

NATIONAL QUALITY FORUM  
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CARDIOVASCULAR STEERING COMMITTEE

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THURSDAY  
APRIL 7, 2011  
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The Steering Committee met at the Venable Conference Center, the Capital Room, 575 7th Street, N.W., Washington, D.C., at 8:35 a.m., Raymond Gibbons, Chair, presiding.

PRESENT:

RAYMOND GIBBONS, Chair, MD Mayo Clinic  
MARY GEORGE, Vice Chair, MD, MSPH Centers for  
Disease Control and Prevention  
CAROL ALLRED, RN, National Coalition for Women  
with Heart Disease  
ROCHELLE AYALA, MD, FACP, Memorial Healthcare  
System  
SUNG HEE LESLIE CHO, MD, Cleveland Clinic  
  
DIANNE JEWELL, PT, DPT, PhD, CCS, American  
Physical Therapy Association\*  
DANA KING, MD, MS, Medical University of  
South Carolina  
BRUCE KOPLAN, MD, MPH, Brigham and Woman's  
Hospital  
THOMAS KOTTKE, MD, MSPH, HealthPartners  
  
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, UAW Retiree Medical

Benefits Trust

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, MPH, Commonwealth of  
Massachusetts  
CHRISTINE STEARNS, JD, MS, New Jersey Business  
and Industry Association  
KATHLEEN SZUMANSKI, MSN, RN, NE-BC, Emergency  
Nurses Association  
SUMA THOMAS, MD, FACC, Lahey Clinic Medical  
Center  
NQF STAFF:  
HEIDI BOSSLEY, MSN, MBA  
HELEN BURSTIN, MD, MPH  
ASHLEY MORSELL, MPH  
KATHRYN STREETER, MS  
REVA WINKLER, MD, MPH  
ALSO PRESENT:  
SANA AL-KHATIB, MD, MHS, Duke Clinical  
Research Institute  
SUSANNAH BERNHEIM, MD, Yale/YNHH Center for  
Outcomes Research and Evaluation (CORE)\*  
LAURA BLUM, Heart Rhythm Society  
  
JOHN BOTT, MSSW, MBA, Agency for Healthcare  
Research and Quality\*  
JENSEN CHIU, MHA, American College of  
Cardiology Foundation  
DEL CONYERS, Heart Rhythm Society  
SHERYL DAVIES, MA, Stanford University - AHRQ  
QI Development Team\*  
  
JOSEPH P. DROZDA, JR., MD, American College of  
Cardiology\*  
N.A. MARK ESTES III, MD, FACC, Tufts Medical  
Center/Tufts University School of  
Medicine  
SUSAN FITZGERALD, RN, MBA, American College of  
Cardiology

JEFFREY GEPPERT, EdM, JD, Battelle Memorial  
Institute\*

JONATHAN HALPERIN, MD, Mount Sinai Medical  
Center\*

FREDERICK MASOUDI, MD, MSPH, American College  
of Cardiology Foundation\*

GREG PAWLSON, MD, MPH, National Committee for  
Quality Assurance

PATRICK ROMANO, MD, MPH, Agency for Healthcare  
Research and Quality\*

KAY SCHWEBKE, MD, Ingenix\*

MELANIE SHAHRIARY, RN, BSN American Heart  
Association

\*Present via telephone

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

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

8:35 a.m.

CHAIR GIBBONS: Welcome. I think we're signed onto the phone line, so we're ready to go. I'm Ray Gibbons from the Mayo Clinic, to remind you from the last time.

We're going to go around the room and each reintroduce ourselves, so everybody remembers who's who, and at the same time ask you if you have any additional disclosures that have occurred since the last meeting, if you could make us all aware of them.

So Bruce, we're going to start with you. Remind everybody who you are, where you're from and whether you have any additional disclosures, please. Put you on the hot seat. Have you had your coffee yet? Good. You're ready to go.

DR. WINKLER: Let me just remind everybody to please use your microphones. That way, the transcriber can get them and also people on the phone will be able to hear

1 you when you're speaking.

2 MEMBER KOPLAN: My name is Bruce  
3 Koplan. I'm a cardiac electrophysiologist  
4 from Boston, Massachusetts. I'm also a member  
5 of the Heart Rhythm Society and I do not have  
6 any additional disclosures from the last  
7 meeting.

8 MEMBER THOMAS: I'm Suma Thomas.  
9 I'm a general cardiologist at Lahey Clinic in  
10 Massachusetts, and I do not have any  
11 disclosures.

12 MEMBER STEARNS: Hi. Christine  
13 Stearns with the New Jersey Business and  
14 Industry Association. I do not have any  
15 disclosures.

16 MEMBER RASMUSSEN: Jon Rasmussen.  
17 I'm the Chief of Clinical Pharmacy,  
18 Cardiovascular Services at Kaiser Permanente  
19 in Colorado, and I have no disclosures.

20 MEMBER SZUMANSKI: Kathy  
21 Szumanski. I am a nurse. I am from the  
22 Emergency Nurses Association, and I have no

1 disclosures.

2 MEMBER AYALA: Rochelle Ayala,  
3 internal medicine physician, administrator and  
4 Chief Medical Officer for Primary Care  
5 Services at Memorial Health Care System in  
6 Florida, and the NAPH, National Association of  
7 Public Hospitals. I have no disclosures.

8 MEMBER KING: Dana King. I'm in  
9 the Department of Family Medicine at the  
10 Medical University of South Carolina. No  
11 further disclosures.

12 MEMBER ALLRED: I'm Carol Allred.  
13 I am with Women Heart, the National Coalition  
14 for Women with Heart Disease. I currently  
15 serve as chairman of the board of WomenHeart.  
16 I am from Texas and I have no other  
17 disclosures.

18 MEMBER CHO: I'm Leslie Cho. I'm  
19 from Cleveland Clinic. I'm an interventional  
20 cardiologist, and I have no disclosures.

21 MEMBER MAGID: I'm David Magid.  
22 I'm from Kaiser of Colorado and the University

1 of Colorado and a member of the American  
2 College of Emergency Physicians. I have no  
3 disclosures.

4 MEMBER SNOW: I'm Roger Snow. I'm  
5 the Deputy Medical Director for MassHealth,  
6 the Massachusetts Medicaid Agency. I have no  
7 further disclosures.

8 MEMBER RICH: I'm Devorah Rich.  
9 I've switched positions from last time. So I  
10 am now with the UAW Retiree Medical Benefits  
11 Trust. We're actually the largest purchaser.  
12 We oversee 845,000 lives, and I am directing  
13 pilots. So I have no further disclosures.

14 MEMBER RUSSO: Hi. I'm Andrea  
15 Russo at Cooper University Hospital. I'm a  
16 cardiologist and electrophysiologist, and no  
17 additional disclosures.

18 MEMBER SANZ: Hi. I'm Mark Sanz.  
19 I'm an interventional cardiologist from  
20 Montana, and I have no additional disclosures.

21 MEMBER PHILIPPIDES: Hi. I'm  
22 George Philippides. I'm a cardiologist at



1 Boston Medical Center, and I have no  
2 additional disclosures.

3 MEMBER SMITH: Good morning.  
4 Sidney Smith, University of North Carolina, no  
5 disclosures.

6 VICE CHAIR GEORGE: Mary George,  
7 Medical Officer for Heart Disease and Stroke  
8 Prevention at CDC, and I have no disclosures.

9 CHAIR GIBBONS: Ray Gibbons. I'm  
10 a Mayo Clinic staff cardiologist and no  
11 disclosures, and on the phone please?

12 MEMBER JEWELL: Hi. Dianne  
13 Jewell. I am on faculty in the Department of  
14 Physical Therapy at Virginia Commonwealth  
15 University. You might have heard of them  
16 lately, and I have no additional disclosures.

17 (Laughter.)

18 CHAIR GIBBONS: Well, we got a  
19 little basketball into the discussion.

20 MEMBER JEWELL: Absolutely.

21 CHAIR GIBBONS: All right, and oh,  
22 we're going to have the staff all reintroduce

1 themselves, please.

2 DR. WINKLER: Hi. I'm Reva  
3 Winkler. I'm a senior director of Performance  
4 Measures at NQF.

5 MS. STREETER: Hi. I'm Kathryn  
6 Streeter, project manager at NQF.

7 DR. BURSTIN: Helen Burstin, NQF.

8 MS. MORSELL: I'm Ashley Morsell.  
9 I'm the project manager of Performance  
10 Measures at NQF.

11 CHAIR GIBBONS: I think we have a  
12 small enough crowd we can ask the people in  
13 the back to also introduce themselves.

14 DR. AL-KHATIB: I am Sana Al-  
15 Khatib. I'm a cardiac electrophysiologist at  
16 Duke in Durham, North Carolina.

17 DR. SCHWEBKE: Good morning. This  
18 is Kay Schwebke. I'm here representing  
19 Ingenix.

20 DR. AL-KHATIB: -- of the Quality  
21 Improvement Subcommittee at the Heart Rhythm  
22 Society and the co-chair of the Measure

1 Development Task Force at the Heart Rhythm  
2 Society.

3 MS. BLUM: I'm Laura Blum. I'm  
4 the Vice President of Health Policy at the  
5 Heart Rhythm Society.

6 DR. ESTES: I'm Mark Estes, a  
7 cardiologist and electrophysiologist from  
8 Boston, representing the ACC, AHA and the  
9 AMA's PCPI.

10 MR. CHIU: I'm Jensen Chiu,  
11 project manager for the ACC/AHA Task Force on  
12 Performance Measures.

13 MS. SHAHRIARY: I'm Melanie  
14 Shahriary. I'm Director of Performance  
15 Measures and Data Standards at ACC.

16 MR. CONYERS: And I'm Del Conyers.  
17 I'm Director of Quality Improvement at the  
18 Heart Rhythm Society.

19 CHAIR GIBBONS: Okay, thank you  
20 very much, and thank you everyone for taking  
21 the time out of your busy schedule for this  
22 meeting. In the spirit of the basketball, I'd

1 like to disclose that since the last meeting,  
2 I spent a wonderful week on vacation in  
3 Charleston, South Carolina, and it was just a  
4 marvelous time. So Dana, I appreciated the  
5 hospitality of your region.

6 So at this point, we're going to  
7 turn it over to Reva, who's going to give us  
8 an update on the status of the project.

9 DR. WINKLER: Right. Thank you  
10 very much for being here. Briefly, I just  
11 want to kind of put us all on the same page  
12 where we are on the project. Today, we are in  
13 Phase 2, as we're looking at the second set of  
14 measures, remembering that the overall purpose  
15 of this project is to look at all the measures  
16 in NQF's portfolio pertaining to  
17 cardiovascular conditions.

18 Phase I, we looked at those  
19 conditions associated with coronary artery  
20 disease, acute myocardial infarction and PCI.  
21 Today, we will be looking at a little bit more  
22 eclectic group of conditions around heart

1 failure, atrial fibrillation, hypertension and  
2 ICD use.

3 So essentially, what we're  
4 expecting to do today is very much as we did  
5 in the first meeting, and that is to review  
6 against NQF standard criteria for  
7 recommendation for endorsement. As we did  
8 previously, we will rate each of the criteria  
9 using our little voting gizmos, and determine  
10 whether the measures have met the criteria.

11 Next slide. Recall that the role  
12 of the steering committee is to act as a proxy  
13 for our membership. That's why around the  
14 table we do have representatives from the  
15 various stakeholder groups, bringing those  
16 different perspectives to the table.

17 So you are, with all of those  
18 email communications, helping us move the  
19 project forward, to reach the goals, and the  
20 recommendations you make will be made to the  
21 NQF membership and the public at large, and  
22 ultimately will go for public comment.

1                   Next. So today's agenda for this  
2 two-day meeting is basically has several  
3 different parts. Phase 2 measure evaluations.  
4 We have fewer measures this phase than we did  
5 the first, so only 24 measures. Fourteen of  
6 them are maintenance review.

7                   Ten new measures, including two  
8 new composite measures that have been frankly  
9 developed since our last meeting by ACC in  
10 response to your comments about all or none  
11 composite measures for process measures. So  
12 they very quickly pulled that together,  
13 developed the measures and tested the  
14 measures, which is why they just got to you  
15 last week.

16                   But given that it was in direct  
17 response to the steering committee's request  
18 for more of those types of measures, we were  
19 pleased to work with them to be able to bring  
20 them to you. Hopefully, we should be through  
21 with those evaluations by tomorrow morning,  
22 and then we move into an interesting part of

1 the agenda, where we're going to be doing some  
2 follow-ups.

3 One of the issues that the  
4 committee raised last time was around data,  
5 around disparities. We have contacted all the  
6 measure developers, asked for additional data.  
7 A goodly amount of data has come your way  
8 around disparities. So we'll take a look at  
9 that.

10 We'll also talk more about an  
11 evolving policy at NQF around something we're  
12 currently calling inactive endorsement, and  
13 that speaks to the issues you all raised  
14 around retirement of otherwise good measures  
15 that seemed to be topped out, and not really  
16 providing any further opportunity for  
17 improvement.

18 We have spent some time internally  
19 discussing that to a greater extent, and  
20 creating policies and process around making  
21 those determinations. So we'll talk more  
22 about those, and how it affects the

1 recommendations you've made.

2           Then you had some conditional  
3 evaluations, you know. Well, we don't like  
4 them measure as is, but if they did this, this  
5 and this, we might like it. So we'll have to  
6 do those follow-ups.

7           Then we'll move into the  
8 evaluation of competing and related measures.  
9 We've created numerous side by sides of  
10 multiple related measures. We talked about  
11 that a great deal at the last meeting.

12           So we're going to be putting  
13 several measures head to head and asking you  
14 to choose between them, and then help us move  
15 the conversation around harmonization along,  
16 because frankly when it comes to looking at  
17 six measures for aspirin use for secondary  
18 prevention, I don't know what to harmonize to,  
19 so I need your guidance.

20           So we're going to be talking about  
21 that tomorrow. So we do have an interesting  
22 agenda tomorrow once we completed the



1 recommendations. Just briefly to wrap it up,  
2 what we are doing, the time line for this  
3 project. We will need our final  
4 recommendations from the steering committee  
5 for the Phase 1 by the end of May, Phase 2 by  
6 mid-July.

7 All of these recommendations will  
8 be going out for public comment and NQF member  
9 comment. That's the opportunity for the folks  
10 out there in audience to provide feedback to  
11 you. The steering committee will review those  
12 comments and make any decisions around whether  
13 it alters any of your recommendations before  
14 it finally goes out for NQF member voting  
15 later this year. So that's the time line  
16 we're working on.

17 So that's essentially what's  
18 happening for the next two days. Does anybody  
19 have any questions about the meeting goals  
20 before we launch into things? Helen, did you  
21 want to add anything at this point? Okay.

22 Well, just a couple of just

1 details. As I mentioned earlier, we are  
2 recording and this meeting will be  
3 transcribed, and that transcript will be  
4 posted on NQF's website. So everybody is on  
5 the record. Also, please use your microphone  
6 so Dianne can hear you, as well as the  
7 transcriber.

8 We have provided you with flash  
9 drives at each of your seats. That contains  
10 all of the meeting materials. We've organized  
11 the measure evaluation forms by day. So if  
12 that's a little bit easier for you, feel free  
13 to use those.

14 Other than that, if there are no  
15 questions, take it away.

16 CHAIR GIBBONS: Okay. So I would  
17 point out that some of what we're going to see  
18 today and discuss tomorrow is the direct  
19 outgrowth of feedback that you as members of  
20 the committee provided during the last  
21 meeting. So two of you specifically raised  
22 the issue of disparities, and the fact that

1 several applications that we looked at the  
2 last time seemed to slough over that important  
3 point.

4 That led to the NQF going back to  
5 the measure developers, and the interesting  
6 array of data that we will look at tomorrow.  
7 Likewise, as part of the discussion of several  
8 of the measures, people pointed out that they  
9 felt there was a need for composites, and that  
10 inspired the ACC response which we'll be  
11 considering.

12 So I think the process the last  
13 time bore fruit, and the contributions that  
14 the committee collectively made in the course  
15 of the discussion had an impact. I'd remind  
16 you from our discussion the last time, there  
17 are really no stupid questions.

18 So everybody ought to be free to  
19 ask questions, because if you sitting here  
20 listening to the presentation have a question,  
21 think about the poor practicing doctor in the  
22 community who finally sees this measure

1 publicly announced. He or she is going to  
2 have a lot more questions.

3 So my job as chair is to try to  
4 keep us reasonably on schedule. But I will do  
5 my best not to stifle important discussion  
6 about issues that come along. I think my  
7 sense of some of these measures today is that  
8 it's going to be similar to the last time.

9 There are going to be some  
10 measures that will be very straightforward in  
11 terms of the discussion and the voting, and  
12 others that are going to be far less so, and  
13 we will therefore have to flex with respect to  
14 the schedule.

15 Are there any questions before we  
16 get going?

17 MEMBER JEWELL: Ray, it's Dianne.  
18 How do you want me to register my votes as we  
19 move along? Are you going to call on me?  
20 Should I just randomly speak up when the vote  
21 is called? What works best for all of you?

22 CHAIR GIBBONS: This is above my

1 pay grade, so Reva's going to answer this  
2 question.

3 DR. WINKLER: Dianne, as they're  
4 registering their votes, I'll ask you.

5 MEMBER JEWELL: Thank you.

6 CHAIR GIBBONS: I hope that  
7 doesn't embarrass you too much.

8 MEMBER JEWELL: Not at all.

9 CHAIR GIBBONS: Okay. We're going  
10 to go ahead and get started, and the first  
11 group of measures are on atrial fibrillation.  
12 So we're going to have a brief presentation  
13 by the developers, and they don't know the  
14 ground rules from the last time. So this is  
15 three to five minutes, and at five minutes, a  
16 giant hook comes out of the ceiling and lifts  
17 you up by the neck. Who is going to present?  
18 Mark, are you the presenter?

19 DR. ESTES: Just for the purpose  
20 of clarification, we do have two measures  
21 we're proposing, the 1524 Assessment of  
22 Thromboembolic Risk, and 1528, Chronic

1 Anticoagulation Therapy. My intent was to  
2 give three to five minutes for two of them  
3 combined, if that's okay.

4 I'd also like to just check and  
5 see if the co-chair of the Performance  
6 Measures that developed this task force, Jon  
7 Halperin, has joined us on the phone.

8 (No response.)

9 DR. ESTES: Okay. Jon is not  
10 here. He may join in later. I'll also  
11 preface this by saying that I will be able to  
12 present these and answer questions, but then  
13 I will have to leave a little bit later this  
14 morning. But staff and Dr. Al-Khatib is very  
15 knowledgeable about these. So any questions  
16 that come up today or tomorrow morning, Dr.  
17 Al-Khatib will be able to address as well.

18 So in the way of background, I  
19 thought I'd spend a couple of minutes just  
20 talking about the rationale, looking at the  
21 standard criteria, talking about the disparity  
22 issue, and then going on to the harmonization,

1 and my comments will be brief in the range of  
2 just three to five minutes.

3 As this group knows, atrial  
4 fibrillation is very common. It's the leading  
5 cause of morbidity and mortality from  
6 arrhythmias, and it is currently increasing.  
7 It accounts for an increase of about 66  
8 percent in hospitalizations, a four to five-  
9 fold increased risk of stroke, and a two-fold  
10 increase of risk of dementia. Approximately  
11 half of the people --

12 OPERATOR: Pardon the  
13 interruption. This is the operator. We're  
14 not hearing anything over the telephone.

15 DR. HALPERIN: Correct. I'm not  
16 hearing anything.

17 CHAIR GIBBONS: All right. Hold  
18 on on the telephone. We thank you for  
19 interrupting. We'll figure out what's going  
20 on. Do you hear me?

21 OPERATOR: Yes, we can hear you.

22 CHAIR GIBBONS: Okay. So thank

1 you, Rochelle.

2 DR. ESTES: Well, I'll start from  
3 the beginning again, to be brief. So in the  
4 three to five minutes allocated, I'd like to  
5 speak about Measures 1524, which is Assessment  
6 of Thromboembolic Risk Factors used in the  
7 CHADS2 score, and 1525, which is Chronic  
8 Anticoagulation Therapy for Non-Valvular Afib.

9 The background for this, as this  
10 group knows, is that afib is common. The  
11 frequency of hospitalization from afib is  
12 increasing, up 66 percent in the last decade.  
13 There's a four to five-fold increased risk of  
14 stroke, and two-fold increase risk of  
15 dementia, with approximately 60,000 strokes  
16 each year that are preventable with  
17 appropriate risk stratification and  
18 anticoagulation with warfarin.

19 The process for development of  
20 this measure was one which was importantly  
21 evidence-based throughout the 1990's and early  
22 2000's. There were a series of prospective



1 randomized trials that served to drive the  
2 guidelines. The Guideline Committee, as you  
3 know in 2006, reviewed systematically all  
4 available evidence.

5 It came up with 60  
6 recommendations, and from that the Performance  
7 Measures Task Force, which I served on, again  
8 co-chairing with Jon Halperin, used a very  
9 structured and rigorous methodology to take  
10 these two measures, based on Class 1  
11 recommendations and level of evidence A, and  
12 developed them into performance measures.

13 There was a formal structure.  
14 There was a formal methodology using  
15 consultants, some of whom are in this room,  
16 and then a period of public comment before  
17 they were published in 2008. Subsequently,  
18 the ACCF/AHA and AMA have advanced these for  
19 the PCPI, and would like to --

20 Now I present them today, but look  
21 at them relative to the importance, the  
22 scientific acceptability, usability,

1 feasibility and reliability. We have  
2 submitted data on all of this, so I'm not  
3 going to really go over that.

4           Importantly, we are extremely  
5 mindful of the disparity issue, and we think  
6 in fact there's a real opportunity here to get  
7 more data, because the data, frankly, is  
8 really not very robust at all.

9           The PINNACLE registry will serve  
10 as the source of the data. At the time of our  
11 submission, we had roughly 12,000 patients  
12 with complete individual records. All of the  
13 data elements that we need for our performance  
14 measure are currently in the PINNACLE  
15 registry, and even since our submission, the  
16 number of patients that are eligible has grown  
17 dramatically with this effort, which is just  
18 to years into it, with now over 1.5 million  
19 individual outpatient records, and over  
20 100,000 patients with atrial fibrillation,  
21 importantly, very specifically identifiable by  
22 gender, by race, by ethnicity.

1                   We've been mindful of the  
2 harmonization process. We've looked at it  
3 relative to the other current or proposed  
4 measures that deal with afib, and very briefly  
5 in conclusion, the measure which is the 0241,  
6 is one that deals specifically with patients  
7 who have had a stroke.

8                   Measure 0624 is one which is  
9 currently endorsed. It includes patients with  
10 mitral stenosis or valve replacement. We  
11 specifically excluded valvular heart disease  
12 because the database that validates those as  
13 risk factors has not been prospectively  
14 validated.

15                   In addition, the time window for  
16 risk stratification is open-ended any time in  
17 the past. Ours is specifically within one  
18 year. We think it's an advantage because the  
19 CHADS2 score has been prospectively validated  
20 and the time frame is one year, and the  
21 factors that constitutes risk are dynamic.

22                   In addition, there's not that

1 complete parity about what the initiating  
2 event is, the drug day supply that extends 30  
3 days from the measurement date. It looks like  
4 initiation of warfarin moving forward, but  
5 there's not clarity about that.

6 And finally, they're using Level 2  
7 claims data and one administrative source as  
8 well. Ours importantly has the strength of  
9 the technical strength of being a single  
10 robust database that's been cross-referenced.

11 Other potential ones just in  
12 closing include the 0084, which is the heart  
13 failure afib, it's being retired; the 066,  
14 which is a thyroid function test, a very  
15 narrow, not evidence-based one. The 1505,  
16 which is the amiodarone LFTs. Again,  
17 consensus opinion, but no data that drives  
18 that.

19 So with that, I'll conclude, and  
20 if Dr. Halperin has joined us, or if Dr. Al-  
21 Khatib wants to make any additional comments,  
22 I'd like to just defer to them for one brief

1 moment.

2 DR. HALPERIN: Thank you very  
3 much, but I don't have anything to add. I am  
4 here and available to answer questions.

5 CHAIR GIBBONS: Thank you, Dr.  
6 Halperin. Any other comments from the back?

7 (No response.)

8 CHAIR GIBBONS: No, okay. So  
9 let's go ahead, and thank you, Mark. Let's go  
10 ahead with the first measure. So it is  
11 Measure 1524, an Assessment of Thromboembolic  
12 Risk. If you're using today's drive, you're  
13 okay. If you're using, as I am, the  
14 originally distributed data, this is in Group  
15 2, if you're looking for it. The discussant  
16 for this one is Devorah, so Devorah, lead us  
17 off.

18 MEMBER RICH: So okay. So in  
19 terms of looking at the importance of the  
20 measure, this is clearly -- sorry. Okay. Is  
21 that better? Okay.

22 CHAIR GIBBONS: Yes.

1                   MEMBER RICH: This is clearly a  
2                   very important measure, as was just stated.  
3                   It affects 2.2 million people, and we've seen  
4                   an increase, 66 percent in hospital admissions  
5                   for AF in the last 20 years. So there's no  
6                   doubt that this is a very, very important  
7                   measure. So I guess that's the first  
8                   question, right? Refresh me. Are we voting  
9                   on --

10                   CHAIR GIBBONS: That's fine.  
11                   We'll vote on each segment, and this first one  
12                   is the most important. Are there other  
13                   questions or comments or discussion about  
14                   importance?

15                   MEMBER SMITH: Just a  
16                   clarification. I agree that this is very  
17                   important. Do we at some point specify the  
18                   risk factors that we want to be documented?

19                   CHAIR GIBBONS: Yes. That's  
20                   coming up in Section 2 of the --

21                   MEMBER RICH: Right. So there,  
22                   there's a comparison of like what are some of

1 the other options, you know, because this is  
2 looking at the CHADS2, but it does discuss  
3 later what are other methodologies that might  
4 be more robust.

5 DR. WINKLER: Just a question to  
6 the group in terms of 1(c) criteria about the  
7 evidence for this measure. Everyone feels  
8 this is solidly evidence-based?

9 MEMBER RICH: This is clearly  
10 highly evidence-based, without any question.  
11 There's very robust data showing that certain  
12 risk factors and without question it's robust.

13 MEMBER SMITH: I have to apologize  
14 for my confusion. What I think I understand  
15 is that in order to meet this measure, one  
16 needs to document risk factors. But whether  
17 it's going to be CHADS2 or something else, is  
18 not clear to me. It can be any set of risk  
19 factors, as long as the physician attending  
20 the patient documents it.

21 MEMBER RICH: Well, my  
22 understanding, you guys clarify, but my

1 understanding is no, that this is actually  
2 proposing the CHADS2 as the methodology.

3 MEMBER SMITH: Why don't we state  
4 this, with an asterisk or have it clear?

5 CHAIR GIBBONS: Well, I think it's  
6 listed under 2(a). I think several of our  
7 developers have struggled with how do you fill  
8 in the blanks of the form, and I think the  
9 actual numerator is outlined in Section 2(a)  
10 of this application. Is that correct,  
11 Devorah?

12 MEMBER RICH: Yes, but I have to  
13 say that I read through this a few times to  
14 get clarity, and I'm not a clinical person.  
15 I actually think that I got clarity on this  
16 and I understand it. But you all bear with  
17 me, because I don't pronounce things  
18 correctly.

19 But I also agree with you, that it  
20 would have been helpful to know with the title  
21 what we were actually -- what was included.  
22 I felt the title was vague, and it could have



1       been more specific, so that you would know  
2       that it was CHADS2 with warfarin, whatever.

3                   CHAIR GIBBONS:   Okay.  So I think  
4       I have a sense from this discussion to try to  
5       move it ahead, that one of our potential  
6       feedbacks here is going to be to change the  
7       title for clarity, as this measure potentially  
8       moves forward through the system, although the  
9       concept, I think, is good.  So Sid, does that  
10      clarify that?

11                   MEMBER SMITH:   Yes.

12                   CHAIR GIBBONS:   Okay.  So let's,  
13      is there any more discussion about importance  
14      before we move ahead to our first vote?  So  
15      you'll have to find your magic gadget at this  
16      point, and just remind you, does the measure  
17      meet NQF criteria for importance, yes or no?

18                   DR. WINKLER:   Dianne, what's your  
19      vote?

20                   MEMBER JEWELL:   My vote is yes.

21                   DR. WINKLER:   Thank you.

22                   CHAIR GIBBONS:   So in fairness to

1 those on the call, I'm going to try to  
2 remember to summarize the vote. So the vote's  
3 18 to 0, yes for importance. All right.  
4 Devorah, Scientific Acceptability.

5 MEMBER RICH: So okay. Sorry, I  
6 took a lot of notes on this, but in terms of  
7 the scientific acceptability, I think it's  
8 been rigorously tested. This is clearly meets  
9 all standards for reliability and validity.  
10 The only issue that I wanted to bring up, that  
11 I'm not sure, and I'm sorry, where it's  
12 brought in, I spent a lot of time on this.

13 But they propose that there are  
14 alternative methodologies that might be more  
15 robust. So that the concern was that there's  
16 a large group of people that might not be  
17 necessarily captured.

18 There are people that are -- let  
19 me just look at my notes. But people who fall  
20 into the intermediary category, not  
21 necessarily clearly defining who's going to  
22 have the stroke, or who's at risk.

1                   That could be clearer. They talk  
2 about the CA-2 -- guys, you want to help me  
3 out with that?

4                   MEMBER SNOW: CHA2, S2.

5                   MEMBER RICH: Right, which --

6                   MEMBER SNOW: To give AH two  
7 points instead of one point. That was --

8                   MEMBER RICH: And then to also  
9 give more credit on the vascular disease. So  
10 that's just something to think about. That's  
11 a more robust measure. I just want to say one  
12 comment that comes at the very end, because I  
13 thought it was really important, was the issue  
14 that some, that a lot of physicians, that the  
15 whole process of this requires good  
16 documentation.

17                   There are concerns that doctors  
18 are performing this but not documenting it  
19 appropriately, so that it might underestimate  
20 the actual physician quality performance, like  
21 giving a false negative, you know what I'm  
22 saying? Or I can -- or maybe Dr. Estes may be

1 able to clarify even further.

2 MEMBER RUSSO: But I think that  
3 the guidelines right now clearly use the CHAD2  
4 score, which gives a point system based on,  
5 you know, the heart failure.

6 It's clearly specified, not listed  
7 in the title, what the values that are being  
8 looked for are heart failure, you know,  
9 history of stroke or TIA, you know, diabetes,  
10 those kind of things, and those are clearly  
11 delineated in numerator and denominator.

12 There are, that's what's in the  
13 guidelines right now, and Dr. Estes, I'm not --  
14 - with additional information, there are some  
15 other moderate, you know, there's moderate  
16 risk factors and then there's some other ones  
17 that may be included in the future.

18 But right now, I think this is --  
19 the plan is to just use this with a standard  
20 CHADS score that's in the ACC/AHA guidelines,  
21 and maybe someone else can, you know, clarify  
22 that a little bit more for us.

1                   But the second part of your  
2                   question was regarding the data using the  
3                   PINNACLE registry, is what I heard from Dr.  
4                   Estes, which is a very robust registry. Just  
5                   there are inpatient registries, this is an  
6                   outpatient registry where the data collection  
7                   points for this particular registry are all  
8                   right in there as a checkbox.

9                   MEMBER RICH: And so for some  
10                  reason, I mean my final notes here, that the  
11                  lack of documentation regarding medical or  
12                  patient reasons for not prescribing the  
13                  warfarin, or collecting the data elements, but  
14                  are either choosing not to document some parts  
15                  in the EHR, or maybe the EHRs have not been  
16                  customized for that.

17                  Hence, an unintended consequence  
18                  of this measure is that clinicians not  
19                  documenting information on the flow sheet  
20                  lowered their score in the performance  
21                  measure, and leaving some these blanks gives  
22                  a false impression of poor clinical

1 performance.

2 MEMBER RUSSO: And I think the  
3 idea was well, this will motivate people to  
4 complete it better. So I'm just really posing  
5 that as a concern. I felt like it should be  
6 brought up in the beginning, rather than just  
7 at the end.

8 CHAIR GIBBONS: Okay. Other  
9 comments about the scientific acceptability?

10 MEMBER SMITH: Just that as a  
11 physician, this documentation is difficult,  
12 that I'd be pretty hard on you've got a  
13 document, and it may be difficult, but it has  
14 to be done.

15 MEMBER CHO: Okay. I have a  
16 question about PINNACLE registry.

17 CHAIR GIBBONS: Yes, Leslie.

18 MEMBER CHO: What's the percentage  
19 of patients, I mean what's the percentage of  
20 outpatients that participate in the clinical  
21 registry?

22 CHAIR GIBBONS: So developers want

1 to comment on that difficult question?

2 DR. ESTES: I'm not sure that this  
3 is working.

4 CHAIR GIBBONS: Okay. So your  
5 Mark, you give your answer, and I'll try to  
6 relay it, or otherwise, you're going to wear  
7 yourself out here.

8 (Laughter.)

9 DR. ESTES: The PINNACLE registry  
10 right now is 1.5 million patients, roughly  
11 100,000 with atrial fibrillation. In terms of  
12 all the patients with cardiovascular disease  
13 in the United States, it's a distinct  
14 minority, but growing very rapidly.

15 CHAIR GIBBONS: Yes, David.

16 MEMBER MAGID: Yes. I mean it's  
17 probably about one percent. So I think we  
18 have to be honest about it. It's, you know,  
19 the coverage of a lot of the NCDR registries,  
20 obviously ICD is 100 percent, you know. Cath  
21 PCI is quite high. It's probably the majority  
22 of the cath labs in the country.

1                   You know, Action's a little bit  
2 smaller than that PINNACLE. You know, let's  
3 be honest here. If you're one percent and  
4 growing rapidly that's not anything like the  
5 other registries. So I think, I was going to  
6 bring up this question under a different  
7 topic. I wasn't sure if it was really  
8 scientific acceptability.

9                   But since we have it out here, I  
10 guess the question is, is you know, what does  
11 that mean when we say it requires the PINNACLE  
12 registry? I mean if this is a data measure  
13 that we can get through a lot of other  
14 sources, that's one thing.

15                   If it's a data measure that  
16 requires PINNACLE registry and it's one  
17 percent or less of the outpatients in the  
18 country that, I think, is a problem.

19                   CHAIR GIBBONS: Okay. We'll ask  
20 Mark to address that, as the developer.

21                   DR. ESTES: Well, it's a very  
22 important question, and the 1.5 million



1 patients are real numbers. The 100,000  
2 patients with atria fibrillation are real  
3 numbers. I don't know what the denominator is  
4 of all outpatients in the country. So I can't  
5 tell you --

6 MEMBER MAGID: 400 million.

7 DR. ESTES: So I can't tell you a  
8 percentage. What I can tell you is this, is  
9 that there's a track record of the ACC with  
10 the NCDR-ICD database, in which there is over  
11 400,000 patients and about 80 percent of  
12 patients who get ICDs are in it.

13 Really looking very carefully at  
14 that data now, with about 20 publications  
15 looking at things such as racial and gender  
16 disparities as well, and part of the PINNACLE  
17 registry's strength, I think, will be that  
18 much like you get with the guidelines, over 65  
19 publications in an inpatient, largely  
20 inpatient registry with heart therapy and  
21 outpatient, that there's a real opportunity  
22 here to use these numbers, even though it may

1 not be a large percentage of all the  
2 outpatients, but to investigate things such as  
3 documentation, which is not ideal.

4 In fact, embedded in the PINNACLE  
5 registry is the documentation that we need.  
6 So if physicians in the course of their  
7 patient encounters just document, it will be  
8 linked, given the CHADS2 score.

9 The CHADS2 score we looked at very  
10 carefully, relatively to CHADS VASc and the  
11 data supporting CHADS2 is much better than  
12 CHADS VASc, prospective validation. The  
13 documentation issue is extremely important.

14 We are hoping that as the PINNACLE  
15 registry gets going, what was initially a  
16 paper documentation being put into a registry  
17 will now become and has the capacity to become  
18 documentation real time when the physicians,  
19 nurse practitioners, PAs are seeing the  
20 patient. You'll actually get the data real  
21 time to alleviate the burden of subsequent  
22 documentation.

1 CHAIR GIBBONS: So I don't want to  
2 cut off the discussion. I think it's helpful,  
3 but I want to point out one aspect of this,  
4 which is this is a little bit academic,  
5 because once the NQF endorses something as a  
6 measure, anybody can then take it on for  
7 whatever registry they have, to measure  
8 performance and hopefully improve performance.

9 The specs that are listed here are  
10 in terms of ICD codes and CPT codes, which  
11 presumably there would be other registries  
12 that would have that data available. So  
13 although it's a good point about the market  
14 penetration, PINNACLE and the like at this  
15 point, we have to remember that the process  
16 here is about creating nationally endorsed  
17 measures. Dana? Oh sorry. Dana was just  
18 being helpful and he ended up being put on the  
19 spot. Any other questions about -- Mark?

20 MEMBER SANZ: So just to be clear,  
21 the measure is not CHADS2 reported to  
22 PINNACLE; the measure is CHADS2?

1                   CHAIR GIBBONS: That is correct.  
2                   Rochelle.

3                   MEMBER AYALA: Yes. I just was  
4                   wondering about the term "documentation,"  
5                   because we're talking about ICD-9 codes and  
6                   things like that. I'm wondering how, what  
7                   kind of format, either in the paper chart or  
8                   the electronic medical record, would this  
9                   documentation have to take on, so that it's  
10                  not just, you know, collecting data based on  
11                  multiple different visits that identify these  
12                  risk factors and the physician not  
13                  synthesizing them, as actual risk factors for  
14                  stroke.

15                  CHAIR GIBBONS: Devorah or anybody  
16                  else want to, who looked at this for the  
17                  group?

18                  MEMBER RUSSO: I think you need to  
19                  be able to say, whether you have a paper  
20                  record or an electronic health record, that  
21                  you've assessed risk factors, you know,  
22                  dictate your note, even your dictated note for

1 thromboembolic prophylaxis CHADS score 2, or  
2 two risk factors, you know, patient should be  
3 on warfarin or dabigatran.

4 You have to make a statement of  
5 that, and it's probably easier and I don't  
6 know how it looks in a PINNACLE registry. But  
7 there's probably some statement or your own  
8 written note. We didn't --

9 MEMBER RICH: And I just want to  
10 comment, although this isn't part of the  
11 PINNACLE registry, there are some other things  
12 other than PINNACLE out there, including we  
13 did a little pilot or something called the  
14 cardiovascular performance improvement  
15 program, separate from PINNACLE right now,  
16 where this was tested in the pilot. So it's  
17 doable, and there are other ways to do it  
18 other than PINNACLE.

19 MEMBER AYALA: I think the details  
20 of that, for example, the statement that shows  
21 that you actually looked at them all, I don't  
22 see that. Maybe I missed it, but I don't see

1 it in this document.

2 MEMBER RICH: The documentation is  
3 really clear around the risk factors. What's  
4 not clear is why a physician would not choose  
5 to prescribe warfarin. So that's where it's  
6 not coming, and that's what needs further  
7 documentation.

8 But I want to say we are in the  
9 scientific acceptability. It is very robust.  
10 It has definitely been measured, and I would  
11 say, in reading the info, it completely meets  
12 all of the criteria. I mean I think it's very  
13 strong.

14 CHAIR GIBBONS: Sid.

15 MEMBER SMITH: My maybe naive and  
16 relatively unison impression is that what we  
17 are asking for is where you list the  
18 diagnosis, it would be non-valvular atrial  
19 fibrillation (CHADS2 score equals 3), and  
20 that's all it would take. For me as a  
21 clinician, to pick that chart up when I see  
22 the patient would be extremely helpful.

1 MEMBER RICH: Okay.

2 CHAIR GIBBONS: Okay. I want to  
3 put one issue on the table for the developers  
4 and potentially Mark to answer, because having  
5 just come from the ACC meeting and from a  
6 lunchtime forum, I was a bit astonished to see  
7 national experts on atrial fibrillation  
8 basically denigrating the CHADS2 score,  
9 because of the relatively low C index in the  
10 original publications.

11 I think that's going to be the  
12 reality of those who simply want to treat  
13 everybody. So as this measure moves forward,  
14 I think that issue is going to be questioned,  
15 to some degree in public, and Mark, do you  
16 want to comment on how the developer is going  
17 to view that kind of criticism subsequently,  
18 because physicians who are being asked to do  
19 this are going to hear that, certainly 120 of  
20 them who were in the room where I was present.

21 DR. ESTES: I might give Jon  
22 Halperin a chance to respond to that. Jon,

1 did you hear the question? Jon?

2 DR. HALPERIN: Yes, I did. Yes, I  
3 did.

4 CHAIR GIBBONS: Yes. Jon, how  
5 would you respond to that, in terms of making  
6 sure that this is a credible measure, when and  
7 if it's endorsed by the NQF?

8 DR. HALPERIN: So it certainly  
9 remains -- there is a certain amount of it,  
10 and the C statistics fall in the range of  
11 about .6 to .7, leaving a great deal of  
12 intrinsic risk as yet unaccounted for. But I  
13 think that the robustness of the CHADS2 score  
14 remains still the most valuable index that we  
15 have in this field.

16 Certainly, very robust for the  
17 risk factor of prior stroke and  
18 thromboembolism. Where some of it is softer  
19 is in the lack of clear definitions for  
20 hypertension, diabetes in terms of criteria.  
21 As those are firmed up, particularly as one  
22 looks at databases that have analyzed



1 individual components of the CHADS score, the  
2 predictive value seems much better.

3 CHAIR GIBBONS: Okay. Well, I  
4 think that's a very helpful point to register  
5 going forward. Personally, I'm very concerned  
6 that some of this is promotional on the part  
7 of the pharmaceutical industry for newer  
8 drugs.

9 Don't bother figuring it out; just  
10 give it to everybody, which seems to me to be  
11 a very worrisome kind of undercurrent that's  
12 going on right now. Certainly it was evident  
13 earlier this week.

14 So I think we're going to move  
15 ahead, unless there are other comments, to  
16 voting on scientific acceptability. So I  
17 remind you, does it meet criteria and those  
18 are all the subgroups listed, completely,  
19 partially, minimally or not at all. Please  
20 vote.

21 DR. WINKLER: Dianne?

22 MEMBER JEWELL: Completely.

1 DR. WINKLER: Thank you.

2 CHAIR GIBBONS: Okay. So the  
3 recorded vote is completely, 12; partially, 6.  
4 Okay. Moving on now to Usability. Devorah.

5 MEMBER RICH: So I think that in  
6 terms of Usability, this does meet the  
7 criteria, and again just the issue that I  
8 brought up earlier regarding reasons why  
9 there's not the documentation. Part of this,  
10 my sense with this measure was that part of  
11 the idea is just to promote better  
12 documentation.

13 It's a very good and important  
14 issue, but I just really wanted to put that  
15 forward. But it does meet the guidelines for  
16 Usability, and I'll just leave it at that.  
17 We've spent a lot of time talking about this,  
18 so I don't want to go into -- unless you have  
19 questions.

20 CHAIR GIBBONS: Other comments  
21 from anybody on the committee?

22 MEMBER SNOW: Well, I'd just make

1 a brief observation that one of the problems  
2 this documentation made clear, CHADS2 is an  
3 awful lot easier to document than some other  
4 things, and if we can teach them to document  
5 something, then maybe we can move them to  
6 doing a better one down the road.

7 CHAIR GIBBONS: Point well taken,  
8 Roger. I agree with that completely. Okay.  
9 I don't see any other comments, so we're going  
10 to go ahead and vote, please, on Usability.  
11 Remind everybody, in case you haven't gotten  
12 into the mold yet, 1 completely, 2 partially,  
13 3 minimally, 4 not at all.

14 DR. WINKLER: Dianne?

15 MEMBER JEWELL: Partially.

16 DR. WINKLER: Thank you.

17 MEMBER SMITH: Ray, was there a  
18 gender issue in the C statistic? It was less  
19 predictive in women. I mean that's the one  
20 publication I'm able to dredge up quickly  
21 here.

22 CHAIR GIBBONS: I don't recall

1 that, but we'll ask Jonathan that in a minute.  
2 So just to complete this vote, we're 13  
3 completely and 7 partially. So that the total  
4 sample is changing, because we had a few more  
5 people in the room.

6 All right, and then final,  
7 Feasibility. I'm sorry, Usability, Devorah.

8 MEMBER RICH: No, Feasibility.

9 CHAIR GIBBONS: Feasibility. I  
10 had it right the first time.

11 MEMBER RICH: Feasibility, sorry.  
12 Okay, Feasibility. So in terms of  
13 Feasibility, the data are available either  
14 through a paper source or through an EHR or  
15 EMR, and in terms of exclusions, there are no  
16 exclusions. It's susceptibility to  
17 inaccuracies.

18 The feedback loop allows practices  
19 to go back and add fields, to better capture  
20 the clinical data, if that is required. I've  
21 already talked about the lack of documentation  
22 as the issue. But it is feasible.

1 CHAIR GIBBONS: Okay. As part of  
2 the discussion, somebody just asked whether  
3 there was a gender difference in the C  
4 statistic. Either Mark or Jonathan, do you  
5 know the answer to that question, because I  
6 sure don't. Mark?

7 DR. ESTES: I don't. Jon may.

8 CHAIR GIBBONS: Jon, do you know?

9 DR. HALPERIN: Not specifically.  
10 The C statistic, the margins of error around  
11 the C statistic overlap across gender. CHADS  
12 scores tend to slightly underestimate the risk  
13 of stroke in women compared to men, and the  
14 converse is also true. But the C statistics  
15 overlap.

16 CHAIR GIBBONS: Okay. Thank you  
17 very much, Jonathan. Yes, Rochelle.

18 MEMBER AYALA: This just goes back  
19 to my original question, and that is that  
20 whatever form the final measure takes, I think  
21 the actual wording of the documentation or the  
22 form that the documentation part has to take

1 has to be really clearly defined and  
2 preferably standardized, because that's really  
3 what you're testing, is the documentation that  
4 the physician has synthesized all of these  
5 different risk factors.

6 MEMBER RUSSO: This is a general  
7 question. If say there's a change in, it's  
8 not going to be CHADS score in the future and  
9 the guidelines change, so right now the CHADS2  
10 score is used in the guidelines. Is there a  
11 process in place in between the measure  
12 development periods to resubmit, if it turned  
13 out in a year or two that it's a CHADS VASc  
14 score?

15 CHAIR GIBBONS: Now that's a  
16 broader policy question, so I'm going to ask  
17 Reva to answer it.

18 DR. WINKLER: Yes. This is  
19 something we see relatively frequently, with  
20 guidelines changing and evidence new all the  
21 time. So depending on how big of an impact it  
22 is, we can always pull together an ad hoc

1 review of a measure, if the evidence changes  
2 or the guidelines change significantly, that  
3 it's not a good idea to wait until the next  
4 three year review to do so.

5 So that's always available, and we  
6 tend to be doing those rather frequently  
7 actually.

8 MEMBER KING: Ray, I have a  
9 comment.

10 CHAIR GIBBONS: Yes, Dana.

11 MEMBER KING: My impression is  
12 that this is actually completely unfeasible.  
13 The reason is because we're trying to get in  
14 the mind of a physician, and we're trying to  
15 figure out and document whether or not they  
16 thought about something.

17 Now my position would be that they  
18 almost always thought about it, and their  
19 information about whether or not the person  
20 has hypertension, heart failure and their age  
21 is on every chart. So it's almost like saying  
22 did you get a thyroid test in someone with

1 atrial fibrillation.

2           Did you check their magnesium  
3 level, and then it would be in the record that  
4 the thyroid results were there and the  
5 magnesium results were there, but then we  
6 would say "But Dr. Smith, did you think about  
7 it when you were going to prescribe  
8 anticoagulant therapy? Did you think about  
9 it?"

10           "Well, I ordered it. It's in the  
11 chart." In other words, do I have a  
12 conversation on rounds? This is not a hard  
13 index to figure. Does the person have  
14 hypertension, heart failure, diabetes and how  
15 old are they? In other words, we can do that  
16 in 18 seconds on rounds, and they said yes,  
17 they meet the criteria. I say okay, go start  
18 them on warfarin.

19           And so the only thing that happens  
20 is that we discussed risk and Dr. King said,  
21 my attending said start warfarin. In other  
22 words, that's all that happened. Now if you



1 want us to fill out a form and it's going to  
2 be a national standard that you have to fill  
3 out a form, then next to the --

4 In other words, if we start doing  
5 that, we have to think about the tsunami wave  
6 of forms that we're going to ask practitioners  
7 to fill out. I thought about it, I assessed  
8 their risk.

9 I think it is a much better  
10 measure to measure whether or not they got on  
11 warfarin, and you can do that by doing  
12 pharmacy records, CMS records, the hospital  
13 records of 100 million people, rather than  
14 taking a one percent aliquot of people that  
15 filled out a form.

16 So I think this is completely  
17 unfeasible, and you're getting into the mind  
18 of doctors, and I think it's completely  
19 inappropriate.

20 MEMBER RUSSO: I have to say Dana,  
21 I didn't disagree with anything you said last  
22 meeting, but this I strongly disagree with.

1 But I strongly -- no, I think it's really,  
2 really important, and out there in real life,  
3 you need to document in the medical record why  
4 these patients are not on Coumadin.

5 I've seen too many patients come  
6 in the hospital with a stroke, who have two or  
7 three risk factors. Now if you have only one  
8 moderate risk factor, your choice is either  
9 warfarin or aspirin. But I think that people  
10 are not thinking about this. I think they're  
11 saying oh, it's an older person. They might  
12 fall. They haven't fallen. But they don't  
13 document the reasoning in the chart.

14 So I strongly disagree. People  
15 need to document it. I document it in my  
16 notes every single visit when I see the  
17 patient, and reassess it, because they may  
18 have been a candidate for warfarin and now  
19 they're no longer, because they fell.

20 So I really think people need to  
21 think about this more and documentation, and  
22 the chart is important.

1                   MEMBER SNOW: That's a point in  
2                   clarity in the measure, because it really --  
3                   its power is really in people who are not  
4                   going on warfarin, not people who are going on  
5                   warfarin.

6                   MEMBER THOMAS: I have the next  
7                   measure, and I think that one of Dana's points  
8                   is, you know, the question of just documenting  
9                   the risk, whether it also includes, you know,  
10                  documenting is the patient on warfarin.

11                  That's addressed in the next  
12                  measure, and the question is do you need both  
13                  of these measures? I guess you could ask  
14                  that. You know, do you need both of these  
15                  measures, and I guess that might be what  
16                  you're asking, you know.

17                  In the next measure you're  
18                  addressing should this patient, is this  
19                  patient on warfarin, with the documentation of  
20                  those risk factors, because the next measure  
21                  does address documentation of the risk factors  
22                  as well. So I don't know if that's something

1 you want to talk about, because could it be  
2 somewhat addressed in one measure rather than  
3 two measures, you know?

4 CHAIR GIBBONS: Helen.

5 DR. BURSTIN: This is a good  
6 discussion and one we tend to have a lot these  
7 days, as people worry a lot about the number  
8 of measures that are out there. I think one  
9 of the things that our Evidence Task Force,  
10 who just completed its work this past year,  
11 said very clearly is when you're focusing on  
12 a process measure, pick the ones closest to  
13 the outcome.

14 There's actually a lot of concern  
15 about assessment measures that are fairly  
16 distal from the actual outcome. So I do think  
17 the point that was just raised is the right  
18 one, can this actually be included as part of  
19 the measure, where you're actually getting at  
20 therapy, or is there truly, and this is the  
21 evidence-based question for all of you, how  
22 strong is the evidence that the assessment

1 alone of the CHADS2 has a significant impact  
2 on the outcome? That's a question for you.

3 VICE CHAIR GEORGE: Yes. I would  
4 just say, in relation to your question Dana  
5 about documenting in relation to a performance  
6 measure, we've done that with many of the  
7 stroke measures, and it has been a struggle to  
8 get that documentation. But we're seeing a  
9 lot of movement on that, because they  
10 specifically require that you've thought about  
11 this in relation to this particular medication  
12 or whatever. So we're doing that. But it's  
13 a challenge.

14 CHAIR GIBBONS: Other comments  
15 before we vote?

16 MEMBER RUSSO: I do.

17 CHAIR GIBBONS: Yes.

18 MEMBER RUSSO: I know Bruce had  
19 one too. So there are, and I'm looking -- I  
20 only see two. My understanding, and I had  
21 nothing to do with the development of these  
22 measures, by the way. But I thought there

1 were originally three, but there was either  
2 prescription for warfarin -- so prescription  
3 for warfarin, and then adequate INR on a  
4 monthly.

5           So there's different things. The  
6 one point brought up is if you -- we want to  
7 know if the patients who are not getting, if  
8 you're prescribing it we still want this one,  
9 because we want to know all those other  
10 people, why they're not on it, and you have to  
11 say there's a contraindication or whatever,  
12 you know, reason they're not on it.

13           Number two, where they prescribed  
14 it, and number three, I thought, was an  
15 adequate INR in the paper that was published.  
16 Monthly INR with it. Not only you're on it,  
17 but is someone following it, and making sure  
18 you get one once a month, and is it  
19 therapeutic. So like I think the discussion  
20 whether or not you need the one in the middle  
21 might be, but I'm not sure if there's some  
22 comments from the people who have developed

1 that.

2 CHAIR GIBBONS: Okay. So now I  
3 need help from the staff. Is there a third  
4 measure in the approved portfolio?

5 DR. WINKLER: We have several  
6 measures around measuring adequate INR in the  
7 portfolio.

8 CHAIR GIBBONS: Yes, because  
9 remember, we're just looking at either new  
10 things this round or maintenance of previously  
11 approved measures. These are not all the  
12 measures. There are other measures, and we  
13 gave a handout the last time of all the  
14 measures.

15 All right. We need to move ahead.  
16 This has been a healthy discussion, but let's  
17 go ahead and vote please.

18 DR. WINKLER: Dianne, what's your  
19 vote?

20 MEMBER JEWELL: Completely.

21 DR. WINKLER: Thank you.

22 CHAIR GIBBONS: So the vote is

1 completely, 7; partially, 12; not at all, 1,  
2 and now we're going to move on to the final  
3 important question, does the measure meet all  
4 the criteria for endorsement. Please vote.

5 DR. WINKLER: Dianne?

6 MEMBER JEWELL: Yes.

7 DR. WINKLER: Thank you.

8 MEMBER JEWELL: You're welcome.

9 CHAIR GIBBONS: So the vote is 17  
10 yes and 3 no. No, there's one telephone vote.  
11 I'm including the telephone vote. So for the  
12 record, there's a little addition that has to  
13 be done here. Okay. So thank you very much.

14 We're going to move on now to the  
15 next measure, which is 1525 already mentioned,  
16 Chronic Anticoagulation Therapy, Suma.

17 MEMBER THOMAS: I'm going to try  
18 to keep it simple, since we've had a lot of  
19 discussion around the first measure, and these  
20 are obviously very closely related. So in  
21 terms of Importance to measure and report, it  
22 definitely has a high impact, as has been



1 discussed by Dr. Estes and Devorah.

2           There's a four to five times risk  
3 of stroke, increased risk of heart failure,  
4 death and dementia. In terms of opportunity  
5 for improvement, there's 45 to 55 percent of  
6 the patients do not receive risk  
7 stratification or treatment, and there are  
8 data disparities.

9           Blacks are one-third as likely to  
10 be aware that they have afib. So blacks are  
11 at higher risk of stroke, and then of those  
12 that are actually aware that they have afib,  
13 blacks are one-quarter as likely to be treated  
14 with warfarin.

15           There's also sex differences in  
16 terms of compliance between women and men. In  
17 terms of outcome data, there's, as we've  
18 discussed, the decreased risk of stroke, at 66  
19 percent. In terms of the strength of  
20 evidence, in the practice guidelines to Class  
21 1 and the level of evidence is A, and the  
22 CHADS2 scores have been readily validated, as

1 discussed before.

2 So I think it's, of course, very  
3 important to measure and report.

4 CHAIR GIBBONS: Other questions  
5 about Importance?

6 (No response.)

7 CHAIR GIBBONS: If not, let's  
8 please go ahead and vote.

9 DR. WINKLER: Dianne?

10 MEMBER JEWELL: Yes.

11 DR. WINKLER: Thank you.

12 CHAIR GIBBONS: Okay. So it's  
13 unanimous, 20 yes. Moving on to Scientific  
14 Acceptability, Suma.

15 MEMBER THOMAS: In terms of, it is  
16 precisely specified. The numerator is all  
17 patients with non-valvular afib or aflutter at  
18 high risk, which includes any patient at high  
19 risk or with greater than one modifiable risk  
20 factor for stroke, for whom warfarin has been  
21 prescribed.

22 The denominator is patients with

1 non-valvular afib or aflutter, with one or  
2 more high risk factor or greater than one  
3 modifiable or moderate risk factor. As we've  
4 discussed, hypertension, CHF, age, diabetes  
5 and stroke being the risk factors.

6 It's a rate in proportion. The  
7 better quality is a higher score, and in terms  
8 of discriminating performance, patient or  
9 physicians are benchmarked annually and  
10 quarterly. In terms of the data source, it's  
11 electronic as well as paper records.

12 So in terms of reliability  
13 testing, the PINNACLE registry has used two  
14 cohorts, and there's been four types of  
15 quality control. These are very similar to  
16 the first measure, and they also, in terms of  
17 the validity testing, basically the validity  
18 testing based on the expertise of the panel.  
19 So that was the measure weight used to  
20 validate the testing.

21 Otherwise, I think that's mostly  
22 everything for the Scientific Acceptability.

1                   MEMBER RUSSO: Suma, I just have  
2                   one question for the developers. So and it  
3                   may be in here, and I'm just not finding it.  
4                   So how do we deal with the other newer anti-  
5                   coagulants. Is there something for  
6                   numerator/denominator exclusion, now that it's  
7                   in the guidelines? How do we deal with that  
8                   in the --

9                   CHAIR GIBBONS: See, that's  
10                  clearly a question, Mark's got to come up to  
11                  the table. Thank you, Dana. At least you're  
12                  going to get plenty of exercise.

13                  DR. ESTES: Yes. It's a very  
14                  important question, one that we'll deal with  
15                  directly. The database for warfarin, for  
16                  aspirin, for clopidogrel is very robust, and  
17                  we know where warfarin stands. The database  
18                  is less robust for dabigatran, the only  
19                  release drug.

20                  It's true that there are at least  
21                  three direct 10A inhibitors and other direct  
22                  thrombin inhibitors that are coming out. We

1 looked very critically about including those  
2 at anticoagulant therapy, but decided that the  
3 evidence base that we have really deals with  
4 Coumadin.

5 These certainly can be adjusted as  
6 more evidence comes out in the future. But we  
7 felt it was insufficient with just now six  
8 months of use of dabigatran, and Jon, do you  
9 have other comments that might supplement  
10 that?

11 DR. HALPERIN: No, I agree. This  
12 is exactly how we decided to handle it.

13 MEMBER SMITH: I don't understand,  
14 though. If the physician decides to use  
15 dabigatran for clinical reasons, are they  
16 going to be dinged by this measure, for not  
17 using -- how do we -- is there some reason for  
18 not using warfarin that could be entered?

19 DR. ESTES: Well, yes, and we  
20 thought that through very carefully. With  
21 respect to the CHADS risk stratification, it  
22 doesn't affect it in any way. With respect to

1 the exclusion of patients in whom it's  
2 physician preference or patient preference to  
3 put them on dabigatran, they would be excluded  
4 by the current measure.

5 So it would not penalize people  
6 for if there's a patient reason or physician  
7 reason for not going on warfarin, dabigatran  
8 currently being the only one, but other ones  
9 in the future. This measure would continue to  
10 work.

11 CHAIR GIBBONS: I see some  
12 existential angst around the table, so those  
13 who want to comment, comment here. Mark?

14 MEMBER SANZ: Yes, my existential  
15 angst level is high. I think that if a drug  
16 has -- we should not be picking winners and  
17 losers, I believe is the latest mantra in  
18 Washington, D.C., even though I am from  
19 Montana. That's what I see happening here, is  
20 the present winner is warfarin and the present  
21 loser would be -- I can't say the name, and  
22 more are coming.

1                   This should be a measure of  
2                   anticoagulation, and if it's an FDA-approved  
3                   drug, then let it go. I mean right now then,  
4                   we would be having more measures coming every  
5                   time based on the drug, and not on the  
6                   concept. The concept is appropriate to  
7                   anticoagulation. The concept, in my opinion,  
8                   is not warfarin.

9                   Number two, I have serious  
10                  concerns, echoing Dana -- I'm on your side  
11                  this time. This doesn't talk about CHADS2.  
12                  This talks about high, intermediate and low  
13                  risk. If we're going to say CHADS2 is the  
14                  appropriate score, and that's an if, but we  
15                  just voted that it is, then let's use it.

16                  Let's not have a separate scoring  
17                  system for this measure from the prior  
18                  measure. We have to be consistent. So at  
19                  least if we tell Dana's residents to write it  
20                  down, they're writing down the same thing,  
21                  whether the patient went on warfarin or stayed  
22                  off warfarin.

1                   These have to be not only  
2                   internally consistent but harmonized.

3                   MEMBER THOMAS: My understanding  
4                   it is the CHADS2 score. It's just stated --

5                   MEMBER SANZ: Well, I'm reading  
6                   the numerator, and I don't see that. I see  
7                   low risk, no risk factors, intermediate risk,  
8                   one moderate risk factor, high risk, any high  
9                   risk factor. I mean that's not CHADS2. Just  
10                  say CHADS2 zero-one, CHADS2 two to four,  
11                  etcetera. That's it.

12                  MEMBER SNOW: I think it's a  
13                  semantic difference, because it goes -- your  
14                  point is well taken, that it's clumsy. But in  
15                  terms of meaning, those descriptors map  
16                  directly to CHADS2 elements.

17                  VICE CHAIR GEORGE: It's specified  
18                  in the denominator rather than the numerator  
19                  in this measure.

20                  MEMBER RUSSO: I think it's  
21                  semantics. It's really exactly the same. I  
22                  think it's just written by, you know,



1 electrophysiology terminology and not, you  
2 know, just more general terminology. I can  
3 understand the difference there.

4 I do have to actually agree,  
5 though, that I would -- it sounds like you're  
6 planning on if the physician thinks it's an  
7 exclusion, but maybe specifically stating in  
8 the specifications that other anticoagulants  
9 would be an exclusion too, and I couldn't find  
10 it stated in there. But I think you need to  
11 give credit for dabigatran.

12 CHAIR GIBBONS: Jon?

13 MEMBER RASMUSSEN: Yes. I would  
14 agree with that point. This drug is now FDA-  
15 approved. It's also part of the new  
16 guidelines that come out, that dabigatran is  
17 an acceptable option. Perhaps we could  
18 future-proof the exclusion criteria by saying  
19 any anticoagulant that's FDA-approved for afib  
20 may allow us to get through the three year  
21 review period.

22 I would also advocate for putting

1       it as an exclusion criteria, because yes, a  
2       physician can exclude a patient from this  
3       measure. But it would be a lot easier if we  
4       could do it administratively, based on a drug  
5       code rather than having to do it manually in  
6       the chart.

7                   MEMBER RUSSO: And the only -- I  
8       would say maybe not FDA approved everything.  
9       But if it gets to the guidelines, I would make  
10      that the stop point, because this, there was  
11      a focused guideline.

12                   DR. ESTES: Yes, that's a key  
13      point, and there has been a focused guideline  
14      which was published in January, which we did  
15      not have when we submitted. We would use the  
16      guideline, and there will be more data coming  
17      on dabigatran. We're very open to --

18                   CHAIR GIBBONS: So just for those  
19      on the phone, Mark is pointing out there was  
20      a focused update released in January, that  
21      recommended dabigatran, that was not available  
22      to the developers at the time this was

1 submitted, for those on the phone.

2 Is there more discussion about  
3 this point, which seems to me to be fairly  
4 critical?

5 (No response.)

6 VICE CHAIR GEORGE: Would the  
7 developers be open to changing it to  
8 anticoagulation rather than warfarin?

9 DR. ESTES: We're open to anything  
10 that will help move this process forward, and  
11 improve patient outcomes. So the answer would  
12 be yes. Jon, you've thought a lot about this  
13 as well. Other comments about dabigatran or  
14 other agents which will be coming out?

15 DR. HALPERIN: No, I agree  
16 completely. I mean it was really a matter of  
17 not having the guideline update at the time  
18 this was developed. I think we would be  
19 pleased to see therapeutic doses of dabigatran  
20 included.

21 CHAIR GIBBONS: Helen?

22 DR. BURSTIN: One more point about

1 the CHADS2, and again, this isn't my area.  
2 But in looking at the form, it's not, it  
3 doesn't actually specifically reference  
4 CHADS2. I do think if we're making the case  
5 that the first one, an assessment measure  
6 using CHADS2 with the scoring is so important.

7 I must admit I agree with Mark. I  
8 think this one needs to be grounded. Just one  
9 thing for your consideration is around this  
10 one, and the same evidence-based index you  
11 just told us was so important on the first  
12 measure. Otherwise, it feels a little  
13 lacking.

14 CHAIR GIBBONS: Okay. So the  
15 chair's got to try to guide this one. Are the  
16 developers amenable to two of the amendments  
17 from the gentleman from Montana, which was  
18 that the CHADS2 score be specifically  
19 mentioned, and that the numerator be  
20 anticoagulation? Can I get a sense from them?

21 DR. ESTES: Absolutely. They are  
22 constructive, they're helpful and we would

1 welcome those additions.

2 DR. HALPERIN: I agree.

3 CHAIR GIBBONS: Okay. So we're  
4 going to vote --

5 MEMBER KING: I'm sorry. I had  
6 one more question.

7 CHAIR GIBBONS: Yes, Dana.

8 MEMBER KING: Is the CHADS2 score  
9 inextricably linked to warfarin?

10 CHAIR GIBBONS: No, to  
11 anticoagulation.

12 MEMBER KING: Okay.

13 CHAIR GIBBONS: All right. So our  
14 vote is going to be -- yes, yes. We have  
15 another comment from the developer.

16 DR. AL-KHATIB: So if you actually  
17 review that focused update of atrial  
18 fibrillation, they refrain from making any  
19 recommendations about dabigatran in that  
20 document. So I agree that we need to be open-  
21 minded and that we need to be considering new  
22 anticoagulants.

1                   But my preference would be that  
2                   until those anticoagulants make it into the  
3                   guidelines, my preference would be to keep it  
4                   to, to kind of hold it, to limit these  
5                   performance measures to anticoagulants that  
6                   are, that have Class 1 or Class 2A  
7                   recommendations in the guidelines.

8                   CHAIR GIBBONS: Okay. So we need  
9                   a single response from the developers before  
10                  we vote. We're about to vote, so is it going  
11                  to be amenable to this amendment or not in  
12                  your view? There's a caucus going on in the  
13                  back right now.

14                  DR. ESTES: Well, so Dr. Al-  
15                  Khatib's point, and I was involved with that  
16                  guideline, focused update development, we did  
17                  not make recommendations. But recommendations  
18                  will be forthcoming in the future. So when it  
19                  gets to the point when it's a guideline-  
20                  approved drug, we'd certainly be willing to  
21                  it.

22                  In the interim, you know, I think

1 that we could certainly make an exclusion,  
2 physician preference, patient preference, or  
3 use of an alternate anticoagulant agent that  
4 has been shown to improve outcomes. That  
5 would be one way.

6 But the methodology, I'd have to  
7 work through with our methodologist. Jon, do  
8 you have comments?

9 DR. HALPERIN: No, I agree. I  
10 think we are, we need to poise this for the  
11 introduction of not only dabigatran but also  
12 upcoming anticoagulants for exactly the same  
13 reason.

14 I mean the current recommendation  
15 in the update is that dabigatran is a useful  
16 alternative to warfarin in this indication.  
17 It's Class 1 level of evidence B therefore in  
18 itself. Because only one trial, it would not  
19 qualify as a basis for a performance measure.

20 CHAIR GIBBONS: Okay, Devorah.

21 MEMBER RICH: Could the language  
22 be changed, though, not to be specific, but to

1 say it more generally, so it doesn't always  
2 have to be changing every time a new drug  
3 would come along that would meet the criteria?

4 CHAIR GIBBONS: We need more sense  
5 from the committee before we keep throwing --  
6 we're putting the developers on the spot too  
7 much. So we need a sense from the committee.  
8 Are we going to stand with the amendments  
9 proposed by Mark for our vote?

10 MEMBER RUSSO: Yes. I think we  
11 need to -- well first of all, we need this  
12 measure for clinical sake. But the question  
13 is you need to have dabigatran in there  
14 somewhere, and I think the developers just  
15 need to help us decide should it just be an  
16 exclusion, and maybe that's the easiest way to  
17 do it, is to put it into the exclusions.

18 So if they're on another  
19 anticoagulant, that's, you know, either  
20 whatever wording, either approved by the FDA  
21 sounds to me too general, but that are in the  
22 guidelines. But this measure wouldn't apply,



1 because they're on another agent.

2 But if we don't do that, it's not  
3 going to be -- a lot of people already are on  
4 dabigatran out there, and --

5 DR. ESTES: Well right, and I  
6 think it is possible, given the current data  
7 that we have, the current status of the  
8 guidelines, and the relatively complex  
9 methodology, which I've become all too  
10 familiar with for developing performance  
11 measures, to use the existing performance  
12 measure as proposed, and have in there patient  
13 or physician preference as the exclusion for  
14 an alternate drug that is approved.

15 Now we will probably have two or  
16 three in a year or two from now. So I think  
17 rather than coming back and reevaluating this  
18 each time, we're very open to developing  
19 appropriate exclusion criteria that would  
20 allow for dabigatran use or other drugs which  
21 are coming out, rather than delay this  
22 process.

1                   Because the reason for delaying it  
2 would be basically that we can't cover  
3 contingencies that are going to develop in the  
4 future. I think we can.

5                   CHAIR GIBBONS: Bruce?

6                   MEMBER KOPLAN: I definitely agree  
7 with everything Dr. Estes said. The only sort  
8 of practical issue here for me is thinking  
9 about how some doctor out in the community  
10 that's going to see this measure and try to  
11 apply it. That's really what we want to -- we  
12 want to, you know, have a very valid kind of  
13 thing that comes out of here.

14                   I would think it's going to seem  
15 confusing, especially because a lot of people  
16 are using dabigatran. As a matter of fact, it  
17 seems like sometimes it gets adopted faster in  
18 community practices for whatever reason. It's  
19 not always good, but I think it's going to be,  
20 it might be confusing, or would you disagree?

21                   CHAIR GIBBONS: So you're saying  
22 it would be confusing to list it as an

1 exclusion? You like the way it's going to be  
2 listed right now.

3 MEMBER KOPLAN: Well, just to be  
4 held to be using Coumadin, but realizing that  
5 there's this dabigatran available --

6 CHAIR GIBBONS: Yes, right. Yes.  
7 No, no, I'm just clarifying. I'm not saying  
8 yes or no, that I agree or disagree. We're  
9 getting a consensus. David?

10 MEMBER MAGID: Yes, and I also  
11 think if you list it as an exclusion for those  
12 practices that switch over, that they're going  
13 to be, they're going to look bad, because all  
14 of their patients who would normally be  
15 counting in the numerator and the denominator  
16 are going to be excluded.

17 So their performance score will be  
18 worse. So I am not in support of making this  
19 an exclusion.

20 CHAIR GIBBONS: Okay, Sid?

21 MEMBER SMITH: Could we have  
22 wording that said they would be on warfarin or

1 another FDA-approved medication for this  
2 indication?

3 CHAIR GIBBONS: That's putting  
4 them in the numerator. So we're, I'm going to  
5 have to move ahead on this. What I propose  
6 we're going to do, if it's okay -- first of  
7 all, can you on the telephone now hear Mark in  
8 the back when he's talking at the mic?

9 MEMBER JEWELL: You know,  
10 actually even in the back, some of the mics  
11 pop in and out. So Helen's mic pops in and  
12 out. I don't know what's happening there, but  
13 the table seems to be better than in the back.

14 CHAIR GIBBONS: The table is  
15 better than the back. Okay. So we are going  
16 to have to work technically on that issue. So  
17 here is what we're going to do. The measure  
18 developer has suggested that they want to  
19 leave it as an exclusion. I think they're  
20 amenable to making CHADS2 score part of the  
21 definition, since we've just approved that in  
22 the previous measure.

1                   So the first vote here on  
2                   Scientific Acceptability is going to be the  
3                   measure, as submitted, with dabigatran as an  
4                   exclusion, but CHADS2 score in the definition.  
5                   So I want the committee to vote on that first.

6                   MEMBER THOMAS: Do you want  
7                   dabigatran, or do we want a more general  
8                   statement again, because that's really --

9                   CHAIR GIBBONS: How is it worded  
10                  right now in the exclusions? How is it  
11                  worded?

12                  DR. ESTES: Yes. So the current  
13                  recommendation is that if there's a physician  
14                  or patient reason for not using Coumadin, they  
15                  would come out of the denominator. Now that  
16                  could include not just dabigatran but other  
17                  drugs moving forward.

18                  So the current measure, as  
19                  proposed would work, would be inclusive of  
20                  future contingencies that we can't anticipate.

21                  CHAIR GIBBONS: That's an  
22                  exclusion.

1                   MEMBER SNOW: I don't like that  
2 one. Ray, I would not be in favor of that,  
3 because -- right. Okay.

4                   CHAIR GIBBONS: So is everybody  
5 clear on what we're voting on? It's going to  
6 be an exclusion right now. CHADS2 score is  
7 going to be more prominently mentioned in the  
8 definition. We need to vote on that right  
9 now.

10                  MEMBER RUSSO: And can it  
11 specifically be stated that other  
12 anticoagulants --

13                  CHAIR GIBBONS: It's just, it's  
14 very broad. It's any physician or patient  
15 reason --

16                  MEMBER RUSSO: They're not going  
17 to understand that.

18                  CHAIR GIBBONS: Well, then you can  
19 reflect that in your vote right now.

20                               Vote again, please.

21                  DR. WINKLER: Dianne?

22                  MEMBER JEWELL: Partially.

1 DR. WINKLER: Okay.

2 CHAIR GIBBONS: Okay. So the vote  
3 is 1 completely, 4 partially, 10 minimally, 5  
4 not at all. So we're now going to have a  
5 second vote, and the second vote is to  
6 recommend to the developer that they change  
7 the numerator to include other approved  
8 anticoagulants. I think Jon gave the best  
9 wording at some point in this discussion,  
10 approved by the FDA for this purpose, blah  
11 blah blah.

12 No, this is the same four  
13 categories for Scientific Acceptability, with  
14 that change.

15 MEMBER THOMAS: I'd like to point  
16 out, though, wouldn't that change the validity  
17 and reliability of the measure if we change  
18 the numerator? So I don't know if that -- I'm  
19 just throwing that out. Wouldn't that change  
20 our whole --

21 MEMBER MAGID: I don't think it  
22 would change it substantially, because it's

1 not -- I mean the issue is can you measure  
2 whether or not people are taking medications?  
3 So if you add another medication, it probably  
4 won't dramatically change the validity.

5 MEMBER PHILIPPIDES: Ray, I have a  
6 question.

7 CHAIR GIBBONS: Yes.

8 MEMBER PHILIPPIDES: Just so I'm  
9 clear, the threshold for acceptable  
10 alternative anticoagulant is FDA approval, not  
11 placement and publication in the evidence-  
12 based guidelines, which is what I think you  
13 had brought up.

14 CHAIR GIBBONS: Right, FDA.

15 MEMBER PHILIPPIDES: Because it  
16 seems to me we have two thresholds that have  
17 been discussed. One is FDA; one is published  
18 in the guidelines.

19 CHAIR GIBBONS: Okay. So I defer  
20 to the gentleman from Montana who first  
21 proposed this amendment. What should the  
22 threshold be? Threshold, FDA or guidelines?



1                   MEMBER SANZ: That's a tough  
2 answer. I personally would go with FDA. I  
3 don't think we should be in the business of --

4                   CHAIR GIBBONS: Mark, developers?

5                   DR. ESTES: Having sat on the  
6 Performance Measures Task Force for the  
7 ACC/AHA, the threshold for that committee has  
8 always been guidelines, and you may consider  
9 that in considering whether there's a  
10 different threshold here. The threshold for  
11 performance measures has been guidelines.

12                   MEMBER SANZ: But we're talking  
13 about physicians, and we're not talking about  
14 electrophysiologists. We're talking about  
15 practicing people, and if it's an FDA-approved  
16 drug, I don't see how you can tell them you  
17 can't use it. I'm sorry. I just --

18                   DR. ESTES: Well, we wouldn't be  
19 presuming to tell physicians how to practice  
20 or what they couldn't use, and we wouldn't --

21                   MEMBER SANZ: You are, if you're  
22 going to make them an exclusion and not part

1 of the numerator.

2 DR. ESTES: No. We're simply  
3 saying in patients in the denominator, and  
4 this again is methodologically based, in whom  
5 there's a patient or physician reason. For  
6 example, the patient doesn't want to go on rat  
7 poison, that would be sufficient to exclude  
8 that patient from the denominator.

9 If the physician says I'm worried  
10 about compliance with INRs, that would be  
11 sufficient, and the patient and physician  
12 could decide to go on dabigatran without being  
13 penalized, without specifying dabigatran or  
14 any other drug. This again would not get into  
15 the methodologic complexities of looking at  
16 reliability and validity, which would come up  
17 if we changed the numerator.

18 MEMBER SANZ: So except for the  
19 physician who practices anticoagulation, which  
20 is the real issue, it may not look good if he  
21 has a high number of exclusions because he's  
22 put them on dabigatran. The real issue is is

1 he appropriately treating to the CHADS2 score.

2 CHAIR GIBBONS: I want others to  
3 comment. David?

4 MEMBER MAGID: I was just going to  
5 say that I understand that the performance  
6 test measures has a certain way of doing  
7 things. But we as a committee don't need to  
8 hold to the way you're doing it. We can make  
9 a recommendation to you, and you can then  
10 decide how you want to take it.

11 CHAIR GIBBONS: Okay. So here's  
12 the rub. We can't actually do an electronic  
13 vote on this, because we're not set up to do  
14 it. So we're going to actually have to have  
15 a show of hands, and that's going to be the  
16 choice of whether the threshold is FDA  
17 approval, or whether the threshold is  
18 inclusion in the guidelines, all right?

19 So I get a sense of the committee  
20 before we have the vote to direct the  
21 developers. Is that clear to everybody? All  
22 right. So a show of hands, who believes the

1 threshold should be FDA approval?

2 (Show of hands.)

3 MEMBER RUSSO: No. There are a  
4 lot of drugs that are approved by the FDA.  
5 For example,. an anti-arrhythmic drug of  
6 flecainide --

7 CHAIR GIBBONS: I'm sorry, too  
8 late. We cannot have further discussion. I'm  
9 sorry. We really have to move ahead. We  
10 cannot -- you may think this is wrong, but  
11 it's too late. We gotta vote.

12 DR. WINKLER: Dianne?

13 MEMBER JEWELL: I would vote for  
14 the threshold to be the guidelines.

15 CHAIR GIBBONS: Okay. Now a  
16 threshold for the guidelines.

17 (Show of hands.)

18 CHAIR GIBBONS: Okay. So there's  
19 a clear sense of the committee that the  
20 threshold should be FDA approval. So now  
21 we're going to have to revote on Scientific  
22 Acceptability, with the threshold being FDA

1 approval for inclusion in the numerator, with  
2 the point that Suma originally made, you know,  
3 the concern that Suma raised about validity.

4 We're voting on the measure being  
5 modified, so that the numerator would include  
6 not just Coumadin or warfarin, but FDA-  
7 approved drugs for anticoagulation and atrial  
8 fibrillation, the Scientific Acceptability.  
9 So we're going to revote with that change.

10 DR. WINKLER: Dianne.

11 MEMBER JEWELL: Not at all.

12 DR. WINKLER: Okay.

13 CHAIR GIBBONS: So completely 3,  
14 partially 13, minimally 3, not at all, 1. So  
15 there's clearly a big shift in the spectrum of  
16 the vote, towards more acceptability with that  
17 change. All right. Now we're going to have  
18 to move on to the next --

19 MEMBER SANZ: Ray, did we vote on  
20 CHADS2 score separately or no?

21 CHAIR GIBBONS: That was accepted  
22 by the developers, so that was part of our

1 first vote. Okay. Suma, you're doing  
2 wonderfully.

3 MEMBER THOMAS: All right. So in  
4 terms of Usability, we're actually -- the  
5 Usability obviously and the Feasibility are  
6 addressed in the original measure.

7 So but in terms of the original  
8 measure, and this measure, not used at all in  
9 public reporting yet, but will be eligible for  
10 use in PQRI in 2012, and the information about  
11 clinician participation in general will be the  
12 first thing that's actually used.

13 In terms of other places that it  
14 can be used, Dave brought up Get With The  
15 Guidelines, CPIP and New Eras, other programs  
16 that this could be used in. Dr. Estes already  
17 talked about the relationship to the other  
18 measures, and this is a unique measure, in  
19 that it's an outpatient-based measure. So I  
20 think the Usability is, it should be  
21 acceptable.

22 CHAIR GIBBONS: Are there other

1       comments or questions?

2                   (No response.)

3                   CHAIR GIBBONS:  The committee is  
4 temporarily exhausted.  All right.  So we're  
5 going to go ahead and vote.

6                   DR. WINKLER:  Dianne?

7                   MEMBER JEWELL:  Completely.

8                   DR. WINKLER:  Thank you.

9                   CHAIR GIBBONS:  So the vote is  
10 completely 13, partially 7.  We're going to  
11 move on now to Feasibility.  Suma?

12                   MEMBER THOMAS:  In terms of  
13 Feasibility, it appears to be feasible, in  
14 that the data's generated through the usual  
15 care processes.  Electronic sources are  
16 available, and it looks like they looked at  
17 susceptibility to inaccuracies and errors as  
18 well.  Obviously, lack of documentation is the  
19 major issue with any of these measures.  But  
20 it appears to be feasible.

21                   CHAIR GIBBONS:  Other comments or  
22 questions?

1 (No response.)

2 CHAIR GIBBONS: Okay. We're going  
3 to go ahead and vote.

4 DR. WINKLER: Dianne?

5 MEMBER JEWELL: Completely.

6 DR. WINKLER: Thank you.

7 CHAIR GIBBONS: So the vote is 14  
8 completely, 5 partially. Okay. So now we're  
9 going to move to the final question, but we're  
10 going to have to have two separate votes on  
11 this. So the first vote on does this meet all  
12 the criteria for endorsement will be the  
13 measure as proposed, with the friendly  
14 amendment to specify CHADS2 score more clearly  
15 in the definitions, which they accepted.

16 With that amendment, but with  
17 other anticoagulants then being an exclusion,  
18 patient or physician preference as currently  
19 proposed. So that's what we're voting on. Is  
20 that clear to everybody, questions before the  
21 vote? Roger.

22 MEMBER SNOW: What's the other



1 vote?

2 CHAIR GIBBONS: The other vote is  
3 going to be with the change that we  
4 recommended with respect to the numerator. So  
5 the first vote is with the friendly amendment,  
6 as agreed by the developers.

7 MEMBER JEWELL: Could I ask a  
8 clarifying question please?

9 CHAIR GIBBONS: Sure.

10 MEMBER JEWELL: In the past, when  
11 we've had recommendations for measure  
12 developers about a significant change in the  
13 definition of the measure, typically that's  
14 gone back to them with the opportunity to  
15 decide whether or not they accept our  
16 recommendation or not. If we vote yes or no  
17 on the second question, are we just agreeing  
18 we're sending back that recommendation, or are  
19 we saying that that's the endorsed measure --

20 CHAIR GIBBONS: We cannot change  
21 it. We are just sending back that message.

22 MEMBER JEWELL: Okay, thank you.

1 CHAIR GIBBONS: In a way, we did  
2 the same thing, if you recall, in our first  
3 meeting to the measure proposed by the  
4 Minnesota Community Measurement Project.

5 MEMBER JEWELL: Okay, thanks.

6 CHAIR GIBBONS: It was the same --  
7 well, yes. It was the same process. All  
8 right. Other questions before we vote? Yes,  
9 Rochelle?

10 MEMBER AYALA: Yes. I was  
11 wondering if NQF has a policy about what is  
12 considered evidence-based? Like does it have  
13 guidelines or FDA-approved, and if this has  
14 come up in the past.

15 DR. WINKLER: I think certainly  
16 there's been a lot of work around, you know,  
17 levels of evidence and the evidence task force  
18 discussed sort of bodies of evidence, in terms  
19 of that sort of thing. When it comes to  
20 things more like drugs, I think it's less  
21 specified. Certainly, I think the discussion  
22 around FDA approval is an important sort of

1 baseline.

2 I think it's highly variable, in  
3 terms of other drug specifications, depending  
4 on the measure, the circumstances and the  
5 drugs. Sometimes measures are very broad and  
6 include just classes of drugs, as opposed to  
7 specified lists of drugs, and I think that's  
8 highly variable depending on the topic at  
9 hand.

10 CHAIR GIBBONS: Helen, anything  
11 else to say on that? Okay. With that  
12 clarification, we're going to go ahead and  
13 have the first vote. The first vote is the  
14 measure, as proposed, with the CHADS2 score  
15 more clearly delineated, but with other  
16 anticoagulants falling under an exclusion.

17 DR. WINKLER: Dianne?

18 MEMBER JEWELL: Yes.

19 DR. WINKLER: Thank you.

20 CHAIR GIBBONS: So the vote is  
21 seven yes, 12 no. So now we're going to have  
22 the second vote, which is with the

1 recommendation to the developers that the  
2 numerator be modified to include other FDA-  
3 approved drugs for the purposes of  
4 anticoagulation and atrial fibrillation. Is  
5 that clear to everybody?

6 MEMBER SNOW: Just a point of  
7 clarification. This does include the CHADS2 -  
8 -

9 CHAIR GIBBONS: Yes. That's  
10 already assumed to be part -- yes. I should  
11 have said that again, Roger. You're correct.  
12 CHADS2 again, and that change in the numerator  
13 definition. This is a recommendation back to  
14 the developer.

15 MEMBER SANZ: So Ray, just a point  
16 of clarification. In the end then, it's the  
17 developer's choice?

18 CHAIR GIBBONS: Yes.

19 DR. WINKLER: Dianne?

20 MEMBER SANZ: So if they choose  
21 not to do it, then it would just withdraw?

22 DR. WINKLER: Dianne?

1 MEMBER JEWELL: No.

2 DR. WINKLER: Okay.

3 CHAIR GIBBONS: So the vote then  
4 is 16 yes, three no. So this a recommendation  
5 then back to the developers, and it's  
6 basically in the category of saying if you do  
7 this, they will come. No, if you do this, the  
8 measure will be favorably received by this  
9 committee.

10 Are there questions from the  
11 developers or from anybody else regarding this  
12 interesting series of events in the last 30  
13 minutes?

14 MEMBER RUSSO: Let me just ask one  
15 question. With the approval from the FDA, it  
16 has to be specifically for the indication for  
17 non-valvular atrial fibrillation?

18 CHAIR GIBBONS: Correct.

19 MEMBER RUSSO: Okay.

20 CHAIR GIBBONS: Yes. We'll, I'm  
21 relying on the staff to get that wording  
22 pretty clearly defined. I think we know what

1 we want, but we've got to get the verbiage  
2 correct, and I think there's actually the  
3 suggestion --

4 MEMBER JEWELL: This is Dianne.  
5 I appreciate the practical implications of not  
6 including some of these other FDA-approved  
7 drugs in the measure. That being said, given  
8 all of the evidence in the first criteria, and  
9 having had some personal experience in my  
10 family with this issue, I feel like we just  
11 threw the baby out with the bath water with  
12 our first vote.

13 CHAIR GIBBONS: Understood. Okay.  
14 We're going to actually have to move on to  
15 another measure, since we're now already one  
16 measure behind on the schedule, and we're  
17 going to ask the developer, who's on the  
18 phone, for Measure 1505 from Ingenix, I think,  
19 to make a brief comment.

20 DR. SCHWEBKE: You hear me okay?

21 DR. WINKLER: Yes Kay.

22 DR. SCHWEBKE: Great, thank you.

1 This is Kay Schwebke. This measure identifies  
2 adults with atrial fibrillation taking  
3 amiodarone, who had at least one serum ALT or  
4 AST in the last 12 months.

5 This is an important patient  
6 safety measure. Amiodarone, one of the most  
7 frequently prescribed anti-arrhythmic  
8 medications, has been associated with liver  
9 abnormalities, including liver failure.

10 The prevalence of abnormal liver  
11 enzymes on this medication ranges from 15 to  
12 30 percent. The incidence is about one  
13 percent per year. These adverse events are  
14 typically reversible through dose reduction or  
15 discontinuation of the medication.

16 Because of this, AST, ALT  
17 monitoring has been recommended at baseline,  
18 and every six months at minimum. I think it's  
19 important to note that amiodarone adverse  
20 event appear to be dependent on dose as well  
21 as the duration of therapy.

22 Now based on our test results,

1 there is a clear opportunity for improvement  
2 with respect to this measure. Based on our 15  
3 million member database, we've demonstrated a  
4 compliance rate of 70 percent. This indicates  
5 a gap in care. It indicates an opportunity to  
6 improve monitoring.

7 Briefly, with respect to clinical  
8 evidence and guidelines report, a  
9 retrospective chart review by Stelfox and  
10 colleagues found that amiodarone adverse  
11 events were documented in eight percent of  
12 patients who were followed for just a period  
13 of one year, and they judged with independent  
14 raters that one-third of these adverse events  
15 were judged to be preventable had the  
16 recommended monitoring occurred.

17 In addition, the North American  
18 Society of Pacing and Electrophysiology  
19 practice guidelines recommend six months'  
20 monitoring at minimum of serum ALT or AST.  
21 Other evidence-based reviews as well as the  
22 manufacture of the medication have identical



1 recommendations. In fact, more than 13 peer-  
2 reviewed publications or guidelines have  
3 recommended this specific monitoring schedule.

4 The measure logic is  
5 straightforward. It uses administrative  
6 claims, including link -- low -- the first  
7 issue is identifying the denominator, where we  
8 identified patients with atrial fibrillation  
9 using claims data. We also have the ability  
10 to identify patients with atrial fibrillation  
11 who are on a disease registry.

12 In addition, for denominator  
13 inclusion, the patient needs to have recently  
14 been prescribed or dispensed amiodarone. We  
15 define that as an amiodarone prescription  
16 filled within the last 120 days, and a  
17 duration of treatment which is the number of  
18 days of medication dispensed has to be greater  
19 than 90 days.

20 For numerator compliance, we then  
21 look for CPT or ICD codes that identify that  
22 an ASP or ALT was done in the last 12 months

1 plus 90 days after report period, to account  
2 for any lag in claims coming in.

3 Let me just conclude by  
4 recognizing that although we have been unable  
5 to identify any studies that explicitly  
6 compare outcomes of patients managed with  
7 different monitoring strategies, as I  
8 mentioned, more than 13 guidelines support  
9 this monitoring recommendation.

10 In addition, we have this one  
11 study, a retrospective chart review, that  
12 estimated that one-third of these adverse  
13 events were judged by independent raters to be  
14 preventable had these monitoring guidelines  
15 been followed. So I'll stop my comments there  
16 and I'm happy to answer any questions.

17 CHAIR GIBBONS: Okay. Are there  
18 any questions for the developer before we  
19 start?

20 MEMBER SNOW: Okay, I have one.

21 CHAIR GIBBONS: Roger Snow.

22 MEMBER SNOW: I'm supposed to talk

1 on this measure. I approached it with a lot  
2 of excitement, because I know I was going to  
3 learn something. I know very little about  
4 amiodarone. Whenever I see it, I reach for  
5 the referral slip and send that person to a  
6 cardiologist.

7 But reading this through, my  
8 question for the developer is this is an  
9 important drug. It's got serious side  
10 effects, a lot of problems. Why only atrial  
11 fibrillation? Shouldn't everyone on  
12 amiodarone be getting the same kind of  
13 surveillance, and if not, why not?

14 DR. SCHWEBKE: Yes, that's a great  
15 question, and actually we have discussed  
16 internally for the past year, changing this  
17 measure to what we call a global measure,  
18 which basically does exactly that. Rather  
19 than looking for patients with atrial  
20 fibrillation, we simply look to see if  
21 patients are taking that medication.

22 I think your point is well-taken,

1 particularly as we're seeing amiodarone used  
2 for different arrhythmias. So that is a  
3 change that we could make and we'd be happy to  
4 make.

5 MEMBER RUSSO: My other questions  
6 would be so the choice of the 12 month period  
7 of time, you know. Again, as much as we try  
8 to do, and I know perhaps we just voted down  
9 use of guidelines for this, but I think the  
10 standard, at least in EP practices, is every  
11 six months, at least, sometimes more often,  
12 every three months. I usually start every  
13 three months.

14 And then also it depends on what  
15 other drugs patients may be on. If they're on  
16 a lipid therapy or you start a lipid therapy,  
17 you might do it more. I think 12 months is  
18 much too long, and I agree. The afib  
19 shouldn't be in there at all.

20 DR. SCHWEBKE: Yes. I think both  
21 your points are well-taken, and I will say  
22 with respect to the 12 month versus six month

1 time frame, you know, historically we've  
2 received feedback concerned about claims lag,  
3 and now we've tried to take that into account  
4 by having the 12 months plus 90 days.

5 But you are absolutely right, that  
6 we could tighten this up. We could change the  
7 time frame to six months plus 90 days, and  
8 I'll also say that we could make both of these  
9 changes, and we could actually test them  
10 fairly quickly, to see how it affects the  
11 compliance results.

12 CHAIR GIBBONS: Do I have a sense  
13 from other members on the committee that they  
14 like both of these suggested modifications;  
15 that is broadening the patient group to  
16 include patients who are taking amiodarone for  
17 other purposes, and six months rather than 12  
18 months?

19 Are those friendly amendments?  
20 Can I get a sense? There's a lot of head  
21 nods. Bruce is the other EP person here. Do  
22 you want to comment?

1 (Off mic comment.)

2 CHAIR GIBBONS: No comment, okay.

3 So --

4 DR. SCHWEBKE: Can I just add  
5 something real quick? So then if did change  
6 that, if people liked that, we'd change it  
7 from 12 months to six months. We'd still keep  
8 the plus 90 days, again just to give providers  
9 the benefit of the doubt, taking into account  
10 lags in claims.

11 MEMBER MAGID: Yes. I just had a  
12 question about the intervals. Is there any  
13 data to suggest that if someone has had no  
14 evidence of toxicity for some period of time,  
15 that interval can be lengthened as opposed to  
16 shortened?

17 CHAIR GIBBONS: A pharmacy  
18 question. Anybody like -- Jon, we're  
19 depending on you.

20 MEMBER RASMUSSEN: I don't believe  
21 there is, and in fact, the evidence base for  
22 testing ALT and AST is consensus-based rather

1 than evidence-based.

2 CHAIR GIBBONS: Okay. So I'm  
3 going to presume then, as we now start the  
4 discussion, that those two friendly amendments  
5 both apply. Is that clear to everybody? Six  
6 months and not just atrial fibrillation. So  
7 the discussion will proceed assuming those two  
8 friendly amendments. Roger, you're on.

9 MEMBER SNOW: Yes. I would start  
10 with a question for NQF. You can ask and  
11 answer this, but one of the features about  
12 amiodarone is it has very narrow indications  
13 of approval by the FDA. The FDA has only  
14 approved it for use in life-threatening  
15 ventricular tachyarrhythmias.

16 We're accepting or we started off  
17 accepting this for atrial fibrillations, which  
18 is off label. Could you comment or respond?

19 DR. WINKLER: That's why we invite  
20 all you all here to discuss that. But I think  
21 it's a very important point to raise.

22 MEMBER SNOW: The other side of

1 that argument, of course, is that the drug is  
2 in use, people are at risk, and one of the  
3 reasons we're here is to promote a higher  
4 quality of care, and there are times when it's  
5 appropriate to, with your eyes wide open and  
6 consciously thinking about it, bend a rule of  
7 practice.

8 With that in mind, my feeling  
9 about this is that the clinical context makes  
10 it very important to measure, and that's  
11 certainly how I'm going to vote. I was  
12 concerned and that other concern was addressed  
13 about the breadth of the description. The  
14 rest of the presentation by Ingenix, I think,  
15 makes the case for importance clearly.

16 CHAIR GIBBONS: Okay. Other  
17 comments? Tom.

18 MEMBER KOTTKE: Yes. I in fact  
19 voted no, for the reason that Ingenix looked  
20 at 15 million records and found 1,000 people  
21 on amiodarone. I mean that means that there's  
22 300 people in the state of Minnesota on



1       amiodarone. I'm worried about measure  
2       overload, and that as we have more and more  
3       measures, there's no time, no energy, no  
4       resources left for other things.

5               And in fact, my organization just  
6       turned down my request to participate in  
7       PINNACLE, because they didn't have the  
8       resources. It wasn't about money. It was  
9       about resources, and they said we're not going  
10      to do that this year. We already do have in  
11      Epic a flag for testing, and so it's already  
12      in there.

13              I think and certainly the other  
14      uses like suppression of VTAC in patients with  
15      defibrillators, those patients are followed by  
16      electrophysiologists. I would assume that any  
17      electrophysiologist worth their salt will also  
18      be testing for amiodarone toxicity. So I  
19      voted no, because I'm simply worried about  
20      measure overload.

21              Of those 15 million people, about  
22      14-1/2 million people have problems with --

1 are at not minimal risk for coronary artery  
2 disease. I'm worried that we don't have, we  
3 no longer have any energy to deal with the  
4 important, because we are dealing with the  
5 measurable.

6 CHAIR GIBBONS: Okay. A very  
7 eloquent statement. Bruce.

8 MEMBER KOPLAN: Kind of along the  
9 same lines, but I was -- what we were going to  
10 mention was, you know, we use a lot of  
11 different anti-arrhythmic drugs, and each one  
12 of them has some unique poison that you have  
13 to kind of watch for, like you know, with  
14 flecainide -

15 CHAIR GIBBONS: Remember this is  
16 on the public record, Bruce.

17 MEMBER KOPLAN: Okay.  
18 (Laughter.)

19 CHAIR GIBBONS: We'll all amend  
20 that to be side effects.

21 MEMBER KOPLAN: Okay. I apologize  
22 for that. But you know, you have flecainide.

1 You have to make sure people don't have  
2 coronary disease. You give somebody  
3 dofetilide, you have to check their QT  
4 intervals.

5 Those are all the same. So it's  
6 just kind of, I realize the amiodarone is a  
7 real bad actor in terms of side effects, but  
8 we're picking one of the anti-arrhythmic, one  
9 of many that we're using, one in which perhaps  
10 there's a little bit less use as time goes  
11 forward.

12 But so I'm not, I'm kind of along  
13 the same lines, a little bit of concern about  
14 why are we picking this one, and then do we  
15 have to pick all the other ones, and how will  
16 that lead to things.

17 CHAIR GIBBONS: Okay. Other  
18 comments?

19 DR. SCHWEBKE: If I could just  
20 make a quick comment as the measure developer  
21 about the number of people in the denominator  
22 of our database?

1 CHAIR GIBBONS: Certainly.

2 DR. SCHWEBKE: I think it's  
3 important to keep in mind that when we test  
4 this measure in our database, the only  
5 population we have available are members under  
6 the age of 65. So we are missing basically  
7 members over the age of 65, where the  
8 prevalence of amiodarone use is higher.

9 So I would just caution you at  
10 feeling as though this is a drug that's not  
11 frequently used. It is frequently used, and  
12 unfortunately our numbers are smaller, because  
13 we're a little bit limited as far as how we  
14 can currently test the measure.

15 CHAIR GIBBONS: Other comments  
16 from -- I ignore my right side, so I'm going  
17 to apologize multiple times to the people on  
18 the right here.

19 MEMBER SANZ: Are you on amiodarone  
20 for your stroke? And which drugs are --

21 (Simultaneous speaking.)

22 MEMBER RUSSO: No, the comments.

1 I think this really does open up the gate to  
2 every drug and drug monitoring. I mean we're  
3 talking about some really robust measures with  
4 a lot of evidence and guidelines, you know,  
5 versus standard of care for monitoring LFTs.  
6 Why not, not only this particular drug --

7 MEMBER KOPLAN: Yes. Why not  
8 pulmonary function test, and why not thyroid  
9 tests every six months?

10 MEMBER RUSSO: Right, PFTs,  
11 exactly.

12 MEMBER SANZ: Why are we doing  
13 this? I mean that's -- thank you. Why are we  
14 doing this one side effect with this one drug?

15 CHAIR GIBBONS: Rochelle.

16 MEMBER AYALA: I was thinking back  
17 to Phase 1, when we had the measures that  
18 talked about ACE and ARBs being prescribed  
19 upon discharge, or in the outpatient setting,  
20 for patients who had had an MI, and also beta  
21 blockers. We were very lenient there on the  
22 physician. I mean I think they only had to

1       like write a prescription in one year or  
2       something like that.

3                   So I'm thinking, you know, when  
4       you put it in perspective, you know, we don't  
5       have enough resources to check those very  
6       important things. Should we be focusing on  
7       these indicators that have less evidence, and  
8       also smaller populations?

9                   CHAIR GIBBONS: Okay. Building on  
10      the point that Tom made. Jon, do you want to  
11      comment further?

12                   MEMBER RASMUSSEN: So let me  
13      preface this by saying all the comments about  
14      the narrow focus of this measure, I certainly  
15      appreciate and agree with. But in the spirit  
16      of the measure submitted, I would say that  
17      this drug almost warrants a composite measure,  
18      because there is a number of side effects on  
19      ALT, TSH, pulmonary testing, EKG testing,  
20      chest X-ray. There's a litany of potential  
21      side effects for this medication.

22                   So again, in the spirit that it

1 was submitted, it may benefit from having a  
2 wider scope of side effect monitoring, if we  
3 consider this measure.

4 CHAIR GIBBONS: Okay, and that  
5 sort of follows on from Mark's point. Sid?

6 MEMBER SMITH: Yes. I'll support  
7 that. I mean I think the number of patients  
8 is relatively small. It's a drug that does  
9 concern me, but you didn't mention  
10 anticoagulation. You put somebody on  
11 amiodarone and coumadin you've got problems  
12 potentially that need to be watched carefully.

13 So to single out liver function  
14 tests in a relatively small group of a large  
15 population of patients with cardiovascular  
16 disease is maybe not a good idea.

17 CHAIR GIBBONS: Okay. I think I  
18 have a sense that we've probably all been  
19 heard. Unless there are more burning  
20 comments, I think we need a vote. Helen?

21 DR. BURSTIN: Just one process  
22 point. The question was raised about the

1 level of underlying evidence. Just remember  
2 that that is a key feature of this criterion.  
3 So it has to meet that threshold to be  
4 considered.

5 CHAIR GIBBONS: Okay, all right.  
6 I think we're going to go ahead and vote on  
7 importance.

8 DR. WINKLER: Dianne.

9 MEMBER JEWELL: Yes.

10 DR. WINKLER: Thank you.

11 CHAIR GIBBONS: So the vote is 1  
12 yes and 17 no. So per the sort of routine,  
13 discussion of this measure is now completed.  
14 Thank you, Roger, for your valiant effort. We  
15 are now going to take our break, and point out  
16 that we are now only 25 minutes behind after  
17 two hours of work.

18 So I'm going to ask people if they  
19 could try to limit their break to 20 minutes.  
20 We're doing wonderfully, and we'll hopefully  
21 come back reenergized.

22 (Whereupon, the above-entitled



1 matter went off the record at 10:29 a.m. and  
2 resumed at 10:53 a.m.)

3 CHAIR GIBBONS: We're out of order  
4 a little bit here. We're scrambling to figure  
5 out who our primary discussant is going to be  
6 on 1530. So we're going to jump to 1523, ACE  
7 and ARB therapy at discharge for ICD-implanted  
8 therapy. Sid isn't back in the room yet.

9 DR. MASOUDI: Dr. Gibbons?

10 CHAIR GIBBONS: Yes.

11 DR. MASOUDI: Hi, Fred Masoudi  
12 here. I'll be presenting the NCDR measures.

13 CHAIR GIBBONS: Okay. So why  
14 don't you go ahead, Fred, and make your  
15 introductory comments while we're waiting for  
16 Sid Smith to come back in the room.

17 DR. MASOUDI: Okay. Is it all  
18 right with you, Dr. Gibbons, if I sort of  
19 address the group, this group of measures,  
20 sort of as an overall, and just provide you  
21 with an introduction?

22 CHAIR GIBBONS: Absolutely. Fred,

1 that's perfectly fine.

2 DR. MASOUDI: Excellent, thank  
3 you. Well thanks to all of you for allowing  
4 us to present these measures. I'm sorry that,  
5 unlike last time, I can't be there in person  
6 to join you.

7 I'm Fred Masoudi. I think we all  
8 met at the last meeting. I'm one of the  
9 senior medical officers of the National  
10 Cardiovascular Data Registries. I think  
11 Kristyne McGuinn and Susan Fitzgerald, who are  
12 ACC staff are in the audience there in person.

13 This group of measures, this is a  
14 set of five measures from the NCDR ICD  
15 Registry. Just by means of background, the  
16 implantable cardioverter defibrillator  
17 registry is actually implemented in all  
18 hospitals that implant ICDs in the United  
19 States, because it is a precondition of  
20 reimbursement for Medicare primary prevention  
21 defibrillator implantations, and thus includes  
22 already more than 700,000 records of patients

1 who have received implantable cardioverter  
2 defibrillators.

3 The use of this expensive therapy  
4 has increased substantially over the last  
5 several years, in large part because of the  
6 expansion of ICD therapy for primary  
7 prevention of sudden cardiac death in patients  
8 with left ventricular systolic dysfunction.

9 In fact, left ventricular systolic dysfunction  
10 is one of the most common reasons for which  
11 implantable defibrillators are placed, and as  
12 many of you know, coronary artery disease,  
13 myocardial infarction is a very common cause  
14 of left ventricular systolic dysfunction.

15 There are a number of process  
16 measures here that are being proposed for your  
17 consideration, including ACE ARB therapy at  
18 discharge for ICD implantations with left  
19 ventricular systolic dysfunction, beta blocker  
20 therapy at discharge for those patients who  
21 either have left ventricular systolic  
22 dysfunction as one measure, or a previous MI

1 as a second measure.

2 Then in anticipation of the  
3 conversation we had during the last meeting  
4 around the PCI measures, we have also provided  
5 an all or nothing composite measure. I will  
6 separate out the antibiotic measure as a  
7 separate piece of discussion.

8 These process of term measures is  
9 similar to those for patients with either  
10 heart failure or MI, the hospitalized patients  
11 with heart failure or MI that's currently  
12 reported at Hospital Compare. One thing I  
13 would say is different is that these patients  
14 who get ICD implantation are almost invariably  
15 excluded from those measures, because they  
16 don't have a primary discharge diagnosis of  
17 heart failure and MI, and therefore they  
18 aren't currently included in those measures.

19 Indeed, data both from the NCDR  
20 and from other sources would suggest that  
21 optimal medical therapy, which includes ACE  
22 inhibitors and beta blockers in eligible

1 patients, are substantially underused in  
2 patients who are receiving this expensive  
3 therapy.

4 These process measures are very  
5 strongly evidence-based. They are supported  
6 by some of the strongest evidence within the  
7 guidelines. They are all currently reported  
8 by the NCDR ICD registry to participants.  
9 They are well-harmonized with the existing  
10 heart failure and AMI measures, for those  
11 patients with principle discharge diagnoses of  
12 heart failure and MI.

13 The data on levels of performance  
14 within the NCDR are included in your  
15 materials. I think you will see that compared  
16 with the rates for some of the other inpatient  
17 measures, the rate of therapies here identify  
18 fairly substantial gaps, with the median rates  
19 for the ACE/ARB measure of 79 percent, and  
20 somewhat higher compliance with the beta  
21 blocker measure, about 90 percent, although I  
22 would note that more than a quarter of

1 patients, more than a quarter of hospitals  
2 perform at rates lower than 85 percent.

3 We also provide information  
4 regarding breakdowns of performance with  
5 respect to safety net versus non-safety net  
6 hospitals, hospitals as a function of the  
7 proportion of patients that care for a white,  
8 primary versus secondary prevention ICDs and  
9 so on. And you can see there are gaps across  
10 the spectrum of these variables.

11 As I said also, in anticipation of  
12 the discussion around the PCI measures, where  
13 there was a strong preference of the committee  
14 for an all or nothing composite, we have also  
15 generated an all or nothing composite measure  
16 of the proportion of patients receiving the  
17 medications for which they are eligible.

18 What that means is the inclusions  
19 and exclusions of the individual composite  
20 measures go into the calculation of this  
21 measure. That is to say if a patient has a  
22 contraindication to a given therapy, just like

1 with the individual measures, they wouldn't be  
2 considered eligible for that given medication.

3 But otherwise, this is an all or  
4 nothing composite that essentially includes  
5 the inclusions and exclusions from the other  
6 measures, and you can see also in your package  
7 the data on hospital performance for each of  
8 these measures at the median rate of 73  
9 percent, only 10 percent of hospitals  
10 performing at a level above 90 percent.

11 And again, data on performance  
12 rates as a function of safety net versus non-  
13 safety net, white versus non-white, I'm sorry  
14 not white versus non-white, but proportion of  
15 white patients treated within a hospital, male  
16 versus female, old versus young and so on.

17 Dr. Gibbons, at this point if  
18 you'd like, I can pause before further  
19 discussion of prophylactic antibiotic measure,  
20 if that's your preference.

21 CHAIR GIBBONS: Yes, I think you  
22 should see if there are any questions from the

1 committee for you.

2 (No response.)

3 CHAIR GIBBONS: Okay. So we have  
4 a little bit of a challenge here, because two  
5 of these were assigned to somebody who has  
6 not, is not in attendance. So we're going to  
7 jump to 1522, Sid, ACE and ARB at discharge  
8 for ICD implant patients, and start with that  
9 one. Okay. Give you a second to get it up.

10 MEMBER JEWELL: Is someone  
11 speaking? I've lost the mic.

12 CHAIR GIBBONS: It's from Group 3,  
13 I believe, where these were. Can you hear us  
14 now?

15 DR. MASOUDI: Is that a question  
16 for me, Ray, or is someone else supposed to be  
17 speaking? I'm sorry.

18 CHAIR GIBBONS: No, I'm sorry.

19 MEMBER SMITH: So this is, if I'm  
20 right, this is 1522. The measure is ACE ARB  
21 therapy at discharge for ICD patients with  
22 left ventricular systolic dysfunction, and the



1 measure would be the proportion of ICD implant  
2 patients with a diagnosis of LV systolic  
3 dysfunction who are prescribed ACE inhibitor  
4 or ARB therapy at discharge.

5 This is an important measure. The  
6 efficacy of ACE inhibitor therapy and ARB in  
7 this group of patients is well-established, as  
8 is the gap in its use. So I guess the first  
9 thing we need to address on this is the impact  
10 is high. It's a patient group of high  
11 morbidity and mortality.

12 The data that I have seen show  
13 that there still is a performance gap, which  
14 is narrowing with some of the current quality  
15 improvement programs. There is also evidence  
16 for disparity in the use of these therapies,  
17 and the outcome evidence is strong, in terms  
18 of the efficacy.

19 CHAIR GIBBONS: Okay. Are there  
20 other questions about importance before we  
21 vote? Dr. Masoudi referred to the performance  
22 gap. I think it's actually truly amazing in

1 the data in the submission.

2 MEMBER KING: Is this the time to  
3 ask the question about harmonization, or does  
4 that come later?

5 CHAIR GIBBONS: That will come  
6 later. But I think there has been certainly  
7 an attempt by the developers here to try to  
8 harmonize where they could. But we will be --  
9 Dana, that's going to be part of our activity  
10 tomorrow. We're going to flag this, among  
11 others, for that issue. Okay. We're going to  
12 go ahead and vote on importance.

13 DR. WINKLER: Dianne?

14 MEMBER JEWELL: Yes.

15 DR. WINKLER: Thank you.

16 CHAIR GIBBONS: Okay. It's a  
17 unanimous vote, 20 to 0. Let's move on to  
18 Scientific Acceptability.

19 MEMBER SMITH: Well again, I think  
20 that in terms of acceptability, the  
21 reliability, validity of the measure are  
22 strong. I really don't see any gaps there in

1 terms of its use. It's a relatively standard  
2 measure for patients with left ventricular  
3 systolic dysfunction.

4 The issue here is its use with, in  
5 the presence of ICDs. I don't know that there  
6 has been any RCT looking at its use or non-use  
7 in the presence of biventricular pacing in  
8 patients with left ventricular systolic  
9 dysfunction, which would be an interesting  
10 question.

11 CHAIR GIBBONS: I'm not aware of  
12 any, but obviously all that data, the  
13 development of the evidence predated the use  
14 of CRT.

15 MEMBER RUSSO: The only comment I  
16 can make is that the indications for CRT  
17 therapy are based on maximum medical therapy.  
18 So those patients were already on maximum  
19 medical therapy, presumably.

20 CHAIR GIBBONS: Yes. That's a  
21 very good point, correct, including -- maximum  
22 medical therapy including this. All right.

1 Other comments about scientific acceptability?

2 (No response.)

3 CHAIR GIBBONS: All right. Let's  
4 go ahead and vote on that.

5 DR. WINKLER: Dianne?

6 MEMBER JEWELL: Partially.

7 DR. WINKLER: Thank you.

8 CHAIR GIBBONS: So the vote is 18  
9 completely, 2 partially. We'll move on now,  
10 Sid, to Usability.

11 MEMBER SMITH: Yes. Again, I  
12 would say that it meets the criteria for  
13 usability, both in terms of public reporting,  
14 and as an additional value to existing  
15 measures.

16 MEMBER KOPLAN: Can I make a silly  
17 comment?

18 CHAIR GIBBONS: Yes. Sorry, no.  
19 There are no silly comments.

20 MEMBER KOPLAN: It just has to do  
21 -- can you show that vote again that you just  
22 said? It just has to do with how you've been

1 reading the votes today, and not to criticize  
2 the speaker in any way.

3 CHAIR GIBBONS: No.

4 MEMBER KOPLAN: Because I just  
5 read -- you know, because it's being recorded.  
6 You said 18 to 2, and I think what you're  
7 doing is reading the number two. 2 equals no,  
8 but it was actually 18 to 1.

9 CHAIR GIBBONS: No. I mean  
10 including the vote on the phone. I'm adding  
11 the vote on the phone.

12 MEMBER KOPLAN: It was a 1.  
13 Actually, are you able to show it or -- oh,  
14 okay.

15 CHAIR GIBBONS: She voted  
16 partially on the phone.

17 MEMBER KOPLAN: Oh, I'm sorry.  
18 Never mind. Okay.

19 (Off mic comments.)

20 CHAIR GIBBONS: Are we keeping  
21 score?

22 MEMBER KOPLAN: That was a

1 mistake.

2 (Laughter.)

3 MEMBER JEWELL: I want to have a  
4 long distance clicker, but the technology  
5 doesn't exist at the moment.

6 MEMBER KOPLAN: I apologize.

7 CHAIR GIBBONS: Not a problem, not  
8 a problem. It's all about quality  
9 improvement. All right. So are there other  
10 comments or questions about Usability?

11 (No response.)

12 CHAIR GIBBONS: All right. Let's  
13 go ahead and vote.

14 DR. WINKLER: Dianne?

15 MEMBER JEWELL: Completely.

16 DR. WINKLER: Thank you.

17 CHAIR GIBBONS: Okay. We are  
18 having problems in the electronics here, so  
19 because that can't be right. So I'm just  
20 going to ask everybody to re-vote, because  
21 unless four people have died in the last 30  
22 minutes, we're having some problem.

1                   So 19 to 0. Okay, so moving on  
2 now to finally, Feasibility. Sid.

3                   MEMBER SMITH: Well again, I think  
4 that it's been demonstrated in its use that it  
5 is a very feasible criteria. So I don't see  
6 any problems here. This is a well-established  
7 measure, in contrast to some of our earlier  
8 discussions this morning.

9                   CHAIR GIBBONS: Other comments or  
10 questions here?

11                  MEMBER RUSSO: And just, you know,  
12 it's easily obtainable from the electronic  
13 source of the registry, which is great and  
14 easy.

15                  CHAIR GIBBONS: Okay. Let's go  
16 ahead and vote.

17                  DR. WINKLER: Dianne?

18                  MEMBER JEWELL: Completely.

19                  DR. WINKLER: Thank you.

20                  CHAIR GIBBONS: It's a unanimous  
21 vote, 20 to 0. So we'll go ahead and take the  
22 final vote on endorsement.

1                   MEMBER SANZ: Ray, I have a  
2 question.

3                   CHAIR GIBBONS: All right, blocked  
4 to my right again. Yes, Mark.

5                   MEMBER SANZ: Is your hearing also  
6 out? A question regarding, is ICD here being  
7 used as a generic or a specific term? In  
8 other words, are we including by the --

9                   DR. WINKLER: Dianne?

10                  MEMBER JEWELL: Yes.

11                  DR. WINKLER: Thank you.

12                  MEMBER SANZ: --CRT, by the ICD,  
13 ICD.

14                  CHAIR GIBBONS: I think that's a  
15 question for the developers. As far as I  
16 know, the registry is if you have an ICD,  
17 you're in. Yes, Fred?

18                  DR. MASOUDI: That's correct, Ray,  
19 that this applies to patients who receive an  
20 ICD implant, and that means an ICD with or  
21 without CRT singly, dually and so on. Again,  
22 because Dr. Russo, I believe, brought up



1 appropriately the guideline recommendation for  
2 implantation of any rhythm management device  
3 in patients with systolic dysfunction is  
4 predicated upon the patient receiving optimal  
5 medical therapy, and that's the recommendation  
6 under which this is based, for patients  
7 receiving any rhythm management device.

8 MEMBER SANZ: So I guess my  
9 question is do you want to expand it, to just  
10 say any rhythm -- well, why would you not want  
11 to be tracking biventricular device without  
12 ICD?

13 DR. MASOUDI: Yes. I guess so.  
14 That's an excellent point. So this would  
15 include patients who get bi-v without ICD. I  
16 think the reality is that is extremely  
17 infrequently used in practice, but that would  
18 be included in this, and could clarify.

19 MEMBER SANZ: So is that in the  
20 actual document? I couldn't find that, or can  
21 we add something like that?

22 DR. MASOUDI: Yes, that could

1 certainly be added. Again, I think the  
2 reality is in practice, that's extremely rare,  
3 but that could certainly be added, and would  
4 be appropriate.

5 MEMBER RUSSO: So I have the  
6 question correct, it's an ICD registry. So if  
7 they got a CRT pacemaker, they would not be  
8 entered into the ICD registry. So we just  
9 wouldn't have that data easily available?

10 DR. MASOUDI: Yes. I think it  
11 depends on it. I think that some places might  
12 do it and other places may not. I think  
13 there'd be sort of maybe less uniform capture  
14 than there would be with ICDs. But to the  
15 extent that those are captured, and again I  
16 think they're pretty unusual, regardless of  
17 whether or not they're entered into the  
18 registry, but that could certainly be a draft.

19 CHAIR GIBBONS: So I want to go  
20 back to the earlier discussion that we had, in  
21 the sense of NQF-endorsed measures could then  
22 be used by anybody.

1                   So in theory, this is an NQF-  
2                   endorsed measure that says ICD, and so I guess  
3                   one of the question is do we want to change  
4                   the wording or suggest a change in the  
5                   wording, to cover a broader range, although  
6                   admittedly the opportunity for anybody else to  
7                   use this is going to be more limited.

8                   MEMBER SANZ: I agree.

9                   CHAIR GIBBONS: So Fred, I would  
10                  sense from what you've said, you would have no  
11                  objection to a broader wording of the scope of  
12                  patients?

13                  DR. MASOUDI: No, I wouldn't, and  
14                  no, I wouldn't.

15                  CHAIR GIBBONS: So that's a  
16                  friendly amendment, and it's just to cover the  
17                  potential application once it's an endorsed  
18                  measure, because that would not be feasible  
19                  within the registry per se.

20                  All right. So the vote here was  
21                  19 to 0. Okay. So we have endorsed this one.  
22                  So we're going to move on to the next one,

1 which is 1528, beta blocker at discharge for  
2 ICD patients with previous MI. George?

3 MEMBER PHILIPPIDES: To jump in as  
4 far as the impact, again, this is a fairly  
5 large population of patients who are at  
6 significantly high risk for sudden cardiac  
7 events, especially sudden cardiac death. So  
8 the impact is great.

9 There's not a lot of data on the  
10 gap in performance, but there was a review of  
11 several thousand patients, and it did seem  
12 like there was a small splay as far as lower  
13 quartiles to upper quartiles, as far as  
14 performance goes. So there is a gap.

15 And this is clearly a relevant  
16 outcome. There are evidence-based guidelines,  
17 clinical trials all showing that beta blocker  
18 use post-MI is very, very important,  
19 especially if you're not receiving reperfusion  
20 therapy but across all patients. So I think  
21 overall, the impact is important and there's  
22 a gap that needs to be dealt with.

1 CHAIR GIBBONS: Other questions or  
2 comments about importance? Dana.

3 MEMBER KING: Is that already  
4 covered by our measures that say if you had a  
5 previous MI, you should be a beta blocker?

6 CHAIR GIBBONS: Well, I think --

7 MEMBER KING: So if they still  
8 had a previous MI and they came in and got  
9 their ICD.

10 CHAIR GIBBONS: I will attempt to  
11 answer that, and then ask Dr. Masoudi to  
12 comment. But I think he mentioned in his  
13 introductory comments, many of those other  
14 measures specifically exclude people with  
15 devices.

16 MEMBER KING: Okay.

17 DR. MASOUDI: Yes. Just as a  
18 point of clarification, I would say that the  
19 medication and discharge measures don't  
20 specifically exclude patients with ICDs, so  
21 much as they don't include them, because they  
22 typically focus on patients with a primary

1 discharge diagnosis of myocardial infarction,  
2 or a primary discharge diagnosis of heart  
3 failure.

4 As a result, these individuals  
5 tend not to be included in those inpatient  
6 measures that are diagnosis-focused, and it  
7 turns out that these people fall through the  
8 cracks of those measures, and as you can see,  
9 there's a significant gap in care when it  
10 comes to the optimal medical therapy, that  
11 they should be receiving around the time that  
12 they get a device like this.

13 CHAIR GIBBONS: So it's an  
14 interesting sort of fall through the crack  
15 idea, but if we actually go back to Tom's sort  
16 of calculations the last time around, the sort  
17 of return on investment here for medical  
18 therapy in these sorts of patients should be  
19 large.

20 DR. MASOUDI: Right, especially  
21 since they're getting a device specifically  
22 because the physician believes they're at

1 substantial risk for sudden cardiac death.

2 CHAIR GIBBONS: Devorah.

3 MEMBER RICH: So how large is the  
4 gap? You said that there's --

5 MEMBER PHILIPPIDES: So the data  
6 that they give us shows that the quartile 1 is  
7 about .83, median about .9, and third quartile  
8 about .96. So between the first quartile and  
9 the third, .83 to .96. Not a huge gap, but  
10 because of the number of patients and the  
11 higher risk of these patients, I think it's  
12 probably somewhat significant.

13 I mean to put it another way, to  
14 be perfectly gross, if you're putting in a  
15 \$50,000 device on somebody, I think part of  
16 good therapy should be at the minimum get them  
17 on the beta blocker if they're not already on  
18 one. That's the very simplistic way of  
19 looking at that.

20 MEMBER RICH: So it should be 100  
21 percent.

22 MEMBER PHILIPPIDES: It should be

1 100 percent. I mean if you're putting a  
2 device in, why aren't they on a beta blocker.

3 MEMBER SANZ: And as Andrea had  
4 mentioned, optimal medical therapy is a  
5 requirement for defibrillator.

6 CHAIR GIBBONS: So I've had a  
7 little ongoing sort of challenge in my own  
8 institution, because I made the bold statement  
9 a few years ago that every year I see somebody  
10 who has an ICD, who has known coronary artery  
11 disease and a previous myocardial infarction,  
12 who in the absence of any contraindications  
13 or bleeding is not taking aspirin.

14 People said oh, that never  
15 happens. It's happened every year. I can  
16 produce a case managed within our health care  
17 system, where that is the case, and that's  
18 obviously loony.

19 MEMBER SANZ: So is this going to  
20 be a composite measure eventually?

21 CHAIR GIBBONS: Well, we're going  
22 to get to the -- we're going to get, we're



1 working towards --

2 (Simultaneous speaking.)

3 MEMBER SANZ: You're getting to  
4 the issue of all of these are important, not  
5 as --

6 CHAIR GIBBONS: Right, yes, and  
7 Dr. Masoudi mentioned that in his intro, and  
8 we're going to get to that later. So other  
9 discussion here before we vote on importance?

10 (No response.)

11 CHAIR GIBBONS: Okay. Let's go  
12 ahead and vote on importance.

13 DR. WINKLER: Dianne?

14 MEMBER JEWELL: Yes.

15 DR. WINKLER: Thank you.

16 CHAIR GIBBONS: So the vote is 19  
17 to 0. Move on to Scientific Acceptability.  
18 George.

19 MEMBER PHILIPPIDES: I think the  
20 measure is well-defined. The numerator and  
21 denominator are pretty clear. The exclusions  
22 include people who don't live to discharge who

1 are deemed dead before discharge, any  
2 contraindications that are well-described by  
3 the M.D., and people who are on research  
4 protocols. Those seem reasonable.

5 What are not in the exclusion  
6 criteria are people who are being discharged  
7 to hospice, or discharged with a CMO  
8 designation. There was some wording saying  
9 that discharge location will be taken into  
10 account, I guess, in the next iteration of  
11 this, in 2012. But as of now, that is not  
12 part of the exclusion criterion.

13 DR. MASOUDI: Can I interject on  
14 that issue?

15 MEMBER PHILIPPIDES: Sure, please.

16 DR. MASOUDI: Yes. Just very  
17 briefly, so that specific exclusion does not  
18 exist. However, if it were documented as the  
19 reason for not -- specifically documented as  
20 the reason for not prescribing the medication,  
21 that patient would be excluded.

22 MEMBER KOPLAN: Can I ask a

1 question? So I'm sorry. You're saying  
2 somebody's going to get implanted with a  
3 defibrillator and then discharged to hospice?

4 MEMBER PHILIPPIDES: So what  
5 they're saying is if that were to happen, that  
6 as of right now, that's not one of the clearly  
7 specified exclusions. But then we just heard  
8 over the airwaves here that if you just write  
9 that down, if the patient is now going to  
10 hospice, that would count as an exclusion.  
11 They'll count that.

12 CHAIR GIBBONS: But remember, they  
13 may just already have an implant.

14 DR. MASOUDI: Well, these are new  
15 implants, so the question is well-taken in  
16 terms of, you know, why would this happen. I  
17 think it would happen in vanishingly rare  
18 circumstances, which I think is another reason  
19 that that specific exclusion is really not  
20 that important in this case.

21 It's conceivable that a patient  
22 gets an ICD implantation, has a complication

1 either related to or unrelated to the ICD, and  
2 then becomes and develops a condition or  
3 conditions that would suggest that they merit,  
4 you know, hospice or comfort care.

5 So that's the circumstance in  
6 which it could occur. I agree with the  
7 earlier comment that in this case with ICD  
8 implantation, new ICD implantation, that this  
9 is presumably of very limited relevance.

10 MEMBER PHILIPPIDES: Bruce, that  
11 complication would never happen at your  
12 hospital, but at other hospitals it might. So  
13 I think they --

14 DR. MASOUDI: No, no, no. Don't  
15 get me wrong. I'm not saying that.

16 (Simultaneous speaking.)

17 DR. MASOUDI: -- is relatively  
18 rare, and that could happen anywhere, my  
19 hospital, anywhere. I just say I think that  
20 in terms of the overall numbers, it's not  
21 going to be a likely circumstance.

22 MEMBER SANZ: But Ray, on your

1 right.

2 CHAIR GIBBONS: Yes. Thank you,  
3 Mark.

4 MEMBER SANZ: I think this is an  
5 important discussion, because I'm going to  
6 bring -- I was going to bring up the exact  
7 same thing on the PCI composite measure this  
8 afternoon.

9 Why are you getting percutaneous  
10 coronary intervention if you're hospice, and  
11 why would you -- unless something bad happened  
12 and you ended up in hospice, in which case you  
13 should not be an exclusion?

14 The same thing might be true with  
15 ICD. I mean I know EP has better outcomes  
16 than interventions. Then if you're  
17 transferred to acute care facility, some  
18 higher level facility, let's say tertiary  
19 care, why is that an exclusion? It's true for  
20 all of these measures.

21 CHAIR GIBBONS: Okay. So Fred,  
22 did you hear those questions?

1 DR. MASOUDI: Yes. In terms -- so  
2 as far as the comfort care hospice, and again  
3 I think these are people who all got these  
4 procedures, and I think, you know, we're not  
5 actively, you know, we can look into that with  
6 newer data versions.

7 But I think the likelihood of that  
8 happening is quite small, as opposed to say  
9 someone who's admitted with a primary  
10 discharge diagnosis of heart failure or AMI,  
11 particularly a Medicare population.

12 You can see much more frequent  
13 likelihood of patient getting comfort care or  
14 hospice. So I do think that's an extremely,  
15 in my opinion, an extremely minor issue in  
16 this population, number one.

17 With respect to the other  
18 exclusions, this is the same exact discussion  
19 we had last time around the PCI measures, the  
20 issue there being attempting to find  
21 concordance and harmonization with existing  
22 measures, and so these are aligned with the

1 specifications of what's used with the CMS  
2 measures in this area, but for different  
3 populations.

4 CHAIR GIBBONS: Okay, and aside  
5 from the harmonization, though, I would like  
6 to point out we're getting -- we need to be  
7 careful not to get confused with this isn't an  
8 ICD implant measure.

9 This is in a patient who has got  
10 an ICD and has an indication for a beta  
11 blocker, who is now going to hospice care. Do  
12 you still want to worry about measuring the  
13 indication from the beta blocker?

14 DR. MASOUDI: Right, and just to  
15 be -- just again to be clear, these are people  
16 who are getting ICD implantations during this  
17 episode of care. So again, I would contend  
18 that the proportion of those patients who are  
19 going to be discharged to hospice, when all is  
20 said and done down the road is going to be a  
21 vanishingly small number of people.

22 Not because it doesn't happen, but

1 because it happens quite rarely.

2 CHAIR GIBBONS: So yes. They've  
3 gotten an implant, but we're not measuring in  
4 any way whether they should have gotten an  
5 implant. We're just measuring whether they  
6 should get a beta blocker.

7 DR. MASOUDI: That's correct.

8 MEMBER SANZ: As they're going  
9 home.

10 CHAIR GIBBONS: As they're going  
11 home, and if they're going home to hospice,  
12 it's reasonable that they not be getting a  
13 beta blocker.

14 DR. MASOUDI: Right. True, that's  
15 correct. I would say that's correct. Again,  
16 I would contend that that's relatively rare,  
17 and the exclusions also accommodate, you know,  
18 sort of concordance with what's done for other  
19 inpatient discharge medication measures, allow  
20 for exclusions.

21 It's not explicitly enumerated  
22 here, as it is in some of the other measures.



1 Again, you know, again I think it would be  
2 relatively rare. It's not explicitly  
3 enumerated here. It certainly could be done.  
4 There's no reason why that couldn't be worked  
5 into it.

6 MEMBER PHILIPPIDES: Okay, and  
7 then we --

8 MEMBER RUSSO: So one other  
9 question in terms of, and it's not specific to  
10 this, because it's harmonized to other  
11 measures in here. But the exclusion for  
12 participation in the research trial, do we --  
13 although it's a very, very small number of  
14 patients in all of these applications, do we  
15 really want to withhold?

16 Is this really appropriate to  
17 withhold evidence-based therapy, just because  
18 they're in some research study, and I don't  
19 understand that exclusion?

20 DR. MASOUDI: Yes. It would be a  
21 research study. You know, there may be a  
22 research study that addresses the use and

1 specifies the use of these particular agents  
2 in a certain way. It may, it seems unlikely  
3 there would be a clinical trial that would  
4 suggest that the patient shouldn't get the  
5 medication altogether.

6 But it's just to accommodate the  
7 possibility of clinical trials that have  
8 specific approaches to the use of these  
9 medications, whereby it would be difficult to  
10 potentially understand what they're getting,  
11 or may specify the approach in which they're  
12 treated.

13 Again, this is an extremely rare  
14 exclusion, a relatively rare exclusion, and  
15 again, is concordant with exclusions that are  
16 used for other existing inpatient discharge  
17 medication measures.

18 CHAIR GIBBONS: Roger.

19 MEMBER SNOW: And also, clinical  
20 trials represent a deviation, a planned  
21 deviation from usual care. So it kind of  
22 upsets the ethos of which we're trying to do.

1 CHAIR GIBBONS: Correct. Okay. I  
2 think we've had good discussion here. Let's  
3 move on and vote on the --

4 MEMBER PHILIPPIDES: I have just  
5 have one last comment on disparities. The sum  
6 total of the description was no disparities  
7 reported. I'm assuming that means that there  
8 was data on disparities, and that there were  
9 no differences there.

10 But they don't offer that up. So  
11 I'm not sure if it's a don't ask don't tell  
12 situation --

13 DR. MASOUDI: George. Let me say  
14 I hope, I have in front of me data, testing  
15 data based on the proportion of hospitals in  
16 quintiles according to the proportion of  
17 patients that are white within those  
18 hospitals, safety net versus non-safety net  
19 hospitals and so on. Is that not -- do you  
20 not all have that?

21 DR. WINKLER: They should have  
22 that in your folders for the measures.

1 They're the accessory documents with --

2 MEMBER PHILIPPIDES: Okay, okay.

3 I guess I was looking more for race and  
4 ethnicity, but I did see that, and there were  
5 no differences between safety net and the  
6 other hospitals. That's correct. Okay.

7 CHAIR GIBBONS: Okay. Can we go  
8 ahead and vote on the Scientific  
9 Acceptability?

10 DR. WINKLER: Dianne?

11 MEMBER JEWELL: Completely.

12 DR. WINKLER: Thank you.

13 CHAIR GIBBONS: So the vote is 19  
14 completely, 1 partially, and now move on to  
15 Usability. George.

16 MEMBER PHILIPPIDES: So the  
17 measure is meaningful, understandable, easy to  
18 use in different formats to date. The measure  
19 specifications, there are other measures that  
20 NQF has.

21 Two apply to bypass, as far as  
22 using beta blocker. One applies to acute MI.

1 This is the first one that actually applies to  
2 people who are having an implant of an ICD  
3 done during this hospitalization.

4 So this one is a little bit  
5 different. This one uses registry data as  
6 opposed to the CMS registries, which I guess,  
7 I'm sorry, reviews which use medical records.  
8 So overall, I think it does have some added  
9 benefit to it, because it's looking at a  
10 different population.

11 CHAIR GIBBONS: Other comments or  
12 questions on this? Yes, Devorah.

13 MEMBER RICH: In looking at the  
14 3(b), the harmonization, it seems really  
15 similar to the CMS Measure 160, except that --  
16 I'm reading it -- except it does not include  
17 exclusions for discharge to hospital against  
18 medical advice or patients with comfort care  
19 measures only.

20 I mean we're just saying like the  
21 discharge to hospice is so small. So I'm  
22 wondering how different is it really?

1                   MEMBER PHILIPPIDES: Is the 160  
2 for prior MI or for acute MI? I'm not sure  
3 I'm familiar with it.

4                   MEMBER RICH: I'm sorry.

5                   DR. WINKLER: It's for  
6 hospitalization of MI discharge.

7                   CHAIR GIBBONS: So 160 is an acute  
8 MI discharge.

9                   DR. MASOUDI: Yes. To clarify the  
10 difference between the two, the CMS measure  
11 focuses on patients who have a principal  
12 discharge diagnosis of acute myocardial  
13 infarction. This measure focuses on those  
14 patients who are undergoing ICD rhythm  
15 management implantation, who have a history of  
16 myocardial infarction, and so the focus  
17 populations are different.

18                   Again, I view the other  
19 similarities with the CMS measure as a  
20 relative strength, in the interest of  
21 harmonization, to the extent that we're able  
22 to provide to practitioners sort of a

1 consistent playing field across certain  
2 processes of care, even though it is in  
3 different populations.

4 MEMBER PHILIPPIDES: I mean the  
5 greater question should be should we have a  
6 different measure just for prior MI, and if  
7 they leave a hospice, should they be on a beta  
8 blocker? This is really one subset of that,  
9 but that's how it's written.

10 CHAIR GIBBONS: Yes, Rochelle.

11 MEMBER AYALA: I'm just wondering  
12 why we're limiting it to the patients who at  
13 this hospitalization are having an ICD-9 in  
14 place. I'm just wondering if the other  
15 patients are falling through the cracks of the  
16 measures, if they had the ICD-9 placed  
17 previously, and then they're in the hospital  
18 and get discharged not on these, you know, not  
19 on a beta blocker or an ACE inhibitor?

20 I'm just wondering is that another  
21 group of patients that may fall through the  
22 cracks?

1 DR. MASOUDI: Just to answer that,  
2 so to the extent that those patients are,  
3 would be admitted for acute heart failure or  
4 for myocardial infarction, they would be  
5 included in the CMS inpatient measures. To  
6 the extent that they're admitted for other  
7 reasons, and that would be common, they would  
8 not, and they would potentially fall through  
9 the cracks.

10 The issue is the data set with  
11 which we're dealing, which is a registry of  
12 those patients, of all those patients,  
13 virtually all the patients for primary  
14 prevention, but a substantial number of  
15 patients who get secondary prevention ICD, who  
16 are undergoing ICD implantations.

17 So the focus on this populations  
18 is it's a substantial population, an important  
19 population, and one that's amenable to  
20 assessment using this registry data source.  
21 Whereas those patients who have an ICD in the  
22 past are not captured in this data source.



1                   CHAIR GIBBONS:  So in light of our  
2                   earlier discussion, I think it's a little  
3                   tricky.  But if you think of this as an NQF-  
4                   approved measure, for somebody getting an ICD  
5                   with a previous MI, it could conceivably be  
6                   used in the future, in other registries or  
7                   data sources that, you know, might then  
8                   incorporate those patients.

9                   When used within this registry, it  
10                  has to be an ICD implant during this  
11                  hospitalization.  But once it's approved, it  
12                  can go anywhere.  It's a nuance, but it, I  
13                  think, addresses your question, Rochelle.  
14                  Okay.  Can we go ahead and vote on this one?

15                  DR. WINKLER:  Dianne?

16                  MEMBER JEWELL:  Completely.

17                  CHAIR GIBBONS:  So the vote is 20  
18                  to 0.  20 completely, sorry.  All right.  Now,  
19                  Feasibility.

20                  MEMBER PHILIPPIDES:  So in regards  
21                  to feasibility, the required data elements are  
22                  routinely generated.  It lends itself well to

1 electronic records. The exclusion should be  
2 easily obtained in the medical record as well.  
3 The data collection strategy seems to, you can  
4 implement it without too much pain.

5 There is \$3,500 fee roughly to  
6 join the registry, and there's always, you  
7 know, the staff that's needed to keep the  
8 registry together. I think, in my opinion,  
9 those costs and that time is always  
10 underestimated. When you start to do it, you  
11 actually realize how much work it takes.

12 But there's nothing here that's  
13 too onerous. So overall, I think that this is  
14 a feasible project, a feasible measure.

15 CHAIR GIBBONS: Other comments or  
16 questions?

17 (No response.)

18 CHAIR GIBBONS: All right. Let's  
19 go ahead and vote please.

20 DR. WINKLER: Dianne?

21 MEMBER JEWELL: Completely.

22 DR. WINKLER: Thank you.

1 CHAIR GIBBONS: So the vote is 19  
2 completely and 1 partially. Now our final  
3 vote on whether or not this measure meets the  
4 criteria for endorsement.

5 DR. WINKLER: Dianne?

6 MEMBER JEWELL: Yes.

7 DR. WINKLER: Thank you.

8 CHAIR GIBBONS: So the vote is 20  
9 to 0 favoring endorsement. Thank you, George.  
10 So now we're going to again skip. We're going  
11 to go to 965, which is the composite measure  
12 for ACE and ARB and beta blocker discharge  
13 following ICD. Bruce.

14 DR. MASOUDI: Dr. Gibbons, I  
15 apologize for interrupting. We're skipping  
16 one of the components of the composite?

17 CHAIR GIBBONS: We are skipping  
18 one of the components, because we do not  
19 currently have a discussant.

20 DR. MASOUDI: Oh yes, I apologize.

21 CHAIR GIBBONS: But we're going to  
22 address that issue, but we don't currently

1 have a discussant.

2 MEMBER KOPLAN: Okay. So the  
3 question here is, that's been raised, or the  
4 question as I see it with this measure is  
5 whether everything should just be put  
6 together, and that seems to be what this  
7 measure's all about.

8 So the title of this measure is  
9 "Patients With an ICD implant who receive  
10 prescriptions for all medications for which  
11 they are eligible at discharge (ACE  
12 inhibitors, ARBs and beta blockers)."

13 I don't know if it's a minor issue  
14 or not, but certainly there are, there may be  
15 other medications that fall under all  
16 medications that people might be eligible for  
17 at discharge, but it seems as if this is  
18 focusing on ACE, ARB and beta blockers.

19 In terms of impact, I think it  
20 seems as if everyone feels that beta blockers  
21 are very important in this population, whether  
22 it's for reduced ejection fraction or prior

1 MI. So I think that's kind of been decided  
2 upon with the previous measures.

3 The issue of ACE inhibitors hasn't  
4 been brought up yet, because we didn't review  
5 that measure, but certainly there's a  
6 tremendous amount of data supporting the  
7 mortality benefit in patients with reduced EF.  
8 So I think that's important.

9 In terms of performance gap, it  
10 seems as if there still continues to be a  
11 reasonable performance gap in these issues,  
12 and we mentioned the evidence. So I would  
13 think that this is an important measure.

14 MEMBER CHO: I have a question.

15 MEMBER KOPLAN: Yes.

16 MEMBER CHO: Is there -- so for  
17 people who get ICD, who have VT but do not  
18 have left ventricular systolic dysfunction, so  
19 people like, I don't know, whatever is the  
20 primary VT without LV systolic dysfunction or  
21 coronary artery disease, is there evidence  
22 that being on ACE inhibitor prolongs life or

1 improves outcome?

2 MEMBER KOPLAN: Well, so that's  
3 where I think when we talk, you bring up a  
4 good point, and it's a concern I have about  
5 combining everything. So we could either talk  
6 about that now, or we can talk about that  
7 under number two, where they talk about  
8 numerator and denominator.

9 DR. MASOUDI: Can I clarify a  
10 little bit? So a patient who doesn't have  
11 systolic dysfunction would not be counted as  
12 eligible for an ACE inhibitor in this measure.  
13 Similarly, a patient without systolic  
14 dysfunction or without MI would not be  
15 considered eligible for a beta blocker.

16 So again, the inclusion and  
17 exclusion criteria of the individual component  
18 measure still apply to this measure, and  
19 that's where this issue of for which they are  
20 eligible is included in the title. The  
21 patient's primary VP and normal systolic  
22 function would not be considered as needing an

1 ACE inhibitor, according to this composite.

2 So it would only be judged  
3 according to whether or not they got a beta  
4 blocker, provided that they had a prior MI.  
5 So when the inclusions and exclusions -- this  
6 doesn't broaden the inclusions or narrow the  
7 exclusions of the individual components of the  
8 composite.

9 MEMBER RUSSO: So to clarify, you  
10 need to be eligible for each of the composite  
11 components of the measure. You can't be --

12 DR. MASOUDI: No. You need to be  
13 eligible for at least one of them, and if  
14 you're eligible for only one, you're judged on  
15 whether or not you were treated with that one  
16 medication. If you're eligible for both, you  
17 have to receive both in order to succeed.

18 MEMBER KOPLAN: Yes, and that's  
19 actually -- is it okay? Just because it's  
20 coming up already, one of my concerns about  
21 this, I think we all would agree -- well,  
22 we've agreed on all of the individual ones,

1       except one that we haven't had a chance to  
2       talk about. I would expect that people would  
3       agree on that one, but I can't, you know, say  
4       for sure. I can only speak for myself.

5                I would agree on it. But my  
6       concern, I do have a little bit of concern  
7       about combining all of these together, and the  
8       way I would kind of express is it, let's say  
9       you combine 1528 and 1529. You have -- what  
10      you then have is this same numerator, but two  
11      different denominators.

12               But if you combine all of them,  
13      you're actually combining different numerators  
14      and different denominators, and it could make  
15      -- the questions that you're asking, I think  
16      it could make this kind of complicated. It  
17      would be easier if you were combining things,  
18      where the denominator was the same for the two  
19      measures you're combining, or the numerator  
20      was the same for the two measures you're  
21      combining.

22               But when you combine two different



1 ones, then it runs into this kind of  
2 questioning, I think, that people raise. So  
3 that's my --

4 DR. MASOUDI: Yes, and I would  
5 just say there's just, for this composite,  
6 that's right. The denominator of this  
7 composite is going to be sort of the overlap  
8 of all the denominators of the component  
9 measures. That is to say if a patient is  
10 eligible for one of the component measures,  
11 they will end up in this composite.

12 So it's actually sort of a broader  
13 denominator, and it includes a denominator of  
14 the patients who are eligible for any one of  
15 the component measures. In the numerator are  
16 those people who receive either or both of the  
17 medications for which they are eligible.

18 MEMBER KOPLAN: Yes. But you  
19 could have prior MI and you could get dinged  
20 for a defibrillator but not for ACE inhibitor.  
21 But there's, I just worry there's a risk of  
22 getting dinged for something that's not the

1 right one for the right part of the  
2 denominator, that's all.

3 DR. MASOUDI: The way it's  
4 specified again is that if you were to  
5 satisfy, if a patient were to satisfy all of  
6 the component parts, they would satisfy the  
7 composite.

8 Again, this brings -- but if they  
9 fail any of the ones for which they're  
10 eligible, then they would fail. So again, it  
11 just rolls -- it rolls the three up. It's a  
12 broader denominator, and it counts for each of  
13 the components.

14 But again, doesn't influence the  
15 inclusion or exclusion criteria of the  
16 individual components that comprise the  
17 composite. So you can't do a good job on both  
18 of them and fail on the composite.

19 CHAIR GIBBONS: David.

20 MEMBER MAGID: So Fred, it's  
21 David. Just a question. Is the reason why,  
22 the rationale for this is that at the

1 individual level, individual measurement,  
2 people score very highly and that this is an  
3 opportunity to sort of --

4 DR. MASOUDI: Yes.

5 MEMBER MAGID: --indicate greater  
6 opportunities for improvement? That's the  
7 reason why, and that's weighed against the  
8 potential --

9 (Simultaneous speaking.)

10 DR. MASOUDI: My personal opinion  
11 is that each of the individual -- each of the  
12 individual components were to stand on their  
13 own with respect to the gaps in care. However  
14 again, this was put together in response to  
15 the discussion that was had around PCI, and  
16 attempt to be responsive to the possibility  
17 that the committee would like it, similar to  
18 what was around PCI, where admittedly the  
19 component measure of performance was higher,  
20 would be interested.

21 We were responding to what was a  
22 strong expression of interest in an all or

1 nothing composite measure, for PCI.

2 CHAIR GIBBONS: Let me just try to  
3 -- I mean we did give the direction for this  
4 at the first meeting, but that direction  
5 reflected a broader history of this issue.  
6 The issue is, has been reflected already in  
7 our discussion, that the devices are supposed  
8 to be put in on top of optimal medical  
9 therapy. So are you getting optimal medical  
10 therapy?

11 That concept was reflected in the  
12 Minnesota Community Measurement Project that  
13 we saw the last time, that's been in use for  
14 ten years, and I can assure you is a success  
15 story, because people suddenly recognized if  
16 I'm doing everything else right, but oh by the  
17 way, I'm not controlling their blood pressure,  
18 maybe the fact that I'm giving them aspirin  
19 and that they're not smoking and that their  
20 cholesterol is controlled is meaningless if  
21 their blood pressure is 260 over 120.

22 That's the spirit, and if you go

1 back and look at the IOM report on performance  
2 measures, it argued very strongly that we need  
3 to think more broadly in terms of what is a  
4 patient supposed to get if they're getting  
5 good care, and one little piece doesn't tell  
6 you the story if you know, as a composite,  
7 from a sort of global perspective, oh, they  
8 should get four things. Then they should get  
9 all four things. So that's the spirit of  
10 this.

11 MEMBER MAGID: So then it seems  
12 like we also then have information to address  
13 the issues that Leslie and Bruce brought up  
14 with, which was is it a problem when you have  
15 different denominators of the individual  
16 measures? It sounds like you're saying it's  
17 not, and we can kind of put that aside.

18 CHAIR GIBBONS: I would argue that  
19 we're trying to get clinicians, as they look  
20 at these patients, to say is this human being  
21 getting all the medical therapy that they  
22 should get?

1                   MEMBER MAGID: No, no, I  
2 understand that. I just want to make sure  
3 that since they have ten years of experience,  
4 if the issue that Bruce and Leslie brought up  
5 was a problem, we'd know it. You're saying  
6 it's not a problem, when we consider --

7                   CHAIR GIBBONS: No. You need to  
8 be careful in this measure specifications for  
9 sure, to reflect the issues for the clinical  
10 decision-making process. But as long as you  
11 do that, you will inspire the appropriate kind  
12 of mindset in the clinician.

13                   MEMBER MAGID: So yes, treat the  
14 patient and not the individual measure.

15                   CHAIR GIBBONS: I would say that  
16 in the example that you gave, the issues in  
17 the numerator apply to everyone in the  
18 denominator. In this example, parts of the  
19 numerator only -- or parts of the numerator  
20 only apply to part of the denominator.

21                   DR. MASOUDI: I think this is a  
22 consistent theme across all, many if not all

1 all or nothing measures, though, that  
2 incorporate say, let's say you're looking at  
3 hypertension therapy, lipid therapy and  
4 another preventive medication or intervention.  
5 It will invariably be the case that the people  
6 for which the individual components apply are  
7 not exactly the same.

8 So it's a fairly common theme  
9 across most all or nothing composite measures.

10 VICE CHAIR GEORGE: Yes. As  
11 defect-free care, at least the way that IHI  
12 has defined it, with bundled care. If you  
13 don't, if you only qualify it for two of the  
14 three and you get two of the three, you have  
15 met the measure.

16 MEMBER MAGID: Okay.

17 VICE CHAIR GEORGE: So it's not a  
18 single numerator/denominator type calculation.

19 MEMBER RUSSO: And I think, just a  
20 comment also, because there's going to be one  
21 later that we have. I think this is actually  
22 a better way than one of the future measures,

1 composite measures we have here, that actually  
2 takes the -- not the individual site, but it  
3 averages, you see that one, it averages the  
4 mean, I think, for all of the measures done  
5 elsewhere.

6 So if you're missing one, you take  
7 other people's data basically. So I think  
8 this is a much more valid way of looking at it  
9 than that. So you have to just decide how you  
10 want to do it.

11 MEMBER SZUMANSKI: Ray, I have a  
12 point. Based upon what you have said, would  
13 it be clearer for the data abstractor and  
14 person who has to enter this data, to say  
15 rather than the title of "all medications,"  
16 should it read "optimal medications for this  
17 patient?"

18 I'm thinking of the individual  
19 who's got to enter this information into the  
20 database. When it says "all medications,"  
21 that could encompass a whole lot more than  
22 ACE, ARB and beta blockers.



1 DR. MASOUDI: First of all, we  
2 struggled with the title. So if there are  
3 specific suggestions from the group about how  
4 you would like to see the title, we're  
5 completely open to that. Your point is well-  
6 taken. The "all" would suggest a lot more  
7 than the two focused medications, which is why  
8 there's the parenthetical statement at the end  
9 of the title.

10 MEMBER KOPLAN: Why not just say  
11 "ACE inhibitors and beta blockers," because  
12 that's what we're talking about?

13 DR. MASOUDI: Yes. That's, yes.  
14 We can work that into the title. I think  
15 again that's sort of this nuance of making  
16 sure that it's clear in the title. One of the  
17 issues that we had when asking people to  
18 review this was this idea that making sure  
19 that the title reflects this idea that, you  
20 know, the inclusions and exclusions are still  
21 there. But I think we can work that out.

22 MEMBER KOPLAN: So that would

1 involve taking out the word "all?"

2 CHAIR GIBBONS: I sense the  
3 committee doesn't like the word "all." So --

4 DR. MASOUDI: We're more than  
5 happy to strike that.

6 CHAIR GIBBONS: All right. So  
7 we've had this interesting discussion. I'd  
8 point out we haven't yet voted on importance.  
9 So we now need to vote on importance.

10 DR. WINKLER: Dianne?

11 MEMBER JEWELL: Yes.

12 DR. WINKLER: Thank you.

13 CHAIR GIBBONS: So the vote is 19  
14 to 1, yes. Scientific Acceptability, are  
15 there additional comments, Bruce?

16 MEMBER KOPLAN: No additional  
17 comments. It seems to be scientifically  
18 acceptable.

19 CHAIR GIBBONS: Are there other  
20 comments or discussion about this?

21 (No response.)

22 CHAIR GIBBONS: All right. Let's

1 go ahead and vote on this one.

2 DR. WINKLER: Dianne?

3 MEMBER JEWELL: Completely.

4 DR. WINKLER: Thank you.

5 CHAIR GIBBONS: 20 votes for  
6 completely, nothing for anything else. Moving  
7 on to Usability, Bruce?

8 MEMBER KOPLAN: Yes. As the  
9 developers point out, this measure is intended  
10 to be used by the ICD registry for future  
11 benchmarking, and also ACCF plans to  
12 incorporate voluntary reporting measures,  
13 including this one. It seems, usability seems  
14 to be met.

15 CHAIR GIBBONS: Additional  
16 comments or questions?

17 (No response.)

18 CHAIR GIBBONS: Better go ahead  
19 and vote on this one.

20 DR. WINKLER: Dianne?

21 MEMBER JEWELL: Completely.

22 DR. WINKLER: Thank you.

1 CHAIR GIBBONS: 20 for completely,  
2 nothing for anything else. And finally,  
3 Feasibility.

4 MEMBER KOPLAN: It seems to be  
5 feasible as well. No further comment.

6 CHAIR GIBBONS: Any other comments  
7 or questions?

8 (No response.)

9 CHAIR GIBBONS: Looks like  
10 everybody's getting hungry. All right. So  
11 let's go ahead and vote on this.

12 DR. WINKLER: Dianne?

13 MEMBER JEWELL: Completely.

14 DR. WINKLER: Thank you.

15 CHAIR GIBBONS: We're on a roll.  
16 20 completely, no votes for anything else.  
17 Then finally, does it meet the criteria for  
18 endorsement?

19 MEMBER KOPLAN: Can I make one,  
20 raise a question? Is this with the  
21 recommended edit of the title?

22 CHAIR GIBBONS: Yes.

1 MEMBER KOPLAN: Okay. So it will  
2 be edited to say to eliminate the word "all"  
3 and to incorporate "ACE inhibitors and beta  
4 blockers?"

5 CHAIR GIBBONS: I assume that's  
6 possible. Fred?

7 DR. MASOUDI: Absolutely, yes, and  
8 we'll be responsive to that request.

9 MEMBER SNOW: For clarity, that's  
10 ACE inhibitors and ARBs?

11 DR. MASOUDI: It's ACE inhibitor  
12 or ARBs and beta blockers.

13 CHAIR GIBBONS: Sorry. We want it  
14 on. If you voted already, vote again and  
15 often. This is in the spirit of Florida.

16 DR. WINKLER: Dianne?

17 MEMBER JEWELL: Yes.

18 DR. WINKLER: Thank you.

19 CHAIR GIBBONS: Okay. The vote is  
20 unanimous, 20 for endorsement. Okay. Now  
21 we've got one issue vis-a-vis this composite,  
22 and another issue, and I want to be

1 transparent so everybody knows. Two of the  
2 measures in this group were assigned to  
3 somebody who is not here, and that was not  
4 anticipated.

5           So we have two measures for which  
6 we're going to need somebody to lead the  
7 discussion, and one of them is a component of  
8 this composite. So it is important that we  
9 have that discussion about that component, in  
10 the spirit of making sure whether or not all  
11 the individual components of the composite  
12 have been endorsed for approval.

13           Once we've had that discussion,  
14 then we'll either be able to take a single  
15 additional vote, and that vote will be  
16 important, because it will be basically do we  
17 need any of the individual components, or do  
18 we just need the composite?

19           But we can't have that vote until  
20 we have discussed the --

21           DR. WINKLER: Bruce is  
22 volunteering.

1 CHAIR GIBBONS: Bruce is  
2 volunteering? Has Bruce just volunteered?

3 MEMBER KOPLAN: Well, I was  
4 pointing at something. I wasn't actually  
5 volunteering.

6 (Laughter.)

7 MEMBER KOPLAN: But I'll be happy  
8 to do my best.

9 CHAIR GIBBONS: Okay. But first,  
10 while you're mentally preparing, George --

11 MEMBER KOPLAN: It shouldn't be  
12 hard.

13 CHAIR GIBBONS: -- are you ready  
14 to take on the antibiotics?

15 MEMBER PHILIPPIDES: I am.

16 CHAIR GIBBONS: Okay. So while  
17 Bruce is preparing ferociously to take on  
18 1529, we're going to ask George, who's kindly  
19 filled in as one of the group who looked at  
20 1530, which is on prophylactic antibiotics, to  
21 lead the discussion on that. Fred, are you  
22 still with us?

1 DR. MASOUDI: I'm present.

2 CHAIR GIBBONS: You're present,  
3 good. Okay. So we're now going to go to 1530  
4 on prophylactic antibiotics. George.

5 MEMBER PHILIPPIDES: Actually, I  
6 might be able to let Bruce off the hook. I  
7 actually did, perhaps erroneously, prepared  
8 1529. I thought that that was under my docket  
9 as well.

10 CHAIR GIBBONS: Not a big deal  
11 either way.

12 MEMBER PHILIPPIDES: Okay, and in  
13 last ten minutes, I looked at the antibiotic  
14 one and scribbled some notes. So if you guys  
15 don't get tired of me, I'm willing to rifle  
16 through both of these. Okay.

17 CHAIR GIBBONS: I sense a lot of  
18 nods and a lot of hungry people, so you're on.

19 MEMBER PHILIPPIDES: Okay. So  
20 1529 is a little bit different than the one  
21 that I talked about about 20 minutes ago.  
22 This is beta blocker at discharge for ICD



1 placement with LV systolic dysfunction,  
2 defined as LVF less than 40 percent. The last  
3 one was with a history of prior MI.

4 So we're probably going to get  
5 into the whole harmonization issue and how  
6 close they are in the overlap. But for the  
7 sake of scientific impact, quality, gap and  
8 all that stuff, all of the same things that I  
9 talked about 20 minutes ago apply.

10 It's important, it's a high risk  
11 population, there is an impact gap. It's not  
12 huge, but because of the numbers and the  
13 morbidity of this disease, it's important. So  
14 I would say this is an important issue.

15 CHAIR GIBBONS: Other questions or  
16 comments on importance, and George has sort of  
17 redirected us to 1529, which I would point is  
18 one of the components of the composite we just  
19 approved. Okay. Let's vote on importance.

20 DR. WINKLER: Dianne?

21 MEMBER JEWELL: Yes.

22 DR. WINKLER: Thank you.

1 CHAIR GIBBONS: Okay, 20 yeses, no  
2 no's. Scientific Acceptability.

3 MEMBER PHILIPPIDES: Again,  
4 similar to past discussion. The  
5 inclusion/exclusion criteria are fairly  
6 precise. It's a beta blocker on discharge,  
7 the same exclusion there. If you don't make  
8 it to discharge and if there's a  
9 contraindication that's well-specified by EF  
10 being less than 40, it's the most recent LVEF,  
11 as documented.

12 There has been reliability testing  
13 for this, looking at a 2008 versus 2009  
14 cohort, and it was reliable across the two  
15 cohorts. There's evidence of validity in the  
16 medical record, the evidence-based guideline.  
17 Clinical trials, that's all good. As I  
18 mentioned, there was the same gap in the  
19 quartiles as before, as far as I looked at it.  
20 It was a small gap but a real one.

21 On this one, hopefully I didn't  
22 get this one wrong as well. I didn't see

1 anything under 2(h) disparities. Am I correct  
2 on this one?

3 CHAIR GIBBONS: They didn't -- in  
4 the composite, there were no disparities  
5 recognized. I would think that applies to  
6 all.

7 MEMBER PHILIPPIDES: Okay. This  
8 one was left blank, I think.

9 CHAIR GIBBONS: Well, he said  
10 there were no disparities. Let's let Dr.  
11 Masoudi answer. Fred?

12 DR. MASOUDI: Yes. I was just  
13 going to say that I believe the data should be  
14 there for safety net versus non-safety net  
15 hospitals, and looking at hospitals, according  
16 to quintiles, of the proportion of patients  
17 that they treat that are white. For the  
18 individual component measure there, there is  
19 greater detail in the composite with respect  
20 to age and gender, I believe.

21 CHAIR GIBBONS: It was a companion  
22 document. I think we've run into that, as we

1 review these. If there's extensive data and  
2 it's in a separate document, it's not  
3 necessarily in the application per se. So I  
4 think that's where the issue was here.

5 MEMBER PHILIPPIDES: Okay, that's  
6 answered. Thank you.

7 CHAIR GIBBONS: So let's vote for  
8 Scientific Acceptability.

9 DR. WINKLER: Dianne?

10 MEMBER JEWELL: Completely.

11 DR. WINKLER: Thank you.

12 CHAIR GIBBONS: Twenty votes for  
13 completely and nothing for anything else.  
14 Usability?

15 MEMBER PHILIPPIDES: So again, I  
16 think that the information produced is  
17 meaningful. It's easy to understand. It's --  
18 this kind of data is being used in registries  
19 to date, without too much muss and fuss. The  
20 harmonization discussion is the same as we had  
21 before. There seemed to be NQF measures that  
22 look at bypass. There are measures that look

1 at acute MI.

2 This one focuses solely on ICD  
3 implant during this hospitalization. I think  
4 the harmonization process that's sort of  
5 strange in my mind, and I need some guidance  
6 here, is what about the two measures that  
7 we're discussing? One is MI, prior MI with  
8 indication for ICD obviously. One is LV  
9 systolic dysfunction. It seems to me that  
10 there's some just great overlap there.

11 Are we trying to say ischemic  
12 myopathy versus non-ischemic? That doesn't  
13 really help us either. So I think that these  
14 two parameters, if left dangling out there  
15 individually, need to be somehow harmonized.

16 DR. BURSTIN: I'd just make the  
17 same argument George made. I guess -- this is  
18 Helen. My one question would be is there any  
19 reason why, especially in the composite, you  
20 felt comfortable listing the two together, why  
21 you couldn't have the individual measure be  
22 either LVSD or prior MI?

1                   MEMBER RUSSO: That's one  
2 possibility, but they are different. So  
3 they're not all severe LV dysfunction. Some  
4 of the EFs may be 48 percent and not be  
5 considered less than 40 percent, which is the  
6 number for LV systolic dysfunction.

7                   (Simultaneous speaking.)

8                   DR. MASOUDI: These individual  
9 components that are being presented here are  
10 those that are currently used as metrics of  
11 the ICD registry.

12                   It would be feasible to have a  
13 sort of intermediate composite, I guess, that  
14 would include, you know, beta blockers for  
15 patients with either systolic dysfunction or  
16 MI, to be sort of halfway between the total  
17 composite we're presenting and the individual.

18                   But again, these are measures that  
19 are -- the individual components are the ones  
20 that are currently being reported back to  
21 sites within the registry, which is why  
22 they're being presented here.

1 CHAIR GIBBONS: I think it while  
2 worthwhile, the discussion is somewhat  
3 academic given the composite that we've  
4 already voted on and approved.

5 MEMBER RUSSO: Right. But I do  
6 think that we're going to have to return to  
7 this issue of whether the individual  
8 components need to be individually endorsed or  
9 not.

10 CHAIR GIBBONS: We are going to  
11 have that vote after we have this vote. We  
12 are not going to forget that one for sure. So  
13 on Usability, let's vote.

14 MEMBER PHILIPPIDES: And this is  
15 just this measure.

16 CHAIR GIBBONS: We are just voting  
17 on this measure, because we have to basically  
18 make certain that we've evaluated separately  
19 each of the components of the composite,  
20 because that's been an issue for other  
21 composite measures that have come forth  
22 through the NQF system, and this one should

1 not be subject to that criticism.

2 You don't need to know the whole  
3 history of that over the last two years, but  
4 it's an enormous history. So we must vote on  
5 this component.

6 MEMBER PHILIPPIDES: Made very  
7 clear, Mr. Chairman.

8 DR. WINKLER: Dianne?

9 MEMBER JEWELL: Completely.

10 DR. WINKLER: Thank you.

11 MEMBER JEWELL: Yes.

12 CHAIR GIBBONS: 18 to 0. Now  
13 Feasibility?

14 MEMBER PHILIPPIDES: So I'm  
15 hungry. All of the things that I said 20  
16 minutes ago apply. I think it's feasible.  
17 Let's vote.

18 (Laughter.)

19 DR. WINKLER: Dianne?

20 MEMBER JEWELL: Completely.

21 DR. WINKLER: Thank you.

22 CHAIR GIBBONS: 19 to 0, and then



1 the final vote, does this measure, this  
2 individual measure, meet the NQF criteria for  
3 endorsement?

4 DR. WINKLER: Dianne?

5 MEMBER JEWELL: Yes.

6 DR. WINKLER: Thank you.

7 CHAIR GIBBONS: Okay. That's a  
8 unanimous vote of 20 to 0. I agree. George  
9 should lead all of these. So now we have had,  
10 I'm going to get all my numbers right. So  
11 we've had, and let me look at the sheet with  
12 my bifocals. We have had individual votes on  
13 Measures 1522, 1528 and 1529, approving them.

14 They are incorporated in the  
15 composite 0965. That composite, as we said,  
16 reflects a longer-term trend, a recommendation  
17 from the Institute of Medicine, some real  
18 world experience, and our own direction to the  
19 developers at the last meeting.

20 So we're now going to take a vote  
21 on whether, in our view, 965 trumps the  
22 others. In other words, that the others go

1 away because there's a single measure that  
2 counts, and it's 965. So that is a yes or no  
3 vote.

4 DR. WINKLER: No, that's not --

5 CHAIR GIBBONS: No?

6 MEMBER RUSSO: Could we discuss  
7 this further or ask a question? So two  
8 questions actually. One is, is there a  
9 standard in NQF for the process?

10 Do you need to have measures,  
11 single individual measures out there before  
12 you make a composite measure, and then the  
13 second question would be if, for some reason,  
14 and not so much in this measure, but I'm  
15 thinking of a subsequent measure we have to  
16 review later today, and we reviewed one last  
17 time that has a very complex kind of  
18 mathematical formula, to come up with a  
19 measurement for that particular composite  
20 measure.

21 If for some reason we find out  
22 that this composite measure turns out to be

1 something that was a mistake in something we  
2 created, are we allowed to go back and divide  
3 that measure up into the individual measures,  
4 without having the individual measures to  
5 give, you know, sites credit for them?

6 So would it be -- what's a  
7 disadvantage, an advantage if we approve the  
8 individual measures and leave them as such, if  
9 we go back and there's something wrong with  
10 the way we've created the composite measure  
11 formula, and again I don't think it's going to  
12 be in this case.

13 But are we allowed, you know, does  
14 that give us the ability to give people credit  
15 for the individual measures? If we excluded  
16 those individual measures and subsequently  
17 when we go out to get this and look at it  
18 again prospectively now in real life, are we  
19 allowed to divide it up after the fact?

20 So I don't know what the  
21 precedence is and --

22 DR. BURSTIN: I'll start. So

1 essentially, our requirements for our  
2 composite framework is that each measure needs  
3 to be individually evaluated as a stand-alone  
4 measure, and its role within a composite.  
5 Then you need to make a decision whether those  
6 individual components have worth on their own  
7 for accountability purposes.

8           Would you want to see, for  
9 example, just beta blocker without ACE/ARB?  
10 Would you want to see any one of those  
11 individually, or is the composite, because  
12 it's all or none, is it a stronger measure  
13 overall, and therefore well of course you  
14 would want to be able to divide this up for  
15 quality improvement purposes internally, to  
16 say hey, we're really failing on ACE/ARBs, but  
17 we're great on beta blockers.

18           But the question is would you want  
19 to use that for an accountability function or  
20 public reporting, or would the composite  
21 really suffice? The issue of whether the  
22 composite's wrong, that can always be

1 addressed and fixed. That's not really  
2 something I would get too concerned about  
3 right now.

4 CHAIR GIBBONS: And I would second  
5 that, just from, you know, and Tom can chime  
6 in, because he probably knows the details of  
7 this. But certainly in terms of the Minnesota  
8 experience using composites, you can correct  
9 the deficiencies on, you know, once you sort  
10 of recognize, oh, we didn't quite get this  
11 numerator or this denominator or whatever.

12 If the overall spirit is correct,  
13 you can correct the deficiencies. That's not  
14 the issue, and it's just that from a public  
15 reporting standpoint, you now have a single  
16 number, and that number really counts more  
17 than the individual components. You do tend  
18 to, on an operational level internally, as  
19 Helen just said, look at what, where are we  
20 fouling up here, when you don't do well on the  
21 composite.

22 But Tom, do you want to comment at

1 all on that? He must be hungry. All right.

2 So I am told now that I misstated the vote, so  
3 especially for the people on the phone, the  
4 vote is supposed to be as follows:

5 One, we recommend the composite  
6 and the individual measures. Two, we  
7 recommend just the composite, or three, we  
8 recommend the individual measures. So further  
9 discussion on this before we vote, for those  
10 three options? Mark.

11 MEMBER SANZ: I'm just confused  
12 what this means. If we vote number one, does  
13 that mean people will have to report to both?

14 DR. WINKLER: It means you will  
15 have recommended for endorsement four  
16 measures, the three individual plus the  
17 composite.

18 CHAIR GIBBONS: So conceivably,  
19 yes. People would then conceivably have to  
20 report four things.

21 MEMBER SANZ: I see.

22 DR. MASOUDI: At the risk of

1 alienating the group, Ray, could I make a  
2 brief comment?

3 CHAIR GIBBONS: Absolutely.

4 DR. MASOUDI: And I apologize,  
5 because I know that you're waiting for lunch.  
6 But I would just say that it seems to me that  
7 based on many of the other measures that are  
8 out there and currently endorsed, that the  
9 individual components of this seem, including  
10 levels of performance, to conform to those  
11 criteria that have been used for endorsement  
12 elsewhere.

13 Also, I would suggest that having  
14 the endorsement of the entire group of  
15 measures will not involve duplicative data  
16 collection on the one hand, and provides us as  
17 implementers with more flexibility in terms of  
18 how to use the measures.

19 MEMBER SMITH: How does the  
20 composite measure work again? If we say we  
21 want the composite measure, then it's an all  
22 or none. Either you're managing your patient

1 correctly or you're not.

2 CHAIR GIBBONS: Right, correct.

3 So for example, you know, just pulling numbers  
4 out of the air, you might be 90 percent on  
5 Measure 1, 90 percent on Measure 2, 90 percent  
6 on Measure 3. But where you really are is 78  
7 percent.

8 MEMBER SMITH: Yes, I resonate. I  
9 think we ought to look at the total approach.

10 CHAIR GIBBONS: Rochelle.

11 MEMBER AYALA: Just an option for  
12 the title of the composite, which I think goes  
13 to a lot of what you've been talking about,  
14 and that is some -- I've seen it before, where  
15 sometimes they refer to these as the measure  
16 of ideal care, the MIC, the measure of ideal  
17 care, and then you define what is ideal care.

18 So like if you're looking at  
19 composite for the AMI indicators and you take  
20 out the ones that you think should be in that  
21 composite. From what you said before about  
22 anyone placing an ICD in a patient should have



1 these anyway, kind of sort of brings it to  
2 that level, as opposed to just is the patient  
3 on an ACE or a beta blocker.

4 CHAIR GIBBONS: We had a  
5 discussion on that for the composite measure.  
6 People didn't like the word all. I have no  
7 idea whether they like the word ideal. But  
8 there was a feeling that we should have the  
9 specific components listed in the title for  
10 clarity, and I think the measure developers  
11 indicated a willingness to do that. Is there  
12 other discussion on this vote before we vote?

13 MEMBER JEWELL: Ray, am I  
14 choosing one, two or three, or we're taking  
15 three separate votes?

16 CHAIR GIBBONS: No, no. The vote  
17 is, one, the composite and the individual  
18 measures; two, just the composite measure; or  
19 three, just the individual measures.

20 MEMBER JEWELL: Thank you.

21 CHAIR GIBBONS: And the question  
22 being asked is what is your recommendation for

1 overall endorsement?

2 MEMBER JEWELL: Thank you.

3 CHAIR GIBBONS: Yes, and that's  
4 fine. I'm glad you asked, so that we're all  
5 clear on that.

6 MEMBER RUSSO: And just one other  
7 question, because I wonder -- so the  
8 developers created the composite measure up  
9 front this time, which is, I think, a little  
10 different than what's been done in the past.

11 So if this were a yearly process  
12 and the group that developed this didn't have  
13 to wait three years, would they have -- I'm  
14 curious as to would you have just put out the  
15 individual measures first, or does it, you  
16 know.

17 If it wasn't waiting three years,  
18 as I'm getting the feeling that, you know,  
19 obviously they want, you know, us to consider  
20 all the measures separately plus a composite.  
21 But if there were a different process in NQF,  
22 maybe it would have been submitted

1 differently? Is that correct or --

2 DR. MASOUDI: Well originally this  
3 was submitted at the original call as the  
4 three individual measures. Again, the  
5 composite was submitted in response to the  
6 discussion at the last meeting around the PCI  
7 measure.

8 So this was an attempt to be  
9 responsive to the request for a composite  
10 measure for these processes of care for  
11 patients with ICDs.

12 CHAIR GIBBONS: And just for  
13 clarity, Fred, so we're entirely transparent,  
14 the developers would like to see everything  
15 approved, or just the composite?

16 DR. MASOUDI: Well, I think our  
17 preference would be that they all be approved,  
18 for the purposes of allowing us flexibility in  
19 terms of implementation. Again, I think the  
20 individual component measures seem to be on  
21 par with a variety of others. That of course  
22 is -- that final judgment is up to you.

1                   But our preference would be, if  
2                   it's possible, to have each of the measures  
3                   endorsed, if it's possible.

4                   MEMBER RUSSO: Just to clarify --

5                   CHAIR GIBBONS: Tom.

6                   MEMBER KOTTKE: Yes, if I could  
7                   just make one comment about the composite used  
8                   by Minnesota Community Measurement, for  
9                   example, the diabetes measurement, which  
10                  includes tobacco use, and the question has  
11                  arisen, if you have tobacco in there and you  
12                  have just smokers who aren't going to quit,  
13                  does this mean that the doc gives up on the  
14                  patient, the patient's other measures, because  
15                  they'll never achieve the composite?

16                  So I think this speaks for the  
17                  composite plus the individual measures for  
18                  that flexibility, if the proposers learn that  
19                  there's something in there that may have an  
20                  unintended consequence.

21                  CHAIR GIBBONS: Other discussion  
22                  before we vote?

1 (No response.)

2 CHAIR GIBBONS: All right. We're  
3 going to go ahead and vote.

4 DR. WINKLER: Dianne?

5 MEMBER JEWELL: One.

6 DR. WINKLER: Okay.

7 CHAIR GIBBONS: So there are 12  
8 votes one, that is the composite and the  
9 individual measures, and 8 votes two, just the  
10 composite measure. So we have approved the  
11 composite and the individual measures, and let  
12 me ask for help here, staff. Okay.

13 Since George is on a roll, and we  
14 have a feeling this will go faster before  
15 lunch than after lunch, we're going to do  
16 Measure 1530 at this time, prophylactic  
17 antibiotics prior to ICD.

18 MEMBER PHILIPPIDES: This measure  
19 looks at the proportion of patients who  
20 receive an ICD implant or lead procedure, that  
21 receive antibiotics within one hour. For some  
22 reason, if it's a fluoroquinolone or

1 vancomycin, two hours, Bruce, maybe you can  
2 help me with that one, prior to the procedure.

3 The impact, I think, has had about  
4 120-140,000 ICDs placed per year. Infection  
5 rates vary between about .7 percent and 3.28  
6 percent, and when these get infected, they're  
7 a huge cost and it's a high-morbidity  
8 situation for the patient. So I think the  
9 impact is high.

10 I could not find evidence of a  
11 performance gap data, but I've been bad at  
12 finding data it seems. Can we ask if there is  
13 such data? They mentioned that in the next  
14 registry, it will become available. But I  
15 didn't see any, as far as the performance gap.  
16 Can I get some clarification on that?

17 DR. MASOUDI: Yes. We do --  
18 Krystine McGuinn, are you there?

19 MS. MCGUINN: (off mic)

20 MEMBER KOPLAN: What is the gap,  
21 because at my institution, if anyone doesn't  
22 get antibiotics, it's a mistake, and also I

1 think the last time like JCAHO came through,  
2 that was one of their requirements, that they  
3 had -- that every patient had to have  
4 antibiotics. So I would think the percentage  
5 is very high.

6 DR. MASOUDI: Yes. The Joint  
7 Commission focuses on, I think, general  
8 surgical procedures, if I'm not mistaken. So  
9 this is an area that I don't believe is  
10 actually captured in the Joint Commission --  
11 and skip the surgical measures.

12 I'm finding the data that we have,  
13 again because this is worked into the more  
14 recent version of the registry, we don't have  
15 the same level of experience with this  
16 particular measure as we do the others. I'm  
17 just looking for the numbers here. I believe  
18 they were supplied, but it was probably as an  
19 appendix. Are ACC staff there?

20 CHAIR GIBBONS: Yes, they are, and  
21 we're all looking for the data as we speak.

22 DR. MASOUDI: Okay.

1                   MEMBER KOPLAN:  The three  
2                   electrophysiologists in the room, is it like  
3                   100 percent at each of our --

4                   MEMBER RUSSO:  A hundred percent,  
5                   I agree, but I don't know what the data is.  
6                   Is that on the ICD registry form or is that --

7                   CHAIR GIBBONS:  You must use the  
8                   mic.

9                   MEMBER RUSSO:  But we should know  
10                  that data, right?  Maybe it's not 100 percent.

11                  DR. MASOUDI:  Yes.  So here's the  
12                  data that I have here.

13                  MEMBER PHILIPPIDES:  I think I  
14                  just found the document that you were looking  
15                  for, Distribution of Prophylactic Antibiotics,  
16                  and I think, if I'm reading this correctly,  
17                  the median was at about 100 percent, and the  
18                  25th percentile was .9889.

19                  DR. MASOUDI:  That's what I have  
20                  as well.  So again, it's sort of like one of  
21                  these -- rather than many of the process  
22                  measures, this is almost like as much a never



1 event as I think you were alluding to before.

2 MEMBER PHILIPPIDES: Okay. Shall  
3 I proceed?

4 CHAIR GIBBONS: Yes. Yes, please.

5 MEMBER PHILIPPIDES: So there is  
6 some evidence in the form of prospective  
7 trial, looking at antibiotics versus not, and  
8 there's no question. It was actually stopped  
9 early, that trial, because the people who  
10 didn't get prophylactic antibiotics had a high  
11 risk of infection.

12 So I think overall, there's a high  
13 risk population. This does matter, this  
14 administration of antibiotics, but I'm a  
15 little bit concerned about the very, very,  
16 very small impact gap across the country.

17 CHAIR GIBBONS: Other discussion  
18 on this point?

19 MEMBER SNOW: Well, if everybody's  
20 getting it, then it's kind of topped out,  
21 isn't it? Of course, it's important. I don't  
22 think, you know, the antibiotics, implanting

1 a device like that. That's almost a no-  
2 brainer. But if everybody's getting it and  
3 it's under a registry and the reporting's 100  
4 percent, there's not going to be any gain from  
5 separately reporting it, is there?

6 MEMBER PHILIPPIDES: Also as a  
7 general rule, there's so much onus now placed  
8 on avoiding hospital infections, that I think  
9 this is just going to take care of itself,  
10 without having to adopt this particular  
11 measure. I mean everybody is on top of  
12 hospital infection rates.

13 CHAIR GIBBONS: It would seem as  
14 if 1(b) is not met.

15 MEMBER PHILIPPIDES: Yes.

16 CHAIR GIBBONS: Is there other  
17 discussion before we vote? Helen?

18 DR. BURSTIN: I was just going to  
19 say, we are in the midst of our surgery  
20 endorsement maintenance project, just like you  
21 guys, and they are reviewing those skip  
22 measures. So one other possibility is to

1 ensure that ICDs are included in the list of  
2 procedures covered by the skip measure.

3 CHAIR GIBBONS: Now there's a  
4 provocative suggestion. The staff are, they  
5 may be hungry, but they're still thinking.  
6 All right.

7 MEMBER RUSSO: Out of curiosity,  
8 do they have a gap or are they up to 100  
9 percent also for other pre-op antibiotics?  
10 Doesn't everyone do that everywhere all the  
11 time? How could you not?

12 DR. BURSTIN: It's dramatically  
13 increased over time. There are still some  
14 areas where there's a gap. But again, it's  
15 one of those interesting areas. We're  
16 starting to look at some of the population  
17 differences. It's not uniform.

18 CHAIR GIBBONS: Okay. I think we  
19 should vote on importance.

20 DR. WINKLER: Dianne?

21 MEMBER JEWELL: No.

22 DR. WINKLER: Thank you.

1 CHAIR GIBBONS: So the vote is 3  
2 yes and 17 no. So per our protocol, we are  
3 through discussing this, but we will urge the  
4 staff to carry the message to the surgical  
5 committee, to try to make sure that ICD  
6 implants are included as a procedure in their  
7 measures.

8 We now want to make sure we make  
9 available time for any other members of the  
10 public present, or present by phone, to  
11 comment.

12 DR. WINKLER: Operator, is there  
13 anyone who'd like to ask a question or make a  
14 comment on the phone?

15 OPERATOR: If you do have a  
16 question or comment over the phone, please  
17 press \*1 at this time. We do have a question.  
18 Christopher, your line is open.

19 MR. DEZII: Great, thank you. My  
20 name is Christopher Dezii from the Bristol-  
21 Myers Squibb Company. We are the makers of  
22 coumadin, as well as having a direct factor

1 10(a) inhibitor in a full development program,  
2 and I am a member of the NQF Supplier and  
3 Industry Council.

4 Just a brief question on 1525,  
5 chronic anticoagulation measure. Just to  
6 confirm, did the steering committee recommend  
7 the measure to include other anticoagulants  
8 with an FDA-approval threshold?

9 CHAIR GIBBONS: That was a  
10 recommendation that we made back to the  
11 developer.

12 MR. DEZII: Thank you, and now  
13 here's a follow-up to that, but this is  
14 probably an NQF question, and it's around  
15 harmonization. If and when the signed measure  
16 approaches, is approved, will that prompt a  
17 review to update all measures containing  
18 exclusive reference to warfarin?

19 DR. BURSTIN: Chris, this is  
20 Helen. All of the VTE measures are going  
21 through currently our processes in safety  
22 later this year, and I'm sure this issue will

1 likely come up. I can't make assurances that  
2 it will be a uniform process.

3 MEMBER SMITH: Wait a minute,  
4 though. Have there, I don't know that  
5 warfarin has been tested in all circumstances.  
6 So I think it would be highly illogical to  
7 broadly include this for all mention of  
8 warfarin. I don't, I'm not sure the basis for  
9 your question.

10 MR. DEZII: Well, the basis of my  
11 question is that there are a number of  
12 different measures, and one that comes to  
13 mind, I believe it's a heart failure measure,  
14 for patients with afib with warfarin  
15 utilization. I just assumed it might be more  
16 reasonable, based on the discussion going  
17 forward and allowing for innovation, that it  
18 would be updated to include other, or you  
19 know, or just anticoagulants, oral  
20 anticoagulants.

21 MEMBER SMITH: Warfarin is used  
22 for patients with prosthetic valves. It may

1 have normal sinus rhythm. Can you quote an  
2 RCT there?

3 MR. DEZII: For what, the measure?

4 MEMBER SMITH: Yes.

5 MEMBER RUSSO: It's the level of  
6 evidence for the other anticoagulant, which is  
7 only one that's in that focused update  
8 guideline. But it's a large randomized  
9 clinical trial, compared to -- it's for a  
10 specific indication, and they excluded  
11 patients with valvular, you know, prosthetic  
12 valves.

13 MR. DEZII: Non-valvular, yes.

14 MEMBER RUSSO: So it's a specific  
15 study looking at a specific indication that  
16 caused it to be approved by the FDA. That was  
17 what they were studying, is it a non-valvular,  
18 atrial fibrillation group that did not have --  
19 you were excluded if you had renal failure,  
20 excluded if you had a metal valve. So in that  
21 group is what the guideline came out with.

22 MR. DEZII: Right, right. Yes.

1 I'm not looking for answers; Helen pretty much  
2 answered it, that there is a prompt to review  
3 these. That's all. But thank you.

4 CHAIR GIBBONS: And you probably  
5 didn't hear that comment, but it is hopefully  
6 based on the evidence, and that is, I think,  
7 what the committee had just kind of --

8 DR. WINKLER: Reinforced.

9 CHAIR GIBBONS: Reinforced, that's  
10 right. That's a good word. Reinforced with  
11 several comments here.

12 MR. DEZII: Great, thank you.

13 MEMBER SANZ: I think the actual  
14 stated vote was on use of FDA-approved drug  
15 for non-valvular atrial fibrillation. It was  
16 not for all warfarin indications.

17 CHAIR GIBBONS: Correct.

18 MR. DEZII: Yes, agreed.

19 DR. WINKLER: Are there any other  
20 --

21 MEMBER SANZ: By the way, it is a  
22 Class 1 indication for dabigatran. We found



1 out later after that vote. So there is no  
2 disharmony between FDA and the guidelines.

3 MR. DEZII: Okay.

4 DR. WINKLER: Okay. Are there any  
5 other questions from the phone?

6 OPERATOR: Not at this time.

7 DR. WINKLER: Thank you. Anybody  
8 in the room?

9 (No response.)

10 CHAIR GIBBONS: All right. We're  
11 going to break for lunch, and we're going to  
12 hope that we can be back and starting to work  
13 at 1:15, please.

14 (Whereupon, the above-entitled  
15 matter went off the record at 12:29 p.m. and  
16 resumed at 1:17 p.m.)

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1:17 p.m.

CHAIR GIBBONS: So we're now going to move on to another sort of composite measure, 0964, which is on PCI. It reflects our discussion at the previous meeting. Fred, do you want to make a comment?

DR. MASOUDI: Yes sure, Ray. Thank you again for having me back. This measure is in direct response to the committee's request for an all or nothing composite for the clopidogrel class. Aspirin and statin after PCI measures that were considered and were viewed as individually scientifically sound during the last meeting.

There were some issues around the level of performance for the two anti-platelet drugs. The data, so this composite is quite similar to the composite that has been discussed before, so I'm sure the issues around the naming would apply to this measure.

This measure differs in that

1 rather than focusing on two medications, it's  
2 three medications. Again, two different anti-  
3 platelet agents and statins. The testing  
4 results should be included in your packages.  
5 The overall performance on this measure, is  
6 about, I believe it's -- I'm sorry.

7 It's 86 percent at the median. So  
8 it's certainly a reasonable gap at the median  
9 level, and around 90 percent below the highest  
10 quartile.

11 The values with respect to safety  
12 net versus non-safety net, the proportion of  
13 patients within a hospital that are white, the  
14 male versus female at the individual level,  
15 the age greater than 65 and race data are all  
16 included in your packets, as requested by the  
17 committee at the last meeting.

18 Again, I believe that conceptually  
19 this is quite similar to the previous measure.  
20 It's just in a different population and using  
21 different processes of care.

22 CHAIR GIBBONS: Okay. Thank you,

1 Fred, and this, the discussion of this measure  
2 will be led by Mark Sanz. Mark, you're on.

3 MEMBER SANZ: Thank you. I'd like  
4 to thank Fred and the ACC for coming up with  
5 this composite measure, because this was  
6 highly asked for at the last meeting. I think  
7 this is very well done. The gap is -- well,  
8 the first thing would be the impact is high,  
9 since this is every PCI in the United States.

10 The performance gap actually is  
11 much higher when you have a composite measure  
12 than with any of the individuals. So  
13 previously, we had been up in the 95 percent  
14 range, but now the mean is down in the 85  
15 percent range, and the evidence is high.

16 CHAIR GIBBONS: Are there other  
17 comments or questions before we vote on  
18 importance?

19 (No response.)

20 CHAIR GIBBONS: If not, let's go  
21 ahead and vote.

22 DR. WINKLER: Dianne?

1 MEMBER JEWELL: Yes.

2 DR. WINKLER: Thank you.

3 CHAIR GIBBONS: So the vote is 19  
4 to 0. Scientific Acceptability, Mark?

5 MEMBER SANZ: The specifications  
6 are good. My only concern was the, again  
7 getting back to, not that I want to bring it  
8 up again, but the warfarin and so on. Do we  
9 want to strictly limit it to these three  
10 drugs?

11 There are newer P2Y12 agents  
12 coming, Ticagrelor and some others, or do we  
13 want to just say P2Y12 approved agent, because  
14 does it say in here, list those three drugs,  
15 Tica, Plavix and Prasugrel.

16 DR. MASOUDI: And could I respond  
17 to that by saying that's an excellent point?  
18 These, the measure is intended to be designed  
19 to be responsive to changes in FDA approval  
20 for medications that might substitute for  
21 these. So should Ticagrelor be approved by  
22 the FDA, the measure can and will be changed

1 to reflect that.

2 MEMBER SANZ: Okay. The other  
3 thing would be, and maybe you can help me with  
4 this, Fred, would be the statin. So it's  
5 pretty obvious if your LDL is over 100, it's  
6 probably obvious if your LDL is over 70. Do  
7 you get dinged if your LDL is 50 and you don't  
8 put someone on a statin, and what if you have  
9 the main problem being a low HDL and you  
10 choose to use niacin and Lopid, something like  
11 that?

12 DR. MASOUDI: Yes. My recollection  
13 -- I'm sorry. I need to find the submission  
14 for the statin measure. My recollection is is  
15 that this only applies, for the purpose of  
16 accountability, to patients with LDLs that are  
17 at or above 100, but allow me to recheck the  
18 specifications.

19 MEMBER SMITH: Are you looking for  
20 data to support the use of statins with LDLs  
21 less than 100?

22 DR. MASOUDI: That's not the issue,

1 the specification.

2 MEMBER SMITH: I can easily give  
3 you the data on that one.

4 DR. MASOUDI: Yes.

5 MS. FITZGERALD: So Fred, this is  
6 Susan from the ACC, and we had originally  
7 required the LDL greater than 100, and the  
8 committees that reviewed this actually took  
9 that requirement off.

10 DR. MASOUDI: Okay.

11 MS. FITZGERALD: Do you remember  
12 that, Fred?

13 DR. MASOUDI: So at this point,  
14 there's no LDL restriction. But if one were  
15 to write that one was not going to prescribe  
16 a statin because of an LDL that they felt was  
17 in the clinical target range, although there  
18 is some debate about that, that patient would  
19 be excluded.

20 CHAIR GIBBONS: There's flexibility  
21 for physician judgment.

22 MEMBER SANZ: All right, and then

1 my only other concern would be 2(a)(8), the  
2 exclusions. We've had a discussion about  
3 hospice already. I really don't want to  
4 relive that. But transfer to an acute  
5 facility. If someone's doing free-standing  
6 cath lab PCI and transfers to another  
7 facility, that would be excluded here and I  
8 don't think that should be.

9 DR. MASOUDI: Yes. This is again -  
10 - this issue was discussed with respect to the  
11 individual component measures. Now there was  
12 some debate about that. Again, this is an  
13 issue of -- you know, again, this just  
14 reflects the specifications of the component  
15 measures, and to that extent, that exclusion  
16 applies across each one of them.

17 This again reflects back to the  
18 conversation that was had at the last time,  
19 when this issue was raised and the measures  
20 were moved forward, but I hear what you're  
21 saying.

22 MEMBER SANZ: Okay. There is a



1 whole thing on disparities separate from the  
2 guidelines. It's nice what they do. So I  
3 don't want to go into it at length.

4 CHAIR GIBBONS: Yes, and we'll be  
5 looking over that data tomorrow. It's pretty  
6 interesting.

7 MEMBER SANZ: It's interesting --

8 CHAIR GIBBONS: It really is  
9 interesting.

10 MEMBER SANZ: Yes.

11 CHAIR GIBBONS: I think we'll be  
12 glad we made that request. Are there other  
13 comments or questions before we vote on the  
14 Scientific Acceptability?

15 (No response.)

16 CHAIR GIBBONS: If not, let's go  
17 ahead and vote.

18 DR. WINKLER: Dianne?

19 MEMBER JEWELL: Completely.

20 DR. WINKLER: Thank you.

21 CHAIR GIBBONS: Sixteen completely,  
22 4 partially. We'll now move on to Usability.

1                   MEMBER SANZ:  So, you know, I think  
2                   this has all been discussed before.  It's very  
3                   usable.  It's been used in most cath labs in  
4                   the United States already.  Unlike a lot of  
5                   other areas, most cath labs already submit to  
6                   NCDR, and more are coming all the time, and it  
7                   clearly adds value to existing measures now  
8                   that it's a composite.

9                   CHAIR GIBBONS:  Other comments or  
10                  discussion?

11                  (No response.)

12                  CHAIR GIBBONS:  Okay.  Let's go  
13                  ahead and vote.

14                  DR. WINKLER:  Dianne?

15                  MEMBER JEWELL:  Completely.

16                  DR. WINKLER:  Thank you.

17                  CHAIR GIBBONS:  So completely, 19;  
18                  partially, 1, and now finally, Feasibility.

19                  MEMBER SANZ:  The data is generated  
20                  during care.  You can get it either on paper  
21                  or electronically, although I think you have  
22                  to submit electronically.  Exclusions we've

1 talked about, and there aren't a whole lot of  
2 reasons for inaccuracy.

3 CHAIR GIBBONS: Other comments or  
4 questions?

5 (No response.)

6 CHAIR GIBBONS: All right. Let's  
7 go ahead and vote on Feasibility.

8 DR. WINKLER: Dianne?

9 MEMBER JEWELL: Completely.

10 DR. WINKLER: Thank you.

11 CHAIR GIBBONS: 19 completely, 1  
12 partially, and then finally, we're going to  
13 vote now. This is just to endorse this  
14 composite, the first vote.

15 MEMBER SMITH: Ray, can I ask a  
16 question about -- I've already voted, no major  
17 hang-ups here, but are we, when we do this  
18 composite, will the single measures be  
19 included like we did with the heart failure  
20 one, where we had -- we're going to look at  
21 the whole thing, and then --

22 CHAIR GIBBONS: We're going to have

1 a subsequent vote right now.

2 DR. WINKLER: Dianne?

3 MEMBER JEWELL: Yes.

4 DR. WINKLER: Thank you.

5 CHAIR GIBBONS: So the vote is 18  
6 yes, 1 no. So we've approved this composite.  
7 So in terms of your question, Sid, we're now  
8 going to have the same discussion that we had  
9 about the earlier composite and the individual  
10 measures.

11 MEMBER SMITH: Okay. So I just  
12 think that we would be well served if there  
13 were some criteria about composite measures.  
14 We said that all composite measures we'll do  
15 one way, whether there are certain concepts  
16 that govern whether or not the individual  
17 measure should be reported.

18 Otherwise, it could be termed  
19 capricious, sort of, you know, have we had  
20 lunch yet? How was the decision -- what is  
21 the basis for the committee to make this  
22 decision? I just think that the process would

1 be well served by some criteria.

2 CHAIR GIBBONS: Okay, staff.

3 Helen, you're on.

4 DR. BURSTIN: Actually, I think  
5 would we'd like to do is actually share with  
6 the committee the composite framework that we  
7 adopted last year.

8 I think just very much in a quick  
9 summary, the idea would be to determine, for  
10 the sake of NQF endorsement, if the end goal  
11 really is its purpose to be used for  
12 accountability and quality improvement, but  
13 not just QI internally, but really some  
14 external-facing function around accountability  
15 and public reporting.

16 Do you need to continue -- I'm  
17 sorry. I'll take that back. Is there  
18 additive value beyond the composite, in having  
19 the individual measures individually reported  
20 on for one of those accountability functions,  
21 and I'll pull up the exact language for you.  
22 But essentially, it's really a value metric,

1 that if you have the overall comprehensive  
2 nature of care, is there a need for the  
3 individual elements, or can it -- or is the  
4 value really fully subsumed in that composite?

5 MEMBER SMITH: Well, my reaction  
6 from a quality-improvement standpoint is there  
7 is value. It would be very important to know  
8 --

9 DR. BURSTIN: Let me just finish  
10 with that, because again, all measures that  
11 are out there for QI, there's no reason the  
12 individual components couldn't be used for QI  
13 at every one of your institutions. The issue  
14 is NQF doesn't endorse measures for only QI.

15 So certainly individual components,  
16 continue to use them, you know, as you see  
17 fit, to improve care. The issue is for  
18 accountability. Is there value in having the  
19 individual measures?

20 MEMBER SNOW: All right. The idea  
21 that I see here is that the best use of the  
22 composite measure is the public use. The

1 individual QI issues remain and they'll still  
2 be available. But for the public, and the  
3 composite is really more like looking at an  
4 episode of care, where the individual ones are  
5 looking at elements of care. So that's where  
6 that comes in, I think, the accountability  
7 piece.

8 CHAIR GIBBONS: Devorah.

9 MEMBER RICH: I want to agree with  
10 Roger. I'm sorry, I want to agree with Roger.  
11 What I was thinking from a public-reporting  
12 standpoint, Mark said that the measures are  
13 relatively high in and of themselves. It's  
14 only when you get to the composite that you  
15 see where the gaps are.

16 The last time we did this vote, I  
17 actually voted for number one, because I felt  
18 that there was an opportunity for the public  
19 to learn more. But I think in this case,  
20 there's not that much of an opportunity, and  
21 we don't want to overwhelm people.

22 So I think from a public-reporting

1 point of view, it makes sense for this measure  
2 only to focus on the composite.

3 CHAIR GIBBONS: David.

4 MEMBER MAGID: Fred, we should  
5 probably -- I don't know, Fred. Are you still  
6 on?

7 DR. MASOUDI: Yes, I'm present.

8 MEMBER MAGID: Fred, you had a  
9 reason why you wanted the individual measures.  
10 Could you just remind us what that was?

11 DR. MASOUDI: Ideally, from the  
12 perspective of implementation, I think that  
13 just having the availability of the capacity  
14 to use for the purposes of reporting the  
15 individual components is useful, because  
16 oftentimes in the reporting, you know, you'd  
17 like to report the overall rate of a  
18 composite, and then provide some insights into  
19 where the deficiency comes from, because of  
20 course, you know, that's the downside of  
21 composites is that you lose some of the  
22 granularity.



1           So from our perspective, ideally we  
2 would have the flexibility to use those things  
3 for public reporting purposes. I do  
4 understand how, particularly for -- I mean I  
5 would say for the statin measure for sure,  
6 levels of performance for the statin measure  
7 are on par with the ACE inhibitor measure for  
8 systolic dysfunction in ICD patients.

9           There actually is still a fairly  
10 substantial persistent gap in care there.  
11 Obviously, not as much so for the aspirin and  
12 clopidogrel. So I understand, you know, the  
13 concerns about the issue of those two measures  
14 in particular being topped out.

15           But again, that's why I was, you  
16 know, hopeful for the possibility of having  
17 the individual component measures used for the  
18 purposes of public reporting. But we  
19 certainly understand with respect to the  
20 latter two measures about the anti-platelet  
21 agents. Their performance is obviously high.  
22 That's apparent.

1                   MEMBER SANZ: Fred, this is Mark.  
2                   As far as QI goes, even if we voted this was  
3                   only composite measure, you could report  
4                   through the NCDR all the individual members to  
5                   the group.

6                   DR. MASOUDI: Yes. There's no  
7                   doubt about that. I think that was Helen who  
8                   made that point, which is a good one. Again,  
9                   I think sometimes in the context of public  
10                  reporting, you know, while composites are  
11                  extremely useful to provide an overall picture  
12                  of care, in many cases, I think experience has  
13                  shown that, you know, for the purpose of  
14                  transparency, it's nice to have the individual  
15                  components reportable, so that there can be an  
16                  understanding of where the composite came  
17                  from, you know, where the performance in the  
18                  composite came from.

19                  MEMBER RUSSO: I guess is there any  
20                  situation we might want, since the individual  
21                  composites might include, not for this example  
22                  we're looking at now, if there was any

1       disparities within, say, you know ACE or ARBs.  
2       Maybe your hospital has a lot of renal failure  
3       patients and maybe if you divided it out --  
4       well, I guess that would be an exclusion.

5               I'm trying to think is there any  
6       situation where we might want to know about  
7       the performance of the individual measure  
8       related to disparities or any other features  
9       that we wouldn't be able to get out of the  
10      whole group of measures together, and the  
11      second part is also do -- it was different  
12      with the previous one, the composite measure.

13              The individual ones really haven't  
14      been out there a while. This would be a  
15      little different. So we already know there's  
16      high performance, or we have a suggestion that  
17      there's probably high performance also on the  
18      one we looked at earlier today. Might we want  
19      to consider those type of things too?

20              For this one, I don't -- it  
21      doesn't, since they're high -- I don't know  
22      that there's much benefit, because they're

1 high performing already, and we know that, for  
2 the public, and even for the individual.

3 CHAIR GIBBONS: Christine?

4 MEMBER STEARNS: Can I just ask how  
5 much more of a burden it is for providers to  
6 provide the individual measures versus the  
7 composite?

8 (Simultaneous speaking.)

9 CHAIR GIBBONS: I think the  
10 answer's none.

11 DR. MASOUDI: Yes. There's no  
12 additional burden, in that public data that  
13 are submitted for the purposes of computing  
14 the individual measures are those that are  
15 used to compute the composite. So that the  
16 onus is basically on the reporter to compile  
17 the data in a different manner. But no  
18 additional onus on the provider.

19 CHAIR GIBBONS: So the only  
20 potential burden is on somebody looking at the  
21 public report being that provider or the  
22 public, to say which one of these four numbers

1 is really important.

2 MEMBER MAGID: Well, and is there  
3 a risk that they won't then report the  
4 composite?

5 MEMBER RUSSO: The only other part  
6 of that is not again, in a subsequent measure  
7 later today, is how they're weighted. In this  
8 one, you know, they may have equal weight or  
9 how are they weighted in the individual. How  
10 is that whole formula calculated? So I think,  
11 I still think there's some value to the  
12 individual measures in many instances.  
13 Probably not this one here, but --

14 MEMBER SMITH: So before, with  
15 failure, we voted for the composite plus the  
16 individual measures. Why is this, and  
17 actually I voted just for the composite  
18 before, and after discussing with Helen, I  
19 understand. I'm actually beginning to come  
20 around. I don't understand why this is any  
21 different from what we did before.

22 I mean if it was correct to say

1 composite plus individual before, why isn't it  
2 correct to say that now, and who are we to say  
3 what the public is interested in? Maybe the  
4 public is a little more interested in than  
5 just a simplified number. Pretty intelligent  
6 people out there.

7 MEMBER KOTTKE: Let, if I can --

8 CHAIR GIBBONS: Tom.

9 MEMBER KOTTKE: And I don't know  
10 how much this has a relationship here, but we  
11 have -- we report a composite lifestyle  
12 metric, physical activity, nutrition, alcohol  
13 and smoking. While I think the lie rates are  
14 very high for alcohol and physical activity,  
15 it's very clear that we can't do anything to  
16 our composite measure unless we improve  
17 nutrition, because only about ten percent of  
18 people say they get five fruits and  
19 vegetables.

20 So there's some advantage. I mean  
21 that really tells us how, what we have to do  
22 to change. So I think there is some advantage

1 at least to knowing the rates of the  
2 individual measures, and I'm still not clear  
3 in my own mind whether we ought to report,  
4 because you can get numbers after numbers  
5 after numbers, you know, page after page after  
6 page of these.

7 MEMBER RUSSO: And I think we  
8 should --

9 CHAIR GIBBONS: They've got to be  
10 in the context of all of the growing number of  
11 measures that are, you know, publicly  
12 reported. Can the public actually find what  
13 is important in these big lists? That's the  
14 downside.

15 MEMBER RUSSO: And I think we  
16 shouldn't assume that the public doesn't want  
17 to know. If you have something combining  
18 outcome measures like mortality with process  
19 measures, depending on how it's weighted, the  
20 public may want to know the mortality is high.  
21 But meanwhile they're using, you know, beta  
22 blockers.

1                   MEMBER PHILIPPIDES: So let's say  
2                   that public knew that at your hospital, after  
3                   the patient was discharged after a procedure,  
4                   there was a 99 percent rate of aspirin use.  
5                   Does that tell them anything?

6                   It tells them part of the story.  
7                   I mean really what you want to know is, does  
8                   somebody who goes to this hospital get all of  
9                   the medications they're supposed to after  
10                  their intervention, so that they've gotten  
11                  adequate care.

12                  So I would argue that if sometimes  
13                  like giving -- as intelligent as the public  
14                  might be, that's debatable, sometimes giving  
15                  them part of the story when they've haven't  
16                  gone to medical school, it's not that helpful.  
17                  Whereas I think this composite measure is more  
18                  helpful.

19                  Internally, I like the individual  
20                  measures. But as far as reporting out to the  
21                  public and rating our performance, I think the  
22                  composite makes more sense to me.



1 CHAIR GIBBONS: Dana.

2 MEMBER KING: As I recall, that's  
3 exactly the rationale for why we wanted the  
4 composite measures. We want them to reflect  
5 proper care in situation X. You had a PCI,  
6 proper care and proper discharge medications  
7 or ICD placement, and that's what we want you  
8 to get.

9 In these instances, we were told by  
10 the people around the table that it should be  
11 100 percent, not in the lifestyle thing, where  
12 it's obviously a little unrealistic, to expect  
13 everyone to be, you know, eating fruit all day  
14 long.

15 (Laughter.)

16 MEMBER KING: I mean some -- I  
17 mean but I don't think that I was alone in  
18 thinking that the composite was a way to  
19 reduce the total number of measures and  
20 measure burden, and also capture the proper  
21 care.

22 The individual things that make up

1 the composite are not lost when we do it this  
2 way, because that's the way they're  
3 calculated, and that can be fed back to any  
4 group or hospital or whatever that wants to  
5 focus on it for QI or other purposes, is my  
6 understanding.

7 So I don't think the information is  
8 lost in the composite when we do it this way.

9 MEMBER JEWELL: This is Dianne.  
10 You know, my sense is that the public wants to  
11 know what is the best way to identify quality,  
12 and when we produce measures or vet measures  
13 and say these measures reflect good quality,  
14 if there are a lot of them that seem to be  
15 talking about the same thing, then the  
16 public's next question is okay, but which one  
17 of these helps me do that best.

18 And it's true that they might be  
19 curious about other things, but I feel like  
20 our obligation is to be as clear as we can  
21 when we know which is the best way to reflect  
22 the good care that was just described. So I'm

1 leaning more towards composite. If the  
2 composite is as good as the sum of its parts,  
3 why do we need the parts?

4 DR. MASOUDI: May I just make an  
5 additional comment, Ray, if I may?

6 CHAIR GIBBONS: Sure, Fred, sure.

7 DR. MASOUDI: I mean, you know, I  
8 wonder though, if to some extent this couldn't  
9 be in the purview of the developer, and what  
10 I mean by that is that, you know, FTS has  
11 engaged in a voluntary public reporting system  
12 whereby they report an overall composite.  
13 It's actually a rollup of processes of care  
14 and outcomes of care. It's a very nice system  
15 that they have.

16 But they also, so when they report  
17 that, they report it out as a one-two-three  
18 star system. It's a very nice composite.  
19 It's extremely rigorous. But they have found  
20 in their experience that people, some people,  
21 and I think it's probably inappropriate to  
22 generalize to the public in general, but some

1 people are interested in understanding what's  
2 under the hood, and which components of that  
3 people are doing well and not.

4 So when I talk about having more  
5 flexibility to use this in the context of a  
6 public reporting program, that's really what  
7 I'm talking about, is you know, again, some  
8 people won't want to know that, and some  
9 people may not be sophisticated enough to  
10 understand it.

11 But I think the public is fairly  
12 heterogeneous, different levels of  
13 sophistication, different levels of desiring  
14 to know, you know, what makes up a composite.  
15 So that's sort of my perspective from the  
16 developer's point of view.

17 CHAIR GIBBONS: Okay, Sid.

18 MEMBER SMITH: So it gets back to  
19 my original question. If we're going to tell  
20 them what's under the hood when they have  
21 heart failure, why aren't we telling them  
22 what's under the hood when a stent's put in?

1       Shouldn't there be criteria that could  
2       uniformly be applied?

3                   DR. BURSTIN:  Yes, and let me just  
4       weigh in.  Again, I think there's lots of  
5       additional.  These meetings are always very  
6       helpful for us, because it does identify  
7       additional areas where we need guidance, and  
8       I think you've identified a clear one.

9                   What we've said to date is that the  
10       determination the committees need to make is  
11       whether the component measure, meaning of the  
12       composite, is important enough in its own  
13       right as an individual measure.  So that,  
14       sure, the composite, you're all agreeing, is  
15       completely -- but should those individual  
16       measures, can they stand alone?  Are they  
17       important enough on their own for a measure of  
18       quality, and that's really the determination  
19       you need to make.  I think there are two  
20       related issues that we've heard a lot about  
21       over the last year that I think we need to  
22       address, one of which is there are different

1 kinds of composites.

2           So sometimes there are things where  
3 the individual elements within a composite are  
4 somewhat co-dependent on each other, and  
5 you've kind of got to do the whole package to  
6 really affect the outcome. One question  
7 should be, is this an example of that.

8           In that instance, those should be  
9 the kind of bundles that we've already  
10 endorsed, like the prevention of VAP or the  
11 prevention of CLAB. Do we need to do all four  
12 or five of those elements to actually get the  
13 desired outcome? This would be a question for  
14 you.

15           Again, we haven't given that level  
16 of guidance, and I think that's -- I think  
17 those are the kind of things I'd be happy to  
18 try to get more guidance for you. But I  
19 think, and I'm sorry. The last point is it's  
20 not exactly clear whether, if you endorse the  
21 composite, it necessarily means you can't look  
22 at the individual components of the composite.

1                   But it doesn't mean you would  
2 necessarily want to look at one of these in  
3 isolation.

4                   MEMBER RUSSO: Or would one other  
5 way to look at it is is when the individual  
6 components no longer have any value. So if  
7 they're out there and everything is 99  
8 percent, get rid of it, as opposed to what we  
9 saw earlier today, with the one we voted down  
10 as individual measures. It really hasn't been  
11 out there showing that it's useless to look at  
12 individuals. So I mean there's different ways  
13 to do it. I don't know which is the best.

14                  CHAIR GIBBONS: Okay. I think this  
15 has been a healthy discussion about an  
16 evolving issue. Let's all agree it's an  
17 evolving issue. So I am usually the one who's  
18 responsible for those sorts of things.

19                  We'll ask two important questions.  
20 Has anybody's voting gadget been compromised?

21                  (Laughter.)

22                  CHAIR GIBBONS: Two? Do we need to

1 test them? Yes. Let's, maybe we can set up  
2 a question. We'll use this question as our  
3 set-up test. It doesn't look like anybody was  
4 hurt, and then the third question is, is  
5 anybody's computer hurt?

6 All right. So before the rest of  
7 us vote, let's have the two of you test your  
8 gadgets and see if they still work, by just  
9 voting on this one right now. Both are  
10 working. The meeting can continue.

11 Okay, there we go. All right. So  
12 I think we'll go ahead, then, and wait a  
13 minute. We'll just wait a second and let  
14 Roger fully recover here. Okay. We'll go  
15 ahead and vote, and just to remind everybody,  
16 it's one is the composite and the individual  
17 measures. Two is just the composite. Three  
18 is just the individual measures.

19 He gave me the high sign. I think  
20 he's going to be back momentarily. We voted  
21 for him. No.

22 (Laughter.)



1 DR. WINKLER: Dianne?

2 MEMBER JEWELL: Two please.

3 DR. WINKLER: Okay.

4 CHAIR GIBBONS: Wow. So the oohs  
5 and aahs you hear on the phone is because  
6 there were 8 votes for the composite and the  
7 individual measures, and 10 for just the --  
8 11. Sorry, 11 for the composite.

9 MEMBER KOTTKE: See, I knew I'd get  
10 you one time for this.

11 CHAIR GIBBONS: All right.

12 DR. BURSTIN: And Ray, we're happy  
13 to come back at a subsequent conference call  
14 and try to give you a little more guidance if  
15 you want to revisit this, because obviously  
16 it's split.

17 CHAIR GIBBONS: Okay. So we have  
18 just approved the composite. So I do want to  
19 sort of reflect that this is an incredible  
20 effort on the part of the ACC and all the  
21 other, all the team there that were involved  
22 in responding with these two composites in

1 very short order, in response to our earlier  
2 meeting and suggestions.

3 So we thank them and recognize them  
4 for all of that effort in doing that.

5 DR. MASOUDI: And just to speak on  
6 behalf of the people who were involved in  
7 doing that, I would say first thank you, and  
8 thank you also for the flexibility and being  
9 willing to hear about these measures during  
10 this meeting. So we very much appreciate it.

11 CHAIR GIBBONS: All right. Thank  
12 you to the others on the phone. So now we're  
13 going to move and shift to a different arena,  
14 which is hypertension, and Mary has conveyed  
15 to me that she believes I've sufficiently  
16 tamed this committee, so that she can now take  
17 over and run the discussion of these measures,  
18 which are actually more in her area of  
19 expertise in terms of public health than mine.  
20 So Mary, you've got to take over.

21 VICE CHAIR GEORGE: All right. So  
22 we'll be moving on to Measure 0018 first, and

1 any comments from the developer.

2 DR. MASOUDI: Is Measure 0018 the  
3 ARQI hypertension?

4 VICE CHAIR GEORGE: It's the NCQA  
5 hypertension.

6 DR. MASOUDI: Oh sorry.

7 DR. PAWLSON: Okay, got it. Thank  
8 you. I'm Greg Pawlson. I'm an internist  
9 geriatrician by background and Executive Vice  
10 President of NCQA, and I think the staff sent  
11 me here to be the old war horse to introduce  
12 the old war horse measure.

13 This is a straightforward blood  
14 pressure control measure. It actually first  
15 got into general use in HEDIS in 1999, and has  
16 been revisited at three intervals since then.  
17 The pluses of it are that it is very widely  
18 used. It is understandable to consumers,  
19 patients and clinicians.

20 It can be readily and reliably  
21 extracted from paper or electronic charts,  
22 with relatively low error rate and relatively

1 straightforward ability to extract the data.  
2 It has not certainly topped out in terms of  
3 performance.

4 The exclusions are relatively  
5 straightforward, and I would add that it has  
6 been reviewed every three years since 1999,  
7 and each year, we have tried to introduce  
8 changes to it, including concerns such as home  
9 blood pressure measurements and some risk  
10 adjustment and some other things.

11 Each time, our technical  
12 measurement expert panel, our technical  
13 advisory panels and our Committee on  
14 Performance Measurement, as well as public  
15 comment, have ended up going back to pretty  
16 much the CORE measure as being, for the  
17 present time at least and the present data  
18 systems we have, the appropriate trade-off  
19 between sort of sophistication of the measure  
20 and measurability.

21 We certainly would be open to and  
22 glad to take back on suggested further changes

1 to the measure. We'll update in a  
2 resubmission, I think, some of the areas that  
3 were not addressed in the original submission,  
4 that was asked for. So with that, if there's  
5 any questions.

6 MEMBER MAGID: When was the last  
7 time it was reviewed?

8 DR. PAWLSON: Two years ago, three  
9 years ago.

10 MEMBER MAGID: Three years ago.

11 MEMBER KOPLAN: On the numerator,  
12 is it the most recent blood pressure or any  
13 blood pressure?

14 DR. PAWLSON: Yes, no. It's the  
15 most recent. We looked at all different  
16 options. It's one of the reasons why the home  
17 blood pressure, groups couldn't decide on how  
18 to bring that in. We looked at trying to do  
19 averages; we looked at, you know, multiple  
20 blood pressures. There's some reasonable data  
21 that shows the last blood pressure is a  
22 reasonable compromise, again, mostly from

1       measurability viewpoints.

2                       We're working on, as are others, a  
3       lot more sophisticated measures that you can  
4       use in electronic data systems, by time  
5       intensity of control over large periods of  
6       time.  But that's where we are now.

7                       MEMBER MAGID:  Just sort of  
8       speaking to that, there was a paper published  
9       in the last year that looked at several  
10      different ways of assessing last blood  
11      pressure, average of the last blood pressure,  
12      the mean of all the blood pressures in a given  
13      period of time.

14                      I think at the aggregate level by  
15      which this kind of quality measure is  
16      reported, that the results were comparable.  
17      There really wasn't, you know, when you looked  
18      at how organizations would be ranked from, you  
19      know, best to worse and so forth, that really  
20      didn't change the rankings.  So I think there  
21      is good data to support the approach.

22                      MEMBER RASMUSSEN:  David, did that

1 include home blood pressures, or were those  
2 office?

3 MEMBER MAGID: Well, that's a  
4 separate issue, and that is something I want  
5 to discuss, but I don't know if this is the  
6 time to discuss it, or whether someone's going  
7 to go through it and we just -- is someone  
8 leading the discussion of this measure?

9 VICE CHAIR GEORGE: Yes. I think  
10 Leslie, why don't you go ahead and start, and  
11 then we can pick that up.

12 MEMBER CHO: So this is Measure  
13 0018, which is controlling high blood  
14 pressure, and it's important, I think, to  
15 distinguish the three blood pressure  
16 measurements that we're going to be talking  
17 about this afternoon.

18 So this is percentage of patients  
19 who have diagnosis of hypertension and are  
20 under control, and the control is defined  
21 differently this time as less than 140 over  
22 90.

1                   As you recall, we had long  
2                   discussions at the last meeting about 140 over  
3                   80, and in certain populations even lower than  
4                   that, and the developers have changed that to  
5                   140 over 90 during the measurement year. So  
6                   the impact, all of us agree that hypertension  
7                   is a leading cause of cardiovascular disease.

8                   Performance gap, as you know,  
9                   exists. Outcome of evidence in terms of --  
10                  and we can debate about the outcomes of  
11                  evidence in particular, subset of patients in  
12                  the second part, I think. But I think the  
13                  importance of measure, all of us agree.

14                  VICE CHAIR GEORGE: And I think  
15                  it's important to realize that this measure is  
16                  the percentage 18 to 85 years old, adequately  
17                  controlled. Are there any comments on the  
18                  Scientific Acceptability, I mean the  
19                  Importance?

20                  (No response.)

21                  VICE CHAIR GEORGE: Okay. We'll go  
22                  to a vote.



1 DR. WINKLER: Dianne?

2 MEMBER JEWELL: Yes.

3 DR. WINKLER: Thank you.

4 VICE CHAIR GEORGE: 20 yes, no  
5 no's. Moving on to the Scientific  
6 Acceptability.

7 MEMBER SNOW: Just one second, to  
8 make sure that I've got it right. It looks to  
9 me as if on the paper it says that it's number  
10 0018. That document there says it's number  
11 0013. Is one of them a typo or --

12 MEMBER CHO: No, no. There's a  
13 0013 and an 0018.

14 MEMBER SNOW: There's both.

15 MEMBER CHO: We discussed -- yes.  
16 We're discussing 0018 first.

17 MEMBER SNOW: Okay, thank you.  
18 I'll look some more.

19 VICE CHAIR GEORGE: Leslie.

20 MEMBER CHO: So the second is  
21 Scientific Acceptability of Measure  
22 Properties, and I have some questions for the

1 developers, if I may, and that is is one of  
2 the concerns that I had, looking at this  
3 measurement, is that if a patient gets  
4 diagnosed with hypertension, and you're  
5 titrating up the dose of medications,  
6 especially in the elderly, how, when is the  
7 time frame for control defined? How is that  
8 defined?

9           Then the second is I know this is  
10 a hybrid measure, which is a CPT code and a  
11 clinical chart. So if a patient comes to  
12 multiple different physicians, a primary care  
13 doctor or endocrinologist or cardiologist, is  
14 just the last measurement of that quarter  
15 taken or year taken? How is it measured?

16           DR. PAWLSON: It's year, right.

17           MEMBER CHO: Year. If a patient  
18 gets diagnosed with hypertension, let's say,  
19 in July of this year, and in by -- or let's  
20 say he gets diagnosed with hypertension in  
21 October of this year and in December he's not  
22 controlled because we're titrating, is that

1 dinged against me or against the clinician?

2 DR. PAWLSON: Yes. That's the  
3 problem with sending an old war horse to the -  
4 - I'm not sure, but I know that the way we use  
5 it in the health claim populations, that it  
6 requires the diagnosis in the year before.

7 So I don't know whether that  
8 applies to -- so there's a continuous  
9 enrollment. I don't know that that applies to  
10 the -- I'll have to check whether that applies  
11 to the clinician.

12 MEMBER CHO: Okay. So the  
13 measurement year is -- from the onset of  
14 diagnosis to the following 12 month period  
15 hopefully.

16 DR. PAWLSON: Yes.

17 MEMBER MAGID: You have to carry  
18 the diagnosis. So those people wouldn't be in  
19 the denominator, because they wouldn't have  
20 carried the diagnosis.

21 MEMBER CHO: Diagnosis for -- okay.  
22 And then the second question I had is for

1 these measurements, when you -- to test the  
2 validity of these measurements, I notice that  
3 you have the product line separated by  
4 insurance, and is the N the number of  
5 companies or is the N the number of -- I hope  
6 it's not the number of patents, because  
7 there's only like 269. Is the N the number of  
8 companies?

9 DR. PAWLSON: Companies, and we  
10 choose -- and again, obviously we can't  
11 control how this measure is used outside of  
12 our own environs, any more than any other  
13 measure developer can. But we believe that  
14 it's important to stratify by insurance  
15 status. But again, it's not a requirement of  
16 the measure.

17 MEMBER CHO: I don't know if this  
18 is a setting to bring this up, but in terms of  
19 the disparities, or a couple of things. The  
20 measure developer said to withhold or they  
21 want to go with the 140 over 90 until the new  
22 JNC-8 guidelines are published, which I think

1 is totally reasonable and acceptable. The age  
2 of 85, how was that chosen?

3 DR. PAWLSON: Helen will remember.  
4 We had a lot of discussion about whether there  
5 should be an age cutoff and how that sort of  
6 harkens back to my own experience as a  
7 geriatrician. We actually took this to our  
8 GMAP.

9 We had discussions with NQF, and  
10 the general consensus was, and it's not an  
11 exact science at all, is that by 85, there's  
12 enough admixture of other issues and problems,  
13 and enough potential exclusions that could be  
14 applied, that the measure becomes much less  
15 precise.

16 So you would potentially have to  
17 put in a whole bunch of other codicils on  
18 patients over 85, even though, you know,  
19 there's at least some evidence from some  
20 systolic measures at least, that that age  
21 group is not immune, obviously, to the  
22 consequences of high blood pressure. But it

1 was really the presence of multiple  
2 comorbidities and functional status issues.

3 MEMBER THOMAS: I had a question.  
4 Is white coat hypertension in the exclusions?

5 DR. PAWLSON: No. This is an  
6 office-based and it's again, the last  
7 measurement recorded. So that it would be,  
8 you know, hopefully clinicians who are aware  
9 of that would do multiple blood pressures, and  
10 it would be last recorded for that visit.

11 But you know, obviously all the, as  
12 far as I'm aware, virtually all of the data on  
13 blood pressure control is based on clinical  
14 trials that were done using office-based  
15 measurements. There's a few studies of home-  
16 based, but not much.

17 MEMBER THOMAS: White coat  
18 hypertension is an office-based phenomenon.  
19 I guess it's real too. It's real, I mean, and  
20 people who get ambulatory blood pressure  
21 monitors, who have white coat hypertension and  
22 it's demonstrated by that, you can write it in

1 your chart as a diagnosis. I mean as more  
2 people are using ambulatory blood pressure  
3 monitors, as many of us are doing, we can  
4 document that, because they say that their  
5 blood pressures are normal at home.

6 Anyway, I see it as a real  
7 phenomenon myself, but I don't know if others  
8 disagree.

9 MEMBER RUSSO: One other question  
10 too, and it may be in here, I just can't find  
11 it. So is there a minimum, is there a  
12 requirement for more than one visit in the  
13 measurement period to be included in the  
14 measure. For example, if you see a patient  
15 for a one-time visit for evaluation of  
16 something else, their blood pressure is high  
17 and it's a one-time consult and you never see  
18 them again, you may refer back to the primary  
19 care doctor or something for the blood  
20 pressure.

21 So is there, or should there be a  
22 consideration of more than one visit in the

1 measurement period to be included in the  
2 measure?

3 DR. PAWLSON: I believe it's one  
4 visit in the measurement period.

5 MEMBER MAGID: It's an interesting  
6 issue because one of the drivers of  
7 therapeutic inertia is when physicians don't  
8 address the hypertension, and they refer them  
9 back to someone else. We've seen that,  
10 particularly when clinical and non-primary  
11 care specialists do that.

12 So rates of blood pressure control  
13 in young women are about half what they are  
14 when, like say an OB/GYN doc is the primary  
15 care doctor, and they refer patients to like  
16 a family doc or an internist, that ends up  
17 with blood pressure control rates half what  
18 they are when the doc, when the primary care  
19 doc is the -- when, I'm sorry, an internist or  
20 a family physician. So I think that that  
21 would be a really bad exclusion.

22 MEMBER RUSSO: No, no, not to the



1 point, but to say that you've made a plan of  
2 action. So you've called the -- and this  
3 happens.

4 You call the doc and you increase  
5 their blood pressure medicine, say they're  
6 going to come to you in a week to get their  
7 blood pressure checked again. You may do an  
8 intervention, but the last recorded blood  
9 pressure that you have in the office is high.

10 You talk to them on the phone and  
11 say I've just increased it, doubling the beta  
12 blocker dose. They're going to see you next  
13 week. But you've only seen that patient once.

14 MEMBER MAGID: Well, but it's not  
15 the last time you've seen them. It's their  
16 last visit in the year. So that shouldn't be  
17 an issue.

18 MEMBER RUSSO: Or it may be outside  
19 the practice somewhat.

20 VICE CHAIR GEORGE: Isn't this  
21 measured at the health plan level, not at the  
22 physician level?

1 DR. PAWLSON: Well, it ultimately  
2 is measured at the physician level, because  
3 health plans don't take care of people;  
4 clinicians do. So it's done by chart review  
5 in a clinician's office, and obviously it  
6 depends on what --

7 MEMBER MAGID: It's in the health  
8 plan, so it's -- yes.

9 DR. WINKLER: Greg, just to  
10 clarify. In the submission, it says the level  
11 of measurement or analysis is the individual  
12 clinician or group of clinicians. It does not  
13 indicate health plan level.

14 DR. PAWLSON: Yes. We obviously  
15 omitted that. It should be both.

16 MEMBER AYALA: I have a question  
17 about exclusions. We talked about this in  
18 Phase 1, especially elderly patients who don't  
19 tolerate blood pressures less than 140 over  
20 90. Is there an exclusion for that if the  
21 physician documents the patient didn't  
22 tolerated it?

1 DR. PAWLSON: No.

2 MEMBER CHO: Actually, there's a --  
3 okay. So according to this form, this is the  
4 -- I know we've had millions of forms, but  
5 this is the response from the developers to  
6 us, based on 0073, which is the blood pressure  
7 management that we discussed at last meeting.

8 DR. WINKLER: Remember, that's a  
9 different measure for patients of coronary  
10 artery disease.

11 MEMBER CHO: Right. But it does  
12 address this issue about lowering the blood  
13 pressure with multiple different medication,  
14 and according to them it says that they fully  
15 support development and testing of risk  
16 adjustment. Now are you guys the same  
17 measurer that developed or are these  
18 different? These are different?

19 DR. PAWLSON: They're different  
20 measures.

21 MEMBER CHO: Okay, nice.

22 MEMBER MAGID: So the issue that I

1 want to discuss, and I'd like our group to  
2 consider, I don't know what it is, an  
3 amendment or a request back to the developers,  
4 is around home blood pressure monitoring. So  
5 I think, you know, three years ago, there was  
6 -- the evidence base around home blood  
7 pressure monitoring was just evolving.

8 But today, we have dramatic  
9 evidence in support of home blood pressure  
10 monitoring. Just in the last three years,  
11 there have been publications in JAMA and  
12 Circulation and several others, and there have  
13 been reviews.

14 And all of those studies have shown  
15 very large differences or very large  
16 improvements associated with home blood  
17 pressure monitoring, on the order of about 10  
18 millimeters of mercury systolic.

19 So remember, at a public health  
20 perspective, people get excited about two or  
21 three millimeter mercury. That's a lot of  
22 MIs, a lot of prevented cases of heart

1 failure, stroke and chronic kidney disease,  
2 and a lot of -- fewer cases of, a lot of lives  
3 saved.

4           So 10 is just huge. I mean and I  
5 know Tom is always talking to us about public  
6 health impact. Hypertension is responsible,  
7 is the second leading cause of preventable  
8 deaths in this country after smoking. So I  
9 think it's really time that home blood  
10 pressure monitoring be included in this  
11 measure.

12           I think some of the concerns about  
13 home blood pressure monitoring probably three  
14 years ago was well, what's the evidence base?  
15 There may be some concerns about the validity  
16 of blood pressure, home blood pressure  
17 monitoring cuffs and it might require a  
18 different cutoff, because home blood pressure  
19 measurements tend to be about five millimeters  
20 of mercury.

21           But I mean if we're going to be up  
22 to date, and this measure doesn't include home

1 blood pressure monitoring, you're really not  
2 up to date with where current practice is. We  
3 know that one of the big barriers to  
4 hypertension control for patients is a focus  
5 on office-based care.

6           When you do focus groups with  
7 patients, to say look, you know, we understand  
8 this disease. You understand you're at risk.  
9 We have relatively inexpensive effective  
10 medications, but we can't get you to keep  
11 coming back to the office.

12           The patients say well, it takes a  
13 half a day out of my life every time I have to  
14 come into the office. I have to travel to  
15 your office, I have to sit around in your  
16 waiting room. I see you for only five  
17 minutes. Then you change my medicines. I  
18 have to go to the pharmacy. I can't take a  
19 half a day off from work.

20           But if you give me an opportunity  
21 to measure my blood pressure at home and  
22 telemonitor them to you over the Internet or

1 by the phone lines, I'll do that. So I think  
2 this, the way the measure is currently  
3 structured, with the absence of home blood  
4 pressure monitoring, really is doing patients  
5 a disservice, and it's time to change the  
6 measure, to allow it to incorporate that.

7 DR. PAWLSON: Could I ask a  
8 question? Are you -- is this both for a  
9 measure of whether home blood pressure  
10 monitoring is done or not, because that seems  
11 to me --

12 MEMBER MAGID: No. It's for  
13 inclusion of those measures in the outcome,  
14 because more and more there are patients who  
15 are saying "I'm not coming into the office  
16 anymore. This is how I'm going to manage."

17 DR. PAWLSON: So I think -- I mean  
18 this is a huge issue, and I think the ACC has  
19 also tackled this to some degree. I think it  
20 deserves, as you're suggesting, very careful  
21 attention. I'm aware of the discussion the  
22 last time, and it ended up not so much that

1       there wasn't really great evidence that home  
2       blood pressure monitoring is important, and  
3       that there should be ways of encouraging it.

4                   It was how practically to  
5       incorporate it into this kind of a blood  
6       pressure measure.  So that would it override  
7       the office thing?  Would it only be if it was  
8       the last one recorded?  How would it -- so  
9       there's a lot of practical issues to be worked  
10      out, which is not, doesn't mean that we  
11      shouldn't address those.

12                   But it would fundamentally alter  
13      the measure.  So and it may be important to do  
14      that, but I'm just putting that out there.

15                   MEMBER MAGID:  It is.  It's very  
16      important to do that.

17                   DR. BURSTIN:  Just one process  
18      point.  Again, keep in mind that the measure's  
19      not been tested at all to incorporate home  
20      monitoring.  So one possibility would be to  
21      ask the developer, and I know Greg's waiting  
22      to update this measure, as new guidelines come



1 out, to consider the inclusion of home  
2 monitoring to follow. I'd be curious to hear  
3 Dr. Smith's perspective.

4 MEMBER SMITH: Somehow, I think we  
5 need to be aware that JNC-8 is going to be  
6 presented in November, a large database.  
7 Unfortunately, I cannot talk about it.

8 But one thing to point out with  
9 regard to home blood pressure monitoring,  
10 which I think is really very good, all of our  
11 RCTs available showing the benefits of  
12 lowering blood pressure come from office-  
13 based. They didn't use home.

14 So when you begin to talk about cut  
15 points, the cut points are derived from  
16 office-based measurement, not from home. So  
17 how you make that comparison and weave it into  
18 a performance measure becomes very difficult,  
19 and even the treatment of hypertension can  
20 find strong data support initiating treatment  
21 at systolic blood pressure of 160.

22 Many of the trials which show an

1 improvement in outcomes do not lower the blood  
2 pressure to less than 140, especially in the  
3 elderly, which gets back to a question that  
4 came up about how hard do you push to get  
5 less.

6 You should treat over 160 in the  
7 elderly, but the data that pushing them down  
8 to 140, particularly in the presence of  
9 multiple drugs, is going to have improve end  
10 points over 148 or whatever is not as strong.

11 I'm not able to comment, other than  
12 to say that there will be an important report  
13 coming in November.

14 VICE CHAIR GEORGE: Thank you for  
15 that.

16 MEMBER MAGID: Yes. I would just  
17 say that I think we know we have a lot of  
18 studies that talk about the relationship  
19 between office and home base, and I think we  
20 know that home blood pressure measurements  
21 tend to be a little bit lower, but not  
22 dramatically lower.

1 I guess at a minimum, I mean my  
2 hope would be that, you know, because what  
3 we're doing here is for three years, right?  
4 So are we going to be having this same  
5 discussion three years from now? I mean that  
6 would be really terrible. So we need to do  
7 something about this issue.

8 MEMBER SMITH: Home blood  
9 pressure's important, and the issue about  
10 peripheral versus central blood pressure and  
11 differential response to medical therapy is  
12 important.

13 MEMBER AYALA: Can we ask for the  
14 developer to consider adding the exclusion of  
15 patients who don't tolerate the blood pressure  
16 less than 140 over 90?

17 VICE CHAIR GEORGE: Is the  
18 developer willing to consider that?

19 DR. PAWLSON: What's the exact?  
20 You want to have an exclusion for patients who  
21 are white coat hypertension, or who don't  
22 tolerate --

1                   VICE CHAIR GEORGE: Patients who do  
2 not tolerate.

3                   DR. PAWLSON: Okay, and that would  
4 be some entry, a note entry or some judgment  
5 of the clinician that that was the case?

6                   VICE CHAIR GEORGE: That would have  
7 to be noted in the record.

8                   DR. PAWLSON: Yes. We could  
9 certainly look at that. But again, it would  
10 probably require retesting of the measure.

11                   MEMBER MAGID: I would like to ask  
12 the developer to conduct, at a minimum to  
13 conduct validity studies on home blood  
14 pressure measurement.

15                   DR. BURSTIN: Just as a process  
16 point, given that these blood pressure  
17 measures are in flux, we are anxiously  
18 awaiting this seminal report in November. It  
19 just seems like perhaps, you know, the reality  
20 is they're not going to change the measure  
21 between now and November.

22                   It would be illogical to do so, and

1 I think what we'd want to do is potentially  
2 suggest that as they update the measures to  
3 reflect JNC-8, they consider the issues raised  
4 here and test them, as David pointed out, for  
5 the next go-round.

6 VICE CHAIR GEORGE: So our  
7 committee would make those recommendations to  
8 the developer, and any other comments before  
9 we vote on Scientific Acceptability?

10 DR. WINKLER: You're in an  
11 interesting situation, because your vote for  
12 Scientific Acceptability will have to be on  
13 the measure as submitted.

14 Dianne?

15 MEMBER JEWELL: Partially.

16 DR. WINKLER: Thank you.

17 VICE CHAIR GEORGE: 4 completely,  
18 12 partially, 3 minimally. Moving on to  
19 Usability?

20 MEMBER CHO: Okay, moving on to  
21 Usability, this has been in use since 1999.  
22 It's clearly been tested. I think it's very

1 usable, minus this point about home blood  
2 pressure monitoring. So I think it's pretty  
3 self-evident.

4 VICE CHAIR GEORGE: Any comments or  
5 questions? Move to a vote on Usability.

6 DR. WINKLER: Dianne?

7 MEMBER JEWELL: Sorry, partially.

8 DR. WINKLER: Thank you.

9 VICE CHAIR GEORGE: We have 12  
10 completely, 6 partially, 1 minimally.

11 MEMBER CHO: Before we go on to  
12 Feasibility, I just have a question for the  
13 NQF people and those of you who have sat on  
14 NQF boards before.

15 If a measure like this over time  
16 has really a penetrance that's kind of leveled  
17 off, which this measure seems to have leveled  
18 off, what is the, you know, in terms of the  
19 90th percentile or whatever? It's still 54 or  
20 70 percent or so, pretty much stable.

21 What's the feeling to hold on to  
22 measures like this? Indefinitely, until -- I

1 mean we all agree hypertension is important,  
2 but what is the sort of philosophical  
3 overview?

4 VICE CHAIR GEORGE: I think they're  
5 more than -- it's not a simple question. The  
6 question you might want to ask is, is there a  
7 characteristic about the measure that causes  
8 it to not perform real well as a reflection?  
9 Is there something going on in the care of  
10 patients that causes that plateauing or  
11 something going on elsewhere?

12 So I think to each circumstance it  
13 is unique. This is an outcome measure, and  
14 for the most part, I guess the question is  
15 philosophically can outcome measures be topped  
16 off? Not really, if your goal is to, you  
17 know, get the entire population to the optimal  
18 levels.

19 MEMBER CHO: I just asked that  
20 because of these new measurements, or new  
21 blood pressure monitoring mechanisms that are  
22 coming into place, and maybe incorporating

1 those in a more dynamic manner is better  
2 suited than holding onto older measures. But  
3 anyway, moving on to Feasibility.

4 MEMBER MAGID: Well, I mean I think  
5 that one of the issues is that if patients, as  
6 I understand it, you'll have to correct me, if  
7 patients are doing home blood pressure  
8 monitoring, and they're not coming in to the  
9 office, their blood pressure is likely under  
10 control.

11 Yet but in this measure, they're  
12 counted as being out of control, because they  
13 don't have a measure, and if you don't have a  
14 measure, you're in the denominator but not in  
15 the numerator.

16 DR. PAWLSON: If they don't have a  
17 visit all year. No visits, that's right. If  
18 you have no visits. I think that at least up  
19 until now, the issues about an office-based  
20 measurement at least once a year have been  
21 fairly strong. I wouldn't also characterize  
22 it as not -- it's showing the same level of



1 slow improvement that virtually all the  
2 outcome measures do.

3 They don't, there's no magic  
4 formula to suddenly, you know, demanding that  
5 everybody record a beta blocker prescription  
6 at discharge, which is one time, easy. This  
7 is tough, this is a tough measure.

8 MEMBER KOTTKE: Also, yes.  
9 Hypertension's very interesting, because it's  
10 been so hard to improve, and Whisnant down in  
11 Rochester, two surveys, identical  
12 methodologies, ten years apart, identified  
13 treated and controlled dropped from 29 percent  
14 to 19 percent in Medical Tone USA, and it was  
15 -- I will blame that it was, the cause was an  
16 emphasis on a novel risk factors, and an  
17 urgent care unit, where people stopped going  
18 to their primary care physician, and just  
19 walked in and this was before the EMR and they  
20 were seen without records.

21 So then, like somebody mentioned  
22 over here, the big problem is oh yes, go back

1 to your primary and get your blood pressure  
2 treated. They have since closed the UCC.

3 MEMBER RICH: In thinking about  
4 this conversation, it strikes me that it's a  
5 great idea to use home monitoring, but  
6 patients should show up at least once a year.  
7 So I would say since your measure is once a  
8 year, they don't need to come in quarterly.

9 That's really taxing. But if  
10 they're not even showing up in your office  
11 once a year, it means not having any kind of  
12 physical, and that doesn't seem to be good  
13 medicine.

14 MEMBER MAGID: It's interesting.  
15 I mean I think for most of the measures that  
16 we've looked at so far, we've had people with  
17 ischemic heart disease or heart failure, and  
18 those patients do come in a lot. People with  
19 isolated hypertension, particularly men of a  
20 certain age, don't make -- it's not uncommon  
21 to find.

22 I mean when you look at the sort of

1       preventative recommendations for men, there  
2       aren't very many, if any, for men who are, you  
3       know, 20, 30, 40, you know, colonoscopy at age  
4       50 or a colon cancer screening. So it's not  
5       uncommon to find men with isolated  
6       hypertension not making regular visits,  
7       particularly if they're doing something like  
8       home blood pressure monitoring.

9                   MEMBER KOTTKE: I would say in my  
10       patient population, they've got a blood  
11       pressure cup at home, but they're not using  
12       it.

13                   DR. BURSTIN: One more point on  
14       Feasibility. This measure has been retooled  
15       already for EHRs, just FYI.

16                   VICE CHAIR GEORGE: Okay. So we'll  
17       vote on Feasibility.

18                   DR. WINKLER: Dianne?

19                   MEMBER JEWELL: Partially.

20                   DR. WINKLER: Thank you.

21                   VICE CHAIR GEORGE: 12 completely,  
22       8 partially. Now we move on to the final vote

1 on endorsement. Any other last comments?

2 (No response.)

3 DR. WINKLER: Dianne?

4 MEMBER JEWELL: Yes.

5 VICE CHAIR GEORGE: Unanimous, 19

6 yes. Okay. Next, we're moving on to another

7 blood pressure measure, number 0013. Any

8 comments from the developer?

9 DR. DROZDA: Yes. This is Dr. Joe

10 Drozda. I'm on the phone. I take pleasure in

11 presenting this measure from the American

12 Heart Association, the ACC and the AMA's PCPI.

13 The measure is a percentage of

14 patients age 18 years and older with a

15 diagnosis of hypertension, with a blood

16 pressure of less than 140 over 90 millimeters

17 of mercury, or patients with a blood pressure

18 of greater than or equal to 140 over 90

19 millimeters of mercury and prescribed two or

20 more anti-hypertensive medications during the

21 most recent office visit within a 12 month

22 period.

1                   This measure is actually very  
2 similar to the blood pressure measure that we  
3 presented as part of the coronary artery  
4 disease set that you considered in February.  
5 It is, was put together by the same writing  
6 group, made up of specialists, primary care  
7 physicians, advanced practice nurses, even  
8 patient consumers and a payor were represented  
9 on this committee.

10                   It was broadly vetted in the usual  
11 fashion through PCPI and its member  
12 organizations, as well as ACC/AHA, and  
13 underwent a 30-day public comment period. It  
14 replaces two measures, hypertension measures  
15 that were published in 2005.

16                   Those were separate measures of  
17 blood pressure control and management. Those  
18 measures actually were tested in the CMS doc  
19 project and are in use in PTRS and meaningful  
20 use Stage 1. The new measure actually  
21 combines these parameters into intermediate  
22 outcome measures, in which we have included

1 patients whose blood pressures are less than  
2 140 over 90, as well as those who have blood  
3 pressures higher than that.

4 The target, I think, reflects the  
5 most recent data out of trials like Accord,  
6 that sort of gives us some caution about lower  
7 blood pressures. The measure also addresses  
8 the complexities of hypertension management,  
9 some of which have been discussed today.

10 It allows the physicians to choose  
11 the blood pressure used for decision-making,  
12 and to identify that blood pressure on the  
13 chart. That blood pressure can be derived  
14 from blood pressures taken in the office, from  
15 home blood pressures, from 24 hour blood  
16 pressure monitoring. It can even be an  
17 average of blood pressure.

18 It also has an exception  
19 methodology to address issues like the elderly  
20 and those patients who might not be able to  
21 tolerate blood pressures of less than 140 over  
22 90. Again, it's based on JNC-7 and we do have

1 provisions made for readdressing the measures  
2 based on the release of JNC-8.

3           There is also, I would advise you,  
4 another panel, NCQA, AMA/PCPI has put  
5 together, to address diabetes, and diabetes  
6 control in the diabetic population will again  
7 be addressed by that group. So this measure  
8 is really focused on the -- it's a clinician  
9 level measure. It's focused on the electronic  
10 health record, although we have specifications  
11 for claims-based administrative data as well.

12           But we would like to see this  
13 utilized in the electronic health record going  
14 forward, as a QI tool, as well as for public  
15 reporting and accountability.

16           VICE CHAIR GEORGE: Okay, and Dana,  
17 I think you're presenting this.

18           MEMBER KING: Well, I couldn't  
19 have said it better myself actually. So the  
20 first one, I guess, number 0018 that we talk  
21 about was kind of like the soil sample of the  
22 United States, and how we're doing on high

1 blood pressure.

2 This one is a little more directed  
3 at what happens on the ground, because of the  
4 exceptions, because of the allowance, to not  
5 be controlled if you're taking two or more  
6 medications.

7 So it's not just the blood  
8 pressure. There are some other qualifications  
9 as well as exceptions. So otherwise, those  
10 are very similar measures. The data that was  
11 just presented for the importance and the  
12 prevalence of hypertension and the gap all  
13 apply to this measure as well.

14 DR. WINKLER: Do we have current  
15 performance data for this particular measure?

16 DR. DROZDA: This measure, as a  
17 combination, is brand new. So we really don't  
18 have current numbers based on it. We have  
19 numbers on the two separate measures that were  
20 approved previously. But I don't have those  
21 right at my fingertips. Maybe others at the  
22 meeting do have that.



1                   VICE CHAIR GEORGE:  Okay.  Any  
2                   further comments on this?

3                   MEMBER JEWELL:  This is Dianne.  
4                   This isn't really an important question,  
5                   because my answer to that vote is yes, this is  
6                   important.  It's really more we had  
7                   discussions this morning about the way  
8                   measures are labeled, and so it feels a little  
9                   counter-intuitive to me to call something  
10                  blood pressure control, but have as a part of  
11                  the measure a situation in which the person is  
12                  not controlled.

13                  So whenever the appropriate time is  
14                  to discuss that, I just want to put that in  
15                  the queue.

16                  MEMBER KOTTKE:  I have one  
17                  question.  Maybe Sid wants to address this,  
18                  that the two or more, and it seems to me that  
19                  it would be three or more, because many of my  
20                  patients are on a beta blocker, an ACE and a  
21                  diuretic, and sometimes they're on a calcium  
22                  blocker too.  It seems to me that two or more

1 is a little bit alligator arms for attempts to  
2 control.

3 DR. DROZDA: This is Joe Drozda.  
4 To respond to that, this was a topic of some  
5 discussion at the work group, and I think we  
6 settled on two or more primarily from a  
7 patient safety perspective, especially  
8 considering that this was going to be a  
9 publicly reported measure.

10 We were most concerned about  
11 patients who a provider might try to either  
12 overly-aggressively try to get a blood  
13 pressure under 140 over 90 or would pile on  
14 three medications just to meet a measure, and  
15 might put the patient at some jeopardy. So  
16 that was -- it was a safety concern that led  
17 us to choose two, rather than three.

18 MEMBER SMITH: So I don't know of  
19 any good data to support this discussion. The  
20 guidelines for renovascular hypertension, one  
21 of the criteria for looking at renal artery  
22 stenosis would be failure to respond to three

1 or more. This whole area would benefit from  
2 a little more evidence, I think, in terms of  
3 what would be the best measure for us to use  
4 even.

5 VICE CHAIR GEORGE: Any other  
6 comments on the importance? If not, we'll go  
7 to a vote.

8 DR. WINKLER: Dianne?

9 MEMBER JEWELL: Yes.

10 DR. WINKLER: Thank you.

11 VICE CHAIR GEORGE: 19 yes, 1 no.  
12 We'll move on, Scientific Acceptability.

13 MEMBER KING: So the  
14 specifications we talked about. It's adults  
15 18 and older. The reliability and validity is  
16 not known for this because it's new.

17 Some of the exclusions we talked  
18 about. The denominator will be people who  
19 have been under care for a year or more, or it  
20 says 12 consecutive months. This information  
21 is obtained from electronic, mostly from  
22 electronic health records.

1                   MEMBER RUSSO: I think this one,  
2                   correct me if I'm wrong, the way I read it is  
3                   different than the other one, in that two  
4                   things. One is that you need to have, it's  
5                   specified in the medical record for more than  
6                   one value. So you had to be seen, I am  
7                   assuming that means within the measurement  
8                   period, more than once. I'm not sure if  
9                   that's correct or not.

10                   Then the other thing is this does  
11                   include the home review, review of home blood  
12                   pressure monitoring. So that would address  
13                   the other issue that was brought up earlier.

14                   MEMBER KING: Right. It says you  
15                   have to have greater than one value.

16                   MEMBER RUSSO: So that means two or  
17                   more, right? But I don't know if that's in  
18                   the same visit or if that's, you know. I like  
19                   it better for the scenario that I outlined  
20                   before, is that you may truly address it with  
21                   more than one period. It's not just a one-  
22                   time person who lives two hours away, that's

1 going to get their follow-up blood pressure  
2 checked somewhere else.

3 MEMBER KING: I believe that  
4 didn't say more than one visit, because it  
5 could be one visit in the office and then a  
6 visit from a home blood pressure. So that's  
7 two measures.

8 MEMBER RUSSO: True. That could be  
9 true. That would follow.

10 MEMBER KING: So that's why they  
11 didn't specify two visits. So they just said  
12 greater than one value.

13 MEMBER RUSSO: Yes, that would make  
14 sense.

15 MEMBER CHO: What is the added  
16 value of this measure on top of the measure we  
17 talked about previously?

18 MEMBER KING: That is a good  
19 question.

20 DR. DROZDA: Yes. This is Joe  
21 Drozda. Let me take a crack at it. By the  
22 way, I'd first like to thank Greg Pawlson for

1 breaking the ice on this section of the  
2 discussion. He did so admirably, and I don't  
3 think that I'm, in trying to -- I don't want  
4 to diss the NCQA measure. It has been around  
5 for a while, as Greg said, and has had  
6 significant utility.

7 But I think this one addresses a  
8 number of issues that I think NQCA is still  
9 struggling with, and that is those patients  
10 whose blood pressures are over 140 over 90.  
11 You know, to say that 70 percent of patients  
12 have blood pressures over 140 over 90, to say  
13 that that means that we're not at our target  
14 yet, I think, is probably not correct, because  
15 I don't think the number for control that we  
16 are shooting for is 70 percent.

17 I'm not sure what it is, but it's  
18 not 100 percent either. Because of what we  
19 talked about earlier, there are patients who  
20 do not tolerate blood pressures of 140 over  
21 90, and shouldn't be driven to that level.  
22 They very well could be under, should be

1 considered under control, along with those who  
2 are doing well under 140 over 90.

3 We're not clear on exactly where  
4 that cutoff is above 140 over 90, and how that  
5 should be quantitated. But this is an effort  
6 to kind of get at that, without setting  
7 another blood pressure cut point. So I think  
8 this again addresses these sorts of  
9 complexities that are very difficult to do  
10 when you take an arbitrary cutoff at any  
11 point, like 140 over 90.

12 So I think we're doing that, and  
13 we're also addressing the issues of how the  
14 blood pressure is taken, and it's not in the  
15 NCQA measure, which depends on the last blood  
16 pressure in the office.

17 We are allowing blood pressure  
18 readings from ambulatory blood pressure  
19 monitoring, blood pressures at home and blood  
20 pressures in the office, and reflecting the  
21 way physicians practice, because those of us  
22 who treat hypertension actually take all those

1 numbers into consideration when we have them,  
2 and make decisions based on treatment, not on  
3 the arbitrary last one we took in the office.

4 So I think this is a little bit, an  
5 attempt to be a little bit more, I don't know,  
6 sophisticated in our approach to measurement.

7 MEMBER JEWELL: So this is Dianne  
8 again. I appreciate the methodology  
9 enhancements that you just described. But the  
10 comments you made prior to that about the  
11 patients who aren't under control but are  
12 getting two or more meds, I'm still stuck with  
13 why we call it a measure of blood pressure  
14 control then.

15 I don't see how the public would  
16 ever understand the difference between what's  
17 controlled and what's not controlled if they  
18 think that 140 over 90 on multiple meds is  
19 controlled, or even not, you know, and they  
20 are having ongoing problems. I think we  
21 potentially lead them astray.

22 So I'm not so sure it's a problem



1 with the measure as what you call it that I'm  
2 wrestling with here.

3 DR. DROZDA: I guess what I said  
4 earlier was that I think it's leading them  
5 astray to say that 140 over 90 is the gold  
6 standard. You're either there or you're not  
7 controlled.

8 Because quite frankly, if you're 75  
9 years old and you get possible hypotension as  
10 soon as your blood pressure is over 150, is  
11 under 150 over 80, you shouldn't be driven to  
12 140 over 90. That's actually poor quality  
13 care. So that was really that paradigm we  
14 were working on.

15 MEMBER JEWELL: And I hear you.  
16 I think it's, I'm really thinking about the  
17 group of patients for whom that is not the  
18 issue, and the physician and the patient are  
19 working very hard together to find the best  
20 combination of interventions to reduce their  
21 risk of adverse events as a result of  
22 hypertension.

1                   Maybe it's semantics to everybody  
2                   and I don't know everybody else. But if you  
3                   call it "control," it sounds like it should  
4                   have a label. Because you include in the  
5                   numerator people who actually are below a  
6                   certain threshold that you've defined, to me  
7                   it feels like it's two measures that don't  
8                   match bundled into one, and that there should  
9                   be two separate things, or call it something  
10                  else.

11                  VICE CHAIR GEORGE: Clearly, the  
12                  devil's in the details of any of these  
13                  measures that we look at. David.

14                  MEMBER MAGID: Yes. I'm just a  
15                  little bit concerned. I understand the  
16                  example that you gave, and I wouldn't disagree  
17                  with the assertion that not everyone should  
18                  have their blood pressure driven below 140  
19                  over 90.

20                  I'm just wondering whether you're  
21                  going to cause more harm than good, because if  
22                  you took the universe of people whose blood

1 pressure -- who are on two blood pressure  
2 medications, whose blood pressure was above  
3 140 over 90, I think the vast majority of  
4 those people would benefit from being on a  
5 third medication, and having their blood  
6 pressure less than 140 over 90.

7           So I'm just wondering whether there  
8 is a better way to address the issue that you  
9 have, than the way you've constructed this  
10 measure, which may do more harm than good.

11           MEMBER RASMUSSEN: Is a percent  
12 reduction in blood pressure a more appropriate  
13 target?

14           MEMBER MAGID: I don't know about  
15 that.

16           DR. DROZDA: I think you'd still  
17 run into the problems we talked about earlier,  
18 and this is a great discussion, and it  
19 reflects actually the discussion in the work  
20 group, as we were balancing off all of these  
21 very important issues, including patient  
22 safety. We obviously came down on the patient

1 safety side.

2 But I don't know that I can argue  
3 with the assertion that a good percentage of  
4 patients who have blood pressures over 140  
5 over 90 need to be on three drugs or more. I  
6 don't think I can argue with that. But these  
7 are just sort of the exigencies of a publicly  
8 reported metric.

9 Now we do believe that by having  
10 this measure out there, that we will now be  
11 drawing attention to that group of patients  
12 that may have not been particularly well  
13 cared-for in the past, and that we think we  
14 will drive improvement, even in that group of  
15 patients.

16 I think we'll find, by the way,  
17 that a number, a great percentage of them will  
18 be African-American, and we do want -- by the  
19 way, I did mention -- I did mean to mention  
20 this earlier.

21 We would like to see this measure  
22 stratified by age, sex and ethnicity, race and

1 ethnicity, so that we can look at the very  
2 important areas of disparities in hypertension  
3 treatment.

4 VICE CHAIR GEORGE: Tom.

5 MEMBER KOTTKE: Yes. This is just  
6 a semantic argument, but I think you've  
7 grabbed the "first, do no harm" cell and not  
8 necessarily the patient safety cell, to argue  
9 that not treating blood pressure increases  
10 patient safety. I don't think there's  
11 evidence for that.

12 I think there is a legitimate  
13 argument not to do harm when in doubt, but to  
14 categorize it as safety --.

15 MEMBER CHO: I think the way this  
16 currently reads, that all of us are having  
17 difficulty with, is if your blood pressure is  
18 greater than 170 over 100, and you're on two  
19 anti-hypertensives, you get a pass based on  
20 this measure. I know that the intention of  
21 the measure developer is not that.

22 So that's, I think, what all of us

1 are having such difficulty, you know, coming  
2 to grasp.

3 MEMBER KOPLAN: I would agree. I  
4 don't think it reflects what's trying to be  
5 achieved. I think it's kind of convoluted and  
6 it would be confusing.

7 MEMBER RUSSO: I think it also, you  
8 could potentially be on subtherapeutic doses,  
9 two very low doses of two different drugs and  
10 not capture it. Is there some other way to  
11 capture the intent or a plan to control, to be  
12 -- so you're at the visit and it's high, and  
13 you're still trying to adjust it. It doesn't  
14 capture that either.

15 I guess that wouldn't be  
16 intermediate outcome, but I'm just trying to  
17 think. It's not capturing, although the  
18 intent's really there, it's not definitely  
19 capturing what I think the intent is.

20 DR. DROZDA: If you look at the  
21 previous two measures that this replaces,  
22 actually the one was a plan of care measure,

1       which sort of approached it just the way that  
2       you view, you describe.

3               We thought it would be more useful  
4       for public reporting to have a single measure,  
5       and then when we got into the details, we ran  
6       into the kinds of issues that you're  
7       describing, and realized that there might not  
8       be ideal care for people included in the  
9       measure, and for which you get credit.

10              But on the whole, we thought that  
11       this would actually move the ball down the  
12       field a little further.

13              VICE CHAIR GEORGE: Thank you, and  
14       we're going to need to move ahead. So we're  
15       going to, if there's no other objections, go  
16       on to voting on Scientific Acceptability.

17              MEMBER KING: This is with two  
18       meds, right?

19              DR. WINKLER: Dianne?

20              MEMBER JEWELL: Minimally.

21              DR. WINKLER: Thank you.

22              VICE CHAIR GEORGE: Three

1 completely, five partially, seven minimally,  
2 five not at all. Usability?

3 MEMBER KING: Would this measure  
4 be usable, meaningful and useful for public  
5 reporting? I think that there has been some  
6 discussion about that. The previous  
7 components were used.

8 VICE CHAIR GEORGE: Any additional  
9 comments? Okay. We will vote on Usability.

10 DR. WINKLER: Dianne?

11 MEMBER JEWELL: Completely.

12 VICE CHAIR GEORGE: Four completely,  
13 nine partially, six minimally, one not at all.

14 MEMBER KING: The next issue is  
15 Feasibility. The data are generated during  
16 care. Blood pressure measurements are  
17 obviously freely available through electronic  
18 sources. There are exclusions. This one has  
19 more exclusions, but more relevant ones  
20 according to our discussion. Data collection  
21 has been and certainly could be implemented.

22 VICE CHAIR GEORGE: Any discussion



1 on Feasibility?

2 (No response.)

3 VICE CHAIR GEORGE: We'll move to  
4 a vote.

5 DR. WINKLER: Dianne?

6 MEMBER JEWELL: Minimally.

7 VICE CHAIR GEORGE: Nine completely,  
8 six partially, five minimally. Now we move,  
9 if there's no further discussion, move to a  
10 vote on the measure as it stands. Any  
11 discussion?

12 (No response.)

13 DR. WINKLER: Dianne?

14 MEMBER JEWELL: No.

15 VICE CHAIR GEORGE: Six yes, 14 no.

16 Now we move on to another hypertension  
17 measure. Any comments from the developer?  
18 This is Measure 0276.

19 MR. BOTT: Yes. This is John Bott  
20 with AHRQ. Just very, very briefly, this is  
21 an AHRQ quality indicator. It's an area level  
22 measure, so we're measuring care at a

1 population level being typically a state or a  
2 county. It's looking at potentially  
3 preventable admissions, in this case for  
4 hypertension with high quality care in the  
5 community.

6 It's a measure that uses electronic  
7 inpatient administrative data sets to compute  
8 the measure, and it was a measure that was  
9 initially endorsed by the National Quality  
10 Forum in 2007. That's all I'll note for  
11 introductory comments.

12 VICE CHAIR GEORGE: Okay.

13 Christine.

14 MEMBER STEARNS: Hopefully, we'll  
15 be able to move through this one quickly.  
16 This is a high impact measure, and I think as  
17 it was introduced, the evidence suggests that  
18 there's a wide variation in admissions for  
19 hypertension, which may well relate to income  
20 and access to care. So this measure would be  
21 useful in looking at the health care delivery  
22 system generally. So I don't know if you have

1 any questions or if you want to move forward.

2 VICE CHAIR GEORGE: I had one  
3 question for the developer. Under the notes  
4 for Opportunity for Improvement, the developer  
5 said little evidence exists regarding the  
6 validity of the indicator. Can the developer  
7 respond to that?

8 MS. DAVIES: Yes. This is Sheryl  
9 Davies. So the issue here is that these  
10 indicators are measures of ambulatory care --  
11 hospitalizations, and these indicators were  
12 originally conceptualized and developed by a  
13 couple of groups independently in the 1990's.

14 At that time, most of the work  
15 surrounding the validation of the indicators  
16 really focused on validating the entire set of  
17 conditions that were identified as ambulatory  
18 care sensitive conditions. So that includes  
19 other things such as COPD and CHF, and some  
20 acute conditions as well.

21 So we have quite a bit of evidence,  
22 you know, showing that either the proxies for

1 access to care or direct measures of access to  
2 care certainly impact the hospitalization rate  
3 for these conditions as a whole. But for this  
4 particular one, there's been, from a published  
5 study point of view, there's been relatively  
6 little additional work looking at hypertension  
7 individually.

8 So we don't have any reason to  
9 believe that hypertension would be  
10 particularly different, and but we don't have  
11 the literature-based evidence for that. We  
12 have taken this particular indicator to a  
13 clinical panel. The clinical panel did  
14 discuss, you know, certainly that hypertension  
15 is an important complication or chronic  
16 disease, and that admission for hypertension  
17 would be important.

18 They did note, as you probably will  
19 discuss, you know, the primary concern with  
20 the indicator was that it was really missing  
21 other manifestations of hypertension, such as  
22 cerebral vascular disease or kidney disease,

1 that would show up. So that was the main  
2 concern about the indicator, and we took it  
3 from a face validity point of view.

4 VICE CHAIR GEORGE: Any other  
5 questions or comments?

6 CHAIR GIBBONS: I'd just make the  
7 comment, to expand on that last point, that in  
8 my practice, the overwhelming majority of  
9 people who come in to the hospital with heart  
10 failure, with normal left ventricular  
11 function, have uncontrolled hypertension.

12 So there's a huge population, huge  
13 public health problem. This doesn't come  
14 close to capturing that.

15 VICE CHAIR GEORGE: Dana?

16 MEMBER KING: I don't also see any  
17 data about the correlation between the  
18 measure we just talked about, blood pressure  
19 control, and admission for it. In other  
20 words, it seems that one would definitely  
21 follow the other. If we were controlling  
22 blood pressure in the community and the public

1 health arena, we would have much fewer  
2 admissions for hypertension, for a variety of  
3 reasons, as Dr. Gibbons said.

4           So having this as a separate  
5 measure and saying there's all these things  
6 that contribute to it, such as socioeconomic  
7 status, minority status, access to care,  
8 etcetera, those are all the things. That's  
9 all the reason why we're only controlling half  
10 the hypertensives, and why half of them get  
11 admitted to the hospital every couple of  
12 years.

13           So it seems like it's just another  
14 way of measuring the same thing, and I'm not  
15 sure what it adds to our already subpar,  
16 suboptimal control of hypertension. It's just  
17 another reflection of that, but I don't think  
18 it really adds a lot of additional data.

19           It seems like it would reflect the  
20 local population with kidney disease, heart  
21 failure, hypertension and poor socioeconomic  
22 status, and it would be at addition.

1 VICE CHAIR GEORGE: Roger.

2 MEMBER SNOW: You know, the PQIs,  
3 in several instances, seem to have this  
4 problem that they've kind of missed the mark.  
5 But the issues are -- a lot of people, people  
6 who have uncontrolled hypertension usually  
7 don't get admitted at the hospital for that.  
8 They get admitted to the hospital for  
9 something else.

10 So you're not capturing what you're  
11 looking for for that reason, just as Dana  
12 previously said, and that when you want to  
13 identify what's causing that, on the other  
14 hand, it's all these other co-morbidities or  
15 other things. So not unlike the PQI around  
16 the angina, we're looking at --

17 We're trying to measure something  
18 by looking at a proxy that doesn't really  
19 capture it.

20 VICE CHAIR GEORGE: Christine.

21 MEMBER STEARNS: I guess I  
22 approached reviewing this, and I don't have a

1 clinical background. So I was looking at it  
2 from the perspective of someone who might be  
3 engaged in the dialogue about wellness in the  
4 community, that in some of the recent data in  
5 a report that just came out that did look  
6 county by county, that came out across the  
7 nation.

8 So in looking at it from the  
9 perspective of those who may be involved in  
10 other sort of state-based initiatives, giving  
11 a basis of comparison to how different regions  
12 of the state are doing and as compared to how  
13 other states are doing. But there are a lot  
14 of initiatives that are going on in the  
15 community, and this gives a basis for  
16 comparison of how the community is doing.

17 But I don't know if folks are  
18 looking at it from that perspective, of being  
19 sort of a useful measure. I'm also not aware  
20 of all the other measures that currently exist  
21 out there.

22 But that, you know, for folks that



1 are engaged in, you know, sort of wellness  
2 initiatives at the employer level or the  
3 community level, having information to be able  
4 to judge your region is useful data, and that  
5 was -- and it does seem that this does measure  
6 something that is accurate and measurable, and  
7 there does seem to be a disparity.

8 But and some of those factors are  
9 things that you perhaps don't need a measure  
10 to tell you socioeconomic status in sort of  
11 different regions of the state. But there are  
12 initiatives sometimes that are going on in a  
13 local area that may be making an impact, and  
14 so that that you would need.

15 MEMBER MAGID: I guess I'd like to  
16 know, I have one general question and then a  
17 specific question. The general question is  
18 how is this information more helpful than the  
19 data we already get from NHANES, which gives  
20 us a great deal of, you know, level, not just  
21 the people with diagnosed but also undiagnosed  
22 hypertension, at I believe the county level.

1                   The second question I have was  
2                   about the ICD-9 codes, and whether this is  
3                   limited just to primary hospital diagnosis  
4                   versus whether, or whether it includes  
5                   secondary?

6                   VICE CHAIR GEORGE: NHANES is not  
7                   geographically localizable.

8                   MEMBER MAGID: Well, it's reported  
9                   that way.

10                  VICE CHAIR GEORGE: That's a  
11                  different survey. BRFSS is state-based, but  
12                  NHANES is not. It's generalizable to the  
13                  entire population.

14                  MEMBER MAGID: But so they don't  
15                  report data at smaller geographical levels?

16                  VICE CHAIR GEORGE: Not for NHANES.

17                  MEMBER MAGID: No, okay.

18                  VICE CHAIR GEORGE: We have a few  
19                  states that have done some sort of state level  
20                  kind of mini-NHANES, but --

21                  MEMBER MAGID: And the answer to  
22                  the question about whether it's primary versus

1 primary and secondary diagnoses?

2 MR. ROMANO: I could address those  
3 questions.

4 VICE CHAIR GEORGE: Thank you.

5 MR. ROMANO: Hello?

6 VICE CHAIR GEORGE: Go ahead.

7 MR. ROMANO: This is Patrick  
8 Romano. I'm the clinical leader of the AHRQ  
9 quality indicator support team. So just to  
10 address a couple of these questions. So yes,  
11 the specification is based on the principle  
12 diagnosis or the principle reason that a  
13 patient is admitted to the hospital.

14 Now we of course recognize that  
15 many patients with hypertension are admitted  
16 for heart failure or for other related  
17 conditions. There is a separate PQI for heart  
18 failure, and that would capture those patients  
19 who are admitted with acute heart failure,  
20 secondary to hypertension.

21 There are also, of course, other  
22 Prevention Quality Indicators that may overlap

1 with hypertension, that may capture patients  
2 as well, such as the PQI related to diabetes,  
3 because diabetic patients sometimes are --

4 MEMBER MAGID: If I could just  
5 interrupt you --

6 DR. ROMANO: -- admitted to the  
7 hospital as a complication of diabetes and  
8 hypertension.

9 MEMBER MAGID: Okay. I was only  
10 concerned if you were going to include  
11 secondary, so that I'm glad to learn that it's  
12 just primary.

13 DR. ROMANO: Yes. One other point  
14 is just that this indicator is really intended  
15 to describe population health. It's an area  
16 level indicator.

17 It's designed for use at the  
18 geographic area level, and so as has been  
19 pointed out, it doesn't really overlap with  
20 NHANES in that sense, and the added value  
21 comes from local public health agencies and  
22 local coalitions that are interested in

1 tracking the performance of the health care  
2 system as it relates to population health.

3 We know, of course, that healthy  
4 people and healthy communities are one of the  
5 three national aims that are part of the new  
6 National Quality Strategy that's been  
7 established or promulgated under the  
8 Affordable Care Act.

9 VICE CHAIR GEORGE: Any other major  
10 comments on the importance of this measure?

11 (No response.)

12 VICE CHAIR GEORGE: Okay. We'll  
13 move to a vote.

14 DR. WINKLER: Dianne?

15 MEMBER JEWELL: Yes.

16 VICE CHAIR GEORGE: Seven yes, 11  
17 no. Okay. We are going to keep going forward  
18 and transition into three heart failure  
19 measures, 0135, 0162 and 0136. Any brief  
20 comments from the measure developers?

21 DR. MASOUDI: Yes hi. This is Fred  
22 Masoudi again. I'll speak on behalf of these

1 measures, which are three or the measures that  
2 have been used by the CMS and Joint Commission  
3 over the last several years, as part of the  
4 Hospital Compare public reporting program.

5 The three measures under  
6 consideration are the evaluation of left  
7 ventricular systolic function, first. The  
8 second is ACE or ARB for patients with left  
9 ventricular systolic dysfunction. It looks  
10 like the title's cut off in the agenda, and  
11 then finally detailed discharge instructions  
12 at the time of discharge for patients with  
13 heart failure.

14 Again, these three measures have  
15 been used for quite some time in the context  
16 of a national public reporting program  
17 currently in use on the Hospital Compare  
18 website. I think of the measures that you've  
19 seen today. They're probably three that  
20 you're perhaps most familiar with. I'll leave  
21 it at that for the time being, unless there  
22 are specific questions.

1 VICE CHAIR GEORGE: Kathleen.

2 MEMBER SZUMANSKI: I have Measure  
3 0135, which is on the evaluation of left  
4 ventricular systolic function in patients with  
5 heart failure. This is a measure that really  
6 does not stand alone as determining outcome,  
7 but it's a building block of the treatment  
8 protocol that's going to be designed for the  
9 particular patient.

10 Obviously, the documentation of the  
11 2D echo result in a medical record is fairly  
12 easily obtained. Some of the issues with this  
13 measure, I think, in terms of importance, is,  
14 comes a little bit further in the discussion.

15 But obviously this is a major  
16 health problem in the U.S., and that we have  
17 to have a jumping off place, and the jumping  
18 off place for this measure is evaluation of  
19 left ventricular systolic function. So I  
20 would suggest that this is probably an  
21 important thing to measure.

22 VICE CHAIR GEORGE: Any comments or

1 discussion on Importance?

2 MEMBER JEWELL: This is Dianne.  
3 I see a lot of P's in our Excel spreadsheet  
4 for this measure, meaning partially by the  
5 other reviewers in the review group. I'm just  
6 curious what some of the hesitation was.

7 VICE CHAIR GEORGE: Not sure.

8 MEMBER SZUMANSKI: Not under  
9 Importance. It's under performance --

10 MEMBER JEWELL: We're looking at  
11 0135, are we not --

12 MEMBER SZUMANSKI: -- evidence.  
13 It's further down in the discussion. I don't  
14 believe it's on the importance of the measure.

15 DR. BURSTIN: It's actually on the  
16 measure gap, because it's actually pretty  
17 small.

18 MEMBER SZUMANSKI: Oh, I'm sorry.  
19 Obviously, you know, the more we focus on  
20 this, the closer we get to achieving the  
21 performance levels that we want.

22 There continues to be a measure gap



1 in some settings, and certainly from a  
2 disparity standpoint, it is identified that in  
3 the Native American population, there is  
4 probably a more significant gap than in other  
5 populations. So it is closing in some areas,  
6 but in others, the gap still exists.

7 MEMBER JEWELL: Thank you.

8 VICE CHAIR GEORGE: Any other  
9 questions?

10 (No response.)

11 VICE CHAIR GEORGE: Okay. We'll  
12 vote on the importance.

13 DR. WINKLER: Dianne?

14 MEMBER JEWELL: Yes.

15 VICE CHAIR GEORGE: Fifteen yes,  
16 three no.

17 MEMBER MAGID: I have just a  
18 general question, and this may apply to a  
19 number of measures. But I just thought about  
20 it in light of this. So we did some  
21 validation of primary discharge diagnosis of  
22 heart failure, and its high positive

1 predictive value. But it was part of a multi-  
2 center study.

3 One of the things we found was  
4 though that there can be upcoding with this  
5 diagnosis, and that sometimes you see  
6 situations where the physician caring for the  
7 patient might, on initial admission of a  
8 patient with shortness of breath, put "heart  
9 failure" in the differential diagnosis, but by  
10 the end of the hospitalization, it was clear  
11 that the patient had pneumonia and not really  
12 heart failure.

13 But for some reason these  
14 specialized coders that the hospitals hire to  
15 enhance reimbursement go through and actually  
16 change the discharge diagnosis to maximize  
17 reimbursement.

18 So we did, one of the studies was  
19 in this, we were looking at cases in which EF  
20 wasn't measured in people with a discharge  
21 diagnosis, and we found that, you know, a  
22 small, not large, but a small number of people

1 really didn't have heart failure on careful  
2 review.

3           Was there a way to get those people  
4 out of the denominator, and have you guys seen  
5 this is other quality measures? That was  
6 really a NQF question, not -- well, it sounds  
7 like Fred's going to respond to it.

8           DR. MASOUDI: I can do that. I can  
9 tell you that you're right, there's a small  
10 amount of misclassification, some of which may  
11 involve miscoding.

12           I would say that in general, any  
13 time this has been looked at within the  
14 Medicare population, and it's not done  
15 systematically with these measures, because  
16 you can imagine the burden of abstraction  
17 involved in corroborating a clinical diagnosis  
18 of heart failure would be prohibitive.

19           We have found that the positive  
20 predictive value of this family of codes as a  
21 principle discharge diagnosis tends to be  
22 extremely high, north of usually 95 percent.

1 Of course that's not 100 percent, and that  
2 work has not been done in a while.

3 But speaking directly to the issue  
4 of is there separate corroboration of a  
5 clinical discharge diagnosis? Well  
6 unfortunately the answer is no, and I think  
7 from a practicality standpoint, that's really  
8 not feasible.

9 MEMBER RUSSO: Although just on a  
10 broad level, many of these measures,  
11 particularly those from CMS, have had  
12 validation sampling, and this one actually  
13 reference that as well. They're small  
14 numbers, but they do do a cross-reference to  
15 an audited sample.

16 MEMBER MAGID: Yes, no, and I  
17 agree. It has a very high -- I was just more  
18 curious as to the people that go through and  
19 collect this data, if they were going through  
20 a chart and they realized hey, this patient  
21 really doesn't have heart failure, it's tough.  
22 It's just reported. Okay, and that makes

1 sense, why it should probably never be 100  
2 percent.

3 VICE CHAIR GEORGE: Is that  
4 situation likely to be improved with  
5 electronic records?

6 MEMBER MAGID: I doubt it.

7 MEMBER PHILIPPIDES: Can I ask a  
8 question about one part of the definition in  
9 there? Plan to check LVF post-discharge. How  
10 do we assess if someone is going to -- it's  
11 planned that they're going to have an echo  
12 after they're discharged?

13 DR. MASOUDI: Yes. This is an  
14 attempt to sort of level the playing field,  
15 for those institutions that don't have the  
16 capacity internally to assess left ventricular  
17 systolic function. As you can imagine, a  
18 small rural hospital may not have the  
19 capacity, say even over a weekend or something  
20 like that, to do that.

21 So what this has done is through  
22 chart documentation, it has to be documented

1 there's a specific plan for it to be assessed  
2 as an outpatient.

3 MEMBER SZUMANSKI: I think under  
4 Scientific Acceptability, there are some  
5 challenges, and I think David has pointed out  
6 one of them, from a documentation standpoint.  
7 Obviously, if there is a test result in the  
8 medical record, it's easy to say okay, the 2D  
9 echo shows.

10 The other two that are difficult,  
11 however, was it done before arrival and if it  
12 was, is it documented somewhere in that  
13 record. Lastly, is it planned after discharge  
14 and when is it going to get done, or does the  
15 report actually get back to the record.

16 So an abstractor is a bit  
17 challenged by trying to find the documentation  
18 if it's not a test that was done during that  
19 hospitalization period.

20 As a result, as again David pointed  
21 out, there is upcoding on this, to say we  
22 assume that the physician has ordered or it's

1 coming, or we don't quite have it but we're  
2 assuming that it's going to be there.  
3 Therefore, this is a patient with heart  
4 failure.

5 That's an unfortunate thing that  
6 happens, but abstractors do this as a rule of  
7 thumb, I think in general, to give the benefit  
8 of the doubt in those measures that are  
9 somewhat difficult to collect. We know with  
10 this one, the numerator and denominator is  
11 fairly clearly defined. Exclusions are  
12 identified, and in the --

13 So from a scientific acceptability  
14 standpoint, I think it does meet the criteria,  
15 even though we know that perhaps there is some  
16 gaming that goes on with this measure that  
17 does not happen with some of the others.

18 MEMBER THOMAS: I have a quick  
19 question with the numerator. In terms of the  
20 time before arrival, is there any limitation  
21 on the amount of time? Is it ten years, you  
22 know? Can it be at any time?

1                   MEMBER SZUMANSKI: From the  
2 numerator time window is from hospital arrival  
3 to the time of hospital discharge.

4                   MEMBER THOMAS: No. I mean that  
5 testing of LV function before arrival? I just  
6 wondered if there was a time limit.

7                   DR. MASOUDI: Yes, there's not, and  
8 this has been a topic of substantial debate.  
9 I think the -- and after a huge amount of  
10 going back and forth on this, the decision has  
11 been not to put a time window around it for  
12 several reasons.

13                   One is that putting a time window  
14 around the variable increases the burden of  
15 abstraction. But perhaps more importantly,  
16 that it's -- that in some cases, a direction  
17 for action obtained a year or two ago may be  
18 adequate, and we don't want to necessarily  
19 stimulate over-use of imaging.

20                   Further, there's not explicit  
21 guideline recommendations as to what an  
22 appropriate time interval is. Sort of the



1 three of those things conspiring together have  
2 led the measure in the direction of not using  
3 an explicit time window around the  
4 documentation.

5 The idea here is for the clinician  
6 to document the EF that they are using to help  
7 guide the management of the patient, and  
8 direct the use of other evidence-based  
9 therapies. So that's sort of the approach  
10 that's been taken here.

11 MEMBER SZUMANSKI: I think the one  
12 thing that this measure may bear scrutiny in  
13 the future on is the use of imaging, and how  
14 many times do you image the same patient in a  
15 given period of time, especially if they're  
16 frequent flyers and admitted regularly.

17 DR. MASOUDI: Right, absolutely,  
18 and the one thing to emphasize about this  
19 measure is that it does not suggest that a  
20 patient who is admitted with heart failure  
21 necessarily needs a new assessment of left  
22 ventricular systolic function. That is to say

1 if a patient had one several months ago and  
2 they say this is a patient with a known  
3 ejection fraction of 20 to 25 percent, that  
4 gets credit.

5 So this is not designed to  
6 stimulate repeat imagining in frequent flyers,  
7 as per the concern you raised.

8 MEMBER THOMAS: I mean I totally  
9 respect that. But just, as we all know, there  
10 is a lot of imaging done, and maybe an  
11 unintended consequence of this. But, you  
12 know, I think it's a good measure overall.

13 DR. MASOUDI: I'm sorry. Could you  
14 clarify the unintended consequence part of it?

15 CHAIR GIBBONS: Fred, this is Ray.  
16 I think Suma's actually correct, because I've  
17 had this discussion with multiple physicians.  
18 They do not realize, people do not actually  
19 realize.

20 They are under the misimpression  
21 that they have to do the EF during the  
22 hospitalization, and use that for

1 justification for doing something that's  
2 clinically actually unnecessary. It's a  
3 misstatement of the specifications in the  
4 measure.

5 DR. MASOUDI: Right. I see, okay.  
6 No, I think that's -- I understand what you're  
7 saying. Thank you for the clarification.

8 MEMBER KING: I have a question  
9 about the meaningful differences. I  
10 understand about the Native American patients,  
11 but nevertheless the national performance  
12 rates for this measure in the first quarter of  
13 2010 were 98 percent.

14 Native American patients were 3,400  
15 of the 773,000 in the data warehouse, which is  
16 well under -- well, one percent. Am I right?  
17 Yes, thank you. Well under one percent, and  
18 we're talking about their performance was only  
19 94-95 percent, versus the 98 of others.

20 When you put that on the front page  
21 of the Arizona news, does everybody really get  
22 upset about it and get motivated to -- I don't

1 know if it's a meaningful difference for a  
2 national guideline from NQF, to keep doing  
3 this, and it is getting near to our, what we  
4 call our retirement warehouse, and we should,  
5 you know, think about that.

6 VICE CHAIR GEORGE: I think we had  
7 some other measures in this. Can you comment  
8 Reva?

9 DR. WINKLER: Well, we need to have  
10 a further discussion about the concept of  
11 retirement, which you all brought up last  
12 time, and prompted a great deal of internal  
13 discussion at NQF, because we really hadn't a  
14 process or criteria, which you also asked for,  
15 for doing that.

16 Since that time, we have developed  
17 those, and it's on the agenda to discuss  
18 tomorrow. If this is a measure that may fall  
19 into that category, we can flow these all  
20 together, if you'd like.

21 MEMBER KOPLAN: Was this raised  
22 when we were talking about number one, because

1 we're already on number two, and this applies  
2 to number one?

3 MEMBER SZUMANSKI: I think the  
4 struggle that I have with this measure is that  
5 it is a starting point for therapy, and if you  
6 eliminate this one, it has impact on the  
7 measures that come below this. So it serves  
8 as a foundational measure.

9 To me, this would be better served  
10 in a composite format, and I know you hate to  
11 hear that word, but it really doesn't stand  
12 alone without what are you going to do for  
13 this patient whose EF is this?

14 DR. BURSTIN: And there's a  
15 composite measure you're going to review later  
16 today, on exactly that point. Just one  
17 comment on the EF alone issue. This comes up  
18 all the time with assessment measures. So in  
19 general, you know, assessment measures have a  
20 place.

21 But the question would be since you  
22 also have therapy measures that depend on the

1 assessment, is the assessment alone important  
2 enough as a stand-alone? The LV, the other  
3 measures about beta blockers and ACE/ARBs  
4 depend on demonstration of low EF. So just a  
5 question about that.

6 MEMBER SANZ: The problem is that  
7 you end up losing all of your -- you only know  
8 then that the patients who got the EF were  
9 treated appropriately. You don't know that  
10 the patients who should have been on treatment  
11 didn't get the test. So they're not mutually  
12 independent.

13 Having said that, if 99 percent of  
14 people are getting the test, what's the value  
15 here?

16 MEMBER PHILIPPIDES: That the  
17 impact is very, very small, almost nothing.  
18 Is that right?

19 MEMBER SANZ: Wasn't that 1(b)  
20 performance gap? We kind of missed it.

21 MEMBER SMITH: Maybe if the impact  
22 is small, my question is not important. I am

1 concerned about what Ray says. The way it's  
2 written now, it would appear that every time  
3 a patient's admitted, you need to get a  
4 systolic ejection fraction.

5 DR. MASOUDI: Well again, just to  
6 speak to the -- and it's quite possible, and  
7 Ray, as you've alluded to it, it is in fact  
8 the case that in some circumstances, this has  
9 been misconstrued.

10 But the measure specifications  
11 themselves, I think, are quite clear, that  
12 this doesn't require actually a repeat  
13 imaging, but rather the documentation of a  
14 left ventricular systolic function, which can  
15 be from before the hospitalization.

16 So and again, these are the  
17 specifications that have been in place over  
18 the last eight to ten years or however long  
19 that CMS and the Joint Commission have been  
20 using these measures for the purpose of the  
21 public reporting program.

22 MEMBER RUSSO: Yes. So it clearly

1 states, I mean, you can have it prior to  
2 admission, and I guess with the comments made  
3 today, we don't know how long before. So  
4 maybe there should just be something saying  
5 that it -- just a little asterisk saying it  
6 does not need to be during this  
7 hospitalization or immediately before.

8 It could be within something  
9 clinically -- a little asterisk saying that  
10 you don't need to repeat it every time you  
11 come in, you know, reflecting the comments  
12 that were made, with that mantra. Just if  
13 there's some clarification needed for overuse.  
14 I don't know if there is overuse or not.

15 VICE CHAIR GEORGE: We have one  
16 option, whether people want to go back and  
17 revote on the Importance, based on the  
18 discussions we've had on scientific validity.

19 MEMBER KOPLAN: I second the  
20 motion.

21 DR. MASOUDI: I have a question.

22 VICE CHAIR GEORGE: Yes.



1 DR. MASOUDI: A process question  
2 about something that I believe NQF staff  
3 mentioned, which was that it was, there was a  
4 plan to circle back to a group of measures,  
5 and decide whether or not about the issue of  
6 topping out. Is that, was that an accurate?  
7 Did I hear that right?

8 DR. WINKLER: It will depend on  
9 what the decision is of the discussion  
10 currently on the table. We will be circling  
11 back for the ones that were previously  
12 discussed, but I think the committee's still  
13 discussing how they feel about this measure  
14 right now.

15 VICE CHAIR GEORGE: Right --

16 DR. MASOUDI: Is that in the  
17 performance level though, or does that include  
18 the performance level?

19 DR. BURSTIN: Right. So let me  
20 just take a moment, because I think we're  
21 operating a little bit in the dark, although  
22 I think you shared the inactive memo with

1       them, is that right, inactive endorsement? So  
2       you've seen what we've proposed. It's going  
3       out for public comment this week. It will  
4       then go to our board.

5               But essentially what we proposed is  
6       that for measures that are otherwise  
7       important, valid, reliable but incredibly high  
8       levels of performance, the idea would be  
9       should we at least keep them somehow in an  
10       inactive status, so people could use them for  
11       periodic surveillance, to make sure that when  
12       you take your eyes off the prize and they're  
13       not being perhaps front and center as the way  
14       they have been for years, which is probably  
15       why they're at 98 percent, because we paid on  
16       them and looked at them constantly, to make  
17       sure that the performance doesn't deteriorate.

18               We can maintain them in an active  
19       status, so that if there was a decrement in  
20       performance over time, that measure wouldn't  
21       need to come back through the process. It  
22       would still already be in this inactive mode.

1                   VICE CHAIR GEORGE:  So we would  
2                   need to endorse a measure in order to have it  
3                   considered for inactive status?

4                   DR. BURSTIN:  This is a little  
5                   complicated, because these measures are  
6                   endorsed.  They're up for maintenance.  So I  
7                   think this might be one of the ones if you  
8                   want to put it as a parking lot.  I think the  
9                   issue would be how important is this measure  
10                  on its merits, if you take away the issue of  
11                  the percent performance, all the issues still  
12                  notwithstanding that you've already talked  
13                  about around the EF.

14                  But still just this issue of it  
15                  being at 98, 97-98 performance consistently  
16                  for years, with really very little variation  
17                  across hospitals.  If you take that out of the  
18                  mix, is this -- does it otherwise meet the NQF  
19                  criteria for evaluation.

20                  MEMBER SZUMANSKI:  Can I just ask  
21                  a clarifying question?  If the issue comes up  
22                  that imaging is being overused in patients

1 with heart failure, and we are not monitoring  
2 the use of imaging in heart failure, and we're  
3 moving directly to treatment, does that have  
4 an impact on whether or not this measure  
5 remains in existence?

6 I don't know if I'm making myself  
7 clear, but I see this measure coming under  
8 fire from the imaging standpoint and the cost.  
9 So I'm just asking if, do we need to continue  
10 to measure it, to see are they actually over-  
11 imaging heart failure patients?

12 MEMBER KOPLAN: You won't get it.

13 MEMBER SZUMANSKI: Okay.

14 MEMBER THOMAS: There are many ways  
15 that that's already being addressed, and so --  
16 no, no. It's a good question, but there are  
17 many other ways that's being addressed on a  
18 national level, that we unfortunately know the  
19 answers, that there's just an increase, a huge  
20 increase in imaging. So I think we do need to  
21 take that into consideration as we are.

22 MEMBER SZUMANSKI: Okay, that's

1 good.

2 MEMBER RUSSO: Is there is any way  
3 to -- so we still know measures are important  
4 and we want to retire it. Is there something  
5 on that last thing that we vote on? Could it  
6 be inactive then, that's going to -- you know,  
7 is there some way that we could specify that  
8 it's still important, all these things are  
9 good to do, but we want to -- we don't really  
10 need to use it still? How would we do that?

11 DR. WINKLER: You need to evaluate  
12 the measure as it is, because we still --  
13 those measures still have to meet all the  
14 criteria. The only one they could maybe fall  
15 off on is the opportunity for improvement. So  
16 they still have to pass everything else  
17 solidly.

18 So some of these other issues  
19 you're raising make me wonder how you feel  
20 about the other criteria. So that  
21 conversation is very important, because it is  
22 a prerequisite to moving them into that

1 inactive category.

2 VICE CHAIR GEORGE: Bruce.

3 MEMBER KOPLAN: Isn't it just  
4 better to have a yes/no, and not like an in  
5 limbo kind of thing, because then it gets  
6 confusing. Like is there, has this been  
7 established as a precedent already? So if it  
8 hasn't yet been established, then what you  
9 just said, just evaluate?

10 DR. BURSTIN: Yes.

11 VICE CHAIR GEORGE: Any more  
12 comments on Scientific Acceptability?

13 MEMBER SZUMANSKI: I heard that  
14 we're going to go back and vote on Importance  
15 again. Are we not doing that?

16 VICE CHAIR GEORGE: A show of  
17 hands?

18 MEMBER AYALA: Can you clarify  
19 first though, because I'm confused. If we did  
20 go back, are we supposed to ignore the  
21 performance part?

22 VICE CHAIR GEORGE: No.

1 DR. WINKLER: No. One of the  
2 issues is it's important to capture the  
3 rationale behind your vote, and if your  
4 discussion focuses strictly on the lack of  
5 opportunity for improvement, and no other  
6 issue such as evidence base or any of the  
7 other concerns, and you think that it won't  
8 meet the importance criteria. That's fine as  
9 a special case.

10 But if there are issues,  
11 particularly around the evidence base, that  
12 means you're kind of failing on that criteria.  
13 We're trying to sort out how to walk you  
14 through these options that are branching,  
15 frankly.

16 VICE CHAIR GEORGE: Right, and it  
17 sounds like we've had a lot of discussion  
18 about other issues outside of the topping out  
19 on performance. So that's fine. We'll just,  
20 we will proceed to evaluate the entire  
21 measure, and vote on Scientific Acceptability.

22 Tom's gone. Everybody voted?

1 DR. WINKLER: Dianne?

2 MEMBER JEWELL: I'm sorry. People  
3 were popping in and out. So which vote are we  
4 taking?

5 DR. WINKLER: Scientific  
6 Acceptability.

7 MEMBER JEWELL: Acceptability,  
8 partially. Thank you.

9 VICE CHAIR GEORGE: So that's seven  
10 completely, six partially, five minimally.  
11 And moving on to Usability?

12 MEMBER THOMAS: I think the  
13 question of does it add value would be based  
14 on some of our prior conversation here, in  
15 terms of is this an important measure to be  
16 used as a stepping stone to other clinical  
17 decisions, or can we gather this information  
18 in another way, or have we proven that there  
19 is no performance gap that is significant  
20 enough?

21 I think the only thing that I would  
22 note under Usability is the issue of imaging,



1       which we've already talked about, and in the  
2       CDAC trial with the audits that were done on  
3       this measure, there was a 4.6 performance  
4       deficiency noted in charts that were reviewed,  
5       and they were all related to documentation of  
6       a note indicating that EF was done, will be  
7       done, had been done in the past. So the  
8       issues were documentation-related, not  
9       performance-related.

10                   VICE CHAIR GEORGE: Any further  
11       discussion on Usability?

12                   MEMBER SNOW: We were talking about  
13       upcoding and those issues, gaming. They  
14       impact this. I'm not sure exactly how much  
15       they impact it, but it affects the Usability,  
16       apart from can people understand the number,  
17       which is the usual way that usability is  
18       described. Because its ability to be used if  
19       the reliability, going back to scientific  
20       acceptability. If that is poorer, then its  
21       usability is less.

22                   VICE CHAIR GEORGE: Any further

1 discussion?

2 (No response.)

3 VICE CHAIR GEORGE: We'll vote on  
4 Usability.

5 DR. WINKLER: Dianne?

6 MEMBER JEWELL: Partially.

7 VICE CHAIR GEORGE: 5 completely,  
8 10 partially, 4 minimally, and Feasibility.

9 MEMBER SZUMANSKI: I think the  
10 measure is feasible to collect. I think the  
11 issue again rests with the documentation, and  
12 the upcoding that does occur we know that it  
13 happens unfortunately. That really is the  
14 bulk of what I can say about feasibility. It  
15 can be collected.

16 MEMBER PHILIPPIDES: But we still  
17 have some concern about the unintended  
18 consequence of perhaps over-ordering imaging  
19 studies; is that correct?

20 MEMBER SZUMANSKI: I believe that's  
21 a concern with this measure. Maybe not now,  
22 but it will be in the future.

1                   VICE CHAIR GEORGE: Any other --  
2 David?

3                   MEMBER MAGID: Did we have any  
4 suggestions for addressing that issue? I  
5 thought Ray, you might have brought up -- you  
6 brought up some specific language, and I  
7 wonder if we could help with that.

8                   CHAIR GIBBONS: Actually, others  
9 have suggested the language. I think the  
10 measure specs are pretty clear. The problem  
11 is how the clinical practice community has  
12 chosen, usually without any knowledge, to  
13 interpret them.

14                   So I'm quite serious. I've had  
15 fairly ferocious arguments with other staff  
16 physicians at the Mayo Clinic, where they say  
17 "no, no, I have to do an echo with this  
18 admission."

19                   I say "no, no, you don't," and you  
20 know, it's really quite fascinating to see how  
21 people, and they will all quote, by the way,  
22 some meeting that they've just gone to, where

1 somebody who was allegedly a, quote, quality  
2 guru in their organization or whatever, stood  
3 up and made that statement, and it's flat-out  
4 wrong.

5 MEMBER MAGID: Right, and the fact  
6 that the financial incentives line up so  
7 nicely doesn't have any impact, right?

8 MEMBER SANZ: Couldn't much of this  
9 be resolved with an explanatory one sentence.  
10 "This measure does not mandate an echo at the  
11 time of admission."

12 CHAIR GIBBONS: You're assuming  
13 somebody would actually read that. They will  
14 not.

15 MEMBER THOMAS: The problem is --

16 MEMBER SANZ: But you will remind  
17 them, on your right or left side. Read the  
18 sentence.

19 MEMBER THOMAS: The problem is, as  
20 all of you are probably aware, those who are  
21 reporting on PQRI for example right now, we  
22 get a short little blip, you know, as an

1 indicator. Are you doing this, are you doing  
2 that? It doesn't have any of the description  
3 of the measure.

4 So this, unless it was changed a  
5 lot, it really would probably continue to be  
6 an issue.

7 VICE CHAIR GEORGE: Any other  
8 comments on Feasibility?

9 (No response.)

10 VICE CHAIR GEORGE: Okay. We will  
11 vote.

12 DR. WINKLER: Dianne?

13 MEMBER JEWELL: Minimally.

14 DR. WINKLER: Thank you.

15 VICE CHAIR GEORGE: 5 completely,  
16 8 partially, 6 minimally.

17 MEMBER MAGID: Just I just ask Mary  
18 then, this is really a question for NQF staff,  
19 have you had a situation like this, where you  
20 think that, you know, on the one hand you have  
21 this measure which you think is fairly  
22 evidence-based in terms of quality, but the

1 introduction of the measure actually had the  
2 negative unintended consequences of driving up  
3 utilization where it might not have been  
4 necessary? Is that a problem you've had  
5 before?

6 DR. WINKLER: Well, not in this  
7 specific thing. But it's certainly not  
8 unusual for us to get the feedback that the on  
9 the ground implementation has issues that  
10 weren't necessarily anticipated or grow with  
11 the implementation of it. We try and solicit  
12 that information from folks, but as yet it  
13 isn't -- it's one of those things that kind of  
14 comes in randomly.

15 DR. BURSTIN: It is. There was one  
16 very prominent example when we had the initial  
17 pneumonia measure, that you had to have  
18 antibiotics in within four hours of coming to  
19 an EDE with presumptive pneumonia. Everybody  
20 walked in, the little old ladies with CHF,  
21 everybody was getting shot up with  
22 antibiotics, from what we heard, instead of

1 getting their CHF managed.

2 And so the measure, and that's an  
3 example of somebody asks well, what do we do  
4 when we hear about that? We did ad hoc  
5 review. The measure was re-reviewed. The  
6 measure was subsequently changed to be either  
7 presumptive diagnosis of pneumonia on the  
8 chest X-ray, as well a six hour window.

9 But again, there are examples like  
10 that, and it's the kind of thing you  
11 oftentimes you don't know about for initial  
12 endorsement, for a measure like this that's  
13 been out for years and years and years. I  
14 think it's an interesting question of how you  
15 would begin to assess whether in fact it's  
16 driven up imaging because of a perception you  
17 need to do it every time.

18 MEMBER PHILIPPIDES: I have this  
19 feeling that in three years, we'll be in the  
20 same room, and we'll have one measure in front  
21 of us getting too many echos in one year  
22 period. Should that be a quality measure of

1 bad quality, and then we'll harken back to  
2 this discussion, and think we didn't get it  
3 right exactly. But it's a tough one, it's a  
4 tough one.

5 MEMBER SNOW: Well, that's because  
6 everything you do drives up imaging. I mean  
7 going to the store drives up imaging,  
8 everywhere.

9 MEMBER PHILIPPIDES: Right. But  
10 lowering reimbursement drives it down.

11 VICE CHAIR GEORGE: Well I mean  
12 certainly, this is an opportunity to take our  
13 comments back to the measure developers, and  
14 you bring up the interesting point of the  
15 complexity of measures, and the education that  
16 needs to be done by developers about the  
17 complexity and exactly what these measures  
18 mean.

19 So any further comments before we  
20 vote on endorsement of the measure as it  
21 stands?

22 MEMBER STEARNS: So will a no vote,



1       how will -- where are we on the -- we've  
2       topped out on performance.  Is that, are we  
3       back to that question again, that voting no is  
4       not a reflection on the quality of the  
5       measure, but rather on the topping out on  
6       performance, or are we not considering that  
7       point at this point?

8                   VICE CHAIR GEORGE:  At this point,  
9       it would be a totality of all of the factors  
10      that we consider.

11                   MEMBER KOPLAN:  And it also sounds  
12      like it's not just the topping out on  
13      performance issues, from our discussions.

14                   VICE CHAIR GEORGE:  Any further  
15      questions?

16                   (No response.)

17                   VICE CHAIR GEORGE:  All right.  
18      We'll vote on endorsing the measure.

19                   DR. WINKLER:  Dianne?

20                   MEMBER JEWELL:  No.

21                   DR. WINKLER:  Okay.

22                   VICE CHAIR GEORGE:  5 yes, 13 no.

1 So we are proposing to take a 15 minutes  
2 break, bring us back at five minutes to 4:00.

3 DR. WINKLER: This is Reva. To our  
4 measure developers on the phone, as you can  
5 see, we're running a bit behind schedule.

6 At this point, we're uncertain as  
7 to whether we're going to be able to get to  
8 all of the measures that are in the last  
9 group. It would be good for us to know if any  
10 of you would be able to let us push your  
11 measure until first thing tomorrow morning, if  
12 time runs out on us.

13 So if you're on the phone and can  
14 tell me right now. If not, if you can email  
15 Katie Streeter, or somehow just let us know  
16 what our options might be.

17 (Whereupon, the above-entitled  
18 matter went off the record at 3:39 p.m. and  
19 resumed at 3:56 p.m.)

20 VICE CHAIR GEORGE: Okay. Our next  
21 measure is Measure 0162. Andrea?

22 MEMBER RUSSO: Okay. So this is

1 0162, which I thought ahead of time it would  
2 be easy, but now I'm not sure. So this is ACE  
3 or ARB for LV systolic dysfunction in heart  
4 failure patients, and basically, the  
5 description of the measure is the percentage  
6 of heart failure patients with LV systolic  
7 dysfunction who are prescribed ACE or ARB  
8 therapy at hospital discharge.

9           So it's an inpatient measure,  
10 right, at the time of possible discharge. For  
11 the purposes of this particular measure,  
12 systolic dysfunction is described as an  
13 ejection fraction of less than 40 percent, as  
14 we've seen, or a narrative description of  
15 moderate to severe systolic dysfunction. So  
16 the quantification for that description would  
17 be equivalent, you know, clinically to less  
18 than 40 percent. It's a process measure.

19           The importance of the measure is  
20 just, you know, it's clear. It affects large  
21 numbers of patients. It's important in both  
22 quality improvement and public reporting.

1 This has a high impact. There is, you know,  
2 we know lots of data, as everyone here knows,  
3 that the therapy reduces mortality and it  
4 improves morbidity also.

5 There are some disparities also  
6 that were mentioned, namely in African-  
7 Americans, who had a lower rate on this  
8 measure of 91.8 percent. Lots of data.  
9 Again, randomized control studies, meta-  
10 analyses. So I don't think there's any  
11 question that this is an important measure.

12 MEMBER RUSSO: There is no concern,  
13 just because based on the earlier discussion,  
14 some of the other ones, I thought, were easy  
15 also. Yes. No concerns, no.

16 VICE CHAIR GEORGE: Any discussion  
17 about this importance of this measure?

18 MEMBER KING: At the risk of  
19 violence, I do have a question. It seems that  
20 we've had several of these ACE or ARB in the  
21 treatment of something, and it seems to me  
22 that the "something" was left ventricular

1 function, 49 or 50 times.

2 I guess we had in the setting of  
3 coronary disease and then we had it in the  
4 setting of an MI, and then we had in the  
5 setting of atrial fibrillation, and now we  
6 have it in the setting of nothing, right?

7 MEMBER RUSSO: They do actually  
8 have a nice --

9 MEMBER KING: Just coming in the  
10 hospital and then leaving, then we have it  
11 again. I don't know. It just seems to be  
12 crying out for harmonization.

13 MEMBER RUSSO: And they do actually  
14 describe that.

15 MEMBER KING: And that doesn't  
16 mean it's not important; what it means is just  
17 a consolidation. So you know, just a little  
18 asterisk for later, that's all.

19 MEMBER RUSSO: I don't know if you  
20 want to discuss that now. They do describe it  
21 later in the application, really nicely  
22 actually, looking at -- they talk about

1 harmonization and comparison and come up with  
2 this particular measure. They said that  
3 there's no NQF endorsed measure with the same  
4 topic and the same target population. That  
5 means the hospital discharge.

6 So I don't know if that's true or  
7 not, but you know, we can clarify that, but  
8 it's -- and they go through some specifics  
9 that it's not harmonized in other settings by  
10 specifications. We can go through that later.  
11 But this is at discharge with not just  
12 coronary disease patients; it could be non-  
13 ischemic cardiomyopathy patients. It's the  
14 time of discharge, so it's not post-MI.

15 MEMBER KING: A follow-up. It  
16 seems like no, that's right. In fact, it  
17 seems like this one -- it's not the other  
18 ones cover this one; it's that this one covers  
19 the other ones.

20 MEMBER RUSSO: A good point.

21 MEMBER JEWELL: So this is Dianne.  
22 I thought that one of our objectives was to

1       vet measures on their own merits, and then  
2       pick best in class, and I realize that if we  
3       already think we know what the one is that's  
4       best in class, that seem like some redundancy.  
5       But I guess that's where I thought this was.

6               CHAIR GIBBONS:   Just to clarify  
7       though, this is principle diagnosis of heart  
8       failure, DRG heart failure.  But that's --

9               MEMBER RUSSO:   So not MI.

10              MEMBER KING:    Not just --

11              MEMBER RUSSO:   Not CAD.

12              CHAIR GIBBONS:   Not an MI, not CAD.  
13       You've got to be in the DRG for heart failure.

14              MEMBER KING:    Even if it was due  
15       to coronary disease, even if it was due to --

16              CHAIR GIBBONS:   It doesn't matter  
17       what it's due to.  It's in your --

18              MEMBER KING:    It doesn't matter.

19              CHAIR GIBBONS:   No.  That's your  
20       principle diagnosis.

21              VICE CHAIR GEORGE:  Any further  
22       discussion on the importance of this measure?

1 (No response.)

2 VICE CHAIR GEORGE: All right.

3 We'll move to a vote.

4 DR. WINKLER: Dianne?

5 MEMBER JEWELL: Yes.

6 DR. WINKLER: Thank you.

7 VICE CHAIR GEORGE: Unanimous, 18

8 yes. All right. Moving on to Scientific

9 Acceptability.

10 MEMBER RUSSO: I think in terms of

11 this category, the things look pretty good

12 here. The specification again is those who

13 have ACE or ARB therapy at discharge, and have

14 the diagnosis of heart failure, as was

15 mentioned. The exclusions, you know,

16 certainly are reasonable ones.

17 They did do some reliability

18 testing, which they outline regarding, you

19 know, and the only question I would have for

20 the measure developers, the one where they

21 validated with a sample of five cases per

22 quarter across all topics, they came up -- the



1 percentage was only like 77 percent for, you  
2 know, validating the reason for no ACE  
3 inhibitor or ARB at discharge.

4 To me, that seemed low, but I don't  
5 know what's considered -- no. Does everyone -  
6 - the other things were 86 or 98 percent, you  
7 know, for validation there. But other than  
8 that, I mean I think I didn't have any other,  
9 you know, difficulties in this category.

10 Disparities, there was the race  
11 disparity that was identified still. So I  
12 think, you know, it looked good to me in this  
13 category. They did say the race disparity,  
14 although they didn't adjust for all others.  
15 It was a univariate analysis. They didn't  
16 adjust for everything else yet, but they did  
17 address disparity.

18 DR. WINKLER: Just a question,  
19 because you had a similar one with the MI  
20 measure, is how is a missing value for a left  
21 ventricular systolic dysfunction handled in  
22 this measure?

1 DR. MASOUDI: If the LVF is not  
2 known, the patient can't be assessed for  
3 compliance on this measure.

4 DR. WINKLER: So you're saying  
5 they're excluded for a missing value?

6 DR. MASOUDI: Yes, which is in part  
7 the reason why the previous measure is, was  
8 intertwined with this particular one.

9 MEMBER SNOW: I have a question  
10 about validity testing. It says here 2(c),  
11 "Face validity is regularly assessed with the  
12 technical expert panel responsible for  
13 reviewing and supporting the measured topic."  
14 My understanding of face validity is that it  
15 is something that you get with people who are  
16 not experts, that content validity is done  
17 with experts, and I mean it's sort of almost,  
18 maybe it's being used in a jargony way.

19 But I don't think it necessarily  
20 changes outcomes here, but am I the only one  
21 who thinks that, or does it matter? I want to  
22 see who responds. Shut up and move on, I

1 guess.

2 MEMBER RUSSO: Point well-taken.

3 VICE CHAIR GEORGE: Any other  
4 concerns or comments on the scientific  
5 acceptability?

6 (No response.)

7 VICE CHAIR GEORGE: Hearing none,  
8 we'll move to a vote.

9 DR. WINKLER: Dianne?

10 MEMBER JEWELL: Partially.

11 DR. WINKLER: Thank you.

12 VICE CHAIR GEORGE: 11 completely,  
13 7 partially. Moving on to Usability.

14 MEMBER RUSSO: This measure is  
15 currently in use, and they actually, you know,  
16 go through some discussion on -- I don't know  
17 if harmonization is under this or not. Is it?  
18 Yes, I think it is, you know, as how it's  
19 something I guess we're talking about more  
20 tomorrow.

21 But they go through a very nice  
22 discussion on how this measure, you know,

1 compares to other measures, and they bring up  
2 that even though some of the specifications  
3 may be a little bit different, this is again,  
4 you know, measured at the time of discharge  
5 and compared to another measure, 610, was an  
6 outpatient measure that had a three-year time  
7 window, based on administrative data.

8           Again, they're totally different.  
9 They're looking at something totally different  
10 in that case, with regard to the setting of  
11 care and the type of data there. So you know,  
12 I think this is fine for this measure.

13           VICE CHAIR GEORGE: Any discussion  
14 about the Usability?

15           (No response.)

16           VICE CHAIR GEORGE: All right.

17 We'll move to a vote.

18           DR. WINKLER: Dianne?

19           MEMBER JEWELL: Completely.

20           VICE CHAIR GEORGE: 14 completely,  
21 4 partially, 1 minimally, and Feasibility.

22           MEMBER RUSSO: The one question I

1 had on a comment they made on feasibility, are  
2 all data elements available electronically,  
3 they say "no," and I think, I'm assuming, is  
4 the only thing that's not available, the  
5 comment about moderate or severe LV systolic  
6 dysfunction? Is that what was meant by that?

7 DR. MASOUDI: Yes. There's, I  
8 think currently, this is going to change over  
9 time, I think undoubtedly. Currently, the  
10 actual value of left ventricular systolic  
11 function can be challenging to ascertain  
12 electronically. It's really a function of the  
13 robustness of the underlying system in which  
14 the measurement occurs.

15 Again, I think with more widespread  
16 adoption of EMRs, the answer to this question  
17 will certainly change.

18 MEMBER RUSSO: So you know, I  
19 think, okay. That answers the question,  
20 because I guess the one difference here  
21 obviously is not just using the EF number, but  
22 it's allowing the moderate or severe systolic

1 dysfunction. I don't know how other people  
2 feel about that. I was fine with it the way  
3 it is, but something to think ahead about in  
4 terms of harmonizing with other measures.

5 I think -- oh, the other thing,  
6 exclusions. They make a comment on what have  
7 you learned from this before. If you're  
8 excluding certain patients from use of an ACE  
9 inhibitor, before they look back and found  
10 that, you know, some of the same  
11 contraindications to ACE inhibitor therapy are  
12 similar for ARBs.

13 So rather than some people may not  
14 repeat it, because it's intrinsically obvious  
15 to everyone that reasons like hyperkalemia or  
16 other renal dysfunction issues. So for the  
17 going forward, that would be included. You  
18 wouldn't have to reabstract that data. You  
19 wouldn't have to redocument the same reason if  
20 you're already documented it for the ACE  
21 inhibitors.

22 So I think, I didn't have any other

1 issues in this category. I think that's fine.

2 VICE CHAIR GEORGE: Any discussion  
3 on Feasibility?

4 (No response.)

5 VICE CHAIR GEORGE: Okay. We'll  
6 take a vote on this.

7 DR. WINKLER: Dianne?

8 MEMBER JEWELL: Partially.

9 DR. WINKLER: Thank you.

10 MEMBER JEWELL: You're welcome.

11 VICE CHAIR GEORGE: 13 completely,  
12 5 partially. And any further discussion on  
13 this before we move to a vote on endorsement?

14 MEMBER RUSSO: I guess the only  
15 other question I alluded to before is I'd just  
16 like to, and this may be just a minor point,  
17 just the thoughts of the developers. You  
18 know, talking about potential overuse for the  
19 exclusion criteria for potentially distorting  
20 the performance rates.

21 Can you just make a comment on the  
22 difference in terms of that 77 percent that

1       came out in that, you know, random sample of  
2       whatever it was, five. Let me see what page  
3       that was on, but is that considered an  
4       acceptable number?

5                   DR. MASOUDI: Yes, I think those  
6       are both important but slightly different  
7       questions, vis-a-vis the 77 percent issue. A  
8       lot of the sort of reproducibility of these  
9       things depends upon the complexity of the --  
10      sort of the data element itself and sort of  
11      the variety of sources where that might be  
12      captured.

13                   I would say, you know, for this  
14      specific data element, an approximately 80  
15      percent, you know, rate of reproducibility is  
16      actually, I think, quite acceptable. That's  
17      obviously just -- that's a subjective  
18      estimate.

19                   With respect to this issue of the,  
20      you know, the exclusions, I think that any  
21      measure with an exclusion, you know, this is  
22      a philosophical that pertains to any measure



1 where exclusions are allowed.

2 And many such measures don't have  
3 a clearly delineated list of exclusions for a  
4 variety of reasons. This construction is the  
5 result of years upon years of field testing,  
6 and responsiveness to the community that uses  
7 these measures. So I think it's always, you  
8 know, a possibility that any exclusion could  
9 lead to gaming.

10 But I think as was suggested before  
11 at the prior meeting, if one is going to write  
12 down why one didn't give an ACE inhibitor,  
13 it's just as easy to give it when you're  
14 thinking about it. So I think the likelihood,  
15 the concern about gaming of this sort of  
16 exclusion is, you know, to the extent that you  
17 have to think about giving a medication in  
18 order to write a reason not to give it down,  
19 sort of minimizes concerns about that.

20 MEMBER RUSSO: Okay, thanks. That  
21 makes sense.

22 VICE CHAIR GEORGE: Any other

1       comments or questions on this?

2                       (No response.)

3                       VICE CHAIR GEORGE: All right.

4       We'll vote on the endorsement.

5                       DR. WINKLER: Dianne?

6                       MEMBER JEWELL: Yes.

7                       VICE CHAIR GEORGE: It's unanimous,  
8       20 yes. Okay, and we'll move on to the last  
9       one in this set, number 0136. Carol?

10                      MEMBER ALLRED: The title of this  
11       measure is heart failure, discharge and  
12       detailed discharge instructions. The brief  
13       description is percentage of heart failure  
14       patients discharged home with written  
15       instructions or educational materials given to  
16       patients or caregiver at discharge or during  
17       hospital stay, addressing all the following:  
18       activity level, diet, discharge medication,  
19       follow-up appointment, weight monitoring and  
20       what to do if things worsen.

21                      Now I have to stop right here and  
22       tell you that this measure gave me a great

1 deal of existential angst. Sorry Ray. I  
2 could not come up with a better word, and this  
3 is where my patient side comes out. I am a  
4 patient. I have been hospitalized with heart  
5 failure, and when I read this, it looks to me  
6 like the importance of this measure is: did  
7 someone in the hospital document whether or  
8 not written instructions were given to the  
9 patient?

10 In my outlook, it is not whether  
11 written instructions were given to me; it is  
12 what is the quality of those instructions?  
13 Was I as a patient able to understand those  
14 instructions, and can I then take them home  
15 with me and apply them to improve the outcome  
16 of my condition.

17 MEMBER SMITH: You're absolutely  
18 right. As a physician, I'll join you.

19 MEMBER ALLRED: All right. That  
20 was my synopsis up front. I don't think that  
21 during a hospital stay, any patient could be  
22 totally educated about what they to know about

1 heart failure. I think the measure misses its  
2 point from that standpoint.

3 But if you back off and look at it  
4 just from written instructions, obviously  
5 that's an important thing. So I'll throw it  
6 out for discussion and let you all decide  
7 where I go from here.

8 MEMBER SZUMANSKI: I think the  
9 other point with this, in conjunction with it,  
10 is we have national standards on health  
11 literacy. It is not spoken to in this measure  
12 at all, and it ties in with what you're  
13 saying. If they can't understand it, it  
14 wasn't explained and they can't even read it,  
15 they're coming back to the hospital with their  
16 instructions still in the sealed envelope and  
17 saying "Somebody gave this to me, but I can't  
18 read them or understand them."

19 MEMBER MAGID: Right. I guess --  
20 I don't know who's supposed to call on me, but  
21 I think that in each of the packets where they  
22 talk about process measures, they talk about

1 the strength of association with outcomes.  
2 The mere, you know, provision of discharge  
3 instructions, I don't know that that in and of  
4 itself is related to outcomes.

5 MEMBER MAGID: Well, about ten  
6 years ago --

7 MEMBER JEWELL: This is Dianne.  
8 It sounds like what, the outcome comments  
9 aside for a moment, it sounds like what this  
10 measure needs to read like is verification,  
11 that there's documentation of verification of  
12 understanding or something along those lines.  
13 Clearly, if there's not understanding, any  
14 link to outcome is luck, not follow-through.

15 MEMBER MAGID: Yes. I was going to  
16 say that I know, I can think of several  
17 examples where the patient was given a  
18 discharge sheet with their medications, and  
19 told to take coumadin, and they went ahead and  
20 continued to take that warfarin they used to  
21 be on and came in with an INR-12, you know.  
22 So they got a written piece of paper. That

1 didn't help them at all.

2 MEMBER SANZ: To go to the other  
3 side, I agree completely with what you're  
4 saying. However, measuring that is not so  
5 simple. It has been shown in Kim Eagle and  
6 the Michigan experience, that just having a  
7 measure saying "Did you provide detailed  
8 discharge guideline change rehospitalization?"

9 So there is evidence for this in  
10 the gap project, gap CHF. There was a gap MI  
11 project too. However, it's not as good as  
12 what you're describing. I just don't know how  
13 you measure that.

14 MEMBER ALLRED: Yes. I don't know  
15 how you measure that either, but there's an  
16 article that came along with this, that was  
17 published in March of last year, and basically  
18 it talked about the change in outcomes being  
19 less than one percent when it was documented  
20 in the record that the discharge instructions  
21 were given.

22 But there's also another one that

1 documented when there was a follow-up with a  
2 nurse, there was a much greater change. So  
3 that's kind of combining what's missing in  
4 this one, is that this is hospital-only, and  
5 the follow-up has got to be important to the  
6 care of the patient too.

7 MEMBER SMITH: So I agreed with  
8 what you said in the beginning, and I know the  
9 way, you know, living in this. What happens  
10 is people will document that they gave their  
11 patient instructions.

12 But there is a baby here, and if  
13 all we say is get an ejection fraction, give  
14 the meds, open the door and send them home,  
15 we're really missing a very important aspect  
16 of care, and that is patient education.

17 Time and time again, the better  
18 educated the patient, the better the outcomes.  
19 It's a confounding variable in many studies,  
20 and a direct relative variable. So the  
21 question is how do we form a recommendation  
22 about the need to educate the patient that

1 will really work? I think that's the issue.

2 MEMBER ALLRED: I found I struggled  
3 with this, because I found that really hard.  
4 If was going to make that recommendation as  
5 the patient that it missed the mark, how do  
6 you actually measure the fact that the patient  
7 understood, and I don't know. I think it  
8 would have to be a follow-up with someone, who  
9 could sit down and take the time to go over  
10 those instructions. How do you document that?

11 VICE CHAIR GEORGE: Yes. We've  
12 certainly struggled with this in stroke in  
13 providing discharge instructions.

14 But I think, you know, one of the  
15 things that we found was more helpful was  
16 including in the measure instructions were  
17 given to the patient or the patient's  
18 caregiver, which is perhaps someone that may  
19 be more receptive, at the time of hospital  
20 discharge, to getting the message.

21 MEMBER JEWELL: This is Dianne.  
22 I guess I'm perhaps not understanding a



1       logistical area here.  Is the issue that  
2       phrasing "verification of understanding" or  
3       some other follow-up, as was described, is  
4       not currently in medical records or not easily  
5       added to a medical record, so that it's still  
6       a check that it occurred?

7                    Is that the problem?  It sounds  
8       like we're defining, and we have a  
9       recommendation for how to redefine the  
10      measure.  What I thought I heard was it's  
11      difficult to capture.  So I guess I don't know  
12      enough about the logistical barriers in that  
13      regard.

14                   MEMBER SZUMANSKI:  I think what I  
15      heard is that it is documented in the record  
16      that it's given, but the patient, no one sits  
17      down with the patient and says "let's go  
18      through your discharge instructions.  These  
19      are important things you need to know.  This  
20      is when you need to call your doctor, and this  
21      is when you need to come back to the  
22      hospital."

1                   Nobody says that to the patient or  
2 explores their understanding of that. They're  
3 just given a packet of information that  
4 they're expected to take home and read, and  
5 they don't understand it.

6                   MEMBER JEWELL:    And so it sounds  
7 like, if I understand what you're saying, is  
8 that if a measure were created that specified  
9 verification of understanding, which would  
10 require the behaviors that you just described,  
11 that perhaps people would game the system and  
12 just check it without still really doing it.  
13 Is that the worry?

14                  MEMBER SNOW:    No, I don't think so.  
15 I think the problem is that it doesn't do  
16 that, that in some venues, there's resource  
17 put to nurses and others sitting down with  
18 patients, and actually verifying that they  
19 understand what's going on to at least some  
20 degree.

21                  But from this measure, I don't  
22 think -- if all you're measuring is that you

1 gave them something, you can't differentiate  
2 that excellent care from just giving them a  
3 piece of paper with nothing on it, except a  
4 problem list.

5 MEMBER JEWELL: Yes, I'm sorry.  
6 I totally see the point of the problem with  
7 the current measure. I was trying to respond  
8 to this issue of how do we give the measure  
9 developer a recommendation that would improve  
10 the measure. So thank you. That helps.

11 MEMBER SANZ: I question whether  
12 this is even needed anymore. We have two 30-  
13 day readmission measures about to be  
14 discussed. This is an upstream measure that  
15 was designed fairly long ago, like I said.  
16 Does it really matter? What counts is the  
17 downstream. Are they readmitted or die in the  
18 next 30 days? So I don't care how you do it  
19 if you have good results.

20 MEMBER KOTTKE: Yes. I guess I  
21 would jump in with Mark and not be too harsh  
22 on the measure, because historically, people

1 were sent home without anything, and this was  
2 good. I mean, you know, this looked good a  
3 long time ago.

4 But now that we have 30 day  
5 readmission and 30 day death, do we really  
6 need this measure, because people are going to  
7 have to do whatever it takes, and we know that  
8 a, particularly for heart failure, a visit  
9 within a week with the clinician is --  
10 changes.

11 Yes, I mean, you know, and so maybe  
12 we just, you know, we've got the stick there,  
13 which is 30- day readmission and 30-day  
14 mortality, and people just tough it out,  
15 figure out what works for them.

16 MEMBER SNOW: So that means that  
17 the creation of those has ripped importance  
18 from this admission, from this measure?

19 MEMBER KOTTKE: Yes.

20 MEMBER ALLRED: Maybe if this  
21 measure was harmonized with outpatient care,  
22 that would be helpful too, so that the

1 instructions were followed up in an outpatient  
2 setting.

3 MEMBER KOTTKE: Well we, from our  
4 experience, I mean as trying to reduce  
5 readmissions at Regents Hospital, we're trying  
6 to figure everything out and talking to people  
7 in Boston and here and there, and this measure  
8 really would be quite superfluous and I think  
9 Mark's idea of just tossing it out and saying  
10 it was great in its day, rather historically.  
11 It's pass, .

12 MEMBER PHILIPPIDES: Perhaps  
13 another view on the 30-day admission rate and  
14 how it pertains to this measure, this is going  
15 to be on the other side. I actually hate that  
16 measure. I think -- no. I think there are  
17 certain things that nurses and physicians in  
18 hospitals and advocates can control. You can  
19 speak to your patients.

20 You can give them the right  
21 medicines. You can check an echo. You can  
22 check 20 echos. But I don't think -- I think

1 it's a degree of arrogance to think that we  
2 can control 30-day death rate or readmission  
3 rate to a real degree.

4 I think some of that stuff, a lot  
5 of it, more than we care to admit, is out of  
6 our control. Yes, we should strive to make  
7 those numbers zero. What we can control are  
8 more of these measures, right? You can  
9 control that you speak to a patient and give  
10 them the right medications.

11 It seems to me that we should be  
12 graded sometimes on the things that we have  
13 some control over, not on some pie in the sky,  
14 we will pay you or not pay you parameter. So  
15 if we're saying that in order to get to 30-day  
16 readmission this is being totally taken care  
17 of, it's 100 percent, then I would agree that  
18 there's no role for any kind of measure like  
19 this.

20 But if we're not at 100 percent on  
21 this, I actually don't think it's a bad thing  
22 to look at, because it's one of the few things

1 that we can control. Now this measure is  
2 imperfect, for all the reasons you stated. I  
3 don't like it for the same reason. I don't  
4 think it's effective.

5 But it doesn't mean that we  
6 shouldn't think about getting another reality-  
7 based parameter, things that we really can  
8 impact on, and look at that as a measure down  
9 the road. I'm just concerned that in going  
10 for 30-day mortality and 30-day admission  
11 rate, we're missing the boat a little bit, and  
12 I don't think that those are really feasible  
13 personally.

14 MEMBER AYALA: Can I talk about the  
15 health care administrators now being focused  
16 on the threat, that they will actually lose  
17 funding or reimbursement for the readmission.  
18 So I've already started seeing like a whole  
19 aggressive approach from the administrators'  
20 side, in terms of developing care coordination  
21 and investment in nurses to do exactly what  
22 you're talking about.

1                   That goes along with something very  
2 much more intensive than just giving patients  
3 the discharge planning. they actually start  
4 with the education in the hospital, having  
5 classes, multiple classes with the patients  
6 while they're still in the hospital, and  
7 following up with them for, you know, a couple  
8 of weeks after they get discharged, and then  
9 handing them off to a disease management team  
10 that follows them in the outpatient setting.

11                   This is being driven rapidly by the  
12 threat that if the health care systems can't  
13 control those readmissions, they're going to  
14 lose a lot of money down the road. So I see  
15 a lot of scrambling to take care of this issue  
16 in a much more thorough way than what's  
17 described in this indicator.

18                   MEMBER MAGID: I wonder if we could  
19 vote on this.

20                   VICE CHAIR GEORGE: Any last minute  
21 comments before we vote on the importance?

22                   (No response.)



1 VICE CHAIR GEORGE: Okay.

2 DR. WINKLER: Dianne?

3 MEMBER JEWELL: No.

4 DR. WINKLER: Thank you.

5 VICE CHAIR GEORGE: 4 yes and 15  
6 no.

7 CHAIR GIBBONS: You were flawless  
8 until that last vote.

9 VICE CHAIR GEORGE: 16 no.

10 CHAIR GIBBONS: All right. I am  
11 going to relieve Mary at this point, as we  
12 move forward to the other heart failure  
13 measures. So the next one is 0358, heart  
14 failure inpatient mortality. It was  
15 originally supposed to be Tom.

16 Then he was supposed to have a  
17 conference call, so it was going to be Suma.  
18 So now I don't know who it's going to be, and  
19 I'm waiting for a signal from the far side of  
20 the room.

21 MEMBER KOTTKE: This is heart  
22 failure 0358. It's AHRQ, heart failure

1 mortality in-hospital. Let me say that yes,  
2 Suma kindly agreed to do this for me, and then  
3 she started really looking at the  
4 documentation, and Ray wanted to learn a new  
5 word, and that's -- there's a new word in  
6 here, gastrointestinal congestive heart  
7 failure.

8           It's in the document,  
9 gastrointestinal congestive heart failure. A  
10 lot of the documentation here appears to be  
11 just stray ball insertion. Like they compare  
12 in patients with and without Alzheimer's  
13 disease and outcomes, and I don't know what  
14 happened.

15           But let me say that that being  
16 said, that the information provided by the  
17 measure is useful and meaningful. The measure  
18 uses the same specifications as the CMS  
19 measure, but CMS uses 30 day mortality rather  
20 than in hospital mortality. The data are  
21 routinely generated. Exclusions do not  
22 require additional data, and many states

1 report the measure and it's operational.

2           So I think it meets, despite all  
3 the random documentation. It meets the  
4 criteria of importance.

5           MEMBER THOMAS: I had one comment  
6 on this just, which I had mentioned to Reva,  
7 that under citations for evidence of high  
8 impact, the citations are 20 years old, and I  
9 think that as a maintenance measure, I would  
10 expect that there would be more recent  
11 citations. Twenty years old to me seems -- we  
12 would expect more than that.

13           CHAIR GIBBONS: Okay. Can I ask  
14 the developer, if you're still on the line, to  
15 respond to that concern?

16           MR. BOTT: This is John Bott with  
17 ARHQ. Yes, I definitely acknowledge the  
18 citations are pretty old. It wasn't brought  
19 up in the submission process. There's an  
20 opportunity for NQF to push back and say could  
21 you update this, and it wasn't brought to our  
22 attention. But we -- yes, we were negligent

1 in providing a more recent citation.

2 I don't know if any of the other  
3 folks are on the call, the IQI team that want  
4 to respond with any comment at this point.

5 DR. MASOUDI: Part of that reflects  
6 the history of the measure, since this was  
7 originally included in the IQI module that was  
8 released in 2001. So there's been sort of an  
9 accumulation of evidence over that time  
10 period. So part of that is sort of reflected  
11 in these submission document.

12 MEMBER THOMAS: But I guess to me,  
13 just this is me just not understanding the  
14 process exactly. When a measure is brought up  
15 -- a maintenance measure is brought up, so  
16 isn't there an expectation that there is some  
17 update to that information, throughout the  
18 document, which I have a problem with some  
19 other things in the document as well.

20 DR. WINKLER: I think that there's  
21 sort of an obligation and expectation on  
22 everybody's part that in order to maintain the

1       measure, you need the most current and up-to-  
2       date information to be able to make an  
3       assessment and an evaluation on that.

4                So I don't think that's  
5       unreasonable to expect more up-to-date  
6       measures than something 20, or information  
7       more than 20 years old.

8                CHAIR GIBBONS:   Okay.  I think  
9       we'll go ahead and vote on importance.

10               DR. WINKLER:   Dianne?

11               MEMBER JEWELL:   Yes.

12               DR. WINKLER:   Thank you.

13               CHAIR GIBBONS:   So we have 12 yeses  
14       and 7 nos.

15               DR. WINKLER:   Just because there  
16       are a substantial number of nos, to be able to  
17       explain that in the document, could somebody  
18       just give me your reason for no?  Oh, there  
19       are seven of you out there.  Give me two,  
20       something.

21               MEMBER RICH:   For me, it's the lack  
22       of keeping it current.  So I don't even know

1 what's happened over the time.

2 MEMBER SNOW: The currency question  
3 is partly for me, although sometimes you can  
4 look at the literature and see that there's  
5 nothing new there. So I have decided in a  
6 venue or other not to put things in a  
7 literature list just to have a recent date.

8 But the more I thought about this,  
9 I just -- I started off saying yes and then  
10 decided no, because the mortality rate in the  
11 hospital from heart failure, it didn't seem to  
12 have a unique benefit to know about, to make  
13 a measure.

14 CHAIR GIBBONS: Scientific  
15 Acceptability.

16 MEMBER KOTTKE: Well, it's well-  
17 defined. It's valid, it's reliable. Risk  
18 adjustment algorithms are available in scoring  
19 and an analysis to allow for identification of  
20 disparities and outcome.

21 I can't really tell you whether the  
22 document gave us rates of disparities, but you

1 know, there's a certain sort of, to respond  
2 to Roger, I guess I'm relying on my sort of  
3 general knowledge of heart failure, that it's  
4 not a good thing to have, and it kills a lot  
5 of people.

6 There's disparities that certainly  
7 we see heart failure in young African-  
8 Americans, where we do not see heart failure  
9 in Caucasians in their 30's. There's very  
10 definite differences in disease. I would say  
11 that it's scientifically acceptable.

12 CHAIR GIBBONS: Other questions or  
13 comments about this criteria?

14 VICE CHAIR GEORGE: I just, I have  
15 a question, which I would say it's probably a  
16 stupid question, but we decided there weren't  
17 any. But in terms of in-hospital mortality  
18 measures, how do advanced care directives, how  
19 are they taken into account?

20 MEMBER KOTTKE: If I'm  
21 understanding, if they're at comfort care,  
22 they're out of the denominator.

1                   CHAIR GIBBONS: The developer want  
2 to comment on that?

3                   DR. MASOUDI: There was no specific  
4 exclusion for, you know, do not resuscitate or  
5 for care indications. The general consensus  
6 has been that that type of -- is too  
7 subjective and prone to gaming type behavior,  
8 not objective enough to include in the model.

9                   CHAIR GIBBONS: So there is no  
10 exclusion for that?

11                  DR. MASOUDI: Right, yes.

12                  CHAIR GIBBONS: Thank you.

13                  DR. MASOUDI: I would just add that  
14 if the patient is admitted specifically for  
15 palliative care, then they would be excluded,  
16 because they wouldn't be considered an acute  
17 care hospitalization.

18                  But if at some point during the  
19 course of an acute stay the patient is  
20 converted to palliative care, that would not  
21 be excluded, because that decision can be made  
22 at any time during the hospitalization, even



1 after a month of unsuccessful care.

2 MEMBER RUSSO: I think you need to  
3 exclude, you know, if you intentionally aren't  
4 going to be treating, you need to have that as  
5 an exclusion if you -- how could you fault?  
6 You may have certain hospitals might be  
7 transplant centers or transferred there and  
8 they're very sick patients, and they won't --  
9 you know, they're being resuscitated.

10 I think you need to have some  
11 exclusion in there, because there will be  
12 patients who'd get admitted and are DNRs. So  
13 I don't know why we wouldn't add that.

14 MEMBER KOTTKE: I guess if, you  
15 know, you actually are trying to save them,  
16 but they're DNR from the start, you know,  
17 they'd be in the numerator and denominator of  
18 this. But if they were just admitted for  
19 palliative care, they wouldn't be --

20 CHAIR GIBBONS: But the question is  
21 if somebody, you know, this is their 14th  
22 admission for heart failure in the last two

1 years, and somebody finally has the frank  
2 discussion that says maybe we should stop  
3 trying to do things, and just keep you  
4 comfortable, they're counted.

5 MEMBER KOTTKE: Right, right. If  
6 the patient changes, the patient is not  
7 allowed to change their own mind. You know,  
8 say that you're treating the patient and  
9 finally he says "Look doc, enough's enough.  
10 I mean stop," you know.

11 DR. MASOUDI: Right. Ideally, we  
12 would want to exclude patients who were DNR at  
13 admission to the hospital. But there's no  
14 data element currently available that would  
15 allow us, or CMS for that matter, to exclude  
16 such patients.

17 There is a lot of concern and  
18 there's empirical evidence of this, that if  
19 you include, if you exclude patients who are  
20 made DNR after a week or so in the hospital,  
21 then it leads to gaming, in that all you have  
22 to do before somebody looks like they're going

1 to die is to write a DNR order and they get  
2 excluded.

3 So it's undesirable, from a  
4 methodologic perspective, to exclude patients  
5 based on an aspect of treatment that occurs  
6 well into the hospitalization. But ideally,  
7 we would certainly want to exclude, based on  
8 DNR at admission or in the first 24 hours, if  
9 that were available.

10 MEMBER SANZ: Did I understand you  
11 to say that DNR is equivalent to palliative  
12 care?

13 DR. MASOUDI: I did not say that.

14 MEMBER SANZ: I thought you just  
15 said that if they're admitted with DNR, that  
16 they'll be excluded?

17 CHAIR GIBBONS: No.

18 MEMBER SANZ: No?

19 DR. MASOUDI: No. What I said is  
20 if they were admitted for palliative care,  
21 they would be excluded. If that was the  
22 reason why they were admitted to the hospital,

1 they would be excluded, because they would not  
2 be counted as an acute care hospitalization.

3 We might also want to exclude  
4 patients who were DNR at admission, but not on  
5 palliative care, but we don't have any  
6 mechanism for excluding such patients.

7 CHAIR GIBBONS: So you know, the  
8 dilemma is, as he pointed out, if somebody has  
9 received intensive treatment and then  
10 everybody gives up, they should be counted,  
11 because otherwise the system can be gamed.

12 But on the other hand, if it's  
13 clear within the first few hours of admission  
14 that this is all futile, and that's a joint  
15 decision or a patient decision or whoever,  
16 they have no means of excluding. That would  
17 not be gaming. That would just be reflecting  
18 the patient's situation and, in some cases,  
19 their decision.

20 VICE CHAIR GEORGE: And the  
21 mortality rate is risk-adjusted?

22 MEMBER KOTTKE: Yes. There's the

1 capability of risk adjustment.

2 CHAIR GIBBONS: So let's go ahead  
3 and vote on Scientific Acceptability.

4 DR. WINKLER: Dianne?

5 MEMBER JEWELL: Partially.

6 CHAIR GIBBONS: So 1 completely, 14  
7 partially, 3 minimally and 1 not at all.  
8 Moving on to Usability, Tom?

9 MEMBER KOTTKE: The information  
10 provided by the measure is useful and  
11 meaningful. The measure uses the same  
12 specifications as the CMS measure, but the CMS  
13 measure uses 30-day mortality. So I would say  
14 that it's usable.

15 CHAIR GIBBONS: Other comments or  
16 questions?

17 (No response.)

18 CHAIR GIBBONS: If not, let's vote.

19 DR. WINKLER: Dianne?

20 MEMBER JEWELL: Completely.

21 DR. WINKLER: Okay.

22 CHAIR GIBBONS: Completely, 8;

1 partially, 7; minimally, 3; not at all, 1.  
2 Feasibility.

3 MEMBER KOTTKE: The data are  
4 routinely generated. Exclusions do not  
5 require additional data. Many states report  
6 the measure. It is operational already. So  
7 it is feasible.

8 CHAIR GIBBONS: Any other comments,  
9 questions?

10 (No response.)

11 CHAIR GIBBONS: All right. Let's  
12 vote.

13 DR. WINKLER: Dianne?

14 MEMBER JEWELL: Completely.

15 CHAIR GIBBONS: So 15 completely,  
16 5 partially. And now the final vote, does it  
17 meet all the criteria for endorsement, yes or  
18 no.

19 DR. WINKLER: Dianne?

20 MEMBER JEWELL: Yes.

21 DR. WINKLER: Thank you.

22 CHAIR GIBBONS: Yes, 13; no, 7. So

1 we'll move on to the next measure, 277, CHF  
2 admission. Mary.

3 VICE CHAIR GEORGE: So this is  
4 similar to one of the hypertension measures  
5 that we looked at earlier. 0277 is congestive  
6 heart failure admission rate, the percent of  
7 county population with admissions for  
8 congestive heart failure.

9 The measure addresses population  
10 health, timely and effective care, and it's  
11 been in use, I think, for the past decade.  
12 It's an outcome measure. It was actually an  
13 objective in Healthy People 2010. It's, as  
14 far as I know, it's not in Healthy People  
15 2020.

16 The impact of the measure,  
17 according to the data presented, is that low  
18 income zip codes in New York City in 1995 were  
19 found to have 4.6 times more heart failure  
20 admissions than those from high income zip  
21 codes. It was noted that this original study  
22 was described as a surrogate for access to

1 care.

2 In terms of opportunities for  
3 improvement, the developer states that the  
4 indicator is measured with high precision, and  
5 most the variants reflects true differences  
6 across areas. It's risk adjusted for age and  
7 gender, and the developer states that this  
8 measure may reflect poor care, poor patient  
9 compliance or lack of access to care.

10 They showed demonstrated gaps by  
11 age, gender, income level and variations on  
12 metropolitan, micropolitan size. They say  
13 that the measure is not supported by a  
14 guideline, and according to the developer's  
15 website, the literature review found no  
16 benchmark for this measure.

17 They suggested some concern that  
18 the measure does not measure outcomes, but an  
19 aspect of care associated with an outcome, and  
20 that it is best used with indicators that  
21 measure similar aspects of care, and I'm not  
22 quite clear what they meant by that.



1                   They also suggested concern that  
2                   the use of the indicator may create perverse  
3                   incentives to improve performance on the  
4                   indicator without truly improving quality of  
5                   care.

6                   CHAIR GIBBONS: Other comments or  
7                   questions about Importance?

8                   VICE CHAIR GEORGE: I think from  
9                   what, a very small literature review that I  
10                  did on some of these ambulatory care sensitive  
11                  conditions, I guess I was struggling with the  
12                  fact that they're sometimes meant to imply  
13                  accessibility issues or quality of care  
14                  issues, or social determinants of health  
15                  issues, or poverty.

16                  There's, you know, there's just so  
17                  much overlap in terms of what the measure is  
18                  actually measuring.

19                  MEMBER RUSSO: I'm having a hard  
20                  time with this, and I guess just trying to  
21                  figure out the importance. So not that it's  
22                  not an important concept in general, but what

1 does this have to do -- doesn't it just have  
2 to do -- it's nothing that is intrinsically or  
3 necessarily, you know. It could be a first  
4 admission for heart failure, that hasn't seen  
5 a provider, right?

6 Is this what's measured? I don't  
7 know how this really measures quality in any  
8 way.

9 VICE CHAIR GEORGE: It's measuring  
10 heart failure admissions at the hospital, but  
11 it's not a hospital measure. It's a  
12 geographic area measure.

13 MEMBER MAGID: I think these  
14 ambulatory- sensitive conditions are, the  
15 thought is that there are a certain number of  
16 admissions for, like we talked earlier about  
17 the hypertension, you know. If hypertension  
18 is properly treated in the ambulatory setting,  
19 then patients presumably won't be coming to  
20 the hospital very often for malignant  
21 hypertension, you know, 240 over 130 or  
22 something like that.

1           You shouldn't see people very often  
2           having to come to the hospital without a  
3           control of hypertension and requiring  
4           admission. I think that's the idea behind  
5           these things, in that somehow it reflects the  
6           quality of ambulatory care in the community.

7           There might be issues around -- but  
8           I think what Mary's saying is that these  
9           things are multifactoral. It could be issues  
10          around access, it could be issues around  
11          quality of care, and maybe that's why we  
12          struggle with them, because we're not-- it  
13          doesn't clearly indicate what the solution to  
14          the problem should be. Is that what you were  
15          saying Mary?

16                   VICE CHAIR GEORGE: Dana or Carol,  
17                   sorry.

18                   MEMBER ALLRED: Yes. I was going  
19                   to ask, if this was part of the 2010 Healthy  
20                   People, do they have some outcome data on  
21                   that? I mean in other words, by concentrating  
22                   on this as one of the issues, did they

1 decrease the poor outcomes or --

2 VICE CHAIR GEORGE: I'm not sure  
3 exactly how Healthy People was measuring this.  
4 There are a number of different states that  
5 post this information on their websites, on  
6 maps. You can go to the state of Hawaii and  
7 each island has their rate posted online, and  
8 a number of other states do as well.

9 MEMBER ALLRED: So I guess I'm  
10 trying to understand what's the benefit of the  
11 measure, and measuring it by county or by  
12 geographic area, if you're not going to do  
13 something with it to improve the plight of the  
14 people.

15 MEMBER KOTTKE: That's exactly the  
16 reason for publishing it. For example, the  
17 University of Wisconsin county health rankings  
18 have [countyhealthrankings.org](http://countyhealthrankings.org), publishes, and  
19 it kicks people in the butt.

20 I mean it creates a tremendous  
21 amount of interest, and while there's nobody  
22 to blame for, you know, you can't really nail

1 a single particular doctor or hospital or  
2 whatever, it is one of the ten ambulatory-  
3 sensitive --

4 I think there's ten: diabetes,  
5 preforative appendicitis, long-term  
6 complications diabetes, chronic lung disease,  
7 etcetera, that are consideration ambulatory  
8 care-sensitive conditions. So it's just sort  
9 of a public shaming kind of thing, I think.

10 MEMBER KING: Well, I don't think  
11 we're trying to just publicly shame when you  
12 say there wasn't any improvement in it. But  
13 like you say, it doesn't mean it's not a  
14 relevant measure. We didn't address the  
15 underlying problem. It's ambulatory-  
16 sensitive.

17 There's no greater ratio of primary  
18 care physicians to population now than it was  
19 ten years ago, and consequently in my mind,  
20 there have been no improvement in this  
21 condition, because there's no one out there to  
22 address the risk factors for congestive heart

1 failure that ends you up in the hospital, and  
2 so there's no improvement.

3           Maybe, I don't know why they didn't  
4 put it on the 2020, because they may actually  
5 be doing something about it. We're trying to  
6 increase the ratio. There's after a decade of  
7 having zero or one or two more medical  
8 schools, now there's eight more and we're  
9 going to have more doctors and hopefully more  
10 primary care doctors and more people in the  
11 community addressing the risk factors that  
12 lead to ambulatory-sensitive admissions.

13           So this is not the time to take the  
14 foot off the gas pedal, it would seem.

15           MEMBER RUSSO: I think it's  
16 interesting and would it be possible to even  
17 construct a measure to look at, to include a  
18 change over time? I guess you'll have that  
19 data, but what you really want to do is to say  
20 you're looking at it. You find the areas you  
21 need to improve and then improve in those  
22 areas, to show you've done better.

1 I guess you'll have that after you  
2 look at it over years.

3 CHAIR GIBBONS: Well so in light of  
4 this discussion, let me just sort of go to one  
5 section of the application, which is 1(c)(4),  
6 Summary of the Evidence, which says "As the  
7 causes for admission may include poor quality  
8 care, lack of patient compliance or problems  
9 accessing care, areas may wish to review CHF  
10 patient records to identify precipitating  
11 causes and potential targets for  
12 intervention."

13 So this measure has been in  
14 existence for a number of years. Do we have  
15 examples that the developer can cite where  
16 that's happened?

17 MR. BOTT: I can't personally cite  
18 an example. We don't really closely track the  
19 end results with the use of the measures,  
20 given software and the measures are freely  
21 available for people to download and use.  
22 We're focused on developing and maintaining

1 measures. But perhaps other members of the  
2 ARQI team have some examples. I'm not sure.

3 DR. ROMANO: We're certainly aware  
4 of county and state health departments that  
5 have implemented this and used this as a tool  
6 to allocate resources toward primary care  
7 workforce development in communities that are  
8 felt to have a disproportionate burden of --  
9 avoidable hospitalizations.

10 But in terms of the success of  
11 those interventions, whether those efforts  
12 have actually reduced disparities, we're not  
13 sure. There is longitudinal research evidence  
14 showing that in general, when primary care  
15 physicians supply increases, that the rates of  
16 these indicators decrease, and of course, CHF  
17 is probably the highest prevalence of these  
18 indicators.

19 But typically, when people do this  
20 in a research context, they look at all the  
21 PQIs together, rather than looking at them  
22 individually.



1                   VICE CHAIR GEORGE: I could imagine  
2 where this would be really useful if you were  
3 using it to look at where you need to put  
4 more federally qualified health centers, and  
5 if the Affordable Care Act sticks around, it  
6 would provide some measure of accessibility to  
7 care pre- and post.

8                   MEMBER AYALA: I think if it's used  
9 correctly, that way you're actually looking at  
10 planning for the community, then that's  
11 appropriate.

12                   But what I've started to see is  
13 non-clinical administrative people who are  
14 looking at these results and they hear the  
15 word "preventable," and what they start doing  
16 is they start seeing every single admission  
17 with this diagnosis as preventable.

18                   They don't really understand that  
19 preventable is like a broad topic, meaning  
20 that some of these admissions are preventable,  
21 not every one is preventable, and that there  
22 are patients that have gotten great care and

1 still end up in the hospital, just because,  
2 you know, the prognosis of their condition or  
3 where they are in the course of their disease.

4 So I think there is a little bit of  
5 a danger there, that there's a lot of pressure  
6 on individual physicians, when they have  
7 patients admitted with these diagnoses,  
8 because there's this concept that every one of  
9 these admissions is preventable individually.

10 MEMBER SNOW: I keep coming back to  
11 the problem here, that the proxy is too far  
12 from what you're trying to do something about,  
13 and I understand that this got started when  
14 there was a concern, understandably, about  
15 ambulatory care quality and no real good way  
16 to get a handle on it. These were seen as a  
17 way to get at that issue, and I think it's a  
18 very clever idea, if you go back to 1993.

19 But we've seen some others where it  
20 was just clear that there were unanticipated  
21 reasons why it didn't work, and the -- if you  
22 think about this, there are circumstances in

1 which an admission to the hospital for  
2 congestive heart failure is in fact a proxy of  
3 care and the quality of care. That's not hard  
4 to imagine.

5 But what about someone who's had  
6 the fifth and sixth and seventh hospital? It  
7 doesn't matter what kind of care they're  
8 getting -- well, it matters. But the hospital  
9 admissions are not going to be a proxy for  
10 their care, because they're on the way out,  
11 and no matter what you do for them, they're  
12 going to be having hospital admissions for  
13 congestive heart failure, quite apart --

14 And then apart from that, of course  
15 they do mention in there other issues, such as  
16 patient compliance and, you know, how much  
17 salt he's got on the table and stuff like  
18 that, beyond the care purview for the most  
19 part. I just find it hard to see this measure  
20 as doing what it's trying to do.

21 CHAIR GIBBONS: Okay, Tom?

22 MEMBER KOTTKE: Yes. You know, we

1 talk a lot about disparities, and I think this  
2 is a measure that really gets us to the heart  
3 of disparities. If we take this off the  
4 table, you mentioned, Mary, for the federally  
5 qualified health centers, I mean that we point  
6 that even in Washington, D.C. here, going from  
7 Southeast to Northwest, that life difference  
8 and life expectancy is like 20 years.

9 I mean, you know, that we have  
10 phenomenal, we have more disparities in this  
11 country in life expectancy than we do between  
12 here and Bangladesh. I just, I hope we don't  
13 take this off the table.

14 MEMBER CHO: I have a question. So  
15 at the Cleveland Clinic we draw from, just  
16 like Mayo, from large proportion of patient  
17 populations. So I would say six county --  
18 we're located in a very poor county. We draw  
19 from 14 counties, but 20 to 30 percent of our  
20 patients come from out of state.

21 So some of them come for heart  
22 failure. They get transferred. We have

1 ambulatory systems. So how is that counted?  
2 What is counted? Our rate of CHF admission,  
3 which does not adequately reflect Cuyahoga  
4 County, or does it count where the patients  
5 come from?

6 VICE CHAIR GEORGE: This measure  
7 specifically excludes transfers from other  
8 hospitals and health care facilities, SNFs,  
9 any intermediate care facilities, admissions  
10 with certain cardiac procedure codes and  
11 pregnancy.

12 DR. MASOUDI: And I might add also  
13 that the measure is based on a population. So  
14 it's based on where patients reside, not where  
15 they seek hospital care.

16 So it's intended as a measure of  
17 population health, and again it's allied with  
18 the concept that as we're trying to improve  
19 our health care system, the fundamental goal  
20 is to improve population health, recognizing,  
21 of course, that some of these individual  
22 hospitalizations are unavoidable.

1                   But I think AHRQ is very clear in  
2                   its guidance, that this is intended as a  
3                   measure of potentially preventable or  
4                   ambulatory care-sensitive hospitalizations.  
5                   There's no implication intended that all of  
6                   these hospitalizations are in fact  
7                   preventable.

8                   MEMBER AYALA: You know, I know  
9                   this sounds kind of crazy, but if you just say  
10                  that, if you make it instead of preventable,  
11                  you know, instead of PQI, call it PPQI, a  
12                  potentially preventable quality indicator, I'm  
13                  telling you that really could shift the focus  
14                  of people who are making decisions about how  
15                  to respond to the results they're getting.

16                  DR. ROMANO: Well, the term  
17                  "prevention quality indicators" is only meant  
18                  to apply, that they are sensitive to  
19                  preventive efforts, however those preventive  
20                  efforts may be organized and delivered within  
21                  the community. But we appreciate your  
22                  concern, that there might be an overt

1       implication from that term.

2                   CHAIR GIBBONS:   Okay.  I think we  
3       need to go ahead and vote on the importance of  
4       this measure.

5                   DR. WINKLER:   Dianne?

6                   MEMBER JEWELL:   No.

7                   CHAIR GIBBONS:   15 yeses and 5  
8       no's.  Moving on to Scientific Acceptability.

9                   VICE CHAIR GEORGE:   Okay.  This  
10       measure is precisely defined.  The numerator  
11       is all discharges 18 and older with an ICD-9  
12       diagnosis of heart failure.  It quantifies the  
13       number of admissions for 100,000 population,  
14       and the denominator is those in the area 18  
15       and older.

16                   I went through the exclusions just  
17       a few minutes ago.  Risk adjustment is by age  
18       and gender only, and results show that areas  
19       with high rates of admission also have high  
20       rates of admissions for other ambulatory care-  
21       sensitive conditions.

22                   The reliability testing used a

1 signal ratio which was 93 percent. Validity  
2 testing was done with expert panels and  
3 empirical analysis from HCUP data, and  
4 disparities, as I said, have been identified,  
5 certainly by age, gender and income level of  
6 zip codes.

7 CHAIR GIBBONS: Other comments or  
8 questions on Scientific Acceptability?

9 MEMBER SNOW: Well now I'm  
10 concerned about the, we're talking about  
11 disparities, and they're risk-adjusting for  
12 age and gender only. Yet a lot of our  
13 concern, and I share that concern, goes to  
14 race and ethnicity, and it isn't broken out.

15 Now I guess you're saying the area  
16 is a proxy for that, but that's also not a  
17 solid proxy. I think it's a concern.

18 DR. GEPPERT: Just to clarify that,  
19 sorry. This is Jeff Geppert.

20 CHAIR GIBBONS: Thank you.

21 DR. GEPPERT: Again, the software  
22 allows you to report by race and ethnicity,



1 and states vary in terms of the quality of  
2 that data and their ability to do so.

3 But AHRQ creates what are called  
4 state snapshots that include these measures,  
5 where they've gone through and sort of  
6 improved the quality of their race ethnicity  
7 data or use only data that have high quality  
8 race ethnicity data. That includes  
9 stratifications by race.

10 We've done some of that analyses  
11 ourselves, and we can provide that to the  
12 steering committee. There's definitely a  
13 racial disparity that's evident in the data.

14 MEMBER SNOW: Given the other  
15 discussion, it would be important to do that.

16 CHAIR GIBBONS: I think I hear a  
17 clear sense that we'd like to see that data  
18 subsequently. Are there other comments on  
19 scientific acceptability? We're hoping we get  
20 power back in time to vote.

21 (No response.)

22 CHAIR GIBBONS: Keep your fingers

1       crossed.  Yes.  Well, we might have to do  
2       that.  We're just going to give it about a  
3       minute here to hope.

4                   MEMBER JEWELL:  Are you all  
5       sitting there in the dark?

6                   CHAIR GIBBONS:  Well, our  
7       projectors are dark.  There are lights in the  
8       room, but our projectors are dark.

9                   MEMBER JEWELL:  It's quite an  
10      image to hear the conversation and not be able  
11      to see.

12                  CHAIR GIBBONS:  Okay.  So I think  
13      we are going to have a hand vote on this.  
14      Completely?

15                   (Show of hands.)

16                  DR. WINKLER:  Raise them and keep  
17      them raised.

18                  CHAIR GIBBONS:  Scientific  
19      Acceptability, Scientific Acceptability.

20                  DR. WINKLER:  One, two, three,  
21      completely.  Completely.

22                  CHAIR GIBBONS:  I mean partially?

1 (Show of hands.)

2 Minimally? Not at all? People may  
3 vote twice. Can't trust them.

4 DR. WINKLER: Dianne?

5 CHAIR GIBBONS: Dianne.

6 MEMBER JEWELL: My hand is up for  
7 partially.

8 CHAIR GIBBONS: We couldn't see it.  
9 All right. So we're going to move on now to  
10 Usability.

11 VICE CHAIR GEORGE: This measure  
12 has been in use for about ten years.  
13 Certainly, the literature shows that it's a  
14 little bit difficult to understand, in that it  
15 could be measuring access to care,  
16 availability of care, quality of care,  
17 appropriateness of care, etcetera, etcetera.

18 Studies in countries with universal  
19 health care have found similar associations in  
20 relation to poverty for this particular  
21 measure. There's no competing measures.

22 CHAIR GIBBONS: Questions or

1       comments?

2                   MEMBER AYALA:   Yes.   Can we ask for  
3       it to be require to be stratified by race,  
4       ethnicity, language, gender?   Can we ask for  
5       that, to make it more usable?

6                   CHAIR GIBBONS:   I think we just  
7       heard from the measure developer that the data  
8       on that point is not always reliable,  
9       depending on the location.

10                  MEMBER KOTTKE:   But the data by zip  
11       code are --   the Ginnie index are quite  
12       reliable, and in fact if you adjust for  
13       poverty and race, you're going to erase  
14       exactly what you're looking for, is the  
15       differences because of those factors.

16                  Those are causative factors and you  
17       don't want to adjust for them.   You may want  
18       to identify for them, but certainly not  
19       statistically adjust for them.

20                  CHAIR GIBBONS:   Other comments?

21                  MS. DAVIES:   This is Sheryl Davies  
22       from the development team, and just to add to

1 that point, we did take these through a  
2 clinical panel process, where we were actually  
3 looking at different types of uses, so not the  
4 uses being considered today.

5 You know, just as a face validity,  
6 our clinical panel felt like SES,  
7 socioeconomic status-related risk adjustment  
8 was extremely important when you were using  
9 this, perhaps at a large provider group, but  
10 agreed that when looking at it as an area  
11 level, that it's important not to adjust away  
12 what you're, you know, hoping to measure. So  
13 that's why the stratification is optional in  
14 the software, so that folks look at it as they  
15 see fit.

16 CHAIR GIBBONS: Okay. So in other  
17 words, that users can do it if they want, if  
18 it's going to serve their purpose. Okay.  
19 Other questions? Thank you for that  
20 clarification. We're going to now vote on  
21 Usability, and we still don't have power, so  
22 we're going to do it -- you're going to have

1 to put your hands up another time.

2 So those who feel completely,  
3 please raise their hands?

4 (Show of hands.)

5 DR. WINKLER: One. Okay.

6 CHAIR GIBBONS: Partially?

7 (Show of hands.)

8 DR. WINKLER: I think everybody's  
9 voted.

10 CHAIR GIBBONS: Phone.

11 DR. WINKLER: Dianne?

12 MEMBER JEWELL: Completely.

13 DR. WINKLER: Okay.

14 CHAIR GIBBONS: Okay, and then  
15 finally Feasibility.

16 PARTICIPANT: What was the vote?

17 DR. WINKLER: I'm sorry.

18 Completely was 2, partially was 18.

19 VICE CHAIR GEORGE: Okay. In terms  
20 of Feasibility, this relies on administrative  
21 data. Exclusions, there are none, so no  
22 required additional resources. In terms of

1       susceptibility to inaccuracy, errors or  
2       unintended consequences, the developers noted  
3       that providers may reduce admissions without  
4       improving quality of care. It does not  
5       include ED admission data; only hospital  
6       admission data.

7                   CHAIR GIBBONS: Other comments or  
8       questions? Carol.

9                   MEMBER ALLRED: I just have one  
10       comment I'd like to make, because I heard the  
11       term earlier in this, non-compliant patients,  
12       and I would hope if we're looking at  
13       stratifying by race and ethnicity and  
14       socioeconomic, that we would not use the term  
15       "non-compliant" but perhaps "uneducated."

16                   VICE CHAIR GEORGE: I think that  
17       was in terms of some of the things that the  
18       measure might actually be measuring. That was  
19       straight from their documentation.

20                   CHAIR GIBBONS: Sorry. Other  
21       comments, questions?

22                   (No response.)

1 CHAIR GIBBONS: All right. We're  
2 going to go ahead and vote on Feasibility,  
3 again by hand. Completely?

4 (Show of hands.)

5 Partially?

6 DR. WINKLER: Dianne?

7 MEMBER JEWELL: Partially.

8 DR. WINKLER: Thank you. So it's  
9 complete and 11 partial.

10 CHAIR GIBBONS: And then the final  
11 vote, does it meet criteria for endorsement by  
12 NQF. All who say yes, please raise their  
13 hand?

14 DR. WINKLER: Dianne?

15 MEMBER JEWELL: Yes.

16 DR. WINKLER: Okay.

17 CHAIR GIBBONS: So that's a  
18 unanimous -- no, I'm sorry. One no vote.  
19 Okay, sorry.

20 DR. WINKLER: 19 yes, 1 no.

21 CHAIR GIBBONS: One no. We have  
22 lost the bulb, all right. Is there a former



1 chief resident in the room? I thought they  
2 were always supposed to carry bulbs.

3 All right. While we're doing that,  
4 we're going to start on the next measure while  
5 we're switching. The next measure is 0229,  
6 which is hospital, 30-day, all cause, risk  
7 standardized mortality rate, otherwise known  
8 as RSMR, for those who are into initials,  
9 which I wasn't familiar with, following heart  
10 failure hospitalization.

11 It is the CMS measure that's posted  
12 on Hospital Compare. Dr. Masoudi or CMS,  
13 representatives on the phone, do you wish to  
14 comment at all at this point, before we start?

15 DR. WINKLER: Is anybody on the  
16 phone?

17 MS. BERNHEIM: Hi. Susannah  
18 Bernheim is here from Yale CORE. I don't know  
19 if Dr. Masoudi was going to speak about the  
20 measure.

21 DR. WINKLER: Well, whoever.

22 CHAIR GIBBONS: All right. Well,

1 that's fine. I think you can just be  
2 available for questions. That would be great.  
3 So I think everybody is probably familiar with  
4 this measure. It's been publicly reported on  
5 the Hospital Compare website. It's obviously  
6 of major public health importance.

7 Heart failure is an enormous  
8 problem from a public health standpoint and  
9 from a care delivery standpoint, and we're  
10 managing to take care of people, so that they  
11 live long enough to develop heart failure, and  
12 seeing more and more. It's the most common,  
13 I think this is right, it's the most common  
14 admission under Medicare and CMS, and it's the  
15 second most costly total bill under CMS.

16 So I think it's pretty  
17 straightforward and it's important to measure,  
18 and there are clearly gaps and differences  
19 across the country. I welcome any other  
20 comments or issues.

21 MEMBER MAGID: I'll speak up in  
22 favor of this measure because it's an outcome,

1 right. Almost all the time we're talking  
2 about a process that we think might be related  
3 to mortality, and this is an outcome measure.

4 CHAIR GIBBONS: So I'll call 0229.  
5 This is the 30-day mortality after heart  
6 failure. Can we please vote on Importance.  
7 Oh, we're there. Look at that. We're ready  
8 to go. So we can once again use our gadgets.

9 Missing one.

10 DR. WINKLER: Dianne?

11 MEMBER JEWELL: Yes.

12 DR. WINKLER: Thank you.

13 CHAIR GIBBONS: So the vote is 19  
14 to 0 unanimous for Importance. For Scientific  
15 Acceptability, this application is noteworthy  
16 for the detail and comprehensiveness of the  
17 way all the entries are completed. It  
18 includes, as an addendum an accompanying  
19 technical report.

20 Just from the standpoint of what  
21 you might say is the ultimate test of  
22 scientific acceptability, the data has

1 actually been published in a manuscript last  
2 year, looking at long term trends in  
3 cardiovascular quality and outcomes.

4 So that the measure specifications  
5 are very carefully delineated. The modeling  
6 is very carefully outlined and defended in the  
7 application, and I really didn't have any  
8 concerns. But I'm welcome to other comments  
9 from anybody.

10 MEMBER MAGID: Can you comment on  
11 the risk adjustment that's included --

12 CHAIR GIBBONS: So the risk  
13 adjustment used is administrative data, but it  
14 is previously validated against clinical data,  
15 and the overall C index for that comparison  
16 exceeded .7. So that they were able to  
17 demonstrate that the results they get using  
18 administrative data are highly comparable to  
19 clinical data, in terms of the risk  
20 adjustment.

21 It follows a similar pattern to  
22 what was done in the MI validation that we

1 went through at the last meeting.

2 MEMBER MAGID: Yes. It's a pretty  
3 sophisticated hierarchical modeling approach  
4 that what's her name, Normand's her last name,  
5 she's a statistician from Harvard, developed.

6 CHAIR GIBBONS: Sharon-Lise  
7 Normand. Other questions or comments?

8 (No response.)

9 CHAIR GIBBONS: Okay. If not,  
10 let's vote on Scientific Acceptability.

11 DR. WINKLER: Dianne?

12 MEMBER JEWELL: Completely.

13 DR. WINKLER: Thank you.

14 CHAIR GIBBONS: The vote is 19  
15 completely and 1 partially. Now moving on to  
16 Usability, it's obviously in use and I think  
17 most hospital administrators and cardiology  
18 chiefs in the country are certainly aware of  
19 their own numbers and paying attention to  
20 them, which is the ultimate test of usability.

21 I think my only sense is that the  
22 public probably doesn't go to this website as

1 often as was hoped originally, but certainly  
2 the doctors and the administrators and other  
3 health care providers are certainly aware of  
4 the data and using the data. So I think it  
5 passes the test for usability.

6 DR. WINKLER: One comment is this  
7 measure is written and submitted and currently  
8 in use for the Medicare population age 65.  
9 Just we've been in conversations with the  
10 developers. There is a very strong interest  
11 on their part, and they're working diligently  
12 towards being able to expand it to all ages  
13 ultimately, with the AMI measure and the heart  
14 failure.

15 But there are methodologic issues  
16 around combining data sets. But they are  
17 actively working on it, and we can expect to  
18 see that going forward.

19 MEMBER SNOW: I'll agree that the  
20 general public probably don't go looking for  
21 this, but they sure do notice it when it pops  
22 up in the newspaper.

1 CHAIR GIBBONS: Yes, which it has  
2 in a variety of cities in a variety of stories  
3 around the country. I actually personally  
4 thought there would be more of those within  
5 the very first week, and was surprised at how  
6 limited they were. But all right. So we'll  
7 vote on Usability.

8 DR. WINKLER: Dianne?

9 MEMBER JEWELL: Completely.

10 DR. WINKLER: Thank you.

11 MEMBER JEWELL: Yes.

12 CHAIR GIBBONS: Responses are 17  
13 completely and 2 partially. And now moving on  
14 to Feasibility, it's clearly feasible. It's  
15 being done. There really, I think, were  
16 minimal problems from the start.

17 There was this one year sort of  
18 trial period roll-in before the actual numbers  
19 were released, when hospital administrators  
20 only saw the numbers before the public saw the  
21 numbers.

22 But it's certainly feasible, and I

1 didn't see any concerns with respect to that.  
2 And again, the application is very complete  
3 with respect to all of those issues. Any  
4 other comments or questions? If not, I  
5 suggest we vote on this, Feasibility.

6 DR. WINKLER: Dianne?

7 MEMBER JEWELL: Completely.

8 DR. WINKLER: Thank you.

9 CHAIR GIBBONS: So 19 completely,  
10 1 partially and now we'll move on to the final  
11 vote, does the measure meet all the criteria  
12 for endorsement. Sorry.

13 MEMBER PHILIPPIDES: I'm sorry. I  
14 should have brought this up before. Can I ask  
15 something about the disparities issue?

16 CHAIR GIBBONS: Sure, sure.

17 MEMBER PHILIPPIDES: I apologize  
18 for not getting it in the right order. Here,  
19 it states that disparities in race and  
20 socioeconomic status have been reported at the  
21 patient level, but not at the hospital level.  
22 They say that "Hospitals with many lower



1 socioeconomic patient populations are able to  
2 do well on this, and therefore CMS does not  
3 plan to stratify the measure."

4           Is there -- it sounds like sure,  
5 those hospitals can do better, but if they  
6 have more of those patients and they tend to  
7 do poorly, are they at a disadvantage? Are  
8 hospitals that have these patients at a  
9 disadvantage? And why not include race and  
10 socioeconomic status, I guess, is my final  
11 question?

12           CHAIR GIBBONS: Can the developer  
13 answer that question?

14           DR. BERNHEIM: Sure, I'm happy to.  
15 Hi, this is Susannah Bernheim from the Yale  
16 CORE team. It was sort of a two-part  
17 question, and I think the first one, let me  
18 just explain the analysis we did a little bit  
19 more clearly.

20           For both the proportion of patients  
21 at a hospital that were African-American, and  
22 then in a subsequent analysis in a similar

1 fashion, looking at the proportion of patients  
2 who come from a low income areas, we looked at  
3 hospitals by deciles of that measurement, to  
4 see whether or not those hospitals that had  
5 higher proportions of patients that were  
6 African-American, consistently performed worse  
7 on the measure.

8           If you look at the median, there  
9 are slight differences from the lowest decile  
10 to the highest decile. But the important  
11 piece of information is that the ranges and  
12 the inner quartile ranges of the hospitals on  
13 the lowest decile, on the highest decile,  
14 again divided into deciles by the percentage  
15 of their patients that are African-American,  
16 are entirely overlapping. There's very little  
17 different in the ranges.

18           So our take on that is that the  
19 proportion of patients in your hospital who  
20 are African-American is in no way  
21 determinative of performance. So there are  
22 high performers with high percentages of

1 African-American patients, and low performers  
2 with high percentages of African-American  
3 patients, and similarly, for the socioeconomic  
4 status.

5 So there's really not an indication  
6 that those hospitals are consistently doing  
7 worse on this measure. So that's the  
8 rationale. I think the phrase that you used  
9 was that "can perform well."

10 What we mean by that is frequently  
11 do perform well in a similar range performance  
12 as the hospitals with much lower percentages  
13 of those patients. So we really don't see  
14 significant evidence of disparities at the  
15 hospital level.

16 MEMBER PHILIPPIDES: Could a  
17 different take on that be that those hospitals  
18 are actually performing better? They're doing  
19 the same with a more difficult patient  
20 population? Wouldn't that be an equally  
21 reasonable way of looking at that data?

22 DR. BERNHEIM: Right. I mean we,

1 we can't answer that question absolutely. But  
2 I think that you can similarly argue that  
3 there is in this a measure of a quality of  
4 care. If those hospitals can perform well,  
5 then the benchmark should be the same for  
6 them.

7 We don't think that it makes sense  
8 to stratify, which essentially condones saying  
9 we expect hospitals with higher proportions of  
10 minority patients to do worse on this measure,  
11 when we know that they can do equally well.

12 MEMBER PHILIPPIDES: If I bat .300  
13 against Sandy Koufax and .300 against a minor  
14 league pitcher, it's certainly reasonable to  
15 say that when I bat against Sandy Koufax I  
16 could be a .300 hitter, but I'm doing a better  
17 job of it. If there were no disparities at  
18 the individual level, I think you'd have a  
19 case. But there are.

20 DR. BERNHEIM: Right, and I think  
21 again the question is what the alternative is,  
22 and I think that we think that -- you're

1 absolutely right. I think what you're trying  
2 to say is that we may actually be hiding even  
3 better performance, right.

4 For those hospitals that have  
5 higher percentages of African-American  
6 patients who do well are probably -- are not  
7 probably, potentially we can't know, even  
8 better performers than they appear to be,  
9 because they're doing this in a population  
10 that at a patient may have worse outcomes.  
11 But we don't know that. But again --

12 MEMBER PHILIPPIDES: And that's the  
13 argument in favor of including socioeconomic  
14 status and race in stratification.

15 CHAIR GIBBONS: Ahh, but see I'll  
16 do the counter, which is you would then  
17 conceivably justify poorer performance at the  
18 other end of the spectrum, when the data would  
19 suggest that it's not actually justifiable.

20 MEMBER PHILIPPIDES: That's  
21 correct, or you would discern better  
22 performance.

1 CHAIR GIBBONS: So I think it's a  
2 mixed, would not necessarily be a good thing  
3 overall.

4 DR. BERNHEIM: Right. It would  
5 certainly look as if CMS was condoning that if  
6 you have a poorer population, we expect you to  
7 do worse in the outcomes of those patients,  
8 and I think that's not where CMS wants to fall  
9 on this measure, and that the evidence  
10 doesn't, really doesn't support that that's  
11 consistently true at all.

12 I mean these distributions are  
13 strongly overlapping. Hospitals are really  
14 doing similarly across the deciles.

15 CHAIR GIBBONS: David.

16 MEMBER MAGID: This is really a  
17 comment that applies both to this measure and  
18 the next measure, which we might be able to  
19 get through.

20 But your answer to this question  
21 has to do with how hospitals perform, and we  
22 do know that in certain cases, hospitals

1 sometimes the association between poor  
2 outcomes for say African-Americans compared to  
3 non-African Americans has been explained by  
4 the fact that sometimes hospitals that have a  
5 high proportion of minority patients often  
6 provide poorer quality care.

7 That was a paper from your  
8 institution by Betsy Bradley. My question is  
9 really not focused on the hospital but in your  
10 risk model, you do not include any  
11 socioeconomic factors.

12 It may be that the reason why you  
13 don't have that is you don't have access to  
14 that data. That would be one thing, versus  
15 saying that socioeconomic factors do not, are  
16 not related to these potential outcomes of  
17 readmission or mortality.

18 If you don't have socioeconomic  
19 data, then just tell us you don't have it, and  
20 I'll be fine with it. If you do have it, I'd  
21 really like to know at the individual level  
22 whether it's associated with the outcomes, and

1 if so, why it's not in the models.

2 DR. BERNHEIM: So there are ways to  
3 look at socioeconomic status with Medicare  
4 claims data. They're not perfect, but there  
5 are certainly ways that we can do that and  
6 that we did for these analyses. You know, I  
7 probably should have said this first, but you  
8 know, the NQF guidance is, you know, to not  
9 risk-adjust.

10 MEMBER MAGID: Okay, that's fine.  
11 You don't need to say anymore.

12 CHAIR GIBBONS: Are there other  
13 comments, noteworthy for the intensity and  
14 quality of the discussion?

15 (No response.)

16 CHAIR GIBBONS: All right. So  
17 we're going to go ahead and vote on does the  
18 measure meet the criteria for endorsement.

19 DR. WINKLER: To the folks on the  
20 phone, we're hearing you. Dianne?

21 MEMBER JEWELL: I'm sorry. All I  
22 could hear was whoever's cell phone that was.



1       What are we doing?

2                   DR. WINKLER:   We're voting whether  
3       the measure meets criteria, yes or no.

4                   MEMBER JEWELL:   Okay, thank you.  
5       Yes.

6                   CHAIR GIBBONS:   Okay.   So the vote  
7       is 17 yes and 1 no.   So I think at this point,  
8       we're going to conclude our work for the day,  
9       but first ask for any public comment from  
10      anyone on the line, or there's no public left  
11      in the room.

12                   So I guess Casper can't comment in  
13      the room.   So anybody from the public on the  
14      line?   Do we need to check with the operator?

15                   DR. WINKLER:   Operator, is there  
16      anybody --

17                   MEMBER MAGID:   Ray, if there's no  
18      public comment, since this next measure is so  
19      closely related -- no.

20                   CHAIR GIBBONS:   No.   I don't think  
21      we want to rush.

22                   MEMBER MAGID:   Okay.

1 DR. WINKLER: Operator.

2 OPERATOR: This is the conference  
3 operator.

4 DR. WINKLER: Yes. Is there  
5 anybody on the line who wants to ask a  
6 question or make a comment?

7 OPERATOR: We currently have no  
8 one. Just another reminder folks, touch \*1 to  
9 ask a question.

10 DR. WINKLER: Okay. And if, while  
11 we're waiting, just for the folks at CMS and  
12 Yale, you had said that you would be  
13 available to be with us tomorrow morning to  
14 start this conversation, and we really thank  
15 you for bearing with us, for not getting  
16 through them today.

17 So we will be starting at eight  
18 o'clock in the morning. Operator, is there  
19 anybody who wanted to say anything?

20 OPERATOR: Still no one has queued  
21 up.

22 DR. WINKLER: Great. Then we'll

1       assume there's no one out there. To everybody  
2       in the room, we will be meeting in the same  
3       room. We'll be starting at eight o'clock.  
4       Access to the building is about no earlier  
5       than 7:30, I believe. So yes. I believe so,  
6       yes.

7                   CHAIR GIBBONS: Continental  
8       breakfast at approximately 7:30.

9                   DR. WINKLER: 7:40.

10                  CHAIR GIBBONS: 7:40, 7:35,  
11       whatever. Don't break down the door. Just  
12       wait for the doors to open.

13                  MEMBER RASMUSSEN: Just a question.  
14       We were going to discuss competing and related  
15       measures tomorrow. I haven't seen the Phase  
16       2 comparisons.

17                  DR. WINKLER: Actually, a couple of  
18       things. We're probably only going to be able  
19       to look at the Phase 1, although on your jump  
20       drive is the Phase 2 side-by-sides. We put  
21       them on there. But frankly, we were throwing  
22       so much stuff at you that, you know, it

1 starting we were getting embarrassed.

2 So you know, I think that in terms  
3 of follow-up, we can do the Phase 1. We can  
4 talk about the implications for Phase 2. But  
5 just as we've had to do it on a two-step  
6 version, I think we'll probably have to do  
7 something similar on the Phase 2 measures too.  
8 But you do have the side-by-sides in there.

9 MEMBER RASMUSSEN: Okay. No  
10 arguments here.

11 DR. WINKLER: Yes. You can keep the  
12 jump drives for tomorrow, load them onto your  
13 laptop, whatever. Ultimately tomorrow before  
14 you leave, we'll ask for them back. Thank you  
15 all very much, and have a good evening.

16 CHAIR GIBBONS: Yes. Thank you all  
17 for all the extended effort and discussion  
18 today.

19 MEMBER JEWELL: Talk to you  
20 tomorrow.

21 (Whereupon, the above-entitled  
22 matter went off the record at 5:36 p.m.)

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In the matter of: Cardiovascular Steering Committee

Before: NQF

Date: 04-07-11

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Court Reporter

**NEAL R. GROSS**

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