9 212:22 229:3,18 230:13 230:20 232:4 237:16 238:1 239:5,10 309:20 310:6,17,21 311:1 311:3,6 313:15,22 314:5,7 315:6,8 316:20 332:14,15 351:16 371:10,13 371:20 385:3 392:1 394:6 400:5 <b>add</b> 31:11 34:3 37:10 57:17 73:7 81:18 86:3 122:2 182:16 208:14 263:9 275:9 298:7 344:12 368:11 <b>added</b> 102:7 104:11 388:20 389:7 391:15 <b>addendum</b> 194:13 <b>adding</b> 101:22 153:14 204:14 276:22 382:22 <b>addition</b> 84:10 152:5 246:15 <b>additional</b> 18:21 59:22 61:1 101:7 156:19 266:18 289:21 336:3 361:9 369:5,10 372:17 384:10 410:3 <b>additive</b> 176:18	<b>addressed</b> 19:4 72:11,12 97:19 99:20 105:15 142:3 159:4 168:12 175:22 176:16,19 177:14 294:13 350:22 <b>addresses</b> 27:15 <b>addressing</b> 29:2 77:20 97:16 99:13 183:18 <b>adds</b> 152:20 <b>adept</b> 293:21 <b>adequate</b> 139:18 <b>adequately</b> 60:20 <b>adhere</b> 90:16 <b>adhered</b> 49:19 <b>adherence</b> 97:15 98:17,20 99:2,19 186:7 187:10,11 188:14 189:7 201:5,11,14 202:10,12,16 203:11,13,18 211:22 237:10 240:20 241:4,10 242:5 251:12 253:15,16 <b>adjourned</b> 418:10 <b>Adjournment</b> 4:22 <b>adjudicated</b> 249:8 249:15,20 258:6 <b>adjusted</b> 272:14 296:21 <b>adjustment</b> 31:1 94:19 156:5 164:12 182:14 185:1,10 188:6
<b>able</b> 26:1 34:14 36:16 51:13 55:8 130:21 170:2 182:3 240:18 242:8 248:12 249:21 264:20 266:12 267:11,14 272:16 301:11 325:14 340:21 382:1 412:5	<b>acceptable</b> 66:8 107:5 208:4 343:12 380:21 385:1,9 <b>acceptance</b> 238:11 267:1 <b>accepted</b> 66:1,3 240:15 417:12 <b>accepting</b> 66:14 265:11 <b>access</b> 86:20 347:9 349:19 364:8 370:21 374:13 394:16 399:15 406:5 407:19,22 409:9 416:13 <b>ACCF</b> 47:8 273:21 <b>ACCHA</b> 8:7 <b>accommodation</b> 120:12 <b>accompanies</b> 399:8 <b>accomplished</b> 417:6	<b>acted</b> 261:17 <b>action</b> 132:16		
<b>above-entitled</b> 113:3 307:15 418:12				
<b>absence</b> 66:10 68:1 94:10 179:2 216:7 256:13 262:3 289:14 365:17				
<b>absent</b> 140:15				
<b>absolute</b> 30:5 145:3 207:9				
<b>absolutely</b> 67:18 275:18,21 326:5 326:10 355:11 377:11 398:5				
<b>abstract</b> 242:8 339:5				
<b>abstracted</b> 249:22 335:5				
<b>abstraction</b> 207:14 258:13,16 301:4 378:10				
<b>abstractor</b> 139:3 144:2,3 205:12,20 206:9 248:7				
<b>abstractors</b> 139:16 335:6				
<b>academic</b> 79:21				
<b>Academy</b> 10:13				
<b>ACC</b> 10:3,7 45:14 47:8 49:17 105:14 106:7 141:12 310:18 355:5				

239:21 296:4,12 296:14,17 366:8 375:20 <b>adjustments</b> 61:12 61:13 <b>administered</b> 369:1 <b>administrative</b> 51:7 75:21 80:21 81:6,13,19 82:7 86:17 239:18 293:14 301:7 <b>administratively</b> 128:10 205:21 <b>administrators</b> 128:19 <b>admission</b> 315:12 413:19 <b>admissions</b> 408:14 <b>admit</b> 290:17 310:6 311:1 315:18 <b>admitted</b> 310:21 312:2 313:15 321:15 322:12 333:12 358:21 359:14 400:4 406:16 408:10 411:14 412:9,15 414:10 <b>admittedly</b> 217:6 <b>admitting</b> 314:13 <b>adopted</b> 23:19 <b>adult</b> 282:13 380:19 381:5 <b>adults</b> 56:7 <b>advanced</b> 47:12 <b>advantage</b> 206:7 <b>adverse</b> 172:13 <b>advising</b> 27:7 <b>advisory</b> 41:17,21 53:15 334:1 <b>advocated</b> 283:3 <b>advocating</b> 276:12 276:12 <b>affect</b> 121:22 246:2 <b>afflicts</b> 47:1 <b>afraid</b> 120:7 290:12	<b>African-America...</b> 389:22 <b>afternoon</b> 55:7,16 <b>age</b> 25:8 56:7 61:15 72:14 85:19,20 86:8 90:19 112:18 117:10 156:10,16 164:4 238:21 245:12 349:3 <b>aged</b> 133:5,6 162:9 192:9 212:9 219:22 <b>agencies</b> 27:18 <b>agency</b> 10:18 <b>agenda</b> 11:9 25:21 72:7 263:12 416:12 <b>agenda's</b> 149:22 <b>agent</b> 193:9,10 206:17 <b>agents</b> 114:7 134:4 <b>ages</b> 245:10 282:13 <b>aggressive</b> 76:8 <b>ago</b> 15:1 24:9 78:21 102:14 189:5 198:11 200:6 215:9 223:21 229:20 313:19 381:20 <b>agree</b> 60:1 87:7 98:18 100:6 140:10,11 143:9 145:21 209:13 216:17 226:9 238:9 275:21 276:3 283:13 325:10 352:17 374:7 396:4 413:6 <b>agreeing</b> 281:16 <b>agreement</b> 27:15 27:16 143:21 274:18 396:20 416:19 <b>agrees</b> 27:20 <b>AHA</b> 10:7 45:14 49:17 105:14 106:8 141:12	287:19 290:14,19 291:9 305:11 308:3 <b>ahead</b> 14:20 35:8 35:20 72:6 108:9 111:10 112:8 114:20 116:22 118:11 124:10 131:15 133:20 138:5 146:12 148:12 150:10 155:6 160:18 161:9,18 163:9 166:4 171:1 175:2 176:6 177:2,20 178:4 192:22 204:1 205:2 209:17 214:1 220:16 224:19 236:14 237:1 238:9 246:12 247:16 309:4 312:11 364:18,22 368:4 369:20 382:13 384:6,14 386:15 392:6 393:8 404:7,10 <b>aimed</b> 348:3 <b>aiming</b> 57:9 181:22 <b>air</b> 308:5 <b>airport</b> 343:18 <b>alert</b> 13:14 328:20 <b>align</b> 139:22 <b>aligning</b> 43:11 <b>alignment</b> 43:20 <b>alive</b> 56:8 151:4 237:20 239:4 294:8 <b>allergies</b> 122:10 134:17 180:5 <b>allergy</b> 119:22 220:7 <b>alleviate</b> 275:16 <b>alley</b> 135:2 <b>allocate</b> 18:18 <b>allow</b> 17:12,15 76:9 109:22 110:11	169:22 178:9 308:15 <b>allowed</b> 86:4 136:15 140:13 214:7 <b>allowing</b> 379:3 <b>allows</b> 34:12 136:7 207:9 <b>Allred</b> 1:15 11:14 11:15 275:9 312:8 312:12 316:15 317:18 318:13,21 319:5,9 322:6 326:1 340:21 341:10 350:9 356:20 357:15 360:18 <b>alluded</b> 249:12 294:3 <b>alluding</b> 261:13 <b>all-inclusive</b> 136:12 152:11 <b>alternative</b> 172:11 <b>Alzheimer's</b> 390:15 <b>AMA</b> 227:13 <b>amalgamated</b> 171:12 <b>ambitious</b> 149:22 <b>ambulance</b> 345:8 374:20 <b>amenable</b> 300:12 <b>America</b> 350:3 <b>American</b> 1:10,19 2:21,22 3:14 9:15 9:20 10:13 11:6 13:6 <b>Americans</b> 47:2 349:18 <b>AMI</b> 4:17 239:5 309:14 316:20 353:10,12 365:4 373:1 400:21 406:18 <b>AMIs</b> 401:4 <b>amount</b> 130:6 197:16 204:11 <b>analysis</b> 300:1	396:2 <b>analytic</b> 102:11 <b>analyzed</b> 52:22 <b>Andrea</b> 2:4 9:13 393:21 <b>ands</b> 273:17 <b>angina</b> 256:13 259:7,9 260:4,14 260:17,19,22 261:21 262:9 263:3 269:5,22 274:20 279:6,12 279:15 281:5,14 333:13 <b>anginal</b> 261:11 264:15 <b>angina-stable</b> 262:6 <b>angioedema</b> 205:19 <b>angioplasty</b> 56:10 127:13 230:3 271:20 276:19,19 <b>animal</b> 387:20 <b>Ann</b> 1:18 2:14 5:18 6:14 <b>Anne</b> 3:10 50:5,7 281:22 282:3 286:8,17 289:1 293:12 297:1 306:9 307:2 390:4 <b>Annie</b> 12:14 <b>announcing</b> 37:6 <b>annual</b> 314:3 <b>annually</b> 53:14 <b>answer</b> 28:4 35:9 35:16 87:5 183:13 208:13 241:20 243:14 246:7 312:4 317:12 334:22 351:21 <b>answered</b> 127:17 <b>answers</b> 36:2,6 74:4 80:16 182:22 <b>anterior</b> 230:4 <b>anti</b> 46:1 137:15 <b>anticipate</b> 18:19 <b>antithrombotics</b>
--	---	---	--	--

113:11,17	115:20 131:11	266:20 357:9	381:18 383:11	113:21 114:2
<b>anti-angina</b> 263:2	187:2 260:7	414:15	385:21 394:5,8,10	115:5 116:12
<b>anti-anginal</b>	<b>applications</b> 131:5	<b>approved</b> 54:1	395:6 397:4	117:6 119:4,22
266:14	<b>applied</b> 296:18	145:10 204:12	404:15 405:6	120:7,14 122:17
<b>anti-hypertensive</b>	310:5 313:8	267:17 302:19,22	<b>arrive</b> 5:6 33:7	126:19 127:11
94:5	314:17 321:6	<b>approves</b> 42:4	328:11 386:4	133:9 134:7 139:6
<b>anti-platelet</b> 8:9	322:14	226:17	404:22 405:1,2	144:4,5,6,22
114:6 117:7 119:4	<b>applies</b> 27:17	<b>approving</b> 303:7	<b>arrived</b> 342:15	146:16 180:16
119:10 132:15	245:10,12 313:14	<b>approximately</b>	<b>arrives</b> 326:13	243:16 244:2
134:4	319:17,19 322:19	61:18	<b>arriving</b> 381:2	282:21 283:7,15
<b>anybody</b> 37:18	332:5 390:20	<b>ARB</b> 192:4 193:10	<b>art</b> 62:3	284:11,11 286:13
44:11,17 57:16	400:3 407:18	195:17 197:9	<b>artery</b> 4:8 21:10	294:3,4 300:16
107:19 138:7	414:8	200:19	37:1 45:4,15	310:17 313:12,14
147:6 177:17	<b>apply</b> 25:11 41:5	<b>arbitrary</b> 97:12,21	46:21 56:10,20	314:8,15 315:4,16
217:15 235:20	109:12 237:6	378:5	93:8 133:8 153:6	365:3,3,7,10
246:22 307:6	238:6 312:22	<b>ARBs</b> 196:8 208:21	162:10 192:15	366:18 367:10
330:15 351:19	314:11 322:20	208:22	205:20 212:4,10	368:22 370:5,15
415:13 418:6	327:8 332:8 391:4	<b>Archives</b> 278:20	220:1 268:12	371:1,15,20 372:1
<b>anybody's</b> 278:3	406:11 412:5	<b>area</b> 2:3 9:11 12:19	282:16	372:5,13,22 374:6
<b>anymore</b> 325:20	<b>applying</b> 88:20	140:7 189:22	<b>articles</b> 274:16	374:9,18,22
<b>anyplace</b> 350:15	289:16	271:16 296:5	<b>Ashley</b> 2:15 5:10	380:12 381:1,5,10
<b>anyway</b> 209:4	<b>appreciate</b> 11:18	297:21 386:7	35:5,8,20 59:14	381:18 383:12,18
251:5 400:8	13:15 48:19	<b>areas</b> 20:15 46:18	60:2 114:20,22	414:1
<b>apart</b> 51:11	185:20 219:18	99:4 145:16	123:18	<b>aspirin's</b> 380:16
<b>apologies</b> 100:15	309:8 349:13	182:10 296:6	<b>Ashley's</b> 36:1	<b>assert</b> 141:1
<b>apologize</b> 309:12	350:3	349:18 350:11	<b>aside</b> 119:8	<b>assess</b> 173:2 194:4
343:18 378:18	<b>appreciated</b> 357:11	364:13 394:16,16	<b>asked</b> 18:5 28:4	263:19
<b>apparent</b> 415:10	<b>approach</b> 23:18	<b>arena</b> 274:16	32:21 33:3 38:10	<b>assessable</b> 257:10
<b>apparently</b> 94:13	40:18 90:2 102:11	<b>argue</b> 93:11 143:9	40:20 140:14,18	<b>assessed</b> 164:20
104:2 208:19	172:19 244:3	174:4 315:15	143:5 146:22	262:1
<b>appeal</b> 74:1 407:8	269:8 271:3	321:5,8 337:6	196:5 321:19	<b>assessing</b> 102:12
<b>appear</b> 120:17,18	379:17,19	346:1 358:13,16	329:14 368:1	274:17 280:3
125:9 138:11	<b>approaching</b>	374:19 378:1	376:5 411:13	281:17
211:5	384:16	<b>argument</b> 67:11	<b>asking</b> 26:17 29:14	<b>assessment</b> 29:7
<b>appeared</b> 92:10	<b>appropriate</b> 25:15	228:13 327:6	32:17 84:8 149:17	84:8,14 181:6,20
<b>appears</b> 100:7	42:10 54:11	329:16	254:8 268:13	256:6 261:3
102:7 117:4,17	201:21 209:11	<b>arguments</b> 244:15	269:3,12 272:19	264:17,18 265:4
125:1 147:10	214:8 268:4 320:6	<b>arisen</b> 184:8	275:13 351:15	265:16 266:11,12
<b>appendix</b> 333:7	<b>appropriately</b>	<b>arm</b> 144:10,10	352:12	276:2
334:12	76:10 89:19	<b>arrest</b> 403:2	<b>asks</b> 371:14	<b>assessments</b> 258:21
<b>appetite</b> 273:8	126:21 206:20	<b>arrhythmic</b> 229:9	<b>asleep</b> 364:20	263:14
<b>applicability</b> 96:10	383:17	<b>arrival</b> 316:18	<b>aspect</b> 174:14	<b>assign</b> 367:9
<b>applicable</b> 31:2	<b>appropriateness</b>	337:21 344:7	183:7 271:11	<b>assigned</b> 37:5
79:4	260:5 267:9	354:17 355:3	<b>aspects</b> 23:22 24:17	412:19,20
<b>application</b> 17:19	<b>approval</b> 19:2	363:8,12 365:4	178:19,20 179:8	<b>assist</b> 60:2
52:7,14 77:12	38:14 42:6 263:11	368:21 370:11,12	344:6	<b>assistants</b> 139:15
96:5 103:19	<b>approve</b> 39:4	370:15 371:15	<b>aspirin</b> 113:10,16	<b>associated</b> 229:9

<b>Association</b> 1:10 1:20 2:8,9 3:16 8:19 9:7 11:7 12:20 285:15 <b>assume</b> 250:6 253:4 370:20 415:15 <b>assuming</b> 287:5 337:3 390:12 <b>assumptions</b> 121:11 <b>Assurance</b> 3:18 <b>assure</b> 307:20 <b>assured</b> 307:19,21 <b>assures</b> 132:12 <b>asthma</b> 243:6,7,7 245:2,22 246:10 <b>astonishing</b> 349:22 <b>asymptomatic</b> 262:22 <b>atenolol</b> 218:11 <b>atomic</b> 340:14 <b>ATP-3</b> 151:17 <b>ATP-4</b> 43:15 175:21 288:13 <b>atrial</b> 145:1 <b>attack</b> 153:3 237:18 <b>attempt</b> 91:10 97:3 98:1 103:3 377:20 <b>attended</b> 51:18 <b>attending</b> 254:10 <b>attention</b> 180:4 385:15 <b>attest</b> 297:20 <b>attitude</b> 16:16 <b>attribute</b> 112:17 398:11 <b>attributing</b> 203:14 <b>attribution</b> 186:19 <b>audience</b> 15:5 <b>audiences</b> 31:9 <b>audited</b> 300:20 <b>Australia</b> 259:22 260:13 279:2 <b>author</b> 251:19 <b>authors</b> 206:13	240:22 <b>automated</b> 155:17 <b>autonomy</b> 170:5 <b>availability</b> 135:14 222:16 <b>available</b> 31:15 79:13 80:12 147:11,14 156:4 161:3 223:11 227:18 254:19 255:6,7 274:10 290:6 360:19 397:18 <b>availing</b> 255:1 <b>average</b> 53:3 115:22 <b>avoid</b> 34:16 110:13 415:17 <b>awake</b> 386:16 <b>aware</b> 43:5 89:22 176:2 199:18,20 226:10 271:10,12 397:10 <b>awfully</b> 377:6 <b>Ayala</b> 1:17 9:5,5 83:18 86:3 128:1 187:22 200:10 211:18 213:16,22 216:4 219:19 220:16 222:5,10 224:16 227:5 232:18 234:6 235:8 237:9 238:12 245:16 247:7,19 268:9 323:6 340:10 341:4 344:12 346:1 349:11 398:18 <b>A-F-T-E-R-N-O-...</b> 192:1 <b>a.m</b> 1:11 5:2 113:4 113:5 385:14 <hr/> <b>B</b> <hr/> <b>b</b> 101:4 219:10 230:19	<b>baby</b> 380:15 <b>back</b> 26:20 33:13 34:3 39:8 41:18 41:21 50:19 59:13 60:15 70:18 73:20 74:2 76:21 83:19 85:12 90:9 91:15 113:1 115:10 124:1,2 142:8 145:19 146:18 149:4,10 170:15 184:2 186:3 193:5 199:19,22 202:22 204:9,15 209:6 219:19 229:2 239:17 241:22 246:8 253:13,22 254:11 265:12 283:2 289:13 291:21 303:16 307:12,14 308:16 325:7,14 332:3 333:7 343:19 345:8 347:14 350:12 375:11 377:9 411:12 415:21 417:17,20 418:5 <b>backdrop</b> 351:17 <b>backed</b> 394:12 <b>background</b> 50:14 284:3 311:8 312:14 <b>backgrounds</b> 16:6 <b>badly</b> 189:18 <b>balance</b> 55:1 98:1 188:19 206:18 <b>balances</b> 187:18 <b>balloon</b> 340:13 363:13 387:16 389:4 391:16 403:9 <b>banged</b> 103:2 <b>bar</b> 181:5 275:2,6 <b>bare</b> 308:8 <b>barriers</b> 190:18 <b>base</b> 59:6 64:15	66:4 67:12 69:1 70:19 95:19 96:11 <b>based</b> 59:5 60:10 81:22 106:16 118:2 151:12 176:3 213:13 217:21 253:3,6,11 284:15 304:6 314:4 316:2 329:18 330:2 347:22 351:4 374:15 397:18 405:9 <b>basic</b> 152:2 337:2 416:8 <b>basically</b> 6:10 56:6 56:15 61:3 126:6 134:11 175:4 214:5 219:12 265:14 283:4 285:2 300:19 352:19 364:2 394:3 404:19 <b>basics</b> 21:12 <b>basis</b> 219:12 285:13 292:7 386:10 397:10 <b>bat</b> 301:12 <b>batch</b> 59:22 60:6,7 93:2 <b>batches</b> 59:21 <b>beat</b> 351:6 <b>becoming</b> 203:8 297:15 <b>bed</b> 377:9 <b>beds</b> 347:10 <b>beginning</b> 7:9 16:3 118:21 195:12 <b>begun</b> 235:3 <b>belabor</b> 154:2 <b>believe</b> 7:2,6 12:11 22:8 43:16 45:17 51:16 63:3 89:6 115:11 118:20 138:14 157:10 186:2 200:8 234:11 278:2	304:21 308:14 372:19,21 376:17 393:3 405:20 406:4 <b>believed</b> 286:20 <b>belong</b> 235:4 <b>Beltrame</b> 278:21 <b>beneficial</b> 216:7 372:11 <b>benefit</b> 63:14,16,17 63:22 65:11 71:3 71:11,12,18 76:2 89:10 136:21 197:9 203:8,10 215:4,11 224:2 229:5 230:11 244:16 251:8 288:2,6,7 347:16 365:10 372:9 373:7 374:6 <b>benefits</b> 114:2 122:18 182:19 229:8 <b>benefitted</b> 229:5 327:19 <b>best</b> 7:5 29:15 33:4 143:1 145:17 146:2 150:15 178:19 189:17 209:5 280:14 306:18 359:1 <b>bet</b> 280:7 354:21,22 <b>beta</b> 46:2 197:13,15 200:22 201:16 211:14 212:4,14 213:3,5 214:13,18 214:22 215:5,10 216:6,13 218:12 219:1,11 220:12 224:21 228:7,15 228:20 229:4,12 229:14,22 230:7 230:11,16 232:1 233:3,15 237:4,13 237:17 238:2,5,14 240:17 243:1,3,10 245:19,20 246:2,4
---	--	--	---	--

<b>better</b> 15:11 24:11 49:3,10 51:20 66:6 118:3 127:20 132:10 149:2,9 166:7 188:2 191:2 210:4 276:18 278:13 289:12 311:12 320:18,21 343:2 348:11 358:5 364:7 385:16 389:12,17	<b>block</b> 111:13 242:21 395:6,9,15 <b>blockade</b> 232:1 <b>blocker</b> 197:13,15 201:16 212:5,14 213:5 215:1,10 220:12 224:21 228:8,15,20 229:12,22 230:7 233:3,15 237:4,13 237:17 238:2,5 240:18 243:1,3,10	299:14,16 301:21 302:11 303:1 304:10 <b>board</b> 11:15 12:15 15:15 106:10 273:11 <b>board-certified</b> 11:2 <b>boat</b> 102:13 <b>Bob</b> 40:6 <b>body</b> 101:12 <b>boilerplate</b> 223:3 223:13 <b>book</b> 275:17 <b>BOSSLEY</b> 2:13 <b>Boston</b> 2:1 8:6 12:5 <b>bothers</b> 370:4 380:22 <b>bothersome</b> 246:18 <b>bottom</b> 35:6 92:14 256:19 296:16 <b>bought</b> 66:19 <b>box</b> 27:3,3 265:7 <b>boy</b> 190:9 <b>bracket</b> 395:7 <b>bradycardia</b> 220:7 <b>branch</b> 395:6,8,14 <b>branching</b> 411:7 <b>Bratzler</b> 2:19 309:1 309:2,10 310:11 313:10 320:14 322:5,8 327:3,20 328:13 332:2,16 334:11 335:19,22 337:10 339:3 343:17 344:1 352:5 353:4 354:1 354:21 358:12 359:4,19 360:4 371:5 374:2 376:9 376:15,19 377:15 379:18 381:7 382:5 388:12 398:4 399:22 400:18	191:2 292:21 307:11,13 <b>breaks</b> 20:5 <b>brief</b> 40:2 45:11 50:14 56:6 113:18 162:8 192:7 279:22 309:11 311:7 <b>briefly</b> 28:7 90:10 309:13 310:15 <b>Brigham</b> 1:22 12:6 <b>bright</b> 208:6 <b>bring</b> 24:17 27:14 33:12 41:21 73:20 99:17 125:7 128:2 225:4 246:8 318:8 328:6 <b>bringing</b> 20:20 26:12 253:13 254:13 <b>broad</b> 119:9 312:22 <b>broaden</b> 313:4 <b>broader</b> 25:10 152:21 313:5 331:14,20 333:14 <b>broadest</b> 41:2 <b>broadly</b> 207:17 282:15 <b>broken</b> 116:6 <b>Bruce</b> 1:22 12:4 113:11,12 115:8 117:2 124:4 132:3 150:15 196:3 <b>Bruce's</b> 132:18 <b>BSN</b> 2:23 <b>Bucindolol</b> 219:2 <b>building</b> 308:5 <b>built</b> 51:6 110:16 <b>bunch</b> 190:13 286:6 <b>bundle</b> 394:7 395:6 395:8,14 <b>burden</b> 31:15 80:5 151:15 207:14 262:15 279:21 392:18 <b>burdensome</b> 86:13	<b>Burlington</b> 10:22 <b>Burstin</b> 2:14 5:14 14:8,11,12 36:10 38:21 88:9,22 125:21 131:2 142:13,14 146:21 189:3 206:3 253:2 273:4,5 290:10 <b>business</b> 2:8 8:18 254:5 <b>busy</b> 6:4 <b>button</b> 35:10 <b>buttons</b> 58:1 <b>bypass</b> 56:10 152:19 <b>byproduct</b> 124:18 161:2 232:19 247:20 360:20 <b>B-E-L-T-R-A-M-E</b> 278:21
<b>betting</b> 355:9 <b>beyond</b> 99:10 175:13 231:1 313:4 385:10 <b>bias</b> 325:22 <b>BID</b> 214:6 <b>big</b> 14:20 119:5 224:6 234:7 280:12 318:3 323:3 325:18 388:2 <b>bigger</b> 87:8 362:4 <b>biggest</b> 26:17 <b>billable</b> 54:15 <b>billion</b> 47:3 <b>bills</b> 252:17 <b>bisoprolol</b> 213:9 <b>bit</b> 34:18 35:19 40:22 67:22 68:5 91:22,22 123:22 131:7 183:9 191:3 194:10 197:3 198:5 242:6 257:4 290:17 295:9 309:7 331:8 370:5 371:21 372:12 385:10 397:2 398:16 <b>bits</b> 150:3 <b>black</b> 29:6 34:2 70:15 <b>blame</b> 83:1 <b>blanket</b> 186:10 <b>bleed</b> 119:22 <b>bleeding</b> 121:5 122:12 134:18	<b>blood</b> 41:5,12 45:20 53:7,11,16 53:18 54:3 55:19 56:5,12,21 60:18 60:20,21 61:5,9 63:15,22 64:6,11 64:18 65:6,6,13 65:22 66:6,7,14 66:19 67:2,10 71:14 74:13,15,16 77:14,16 86:6 88:1,18 89:9,15 90:3,20 91:4 92:7 93:7,10 94:2,3 95:2 96:16,21 97:5 98:9 99:15 100:16,20 101:21 104:7,9 107:1 111:5 120:3,8 144:9 179:20 180:15 262:21 265:5,15 282:20 283:7,14 284:15 285:4,16 286:16 287:3 288:3,8 291:9 294:21 295:13 298:14	<b>break</b> 71:10 111:18 112:16,21,22	<b>bring</b> 24:17 27:14 33:12 41:21 73:20 99:17 125:7 128:2 225:4 246:8 318:8 328:6 <b>bringing</b> 20:20 26:12 253:13 254:13 <b>broad</b> 119:9 312:22 <b>broaden</b> 313:4 <b>broader</b> 25:10 152:21 313:5 331:14,20 333:14 <b>broadest</b> 41:2 <b>broadly</b> 207:17 282:15 <b>broken</b> 116:6 <b>Bruce</b> 1:22 12:4 113:11,12 115:8 117:2 124:4 132:3 150:15 196:3 <b>Bruce's</b> 132:18 <b>BSN</b> 2:23 <b>Bucindolol</b> 219:2 <b>building</b> 308:5 <b>built</b> 51:6 110:16 <b>bunch</b> 190:13 286:6 <b>bundle</b> 394:7 395:6 395:8,14 <b>burden</b> 31:15 80:5 151:15 207:14 262:15 279:21 392:18 <b>burdensome</b> 86:13	<hr/> <b>C</b> <hr/> <b>C</b> 2:6 326:7 <b>CABG</b> 151:4 152:5 152:19 <b>CAD</b> 40:9 41:11 44:4 132:15 134:12 163:5 192:10 193:11,11 193:12,20,21 196:12 197:9 233:16 256:7 302:12 <b>calculate</b> 127:9 202:4 <b>calculated</b> 177:11 <b>calibrate</b> 340:22 <b>calibration</b> 66:18 <b>call</b> 18:22 27:6 34:1 41:17 73:14 140:21 144:18 146:1 147:7 151:20 155:3 206:4 251:16 280:19 328:2 332:4 343:19 369:20

<b>called</b> 36:13 42:3	89:11 274:22	112:20 148:21	72:2 74:1 90:19	154:5 282:4
<b>calls</b> 336:10 416:12	279:7 313:20	243:17 258:8	100:6 103:3	<b>chances</b> 222:3
<b>Canadian</b> 274:22	<b>cardio-hit</b> 266:8	285:8 314:6	130:12 172:18	255:9
279:6	<b>care</b> 9:6 22:17,21	321:14 327:8	182:10 197:14	<b>change</b> 43:8 54:3
<b>Candidate</b> 4:6	23:8,9 24:1 25:14	334:17 335:1	216:6 252:2	88:15,16 101:9
<b>candidates</b> 325:20	47:3 50:13,17	346:10 360:3	266:19 296:5,6,8	106:13 142:22
<b>capability</b> 399:21	51:15,18 52:2,5	362:9 385:13	320:6 326:18	148:19 211:22
<b>capable</b> 312:19	96:15,20 98:11	389:13 400:22	377:16	222:3 226:4,13
<b>capacity</b> 266:13	108:19 117:14	401:1,2,4	<b>certainly</b> 7:14	231:5,10 287:10
<b>capped</b> 318:3	124:18,19 161:2	<b>cases</b> 88:4 271:21	20:17 24:22 70:15	290:6 292:6 295:2
<b>capture</b> 34:12	162:13 163:20	314:4 315:10,14	75:18 119:3 120:5	306:5,14,15
140:7 200:17	182:12 187:12	329:6 376:12,14	122:10 123:13	343:14,15
266:6 341:19	201:21 204:13	376:15 377:2,7,12	171:20 173:12	<b>changed</b> 53:7
406:20 410:15	208:1 232:19	380:5,7 400:19,21	185:1 190:1 223:5	285:10 295:14
<b>captured</b> 86:12	242:10 247:20,21	401:6 402:17	263:17 268:16	298:16 382:8
382:21 406:15	252:18 264:9	<b>catch</b> 195:22 248:9	294:7 298:9 321:7	389:15
408:9,11 411:11	268:12 270:7	309:13	382:7 395:1	<b>changes</b> 54:1 176:4
<b>captures</b> 41:3	271:7,11 272:4	<b>categorically</b> 120:2	405:10 414:11	225:22 226:13
<b>capturing</b> 406:14	275:12,14 280:13	<b>categories</b> 41:11	<b>certification</b> 11:12	231:20 296:19
<b>carbetalol</b> 213:9	281:22 283:5,9,14	110:2,3 121:13	<b>cessation</b> 129:10,14	<b>changing</b> 24:7
214:17	297:6 298:1	<b>categorization</b>	130:1,4	123:22 287:5
<b>card</b> 392:21	299:11,13 300:11	194:11	<b>cetera</b> 99:9 114:9	<b>Chapel</b> 2:6
<b>cardboard</b> 250:18	302:12 311:6,22	<b>category</b> 41:2	120:1 154:13	<b>characteristic</b>
252:22	312:3 316:2 342:5	110:3 195:13	158:8 180:15	405:4
<b>cardiac</b> 12:7,16	344:22 345:11,20	201:6 220:13	222:17,17	<b>characteristics</b>
222:19,20 223:9	360:20 364:8	<b>cath</b> 230:2 328:16	<b>chad</b> 82:22	29:22 182:1
311:6 315:7,8	368:21 383:14	328:18,20	<b>chair</b> 45:1 102:22	<b>characterized</b>
316:21 327:12	386:8 392:11,16	<b>catheter</b> 322:18	112:13 124:13	181:11
332:21,22 333:6	408:6	<b>Caucasian</b> 297:10	132:13 292:21	<b>charge</b> 54:15
334:6,21 335:17	<b>careful</b> 64:21	<b>Caucasians</b> 389:20	303:11 364:19	<b>chart</b> 81:11,17,21
344:9 345:13	348:15	396:13,16	<b>chaired</b> 324:15	82:4,4,9 157:3
351:11 352:2	<b>carefully</b> 7:5	<b>caught</b> 257:7	<b>Chairman</b> 11:15	180:7 207:16
353:16,16,19,20	286:13 296:17	<b>cause</b> 47:4 57:2	<b>chairs</b> 5:22 49:1	262:7 334:15,17
359:8 371:13	300:20	352:8	<b>challenge</b> 17:2 18:7	335:4 336:5 355:6
374:17 403:2	<b>caregiver</b> 100:21	<b>cautious</b> 128:15	60:2 107:16 154:1	355:7 366:10
<b>cardiogenic</b> 403:6	<b>Carol</b> 1:15 11:14	<b>CCS</b> 1:19 269:6	202:1 274:15	369:2 381:17
<b>cardiologist</b> 10:1,6	316:11 365:9,9	<b>CDAC</b> 387:1	301:11 343:9	383:15 402:10
10:21 11:22 12:7	390:4	<b>CDC</b> 8:3	417:8	403:8
49:13 127:20	<b>Carolina</b> 1:21 2:6	<b>ceiling</b> 18:1 210:7	<b>challenged</b> 29:8	<b>charts</b> 245:5
279:16	10:5,12	<b>census</b> 297:9,10	<b>challenges</b> 203:5	252:10 271:18
<b>cardiologists</b> 47:9	<b>carotid</b> 282:17	<b>center</b> 1:10 2:1,10	203:12 234:1,4,6	<b>chart-abstracted</b>
47:10 271:18	<b>Carpe</b> 385:18	8:7 79:22 325:12	<b>challenging</b> 90:22	335:3
<b>Cardiology</b> 2:21,23	<b>carry</b> 147:17	338:17 378:10	257:4 275:6	<b>chases</b> 252:3
9:16,20 12:2	<b>cart</b> 340:7	<b>centered</b> 267:6	288:14	<b>cheaper</b> 255:2
<b>cardiovascular</b> 1:3	<b>cart's</b> 327:1	<b>Centers</b> 1:14 7:18	<b>champion</b> 311:10	<b>check</b> 304:21
1:9 5:11 8:1 11:3	<b>carvedilol</b> 221:11	<b>CEP</b> 106:7	<b>chance</b> 35:8 71:10	344:17 356:15
21:5,6 40:13 63:6	<b>case</b> 43:7 89:16	<b>certain</b> 16:15 61:2	73:19 106:13	<b>checkbox</b> 169:3



<b>checked</b> 265:7	253:3,11 315:13	368:16 372:2	400:2	402:9
<b>checkered</b> 92:1	354:5	391:16 409:20	<b>closely</b> 15:14	<b>collecting</b> 259:4
<b>checklist</b> 340:6	<b>claims-based</b> 81:5	<b>Cleveland</b> 1:18	<b>closer</b> 77:2 270:13	266:18,21 397:21
<b>checks</b> 340:7	81:6	12:1	344:19 346:15	<b>collection</b> 78:22
<b>chest</b> 311:4 315:6,7	<b>clarification</b> 37:22	<b>click</b> 409:19	<b>closest</b> 394:8 395:6	147:20 250:7
316:20,21 319:20	42:22 67:5 88:17	<b>clicked</b> 404:9	<b>clothes</b> 308:9	369:8 384:1
327:9 329:9	91:16 121:10	<b>clicker</b> 85:4 404:12	<b>CMS</b> 22:1 46:13	<b>College</b> 2:21,22
331:15 332:7,18	131:3 157:14	<b>clickers</b> 82:15	207:21 233:2	9:15,20 13:6
332:20,21 333:6	304:16	<b>climbing</b> 262:9	235:11 308:14,16	<b>Collette</b> 2:23 50:2
333:14,16 334:6	<b>clarified</b> 179:17	<b>clinic</b> 1:15,18 2:10	308:20 311:18	298:6
334:14,20,20	<b>clarify</b> 38:10 100:4	10:21 12:1 263:7	313:18 351:20	<b>Colorado</b> 1:23 2:2
335:12,18 344:9	201:1 234:11	279:15	357:8 376:21	8:15,16 9:3,4
351:11 352:2,7,14	245:12 265:1	<b>clinical</b> 86:15 96:1	378:9 398:8	<b>Colorado-Denver</b>
352:21 353:10,14	289:1 302:21	96:5,10 98:1	414:15	44:22
353:16,20,21	378:20 380:10	114:8 120:12	<b>coagulation</b> 134:18	<b>combination</b> 82:4
359:8 367:8	<b>clarity</b> 106:19	121:19 122:4,6	<b>Coalition</b> 1:15,18	<b>combined</b> 154:16
371:13 372:21	<b>class</b> 33:4 143:1	128:20 151:13	11:16	<b>come</b> 20:4 26:20
374:17,22 380:17	145:17 146:3	155:4 167:3 172:9	<b>code</b> 54:12,15	33:22 43:6,16,17
<b>chewed</b> 370:8	269:6 313:5	175:9 184:19	233:6,14,17 245:4	43:18 48:18 55:6
<b>Chicago</b> 12:19	333:14 360:11	185:4,9 201:21	335:10	58:8 59:9 74:2
<b>chime</b> 387:10	<b>classic</b> 258:14	204:13 207:19	<b>coded</b> 153:8 154:5	82:17 85:12 91:15
<b>Cho</b> 1:18 11:21,22	<b>classification</b>	208:1 212:21	<b>codes</b> 117:19	103:12 106:16
<b>choices</b> 30:2 35:20	152:21 275:1	263:15 274:16	153:15 154:8,12	107:22 119:11
<b>cholesterol</b> 41:6,13	279:7	292:1 293:15	154:13,13 205:9	127:20 141:20
180:15 283:14	<b>classifications</b>	301:8 378:9 392:9	235:19 239:14,15	145:19 146:17
<b>choose</b> 136:8	331:15	<b>clinically</b> 76:10	239:20 240:7	165:17 166:10
241:12	<b>clear</b> 24:14 46:20	95:3,17 126:17	286:11 333:14	169:4 175:20
<b>chose</b> 209:17	92:3 93:11 97:2	158:19 174:11	334:13,14	189:8 201:4 208:4
219:13 244:1	104:5 117:1 121:8	197:19 209:11	<b>coding</b> 41:10	218:7 250:14
<b>Christine</b> 2:8 8:17	134:13 135:4	<b>clinically-enhanc...</b>	153:17	256:22 265:18
<b>Christine's</b> 256:7	136:4 157:17	51:6	<b>coffee</b> 416:17,22	272:22 303:16
<b>chronic</b> 193:21	165:13 167:2	<b>clinician</b> 76:18	<b>cognizant</b> 98:4	315:5 336:17
212:4 260:8	182:17 202:9	81:16,20 86:5	<b>cohort</b> 76:6 246:15	344:4 347:6 348:5
<b>chronically</b> 120:4	207:6 229:4	222:2 240:10,12	<b>cohorts</b> 193:18	358:2 361:22
381:13 382:10	273:12 292:20	<b>clinicians</b> 26:8	<b>cold</b> 11:18	364:12 367:14
<b>cite</b> 317:16,18	295:20 301:9	80:20 139:14	<b>collaborative</b> 51:3	380:18 415:21
<b>cited</b> 223:16,17	303:12 305:10	<b>clinics</b> 52:17,18	<b>collect</b> 11:12 61:21	<b>comers</b> 321:20
365:13	310:10 339:13	53:1 259:22	148:6 258:5	<b>comes</b> 18:1 25:7,8
<b>Cities</b> 297:21	373:4,5 375:10	260:13,16 279:2	266:13 267:11	61:16 131:5 139:4
<b>city</b> 49:13 328:19	413:16 414:8	<b>clock</b> 59:14 340:18	274:14	153:1 165:13
399:20	<b>clearly</b> 31:17 52:7	388:1	<b>collected</b> 78:21	186:12 189:13
<b>CKD</b> 305:14,15	66:12 94:1 95:6	<b>clocks</b> 340:12,15	79:5 108:19	198:8 199:22
<b>claim</b> 235:19,21	117:17,21 160:8	341:8	124:21,22 125:2	200:4 221:1 229:1
249:8	179:9 181:8	<b>clopidogrel</b> 133:9	148:5 232:20	319:19 352:20
<b>claims</b> 51:7 61:22	182:20 190:14	134:7	247:22 258:7,12	380:11 389:2
81:14 164:14	273:8 293:1	<b>close</b> 173:14 223:6	263:6 267:11	<b>comfortable</b> 78:13
233:2 249:15	327:21 365:12	318:16 342:1	274:2 397:18	110:15 262:18

<b>coming</b> 99:6 127:19 141:18 142:4 159:12 190:21 195:6 210:6,9 215:13 231:12 290:21 328:19 346:22 348:13	161:15 176:20 177:15 178:3,9,12 192:17,18 203:19 210:21 212:1 236:19 237:5 241:13 247:12 293:13 301:12 305:6,22 309:12 349:13 366:15 368:12 369:10 372:17 384:3 386:12 392:3 395:4 398:19,22 399:6 402:1 403:14 404:3 405:13	187:14 <b>communication</b> 265:21 <b>communities</b> 26:11 <b>Community</b> 2:24 3:10 50:1,3,11,16 51:1,4 107:13 123:2 282:1 298:7 306:8 <b>comorbidity</b> 53:10 <b>companion</b> 416:2 <b>company</b> 249:9 <b>comparability</b> 156:5 165:3 375:22 <b>comparable</b> 31:5 <b>compare</b> 52:4 376:10 407:11 <b>compared</b> 14:19 92:1 110:20 142:16 320:4 341:6 389:21 <b>comparing</b> 326:8 <b>comparison</b> 31:12 83:14 146:10 179:14 387:1 <b>comparisons</b> 143:17 184:15 <b>compete</b> 142:22 <b>competing</b> 29:2 31:22 33:4 83:15 143:13 <b>competitive</b> 255:7 <b>compiled</b> 336:21 <b>complain</b> 353:13 <b>complaining</b> 352:14 <b>complaint</b> 352:21 <b>complete</b> 28:4 108:13 151:9 157:16 402:6 <b>completed</b> 33:7 60:3 103:21 161:22 <b>completely</b> 30:3 90:17 111:21 138:8 147:7	148:14 172:14 176:9 177:5,22 186:20 204:4 205:4 210:18 227:2 232:16 236:15 246:20 247:17 255:12 276:3 292:15 300:9 301:17 357:12 360:15 361:5 368:18 369:14 382:14 383:7 384:8 391:10 401:14 403:22 <b>complex</b> 99:2 153:14 273:17 285:5 <b>complexity</b> 110:5 152:8 <b>compliance</b> 128:5 128:17 190:7,13 211:21 <b>compliant</b> 182:9 <b>complicated</b> 65:10 <b>complications</b> 119:22 <b>complimented</b> 288:11 <b>complying</b> 188:19 <b>component</b> 51:14 53:8 <b>components</b> 51:13 330:17 <b>composite</b> 51:12,16 267:20 283:3 298:12 <b>composites</b> 24:18 <b>comprises</b> 30:11 <b>computer</b> 82:6,7 <b>computers</b> 417:19 <b>conceivably</b> 109:12 <b>concept</b> 41:20 190:12 320:8 323:2 <b>concern</b> 17:18 58:6 62:6,9,16 63:1,19	64:14 77:19 86:10 88:20 105:17 109:11 123:4 127:1 168:4 169:12 188:20 200:20 273:10 289:18 291:19,20 293:19 296:15 298:4 302:3 389:8 <b>concerned</b> 17:7 90:6 101:19 102:3 200:20 208:11 286:15 364:19 <b>concerns</b> 62:21 63:10 65:1 66:17 94:18 108:22 172:1 177:13 236:10 283:18 <b>conclude</b> 55:4 <b>concluded</b> 54:2 <b>conclusion</b> 99:1 <b>concomitant</b> 134:19 <b>concomitantly</b> 389:6 <b>concordance</b> 275:4 <b>concur</b> 101:13 175:15 <b>concurrent</b> 147:12 <b>condition</b> 24:1 39:7 58:16 295:12 360:7 <b>conditional</b> 84:12 <b>conditionally</b> 39:5 <b>conditioning</b> 308:5 <b>conditions</b> 27:13 61:4 85:9 86:1 265:10 <b>conducted</b> 274:11 <b>conference</b> 1:10 18:21 140:21 144:18 146:1 336:10 <b>confident</b> 235:9 <b>confirm</b> 164:2 389:12 <b>conflict</b> 6:16 7:6
<b>comment</b> 4:13 13:10 20:7 33:11 33:19 42:15 48:5 48:10,14 65:17,19 72:9 73:6 75:17 77:10 94:22 95:9 98:19 103:6,10 105:4 109:6 121:15 122:8 126:10 127:6 131:17 135:19 141:4 157:5 169:9 171:2 173:4 178:13 179:16 186:1,5 199:4 205:11 214:11 216:4 245:9 253:2 253:13 286:17 291:16 296:1,10 298:8 308:17 320:11 330:2 331:20 379:16 403:12 418:1,5	<b>Commitment</b> 105:10 <b>commitment</b> 293:10 364:14 <b>committed</b> 48:7 <b>committee</b> 1:4,9 3:17 6:1 13:3,15 14:14 19:14 21:17 26:5,15 30:7 32:21 33:3,8 36:11 37:10,12,19 39:2,21 42:3,3 49:1,11 53:15 54:1 85:9,16 88:17,20 98:22 106:6 107:12 115:15 123:21 132:6 145:19 147:1 161:22 162:22 186:4 189:6 205:16 225:2 226:17 286:20 302:1 308:3	<b>Commission</b> 105:10 <b>commitment</b> 293:10 364:14 <b>committed</b> 48:7 <b>committee</b> 1:4,9 3:17 6:1 13:3,15 14:14 19:14 21:17 26:5,15 30:7 32:21 33:3,8 36:11 37:10,12,19 39:2,21 42:3,3 49:1,11 53:15 54:1 85:9,16 88:17,20 98:22 106:6 107:12 115:15 123:21 132:6 145:19 147:1 161:22 162:22 186:4 189:6 205:16 225:2 226:17 286:20 302:1 308:3	<b>commentary</b> 16:2 17:22 19:6 33:12 37:7 42:20 48:22 62:17,21 65:1 68:13 72:10 76:6 79:8 83:19 86:5 104:10,14 108:5 109:1 111:6,16,19 112:5,10 114:17 118:8 119:16 124:7 125:19 126:9 127:14 138:21 145:5 148:9 149:2 150:9 154:22 156:7 157:21 160:14	<b>committees</b> 16:8 29:8 284:19 291:6 <b>common</b> 41:8 200:8 <b>Commonwealth</b> 2:7 11:5 <b>communicating</b>

144:15,21 284:18	<b>consistency</b> 141:1 285:11	<b>control</b> 1:14 7:18 45:21,21 56:13 66:7 74:17,20 93:8,10 95:14 96:16,22 97:5,13 98:7,9 99:7,11,17 100:21 101:1,4,5 120:8 150:19 154:16,18 159:11 218:10 222:13 224:14 260:10,21 261:4,21 263:3 265:5,15 266:5 272:15 276:11 279:12 285:16 287:4 288:5 298:2 299:2 345:4	228:14,19 229:13 229:18 230:11,13 230:20 231:10 232:2 260:2,8 262:6 263:8 264:10 268:12,21 269:21 279:21 282:16 283:16 285:15 287:22 288:9 291:1 332:14,15 351:16	408:15 <b>counting</b> 34:16 <b>country</b> 16:5 297:12 362:5 374:21 <b>counts</b> 57:21 <b>couple</b> 40:13,16,19 43:13 44:3,6 62:7 68:12 149:16 189:5 273:7 295:6 344:3 365:16 374:3 399:4 417:15 <b>coupled</b> 25:16 <b>course</b> 38:22 41:18 42:8,16 48:16 56:17 74:22 90:14 105:12 226:2 238:13 246:1 301:3 317:2 318:16 367:9,14 <b>cover</b> 40:16 41:3 107:6 121:4 <b>coverage</b> 99:8,9 252:1 <b>covered</b> 56:18 87:4 106:14 123:6 <b>co-chair</b> 1:14,15 6:3 7:11,17 15:6 15:19 19:9 38:8 39:20 44:15 49:4 49:9,21 55:5,10 57:12,16,19 58:5 58:9,12 59:12,16 60:1,14 62:4,20 64:22 65:18 67:16 67:19 70:17 72:5 72:20 73:5,6,13 73:22 74:9 75:18 76:20 77:1,9,18 79:7 80:7,18 81:1 82:10,14,19 83:2 84:17 85:3,13 88:7,19 89:4 90:8 91:12 93:16,19 95:5 97:8 98:14 100:3 101:6,16
<b>confused</b> 409:2 411:7 <b>confusing</b> 75:1 91:22 331:8 <b>congestive</b> 229:16 324:18 333:1 <b>congratulate</b> 161:21 <b>congratulations</b> 132:3 <b>conjunction</b> 45:3 <b>connotes</b> 353:21 <b>consecutive</b> 252:9 <b>consensus</b> 21:15,20 27:2 <b>consequence</b> 57:8 <b>consequences</b> 98:5 98:6 109:3 110:13 110:17 125:10,12 125:17 131:18 135:3 182:8 277:22 300:18 369:7 402:14 <b>consequently</b> 336:9 <b>conservatively</b> 384:21 <b>consider</b> 57:6 67:7 70:2 85:12 91:6 101:8 107:5 183:17 185:18 205:17 246:3 277:19 321:20 <b>considerable</b> 141:16 162:16 <b>considerate</b> 7:21 <b>consideration</b> 4:6 70:13,16 73:12 91:18 96:13 193:17 281:1 <b>considerations</b> 290:1 <b>considered</b> 67:8 69:7 92:12 161:14 310:7 <b>considering</b> 107:1 182:14 216:9	<b>consistent</b> 185:14 221:12 225:3 226:18 231:16 232:11 343:15 <b>consistently</b> 343:7 <b>constantly</b> 355:12 <b>construct</b> 353:7 <b>constructed</b> 69:13 <b>constructing</b> 152:9 <b>construction</b> 129:19 <b>constructive</b> 123:21 <b>consumer</b> 167:9 320:17 363:22 364:4 <b>consumers</b> 26:10 52:1 138:13 <b>contains</b> 109:18 <b>content</b> 164:20 <b>context</b> 15:3 141:22 166:2 <b>contextual</b> 130:8 <b>continue</b> 22:14 55:2 <b>continued</b> 41:22 146:4 193:15 <b>continues</b> 166:16 <b>continuing</b> 25:22 367:4 <b>continuous</b> 239:1 <b>continuously</b> 335:7 <b>contract</b> 347:19 379:22 <b>contraindicated</b> 230:21 <b>contraindication</b> 240:16 <b>contraindications</b> 206:14 207:7,10 208:6 209:3,15 284:11 294:4 300:14 375:1 <b>contrary</b> 297:18 <b>contrast</b> 240:4,19	<b>controlled</b> 60:21 <b>controlling</b> 77:14 99:15 278:13 299:16 <b>convened</b> 47:8 <b>convenient</b> 82:5 <b>conversation</b> 113:9 186:7 313:12 320:15 <b>conversations</b> 25:1 <b>converse</b> 206:12 <b>convert</b> 355:16 <b>coop</b> 231:12 <b>Cooper</b> 2:4 9:14 <b>cooperate</b> 186:13 <b>Cooperative</b> 313:20 <b>coordinate</b> 105:12 <b>coordination</b> 23:10 <b>COPD</b> 245:22 <b>core</b> 69:11 218:3 <b>corollary</b> 360:6 <b>coronary</b> 4:8 21:10 37:1 45:4,15 46:16,21 56:10,20 92:8 93:8 133:7 153:5 162:10 167:13 175:10 192:15 196:8 212:4,10 220:1,19	<b>corporations</b> 250:12 <b>correct</b> 38:20 58:9 58:12 80:9 145:20 157:4 174:1 196:10,11 253:5 253:10 287:12 289:5 290:9 297:2 322:9 332:5 338:21 362:11 371:4,5 381:8 388:17 395:20 398:5,5 <b>correctly</b> 80:8 157:3 196:7 233:16 287:9 343:1 361:12 370:9 <b>cost</b> 25:16 116:19 151:14 290:1 <b>costs</b> 47:3 79:3,3 177:10 <b>coumadin</b> 144:22 <b>Council</b> 2:4 9:11 <b>counsel</b> 5:19 6:15 <b>counseled</b> 114:1 <b>counseling</b> 121:1,3 121:3,7,12 122:14 122:17 130:1 <b>count</b> 195:17 243:4 248:13 328:9 333:1 337:5,8 <b>counted</b> 82:21 186:13 195:6,10 209:19 243:5,17 373:16 403:15	

102:16 103:18	210:2,16 211:2,9	392:3,5 393:7	197:22 201:8	357:16 388:14
104:20 105:2,5,16	213:17,20 214:9	395:3,22 396:18	205:13,18 206:8	<b>cut</b> 289:16
105:22 106:17	214:21 215:16	398:3 400:11	210:21 236:18	<b>cutoff</b> 376:7,21
107:10,18 108:8	216:2 217:15	401:11,14 402:1,3	240:6 243:19	399:12 400:12
109:5,10,16	218:17 220:20	402:6 403:19,22	244:14,15,19	<b>cut-off</b> 86:8
110:18 111:4,9,17	221:5,18 223:19	404:6,11 405:14	248:5 255:15	<b>cycle</b> 43:7 266:20
111:20 112:7,11	224:9,12,17	411:4 415:2,12	271:9 273:14	<b>C-O-N-T-E-N-T-S</b>
113:6 114:16,19	226:20 232:14	416:20 417:5,22	280:20 281:10,13	4:1
115:8,12 116:4,21	233:10 236:9,13	418:4,8	281:19 301:19	
118:7,10,14	236:22 238:8	<b>Co-Chairs</b> 1:12	324:16 343:12	<b>D</b>
119:15 121:14	239:22 245:8	<b>co-pay</b> 255:3	361:8 369:16	<b>daily</b> 270:3 282:21
122:21 123:12	246:11,19 247:3	<b>co-pays</b> 99:9 251:6	375:16 382:18,22	381:10
124:6,9 125:19	247:12,15 248:15	<b>CPHQ</b> 2:23 3:10	384:10 391:7	<b>Dale</b> 2:19 309:1,3
126:2 127:7,16	254:16 255:20	<b>CPT</b> 154:13	393:11 404:3	312:12,13 320:10
129:3 131:1,14,16	270:15 273:3	<b>CPT-2</b> 233:14,17	<b>criterion</b> 58:14	329:12 332:2
131:22 133:2,15	280:18 281:20	<b>crack</b> 166:6	59:10 68:19 74:22	333:2 343:17,21
133:19 135:18	282:7 283:21	<b>cracks</b> 408:16	85:19 103:16	351:19 354:12
138:1,4,21 139:11	284:6 287:8,13	<b>crash</b> 340:7	204:6	370:19,20 374:2
140:17 141:5	288:15,22 290:3	<b>create</b> 96:14 197:4	<b>critical</b> 226:15	376:4,6 379:14
142:12 143:19	290:16 291:14	266:2,21 267:20	255:14 340:20	388:12 398:2,3
145:5,12,20	292:2,14,19	<b>created</b> 296:18	347:9 370:21	400:11 408:13
146:11 147:4	295:22 296:13	409:22	399:14 406:5	412:18
148:8,11 150:8,20	297:3 298:9 300:3	<b>creating</b> 68:6 96:18	407:19,21 409:8	<b>Dale's</b> 331:9
151:1,19,21 152:6	300:7 301:15	199:10	<b>criticized</b> 345:11	<b>Dallas</b> 308:3
152:12 154:10,19	302:18 303:4,10	<b>credit</b> 97:7 165:18	<b>cross</b> 108:2	<b>Dana</b> 1:21 10:10
155:1,8,12 156:7	303:22 304:13,18	209:16 244:6	<b>crystal</b> 24:14	55:19,20 57:13
156:14,22 157:4	305:1,5,9,15,19	381:22	<b>CSAC</b> 15:14 169:7	60:15 74:10 77:9
157:10,22 159:19	306:4,17 307:1,5	<b>crisper</b> 91:16	186:16	78:17 119:18
159:22 160:3,5,14	307:10,18 309:5	<b>criteria</b> 15:15,18	<b>cup</b> 67:11	153:19 179:15
160:17,20,22	310:9 312:6,10	22:13 28:5,7,10	<b>curious</b> 240:22	<b>Dana's</b> 184:3
161:8,12,17,20	316:8,13 317:13	28:15,17,19 29:6	<b>currency</b> 27:22	<b>dangerous</b> 72:3
162:6,20 163:8,12	319:6,12 320:10	29:11,16,18,22	<b>current</b> 53:8 58:22	<b>data</b> 11:13 31:5,14
163:15 164:3	324:5 329:11	30:1,9 32:9,11	62:3 151:17	51:7 52:17,20
166:4 168:1,9	330:9 331:17	33:2 37:8,11,15	158:13 165:11	61:16,20,21,22
169:9 170:14	342:6,22 343:20	49:20 54:10,19	198:15 212:12	63:13 68:1 70:4,9
171:3 175:18	349:14 351:19	55:2 56:16 57:4	215:12 217:2	70:12 71:20 74:14
176:5,9,12,20	357:1,10 360:13	58:7 60:16 71:5,7	220:3 276:4	75:2,21 76:1
177:1,4,7,15,19	360:22 361:3	72:14 74:10,11	290:11,14 291:9	78:20 79:13 80:12
177:22 178:7	364:17 365:1,19	75:8 78:19 81:22	295:11 301:21	81:11 91:18 92:11
179:12 184:1	365:22 366:14,20	83:11,17 93:21	304:20 355:4	94:11,12,14,16,20
185:22 189:21	368:3,12,14 369:9	102:20 111:10	<b>currently</b> 31:18	102:12,18 103:22
191:1 192:3,18,21	369:12,19 370:14	112:4 126:3,7	55:11 66:13	104:2,13 108:18
193:3 194:21	372:16 375:5	144:12 148:16	104:12 106:8	115:2,7,9,11,19
195:3 196:3 198:3	376:3 377:4,10	161:14 168:4,11	113:21 118:18	124:16,17,22
199:3,7 203:19,22	382:3,12 383:2,5	177:6 181:22	176:13 194:19	125:1 127:21
204:3,20 205:1	384:2,5,13 385:19	182:2 186:11	227:7 231:5	131:5 147:10,12
207:2 208:10	386:11,14 391:8	187:6 194:8 196:1	299:14 353:7	147:15,17 148:4

151:14 161:1,3 164:13,14,15 165:4 168:10 170:8 175:6,7 177:8 189:7,10 193:8 194:14,20 203:3,5,10 204:9 212:19 213:14 214:22 215:3,7 217:8 219:13 227:18,19 232:18 233:2,19 234:2,15 239:19 242:9,16 247:21 248:7,17 249:21 250:7,12 251:12 252:4,9 253:3,21 256:21 257:5,8,17,18,20 258:4,5,10,11,15 258:17 263:13,14 266:18,22 267:11 267:15,18 268:5 272:1 273:22 274:1 275:8 276:15,16 277:14 278:1,7 279:4 285:17,17 293:4,8 293:14,15 296:14 296:19,21 297:1,9 299:1 301:4,7,8 329:2,15,18 330:7 333:20 334:2,4,5 334:15,15 335:1,8 335:13,17 336:4 336:21 339:1,5,8 342:11 343:4 351:8,12 352:1,4 354:22 356:21 357:7,17,17 359:21 361:15,16 362:8 366:6,9 368:20 369:5,8 372:11 376:1,2,20 378:9 383:10,15 383:18 384:1 386:8 387:2 389:10,11 397:17	397:21 398:7 402:8 414:7 <b>data's</b> 79:5 247:19 300:19 360:19 <b>data-driven</b> 258:1 <b>date</b> 73:20 147:17 239:1,2 342:12 354:15 392:10 393:2 <b>dated</b> 335:15 336:19 <b>Dave</b> 171:3 <b>David</b> 1:23 8:14 65:18 97:8 129:3 304:1,10 305:3 365:4 368:14 370:16 393:16 411:13 415:2 <b>David's</b> 304:8 415:14 <b>day</b> 36:9 60:10 120:8 147:1 238:13,17,18 239:3 249:4 270:4 347:11 366:3 396:21 415:18 417:3 <b>days</b> 42:16 201:17 238:16,16 241:5 241:10 242:1,4 249:3 298:15 397:13 <b>de</b> 1:18 12:13,14 363:21 <b>deal</b> 32:3 36:7 38:16 110:5 119:3 139:5 150:3 151:12 222:12 225:2 246:9 348:22 366:22 401:20 405:12 416:7 <b>dealing</b> 25:21 139:19 150:19 <b>dealt</b> 389:6 <b>deal-breaker</b> 389:14	<b>death</b> 47:4 57:2 351:7 <b>deaths</b> 229:9 <b>debate</b> 297:6 <b>decade</b> 22:6 24:2 <b>December</b> 156:13 238:22 <b>decide</b> 145:2,15 352:3 416:5 <b>decided</b> 106:11 145:8 172:15 209:5 288:21 <b>decimal-best</b> 246:17 <b>decision</b> 53:17 195:8 241:17 288:12 324:12 374:15 <b>decisions</b> 110:11 130:22 147:2 167:4 <b>decision-making</b> 190:12 <b>declare</b> 284:18 <b>decline</b> 170:2 <b>declined</b> 164:8 220:10 <b>declines</b> 135:11 <b>decrease</b> 336:14 <b>deemed</b> 375:16 <b>default</b> 339:12 340:17 346:16 <b>defense</b> 280:1 344:20 <b>defer</b> 19:3 83:3 <b>deferred</b> 119:1 <b>deficiency</b> 280:12 <b>deficit</b> 127:11 <b>define</b> 154:20 248:7 <b>defined</b> 41:8 52:2 94:1 95:14 108:20 282:15 329:5 349:19 <b>defines</b> 38:22 285:1 <b>defining</b> 155:15 <b>definite</b> 317:3	<b>definitely</b> 44:12 67:7 101:14 132:1 146:9 187:17 231:18 242:1 246:8 336:13 <b>definition</b> 188:3,16 200:11 201:1 <b>definitions</b> 141:2 165:6 294:2 300:15 301:4 <b>degree</b> 29:13,21 33:1 117:12 140:6 146:2 237:12 242:21 246:3 335:5 410:1 <b>degrees</b> 308:4 <b>delay</b> 78:3 325:15 325:18 393:1 403:13 <b>delayed</b> 337:7 <b>delaying</b> 385:11 <b>delineate</b> 414:18 <b>delivered</b> 371:1 <b>delivering</b> 374:22 394:18 <b>delivery</b> 124:19 161:2 247:21 <b>delve</b> 221:19 <b>demanding</b> 275:8 <b>demo</b> 34:22 <b>demonstrate</b> 69:14 271:6 <b>demonstrated</b> 151:15 190:7 266:9 281:10 <b>demonstration</b> 34:11 117:13 <b>denominator</b> 25:9 61:3 81:12 109:19 117:6,9,18,22 134:11 148:2 152:9 154:11 156:11 164:5 198:2 206:10,20 208:20 209:8 219:21 238:15,21 240:8,11 243:18	245:11 248:8 315:3,9 321:14 327:4 329:5 331:14 333:5,19 337:15 344:8 350:17 353:8,12 354:19 371:6,8 373:15 377:3 396:15 397:6 <b>denominators</b> 397:7 <b>dense</b> 359:13 <b>department</b> 4:17 25:3 308:13 309:14 311:14 313:1 316:10,18 321:7,21 338:3 342:15 354:11 371:2,16 383:12 <b>departments</b> 311:20 312:1 314:22 318:5 321:13 414:9 <b>depend</b> 258:11 355:18 <b>depended</b> 235:18 <b>dependent</b> 324:13 <b>depending</b> 42:11 248:6 270:6 385:6 <b>depends</b> 38:21 144:11,12,13 153:8 226:3 278:17 355:7 <b>deployed</b> 383:19 <b>depth</b> 16:22 <b>Deputy</b> 10:16 <b>derived</b> 392:16 <b>descending</b> 230:4 <b>descends</b> 45:9 <b>describe</b> 23:6 30:5 92:2 251:20 <b>described</b> 21:16 109:18 149:19 152:17 194:8 220:19 392:1 394:6 <b>describes</b> 257:16
---	---	--	---	--

259:18 331:9	38:18 39:7 72:13	303:14 305:3	189:19 194:3	405:2
<b>describing</b> 189:9	73:18 81:2 85:11	<b>diabetic</b> 196:21	196:19,20 197:5	<b>director</b> 5:7 10:16
<b>description</b> 37:7	91:15 108:14	<b>diabetics</b> 53:17	197:20 208:2	15:10 50:10
56:6 102:11	114:6 115:9 118:6	54:14 305:13	213:7 244:12	<b>directors</b> 12:15
113:18 120:21	118:17 119:7	<b>diagnosed</b> 364:4,15	246:1,2 274:17	15:13 273:12
122:16,19 151:3	124:16 125:8	<b>diagnoses</b> 270:10	279:11,17 299:6	<b>disadvantaging</b>
152:17 162:8	142:8 169:10	<b>diagnosis</b> 54:12,15	302:5 309:15	185:16
192:8 212:8	218:4 222:10	56:11 117:16,19	313:7,9 315:10,11	<b>disagree</b> 413:7
245:10 300:18	247:9 290:5 292:5	133:7 151:7 153:1	315:22 316:2,3,4	<b>disapprove</b> 38:17
316:17 386:2	306:1 329:2 410:1	162:10 192:10	349:3 350:11	<b>discharge</b> 204:19
395:11 404:19	<b>developers</b> 11:9	212:10 220:1	352:18 353:1	237:12 238:3,17
<b>descriptive</b> 70:7	15:20 17:21 27:7	233:6,15,19 235:6	355:6 387:19	239:1,2,3,13
276:7	27:10 32:17 33:17	238:1 309:20	391:14,21 397:6	314:5,7 315:13
<b>descriptors</b> 152:14	36:21 39:15 40:4	314:5,7 315:13	406:3 411:20	359:16 400:4
<b>designated</b> 17:9	43:21 44:6 55:13	333:16 342:4	412:1,7	403:14
<b>designation</b> 81:20	65:16 107:16	352:11 371:10	<b>differentiation</b>	<b>discharged</b> 56:8
<b>designing</b> 241:17	121:15 135:19	375:2 400:4	80:20 219:17	151:4 237:20
<b>desire</b> 272:3	146:17,22 177:9	406:17	374:4	239:4 332:9
<b>desired</b> 60:22	183:18 199:4	<b>diagnostic</b> 41:10	<b>differently</b> 407:4	362:16 371:9
<b>despite</b> 113:8 367:4	214:10 227:6	317:4	415:7	406:17 412:16
<b>detail</b> 17:16,17	233:6 245:9 246:3	<b>Dianne</b> 1:19 11:2	<b>difficult</b> 65:14 80:2	<b>discharges</b> 362:15
28:6 46:22 123:1	256:15 345:22	<b>dictated</b> 269:22	96:16,21 98:9	<b>disclose</b> 7:2
170:11 382:2	399:6 417:14	<b>dictionary</b> 335:8	135:15 137:22	<b>disclosing</b> 13:16
<b>detailed</b> 49:17 65:8	<b>developer's</b> 90:13	<b>die</b> 337:3 351:2	142:6 148:5 173:2	215:19
269:8 286:13	179:5 221:21	<b>died</b> 327:17	180:7 202:3 203:9	<b>disclosure</b> 4:4 6:12
395:13	295:17	<b>diem</b> 385:18	268:19 269:1	6:17,20 7:8 8:11
<b>details</b> 38:11	<b>developing</b> 41:14	<b>difference</b> 65:15	292:8 296:7	9:18 11:20
156:12	45:14 47:21 48:12	164:17 165:2	341:19 417:6	<b>disclosures</b> 7:4,13
<b>determination</b>	321:11	205:15 302:16,17	<b>difficulties</b> 35:2	7:16 8:4,16,20 9:1
22:13	<b>development</b> 7:22	318:1,9,14 372:5	139:18 199:8	9:4,9,12 10:3,8,14
<b>determine</b> 206:21	10:7 21:16 27:2	389:20 405:15	248:1	10:19,22 12:3,12
256:11	40:18 41:15 42:9	407:15 416:9	<b>difficulty</b> 99:15	12:17 13:1 14:2
<b>determining</b> 271:4	42:17 44:7 47:6	<b>differences</b> 32:18	148:3 205:10	<b>disconnect</b> 79:14
<b>Detroit</b> 2:3 9:11	47:14 117:8 187:1	139:20 194:12,15	<b>diffuse</b> 324:16	144:17
<b>develop</b> 12:10	207:5 226:11	279:10 318:11	<b>digging</b> 87:21	<b>discontinue</b> 195:8
49:18 311:18	277:8 310:3 311:8	356:9,10 375:21	<b>digits</b> 400:16	<b>discontinued</b> 200:1
364:6	316:3	<b>different</b> 16:5	<b>dilemma</b> 112:14	<b>discordance</b> 179:9
<b>developed</b> 22:17	<b>develops</b> 222:1	20:22 39:14 44:8	<b>diligence</b> 418:9,9	<b>discovered</b> 92:18
45:4 46:10 48:4	<b>devices</b> 103:1	53:11 65:8 72:14	<b>diminish</b> 394:18	<b>discrepancies</b>
98:22 241:21	<b>Devorah</b> 2:3 9:10	77:13,17 78:1	<b>dinner</b> 357:4	336:5 355:1,10,11
259:7 261:10	<b>diabetes</b> 46:6 53:10	79:18 90:20 99:21	409:18	<b>discriminating</b>
309:15,18,22	53:20,21 159:6,10	105:18 107:2,14	<b>direct</b> 9:18 261:2	31:4 360:1
311:15 313:19	159:17,18 192:12	107:22 108:1	<b>directed</b> 272:9	<b>discriminatory</b>
314:9 315:20	193:11 196:9	117:20 123:10	<b>direction</b> 273:12	298:4
321:10 354:8	197:18 280:5,6	131:7 144:11	<b>directive</b> 187:20	<b>discuss</b> 28:12,18
379:20	285:8,20 288:17	146:15 164:17	<b>directive</b> 187:20	33:14 37:15,16
<b>developer</b> 27:20	289:4 298:12	166:19 183:9	<b>directly</b> 51:8	68:16 178:16
			253:22 259:17	

362:22 363:5 386:5,20 <b>discussant</b> 37:5 150:21 282:10 <b>discussed</b> 98:21 123:1 187:19 206:13 219:21 251:14 268:8 286:12 320:16 375:13 382:7 <b>discussing</b> 37:3 45:16 196:6 231:14 262:19 <b>discussion</b> 17:13 18:17,21 19:18 32:22 36:15 37:11 37:21 55:7 68:14 68:15 83:8,8 93:9 101:8 102:19 104:8 112:5 114:17 118:21 134:22 178:3 185:5 211:19 218:14 236:19 238:4 244:11,13 282:15 291:15 300:8 301:20 305:6 327:7 342:7 347:7 360:22 361:9 365:20 373:10 384:11 385:6 388:4 403:16 417:9,11 <b>discussions</b> 19:21 28:11 130:10 <b>disease</b> 1:14,16,19 4:8 7:18 8:1 11:17 12:17 21:10 37:1,2 41:1,7 45:5 45:16 46:16,21 56:4,12,20 57:8 63:6 92:8 93:9 113:16,20 114:1,8 117:16 133:8 151:7,15 152:4 153:6 154:4 162:10 167:13	175:10 192:16 193:21 196:9 197:8,14 212:4,10 220:1,19 228:9,15 228:19 229:13 230:11 231:4,10 232:2 260:2,8,11 262:6 263:8 264:10 268:13,22 269:21 272:10 279:21 282:14,16 282:17,17,18 283:16,17 285:16 287:22 288:9 291:2 390:15 <b>disincentives</b> 182:11 <b>disincentivized</b> 96:19 <b>disorders</b> 134:18 <b>disparities</b> 24:19 24:20 31:7 96:18 156:6 194:18 350:15 356:7,19 357:8 366:11 376:2 389:17 390:7 396:2,11 398:16,20 399:19 <b>disparity</b> 318:4,17 350:13 356:16,21 <b>dispense</b> 238:16 <b>display</b> 34:14 376:22 <b>distinct</b> 360:11 <b>distinction</b> 81:3 227:14,20 407:14 <b>distinguish</b> 277:13 278:7 <b>distinguished</b> 322:15 <b>distinguishing</b> 277:20 405:4 <b>distribution</b> 330:8 <b>diverse</b> 297:13,15 <b>divide</b> 197:1 <b>doable</b> 75:7 <b>doc</b> 250:17	<b>docs</b> 131:13 <b>doctor</b> 96:20 128:7 128:12 252:22 262:7 276:5,7,16 <b>doctors</b> 97:7 261:1 274:17 <b>doctor's</b> 23:2 251:15 <b>document</b> 102:7,9 156:19 323:21 343:9 392:22 403:1,5 412:13 414:1 <b>documentation</b> 118:5 121:1,6 126:18 129:21 139:18 156:2 157:12 160:10 164:6,9 171:6 220:8,11 251:10 262:3,14 263:16 269:10,15 339:13 343:15 354:14 355:13,14 381:17 392:17 <b>documented</b> 121:3 134:21 161:1 162:13 163:20 165:10 168:5 261:16 262:5 266:4 268:22 271:19,20 334:19 342:11,14 <b>documenting</b> 126:21 260:2 268:16 279:9 <b>documents</b> 75:8 333:9 <b>doing</b> 20:12 22:3 35:14 36:8 37:19 51:9 59:2 64:16 68:8 86:18 104:12 106:5 115:16 129:22 136:3 137:17 150:5 164:18 165:22,22 196:21 241:15,16	248:22 268:1 269:14 275:15 276:9 278:13 285:3 293:21 294:17 323:21 324:9 326:11,13 328:6 343:14 345:3 359:5 362:13 374:21 391:2 394:13 <b>domain</b> 259:13 <b>door</b> 340:13 352:7 352:13 353:14 358:14 387:15 391:16 400:2 <b>doors</b> 20:2 <b>DOQ</b> 147:22 <b>dose</b> 380:15,19 381:5 <b>doubt</b> 56:19,21 70:22 399:15 <b>downgrade</b> 292:7 <b>dozens</b> 48:7 143:3 <b>DPT</b> 1:19 <b>Dr</b> 5:4 6:2,2 7:10 8:5,14,17,21 9:2,5 9:13 10:4,10,15 11:1,21 12:4 13:5 14:6,7,11 15:4,8,9 19:8,11 31:20 34:4 36:10,18 37:22 38:5,21 40:1 44:17,18,19 48:21 49:2,7,12 49:22 50:7 56:1 58:3,6,10 59:15 59:17 60:6,17 62:6 63:1 65:2,20 67:9,20 70:18 73:16 74:11 75:16 75:19 76:5,14,17 77:12 78:18 79:10 80:1,19 81:15 82:1 83:6,18 84:7 85:7,15 86:3,10 86:14,19 87:7,20 88:9,22 89:5	90:10,12 94:22 95:8,10,10,13,17 95:21 96:12 97:9 97:22 98:12,16 100:14 101:13,18 102:6 104:16 105:1,3,6,20 106:3 107:9,15 109:2,7,14,17 111:3 113:14 115:2,10 116:8,18 117:3 118:16 119:19 120:17 121:9 122:8 123:7 124:5,15 125:21 126:10 127:5,8 128:1 129:4 131:2 132:21 133:4 134:1 135:7,21 136:18 137:6 138:10 139:1 140:9 141:3,7 142:13 143:8 144:1 145:7,18 146:13,21 147:9 149:3,16 152:1,10 152:13,15,18,22 153:16 154:2,15 156:8,17 157:1,5 157:13 158:2,10 158:18 159:2,5,6 159:9,12,14,17,18 162:21 164:1 165:5 166:3,5,22 167:11,22 168:2 169:11 170:6 171:2,4,22 173:3 173:20 174:16 175:15 176:1 178:12,14 179:16 181:2 182:4,18 186:6 187:22 189:3 190:16 192:7 193:7 195:1 195:4,15,18,19 196:4,11,13 197:6 198:4 199:5,9
---	--	---	---	--

200:10 201:2	298:22 299:8,19	382:5,17 383:10	167:11 169:11	293:12 298:15
202:1,8,18 204:7	300:5 302:9,21	385:18 386:1,19	171:22 175:15	411:13
205:6 206:1,3,6	303:6,8,18,20	388:5,9,11,12,16	176:1 199:5,5,9	<b>earliest</b> 342:12,14
207:2,3 208:14	304:12,21 305:4	390:12,19 391:6	202:8,8 209:13	<b>early</b> 55:7 115:1
209:13 210:8,11	305:14,16 306:3	391:12 392:9	217:17,18 222:18	229:5 234:2 256:3
210:14,14 211:18	306:18 307:3	394:1 395:5,10,12	223:15 224:11	266:7 317:20
213:16,19,21,22	308:19 309:1,3,10	395:18 396:3	226:9 228:2 231:3	324:17 364:15
214:2,12,22	310:11,19 311:9	397:1,16 398:4,13	231:18 232:5,13	365:7,10 386:8
215:19 216:4,10	313:10 316:6,12	398:15,18 399:4	235:17 247:1	<b>ease</b> 397:20
217:9,17 218:2	317:15 318:6,19	399:12,22 400:18	253:12,12 257:5	<b>easier</b> 34:18 60:13
219:18,19 220:14	318:22 319:1,15	401:3,16 402:8	258:2 259:13	206:9,19 392:13
220:16,17 221:3,7	320:14 321:17,22	404:17 405:15,18	261:19 264:3	<b>easily</b> 119:14
222:5,7,10,11,18	322:3,5,8,10,13	405:20 406:8,9,19	266:2 271:14	138:12 383:13
222:22 223:15	323:6,19 324:2,7	406:22 407:5,7,12	274:4 275:19	<b>easy</b> 85:14 186:15
224:7,11,16,19	324:9 325:5,10,17	407:13,21 408:3,8	276:4 278:10	189:1 226:6 374:6
225:6,9,11,12,14	326:5 327:1,3,13	408:12,17,19,22	281:4	374:9
226:9,15 227:5	327:16,20 328:5	409:4,6,7,10,11	<b>drug</b> 99:8 135:13	<b>eat</b> 132:8 416:17
228:2,6,12 231:3	328:10,13,15,17	409:17,20,22	222:3	<b>ECG</b> 316:11,17,18
231:12,18,21	329:1,13,18,20	410:5,12,17,18,20	<b>drugs</b> 111:1 119:4	317:7,22 318:5
232:5,6,13,18	330:4,5 331:7	410:21 411:1,19	218:8,21 219:14	330:7,12,20
234:6,17 235:8,10	332:2,16,20 333:2	412:12,17 413:3,4	219:16 221:1	331:22 332:8
235:17 237:9	334:11 335:14,19	413:6,10,13,17,20	<b>due</b> 21:7 27:8 52:16	338:6,8,17 339:11
238:12 240:2	335:20,22 336:18	413:21,22 414:3,4	129:19 158:7	339:12,18 340:5,8
242:3,17 243:13	337:2,10,18 339:3	414:21 416:11	164:10 170:2	341:12,13 342:12
244:4,6,9,22	340:10 341:4	417:4,15 418:2	233:5	344:5,8 354:15
245:16,17 246:14	343:17 344:1,2,12	<b>draft</b> 41:20 42:5	<b>dummy</b> 393:12	373:10 375:14
247:1,7,19 248:2	344:20 346:1,20	<b>draw</b> 187:13 208:6	<b>duplicate</b> 162:4	376:5 394:8 395:6
248:16 249:5	347:3,5,6 349:11	227:20	<b>duplication</b> 401:19	398:21 413:22
250:1,8,16,22	351:6,22 352:5,17	<b>drive</b> 24:15 26:4	405:12 416:8	<b>ECGs</b> 338:9 339:16
251:15,19 252:11	353:4,18 354:1,12	60:11 72:18 102:6	<b>duration</b> 389:16	<b>ED</b> 316:19 327:9
253:2,12 256:9	354:21 356:1,13	111:5 234:20	<b>dying</b> 348:13	329:9 332:9
257:5,13 258:2,8	357:21 358:12,17	286:22	<b>dysfunction</b> 46:4,7	337:17 338:9
259:5,13 261:8,19	359:4,12,19,20	<b>drives</b> 60:9 156:18	196:10,22 212:6	340:4 341:7
263:9 264:3,5	360:4,6 361:10	417:18	214:16,20 216:14	344:16 346:13
265:1 266:2	362:11,17 363:3	<b>driving</b> 218:14	216:19 229:17	372:6 404:15
267:19 268:3,9,15	363:16,20 365:6	309:12	231:7	405:6
269:18 270:19,21	366:5,16,19,21	<b>drop</b> 126:15	<b>D.C</b> 1:11	<b>EDAs</b> 354:2
271:14 272:11	367:6,18,19,21	<b>dropped</b> 92:13		<b>education</b> 190:2
273:4 274:4	368:1,8,20 369:17	<b>Drozda</b> 2:21 48:21	<hr/> <b>E</b> <hr/>	270:17
275:18,19,21	370:3,12,18 371:5	98:12,12,16	<b>e</b> 355:16	<b>educational</b> 190:16
276:4,14 277:4	371:18 372:18	101:13,18 105:3,3	<b>earlier</b> 72:10 79:11	336:10
278:10 279:22	373:2 374:2 375:3	105:6,20 106:3	80:8 104:8,9	<b>EF</b> 220:3
281:3,4,8 284:2	375:9 376:9,15,19	107:9,15 109:14	109:11 110:20	<b>effect</b> 129:1 168:16
287:17 288:19	377:15 378:6,11	109:14,17 111:3	121:13 149:19	341:16
289:6 290:10,13	378:13,15,17,19	135:21,21 137:6	170:15 203:14	<b>effective</b> 116:19
291:4,8,11 294:10	379:5,10,14,18	141:3,3,7 143:8	208:18 253:14	133:12 187:14
296:1 297:22	380:9 381:7,11,14	164:1,1 166:3,3,5	257:16 286:12	190:22



<b>effectiveness</b> 114:4 281:11	213:2,6	<b>element</b> 257:18 334:5,15,16 335:1 335:13,17 336:4 339:1,8 342:11	<b>EMTs</b> 367:14	<b>epidemiologic</b> 285:14,17
<b>effects</b> 289:22	<b>EKG</b> 323:1,1,3,9 323:20 324:9,11 324:14,22 326:11 326:17,21 327:15 327:18 328:2,4,9 328:22 337:7 344:18 346:3,5,11 346:16 347:16 348:17 351:14,18 352:1,15,22 353:17 358:4,10 358:17,20 364:11 395:19 396:10	<b>elements</b> 30:10 70:10 108:18 147:10 247:21 334:4 342:17 343:5 383:10 386:3 410:3	<b>encourage</b> 16:10 342:1	<b>episode</b> 22:17,20 23:8,22 239:10
<b>efficacious</b> 214:19 218:22 219:3,4 381:3	<b>EKGs</b> 326:2 328:6 348:19 351:9 358:1	<b>elevation</b> 324:17 374:8 394:7	<b>encouraged</b> 340:3	<b>episodes</b> 25:14
<b>efficiency</b> 267:9	<b>elderly</b> 63:2,11,13 64:10,17 71:1,21 88:21 89:9,18 91:18 109:12 110:8	<b>eligible</b> 314:15 329:6 400:19,22	<b>ended</b> 63:18 340:14 371:10	<b>equal</b> 94:4 95:7,8 95:11 101:9,15 155:19 162:13 163:18,20,22 167:14 199:14
<b>efficient</b> 32:3	<b>elections</b> 256:5	<b>eliminate</b> 7:5 205:21 206:19	<b>endorse</b> 294:22	<b>equally</b> 22:11 323:4
<b>effort</b> 5:11 24:21 26:17,21 47:17 100:22 162:4	<b>electrocardiogram</b> 352:9	<b>eloquently</b> 349:16	<b>endorsed</b> 20:13,21 21:13,19,22 24:9 46:12 50:20 58:21 159:10 163:3	<b>equals</b> 100:5 155:18
<b>efforts</b> 45:13 105:7 143:18 190:2 270:16,20	<b>electrocardiogra...</b> 359:7	<b>else's</b> 142:10	<b>endorsement</b> 1:3,9 5:12 14:13 22:14 28:5 32:11 70:2 83:4,11,22 112:2 112:4,9 126:7 132:2 148:17 150:14 161:14 178:2 210:21 236:19 255:15 361:8 369:16 384:10 393:11,17 399:9 404:3	<b>equipment</b> 66:18 66:18
<b>EHR</b> 81:8	<b>electronic</b> 61:17,19 61:22 62:1 79:20 80:12 81:4,11 82:5 86:21 87:2,4 147:16 161:3 164:14,14 166:12 236:6 248:18,19 249:16 270:1 280:8 355:19 369:2 383:14 392:11 402:9	<b>email</b> 18:5 290:21 306:20,21	<b>endorses</b> 21:13	<b>ER</b> 328:7,8
<b>EHRs</b> 79:16 88:11 89:3 126:1	<b>electronically</b> 34:13,13 79:13 80:13 86:12 124:22 125:2 177:8 232:20 247:22 274:2 366:9	<b>emanate</b> 47:18	<b>endorsing</b> 131:18 184:5	<b>erase</b> 127:10
<b>eight</b> 24:9 50:18 64:4 71:3,9,11,13 89:7,14 249:2 288:1 347:10,12 384:19 416:12,16 416:17	<b>emerged</b> 262:1	<b>embarrassment</b> 290:18	<b>ends</b> 226:8	<b>error</b> 148:3 292:20 339:14
<b>either</b> 20:2 42:10 56:8 61:6 68:9 70:9 81:11 85:18 89:3 95:14 100:20 117:10 120:22 122:18 125:12 134:17 171:13 178:11 186:16 188:12 192:11 196:2,9 239:18 244:17 252:12 257:18 259:15 262:21 266:14 268:5 276:17 290:15 295:18 308:20 353:9 366:9 369:2 371:13,15 383:14 395:15 399:13 402:9	<b>emergency</b> 2:9 4:17 12:20 13:6 308:13 309:14 311:13,22 313:1 316:10,18 318:4 319:19 320:2,9 321:7,20 326:4 337:4 338:3 342:15 347:17 352:7 354:11 360:10 364:3 371:2,16 374:20 380:13,18 383:12 404:20,22 413:18 414:9	<b>embrace</b> 25:17	<b>engaged</b> 52:9	<b>errors</b> 100:15 161:6 300:17 402:13
<b>effectiveness</b> 114:4 281:11	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>engaging</b> 270:12	<b>especially</b> 47:4 58:20 166:8 202:19 337:7 385:2
<b>effects</b> 289:22	<b>emerged</b> 262:1	<b>emerged</b> 262:1	<b>engaged</b> 52:9	<b>ESRD</b> 73:9 110:8
<b>efficacious</b> 214:19 218:22 219:3,4 381:3	<b>emergency</b> 2:9 4:17 12:20 13:6 308:13 309:14 311:13,22 313:1 316:10,18 318:4 319:19 320:2,9 321:7,20 326:4 337:4 338:3 342:15 347:17 352:7 354:11 360:10 364:3 371:2,16 374:20 380:13,18 383:12 404:20,22 413:18 414:9	<b>embrace</b> 25:17	<b>enhance</b> 270:12	<b>essence</b> 415:4
<b>efficiency</b> 267:9	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>enormous</b> 145:21 190:8 268:18 269:16 271:15 279:4	<b>essentially</b> 181:2 249:16 259:15 407:2
<b>efficient</b> 32:3	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>ends</b> 226:8	<b>essentials</b> 308:9
<b>effort</b> 5:11 24:21 26:17,21 47:17 100:22 162:4	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>engaged</b> 52:9	<b>establish</b> 54:12 220:22
<b>efforts</b> 45:13 105:7 143:18 190:2 270:16,20	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>enhance</b> 270:12	<b>established</b> 54:10 54:19 55:2 283:16 296:18
<b>EHR</b> 81:8	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>enormous</b> 145:21 190:8 268:18 269:16 271:15 279:4	<b>estimate</b> 201:10 282:3
<b>EHRs</b> 79:16 88:11 89:3 126:1	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>enrollment</b> 239:2	<b>et</b> 99:9 114:9 119:22 154:13 158:7 180:15 222:16,17
<b>eight</b> 24:9 50:18 64:4 71:3,9,11,13 89:7,14 249:2 288:1 347:10,12 384:19 416:12,16 416:17	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>ensure</b> 359:6	<b>ethnicity</b> 350:18 399:2
<b>either</b> 20:2 42:10 56:8 61:6 68:9 70:9 81:11 85:18 89:3 95:14 100:20 117:10 120:22 122:18 125:12 134:17 171:13 178:11 186:16 188:12 192:11 196:2,9 239:18 244:17 252:12 257:18 259:15 262:21 266:14 268:5 276:17 290:15 295:18 308:20 353:9 366:9 369:2 371:13,15 383:14 395:15 399:13 402:9	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>enter</b> 110:10	<b>European</b> 287:21
<b>effectiveness</b> 114:4 281:11	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>entered</b> 355:19	
<b>effects</b> 289:22	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>enterprise</b> 22:5 24:3	
<b>efficacious</b> 214:19 218:22 219:3,4 381:3	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>entire</b> 272:3 310:3 336:22 372:1	
<b>efficiency</b> 267:9	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>entirely</b> 47:15 80:13 301:8 410:8	
<b>efficient</b> 32:3	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>entrance</b> 341:6	
<b>effort</b> 5:11 24:21 26:17,21 47:17 100:22 162:4	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>environment</b> 250:4	
<b>efforts</b> 45:13 105:7 143:18 190:2 270:16,20	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>EPIC</b> 250:19 253:8	
<b>EHR</b> 81:8	<b>embrace</b> 25:17	<b>embraced</b> 23:19	<b>epidemic</b> 280:4,5	
<b>EHRs</b> 79:16 88:11 89:3 126:1	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>eight</b> 24:9 50:18 64:4 71:3,9,11,13 89:7,14 249:2 288:1 347:10,12 384:19 416:12,16 416:17	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>either</b> 20:2 42:10 56:8 61:6 68:9 70:9 81:11 85:18 89:3 95:14 100:20 117:10 120:22 122:18 125:12 134:17 171:13 178:11 186:16 188:12 192:11 196:2,9 239:18 244:17 252:12 257:18 259:15 262:21 266:14 268:5 276:17 290:15 295:18 308:20 353:9 366:9 369:2 371:13,15 383:14 395:15 399:13 402:9	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effectiveness</b> 114:4 281:11	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effects</b> 289:22	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficacious</b> 214:19 218:22 219:3,4 381:3	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficiency</b> 267:9	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficient</b> 32:3	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effort</b> 5:11 24:21 26:17,21 47:17 100:22 162:4	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efforts</b> 45:13 105:7 143:18 190:2 270:16,20	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>EHR</b> 81:8	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>EHRs</b> 79:16 88:11 89:3 126:1	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>eight</b> 24:9 50:18 64:4 71:3,9,11,13 89:7,14 249:2 288:1 347:10,12 384:19 416:12,16 416:17	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>either</b> 20:2 42:10 56:8 61:6 68:9 70:9 81:11 85:18 89:3 95:14 100:20 117:10 120:22 122:18 125:12 134:17 171:13 178:11 186:16 188:12 192:11 196:2,9 239:18 244:17 252:12 257:18 259:15 262:21 266:14 268:5 276:17 290:15 295:18 308:20 353:9 366:9 369:2 371:13,15 383:14 395:15 399:13 402:9	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effectiveness</b> 114:4 281:11	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effects</b> 289:22	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficacious</b> 214:19 218:22 219:3,4 381:3	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficiency</b> 267:9	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficient</b> 32:3	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effort</b> 5:11 24:21 26:17,21 47:17 100:22 162:4	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efforts</b> 45:13 105:7 143:18 190:2 270:16,20	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>EHR</b> 81:8	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>EHRs</b> 79:16 88:11 89:3 126:1	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>eight</b> 24:9 50:18 64:4 71:3,9,11,13 89:7,14 249:2 288:1 347:10,12 384:19 416:12,16 416:17	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>either</b> 20:2 42:10 56:8 61:6 68:9 70:9 81:11 85:18 89:3 95:14 100:20 117:10 120:22 122:18 125:12 134:17 171:13 178:11 186:16 188:12 192:11 196:2,9 239:18 244:17 252:12 257:18 259:15 262:21 266:14 268:5 276:17 290:15 295:18 308:20 353:9 366:9 369:2 371:13,15 383:14 395:15 399:13 402:9	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effectiveness</b> 114:4 281:11	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effects</b> 289:22	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficacious</b> 214:19 218:22 219:3,4 381:3	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficiency</b> 267:9	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficient</b> 32:3	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effort</b> 5:11 24:21 26:17,21 47:17 100:22 162:4	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efforts</b> 45:13 105:7 143:18 190:2 270:16,20	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>EHR</b> 81:8	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>EHRs</b> 79:16 88:11 89:3 126:1	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>eight</b> 24:9 50:18 64:4 71:3,9,11,13 89:7,14 249:2 288:1 347:10,12 384:19 416:12,16 416:17	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>either</b> 20:2 42:10 56:8 61:6 68:9 70:9 81:11 85:18 89:3 95:14 100:20 117:10 120:22 122:18 125:12 134:17 171:13 178:11 186:16 188:12 192:11 196:2,9 239:18 244:17 252:12 257:18 259:15 262:21 266:14 268:5 276:17 290:15 295:18 308:20 353:9 366:9 369:2 371:13,15 383:14 395:15 399:13 402:9	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effectiveness</b> 114:4 281:11	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effects</b> 289:22	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficacious</b> 214:19 218:22 219:3,4 381:3	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficiency</b> 267:9	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficient</b> 32:3	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effort</b> 5:11 24:21 26:17,21 47:17 100:22 162:4	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efforts</b> 45:13 105:7 143:18 190:2 270:16,20	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>EHR</b> 81:8	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>EHRs</b> 79:16 88:11 89:3 126:1	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>eight</b> 24:9 50:18 64:4 71:3,9,11,13 89:7,14 249:2 288:1 347:10,12 384:19 416:12,16 416:17	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>either</b> 20:2 42:10 56:8 61:6 68:9 70:9 81:11 85:18 89:3 95:14 100:20 117:10 120:22 122:18 125:12 134:17 171:13 178:11 186:16 188:12 192:11 196:2,9 239:18 244:17 252:12 257:18 259:15 262:21 266:14 268:5 276:17 290:15 295:18 308:20 353:9 366:9 369:2 371:13,15 383:14 395:15 399:13 402:9	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effectiveness</b> 114:4 281:11	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effects</b> 289:22	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficacious</b> 214:19 218:22 219:3,4 381:3	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficiency</b> 267:9	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efficient</b> 32:3	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>effort</b> 5:11 24:21 26:17,21 47:17 100:22 162:4	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>efforts</b> 45:13 105:7 143:18 190:2 270:16,20	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>EHR</b> 81:8	<b>embrace</b> 25:17	<b>embraced</b> 23:19		
<b>EHR</b>				

306:19	68:14,18 69:1,5	222:18 224:11	240:6 241:8 243:3	<b>expand</b> 258:3
<b>evaluate</b> 23:7 29:10	70:19,21 72:4	294:2 300:16	243:4,20 244:14	321:14 325:11,15
29:16 32:21 48:19	73:2,8 89:21 95:1	313:13 319:7	244:14,19 246:10	329:17 331:4
311:21	95:4,19 96:11	323:18 330:20	248:5,12 388:20	<b>expanded</b> 315:16
<b>evaluated</b> 22:12	97:3 137:13	334:18 340:14	389:1 391:7	<b>expect</b> 5:5 124:19
29:1 256:11	151:12 162:17,19	346:3	<b>exclusions</b> 31:1	162:3 184:20
<b>evaluating</b> 32:7,14	172:3 192:16	<b>examples</b> 136:11	39:18 77:22 79:2	201:17 336:16
33:15 258:17	218:6 220:22	201:15 208:20	83:20 84:3,6 86:4	341:1 396:7
265:22	228:18 229:1,22	<b>exceeded</b> 418:9	118:1 119:20	<b>expectation</b> 142:20
<b>evaluation</b> 4:5	230:6,10,12,18	<b>exceedingly</b> 202:3	120:18 121:20	<b>expectations</b> 19:13
15:15,17 22:12	231:20 232:7,7	<b>Excel</b> 92:22	122:3,10 125:4,6	181:5
26:18,22 29:6	259:10 281:11	<b>excellent</b> 123:14	134:16 135:4,8	<b>expected</b> 54:7
30:1 32:5 83:10	285:1,14 287:20	366:6	140:4 147:13	119:13 251:16
147:14,22 150:5	288:8 289:8,14	<b>exception</b> 29:18	155:20 158:3,5	334:22
168:11 180:2	290:12 291:19	110:12 213:12	161:4 164:5,6	<b>experience</b> 22:22
183:7 187:6 257:3	292:1 306:13	407:3 410:9	168:7,13 177:9	29:15 142:2 168:3
265:11 352:11	326:6 365:13	<b>exceptions</b> 109:19	179:2 180:5 194:6	182:22 183:21
<b>evening</b> 102:8	371:19 372:1,8	109:22 110:4	208:3 209:22	208:16 249:6
<b>event</b> 232:4	373:5,21 374:6	136:6,11,14 137:9	220:6 223:1,5	<b>experienced</b> 39:6
<b>events</b> 63:6 89:11	381:1,8 382:9	169:18,19 170:8	239:16 242:19	<b>expert</b> 5:17 41:9
<b>everybody</b> 6:9	390:11 394:22	170:11 208:20	245:21 286:11	117:20 219:12
14:11 16:1,10	<b>evidences</b> 344:4	209:11	300:13 351:1,2	<b>expertise</b> 16:4,20
19:16 35:7,9,12	<b>evidence-based</b>	<b>exclude</b> 73:9 76:9	352:15 366:7	16:22 29:14 47:13
35:21 36:5 78:10	30:15 97:21	76:19 81:22 85:18	369:4 375:20	<b>experts</b> 130:20
82:12,13 92:3	215:14 218:6	121:13 135:2,17	383:16 388:19	<b>explain</b> 40:22
93:14 111:14,15	<b>evident</b> 74:12	155:21,22 198:1	389:9,15 390:13	58:13 80:22 81:3
113:1,8 118:12	<b>evolution</b> 22:4 24:4	240:10,13 244:5	392:14 397:11	313:6,11 350:19
127:12 152:22	100:1 190:1 273:6	245:3 334:17	403:12	<b>explained</b> 316:4
191:3 228:14	<b>evolve</b> 253:17	335:1 402:17	<b>excuse</b> 44:1 137:17	370:19
232:1 277:2 287:6	<b>evolved</b> 293:14	<b>excluded</b> 120:2	177:7 317:15	<b>explanation</b> 241:1
297:4 307:12,13	<b>exacerbating</b> 96:18	135:12,14 187:17	<b>exercise</b> 16:12 29:9	241:2 403:3
317:7 364:21	<b>exacerbation</b>	197:21 209:22	34:11	<b>explanatory</b> 317:2
384:18 385:2	262:10	240:7 243:12,22	<b>exhaustive</b> 208:5	317:11
404:9 416:15,20	<b>exact</b> 62:13 122:11	245:2,6 398:12	272:1	<b>explicit</b> 205:18
417:2	184:11 197:13	<b>excludes</b> 388:14	<b>exist</b> 24:20 114:11	207:7 216:15
<b>everybody's</b> 112:13	213:5 246:7 321:1	<b>excluding</b> 172:21	<b>existence</b> 24:12	262:14
115:15 362:21	355:4 409:12,15	243:8 245:5	141:15 143:14	<b>explicitly</b> 143:5
385:14 386:16	<b>exactly</b> 89:2 215:21	<b>exclusion</b> 72:13	175:12 283:10	231:7
415:12	222:9 225:9	73:11 85:6 120:12	<b>existent</b> 232:8	<b>expressing</b> 290:5
<b>everyone's</b> 59:2	304:19 323:19	120:16 121:18,19	<b>existing</b> 14:18	302:1
129:22 273:1	388:17 407:2	122:2,6 137:2	142:16 157:6	<b>extend</b> 154:3
<b>evidence</b> 25:6	411:1 414:3	158:8 168:4,12	204:14 217:8	264:12
30:13 43:5 46:18	<b>example</b> 39:3 43:13	186:11 194:7	225:3 289:2	<b>extended</b> 223:22
53:8,16 54:3,6	77:22 123:20	195:13 196:1	305:10 368:10	<b>extending</b> 231:1
59:4,6 62:9,10,14	129:7,13 140:4	197:21 201:8	382:21 383:1	<b>extensive</b> 48:6
62:16 63:21 64:15	158:4 197:19	205:13,18 206:8	<b>exists</b> 147:15	<b>extensively</b> 16:18
66:4 67:12 68:3	205:19 220:7,9	223:13 226:5	<b>exit</b> 256:3	66:16

<b>extent</b> 31:8,14 47:22 91:1 216:20 222:22 228:4 347:1 377:16	336:2 349:17,20 384:19 399:15 407:3 410:9	<b>far</b> 19:6 92:20 109:7 133:14 194:12 209:10 239:17 283:12 286:10 300:16 387:1,3 389:9 390:11	125:18 202:5 274:14 393:5	212:17 235:20 238:19,19 249:20 254:9
<b>extra</b> 78:15 81:20	<b>factor</b> 41:4 51:22 408:13	<b>fascinating</b> 356:11	<b>FEBRUARY</b> 1:6	<b>fills</b> 203:2
<b>extract</b> 403:10	<b>factored</b> 224:15	<b>fashion</b> 147:19 150:2 154:9 389:21	<b>feedback</b> 67:15 91:14 295:1 306:11 310:12 365:8	<b>final</b> 19:2 26:18 33:7 42:5,6 73:21 78:3 83:4 99:1 126:6 148:16 161:13 177:6 178:2 210:20 236:17 302:7 361:7 369:15
<b>extractable</b> 205:8 205:10	<b>factors</b> 41:9,12 51:17 110:10 179:15 222:12 282:19 298:5	<b>fast</b> 129:12 130:11 150:12 169:6 255:21,22 323:8 344:15,16 352:19	<b>feel</b> 20:4 29:8 76:7 85:10 93:20 110:15 139:2 149:1,2 189:17,17 189:18 295:9	<b>finalize</b> 35:10
<b>extracted</b> 177:8 300:12 334:15	<b>faculty</b> 11:4	<b>fatal</b> 38:14,19,22 39:13	<b>feeling</b> 133:11 138:19	<b>finally</b> 124:13 300:10 301:18 384:9 404:1
<b>extracting</b> 236:5 242:15	<b>failed</b> 308:6	<b>fatigue</b> 240:15	<b>feelings</b> 62:5	<b>financial</b> 164:10
<b>extraction</b> 180:7	<b>failure</b> 200:22,22 218:20 219:7,9,10 220:18 221:2,9,17 222:1 229:16 230:13 268:21 324:18 332:18 333:1 337:6	<b>fault</b> 119:7	<b>feet</b> 289:19	<b>find</b> 24:15 60:8 88:5 98:1 142:6 264:19 267:5 333:8,22 334:19 357:7 359:18 381:16
<b>extractors</b> 171:7	<b>fair</b> 97:10 417:14	<b>favor</b> 409:19	<b>felt</b> 94:8,19 96:17 99:12 104:4 108:18 148:6 169:21 206:10 243:21 287:2 315:7 354:17,20	<b>finding</b> 209:9
<b>extraordinarily</b> 397:22	<b>fairly</b> 48:6 56:18 117:17 131:9 134:13,15 137:11 138:20 153:6 170:12 181:5 185:14 190:9 246:15 251:11 296:18 317:1 341:1	<b>favorable</b> 85:10 178:21,22	<b>female</b> 397:8	<b>findings</b> 156:1 299:5 324:14
<b>extraordinary</b> 260:3 278:22	<b>fairness</b> 110:19 225:16	<b>fed</b> 224:1	<b>fence</b> 373:3	<b>fine</b> 17:1 145:18 172:16 247:3 308:11 325:11 356:4
<b>extrapolate</b> 219:13 221:3	<b>faith</b> 100:22 266:3 267:10	<b>feasibility</b> 28:22 31:13 37:17 62:18 67:1 78:17,19 79:8 82:11 108:17 111:12 124:13,16 125:4 126:4 147:8 147:10 148:7,9,13 160:21 161:9 177:6,20 202:2,19 205:5 210:17 232:17 236:11 242:15 247:18 248:1 250:17 252:21 255:11 258:4,10 292:17 300:10 301:13 360:17,19,21 361:1,4 368:19 369:13 383:9 384:6 392:8 393:8 402:7,8 403:20	<b>feet</b> 289:19	<b>fire</b> 289:19
<b>extrapolation</b> 266:10	<b>fall</b> 54:7 123:8 169:19 202:2 244:10 373:11,14 373:20 385:3 408:16 410:14,14	<b>fed</b> 224:1	<b>feet</b> 289:19	<b>first</b> 6:7 14:17 19:15 20:11 21:4 32:6 36:20 40:6 50:18 51:4,10 52:19 55:18 56:16 58:2 60:7,22 63:2 84:7 100:14 114:20 132:12 142:1 152:3 170:18 173:8 188:21 200:5 229:6 239:13 241:7 248:8
<b>extremely</b> 71:19 126:12 129:15 223:17	<b>fallen</b> 364:20	<b>feasible</b> 78:20 108:21,22 124:20	<b>female</b> 397:8	
<b>eyes</b> 201:13 393:12	<b>falling</b> 361:14		<b>fence</b> 373:3	
<b>ezetimibe</b> 174:22	<b>falls</b> 248:3		<b>fess</b> 250:15	
<b>e-Prescription</b> 203:1	<b>false</b> 168:7 389:9 402:16 403:12		<b>fewer</b> 56:21	
	<b>familiar</b> 407:17		<b>fib</b> 145:1	
	<b>family</b> 10:13 47:11 401:5		<b>fibrates</b> 174:22	
	<b>famous</b> 308:2		<b>fibrinolysis</b> 394:11 397:5 405:5,7 408:1,4 416:2	
			<b>fibrinolytic</b> 393:19 394:4,19 400:7,15 400:22 402:17 403:3 404:14,20	
			<b>field</b> 24:5 42:9 326:13 328:6,14 339:19 370:8	
			<b>figure</b> 6:8 82:20 250:19 254:6 330:17 337:15	
			<b>file</b> 118:6	
			<b>files</b> 356:17	
			<b>fill</b> 195:16 201:22 253:5,6,21 276:7	
			<b>filled</b> 6:19 200:14	

261:22 262:2,12 263:4,18 276:10 278:5,10 303:8 304:3 324:3 327:22 336:21 337:3 339:17 346:5 348:18 350:6 358:14 363:13 365:3,7 367:1,2 373:4 386:5 399:5 409:1 410:7 412:2,9 415:22 <b>first-line</b> 193:9 <b>fit</b> 139:9 <b>fits</b> 391:21 <b>five</b> 17:7,12,12,13 17:21,22 40:8,15 48:15 51:9 65:8 121:22 122:1,5 170:13 191:5 308:17 319:8 349:7 354:2 376:14,15 377:2 384:16 388:7 <b>five-ish</b> 102:8 <b>fix</b> 85:22 <b>fixed</b> 103:4 235:9 235:12 345:19 <b>flare-up</b> 153:11 <b>flash</b> 417:18 <b>flaw</b> 38:15,19,22 39:13 <b>flexibility</b> 282:2 <b>flight</b> 262:9 309:13 <b>flip</b> 285:22 365:9 <b>floated</b> 203:6 <b>floor</b> 55:20 <b>Florida</b> 9:6 83:1 349:12 379:21,21 <b>flow</b> 254:15 <b>fly</b> 39:16 <b>focus</b> 17:18 25:14 30:10 32:7 38:6 59:5 69:5 143:6 179:3 230:9 281:12 311:14	316:1 363:5 382:19 390:7 <b>focused</b> 25:9 314:21 354:9 <b>focuses</b> 310:20 311:3 <b>focusing</b> 51:22 58:17 174:21 194:16 211:20 363:16 <b>folder</b> 156:18 282:11 <b>folks</b> 5:5,13 24:5 26:2 129:5 206:3 289:19 <b>follow</b> 216:21 286:21 <b>followed</b> 215:6 <b>following</b> 56:13 153:5 166:14 216:22 217:5 238:17 <b>follows</b> 23:8 136:13 <b>follow-up</b> 153:2,9 <b>food</b> 193:1 <b>footnotes</b> 187:5 <b>fora</b> 46:13 <b>Force</b> 45:3,7 <b>foremost</b> 19:15 278:6 <b>forget</b> 350:1 <b>form</b> 6:20 73:4 115:18 131:4 163:4 273:21 378:7 <b>formal</b> 21:15 <b>formally</b> 167:21 <b>forms</b> 235:19 <b>forth</b> 202:11 220:8 347:14 <b>fortunately</b> 398:13 <b>Forum</b> 1:1 5:9 <b>forward</b> 18:8 20:12 20:20 33:9 43:19 44:10 48:9 67:7 69:21 87:13 103:17 140:14	143:6 144:19 145:16 190:10 267:15 292:3,4 298:19 366:12 390:5,8 399:3 <b>found</b> 52:18 53:2,9 137:9,12 141:17 166:9 169:15 207:11 209:6 333:17 354:16 375:17 <b>foundation</b> 2:19 69:2 279:18 330:1 <b>foundations</b> 267:8 <b>four</b> 28:7 32:8 51:13 59:21 78:17 82:11 87:19 102:1 108:16 111:7 197:7 215:9 288:6 338:9,12,17 340:5 348:8 <b>fourth</b> 28:21 124:14 <b>fraction</b> 192:12 193:12 198:7,9,14 198:18 199:14,21 212:6,13 213:2,6 246:16 <b>fractions</b> 198:20 <b>frame</b> 38:18 201:11 201:17 224:5 225:8 320:7 <b>frames</b> 225:22 <b>framework</b> 385:3 <b>frankly</b> 96:21 196:2 223:15 348:10 <b>Fred</b> 44:21 49:3 90:9 104:15 170:15 210:5 214:10 218:18 226:22 231:15 232:10 269:20 310:19 400:20 <b>FREDERICK</b> 2:22 <b>Fred's</b> 208:13 <b>free</b> 20:4	<b>frequent</b> 54:16 <b>frequently</b> 169:13 229:8 297:6 336:1 341:3 <b>friend</b> 154:7 <b>front</b> 77:3 138:19 149:12 380:1 <b>fronts</b> 134:14 <b>frustrating</b> 264:19 <b>frustration</b> 112:14 <b>fudge</b> 347:11 <b>full</b> 41:3 303:11 <b>fully</b> 63:7 203:10 <b>function</b> 198:22 215:1 228:19 229:21 230:5,21 231:2 232:3 259:19 <b>fundamental</b> 63:4 218:3 277:5 <b>fundamentally</b> 277:17 <b>fundamentals</b> 123:3 <b>funders</b> 25:1 <b>further</b> 18:17 104:10 109:6 146:10 150:9 186:5 329:16 390:2,16 <b>future</b> 68:15 119:12 120:10 140:15,21 179:19 180:2 187:21 <b>FYI</b> 102:15	269:16 271:6,15 273:14 281:11 317:5,16,19 318:18 365:15,17 372:12 <b>gaps</b> 114:11 329:3 350:20 <b>gather</b> 118:21 248:17 366:9 <b>gee</b> 345:13 <b>geekness</b> 112:18 <b>geez</b> 115:15 380:15 <b>gender</b> 61:15 350:18 356:9 357:7 399:2 <b>general</b> 5:19 6:15 10:21 19:12 40:19 57:5 68:10 119:12 131:7,12 137:10 149:3 170:12 182:4 242:17 259:22 302:2 <b>generally</b> 28:3 170:12 215:5 251:21 293:16 294:11 <b>generate</b> 41:19 267:15,18 <b>generated</b> 124:17 161:1 232:18 247:20 279:5 300:11 368:21 383:13 <b>generating</b> 266:22 <b>generation</b> 147:12 <b>generic</b> 136:13 218:12 223:22 236:3 254:20 <b>George</b> 1:11,14 2:1 6:2 7:17,17 8:6 14:22 73:6 82:14 109:5 131:16 132:16,17 147:8 150:15,20 151:1 151:21 152:6,12 154:10 155:12 156:14,22 157:4
--	---	--	--	---

157:10 160:5,22	85:3,13 88:7,19	211:9 213:17,20	398:3 400:11	40:5 61:8 70:18
162:6 163:15	89:4 90:8 91:12	214:9,21 215:16	401:11,14 402:1,3	72:18 76:18 79:21
164:3 168:1,9	93:16,19 95:5	216:2 217:15	402:6 403:19,22	82:8 89:17 106:11
175:18 176:12	97:8 98:14 100:3	218:17 220:20	404:6,11 405:14	108:8 111:10
177:7 245:8	101:6,16 102:16	221:5,18 223:19	411:4 415:2,12	112:8 116:13,22
270:15 294:15	103:18 104:20	224:9,12,17	416:20 417:5,22	118:10 124:1,10
377:10 395:22	105:2,5,16,22	226:20 232:14	418:4,8	124:12 131:15
<b>getting</b> 8:8 36:19	106:17 107:10,18	233:10 236:9,13	<b>give</b> 31:2 33:17	133:20 138:5
67:1 78:10 88:15	108:8 109:5,10,16	236:22 238:8	35:7 40:8 50:14	140:13 142:8
89:20 92:6 97:2	110:18 111:4,9,17	239:22 246:11,19	60:12 70:8 81:16	145:16 146:17
115:6 128:6	111:20 112:7,11	247:3,12,15	107:20 108:12	148:12 149:10
132:10 134:16	113:6 114:16,19	248:15 254:16	120:7 129:7	150:10 155:6
153:20 155:2	115:8,12 116:4,21	255:20 273:3	144:22 162:7	160:18 161:9,18
165:18 168:21	118:7,10,14	280:18 281:20	166:15 170:1	163:9 165:16
171:17 172:22	119:15 121:14	282:7 283:21	172:8 180:22	166:4 171:1 172:2
253:18 258:19	122:21 123:12	284:6 287:8,13	209:16 238:18	175:1,13 176:6,11
261:5 262:17	124:6,9 125:19	288:15,22 290:3	244:6,7 259:2	177:2,20 178:4
263:18 264:8,21	126:2 127:7,16	290:16 291:14	280:3 295:1,5	179:7,10 184:2
272:5 279:16	129:3 131:1,14,22	292:2,14,19	306:21 309:11	186:22 192:22
283:8 284:3	133:2,15,19	295:22 296:13	367:21 374:18	196:1,2 199:19
310:12 317:7	135:18 138:1,4,21	297:3 298:9 300:3	381:19,22 400:15	204:1 205:2 206:4
326:14 340:14	139:11 140:17	300:7 301:15	403:3	209:17 213:20
343:7 344:19	141:5 142:12	302:18 303:4,10	<b>given</b> 85:7 91:14	214:1 217:18
346:15 348:6	143:19 145:5,12	303:22 304:13,18	104:4 112:1 134:6	218:4 220:16
351:8,9,13,17	145:20 146:11	305:1,5,9,15,19	165:8 186:16	224:19 236:13
352:1 353:2	147:4 148:8,11	306:4,17 307:1,5	200:12 250:4	237:1 238:6,9,11
359:21 372:4,6,6	150:8 151:19	307:10,18 309:5	255:7 273:12	246:12 247:16
373:13 387:8,17	154:19 155:1,8	310:9 312:6,10	282:2 295:7	271:18 291:21
411:7	156:7 157:22	316:8,13 317:13	311:22 347:11	305:20 309:4
<b>GI</b> 119:21 122:12	159:19,22 160:3	319:6,12 320:10	370:6 381:5	312:5,7,10 318:15
<b>giant</b> 18:1	160:14,17,20	324:5 329:11	383:12 402:18,20	322:17 324:18
<b>Gibbons</b> 1:12,15	161:8,12,17,20	330:9 331:17	414:19 415:17	325:7 328:16
6:2,3 7:10,11 15:6	162:20 163:8,12	342:6,22 343:20	<b>gives</b> 18:9 81:20	340:7 341:15
15:19 19:9 31:20	166:4 168:1 169:9	349:14 351:19	212:21 311:7	343:18 350:12
34:5 38:8 39:20	170:14 171:3	357:1,10 360:13	<b>giving</b> 13:9 127:12	364:18,22 367:9
44:15 49:4,9,21	176:5,9,20 177:1	360:22 361:3	403:13 408:4	367:10 368:4
55:5,10 57:12,16	177:4,15,19,22	364:17 365:1,19	<b>gizmo</b> 33:22 34:7	369:20 375:11
57:19 58:5,9,12	178:7 179:12	365:22 366:14,20	35:3,8 103:2	382:12,15 384:6
59:12,16 60:1,14	184:1 185:22	368:3,12,14 369:9	417:16	384:13 386:15
62:4,20 64:22	189:21 191:1	369:12,19 370:14	<b>gizmos</b> 34:2 36:15	392:6 393:8
65:18 67:16,19	192:3,18,21 193:3	372:16 375:5	<b>glad</b> 211:18 385:14	395:19 400:1
70:17 72:5,20	194:21 195:3	376:3 377:4 382:3	<b>glitch</b> 211:6	404:7,10 412:5
73:5,13,22 74:9	196:3 198:3 199:3	382:12 383:2,5	<b>go</b> 6:16,21 7:4	414:11 415:1
75:18 76:20 77:1	199:7 203:19,22	384:2,5,13 385:19	17:16 20:4 22:19	416:18
77:9,18 79:7 80:7	204:3,20 205:1	386:11,14 391:8	28:11 32:4 33:9	<b>goal</b> 76:8 144:14
80:18 81:1 82:10	207:2 208:10	392:3,5 393:7	34:10 35:8,20	145:4 175:4,4,5
82:19 83:2 84:17	210:2,15,16 211:2	395:3 396:18	36:7 37:18 39:11	272:8 279:20

288:3 291:2	199:18 200:21	57:3 60:5 68:15	101:14 121:22	273:19 286:18
344:21 345:21	202:3 203:7	69:12 100:22	147:19 155:18	315:15 328:18
<b>goals</b> 26:2,16 28:2	210:19 211:6,10	108:10 109:13	162:12 163:17,21	337:10 351:15
109:8 181:3 267:7	211:13 212:20	112:19 120:7	167:14 260:4	356:3 379:13
296:7 298:5	226:18 228:4	126:12 131:10	355:16 379:8	385:7 396:7,10
<b>God</b> 210:6	229:2,10 234:13	138:2 142:21	380:7 397:7,12	401:19 403:1
<b>goes</b> 18:8 218:2	237:3 243:15	143:16 148:5	<b>green</b> 225:15	404:21
248:20 283:13	244:18,20 245:1,4	169:1 189:9	<b>ground</b> 139:17	<b>guidance</b> 68:8
293:5 387:4,11	249:7 253:17	197:22 201:3	<b>group</b> 1:24 12:10	169:7 186:17
390:11	255:22 261:11	216:1 220:5	14:10 16:3 25:5	187:5 216:12
<b>going</b> 6:8,10 7:9	270:17 272:12,16	222:18 232:9	47:7,9 48:4 60:7	290:4 339:10
16:19 17:14 18:2	275:3,4 280:19	240:3 246:20	68:9 70:7 87:6	340:1
18:16,20 19:1	281:21 284:7	258:3 270:14	93:2 105:11 107:8	<b>guide</b> 269:15
20:12,20 29:3,20	286:1 287:9 292:8	277:3 278:12,15	129:1 131:10	<b>guideline</b> 10:6
30:6 32:2,4 33:16	292:17 305:19,22	280:16 283:6,9	133:6 151:2 152:9	43:20 46:18 96:2
34:10,22 35:7,14	306:5 307:11	289:15,18 293:17	159:16,17 162:8	105:21 106:14
36:2,3,8,20 37:20	308:10,11,15	294:14,19 304:1,2	164:22 177:16	158:14 175:12
40:6,16 41:18	309:10 310:13	310:11 372:8	178:16 193:17,19	199:11,12,18,20
43:18 45:12 55:8	312:7 313:8,12	374:5 380:16	193:22 221:17	217:21 221:6,21
57:22 59:13 60:15	316:9 319:1,17	383:17 385:15,17	231:6 235:1	225:3,7,17 226:8
71:22 72:6,20	320:11 322:14,16	386:2,8,17 394:19	237:15 260:5	289:3 291:6
78:2,5,14 83:3,19	323:8,15,22	396:6 417:9 418:2	266:3 290:20	298:16 388:6
84:17 86:8,15,18	324:10,21 325:2,3	<b>gotten</b> 215:11	294:13 298:11	<b>guidelines</b> 7:15 8:8
87:13,22 91:20	325:5,8 330:16	266:22 273:7	309:21 319:16	43:5,12 47:17,19
92:11,21,22 93:21	341:11,14 343:18	358:10 380:21	326:19 327:10,20	90:15,15,18 95:15
94:16 97:11 101:8	345:3 346:18	<b>GP</b> 279:2	331:20 334:1	106:8,16 114:9
103:10,17,22	350:4,5 355:21	<b>grab</b> 198:10 416:16	348:22 351:10	151:12,18 162:19
108:2 111:17	356:17 357:2,22	416:21	354:9 357:20	175:16,21 176:2
112:15,21,22	358:7,15 360:16	<b>gradation</b> 389:22	359:10,22 361:13	176:15 199:12
113:7,11 115:21	361:4,6 365:2	<b>graded</b> 188:10	361:19 363:15	214:15,19 215:12
116:21 118:22	367:12 368:4,6,15	<b>grades</b> 133:14	366:2 387:6	216:11,12,16,21
120:13 123:16	368:15,16 369:13	<b>gradually</b> 293:11	406:11 407:17,18	217:3,6,9,11,19
124:21 125:13	370:15 377:8,9	<b>gram</b> 232:3	410:22 411:2,14	218:5,5 219:11
131:10,11 132:2,7	378:5 381:16,19	<b>grand</b> 18:13,15	411:17 412:2,3	221:5,13 226:1
132:8,14 133:1	383:8 388:22	44:11	<b>groups</b> 25:9 48:11	228:10 231:5
134:9 136:21	389:20 390:7,21	<b>grappling</b> 185:20	51:8 52:8 59:21	252:7 284:17
140:20,22 143:6	390:22 392:1	<b>great</b> 43:20 46:22	87:2 107:7 128:10	286:22 287:1,21
144:16,16,18	393:3,8,12,18	55:11 110:5	194:3,15 227:10	290:12,14 291:12
146:20 147:2	394:17 399:2,17	144:14 151:12	293:15 296:8	304:20 305:11
148:12 150:10,17	399:18 400:1,2	201:13 224:2,11	300:21 301:10	324:15 326:1,7,11
153:17 159:14	401:8 403:20	260:20 261:20	390:1 396:16	364:10 370:7
162:2 163:13	404:13 406:14	279:19 330:20	415:1	388:9
167:16,19,21	409:21 415:7,15	348:16 366:22	<b>guess</b> 11:19 105:17	<b>guideline's</b> 229:12
168:14 173:7,14	415:20,22 416:5,7	390:6	142:5 149:14	<b>guideline-based</b>
174:11 175:18	<b>good</b> 5:4 6:3,13	<b>greater</b> 2:3 9:11	167:1,11 175:19	47:16 405:8
178:1,8 180:1	11:1 12:13 14:5	57:7 64:6 89:10	221:15 228:13	<b>guinea</b> 148:22
188:8 197:3	36:7 39:12 40:10	95:2,6,11 100:11	252:2 259:6 267:3	149:1

<b>gun</b> 323:17	<b>harmonization</b>	187:11 202:6	<b>held</b> 90:20 189:18	<b>higher</b> 24:16 87:16
<b>guy</b> 367:10	18:6,11 19:1	242:10,12 251:21	289:12	87:16 118:3
<b>guys</b> 14:13 250:15	24:21 29:3 31:21	252:19,20 253:20	<b>Helen</b> 2:14 5:14	131:11 250:5
310:8 323:22	32:14,19 33:1	259:19 272:4	14:7,12 72:10	289:22 302:11
351:13 378:16	44:2,5 48:18	280:13 297:6	88:8 91:17 125:20	339:7 348:12
407:5	77:11 78:4 83:5,9	298:1 299:19	131:1 132:11	<b>highest</b> 103:15
<b>H</b>	83:15 104:6 105:4	302:14 334:1	142:12,13 145:12	334:5 335:16
<b>hairs</b> 108:2	105:8 106:21	386:7 402:9	186:16 273:3,4	<b>highlight</b> 321:9
<b>half</b> 61:18 79:15	107:4 118:20	<b>Healthcare</b> 1:17	<b>hello</b> 10:15 12:4	327:4 382:6
80:3 86:11 260:16	119:5,11,17 123:4	<b>hear</b> 21:21 40:2,14	14:9	<b>highlighting</b>
270:3 271:21	124:3 126:8	50:6,8 98:13	<b>help</b> 6:5 14:21 27:4	377:16
<b>half-day</b> 20:8	138:13 139:2	169:12 171:20	29:10 41:19 64:12	<b>highly</b> 223:8
<b>Hammersmith</b>	140:19 141:4	172:1 199:6 200:7	70:21 130:14	<b>high-performing</b>
2:14 5:19 6:13,15	142:3 143:5,13	208:13 210:4,5	141:2 152:5 172:7	127:3
8:13 13:2,8,22	144:14 145:3,9	240:22 310:8	181:22 188:19	<b>Hill</b> 2:6 297:19
14:4	149:4 176:16	316:15 327:6	219:15 223:20	<b>historically</b> 271:2
<b>Hampshire</b> 256:4	178:15 179:7	329:10	227:6 257:1	<b>history</b> 92:1 120:9
<b>hand</b> 60:12 85:2	204:15 244:11	<b>heard</b> 55:13 79:10	275:16 286:8,9	239:18 243:7
112:2 180:18,20	293:22 357:18	85:16 91:13 104:1	304:19 305:13	268:1 285:3,4
274:1 295:17	391:20 401:19	110:7,8,9 241:9	<b>helped</b> 361:11	301:6
399:16 415:14	410:4	242:14 288:19	<b>helpful</b> 59:22	<b>hit</b> 35:22 36:5
<b>handed</b> 33:22	<b>harmonize</b> 78:2	351:2	106:18 110:19	95:20 249:16
<b>hand-raising</b> 34:16	105:12 141:9	<b>hearing</b> 24:4 44:12	179:5 302:19	353:14 356:7
<b>hanging</b> 82:22	142:18 143:18	77:3 114:19 241:1	306:13 328:22	<b>hits</b> 186:22 352:6
<b>happen</b> 150:7	145:13,14 146:22	241:12	335:15 416:19	352:13 358:13
359:9	<b>harmonized</b> 31:11	<b>heart</b> 1:16,19 2:5	<b>helping</b> 5:20 12:9	<b>hold</b> 43:15 159:2
<b>happened</b> 35:22	47:22 77:16	9:21 11:16,17	12:10 14:15 130:3	271:1
159:15 215:15	105:13 145:11	12:8,15,16 14:16	203:18	<b>holding</b> 34:4
<b>happening</b> 222:4	160:8 176:17	115:20 131:6	<b>helps</b> 23:6 96:5	289:18
363:18	231:14 409:21	153:3 200:21,22	358:18	<b>home</b> 65:22 66:5,14
<b>happens</b> 25:2 73:18	410:2,8	218:20 219:7,9,10	<b>Hey</b> 259:5	67:2 214:6 248:20
105:19 352:3	<b>harmonizing</b>	220:18 221:2,9,16	<b>Hi</b> 10:10,20 11:14	347:13
398:22	146:15,17 196:14	222:1 228:9	11:21 14:11 15:12	<b>honest</b> 407:1
<b>happy</b> 5:22 102:22	<b>hate</b> 197:1	229:16 230:13	142:13 273:4	<b>honestly</b> 335:22
297:15 306:15	<b>HDL</b> 155:22	231:4 237:17	309:3	<b>honor</b> 170:4
312:4 317:11	<b>head</b> 12:1 14:19,19	268:21 272:10	<b>hick</b> 347:8	<b>hook</b> 18:1 45:9
<b>hard</b> 70:14 88:5	271:10 387:20	285:15 324:18	<b>hiding</b> 67:13	244:8
129:11 130:11	<b>header</b> 101:11	332:1,17 333:1	<b>hierarchy</b> 248:11	<b>hope</b> 75:10 103:21
158:6,21 169:6	<b>heads</b> 143:20,20	<b>heavily</b> 69:19	<b>high</b> 75:13 77:14	138:16 267:4
180:3 187:15	<b>health</b> 1:23 2:3	284:20 294:5	79:17 87:14 128:4	278:4 281:22
208:3 250:18	3:13 8:22 9:6,11	<b>heavy</b> 132:22	128:17 129:6,12	316:4 360:2
263:21 269:3	10:17 22:2 25:3	<b>HEDIS</b> 42:7 75:20	129:15,18 133:11	<b>hopefully</b> 34:17
333:17	42:11,13 47:3,20	160:7 201:16	133:13 158:21	36:16 187:8 228:1
<b>harder</b> 35:19	50:19,21,22 61:6	247:8 252:8,18	159:7 181:5,12	236:4 288:13
221:14	61:7 117:10,11,11	299:15	192:14 299:16	308:15
<b>hard-nosed</b> 68:10	124:18 130:15	<b>HEE</b> 1:18	338:16 367:3	<b>hopes</b> 175:3
	131:20 185:2	<b>HEIDI</b> 2:13	386:7 394:21	<b>hoping</b> 44:16 233:6

287:17 343:1 359:3 <b>horror</b> 364:2 <b>horse</b> 327:2 <b>hospital</b> 1:22 2:4 12:6 23:1 47:11 188:6 204:19 309:18 310:21 311:19,22 312:2 312:19 314:2,21 315:18 321:12,16 323:3,7 327:18 328:4,19 330:10 333:12 334:22 337:9,22 339:5 345:3 347:17,21 348:4,14 349:20 354:11 359:15,15 361:17,18 362:2 362:12,14 363:13 367:16 371:9 373:18 376:10,19 377:7,13 381:2 387:2,12 394:5,9 394:10 397:4 398:1,10 399:20 400:9,10 406:5,16 406:17 407:10 408:11 411:14 412:10 <b>hospitalization</b> 153:10 <b>hospitalized</b> 237:20 <b>hospitals</b> 9:8 139:16 310:5,22 311:15 312:16 314:2,12,12,14 315:2,5 321:12 322:21 323:16 324:4,6,7 326:16 328:1 331:5 343:5 343:13 345:6 346:11 347:10 348:17 358:20 359:5 361:19 362:6,19,20 370:22 373:13,17	374:4,13 377:18 377:21 382:20 399:15 400:6,13 400:14 406:13 407:19,22 414:7 <b>hostage</b> 90:14 <b>hour</b> 270:4 415:18 <b>hours</b> 348:8 365:7 370:6 372:7,14 380:13 381:2 384:21 385:11 <b>housekeeping</b> 20:1 <b>huge</b> 24:21,21,22 63:4 269:12 318:10 396:1 <b>hugely</b> 115:13 194:15 <b>Human</b> 25:3 <b>hybrid</b> 76:2,12,14 77:5 79:11,19 80:6,9,10,14,21 81:7,18,19 82:3 <b>hyperkalemia</b> 208:8 <b>hypertension</b> 57:3 63:4 64:7,10 71:2 71:8,21 77:20 89:7,19 97:13 110:6 174:18 193:20 228:21 229:21 230:5 266:5 306:20 <b>hypertension's</b> 58:11 63:8 <b>hypertensive</b> 111:1 299:18 <b>hypotension</b> 206:15 208:9 <hr/> <b>I</b> <hr/> <b>ICD-9</b> 117:19 154:8,12,12 205:9 286:11 334:13 335:10 <b>ICSI</b> 284:17,19,20 284:22 285:10,18 298:16	<b>idea</b> 22:18 25:17 63:8 64:9 69:12 83:16 96:6 100:19 251:2 252:16 262:8 280:9 304:1 324:19 418:3 <b>ideally</b> 388:7 <b>identical</b> 410:7 <b>identifiable</b> 195:20 <b>identification</b> 314:20 <b>identified</b> 18:22 268:11 309:19 314:4 315:4 317:6 317:19 334:8 337:12 354:5 <b>identify</b> 49:5,10 81:12 135:9 154:14 161:5 233:16 238:14 315:10,14 337:16 358:22 374:10 410:3 <b>identifying</b> 25:9 77:7 99:14 166:20 <b>illusive</b> 145:4 <b>imagine</b> 263:21 298:20 <b>immediate</b> 127:13 372:22 <b>immediately</b> 43:9 198:1 204:18 <b>Immigration</b> 1:10 <b>impact</b> 30:12 58:15 99:6 127:9,12 130:9 133:11 151:13 162:18 187:9 192:14,15 218:15 222:14 365:7,12 367:3 373:22 386:7 <b>impacts</b> 99:3 317:4 <b>impatient</b> 36:12 <b>implementation</b> 227:22 234:2 235:14 <b>implemented</b> 31:16	129:20 337:1 369:8 384:1 399:11 <b>implementing</b> 166:8 177:11 <b>implication</b> 107:20 251:18 <b>implications</b> 196:15 <b>implicit</b> 403:8 <b>importance</b> 28:8 28:13,14,15,17 29:19 30:8 37:8 37:11 38:1,1 46:20 56:17 57:4 57:6,14,20 58:14 63:5 68:4,17,19 69:8 93:10,13 107:17 114:5,13 114:17 116:22 133:16,20 140:10 140:12 155:7 163:9 192:19,22 212:19,22 213:18 215:18 226:21 238:7,9 280:21 281:13 283:13,18 283:19 291:22 292:7 317:14 350:6 365:20 366:1 372:15 375:6 386:15 395:2 396:18 405:10 <b>important</b> 8:11 21:18 24:17 30:10 34:9 35:4 38:9 39:19 56:22 58:11 68:7 71:20 73:9 73:12 89:6 93:12 93:20 98:18 99:13 99:18 107:12 115:13 116:5,14 130:18 131:20 137:1,7 140:6 153:17 170:19 174:12 180:11	183:6 202:16 206:11 209:16 210:3 213:13 217:7 231:17 236:17 252:18 256:16 270:11 278:18 281:5,6,14 281:16 283:17,22 284:9 286:21 287:2 288:15 293:9 296:11 315:21 317:2 323:13 324:11 330:11 346:4 350:21 362:9 363:17 365:16 367:3 372:20 386:9 388:21 389:18 390:9 396:12 401:17 405:8 417:13 <b>impressed</b> 126:18 <b>impressive</b> 126:22 <b>improve</b> 52:11 130:15 271:11 354:13 355:14 <b>improvement</b> 8:2 21:15 26:4 28:2 46:19 52:10 53:5 58:19 114:13 131:4 151:16 162:18 181:16 184:6 194:17 279:19 294:16 317:9,17,20 319:13 321:4 <b>improving</b> 190:7 <b>inaccuracies</b> 161:5 232:21 248:4 300:17 369:6 383:22 392:20 402:13 <b>inaccurate</b> 233:5 <b>inadequate</b> 64:20 <b>inaugural</b> 14:13 <b>incentive</b> 96:14 175:1
--	--	---	---	---



<b>incentivize</b> 98:10	<b>indefinitely</b> 193:15	348:12	<b>injection</b> 198:9	97:14
<b>include</b> 45:17,20	199:16 231:8	<b>inflation</b> 363:13	<b>inner</b> 399:20	<b>intent</b> 38:2
47:9 67:3 81:21	<b>independence</b>	<b>influenced</b> 187:11	<b>inner-city</b> 348:3	<b>intercede</b> 180:21
101:11 107:7	170:1	<b>inform</b> 162:22	<b>inpatient</b> 239:5	<b>interest</b> 4:4 6:12,17
121:20 134:6	<b>independent</b>	<b>information</b> 28:3	311:11 313:21	6:20 7:7 91:19
152:16 165:7	172:14	31:3,10,19 69:16	315:12,17 347:11	209:5
167:17 200:12	<b>independently</b>	70:5,9 84:15	355:5 360:8	<b>interested</b> 166:18
209:7 239:13	149:18 258:6	86:12,15 88:6	376:11	260:6 270:6 396:1
243:9 311:20	<b>indicate</b> 157:15	102:14 104:5	<b>inpatients</b> 309:19	<b>interesting</b> 250:10
322:2 339:17	260:20	130:21 170:6	313:15 314:16	299:1,5 312:13
350:17 381:9	<b>indicated</b> 88:12	171:17 184:15	323:12	359:21 396:11
390:13 411:15	100:4 103:19	202:22 205:7,8	<b>inpatient/outpati...</b>	<b>interfere</b> 188:13
<b>included</b> 54:21	202:14 207:18	237:14 249:4	117:15	<b>intermediate</b> 155:3
111:2 122:20	256:15 390:15	254:8,15 257:14	<b>input</b> 16:12 41:22	184:18 185:4,9
153:19 154:8	<b>indicating</b> 64:15	257:15 258:18	123:21	<b>internal</b> 47:10
168:14 187:7	343:13	259:3 265:17	<b>input's</b> 39:19	278:20
193:19 269:22	<b>indication</b> 292:20	287:14 300:10	<b>insertion</b> 322:18	<b>International</b> 2:5
302:6 413:10	<b>indicator</b> 69:3	306:10 328:21	<b>inside</b> 287:14	<b>interpret</b> 342:3
414:5	213:4 233:4	333:21 350:13,18	<b>insight</b> 180:22	<b>interpretation</b>
<b>includes</b> 46:16	260:11	361:20 376:11	<b>insights</b> 350:2	153:15 217:7
299:13 315:5	<b>indicators</b> 128:21	391:12 414:4,18	<b>instance</b> 105:10	341:20
<b>including</b> 46:13	<b>individual</b> 32:8	<b>infrequent</b> 137:11	179:1 222:15	<b>interpreting</b>
47:19 118:19	37:4 48:13 55:18	<b>infrequently</b>	233:9,12 310:16	266:17
134:17 162:14	99:22 146:7 283:4	400:16	391:2	<b>interrelated</b> 274:9
202:18 220:6	299:22 312:5	<b>inhibitor</b> 199:15	<b>instances</b> 82:1	<b>interrogate</b> 367:19
414:22	334:6	200:19 205:19	<b>instant</b> 18:12,14	<b>interruption</b>
<b>inclusion</b> 58:7	<b>individually</b> 29:1	208:8	<b>instantaneously</b>	117:12,14 205:22
153:18 201:7	<b>individuals</b> 13:15	<b>inhibitors</b> 46:5	34:15	<b>interval</b> 363:10
235:7 351:7	13:18 16:4 23:14	196:8,15,16 199:2	<b>Institute</b> 2:5	<b>intervention</b>
<b>inclusions</b> 402:16	47:13 48:7	<b>inhibitor's</b> 207:17	<b>institution</b> 139:3	133:13 332:15
<b>inclusive</b> 149:7	<b>industry</b> 2:8 8:19	<b>initial</b> 26:22 120:21	340:11 359:11	344:19 346:10,15
153:13	218:9	133:14 265:6	387:22 399:13	387:9
<b>incompleteness</b>	<b>inefficiency</b> 25:17	322:18 331:21	<b>institutions</b> 147:18	<b>interventional</b> 10:1
68:3	<b>infarct</b> 198:13	336:8 337:8	<b>instructions</b> 234:13	11:22 127:19
<b>inconsequential</b>	230:6 242:22	402:20 412:10	339:9,15 343:11	<b>interventions</b>
249:11	<b>infarction</b> 21:11	<b>initially</b> 51:5 235:2	<b>instrument</b> 261:7,9	190:17 271:10
<b>inconsistent</b> 228:8	46:4 56:9 215:2,4	309:15,18 311:15	269:9	272:8
<b>incorporate</b> 53:18	215:9 229:3	313:19 354:8	<b>insurance</b> 203:8	<b>inter-rater</b> 258:14
84:1	237:16 308:12	373:18 375:16	222:16 249:9	<b>intolerant</b> 220:7
<b>increased</b> 53:3	309:21 310:6	<b>initiated</b> 64:5	250:3,6,9 255:3	<b>intricate</b> 185:18
<b>increases</b> 207:14	313:16 314:6	<b>initiating</b> 64:9	<b>insurers</b> 22:2	<b>introduce</b> 5:18,22
<b>increasing</b> 137:4	316:20 326:17	70:22 71:5	<b>intact</b> 76:11	14:7 15:5,9,21
249:13 254:18,22	371:11,14 400:5	<b>initiation</b> 64:3 89:8	<b>intellectual</b> 27:16	33:18 40:7 308:21
<b>increasingly</b>	<b>infarctions</b> 310:18	<b>initiative</b> 227:9	<b>intended</b> 28:1	<b>introduced</b> 262:13
249:17 250:3	<b>inference</b> 64:16	362:20	157:11 312:22	<b>introducing</b> 6:9,22
<b>incremental</b> 372:9	<b>inferior</b> 242:22	<b>initiatives</b> 9:19	<b>intending</b> 69:6	16:1 309:9
<b>indefinite</b> 217:4	<b>inferoposterior</b>	118:18 266:7	<b>intensification</b>	<b>introduction</b> 4:5

36:21 40:2 293:13	167:21 170:20	<b>J</b>	<b>John's</b> 264:7	<b>Kathryn</b> 2:16 5:10
<b>introductions</b> 5:3	174:20 178:15	<b>J</b> 2:1	<b>join</b> 5:5,6 55:8	<b>Kathy</b> 12:18
5:20	186:6 189:11	<b>January</b> 151:5	<b>joining</b> 5:14,16	<b>keep</b> 17:8,14 41:18
<b>Introduction/Ov...</b>	199:4 201:4 207:6	287:18 290:7	<b>joint</b> 45:13 105:10	76:10 92:6 103:17
19:10	207:19 208:1	335:15	<b>jokes</b> 385:16	106:11 108:21
<b>introductory</b>	209:14 216:10	<b>JD</b> 2:8	<b>Jon</b> 2:2 9:2 192:4,5	116:20 189:20
309:11	217:1 224:13	<b>jeopardy</b> 102:2	193:6 204:6	204:7,8 244:20
<b>invalid</b> 354:16,18	234:17 235:13	<b>Jersey</b> 2:8 8:18	<b>JONES</b> 2:22	360:14 393:11
354:20 375:17	246:5,9,9 277:5	<b>Jewell</b> 1:19 11:1,2	329:22 332:7	<b>Kentucky</b> 297:14
<b>invasive</b> 390:16	286:2 292:5	67:20 102:6 123:7	336:6,20 339:6	<b>key</b> 53:6 179:15
<b>invisible</b> 184:13	294:20 301:18	156:17 157:1	341:17 342:19	210:20 281:12
<b>involve</b> 104:7 163:6	312:16 319:3	165:5 166:22	343:3 356:14	308:12 339:2
<b>involved</b> 7:22 8:7	325:22 350:21	167:22 186:6	357:6 376:14,17	361:7 386:3 404:1
10:6 12:9 30:4	359:13 367:2	195:1,4,18 277:4	377:1 380:4	<b>keypads</b> 34:19
49:14 114:10	373:8 375:20	329:1,13,20 330:4	<b>JOSEPH</b> 2:21	<b>kid</b> 308:4
116:10 186:8	376:1 377:19	378:6,13,17 414:4	<b>journey</b> 23:15	<b>kidney</b> 193:21
202:21 251:9	381:15 388:2	<b>JNC</b> 285:9,22	<b>JR</b> 2:6,21	<b>kind</b> 15:2 16:16
<b>involvement</b> 11:10	390:9 393:4	287:3,10 288:13	<b>judge</b> 182:2	51:11 59:1 61:20
236:7	<b>issues</b> 16:19 17:18	302:4 305:11	<b>judgment</b> 29:15	72:9 89:5 123:4
<b>involves</b> 107:1	18:11 20:1 25:22	<b>JNC-8</b> 43:15 54:6	30:4	136:12 137:20
<b>in-house</b> 5:17	29:2,4 39:17	105:17 106:7	<b>judiciously</b> 187:8	150:5 172:8
<b>IOM</b> 283:1,2	42:20 43:10 47:6	290:6	<b>juice</b> 127:1	173:15 180:22
<b>Iowa</b> 379:20	98:3 110:9 118:20	<b>job</b> 45:12 241:15	<b>July</b> 237:21 239:6	181:16 184:9
<b>irrelevant</b> 223:6,7	125:3 126:8	241:16 278:13	239:10	200:2 208:15,18
330:14 331:6	132:11 148:2	280:3 293:17	<b>jump</b> 133:10	218:13 227:20
347:8	176:16 183:19	322:21 358:5	156:18	233:21 261:12
<b>irrespective</b> 401:5	184:21 185:21	403:18	<b>jumped</b> 341:11	275:7 293:6
<b>ischemic</b> 37:2 41:1	194:5,22 202:17	<b>Joe</b> 48:21 49:4,5	<b>jumps</b> 240:14	319:18 320:7
41:7 56:4,11	203:14 204:21	98:12,14 101:17	<b>June</b> 237:22 239:7	322:19 330:8
113:15,20,22	207:15 222:8,11	105:3 106:1	239:11	338:15,21 373:20
114:7 117:15	235:22 236:8	109:14,16 135:20	<b>justice</b> 86:18	379:11 381:21
151:7 152:4 228:9	240:1 242:15	135:21 138:2,7	<b>justification</b> 30:22	<b>kinds</b> 185:20
272:10 282:14	247:10 270:8	141:3,6 142:13	70:3	<b>King</b> 1:21 10:10,11
<b>issue</b> 18:6 19:1,3	281:13 286:12	143:21 147:6	<b>justify</b> 172:5	55:19 56:1 60:17
24:22 31:21 32:2	293:22 294:6	164:1 166:3,4	276:22 306:14	62:6 74:11 77:12
38:1 44:1 46:22	319:2 335:9 344:3	199:5,7 202:8	<b>K</b>	78:18 85:15
48:17 71:22 78:4	374:11 375:13,18	208:12 217:17	<b>Kaiser</b> 2:2 8:15 9:3	119:19 121:9
89:17 91:9 95:9	375:19 377:17	226:22 232:11	<b>Kansas</b> 49:13	152:22 171:2,4
96:4 98:4,17	388:18 390:10,14	253:12 272:11	<b>Karen</b> 2:15 5:16	179:16 190:16
104:14 105:15	411:5	273:20	15:9,11,12 72:15	217:9 245:17
107:4 109:3	<b>item</b> 124:13 176:11	<b>John</b> 3:12 48:21	146:4 148:18	317:15 318:6
110:21,22 119:5	302:3	49:7,9,12 96:12	184:1 291:15	366:16
121:16,18 123:1	<b>IVD</b> 44:4 51:19	100:4 208:12	295:4	<b>knew</b> 314:12
125:7 128:2	53:19,21 54:4,17	228:6 259:5	<b>Karen's</b> 36:11	339:22 417:7
135:19 138:14	54:20,21 152:11	273:20 278:20	<b>Kate</b> 72:19	<b>know</b> 6:14 8:10
140:19 141:4	152:16,20,20	280:1	<b>KATHLEEN</b> 2:9	15:1 24:20 29:9
144:2 155:11	287:4	<b>Johnson</b> 9:14		30:20 33:22 39:9

44:3 48:21 54:6	261:22 262:21	235:21 349:6	<b>laugh</b> 385:15	<b>lengths</b> 397:18,22
61:18 65:16 66:11	263:1,4 265:15,17	<b>Koplan</b> 1:22 12:4,5	<b>Laughter</b> 127:15	<b>lesion</b> 230:4
66:19 67:15 68:14	266:3,16 267:3,10	113:11,14 115:10	127:22 210:10,13	<b>Leslie</b> 1:18 11:21
69:10,21 72:19	269:14 270:21,22	116:8 117:3	250:21 255:19	<b>lessons</b> 40:19 54:9
77:15 82:17 84:11	271:6,12,15,17,22	118:16 120:17	256:2	174:22
84:14 86:17 90:1	272:7 273:2 274:4	124:5,15 152:15	<b>Lawyers</b> 1:10	<b>letting</b> 190:19
90:13 92:20 95:21	274:10,12,14,15	196:4,13 325:5,17	<b>lay</b> 267:8	<b>let's</b> 35:15 63:20
95:22,22 97:2,14	274:21 275:2,4	409:20 410:12,18	<b>LDL</b> 151:10 155:17	64:11 78:16 108:8
97:17 99:19,20	276:9 277:16	<b>Kottke</b> 1:23 8:21	155:22 157:7,16	111:10 123:18,22
101:20 105:6	278:16,17,22	8:21 127:5,8	158:11,14 159:10	159:8 160:17,21
109:21 110:9	279:3,13,18	144:1 243:13	162:11,12,14	170:22 177:2
115:13 116:20	280:10,14 287:13	244:6 246:14	163:6,19 172:2,10	192:21 205:2,4
117:20 120:9,14	289:20 293:5	250:16,22 252:11	173:22 174:8	213:17 236:13,16
122:11,12,18	294:20 295:13	291:8 299:8,9,19	179:21 282:20	236:22 238:9,10
128:1,8 130:5,9	297:5 298:1	302:9 322:10	283:6 284:12	247:15,18 250:6
130:11 136:1,2,14	318:15 320:6,17	359:12 360:6	294:6	301:16 302:4,7
137:22 139:5,11	321:5 325:1,3,13	362:11 363:20	<b>LDLC</b> 167:14	304:3 307:11
141:1,9,22 142:7	329:21 331:3,19		<b>LDLs</b> 158:21	364:18 375:7
142:9 143:3,11,15	332:4 333:7,10,11	<b>L</b>	<b>lead</b> 37:5,21 93:4	380:14 382:12
144:8,21 150:3	335:4,11 337:11	<b>lab</b> 54:17 230:3	135:3 168:6 389:9	384:13 386:15
155:4 158:5,19	337:13,20 338:16	328:16,18,20	<b>leadership</b> 290:20	401:15 404:7
166:11,15,20	340:6,10,22	<b>lack</b> 112:18 117:12	<b>leading</b> 47:4	410:13 411:6,8
167:20 168:7	341:14 343:4,8,11	117:13 135:13	<b>leads</b> 66:6 120:19	<b>level</b> 42:11,12 68:2
169:2,11,13,18	344:2 347:6 349:5	240:9 367:4	348:18	70:10 74:20 75:14
171:4 172:12,15	349:6 350:14	<b>lacking</b> 62:11	<b>lean</b> 181:1	81:16 88:18 99:21
172:20 173:4,13	355:3,15,17 356:3	<b>Lahey</b> 2:10 10:21	<b>leap</b> 266:3	126:18 128:17,19
176:3 178:18,20	356:4,11 358:14	<b>laid</b> 29:22	<b>learn</b> 132:11 358:7	128:21 153:17
180:7,13,14,18,21	358:16 362:13,18	<b>language</b> 223:13	390:8	163:6 168:18,20
182:5,22 184:4	363:1 372:3,7,8	<b>large</b> 20:14,14 21:6	<b>learned</b> 36:11	172:22 175:10
185:11,18,19	373:3,7 376:13	21:7 33:10 114:8	40:19 54:9 183:5	184:20 185:13
186:19 187:12,13	377:5,15 378:1	130:17 135:2	301:2	202:20 203:16,16
187:15,15 188:20	379:15 380:1,22	147:18 202:4	<b>Learning</b> 149:1	203:16 230:18
189:11 190:19	381:11,12,17	246:15 250:12	<b>leave</b> 85:18 91:15	242:13,13 252:6,6
196:13 199:12,15	382:6 387:20	293:3,4,17,18	206:21 338:3	253:15 256:12
200:7,17 207:8,22	389:11 394:3,13	315:18 317:4	388:4 417:17	257:18,19 258:21
208:2 209:7	397:6 401:19	365:14,17 378:22	<b>led</b> 229:10	264:17 272:21
217:13 218:15	404:18 405:3,8,11	399:20 400:9,10	<b>left</b> 20:4 46:6	277:6,10,12 278:8
222:14 226:7	412:21 414:15	<b>largely</b> 87:18	144:10 196:9,22	281:6 325:18
228:17 231:8,22	417:10	285:13	198:7,21 212:5,12	326:6 364:7 367:2
232:8 235:1,12,20	<b>knowing</b> 324:21	<b>larger</b> 250:3,4	213:1 214:15	382:1 394:21
236:2,6 241:1	391:16	334:9 363:10	228:18 230:4	<b>leveling</b> 380:8
243:13 244:9	<b>knowledge</b> 70:12	371:21 372:13	394:7 395:5,8,14	<b>levels</b> 184:12
246:6 250:20	140:15	<b>largest</b> 25:5 26:21	<b>legislation</b> 315:22	299:10
251:1 253:7,14	<b>known</b> 6:6 21:20	<b>late</b> 213:21 265:18	<b>legislative</b> 273:15	<b>life</b> 34:2 259:20
254:22 256:22	269:11 274:8	396:21	315:22	264:12 277:17
257:6 258:18	395:15	<b>latest</b> 46:17 297:9	<b>length</b> 98:21 385:6	390:14
259:6 260:4 261:4	<b>knows</b> 169:1 203:3	324:14	397:12 398:6	<b>lifestyle</b> 180:8

280:6	136:10 156:10	417:10	23:16 24:15,16,18	189:6 192:15
<b>lifting</b> 132:22	177:10 239:14,15	<b>longitudinally</b>	25:18 30:14,20	202:17 203:12
<b>lifts</b> 18:2	240:15 242:19	166:14	31:4,6 69:11	205:15 207:20
<b>light</b> 280:17 301:20	243:2 395:10	<b>long-acting</b> 214:17	80:13 93:4 102:17	231:11 241:6
304:8 342:7	<b>listen</b> 93:1 364:1	<b>long-standing</b>	113:19 114:3	262:4 263:15
<b>lights</b> 205:2	<b>literally</b> 74:15	310:18	141:11 148:1	271:16 273:10
<b>liked</b> 412:1	313:19	<b>look</b> 20:18 24:19	149:5,7 156:15	280:3 282:2,7
<b>Likewise</b> 294:6	<b>literature</b> 394:12	25:4,20 27:13	157:19 172:9	284:3 291:18
339:17	<b>little</b> 34:2,18 35:5	29:5 34:3 35:13	181:14 189:6	295:2,3 301:3
<b>lily</b> 297:4	35:19 39:14 40:22	36:1 58:21 65:4	198:10 200:2	310:12 312:20
<b>limit</b> 18:3 54:20	62:15 68:8 79:14	83:21 106:20	204:17 205:11	315:1 341:18
86:16 321:2 325:1	91:22,22 131:7	126:13 129:17	207:16 217:10	344:10 348:4
353:11 376:13	144:17 152:7	130:21 131:3,10	241:4 244:12	349:4 350:10,13
378:4	174:10 183:9	140:3 142:9	251:21 257:22	364:12 374:3,12
<b>limitation</b> 54:22	191:3 194:10	143:12 149:17	259:1 262:19	374:20 396:20
319:22	196:19 197:3,5	152:18 170:10	264:11,14,22	399:18 404:18
<b>limitations</b> 25:8	198:4 208:11,12	173:11,18 182:1	267:8 268:20	408:2 417:6
251:13	215:20 218:9	182:13 183:20	272:20 273:1	<b>lots</b> 87:22 202:6
<b>limited</b> 183:12	221:14,16 242:6	184:15 190:3	276:5 277:15	212:19 239:15
194:20 321:18	257:4 295:9 309:7	199:19 200:21	278:2 310:4	274:16 277:9
322:2 327:5	313:7,8 318:6	207:15 228:12	311:16 314:10,17	294:15 394:12,22
352:10 353:8	319:10 331:8	232:12 239:17	317:21 323:5	<b>loud</b> 310:9 364:5
354:3	370:5 371:21	250:1 256:10	324:4,6,20 326:21	364:13
<b>limits</b> 17:3 322:2	385:10 397:2	260:1,9 263:5	327:11,13 329:4	<b>love</b> 350:16 356:3
<b>line</b> 50:1,3 70:15	416:14	267:7 269:18	330:16 342:8	<b>low</b> 97:6 198:11
72:1 182:7 187:13	<b>live</b> 11:17 349:18	279:3 280:17	345:2 346:9,22	376:8 377:6
296:12,16 305:11	<b>lives</b> 6:5	286:6 287:21	353:13 354:6	389:10
<b>lines</b> 96:10 105:7	<b>living</b> 349:8	289:10 290:8,10	357:22 360:7	<b>lower</b> 52:19 86:6
152:3 208:6	<b>load</b> 417:19	290:11 296:11	362:7 370:21	101:20 111:5
<b>line's</b> 186:2	<b>local</b> 181:15 222:20	299:1 306:19	371:1 399:19	116:16 173:15
<b>lingers</b> 370:4	<b>location</b> 18:2	315:17 318:1,9	402:12,19 405:17	174:8 231:9
<b>linked</b> 54:15	<b>locus</b> 99:7,11	325:7,14 330:16	412:13 417:7	297:16 376:13
<b>lip</b> 280:4	222:12	346:2 352:16	<b>looks</b> 30:17 60:3	377:11 378:4
<b>lipid</b> 45:21 150:19	<b>logged</b> 82:16	354:1,22 355:8	149:9 211:2	379:12
151:9 154:15,17	<b>logistical</b> 128:3	356:11,17 359:16	261:21 320:12	<b>lowering</b> 158:15
157:16 158:15	417:16	359:17 360:8,10	331:22 355:7	288:3,8
159:3 160:9	<b>logistically</b> 243:5	362:7,14 376:7	363:7 371:12	<b>low-dose</b> 380:12,15
176:18	<b>logistics</b> 417:21	395:17	374:16 408:19	381:1
<b>lipids</b> 231:13	<b>long</b> 6:6 132:12	<b>looked</b> 107:21	<b>looms</b> 119:17	<b>low-end</b> 376:7
<b>list</b> 92:14 136:12	231:15 241:4,5	137:8 143:12	<b>lose</b> 248:13 349:17	400:12
154:7 165:11	285:3 286:7	194:3 240:5	<b>lost</b> 249:18 329:12	<b>lumping</b> 197:3
166:10 207:7,9,13	300:18 301:6	312:17 314:16	<b>lot</b> 24:4 34:1 62:13	<b>lunch</b> 132:8 133:1
208:5 220:5	327:14 381:20	338:10 356:22	67:4 95:18 99:9	191:2,4,6 195:5
239:19 248:1	397:22 398:6	363:18 376:6	114:14 122:22	<b>lungs</b> 245:21 246:2
252:12 256:19	417:3	402:22	128:9,11 136:20	<b>lung-sparing</b> 246:4
316:9 334:13	<b>longer</b> 57:21 92:19	<b>looking</b> 21:2,5,9	143:20 182:19	<b>LV</b> 215:1 229:21
<b>listed</b> 73:10 92:19	217:2 403:14	22:8,11 23:12,14	185:8,17 188:8	230:5,20 231:2,7

232:2,3	43:1 45:19,22	<b>manufacturers</b>	<b>matter</b> 29:13 73:17	46:14 87:14
<b>M</b>	46:2,5,7 141:13	223:22	113:4 215:12	125:22 138:12
<b>MA</b> 2:8	141:19 142:17	<b>MAP</b> 41:17	307:16 355:2	166:9 194:12
<b>machine</b> 340:17	148:20 163:1	<b>margin</b> 84:21	418:12	227:16 267:7
341:5 347:16	182:20 183:8,19	<b>Mark</b> 2:5 9:22	<b>matters</b> 331:1	269:13 271:7
348:18	251:22	59:16 65:1 80:18	<b>maximally</b> 263:3	272:6 320:4 368:9
<b>machines</b> 338:17	<b>major</b> 28:2,7 40:20	138:22 139:12	<b>maximum</b> 318:1,2	375:21 377:11,13
340:5,8,22 341:5	88:20 89:11 143:5	141:2,9 248:15	347:15	382:18 391:13
358:5	218:15 344:6	349:15 350:2	<b>Mayo</b> 1:15	401:17
<b>Magid</b> 1:23 8:14,14	348:9 361:18	373:14	<b>MBA</b> 2:13	<b>meaningfully</b>
13:5 65:20 67:9	375:19 391:19	<b>marked</b> 279:10	<b>MD</b> 1:14,15,17,18	263:21
87:20 97:9 129:4	<b>majority</b> 89:14	<b>Mark's</b> 377:9	1:21,22,23,23 2:1	<b>means</b> 126:14
259:5 261:8	169:19 274:13	<b>marry</b> 266:13	2:4,5,6,7,10,14,17	172:5 221:22
294:10 304:12	355:1,9	<b>Mary</b> 1:11,14 6:2	2:21,22 3:12	254:6 262:13
305:4 316:6 319:1	<b>making</b> 62:15 86:2	7:17 36:16 73:5	<b>mean</b> 74:19 76:3	277:16 364:7
321:17 322:3	100:22 132:9	150:20 162:3	83:12 88:4 90:2	<b>meant</b> 29:10
328:15 330:5	165:16 247:4	<b>Masoudi</b> 2:22	115:12 116:19	171:14 318:7
331:7 333:2	355:12 374:15	44:18,19,21 49:7	122:16 123:13	<b>measure</b> 4:9,9,10
335:14,20 336:18	<b>male</b> 397:8	90:10,12 95:9,13	129:10 143:9,16	4:10,11,12,14,14
337:18 344:2	<b>manage</b> 209:12	95:21 97:22	144:10 158:20	4:15,15,16,18,18
346:20 347:5	416:21	100:14 104:16	159:7 167:19	4:19,19,20,21
354:12 363:3	<b>manageable</b> 150:3	105:1 170:6	168:18 171:10	7:22 11:9 15:20
365:6 366:5,19,21	<b>managed</b> 252:18	174:16 178:12,14	173:4 175:6	17:3,10,12,16,20
367:18,21 368:8	261:2 282:18	207:2,3 210:8,14	179:21 180:17	19:3 21:19 25:4
368:20 369:17	361:21 362:8	214:12 216:10	187:17 202:3	25:13 26:1,18
370:18 371:18	<b>management</b> 46:1	222:22 224:7	219:15 222:9	27:7,10,15,19,21
373:2 375:3,9	56:5,22 189:5	225:6,11,14	224:10 231:15	27:22 28:8,15,16
378:15 379:5,14	262:20 263:10	234:17 235:10	250:18,22 253:19	28:20 29:21 30:1
381:14 382:17	264:14,21 265:3,4	263:9 268:15	268:16 269:19	30:17,21,22 31:6
383:10 405:15	265:19 272:9	270:21 275:18,21	271:1,2,15,16,19	32:10,11,16,17
407:5,12 408:8,17	274:8 275:20	310:19 311:10	277:15 278:12,16	33:4,17 36:21
408:22 409:7,11	276:1,3 278:4	329:18 388:5,11	281:15 288:13	38:2,3,6,15,17,17
409:17 411:19	<b>Manager</b> 203:10	390:19 395:12	289:8,21,22 299:4	39:3,6,7,15 40:4
412:17 413:13,20	<b>managers</b> 5:9	397:16 398:13	304:16 319:21	40:17,18 41:15,19
413:22	<b>managing</b> 10:16	401:3 405:20	321:17 330:6,14	41:21 42:8,17
<b>magnitude</b> 116:9	64:17	406:22 407:7,13	346:4 347:9 348:1	43:1 44:6,7 45:21
<b>mailed</b> 190:20	<b>Manasi</b> 3:17 40:11	407:21 408:3,12	348:21 351:1	45:22 46:1,2,5,8,9
<b>main</b> 29:11 127:1	45:12	408:19 409:6	353:6 359:22	47:6,14 48:1
347:21 390:10	<b>mandate</b> 273:16	410:5,17,20 411:1	366:17 373:9	50:13,17 51:2,4,6
<b>maintain</b> 27:20	276:15 277:2	<b>mass</b> 10:16 254:19	374:7 376:11	51:11,13,16 52:4
43:22	<b>manner</b> 21:3 32:4	<b>Massachusetts</b> 2:7	380:10 388:6	52:9 53:18 54:5
<b>maintaining</b> 40:12	391:1	10:17 12:5 250:8	390:17 399:5	55:6,13,22 56:16
<b>maintains</b> 27:22	<b>mantra</b> 158:13	<b>match</b> 22:4 89:3	403:15 406:22	58:8,16,20 59:1,7
<b>maintenance</b> 1:4,9	<b>manual</b> 75:22	139:6	409:1	59:10 61:14 62:19
5:12 14:14 22:10	206:21 414:6,19	<b>matched</b> 233:19	<b>meaning</b> 75:21	65:16 68:9,21
24:14 27:8 38:12	<b>manually</b> 76:4	<b>material</b> 123:11	387:14	69:5,13,13,15,21
	81:17	<b>materials</b> 60:10	<b>meaningful</b> 31:3	70:5,20 71:16,22

72:18 73:3,3,10	187:1 192:4,6,8	298:13,20 299:13	414:16,22 415:8	41:14,20 42:1,21
73:11,15,18 75:15	192:17 194:1,17	299:15 301:19	416:1 417:14	43:4,12,13,22
75:21 76:2,3,11	194:19 195:5,16	302:2,12,19,22	<b>measured</b> 61:5	44:4,21 45:2,4,13
76:16 77:6,13	195:22 196:7,17	303:13 304:3,7	74:13 88:2 272:2	45:15,17,18 46:11
78:1,18 79:11,15	197:1,12 199:3	306:1,15 310:3,16	<b>measurement</b> 2:24	46:15,17 47:5,15
80:6,9,16 81:7,8	200:17,21 201:10	310:19 311:2	3:11 15:16 22:5	47:21,21 48:1,4,9
81:19 82:3 83:9	201:14,16 202:9	312:17 313:13,17	24:3 31:17 41:16	48:13,15,17 49:16
83:16,21 84:9,14	202:10,12,16	314:8,15 315:4,16	42:4 50:1,4,10	49:19 53:14 55:14
84:18 85:8,11,11	203:17 204:10,12	316:14,16 319:18	51:2,5 53:22	55:18 59:19 68:2
86:13,14 88:6,10	204:16 210:20	319:22 320:1,3,19	55:19 59:5 61:9	68:6,15 70:1 75:7
89:2,20 90:6,12	211:14,17,20	320:21 321:3,3,6	61:10 88:18 92:7	77:20 82:2 83:15
91:7,14,21,21	212:3,19,20	321:9 322:13	99:21 104:9	86:17 91:5 96:5
92:4,5 94:8,21	213:13 214:3,10	324:1 325:6 328:1	107:13 123:2	98:3 99:1 100:2
99:3 103:11	214:13 218:4	329:2,17,19	151:6,8,9 165:9	104:7 105:13,14
105:20 106:15	221:9 223:18	330:12 331:1	185:17 228:11	106:12 107:21,22
107:3,5,16 108:14	224:4,15 225:16	332:5,13,19 334:6	237:19,21,22	109:21 119:3,10
109:4,17 110:2,20	226:6 227:8	335:2,4 336:15,22	238:22 239:7,8,11	125:13 126:12
112:3 113:7,9,13	232:10 233:18	337:5 339:2	239:12 282:1	129:6,14,18
113:15,18 114:3,5	234:18,20 235:7	341:13 344:7,11	285:4 286:17,19	131:18 133:1
114:12,13 115:5	235:13,15 236:4	344:15,21,21	298:7 306:8 319:2	136:20 139:20
119:6,8 120:19,21	236:18 237:3,6,8	345:5,19 346:21	361:7 374:1	140:7,12 141:20
121:6,15 122:16	238:7 240:2,20	346:21 351:3	377:22 397:2	142:3,15,17,21
123:6 125:21	241:2,3,13,18	352:18,22 353:3,8	408:18	143:4,14 144:17
127:2 129:19,20	242:12 244:2,19	355:22 356:2,20	<b>measurements</b>	145:15 146:16
130:3,4,13 132:15	245:9 247:2,9	356:22 357:19	50:12 65:15,22	148:20 150:19
132:20 133:12	248:14 251:20	362:10 363:6	66:15 67:1 240:5	156:20,20 160:7,9
134:1,14 135:10	255:14 256:8,10	365:5 368:10	257:18 345:14	164:19 166:10
135:16,18 136:17	256:16,18 257:19	369:15 370:17	<b>Measurement's</b>	168:20 169:5
138:11,17 139:6	258:11,22 259:12	371:7,12 372:15	50:16	174:17 176:18
140:3,11 141:11	259:16,17,18	376:5 377:8 378:6	<b>measures</b> 4:6 5:8	178:20 181:6,9,14
141:13,17 142:8,9	261:11,21 262:12	378:8 382:8,21	5:15 7:14 11:10	182:6,15,19,20
142:10 144:21	262:18 263:10,18	383:1,18 384:9	12:11 14:9,17	183:8,10,20,22
146:2,7,8,21	263:22 264:19,20	385:22 386:20	18:8 20:14,16,18	184:4,5,17,19
148:16,18 150:14	266:5 267:4,20	387:4 388:13	20:21 21:5,6,10	185:2,4,9 187:7
150:22 151:2,11	268:5,7,20 270:18	390:19 391:5,21	21:13,13,22,22	188:8 189:7 201:5
151:14 153:22	271:1,4 272:22	393:10,22 394:3,5	22:10,10,16 23:6	204:15 205:7
157:6 158:10	273:16,16 274:8	395:2,22 396:19	23:12,21 24:6,8	207:5,21 208:16
159:3,10 160:11	275:7,20,22 276:2	399:6,9,10 400:3	24:11,15,17,18	216:21 223:2,14
161:10,13 162:3,5	276:5,11 277:6,8	400:10 401:18	25:4,15,15,16,17	227:14,22 241:9
163:1,2,10 164:6	278:8,16 279:8	402:14,17 404:2	25:18,20 26:3	241:10 243:15
165:5,21 167:3,8	280:20 281:2,12	404:14,16 405:10	27:5,6,8,9,17	249:18 253:15
168:15 169:16	281:19 282:5,12	405:21 406:2,2,5	28:22 29:2,16	262:2 264:6,7
171:12 172:2	282:22 284:1,15	406:16,21 407:3	30:14,14 31:9,12	265:2,3,5,8 266:1
174:1,18,19,21	285:7 286:3,21,22	407:20 408:6,15	31:17,22,22 32:2	267:6,12,16 273:9
175:14 179:8,10	290:4,8,11 292:1	410:7,14,15	32:8,15 33:5,15	273:11,13 274:3
181:4 182:1,16	292:5 293:1	411:20 412:7	36:22 37:4 38:11	277:9,19 283:2,3
184:9 186:11	295:10,15 297:22	413:11 414:5,14	39:14,16 40:3,13	283:4 294:5 296:2

308:13,14,22	<b>Medicaid</b> 10:17	<b>meet</b> 26:2,2 29:22	354:18	406:4
309:14,16,17,21	251:5,6	32:11 33:2 39:10	<b>Mercy</b> 253:20	<b>mid-afternoon</b>
310:1,4,7,14	<b>medical</b> 1:21,24 2:1	60:21 78:18 83:11	<b>mere</b> 121:11	20:6
311:8,9,11,14,17	2:10,20 3:14 8:6	83:17 112:3 126:7	<b>merely</b> 279:9	<b>mid-morning</b> 20:5
311:21 312:5,15	9:14 10:11 51:8	132:18 135:10,16	<b>merit</b> 133:14	<b>mild</b> 243:6
312:21 313:3,14	52:8 61:17,19,19	136:4 142:9	<b>message</b> 51:17	<b>million</b> 57:2
314:1,17,21 315:1	62:1 77:7 79:22	148:16 161:13	131:21 295:5,7,17	<b>millions</b> 47:1,1
315:19 316:1,4,10	80:15 81:7 86:21	182:3 210:21	303:16 306:1	<b>mind</b> 103:17 171:7
321:11 322:17	87:2,2,5,9 109:19	236:18 255:15	364:5,13	179:18 180:13
327:10 330:19	134:20 135:1	301:19 343:12	<b>met</b> 1:9 37:17	189:20 240:14
332:8 333:5 334:2	136:7,8,16 164:15	361:7 369:15	243:19 396:16	358:18 401:22
335:5 336:8,22	169:20 194:3	375:16 379:2	<b>metaphors</b> 171:9	<b>mine</b> 133:2 210:8
343:3 354:2,6,7	220:6 236:5,7	382:18,22 384:9	<b>method</b> 54:19	<b>minimal</b> 103:15
354:10 355:5,13	239:19 248:19	393:11 404:2	80:14,15 138:20	104:5 108:13
355:17 357:8	256:10,14 270:1	<b>meeting</b> 6:1,7 14:5	<b>methodologic</b> 5:17	347:15
363:4,14 376:12	280:8 330:1	66:16 115:4,15	<b>methodologies</b>	<b>minimally</b> 30:3
377:14 384:19	355:19	121:5 281:19	15:16	176:10 177:5
392:10 393:19	<b>Medicare</b> 347:16	302:17 308:2,7	<b>methodology</b> 49:18	178:1 204:5 227:3
395:14 398:12	349:5,7	367:7	109:21 110:16	232:17 236:16
401:5,10 406:10	<b>medication</b> 126:20	<b>meets</b> 248:4 280:20	136:5,13	246:21 247:17
406:11 407:16	136:1 165:11	372:14 405:10	<b>metoprolol</b> 213:10	255:13 292:16
412:18 413:14,16	166:10,13 170:3	<b>member</b> 11:8 44:22	214:6,17 219:3,4	357:13 360:16
414:16	189:4 195:7,9,21	45:6 155:16 239:9	222:2 224:1	361:6 368:19
<b>measure's</b> 242:7	201:12,18,22	290:19	<b>metrics</b> 311:19	382:15 383:8
<b>measuring</b> 38:7	207:1 214:4	<b>members</b> 13:3	314:11 373:16	<b>minimize</b> 110:16
57:4 60:18 65:11	222:16 223:8	21:17 24:5 117:5	<b>MI</b> 151:4 152:5	279:20
115:16 116:20	240:4 241:9 242:9	151:3 177:16	211:15 212:5,12	<b>minimum</b> 162:15
144:9,13 154:17	248:6,9 252:12,15	178:10 186:4	212:22 217:2,4	379:13 401:3
202:16 203:13	<b>medications</b> 8:10	238:15 302:1,13	220:3 226:7	<b>Minnesota</b> 2:23
240:21 272:17,19	91:10 94:6 95:3	418:4	229:20 230:19	3:10 9:1 50:1,3,11
272:20 279:9	95:16 96:8 97:2	<b>membership</b> 23:20	231:6 238:1	50:16 51:1 107:13
345:9,9 377:17	97:11,18 99:17	26:7,19 33:10	239:10 248:20	123:2 282:1
398:20	100:13,18 101:2,4	<b>Memorial</b> 1:17 9:6	310:21 311:1,3	283:11 284:17
<b>Mecca</b> 348:4	102:1 134:18	<b>mental</b> 111:13	313:4,22 314:7	285:3 286:10
<b>Meccas</b> 348:6	172:6 175:2	<b>mention</b> 8:12 18:11	315:6,8 333:12	288:11,20 289:2,9
<b>mechanism</b> 203:2	190:20 244:12	54:9 119:2 120:16	348:12 371:20	293:2 294:8 297:4
225:20 231:19	<b>medication-related</b>	189:4 323:6	372:2 373:6 374:8	297:11 298:7
406:3	205:7	335:19 341:13	392:1 394:6	306:7
<b>mechanisms</b>	<b>medicine</b> 47:11,11	388:19 396:3	<b>Miami</b> 229:1	<b>minus</b> 179:3,4
315:11	47:12 166:17	<b>mentioned</b> 22:7	<b>mic</b> 76:21 208:11	<b>minute</b> 40:8 60:4
<b>median</b> 316:10,16	173:7 180:9	31:21 74:21 79:2	233:10 316:13	78:15 132:7
316:17 317:8,22	190:13 209:6	79:4 106:1,4	<b>Mickey</b> 190:4	307:13 338:14
318:2 320:3,15	278:20 289:21	125:6 126:8 130:7	<b>Microphone</b> 90:11	403:4
321:2 376:5	<b>medicines</b> 182:10	179:13 203:14	204:6 316:12	<b>minutes</b> 5:21 17:4
405:16,22 407:2	189:12 263:2	214:14 254:18	405:14	17:5,7,12,13,13
408:18 409:2	<b>medium</b> 400:9	255:5 287:20	<b>microphones</b> 19:17	17:22,22 40:15
410:11 416:1	<b>meds</b> 266:14	300:15 314:19	<b>middle</b> 43:6 318:16	45:8 67:10 113:2

132:4 162:1 191:5 262:19 308:17 318:2,12 319:7,11 326:3,12 338:14 346:5,6,13 348:7 355:2 358:14 385:20 386:3,21 387:7,7,14,14,15 388:2,7,8 393:20 394:4,11 396:9 397:5 404:15 405:7,19 407:1 410:11 416:4 <b>MI</b> s 276:20 314:13 315:19 <b>mish-mosh</b> 171:5 <b>misleading</b> 167:10 318:7 <b>mismatch</b> 335:6,20 339:8 <b>mismatched</b> 334:5 335:17 336:1 342:11,16 <b>missed</b> 115:1 290:22 327:21 <b>missing</b> 163:17 <b>Missoula</b> 10:1 <b>mistake</b> 245:15 <b>misunderstanding</b> 158:9 <b>mixes</b> 184:9 <b>mixing</b> 171:9 <b>mode</b> 38:13 <b>model</b> 22:17 23:8 254:5 296:17 363:1 <b>modest</b> 296:18 <b>modifiable</b> 282:18 <b>modification</b> 49:15 83:21 303:7 305:7 305:21 306:7 <b>modifications</b> 39:3 74:3 <b>modify</b> 142:8 176:3 217:21 <b>moment</b> 78:21 178:9 221:22	<b>monetarily</b> 180:20 <b>money</b> 254:7 349:4 <b>money's</b> 87:16 <b>monitor</b> 66:19 137:2 <b>monitoring</b> 66:6 97:14 155:22 176:1 <b>monitors</b> 67:2 <b>Montana</b> 2:5 10:2 347:7 <b>month</b> 133:8 134:5 162:11 200:15 212:11,18 220:2 224:5 248:22 336:19 <b>monthly</b> 336:16 <b>months</b> 134:13 192:11 198:11,15 230:17,18 238:3 249:1,2 <b>moot</b> 84:22 <b>morning</b> 5:4 6:3,13 11:1,19 12:13 40:10 214:3 367:12 <b>Morsell</b> 2:15 5:10 60:9 <b>mortality</b> 256:16 264:12 278:15 360:7,8,9,10 <b>Mouse</b> 190:4 <b>mouthfuls</b> 193:1 <b>move</b> 28:16,18 57:10,20 60:15 69:21 72:6 78:16 91:20,20 93:21 113:7 114:20 124:12 132:14 133:21 146:12 147:18 150:17 155:9 160:21 162:2 163:13 178:2 193:5 204:5 205:5 210:19 211:13 227:3 236:17 237:3	247:18 256:5 273:13 281:21 284:7 287:5 292:3 292:4,17 308:12 347:14 360:16 361:6 365:2 366:12 368:7 370:15 375:7 383:8 393:18 401:15 404:13 <b>moved</b> 50:22 124:2 215:17 <b>moves</b> 267:15 366:3 <b>moving</b> 43:19 44:10 67:7 74:10 87:15 108:16 118:16 130:16 138:10 147:8 155:13 160:3 190:10 280:6 357:13 360:14 390:5 391:11 393:10 402:7 <b>MPH</b> 1:21,22,23 2:14,17,19 3:10 3:12,14 <b>MSN</b> 2:13,22 <b>MSPH</b> 1:14,23 2:22 <b>multi</b> 26:6,12 <b>multiple</b> 31:5 51:17 99:3 104:7 165:3 254:19 270:8 301:22 339:11,16 405:9 414:16 <b>multi-disciplinary</b> 47:7 <b>muscle</b> 158:7 <b>mushy</b> 181:1 182:16 <b>mute</b> 206:4 284:5 <b>mutual</b> 16:16 <b>myalgia</b> 158:7 <b>myocardial</b> 21:11 46:3 56:9 215:2,4 215:8 229:3	237:16 308:12 309:20 310:6,17 313:16 314:6 316:20 326:17 371:11,14 400:5 <b>myopathy</b> 158:16 <hr/> <b>N</b> <b>N</b> 75:6 <b>nailed</b> 141:10 <b>name</b> 8:5 10:10 11:2,21 40:11 <b>name's</b> 49:12 <b>narrowly</b> 25:8 <b>national</b> 1:1,15,18 3:17 5:8 9:7 11:16 301:10 <b>nationwide</b> 276:16 277:2 <b>natural</b> 23:8 <b>nature</b> 226:3 255:8 <b>navigate</b> 60:13 <b>NCQA</b> 40:5,12 48:17 66:2 75:20 105:10 115:21 156:20 241:22 251:20 <b>nearly</b> 47:2 <b>necessarily</b> 16:22 54:17 75:22 77:16 91:2 96:7 98:2 110:1 153:4 172:4 200:13 244:10 371:22 <b>necessary</b> 82:2 152:14 239:21 <b>necessity</b> 61:21 <b>need</b> 16:12 17:11 20:4 24:13 32:1 46:19 51:17 55:1 55:1 56:16 64:20 68:8 69:18 70:11 77:11 82:8,11,20 86:8 97:16 98:19 104:6 120:1 130:4 134:21 141:8 142:22 143:10,12	147:4 160:8 175:21 176:6,10 176:17 179:13,17 180:4 185:1 216:21 217:20 224:18 227:3,5 228:15 229:13 230:7 231:13 232:15 250:1 276:16 278:6 290:4 291:21 292:21 294:13 302:21 307:12,13 317:16 323:1 324:21 326:20 360:13,14 364:11 372:19,22 381:22 383:11 384:17 395:7 403:7 406:8 412:5 413:11 416:14 <b>needed</b> 172:15 224:14 <b>needs</b> 24:6 26:2 77:15 97:19 99:20 120:11 300:12 352:3 372:21 413:10 <b>neglect</b> 204:8 <b>net</b> 189:15 <b>never</b> 72:7 120:13 173:14 214:2 249:16 277:11 314:6,14 333:8 343:5 352:10 368:1 412:13,14 <b>nevertheless</b> 75:5 208:21 <b>new</b> 2:8 8:18 14:18 20:12 38:14 43:5 45:18,21 46:1 52:17 63:5 106:16 141:20 142:3 183:10 217:21 226:7 256:4 265:4 314:20 343:3,4 358:5,5 370:1
---	---	--	--	--



387:15 395:5,10 395:15,17,20,21 395:21 <b>newer</b> 336:16 395:17 <b>newly</b> 22:9 <b>ne'er-do</b> 120:5 <b>NHLBI</b> 47:20 <b>nice</b> 45:12 53:4 402:12 403:16,18 <b>nicely</b> 23:21 148:18 391:22 <b>night</b> 94:13 104:1 104:22 257:14 265:18 <b>nightmare</b> 139:10 <b>NIH</b> 10:8 <b>nine</b> 22:9 89:14 357:3 409:18 <b>nobody's</b> 218:10 362:7 <b>nodding</b> 123:16 143:20,21 415:13 <b>nods</b> 85:21 123:15 <b>noes</b> 112:12 <b>noise</b> 258:22 284:4 <b>nominated</b> 13:18 <b>non-adherence</b> 188:16 <b>non-adherent</b> 98:8 120:4 <b>non-cardiac</b> 335:12 352:8 <b>non-Caucasians</b> 396:17 <b>non-compliance</b> 188:3,16 <b>non-compliant</b> 155:16 <b>non-governmental</b> 27:18 <b>non-laboratory</b> 156:2 <b>non-PCI</b> 312:19 <b>non-prescription</b> 126:19 <b>non-STEMI</b> 374:5	<b>non-system</b> 392:22 <b>normal</b> 215:1 228:18 229:21 230:5,20 231:1 232:2,3 <b>North</b> 2:6 10:5 <b>note</b> 91:8 92:12 109:9 118:17 155:13 194:18 280:1 <b>noted</b> 104:17,21 114:5 156:6 165:4 352:15 <b>notes</b> 156:1 <b>notice</b> 34:20 132:17 <b>notion</b> 63:7 <b>November</b> 151:5 287:19 <b>no's</b> 237:2 304:6 <b>NQF</b> 2:12 5:12,13 15:11,14 16:8 20:13 21:12,13 22:18 23:19 24:5 26:19 33:9 45:6,7 46:12 56:2 74:11 108:2 112:3 129:5 148:16 159:9 168:3 178:10,10 179:18 181:8 186:8 188:1 210:21 236:18 255:15 260:6 266:20 290:3 298:13 301:19 310:15 321:18 361:8 369:16 384:9 393:11 404:2 414:13 <b>NQF's</b> 6:15 19:20 20:11 26:6 28:2 30:1 181:2 <b>nuance</b> 107:11 233:21 415:9 <b>nuances</b> 155:2 208:1 217:7 397:17 <b>nubbin</b> 264:9	<b>nudging</b> 128:12 <b>number</b> 13:10 15:20 20:14,14 21:6,7 34:4,5,6,8 35:18 37:6 54:20 57:2 60:19 68:2 78:6,17 82:11,17 92:6 97:10 105:18 107:14 108:6,16 111:7 114:4 117:2 117:5 118:3,15 119:3,16 124:2 131:12 133:21 140:9,11,12 142:21 151:2 169:17 173:12 186:9 196:6 198:19 202:4 227:15 249:13 254:22 264:11,12 264:13,16 272:8 283:12 284:21 293:3,4,17 295:7 297:13 317:4 321:1 328:1 336:14 342:16 377:12 378:4,20 378:22 379:13 410:20 <b>numbered</b> 34:19 <b>numbers</b> 20:15 58:1 63:10 108:1 116:15 173:1 293:6 360:12 411:15 <b>numerator</b> 60:19 81:12,18 93:22 95:8,20 100:13 111:2 117:5,18,22 122:14 134:2 148:1 155:14,15 157:8 163:18 195:10,17 209:8 209:19 219:20 238:13,20 243:18 248:13 284:8 350:17 397:3	<b>numerators</b> 65:8 <b>numerator/deno...</b> 410:6 <b>numerical</b> 175:4 <b>numerous</b> 336:10 <b>nurse</b> 12:16 139:14 139:15 252:13 363:22 392:22 <b>nurses</b> 2:9 12:20 128:11 <b>nursing</b> 47:12 347:13 <b>N's</b> 396:14 <b>N.W</b> 1:10 <hr/> <b>O</b> <hr/> <b>obesity</b> 280:4 <b>object</b> 415:6 <b>objecting</b> 415:14 <b>observation</b> 69:9 <b>obtain</b> 347:15 <b>obtainable</b> 392:10 <b>obtained</b> 369:1 <b>obvious</b> 153:7 255:21 264:7 273:14 352:8 375:1 <b>obviously</b> 16:3,14 17:15 39:13 57:1 93:20 104:11 119:21 134:3 144:12 179:15 189:19 233:13 293:22 306:7 318:3 330:11 338:18 353:15 402:19 <b>occur</b> 223:21 226:3 229:5 279:20 287:16 <b>occurred</b> 22:5 293:10 <b>occurrence</b> 137:11 <b>offer</b> 16:20 18:13 72:8 85:9 295:12 <b>offered</b> 387:1 <b>offering</b> 11:18	249:14 250:11 <b>office</b> 23:2 66:21 94:6 165:18 229:20 <b>offices</b> 61:19 79:16 251:15 <b>officially</b> 219:10 <b>oftentimes</b> 39:11 158:6,21 <b>oh</b> 15:1 44:18 108:10 153:5 211:9 229:1 303:10 316:6 386:16 <b>okay</b> 6:11 13:3 14:4 19:11 34:9,22 35:12,13,13 36:1 36:3,7,18 38:4 39:12 40:7,14,14 49:9 50:2,9 56:1 57:19 60:14,17 72:5 74:11 77:4,9 79:7 82:10 83:2 85:3 88:7 91:12 93:18,19 101:6 102:18 103:13 105:2,16,22 106:17 108:8,16 110:18 112:7,11 113:6 117:3 118:10 119:15 123:22 124:6 126:2,5 129:12 132:3 138:4,8 146:11 147:4,6 148:11,15 149:11 150:8,17 155:6,8 157:20 159:5 161:12,20 163:8 163:12 164:3 166:22 167:22 176:5 177:4 191:1 193:3 195:18 204:3,20 205:1 210:2,18 211:12 215:16 219:19 224:16,17 226:20
--	--	---	--	--

232:14 233:12	205:13 216:8	385:10	353:17 374:8	<b>oversight</b> 42:3
236:9,13 237:9	217:12,14 257:15	<b>optimal</b> 50:13,17	399:19	<b>overview</b> 4:5 19:12
238:10,12 246:11	305:17 323:14	51:15,18 52:1	<b>outcome</b> 25:15	<b>over-counting</b>
246:20 247:7,19	339:7 391:22	264:1 272:15	56:15 99:2 154:16	125:13
248:22 252:5,10	<b>one's</b> 35:19 132:12	281:21 299:11,13	154:17,21 155:3,4	<b>owned</b> 27:18
255:12,22 256:5	144:10 372:19	302:12,17	184:19 185:2,4,9	<b>o'clock</b> 55:12,15
280:18 281:20	<b>one-vote</b> 84:21	<b>optimally</b> 261:2	200:18 204:18	107:1 282:3 309:7
282:9 284:6	<b>one-year</b> 134:10	282:18	259:16,18 261:12	357:4 384:16
291:15 295:6	<b>ongoing</b> 24:13	<b>optimizing</b> 264:14	261:18 263:5	409:18 416:13,16
299:19 300:7	42:18,18,22 78:22	<b>option</b> 92:19	264:19 272:22	416:18
301:15,17 305:1	311:5	136:19,22 240:10	277:9 278:15	
305:20 306:4	<b>online</b> 27:11	240:13	346:9	<b>P</b>
307:10,20 309:10	<b>Oops</b> 375:11	<b>optional</b> 80:11	<b>outcomes</b> 51:20	<b>P</b> 2:21
310:8,11 316:8,15	<b>open</b> 44:3,11,12	<b>options</b> 35:1	129:2 155:5 172:9	<b>PA</b> 347:18
317:13 329:20,21	186:2 211:3,11	279:17	172:13 175:5	<b>Pace</b> 2:15 5:16 15:9
336:18 350:9	244:14,21 268:6	<b>oral</b> 7:8	259:10 264:1	15:12,12 58:13
357:1,15 358:12	282:11 308:17	<b>order</b> 105:11	267:7 272:5	68:12 72:16,22
360:18 364:22	388:4 418:1	110:13 130:12	276:18 299:6	74:7 82:12 83:1
365:6 368:6	<b>opened</b> 114:22	170:16 292:22	362:22	83:12 85:2 90:11
369:14 370:13,14	211:10	318:11 337:19	<b>outline</b> 402:15	93:14,18 103:5
371:18 372:16	<b>opening</b> 241:8	347:15	<b>outlined</b> 109:8	111:14 115:18
375:5 378:17	<b>openness</b> 7:7	<b>ordinary</b> 219:3	148:18 386:20	118:12 129:9
382:12 383:5,8	<b>operational</b> 128:19	<b>organization</b> 13:12	<b>outlived</b> 24:10	146:5 184:2 187:3
384:5,13,15	<b>operationalization</b>	13:17,19 87:4	<b>outpatient</b> 176:15	291:17 295:6
388:18 389:4	323:10	239:12 272:3	188:7 214:13	364:21 404:9
391:8,10 392:5	<b>operational-type</b>	284:16	311:13,19 314:18	<b>packages</b> 170:7
393:7 401:11	128:3	<b>organizational</b>	314:21 321:13	<b>packet</b> 363:4
407:12 409:11	<b>operations</b> 340:4	277:12	357:17	<b>packets</b> 59:19
415:2	<b>opinion</b> 74:3 165:3	<b>organizations</b> 48:8	<b>outright</b> 144:15	<b>page</b> 4:1 303:3
<b>Oklahoma</b> 2:19	219:12 326:7	118:19 127:4	<b>outset</b> 417:7	318:19,21
308:21 330:1	<b>OPP</b> 414:8	164:18 181:9	<b>outside</b> 61:7 99:6	<b>pages</b> 290:21
<b>old</b> 395:8,16	<b>opportunities</b>	242:10 249:13	181:17 222:12	<b>paging</b> 100:9
<b>older</b> 56:8 133:6,7	23:16 42:18	251:22 252:19	250:2 253:9 308:4	<b>pain</b> 315:6,7
134:12 156:12	<b>opportunity</b> 13:13	<b>organized</b> 150:4	373:6 387:12	316:21 319:20
162:9 164:4 192:9	14:7 20:6 26:14	<b>organizing</b> 22:15	<b>outstanding</b> 194:4	329:9 332:8,18,20
212:9 219:22	30:12 33:13,17,18	<b>orient</b> 72:17	<b>overall</b> 67:22 83:22	333:6,15,16 334:7
237:19 238:21	37:20 39:1 58:19	<b>oriented</b> 267:6	88:18 91:3 125:18	334:14,20 335:18
245:11,12,15	59:3 76:9,18	<b>origin</b> 231:21 315:7	130:15 138:19	351:11 352:2,7,14
289:17	81:17,21 109:18	315:8 320:13	148:6 386:7 392:2	352:21 353:10,14
<b>once</b> 18:22 21:19	131:4 151:16	334:22	414:6,19	353:17,20,21
75:21 160:21	162:18 201:3	<b>original</b> 49:15	<b>overlap</b> 48:16	359:8 367:8
248:7 287:10	260:9 289:9 292:6	163:3,4 282:2	294:4 310:14	371:13 372:21
339:22 343:10	319:13	<b>originally</b> 46:9	311:9	374:17,22 380:17
380:7	<b>opposed</b> 81:13	50:20 182:5	<b>overlaps</b> 398:1	<b>pains</b> 311:4 316:22
<b>onerous</b> 82:4	190:20 211:22	<b>ought</b> 78:2 93:12	<b>overly-excluding</b>	327:9 331:15
<b>ones</b> 45:16 154:6	289:21 299:3	116:20 126:3	243:11	332:21 335:12
189:15 190:17	323:14 338:7	158:12 326:18	<b>oversee</b> 8:2	344:9

<b>pair</b> 393:20	292:15 300:9	154:14 164:7,8,9	96:15 97:6,10	322:7,11 323:20
<b>paired</b> 264:6 276:2	301:17 357:13	165:8,9 166:16,21	98:8 100:16 101:3	324:20 325:6,18
<b>panel</b> 7:9 41:17,22	360:15 361:5	168:3,12,13 169:2	113:20,22 114:7	326:16 327:5,11
66:15 117:20	368:18 369:14	169:8,16 170:5,10	115:6 133:5,6	327:17 329:4,7,9
271:17	382:15 383:7	170:17 175:10	134:3,12 152:4,16	329:15 330:3
<b>panels</b> 41:10 186:9	384:8 391:10	187:6 188:4,18,21	158:3 162:9 163:5	331:10,12,13,18
<b>panned</b> 44:9	401:15 404:1	188:22 190:2	163:19 168:21	331:20 332:6,12
<b>paper</b> 61:16,21	<b>PARTICIPANT</b>	195:10,21 197:18	169:22 182:8,12	332:20 333:6,11
64:2 81:8,11	127:18 292:18	197:18 198:8,16	186:12 189:12	337:3,12,14,16
104:17,21 250:17	319:10 370:10	200:12 202:10	190:19 192:9	344:8 353:9 354:3
251:4,16 253:8	<b>participate</b> 26:14	206:15,22 209:3	193:11,16,20,21	354:4,10,20
285:14 290:17	<b>participated</b> 7:15	209:19 212:17	195:6 199:13	358:21 359:7,14
291:1 300:6	<b>participating</b>	220:8,10,10	206:9,19 208:19	359:22 360:5
<b>papers</b> 349:21	377:21	221:22 222:13	209:7,12 211:15	361:13 362:8
<b>parameters</b> 51:21	<b>particular</b> 13:11,17	237:13 240:17,21	212:9,22 213:6	364:14 370:22
<b>parcel</b> 278:11	13:19 24:1 29:4	241:3 243:8,17	214:6,15,19 215:4	371:3,8,12 373:9
<b>pardon</b> 152:2	46:15 55:14 58:7	248:4,20 249:7	215:8 216:14,19	373:11,14,15
<b>parlance</b> 75:19	62:10 70:5 136:17	252:14 253:16	217:4 218:19	374:22 375:15
<b>part</b> 17:4 21:18	166:16 201:9	256:11 259:17	219:8,22 224:3	378:21,22 379:1,2
52:16 78:9 97:20	228:11 271:11	261:2 262:8	229:4,13,15	379:6,7 381:9
129:11 130:17	281:12 319:22	264:10 267:5	230:10 231:9	388:14 390:20
135:5 147:13	320:21 335:2	269:21 274:19	233:16 235:4	391:17 394:7,15
159:6 160:6 188:3	340:17 390:7	275:10 276:17	237:18 238:21	397:3,12,21
188:11 189:4	402:14	277:1,6,10 278:4	239:17 240:7,10	398:12,14 399:2
234:7,9,15 241:7	<b>particularly</b> 23:10	279:20 282:9	240:13 241:16	400:3,8 401:9
267:21,22 274:11	25:7 41:12 97:21	285:17 296:8	243:11 245:3,6	406:11,15 408:4
278:11 284:19	131:19 183:7	312:18 313:3	248:9 249:17	410:10,12,13,18
285:6 309:22	198:22 201:13	315:17 323:16	250:2,5,9 251:3,6	411:10,16,17
311:15 314:2	246:18 286:11	327:8 332:9,17	251:22 252:9	414:10
316:2 317:6,7	397:15	341:7 342:15	255:1 257:12	<b>patient's</b> 22:19
318:15 321:10	<b>Partners</b> 1:23 8:22	344:15 345:7	259:20 260:2,3,8	86:6 97:18 155:21
323:13 324:20	50:19,21,22	346:13 348:10	260:10,14,17,18	165:14 278:14
340:4,6 342:20	299:20 302:14	352:6,13,13 358:3	260:21 261:1	324:21
362:3,21 364:15	<b>part's</b> 373:1	358:13,15 360:9	263:7 264:2,22	<b>patient-centered</b>
377:20 383:13	<b>pass</b> 28:15,17 248:8	371:21 374:15	268:12 269:13	256:18 264:18
386:6 399:7	<b>passed</b> 311:18	380:11 398:6	271:8 272:6,14	272:5
406:10	<b>patient</b> 11:20 23:15	403:2 412:14	274:13,18 279:12	<b>patient-focused</b>
<b>partial</b> 108:13	41:1 51:20 54:10	413:17	279:13,14 282:13	22:16 23:7 25:14
288:7 402:7	54:12,19 55:2	<b>patients</b> 26:9 41:4	283:15 287:4	<b>pause</b> 160:2,19
<b>partially</b> 30:3	76:10,19 95:1	46:3 53:10,20,21	289:11,17 293:4,6	161:11,19 163:11
111:22 138:8	99:15 100:20	54:4,20 56:7	294:14 299:22	176:8 177:3,21
147:7 148:14	102:1,4 109:20	60:20 61:2 64:17	302:13 309:19	178:6,9 193:2
176:10 177:5	110:10 126:15	66:9 70:8 71:1	310:6,20 311:1,3	204:2 211:8
178:1 204:4 205:4	133:11 134:7,9	73:9 76:7 77:7	312:1 313:1,5,22	401:13 402:5
210:18 227:2	135:9,11,16,22	81:22 85:20 86:18	314:15 315:5	403:21 404:8
232:16 236:16	136:16 137:15	89:9,18 90:3,19	316:21 319:17	<b>pay</b> 180:2,4,19
246:21 255:12	139:6 144:4	92:8 93:8 94:2	320:5 321:15,19	251:6,7

<b>paying</b> 385:15	153:18,20 154:20	270:14 272:14	282:22 283:1	<b>pharmacotherapy</b>
<b>payment</b> 23:17	166:14 172:21	274:6 275:3 280:5	311:19 314:11	97:4
314:3	174:12 178:11	297:10 300:21	317:5,8 318:4	<b>pharmacy</b> 189:7,10
<b>PBM</b> 203:5,9	181:11 185:12	302:13,15,16	320:1,8 321:3,11	190:21 203:9
<b>PCI</b> 223:11 312:18	186:1 193:5 196:8	320:5 335:21	354:9 355:13,22	224:2 249:7 253:3
323:8,17,19	196:18 197:4	342:13,17 349:7	365:14,17 372:12	253:11,22
324:14 325:14	215:13 226:16	349:17 354:15,16	377:18 396:5	<b>PharmD</b> 2:2
330:13,21 332:13	228:16,18 233:13	354:19 366:17	<b>performed</b> 63:13	<b>phase</b> 21:8,8,9 22:7
346:3 349:20	233:13 234:13	375:15,15 380:6	157:20 316:19	26:22 46:13
363:12 385:20	235:1 242:8	389:19 410:15	<b>period</b> 69:22 117:8	141:19
386:8 389:1,21	243:22 246:14	<b>percentage</b> 53:5	133:8 134:5,8,10	<b>PhD</b> 1:19 2:3 3:17
390:21,22 391:4	250:11 254:14	56:7 113:19,22	162:11 165:9	<b>Philippides</b> 2:1 8:5
394:14,16 398:21	259:6 270:5	130:16 133:5	200:15 212:11,18	8:6 86:14 109:2,7
399:21 400:14	271:17 281:4,17	137:4 151:3 162:9	220:2 237:12	132:21 133:4
402:18,20	294:17 297:14,18	192:8 212:8	238:17 394:19	134:1 138:10
<b>PCPI</b> 44:17,19 45:3	297:19 299:17	237:18 282:13	403:4	147:9 152:1,10,13
45:14 47:8 91:7	302:17 307:20	302:16 349:22	<b>period's</b> 396:8	152:18 154:2
92:9 94:20 105:14	308:8 317:5,19	389:11 394:6	<b>peripheral</b> 154:4	168:2 173:20
109:20 136:5,13	320:4 322:14,16	405:16 408:18	282:17	279:22 337:2
137:8,8 141:12	322:20,22 348:5	<b>percentages</b> 87:17	<b>Permanente</b> 1:23	351:6,22 352:17
164:19 169:15	358:1,6,8 361:16	148:2	2:2 9:3	353:18 386:1,19
194:1,14 227:1,13	361:18 363:7	<b>percentile</b> 74:18	<b>permeated</b> 186:7	388:9,16 391:12
257:6,14 265:12	364:12 365:16	75:4 116:5,6	<b>permissive</b> 207:8	392:9
266:7	366:17 372:4	126:13,16 319:7,8	<b>perseverance</b> 417:2	<b>phone</b> 13:3 20:8
<b>PCQRI</b> 233:2	373:6 385:9 387:5	<b>percentiles</b> 329:4	<b>persistence</b> 237:4	33:19 48:20
<b>PDD</b> 41:11	393:13 407:22	<b>perception</b> 179:10	237:11,16 238:5	108:12 111:21
<b>peer</b> 48:5,8,14	416:3	<b>perfect</b> 13:9 173:11	<b>persistent</b> 200:18	112:13 135:20
<b>pending</b> 78:4 83:4	<b>people's</b> 171:20	<b>perfectly</b> 167:12	238:2	138:8 150:13
83:14 94:19 126:7	179:20	<b>perform</b> 48:8 149:8	<b>person</b> 37:4 115:14	178:12 186:1,2
140:18 146:9	<b>perceive</b> 139:17	390:22	<b>personally</b> 112:16	217:16 246:22
<b>penetration</b> 293:18	<b>percent</b> 53:4,4	<b>performance</b> 5:8	175:9 202:21	284:3 286:8
<b>people</b> 7:5 16:7,17	74:18,19 75:11	5:15 14:9 24:16	286:1	288:20 307:7
26:11 33:19 36:12	86:20 87:1,3	30:12 31:4,16	<b>perspective</b> 20:19	308:20,21 331:9
36:12,14 38:10	115:5 116:2,2,3	42:4 45:2,15	22:19 26:13 90:13	350:8 351:20
42:19 51:19 57:3	116:13,16 120:14	46:19 47:13 49:16	179:6 180:12	370:1 418:6
58:1 59:17,18	121:21,22 122:1,5	49:18 50:10 58:22	181:13 189:11	<b>physical</b> 1:20 11:3
60:8 61:4 70:19	126:14 170:13	59:7 96:19 105:14	207:12 211:21	11:6 115:20
72:1,17 73:1,16	171:13 173:8,14	126:12 128:21	320:18 345:12	266:11 270:2
74:16,19 85:19	184:21 192:13	129:6,12,16,18	<b>perspectives</b> 16:14	277:7
86:2 93:15,16	193:13 198:14	130:5,12 149:14	202:6	<b>physician</b> 42:11
101:19 106:10	199:14,22 200:4,6	168:18,20 173:2	<b>pharmaceutical</b>	70:10 79:12 98:10
108:1 114:10	201:19 212:7,13	175:14 180:2,19	218:8	99:14,22 100:21
115:4 116:10	213:2,7 220:4	181:7,20 185:17	<b>pharmacies</b> 203:1	131:5 136:7 139:4
117:9 119:21	230:4 233:4,13	188:10 216:20	251:9,17	139:15 172:22
120:3 123:9	237:11 238:18	227:19 228:11	<b>pharmacist</b> 399:16	188:9 195:7
126:20 128:9,11	250:9 257:11	259:11 262:2	<b>pharmacists</b>	202:20 203:3
135:20 137:21	260:15,16,18	267:12 281:10	128:11	209:5 212:16

222:13 227:18	<b>placing</b> 215:10	170:15 175:17	188:11 194:7	174:6 201:16
241:14 242:13	<b>plan</b> 42:11,13 61:6	178:8 186:14	234:8 238:15	240:20 241:11
252:5,6 253:15	61:7 117:11,11	187:20 189:22	252:2 297:11	<b>potential</b> 17:18,19
254:10 270:8,16	162:13 163:20	193:16 201:10	313:4,21 315:3,9	125:11,17 157:6
275:12 276:22	167:15 169:1,1	210:3 227:17	321:14 325:2	183:19 197:8
278:8,13 326:4	183:18 184:10	246:20 249:11	327:4 329:8 330:3	260:1,12 287:15
334:19 341:20	203:16 218:1	251:8 261:20	337:14 350:1	302:4 332:22
347:18 367:8	242:12 263:1,19	272:13 273:5,7	351:7 353:9,12	373:19
392:22	266:5 342:4	275:10 278:18	354:4 363:6 371:6	<b>potentially</b> 38:19
<b>physicians</b> 10:13	415:14	285:6 289:16	371:8,21 372:2	72:3,11,11 142:22
13:7 79:16 96:15	<b>plane</b> 400:2	290:7,22 293:9	374:18 411:21	186:15 193:18
97:16 98:19 190:3	<b>planned</b> 309:7	297:8 302:8 304:2	412:6,7	289:7 295:12
203:15 209:10,17	<b>plans</b> 22:2 147:17	305:10 307:6,11	<b>populations</b> 77:15	410:14
211:21 235:19	182:15 252:20,20	319:4 321:5	390:4 412:1	<b>powerful</b> 66:5
241:15 268:11	<b>plan's</b> 202:6	323:11 330:10	<b>population-weig...</b>	295:16
269:2,20 270:13	<b>platelet</b> 46:2	332:16 336:7	279:1	<b>PQRI</b> 233:21 234:3
280:2 296:21	137:16	337:11 338:18	<b>portfolio</b> 14:18	234:10,14,15
<b>physician's</b> 66:21	<b>play</b> 119:12	342:7 345:20	20:15,18 21:7	235:17
99:6,11	<b>please</b> 18:13 19:17	346:8,19 349:16	22:4 23:6 24:14	<b>PQRS</b> 46:13
<b>physician-level</b>	34:6 56:2 113:2	350:12 357:20	273:15	227:15
42:13 76:16 77:6	178:5 191:5 205:3	364:4 371:7	<b>portion</b> 6:17	<b>practical</b> 79:15
<b>physiological</b> 51:21	206:4 255:18	384:18 388:13,17	168:22	81:15
<b>pick</b> 35:8,9 143:1	284:4 292:14	400:1 411:13	<b>Portland</b> 12:21	<b>practicalities</b>
173:12 201:12	384:7 389:12	415:20,21	<b>pose</b> 161:4 399:5	254:17
<b>picking</b> 262:7	410:4 417:16	<b>pointed</b> 91:17	<b>posing</b> 184:7	<b>practice</b> 10:2 35:1
294:19	<b>Pleasure</b> 14:12	294:15 301:5	<b>position</b> 265:22	47:12 54:13 120:6
<b>pictorially</b> 27:1	<b>plenty</b> 91:14 293:8	<b>pointing</b> 143:10	291:9	173:19 185:16
<b>pieces</b> 150:4	<b>plunked</b> 416:22	157:11 349:15	<b>positions</b> 139:15	251:1 281:17
<b>pigs</b> 148:22 149:1	<b>plus</b> 59:21 154:17	<b>points</b> 17:1 26:21	<b>positive</b> 95:20	343:16
<b>pilot</b> 227:10	179:2,4 349:5,7	40:16 50:15 123:5	180:19 195:10	<b>practiced</b> 189:14
<b>ping</b> 254:11	<b>point</b> 20:16 32:10	123:7 130:16	401:21	<b>practices</b> 52:20
<b>Pinnacle</b> 257:9	37:22 39:12 51:10	173:6 302:16	<b>possession</b> 201:18	87:9,12,17 180:3
273:22	52:6,11 53:5,6	374:3	240:21	180:17 185:12,15
<b>PITZEN</b> 2:23	59:14 66:5 67:14	<b>policy</b> 42:21 67:5	<b>possible</b> 16:14 25:5	273:22 274:6
146:19 298:6,10	78:8 83:10 84:20	<b>poll</b> 256:4	47:22 139:22	293:3 343:14
304:15	88:9 95:13 96:2,6	<b>pool</b> 260:7	140:22 208:3	<b>practitioner</b> 259:22
<b>pivotal</b> 27:3	100:10 102:18	<b>poor</b> 297:19 330:22	239:17 254:3	<b>practitioners</b>
<b>place</b> 53:14 87:15	104:3 106:18	<b>popular</b> 297:5	267:20 334:13	139:14 343:8
106:5 119:20	109:13 110:20	<b>population</b> 25:10	342:2 351:10	<b>practitioner's</b>
145:9 225:20	112:1 113:1	41:2 57:6 62:10	398:7	279:14
231:19 268:17	122:22 123:11,14	62:13 75:12 77:17	<b>possibles</b> 92:15	<b>preamble</b> 412:21
282:11 306:18	128:3 131:2,14	79:1 81:13 86:22	<b>possibly</b> 338:20	412:22
348:16 359:6	132:1,5 134:16	87:3 121:21	357:19	<b>precipitated</b>
377:9 387:21	136:18 137:5,7,12	122:11 130:15,18	<b>post</b> 204:18	262:15
<b>placed</b> 199:15	138:2 142:14	131:8,12 133:12	<b>posted</b> 19:20	<b>precise</b> 386:21
<b>places</b> 251:1	143:21 145:22	136:4 154:14	<b>post-ACS</b> 231:6	<b>precision</b> 30:18
396:10	146:14 149:8	156:10,16 164:4	<b>post-MI</b> 153:4	<b>preempting</b> 122:22

<b>preference</b> 168:13 169:2,8 187:6 390:16	<b>presents</b> 374:16	<b>presumption</b> 341:21 390:22	<b>prior</b> 83:8 134:14 151:5,8 198:8,18 198:19 211:15 212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18	330:18 344:6,10 345:16 354:14 391:20	
<b>preferences</b> 23:15	<b>president</b> 5:15 14:8 15:10	<b>presumptions</b> 121:11	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18	<b>procedure</b> 21:1 58:16 154:12	
<b>preferred</b> 407:6	<b>presidential</b> 256:4	<b>pretty</b> 57:3 65:15	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18	<b>procedures</b> 390:17	
<b>preliminary</b> 287:19 389:10	<b>presiding</b> 1:12	69:18 75:13 93:11 117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18	<b>proceed</b> 16:6,15 55:17 93:12 283:22	
<b>preparing</b> 32:15	<b>press</b> 78:11	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18	<b>process</b> 4:5 16:7 18:7 21:16,18 23:7 26:15 27:2,4 27:11 33:14 34:17 41:15 42:9,10,15 42:18 48:3,6 53:13 67:22 74:1 77:7 106:5,15,20 110:12 114:3 124:18 154:17,21 156:4 170:18 221:6,20 226:12 227:1 257:4,16 259:16 265:11 284:20 300:11 301:2 309:22 317:3 321:10 323:10,14 341:9 345:6 347:2 354:5 417:6	
<b>prerogative</b> 304:9	<b>pressed</b> 132:16	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18	<b>proceeds</b> 390:17	
<b>prescribe</b> 97:17 254:1	<b>pressing</b> 58:1	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18	<b>processed</b> 391:13 414:6	
<b>prescribed</b> 94:5 120:22 133:9 134:3 136:1 144:6 165:7 166:21 200:11 212:14 222:15 233:14 252:13 263:2	<b>pressure</b> 41:6,13 45:20 53:8,11,16 53:18 54:3 55:19 56:5,12,22 60:19 60:20,21 61:5,10 63:15,22 64:6,11 64:18 65:6,7,22 66:6,7,14,19 67:2 67:10 71:14 74:13 74:17 77:14,17 86:7 88:2,18 89:9 89:15 90:3,21 91:4 92:7 93:7,10 94:3,4 95:2 96:16 96:21 97:5 98:9 99:16 100:20 101:21 104:8,9 107:2 111:6 120:3 120:8 144:9 179:20 180:15 262:21 265:5,15 282:20 283:7,14 284:15 285:4,16 286:16 287:4 288:3,9 291:9 294:21 295:13 298:14 299:14,16 301:22 302:11 303:1 304:10 389:3	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18	<b>product</b> 108:19 330:15,16	
<b>prescribes</b> 202:14	45:20 53:8,11,16 53:18 54:3 55:19 56:5,12,22 60:19 60:20,21 61:5,10 63:15,22 64:6,11 64:18 65:6,7,22 66:6,7,14,19 67:2 67:10 71:14 74:13 74:17 77:14,17 86:7 88:2,18 89:9 89:15 90:3,21 91:4 92:7 93:7,10 94:3,4 95:2 96:16 96:21 97:5 98:9 99:16 100:20 101:21 104:8,9 107:2 111:6 120:3 120:8 144:9 179:20 180:15 262:21 265:5,15 282:20 283:7,14 284:15 285:4,16 286:16 287:4 288:3,9 291:9 294:21 295:13 298:14 299:14,16 301:22 302:11 303:1 304:10 389:3	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18	<b>profile</b> 151:10 157:16,19	
<b>prescribing</b> 99:16 128:13 136:9 164:7,10 220:12 254:10	45:20 53:8,11,16 53:18 54:3 55:19 56:5,12,22 60:19 60:20,21 61:5,10 63:15,22 64:6,11 64:18 65:6,7,22 66:6,7,14,19 67:2 67:10 71:14 74:13 74:17 77:14,17 86:7 88:2,18 89:9 89:15 90:3,21 91:4 92:7 93:7,10 94:3,4 95:2 96:16 96:21 97:5 98:9 99:16 100:20 101:21 104:8,9 107:2 111:6 120:3 120:8 144:9 179:20 180:15 262:21 265:5,15 282:20 283:7,14 284:15 285:4,16 286:16 287:4 288:3,9 291:9 294:21 295:13 298:14 299:14,16 301:22 302:11 303:1 304:10 389:3	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18	<b>program</b> 6:18 8:3 11:11 15:13 46:13 88:10 115:21 131:6 176:15 222:21 233:22 234:3,10,14,19 235:2,14 308:3 311:16 362:3	
<b>prescription</b> 99:8,8 120:15 134:6 162:15 165:7 166:9,12,15 167:18 200:13 212:16 223:7 242:16 249:19 251:11 254:4,9,20	45:20 53:8,11,16 53:18 54:3 55:19 56:5,12,22 60:19 60:20,21 61:5,10 63:15,22 64:6,11 64:18 65:6,7,22 66:6,7,14,19 67:2 67:10 71:14 74:13 74:17 77:14,17 86:7 88:2,18 89:9 89:15 90:3,21 91:4 92:7 93:7,10 94:3,4 95:2 96:16 96:21 97:5 98:9 99:16 100:20 101:21 104:8,9 107:2 111:6 120:3 120:8 144:9 179:20 180:15 262:21 265:5,15 282:20 283:7,14 284:15 285:4,16 286:16 287:4 288:3,9 291:9 294:21 295:13 298:14 299:14,16 301:22 302:11 303:1 304:10 389:3	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18		
<b>prescriptions</b> 203:6 203:7 249:14 250:11	45:20 53:8,11,16 53:18 54:3 55:19 56:5,12,22 60:19 60:20,21 61:5,10 63:15,22 64:6,11 64:18 65:6,7,22 66:6,7,14,19 67:2 67:10 71:14 74:13 74:17 77:14,17 86:7 88:2,18 89:9 89:15 90:3,21 91:4 92:7 93:7,10 94:3,4 95:2 96:16 96:21 97:5 98:9 99:16 100:20 101:21 104:8,9 107:2 111:6 120:3 120:8 144:9 179:20 180:15 262:21 265:5,15 282:20 283:7,14 284:15 285:4,16 286:16 287:4 288:3,9 291:9 294:21 295:13 298:14 299:14,16 301:22 302:11 303:1 304:10 389:3	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18		
<b>prescriptive</b> 207:13	45:20 53:8,11,16 53:18 54:3 55:19 56:5,12,22 60:19 60:20,21 61:5,10 63:15,22 64:6,11 64:18 65:6,7,22 66:6,7,14,19 67:2 67:10 71:14 74:13 74:17 77:14,17 86:7 88:2,18 89:9 89:15 90:3,21 91:4 92:7 93:7,10 94:3,4 95:2 96:16 96:21 97:5 98:9 99:16 100:20 101:21 104:8,9 107:2 111:6 120:3 120:8 144:9 179:20 180:15 262:21 265:5,15 282:20 283:7,14 284:15 285:4,16 286:16 287:4 288:3,9 291:9 294:21 295:13 298:14 299:14,16 301:22 302:11 303:1 304:10 389:3	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18		
<b>presence</b> 179:1 256:13	45:20 53:8,11,16 53:18 54:3 55:19 56:5,12,22 60:19 60:20,21 61:5,10 63:15,22 64:6,11 64:18 65:6,7,22 66:6,7,14,19 67:2 67:10 71:14 74:13 74:17 77:14,17 86:7 88:2,18 89:9 89:15 90:3,21 91:4 92:7 93:7,10 94:3,4 95:2 96:16 96:21 97:5 98:9 99:16 100:20 101:21 104:8,9 107:2 111:6 120:3 120:8 144:9 179:20 180:15 262:21 265:5,15 282:20 283:7,14 284:15 285:4,16 286:16 287:4 288:3,9 291:9 294:21 295:13 298:14 299:14,16 301:22 302:11 303:1 304:10 389:3	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18		
<b>present</b> 1:13 2:18 3:20 162:16 263:15 359:7 389:16	45:20 53:8,11,16 53:18 54:3 55:19 56:5,12,22 60:19 60:20,21 61:5,10 63:15,22 64:6,11 64:18 65:6,7,22 66:6,7,14,19 67:2 67:10 71:14 74:13 74:17 77:14,17 86:7 88:2,18 89:9 89:15 90:3,21 91:4 92:7 93:7,10 94:3,4 95:2 96:16 96:21 97:5 98:9 99:16 100:20 101:21 104:8,9 107:2 111:6 120:3 120:8 144:9 179:20 180:15 262:21 265:5,15 282:20 283:7,14 284:15 285:4,16 286:16 287:4 288:3,9 291:9 294:21 295:13 298:14 299:14,16 301:22 302:11 303:1 304:10 389:3	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18		
<b>presentation</b> 18:10	45:20 53:8,11,16 53:18 54:3 55:19 56:5,12,22 60:19 60:20,21 61:5,10 63:15,22 64:6,11 64:18 65:6,7,22 66:6,7,14,19 67:2 67:10 71:14 74:13 74:17 77:14,17 86:7 88:2,18 89:9 89:15 90:3,21 91:4 92:7 93:7,10 94:3,4 95:2 96:16 96:21 97:5 98:9 99:16 100:20 101:21 104:8,9 107:2 111:6 120:3 120:8 144:9 179:20 180:15 262:21 265:5,15 282:20 283:7,14 284:15 285:4,16 286:16 287:4 288:3,9 291:9 294:21 295:13 298:14 299:14,16 301:22 302:11 303:1 304:10 389:3	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18		
<b>presented</b> 11:11 151:11 194:13 298:13 313:9	45:20 53:8,11,16 53:18 54:3 55:19 56:5,12,22 60:19 60:20,21 61:5,10 63:15,22 64:6,11 64:18 65:6,7,22 66:6,7,14,19 67:2 67:10 71:14 74:13 74:17 77:14,17 86:7 88:2,18 89:9 89:15 90:3,21 91:4 92:7 93:7,10 94:3,4 95:2 96:16 96:21 97:5 98:9 99:16 100:20 101:21 104:8,9 107:2 111:6 120:3 120:8 144:9 179:20 180:15 262:21 265:5,15 282:20 283:7,14 284:15 285:4,16 286:16 287:4 288:3,9 291:9 294:21 295:13 298:14 299:14,16 301:22 302:11 303:1 304:10 389:3	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18		
<b>presenting</b> 204:17 370:6	45:20 53:8,11,16 53:18 54:3 55:19 56:5,12,22 60:19 60:20,21 61:5,10 63:15,22 64:6,11 64:18 65:6,7,22 66:6,7,14,19 67:2 67:10 71:14 74:13 74:17 77:14,17 86:7 88:2,18 89:9 89:15 90:3,21 91:4 92:7 93:7,10 94:3,4 95:2 96:16 96:21 97:5 98:9 99:16 100:20 101:21 104:8,9 107:2 111:6 120:3 120:8 144:9 179:20 180:15 262:21 265:5,15 282:20 283:7,14 284:15 285:4,16 286:16 287:4 288:3,9 291:9 294:21 295:13 298:14 299:14,16 301:22 302:11 303:1 304:10 389:3	117:1,21 119:14 124:4 140:5 170:18 186:22 189:9 216:1 284:10,13,20 317:10 318:16 337:22 349:22 377:5 394:2 404:18	212:5,12,12 213:1 220:2,3 237:21 239:6,11 270:17 302:4 316:19 371:15,16 381:18 383:18		
	<b>presumably</b> 395:17 395:21	<b>prevent</b> 264:12	<b>priority</b> 181:3		
	<b>presume</b> 38:13 94:15	<b>preventing</b> 63:5	<b>private</b> 10:2		
	<b>presumed</b> 395:21	<b>prevention</b> 1:14 4:8 7:19 37:1 40:3,9 57:9 90:18 91:3,5 217:3,13 298:3 305:17	<b>probable</b> 332:21 333:6 334:6 335:17 344:9 351:11 352:2 353:19 372:21 374:17		
	<b>presuming</b> 107:4	<b>Preventive</b> 12:2	<b>probably</b> 18:20 57:10 62:11,12 88:14 99:5 129:18 138:15 140:1 142:21 144:2,8 163:16 165:1 180:4 201:7 203:15 211:6 233:22 237:6 238:6 280:16 291:21 296:3 305:18 308:19 316:21 349:6 351:3 372:14 376:4 380:16 381:21 385:9 394:15 417:10	<b>problem</b> 56:20 66:10 87:18 89:13 94:9 97:20 139:13 174:17 186:20 209:4 214:5 218:3 218:16 221:16,20 234:10,16 289:7 321:22 331:22 353:5,6 358:11 360:21 382:11	
		<b>previous</b> 61:6 237:6 282:15 297:10 301:20	<b>problems</b> 112:17 112:20 160:12 161:4 177:9 224:6		
		<b>previously</b> 403:1			
		<b>pre-arrival</b> 339:18			
		<b>primacy</b> 175:6			
		<b>primarily</b> 32:6 99:7 310:4			
		<b>primary</b> 17:10 18:9 55:20 59:21 92:17 93:1 113:12 150:20 192:5 211:16 223:11 270:7 282:10 312:18 333:16 352:21 385:20 387:9 390:21 400:14			
		<b>primitive</b> 190:6			
		<b>principal</b> 309:20			
		<b>principle</b> 255:6 314:5 371:10			
		<b>printed</b> 318			

363:2	<b>provide</b> 31:18	401:17 418:1,5,9	<b>puts</b> 295:17	83:18,22 87:6
<b>programs</b> 139:16	42:19 43:1,21	<b>publication</b> 8:9	<b>putting</b> 71:16 72:1	88:12 89:1 112:3
224:3 227:15,22	67:15 115:9 175:1	42:7	102:1 106:15	112:9 120:20
228:3 254:20	181:19 275:7	<b>publicly</b> 51:14	196:18 197:4	124:1 126:6
357:17 359:6	296:20 306:10	204:10 283:11	202:11 232:1	133:16 135:8
<b>progress</b> 132:10	339:9,15	296:22 407:10	235:19 269:6	142:6 148:19
156:1	<b>provided</b> 6:21	<b>published</b> 16:18	<b>P-R-O-C-E-E-D-...</b>	149:4 151:20
<b>project</b> 4:5 5:9,11	66:20 70:6 74:15	49:19 225:5 257:6	5:1	152:2,8 156:8
6:5 7:16 19:10,13	118:6 160:10	257:9 378:3	<b>p.m</b> 191:6 192:2	157:14 158:3
20:10 23:20 25:2	233:1 333:20	<b>pull</b> 81:10 218:9	307:16,17 418:11	161:13 167:12
26:17 29:4 38:12	336:9 340:1	252:10 271:18		175:19 178:2
107:13 123:2	343:11 408:7	<b>pulled</b> 92:14	<b>Q</b>	182:5 183:4 184:3
147:22 189:5	<b>provider</b> 187:12	195:13	<b>QI</b> 379:21,21	184:7,16,22
266:8 282:1	188:17 189:2	<b>pulling</b> 128:11	<b>QMI</b> 213:1	185:10 187:4,22
313:20 314:10	192:10 202:12,13	366:2	<b>qualified</b> 326:4	195:2 196:5
386:2	241:2 254:4	<b>pulls</b> 248:7	<b>qualifies</b> 279:8	200:10 204:16
<b>projects</b> 20:22	277:11	<b>pulmonary</b> 11:3	<b>qualify</b> 218:19	210:20 213:19
<b>prominent</b> 32:2	<b>providers</b> 52:5	<b>pumped</b> 389:4	258:3 273:18	220:15 221:8
<b>promise</b> 45:10	66:9 138:13	<b>pumps</b> 403:9	401:9	222:8 232:22
<b>promote</b> 23:13	184:10 187:13	<b>punished</b> 180:20	<b>qualities</b> 261:9	236:17 241:20
25:12	277:13,20 279:11	<b>purchaser</b> 10:18	<b>quality</b> 1:1 2:20	242:6,18 243:12
<b>promptly</b> 231:20	336:11 343:8	<b>purchasers</b> 26:10	3:18 5:8 8:2 9:19	243:14 245:17
328:22	414:9	<b>purchasing</b> 378:3	12:10 21:14 22:5	246:7,18 248:16
<b>proper</b> 120:15	<b>provides</b> 69:2	<b>pure</b> 190:13	24:3 25:16 26:4	250:16 252:3
364:16	240:3,3 257:16	<b>purpose</b> 20:10	28:2 52:10 69:3	255:14 259:6
<b>properties</b> 28:20	414:19	<b>purposes</b> 80:1,5	139:16 181:15	267:19 268:6
30:17 59:11 68:21	<b>providing</b> 51:18	321:18 327:10	184:6 259:20	273:19 280:19
<b>property</b> 27:17	<b>provision</b> 223:9,10	<b>pursue</b> 270:9	260:10 261:3	281:9,9 302:8
<b>proportion</b> 118:2	<b>provisional</b> 146:9	<b>pursued</b> 97:4	275:11,16 277:13	304:8 306:2 312:9
164:13 235:3	267:1	<b>purview</b> 253:9	277:20 278:7,11	319:16 320:3
320:16,18 321:2	<b>provisions</b> 284:10	<b>push</b> 35:10 144:19	278:12,16 279:19	327:22 329:14
372:4 398:14	<b>proxy</b> 26:6	346:11 385:18	317:20 324:12	333:3,4 337:2,18
405:22 407:1	<b>PT</b> 1:19	<b>pushback</b> 352:6	330:1 357:17	345:1 361:10
408:20 409:2,6,7	<b>PTCA</b> 151:4	<b>pushing</b> 25:19	373:16 377:21	366:21 369:15,20
409:9 410:10	<b>public</b> 3:13 4:13	254:14	<b>quarter</b> 342:9,10	370:3 372:18
416:3	9:8 20:7 21:14	<b>put</b> 43:14 48:9	376:16,18 380:5	376:4 381:8 387:6
<b>proposal</b> 91:16	22:1 28:1 33:10	72:19 84:15	398:10	393:13 395:1
<b>propose</b> 383:6	33:11 42:15 46:12	139:12 149:19	<b>quarterly</b> 254:19	398:18 399:5
384:22 409:14	47:20 48:5,10,14	153:21 154:4	398:8	404:2,21
<b>proposed</b> 70:20	67:17 74:5 80:1,5	167:15 175:10	<b>quarters</b> 398:1	<b>questionable</b> 253:1
80:9 267:16	118:17 131:20	180:19 195:12	<b>quartiles</b> 318:10	288:10
<b>proposing</b> 412:11	155:5 176:14	215:13 221:10	<b>queried</b> 75:22	<b>questioned</b> 265:9
<b>propranolol</b> 216:18	178:10,13 181:4	223:4 241:6 243:1	<b>question</b> 32:1	<b>Questionnaire</b>
218:11	181:18 184:6	256:18 265:21	36:13 38:9 57:11	259:8,9 274:20
<b>prospective</b> 325:9	186:2 227:9,18,21	284:4 292:9 306:2	58:3,4 65:3,19	279:6
<b>proven</b> 133:13	228:4 242:7 368:9	338:11 340:6	67:4,19,21 73:1	<b>questions</b> 13:20
229:15	376:21 382:19	357:20	73:14 80:17 81:2	14:1 16:11,11

18:5 19:5 28:4	193:8 223:15	126:10 135:7	338:19,20 415:10	283:8 289:17
37:19 39:8,21	228:10 286:9	136:18 157:5	<b>ready</b> 8:8 36:19,19	294:18 295:3
44:13 57:13 62:3	297:15 300:18	192:5,7 193:7	210:17 211:3	296:5 298:17
74:4 79:8 104:14	304:5 370:18	195:15,19 196:11	245:16 342:3	311:10 312:13,22
118:7 119:16	372:12 407:11	197:6 201:2 204:7	<b>real</b> 10:3 34:9	319:16 331:1,3,5
125:20 126:9	<b>quote</b> 58:22 326:2	205:6 206:1,6	66:10 122:19	333:18,19 336:16
133:15 135:5	<b>quoted</b> 287:22	222:7 240:2 242:3	139:13 251:10	340:15,18,20
138:2,22 149:21	<b>quote-unquote</b>	244:9 248:2 249:5	277:17 295:20	344:13,17,19
150:9 151:21	137:13	251:19	319:3 321:11	345:7 346:3,4,11
155:10 158:1	<b>quoting</b> 116:15	<b>rate</b> 29:20 52:14	356:9,18 358:11	346:17 356:8
159:19 160:15	378:16	53:3 92:18 116:1	<b>reality</b> 143:2,7	372:3 395:7 396:6
161:6,15 169:4		120:15 164:13	173:5,18 225:13	400:9 402:11
170:21 171:7	<b>R</b>	300:22 339:8	<b>realize</b> 107:17	403:16 404:17
176:21 177:16	<b>race</b> 61:15 362:3	<b>rates</b> 52:20,22	255:2 264:4	405:11
183:1,14,17	399:2	128:5,6 253:5,6	297:14 364:9	<b>realm</b> 392:1
185:21 192:19	<b>racial</b> 357:7	389:20	380:15	<b>realms</b> 259:2
194:21 203:20	<b>raise</b> 60:11 415:14	<b>rating</b> 29:17	<b>realizing</b> 195:4	<b>reason</b> 6:16 16:13
204:20 210:22	<b>raised</b> 74:4 109:11	103:15	<b>really</b> 36:13 39:19	110:4 121:18
213:11 236:10,20	110:21 123:5	<b>ratings</b> 92:16,20	52:9 59:2 67:14	122:5 136:3,6,8
239:22 247:13	184:16 286:6	<b>ratio</b> 155:22 201:18	67:21 68:17,22	139:8 141:10
268:13 283:19	<b>raises</b> 175:19	240:21	69:1,4,22 70:1,3,8	144:5 148:20
286:6 292:11	<b>raising</b> 123:8	<b>rationale</b> 40:17	88:5 94:17,19	168:17 175:8
301:12 305:21	<b>ran</b> 286:19	51:19 242:1	96:4,9 99:3,10	195:9,20 207:18
312:4 317:12,12	<b>random</b> 185:15	<b>Ray</b> 6:2 36:16 45:9	103:15 116:19	208:7 209:21
317:14 319:14,16	271:18 279:1	58:4,4 59:15	121:8 122:17	227:13 254:12
336:15 339:21	379:19 380:3	73:16 115:2 127:5	129:22 130:3,7,20	263:13 325:16
366:14 372:17	<b>randomized</b> 218:10	146:13 246:14	143:16 145:15	329:13 341:18
382:4 383:3 384:2	219:6 287:21	302:9 307:3 370:3	149:9 152:14	353:18 372:10
386:11 395:3	299:4 326:8	380:9	153:11,19 158:12	373:3,20 393:1,3
417:21	394:22	<b>Raymond</b> 1:12,15	158:21 163:6	403:10,13 409:12
<b>quick</b> 65:2 85:14	<b>range</b> 63:18 74:16	<b>Ray's</b> 362:13	166:10,17 168:20	412:8
131:16 267:19	89:16 90:4 116:5	<b>reach</b> 23:5 26:16	181:16,19,21	<b>reasonable</b> 75:10
361:10	156:16 242:10	185:13	182:17 183:11,20	89:1 94:16 121:9
<b>quickly</b> 57:11	349:8	<b>reachable</b> 75:12	184:14,20 185:11	148:4,7 173:17
79:10 103:9	<b>ranges</b> 174:9	<b>reached</b> 75:14	185:16 187:7	180:21 205:17
133:10 139:17	<b>rank</b> 297:11	288:4,5	202:15 203:10	232:12 242:5
312:17 323:1,2	<b>ranking</b> 297:17	<b>reaching</b> 128:17	208:3 209:14	244:3 271:5 366:8
326:17 346:12,17	<b>rapid</b> 352:1 374:13	<b>read</b> 135:8 251:5	217:5 228:17	375:4,11 387:3
351:9 352:16	<b>rapidly</b> 22:6	265:7 289:1	230:11,12 232:9	389:1,16 392:2,15
356:18 358:22	298:17 364:3	290:20 338:12	234:18 251:2	<b>reasonably</b> 208:5
<b>quintile</b> 297:12	<b>rapid-fire</b> 351:18	341:14,15 370:8	252:16 253:11,16	374:9
<b>quintiles</b> 318:10,14	<b>rare</b> 223:17	380:21	257:7 260:9	<b>reasons</b> 79:6
<b>quirk</b> 174:10	<b>rarely</b> 170:9,12	<b>readily</b> 31:14	261:17 263:22	109:20 120:13
<b>quit</b> 415:20	<b>Rasmussen</b> 2:2 9:2	147:11 320:7	264:5,21 265:12	121:19,21 122:4,7
<b>quite</b> 123:22	9:2 75:16,19	360:19 369:8	268:4 269:12	134:20 135:1
127:18 132:5,6	76:14,17 81:15	415:10	273:6,9,18 275:12	136:16 164:7,9,10
150:15 192:16	86:19 94:22 95:17	<b>reading</b> 182:5	277:14 278:1	164:11,11 169:18



171:6 180:7 208:22 220:6,9,10 220:11 223:6 264:7 268:18 403:15,17 <b>reassure</b> 298:11 <b>Rebecca</b> 2:22 329:22 332:4 336:7 339:3 356:14 357:6 376:12 380:1 <b>recall</b> 6:19 283:1 379:9 <b>recalling</b> 375:14 <b>receipt</b> 94:20 <b>receive</b> 74:6 <b>received</b> 59:20 67:4 238:1 257:13 268:4 371:15 <b>receiving</b> 243:19 330:10 362:12 373:13 394:3,8 405:5 <b>recess</b> 191:7 <b>rechallenge</b> 206:16 240:17 <b>rechallenged</b> 209:4 <b>recognition</b> 115:21 131:6,13 <b>recognize</b> 16:21 54:22 <b>recognized</b> 18:5 298:3 <b>recognizing</b> 93:5 282:8 <b>recommend</b> 32:10 39:5 83:20 84:3,4 84:5 290:14 326:11 365:18 366:11 369:17 399:10 414:14 <b>recommendation</b> 26:19 84:12 95:19 96:2 117:20 145:11 175:13 193:14 216:16,22 231:9	<b>recommendations</b> 33:8,9 41:5 43:16 176:4 197:7 217:22 226:14 228:8 399:8 414:12 <b>recommended</b> 158:16 219:11 <b>recommending</b> 83:13 340:16 <b>reconcile</b> 32:18 <b>reconciliation</b> 252:15 <b>record</b> 19:22 31:19 34:6,13 35:4 67:17 74:5 80:15 81:7,9 93:6 111:16,19 112:10 113:4 150:11 154:22 157:21 168:8 170:17 182:21 183:11,21 190:8 236:6,7 239:19 248:19 249:9,17,19 251:3 252:22 253:8 256:14 262:5 270:1 276:6 280:8 307:16 355:19 368:15,16 370:2 405:13 415:16 418:12 <b>recorded</b> 19:18 144:5 274:5 338:7 355:6 409:14 <b>recording</b> 19:19 247:5 <b>records</b> 61:17,20 62:1 77:8 79:21 80:3 86:21 87:3,5 87:10,22 147:16 164:15 198:10 250:18 251:2,4,16 255:5 256:10 257:11 338:1,4 392:12 402:10 <b>recovery</b> 198:22	<b>recurrent</b> 63:6 <b>redo</b> 36:4 <b>redosed</b> 382:10 <b>reduce</b> 139:22 140:2 190:17 256:16,17 <b>reduced</b> 273:9 <b>reduces</b> 89:11 <b>redundant</b> 347:4 <b>reevaluate</b> 42:1 43:4 <b>reevaluated</b> 279:17 <b>reevaluating</b> 43:14 382:11 <b>reevaluation</b> 43:7,8 <b>reevaluations</b> 43:21 <b>refer</b> 21:21 91:2 110:14 333:7 <b>referred</b> 82:6 <b>referring</b> 102:10 227:10 299:15 306:14 334:12 <b>refers</b> 158:14 <b>refill</b> 203:3 249:10 <b>refills</b> 190:18 203:2 <b>refining</b> 22:3 <b>reflect</b> 53:8 181:6 198:21 334:14 <b>reflected</b> 226:22,22 <b>reflecting</b> 46:17 285:9 <b>reflects</b> 293:10 324:12 <b>reform</b> 23:17 297:6 <b>reformat</b> 242:6 <b>refreshments</b> 20:3 <b>refusal</b> 168:3 169:17 170:10 <b>refusals</b> 170:17 <b>refused</b> 180:6 <b>regard</b> 66:2 216:5 247:2 <b>regarding</b> 14:1 67:21 86:5 95:1 204:21 205:9 213:11 232:22	248:4 294:6 <b>regardless</b> 305:2 376:20 <b>regards</b> 138:17 147:9,20 392:14 <b>region</b> 51:3 331:18 <b>register</b> 103:9 <b>registries</b> 391:14 <b>Registry</b> 273:21 <b>regular</b> 408:9 <b>regularly</b> 43:4 <b>rehab</b> 23:2 <b>rehabilitation</b> 12:2 12:16 222:19,20 223:10 <b>reiterate</b> 218:18 <b>rejected</b> 233:5 <b>relate</b> 44:4,4 <b>related</b> 10:9 32:14 40:16 41:5,12 79:12 99:7 119:10 168:19,21 233:22 309:22 336:15 337:20 381:15 404:14 <b>relates</b> 35:18 120:20 121:17 167:3 204:13 <b>relationship</b> 13:16 <b>relative</b> 127:10 186:19 206:14 209:2,15 <b>relatively</b> 170:9 223:3 225:21 226:6 394:2 396:8 396:15 <b>release</b> 213:9 223:22 225:17 287:15 <b>released</b> 105:18 287:11,18 291:13 <b>relevant</b> 7:2 10:14 47:17 86:15 116:11,17 125:3 185:6 189:7 223:1 223:8 228:10 259:17 278:14	397:13 405:3 <b>reliability</b> 30:21 59:9 68:1,22 69:9 69:17 70:6,9 75:3 94:12,20 102:12 102:18 103:14 118:4 156:3,19 157:2,15 164:16 164:21 171:8,16 194:2 256:21 257:7,17,21 258:4 258:9,10,14,17,20 261:6 268:7 274:10 275:8 278:6 366:7 375:10 378:7 386:22 387:3 <b>reliable</b> 69:14 259:4 345:19 <b>reliably</b> 251:12 <b>relief</b> 268:20 311:18 314:20 <b>reluctant</b> 353:11 <b>rely</b> 340:16 <b>relying</b> 338:6 <b>remain</b> 101:3 <b>remained</b> 52:15 <b>remarkable</b> 260:22 <b>remarks</b> 15:22 <b>remember</b> 35:17 103:6 186:16,17 190:5 <b>remind</b> 7:12,20 17:20 19:16 30:9 <b>reminders</b> 190:18 <b>removed</b> 41:10 263:12 264:4 267:4 <b>renal</b> 205:19 282:16 <b>repeat</b> 65:14 <b>repeated</b> 328:10 <b>reperfusion</b> 331:2 344:5 345:1,4 349:2 365:11 <b>report</b> 28:8 51:14 102:22 104:17
---	---	--	---	---

113:21 227:18 234:14 261:12 270:1 278:19 283:1,2 287:19 288:20 289:13 299:9,20 333:22 334:2 335:15 336:7 342:2 356:17 372:15 377:8,13 379:1 402:11 407:4 416:6 <b>reported</b> 50:18,19 51:4 56:12 61:14 156:1 204:10 205:14 236:4 274:12 283:12 293:3 296:22 302:10 378:2 379:7 383:22 400:17 401:2,7,7 407:9,10 416:9 <b>reporter</b> 236:1 <b>reporting</b> 21:14 22:1 28:1 50:11 53:22 80:2,5 118:18 176:14 181:4,18 184:6 227:9,21 228:5 233:18 234:12 235:2 247:10 286:19 314:3 368:9 376:10 377:22 382:19 401:17 406:3 <b>reports</b> 124:16 336:17 342:9 410:9,11 <b>report's</b> 336:18 <b>represent</b> 9:7 12:14 26:11 44:20 45:7 45:13 86:22 392:18 <b>representation</b> 105:9 106:6 201:21 <b>representatives</b>	15:20 100:6 <b>representing</b> 9:15 10:2,12 12:8 13:6 13:11 308:16 <b>represents</b> 130:17 <b>reproducibility</b> 261:6 <b>reproducibly</b> 262:1 263:6 <b>request</b> 121:10 356:7,12 399:1 <b>requested</b> 356:16 <b>require</b> 97:11 101:4 219:9 369:4 410:3 <b>required</b> 31:14 200:14 314:20 343:6 380:6 <b>requirement</b> 252:8 257:8 341:2 <b>requirements</b> 316:1 <b>requires</b> 200:18 382:9 <b>requiring</b> 97:1 137:15 353:19 <b>research</b> 7:14 40:11 271:16 277:3 <b>researchers</b> 26:9 <b>reservations</b> 357:4 <b>resident</b> 15:1 <b>resolution</b> 83:5 140:18 <b>resolve</b> 87:18 149:20 <b>resonated</b> 267:6 <b>resource</b> 15:17 25:16 <b>respect</b> 16:16 17:3 94:11 110:10 170:1 178:15 194:6 216:13 217:1 219:14 235:22 407:15 <b>respectfully</b> 292:3 <b>respects</b> 174:19	<b>respond</b> 39:7,11 295:18 <b>responding</b> 48:13 167:5 <b>response</b> 13:21 14:3 19:7 27:6 39:22 57:15,18 72:12 108:7 111:8 112:6 114:18 118:9 124:8 133:18 138:3 142:11 148:10 159:21 160:16 161:7,16 176:22 177:18 192:20 203:21 204:22 211:1 213:15 236:12,21 247:14 261:13 283:20 292:13 301:14 305:8 361:2 365:21 368:13 369:11 383:4 384:4,12 386:13 392:4 399:7 401:21 402:2 404:5 415:11 418:7 <b>responses</b> 35:18 <b>responsibility</b> 303:11 358:19 <b>responsible</b> 47:2 284:16,22 <b>responsive</b> 216:11 216:15 225:21,21 388:6 <b>rest</b> 12:20 37:9 121:6 286:3 317:10 318:17 <b>restrooms</b> 20:2 <b>result</b> 54:18 155:17 257:21 <b>results</b> 31:2,5,9 32:22 34:15 35:13 51:3 52:10 75:3 119:13 157:14 257:9 266:10,17	274:7 378:12 412:6 <b>resumed</b> 113:5 307:17 <b>retail</b> 255:8 <b>retailer</b> 254:19 <b>retooled</b> 88:10 89:3 125:22 126:1 <b>retract</b> 127:14 <b>retrievable</b> 31:15 147:11 <b>retrospectively</b> 327:14 <b>return</b> 254:7 <b>Reva</b> 2:17 5:6 82:14,14 184:4 <b>reverse</b> 400:13 <b>review</b> 19:12 28:7 48:6,9,14 53:14 53:15 55:3 56:2,5 76:1,4 81:8,17,21 82:4,5,20 94:17 104:18 136:21 206:21 212:21 239:19 335:7 336:5 366:10 369:3 383:15 402:10,10 <b>reviewed</b> 28:6 45:19 54:1 68:9 68:18 160:11 165:1 229:11 305:18 333:4 387:6 <b>reviewer</b> 17:10 18:9 55:20 92:17 93:1 113:12 192:5 211:16 <b>reviewers</b> 62:7 177:13 <b>reviewing</b> 45:5 54:5 94:11 149:13 285:1 <b>reviews</b> 56:3 <b>revise</b> 106:15 <b>revised</b> 46:10 105:21 217:10	224:22 232:11 402:16 403:17 <b>revising</b> 403:17 <b>revision</b> 106:9 229:10,11 <b>revisions</b> 163:2,7 301:3 <b>revisited</b> 190:4 285:19 <b>revote</b> 123:13,16 123:18 211:7 303:18 305:22 306:3,5 <b>revoted</b> 84:22 <b>revoting</b> 211:11 415:5 <b>rewrite</b> 39:14 <b>rewriting</b> 39:15 <b>re-abstract</b> 274:9 <b>re-endorsed</b> 129:15 <b>re-endorsement</b> 50:12 <b>re-reviewed</b> 300:22 <b>rhetorical</b> 142:5 <b>Rhythm</b> 9:21 12:8 <b>Rich</b> 2:3 9:10,10 80:1 86:10 303:6 303:18 <b>rid</b> 267:1 <b>right</b> 20:9 33:20 36:4,7 38:3 39:20 40:1 55:10,12 59:12 69:1 72:22 74:1,2,9 78:16 84:7,13,19 85:5,6 88:22 90:8 95:13 101:16 104:15 107:10 108:5 111:6,9,20 112:22 114:16 115:3 117:1 118:14 123:18 124:4,9,12 124:14 127:16 128:8,12 129:1,2 129:10,16 130:6 132:1,11 133:19
---	--	--	--	---

133:21 141:11	416:18 417:1	<b>rooms</b> 364:3	<b>S</b>	<b>says</b> 34:3 65:5
142:6 144:10	418:1,10	<b>roster</b> 92:15	<b>safety</b> 102:4 189:15	79:12 80:14 139:4
145:19 146:6	<b>right-hand</b> 34:20	<b>roughly</b> 387:15	<b>Sam</b> 227:12	144:21 145:2
148:8 150:14	<b>rigorous</b> 149:6	389:19	<b>SAMANTHA</b> 3:14	155:15 156:12,16
152:6,12 155:12	<b>rises</b> 380:7	<b>round</b> 142:19	<b>sample</b> 279:1 300:4	165:7 186:12
156:14,22 158:18	<b>risk</b> 31:1 41:4,9,12	310:3	337:12 359:9	200:11 227:7,8
160:20 161:17	61:12 94:18 156:4	<b>rounds</b> 167:5	379:8 380:6	232:10 233:3
162:6 170:22	159:7 164:12	<b>routine</b> 53:13	399:13	245:10,11 261:17
171:18 174:18	172:13 182:14	54:17 147:12,14	<b>sampling</b> 378:22	331:10 335:16
176:10 177:1,12	185:1,10 188:5,9	276:22 340:3	379:11,16,18,19	367:11,11,20
185:19 190:10	239:20 272:13	383:14 392:11	380:2	370:10 378:7
202:21 208:7	282:19 296:4,12	<b>routinely</b> 263:15	<b>sanction</b> 224:1	405:18 412:15
210:12,16,19	296:14,16,20	314:13	<b>Sanz</b> 2:5 9:22,22	<b>scale</b> 29:17
211:10,13 213:22	348:13 366:8	<b>rudimentary</b>	59:15,17 60:6	<b>scenarios</b> 339:10
215:21 217:19	375:20	147:21	65:2 73:16 80:19	<b>schedule</b> 7:21 17:8
225:5,6,11,15	<b>risks</b> 114:1 122:18	<b>rule</b> 132:13 169:6	139:1 140:9	384:17
229:22 232:5	<b>RN</b> 1:15,18 2:9,22	335:11 378:3	146:13 159:6,12	<b>scheduled</b> 384:19
234:9,17 236:16	2:23	<b>rummaging</b> 228:16	159:17 213:19,21	<b>scheme</b> 380:2
241:15,16 242:2	<b>road</b> 11:5 37:18	<b>run</b> 356:16	214:2 248:16	<b>School</b> 3:13 9:14
252:19 253:8	348:13	<b>running</b> 336:12	250:1 276:14	<b>science</b> 189:22
255:13 268:8	<b>Robert</b> 9:14	387:18	347:6 372:18	215:21 220:21
275:5 278:11	<b>robust</b> 240:11	<b>runs</b> 379:22	399:12 412:12	<b>scientific</b> 28:18,19
281:3 282:11	<b>Rochelle</b> 1:17 9:5	<b>rural</b> 312:16 314:9	413:3,6,17	30:16 37:14 59:10
288:10 296:22	211:15 237:7	314:12,14 315:1,5	<b>SAQ</b> 259:7	60:16,17 62:5,19
297:1 301:11	<b>rock</b> 278:3	322:21 324:4,8	<b>sat</b> 137:14	62:21 63:21 68:21
304:9 305:3 306:6	<b>Roger</b> 2:7 10:15	349:18 350:2	<b>satisfactory</b> 66:9	69:11 73:7,15
307:5 309:4	249:12 346:20	364:12 377:18,21	<b>satisfied</b> 276:18	93:22 102:20
312:13 319:5,9	<b>role</b> 26:5	399:20 406:13	<b>satisfies</b> 271:8	103:13 117:2,4
324:4,13 325:8	<b>roles</b> 27:12	<b>rural-sensitive</b>	<b>saw</b> 52:13 177:9	118:8 123:17
326:6,10 328:11	<b>rolled</b> 52:2 300:14	310:1,7 311:16,21	265:17 276:9	133:14,22 138:5
328:16 332:7	323:9 327:22	314:22 354:8	339:20 372:13	155:9 159:20
336:6,20 338:8	330:12 343:4	<b>Russo</b> 2:4 9:13,13	<b>saying</b> 72:13 73:1	163:13 170:22
339:6 341:17	<b>rollout</b> 301:10	122:8 149:3	88:15 92:12 98:7	171:15 176:6
342:19 343:20	302:4	154:15 173:3	158:12 168:18	193:6,8 194:22
346:18 361:3	<b>room</b> 15:21 16:17	182:4 220:14,17	172:1 180:13	203:20 215:17
366:3 368:3	19:21 20:7 33:20	221:3,7 242:17	184:4 198:16	219:20 220:22
369:12,19 370:1	77:3 178:11 186:3	244:4,22 267:19	207:17 215:3	224:18 238:11
373:1 385:17,19	208:11 210:6	296:1 325:10	225:10 226:12	240:1 246:12
386:14,17 388:18	218:13 281:16	328:5 356:1	228:17 233:14	284:8 285:1 286:2
392:7 393:10,15	282:8 294:16	378:19 379:10	254:5 261:15	286:16 291:5
393:17,18,20	317:9 319:20	394:1 395:10	265:7 269:4	292:10 350:8,9
396:20 402:3	320:2,9 337:4	396:3 397:1	278:15 291:17	351:8 357:2 366:3
403:19 404:6,13	347:17 348:5	398:15 401:16	294:12 307:8	368:5 375:8
408:12,22 409:18	352:7 360:10	402:8 404:17	347:3 352:19	382:13 386:10,17
409:21 410:2	380:13,18 404:21	405:18 406:8,19	370:5 387:21	390:11 391:9
411:8,19 413:13	405:1 413:18	410:21 413:4,10	388:2 412:4 413:7	396:21 401:12
413:21 414:3	416:13	413:21 414:3,21	413:8	<b>scientist</b> 40:12

<b>scope</b> 167:7	160:12 165:1	235:18	46:15 150:11	279:4,10 359:15
<b>score</b> 51:14,15 52:2	187:20 205:2	<b>self-select</b> 252:1	201:17 228:11	373:17 387:21
70:10 118:2	215:3 221:15,20	<b>seminars</b> 364:1	262:2 294:1	<b>showed</b> 63:16
184:11 257:19	223:16 232:6	<b>send</b> 35:10,22 36:5	309:17 321:1	71:17 164:17
258:11,22 366:12	240:12 248:22	78:12 104:16	334:9 336:22	195:11 288:2,6,7
<b>scores</b> 52:4	254:22 269:20	131:20 214:5	370:1 400:14	327:9
<b>screen</b> 34:20	271:19 275:3	303:15 305:22	406:6 416:15	<b>showing</b> 89:8 172:4
<b>screening</b> 157:19	278:5 296:4	306:20	<b>sets</b> 48:2 51:11	173:9 215:10,14
<b>se</b> 44:20 96:11	304:11 307:12	<b>sending</b> 347:22	138:17 309:16	216:6,7
168:10 235:13	309:6 310:13	387:17	<b>setting</b> 188:6,7	<b>shown</b> 190:14
<b>seated</b> 113:8	314:6 334:16	<b>sends</b> 51:17 295:16	239:5 314:18	<b>shows</b> 174:8 188:17
<b>Seattle</b> 259:7,9	343:13 350:16	364:5,13	315:17 321:7	278:21
274:19 279:6	355:4 356:3,18	<b>senior</b> 5:7,15 14:8	359:6 371:20	<b>Sid</b> 10:4 62:22
<b>second</b> 28:19 58:18	360:4 362:15	14:22 15:10,10,13	<b>settings</b> 23:4	70:17 89:4 109:11
85:6 97:12 173:9	378:18 385:5	<b>sense</b> 83:7 95:18	196:16 202:5	110:21 198:3
194:10 211:7	387:20 390:8	118:4 119:12	267:13 316:2	214:21 228:7
241:8 242:21	<b>seeing</b> 15:2 24:22	123:15 165:16	<b>setting-specific</b>	287:13 291:8
261:20 309:21	85:21 173:5 178:4	167:1 190:22	21:1	304:18 305:13,20
320:2 412:3,6	203:4 209:10	197:22 222:6	<b>settle</b> 146:1	361:9
<b>secondary</b> 4:8	255:9 279:16	234:5 259:3 261:1	<b>seven</b> 96:7 146:15	<b>side</b> 32:15,15 113:9
36:22 40:3,9 57:9	326:16	311:20 312:14,20	389:19	149:19,20 179:14
90:18 91:3,5	<b>seek</b> 131:13	315:1 330:5,6,22	<b>severe</b> 332:17	179:14 187:10
217:3,13 305:16	<b>seeking</b> 50:12	331:16 333:13	390:14	242:18 254:14
335:6	<b>seeks</b> 38:4	352:9 384:17	<b>sex</b> 350:18	289:22
<b>seconds</b> 80:22 81:2	<b>seen</b> 24:3 52:10	408:2	<b>shaking</b> 387:20	<b>sides</b> 244:16 407:8
132:5 162:1	54:18 133:8	<b>sensitive</b> 314:10	<b>shame</b> 331:8	<b>SIDNEY</b> 2:6
<b>second-line</b> 193:10	134:12 162:10	<b>sensitivity</b> 261:7	<b>share</b> 16:22 287:14	<b>sign</b> 163:18
<b>section</b> 12:1 94:10	190:5 192:10	<b>sent</b> 92:11 104:18	<b>shared</b> 23:13 25:12	<b>signal</b> 258:22
94:12 101:12	200:5 208:16	307:3 333:22	190:11	<b>significance</b> 355:16
103:20 123:8,11	212:10 214:2	342:9 357:9	<b>shares</b> 112:13	394:18
123:13,17,19	215:8 220:1	378:11	<b>sharing</b> 181:17	<b>significant</b> 18:22
125:3,4 163:16	248:21 317:19	<b>separate</b> 65:14	250:13	29:4 97:3 99:5
308:18 396:4	326:3 330:6 332:9	118:6 310:3	<b>sheet</b> 318:8	105:7 106:13
402:12	336:13 337:17	313:14 323:13	<b>shelve</b> 138:16	107:16 114:11
<b>security</b> 343:19	352:11 381:4	406:6 407:20	139:2	118:1 160:12
<b>see</b> 18:14 22:22	<b>sees</b> 155:5	<b>separately</b> 51:15	<b>shift</b> 304:6	163:2,7 188:11
30:6 34:15 36:17	<b>segment</b> 324:17	118:6 310:3	<b>shock</b> 389:3 403:6	194:16 204:11
43:20 45:9 57:22	374:8	313:14 323:13	403:9	336:14 366:11
64:2,13 65:4,11	<b>segue</b> 13:9	406:6 407:20	<b>short</b> 225:22	369:6 393:4
70:21 72:13 106:1	<b>select</b> 33:3 35:21	<b>seriously</b> 128:22	354:18 396:8	<b>significantly</b> 39:4
108:22 109:8	340:2	353:22	<b>shorten</b> 191:4	273:9 354:13
112:19 123:15	<b>selected</b> 131:10	<b>served</b> 186:9	<b>shortly</b> 103:22	<b>Siler</b> 328:19
126:11 128:4	<b>selection</b> 325:22	284:19	416:13	<b>silos</b> 23:1
132:18 137:3	<b>self</b> 131:9 155:21	<b>service</b> 7:3 47:20	<b>show</b> 35:17 63:12	<b>similar</b> 32:1 133:1
143:19 148:1	236:3 317:1,10	280:4	63:17 66:5 71:3,9	138:15 141:21
149:8,14 153:21	<b>self-report</b> 155:21	<b>services</b> 25:3 254:4	71:11,11 82:15	145:10,16 194:7
156:9 159:15	<b>self-reported</b>	334:1 374:21	194:14,17 274:17	195:5 200:20
		<b>session</b> 55:14		
		<b>set</b> 40:17 41:8 46:9		

204:18 205:6,13 257:15 259:1 262:20 298:12 311:2 394:2 <b>Similarly</b> 147:13 <b>simple</b> 29:7 190:9 190:18 349:1 <b>simplest</b> 356:2 <b>simply</b> 300:12 321:9 337:14 <b>Simultaneous</b> 342:21 409:16 411:3 413:2,9 <b>single</b> 61:9 148:17 186:11 195:16 201:10,22 257:21 400:16 414:14 <b>singled</b> 219:5 <b>Sisters</b> 253:20 <b>sit</b> 13:14,17 416:17 <b>site</b> 54:13 <b>sites</b> 375:22 <b>situation</b> 165:13 183:10 196:21 200:3,9 202:14 207:20 258:15 313:2 340:20 362:18 <b>situations</b> 181:15 188:13 <b>six</b> 45:8,17 96:7 224:5 229:20 238:2 377:9 <b>size</b> 300:4 399:12 399:13,13 <b>slated</b> 55:6 <b>slide</b> 29:5 34:21 35:17 71:9 <b>slight</b> 416:8 <b>slightly</b> 337:19 353:1 <b>slim</b> 65:16 <b>slowing</b> 78:9 <b>small</b> 39:2 148:3 169:17 173:1 255:10 300:3 310:22 311:14	322:21 325:18 345:3,5 348:11 355:11 363:1 374:4,12 377:18 396:15 398:14 400:6 406:13 <b>smaller</b> 87:11 116:10,11 377:20 <b>smiling</b> 343:21 <b>Smith</b> 2:6 10:4,4 58:3,6,10 63:1 70:18 89:5 115:2 116:18 145:7,18 158:10 198:4 214:22 215:19 224:19 225:9,12 226:15 228:12 231:12,21 232:6 269:18 270:19 287:17 288:19 289:6 290:13 291:4,11 297:22 298:22 300:5 304:21 305:14,16 306:18 307:3 324:2,9 326:5 327:16 328:10,17 357:21 358:17 359:20 361:10 362:17 363:16 370:3,12 380:9 381:11 385:18 390:12 391:6 <b>Smith's</b> 76:6 <b>smoking</b> 129:10,14 129:22 130:4 283:6,15 <b>Snow</b> 2:7 10:15,15 37:22 79:10 82:1 87:7 153:16 218:2 219:18 250:8 251:15 322:13 323:19 324:7 327:1,13 332:20 344:20 347:3 367:6,19 368:1 395:5,18	<b>Snowden</b> 3:10 50:5 50:6,9 55:9 282:6 286:18 287:12 289:5 297:2 299:7 299:12,21 306:12 307:8 <b>snowstorms</b> 349:12 <b>social</b> 99:10 <b>society</b> 9:21 12:9 272:6 274:22 <b>socioeconomic</b> 188:13 296:8 <b>soft</b> 208:12 <b>soliciting</b> 33:11 <b>solid</b> 59:6 69:4 <b>solidly</b> 30:15 <b>solution</b> 18:13 <b>solutions</b> 18:15 44:12 <b>solvable</b> 186:20 <b>solve</b> 112:21 218:16 <b>solved</b> 144:18 <b>somebody</b> 18:12 50:2 82:21 96:20 100:12 112:20 143:22 154:5 170:16 223:19 229:19 230:2 250:14 284:2 304:18 308:15,20 328:2 334:19 341:15 349:6 352:2,12,20 353:15 367:8,10 387:11 388:21 389:2,5 <b>somebody's</b> 166:13 189:14 196:21 <b>someone's</b> 198:10 364:19 <b>somewhat</b> 74:22 90:14,21 378:5 407:4 <b>soon</b> 255:9 298:18 324:18 345:6 400:1 412:22	<b>sooner</b> 320:21 358:4,10 <b>sophisticated</b> 269:7 <b>sorry</b> 13:5 76:20 81:5 83:2 87:21 92:5 106:3 108:17 108:18 152:21 171:3 227:12 233:11 238:20 241:6 255:17 268:9 292:19 303:10 310:8 332:3 346:21 <b>sort</b> 17:19 19:12 20:12 34:16 36:14 72:8 74:6 108:3 123:3 134:15 135:2 139:12 140:18 142:1 144:9 147:18 168:6 170:3 179:7 179:22 181:11 190:4,11 208:4 209:2 215:17 221:19 228:3 243:22 247:4 252:7 254:15 256:3 260:22 261:4 267:1 269:13 274:9 323:9 351:17 356:16 359:12 370:4 373:9 382:1 390:10,17 397:17 401:4 405:21 406:1,6 407:13 411:21 416:8 417:21 <b>sorts</b> 109:22 110:16 223:16 236:8 <b>sound</b> 95:3 126:17 <b>sounds</b> 88:16 89:2 235:8 291:18 <b>source</b> 164:14 248:18 250:7 258:6 332:22 <b>sources</b> 31:5 79:1	165:4 369:2,5 376:1 383:15 <b>South</b> 1:21 9:6 10:11 <b>sparse</b> 377:5 <b>sparsely</b> 268:22 <b>speak</b> 66:11 235:15 311:11 334:10 339:4 398:2 408:21 <b>speaking</b> 19:16 158:19 206:5 223:3 247:4 284:4 342:21 409:16 411:3 413:2,9 <b>speaks</b> 130:2 <b>spec</b> 80:14 405:19 <b>specialists</b> 47:10 <b>specific</b> 7:15 21:2 96:1,11 136:2 178:20 179:8 188:15 197:16 206:8 207:15 214:4 216:12 240:6 242:19 243:14 245:18,20 246:4 271:10 302:3 332:12 338:1 339:1 <b>specifically</b> 18:10 63:11 77:10 90:18 120:1 121:12 168:11 214:14 312:15 313:2 324:8 332:12 339:9 346:22 414:17 <b>specification</b> 42:12 67:3 73:11 76:13 77:5 80:11 252:6 395:13 <b>specifications</b> 30:19 32:16 42:5 42:6,14 77:21 154:11 156:9 157:18 165:6 234:20 286:4,10
---	--	--	---	--

287:10 322:1	394:7	309:8 316:9	<b>status</b> 259:19	284:14
339:4 340:2	<b>stabilized</b> 388:22	348:16,22 349:2	263:20 282:21	<b>strange</b> 15:2
355:17 375:10	<b>stable</b> 212:4 228:9	350:4,5 385:13	296:9	173:21 174:14
382:8 395:13	262:5 272:9	416:10 417:1	<b>stay</b> 288:12,21	<b>strategies</b> 147:21
397:3 414:5,17,20	<b>staff</b> 2:12 15:15	<b>started</b> 5:21 36:12	361:17 394:9	<b>strategy</b> 283:4
<b>specificity</b> 30:18	26:16 27:12 41:20	36:20 43:14 59:14	397:12,22 398:7	<b>stratification</b> 61:14
<b>specifics</b> 59:8 88:15	92:11 94:17 290:3	193:15 229:4	398:11	399:1
<b>specified</b> 59:8	306:22 307:2	241:21 293:13	<b>staying</b> 289:2	<b>stratified</b> 390:2
88:11,13 95:6,16	328:3	301:7 314:9 389:4	322:20	399:10
134:2,16 168:15	<b>stage</b> 64:7,8 71:7,8	397:1	<b>stays</b> 397:19	<b>Street</b> 1:10
169:5 197:12	142:7 219:10	<b>starting</b> 416:12	<b>steady</b> 52:15	<b>Streeter</b> 2:16 5:10
214:14,18 281:19	<b>stages</b> 22:20	<b>starts</b> 103:7 228:16	<b>Stearns</b> 2:8 8:17,18	<b>strength</b> 373:21,21
291:20 322:1,4,6	<b>stairs</b> 262:9	292:21 380:8	256:9 258:8	<b>strict</b> 244:13,18
329:19 366:6	<b>stakeholder</b> 26:7	<b>state</b> 52:8 62:2 63:3	<b>steering</b> 1:4,9 26:5	335:11
383:17 386:21	26:13	198:21 283:11	26:15 29:7 32:20	<b>stricter</b> 62:11,15
395:16	<b>stakes</b> 181:12	284:17 285:2	33:3 39:1	305:12
<b>specify</b> 225:7	<b>stamp</b> 338:6	286:9 293:2,18	<b>STEMI</b> 199:1,1	<b>strictly</b> 49:20
<b>specifying</b> 172:18	381:19	294:7 295:11	328:15 331:13,18	<b>stringent</b> 302:14
175:14 226:8	<b>stance</b> 205:12	296:15 326:2	358:21 370:7	<b>strip</b> 339:12
<b>spectrum</b> 41:3	244:17	362:4	380:11 381:3,6	<b>striving</b> 23:5
101:20 102:5	<b>stand</b> 103:11	<b>stated</b> 65:21 66:12	391:18	<b>stroke</b> 8:1,2 89:12
170:4 312:22	<b>standard</b> 21:20	117:18,21 135:4	<b>STEMIs</b> 127:13	115:20 131:6
345:20	62:11 88:21 96:19	181:3 291:11	330:11 351:9	389:5
<b>speculation</b> 87:8	132:7,19 180:13	293:12 297:7	<b>STEMI-receiving</b>	<b>strong</b> 192:16
<b>speed</b> 78:14 190:11	182:3 189:19	<b>statement</b> 127:19	331:4	193:9 230:1,8,12
<b>spelling</b> 206:7	270:22 285:19	155:14 163:18	<b>stenosis</b> 205:20	232:7 365:12,12
<b>spend</b> 12:21 140:19	390:17	186:10 238:13	<b>step</b> 32:12 57:11	371:19,22
<b>spent</b> 87:16 141:16	<b>standardization</b>	241:7 291:5	99:18 100:1	<b>strongly</b> 30:15
189:6	66:17 338:15,22	<b>statements</b> 231:3,4	149:18 150:6	237:15
<b>Spertus</b> 3:12 48:21	<b>standardized</b>	<b>states</b> 22:2 125:8	170:18 261:22	<b>struggled</b> 207:4
49:2,8,12,13	337:22	197:8 199:13,21	263:4,18 276:10	<b>struggles</b> 277:8
95:10,10 96:12,13	<b>standards</b> 107:2	410:16	317:3 340:13	<b>struggling</b> 67:22
100:4 202:1,18	179:18 285:2	<b>state-wide</b> 52:14	<b>steps</b> 33:6	71:15 253:19
208:14 210:11	294:1	284:16 362:19	<b>stepwise</b> 150:2	<b>stuck</b> 127:8 172:10
222:11 228:6,7	<b>standing</b> 83:16	<b>statin</b> 158:4,7,13	<b>step-wise</b> 32:5 77:6	<b>studied</b> 216:18
264:5 272:11	<b>standpoint</b> 86:20	158:17 159:1	<b>stern</b> 91:8	218:21 219:2,2,4
<b>spirit</b> 7:7,13	106:19 109:1	162:15 164:8	<b>steward</b> 27:15	219:16
<b>split</b> 21:8 289:10	166:7 167:9 200:3	165:8,10,14,17	<b>stewards</b> 151:11	<b>studies</b> 216:6,7
<b>splitting</b> 196:14	221:21 286:2	166:21 167:18	<b>stewardship</b> 51:1	259:10 324:17
<b>spoken</b> 349:16	293:20,20 301:9	172:19 173:22	<b>stick</b> 18:3 411:6,8	381:4,9 395:1
<b>sponsors</b> 115:21	358:19	174:2,5,6,9,18	<b>stop</b> 28:14 174:12	<b>study</b> 53:9 215:14
<b>spread</b> 59:20	<b>start</b> 7:10 35:9,21	175:11 195:11,14	411:5	279:7 298:14
<b>spreadsheet</b> 92:22	149:20 172:21,22	<b>stating</b> 63:20 295:8	<b>stories</b> 364:2	<b>studying</b> 218:11
127:9 165:2 212:2	191:5 228:16	<b>statins</b> 163:5	<b>storms</b> 348:9	<b>stuff</b> 14:16 82:6
<b>squealing</b> 204:8	229:22 254:14	174:13,21 175:8	<b>straight</b> 270:17	215:22 322:19
<b>squeeze</b> 127:2	255:17 256:1	179:3	<b>straightforward</b>	<b>stupid</b> 16:11
<b>ST</b> 324:16 374:7	272:4 280:16	<b>statistics</b> 70:7	20:11 284:10,13	<b>subcriteria</b> 28:9,13

29:9 30:11 58:15 68:20 <b>submission</b> 17:17 27:11,13 73:4 75:1 100:8,16 101:10 104:1,21 106:2,22 107:14 115:18 157:18 273:20 293:5 296:14 378:7 <b>submissions</b> 106:21 233:5 265:6 <b>submit</b> 52:19,20 252:8 314:2 376:20 <b>submitted</b> 22:9 27:5,9 48:5 51:8 53:1 73:2,8 75:2 84:9,15,18 85:8 92:8 94:13 101:9 107:8 193:22 212:1 233:14,17 256:21 257:2,20 263:11 290:8,11 301:21 303:13,13 304:3,7 398:8 <b>submitter</b> 74:14 <b>submitters</b> 56:19 <b>submitting</b> 52:17 <b>subpopulation</b> 359:9 <b>subsequent</b> 18:21 32:13 84:13 167:3 <b>subsequently</b> 285:10 311:4,17 312:2 321:12,15 359:10 <b>subset</b> 229:14 363:9 <b>substantial</b> 175:7 <b>subtleties</b> 139:19 <b>subtraction</b> 246:16 <b>successful</b> 277:19 <b>successfully</b> 242:9 277:12 <b>suffers</b> 375:12 <b>sufficient</b> 33:2	<b>sufficiently</b> 276:6 <b>suggest</b> 78:6 85:15 90:19 91:13 101:7 140:8 160:1 216:9 217:3 269:16 292:3 334:21 385:4 396:19 402:4 <b>suggested</b> 121:13 415:3 <b>suggesting</b> 64:19 221:22 411:21 <b>suggestions</b> 42:20 305:21 <b>suitable</b> 24:9 181:4 <b>Suma</b> 2:10 10:20 <b>summarize</b> 17:11 344:3 <b>summary</b> 40:8 74:6 108:12,15 115:19 171:5 220:5 317:22 <b>sun</b> 197:15 <b>sundry</b> 79:6 <b>SUNG</b> 1:18 <b>supplement</b> 232:22 <b>supplemental</b> 118:5 <b>supply</b> 238:16,18 253:6 <b>support</b> 63:7 64:15 69:5 71:20 73:2 96:3 128:22 151:13 235:6 259:11 266:21 282:8 289:8 295:10,14 298:18 302:2 371:19 372:1 386:9 <b>supported</b> 25:5 89:21 114:8 128:10 151:17 310:19 <b>supporting</b> 150:13 153:19 351:12 352:4 <b>supports</b> 30:13	64:2,13 292:1 381:1 <b>suppose</b> 109:10 178:17 270:12 <b>supposed</b> 43:17 65:9 153:22 163:21 165:22 216:3 220:17 222:3 379:19 380:3 <b>sure</b> 27:4 34:8 78:11 80:16 81:4 89:18 90:17 91:1 93:3 103:10 104:20,20 109:16 115:7 121:5 127:7 131:15 137:2 141:5 145:7 168:1 182:6 213:20 224:20 226:17 228:7 241:14 247:4 251:4 262:13 263:6 273:1 286:18 303:3 306:17 312:10 320:22 324:2 326:15 340:8 346:18 352:4 357:22 393:13 397:14 401:20 408:20 <b>surely</b> 75:11 <b>surface</b> 190:3 <b>surprising</b> 114:10 <b>surrogate</b> 168:5 242:5 259:16 <b>surrounding</b> 44:2 <b>surveillance</b> 75:13 <b>survey</b> 61:22 <b>survives</b> 79:17 <b>survivor</b> 12:17 <b>susceptibility</b> 161:5 232:21 248:3 383:21 392:19 402:12 <b>susceptible</b> 369:6 <b>suspect</b> 131:12	326:20 357:18 <b>suspected</b> 315:6 <b>suspicion</b> 269:11 358:21 <b>sustained</b> 213:9 <b>sweet</b> 218:9 <b>swing</b> 416:21 <b>switch</b> 224:3 <b>symbol</b> 36:14 <b>sympathetic</b> 141:8 <b>symptom</b> 45:22 260:10 263:10,14 263:20 264:17 265:3,16 266:11 268:20 274:5,7 276:2,3 <b>symptomatic</b> 218:20 219:6,9,13 220:18 221:2 222:1 260:11 261:3 <b>symptoms</b> 256:6,13 256:17 259:19 261:11 262:16 264:15 268:14 272:7,15,21 275:11,13,15 276:1 278:14 279:21 281:5 381:3 <b>synchronization</b> 341:8 <b>synchronized</b> 340:19 <b>synchronizing</b> 340:12 <b>syndrome</b> 229:18 230:20 332:14 351:16 <b>syndromes</b> 230:14 <b>system</b> 1:17 9:6 42:22 67:5 82:15 109:20 136:16 164:11 203:16 220:11 224:8,13 235:18 253:21 262:14 272:4	280:13 290:19 303:17 307:19,21 314:3 336:11 361:15 362:1 379:12 <b>systems</b> 23:14 222:8,11 223:5 298:1 363:19 <b>systolic</b> 46:4,6 63:15,18 64:1,6 64:11,18 71:5,14 89:10,15 90:4 212:6 214:16,20 216:14,19 218:20 229:17 <b>Szumanski</b> 2:9 12:18,19 <b>S-E-S-S-I-O-N</b> 192:1
<b>T</b>				
<b>t</b> 103:12				
<b>table</b> 6:10,22 26:8 26:13 103:2 130:20 239:14 270:9 333:8 342:8				
<b>take</b> 13:13 14:7 17:5,6 18:16 19:2 45:8 65:9 73:19 78:15 96:15 98:8 98:10 112:22 117:6 128:20 129:13 140:21 144:4,5 145:9 150:2 152:2 165:19 166:5 182:9,11 188:2,21 206:9 213:12 228:12 230:2 240:18 264:9 266:10 267:10 269:15 301:11 307:11,12 328:5 339:17 350:5 367:13,15 382:10 385:9 396:9 417:18				

<b>taken</b> 129:6 131:14 136:19 191:7 283:5,14 355:15 381:18	77:22 288:14 301:22	71:15 77:21 94:9 104:19 114:4	44:15 49:21 50:8 55:5 56:1 57:12	84:7 91:7 97:13 119:17 122:9,13
<b>takes</b> 41:15 55:15 67:9 87:15 213:4 303:11 338:8	<b>tartrate</b> 219:3 222:2 224:4	117:18 118:4,20 119:11 124:15	67:20 101:17 102:16 113:14	128:8,13 137:21 181:16 184:18
<b>talk</b> 14:16 40:21 77:1 194:2 197:11 207:21 233:7 243:16 268:17 273:21 291:22 296:3 310:20 316:6 319:4 334:3 389:18	<b>task</b> 14:20 45:2,7 139:21 145:22	130:5 155:4,20 160:5,13 162:17 164:4,16,22 165:3 170:2,7 172:8 176:12 179:6 182:7 193:7	123:17 138:16 148:22 164:3 179:12 206:5 237:2 238:8 256:9 307:9 309:3 312:6 329:21 330:4 343:21 349:11 350:2 354:12 357:11 364:17 395:5 417:2,4	189:3 218:13 224:21 230:16 231:17,22 232:12 242:20 248:12 252:17 261:10 270:14 289:15 293:7 331:7 338:2 341:10 346:14 350:11 353:1,5 355:4 363:17 367:11 370:4,20 379:11 388:19 397:9,11 415:22
<b>talked</b> 44:5 65:3 66:16 119:20 184:22 192:14 196:13 259:15 262:8 310:14 350:14 365:15 367:1 383:20 398:15,20	<b>Tax</b> 311:17 314:19	203:17 207:15 208:15 223:3 232:20 234:12 240:5 253:15 265:22 268:6 269:10,12 270:16 271:3 278:3 282:16 297:10 308:9 334:16 342:16 351:1 365:6 379:12 394:22 397:11 402:16 416:11	<b>Thanks</b> 309:5 316:7	367:11 370:4,20 379:11 388:19 397:9,11 415:22
<b>talking</b> 80:21 87:21 116:12 170:13 201:5 258:9 277:6 281:18 294:11 312:15 344:22 347:9 348:21 349:2 397:1 408:13 409:5	<b>team</b> 5:11 12:21 128:9 129:1 362:21 387:17	<b>terrible</b> 280:2	<b>theory</b> 277:3 387:16	<b>things</b> 20:12 25:19 33:21 35:4 39:18 40:20 65:21 68:13 70:1,11,14 73:19 78:14 97:9 99:10 103:10 123:22 127:10 128:13 139:22 140:4 143:11 147:22 149:17 173:18 180:21 182:16 185:18 190:9,14 196:18 207:13 223:16 225:15 226:10 227:16 228:1 236:5 281:18 294:12,18 295:3,7 322:16 334:9,21 343:13 345:18 364:6 374:14 399:4 411:22 417:11,12 417:16
<b>talks</b> 120:22 233:1 341:12 412:14	<b>tech</b> 79:17 87:14	<b>terrific</b> 278:19	<b>therapeutical</b> 262:22	70:1,11,14 73:19 78:14 97:9 99:10 103:10 123:22 127:10 128:13 139:22 140:4 143:11 147:22 149:17 173:18 180:21 182:16 185:18 190:9,14 196:18 207:13 223:16 225:15 226:10 227:16 228:1 236:5 281:18 294:12,18 295:3,7 322:16 334:9,21 343:13 345:18 364:6 374:14 399:4 411:22 417:11,12 417:16
<b>tall</b> 275:2	<b>technical</b> 107:11 112:17,18 166:7 211:5	<b>test</b> 54:17 57:21 58:2 66:22 155:17 263:22 268:19 269:1 274:2 341:22	<b>therapist</b> 11:4	103:10 123:22 127:10 128:13 139:22 140:4 143:11 147:22 149:17 173:18 180:21 182:16 185:18 190:9,14 196:18 207:13 223:16 225:15 226:10 227:16 228:1 236:5 281:18 294:12,18 295:3,7 322:16 334:9,21 343:13 345:18 364:6 374:14 399:4 411:22 417:11,12 417:16
<b>target</b> 41:1 53:11 54:3 72:2 78:1 100:17 101:22 156:10,15 164:4 165:15 168:21,22 172:11 184:9,12 184:19 287:15 291:19 294:21 295:13 302:5 303:1 305:12	<b>tell</b> 59:18 69:20 259:8 275:14 295:19 307:22 310:13 327:21 346:12 367:12 399:14 413:4,5,8	<b>tested</b> 183:12 212:18 265:8 266:19 267:21 273:13 277:11 296:5	<b>therapy</b> 1:20 11:6 46:2 64:4,20 70:22 71:5 89:8 117:7 119:10 132:16 134:19 137:16 158:13,15 192:4 197:10 209:18,21 212:5 212:14 215:1 217:4 220:12 222:15 233:4 237:4 238:6 277:7 325:13 327:12 337:6 365:11 380:22 385:4 393:19 394:4,9,19 400:7,15 401:1 402:18,21 403:4 403:13 404:14,20 406:12	417:16
<b>targeted</b> 291:10	<b>telling</b> 7:1 297:16	<b>testing</b> 40:18 42:10 103:20 141:17 156:3 157:15 164:15,18,21 169:14 170:8 208:17 234:8 257:15,22 263:13 263:14 268:5 374:14 386:22	<b>thereabouts</b> 254:21 416:22	<b>think</b> 6:5 16:14 18:16 22:9 25:19 38:9,22 39:4,19 40:5 44:16 46:20 55:12 56:17,18 58:10 60:4 64:20 66:1,4 67:11,13
<b>targeting</b> 55:11	<b>temperature</b> 308:4	<b>thank</b> 6:4 8:13 13:2 13:8 14:4,15	<b>they'd</b> 37:10 111:1	
<b>targets</b> 53:16,19	<b>tempted</b> 45:8		<b>thing</b> 34:1 35:5 37:13 54:8 60:7 64:3 72:9,16 82:8	
	<b>ten</b> 22:8 63:12,14 64:4,5 67:9 71:2,6 71:11 89:8 260:15 260:17 271:18 286:8 326:3,11 346:6 358:14 388:7			
	<b>tend</b> 52:19 349:17 350:1			
	<b>tendency</b> 224:2			
	<b>tends</b> 87:10			
	<b>tension</b> 272:1			
	<b>term</b> 241:4,5			
	<b>terminology</b> 21:21 38:6 155:2			
	<b>terms</b> 48:3 54:9			



69:10 70:21 73:12 73:13 74:8 76:5 77:18 78:2 80:2,4 82:10,19 83:3 85:22 86:7 88:14 89:1 91:12 92:13 94:8 98:2 99:1,12 99:18,19,22 102:8 102:19 103:21 104:4 108:12 110:19 112:1,8 114:14 116:17,18 116:20 118:12 120:11,21 121:2,9 122:9 123:13,15 123:20 124:10 126:2 128:5,18 130:6 132:2,9 133:13 136:3,20 137:1,6,14,15,18 138:4 139:1,7,12 140:2,5 141:9 144:19 145:3,13 152:6,15,19,20 153:13 154:19 155:6,14,18 156:15,20 161:8 161:18 163:8,16 163:21 164:22 168:10 169:14 170:9,16 172:12 173:10,17 174:11 174:12,20 176:5 176:17 177:19 178:15 179:4,13 180:11 181:13 182:18 183:6,16 183:20 184:3 187:3 191:2 196:17 201:3,6 202:17 203:4,22 207:11 209:9,14 210:2,17,19 211:6 214:7 215:21 217:11 221:7,10 224:17 226:21 231:15 232:9,14	234:15 235:10 236:2 242:4 243:22 244:15 246:11,17 250:13 252:17 253:10 254:16 255:8,10 256:19 257:1,3,6 261:8,10 265:6 266:8 269:3,19 271:2,14 275:1 278:12,17 279:8 280:2,11,12,16,18 281:15 283:13 284:13 286:1 288:10 289:6,17 290:1,13,15 293:15,19 294:22 295:19 296:2,6,11 296:21 298:1 299:8 300:5,7 301:2,5,19,22 304:7,8 307:6 313:10 317:10 318:6 319:3,13 320:17,20 323:12 324:20 325:11 326:15 329:12 331:5 333:10 334:12 336:1 337:19,20 340:19 341:17,21 342:19 343:10 344:13,14 345:11,21 347:5 348:15 349:15 350:3,10 351:22 352:6,18 353:1,4 354:13 356:4,7,10 356:15 357:1,16 359:4 360:13,18 361:11 362:1 363:1 364:5,13 365:11,15 366:5 367:2 368:8 369:5 369:7 370:10 372:10 373:2,4,5 373:8 374:5,11 375:3,5,9,22	377:6,16,19 378:4 379:21 381:7,14 382:9,17 383:13 383:16,20 384:5 386:5,9,19 387:7 387:11,19 388:3,6 388:20 389:13,15 389:18 390:5,9 391:8,15 392:2,5 392:15,17 393:5 393:15 394:21 396:11,13 400:20 401:11,16,21 403:11,18 404:12 405:9 407:7 409:17 411:5,6 414:13,21 415:19 416:20 417:5,9,13 418:8,10 <b>thinking</b> 135:15 170:3,19 269:7 313:6 400:13 <b>thinks</b> 297:5 364:21 <b>third</b> 28:21 59:4 204:5 250:5 360:11 367:16 407:16 410:7 <b>Thirteen</b> 281:4 <b>Thirty</b> 81:2 <b>Thomas</b> 1:23 2:10 10:20,20 158:2,18 159:5 <b>thorough</b> 102:10 <b>thoroughly</b> 183:14 <b>thought</b> 8:11 97:7 103:8 106:12 108:20 122:4 124:4 141:11 154:3 159:1,3 171:5 185:6 189:8 245:18 248:2 288:19 303:6 350:21 353:2,16 356:1 379:5 <b>thoughts</b> 17:11 123:10 171:20	<b>thousands</b> 74:16 290:21 <b>thread</b> 349:8 <b>three</b> 17:21 27:21 28:9 30:11 36:21 40:4,8,15,20 42:2 43:3,8 45:18 50:14 52:15 53:4 58:14 78:6 87:19 100:7,10 101:22 108:6 110:2,3 118:15 119:16 140:13 149:13 152:3 198:15 215:2,6,9 218:21 219:5 229:7 230:17,19 249:1 264:16 273:14 308:17 318:21 319:11 337:1 338:14 348:8 406:7,8,9 <b>three-year</b> 43:6 <b>threshold</b> 28:9 29:18 30:9 60:22 62:8 65:6,7 90:20 90:21 91:9 173:16 174:17 175:8 197:20 <b>thresholds</b> 378:2 <b>threw</b> 180:9 <b>thrombolysis</b> 330:13,21 <b>thrombolytic</b> 325:13 394:9 <b>thrombolytics</b> 323:9 <b>throw</b> 85:17 127:21 175:2 367:15 393:12 <b>thumb</b> 60:9,11 72:17 102:6 <b>tie</b> 393:16 <b>TIERNEY</b> 3:14 227:12 233:8,11 234:9 <b>tight</b> 7:21	<b>time</b> 6:4,6,8 7:21 14:17 16:1 17:3 17:14 18:3,18 20:16,17 23:9 35:15 38:18 40:2 52:19,21 55:8 62:3 72:21 83:10 83:13 91:19 94:10 115:5,16 128:8 135:15 137:4 140:20 141:17 169:13 171:13 173:6 178:18 188:21 189:6 200:5,15 201:11 201:11,17 209:12 212:17 224:5 225:8,22 236:4 237:11 250:10,19 251:10,12 254:9 255:9 267:18 271:20 274:6,19 280:11 285:6 286:7 290:22 293:11 301:3 315:20 316:17,17 317:8,22 318:5,18 320:2,4,6,15 323:17,17 325:13 325:15 327:18 328:7,12 330:7,12 330:13,20,21,21 331:2 335:21 336:21 337:21 338:2,6,7,13,19 338:21 339:12 340:2,17 341:12 341:13,19,22 342:2,12,14,14,18 344:5,5,7,8,18,18 344:22 345:7 346:2,3,22 347:18 348:1 349:2 354:15,15,17,17 354:19 355:1,3,10 357:5,20 363:8,10 363:12 368:21,22
--	---	---	--	---

373:10 375:14 381:5,19 383:11 384:18 387:16 391:17 394:8,10 394:20 395:7 396:7 397:4 398:21,21 403:4 405:6,16,18,22 407:2,11 410:11 412:15 413:22 416:1,10,14 <b>timed</b> 322:17 323:7 340:8 341:6 <b>timeliness</b> 20:19 226:2 <b>timely</b> 324:11 359:6 389:21 391:1 <b>timer</b> 103:7 348:19 <b>timers</b> 348:20 <b>times</b> 42:2 100:8,10 128:9 167:2 262:4 320:16 339:11,21 355:6,18 410:6 <b>time-tested</b> 286:7 <b>timing</b> 332:13 339:18 341:6 345:16 350:20 <b>tip</b> 36:10 <b>tired</b> 415:19 <b>Tirodkar</b> 3:17 40:10,11 66:13 67:18 76:12,15,22 77:4 80:10 81:4 121:17 241:19 242:11 245:14 246:6 252:5 <b>title</b> 37:6 101:11 113:15 212:3 316:16 <b>TNK</b> 399:17 <b>tobacco-free</b> 282:21 284:12 <b>today</b> 7:3,21 21:9 24:10 25:21 28:12 32:6 45:5,17 107:8 118:21	136:21 150:1,6 291:12 307:4 354:7 363:5 384:20 385:1 <b>today's</b> 6:17 <b>told</b> 17:21 265:14 308:10 <b>tolerate</b> 86:6 158:4 158:7,22 209:20 <b>Tom</b> 8:21 127:7 143:22 145:21 297:19 299:9 302:19 361:11 <b>tomorrow</b> 34:7,8 140:20 363:5 385:12 415:21 416:12 417:17,20 <b>tool</b> 280:15 317:4 <b>tools</b> 190:2 <b>top</b> 88:3 271:9 297:11 <b>topic</b> 20:15 143:4 <b>topics</b> 70:13 <b>topic's</b> 281:16 <b>topic-specific</b> 21:3 <b>topped</b> 59:1 <b>top-ranked</b> 342:10 <b>total</b> 140:14 401:4 <b>totally</b> 243:9 397:19 <b>touch</b> 225:12 <b>touched</b> 125:5 350:10 <b>to/greater</b> 101:10 <b>TPA</b> 399:16 <b>trace</b> 343:6 <b>track</b> 31:19 93:6 105:21 106:11 168:7 182:21 183:11,21 190:8 199:11 316:3 332:11 343:6 349:17 414:7 <b>tracking</b> 175:16 341:22 <b>trade-offs</b> 23:11 187:18	<b>trained</b> 328:3 <b>trajectory</b> 23:9 <b>transcript</b> 19:18,20 <b>transfer</b> 311:2 312:18 316:19 321:19 324:6 325:3,4 328:21 342:5 344:18 347:1 353:20 354:7 358:3,8,15 359:1,17 370:22 371:2,17 373:13 405:2 <b>transferred</b> 311:5 312:3 319:18 322:7,11,15 323:15 324:10,22 325:7,19 326:20 327:6,12,17,19 329:8,16 330:3 331:11,13,19,21 332:6,10,13,18 337:4,13 344:16 348:11 351:12 352:3 353:10 354:3,10 358:2,9 359:10 360:2 361:14,20 362:6 363:7,9,12 364:11 371:3 380:12,14 380:20 387:12 388:14 406:12 411:10,16,18 412:16 413:18 <b>transferring</b> 313:3 315:2 323:16 324:7,13 362:2,14 400:8 407:22 408:3,5 <b>transfers</b> 312:16 332:14 386:4 <b>transient</b> 188:12 242:20,21 <b>transit</b> 332:3 <b>transitions</b> 23:10 <b>transmitted</b> 326:14 <b>transparency</b> 7:8	<b>transparent</b> 168:16 187:9 <b>transpired</b> 265:2 265:21 <b>transport</b> 347:22 <b>transports</b> 348:6 <b>transposed</b> 92:6 <b>trash</b> 180:9 <b>trauma</b> 333:15 334:18,20 <b>travel</b> 23:3 387:14 <b>traveling</b> 35:2 <b>treated</b> 63:9 76:8 89:19 90:4 263:8 391:17 411:14,17 416:3 <b>treating</b> 71:7 212:22 <b>treatment</b> 63:3,14 64:5,10 71:1,21 89:6 110:6,11 198:13 217:2 237:17 238:2,14 260:1 279:17 342:5 364:16 <b>treatments</b> 41:9 <b>tremendous</b> 18:7 67:12 274:15 <b>trending</b> 336:17 <b>trends</b> 336:16 <b>trial</b> 63:16 64:13 96:1 218:10 <b>trials</b> 63:12,14,17 64:5 71:2,4,6,8 89:8,14 91:2,3,4 114:8 151:13 219:6 221:1 229:2 229:2,6 274:16 287:22 288:6 326:8 405:9 <b>tried</b> 107:6 230:9 234:11 <b>triggered</b> 35:5 228:14 <b>troponin</b> 374:14 <b>trouble</b> 77:2 215:20 359:2	<b>true</b> 152:22 198:21 216:17 251:4 323:4 399:20 412:17 413:14,15 <b>truly</b> 183:1 240:20 241:10 249:19 261:18 <b>try</b> 6:8 35:15,15 36:4 82:18 85:5 91:11 93:4 97:4 105:11 106:10 112:15,21 124:14 139:21 140:19,22 145:13 154:13 162:7 189:17 191:4 225:14 240:17 263:3 268:19 271:10 272:4 275:7 335:8 336:4 340:3 343:14 384:22 385:4 <b>trying</b> 14:21 60:8 71:19 101:21 135:9 137:19 142:18 150:1,2 153:12,13 165:20 171:10 180:3 190:5 199:11 200:17 202:22 220:21 225:4 226:16 232:6 234:14,19 250:19 253:21 254:6 278:18 344:14 364:6 388:18 <b>TUESDAY</b> 1:6 <b>turn</b> 6:1 19:8,9 56:2 94:16 204:9 235:11 <b>turned</b> 298:17 417:11 <b>turning</b> 204:7 <b>turns</b> 149:5 234:22 <b>Twenty-five</b> 354:16 <b>twice</b> 127:12 133:3 221:10
---	---	--	---	--

<b>Twin</b> 297:20	185:8 310:5 338:5	391:13	46:16 314:4 336:3	264:20 274:1
<b>twirling</b> 36:15	408:5	<b>understanding</b>	355:12	282:21 283:15
<b>two</b> 35:20 45:18	<b>typo</b> 95:11 100:5,7	157:3,7 167:12	<b>upstairs</b> 322:17	293:1,2,8,9,21
53:18 54:11,11	101:14 155:15	179:6 260:6 320:8	<b>up/no</b> 73:21	310:17 313:12,18
55:15 59:21 65:14	157:6,12 163:17	348:2 364:7	<b>urban</b> 394:15	342:4 377:11,13
79:16 91:10 94:5	164:2	<b>understands</b>	<b>urge</b> 16:20 286:5	383:14 399:17
95:2,15 97:1,9,11	<b>U</b>	202:13	<b>urgency</b> 351:13	414:7
97:17 99:16	<b>ultimate</b> 172:8	<b>understood</b> 80:8	<b>usability</b> 28:21	<b>useable</b> 119:14
100:12,18 101:1	272:22	119:14 224:21	31:8 37:16 74:10	<b>useful</b> 31:3 141:18
107:22 110:22	<b>ultimately</b> 272:12	320:7	74:12 78:7 103:19	178:16 184:5
117:2 124:2	276:11	<b>undertaken</b> 293:16	104:15 108:17	203:17 320:4
133:21 134:4	<b>unable</b> 64:18	<b>under-use</b> 260:1,12	111:11 118:15,17	325:12 368:9
140:11 145:15	<b>unadjusted</b> 297:1	<b>undoubtedly</b> 103:4	119:17 124:1,7,11	382:18
149:5 150:18	<b>unanimous</b> 150:13	<b>undue</b> 31:15	138:9,11 147:5	<b>usefulness</b> 20:19
157:15 166:19	161:21 211:12	392:18	160:4,6,13,18	24:11 171:16
173:6 184:10	238:10 386:17	<b>unfortunate</b> 264:4	167:9 176:11,13	<b>user</b> 144:8 236:7
193:18 197:2	392:7 393:9,17	<b>unfortunately</b>	177:2 204:6,9,21	<b>uses</b> 107:2 181:12
200:6 207:13	<b>unawares</b> 257:7	172:3 241:19	205:3 227:4	181:19 376:21
210:4 215:6	<b>uncertain</b> 326:21	256:20	232:15 247:8,13	<b>usual</b> 390:13
255:20 263:2	<b>unclear</b> 398:10	<b>unintended</b> 98:4,6	292:18 300:8	392:16
264:6,13 265:3	<b>uncomfortable</b>	109:3 110:13,17	357:14,15 360:14	<b>usually</b> 41:15
266:14 267:21	189:16	125:10,11,17	368:7,17 382:16	137:21 354:4
274:17 288:2,7	<b>uncommon</b> 240:16	131:17 135:3	383:3,6 391:11	358:16 374:9
295:2 298:14	<b>uncontrolled</b> 120:3	182:7 277:21	392:6 401:15	<b>utilize</b> 41:16
303:20,22 309:7	<b>undercounting</b>	300:17 369:7	402:4	<b>U.S</b> 272:4
309:15 313:13	125:12	402:13	<b>usable</b> 75:7,15 80:3	<b>V</b>
316:4 318:12	<b>undergoing</b> 106:9	<b>unit</b> 405:3	108:21 124:4	<b>vacation</b> 276:8
319:16 324:17	378:8	<b>United</b> 410:16	138:20 294:9	<b>vacillate</b> 186:9
330:19 338:12,13	<b>underlying</b> 235:6	<b>universal</b> 36:14	357:16 392:2	<b>valid</b> 69:2,15
342:16 363:3,14	<b>understand</b> 29:10	<b>universe</b> 250:2	<b>use</b> 19:17 21:15	130:13 138:18
384:21 385:11	31:10 71:20 80:19	<b>University</b> 1:21 2:4	24:6 27:16 29:14	173:10 181:6,19
407:15 411:4	100:11 107:9	2:6 3:12 8:15,22	29:17 31:10 34:7	183:17 334:9
412:1	141:7 145:8	9:3,15 10:5,11	38:5 46:14 51:7	352:22 355:20
<b>two-physician</b>	165:20 166:1	11:5 44:22	81:10 87:14 91:10	387:3
87:12	196:6 203:11	<b>unnecessary</b> 67:14	113:10,16 114:6	<b>validate</b> 67:10
<b>two-step</b> 170:18	221:11 226:21	<b>unreasonable</b>	114:11 118:18	<b>validated</b> 277:10
<b>type</b> 125:1 128:22	261:5 277:18	75:11 206:16	122:17 125:22	<b>validation</b> 336:8
158:15 168:13,19	281:7 284:9 287:9	<b>unstable</b> 388:21	143:17 160:6	338:22 378:9
197:13 213:5	319:21 324:3	<b>untested</b> 70:1	163:4 166:9	<b>validity</b> 30:22 59:9
242:20 254:1	327:7 333:18	103:11,13 273:8	171:15 179:18	62:19 64:16 68:1
258:14 298:2	343:1 351:8	273:11	181:8 183:22	68:22 69:10,17
403:12	357:22 361:12	<b>update</b> 27:20 43:11	195:8 200:19	103:15 118:5
<b>types</b> 128:20	370:19 397:19	106:8 231:19	214:4 227:7,14,16	164:20 171:8,16
184:17 208:2	415:9	306:20 324:14	227:21 234:19	194:2 200:16
258:15	<b>understandable</b>	335:7 414:12	239:14 243:16	256:21 257:8
<b>typical</b> 158:20	52:3 138:12	<b>updated</b> 231:4	247:8 251:7,10,16	278:6 333:18
<b>typically</b> 155:5		<b>updates</b> 43:12	254:18 259:9	

366:7 375:12,19 378:8 <b>value</b> 30:4 31:11 71:2 104:12,19 176:18 204:12 229:15 295:13 368:11 382:22 391:15 <b>values</b> 157:15 204:14 299:22 <b>value-based</b> 378:3 <b>vanishingly</b> 169:17 173:1 223:6 398:14 <b>variability</b> 260:3 260:21 278:22 279:5,10 366:22 367:5 401:8 <b>variation</b> 185:11 <b>varied</b> 16:4,13 <b>variety</b> 20:22 22:20 79:1 154:12 181:9 181:10 190:2,11 <b>various</b> 26:21 56:3 79:5 141:1 349:19 <b>vary</b> 270:6 <b>vascular</b> 37:2 41:1 41:7 50:13,17 56:4,11 113:16,20 113:22 114:7 117:16 151:7 152:4 154:4 281:22 282:14,17 283:16 299:11,13 <b>vast</b> 169:19 208:2 274:13 293:5 355:1 <b>Velasco</b> 1:18 12:13 12:14 363:21 <b>vendors</b> 414:7 <b>ventilation</b> 307:19 307:21 <b>ventricular</b> 46:6 196:10,22 198:7 198:21 212:5,12 213:1 214:16 228:19	<b>version</b> 49:16 <b>versus</b> 62:8 65:12 80:21 91:3 129:21 179:3 196:21 207:7,8 241:15 300:2 320:15 372:6 387:7 399:20 405:16 407:6 <b>vexing</b> 138:14 <b>vice</b> 5:15 14:8 15:10 <b>view</b> 275:10 364:4 <b>Virginia</b> 11:4 <b>virtual</b> 393:15 <b>virtually</b> 123:5 <b>vis</b> 286:12 <b>visit</b> 88:1,1,3 94:7 117:15 173:8,9 195:12,14 198:15 263:7 270:7 275:13 277:1 <b>visits</b> 54:11,16 134:8,10 153:9 165:9 <b>vis-a</b> 286:11 <b>vis-a-vis</b> 265:2 294:1 <b>voiced</b> 169:13 <b>voices</b> 210:6 <b>volume</b> 252:8 338:17 376:20 377:19 401:4 <b>volumes</b> 376:8 <b>voluntary</b> 21:20 <b>vote</b> 19:2,3 28:14 29:19 35:11,21 36:5,16 37:12,16 37:16,17 57:14,20 60:4 69:7 73:14 78:3,6,13 82:11 83:4 84:13,18,20 85:2,6,7 93:12 102:20 103:12 108:6,9 111:7,10 111:14,15 112:5,8 114:20,21,22	116:22 118:11 124:10 126:3,9 131:15 132:2 133:16,20 138:5 140:14,18 146:12 147:5 148:12,16 150:10,11 155:7 160:1,18 161:9,18 161:21 163:9 170:21 171:1 176:6 177:2,20 178:4,4 192:22 201:7 204:1 205:2 210:17,22 211:3 211:12 213:17 215:22 224:18,20 227:2 232:15 236:14,20 237:1 238:7,9 245:16 246:12,20 247:16 255:10,17 280:20 280:22 283:22 291:21 292:12,14 295:11 301:16 302:7,20 303:5,9 303:12 304:3 306:6 351:4 357:2 357:12 360:14 361:4,7 364:18 365:1,18,22 368:4 368:16 369:13,20 375:6 382:13 383:6 384:6,14 385:7 386:15,17 391:9 392:6 393:8 393:9 396:19 401:12 402:4 403:20 404:4,7 409:12 415:3,7 <b>voted</b> 74:7,8 82:12 82:13 93:14 103:8 103:8 118:13 123:10 133:2 215:18,20 237:15 364:22 411:9 <b>votes</b> 17:6 30:7 34:12 78:10 193:4	247:6 303:21 304:1 350:4,5 409:14,15 415:16 <b>voting</b> 17:14 30:6 34:11,17,21 59:13 59:18 73:17 78:11 92:15 93:6 112:14 146:6 246:15 302:10 393:14 412:6 415:17 417:16 <hr/> <b>W</b> <hr/> <b>wacko</b> 360:12 <b>wait</b> 103:7 114:21 287:3 378:19 411:5,5,5 <b>waiting</b> 357:12 <b>Walgreen's</b> 66:20 <b>wall</b> 334:20 <b>want</b> 7:19 14:9 15:4,8 16:15 25:4 25:12 34:7 49:5 55:17 57:10,16 58:21 65:17 67:3 68:18 70:2 84:13 85:5 89:5 92:2 93:3 95:9 96:7,14 98:16 100:3,5 107:20 109:6 113:1 115:6 120:16 135:19 142:14 145:7,15 146:5 151:19 153:18 162:21 166:5 167:6 171:20 173:16 174:9 179:19,22 182:11 183:20 184:4 186:1,4,21 189:1 199:4 202:9 209:7 214:10 217:16 218:5,14 221:19 224:20 241:14 243:1,6 244:4 245:1 246:12 255:10	261:5 263:22 269:19 273:5 277:16 278:5 291:16 294:22 295:1 303:3 307:20 320:11 327:3 330:15 331:4 339:4 344:12,13,17 346:17 351:20 357:4,21 358:3,8 358:20 387:13 409:17 416:6 <b>wanted</b> 36:13 51:10 52:6,11 53:6 54:8 110:11 128:2 172:18 209:16 264:6 298:10 329:21 <b>warfarin</b> 134:19 140:5 <b>warp</b> 190:10 <b>Washington</b> 1:11 3:13 12:22 <b>wasn't</b> 49:5 52:7 65:21 106:4 121:7 303:12 305:19 334:21 397:14 <b>wasting</b> 115:4,16 <b>waterfront</b> 107:6,7 <b>way</b> 14:22 20:12 38:16 78:13 90:1 90:2,5 92:18 101:18 108:3 132:7 145:2 150:4 152:19 154:6 167:6 169:5 173:2 173:10,17 174:14 180:10 181:1 183:12 185:19 187:8 195:15 196:2 197:6 198:20 201:13 209:12 210:11 216:2 220:19 234:21,22 244:17 262:20 267:22
---	--	---	--	---

269:13 272:12,14 273:19 274:1 276:6 277:12 292:9 295:5 297:3 313:8 323:5 325:12 337:16 338:2 340:13 347:2 356:5,6 359:3,18 373:7 380:21 385:7 390:3 395:16 396:14 401:7 406:19 409:13 413:3 415:3 416:9	<b>well-taken</b> 132:1 137:5 <b>went</b> 71:17 78:20 113:4 128:6 129:21 229:6 241:17 265:12 280:7 298:11,19 307:16 321:2 338:10 403:15 418:12 <b>weren't</b> 92:10 283:6,8 320:22 327:17 333:19 338:19 <b>we'll</b> 5:5 14:16,21 21:9 22:8 28:12 29:17 30:5 32:15 33:12,14 34:14 35:14 36:4 37:9 37:13,15,16 40:5 72:6 82:19 85:2 106:22 114:20,21 118:10 123:16 124:10,12 126:11 138:15 149:14 150:6 155:8 162:7 175:16 178:8 193:5 197:11 201:3,6 207:21 226:12 236:4 283:13,21 297:16 307:1,12,12,13 316:6 363:4 369:20 384:6 385:20 399:5 416:14 417:17,20	60:14,18 69:11,22 72:5,20 75:9 77:2 78:2,8,14 83:3 84:8,17 86:17 87:21,22 90:13 91:20 92:21 101:8 102:13 104:12 108:10 111:17 112:15,21,22 113:6 116:21 120:13 126:5 132:2,5,6,7,9,10 132:14 133:1 136:20 140:14,22 141:18 142:18 143:13 146:20 148:12 149:5,13 149:17 150:1,1,10 150:17 155:1 162:2 163:12 166:17 170:13 173:13 176:2,3 178:1,8 181:21 183:9 184:5 189:18 199:8,10 199:11 200:2 201:5 202:11,15 203:4 204:15 209:9,10 210:17 210:19 211:3,6,10 211:13 215:16 216:21 231:14 237:3 242:21 244:11,18,20 253:17,19,21 254:8 255:22 258:9 259:1 261:11 264:8 265:10 272:12,15 272:16,18,19,19 272:20 277:5,14 278:1,18 280:19 281:18,20 284:3,7 287:17 292:16 294:19 303:3 305:10,22 306:4 307:11 308:10,11	308:14 312:7 316:8 321:19 323:4,21 324:5,19 325:2,3 328:6 334:3 338:6 343:21 350:3,5 352:12 353:8,13 354:6 355:11 357:2,11,22 358:7 360:16 361:4,6 365:2 368:4,6,16 369:13 370:5,14 370:21 377:16 379:3 383:8 393:7 393:10,18 394:13 403:20 404:13 405:17 411:7 415:15,19,22 416:7 418:10 <b>we've</b> 18:22 21:8 21:16 24:3 28:6 34:21 43:10 54:18 55:12 59:19 60:3 75:13 91:14 93:9 102:19 103:22 110:7,8,8,15 126:8 127:2 141:16,16 143:4 145:8 146:11 150:4 158:20 169:14 184:22 192:14 201:15 207:3 208:16,17 215:11,18 230:9 237:5 241:8 251:13 259:14 267:3,11,16 271:15 300:8 308:11 313:11 336:9,11,13 337:12 343:10,22 344:6 350:10 351:4 352:10 353:11 391:22 398:20 409:13 417:9 <b>whatsoever</b> 283:18	<b>white</b> 29:7 70:15 297:4 <b>whoever's</b> 245:4 <b>Whoops</b> 331:22 <b>wide</b> 181:9,10 242:9 <b>widely</b> 22:1 23:19 183:13 194:20 <b>widespread</b> 392:12 <b>wide-eyed</b> 36:1 <b>wilderness</b> 247:5 <b>willing</b> 176:3 182:9 <b>willingness</b> 48:19 290:5 <b>Winkler</b> 2:17 5:4,7 14:6 15:4,8 19:8 19:11 36:18 38:5 40:1 44:17 49:22 50:7 83:6 84:7 85:7 149:16 156:8 157:13 159:2,9,14 159:18 162:21 181:2 182:18 257:13 265:1 268:3 281:3,8 284:2 302:21 303:8,20 306:3 308:19 309:3 316:12 318:19,22 319:15 321:22 356:13 378:11 399:4 406:9 409:4 409:10,22 416:11 417:4,15 418:2 <b>wins</b> 145:17 146:3 <b>winter</b> 348:9 <b>wish</b> 417:19 418:5 <b>withholding</b> 208:7 <b>Woman's</b> 1:22 <b>women</b> 1:15,19 11:15,16 12:14 47:4 230:19 364:2 <b>women's</b> 12:6 217:10 225:7,17 291:12 <b>wonder</b> 116:9 123:9 125:10
--	--	---	---	---

167:1 205:16 206:6 244:16 344:2 356:8 408:22 <b>wonderful</b> 18:13,15 113:9 149:1 <b>wondering</b> 76:1 198:5,17 206:1 338:15,21 <b>Wood</b> 9:14 <b>word</b> 121:12 <b>worded</b> 304:19 <b>wording</b> 148:19 <b>words</b> 75:9 141:14 153:12 179:19 272:18 310:2 377:7 391:3 408:9 409:13 <b>wordsmithing</b> 198:5 <b>work</b> 8:6 9:17 15:14 19:14 47:7 48:4,12 143:6,15 149:11,15 165:21 190:7,15 194:1 202:22 219:16 226:6 253:20 272:12 298:15 362:18,20 384:22 385:11 404:12 417:1 <b>worked</b> 207:20 234:3,7 340:10 393:5 <b>working</b> 9:19 82:21 85:4 103:1,3 108:10,11 173:6 225:4 241:21 305:17 307:20,22 359:2 379:3 <b>works</b> 23:20 26:15 27:4 166:1 221:15 <b>world</b> 26:3 250:4 251:6 255:8 277:7 278:3 <b>worried</b> 132:13 <b>worry</b> 68:5 379:10	<b>worse</b> 308:1 <b>worsening</b> 262:10 <b>worth</b> 127:2 349:15 367:4 385:11 <b>worthwhile</b> 250:14 414:22 <b>wouldn't</b> 111:4 135:16 158:8 214:7 221:10 236:8 244:4 253:7 280:9 360:3 367:21 405:2 408:8 <b>wrestle</b> 186:18 <b>wrinkle</b> 173:21 <b>write</b> 144:3 153:3,4 403:7 406:20 413:11 <b>writes</b> 153:1 <b>writing</b> 48:11 49:1 98:22 105:11 <b>written</b> 109:4 163:19 166:11 174:15 195:16,22 197:7,17 225:16 230:15 231:6 <b>wrong</b> 107:19 108:21 131:21 253:5,10 342:13 342:17 <b>wrote</b> 225:1 226:16	239:12 249:2 302:11 348:1 376:12 377:8 400:16,19,21 401:6 <b>yearly</b> 249:2 <b>years</b> 15:1 20:13 24:9 27:21 40:14 43:3,8 50:18 51:9 52:15 54:11 56:7 79:17 87:19 133:5 133:7 134:12 149:14 156:11,12 189:5 200:6 212:9 215:2,6,9 219:22 223:21 229:7,20 230:17,19 237:19 238:21 242:8 273:7 283:12 284:21 286:8 313:18,19 337:1 397:8 <b>year-old</b> 63:20 395:19 <b>yellow</b> 27:3 <b>yeses</b> 112:12 193:4 237:2 284:7 304:6 306:9 <b>yesterday</b> 18:19 102:8 217:13 225:5 <b>yes/no</b> 29:19 73:21	<b>0065</b> 4:15 256:6,8 <b>0066</b> 4:14 192:4,6 <b>0067</b> 4:10 132:15 132:20 133:4 <b>0068</b> 4:10 113:10 113:13,15 <b>0070</b> 4:14 211:14 211:17 <b>0071</b> 4:15 237:4,8 <b>0073</b> 4:9 55:18,22 56:2 <b>0074</b> 4:12 162:3,5,7 <b>0075</b> 4:11 150:18 150:22 151:2 <b>0076</b> 4:16 123:1 281:21 282:5,12 <b>0132</b> 4:18 365:3,5 <b>0163</b> 4:19 385:22 <b>0164</b> 4:20 393:19 393:22 394:5 <b>0286</b> 4:19 370:15 370:17 <b>0288</b> 4:21 393:21 <b>0289</b> 4:18 316:14	126:14 127:11 151:10 155:18,19 157:7,17,20 158:6 158:11,22 159:11 162:12,13,14 163:20 167:14,17 171:10 172:3,7,12 172:16,17,20 173:8,14 174:7 179:21 184:20 270:14 275:3 284:12 380:6 410:15 <b>101</b> 173:22 174:5 <b>105</b> 366:17 <b>108</b> 308:4 <b>11</b> 20:13 111:21 177:5 178:1 246:21 255:12 361:5 382:14 <b>11:15</b> 113:2 <b>11:17</b> 113:5 <b>113</b> 4:10 <b>12</b> 108:13 112:12 133:8 134:4,13 162:11 192:11 200:15 204:4 205:4 212:11,18 220:2 230:17,18 326:8 348:18 360:15 <b>12-month</b> 117:7 <b>12:45</b> 191:6 <b>120</b> 100:12 283:8 397:13 <b>123</b> 288:4 <b>13</b> 210:18 256:5 280:22 292:15 297:13,16 302:20 <b>130</b> 53:20 61:1 62:8 65:3,5 75:3 85:17 285:9,11,21 288:4 288:9,16 289:3,11 289:11,20 290:14 291:3 299:2,10 300:2 303:1,14 305:13
	<hr/> <b>X</b> <hr/> <b>X</b> 72:14,14 188:18 295:14 <hr/> <b>Y</b> <hr/> <b>Y</b> 188:18 <b>year</b> 41:16,19 42:2 42:19 43:2,18 52:18 53:5,15 56:14 61:6,11 88:11 115:22 151:5,6,8,8,9 166:16 167:15 225:8 226:7 229:6 237:19,21,22,22 239:1,6,7,8,10,11	<hr/> <b>Z</b> <hr/> <b>Z</b> 188:18 <b>zero</b> 140:1 171:17 222:5 328:7 342:2 377:12 <hr/> <b>\$</b> <hr/> <b>\$10</b> 254:20 <b>\$200</b> 47:2 <b>\$4</b> 203:5 249:14 250:11 251:7 <hr/> <b>0</b> <hr/> <b>0</b> 34:19 238:10 393:17 404:11	<hr/> <b>1</b> <hr/> <b>1</b> 21:8,9 22:7 32:12 35:3 46:13 57:11 57:11 60:7 64:8 65:6 71:7 93:2 111:22 150:6 151:5,5 178:1 204:4 247:17 255:13 292:15 306:9 342:10 368:18 369:14,22 383:7 384:15 401:15 404:1 <b>1B</b> 115:19 <b>1B.2</b> 318:22 <b>1st</b> 237:21 239:6,10 <b>1.0</b> 333:8 <b>1:06</b> 192:2 <b>10</b> 232:16 357:12 <b>10th</b> 74:17 75:4 <b>10:59</b> 113:4 <b>100</b> 75:10 120:14	

<b>132</b> 4:10	365:1	<b>20</b> 191:4 260:15	<b>3</b>	<b>47</b> 273:22
<b>133</b> 288:5	<b>178</b> 4:13	284:7 326:9	<b>3</b> 74:10 133:6,6	<b>48</b> 198:14 200:4
<b>1331</b> 1:10	<b>18</b> 56:7 117:10	335:20 348:6	301:17 375:7	<b>5</b>
<b>135</b> 238:16 249:3	133:5,6 134:12	354:19 375:15	382:15	<b>5</b> 4:2 108:13 138:8
288:5	151:3 156:10,12	403:22 404:11	<b>3A</b> 103:20	147:7 255:13
<b>14</b> 161:22 300:9	156:16 162:9	<b>2003</b> 46:10	<b>3B</b> 77:10	292:15 304:6
319:7 383:7	164:4 192:9 193:4	<b>2004</b> 50:19	<b>3rd</b> 237:22	<b>5:30</b> 94:13 385:10
<b>14,000</b> 257:11	198:11 212:9	<b>2005</b> 46:10,11,17	<b>3:12</b> 307:16	<b>5:32</b> 418:11
<b>140</b> 53:12,19 54:4	219:22 238:21	115:22 116:1	<b>3:25</b> 307:14	<b>50</b> 86:20 87:1 396:6
60:22 62:7,12	245:12,15 282:13	<b>2006</b> 116:1 302:10	<b>3:32</b> 307:17	<b>540</b> 318:2
63:16 64:1,7,12	301:17 302:16,16	<b>2007</b> 51:5 116:1	<b>30</b> 42:16 80:22	<b>55</b> 302:15
64:19 65:4,5,6,12	368:18 369:22	<b>2008</b> 116:2 233:2	252:9,10 387:14	<b>56</b> 4:9
65:12 71:14,17	375:7 397:7	<b>2009</b> 43:14 53:2	393:19 394:4,11	<b>6</b>
74:20 75:1,14	<b>180</b> 201:17 237:11	115:22 116:3	396:9 397:5 403:4	<b>6</b> 4:4 177:4
85:17,18 88:13	238:13,16 239:2	306:19 342:9	404:15 405:7,18	<b>6:00</b> 385:14
89:21 94:3,4 95:2	241:4,10 242:1,4	<b>2010</b> 43:17 52:22	407:1 410:10	<b>60</b> 387:7,15 388:3
95:8,12 100:5,12	249:4	53:2 293:6 342:10	416:4	<b>600</b> 20:15
101:15,21 179:20	<b>19</b> 4:5 132:4 148:14	<b>2011</b> 1:6 335:16	<b>30th</b> 239:7,12	<b>62</b> 75:5
285:7,20 287:6,6	306:9 342:17	<b>2012</b> 287:18 290:7	<b>31st</b> 156:13 238:22	<b>63.67</b> 233:4,13
288:12,17,21	368:6 369:14	<b>207</b> 259:22	<b>316</b> 4:18	<b>65</b> 85:19,20
289:12,21 291:11	384:15 391:10	<b>21</b> 78:10 103:1	<b>32</b> 354:14	<b>67</b> 139:9
291:14 299:3,10	401:14 402:6	108:11 238:10	<b>325</b> 380:19	<b>68</b> 74:18 139:7
299:17 300:1	<b>19.5</b> 375:15	377:7 393:17	<b>33</b> 53:3	<b>69</b> 157:3
302:12 303:15	<b>192</b> 4:14	<b>211</b> 4:14	<b>35</b> 237:18 245:10	<b>7</b>
304:12,13,16,22	<b>2</b>	<b>220</b> 100:12 283:8	<b>36</b> 53:4	<b>7</b> 285:9,22 300:9
305:2	<b>2</b> 21:9 35:3 60:16	<b>23.4</b> 342:13	<b>365</b> 4:18	302:20 305:11
<b>145</b> 63:19 89:16	64:7 65:7 71:8	<b>237</b> 4:15	<b>370</b> 4:19	357:12 360:15
<b>148</b> 64:11 89:16	93:2,21 94:10	<b>24</b> 365:7 370:6	<b>386</b> 4:19	382:14
<b>1486</b> 4:9 92:4,6,7	102:20 108:13,14	372:13 380:12	<b>394</b> 4:20	<b>7:30</b> 416:14
<b>1489</b> 92:5	123:9,11,13,17,19	381:2	<b>4</b>	<b>7:45</b> 416:21
<b>15</b> 1:6 17:4,5 34:5	148:14 227:2	<b>25</b> 15:1 22:10	<b>4</b> 60:6,7 111:10	<b>70</b> 57:2 174:7
113:1 132:7	232:16 236:16	349:17 376:12	124:13 126:3	<b>73.5</b> 302:13
307:13 326:8	246:21 247:17	400:19,21 401:6	151:2 162:8	<b>75</b> 74:19 75:14 87:3
<b>150</b> 89:16	292:16 342:8,9	401:10	176:10 177:5	151:4 156:10,16
<b>151</b> 4:11	360:15 361:5	<b>25th</b> 116:6 319:6	178:7 227:2 237:2	201:18 237:11
<b>155</b> 63:19	365:2 368:6,18	<b>256</b> 4:15	255:12 350:7,7	238:18 282:13
<b>16</b> 138:8 147:7	386:6 391:10	<b>26th</b> 116:5	357:13 383:7	289:16
304:6 384:8	402:6	<b>28</b> 75:5	384:8	<b>75th</b> 126:15 319:8
<b>160</b> 64:6,8 71:6	<b>2A</b> 101:12,12	<b>282</b> 4:16	<b>40</b> 4:8 192:13	<b>8</b>
85:19 89:10 90:3	412:14	<b>287</b> 405:21 406:10	193:12 199:14,22	<b>8</b> 112:12 176:9
<b>162</b> 4:12	<b>2A.1</b> 65:4 165:6	411:8 416:1	200:6 212:7,13	177:22 204:4
<b>163</b> 385:5,20	<b>2A.3</b> 65:7 163:16	<b>288</b> 385:5 404:14	213:2,7 220:3	210:18 236:15
<b>164</b> 385:5 405:20	<b>2A.4</b> 156:15 397:7	404:16 406:10	<b>41,000</b> 329:6	246:20 256:5
411:6,8,9,12	<b>2B</b> 94:12	411:6,9,9	<b>414</b> 4:21	280:22 287:3,10
416:2	<b>2,300</b> 75:7	<b>289</b> 316:10	<b>418</b> 4:22	
<b>17</b> 178:7 237:2	<b>2:40</b> 282:3	<b>290</b> 406:10	<b>45</b> 132:4 162:1	
247:17 350:7,7				

302:5 326:8 361:5  
**80** 53:21 61:1 62:8  
 65:3,5,5,12 75:2,3  
 75:11 85:17,18  
 116:5 230:3 285:9  
 285:11,21 288:16  
 289:3,11 291:3  
 299:2,10 300:2  
 303:1,14 305:13  
 379:6,8,16 380:5  
 380:8  
**85** 63:20  
**86.95** 116:1  
**88** 116:2,6  
**89** 116:2 257:10  
 274:6

---

**9**

---

**9** 34:19 111:22  
 176:9 205:4 227:2  
 232:16 236:15  
**9:00** 1:11  
**9:02** 5:2  
**90** 53:12,19 54:4  
 61:1 62:8,12 65:4  
 65:6,12 74:20  
 75:11,14 85:18,20  
 88:13 94:3,4 95:8  
 95:12 101:15  
 116:7,13,16  
 173:14 179:21  
 230:3 280:5 285:7  
 285:20 287:6,7  
 288:12,18,21  
 289:13 291:14  
 299:3,11,17 300:1  
 300:21 302:12  
 303:15 304:13,17  
 304:22 305:2  
 346:5 366:17  
 385:20 386:3,20  
 387:7,14 388:2,10  
**90th** 74:17 75:5  
 126:13  
**90,000** 300:4  
**91** 74:18 116:1  
**92** 4:9 101:22

127:11  
**92.06** 116:3  
**94** 116:13  
**95** 115:5  
**96,000** 293:6  
**98** 250:8  
**98.5** 366:20  
**99** 171:13 174:2,5



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This is to certify that the foregoing transcript

In the matter of: Cardiovascular Endorsement  
Maintenance Steering Committee

Before: National Quality Forum

Date: 02-15-11

Place: Washington, DC

was duly recorded and accurately transcribed under  
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Court Reporter

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