

# NATIONAL QUALITY FORUM

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## CARDIOVASCULAR MEASURE ENDORSEMENT PROJECT 2014 STANDING COMMITTEE

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THURSDAY  
DECEMBER 4, 2014

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The Standing Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., Mary George and Thomas Kottke, Co-Chairs, presiding.

### PRESENT:

MARY GEORGE, MD, MSPH, FACS, FAHA, Co-Chair

THOMAS KOTTKE, MD, MSPH, Co-Chair

SANA AL-KHATIB, MD, MHS, Duke University  
Medical Center

CAROL ALLRED, Immediate Past Chair,  
WomenHeart: The National Coalition of  
Women with Heart Disease

LINDA BRIGGS, DNP, George Washington  
University School of Nursing

LESLIE CHO, MD, Cleveland Clinic\*

JOSEPH CLEVELAND, MD, University of  
Colorado-Denver

MICHAEL CROUCH, MD, MSPH, FAAFP, Texas A&M  
School of Medicine

ELIZABETH DeLONG, PhD, Duke University  
Medical Center

TED GIBBONS, MD, FACC, FACP, FASE,  
Harborview Medical Center; University  
of Washington Medical Center\*

ELLEN HILLEGASS, PT, EdD, CCS, FAACVPR,  
FAPTA, American Physical Therapy  
Association

JUDD HOLLANDER, MD, FACEP, Sidney Kimmell

Medical College; Thomas Jefferson  
University  
THOMAS JAMES, MD, AmeriHealth Caritas Family  
of Companies  
JOEL MARRS, PharmD, FNLA, CLS, University of  
Colorado Anschutz Medical Campus;  
American Society of Health-System  
Pharmacists  
GERARD MARTIN, MD, Children's National  
Health System  
KRISTI MITCHELL, MPH, Avalere Health  
GEORGE PHILIPPIDES, MD, Newton-Wellesley  
Hospital  
JASON SPANGLER, MD, MPH, FACPM, Amgen, Inc.  
HENRY TING, MD, MBA, New York-Presbyterian  
Hospital and Health System\*  
MLADEN VIDOVIĆ, MD, Jesse Brown VA Medical  
Center; University of Illinois at  
Chicago

NQF STAFF:

HELEN BURSTIN, MD, MPH, Chief Scientific  
Officer  
SHARON HIBAY, RN, DNP, Senior Director  
WUNMI ISIJOLA, MPH, Project Manager  
KAREN JOHNSON, Senior Director  
VY LUONG, Project Analyst

ALSO PRESENT:

JOSEPH ALLEN, American College of Cardiology  
LISA BERGERSEN, MD, Boston Children's  
KYLE CAMPBELL, PharmD, FMQAI\*  
STEPHEN CANTRILL, MD, Denver Health\*  
JENSEN CHIU, MHA, ACC/AHA  
FRED KUSUMOTO, MD, Mayo Clinic  
MICHAEL HO, MD, PhD, ACC/AHA  
SAMANTHA TIERNEY, MPH, PCPI\*

\* present by teleconference

T-A-B-L-E O-F C-O-N-T-E-N-T-S

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

2 (9:05 a.m.)

3 MS. ISIJOLA: Good morning, everyone  
4 and thank you again for joining us. Today is day  
5 1 of our Cardiovascular Phase II project. My  
6 name is Wunmi Isijola. I'm a senior project  
7 manager here. I also have Sharon Hibay, Karen  
8 Johnson and Helen Burstin, our chief scientific  
9 officer.

10 Would you like to say a few words?

11 DR. BURSTIN: Just add my welcome to  
12 everybody. Thanks so much for coming back again.  
13 I think you guys are one of our first standing  
14 committees, so I think part of what we'd like to  
15 see is how much easier is it to kind of do the  
16 second round having been through the first  
17 rounds, and is there a good steep learning curve?  
18 But also we also continuously try to improve on  
19 what we're doing, so please let us know if some  
20 of the tweaks we've made are helping or not. And  
21 I was just talking to Wunmi earlier about making  
22 sure we get you guys a survey as well to make

1       sure you can actually tell us what worked and  
2       what didn't.

3               But thank you so much for coming back  
4       again. And I think there are a couple process  
5       improvements including better clickers, which I'm  
6       told will not be the "could you push it one more  
7       -- one more time, please?" That should be over.  
8       And you'll know in fact whether you voted, so  
9       that will be very positive.

10              So with that, thank you so much.

11              MS. ISIJOLA: Okay. And also Vy  
12       Luong, our project analyst.

13              Before we get started I wanted to turn  
14       it over to our co-chairs to provide a brief  
15       introduction, Dr. Tom Kottke and Dr. Mary George.

16              CO-CHAIR KOTTKE: Sure. Tom Kottke,  
17       medical director for Population Health and Health  
18       Partners. Welcome and thank you for making the  
19       effort to come out. And I don't think I'll say  
20       any more right now.

21              CO-CHAIR GEORGE: Mary George from  
22       CDC. Just welcome. It's good to see you all

1 again and thank you for taking the time to do  
2 this important work.

3 MS. ISIJOLA: Thank you. Sharon,  
4 would you like to say a few words?

5 MS. HIBAY: Well, good morning. I  
6 think I introduced myself to mostly everyone. My  
7 name is Sharon Hibay. I'm the new senior  
8 director for the cardiovascular project. I've  
9 been with NQF for about two months, but I've been  
10 pretty involved in the cardiovascular space, the  
11 measure space for quite some time. Thank you for  
12 all your efforts. We appreciate them.

13 MS. ISIJOLA: And, Karen, would you  
14 like to say a few words?

15 MS. JOHNSON: I'll just say hello.  
16 I'm Karen. Nice to see you.

17 MS. ISIJOLA: Great. Thank you. So  
18 just some housekeeping rules. As you know, the  
19 restrooms are outside of this room. We will have  
20 several breaks throughout the day.

21 Please utilize the wireless network  
22 that we have available, and please make sure that

1       you're muting your cell phones and any other  
2       devices. We do ask also individuals on the line  
3       if you can mute your line and not place on hold.

4               And before we get started, I wanted to  
5       also make notice of Dr. Gerard Martin. He is one  
6       of our newer committee members.

7               So if you'd like to say a few words,  
8       a brief introduction of yourself?

9               MEMBER MARTIN: Gerard Martin. I'm a  
10       pediatric cardiologist at Children's National  
11       here in Washington, D.C., and I'm very pleased to  
12       join the Committee. Have been involved with  
13       quality efforts, both nationally and  
14       internationally, through our hospital and the  
15       American College of Cardiology for a number of  
16       years and excited to learn about your work.

17               MS. ISIJOLA: Great. Thank you. And  
18       now we'll turn it over to our general counsel,  
19       Ann Hammersmith, and she will go over our  
20       disclosure of interest policy.

21               MS. HAMMERSMITH: Thank you, Wunmi.  
22       As Wunmi said, we're going to combine

1       introductions with the disclosures of interest.  
2       For most of you it's your second year on the  
3       Committee, so I know you're expert disclosers,  
4       but I'll just go over a few of the ground rules  
5       to remind you.

6               I understand there are some committee  
7       members on the phone. I will call on you for  
8       your disclosure once we do the disclosures of the  
9       people in the room.

10              You received a fairly involved form  
11       from us where we asked you about your  
12       professional activities, community service,  
13       grants, so on and so forth. What we're looking  
14       for you to today is to disclose information that  
15       you believe is relevant to your service on the  
16       Committee. We don't want you to summarize your  
17       résumé. Please don't do that. We'll be here all  
18       day. But just reveal things that you believe are  
19       important, relevant to the work of the Committee  
20       that you want people to know and that people need  
21       to know.

22              So we are particularly interested in



1 grant activity, research support you may have  
2 received, Committee service and speaking. But  
3 only if it is relevant to what's before the  
4 Committee.

5 A few other reminders: You sit as an  
6 individual. You're here because you're an  
7 expert, because you have something special to  
8 bring to our table. You do not represent your  
9 employer. You do not represent the interests of  
10 anyone who many have nominated you or supported  
11 your nomination.

12 The other thing that I want to remind  
13 you of is that NQF is somewhat unique in our  
14 conflict of interest process in that we look at  
15 potential financial conflicts, but we also look  
16 at non-financial conflicts. And by that I mean  
17 you may have served on a committee for a  
18 professional society or somebody else where you  
19 looked at measures and that would be something  
20 that we would look for you to disclose but only  
21 if it's related to the subject matter before the  
22 Committee. Because of the nature of the work

1 that we do, we look very broadly to make sure  
2 that we cover the waterfront.

3 So I'll ask each of you to tell us who  
4 you are, who you're with and then if you have  
5 anything to disclose. And I always start with  
6 the co-chairs.

7 CO-CHAIR KOTTKE: Sure. Tom Kottke.  
8 Health Partners. I have no conflicts to declare.

9 CO-CHAIR GEORGE: Mary George at CDC  
10 and I have no conflicts of interest. Most of my  
11 major development work has been in stroke,  
12 cerebrovascular disease rather than  
13 cardiovascular.

14 MEMBER CLEVELAND: Good morning. I'm  
15 Joe Cleveland. I'm an adult cardiac surgeon at  
16 University of Colorado Health Sciences Center. I  
17 have participated in measure development through  
18 the Society of Thoracic Surgeons for surgical  
19 measures, but have no disclosures for any of  
20 these measures that are before us today.

21 MEMBER JAMES: Tom James. I'm an  
22 internist pediatrician with AmeriHealth Caritas,

1 a family of companies, a Medicaid-managed care  
2 company. I run the clinical policies. Formerly  
3 was on the AMA Cardiovascular Work Group, but  
4 that was some 10 years ago.

5 MEMBER MARTIN: I'm Gerard Martin.  
6 I'm representing the Children's Hospital  
7 Association. My disclosures are the American  
8 Board of Internal Medicine, where I'm on their  
9 sub-board for adult congenital heart disease and  
10 the American College of Cardiology, where I  
11 participated in the formation of the IMPACT  
12 Registry which measures quality income in cardiac  
13 catheterization and the quality network of the  
14 ACC. It's a set of measures to improve quality  
15 in pediatric cardiology practices.

16 MS. HAMMERSMITH: Just a reminder:  
17 You sit as individuals. You're not representing  
18 an organization or their interests. So I just  
19 want to highlight that.  
20 So you may work for the ABC Hospital, but you're  
21 not representing their interests on the  
22 Committee.

1                   MEMBER VIDOVIICH: I'm Mladen Vidovich.  
2 I'm an interventional cardiologist, University of  
3 Illinois at Chicago and I also am chief of  
4 cardiology Jesse Brown VA in Chicago. I don't  
5 represent any of those, so not the Department of  
6 Veterans Affairs or University of Illinois. I am  
7 the upcoming governor-elect of the Department of  
8 Veterans Affairs for ACC, but again I don't  
9 represent any of those.

10                  MEMBER HOLLANDER: Hi, Judd Hollander.  
11 I'm an emergency physician at Thomas Jefferson  
12 University. I got here through ACEP and I'm on  
13 their Quality and Performance Committee. I don't  
14 think there's any direct conflicts with anything.

15                  MEMBER CROUCH: I'm Michael Crouch.  
16 I'm a family physician representing the American  
17 Academy of Family Physicians. I'm in a family  
18 medicine residency program. Don't have any  
19 conflicts of interest to report.

20                  MS. HAMMERSMITH: I hate to beat a  
21 dead horse, but I'm going to because I'm a  
22 lawyer. You don't represent any organization

1 when you sit on this Committee. You're here as  
2 an expert, so you're not carrying anybody's  
3 water. You're here because of what you know as a  
4 professional, as an individual. So I just want  
5 to remind you.

6 CO-CHAIR KOTTKE: Yes, so don't use  
7 the R word.

8 MEMBER SPANGLER: Jason Spangler. I'm  
9 the Executive Director of Medical Policy and  
10 Quality Strategy at Amgen, and I don't have any  
11 conflicts.

12 MEMBER DeLONG: I'm Liz DeLong. I'm  
13 the chair of Biostatistics and Bioinformatics at  
14 Duke. I have worked with respect to data  
15 analysis, both with the NCDR and STS, but I have  
16 no conflicts.

17 MEMBER ALLRED: I'm Carol Allred. I  
18 have just finished a term serving six years as  
19 chairman of the board of directors at WomenHeart.  
20 I come at this from a different perspective than  
21 anyone else in this room, I think; i.e., I'm a  
22 patient. I am very interested in many of the

1 measures because they affect me directly and many  
2 people I know.

3 MEMBER PHILIPPIDES: Good morning. My  
4 name is George Philippides. I'm a cardiologist  
5 and chief of cardiology at Newtown-Wellesley  
6 Hospital in Massachusetts. I'm the president-  
7 elect for the Founders Board of the American  
8 Heart Association, but I have nothing to  
9 disclose.

10 MEMBER MITCHELL: Good morning. I'm  
11 Kristi Mitchell. I'm a senior vice-president at  
12 Avalere Health. I don't have anything to  
13 disclose except for the fact that I worked 12  
14 years at the American College of Cardiology.

15 MEMBER HILLEGASS: I'm Ellen  
16 Hillegass. I'm a physical therapist. I'm on  
17 faculty at Mercer University in Atlanta, Georgia  
18 and I have no conflicts to disclose.

19 MEMBER AL-KHATIB: Good morning. I'm  
20 Sana Al-Khatib. I'm an electrophysiologist at  
21 Duke University. I actually serve on the  
22 steering committee for the ACC NCDR, but I don't

1 have any conflicts in relation to that because I  
2 did not participate in their performance  
3 measures. I am a member of the board of trustees  
4 for the Heart Rhythm Society, and I co-chair  
5 their Measure Development Task Force, so I do  
6 have a direct conflict with two of the measures  
7 that they developed and I'll stay calm and quiet  
8 while you discuss them.

9 MEMBER BRIGGS: Hi, I'm Linda Briggs.  
10 I'm faculty at George Washington University here  
11 in D.C. I am particularly in the nurse  
12 practitioner group, and I am a nurse practitioner  
13 myself. I have no conflicts of interest.

14 MS. HAMMERSMITH: Okay. Thank you.  
15 I'm going to call the names of the people who are  
16 on the phone so that you can introduce yourselves  
17 and disclose anything you want to disclose.  
18 Leslie Cho?

19 MEMBER CHO: Hi, it's Leslie Cho. I'm  
20 from Cleveland Clinic and nothing to disclose.

21 MS. HAMMERSMITH: Okay. Thank you.  
22 Ted Gibbons? Is Ted Gibbons on the line?

1 (No response.)

2 MS. HAMMERSMITH: Henry Ting?

3 (No response.)

4 MS. HAMMERSMITH: Have a little  
5 feedback here. Is Henry Ting on the line?

6 OPERATOR: Sorry, Ann, I didn't mean  
7 to step on you. Just a reminder for those folks  
8 joining us by phone, please make sure you keep  
9 your computer speakers turned down or off to  
10 reduce feedback.

11 MS. HAMMERSMITH: Thank you. Joel  
12 Marrs?

13 MEMBER MARRS: Hi, I'm Joel Marrs.  
14 I'm on faculty at the University of Colorado and  
15 a clinical pharmacist. I have nothing to  
16 disclose.

17 MS. HAMMERSMITH: Thank you. Thank  
18 you for making those disclosures. Just a few  
19 final words before I go away and let you get on  
20 with your work. For any conflict of interest  
21 process to really work, everybody has to take  
22 some responsibility for it, including the



1 Committee members. So if while you're  
2 discussing/deliberating you think you have a  
3 conflict of interest, you think somebody on the  
4 Committee has an conflict of interest or is  
5 behaving in a way that's biased, we look to you  
6 to speak up, preferably in real time.

7 You can do that by bringing it up  
8 directly at any time. If you don't want to do  
9 that, you can go to your co-chairs, who will then  
10 go to NQF staff, or you can go directly to NQF  
11 staff so that we can deal with it on the spot.  
12 We don't want you sitting there in silence  
13 thinking, ooh, I think I may have a conflict, or,  
14 gee, that person seems really, really biased. We  
15 really want you to speak up.

16 So having said all that, do you have  
17 any questions of each other, anything you want to  
18 discuss, any questions of me?

19 (No response.)

20 MS. HAMMERSMITH: Okay. Thank you.

21 MS. ISIJOLA: Thank you, Ann. So just  
22 to kind of provide additional feedback based on

1        what Ann spoke to and just a refresher for your  
2        role as Standing Committee members, we do ask you  
3        not to represent your organization but  
4        yourselves. You are providing your expertise  
5        based on an NQF multi-stakeholder perspective.

6                And you all have received your two or  
7        three-year term. If you have any issues with  
8        that, please do let us know. And really your  
9        charge is to work with NQF and the goals of this  
10       project, which is essentially to review and  
11       endorse these measures based on our criteria.

12               And also, we do at times have  
13       responses from CSAC and for you, specifically the  
14       co-chairs, to respond to any requests based on  
15       the measures within this portfolio, but also  
16       oversee the portfolio of cardiovascular measures.

17               And as I mentioned, your role is to  
18       oversee the cardiovascular portfolio, and Sharon  
19       Hibay will review that with you shortly, but  
20       really consider the issues and the measures  
21       within this portfolio based on our criteria, but  
22       to identify if there are in fact any gaps,

1 measures that may potentially be relating or  
2 competing with various measures within our  
3 portfolio.

4 So with that being said, I will turn  
5 it over to Sharon Hibay and she'll speak more to  
6 some of the measures we have in this portfolio as  
7 it relates to our Phase I of this project and  
8 some of the measures that you've in fact  
9 endorsed.

10 Sharon?

11 MS. HIBAY: Next slide, please. Okay.  
12 So what you have in front of you here is the list  
13 of measures that we're going to be talking about  
14 in today's project. There are 16 of them that  
15 we'll be reviewing over the next couple of days.

16 Next slide, please. So of course  
17 we're all reasonably familiar, I hope so, with  
18 the National Quality Strategy and the National  
19 Quality Strategy priorities. Of course they're  
20 based upon the triple aim: better care, healthy  
21 people/healthy communities and affordable care.  
22 So much of the work that the whole health care

1 industry enterprise is doing is all around  
2 building healthier communities and having better  
3 outcomes.

4 So one of the National Quality  
5 Strategies very specifically calls out  
6 cardiovascular disease, promoting the most  
7 effective prevention and treatment practices for  
8 the leading causes of mortality, starting with  
9 cardiovascular disease. So it's the only disease  
10 specifically that was actually called out in the  
11 National Quality Strategy priorities. So we have  
12 some important work to continue to do.

13 Next slide, please. So I'm not going  
14 to go into great detail. There's a whole bunch  
15 of slides that are going to follow. We talked  
16 about this in Phase I. At that point, Reva  
17 Winkler provided a really nice overview of the  
18 work that we're doing that are reflective of the  
19 cardiovascular measures in our portfolio. Just  
20 in general they are coronary artery disease, AMI,  
21 heart failure and rhythm disorders. And then  
22 there are some other measures related to cardiac

1 cath, hypertension and cost and resource use.

2 Not all of the measures that are in  
3 the 70 measures within the CD portfolio will be  
4 reviewed by this Committee. They're reviewed by  
5 -- throughout all of the projects in different  
6 committees at NQF. So the preponderance are  
7 within this Committee, but they also are  
8 pertaining to some other committees as well.

9 Okay. So this is a framework that you  
10 saw, and it was I think also in the final report  
11 of Phase I, which is up and posted and I'm sure  
12 you've all taken a look at the good work that you  
13 have already done, and that now we continue.  
14 This is patient-focused episode of care framework  
15 for CAD and AMI. We're all very familiar with  
16 the framework, which is populations at risk. We  
17 talk about those. So it's either primary  
18 prevention, secondary prevention and with or  
19 without an AMI.

20 So we have focused on staying healthy,  
21 getting better, living with illness and  
22 disability and coping with end of life. We start

1 with your primary prevention. And if you have an  
2 event or an episode or a disease, you move to  
3 some sort of acute phase, post-  
4 acute/rehabilitation phase and then secondary  
5 prevention.

6 So what we've provided for you in the  
7 list of some of the subsequent slides are the  
8 measures that are within NQF's portfolio that  
9 represent these categories that I just kind of  
10 referenced. So we have these here for your  
11 reference. I'm going to go through some slides  
12 reasonably quick, but the way we have it  
13 formatted will help you identify the ones that  
14 we're going to be reviewing in these two days of  
15 discussions.

16 So starting with populations at risk,  
17 primary prevention. So we have a number of  
18 slides, and you can see three of the cardiac  
19 imaging ones we'll be discussing at this meeting.

20 Next populations at risk, secondary  
21 prevention. And one of those as well will be  
22 reviewed/bolded, you can see, at this meeting.

1                   Now we move onto the acute phase AMI,  
2                   and you can see we have one measure here as well.

3                   Acute phase outcomes. We won't be  
4                   reviewing any of these measures today, but again  
5                   these slides are provided for your reference.

6                   Next we talk about PCI. Again, not  
7                   today.

8                   And then for CABG patients these are  
9                   in the surgery portfolio, but obviously very  
10                  related to cardiovascular disease. These are not  
11                  measures that we will be seeing.

12                  And then post-acute/rehabilitation  
13                  phase. And again, we will not be reviewing any  
14                  of these today.

15                  Populations at risk, secondary  
16                  prevention for patients with CAD/AMI. And you  
17                  can see a measure at the bottom.

18                  Okay. So that is the CAD/AMI list.  
19                  Now we kind of move on to heart failure. Excuse  
20                  this slide; it's a little bit fuzzy. So  
21                  basically we have populations at risk again for  
22                  heart failure. Evaluation and ongoing

1 management. And then the acute phase and  
2 hospitalization. And then we move to outcomes.  
3 So we're going to show you the same format.

4 So populations at risk. We will not  
5 be looking at these measures today.

6 Evaluation and ongoing management.  
7 Oh, actually we're looking at one of the measures  
8 on there. It's 0083. So that one should be  
9 highlighted. Excuse me.

10 Acute phase hospitalization. We're  
11 looking at 2455 on this slide.

12 And these are now related to heart  
13 rhythm disorders. So A-fib, you can see we're  
14 looking at a couple of those.

15 And these are measures related to  
16 cardiac cath, and we'll be looking at one of  
17 those. That's a pediatric one.

18 And we have a measure for  
19 hypertension. Not today. Actually I think  
20 that's a population health measure as well, so I  
21 think that goes to another committee. I think.  
22 I don't know all of the measures yet. I'm on my



1 own steep learning curve; it's only the beginning  
2 of month three for me here at NQF.

3 And lastly is a cost and resource use,  
4 and that is also another committee as well.

5 Okay?

6 Are there any questions on the  
7 portfolio or the information that has been  
8 presented so far?

9 (No response.)

10 MS. HIBAY: Okay. I'd like to move on  
11 to talk a little bit about updates to the process  
12 for measure evaluation. We did some work.  
13 Recently we talked a little bit about this again  
14 at the Q&A call that we hosted a couple weeks  
15 ago. Starting off in Phase I of the CD project,  
16 the staff did reviews of the measures. There was  
17 a call for multiple different approaches for us  
18 to provide some additional information, the staff  
19 to do some sort of look-see at the measure  
20 details.

21 We did some work with the consensus  
22 task for it which was approved by the Board. We

1       also had lots of our stakeholders, including  
2       members of this Committee as well, come to NQF  
3       and say, you know, this is a big bite to chew on.  
4       Can you have a little bit more predigested  
5       information for us?

6               We heard definitely from measure  
7       developers as well that they would like to have a  
8       little bit more supportive understanding of what  
9       will constitute the content of the conversation?  
10      And we also heard that people wanted what was  
11      perceived as a little more even playing field,  
12      that we all kind of started off on the same  
13      footing and made sure we talked about the  
14      measures in a consistent manner.

15             Lastly, we recognized that being an  
16      organization that convenes multi-approached  
17      stakeholders that we all come to the table with  
18      different gifts and different knowledge/  
19      experience and that the idea of convening a  
20      stakeholder group brings all of that richness  
21      together, but that richness means that we have  
22      areas of strength and areas that we could learn

1 or need a little more understanding.

2 So all of this together, we put  
3 together the staff review that I believe we did  
4 for all of the measures in Phase 1, and we went  
5 back after Phase 1 and kind of tweaked it. The  
6 staff reviews go through the five criteria  
7 themselves, and we provide kind of a pre-look  
8 from the staff perspective. And after we tweaked  
9 it, now the preliminary analysis which I  
10 understand is some alignment work with the MAP,  
11 that they also do some preliminary analysis there  
12 as well.

13 So we provided this information to the  
14 members of the Committee, and we also provided it  
15 to our developers. Then the Committee went  
16 through the process of reviewing the individual  
17 measures they were assigned as discussants. And  
18 then, as you all know, you added that information  
19 in your surveys so we could put this information,  
20 coordinate it one more time together. And the  
21 information that you have on the measures now  
22 includes the preliminary analysis, comments from

1 the staff members of NQF, and as well as your  
2 comments. And we also sent those back out again  
3 to the measure developers so they had an  
4 understanding of what we might be talking about  
5 today in relation to their measures individually.

6 Like everything that we do -- we all  
7 live in quality improvement, so we know that the  
8 journey doesn't end. So this is a process. And  
9 so we will be seeking your feedback, as Helen  
10 said earlier, as to how these changes are going,  
11 how the process is working. We're very  
12 interested in making sure we continue to move  
13 this along and be as efficient and helpful as  
14 possible.

15 We're also going to be after this  
16 Committee meeting reaching out; I will be  
17 personally reaching out to each one of the  
18 developers to see what did they think of this  
19 preliminary analysis process? So the idea of  
20 this is to expand opportunities for robust  
21 discussion.

22 I'm not going to read this slide here,

1 but the last thing I really want to enhance is  
2 that by no means is this staff review/preliminary  
3 analysis to replace the great work that the  
4 Committee members do. And I have to tell you --  
5 so I spent a lot of hours last night looking at  
6 every single form. I'm very impressed with the  
7 work that they did; I'm quite pleased. It's  
8 quite obvious the detail and time that everyone  
9 has taken. So I thank you in advance for all of  
10 your efforts. But again, this is not supposed to  
11 replace; it's supposed to enhance and start as a  
12 springboard for conversation -- a consistent  
13 springboard, as you will.

14           So the other thing that I want to  
15 share with you that you all have access to, the  
16 Committee members, is the wonderful information  
17 provided to us by the measure developers. When  
18 they submit their measures, we go through what's  
19 called a completeness check. And we just want to  
20 know that all the documentations that we need to  
21 review for review and evaluation are available  
22 and then we compile that information. The

1 information you looked at was the measure work  
2 sheet, which had the preliminary analysis. If  
3 there was an e-measure that has that information  
4 as well, we did an e-measure review.

5 You have the pre-evaluation comments  
6 and you have pre- and public member comments.  
7 Just to put that out as a caveat, we actually for  
8 all of these measures received no comments from  
9 the public before the meeting.

10 We also have the measure information  
11 form and we have the evidence and testing  
12 attachments. And we tried to put it in an order  
13 that was easy for you to utilize. So we'll see  
14 how that goes as well. And we're very interested  
15 in hearing your feedback. We also have  
16 spreadsheets and any other additional  
17 documentation they may have provided.

18 So that's kind of the structure of  
19 what we did, why we did it and the background of  
20 this continued evolving work.

21 Are there any questions about the  
22 preliminary analysis at this point, or the

1 updates to the evaluation process?

2 Okay. Hearing no comments or  
3 questions, I'll turn it over to Wunmi for the  
4 next slide.

5 MS. ISIJOLA: Okay. Thank you,  
6 Sharon. So most of you are familiar with our  
7 process and how we will proceed with today's  
8 deliberations. We are expecting every committee  
9 member to have reviewed every single measure. I  
10 know you have been designated certain measures to  
11 provide your evaluations, but we want a robust  
12 discussion; we want to make sure that everyone is  
13 participating in the discussion, and obviously  
14 Dr. George and Dr. Kottke will facilitate that.  
15 And really to remain engaged during the  
16 discussion without distractions. I know everyone  
17 has their laptops and busy, but let's really  
18 remain engaged with the discussion for today.

19 And we do have discussants for each  
20 measure. We specifically did not identify a lead  
21 discussant because we want to make sure that  
22 everyone is engaged in the discussion. As you

1 know, you have your microphones. Please utilize  
2 them. Speak into them. If you're not speaking,  
3 please turn them off.

4 And the way we will proceed, and I'll  
5 turn it over to the co-chairs in a second, we  
6 will have the developers present a brief  
7 introduction of their measures, two to three  
8 minutes, and then we will turn it over to the  
9 discussants to provide their analyses of their  
10 measures. And we will open it up for discussion.  
11 Thereafter, we will then vote on each individual  
12 criteria of the measure and then an overall  
13 recommendation for endorsement.

14 And with that being said, I'll turn it  
15 over to the co-chairs to begin.

16 CO-CHAIR GEORGE: I would just add  
17 that it would be helpful if you want to make a  
18 comment to turn your name card vertical so we'll  
19 know to call on you. And try not to interrupt  
20 each other. For those on the phone, be sure and  
21 chime in when you have comments to make.

22 CO-CHAIR KOTTKE: So, now we get down



1 to business. Measure 0543, coronary artery  
2 disease and medication possession ratio for  
3 statin therapy. And the discussants are Sana and  
4 Kristi and Liz. And who's going to take the  
5 driver's seat? Sana?

6 MS. ISIJOLA: And, I'm sorry, are  
7 there any representatives from ACC with us today?

8 DR. CAMPBELL: Wunmi, this is Kyle  
9 Campbell from FMQAI. Can you hear me okay?

10 MS. ISIJOLA: Yes.

11 DR. CAMPBELL: Okay. Good. All  
12 right. Well, good morning. My name is Kyle  
13 Campbell and I'm a pharmacist and vice president  
14 for pharmacy and quality measurement at FMQAI.  
15 We are the measure developer and we're  
16 representing CMS today.

17 This particular measure was developed  
18 for CMS under the Medication Measure Special  
19 Innovation Project and it was originally fully  
20 endorsed in 2011. The measure has recently  
21 undergone a comprehensive review of underlying  
22 evidence and additional testing of the revised

1 specifications at several levels of analysis,  
2 including the accountable care organization  
3 level. The project was under the direction of a  
4 multi-disciplinary technical expert panel.

5 Major changes to highlight for you of  
6 the measure are the results of the process to  
7 align the eligible population with the 2013  
8 ACC/AHA guidelines for the management of  
9 cholesterol. So, typically, rather than the  
10 denominator's eligible population being limited  
11 to those with coronary artery disease, the  
12 denominator has been expanded to include patients  
13 with atherosclerotic cardiovascular disease as  
14 defined in the guidelines.

15 In addition, the age criteria has also  
16 been modified to align with the guidelines.  
17 Therefore, the denominator is individuals of at  
18 least 21 years of age with cardiovascular disease  
19 presumed to be of atherosclerotic origin and at  
20 least two claims for statins during the  
21 measurement period.

22 And the numerator is individuals with

1 CVD who had at least two prescription drug claims  
2 for statins and have a proportion of days covered  
3 for statin medications of at least 0.8.

4 In terms of importance, this measure  
5 clearly addresses the National Quality Strategy  
6 goal of promoting the most effective treatment  
7 for leading causes of mortality, starting with  
8 cardiovascular disease. As you know, CVD affects  
9 large numbers, represents a leading cause of  
10 morbidity and mortality and has high resource use  
11 on the healthcare system.

12 Based on the data analyzed, the  
13 measure has ample room for improvement with mean  
14 rates of approximately 72 percent at each of the  
15 levels that we looked at. Additionally, with the  
16 new guidelines shifting away from the use of  
17 specific clinical targets, medication adherence  
18 to statins is an important concept for providers  
19 to understand and communicate to their patients.

20 The measure was found to be reliable  
21 and valid, and the method of measuring adherence  
22 as the proportion of days covered is harmonized

1 with the majority of adherence measures in the  
2 NQF portfolio.

3 We greatly appreciate your  
4 consideration of the measure today and look  
5 forward to answering any questions from the  
6 Committee concerning the measure submission.  
7 Thank you.

8 CO-CHAIR KOTTKE: Okay, now.

9 MEMBER AL-KHATIB: Okay. So, as we  
10 heard, in terms of description of the measure,  
11 introduction of the measure, it's the percentage  
12 of individuals with cardiovascular disease,  
13 including CAD, cerebrovascular disease, PAD  
14 presumed to be of atherosclerotic origin who are  
15 prescribed statin therapy that had a proportion  
16 of days covered for statin medications of at  
17 least .8 during the measurement period.

18 The level of analysis is the  
19 clinician, group practice, health plan,  
20 integrated delivery system, population, state.  
21 And as you heard, this actually was initially  
22 endorsed in 2009 and is being revised to

1 incorporate some of the emerging data and the  
2 guideline document that the developer referred  
3 to.

4 So this is a process measure and the  
5 hope is that this measure will help physicians  
6 identify patients who may benefit from a statin  
7 who are not adherent to it, may help providers  
8 develop communication and education tools to  
9 improve adherence to statins. And they clearly  
10 provide the argument that higher statin adherence  
11 rates are expected to result in lower rates of  
12 hyperlipidemia, cardiovascular events and  
13 mortality. And so they certainly state that  
14 adoption of this performance measure will improve  
15 the quality of care of patients and eventually  
16 improve outcomes.

17 In terms of the evidence that they  
18 provide, I think they did an excellent job  
19 providing this evidence referring us to the 2013  
20 ACC/AHA guidelines, but also summarizing the  
21 results of a 2010 meta-analysis, which was a  
22 systematic review of 21 randomized control

1 trials. They also reported a summary of eight  
2 more recent studies of adherence to statins that  
3 consistently found high adherence to statins in  
4 persons with CAD was associated with lower all-  
5 cause mortality. So when it comes to the  
6 evidence, I think that the developer did an  
7 excellent job there.

8 I'm not sure if you want to move on to  
9 the other aspects or if you want to hear from  
10 other people?

11 CO-CHAIR KOTTKE: Anybody else want to  
12 comment at this time? Kristi or Liz?

13 MEMBER MITCHELL: I just have a  
14 question.

15 CO-CHAIR KOTTKE: Kristi? Yeah.

16 MEMBER MITCHELL: Yes, sorry. Again,  
17 being a non-clinician, I just need a point of  
18 clarification regarding the use of the term  
19 "cardiovascular" being inclusive of peripheral  
20 vascular disease or peripheral arterial disease.  
21 Because the documentation, I was a bit confused  
22 by that. I did appreciate the ASTVD reference.

1 I think that was very helpful, but I was just  
2 curious again as sort of a consumer as to whether  
3 or not PAD is inclusive within CVD or CAD.

4 CO-CHAIR KOTTKE: Yes.

5 MEMBER AL-KHATIB: Maybe the developer  
6 would want to comment. But, yes, so this is what  
7 the developer was talking about, that now the  
8 definition of cardiovascular disease includes  
9 either CAD or cerebrovascular disease or  
10 peripheral arterial disease because the  
11 pathophysiology is the same in terms of having  
12 atherosclerosis. But maybe the developer would  
13 want to add to that as well.

14 DR. CAMPBELL: Sure. Yeah, I think,  
15 just consistent with everything that's been said,  
16 one of the things that we looked at in the  
17 titling of the measure was to use the simple term  
18 of cardiovascular disease because we were  
19 concerned that if we used, like, arteriosclerotic  
20 cardiovascular disease, patients might be  
21 confused. And so that's why we limited the name  
22 of the title in the description.

1 CO-CHAIR KOTTKE: Thank you. Liz, do  
2 you want to --

3 MEMBER CHO: I'd at least consider,  
4 you know, that the guideline says it's coronary  
5 artery disease equivalent. Is that part of the  
6 population?

7 CO-CHAIR KOTTKE: Sana? The question  
8 was, was coronary artery disease equivalent part  
9 of the guideline? Diabetes, for example. I  
10 think the answer is no, that it's patients with  
11 established disease.

12 MEMBER AL-KHATIB: That's exactly  
13 right.

14 CO-CHAIR KOTTKE: Yeah, so it's not --  
15 I assume -- was that you, Leslie?

16 MEMBER CHO: Yeah. Yeah, it's me.

17 CO-CHAIR KOTTKE: Yeah.

18 MEMBER CHO: Hi.

19 CO-CHAIR KOTTKE: Folks on the line,  
20 if you'd address yourselves until we get used to  
21 your voices, that will help.

22 It doesn't include CAD equivalents.



1 It's established disease?

2 MEMBER AL-KHATIB: Right.

3 MEMBER HOLLANDER: Yeah, I have sort  
4 of a philosophical question on this. And I can't  
5 tell from reading the measure, it's measured at  
6 what level? Like I see it's ACO and health  
7 plans, but it also appears to list just group  
8 practices. And so a lot of these adherence  
9 things, it seems to me that the individual  
10 clinician has very little control. So if you  
11 give somebody a prescription and you give them  
12 refills for six months and you're not supposed to  
13 see them for six months, how do you as an  
14 individual practice have any idea if they've  
15 filled their scripts at two months?

16 So I see the measure where it's at the  
17 health plan level and they have access to the  
18 data and can set up quality controls, but I  
19 frankly feel it's a totally inappropriate measure  
20 at the group practice level because it will just  
21 drive up costs. It will require them to see  
22 patients more often than they do it and they're

1 never going to develop a robust infrastructure to  
2 monitor refills between visits. And so I raise  
3 that question. I think this may be the only  
4 measure that we're seeing today that that's an  
5 issue in, but I know we discussed it last time.

6 MEMBER AL-KHATIB: I mean, this  
7 measure has been in use, so maybe the developer  
8 can share some information with us regarding how  
9 this has been done since 2009.

10 DR. CAMPBELL: Yeah, so this is Kyle  
11 Campbell again. The measure has been in use with  
12 the CMS QRUR Program where reports have been sent  
13 out to individual group practices to advise them  
14 of the measure rates related to adherence. The  
15 measure would be, as we specified, useful at all  
16 levels, but the physician groups would be limited  
17 to, based on the reliability, very large  
18 physician groups. And oftentimes those groups do  
19 have the resources to provide interventions for  
20 the patients in terms of education related to  
21 adherence. And so I think for that reason we  
22 would consider it appropriate at the physician

1 group level.

2 MEMBER AL-KHATIB: And I would also  
3 add, especially now that we have more widespread  
4 use of EMR, I think this is something that could  
5 potentially be accomplished within a health  
6 system where you can embed certain tools within  
7 the EMR to track, you know, at least that the  
8 name of the medication is on their list. Now,  
9 whether they're taking it or not is a different  
10 issue, and maybe that's what you were trying to  
11 get at.

12 DR. CAMPBELL: Yeah. No, just to  
13 clarify, I'm all good with large group practices  
14 in places that have the resources. I couldn't  
15 see that clearly delineated in here. I was not a  
16 primary reviewer. It may be in there. It would  
17 be nice to see a definition of large group  
18 practice, because if we're going to have it as a  
19 measure, somebody may consider it five and  
20 somebody may consider it 50 physicians. So I  
21 would say, going forward, that would be sort of a  
22 friendly amendment to the measure to define who

1       it applies to. I think it's very hard to have a  
2       measure without a clearer definition.

3               MEMBER DeLONG: I don't know if we're  
4       getting ahead of ourselves in terms of the  
5       criteria, but that was one of my concerns. If  
6       you look at the reliability specifications, there  
7       are several levels. And I can't remember the  
8       exact numbers, but group practices had to have a  
9       certain number in order to be considered reliable  
10      for this measure. But that creates a fair amount  
11      of bias in terms of who's being evaluated. I  
12      don't know if you want to get into that now, or  
13      I've got comments later.

14             CO-CHAIR KOTTKE: Tom?

15             MEMBER JAMES: Thank you. I had one  
16      comment, but since Judd, who practices right down  
17      the street from where I live, raised an issue, as  
18      a primary care physician, part of what I've been  
19      involved with in my practice is trying to improve  
20      the adherence rates, and there is a lot of  
21      techniques that have been done. I've discussed  
22      this with the ACP. They don't have any problem

1 with looking at the skill of physicians in being  
2 able to improve adherence rates.

3 But the second part, from working  
4 within health plans -- and I think, Tom, that  
5 you're very much aware of this -- is this whole  
6 idea of the units for measurement in terms of the  
7 pharmacy is now being challenged. It's not just  
8 the fill rate, but it's the utilization. And a  
9 lot of organizations are now looking at different  
10 methods, such as pill counters, to be able to get  
11 to this. We're not at that point in general, so  
12 this is fine as far as I'm concerned for now, but  
13 I suggest to the developer that they look at  
14 these newer techniques for the future.

15 CO-CHAIR KOTTKE: Thanks. Does  
16 anybody want to go back and address Liz' comment?  
17 Do you want to restate that, Liz?

18 MEMBER DeLONG: Well, the complete  
19 statement would be that there are a number of  
20 levels that they have dealt with, and as they  
21 analyzed the data, they found that I think over  
22 50 percent of physician groups did not have

1 adequate numbers to be considered reliable. So  
2 they're not evaluating all physician groups. And  
3 I guess the group is fine with evaluating some  
4 and not others.

5 I think this measure has been in use  
6 since 2009, and they didn't produce any evidence  
7 that it has been effective, that it's improved  
8 care or adherence. It seems to be operating in a  
9 bit of a vacuum.

10 DR. CAMPBELL: This is Kyle Campbell  
11 for the measure developer. Just to address a  
12 couple of those comments, which I think we get to  
13 later in the evaluation, the minimum denominator  
14 threshold that we established for reliable  
15 measurement at the physician group level was at  
16 least 250 eligible patients. So it gets back to  
17 the original comment that, should the measure be  
18 publicly reported, it would be appropriate for  
19 large physician group practices.

20 CMS didn't implement the measure  
21 until, I believe, approximately 2011 in the QRUR  
22 program. And in the QRUR program, those measure

1 rates are not publicly reported. So they are  
2 provided to physician groups that are smaller  
3 than that, since the data are not comparative,  
4 but they're meant for internal quality  
5 improvement within the practices. We don't have  
6 yet any trend data from that program to indicate  
7 improvement that has occurred. We just don't  
8 have that data available to us yet.

9 CO-CHAIR KOTTKE: Thank you. This  
10 issue of the number of patients seen, I think  
11 this is a cross-cutting issue across all  
12 measures, that if you simply don't see enough  
13 patients in any particular area, you're not  
14 evaluated. And so, I mean, every single measure.  
15 So I mean, I'm comfortable with that. If you  
16 only have a few patients, we understand it's very  
17 unreliable and therefore you're out. And so the  
18 way to get out of the measure is not to see  
19 patients that apply to that measure. If that's  
20 what you want to do, you can do it.

21 Any other comments on evidence?

22 MEMBER DeLONG: Actually I think they

1 mentioned some disparities there. I don't know  
2 if that comes under --

3 (Off-microphone comment.)

4 MEMBER DeLONG: Okay.

5 MS. LUONG: So, for evidence, I'm  
6 going to start again with the ratings. One is  
7 for high, two is for moderate, three is for low,  
8 four is for insufficient evidence, and five for  
9 is insufficient evidence with exception. And the  
10 voting starts now.

11 (Voting.)

12 MEMBER CHO: For the people on the  
13 phone, how do we vote? It's Leslie Cho.

14 MS. ISIJOLA: Hi, Leslie. Could you  
15 provide your vote in the chatting tool?

16 MEMBER CHO: In the chatting tool?

17 MS. ISIJOLA: The chat box in the  
18 webinar. Or email.

19 MEMBER CHO: The chat box appears to  
20 be not working. It just says "welcome," and it  
21 won't let me talk. Oh, okay. Hold on.

22 MS. LUONG: Can everyone just point



1       towards me, just to make sure? Sorry, I should  
2       have reminded you. You should see your vote  
3       number. Thanks.

4               Okay. The ones that voted, you don't  
5       have to vote again, but I'm just going to reopen  
6       the polls so that -- do you have another one?

7               MEMBER CHO: Wunmi and Vy, did you get  
8       my vote?

9               MS. LUONG: Wunmi, did you get the  
10      vote? We are checking right now, Leslie.

11              MEMBER CHO: Okay. Can you put up the  
12      criteria on the webinar again?

13              MS. LUONG: Sure. So the criteria  
14      again, Leslie, is one for high, two for moderate,  
15      three for low, four for insufficient evidence,  
16      and five for insufficient evidence with  
17      exception. And this is for evidence.

18              Wait, let me do it again. I didn't  
19      know you were still voting. Go.

20              So we have 47 percent for high and 53  
21      for moderate.

22              CO-CHAIR KOTTKE: Okay. Sana, do you

1 want to move on?

2 MEMBER AL-KHATIB: Yeah, so, for  
3 opportunity for improvement, the developer  
4 presented results from 10 states where they  
5 looked at 38 prescription drug plans and 434  
6 physician groups and 31 ACOs. And as the  
7 developer stated early on, compared to the  
8 average measure result for all patients, they  
9 found the average to be 70.4 percent.

10 And since we're hoping that that will  
11 be much higher, I think there's certainly an  
12 opportunity for improvement. And here's where  
13 they presented the results on disparities, where  
14 they talked about the rates for African-Americans  
15 and Hispanics are lower, 58 percent and 60.4,  
16 respectively.

17 And, so, while I completely agree with  
18 Liz that it would be important to share data on  
19 the impact of the measure and whether it has led  
20 to improvement -- I would love to see that one  
21 day for all the measures. You know, I don't know  
22 that we should hold this developer to a higher

1 standard than all the other developers that we  
2 interacted with in Phase 1, where none of them,  
3 as best as I can recall, provided information  
4 about the impact of the measure.

5 In terms of priority, I think it's  
6 definitely very important, a very important  
7 disease, very prevalent, and the evidence  
8 supporting the use of statins in this patient  
9 population is very robust. So I don't have any  
10 concerns about the priority.

11 CO-CHAIR KOTTKE: Liz?

12 MEMBER DeLONG: I'm afraid I have to  
13 disagree with my colleague Sana. If a measure  
14 has been in use for several years, it seems there  
15 should be evidence of its impact. And as we  
16 accumulate more and more measures, I worry that  
17 we're going to flood the market with measures  
18 that haven't really proven out. So that's my  
19 caution.

20 I don't understand completely who has  
21 Part D insurance, but you have to have Part D in  
22 order to be evaluated with this measure. Is that

1 not a concern? I mean, I confess ignorance here.

2 CO-CHAIR KOTTKE: Does the measure  
3 developer wish to address the Part D question?

4 DR. CAMPBELL: Sure. This is Kyle  
5 Campbell again. So, this measure, the eligible  
6 population, based on administrative data that's  
7 available to us, includes the patients with Part  
8 D and that are fee-for-service. So this measure  
9 does not include patients that are in an MAPD or  
10 management care under Part D. This would be  
11 limited to fee-for-service Medicare patients with  
12 Part D coverage. And that limitation is simply  
13 the limitation of the administrative data source  
14 upon which the measure is based.

15 CO-CHAIR KOTTKE: Right. The short  
16 answer is there's data on fee-for-service Part D  
17 patients. There's no data otherwise. And the  
18 cost of collecting data otherwise is prohibitive.

19 DR. CAMPBELL: Correct.

20 MEMBER DeLONG: Well, when we talk  
21 about disparities, there is an implicit disparity  
22 in terms of requiring Part D insurance for this

1       measure, right?

2                   CO-CHAIR KOTTKE: Absolutely. I think  
3       there's no question that probably somebody -- you  
4       know, an African-American who has no health  
5       insurance is less likely, but we can set the bar  
6       on measures too high and have nothing.

7                   Any further questions? Do we vote or  
8       --

9                   MEMBER JAMES: One clarification,  
10       because it notes that health plans are a part of  
11       the accountability structure, so that would take  
12       it beyond just fee-for-service Medicare.

13                   CO-CHAIR KOTTKE: Okay.

14                   MS. LUONG: So we are voting now on  
15       performance gap. You can vote one for high, two  
16       for moderate, three for low, and four for  
17       insufficient. If you can just point towards me  
18       and vote. Thank you.

19                   (Voting.)

20                   MS. LUONG: So for this performance  
21       gap criteria we have 37 percent high, 53 percent  
22       moderate, and 11 percent low.

1 CO-CHAIR KOTTKE: Sana?

2 MS. HIBAY: Excuse me. Can you  
3 provide the numbers, the actual count as well or  
4 --

5 MS. LUONG: We can provide the number  
6 of the actual count after the report is generated  
7 with this tool.

8 MS. HIBAY: Okay. Thank you.

9 MEMBER AL-KHATIB: Okay. So, moving  
10 onto scientific acceptability specifications. So  
11 the numerator is individuals with CVD who had at  
12 least two prescription drug claims for statins  
13 and have a PDC for statin medications of at least  
14 .8. Denominator is individuals at least 21 years  
15 of age, as of the beginning of the measurement  
16 period, with CVD, including CAD, cerebrovascular  
17 disease, PAD presumed to be of arteriosclerotic  
18 origin, and at least two claims for statins  
19 during the measurement period, in a 12  
20 consecutive month period.

21 For denominator exclusions, they said  
22 not applicable. And here's where I had a

1 question for the developer. What about patients  
2 with contraindications? I mean, I realize this  
3 is using claims data, so it may not be easy to  
4 find those patients. But, I mean, I don't expect  
5 that this rate will ever be 100 percent, because  
6 you're going to have patients who have  
7 contraindications to statins or who have  
8 allergies, intolerance, what have you. How do  
9 you envision that being incorporated once this  
10 measure starts getting applied in other settings?

11 DR. CAMPBELL: Sure. Kyle Campbell  
12 again. Thank you for the question. Because the  
13 measure denominator actually requires at least  
14 two fills by the patient, we feel like that does  
15 confirm the physician's intent to continue the  
16 medication. So any severe allergic reaction or  
17 intolerance to a statin would be identified most  
18 likely before the second fill.

19 In terms of absolute  
20 contraindications, you know, statins are  
21 contraindicated in pregnancy, but in our  
22 particular data set, the prevalence of pregnancy

1 is extremely low, you know, much, much less than  
2 one percent. There are very few pregnancies  
3 among patients in this data set. So for that  
4 reason we didn't specify any exclusions for the  
5 measure.

6 MEMBER DeLONG: I'm a bit confused.  
7 I'm always confused. But maybe somebody can  
8 explain why the selection of patients claims to  
9 be 21 and over, but they have to have Medicare  
10 coverage. I thought you couldn't have Medicare  
11 coverage unless you were ESRD or a special  
12 population. So how does this cover those people  
13 between 21 and 65? Also you had to have two  
14 prescription refills. Well, doesn't that  
15 eliminate a number of people who got one filled  
16 right there at the pharmacy, at the hospital or  
17 something, and then never went back? I would  
18 think that would be a lack of adherence.

19 CO-CHAIR KOTTKE: Developer?

20 DR. CAMPBELL: Kyle Campbell again.  
21 Yeah, appreciate the question. So the first  
22 question is, in the Medicare population, patients



1 can actually be dual-eligible, and those patients  
2 are included in here. So they would be  
3 Medicaid/Medicare. And that represents, in our  
4 data set, approximately 20 percent of the  
5 population.

6 In terms of the two-fill requirement,  
7 I think it really was a trade-off in terms of  
8 harmonization and the concern that was brought up  
9 about intolerance to therapy. The majority of  
10 measures in the NQF portfolio that measure  
11 adherence use the two-fill requirement in the  
12 denominator. And, again, we didn't want to  
13 unnecessarily penalize folks if they had tried a  
14 statin and for whatever reason had an intolerance  
15 to it and the physician didn't decide to continue  
16 it.

17 CO-CHAIR KOTTKE: Right, so the  
18 denominator is smaller than all people who ought  
19 to be taking a statin, but it also is a nod to  
20 the problem that there are patients who simply  
21 don't tolerate them. So this is looking at  
22 people who ought to be taking -- you know,

1       there's good evidence they ought to be taking a  
2       statin. And the question is, are they? So, it's  
3       smaller than the totality of the population that  
4       ought to be on a statin and would tolerate a  
5       statin.

6                   Further comments?

7                   (No response.)

8                   MS. LUONG: So we will vote now on  
9       high priority. Number one is for high, number  
10      two is for moderate, three is for low, and four  
11      is for insufficient. And the polling starts now.

12                   (Voting.)

13                   MS. LUONG: Fifty-six percent voted  
14      high, thirty-three voted moderate, and eleven  
15      voted low for high priority.

16                   CO-CHAIR KOTTKE: Your mic is not on.  
17      There, now it's on.

18                   MEMBER AL-KHATIB: All right. So we  
19      talked about the numerator, denominator and  
20      denominator exclusions with regard to the data  
21      source. So for this measure the data source is  
22      encounter and pharmacy claims. So they used ICD-

1 9 and ICD-10 codes, you know, provided to  
2 identify patients with these conditions under  
3 cerebrovascular disease, CAD and PAD.

4 The proportion of days covered. This  
5 is the PDC method that they used. It is a  
6 commonly used calculation, is what they said, of  
7 medication adherence, patient compliance. And  
8 this is calculated through pharmacy claims and  
9 they said that seven statin medications and  
10 several combinations are specified, and indeed  
11 they did that. And a calculation algorithm is  
12 provided in the document that they submitted as  
13 well.

14 In terms of any issues/concerns we may  
15 have about the specifications, definitions or  
16 coding, I mean, the only concern I would have is  
17 the accuracy of the coding. I'm not sure if any  
18 of these ICD-9 and ICD-10 codes have been  
19 validated in terms of their accuracy. But I  
20 suspect that the validity is on the high side,  
21 but if the developer has any information about  
22 validation of those codes, that would be helpful.

1  
2 DR. CAMPBELL: Yeah, we don't have any  
3 additional information to provide with regard to  
4 the validity of the claim data other than to say  
5 that it is in keeping with other cardiovascular  
6 measures in the NQF portfolio in terms of  
7 harmonization of coding.

8 CO-CHAIR KOTTKE: Further comments?

9 (No response.)

10 MS. LUONG: We will be voting on  
11 Criteria 2(a)1 on reliability. One for high, two  
12 for moderate, three for low, and for four  
13 insufficient. And the polling starts now.

14 (Voting.)

15 MS. LUONG: Zero percent voted for  
16 high, seventy percent voted for moderate, sixteen  
17 voted for low, and five percent voted for  
18 insufficient for reliability.

19 CO-CHAIR KOTTKE: Okay. Sana?

20 MEMBER AL-KHATIB: I'm not sure if we  
21 want to go through the -- or if we needed to go  
22 through reliability testing before we voted on

1 the reliability issue, but I do want to cover  
2 that as well.

3 So they did that at the measure score  
4 level, and they talked about empiric reliability  
5 testing was performed on the measure score, as I  
6 indicated, using the data source and all levels  
7 of analysis as specified for the measure.

8 They talked about the results of a  
9 signal-to-noise analysis for 10 states, and the  
10 aggregate results for drug plans and physician  
11 groups were presented by them. And they showed  
12 that the reliability for the states ranged from  
13 .99 states. Mean results for drug plan, .71.  
14 Mean result for physician group was .72. And for  
15 the ACOs, 31 ACOs that they studied, that ranged  
16 from .69 to .98. And then they clarified that  
17 the signal-to-noise testing is a commonly used  
18 test of measure score reliability. And they tell  
19 us that measure score reliability varies between  
20 zero and one. A value of .7 is considered the  
21 minimum accepted threshold for reliability.

22 I don't know if, Liz, you want to

1 comment on this as a statistician.

2 CO-CHAIR KOTTKE: She sure does.

3 MEMBER DeLONG: From my perspective,  
4 there are two components of reliability, one of  
5 which is the one they addressed, which is that  
6 you could actually separate the signal from the  
7 noise. So you could say this group is  
8 statistically significantly on the low side, and  
9 this is on the high side. I think they did an  
10 adequate job of that.

11 They did not provide any assurance  
12 that -- for example, if they had randomly  
13 separated into two groups, would the same state  
14 have the same level of -- would that be a  
15 reliable measure? Could they repeat that measure  
16 reliably? And I didn't see that part.

17 CO-CHAIR KOTTKE: Judd?

18 MEMBER HOLLANDER: Sort of a  
19 statistics question, and maybe you could help me  
20 with this. I obviously don't want to get too  
21 drilled down in this. I don't understand signal-  
22 to-noise being a function of reliability, but yet

1 a lot of these measures do that. Is there like a  
2 two-sentence layperson's way you could describe  
3 that?

4 MEMBER DeLONG: I actually don't see  
5 that as reliability. I see it as discrimination.

6 MS. JOHNSON: So maybe I can help a  
7 little bit here. Here at NQF we allow two  
8 different ways of looking at reliability; one at  
9 the data element level and one at the score  
10 level. So at the score level what you're trying  
11 to do is be able to say that you can actually  
12 distinguish providers, which is what you'd like  
13 to do if you're doing something with  
14 accountability. So that's what this reliability,  
15 this signal-to-noise, actually does. It tells  
16 you how well you're going to be able to  
17 distinguish providers in their quality. So does  
18 that help?

19 MEMBER DeLONG: It's really a  
20 discrimination measure.

21 MS. JOHNSON: Yes, it is. Yes.

22 (Simultaneous speaking)

1 MS. JOHNSON: Yes. Yes. And to get  
2 to your point, Liz, too, our criteria for testing  
3 is not -- we don't really have a really high bar  
4 for testing. Although some may disagree with  
5 that. But you're right that they could have done  
6 some additional testing, but that is not a  
7 requirement. So the fact that they did at the  
8 level they did would be fine.

9 CO-CHAIR KOTTKE: So I have been  
10 informed that we need to re-vote on reliability  
11 since we did not discuss reliability testing.  
12 Yes, we failed to be reliable.

13 MS. JOHNSON: Let me just tell you why  
14 we're doing that, just in case you're unsure.  
15 Both specifications and testing is what you're --  
16 both of those roll up together for your vote for  
17 reliability. So that's why you're re-voting  
18 here. This is thinking about your conversation  
19 on specs and thinking about your conversation on  
20 testing.

21 MS. LUONG: Polling starts for voting  
22 on 2(a), reliability. One for high, two for



1 moderate, three for low, and four for  
2 insufficient. And this includes 2(a)1 and 2(a)2.

3 (Voting.)

4 MS. LUONG: So the voting results for  
5 reliability concludes with 74 percent for  
6 moderate and 26 percent for low.

7 CO-CHAIR KOTTKE: Okay. Let's do  
8 validity and validity testing together.

9 MEMBER AL-KHATIB: So, in terms of the  
10 validity testing, the first question is whether  
11 the specifications align with the evidence. And  
12 I think they do in terms of whether the measure  
13 was tested for validity at the data element level  
14 or the measure score level. And they did it at  
15 the measure score level.

16 And then the question of whether the  
17 testing demonstrates the measure is valid, my  
18 answer is actually yes. The way they did it is  
19 they did convergent validity by comparing the  
20 measure results to similar NQF-endorsed measures  
21 for adherence to medications. And they said that  
22 they found that the measure results are in the

1 same range of 70 to 76 percent for this measure  
2 as three other measures of adherence for ACO  
3 plans, groups and states, with correlation  
4 coefficients of greater than .9 for states, but  
5 lower correlations for drug plans and lower still  
6 for physician groups.

7 In terms of the inaccuracy of the  
8 coding, that certainly remains a question for me,  
9 but that's true of all claims data.

10 And for missing data, they said that  
11 they identified that as a possible threat to the  
12 validity of this measure, and so they ran an  
13 empirical assessment of this potential threat.  
14 And so a potential bias they said may exist if  
15 day supply within the prescription drug event  
16 data is missing, which is a required data element  
17 to calculate medical adherence.

18 In order to evaluate this scenario  
19 they analyzed the number as a percentage of  
20 beneficiaries in the measure denominator with one  
21 or more claims that had missing days. And they  
22 presented the results on pages 46 and 47 of the

1 document that we have, which is the preliminary  
2 analysis document. And based on what they  
3 showed, I think their argument is reasonable. I  
4 don't have major concerns about that.

5 CO-CHAIR KOTTKE: Any other comments  
6 on validity?

7 MEMBER DeLONG: I think it was good  
8 that they correlated this with other measures,  
9 but in order to buy into that you have to buy  
10 into the whole definition and the denominators  
11 and whatever. So they're consistently applying  
12 their methodology and getting similar results.

13 CO-CHAIR KOTTKE: Judd, are you -- oh.  
14 Gerard?

15 MEMBER MARTIN: So, just a question  
16 about -- this is, I guess, a process that they're  
17 doing. And the question is now that this has  
18 been in use -- and it goes back to one of the  
19 previous comments was, if it's valid that they  
20 are able to show that some people are more  
21 compliant than others, wouldn't at some point the  
22 natural thing be to see that cholesterol values

1       that were changing in that population? Is that  
2       part of the -- or does that come down the road?

3               CO-CHAIR KOTTKE: That would be nice  
4       to show. The cholesterol values are not  
5       accessible in administrative data. So the  
6       developer doesn't have access to cholesterol  
7       values. That's the short answer.

8               MEMBER BRIGGS: Just in response to  
9       that, because of the new cholesterol guidelines,  
10      there are no longer any hard targets for  
11      cholesterol levels, so trying to get at that data  
12      would be very difficult. Because you could look  
13      at -- I mean, in the past we've used 100 as a  
14      value of LDL that we would like people to get to,  
15      or 70 for people that are high risk. But that's  
16      no longer the case. So did it decrease by 10  
17      percent, 15 percent? You'd have to know where  
18      the patient actually started at and then know  
19      when they were tested next, which gets a little  
20      bit more difficult.

21              CO-CHAIR KOTTKE: Way down on the end  
22      and then Liz.

1                   MEMBER SPANGLER: Yeah, I was just  
2 going to comment. There is no targets but there  
3 is lots of talk about percent reduction. So  
4 maybe that's what you're asking, you know, are  
5 there any results around that, or is that  
6 something we should be considering? Because they  
7 do talk about that in the guidelines.

8                   CO-CHAIR KOTTKE: Of course then you'd  
9 have to have LDL levels. I mean, you have to  
10 have access to the actual --

11                  MEMBER DeLONG: I just agree that  
12 there should be some impact to some of these  
13 measures, and we haven't seen impact. And  
14 especially for a measure that's been in use, I  
15 think we need to start seeing impact. Maybe we  
16 don't require it now, but to be useful it has to  
17 have some impact.

18                  CO-CHAIR KOTTKE: Just one last  
19 comment. I think Kaiser is probably the only  
20 organization in the country that could do that,  
21 because they have virtual identity between  
22 membership and care -- sorry, service delivery.

1 Even at Health Partners we have a very large  
2 discrepancy between membership in our health plan  
3 and service delivery.

4 Tom?

5 MEMBER JAMES: I was just going to  
6 say, one of the things about measures is that  
7 they're also useful tools. So while we have not  
8 seen the kind of change we'd like to see, I think  
9 it's more attention. The health plans  
10 particularly are feeling the pressure to go about  
11 and do something. That's what's going to be  
12 measured.

13 CO-CHAIR KOTTKE: Yes, Liz.

14 MEMBER DeLONG: I will stop, but I  
15 always worry about unintended consequences. For  
16 example, what Judd brought up. Now we're going  
17 to make people come back for extra visits to make  
18 sure they're filling their prescriptions, and all  
19 they have to do is really fill it. I just worry  
20 that we impose overhead on some measures when  
21 we're not sure they're working.

22 CO-CHAIR KOTTKE: Judd?

1                   MEMBER HOLLANDER: Obviously I'm going  
2 to agree with her agreeing with me, but I'm going  
3 to raise an issue that I don't think we should  
4 settle here, but I think gets more important as  
5 we go on and was raised in the last round of us  
6 doing this, which is what is the bar that it  
7 really needs to get over in order to implement?

8                   So one could put together a  
9 hypothetical scenario where there's 16 measures  
10 that are measurable, that are reliable and valid,  
11 that aren't really going to improve patient care,  
12 but are going to take a lot of time and money to  
13 implement. And it seems to me -- and maybe I'm  
14 interpreting this wrong, and I know that no one  
15 will confirm this is true -- that the default  
16 here is that everything goes through and that  
17 everything that already existed was good enough  
18 to exist, so it should continue to exist.

19                  And I know we sunsetted, or whatever  
20 we called it, a couple measures last time and we  
21 had a lot of discussion around it. And I think  
22 it would be really good if there was a bar that

1 if a measure existed it had to do something. And  
2 if it was really successful, it should go away  
3 because it was really successful. If it wasn't  
4 really successful, it should go away because it  
5 didn't do what it should do. But if it's on the  
6 path to getting it done, then that's a good  
7 measure.

8 And I think it's probably a discussion  
9 that's an NQF or CMS discussion rather than  
10 around this table, but I raise that because I  
11 think it is important feedback to go back. I  
12 don't want to go home saying, oh, we approved 16  
13 other measures, I have no idea if they're going  
14 to help anybody.

15 CO-CHAIR KOTTKE: You have obviously  
16 raised the bar for several people on the other  
17 side of the room. We'll start with Ellen and  
18 then --

19 MEMBER HILLEGASS: Well, I want to go  
20 along with Judd because I have some measures that  
21 I have a lot of problems with, and so this is  
22 speaking towards tomorrow as well. And my



1 concern is, is what is the bar? If this has  
2 already been out there and this is acceptable and  
3 we don't have data, then we should I guess be  
4 continuing to accept other measures that are  
5 looking at things like, did they fill their  
6 prescriptions, rather than did their  
7 prescriptions work, those kind of things.

8           So I guess the question is, what is  
9 the bar at NQF? Do you want us to accept  
10 measures that really don't have a lot of evidence  
11 but could do good? Or do you want us to look at  
12 measures that in the future may make a difference  
13 in practice? So there's a difference here. And  
14 I guess I'm confused, as a person on the  
15 Committee, as to where we're going with this.  
16 And if this measure comes back again in a couple  
17 years, do we accept it without valid data that  
18 it's worked?

19           So where are we going with these  
20 measures? Because some measures are just  
21 starting. They don't have any evidence, but they  
22 might do well. But then there's this other one

1       that doesn't have evidence that it's done well.  
2       We believe that it's done well, but do we  
3       continue to keep it? So where should we function  
4       as members of this group and where should we cut  
5       off and say, no, this shouldn't be accepted and,  
6       yes, this should? Is it based on evidence? Is  
7       it based on we think it's going to do well for  
8       the consumer? Which is important for Carol.

9                   CO-CHAIR KOTTKE: Yes, I think we're  
10       the bar-setters. I mean, I think that's why  
11       we're in this room.

12                   MS. JOHNSON: I can also take a shot  
13       at your question. That's actually why we have  
14       the criteria that we have and why it is set up in  
15       the way that it is. So we really want you to --  
16       to the extent you can, because we're all humans  
17       and it is hard, but to try to adhere to the  
18       criteria to the extent that you can.

19                   And also remember that some of our  
20       criteria are what we call must pass, and those  
21       are the ones that we really want you to pay  
22       attention to. That's the evidence -- well, it's

1 the importance and the scientific acceptability  
2 criterion. So those are the ones that are really  
3 -- if they don't quite make those, then you  
4 should seriously consider you're not recommending  
5 for endorsement.

6 The conversations that you just had in  
7 terms of seeing improvements and that sort of  
8 thing, that comes under actually the usability  
9 and use criterion. And while it is extremely  
10 important, it is not a must pass. So that's  
11 where you have to weigh basically your own  
12 feelings about the utility of the measures.

13 So I'm not sure that I really answered  
14 your question, but again the criteria are  
15 hierarchical in a way that we did on purpose.

16 MEMBER AL-KHATIB: I guess what we're  
17 trying to say is that we hope to see potentially  
18 a change to the process, if that's possible. I  
19 mean, because we all agree that we -- and at some  
20 point the measure has to prove that it has led to  
21 improved patient outcomes. And so why not make  
22 this, for existing measures that have been in use

1 for five years, why don't you make that a  
2 requirement that the developers should prove that  
3 there was some impact, some improvement in  
4 patient outcomes?

5 MS. JOHNSON: Yes, so I don't think  
6 anybody at NQF would disagree that that's what we  
7 want. We want measures that most quickly drive  
8 improvement.

9 I think there's a couple things. One  
10 is, as Tom said earlier, it is sometimes very  
11 hard for the developers to get that data, so it  
12 can be very hard to show. I think the other  
13 thing that NQF struggles with is the bar, as Tom  
14 mentioned, and some people feel that our bar is  
15 already too high. So that would really be  
16 setting a very high bar, so we have not enforced  
17 that sort of thing. But you are right that we  
18 would prefer to see more information, more data,  
19 et cetera for measures that are coming back for  
20 maintenance review, especially if they've been in  
21 use.

22 CO-CHAIR KOTTKE: Carol and then

1 George and then Judd.

2 MEMBER ALLRED: Okay. As I've gone  
3 through a number of the measures, as we're  
4 studying them, I'm struck by the lack of patient  
5 responsibility. We're putting a major burden on  
6 health care providers, increasing cost there, but  
7 we're really not looking at it's up to the  
8 patient in the bottom line to be compliant or not  
9 compliant, and no one can make that patient do  
10 that. So are we adding to the cost of health  
11 care and making it less efficient, and how do we  
12 get at the bottom line of what is the patient's  
13 responsibility?

14 CO-CHAIR KOTTKE: George?

15 MEMBER PHILIPPIDES: So, I agree with  
16 Judd, who agreed with Liz, who agreed with Judd  
17 --

18 (Laughter.)

19 MEMBER PHILIPPIDES: -- that we need  
20 to be very careful about adding on too many  
21 measurements, too many metrics that are difficult  
22 to pull off given how busy the whole health care

1 system is.

2 Having said that, I'd like to now take  
3 the opposite side of some of the things  
4 mentioned. Yes, I think we do want to see  
5 outcomes after these are performed, but this is a  
6 process measure. This is a change in practice  
7 that helps us get to a platform that will later  
8 get to assess outcomes.

9 I don't think that we expect the  
10 developers here to create something that is going  
11 to prove that cholesterol management is good for  
12 cardiovascular outcomes. That's been done. I  
13 think we know that if you take statins things go  
14 well. This is really looking at something very  
15 basic that I think is a broad theme, which is can  
16 we change adherence? Okay? And you can take  
17 that concept in the cholesterol realm, in  
18 hypertension.

19 What we're looking at is given the  
20 reality that people are imperfect and they  
21 oftentimes are irresponsible, I think you have to  
22 take that as a given. That's not going to

1 change. Is there a way that we can create a  
2 system to improve health care outcomes for those  
3 people? To me that's what this is getting at.  
4 And I actually think that that's an important  
5 thing. Whether or not you think it's the  
6 patient's fault -- I actually don't like the word  
7 fault in this, it is what it is. Humans are  
8 humans. What we're looking at is can we change  
9 adherence?

10 So I think this should be measured,  
11 not on whether or not the cholesterol levels go  
12 down or that they've had fewer strokes. We know  
13 if you take the statins that will happen. We  
14 should measure this on can we get people to take  
15 statins for longer? And I actually think that  
16 that's not an inconsequential endeavor.

17 So I'm going to take sort of the  
18 opposite side and say if we look at this as a  
19 process measure not an outcome measure, I think  
20 there's some validity to doing this. I'm not  
21 sure I believe that, but I wanted to throw that  
22 out there.

1 CO-CHAIR KOTTKE: Okay. Thank you.

2 Leslie has a question or a comment on line.

3 MEMBER CHO: Hi. So, two things: One  
4 is that even at Cleveland Clinic our employees --  
5 when given a prescription for statins, only 50  
6 percent of those people/employees refill their  
7 prescription a second time. And I think that  
8 when, you know and that's us closely  
9 monitoring our employee population. And I think  
10 that as NQF moves towards these measures that are  
11 more nebulous than did you get your aspirin  
12 within however many minutes when you came with a  
13 STEMI, or did you get your EKG, I really think  
14 it's important for re-endorsement process to have  
15 some kind of an effect, that you show some kind  
16 of an effect. Without that, to keep on re-  
17 endorsing these sort of more nebulous measures, I  
18 don't know what it does.

19 MEMBER BRIGGS: So I would kind of  
20 echo that. This is a CMS measure and I would  
21 hope that CMS has some resources to measure their  
22 effect across years. So I would expect if this



1 measure has been in place for three to four  
2 years, that there would be at least a year's  
3 worth of analyzable data that they could come  
4 back to us and say, okay, it was the  
5 compliance rate was 74 percent among ACOs during  
6 this time period and now it's 54 percent, or  
7 maybe it's 80 percent. So it got better, and  
8 whether that better is significant or not. But  
9 there should be some change in it, otherwise the  
10 measure really didn't do what it was intended to  
11 do.

12 The idea in a process measure is to  
13 get people to use the process. To do what they  
14 can to make patients, through education and  
15 reminders and things like that, to improve the  
16 number of prescriptions filled and hopefully  
17 taken. Medicare should see a change in that  
18 total amount of prescriptions filled over time.  
19 So if they come back to us for renewal, there  
20 should be some data to say that the process  
21 actually did improve or didn't improve.

22 CO-CHAIR KOTTKE: Judd, you had a

1 question?

2 MEMBER HOLLANDER: I'm just going to  
3 make a proposal, because I think we're all on the  
4 same page in this room. And so, my proposal,  
5 which is way above the scope of this Committee,  
6 is that somewhere in the document there is a  
7 specific question and a vote is there evidence  
8 that this measure has changed anything in the  
9 world? Better language than that.

10 And it should actually be recorded so  
11 it goes forward and, if NQF and whoever else  
12 wants to use it as a measure, they can. We're  
13 not saying you can't use it as a measure, but  
14 we're saying 20 experts around the table have  
15 looked at the data and found it did squat or it  
16 was great. And so, for any measure that's been  
17 in existence longer than X time, three or four  
18 years, or whatever everybody thinks is  
19 appropriate, that should be a line item that we  
20 vote on, that we record, and it probably should  
21 happen across everything.

22 CO-CHAIR GEORGE: I think we've talked

1 about this recommendation that we all are sort of  
2 feeling we're giving back to NQF for quite a  
3 while, and I think a lot of us are in agreement  
4 with that concept that if you've been using it,  
5 show us where you were at the beginning, show us  
6 where you are now. But I think we need to stick  
7 to validity right now, that part of the  
8 discussion.

9 MEMBER DeLONG: Could I just add to  
10 Judd's proposal that we elevate usability and  
11 feasibility under these circumstances? If it  
12 comes back, that should be a priority.

13 MS. JOHNSON: We'll certainly take it  
14 to our governing body. So thank you for that  
15 feedback, it is very good and we are often  
16 thinking about our criteria and they have evolved  
17 over the years and we will expect that they will  
18 continue to evolve.

19 So, and just to make sure that you're  
20 not confused, what you're talking about is  
21 improvement. And you will be talking about that  
22 under the usability and use criteria. So as you

1 vote on validity, try to think about the  
2 conversation of improvement, try to move that  
3 over in your mind. Vote only on validity and  
4 then bring it back when you're ready to vote on  
5 usability and use.

6 CO-CHAIR KOTTKE: Right. So we're  
7 ready to vote, but don't vote on what I'm about  
8 to say.

9 Health Partners, about ten years ago  
10 came up with a composite measure for diabetes,  
11 and much to our chagrin, six percent of our  
12 patients met the composite. Today 50 percent do.  
13 And so for like the D-5 composite measure we'd be  
14 able to show when you really put your mind to it,  
15 you can change things. I think it's quite valid  
16 to say, you know, does a measure change things  
17 over time? But that's a different conversation.

18 Okay. We're ready to vote on  
19 validity. And do we have anything about threats  
20 to validity that you wanted to say?

21 Okay. Sana says no.

22 MEMBER AL-KHATIB: I actually

1 mentioned that when I talked about -- they  
2 pointed out the issue with missing data and then  
3 they did that additional analysis, and as I said,  
4 I don't have any major concerns about that.

5 CO-CHAIR KOTTKE: Okay. We're ready  
6 to vote on validity.

7 MS. LUONG: For validity, one you can  
8 vote for high, two for moderate, three for low,  
9 and four for insufficient. And polling starts  
10 now.

11 For validity, five percent voted high,  
12 74 voted moderate, and 21 voted low. So validity  
13 passes.

14 CO-CHAIR KOTTKE: Usability and use?

15 MEMBER AL-KHATIB: So, the data source  
16 is encounter and pharmacy claims. Costs and  
17 burden are low. All data elements are in defined  
18 fields in electronic claims. So I think it's  
19 actually feasible.

20 MS. HIBAY: Yes, we're talking about  
21 feasibility right now, just to make sure  
22 everyone's clear.

1 MEMBER AL-KHATIB: That's correct.

2 CO-CHAIR KOTTKE: Okay. Oh, I'm

3 sorry.

4 MS. HIBAY: Okay.

5 MEMBER AL-KHATIB: That's what you

6 were talking about.

7 MS. HIBAY: Yes. Very good. Thank

8 you. I just was clarifying. Thank you.

9 CO-CHAIR KOTTKE: Go ahead.

10 MEMBER AL-KHATIB: That's all I have.

11 CO-CHAIR KOTTKE: Okay.

12 MEMBER AL-KHATIB: I mean, as I said,

13 the data exists, I think it can be used. I think

14 it's feasible. That's all I said.

15 CO-CHAIR KOTTKE: That was so short,

16 I missed it.

17 MS. LUONG: So the polling already

18 started. You can vote for feasibility with one

19 for high, two for moderate, three for low, and

20 four for insufficient.

21 For feasibility it passes with 47

22 percent for high and 53 percent for moderate.

1 CO-CHAIR KOTTKE: Okay. Usability and  
2 use.

3 MEMBER AL-KHATIB: Okay. So this  
4 measure is used in the CMS' physician feedback  
5 quality and resource use report with benchmarks.  
6 Though it's not publicly reported or presented,  
7 it has been submitted through the measures under  
8 consideration process for the CMS ACO Shared  
9 Savings Program.

10 And here's the question that we've  
11 been battling with: Indicate whether there's any  
12 information on improvement over time.  
13 Unfortunately, there is not -- and so that  
14 remains a concern that we can discuss it as a  
15 group.

16 CO-CHAIR KOTTKE: Any comments on  
17 usability and use? Judd, are you still --

18 MEMBER HOLLANDER: I echo my comments  
19 from before, and I guess this is the area based  
20 on direction that should let that impact our  
21 voting.

22 CO-CHAIR KOTTKE: Time to vote.

1 MS. LUONG: Polling starts now. Oh --

2 DR. CAMPBELL: This is the measure  
3 developer. I wondered if I could make a comment  
4 as it related to the prior conversation on  
5 usability?

6 CO-CHAIR KOTTKE: Sure, go ahead.

7 DR. CAMPBELL: So I think, while this  
8 measure was originally time-limited endorsed in  
9 2009, the full endorsement didn't happen until  
10 2011. And if you look at the data that we have  
11 available, the data were for calendar year 2011  
12 as it was reported to physicians and those data  
13 were not available in a summary report until  
14 2012.

15 So I just wanted to make the Committee  
16 aware, as far as this measure goes and maybe this  
17 overall conversation, that the implementation  
18 process and rulemaking process can be fairly  
19 lengthy. And then there is a lag in terms of  
20 actually getting data from the program that can  
21 be used for analysis and trend analysis. And so,  
22 in the case of this particular measure, although



1 it has been endorsed since 2011, we really only  
2 have data from the program since 2012. And so, I  
3 just wanted to make you aware of that issue.

4 CO-CHAIR KOTTKE: Yes, that is a good  
5 point, that it takes time to get time data.

6 Are we ready to vote on usability and  
7 use?

8 MS. LUONG: Polling starts now for  
9 usability and use. One for high, two for  
10 moderate, three for low, and four for  
11 insufficient information.

12 For usability and use we have 16 for  
13 high, 26 for moderate, 32 for low, and 26 for  
14 insufficient information.

15 CO-CHAIR KOTTKE: I heard that we had  
16 a lot of competing measures.

17 MEMBER AL-KHATIB: Yes, there a lot of  
18 competing measures. And if you haven't had a  
19 chance to look at them, you can actually see them  
20 on pages 53 and 54 of the preliminary analysis.

21 I just want to highlight certain  
22 points, because we don't have time to delve into

1 all the details. Basically what they described  
2 is that this measure also includes -- in addition  
3 to CAD, includes cerebrovascular disease,  
4 peripheral artery disease, and those were not  
5 included in the previous measures.

6 They also point out that the age range  
7 for this particular measure is different. They  
8 use 21 years of age and older as a cut-off  
9 compared with the previous measures. And then  
10 they also talk about the entire 12-month  
11 measurement period for this particular measure,  
12 unlike other measures that don't cover the entire  
13 12-month measurement period.

14 Those were the main differences that  
15 I saw, but certainly if other people noticed  
16 other differences, please bring them up.

17 CO-CHAIR KOTTKE: Yes, at the end?

18 MEMBER SPANGLER: I just had a  
19 question for the developer, because I think the  
20 developer is the same. And I didn't know whether  
21 this is a discussion we should have here, but  
22 obviously the MAP process is included. I don't

1 know how many have seen the MUC list yet.

2 There's a brand new statin measure that's being  
3 proposed. And I'm just wondering, that measure  
4 seems to be very, very similar to this.

5 Actually a little well, a little more

6 encompassing I would say because it's not

7 adherence, it's actually initiation and

8 adherence. And I just wondered what the --

9 because I think the developer, that is CMS as

10 well, and what they think about -- is that

11 measure going to replace this current measure

12 that we're thinking about or do they think that's

13 going to be in conjunction with this measure?

14 I'm just wondering to get thoughts.

15 MS. HIBAY: I can address that. So we  
16 kind of set up a standard for those measures that  
17 are going to be coming in the future, that if it  
18 does become a measure that would be competing or  
19 related, we would have that conversation when  
20 that measure presented.

21 I think we all know that there's yet  
22 one more happy phase -- many more phases on this

1 project. And so we do anticipate at our next  
2 phase with the measure -- call for measure is  
3 ending June 30th, Wunmi? We do anticipate some  
4 statin measures coming our way. So if they do,  
5 and we anticipate that they will, we will review  
6 them at that next Committee meeting.

7 MEMBER SPANGLER: Okay. So I guess  
8 it's a process question for me.  
9 We know there are measures coming. We've seen  
10 one of them already. I think some of us have an  
11 idea of what the other ones are going to be, but  
12 that shouldn't affect what we're looking at this  
13 one right now.

14 MS. HIBAY: That should not affect --  
15 only what you have in front of you. If we were  
16 going to do a competing and related discussion  
17 about this measure at this time, yes, but not at  
18 this time. Only what's in front of you at this  
19 time. Thank you.

20 Are there questions about that?

21 CO-CHAIR KOTTKE: Okay. We need an  
22 overall vote.

1 MS. LUONG: So the polling starts now  
2 for overall suitability for endorsement for  
3 Measure 0543. One is for yes, and two is for no.

4 So for Measure 0453, for overall  
5 suitability for endorsement, 79 percent voted yes  
6 and 21 percent voted no. And that concludes the  
7 polling for this measure.

8 CO-CHAIR KOTTKE: So time for a break?  
9 Okay. So obviously everybody has thought long  
10 and hard about these things and taken the job  
11 very seriously. Liz has one more comment, or  
12 not.

13 Oh, do you?

14 MEMBER SPANGLER: I have one more. I  
15 had a question. I'm sorry. Again a process  
16 question. I know for reliability and validity  
17 there's a threshold percentage that we have to  
18 reach. Is that not true for usability?

19 (Off-microphone comment.)

20 MEMBER SPANGLER: Okay. It's not.  
21 Got it. Okay. Thanks. That's what I thought.

22 CO-CHAIR KOTTKE: So we'll be back at

1 11:00.

2 (Whereupon, the above-entitled matter  
3 went off the record at 10:45 a.m. and resumed at  
4 11:02 a.m.)

5 MS. ISIJOLA: I think we are going to  
6 go ahead and get started.

7 CO-CHAIR GEORGE: We're on 0670?

8 MS. ISIJOLA: Yes.

9 CO-CHAIR GEORGE: Okay. The next set  
10 of measures that we're going to take up are  
11 related to cardiac stress imaging. We begin with  
12 0670. Discussants are Joe and Sana.

13 MEMBER CLEVELAND: Hi, good morning.  
14 And I think Sana and I agree that since she  
15 presented the bulk of the last one, she'll chime  
16 in, but I'll take the lead on presenting this.

17 CO-CHAIR GEORGE: We'll have the  
18 measure developers give us a little overview.

19 MEMBER CLEVELAND: Yes, please.

20 MR. ALLEN: I'm Joe Allen from the  
21 American College of Cardiology, and I've been  
22 working on the appropriate use criteria

1 development and implementation for the past, oh,  
2 I guess ten years or so, and so these measures  
3 are derivative of those efforts, and you know,  
4 I'll just say a few words to set the context  
5 because these are quite different measures than  
6 most people are used to.

7           They are looking at avoiding things  
8 rather than doing things. As well, they are not  
9 necessarily what you might typically think as a  
10 process measure. I know it says in your notes  
11 that, you know, these may be thought of as a  
12 process measure, but they're not an action in  
13 that you're not looking at giving a beta blocker  
14 or filling a prescription. You're really -- it's  
15 a culmination of looking at resource and clinical  
16 use and then assigning a value to that.

17           And so we really look at them as  
18 efficiency measures and, in part, outcome  
19 measures because they are -- when we go through  
20 the process of developing what should be done and  
21 what should not be done, we're looking at its  
22 clinical value to the patient and to the

1 population, as well as the resource use for that  
2 population. And so, it is quite different from  
3 what you might see in other measures. And again,  
4 these are inverse measures. So lower is better,  
5 that's another difference than, you know, you see  
6 in a lot of measures.

7 The testing and validation that we  
8 took on has spread over a number of years. I did  
9 include a number of publications in the  
10 Reliability and Validity section. There wasn't  
11 enough space to include all the detail from the  
12 various studies that we've conducted.

13 We've gone from back in 2008 looking  
14 at whether or not we could reliably collect the  
15 information to, could we actually put this out in  
16 practice and have labs contribute the  
17 information? Could we produce change? And then,  
18 what were the outcomes? Were there unintended  
19 consequences?

20 And you know, you might think  
21 outcomes, typically again, are thought of, are  
22 people getting better? Here, we are trying to



1       avoid unintended consequences of not testing  
2       someone that might really need testing, and we  
3       want to make sure that if we are saying don't do  
4       something, that it truly shouldn't be done. And  
5       we have changed the terminology to be rarely  
6       appropriate rather than inappropriate. You may  
7       be familiar with those terms.

8               So currently there are over 1500  
9       institutions that we've collected data on  
10       nationwide in our various activities, and greater  
11       than 31,000 cases. We actually have a statewide  
12       project in Delaware, as well as a partial state  
13       project in Pennsylvania with a large private  
14       payer that has been going on for the past three  
15       years, and so unfortunately, I wasn't able to  
16       include that in this data set because it is not  
17       completed. But I just wanted to, given all the  
18       usability discussion in the last measure, to say  
19       we have lots of data from that experience and  
20       some really interesting things that I hope to  
21       publish shortly, but we won't be able to get  
22       those published and out there, but I can speak,

1       you know, to some generalities if we get into  
2       that section.

3               It is widely used for private payers,  
4       as I said, lab accreditation, PQRS, QCDR. And in  
5       2017, CMS will require clinical decision support  
6       for any advanced imaging such as nuclear imaging,  
7       that's covered here, CT and MR.

8               So despite some concerns about ability  
9       to do this, we are working hard to make it easy  
10      for folks to do it in 30 to 90 seconds. You are  
11      really just ordering a test and saying why you  
12      are ordering it with a few data variables, and  
13      we've actually streamlined that over time, and so  
14      we can talk about that as questions come up  
15      related to that.

16              And then lastly, I'll just say that  
17      this is a population review. There are a lot of  
18      things that you can do on an individual referral  
19      to, you know, ordering physicians to give  
20      feedback back. This measure looks at an  
21      aggregate population and how often testing is  
22      done in various populations. Once you have that

1 population measure, you can go back and say, what  
2 are the specific actions I want to do on  
3 individual cases?

4 But what we really try to do is  
5 emphasize a population because the private payer  
6 approach before these measures, and still  
7 continued today, is what is known as prior  
8 authorization. And so we really wanted to  
9 provide an alternative that was more based on  
10 quality improvement and helping people change  
11 their practice patterns over time, where prior  
12 authorization looks at individual cases and says  
13 yes, no.

14 And that's not what we're really  
15 trying to do here. We're not trying to say don't  
16 ever do this. We're just trying to look at how  
17 often it is done, and then over time, reduce the  
18 use in populations where it does have low value.  
19 There may be exceptions to the rule, as people  
20 brought up in some of the comments.

21 And in general, I'd also want to say  
22 that these pick out three particular indications

1 that were highest amongst our populations that we  
2 tested of rarely-appropriate use of these types  
3 of procedures, but it is in a universe of about  
4 sixty different other things that we do collect  
5 as a part of that data registry collection  
6 effort, and so you may think of other things,  
7 like incomplete revascularization on some of the  
8 later measures that we'll want to talk about.  
9 There are indications for that, and they aren't  
10 included in that particular measure, but there's  
11 an ability to say another reason -- it's just not  
12 captured in that particular measure because it's  
13 only looking at that particular reason.

14 So I'll close with that, and I'm sure  
15 we'll have other questions that come up as we go  
16 through the measure. Thanks.

17 MEMBER CLEVELAND: Thank you. I'll  
18 introduce the measure. Just as Joe mentioned,  
19 this is a family of three measures. This is  
20 Measure 0670, which is Cardiac Stress Imaging not  
21 Meeting Appropriate Use Criteria, Pre-Operative  
22 Evaluation in Low-Risk Surgery Patients. As we

1 have heard, the measure steward is from the  
2 American College of Cardiology Foundation.

3 So a brief description of this measure  
4 is the percentage of stress SPECT MPI, stress  
5 echo, CCTA, or CMR performed in low-risk surgery  
6 patients for pre-operative evaluation. So as  
7 we've heard, this is I guess a little bit of a  
8 new look for us. At least in our first meeting,  
9 I don't think we had any appropriate use  
10 criteria.

11 So really, this is kind of starting to  
12 look into this area where trying to find when to  
13 do, when not to do a given procedure or a test in  
14 the environment, and as such, I think that's  
15 something that is certainly novel here.

16 If it's okay, this is -- the data  
17 source for this, obviously registry data, is that  
18 the level analyst or the clinician group practice  
19 in facility. And I think primarily targeted at  
20 the facility as I read this, I think that's  
21 correct.

22 If I can jump into the evidence -- and

1 I think this is probably where we'll spend a fair  
2 amount of time because, again, when one looks at  
3 the evidence provided, certainly there are a lot  
4 of guideline specifications that were provided.  
5 To try to look at those guidelines and map them  
6 specifically to this is difficult.

7 The developer references the RAND  
8 Delphi process that was used in -- I've done that  
9 once. And obviously for people that may or may  
10 not be familiar with that, that's basically  
11 convening, if you will, a group of experts who  
12 then sit around a table and vote from a score of  
13 one to nine whether something is inappropriate,  
14 unknown, or appropriate, given various patient  
15 scenarios. And I know when we did this for a  
16 coronary bypass, it was over 90 different  
17 scenarios and things like that.

18 So at the end of the day, I guess to  
19 jump into the -- at least our measure review  
20 document and answer some of these questions. I  
21 think that, you know, as I say, I think the  
22 question for the Committee, is the evidence

1 directly applicable to the process of care being  
2 measured? I think so, as we have it, but I think  
3 we need to have some discussion about how we feel  
4 about the RAND process.

5 I think the process is proximal and  
6 directly related to desired outcomes. And then,  
7 I think there are -- is there evidence of  
8 systematic assessment? Expert opinion. Beyond  
9 those, I don't think there is a lot of evidence  
10 for systematic evidence beyond expert opinion,  
11 and so I think we'll have to figure out if we  
12 really think this is a level of evidence we can  
13 support without other evidence.

14 CO-CHAIR KOTTKE: Sana.

15 MEMBER AL-KHATIB: The first thing  
16 that I want to bring up is the whole issue of the  
17 level of the measure, in terms of the level of  
18 analysis.

19 You know, I think I am struggling with  
20 making the imaging facility the level for this  
21 analysis because for the most part, I mean yes,  
22 they need to be looking to see if the indication

1 for the procedure is appropriate or not  
2 appropriate. That decision and determination are  
3 largely made by the ordering physician, not the  
4 imaging facility.

5 So I am struggling with that concept,  
6 of holding the imaging facility responsible for  
7 something -- I mean, unless it's dangerous, I  
8 think they're going to do it, but are they really  
9 the responsible entity for the appropriateness of  
10 the test? It's really the person who ordered the  
11 test, not the imaging facility. So I'll start  
12 with that.

13 CO-CHAIR GEORGE: Do you want to  
14 address that?

15 MR. ALLEN: Sure. We did look at both  
16 referring physicians and measuring at the  
17 facility level, especially at the imaging  
18 facility, and we find that it is a partnership  
19 between both sides. In our statewide Delaware  
20 project, it is the onus on the imaging lab to  
21 look at this, and lab accreditation also requires  
22 labs to look at it.



1 I know it is a different approach,  
2 though what we found when we measured at the  
3 individual ordering physician or even group  
4 level, often they didn't have enough cases to  
5 reliably give a pattern that we could give  
6 community feedback on.

7 And we found, in our partnership with  
8 the referring -- or the centers performing  
9 imaging in the cases where it's done, including  
10 the studies that are cited here. They found,  
11 surprisingly so, that the referring physicians  
12 really do want that guidance and partnership, and  
13 despite, you know, initial thoughts that referral  
14 centers would push back and say, well I won't  
15 send my imaging to you if you talk about this  
16 with me.

17 In general, if it's not about  
18 individual cases -- remember, they are having to  
19 go through prior authorization anyway through  
20 private firms that they really hate. This is not  
21 that. This is about a population, and so when  
22 you give feedback, it's not on an individual

1 case. It's on, we're seeing this generally in  
2 our community, and we'd like to remind you of  
3 different information that -- other alternative  
4 tests that could be done in these situations.

5 Or in the case of a pre-op, that  
6 here's a great evidence base from the guidelines,  
7 from actually randomized trials that have looked  
8 at this issue, and we don't need testing. You  
9 can be reassured, many of the protocols are set  
10 at the facility level.

11 And so we felt this particular measure  
12 as well as the other two, it is a partnership.  
13 And you can look at the other side for quality  
14 improvement, but for accountability, there  
15 weren't enough cases to hold individual ordering  
16 physicians accountable.

17 CO-CHAIR GEORGE: Liz and then Judd.

18 MEMBER DELONG: I guess I would  
19 question the rationale of we don't have enough  
20 cases for the appropriate victims, so to speak,  
21 so we'll move it up a level to a different  
22 entity. And I do wonder about the interaction

1       there, when -- and you guys all know more about  
2       this than I would -- when a physician refers to a  
3       facility and the facility pushes back. You sort  
4       of addressed that, but I would think it would  
5       create a little bit of tension.

6                   MEMBER HOLLANDER: So that's one of  
7       the points I was going to make. And from my  
8       point of view -- now I am an emergency physician,  
9       but at every place I've ever practiced radiology  
10      has no right of refusal of tests. The clinician  
11      who knows the patient decides.

12                   So to me that's a nonstarter and I  
13      totally, this time I will echo Liz's comments,  
14      that you made it very clear there was a place you  
15      wanted to measure, but there wasn't enough data.  
16      In my world that means stop and let's do  
17      something else, rather than just lay it on the  
18      imaging center. So to me, that's like a  
19      critical, critical thing.

20                   The second thing that I have real  
21      issues with is I am not sure that I want measures  
22      being developed by a Delphi process that is just

1 coming forward. Now, I recognize that ACC/AHA  
2 guidelines are some sort of a modified Delphi  
3 process anyway, but they should be guidelines  
4 from a society, not from a group of people  
5 putting together the measures. They should be  
6 published, they should be vetted, they should be  
7 signed off on the appropriate boards, and  
8 everybody else, and then they are guidelines that  
9 we should be holding people to.

10 My fear is that, you know, you get any  
11 ten people in a room, say you went through a  
12 process, and say now there's expert support for  
13 it. I have real problems with that. So those  
14 are my major two items at a 10,000 foot view for  
15 this.

16 CO-CHAIR GEORGE: Tom Kottke, Tom  
17 James, and Gerard.

18 CO-CHAIR KOTTKE: Yes, thanks. We --  
19 when I was down at Mayo for 17 years, we would  
20 get a call from the radiologists, and they'd say,  
21 you know there's a better test. And we get the  
22 same thing in the Twin Cities.

1                   And I have on my screen right now,  
2           since 2006, we have had a -- basically what you  
3           described as it's just a decision in support of,  
4           you know, why you are doing this. And we've  
5           flattened the curve. I mean, basically since  
6           2006, there's been no growth in high-tech  
7           diagnostic imaging in our market, where it was  
8           just going through the study itself, if somebody  
9           wants to put it up afterwards I will show it to  
10          you.

11                   The system works. I think you can  
12          create this partnership, and it's part of  
13          choosing wisely that, you know, you talk.  
14          Doctors talk to each other from time to time  
15          about, you know, is this the best test? Because  
16          typically the radiologists, or the nuclear  
17          cardiologists, know a little better about what --  
18          you know, and if you have shared decision-making  
19          about do you really need this patient who is  
20          going to have an extraction of a cataract, do  
21          they really need a pharmacological stress test of  
22          their myocardium? And the answer is no.

1                   MEMBER JAMES: Couple different  
2 things. First, I would consider this to be more  
3 of a resource use measure rather than a true  
4 cardiology measure, just for the reasons about  
5 who is accountable. In which case, it may be  
6 better held in another venue.

7                   Secondarily, and I do have admit that  
8 I was on the PCPI work group under Joe Drozda  
9 that looked at some other prior-to-surgery  
10 measures, and I provided data from Humana on  
11 that. But one of the things that I learned about  
12 that is that you have to look at the timeframe.

13                   This is a 60 day window, as I read  
14 this. As a practicing -- part of my life as a  
15 practicing internist, is being in a hospital.  
16 The typical scenario that at least that I used to  
17 see a lot in a couple of different states -- I  
18 can't hold a job and stay in one place. But what  
19 I used to see was a patient would come in with  
20 chest pain, be evaluated, have an acute MI, and  
21 would be followed if they're low risk for a  
22 while, and then have a decision for surgery.

1 That imaging test was done way back early on, and  
2 so it may be outside of the timeframe. So I've  
3 got that particular concern.

4 So those are my points. Thank you.

5 MEMBER MARTIN: So I just -- maybe  
6 it's beating a dead horse, but this partnership  
7 thing is I think a critical one. We've attacked  
8 this in pediatrics, and you know, at our  
9 hospital, you can't order an echocardiogram.  
10 Pediatricians can't do that.

11 And the idea that you can send a  
12 patient to radiology for a cardiac test and they  
13 will just do it, I think there is a flaw in that.  
14 I think that there should be a partnership, and I  
15 think we -- particularly where imaging was so  
16 drastically out of control in the cost curve, you  
17 know, I think it does take the person with  
18 expertise in the disease working together with  
19 the community physician to limit overuse.

20 CO-CHAIR GEORGE: Thank you. Sana and  
21 then Linda?

22 MEMBER AL-KHATIB: So I mean I

1 completely agree that in an ideal world, that's  
2 what should take place. That you know, as an  
3 ordering physician, you talk to the imaging  
4 person, and then you discuss and decide regarding  
5 the best test to order, or if it's appropriate  
6 even, to order it in the first place.

7 But that's not what takes place  
8 everywhere. And I can tell you, at least where I  
9 practice, nobody asks me anything. I order a  
10 test, it gets done. So maybe there is  
11 variability in practice, and so again that would  
12 raise a concern for me, if that's not the model  
13 that is being used in different places.

14 But in terms of the evidence, just a  
15 couple of questions. I was one of the reviewers  
16 assigned to it. I mean, I agree that ordering  
17 these tests that are not necessary is not a good  
18 thing. I think we need to see more evidence that  
19 it's actually, you know, harming people, hurting  
20 people.

21 I hear you about the application of  
22 the AUC, but I am not aware of anything that has



1 shown that if you actually follow the AUC to the  
2 letter, that actually patients do better. I  
3 haven't seen those data. So if you have any data  
4 like that and you can share it, even like in  
5 general terms, I think that would help me focus  
6 my thinking about this measure.

7 MEMBER BRIGGS: So in the discussion  
8 about facility and whether facilities should be  
9 held accountable. For this particular measure,  
10 because it's a pre-operative measure, many  
11 pre-operative evaluations are actually done at  
12 the facility level.

13 They have nurse practitioners, PAs,  
14 other people actually that are doing those pre-op  
15 exams and potentially ordering those tests. So  
16 the facility has some involvement at that level,  
17 and many of these facilities also have large  
18 cardiology groups that work within them.

19 And again, so there could be a level  
20 of responsibility of the facility related to  
21 that. So I'd -- in some areas where primary care  
22 physicians might be ordering, maybe the facility

1       isn't as responsible. But in a lot of  
2       metropolitan areas in particular, you get a lot  
3       of pre-operative evaluation actually done at the  
4       facility level.

5                   CO-CHAIR GEORGE: George and then  
6       Michael, did you have a comment? I'll take yours  
7       after George.

8                   MEMBER CROUCH: Another comment from  
9       the non-ideal world. As a primary care  
10      physician, I was very surprised to see data on  
11      primary care physicians ordering these tests. I  
12      never order these tests. I send them to a  
13      cardiologist and may suggest I would like for  
14      them to have to go to a stress test, but that's  
15      as far as it goes for me as a primary care  
16      physician in the Houston area, suburban Houston.  
17      And my strong sense is that, if the test gets  
18      ordered, it gets done most places. I think it  
19      would be nice to have the partnership where you  
20      get the feedback.

21                   And I do have, interestingly, other  
22      imaging people call me with some regularity and

1 say Dr. Crouch, do you really want this test? I  
2 think that you may perhaps want this other test.  
3 I say, fine, because I know they know more about  
4 which is the better test for neurology imaging,  
5 or whatever. But that isn't happening in our  
6 area in cardiology stress testing.

7 MEMBER PHILIPPIDES: In our facility,  
8 if I order a nuclear test, it gets done. But it  
9 might not be a bad idea for there to be somebody  
10 on the other end who says, you know George, I was  
11 looking at this, would you consider doing this or  
12 not doing it, because four months ago they had  
13 the same test and it was okay? So in a weird  
14 way, adopting this kind of measure might actually  
15 create a system which is facility-wide and not  
16 based on one individual, and I think that would  
17 be working better.

18 In regards to data about the harm  
19 here, I don't know of any direct data, but there  
20 is now a lot of indirect data suggesting that all  
21 of these nuclear tests that we do cause cancers,  
22 right? So if you look, you know, nationwide at

1 the number of SPECTs, CCTA as well, that's a lot  
2 of radiation. And we will cause X number of  
3 cancers, this has been sort of calculated, by  
4 doing nuclear tests at least, that are perhaps  
5 not necessary. And I have seen people going for  
6 cataract procedures who go and get a nuclear  
7 stress test. And if that were my mom or my  
8 spouse, I would be very unhappy about that.

9 So I think there probably is some  
10 downside. Again, I am not sure this measure gets  
11 there perfectly, but I think there's reason for  
12 us to start to look at these kind of things.

13 CO-CHAIR GEORGE: So keep in mind, we  
14 are talking about the evidence. Comments from  
15 Tom, Mladen, and Judd.

16 MEMBER VIDOVICH: I just have one  
17 brief question for the developers. Is -- the  
18 measure is supposed to be lower is better, right,  
19 you know? And that's a continuum of lower  
20 reaching zero. How low is acceptable, meaning is  
21 there a target you are looking for? Meaning are  
22 we looking at ten percent, 20 percent, or should

1 we have maybe a grading scale? Maybe there will  
2 be like, I don't know, less than 20 percent, less  
3 than 30 percent, or something?

4 It seems that lower is better than  
5 nobody should ever get a stress test for any  
6 reason for low pre-op surgery, which is unlikely  
7 to happen. So people don't get penalized for, I  
8 don't know, not reaching zero, or one, whichever  
9 number you pick.

10 MR. ALLEN: Great question. The goal  
11 of this measure is not to get it to zero. It  
12 measures what generally should not be done. On  
13 this particular one, there's a lot of evidence  
14 that you shouldn't, but because of -- you know,  
15 like cataract surgery or whatnot. And so this  
16 particular one, we do see people driving closer  
17 to zero.

18 But we generally look at these  
19 measures as a collection, and when you look  
20 across the different rarely appropriates,  
21 especially the ones that are captured in these  
22 measures, folks generally start at about

1 somewhere between 15 and 30 percent rarely  
2 appropriate cases, and if they have a systematic  
3 process in place like has been talked about today  
4 through decision support, and again, remember  
5 this is about a population, not individual cases  
6 -- understand the sensitivity of referral and  
7 ordering physicians. Some people may feel great  
8 about doing that, other folks may rather talk  
9 about general, like, let's have a faculty meeting  
10 and talk about how do we work as a facility on  
11 this.

12 Different approaches. That doesn't  
13 mean -- the measure is to capture information.  
14 What you do with that information across the  
15 population is really meant to help facilitate the  
16 conversation, either individual or group, so.

17 And it's not, again, to go to zero.  
18 Generally, we start at 15 to 30 and we go down to  
19 five to eight percent rarely appropriate, and  
20 almost nobody gets to zero.

21 CO-CHAIR KOTTKE: I think we have to  
22 be very careful about conflating community

1 standard with quality care. And if it were, we  
2 wouldn't be sitting here.

3 MEMBER CLEVELAND: I guess a comment  
4 and a question. I guess, in -- my question is  
5 for, I guess, our NQF staff. Joe alluded to some  
6 data that, you know, is coming out on some things  
7 that's not in the packet. Is that permissible to  
8 share with us here? Because I think that's part  
9 of what we're struggling with.

10 I mean the process of evidence for  
11 this is just, this is a little bit outside the  
12 bounds of what we've had to look at. And I like  
13 it because there is some tension with the  
14 appropriate use criteria, and I tend to be an AUC  
15 advocate where I think we need to look at this.  
16 But I think that's where some of the -- I guess  
17 where I've struggled in terms of trying to put  
18 this into what our current evidence statements  
19 are and, you know I mean, this is like one of  
20 these motherhood and apple pies. It's like yes,  
21 nobody should get a stress test for a cataract.  
22 I get that, but how do we get there with what we

1 have?

2 MS. JOHNSON: Right, so in this  
3 particular instance, I think the developer can  
4 certainly -- and anybody else in the room that  
5 understands the evidence and would be able to  
6 share that verbally, that would be totally  
7 appropriate and you could act on that.

8 We would probably ask, and take it a  
9 little bit further, we may actually ask the  
10 developer if there is more evidence that they  
11 could actually put into the form so that it is  
12 there for posterity. We might ask them to come  
13 back and actually put some of that verbal stuff  
14 into the form. Does that help?

15 CO-CHAIR GEORGE: Judd?

16 MEMBER HOLLANDER: I am having a  
17 little trouble with a couple things on this that  
18 maybe the developer can help clarify.

19 One is, you know you mentioned you may  
20 be publishing stuff. We have not limited the  
21 evidence base here to published materials. In  
22 fact, most of these things are totally



1 unpublished materials. So I would ask you to  
2 comment on the data which is maybe in press,  
3 which, you know, in the outside world can't be  
4 shared publically, but in this world, we can't  
5 make a decision unless we see. So keeping things  
6 from us, you know, to protect publication rights,  
7 I don't think does the public service. Which is  
8 what we're in this room to do.

9           The other thing is, and maybe I  
10 interpreted this wrong because nobody followed up  
11 on my comment before. Are these appropriate use  
12 criteria, are these widely accepted? Are these  
13 ACC/AHA appropriate use criteria? Because it  
14 doesn't say that in the documents that I see, but  
15 if they are, then I would think of it very  
16 differently than if a group of people developing  
17 a measure got together and decided what  
18 appropriate use was.

19           And then I'll kick back on my  
20 colleague George over there, in that I don't know  
21 that there are actually harms associated with  
22 this. There's a lot of modeling. Like if you

1 blow up a Chernobyl or Three Mile Island,  
2 radiation is bad. But there is certainly a lot  
3 of debate, and two broad camps.

4 One is, you know, less radiation is  
5 always better than more radiation, and I could  
6 agree with that. But the other is that there is  
7 no evidence that medical radiation in an adult  
8 population does anything outside of make for good  
9 modeling papers, and we don't know the answer to  
10 that. So I think it's actually really important  
11 to know what is the evidence and how did these  
12 criteria come to be, and will the world accept  
13 them?

14 MR. ALLEN: Great question. I  
15 apologize for any confusion. In the measure  
16 packet you'll see a number of publications. They  
17 are through a society joint process following a  
18 rigorous process that is derivative and based on  
19 guidelines, but takes it one step further and  
20 looks at particular clinical scenarios, as was  
21 discussed.

22 But it is through a rigorous process.

1 It's not just some random ten people in a room,  
2 and in fact, you know, we get into debates all  
3 the time, whether it be imagers or cardiologists  
4 or interventionalists or practicing physicians,  
5 how do we do this?

6 I will speak just briefly to it. We  
7 do go through a multi-step process. We have a  
8 writing group that's independent from the rating  
9 panel, so when you describe the scenarios, the  
10 writing panel can think of all the things that  
11 they want to ask, but they can't dictate what the  
12 scores will be at the end result. So there's  
13 separation between those that are writing the  
14 scenarios and looking at the evidence and the  
15 people that are actually saying is this reliable  
16 and should it be done?

17 And then there's a rule that less than  
18 50 percent of the panel can represent any  
19 particular treatment or diagnostic choice on the  
20 panel, so we're not just putting a bunch of  
21 imaging folks in the room and saying would you  
22 like to do more imaging? We are, you know, we

1 have a strict process that requires only 50  
2 percent or less the imagers and then put it  
3 through a whole review process, and then it gets  
4 endorsed and looked at by societies.

5 And so it is very similar to the  
6 guidelines. We just don't do the systematic  
7 reviews because the guidelines do that for us,  
8 and so we map every clinical indication to those  
9 systematic reviews. So it's a lengthy process,  
10 can't describe it fully here, but that gives you  
11 an insight.

12 You asked about harms as well. You  
13 know, there is an article in the packet that  
14 does look at the predictive value of these tasks  
15 within the particular areas that we're looking at  
16 for rarely appropriate and shows that, you know,  
17 compared to appropriate or maybe appropriate  
18 studies where you actually get value that tells  
19 what you should be doing with a patient, in these  
20 rarely appropriate circumstances collectively,  
21 they don't actually contribute to the  
22 decision-making process.

1                   And so that's a 2013 publication.  
2       There are a couple other abstracts that have been  
3       in process that I haven't seen actually  
4       published, but there is a published paper in  
5       circulation on that particular issue of -- you  
6       know, it doesn't help, it's taking resource use  
7       and as has been discussed, although any one test  
8       would not necessarily contribute to radiation, we  
9       shouldn't be exposing people to radiation if  
10      there's not a clinical value to it, so both from  
11      the financial and the no clinical benefit, that's  
12      where that's coming from, and I think we have  
13      pretty strong evidence in that case as well.

14                   On the unpublished data, I wish I  
15      could share it with you. It is a partnership  
16      with a private health plan, and so that is their  
17      data, and it's a part of a partnership with them,  
18      and so even to discuss, you know, specifics on  
19      that, I would be violating both some HIPAA and  
20      business associate arrangements to give you any  
21      specifics or to provide it to NQF where it may be  
22      then posted later on.

1                   And so that's why I am talking in  
2                   generalities about it and available data that we  
3                   have, because later on, you'll talk about whether  
4                   or not this can be collected and done a regular  
5                   basis. I can tell you we've been doing it for  
6                   three years, and it is done on a regular basis,  
7                   and so I am not trying to withhold, and my  
8                   chapters and my members actually beat me up on a  
9                   weekly basis about why can't we release the data  
10                  -- in part they wanted to get three years of  
11                  solid data so that they would know that the trend  
12                  is reliable.

13                   They didn't want to just release it  
14                   and say hey, we're doing better, and then, you  
15                   know, have some relapse as you often see on these  
16                   types of observational studies, so.

17                   CO-CHAIR GEORGE: Yes, Sana?

18                   MEMBER AL-KHATIB: So I have a comment  
19                   and a question. The comment has to do with your  
20                   question about well are the AUC accepted, you  
21                   know, within the cardiology world?

22                   And first of all, I have to say that

1 overall, I am supportive of the AUC, but I have  
2 some reservations about them. I could use a  
3 couple of examples from the ICD, the implantable  
4 cardioverter defibrillators AUC document. They  
5 had more than 250 different scenarios that that  
6 document summarizes, so it's actually not very  
7 user-friendly for the average clinician who  
8 doesn't have time to go through all the whole  
9 document.

10 A couple of their criteria went  
11 against the guidelines. So I think that those  
12 things really need to be better aligned, in my  
13 opinion.

14 And I still think, as somebody who  
15 believes in the evidence, that we need to see  
16 data on the association between applying the AUC  
17 and good outcomes. And I still, as I said, see  
18 that this is a missing piece, I think in relation  
19 to all the AUC criteria, but please correct me if  
20 I am wrong.

21 The question that I have to you is  
22 when can we expect to see some of these results?

1 I mean, are we looking that these will come out  
2 within six months, within a year, within five  
3 years? I mean, just kind of getting a sense of  
4 when they'll be out.

5 MR. ALLEN: Sure. Well first I want  
6 to say, you know, despite the Highmark data not  
7 being available, you know, in your publication  
8 materials you have several articles over, you  
9 know, ten years of data, and this has been looked  
10 at in several publications. And so we don't have  
11 the particulars on the statewide mandatory use  
12 type thing, which is the broadest application,  
13 but we have a lot of single center as well as  
14 multi-center looks at imaging-appropriate use.

15 And I know there may be differences  
16 around defibrillators or stents and things like  
17 that, and those are newer things, we are looking  
18 at them, and you know, the imaging criteria, I  
19 have to say, we didn't even develop measures on  
20 them until the second round of appropriate use  
21 because we knew there were some limitations and  
22 we wanted to get those single-center studies done



1 to better refine and give us feedback, when was  
2 there value, when was there not value?

3 We also work a lot on shortening.  
4 Even though we might publish 250 different  
5 things, we work on decision support, and  
6 especially in imaging, to break it up. And so  
7 you might see 60 scenarios in our criteria, but  
8 then we break it up into one to five questions in  
9 one particular area that any physician has to  
10 answer at the time that they're ordering.

11 So they're not looking up 60 different  
12 things, we're saying, well why are you ordering?  
13 Well, it's for pre-op. Okay, so what type of  
14 surgery? Low-risk surgery. Okay, well you don't  
15 really need a test because it matches this  
16 particular indication.

17 It's as quick as that. It's a one to  
18 two question survey at the time of ordering that  
19 then matches that you're not trying to order for  
20 all 250 things, you're trying to order for a  
21 particular patient at that particular time, and  
22 then we report across the population on those 250

1 or 60 things to help you understand what's your  
2 patient mix at your facility, to help you then  
3 reflect upon that and work within your facility  
4 however you see fit to do the quality improvement  
5 around that.

6 So -- and, you know, looking at  
7 outcomes I guess, whether it be imaging or  
8 stenting or defibrillators, I mean there are  
9 randomized trials that try to look at these  
10 issues. I mean the question, a lot of the  
11 questions that we're facing on imaging are  
12 related to, you know, ischemic outcomes in stable  
13 populations where most of the trials have not  
14 shown a benefit to even doing what you would do  
15 after the imaging.

16 There's symptom relief and other  
17 things quicker, and you know, I am very  
18 supportive, even in our stenting criteria, not  
19 limiting people's ability to do that. But if  
20 you're having asymptomatic patients, like in this  
21 particular case where they're just coming in for  
22 a pre-op evaluation, even if you got an imaging

1 test that was positive, what would you do with  
2 it?

3 You're not relieving symptoms at that  
4 point. You might randomly find something that  
5 shows a mild defect in a woman who, you know, has  
6 an attenuation artifact on a nuclear study, and  
7 then there are case studies published in the  
8 literature showing that you then go on to cath  
9 and then have a perforation. I mean, these are  
10 not -- there are adverse events in these things,  
11 and they're only case studies because nobody sets  
12 out for a \$30 million randomized trial to show we  
13 shouldn't do something.

14 CO-CHAIR GEORGE: So we've had quite  
15 a bit of discussion here. Are we ready to move  
16 on and vote on the scientific evidence?

17 CO-CHAIR KOTTKE: Now this may make  
18 everybody uncomfortable as hell, but you know,  
19 the problem isn't the harm to the individual  
20 patient, it's the harm to society.

21 And I've got a graphic right here.  
22 Massachusetts, FY01 to FY14, growth adjusted for

1 inflation of consumer price index, health care 81  
2 percent, early childhood education and care minus  
3 27 percent.

4 And so what we're doing when we're  
5 doing these useless tests is we're taking  
6 education out of the brains of little kids. We  
7 may not be able to process that here --

8 CO-CHAIR GEORGE: All right, we'll go  
9 ahead and vote on the evidence.

10 Are there any comments on the phone?

11 MEMBER CHO: Yeah, I just wanted to  
12 sort of validate Tom's point. And I think that  
13 for the next three measures, the evidence is  
14 quite low.

15 I think that we all agree as, you  
16 know, as physicians that there's over-testing in  
17 America, and if this is a small way for us to  
18 start the talk about over-testing in America,  
19 then I think it's okay to pass measures like this  
20 that have low evidence, but the intention I think  
21 all of us are in perfect alignment with.

22 MS. LUONG: Voting begins now for

1 evidence. One for high, two for moderate, three  
2 for low, four for insufficient evidence, and five  
3 for insufficient evidence with exception.

4 For evidence, 39 percent voted  
5 moderate, 50 percent voted low, 6 percent voted  
6 insufficient evidence, and 6 percent voted  
7 insufficient evidence with exception, so the  
8 measure does not pass.

9 MS. JOHNSON: Okay, just to remind  
10 everybody, we were looking for at least a 40  
11 percent to 60 percent gray zone area in either  
12 high or moderate together to make it pass, so it  
13 actually just came in under the level, so at this  
14 point we're not going to continue the discussion  
15 of the measure.

16 And we will be talking with the  
17 developer a little bit later just to see if  
18 there's something else, maybe, that the Committee  
19 was not aware of, and if there is, he would have  
20 the opportunity to bring it back after public  
21 comment and see if there's, you know, something  
22 else that he may want to bring forward.

1           So that's where we are now. And it  
2 looks like Liz has a question, and --

3           MS. DELONG: Why wouldn't this measure  
4 be transferred over to possibly resource or cost  
5 division? Because what our problem is, there  
6 isn't evidence for some of this harm, et cetera,  
7 but there is evidence about cost.

8           MS. JOHNSON: Well for one thing, it's  
9 not so much that the evidence is about cost. The  
10 cost and resource use groups are a little bit  
11 more technical group that is looking at much more  
12 technical measures than this, so this one  
13 actually, we think, fits with the CV. And Tom,  
14 you can --

15           CO-CHAIR KOTTKE: I was just going to  
16 say that I voted low because I followed the  
17 directions. I mean, you know, if you take the  
18 algorithm down, it makes you vote low because  
19 there's no QQC or meta-analysis.

20           And you know, I mean, I think it's a  
21 good measure, but I just followed the directions.

22           MS. JOHNSON: And what we can do there

1 is work with the developer because as I was  
2 reading it, and the AACs were new to me as well,  
3 but my understanding of those, and maybe I'm  
4 incorrect, my understanding is they were based at  
5 least on an evidence review, a systematic review.

6 That didn't necessarily come through  
7 in the submission, and I also know that you cited  
8 several articles but didn't really summarize  
9 them. So that may have affected people's  
10 viewpoint, is how they went through the  
11 algorithm, so.

12 MEMBER DELONG: So Judd made a  
13 proposal earlier, and I would like to make  
14 another one. I think it's a shame that the  
15 evidence killed this, given that the comparison  
16 between this measure and what its potential is  
17 relative to the previous measure, it seems that  
18 this measure has a lot more potential for an  
19 impact.

20 MEMBER VIDOVICH: I mean, I just want  
21 to say something I thought initially I wouldn't  
22 say, but let me just briefly discuss this.

1                   And I completely agree with you. This  
2                   measure has great potential. But it contains so  
3                   much paramedical stuff that it's hard to measure,  
4                   such as medical legal considerations, such as  
5                   billing considerations which are well above and  
6                   beyond what we can figure out.

7                   Yes, this measure will address this,  
8                   but again, that is well above and beyond what I  
9                   can even possibly imagine anybody fixing in our  
10                  lifetime. So again, and I don't know how to  
11                  incorporate it, and it's very similar to the next  
12                  measure, 0671, that we'll discuss. And it does  
13                  contain it somehow implicitly in there.

14                 CO-CHAIR GEORGE: So we will move on  
15                 -- oh, I am sorry, I'll just take you in order.  
16                 Joe, Tom, and Judd?

17                 MEMBER CLEVELAND: I thought the  
18                 insufficient evidence with exception, can that  
19                 not fall into kind of putting us into the  
20                 moderate range? Where again, because on the body  
21                 of evidence, I agree with Tom, it's low, and it's  
22                 even -- to quote him, but it's such a good



1       measure, it's like well based on the evidence  
2       alone I can't really say, again, within the  
3       structure that we have, that I can stamp this and  
4       say good.

5               I like it. I kind of thought that  
6       might be a vote that would also be one that would  
7       not count against the evidence, but I guess  
8       that's just -- what does exception then mean? If  
9       that is exception, that we could move on unless  
10      that's a majority, is what you're saying.

11             MS. JOHNSON: Right, but we can't add  
12      exception with evidence with moderate to get  
13      above your 40 to go forward.

14             MEMBER CLEVELAND: Got you.

15             MS. JOHNSON: So, I mean, if enough  
16      people are uncomfortable and they would have  
17      said, you know, knowing that they may have  
18      switched their vote, I mean we could talk about  
19      potentially re-voting. That's a little bit  
20      irregular. So --

21             MEMBER CLEVELAND: I certainly don't  
22      want to be the lone rebel -- as a heart surgeon,

1 we're in the minority enough here, so.

2 MEMBER JAMES: I'd like to go with Tom  
3 and Ellen that this really is a resource measure  
4 as far as I'm concerned, but if we're going to be  
5 looking at it strictly from the scientific point  
6 of view, the use of Delphi technique -- and you  
7 started to address it, but it's not written very  
8 well.

9 The Delphi technique is part of -- is  
10 on the AHRQ evidence, hierarchy of evidence, is  
11 way down there. And being able to use more in  
12 the way of good, clinical studies would raise the  
13 level of evidence, and that would be one  
14 suggestion that I would be making on this thing.

15 The other thing is looking at an  
16 episode of care as opposed to this arbitrary 60  
17 day period, if that's possible. It is with  
18 health plans, but I don't know if with other data  
19 sources.

20 MEMBER HOLLANDER: Yeah, I was going  
21 to say, I think what you're hearing is we all  
22 love the idea. It's things within the measure

1       that could be tweaked.

2               I for one would rather see it at a  
3       health-plan-wide or institutional-wide rather  
4       than the imaging facility. I mean, I hear what  
5       Tom's saying, and frankly I agree with it. I  
6       love if I am calling for a test and they say this  
7       is a better test. I hate if they say no, you  
8       can't have the test you want, and there's no  
9       alternative.

10              But regardless, it's the system as a  
11       whole that needs to work it out, and that's what  
12       everybody said while we were debating imaging  
13       facility or doctor. So make it for the system as  
14       a whole, and then, you know, maybe hopefully soon  
15       you'll have more of the evidence to get us over  
16       the hump to do that.

17              But I'm just trying to express  
18       encouragement because I think everybody is saying  
19       we went down the list and this is where it falls  
20       out, and yet you're sitting on a pot of gold, and  
21       I understand the reasons you can't disclose it.  
22       But when that's disclosed, that would probably

1 change the boxes in here and get to the next  
2 thing.

3 But it really does give you a unique  
4 ability because you now have time to change the  
5 measure based on the feedback you're getting  
6 here, so when it does come back with more  
7 evidence, it might actually work well.

8 And then my final comment is if the  
9 world really does move to many more ACO type  
10 models, this will become sort of irrelevant  
11 because it will take care of itself. And so  
12 focusing at the system-wide level will set up  
13 institutions that play into an ACO better rather  
14 than focusing just at an imaging center level.

15 CO-CHAIR GEORGE: Liz, did you have a  
16 comment?

17 MEMBER DELONG: No.

18 MS. JOHNSON: Go ahead, and since the  
19 developer has asked, let's hear what he has to  
20 say real quick --

21 MR. ALLEN: Yes, so I am a little  
22 confused on the conversation because we are

1 talking about two types of evidence: one which is  
2 evidence for the measure and its impact on care,  
3 and we have quite a bit that we can measure it  
4 and that it does have an impact in changing  
5 practice behavior.

6 The other is the evidence for not  
7 doing something. And although we have some data,  
8 and actually the peri-op probably has the best  
9 data on it, I didn't quote it in the measure form  
10 because it's all in the actual publications that  
11 we provided, although, you know, we can pull some  
12 of that out in the future -- but I mean, there  
13 have been randomized trials looking at whether  
14 imaging improves outcomes related to  
15 cardiovascular and the surgical outcomes, and yet  
16 everybody voted that it had low evidence. I am a  
17 little confused by that.

18 And I know that it wasn't directly,  
19 you know, brought out because we relied on folks  
20 knowing the process, and the last time this was  
21 reviewed, it was reviewed in the Resource, so  
22 maybe the level was a little bit different, but

1       you know there are randomized trials showing that  
2       imaging does not contribute to better outcomes,  
3       and we are saying don't do it, and CMS has  
4       approved this for QCDR. They actually have a  
5       parallel measure that measures this on claims.

6               And it's going to be mandated in a  
7       couple of years. And so it seems odd that NQF  
8       would step back from this measure as it's about  
9       to be mandated nationwide. Just -- so and that  
10      applies to any of the other two measures as well.

11              So we'll see how we go through on the  
12      other two, but just want to say that.

13              CO-CHAIR KOTTKE: Yeah, I mean, and  
14      maybe I misinterpreted the algorithm. But I'd  
15      ask, you know, is there either a meta-analysis or  
16      a discussion of quality, quantity, and -- what's  
17      the C? Consistency.

18              You know, and I guess -- and maybe I  
19      missed that.

20              MEMBER BRIGGS: So I'm thinking that  
21      a lot of it has to do with just what data  
22      actually was presented in the document because

1 while the Delphi process was your ultimate use  
2 for -- determination for the appropriate use  
3 criteria, that was supported, as you said, by  
4 guidelines, which are supported then usually by  
5 multiple, multiple studies.

6 Perhaps pulling out some of those key  
7 studies and citing them within this, the  
8 structure for the evidence here, would be helpful  
9 for people, because again, trying to dig too deep  
10 in multiple, multiple documents is difficult at  
11 times.

12 I mean, you live these things and live  
13 and breathe them, and I can understand why you  
14 think oh, they should know. But not everybody at  
15 the table may have read every supporting study  
16 that was involved in creating the scenarios that  
17 you're talking about.

18 CO-CHAIR GEORGE: Michael?

19 MEMBER CROUCH: I just want to  
20 reiterate that the strongest measure applications  
21 that we've had have included all of the relevant  
22 evidence summarized succinctly, and that wasn't

1 done here, and so we're missing a lot of  
2 information.

3 I didn't have time to read all the  
4 articles that were attached to all the measures.  
5 Even the ones I was assigned to, I barely had  
6 time to skim. So if you want to maximize the  
7 chances of it doing well, you need to give us all  
8 the bullets you've got, lay them out there in the  
9 application.

10 CO-CHAIR GEORGE: Sana?

11 MEMBER AL-KHATIB: Also, so the  
12 question here that you posed to us is that  
13 briefly explain the evidence presented by the  
14 developer that supports the relationship to  
15 outcomes.

16 And so in thinking about that, I mean,  
17 correct me if I'm wrong. I mean, I am an  
18 electrophysiologist, I am not an imaging person.  
19 But I am not aware that there are well-designed  
20 and conducted studies, not necessarily randomized  
21 clinical trials, but even, you know,  
22 observational studies, that show this association



1 between if you order a lot of these tests, the  
2 patients end up getting harmed because of this  
3 and that.

4 Now, of course, we know of people  
5 where, you know, you had false positive results  
6 and people ended up having invasive procedures  
7 and had a complication. Of course, we do know of  
8 those cases. But what is the magnitude of that  
9 problem? I, you know, I don't know.

10 And then the other thing about the  
11 association with radiation and those bad  
12 outcomes, you know, give us more information that  
13 yes, here's the association there. If you can't  
14 do that, you know, even if this is to be  
15 revisited, if you cannot do that, I still think  
16 that your best bet is with the cost and resource,  
17 because there the association is very clear. And  
18 that's why I'm not surprised that CMS approved  
19 this measure. Of course they want to save money.

20 But -- and I'm all for that, you know,  
21 from the societal perspective. But as a  
22 clinician, I need more information to support the

1 issue of yes, people are getting harmed.

2 MS. JOHNSON: Yes, so we will  
3 definitely be working with Dr. Allen to see what  
4 we can do with his submission. So he may be able  
5 to bring it back, if not by -- I am not sure if  
6 he would be able to do it in our post-meeting  
7 call which we have scheduled a couple weeks down  
8 the road. If not, then perhaps after the public  
9 comment period.

10 CO-CHAIR GEORGE: Okay. I think we'll  
11 move on to the next measure, which is 0671.  
12 Discussants are Leslie, who is on the phone, Tom  
13 Kottke, and Mladen.

14 MEMBER CHO: Hi. Is the measure  
15 developer joining us?

16 CO-CHAIR KOTTKE: Yeah, he's right  
17 here. But Leslie, Tom here, if I can have a  
18 question. I mean, the foundation for this  
19 measure is exactly the same as the foundation for  
20 the prior measure, as is the foundation for the  
21 next measure. And so is there any sense in  
22 discussing it?

1           MEMBER CHO: Yeah, so I am just going  
2 to make a pitch for this. And bear with me while  
3 I just go through this thought.

4           I totally agree that the evidence for  
5 this measure is very low, as is the evidence for  
6 other measures in this group.

7           However, I think that given the  
8 over-testing that's prevalent in this country and  
9 given the fact that these are measures that were  
10 previously endorsed by the Committee -- by the  
11 Cardiovascular Committee, I still think that  
12 these are worthy measures for us to vote on.

13           And even though the evidence might be  
14 low, it really is, if you think about it, it has  
15 very high priority. And because of the high  
16 priority, while the evidence might be not as  
17 good, I still think these measures should be  
18 re-endorsed.

19           CO-CHAIR GEORGE: Ellen?

20           MEMBER HILLEGASS: For clarification,  
21 was this measure and the previous measure  
22 endorsed by this committee or by the Resource

1 Committee? Because I am reading that they were  
2 endorsed, but my understanding is the last  
3 measure was endorsed by the Resource Committee.

4 So was this one also endorsed by the  
5 Resource Committee? Yes.

6 MR. ALLEN: Yes, all these measures  
7 came through the cardiac efficiency call for  
8 measures. It got wrapped up into the CV update.

9 We agree we're not sure that it's the  
10 right place for this discussion. You know, I  
11 really do appreciate the, you know, the feedback  
12 on, you know, the clinical information. This is  
13 the exact same information we provided to the  
14 Resource Committee, and they understood the  
15 reason why in a Resource Committee you don't have  
16 clinical evidence for not doing something in  
17 general.

18 You know, I can't come back before the  
19 next call. I could pull up the studies, you  
20 know, when I get back to the office that show  
21 that peri-op testing has been shown not to have  
22 evidence, and I can give you, you know, multiple

1 citations there. And this one, testing on  
2 asymptomatic patients does not generally  
3 contribute to anything else.

4 And you know, I think harm is a higher  
5 bar -- I know, Sana, you asked for that, but I  
6 don't know that you have to harm patients not to  
7 do something to them when there's no clinical  
8 value. I mean, I think most of our appropriate  
9 use, especially around imaging, is about if  
10 you're not getting clinical value for the  
11 patient, then I don't have to harm the patient in  
12 order to say I shouldn't do it. I mean, it's my  
13 ethical responsibility not to do something to a  
14 patient that has no clinical value.

15 And I think all these measures on the  
16 evidence would pass from they do not provide  
17 clinical value to the decision-making process.  
18 And as I said, you know, there's been outcome  
19 studies now, more so than most of the measures  
20 that we'll see before you today, showing that  
21 they actually align.

22 I mean, we re-proved that these do not

1 contribute to clinical value in outcomes. And so  
2 most of your other measures are derivative  
3 measures on process things that don't have direct  
4 impact on outcomes. We went through the trouble  
5 of actually showing that they do not provide  
6 clinical value, which is the bar that we thought  
7 -- at least the Efficiency Measure Group wanted  
8 us to show, and now today we're not passing them  
9 based on other considerations.

10 So you know, again, I will just say  
11 that, you know, I will make the pitch for this  
12 one again that there is no clinical value that  
13 has been shown. We have outcome studies  
14 stratifying appropriate versus rarely  
15 appropriate, and they're not contributing to the  
16 decision-making process.

17 We have studies showing that people  
18 have implemented these measures and reduced  
19 resource use dramatically, and avoided doing  
20 things to patients that they don't need to have.

21 And now, I recognize we can come back  
22 and provide additional things in the forms that

1 may have not been apparent, and bring those out  
2 based on these questions, but you know, I guess,  
3 you know, like others have said, we needed to  
4 understand what bar we're passing. If it's the  
5 harm bar, I don't think we'll pass the harm bar  
6 because I'm not going to argue whether radiation  
7 in an individual patient on an individual case  
8 when you're 80 years old is going to ever result  
9 in cancer. I mean, I think those arguments are  
10 kind of funny to have.

11 And you know, I think the 40 year olds  
12 on the asymptomatic, low-risk patient that, you  
13 know, we see a lot of 40 year old women get  
14 nuclear tests for whatever reason and we're not  
15 sure that's the best -- they should have an echo  
16 or a stress treadmill, but you know, those are  
17 the types of things that we're really looking at.

18 But so harm is hard to show, and I'll  
19 never come back with evidence that shows, at  
20 least on these, that we're harming patients by  
21 doing things, but they're not benefitting, and  
22 that's the bar that we set.

1                   MEMBER CHO: I -- this is Leslie,  
2                   sorry to jump in.

3                   For the measure developers, since this  
4                   was endorsed many years ago, do you have any data  
5                   that there has been improvement? Measure 0671?

6                   MR. ALLEN: Yes, we have seen  
7                   improvement, and there are two studies cited, as  
8                   well as when we get to those places, that we  
9                   pulled them into the measurement form. I mean,  
10                  most folks have improved, you know, on -- between  
11                  30 and 50 percent reduction in rarely appropriate  
12                  tests, which means you're cutting a significant  
13                  number of these tests, and especially, you know,  
14                  as you look at these particular measures both  
15                  pre-op and routine use after PCI, centers have  
16                  done a lot of effort to avoid that.

17                  And it used to be an annual thing,  
18                  just like a dentist appointment, you'd come back  
19                  in for your nuclear tests. And we've reset that  
20                  expectation over the last ten years. Now there  
21                  are still pockets where people do that, but, you  
22                  know, it's because of measures like these that



1 we've reset expectations, and you know, it's been  
2 endorsed under Choosing Wisely.

3 MEMBER CHO: Why doesn't the measure  
4 0671 include bypass surgery? Why does it only  
5 include PCI?

6 MR. ALLEN: We saw that it was the  
7 more frequent use of kind of the routine testing.  
8 We didn't see a lot of folks routinely testing  
9 folks after CABG surgery.

10 And there were some questions, as you  
11 got further out from CABG, about its use, and so,  
12 you know, this was the one that we saw repeatedly  
13 in our studies that came up as a routine thing  
14 that we wanted to focus people on. It's not that  
15 CABG wasn't sometimes an issue, but it was less  
16 frequent, so we decided to focus on this.

17 CO-CHAIR GEORGE: Tom and then Gerard.

18 MEMBER MARTIN: So I guess since Tom  
19 spoke about how he voted, I guess what I would  
20 say is kind of where you said you followed the  
21 rules for the level of evidence, it's really  
22 funny because I sat there as a pediatric

1 cardiologist and said we're always complaining  
2 that we don't have appropriate use documents in  
3 pediatric cardiology because we don't have enough  
4 evidence.

5           You don't become an appropriate use  
6 paper or guideline paper within ACC or AHA  
7 without a lot of evidence. And so I sat there  
8 and said, they've got evidence. And I know that  
9 because you don't become a manuscript without the  
10 evidence.

11           And I do know, looking at over the  
12 last several years the cost curve for imaging,  
13 and that not only that cost curve but actually  
14 some of the cost curve has been bent over --  
15 since there's been greater awareness, the curve  
16 is being bent.

17           So I think it is, probably there is  
18 evidence, and it becomes a question of just kind  
19 of the declaration of the evidence and for people  
20 to know that. And there is risk to families with  
21 excess testing because now that cost is being --  
22 you know, most of the cost that's now going into

1 the system has now been shared with the patient.

2 So if there is an unnecessary test  
3 done, that patient is going to be paying for it.

4 CO-CHAIR KOTTKE: If I could jump in  
5 that. Yes, I would agree. And we need to think  
6 of harm more broadly than a patient getting  
7 cancer or whatever, we need to think about social  
8 harm in this year's costs or next year's.

9 I mean, you know, they don't go just  
10 into space somewhere. They come -- every dollar  
11 spent in healthcare comes out of the patient's  
12 pocket somehow or other. And we need to think of  
13 harm broadly.

14 MEMBER JAMES: From working within  
15 several different health plans, this particular  
16 measure is really a tip of an iceberg. I would  
17 -- what I have seen is the wide variation in the  
18 use of this technology preoperatively,  
19 pre-procedure, as opposed to post-procedure.

20 And I wondered if that had not been  
21 addressed, the importance level would be really  
22 great.

1           MR. ALLEN: Again, the reason why we  
2 put these particular ones forward, they were the  
3 most common ones. And so we did see a lot of you  
4 know, in particular hospital-based settings where  
5 the facility was an imaging center based around a  
6 hospital that these ended up -- pre-op ended up  
7 being the issue in the outpatient cardiac space  
8 where you know, somebody was in Florida and  
9 coming as a snowbird and getting their annual  
10 treadmill with a nuclear scan, we saw it as a  
11 common issue.

12           They're slightly different settings of  
13 imaging facilities of where these are done and  
14 where those issues came up. And again, we picked  
15 the top ones that showed up in our studies.

16           MEMBER VIDOVIICH: So for this measure  
17 671, I was one of the reviewers. So I have some  
18 comments and I just wanted to see what the group  
19 thinks about it.

20           And I don't want to sound as a  
21 stickler. But I was bothered a little bit about  
22 the unintended consequences of this measure.

1           So I'm an interventionalist and I  
2 completely agree that tests doing a nuclear once  
3 a year after a PCI is wrong. And I don't do it.  
4 So I think the measure captures the gist what  
5 it's supposed to do.

6           But I think the problem is with some  
7 of the details, and usually the devil's in the  
8 details. First, the title routine. What is  
9 routine? How do we define routine?

10           What is routine? Once a year? Twice  
11 a year? Or does routine -- is this a surrogate  
12 word for asymptomatic? Right, that's one thing  
13 that I would like a better understanding here.

14           Next thing is all PCIs are considered  
15 the same, right. Well, they are not the same,  
16 right. Because some may be intentionally  
17 incomplete then you had to bring them back to see  
18 if there's ischemia. Some may be after a STEMI,  
19 some may be for stable angina, you -- there --  
20 it's a big heterogeneity, which is all lumped in  
21 one category.

22           So sometimes you actually do have to

1 stress asymptomatic patients to find out what's  
2 going on. Another concern I have is well,  
3 asymptomatic may mean no symptoms, but some of  
4 these patients presented with newly diagnosed low  
5 ejection fraction after PCI for whatever reason,  
6 right. Which may not be captured in the measure.

7 And then you do have to further tease  
8 it out. Some patients have asymptomatic ECG  
9 changes. Some patients present with arrhythmia,  
10 which may be asymptomatic, which we may have to  
11 tease out. This is not captured in the measure.

12 So as an interventionalist, I have a  
13 little trouble about just the definitions in the  
14 title. And then another thing is that I may need  
15 some statistical help to understand, is about the  
16 numerator and denominator.

17 It says numerator, number of stress  
18 tests for asymptomatic patients within two years  
19 of most recent PCI. So that's fine.

20 Denominator, number of stress tests. So that's  
21 number of stress tests within the facility? Or  
22 number of stress tests in patients who had

1 received the PCI? Number of what stress tests?

2 That is what I don't understand.

3 So is this all the stress tests in a  
4 stress lab? That hospital stress labs? That  
5 interventionalist? Anyway, I'm being a bit long.

6 And then where does the two year come  
7 from? I would imagine from our cardiology data  
8 that PCI has a two year warranty, CABG has a five  
9 year warranty.

10 You know, that word on the street is,  
11 but you know, the evidence is somewhat limited.  
12 How does this end up in the title of the measure?  
13 Anyway, too long, I'm sorry.

14 CO-CHAIR GEORGE: Before you respond  
15 we have a comment on the phone. So I think we'll  
16 take that and then. Leslie, did you have a  
17 comment?

18 MEMBER CHO: Oh, no. I already said  
19 my peace.

20 CO-CHAIR GEORGE: All right. Thank  
21 you.

22 MR. ALLEN: Okay, so for the time

1 frame, the two years, that is the you know, what  
2 is considered routine within two years. And so  
3 you know, the measured title is a generic  
4 description. Of course the specifications  
5 actually come out and define what the routine is.

6 And so of course, you know, you can  
7 use different words in general titles. And we  
8 picked this one to try to communicate you know,  
9 in general. But when people drill down, it is  
10 the two years.

11 The two years did come from -- there  
12 were studies that we provided within the  
13 appropriate use criteria development that looked  
14 at when you might want to look at this. And  
15 there were periods around three years where some  
16 people were looking, maybe you need to bring them  
17 back for various reasons.

18 And so we didn't want to put it out at  
19 three years because it was starting to show that  
20 there was some reason to bring them back. We set  
21 it at two years because that is where most of the  
22 studies you know, started to show a change after



1 two years. And so we put it at two years trying  
2 to avoid the annual testing.

3 The incomplete revascularization are  
4 other reasons for bringing the patient back  
5 related to stenting. We do have -- remember this  
6 is on a clinical registry data sheet where we're  
7 looking at a universe of potential indications  
8 for why the test is done. This is not like a  
9 claims based measure where we're relying to other  
10 reasons why patients might be getting these  
11 tests.

12 So the physician has the opportunity  
13 to indicate those other types of reasons.  
14 Whether they be related to complications of acute  
15 coronary syndromes, a staged procedure. We  
16 actually have a specific indication on incomplete  
17 revascularization and wanting to look at.

18 So this measure is from a clinical  
19 registry that looks at a universe of things. And  
20 then picks out -- if you haven't selected all  
21 those other things and you're just saying you're  
22 doing it for this reason, then it is rarely

1 appropriate to do.

2 And so we are covering that. We can't  
3 cover it in the universe of measures. If we  
4 measured all 60 different indications, we'd have  
5 60 measures in front of you.

6 And so picked only the ones where  
7 people explicitly said that they were doing it  
8 for this reason and this reason alone. And they  
9 had the opportunity to indicate other clinical  
10 reasons as you just said.

11 The systematic definition as well,  
12 covers a lot of different things. And so  
13 asymptomatic is the absence of those things.  
14 That's not just typical chest pain, oh my gosh,  
15 you know, I feel this crushing pain. It's a  
16 universe of symptoms that may be ischemic in  
17 relation. And so some of the things that you  
18 talked about would be covered there.

19 And you know, the denominator is  
20 facility -- is for the imaging facility. And so  
21 it is all the stress imaging orders at that  
22 particular facility to give us a broad dominator

1 so that we can get that population view and have  
2 the facility discuss that.

3 And if we put it at a facility level,  
4 it wouldn't be all that different from you have  
5 to measure it somewhere. And just measuring who  
6 got PCI or who got surgery, even CMS originally  
7 proposed looking at all patients that got surgery  
8 and then who got testing.

9 You end up with this huge denominator  
10 and very small number of patients. But it  
11 doesn't mean that those patients weren't  
12 meaningful in the universe of the people that got  
13 imaging. And so we defined it at the facility  
14 level.

15 CO-CHAIR GEORGE: Liz?

16 MEMBER DeLONG: I guess I'm seeing  
17 this as another example of switching the  
18 population to meet the numbers rather than the  
19 rationale. Suppose you've got -- didn't you  
20 mention a scenario in Miami where you're sending  
21 people for routine stress imaging. And the  
22 facility throws back most of those as

1 inappropriate.

2 So they end up with very few in the  
3 denominator that they actually do. And of those,  
4 maybe several are inappropriate. They get a low  
5 score -- or a high score, which is low because  
6 they really appropriately sent back most of them.

7 MR. ALLEN: So you know, the universe  
8 of patients that we're looking at remember, is  
9 all imaging tests that are ordered at that  
10 facility. And what you're looking at is the  
11 number that were done for reasons that don't have  
12 a good clinical rationale about them.

13 And so when you reduce that number of  
14 folks that are coming back for that routine, you  
15 are getting a lower score in this measure, which  
16 is better performance in this case. And so it is  
17 an inverse measure.

18 You're not affecting the denominator  
19 by not doing that per se. Other than you are --  
20 well, so you are shrinking the number of patients  
21 that are getting imaging.

22 MEMBER DeLONG: You're not giving

1 credit for the ones that get sent back. Right?

2 MR. ALLEN: True. But we can capture  
3 the absence of an action.

4 MEMBER DeLONG: Right.

5 MEMBER VIDOVICH: Correct me if I'm  
6 wrong. Shouldn't the denominator be of all the  
7 PCIs that you've done, how many inappropriate  
8 stress tests have you done? Rather than within  
9 an image facility, which can have a wide variety  
10 of imaging tests required, right?

11 Because that's -- is that a quality  
12 measure of the intervention -- or the physician  
13 ordering or of the imaging facility? That's what  
14 I'm wondering.

15 MR. ALLEN: Again, this is  
16 accountability and who you'd want to have the  
17 discussion, I know we had the discussion in the  
18 last measure, would you want to hold accountable  
19 the imaging lab? I think it would be even more  
20 tenuous to hold accountable the surgeon or the  
21 interventionalist for a procedure that was  
22 ordered prior to them or after they performed.

1                   And so we didn't believe  
2                   accountability wise that it was appropriate to,  
3                   not just for a numbers sake, but to tie it to  
4                   somebody that was not even a part of the  
5                   discussion about whether or not the test was  
6                   done.

7                   At least with the imaging facility,  
8                   generally, especially now a days, these are large  
9                   systems where the imaging facility is related to  
10                  the folks that are ordering. And the  
11                  accountability level is at least at a place where  
12                  they could have a direct input.

13                  I'm not sure that you would want to  
14                  have a conversation about why PCIs had imaging  
15                  done before or after.

16                  MEMBER VIDOVIK: So as written, as I  
17                  understand it, this looks at the quality of the  
18                  imaging facility, not of the person ordering the  
19                  test after PCI, right?

20                  MR. ALLEN: Right.

21                  MEMBER VIDOVIK: That, yes? Okay.

22                  All right.

1 CO-CHAIR GEORGE: Judd?

2 MEMBER HOLLANDER: So, who typically  
3 orders these tests? I guess it's getting a  
4 little bit of what Liz was talking and a little  
5 bit what we're saying here is the imaging  
6 facility we know doesn't order it. We know the  
7 interventionalist probably is not caring for that  
8 patient anymore.

9 And so we haven't figure out -- what's  
10 that?

11 CO-CHAIR KOTTKE: Yes they are.

12 MEMBER HOLLANDER: Are they?

13 CO-CHAIR KOTTKE: As a practicing  
14 cardiologist, I think there's a lot of that  
15 that's going on.

16 MEMBER HOLLANDER: Okay, so I'm just  
17 say --

18 CO-CHAIR KOTTKE: A routine, two  
19 months after you get the angioplasty they order  
20 it and they get you know.

21 MEMBER HOLLANDER: Right. Okay, so my  
22 question is actually, do we have any insight into

1 who orders the majority of these tests? Is it  
2 the cardiologist that referred them to the  
3 interventionalist? Is it the primary care  
4 provider? Is it the interventionalist?

5 You know, and so I'm trying to figure  
6 out sort of the you know, in the court, the chain  
7 of evidence or chain of responsibility. And  
8 where would be the right person, and maybe it's  
9 all over the map and it should be a health system  
10 issue.

11 But I think we should figure out who's  
12 likely to fix it and who's responsible for it.

13 CO-CHAIR KOTTKE: Well, if I can  
14 answer, a couple of questions. Liz, you know if  
15 you have 20 percent -- say you have 100 patients  
16 that are sent, 20 of them are inappropriate. If  
17 you send back 19 of them your score goes from .2  
18 to 0.12.

19 So in fact your score gets better by  
20 sending. Unless you have a very high proportion  
21 of inappropriates.

22 If you're doing 100 tests, 20 percent



1 are inappropriate. You send 19 of them back so  
2 you're only doing 81 tests and one inappropriate,  
3 your score is .012. Your score is better by.

4 MEMBER DeLONG: Yes, but you're not  
5 capturing the fact that --

6 CO-CHAIR KOTTKE: That we're being  
7 good guys?

8 MEMBER DeLONG: You know, if it gets  
9 large, you're really not capturing --

10 CO-CHAIR KOTTKE: Yes, they're not --  
11 people don't do it -- I hope 80 percent  
12 inappropriate tests, you know.

13 MEMBER DeLONG: Yes.

14 MEMBER HOLLANDER: The fact that it's  
15 not being caught, and not -- if you were  
16 measuring it on the interventionalist and talking  
17 about what percent of his caths subsequently got  
18 an inappropriate stress test, the numbers you're  
19 saying are right. And you're then attributing it  
20 effectively by the denominator as a relationship  
21 to the interventionalist.

22 But the denominator here is the number

1 of stress fact --

2 CO-CHAIR KOTTKE: Right. No, I'm  
3 talking about the number of tests done by a  
4 testing facility, not a cath.

5 MEMBER HOLLANDER: Right.

6 CO-CHAIR KOTTKE: But, you know, we  
7 have a bit of problem here because if we accept  
8 this one and don't accept the last one, what do  
9 we say, well we just made a mistake the first  
10 time and we didn't.

11 And so what I would sort of as a --  
12 what?

13 CO-CHAIR GEORGE: I think there's been  
14 some other concerns raised on this one that we  
15 didn't raise on the last one.

16 MS. HIBAY: This is really just to  
17 answer Liz's question. I think that you were  
18 posing how many were ordered and then how many  
19 were completed.

20 And so -- I think that's the variation  
21 of the two -- the two data points that Tom was  
22 referring to. So I think what you're suggesting

1 is, is you know, so did they start off on the  
2 wrong foot, someone caught them. And they went  
3 back. And that's not being completed.

4 But this one is how many patients got  
5 the test as opposed to how many were  
6 inappropriately ordered, but the system caught it  
7 and then they went back. I think that's the  
8 difference between those two populations if I  
9 understand the question correctly.

10 CO-CHAIR GEORGE: Mladen?

11 MEMBER VIDOVIICH: I'm being difficult.  
12 But there should be some allowance for --  
13 adjustment for the baseline differences between  
14 the imaging facilities. Or different imaging  
15 facilities will have different mix of patients,  
16 right?

17 And this measure will not capture  
18 this, right. You know, so if you are maybe, I  
19 don't know, facility A, maybe your percentage  
20 will be different than the others. And then how  
21 do you account for that, right?

22 You know, because some may be

1 penalized because they get more of one and less  
2 of the other. Because it takes the aggregate of  
3 all stress tests of variety of the patients that  
4 come in, right?

5 And so the different test facilities  
6 will have different tests. I mean, I know that  
7 myself. At the VA, I have a complete different  
8 population at the University. And they're just a  
9 half a block away, right.

10 And then you couldn't call them to the  
11 same standard I think, without some adjustment or  
12 based on differences.

13 CO-CHAIRMAN GEORGE: So, is that  
14 concern I would -- just, is that concern related  
15 to the evidence or related to the specifications?

16 Okay. Any other comments on the  
17 evidence for this measure.

18 MEMBER CHO: So, it's Leslie, and my  
19 final comment is this. If we follow the  
20 algorithm, the evidence is low. But I still  
21 think based on the intention of the thing, my  
22 feeling is to let this measure pass on the

1 evidence.

2 Now, here's the thing, if this measure  
3 was initially approved by the Resources  
4 Committee, then maybe it should go back there for  
5 their re-endorsement. But honestly, if this is  
6 the final stop for this measure, I would be kind  
7 of sad to see this measure fall.

8 I mean, the evidence is low. I mean,  
9 there's no way to get around. By the NQF  
10 algorithm, there's no way to get around that.  
11 The evidence is low.

12 But I still think the intention of  
13 this measure is so good that it should go to  
14 someplace else to have it be re-endorsed again.

15 CO-CHAIR GEORGE: We are trying to  
16 find out whether we can get any more clarity on  
17 that issue. We haven't -- don't have an answer  
18 yet.

19 MS. JOHNSON: I will remind people  
20 that you do have the option of insufficient  
21 evidence with exception. So if that is something  
22 that you feel strongly about, you could vote

1 option five here, and it would go on for  
2 additional discussion.

3 Again, we also have the option of  
4 potentially having the developer come back and  
5 add to his submission to beef up that evidence if  
6 you think it exists. Which you know, I think I  
7 heard the developer say that it does.

8 So it's a little hard for me, I'm not  
9 clinical at all. It's really hard for me to  
10 understand. Was it a -- just the submission  
11 itself is not quite where it needed to be for you  
12 guys to be able to vote a higher thing on  
13 evidence.

14 In terms of turning it over to the  
15 Resource -- cost and resource use project, that's  
16 certainly not something that I could say we would  
17 do right now. And I think at least until Helen  
18 gets back in the room, I think we have to assume  
19 that it's going to stay with CV.

20 The other thing that I will point out  
21 is that we talked about this earlier, our  
22 criteria and our guidance. And how we ask you to

1       apply the criteria evolve over time.

2               So it was passed earlier in a  
3       different Committee, but that was in I think  
4       2011. And our criteria and guidance have  
5       changed.

6               So the idea that something went  
7       through before and doesn't now, should not  
8       necessarily be surprising because of the  
9       evolution of the criteria and the guidance.

10              MEMBER DeLONG: But I would say if we  
11       were to vote on this as insufficient with  
12       exception that perhaps there's other people who  
13       would have changed their mind in the room on the  
14       previous measure.

15              MS. JOHNSON: And if that is the  
16       sentiment, then we could potentially go back and  
17       do a revote.

18              CO-CHAIR KOTTKE: I mean, I guess, I  
19       for one didn't understand the implications of  
20       insufficient with exception. I thought that was  
21       just you know, like insufficient and here's some  
22       things.

1           But I didn't realize things would go  
2 forward on an insufficient with exception. And I  
3 don't know if anybody else made that same  
4 interpretive error. But I didn't.

5           MS. JOHNSON: Right. So let me  
6 explain. This is a must pass criteria. So the  
7 way that it would must -- the way that it would  
8 pass would be if it gets at least 40 percent and  
9 either high or moderate. Or if it gets that  
10 level in the insufficient with exception.

11           So what you're saying is I think that  
12 there is not -- if you vote for number five, what  
13 you're saying is, I do not believe that there is  
14 sufficient evidence to pass this. However, I  
15 believe that the benefits versus the harms is  
16 such that we would be willing to offer an  
17 exception to this measure.

18           MEMBER DeLONG: Could I just say, I  
19 think it is a shame if we killed the first one  
20 and pass this one. The first one had a lot more  
21 clarity to it.

22           For this particular one, I would like



1 to emphasize what Mladen said. Because the  
2 denominator really does depend on the patient mix  
3 and what they're being sent for.

4 And I think Tom's example was a good  
5 one when you have small numbers. But when you  
6 have big numbers and a lot of them are for other  
7 reasons, and they're in the denominator and you  
8 send back your 19, you're not going to get credit  
9 for sending those back.

10 CO-CHAIR GEORGE: I'm going to take  
11 the prerogative of seeing if you would like to do  
12 a show of hands of going back and revoting on the  
13 first measure given Karen's explanation of  
14 insufficient with exception.

15 MEMBER AL-KHATIB: I have a question  
16 about the explanation that you gave though.  
17 Because I think we certainly need more guidance  
18 from you as to what the exception refers to.

19 You talked about you know, the net  
20 benefit and harm. But that's actually pretty  
21 vague in my mind. Like how much benefit are we  
22 talking?

1 I mean, does that ratio have to be  
2 really high for us to make an exception? Or even  
3 if the potential benefit might outweigh the  
4 potential harm, we're okay to use that response?

5 MEMBER HOLLANDER: Can I add before  
6 you answer, because it will be a coupled answer  
7 to Sana's comments. My interpretation to what we  
8 said in the first measure is nothing is dead if  
9 it doesn't pass. That they could come back on  
10 the conference call a couple of weeks later.

11 And I think we're all acting like that  
12 vote means it's dead and we can never talk about  
13 it again. And at least what I thought I heard is  
14 they could come back, revamp the measure in a  
15 couple of weeks. We could talk about it on the  
16 conference call and pass it at that time.

17 So I'm wondering if this is actually  
18 a big deal? Because right now we would be  
19 passing something we don't think is perfect. And  
20 I frankly like the idea of making them retool it,  
21 come back and have a three week delay. And it  
22 would still be out there in the real world on the

1 exact same date if they did that.

2 Am I hearing that correctly?

3 MS. JOHNSON: You are hearing that  
4 correctly that we could ask them to bring back  
5 and just beef up the evidence section.

6 So I think the question for you guys  
7 is, do you think that he can beef up the evidence  
8 section enough, knowing what you know, so that in  
9 three weeks, you would either vote moderate or  
10 high. Or you would still go exception with  
11 evidence. I think that's really the question for  
12 you.

13 In terms of the guidance about  
14 exception, the exception option is something that  
15 we hope is rare. Because what we would really  
16 like to have is evidence based measures.

17 But with that said, you know, we don't  
18 give any kind of a threshold. So this one really  
19 is your gut feeling about whether you think it is  
20 -- it deserves an exception if there isn't  
21 adequate evidence.

22 CO-CHAIR GEORGE: And Sana, to address

1 the question about rate it as insufficient with  
2 exception, I'll just read you from the algorithm.

3 Does the Steering Committee agree that  
4 it is okay or beneficial to hold providers  
5 accountable in the absence of empirical evidence  
6 of benefit to patients. Consider potential  
7 detriments to endorsing the measure, focus  
8 attention away from more impractical practices,  
9 more costly without benefit. Divert resources  
10 from developing more impactful measures. If the  
11 answer to that is yes, then rate as insufficient  
12 with exception.

13 MEMBER HILLEGASS: Could I also ask  
14 that when might we find out if this could be  
15 transferred to a different group? Or this would  
16 possibly be transferred to Resource?

17 Because that would make a decision --  
18 my decision on how I vote. If we got an answer  
19 today, then we could table this until later to  
20 vote on.

21 MS. JOHNSON: Well, I think Helen  
22 would be the one that would make that decision.

1 And I think she is coming back today. I have  
2 emailed her. We've been -- but she hasn't gotten  
3 back to me. She had a meeting today.

4 So to be honest with you, I don't know  
5 when she would be able to make that  
6 determination. I will tell you that the cost and  
7 resource use projects really are much more  
8 technical in nature than these are.

9 These are the groups that will get  
10 episode groupers. And they're looking at kind of  
11 a different flavor of measures than what this is.

12 So again, I don't know what Helen's  
13 decision would be. But that's what I can tell  
14 you about that.

15 CO-CHAIR GEORGE: Well, I'm going to  
16 go back to my original question about a show of  
17 hands of people that would like to revote on the  
18 evidence for the previous measure, which was 670.

19 (Show of hands.)

20 CO-CHAIR GEORGE: And any from the  
21 phone? Wunmi?

22 MEMBER CHO: I mean, I'll go with the

1 majority.

2 (Laughter.)

3 MEMBER CHO: Am I the deciding vote?

4 Oh God. No? What is the majority saying?

5 CO-CHAIR GEORGE: So that was seven to  
6 -- we're split on this.

7 MEMBER CHO: Oh, my God no. So here's  
8 the thing, it is my gut feeling tells me I want  
9 to kind of revote. But I mean -- I don't know.

10 MEMBER AL-KHATIB: But we will revote  
11 after we have more information from the developer  
12 and from you know, answers to the questions. So  
13 we're not saying we're not going to revote.  
14 We're asking just to delay the revote if that's  
15 possible.

16 MEMBER CHO: Okay.

17 CO-CHAIR GEORGE: So given that, we --  
18 I think we're ready to vote on the evidence for  
19 671. Carol?

20 MEMBER ALLRED: Yes, I still have a  
21 question. I guess in my mind I'm not clear.  
22 What are we setting the standards at? And do we

1 have a consistent standard that we're setting  
2 here?

3 Because if there is evidence out  
4 there, I would like to hear his additional  
5 evidence so that we had a clear -- a clear thing  
6 we're working on. Right now it doesn't appear  
7 that we're clear cut.

8 We didn't hear the evidence. We hope  
9 it's there. What are we voting for? Can he come  
10 back and bring us the evidence?

11 MR. ALLEN: Yes, let me ask again,  
12 what the evidence that we're really asking for?  
13 You know, we heard we wanted a harm evidence.  
14 I'm not going to be able to provide that.

15 If that's going to be indirect  
16 evidence that there is no benefit, but the trials  
17 that I would present to you would be on where it  
18 would benefit patients. And in many of those  
19 trials they also looked at populations similar to  
20 these that there would be a lack of benefit.

21 For this particular one, most of the  
22 evidence that appropriate use cites, is you know,

1 follow up studies that are observational. That  
2 you know, where is the kind of the cut point.

3 I don't know that I'm going to come  
4 back. People don't set out to do trials to avoid  
5 things. This is a very different type of  
6 measure. You're asking questions about evidence  
7 of things that generally would benefit patients.

8 And I feel like the evidence review  
9 process for NQF isn't set up well, at least in  
10 this particular circumstance to judge these  
11 measures. Because nobody is going to fund a  
12 trial to show a lack of benefit for something.

13 In general, I can only point to places  
14 where it does provide benefit. And a few studies  
15 that show that there's a lack of clinical  
16 benefit, as I provided already in the packet.

17 And so you know, I have some evidence,  
18 but I won't have a whole lot of evidence. And  
19 you know, there are other issues that came up  
20 around you know, whether that particular part of  
21 -- like this measure on PCI, you know, is it the  
22 best one to go after.



1                   But you know, just on the general  
2                   evidence, I don't know that I'm going to come  
3                   back with something that's going to be so  
4                   compelling versus what we've discussed today.

5                   MEMBER VIDOVICH: I would just say, if  
6                   you can just perform a cost effectiveness study  
7                   that would look into cost as outcome measures,  
8                   that would solve that issue, right. Because  
9                   there's costs associated with each. I mean  
10                  that's an easily measurable discrete granular  
11                  measure.

12                 MR. ALLEN: Right. And the  
13                 information that's provided that we would talk  
14                 about later in usability if we got past this  
15                 evidence, would talk about the impact that we've  
16                 had on resource use and the ability to change  
17                 this based on this measure.

18                 I mean, that's the application of the  
19                 measure once you put it forward and you say  
20                 there's enough evidence, I can show that it  
21                 reduces costs. It changes how people are  
22                 ordering tests.

1 Patient mix I know was asked. That's  
2 the whole point of this set of measures is to  
3 look at your patient mix. And so if you have a  
4 patient mix that you're ordering a lot of tests  
5 for appropriate reasons, great. That is going to  
6 show up in these measures because you're not  
7 going to be doing it for really appropriate.

8 These measures are again, population-  
9 based measures and telling you what your patient  
10 mix is. And in these three, they're saying you  
11 have patients that are potentially in the mix  
12 that aren't going to get clinical benefit based  
13 on what we know of who would get clinical  
14 benefit.

15 Asymptomatic patients do not benefit  
16 from subsequent procedures in this, except in the  
17 circumstances we already talked about, in  
18 complete revascularization, instability and other  
19 -- and those are already captured in the  
20 registry.

21 So I can bring back information. I  
22 just don't know that it's going to be

1 incrementally, you know, hugely more than what's  
2 in here.

3 CO-CHAIR GEORGE: Right. So our  
4 choices right now as I understand it, are we can  
5 vote on the evidence. We can choose to delay our  
6 vote. And delaying that vote could depend on  
7 what Helen has to inform us about if she's able  
8 to come back. Or could delay our vote until the  
9 developers come back with more evidence.

10 So delaying a vote could end up in one  
11 of those two scenarios. Or the third option is  
12 to vote on the evidence now. Any more?

13 MEMBER CROUCH: Yes, I'd just like to  
14 hear some data. You keep talking generalities  
15 about -- I'm all in favor of reducing unnecessary  
16 tests, don't get me wrong.

17 But I'd like to hear some specific  
18 data about how much -- how much money or how many  
19 tests you were -- the impact that this has had.  
20 And I'm happy to listen to data.

21 But I'm not convinced by you're saying  
22 we've got data and you should have read the

1 article, it's there. You've got to give us some  
2 facts please, to work with.

3 MR. ALLEN: We didn't get to the  
4 section that we would talk about those things  
5 because we haven't gotten past the scientific  
6 evidence. There are data tables in the  
7 presentation showing the things that we're  
8 talking about.

9 But we're not going to be able to have  
10 that conversation if we don't get past the  
11 science, so.

12 MEMBER BRIGGS: So I think one of the  
13 things that the developer is trying to say, and  
14 maybe we just need to say it a little bit  
15 different way. Is that ethically you don't do  
16 studies that have no useful impact.

17 You can't say I want to do this test  
18 to see if it would harm somebody. You just can't  
19 ethically do those tests. You wouldn't get past  
20 your IRB, the Institutional Review Board to do  
21 that.

22 So there's certain things that you

1 just are not going to have a randomized control  
2 trial for. I mean it's really hard to do  
3 randomized control trials on patients for example  
4 that are coming in in full arrest to a facility.  
5 Because who gives informed consent for that  
6 patient?

7 I mean there are some ways around  
8 things like that. But there are -- the  
9 randomized control trial, while we hold it in  
10 very high regard, is not always the be-all and  
11 end-all of all evidence.

12 So that looking at with exception  
13 might make sense for these types of indicators.  
14 Because again, the evidence is, is there more  
15 evidence that this might be beneficial than  
16 harmful? And then can get into the cost and all  
17 of those kinds of things down the line.

18 CO-CHAIR KOTTKE: But there are --  
19 there are randomized trials that fail. I mean,  
20 for example, a very recent in the last week, a  
21 report of a randomized trial doing coronary CTs  
22 in patients with diabetes. Does it help? Does

1       it help manage -- reduce events? No, it does  
2       not.

3                       And so -- but I think it was just you  
4       know, re -- I mean, just restating, stating a  
5       little more clearly. I mean, I think we're going  
6       to have a split vote right now.

7                       Come back in a couple of weeks, I  
8       think the Committee would probably be fairly  
9       favorable just have some -- just a restating of  
10      the evidence, not looking for new evidence.

11                      MEMBER AL-KHATIB: Yes, can I also  
12      just make one final comment if I may? I reviewed  
13      the first measure, the 670, not the other ones.  
14      I mean I looked at them, but not that closely.

15                      But you talked about how you provided  
16      information about the cost under usability and  
17      use. And I actually couldn't find this  
18      information.

19                      So I mean, I echo what was said by my  
20      colleague here, that if this information needs to  
21      be really readily available to us as we're  
22      reading. Because we are delving into like a lot

1 of documents to review. So if you can make that  
2 clear.

3 And if costs is what we're going to  
4 focus on, I'm all for it. I'm the last one who  
5 you know, would want us to order tests that  
6 patients don't benefit from them. But if we're  
7 going to focus on costs, we would want to see the  
8 data for that.

9 CO-CHAIR GEORGE: Okay, so Judd and  
10 then --

11 MEMBER HOLLANDER: I just want to say  
12 you know, this is supposed to be about the  
13 evidence. And I think we have an obligation to  
14 follow the algorithm, however imperfect the  
15 algorithm is. That's our charge to do that.

16 And I think you know, I think Ellen  
17 sort of said this before, you know, we don't want  
18 to layer more work on the people unless it meets  
19 the criteria.

20 I think this is a great thing. I  
21 think all these appropriate use things and  
22 driving down test results are critical.

1           But I don't frankly feel ethically  
2 right sitting around the table looking at a work  
3 around. If there's a process, we should follow  
4 the process. And a no vote on this measure now  
5 doesn't prevent it from going forward and hitting  
6 the public at exactly the same time it would.

7           I realize it's a little extra work for  
8 all of us and the measure developer to get to  
9 that point. But I just personally would feel bad  
10 about it from the work around.

11           Either the evidence makes it now, or  
12 the evidence doesn't make it now. And then  
13 there's a next step. It's not dead in the water.

14           There's no -- there's no reason why we  
15 should want to compromise on changing the process  
16 the way it's laid out.

17           CO-CHAIR GEORGE: So once again, we  
18 have a choice of halting our debate and coming  
19 back at a later point in time with the developer.  
20 Or we could vote on the evidence now.

21           MEMBER CHO: Are we still talking  
22 about 670?



1 CO-CHAIR GEORGE: No, 671.

2 (Laughter.)

3 MEMBER CHO: I'm like, God bless,  
4 okay. Let's go for it.

5 CO-CHAIR GEORGE: How many are in  
6 favor of voting on the evidence at this point in  
7 time?

8 (Show of hands.)

9 MEMBER CHO: Me.

10 CO-CHAIR GEORGE: And how many are in  
11 favor of delaying our vote at this time and  
12 coming back at a later time with further evidence  
13 from the developer?

14 (Show of hands.)

15 CO-CHAIR GEORGE: Did everybody vote?  
16 So we will come back at a later point in time.

17 MEMBER CHO: Oh, I just have one  
18 comment I want to make to the developer before  
19 they bring the 0671 back.

20 You know, when I was looking through  
21 the measure, the biggest problem I had was the  
22 numerator of the -- I'm sorry, the denominator of

1 the measure of 671.

2 So the numerator is I understand all  
3 the people who get a PC -- who get a stress test  
4 without symptoms who got PCIs. But really the  
5 denominator should be all the patients who had  
6 PCI without symptoms.

7 That actually should be the  
8 denominator. But that's not the denominator.  
9 And that is my biggest problem with measure 671.  
10 Do you understand what I'm trying to get at?

11 So, what we're trying to answer is  
12 this. All the patients who had PCI, let's say  
13 that's 100. 90 percent of -- 90 patients out of  
14 100 didn't have symptoms. That should be your  
15 denominator. Not the denominator that's  
16 currently listed as number of stress spec -- MPI  
17 stress spec that go CCTA and CMR. That should  
18 not be a denominator.

19 MR. ALLEN: I understand what you're  
20 recommending. Our use of this measure, now  
21 nationally for many years, which has shown  
22 significant improvement and we'll talk about that

1 when we come back, is at the imaging facility  
2 level and in giving us feedback.

3 CMS failed miserably when they tried  
4 the peri-op measure by putting the denominator as  
5 all surgeries, even if they were just low risk  
6 surgeries. And the number of patients that  
7 received imaging as the numerator. It got to be  
8 such ridiculously small numbers, it was hard to  
9 differentiate.

10 And this particular measure, the way  
11 it's structured, again looks at case mix across  
12 all your imaging tests. And looks at three  
13 particular ones that are high frequency issues  
14 for rarely appropriate.

15 And so this should be looked at in  
16 general as a set. And it is looking at all  
17 imaging tests that are performed. And of those,  
18 what's your patient mix receiving it for rarely  
19 appropriate clinically without value tests.

20 And so I understand what people are  
21 saying. You know, could we put the PCIs  
22 underneath, could we put the surgeries

1 underneath, could we put all asymptomatic  
2 patients underneath?

3 I mean on the last measure, which I --  
4 you know, we're deferring I guess all three, you  
5 know, putting all asymptomatic patients that show  
6 up in any health system as the denominator and  
7 then how many people got imaging tests, you have  
8 you know, in some health system, a couple of  
9 hundred thousand patients. And you know, maybe a  
10 handful you know, 100 or 200 that might receive  
11 it in that category.

12 The percentages would be meaningless  
13 for action and for improvement. We're trying to  
14 get to a collection of information that a  
15 facility and an imaging facility can use to work  
16 with their referring providers to actually impact  
17 change.

18 And a number of centers have done  
19 that. And so, we'll bring back the evidence.  
20 You know, I'll bring back as much as I can  
21 because we've touched on everything from cost,  
22 which is implementation of the measures, to harm,

1       which I don't know that I'll have. To clinical  
2       evidence around you know, is this valuable.

3               And you know, I guess I'll just bring  
4       it all back. Because you know, we don't get to  
5       the next section to talk about that if we don't  
6       get past that. And then you can use it as you  
7       see fit through the rest of the section.

8               CO-CHAIR GEORGE: Okay, I think we're  
9       going to break for lunch and come back refreshed  
10      for more discussion.

11              MEMBER CHO: What measure are we going  
12      to talk about when we come back? I'm sorry,  
13      which measure?

14              MS. HIBAY: 672. We're still going to  
15      have some conversation about 672 that's specific  
16      to the measure itself.

17              So when we come back at the post-call  
18      meeting, which is December 19th, we will have had  
19      some conversation about the measure. Not  
20      starting off from fresh.

21              (Whereupon, the above-entitled matter  
22      went off the record at 12:43 p.m. and resumed at

1 1:17 p.m.)

2 CO-CHAIR KOTTKE: Okay, so Sharon is  
3 going to lead us through what the order of  
4 worship is going to be this afternoon.

5 MS. HIBAY: Okay, so I think you saw  
6 us all feverishly discussing next steps for these  
7 three measures over the lunch break. So, I just  
8 want to kind of give you a status report on kind  
9 of where we are.

10 For measure 0670, that was the first  
11 measure, that was not recommended, based upon  
12 evidence. That will go out for public comment  
13 and we have asked the measure developer to come  
14 back with some additional information and we will  
15 reconsider that after the post-comment period.  
16 And then, as a group, we will revisit it on a  
17 post-comment call. Okay?

18 For 0671, the committee has  
19 recommended to defer that for discussion. Excuse  
20 me. Defer the voting until the post-meeting  
21 call. We have decided what we think we would  
22 like to do is move that also to the post-comment

1 call so we can talk about that measure. You know  
2 they all are in tandem. And we would like not to  
3 vote, the group has decided not to vote on 0671  
4 today.

5 On 0672, we would like to have a vote  
6 for the same recommendation as 0671. A show of  
7 hands and show of voice on the phone to see if  
8 you are in agreement with deferring, and that  
9 would be the discussion and voting for 0672 until  
10 the post-comment call.

11 And Wunmi, I don't know if you were  
12 able to capture that date. March 18th is when  
13 would be the post-comment call. So, that gives  
14 our developer some time to bring back the  
15 information and represent this and also for us to  
16 capture more comments from our stakeholders as  
17 well.

18 So, just in general, are you okay with  
19 the plan for re-voting on deferring 0672 to the  
20 post-comment call as well? You are okay? Okay.

21 Show of hands of how many, please, and  
22 show of voices, are okay about deferring the

1 voting and discussion for 0672. Are we  
2 unanimous? Okay, and on the phone, please? Are  
3 you still at lunch or are you on mute? You can't  
4 answer if you are still at lunch, I recognize.

5 MEMBER GIBBONS: It's okay by me, Ted  
6 Gibbons.

7 MS. HIBAY: Okay, very good. And is  
8 Leslie on the call? She just left. Okay.

9 Okay, so by unanimous vote we have  
10 decided to defer 0672 discussion and vote to the  
11 post-comment call on March 19th. Okay, very  
12 good. Okay. Okay, very good. That's where we  
13 are.

14 MR. ALLEN: Thank you everyone.

15 CO-CHAIR KOTTKE: Thanks. Okay, so we  
16 are at 0900: Electrocardiogram Performed for  
17 Non-Traumatic Chest Pain. The discussants are  
18 Gerard, Jason and Judd. Who is going to lead  
19 off?

20 Oh, the developer will lead off.

21 MS. HIBAY: Is the developer on the  
22 line?



1 DR. CANTRILL: This is Dr. Steve  
2 Cantrill from Denver. I'm on the line. I think  
3 I was going to give the initial presentation.

4 CO-CHAIR KOTTKE: Okay, go ahead. The  
5 floor is yours.

6 DR. CANTRILL: Thank you very much.  
7 Chest pain, as you all know, is a real problem  
8 for us in emergency medicine. We see more than  
9 five million patients a year that present to our  
10 EDs. They present with non-traumatic chest pain.  
11 And more than 1.4 million of those patients end  
12 up being hospitalized for ST segment elevation in  
13 terms of having an actual heart attack, an MI.

14 So, this continues to be a very  
15 important issue for us. The EKG is instrumental  
16 in terms of determining whether a patient with  
17 chest pain in fact might be suffering an ST  
18 elevation MI. And this continues to be a very  
19 important issue.

20 We realize there is a minor  
21 performance gap with our latest data. We have  
22 many, many physicians that are still reporting on

1 this. They feel it is an important measure and  
2 we would like to have it continue be at the  
3 reserve status, if at all possible.

4 I will take any questions.

5 MEMBER HOLLANDER: So, this is  
6 actually right in my wheelhouse ad I am actually  
7 one the authors on one of the references on this.  
8 And I think it is obviously a critically  
9 important thing.

10 So, I think it is a critically  
11 important thing but I am just wondering if the  
12 focus of this, which has been out there, might be  
13 a little off and want to open that for  
14 discussion.

15 So, the numbers that were presented  
16 are actually really old numbers and it is really  
17 different now but they are focusing on people  
18 with disease. So, right now, although there is  
19 five to eight million chest pain patients who  
20 come to the ED with chest pain, it turns out the  
21 likelihood of having an MI, STEMI or non-STEMI is  
22 actually closer to the five percent range. It is

1 a much smaller number and many more of those are  
2 NSTEMI than STEMI, as compared to 15 years ago  
3 when the majority was STEMI. Now, it is actually  
4 the minority are STEMI by a decent margin. And  
5 the whole idea of the EKG is to identify the only  
6 time-sensitive thing we do in emergency medicine,  
7 which is reperfusion for STEMI patients. But yet  
8 this measure looks at people discharged from the  
9 ED and whether they got an EKG. One of the  
10 competing measure, 0289 looks at time or median  
11 time to EKG. So, there is great data on time to  
12 EKG. There is guidelines that say it should be  
13 done within 10 minutes of ED arrival. That is a  
14 critically important process measure that has  
15 been shown to correlate very nicely with outcome  
16 in early reperfusion. The earlier you get the  
17 EKG, the earlier you get your reperfusion.

18 This is the other end of the spectrum.  
19 These are the people nobody thinks have a STEMI  
20 or NSTEMI and they are going home. And although  
21 they don't present the data, there is a lot of  
22 data that circulates out there that says we miss

1 two to five percent of MI patients but that is  
2 way old data. And with the advent of observation  
3 units and everything else over the last 10 to 15  
4 years since we realized we are missing tons of MI  
5 patients, it is really relatively rare. You know  
6 they show up as single digit numbers in  
7 malpractice cases.

8 So, the evidence is if you have a  
9 STEMI, you need to find it out fast. But the  
10 measure is nobody thinks you have a STEMI and did  
11 you get an EKG before somebody sent you home.  
12 And they are not the same thing.

13 So, I think measures on time to EKG  
14 for the patients that have cardiac disease are  
15 critical. I am not sure we are accomplishing  
16 much by doing this and the evidence really,  
17 again, speaks to the importance of detecting the  
18 STEMI patient and not the importance of missing  
19 the MI patient, which is really what this is  
20 focused on.

21 DR. CANTRILL: Well, you make some  
22 very good points. And one of the thoughts of

1       this measure is that, as you pointed out, that  
2       years ago it was a five percent number of missed  
3       MIs in patients that we sent home from the  
4       Emergency Department, which is terrible when you  
5       think about it. We have gotten better.

6               But still, the at-risk population here  
7       are those that where you don't think they are  
8       having an MI and in fact you missed it. And  
9       granted, those numbers are small. If you are the  
10      one that gets missed, the numbers aren't so  
11      small.

12              But it really is the at-risk  
13      population where people think oh, that chest pain  
14      couldn't be having a STEMI and we are not going  
15      to get an EKG. So, those are still the at-risk  
16      people. And again, we feel it is important and  
17      looking at even at close claims data that still  
18      does represent a problem for us in emergency  
19      medicine.

20              But I thank you for your comments.  
21      Those are very good comments.

22              CO-CHAIR KOTTKE: Other discussants?

1 Gerard, did you want to say anything?

2 MEMBER MARTIN: I did not have  
3 anything else to add on that.

4 MEMBER SPANGLER: Tom?

5 CO-CHAIR KOTTKE: Yes.

6 MEMBER SPANGLER: And I am not an  
7 expert like the other two gentlemen but there  
8 doesn't seem to be much of a performance gap  
9 here, based on this data. I mean it seems like  
10 this has done pretty well. I mean so I don't  
11 know if that is because of the measure or not.  
12 So, that was one concern that I had just because  
13 we are at the 95 plus percentile for this  
14 performance rate and even higher in the  
15 aggregate. So, that was one thing that I had a  
16 concern about.

17 MEMBER HOLLANDER: I will speak to  
18 that. The performance numbers are the 50th  
19 percentile is at 100 percent. The 25th  
20 percentile is 96 percent and change. The 10th  
21 percentile is less. It is 88 percent. But I  
22 think I would agree, there is little performance

1 gap.

2 I mean, that being said, you know I do  
3 med mal consulting and I see patients where  
4 people went home without an EKG every once in a  
5 while. And you know somebody may have missed an  
6 MI that day because something bad happened a  
7 couple of days later. So, there is clearly  
8 single digits, numbers of these cases going  
9 around. It is an e-measure. It is not terribly  
10 hard to measure. It is something that is  
11 important. I would agree the performance gap is  
12 relatively little.

13 DR. CANTRILL: I would agree with that  
14 as well, if I could respond. And again, your  
15 points are excellent.

16 Just looking at the numbers  
17 historically, again, how much of this is the  
18 Hawthorne effect, the effect of measurement on  
19 the measure we may never know. But our numbers  
20 have improved over the last five years that we  
21 have data for.

22 So, I think part of that is the impact

1 of the measure and we would hate to give that up  
2 because we think it does have a very positive  
3 impact in terms of the health and safety of our  
4 patients.

5 MS. TIERNEY: This is Sam Tierney with  
6 the PCPI. If I could just add to Dr. Cantrill's  
7 comment on the gap, I would also say that the  
8 PQRS program, which is the program from which  
9 most of the data came, most recently was a  
10 voluntary reporting program with minimal rates of  
11 participation. So, we would say that the rates  
12 suggested her, the performance rates are probably  
13 not nationally representative. And this measure  
14 does have a high reporting rate, I think around  
15 60 percent of emergency physicians report on this  
16 measure but that is still not 100 percent.

17 I would also add that the measure, the  
18 PQRS program focuses on the Medicare population  
19 and the measure focuses on patients who are aged  
20 40 and older. So, it is a little broader.

21 So, again, just to put the data that  
22 you see in a little bit more context.



1 DR. CANTRILL: Thank you, Sam, for  
2 those comments.

3 CO-CHAIR KOTTKE: Okay, Judd, do you  
4 want to -- so, this is evidence. Do you want to  
5 give us some guidance on --

6 MEMBER HOLLANDER: I think that the  
7 EKG is important. It is a little different  
8 interpretation. We have had a lot of  
9 conversations about did you show a medical, which  
10 is sort of a paradox. It just seems sort of  
11 better on the back.

12 CO-CHAIR KOTTKE: Right, so you have  
13 moved into opportunity for improvement.

14 MEMBER HOLLANDER: What?

15 CO-CHAIR KOTTKE: You have moved into  
16 opportunity for improvement.

17 MEMBER HOLLANDER: So, I think there  
18 are minimal opportunities.

19 CO-CHAIR KOTTKE: Yes, but we need to  
20 go back and vote on evidence.

21 MEMBER HOLLANDER: Oh, okay. Yes, so  
22 I think that that, personally, if I was deciding

1 for myself, it would be much more about EKG, than  
2 did they just get one. But I guess we can get an  
3 EKG.

4 CO-CHAIR KOTTKE: So, are we ready to  
5 vote on evidence?

6 MS. LUONG: Polling for evidence start  
7 now for Measure 0090. You can have 1 for high, 2  
8 for moderate, 3 for low, 4 for insufficient, and  
9 5 for insufficient evidence with exception.

10 The evidence criteria passed with 59  
11 percent voting for high, 35 voting for moderate,  
12 and 6 voting for low.

13 CO-CHAIR KOTTKE: So, opportunity for  
14 improvement. Anything else you want to say,  
15 Judd?

16 MEMBER HOLLANDER: Twelve percent rates  
17 the 10th percentile and --

18 CO-CHAIR KOTTKE: Of a population of  
19 ER docs who are voluntarily reporting. Sixty  
20 percent of ER docs report this?

21 MEMBER HOLLANDER: Yes, I think I  
22 would ask the developer. I think it is actually

1       probably group practice reporting rather than  
2       individual physicians but it is 69,000 providers  
3       are reporting. So, it is a pretty robust number.

4               CO-CHAIR KOTTKE: Other comments? So,  
5       can I ask the proposer, there was a hint that  
6       this is a biased estimate, performance is biased  
7       upwards. Is that correct or not?

8               DR. CANTRILL: Sam, do you want to  
9       take that?

10              MS. TIERNEY: Yes, sure. So yes, I  
11       think we have seen with other measures in the  
12       PQRS program that the performance rates are quite  
13       high and oftentimes not consistent with the rates  
14       for the medical literature. I think that largely  
15       stems from the nature of the program being  
16       voluntarily, up until recently. And all the data  
17       we have is from when the program was a voluntary  
18       reporting program.

19              So, I think that tends to include  
20       people who are already performing well on these  
21       types of -- on this aspect of care. And as a  
22       result, I do think the performance is skewed

1 upward.

2 CO-CHAIR KOTTKE: Any other discussion  
3 or should we vote on opportunity for improvement?  
4 Linda.

5 MEMBER BRIGGS: Are we talking about  
6 disparities, too, here, in this section?

7 CO-CHAIR KOTTKE: Yes.

8 MEMBER BRIGGS: Okay because one of  
9 the things that is in the bullet points is that  
10 there were no data related to disparities here.  
11 And I think one of the areas that is of most  
12 concern is groups that are listed, it would be  
13 good to have some data if there is data available  
14 about older people, females, in particular, and  
15 non-white patients and exactly what does happen  
16 in those groups? Because those are the people  
17 who get missed and then there are consequences  
18 because of that.

19 CO-CHAIR KOTTKE: Other comments? Are  
20 we ready to vote? Let's vote.

21 MS. LUONG: Voting starts now for  
22 performance gap: 1 for high, 2 for moderate, 3

1 for low, and 4 for insufficient.

2 For performance gap, we have 59 for  
3 moderate and 41 for low. We'll keep going.

4 CO-CHAIR KOTTKE: Okay, priority.

5 MEMBER HOLLANDER: So this is where I  
6 think I was a little tougher on this one because  
7 we have done the improvement. So, identifying  
8 patients with STEMI is really important.

9 Identifying patients to make sure they had an EKG  
10 when you think they nothing and presumably had  
11 some other explanation before you send them home,  
12 which is who this measures, is ED discharges, I  
13 don't believe now has the same national priority  
14 and I don't believe they compare to ten years ago  
15 the missed MI rate is the same. I mean troponins  
16 are identifying patients and pretty much  
17 everybody gets an EKG and a troponin no matter  
18 why they are there these days.

19 And so I think the missed rate, there  
20 is no real data but I think it is now very, very  
21 low. And so I think the degree of priority this  
22 may have had when it was approved is probably

1 less now.

2 CO-CHAIR KOTTKE: This is an  
3 e-measure. So, does that change it up?

4 MEMBER HOLLANDER: Well, I think it  
5 makes it relatively easy to measure. I mean  
6 there is one or two things we will talk about  
7 logistics later when it comes up. But I think if  
8 it is a well-done e-measure and it is not really  
9 hard to collect and could report back, then I  
10 think there is no harm in doing it and it is not  
11 unduly burdensome. But I still think the  
12 priority itself is not high.

13 CO-CHAIR KOTTKE: Anybody else care to  
14 weigh in?

15 CO-CHAIR GEORGE: I notice that says  
16 this is a National Quality Strategy priority. Is  
17 that correct?

18 CO-CHAIR KOTTKE: They all say that.

19 MEMBER HOLLANDER: I'm not going to  
20 comment on the specifics but I think the  
21 specifics are to identify the acute MI patients.

22 And you know just because there is

1 obviously a lot of cardiologists in this room,  
2 one good example is like identifying hypertension  
3 is usually predictive of someone having an MI and  
4 following them years later. Knowing somebody  
5 with chest pain in the ED, has hypertension has  
6 zero predictive value for whether or not they are  
7 having an MI now.

8           So, not everything that is really  
9 important in the outpatient setting or for the  
10 specialist is important in the ED. So, knowing  
11 that, identifying patients with STEMI early is  
12 usually important, everybody agrees, looking at  
13 the EKGs on the people you think probably don't  
14 have STEMI in the small percentage you are  
15 missing. It probably doesn't have the same  
16 importance.

17           So, you have to separate out which end  
18 of the spectrum you are looking at a little bit,  
19 as you think about this.

20           MEMBER SPANGLER: Mary, I was going,  
21 to address your question, I feel like almost all  
22 of these measures, when it comes to the National

1 Quality Strategy, says it is a priority because  
2 of the one bullet that says starting with  
3 cardiovascular disease. So, these are all  
4 cardiovascular disease, they all say it is an NQS  
5 priority.

6 So, I think Judd saying we need to dig  
7 a little deeper, is it really a priority or not  
8 just because it mentions cardiovascular disease  
9 and the National Quality Strategy and all of  
10 these are cardiovascular measures doesn't mean  
11 they are all high priority.

12 CO-CHAIR KOTTKE: Right, everybody  
13 loves their mother.

14 Okay, well we looked at trying to use  
15 ECGs to identify non-STEMIs and off the readings,  
16 it is nearly impossible because they are read  
17 hours or a day later.

18 So, are we ready to vote on priority?

19 MS. KAYE: This is Toni with AMA PCPI.

20 CO-CHAIR KOTTKE: Yes.

21 PARTICIPANT: I guess we just wanted  
22 to comment in terms of looking at the questions



1 in terms of priority for the committee, you know  
2 does this address a significant health problem,  
3 either high prevalence, high severity, high cost.  
4 So, I think we would make the point that chest  
5 pain is a very high prevalence issue and the  
6 severity, if it is missed, if you miss an MI,  
7 even though it may not be that common, it is the  
8 type of event that has, we think, large  
9 consequences, if it is missed and so we kind of  
10 view this almost in light of like a never event.

11 And so we make that as our case for  
12 the high priority.

13 CO-CHAIR KOTTKE: Thank you. Mladen.

14 MEMBER VIDOVIICH: I mean it is not the  
15 most specific or sensitive test. As you will  
16 notice, you mentioned in the emergency  
17 department, everybody gets a battery of tests, no  
18 matter whether they need it or not and probably  
19 ultra-sensitive troponin will be out soon in the  
20 United States or in the world and that will  
21 probably be a better test than everything that  
22 walks with chest pain gets an EKG before they are

1 discharged. I think that is what you somehow  
2 alluded. I maybe have not used the most refined  
3 language but I mean it is a cheap test. There is  
4 not risk.

5 CO-CHAIR KOTTKE: Right.

6 MEMBER HOLLANDER: I just have to say  
7 this on priority. It is not meant to be funny  
8 but it might actually seem funny. The  
9 appropriate use discussions we have had for the  
10 last 12 hours, they pick up a higher percentage  
11 of people with disease than an EKG at the time of  
12 discharge than somebody you think is wrong is  
13 going to pick up a missed MI.

14 So, missing an MI is bad. I am not  
15 trying to downplay it. But the missed MI rates  
16 15 years ago were two to five percent. Now, we  
17 are trying to look at people that someone thinks  
18 has pneumonia or has a clear shoulder sprain or  
19 something and get an EKG on them. It should  
20 actually be a one percent event rate. That's  
21 fine. It is a cheap, it is an easy test. It is  
22 harmless. I have never seen anybody get hurt

1 from it. It might lead to additional testing if  
2 you find some other things. It is not without  
3 unintended consequences. And so I just want to  
4 frame it that you could do things to find rare  
5 events. This is one of them but so are all the  
6 other things that we tried to do away with over  
7 the last two or three hours.

8 MS. TIERNEY: This is Sam Tierney  
9 with the AMA PCPI. If I could just add a  
10 clarifying comment. I think it was Dr. Chiu, I  
11 think that might have been you who was just  
12 speaking. I think you mentioned that the measure  
13 looks at whether they got an EKG on discharge.  
14 And that is not, I just wanted to clarify that is  
15 not the focus of the measure. The denominator  
16 is, in terms of sort of looking at this  
17 retrospectively, we are looking at patients who  
18 had an ED discharge diagnosis of non-traumatic  
19 chest pain and then seeing whether or not they  
20 had an EKG performed before that but not  
21 necessarily at diagnosis -- I mean at discharge.  
22 We would expect it to happen more at

1 presentation.

2 So, I just wanted to clarify the  
3 timing around the measure and that is actually  
4 how it is constructed.

5 MEMBER HOLLANDER: Okay, no, I  
6 understood that. But let me ask you one  
7 clarifying question. When you say ED discharge,  
8 does that include patients admitted to the  
9 hospital or is it just people actually physically  
10 discharged home?

11 For example --

12 MS. TIERNEY: We would have to look  
13 into that. I think it includes patients  
14 discharged home and to the hospital but we would  
15 have to look at that more in our specifications.

16 MEMBER HOLLANDER: Yes, because I  
17 can't tell that and that would actually be an  
18 important point to me because most chest pains  
19 admitted to the hospital, they are obviously  
20 getting an EKG. So, the way I read this, and  
21 maybe it is incorrect was just for ED discharges,  
22 not for patients within the ED stay, which would

1 include observation, admission, and discharge  
2 home. It would be helpful to know that.

3 MS. TIERNEY: We could certainly look  
4 more closely at our specifications and add that  
5 clarification.

6 CO-CHAIR KOTTKE: Other comments?  
7 Mladen, you have commented?

8 MEMBER VIDOVIK: Yes.

9 Okay, it looks like we are ready to  
10 vote on priority.

11  
12 MS. LUONG: Polling for high priority  
13 starts now; 1 for high, 2 for moderate, 3 for  
14 low, and 4 for insufficient.

15 For high priority, 6 percent voted for  
16 high; 47 percent voted for moderate; 47 for low.

17 So, can we keep going?

18 MS. HIBAY: So, this measure has not  
19 met 60 percent but it is in the 40 to 60 percent,  
20 which it means it is in the gray zone. So, what  
21 we do is we just keep moving forward with the  
22 measure discussion.

1 CO-CHAIR KOTTKE: Thank you.

2 MS. HIBAY: Is that correct? Yes.

3 Sharon is showing she is a bit of a novice.

4 CO-CHAIR KOTTKE: Scientific  
5 acceptability.

6 MEMBER HOLLANDER: Or do they come up  
7 on the next slide?

8 CO-CHAIR KOTTKE: Well, yes. Talk  
9 about reliability.

10 MEMBER HOLLANDER: Okay. So, from a  
11 reliability point of view, they did testing in  
12 one urban medical center and one EMR, which I  
13 don't think is terribly adequate. They did have  
14 100 percent agreement for the numerator, which is  
15 whether they got the EKG and only 94 percent  
16 agreement for the denominator, which is, I guess  
17 patients in the ED or non-traumatic chest pain,  
18 patients being discharged from the ED. They did  
19 not give a kappa value for that.

20 And Liz could weigh in. I mean those  
21 numbers sound like they are good numbers but I  
22 think the kappa could probably be wildly

1 different within those numbers. So, it is hard  
2 for us to really say there is robust reliability.  
3 My sense is that this should be reliable and not  
4 that difficult.

5 But if it is an e-measure, it should  
6 probably be tested in more than on EMR because  
7 there is a whole bunch of EMRs that need to make  
8 this work and it probably should be tested in one  
9 medical center.

10 So, I don't think there is very high  
11 reliability testing here.

12 MS. HIBAY: Do you mind if I just put  
13 a little input into there? So, based upon the  
14 time constraints of this submission, this  
15 actually came to us last year and it is quite  
16 extensive, protracted, and onerous to do the EHR  
17 testing. We did give a wave, and I did put that  
18 in, in the preliminary analysis related to the  
19 testing. We gave them a wave on our preferences,  
20 three different EMRs at three different sites.  
21 So, we did say that for this measure it is  
22 acceptable.

1           Future e-measures will be required to  
2     have testing in three EMRs in three different  
3     sites. So, just to be clear if that drum keeps  
4     getting beat, that they should not be held to  
5     that level of account.

6           CO-CHAIR KOTTKE: I've been instructed  
7     to ask you about numerator, denominator  
8     exclusions, beta source.

9           MEMBER HOLLANDER: Let me pull up and  
10    read it exactly. The numerator, I believe was,  
11    and I don't see it right here and I don't have it  
12    on the notes, was basically -- oh, here it is.  
13    Patients who have a 12-lead EKG performed the  
14    denominator was all patients aged 40 and older  
15    with an ED discharge of non-traumatic pain, which  
16    seems reasonable. The exclusions are -- and this  
17    is not reasonable, is the medical reasons for not  
18    performing an EKG being documented. And I can  
19    safely see having reviewed tens of thousands of  
20    charts in my research studies. I have never seen  
21    somebody write I did not do an EKG because of.

22           So, there are effectively no



1 exclusions.

2 CO-CHAIR KOTTKE: So, does that make  
3 the exclusions inappropriate? If a tree doesn't  
4 fall in the forest --

5 MEMBER HOLLANDER: So, I think it sort  
6 of makes them a little funny but the goal is  
7 there is really, I can't think of many reasons  
8 why someone should write I didn't do an EKG. You  
9 know, what is that, all four limbs are amputated?  
10 I mean they can still do that.

11 So, I don't see it as being terribly  
12 relevant but I think it is not terribly  
13 well-addressed either. So, I could live with  
14 that exclusion, even though I think it is a  
15 little silly.

16 CO-CHAIR KOTTKE: Okay, yes, Liz.

17 MEMBER DELONG: So, Judd, your  
18 previous question didn't seem to get an answer.  
19 And that would have implications for the  
20 denominator. Are you satisfied that the -- I  
21 mean the developer wasn't clear on the  
22 denominator either as to whether those were

1 patients who were not admitted to the hospital or  
2 came through the ED and -- does this clarify it?

3 MEMBER HOLLANDER: So, I don't think  
4 I have a good understanding of that, as you  
5 obviously have. I think, however, the  
6 reliability of that is probably not different.  
7 So, whether they want to say it is all admitted  
8 and discharged patients or just discharged  
9 patients, I believe both of those should probably  
10 be reliable to pull out.

11 Obviously, before we approve a final  
12 measure, I think we need to know what we are  
13 approving with certainty and I don't know the  
14 answer to that. But I think I can be okay with  
15 the reliability.

16 MS. TIERNEY: This is Sam Tierney. We  
17 just want to add we have since looked at our  
18 specifications and apologize for not knowing  
19 earlier, Kim, my colleague, will speak to that  
20 issue.

21 MS. SMUK: Yes, so our specification  
22 does not limit the population based on their

1 discharge disposition and where they are going  
2 to. So, it is open to all discharge locations.

3 MEMBER HOLLANDER: So, let me just ask  
4 you, and maybe you don't have any insights into  
5 this, but your agreement for the denominator was  
6 only 94 percent. And based on what you just  
7 said, all they basically needed to do, I guess  
8 the non-traumatic chest pain would be where there  
9 is disagreement or lack of concordance over  
10 whether they meet the criteria. I am trying to  
11 figure out where there could be disagreement on  
12 the review in the denominator.

13 MS. TIERNEY: Well, for the  
14 disagreement on the denominator, what was found  
15 on the automated report versus the abstractor was  
16 different for three cases. But otherwise, for  
17 the other cases, they all were in agreement just  
18 for the denominator.

19 MEMBER HOLLANDER: Thank you.

20 CO-CHAIR KOTTKE: Okay, seeing no  
21 other action, let's vote on reliability.

22 MS. LUONG: Polling for high

1 reliability starts now; 1 for high, 2 for  
2 moderate, 3 for low, and 4 for insufficient.

3 Reliability passes with 18 percent for  
4 high, 82 percent for moderate.

5 CO-CHAIR KOTTKE: Validity.

6 MEMBER HOLLANDER: Yes, I have no  
7 issues with validity. You sort of either got an  
8 EKG or you didn't get an EKG. It is kind of a  
9 simple concept. I think it has face validity and  
10 it is an important thing to be doing for these  
11 patients.

12 CO-CHAIR KOTTKE: Seeing no other urge  
13 to comment, let's vote on validity.

14 MS. LUONG: Polling for high validity  
15 starts now; 1 for high, 2 for moderate, 3 for  
16 low, and 4 for insufficient.

17 CO-CHAIR KOTTKE: People on the phone,  
18 be sure to comment, if you have the urge to  
19 comment.

20 MS. LUONG: For validity, 65 percent  
21 voted high, 35 voted for moderate and it passes.

22 CO-CHAIR KOTTKE: So, Judd, an ECG is

1 not just an ECG. Feasibility.

2 MEMBER HOLLANDER: So, this I actually  
3 have questions based on the comment that Sharon  
4 had. You know if we expect everybody to do an  
5 e-measure but yet we don't expect it is  
6 reasonable to ask them to test it within a year's  
7 period of time, well, then how feasible is it to  
8 really do this?

9 And so I wouldn't have thought of that  
10 until I heard Sharon's comment. I thought they  
11 just did it because it was easy with one EHR.  
12 But if sort of the official explanation is it is  
13 really, really hard to do this, then it is not  
14 terribly feasible.

15 CO-CHAIR KOTTKE: Sharon, do you want  
16 to explain?

17 MS. HIBAY: Yes, so, there is a  
18 difference between the measure being feasible and  
19 testing within feasible. So, testing itself  
20 requires the recruitment of both vendors and as  
21 well as practices. And you know when you put a  
22 testing model together and I say this with

1 experience, as an e-measure tester and an  
2 e-measure developer, it is very hard in this  
3 environment we are in, people trying to work  
4 toward meaningful use, people trying to work with  
5 the ICD-10 conversion, people working with all  
6 sorts of constraints to get people to buy on.

7 I can tell you when I did my  
8 recruitment for e-measure testing, well, how hard  
9 could it be? It took six months and I came  
10 begging, screaming, kicking, trying to get people  
11 to come onboard because there are so many pulls,  
12 twists, and turns that practices have coming at  
13 them. So, it really is hard.

14 The ability to get testers is not the  
15 same as the measure is feasible. The feasibility  
16 of testing itself, the process of getting people  
17 to test, it is a little challenging right now.

18 So, one of the things I also want to  
19 share with you is we were in very good  
20 discussions with the developer about the process  
21 and about testing itself. And this measure,  
22 initially, was potentially going to come to us in

1 phase 1, as opposed to this phase in phase 2.

2 And so to get testing up and running, they would  
3 have had to have it completed when it was a very  
4 new requirement as of October last year and they  
5 never would have been able to get it done by  
6 December of last year, when phase 1 measures were  
7 due.

8 And so by the time we were able to  
9 make decisions about what was phase 1, what was  
10 phase 2, it still left them with a gap. And we  
11 recognize the onerous amount of effort that goes  
12 and expense, et cetera, that goes to testing.  
13 So, we gave them a wave on having to have three  
14 EMRs at this time.

15 Just to let you know, the data does  
16 come from data abstracted or reported from and  
17 EHR and it was identified. And Sam, can you  
18 correct me if I am wrong? It was identified and  
19 tested in 2010, based upon claims generated at  
20 that time for visits during that time. But the  
21 data itself was abstracted from EHRs and other  
22 electronic data.

1                   PARTICIPANT: So, this is Joy from the  
2                   AMA PCPI. At the time the testing project was  
3                   conducted in 2010 on data pulled from 2009, the  
4                   feasibility of the data are not required for  
5                   certified EHRs and we did encounter some  
6                   difficulty with capturing the measure exceptions  
7                   in a structured format. But since that time, we  
8                   were able to determine at the site that 93.6  
9                   percent of the data was stored in a codified  
10                  format and documented in an ED EKG flow sheet.  
11                  And all of the information was pulled from the  
12                  EHR.

13                 MS. HIBAY: Does that provide you with  
14                 the answer? Okay.

15                 CO-CHAIR KOTTKE: Okay, any urge to  
16                 comment on feasibility? Let's vote on  
17                 feasibility.

18                 MS. LUONG: Voting starts now for  
19                 feasibility: 1 for high, 2 for moderate, 3 for  
20                 low, and 4 for insufficient.

21                 Feasibility passes with 29 percent for  
22                 high, 65 percent for moderate, 6 percent for low.



1 CO-CHAIR KOTTKE: Usability and use.

2 MEMBER HOLLANDER: I don't think I  
3 have much to say over the discussions we have  
4 already had. And this seems like this should be  
5 able to be done and be useful for the people at  
6 the tail end and be laggards and move them up.

7 I think in the future we should look  
8 and see whether or not there is going to be  
9 continued improvements and there will be utility  
10 down the road but for now, I think we have made  
11 it past that point. I thought it was reasonable.

12 CO-CHAIR KOTTKE: Any discussion?

13 MEMBER SPANGLER: Tom, just a quick  
14 comment about I know this happens with e-measures  
15 but I am always a little concerned when there is  
16 no public reporting of this and it is planned to  
17 be done because we never really know if it is  
18 going to happen. I mean we are hopeful that it  
19 will happen but just a caution because I think  
20 this will come up again and it has come up in the  
21 past.

22 I am not saying that we should rate it

1 low usability because I agree with Judd, I think  
2 the usability and use will probably be good. But  
3 I'm always just flagged that just because there  
4 is no public reporting on this at all but we are  
5 planning on doing this in the future.

6 MS. HIBAY: So, Sam, do you want to  
7 give some clarification on the current state of  
8 reporting now?

9 MS. TIERNEY: Sure. So, the measure  
10 is being used in PQRS. The PQRS program, as we  
11 noted in the form and as many of you are aware  
12 has publicly reported some measures but this  
13 measure is not currently one of the ones that is  
14 publicly reported. I mean we know we are moving  
15 towards that and having more of the measures in  
16 the PQRS program to be publicly reported but this  
17 one currently isn't one of them.

18 MS. HIBAY: Correct. And that is in  
19 its current state in claims and registry. This  
20 is an EHR submission and so just for the  
21 committee's use, you will see this, as Jason is  
22 saying, you will see this come again with other

1 measures that there is a plan to submit  
2 meaningful use three or whatever. And a lot of  
3 that ends up impinging upon what we do here.

4 CO-CHAIR KOTTKE: Okay, ready to vote  
5 on usability/use?

6 MS. LUONG: Polling for usability and  
7 use; 1 for high, 2 for moderate, 3 for low, and  
8 4 for insufficient.

9 Usability and use passes with 6  
10 percent for high, 82 percent for moderate, 6  
11 percent for low, and 6 percent for insufficient  
12 information.

13 CO-CHAIR KOTTKE: So, now, overall  
14 vote.

15 MS. LUONG: Polling starts now for  
16 overall suitability for endorsement; 1 for yes,  
17 2 for no.

18 Measure 0090 passes for overall  
19 suitability for endorsement with 88 percent yes  
20 and 12 percent for no.

21 CO-CHAIR KOTTKE: Related competing  
22 measures, anything Judd?

1                   MEMBER HOLLANDER: And I don't recall  
2 whether 0289 was just for STEMI or AMI patients  
3 or for everybody. I think it was just for MI  
4 patients. So, I think they are a little bit  
5 complementary. They are not really strictly  
6 overlapping.

7                   CO-CHAIR KOTTKE: Okay, thanks. I  
8 think that is it for -- go ahead. Sorry.

9                   MEMBER SPANGLER: Actually, I had a  
10 quick question for Sharon. Can you remind me the  
11 process of retiring a measure? Because I am  
12 trying to remember if it is the same as this  
13 process where we are looking at maintenance of  
14 measures we decide no, which is different than,  
15 obviously, rejecting the measure.

16                   And because I think this is an example  
17 of I think some of us probably had the feeling,  
18 should this be retired now. Should we do one  
19 more round and then see what performance is and  
20 then maybe retire it?

21                   But I wanted to know, is that the same  
22 as this process or is that a different process?

1 MS. HIBAY: Yes, I'll let Karen speak  
2 to the reserve status.

3 MS. JOHNSON: I think you are talking  
4 about reserve status. You may have remembered  
5 that from before. So, actually, I think since  
6 the last time you met, we have clarified our  
7 reserve status policy. So, what we would have  
8 done with this measure, if you had voted that  
9 there was no opportunity for improvement, that  
10 you felt that it was totally topped out, you  
11 would have been thinking about this only for  
12 reserve status.

13 So, if it had passed, we would have  
14 automatically now put that into reserve status.

15 Since you did not say with your vote  
16 that it was topped out, then it is just regular  
17 endorsement.

18 CO-CHAIR KOTTKE: Okay, that is it.  
19 The next two measures are 1524 and 1525. Sana,  
20 you have to recuse yourself. And I think those  
21 are the -- aren't those yours?

22 MEMBER AL-KHATIB: No.

1 CO-CHAIR KOTTKE: Oh, those aren't  
2 yours?

3 MEMBER AL-KHATIB: No, those are not  
4 the ones.

5 CO-CHAIR KOTTKE: Oh, you are right.  
6 Sorry. I woke you up.

7 CO-CHAIR GEORGE: Okay, the  
8 discussants are Leslie, who is on the phone,  
9 Judd, and Joel. And we will start with the  
10 developers.

11 DR. HO: Thank you. My name is  
12 Michael Ho. I am a general cardiologist from  
13 Denver, representing the ACC/AHA today.

14 As many of you know, atrial  
15 fibrillation is one of the most common cardiac  
16 arrhythmias in the U.S. It is estimated that  
17 between 2.7 and 6.1 million American adults have  
18 this condition. And it is expected to double in  
19 the next 25 years and it accounts for significant  
20 morbidity and mortality. And the cost for  
21 treating atrial fibrillation has been estimated  
22 to range from \$6 to \$26 billion a year.

1                   So, given kind of the high incidence  
2                   and prevalence of this condition, we are  
3                   proposing two measures. Measure 1524 is about  
4                   assessment of thromboembolic risk in patients  
5                   with atrial fibrillation and then 1525 is about  
6                   appropriate anticoagulation therapy in patients  
7                   who are candidates.

8                   Both of these measures have strong  
9                   support from evidence. They are both class 1  
10                  recommendations from guidelines. Both of these  
11                  measures were developed by the ACC/AHA and the  
12                  AMA PCPI and they have been both through peer  
13                  review and public comment process. And they have  
14                  also been tested for feasibility, validity and  
15                  reliability. And these were assessed through the  
16                  PINNACLE Registry, which currently has 172  
17                  practices, 3,000 providers. There is over 3.6  
18                  million patients in the registry and there is  
19                  over 690,000 patients with atrial fibrillation in  
20                  this registry.

21                  And so with that, I am happy to take  
22                  any questions.

1 CO-CHAIR GEORGE: Okay, we will go on  
2 to our discussants to talk about the evidence.

3 Leslie or Joel?

4 CO-CHAIR KOTTKE: Leslie's not on.

5 MEMBER HOLLANDER: No? She's off.  
6 Okay, sorry you guys have got to listen to me  
7 some more.

8 I actually love this measure. There  
9 is only one thing about it I don't love. I mean  
10 the developers actually made a great case that  
11 this is a really important thing. The CHADS2  
12 score is well-validated. There is no shortage of  
13 data. It is a great way to move the field  
14 forward. There is a total lack of appropriate  
15 anticoagulation in all cases, from the evidence  
16 to support the measure.

17 It is really good.

18 CO-CHAIR GEORGE: Any comments on the  
19 evidence?

20 Are we ready to vote on the evidence?

21 MEMBER HOLLANDER: It is the only  
22 conversation we had that lasted less than like



1 five minutes.

2 MS. LUONG: Polling starts now for  
3 evidence for measure 1524: 1 for high, 2 for  
4 moderate, 3 for low, and 4 for insufficient, and  
5 5 for insufficient evidence with exception.

6 Evidence passed with 94 percent and 6  
7 percent for moderate.

8 CO-CHAIR GEORGE: We'll move on to  
9 performance gap disparities.

10 MEMBER HOLLANDER: Oh, the performance  
11 gap is huge. I mean the median documentation in  
12 the clinical registry in 2012 was 22 percent.  
13 There is a long way to go.

14 CO-CHAIR GEORGE: Any discussion? All  
15 right, we will vote on the performance gap.

16 MS. LUONG: Polling starts now for  
17 performance gap: 1 for high, 2 for moderate, 3  
18 for low, and 4 for insufficient.

19 Performance gap passes with 100  
20 percent.

21 CO-CHAIR GEORGE: Moving on to  
22 priority.

1 MEMBER HOLLANDER: It is a high  
2 priority.

3 (Laughter.)

4 CO-CHAIR GEORGE: Any discussion on  
5 priority? All right, we will vote.

6 MS. LUONG: Polling starts now for  
7 high priority: 1 for high, 2 for moderate, 3 for  
8 low, and 4 for insufficient.

9 High priority passes with 100 percent.

10 CO-CHAIR GEORGE: Okay, we will move  
11 on to the specifications and reliability.

12 MEMBER HOLLANDER: So, I don't  
13 remember exactly where I am supposed to say the  
14 numerator and denominator but I thought as we got  
15 into this, this would be a good spot.

16 So, the numerator is whether off the  
17 PINNACLE Registry they are measuring the  
18 individual elements. I think is what Linda was  
19 going to say before, somebody smarter than me and  
20 Linda, who is also smarter to me, pointed this  
21 out and I think it is actually really relevant.  
22 It is that they are recording the individual

1 elements of the CHADS2 score, which is heart  
2 failure, hypertension, age greater than 75 but  
3 nowhere are they actually recording whether  
4 anybody adds that up to calculate the CHADS2  
5 score, which is the basis for the  
6 decision-making.

7           So when you do clinical decision rule  
8 validation, you have to actually apply the rule,  
9 not the individual elements. And I think that is  
10 actually the big flaw -- maybe the only flaw in  
11 this measure, as I see it. So as best I could  
12 tell, they are just looking at whether the  
13 doctors collected the individual information and  
14 collected it -- and documented it, but they are  
15 not looking at whether they actually ever figured  
16 out what is important in that. So is that clear  
17 to everybody, the difference I am making?

18           That being said, when they looked at  
19 signal-to-noise ratio, it provided the high  
20 discriminatory value that we accept for  
21 reliability being okay. And so I think it passes  
22 the reliability, but we don't actually know that

1 anybody is ever thinking about the CHADS2 score  
2 on the basis of what is being measured. Unless I  
3 am misinterpreting something.

4 CO-CHAIR GEORGE: Can you address  
5 that?

6 MR. CHIU: So my name is Jensen Chiu.  
7 I am from the American College of Cardiology. I  
8 think it is a good point you raise.

9 A lot of elements that make up the  
10 measure are on the form, the PINNACLE form. That  
11 is a slight limitation that, hypothetically  
12 speaking, someone could just check yes, as  
13 assessing from the risk factors or not.

14 But the key point is that a lot of  
15 those elements are easy -- already we are jumping  
16 ahead to feasibility. A lot of those elements  
17 are easy to capture, and they actually do have to  
18 capture all of the different elements of the  
19 CHADS2 score. So even though they say yes or no,  
20 you still have to -- the data quality, you still  
21 have to check if they have had all of the other  
22 elements of it that make up the thing you

1 actually -- the physician or whoever is doing the  
2 form, needs to actually check those elements.

3 But you are right, it isn't exactly, you know, in  
4 terms of the equality -- it isn't exactly a one  
5 for one, the ideal to do that. That is true.

6 But the other thing I would just add  
7 is, the challenge is when we eventually move  
8 to like CHA2DS2-VASc and other risk scores, the  
9 challenge also is balancing the burden, as well  
10 as to some degree. Because if you have that in  
11 one form, it starts to getting a little unwieldy,  
12 because not just CHADS2, CHA2DS2-VASc. There's  
13 other HAS-BLED and others. You know, it is  
14 kind of balance.

15 With PINNACLE -- two things I would  
16 add. PINNACLE first off, captures both A-fib,  
17 CAD, heart failure and hypertension. So, it  
18 doesn't just focus on A-fib. And then secondly,  
19 while these measures were tested in the PINNACLE  
20 Registry, they really could be used in any  
21 modality in a physician office. So, that is the  
22 other thing I would add.

1 CO-CHAIR KOTTKE: So you don't  
2 actually know that the doc calculated the CHADS2  
3 score?

4 CO-CHAIR GEORGE: I could see the  
5 reverse, if the measure was to document CHADS2  
6 score there could be problems in just asking for  
7 that as well.

8 DR. HO: I guess you could have some  
9 sort of consensus where they didn't really know  
10 what all the components and said it was a score  
11 of three. But then they didn't necessarily have  
12 all the risk factors. So, I think it is  
13 important to have those components to be able to  
14 calculate the score.

15 MEMBER DELONG: This is Liz. Just a  
16 clarification. This is sort of an all or none  
17 measure. They get credit for an individual  
18 patient if they record that they saw all six. Is  
19 that what it is?

20 MR. CHIU: I would suppose, yes. We  
21 didn't call it an all or none composite but in  
22 essence, it is like that, yes.

1 CO-CHAIR GEORGE: Tom?

2 MEMBER JAMES: I figure this is  
3 probably the place to bring this thing up, that  
4 this is based on the PINNACLE Registry. Not all  
5 cardiologists are involved in that. So, we are  
6 talking about a smaller subset. And a large  
7 percentage of patients with atrial fibrillation  
8 are managed by primary care doctors, who  
9 certainly never have access to the PINNACLE  
10 Registry. Which means then, we are going to be  
11 dealing with -- instead of a national measure, we  
12 are dealing with a measure which is a small  
13 population of physicians. That is my concern.  
14 Whether that affects the validity, I will leave  
15 to Liz.

16 CO-CHAIR KOTTKE: I question that. I  
17 mean, aren't we talking about CHADS -- as  
18 endorsing CHADS2 as a measure? That doesn't mean  
19 it has to go through PINNACLE. It just says this  
20 is an appropriate measures for risk of stroke  
21 with atrial fibrillation and then we have got to  
22 figure out how to get it out into primary care.

1                   MEMBER JAMES: Yes, that is one of the  
2 issues that we have dealt with at the AQA, was  
3 trying to see how can we take registry-based  
4 information and be able to apply it outside of  
5 the registry so we have got a much broader scope  
6 of physicians? Because I agree with the concept.  
7 It is just, are we going to be measuring  
8 everybody? Or do we have, in fact -- is that the  
9 point that we need to use the measure as a lever  
10 to change clinical practice across the country?

11                  CO-CHAIR GEORGE: Linda and then Sana.

12                  MEMBER BRIGGS: So, I think that we  
13 all agree that doing the CHADS score is an  
14 important step in deciding whether  
15 anticoagulation is important for patients, but  
16 collecting those six data points by themselves  
17 contributes nothing.

18                  So, if your primary care physician  
19 fills in the check boxes but he doesn't say that  
20 this patient has a risk score of three and I need  
21 to put this patient on warfarin, what is the  
22 point?



1                   So, I don't think this measure really  
2 gets at what we really intend. They need to  
3 understand that they need to calculate a CHADS  
4 score and what those components are. So, you  
5 really need to see the CHADS score or the  
6 CHA2DS2-VASc score, rather than just the  
7 components in a registry.

8                   MEMBER AL-KHATIB: I completely agree  
9 with that but I also wanted to add one comment  
10 that as we continue to use more EMR. I could  
11 easily see that being captured, you know, from  
12 EMRs. In terms of not just capturing the  
13 different data elements, but also whether a  
14 documentation of what the CHADS score is or  
15 CHA2DS2-VASc score is, in the EMR and then  
16 deciding on whether the patient needs to receive  
17 an anticoagulant or not.

18                   So, that is why I am not as bothered  
19 by the fact that this was done in PINNACLE. I am  
20 really hopeful that with EMR, maybe many health  
21 systems and places will be able to benefit from  
22 this measure. But I do echo the concern that

1 Linda voiced, and I wonder if the developer can  
2 shed some light on that.

3 MR. CHIU: The thing I would add to  
4 both your comments. You know good points about  
5 actually having to score. You know, it was  
6 somewhat -- in terms of feasibility and burden,  
7 there was a decision not to do that, but that's  
8 something we could take back.

9 But one point I would add is that --  
10 I know it is somewhat biased with ACC and AHA, a  
11 lot of the practices we do would be EHR. Unlike  
12 our inpatient sister industries, if you will, the  
13 Cath and all the other heart registries, that  
14 issue isn't as a big a issue for us because  
15 almost -- I think, PINNACLE, if I remember  
16 correctly now. When it first started we had  
17 paper charts and EHR -- a lot of it was EHR. I  
18 think all of it, almost 100 percent, 99.9 percent  
19 EHRs. So, that issue really is, through the  
20 uptake, it automatically is -- you can  
21 technically know the score by just -- because all  
22 of the elements are actually there.

1                   MEMBER AL-KHATIB: The elements are --  
2                   take any medical record. If it is an EHR, in  
3                   particular, will document a patient's sex, their  
4                   age, whether they have hypertension or not. If  
5                   they have had an HMP in the EHR, they would have  
6                   whether they had a stroke or not. Those are like  
7                   key elements to this.

8                   But whether anybody connects the dots  
9                   between those pieces needs to be captured. That  
10                  is what you really want because you want people  
11                  to say, I need to calculate the CHADS score for  
12                  this patient and then I need to do something with  
13                  that data. That is the piece that you are really  
14                  trying to get to.

15                 MR. CHIU: And if I can just add  
16                 really quickly. I think that is a great point.  
17                 I think one thing that we do, separated from  
18                 obviously the measurements used by many groups  
19                 focused in discipline, and on PINNACLE, since ACC  
20                 implements it mainly in PINNACLE at this point.  
21                 In the form itself, we do, it is kind a work  
22                 around in that, in two ways.

1                   One, is there is asterisk to let  
2 people know what the elements are in it. Just so  
3 that they know what it is. I mean most doctors  
4 should know it, but we just put it there. A.

5                   And then B. When you go and calculate  
6 it, it is kind of linked to 1525, the  
7 anticoagulation measure, which I know we are not  
8 on that one. But you would hope -- we hope that  
9 the doctor would know that those elements are  
10 there, then oh, they have got to be given the  
11 meds. And if they aren't given the med, they  
12 have to give a reason why they are not. I know I  
13 am jumping to 1525, but this is kind of linked to  
14 1525 -- both of them are kind of linked together.

15                  CO-CHAIR GEORGE: Mladen?

16                  MEMBER VIDOVICH: In the previous  
17 measure we looked at obtaining an EKG, but it  
18 assumed that the interpretation is included with  
19 an EKG and that actually somebody looked at an  
20 EKG. Similar to this is right, you know?

21                         So data are collected but  
22 interpretation is not assumed, right, as you

1 mentioned. So, this is just to corroborate what  
2 you said. CHADS2 score data are very simple.  
3 They are everywhere. Right? I mean gender, age.  
4 I mean so it is not that hard to collect, but it  
5 is more than the sum of its parts. I mean that  
6 is the great thing about the CHADS2 score.

7 So, I do feel very strongly that I  
8 think there should be some evidence of  
9 documentation of interpretation because there is  
10 more to it than just collecting the data. It is  
11 actually very easy to say in any EHR they looked  
12 at the CHADS2 component. Meaning, ten years ago  
13 we did look at those components and we didn't  
14 know what to make out of it and then CHADS2 came  
15 out. Right? And now we --no more. Right?

16 CO-CHAIR GEORGE: Judd?

17 MEMBER HOLLANDER: I was going to say  
18 this sort of process recommendation to NQF,  
19 because I could imagine that the first thing you  
20 need to do if you want people to pay attention to  
21 it, is get them to collect the data elements.  
22 Right?

1           So let's say, hypothetically, we  
2   approve this measure today and it collects the  
3   data elements and then we have data three years  
4   from now or whenever it is up for renewal that  
5   people are doing it right or not doing it right  
6   or somewhere in the middle. And someone around  
7   the table is going to say well, they did it three  
8   years ago, we should keep it going. There should  
9   be a way for us to potentially approve this  
10   measure today with a note that stays with it  
11   that says the goal is, in three years this should  
12   be looking at do you actually calculate the  
13   CHADS2 score?

14           Because continuing to just collect  
15   these things, we don't think, is terribly useful.  
16   And the next committee could choose to use that  
17   recommendation or not, but it transmits thinking  
18   now. Because I think, listening to comments,  
19   there is nobody in this room that would disagree  
20   that if you just collect the data and don't use  
21   it, it is useful. But we need to a way to  
22   transmit it so we could go to the next step

1 because otherwise, these things just have a life  
2 of their own, staying at the low level.

3 CO-CHAIR GEORGE: Yes, I just feel  
4 like it is important to, if you are looking at  
5 your A-fib population, you do want to make sure  
6 that you have recorded these things.

7 MEMBER DELONG: I guess I was  
8 concerned about the linking with the next  
9 measure. The next measure is almost conditional  
10 on what is found at this stage, is that correct?  
11 Or is that a broader population?

12 DR. HO: I mean, it is the same  
13 population. I mean, you have to assess risk  
14 before you find --

15 MEMBER DELONG: Right.

16 MS. JOHNSON: If I might, let me go  
17 ahead and just address Judd's question, or  
18 comment, actually. Those kind of  
19 recommendations, we do try to make sure are in  
20 the report and next time around, especially as  
21 you -- as the Standing Committee, the idea would  
22 be that you would have that history and be able

1 to look at that and hopefully think about that in  
2 the future, when you look at these again.

3 But we don't have any -- it wouldn't  
4 be a formal condition, or anything like that, on  
5 re-endorsement next time. But it would be a  
6 recommendation from the Committee that would go  
7 with the report.

8 MEMBER MITCHELL: At what point in  
9 time would you consider this measure and the  
10 following measure as paired measures?

11 MS. JOHNSON: You could consider it  
12 today. Basically paired measures can be asked  
13 for by the developer. If they ask that they be  
14 paired, we can certainly do that. The Committee  
15 can ask that measures be paired.

16 So, the pairing is really more in  
17 thinking about how things are reported together.  
18 So, basically anybody can ask that something be  
19 paired, and if the Committee pretty much agrees  
20 with that, in a very informal way, that is fine.

21 MEMBER MITCHELL: Have you guys  
22 thought about pairing these measures?



1 MR. CHIU: No, we have -- just like  
2 many others, like heart failure beta blocker, ACE  
3 are paired together, we could definitely consider  
4 it. I think just the challenge has been that a  
5 lot of the people that we serve, physicians,  
6 really like to have those individual -- to see it  
7 up, to see individual components.

8 Because at least for the PINNACLE  
9 side, there is like a dashboard, a physician  
10 dashboard, as you know. That all the PINNACLE  
11 measures, there is like 40 or 45 of them, are  
12 basically rolled into the dashboard but all of  
13 them we don't actually send to National Quality  
14 Forum. But this one and the subsequent one we  
15 thought, last time we submitted this, were very  
16 important measures to submit forward. That is  
17 something we did consider. The difference  
18 between paired and composite, we can also  
19 explore, too. I know there are differences in  
20 that.

21 But we did want to in A-fib there  
22 really only are a handful of measures that

1 PINNACLE has. This is two of the three. So, I  
2 know NQF has moved to just having like one  
3 measure on multiple things. But it is something  
4 to take under consideration.

5 CO-CHAIR GEORGE: Any other comments  
6 before we vote on reliability?

7 MEMBER AL-KHATIB: I just have a quick  
8 question for you. It says here that this measure  
9 was endorsed back in 2012. Is that correct?

10 MR. CHIU: That was during the last  
11 cycle, I believe it was 2012, yes.

12 MEMBER AL-KHATIB: And so how is this  
13 different from the previous measure? Could you -  
14 -

15 MR. CHIU: Different than the previous  
16 from the --

17 MEMBER AL-KHATIB: From the one that  
18 was endorsed in 2012.

19 MR. CHIU: So the only thing that is  
20 different is the specifications itself. We added  
21 the -- actually, no. The assessment, this one, I  
22 don't think anything has changed, 1524, but 1525

1 has changed. The only thing that has changed in  
2 1524 is the title, CHADS2. We originally didn't  
3 put the title CHADS2.

4 MEMBER AL-KHATIB: Okay.

5 MR. CHIU: So people on the previous  
6 steering panel, steering committee, thought that  
7 this might have related to something else. But  
8 this measure really related to CHADS2, realizing  
9 that there is a new title

10 MEMBER AL-KHATIB: But all the  
11 specifications are the same?

12 MR. CHIU: All the specifications in  
13 1524 are the same. 1525 they are different.

14 MEMBER HILLEGASS: So for  
15 clarification, I may have had a lapse. Can we  
16 determine how we would vote on this in the sense  
17 of, if we want them to incorporate this, not just  
18 individual factors but to actually come out with  
19 a CHADS2 score, can we turn this back to the  
20 developer while we accept this? Or if we feel  
21 it is very important to have a CHADS2 score come  
22 out of this, then we have to reject this measure?

1 I mean, is that on the table? Did I lose  
2 something somewhere along the line?

3 MS. JOHNSON: No, you basically need  
4 to think about this measure as it is in front of  
5 you. So, this measure is what it is. And that  
6 is what you are voting on.

7 You could certainly, and I think I  
8 have already heard a recommendation from the  
9 Committee to go further and to maybe, either make  
10 an additional measure or something that would  
11 actually look at the calculation of the CHADS2  
12 score, and maybe even further than that. But --  
13 so, does that answer your question, enough?

14 MEMBER HILLEGASS: Well, you sort of  
15 did, but so we could send this back, but we  
16 could accept this and ask them to develop  
17 another?

18 MS. JOHNSON: Right. But you would  
19 only send it back if you feel like it is not  
20 conforming to our criteria. So, the basic  
21 question before you in reliability is, is this a  
22 reliable measure. The recommendation to go

1 further or do something else would be simply a  
2 recommendation.

3 Now at the end of the day, if you go  
4 through all the criteria and you still don't like  
5 it, you still have the option of your thumbs up,  
6 thumbs down recommendation for endorsement. But  
7 that is kind of after you have weighed all the  
8 criteria and what you feel like --

9 MEMBER HILLEGASS: Okay, but your  
10 actual title says Assessment of Risk Factors,  
11 which they do, but then there is this  
12 parenthesis, CHADS2, which they don't.

13 Correct? Am I reading that correct?

14 CO-CHAIR KOTTKE: Can I ask a quick  
15 question while we are asking these?

16 MS. JOHNSON: Go ahead.

17 CO-CHAIR KOTTKE: So tell me again,  
18 the reason you did put a calculation of CHADS2 in  
19 there, is that the PINNACLE form doesn't have  
20 that on it? Is that -- did I misunderstand?

21 MR. CHIU: The PINNACLE form can  
22 certainly add it on there, just at the time we

1 didn't. We just thought, simply -- I mean, I  
2 guess it could be a simple oversight, but the  
3 thought is really to simply assess to get to the  
4 1525 that we have actually done the medication in  
5 1525, anticoagulation.

6 The other issue simply is that there  
7 is going to be multiple scores. Assume the  
8 CHA2DS2-VASc, HAS-BLED, and so do we actually  
9 build in all those scores in there. That is  
10 actually kind of a tricky --

11 CO-CHAIR KOTTKE: I mean, my interest  
12 is not the PINNACLE Registry. And I think, I  
13 mean probably cardiologists do not such a bad job  
14 on this, even though it doesn't look all that  
15 great. I mean the problem is most atrial fib is  
16 taken care of, probably by primary care and this  
17 is a tool. Let's try and get docs to really use  
18 CHADS2 and just not have it, somehow, in the  
19 electronic record.

20 Yes -- so, I mean, the answer was in  
21 1524 that all the elements were in the PINNACLE,  
22 but not -- except for the calculation.

1 MR. CHIU: That is correct.

2 CO-CHAIR KOTTKE: Okay.

3 MR. CHIU: And also just to add  
4 this. The rate of documentation is very poor in  
5 this estimate. So anticoagulation, it is also  
6 very low, but this is kind of a gap in that  
7 that we need to be documenting better. And that  
8 is partly why the measure is made, realizing that  
9 it is not the best flavor of a measure as opposed  
10 to some of the others we put forward.

11 CO-CHAIR GEORGE: Gerard and then  
12 Sana.

13 MEMBER MARTIN: I was just about ready  
14 to say that it seems like 1525 is the action that  
15 you are really interested in, that you identify  
16 the high-risk patient, that you actually add up  
17 the risk elements, and come up with a score that  
18 says you need to have anticoagulation and you  
19 treat them.

20 But then as I look back, it isn't  
21 completely. 1524 is, probably deals with the  
22 that you are not treating some people

1 unnecessarily. So, you have they really are  
2 paired. So, one is you are getting at don't  
3 treat someone unnecessarily and the other one,  
4 you are trying to treat the person who needs to  
5 be treated.

6 And it could be solved very easily,  
7 that one thing, by either truly pairing them or  
8 by spelling out that -- in 1524, that you are  
9 adding up the elements and coming up with a risk.  
10 Which is what you want, rather than just by blind  
11 luck having an EHR that tracks those things,  
12 which is not the intent.

13 MEMBER AL-KHATIB: So just to go back  
14 to the comment that was made by Ellen. When I  
15 look at the validity and the reliability testing  
16 that you did, you actually did do those based on  
17 the score, not on the individual elements. Am I  
18 correct in interpreting those data?

19 MS. JOHNSON: Perhaps I could just  
20 make sure that, from what I am seeing, it looks  
21 like that they did what we call performance score  
22 testing. So that is, the overall percentage of



1 the -- this is at the clinician level, facility  
2 level -- clinician level. So, when we say  
3 performance measure score, we are not talking  
4 about the CHADS score. We are talking about the  
5 computed score for the clinician.

6 MEMBER AL-KHATIB: Oh, I see. Okay,  
7 got it. Thank you.

8 CO-CHAIR KOTTKE: So, it's actually  
9 worse than it looks. If only 22.8 percent had  
10 all of the elements, then the actual calculation  
11 was probably far worse.

12 MEMBER HOLLANDER: I guess the  
13 question is, because now I'm confuse. You know  
14 there is reliability testing with a good number,  
15 but if it is not reliability testing that gets to  
16 a CHADS2 score in the document, which is what the  
17 measure is sort of calling for, then should it  
18 fail that because there was no testing?

19 And you know and then I am stuck with  
20 so if it passes this, it might actually go  
21 through and pass every single data point and then  
22 half this room might vote against it because they

1 think it is not a measure that is useful, even  
2 though it is a step in the process to get there.

3 And so, I am a little confused about  
4 how to think about it at this point, and I think  
5 that is what I hear Ellen saying as well, is do  
6 we want to approve something that we really think  
7 can't accomplish anything but would just be a  
8 step to accomplishing it? And then there is a  
9 measure coming afterwards that says we  
10 accomplished it or we didn't.

11 And so what is the added value of  
12 this? And I think the, sort of the branding  
13 point, like CHADS2 score should clearly be out of  
14 the title if it is approved. I don't think we  
15 can approve something that says we are measuring  
16 the CHADS2 score when we are not. That is just a  
17 bad name for it to begin with.

18 So, there has to be some tweak on it,  
19 I think, to go forward from what we are hearing.  
20 But I am not really sure how to assess  
21 reliability of individual data elements if it is  
22 actually the CHAD2 score that we are trying to

1 get at.

2 So, I can either say yes, each data  
3 element is really reliable where it is documented  
4 but the CHADS2 score, there is not testing at  
5 all. So, do I vote yes or do I vote no?

6 CO-CHAIR GEORGE: I have one question  
7 I think you can answer relatively quickly but it  
8 says in the registry, most missing values are  
9 interpreted as no.

10 MR. CHIU: That just means if you are  
11 missing an element, that basically that would  
12 fail the measure because you are hoping that  
13 someone actually -- basically it is like a meta.  
14 If they didn't give it, you have to assume -- if  
15 they didn't document it, you are actually failing  
16 it.

17 So, it is not gaining it because it is  
18 something missing and somebody didn't put it,  
19 arguably, to be gained and then be removed from  
20 the denominator. When in fact, now, you have to  
21 have all those elements that it is missing or you  
22 are actually not treating the patient.

1 CO-CHAIR GEORGE: -- individual risk  
2 factor are those default no, as well?

3 MR. CHIU: All those risk factors  
4 need to be all those risk factors, the EHR or  
5 whatever, actually needs to follow all of those.

6 CO-CHAIR GEORGE: So missing for those  
7 doesn't mean no, with a default no.

8 MR. CHIU: Correct. The other thing  
9 I would add, if I could just add about the CHADS2  
10 in the title. Historically, we actually didn't  
11 have that in the title but it was actually asked  
12 by the previous steering committee to add CHADS2  
13 back in the title. But we could actually remove  
14 it. We are open to removing it again.

15 CO-CHAIR KOTTKE: You could put CHADS2  
16 elements instead, but you know, Judd, this caused  
17 a question about what we were voting on in  
18 priority.

19 Was it priority of the measure or  
20 priority of treating atrial fibrillation with  
21 anticoagulation? I mean, very high if we went  
22 back and said well, it is high priority to treat

1       atrial fibrillation with anticoagulation, but is  
2       this measure high priority?

3               MEMBER HOLLANDER: Well, I think it is  
4       a high priority to assess the risk and this is a  
5       way in the risk. And the way I interpreted that  
6       is, as long as it is anything in the process that  
7       gets you towards treatment, we accept process  
8       measures along the line. And I suppose it is  
9       perfectly fair to have the individual elements as  
10      the first process measure but the next process  
11      measure would be, did someone add it up and do  
12      it?

13             MEMBER DELONG: Could I get a couple  
14      clarifications? Number one, Mary read that the  
15      coding, at least in this PINNACLE database, says  
16      if it is not captured, it defaults to no. But  
17      you are saying that is not correct? If an item -  
18      - if a risk factor isn't captured, it defaults to  
19      it doesn't exist. Are you saying that statement  
20      is incorrect?

21             MR. CHIU: It defaults to missing.

22             MEMBER DELONG: It does default to

1 missing.

2 MR. CHIU: Right.

3 MEMBER DELONG: So, wherever that  
4 statement came from, that is not correct.

5 MEMBER HOLLANDER: When I looked at  
6 the form, and the instructions for the form, and  
7 I did this briefly. I could be totally wrong. I  
8 only saw two options, yes and no. I didn't see  
9 an option for missing.

10 MEMBER DELONG: And my other question  
11 is totally out of naiveté. Are you saying,  
12 Gerard, that this measure is basically a rule out  
13 measure, in terms of whether they need  
14 anticoagulation?

15 MEMBER MARTIN: No, what I was saying  
16 is that -- and I am not a developer, but I'm just  
17 saying as I read the two of them, that the second  
18 one, 1525, is identifying the high risk and  
19 getting them started on appropriate treatment.

20 This one is that you just measure the  
21 risk. And presumably, you measure the risk, you  
22 wouldn't start them on treatment. So to me, it

1 makes -- they are kind of asking, did you do it?  
2 They are complementary but it almost seems that  
3 what you are trying to get at is don't treat the  
4 patient that doesn't need it. Treat the patient  
5 that needs it. And how can you -- and it is a  
6 really important measure. So, how could you  
7 correct that?

8 MR. CHIU: Like I said, we can  
9 certainly take that idea of a paired I mean  
10 the only thing I would say, you know, kind of  
11 considering pairing it. The only thing I would  
12 say is one of the measures is being used -- I  
13 keep saying 1525, because they are both kind of  
14 related. 1525 is in PQRS QCDR, 1524 is not. And  
15 so if we do pair it, we just have to figure out  
16 logistically how we do that. That is something  
17 we can definitely take up.

18 It is easier probably, for us, to do  
19 a paired than a composite. A composite is a  
20 little trickier conceptually and things of that  
21 sort. I see a lot of people not agreeing, so  
22 that's -- I know sometimes NQF prefers us to do

1 composites but when we tried in some measures --  
2 some that you have seen, the Action Registry,  
3 there have been a few you have seen. But I think  
4 we decided not to do a composite but we can  
5 certainly take up a paired issue, take that back  
6 up.

7 No, I'm sorry. So the missing actually  
8 is interpreted as no. The options are just yes  
9 or no.

10 MEMBER DELONG: If that is incorrect,  
11 if missing is coded as no, then that has a huge  
12 impact on the CHADS score. Right?

13 MR. CHIU: That is correct.

14 MEMBER AL-KHATIB: But in the  
15 implementation of the Registry, at least with  
16 other NCDR registries, you could, if you had a  
17 performance measure and you determined that  
18 certain data elements are so crucial to the  
19 measure that you wouldn't accept the submission  
20 of the form by the practice, unless they complete  
21 those particular data elements. So, there is a  
22 way around that.



1 MR. CHIU: Right.

2 MEMBER AL-KHATIB: Thank you.

3 MR. CHIU: So, it is like the data  
4 quality program -- PINNACLE's function is a  
5 little different than the inpatient setting. But  
6 the inpatient setting is a little bit more robust  
7 but there is, what they call data quality  
8 program. Where there are certain elements that  
9 are truly key elements, variables and things of  
10 that sort. I would say Cath is probably the most  
11 robust. But those basically you would have, in  
12 most Caths, a certain amount of threshold. 80  
13 percent or something like that for certain key  
14 elements, LEVF, heart failure, things of that  
15 sort. You can miss a few times but if you are  
16 missing too many of them, you basically don't  
17 pass, basically green, if you will. So, they  
18 can't even get through getting --

19 MEMBER AL-KHATIB: No, but the issue  
20 right here is capturing elements with the CHADS  
21 score.

22 MR. CHIU: Right.

1                   MEMBER MITCHELL: Jensen, just for  
2 clarification. There are singular elements that  
3 comprise the thromboembolic risk factors that are  
4 yes/no. And then there is a separate data  
5 element that says thromboembolic risk factors  
6 assessed yes/no. True?

7                   MR. CHIU: Correct.

8                   MEMBER MITCHELL: Okay. And so the  
9 question here is it talks about the number of  
10 practices missing, the variable thromboembolic  
11 risk factors assessed. There are 33 who are  
12 missing that information. Would they then be  
13 coded no?

14                   I think this is why I am trying to  
15 link what Liz was saying to what is written in  
16 this code.

17                   MR. CHIU: If I remember, those would  
18 probably be coded as -- I see what you are trying  
19 to say.

20                   Yes, those would probably then be --  
21 those would be, I guess, ones that, if they were  
22 missing a lot of data, we would not be able to

1 capture.

2 MEMBER MITCHELL: And so the following  
3 question is that, since I left before this part  
4 of the project was completed, do you have a data  
5 auditing program in place for PINNACLE?

6 MR. CHIU: That is ongoing. It is not  
7 as robust as Cath in an inpatient setting. So,  
8 that, unfortunately, we do not have. I don't  
9 know what we cited here but that is something  
10 that we are working on in the PINNACLE setting.

11 It is a little bit tricky, not to give  
12 PINNACLE an out. But in the EHR environment, it  
13 is a little bit tricky to do chart audits, if you  
14 will, and things of that sort. That's something  
15 we are actively working on. I don't have an  
16 exact time when that will be sorted out but it  
17 something that we are there is a limitation in  
18 the outpatient setting.

19 And that is not just applicable to  
20 this one, but unfortunately, it is applicable to  
21 many of our measures that have been endorsed or  
22 are still under review right now.

1 CO-CHAIR GEORGE: George.

2 MEMBER PHILIPPIDES: So what Liz just  
3 mentioned, stirred some thoughts. So, here if  
4 data elements were missing, the hypertension,  
5 diabetes, and it is coded as no, sort of by  
6 default. It would change the CHADS score  
7 commission but this measure is not looking at  
8 CHADS score. It is not calculating CHADS score.  
9 It is only calculating what percentage of the  
10 time you gather the data, the parts for the CHADS  
11 score.

12 So, that wouldn't change what -- you  
13 guys are basically saying, if you don't document  
14 it, we are calculating it as if you didn't do it.  
15 And that probably makes sense for this.

16 However, on the next one, where there  
17 is an assumption that we have a CHADS score that  
18 is accurate and, based on that, we are going to  
19 see how you did as far as treatment. If you use  
20 the same methodology there, then we have  
21 problems. And I had not actually contemplated  
22 that until you mentioned that for this score.

1       So, and that is the most I can say before my  
2       brain is about to explode, I think, on that.

3               So, I think on this one -- I think  
4       there are three parts to treating A-fib  
5       correctly. One, is do you gather the data? That  
6       is this element. The second is, now that you  
7       have got the parts to the car, can you put it  
8       together and come up with a risk score? That is  
9       not being done here. It is actually not being  
10      done in the next one     I'll get back to that.  
11      The third part is, once the risk score is high  
12      enough, are you getting people, like you said, on  
13      proper anticoagulation?

14              The other one does the back end of  
15      that. It looks as if a risk score is calculated  
16      by the EMR, are they on anticoagulation? But it  
17      never assesses whether anybody stopped and said  
18      this is the CHADS risk score.

19              So, we have two ends of the process.  
20      What I think is missing is the middle part, the  
21      contemplative part, where someone says this is  
22      the risk. So, we can either --

1 MEMBER DELONG: But even --

2 MEMBER PHILIPPIDES: just let me  
3 finish because it is hard for me to think of  
4 this.

5 (Laughter.)

6 MEMBER PHILIPPIDES: So, we can either  
7 say this is not adequate or we can say this is  
8 the first good lead-off batter and we will go  
9 with this because there is a performance gap.  
10 People are not even documenting this stuff.  
11 Without documenting this, we can't get to the  
12 CHADS score. Those are the choices there, I  
13 think.

14 So, that is my feeling on this  
15 measure.

16 MEMBER DELONG: So, I agree with Sana  
17 that there is a workaround for the first one.  
18 But for the first one, if it is missing, it is  
19 not coded as missing. It is coded as no. So, in  
20 the overall assessment, it is coded. So it gets  
21 credit for being there when it is not.

22 MEMBER PHILIPPIDES: Correct. So,

1 missing data is coded as --

2 MEMBER DELONG: As no, and present.

3 MEMBER PHILIPPIDES: So then, this  
4 measure doesn't do anything based on the form.  
5 Right? Because all you want to know is whether  
6 it is assessed and there is no way to say it is  
7 not assessed. It is present or absent and it is  
8 assumed to be assessed. So, it would not be  
9 valid then. Right? Is that what we are saying?

10 MEMBER DELONG: But they are finding  
11 some that aren't there. So, I don't know how  
12 that happened.

13 MR. CHIU: If I could just add. I  
14 would say that 1525 is -- the denominator in 1525  
15 is the patients in 1524 that you have assessed.  
16 A lot of people that are missing, obviously,  
17 those individuals are missing.

18 But 1525, that measure is measuring  
19 anticoagulation medication given. If something  
20 is blank there, it is actually failed.

21 MEMBER DELONG: I think where we are  
22 confused is how do you come up with a not

1 measured, if every one of the six is either a yes  
2 or no, and if it is missing, it gets coded as  
3 node?

4 MR. CHIU: So the assessment score --  
5 if I could just answer really quickly. If the  
6 assessment score is a yes, and thromboembolic  
7 risk factors is yes, that is the denominator of  
8 the anticoagulation.

9 If somebody decides not to give a med,  
10 any of the oral anticoagulants, dabigatran,  
11 warfarin, all those others. If that is blank,  
12 that is actually performance fails. Because in  
13 measures --

14 MEMBER DELONG: Now, you are talking  
15 about 1525.

16 MR. CHIU: That is what I am saying.  
17 So, that one -- I think you alluded to, but that  
18 second measure is different than 1524. It  
19 actually is. 1525 is different than 1524. If  
20 you are leaving that blank, that is actually  
21 performance failed. Because the point of the  
22 second one is giving the medication.



1                   MEMBER DELONG: I am talking about the  
2 first one.

3                   MEMBER HOLLANDER: So, I am going to  
4 read right from the PINNACLE form and we are  
5 going to, I think, solve this problem, which is  
6 the unfortunate answer.

7                   So diabetes, in an example, the coding  
8 instructions are: Indicate if the patient has a  
9 history of diabetes, regardless of duration or  
10 disease or a need for anti-diabetic agents, and  
11 the selection choices are only no or yes. Which  
12 means you can't say they didn't document it,  
13 which means that this measure can't document  
14 whether information is missing.

15                   (Simultaneous speaking.)

16                   MEMBER HOLLANDER: But nowhere in the  
17 instructions does it say, you can leave it blank.  
18 So, if I am a coder -- I am looking at the Coder  
19 Data Dictionary right now. And that is what the  
20 Coder Data Dictionary says. It doesn't say I  
21 have a choice to leave it missing. So, some  
22 people may be doing that but that is not in the

1 directions in how to code it.

2 CO-CHAIR GEORGE: I think some of this  
3 conversation pertains to how it is implemented in  
4 a system, which we don't necessarily have to be  
5 so concerned about. We can just provide that  
6 information so that maybe clarification can be  
7 updated.

8 MEMBER DELONG: But the report they  
9 presented is based on that database also.

10 MR. CHIU: The testing, that is  
11 correct.

12 CO-CHAIR KOTTKE: And this may have  
13 huge implications of not having or not recorded.  
14 When we were doing this for a history of  
15 myocardial infarction -- this was a hell of a  
16 long time ago when I was a fellow, but case  
17 fatality rate for yes, prior history, was 12  
18 percent. The case fatality rate for no was 12  
19 percent. The case fatality rate for not recorded  
20 was 18 percent.

21 You know, you just can't record it as  
22 not no.

1                   MEMBER HOLLANDER: I now don't know  
2 what I am interpreting, which is actually back to  
3 at least the reliability.

4                   CO-CHAIR GEORGE: So yes, we are still  
5 talking about reliability.

6                   MEMBER HOLLANDER: So, I really just  
7 have no idea how to interpret a no answer at this  
8 point, which makes it really hard to have some  
9 confidence in the reliability of the data.

10                  I mean I suppose if there was  
11 something up-front that said, if it is not yes or  
12 no, leave it blank. That would be great, but  
13 that is not provided in the data dictionary, or  
14 at least the portion of it that we have access  
15 to.

16                  CO-CHAIR GEORGE: And I agree but we  
17 are not telling them how to implement PINNACLE.

18                  MEMBER HOLLANDER: No, but --

19                  CO-CHAIR GEORGE: We are telling them  
20 this could be a potential issue, depending on how  
21 you have it coded and implemented in your system.

22                  MEMBER HOLLANDER: Well, but it is

1 our job to say whether we believe the  
2 measurements and I am saying that if I don't  
3 see direction to say leave it missing, if it not  
4 addressed. I don't have any way that I could say  
5 this is reliable or valid because the  
6 instructions I see force you into a yes or no  
7 answer and both a yes and a no answer means they  
8 addressed it.

9 So, I don't see a way to document it  
10 is not addressed.

11 MEMBER MITCHELL: So if you look, in  
12 that same document that you were referring to,  
13 there is a measure called thromboembolic missed  
14 factors assessed. And the actual definition of  
15 this is indicate if the patient's thromboembolic  
16 risk factors for AF or AF flutter were assessed  
17 and documented in the chart. And then the  
18 answers are yes with, in parentheses, all risk  
19 factors were assessed. Two, no. Medical reason,  
20 two, no. Patient reason, four, no. System  
21 reason.

22 So, the question is, this data

1 element, in and of itself, just about answers his  
2 question here about whether or not thromboembolic  
3 risk factors were assessed because it  
4 specifically asks the question yes/no.

5 What we are talking about right now is  
6 each individual measure, whether or not age --  
7 all the different, six different, risk factors  
8 were individually documented. There is a  
9 failsafe in quotation marks, in the data set  
10 itself, that specifically asks the question about  
11 all six risk factors.

12 This is separate, a completely  
13 separate data element. It is not derived -- it  
14 is an absolute data element that you have to fill  
15 out. At least that is how I built it.

16 CO-CHAIR KOTTKE: So, I now found that  
17 but there is no instructions on -- it says all  
18 risk factors. It doesn't say all of CHADS2 risk  
19 factors. It is whatever somebody thinks is  
20 there. We don't have reliability testing. We  
21 don't have reliability testing as far as I know  
22 for that, as a matter of fact, I couldn't even

1 find that measure on the case report form but I  
2 find it in the data dictionary.

3 CO-CHAIR GEORGE: So, we do have the  
4 signal-to-noise.

5 MR. CHIU: We have that -- at least in  
6 the PINNACLE data collection form, on the bottom,  
7 we do note that the six factors have to be the  
8 ones you are using. Obviously, we agree the  
9 limitation is, the score is not, we don't  
10 actually have a score at this point.

11 MEMBER BRIGGS: So, I just have one  
12 comment on that. This measure was approved in  
13 2012 and you have been collecting data on that.  
14 And we are talking about this measure being a  
15 process or a baby step. If this was already  
16 approved in 2012 and we still aren't calculating  
17 a CHADS score, isn't the next thing that we  
18 should be doing actually the CHADS score? So,  
19 that is what we should be doing now, rather than  
20 saying let's continue this measure the way it is.

21 MS. HIBAY: Do you mind if I provide  
22 a little bit of clarity for the missing data? I

1 think it is actually quite easy, just to  
2 remember, we are going to focus on the measure  
3 here that is in front of us as we continue to  
4 talk.

5           So S22, missing data. This is what  
6 the developer provides: If data required to  
7 determine if an individual patient should be  
8 included in a specific performance measure based  
9 upon defined criteria is missing, those cases  
10 would be ineligible for inclusion in the  
11 denominator and, therefore, the case would be  
12 deleted. So, you don't have all the data  
13 elements related to an encounter or the patient  
14 population. Right? Okay.

15           If data required to determine if the  
16 denominator-eligible patient -- so now you know  
17 your population, qualifies for the numerator.  
18 The numerator here is do you have six risk things  
19 documented.

20           So again, if denominator-eligible  
21 patients qualify for the numerator, or has a  
22 valid exclusion or exception -- if it is missing,

1       these cases would represent a quality failure.

2       That is an answer to your question. they not

3       thrown out of it.

4               MEMBER DELONG: Sorry. I think Sana  
5       made a great point. There is a workaround here.  
6       But what you are saying is it has to show up in  
7       the file as missing and that is what we are  
8       having a problem with, because it doesn't show up  
9       as missing in the coded file. It defaults to  
10      zero if it -- if it is not filled in, it defaults  
11      to zero.

12             But as Sana said, there is a  
13      workaround. They can fix that. And as Kristi  
14      said, if we accept that all of the CHADS  
15      measures, all six of them, are incorporated in  
16      that summary score then that fixes it. But  
17      missing doesn't show up and that is the problem.

18             MS. JOHNSON: So, I wonder. I'm  
19      confused now, unfortunately. I think I hear that  
20      there are six data elements that go into a CHADS  
21      score and there is boxes that you would check or  
22      not, depending on your patient. And then there



1 is a seventh box that says did you or did you not  
2 assess it. So, my question for the developer is  
3 are you basing this measure on that seventh box?

4 MR. CHIU: 1524, yes, we are basing it  
5 on that.

6 MS. JOHNSON: So, on that one box that  
7 is yes or no -- or actually it is not yes or no.  
8 There is a few other things. Okay.

9 MR. CHIU: It is basing it on that and  
10 the six -- all those seven, but again, it doesn't  
11 actually have a score itself, the exact score.  
12 It is basing all the seven -- so all seven, if  
13 something is missing, there is still that issue  
14 as you are talking about, but it is going on that  
15 yes/no, for environmental risk factors, and all  
16 those elements need to be there.

17 So, the stroke, TIA, diabetes, and all  
18 those other things.

19 MS. HIBAY: So just a clarifying  
20 question. So if any of those seven boxes, six  
21 being the risk factors, the other one being the  
22 yes, they are all there. If any of those are

1 blank, it is a quality failure.

2 MR. CHIU: Although we will check in  
3 our notes, I am pretty certain that if something  
4 is blank it is a failure because the thought is  
5 that they need to be documenting the measure -- I  
6 mean documenting the risk factors. The point is  
7 so low, people aren't documenting this measure.  
8 So, if they are not documenting, you can assume  
9 that they are not doing their job.

10 MS. JOHNSON: Right, Nursing 101. If  
11 it is not documented, it is not done. I'm sure  
12 Medicine 101 as well.

13 MEMBER HILLEGASS: Okay, so I'm  
14 confused because on 2(b)(7) under Missing Data,  
15 it states here the developer notes that in the  
16 PINNACLE registry, most missing values are  
17 interpreted as no.

18 So, I hear what you said, Sharon, but  
19 that contradicts what you are saying, I think.

20 CO-CHAIR GEORGE: Well again, I think  
21 it depends on how that is implemented. They say  
22 most, I'm not sure what most means, but you can

1 implement it as a checkbox where one has to be  
2 checked. If they are both unchecked, it is  
3 missing. Or you can implement it as a radio  
4 button, where it has a default and you have to  
5 change it. So, it depends how they implemented  
6 that in the coding that -- how they built their  
7 system.

8 MEMBER HILLEGASS: But the developer  
9 is reporting this.

10 MR. CHIU: Which section are you  
11 referring to?

12 MEMBER HILLEGASS: Under 2(b)(7), page  
13 6, on 1524 under Missing Data. Page 6, 2(b)(7).  
14 It is called Missing Data.

15 MR. CHIU: Yes, I actually think that  
16 is inaccurate, the description, the 2.2(b)(7),  
17 because there is another section in S -- that  
18 section you guys pulled up earlier, S-33.  
19 Sharon, you pulled up something in S.

20 MS. HIBAY: I did, it was S-22, but if  
21 you go to page 39 on the full, it says in  
22 PINNACLE, missing values are interpreted as no.

1       So, you are correct that there is conflicting  
2       information here.

3               So, you have the S-22, which says they  
4       are a quality failure if they are blank. And you  
5       have in 2(b)(7)(1), which is on page 39, it says  
6       in PINNACLE missing values are interpreted as no  
7       for most variables.

8               MR. CHIU: So, I think that we will  
9       have to take this testing back just to see why  
10      there is incongruency here. Just when we  
11      submitted this last year -- this was submitted a  
12      year ago, or I actually didn't submit this  
13      document. So, we will have to take this back in  
14      terms of the testing.

15              But the intent of the measure is that  
16      you have assessment and all those variables need  
17      to be present. If they are missing, that is  
18      actually performance failure because you need to  
19      be actually having those things noted, realizing  
20      we don't have the score. That is a limitation.

21              CO-CHAIR GEORGE: Are there any new  
22      issues to bring up in regards to reliability?

1                   MEMBER HOLLANDER: It is sort of a new  
2 issue. I don't know what I would be voting on,  
3 and I am being totally serious. I actually think  
4 that sort of I throw it out there for a proposal  
5 is whether we should defer this one, too, from  
6 this point forward.

7                   If there is no missing data, the whole  
8 measure can't go through. It is totally invalid.  
9 It is fatally flawed. And I don't know whether  
10 that is the case. And so, I can't vote because  
11 nobody could tell me how this stuff is coded and  
12 I see that there is a good noise to signal --  
13 signal-to-noise ratio but now I don't know of  
14 what.

15                  And so if there is a great signal-to-  
16 noise ratio of meaningless stuff, it doesn't help  
17 me.

18                  CO-CHAIR GEORGE: So, I think we do  
19 need to vote on what we have before us today. I  
20 think the developer had one last comment.

21                  DR. HO: I mean I guess the question  
22 here is about reliability of the measure

1 regardless of where it is implemented. So, I  
2 guess, isn't the question whether this can be  
3 assessed in any healthcare system, not just  
4 whether it is in PINNACLE or not? Is that  
5 correct?

6 CO-CHAIR GEORGE: In a reliable basis  
7 that you are assessing.

8 DR. HO: Right.

9 MEMBER VIDOVIK: If I understand you,  
10 Mary, it doesn't have to be done in PINNACLE. It  
11 can be done at Department of Veterans Affairs,  
12 whatever, anything. Right?

13 CO-CHAIR GEORGE: Well, if there is no  
14 new issues to raise, I think we will go ahead and  
15 vote on reliability.

16 MS. LUONG: Polling for reliability  
17 starts now for measure 1524; 1 for high, 2 for  
18 moderate, 3 for low, and 4 for insufficient.

19 For reliability testing, it did not  
20 pass; 17 percent voted moderate, 28 voted low,  
21 and 56 voted for insufficient.

22 CO-CHAIR GEORGE: Okay, we'll move on

1 to validity.

2 MS. JOHNSON: No, actually since it  
3 did not pass reliability and this is a must-pass  
4 sub-criterion, we are going to stop discussion  
5 right now.

6 I think just since the developers are  
7 going to be here tomorrow, I think it might  
8 behoove us to let them look at their specs again,  
9 think about it. And if they can explain things a  
10 little bit better tomorrow, we can see if that  
11 might help.

12 I think part of it, at least in my  
13 mind, is I am not quite sure how this measure is  
14 being calculated. I still don't quite know that.  
15 I think that might be part of the concern. It is  
16 not the testing results. It is the precision of  
17 the specs and understanding how the specs work.  
18 That is the part of reliability that people are  
19 hanging up on.

20 MR. CHIU: Also, the reason we would  
21 like to back is there are multiple areas in the  
22 form where I see there is inconsistencies. So,

1 2(b)(7) you brought up and then earlier in S,  
2 page 6 there are some inconsistencies. So, we  
3 will take a look at that to see why there is  
4 inconsistency in how it is tested.

5 MS. HIBAY: Does that sound like a  
6 reasonable plan to the committee? Okay.  
7 Especially since the earlier voting was so  
8 stellar.

9 CO-CHAIR KOTTKE: Okay, 1525. Do we  
10 want to move forward or take a break is the  
11 question. We are 15 minutes past the break. We  
12 could take a 15-minute break right now and then  
13 come back. What's that?

14 (Simultaneous speaking.)

15 CO-CHAIR KOTTKE: Okay, the consensus  
16 is do 25. We will hear from -- is Joel on the  
17 phone? No. So, it is George and Mladen. The  
18 developers here can give us a quick -- which they  
19 have probably already done.

20 DR. HO: So, on 1525 is appropriate  
21 anticoagulation in patients at moderate to high  
22 risk for thromboembolic events and those with



1 atrial fibrillation. So, I mean we have alluded  
2 to this measure in the earlier discussion. And  
3 as you can see from the data that was provided,  
4 there is quite a bit of variability in terms of  
5 patients being on anticoagulation in those four  
6 moderate to high risk.

7 CO-CHAIR KOTTKE: Who is discussing  
8 this? Were you making motions there, George?

9 MEMBER PHILIPPIDES: I will start.  
10 So, this is, as we discussed, sort of the next  
11 step in sort of the A-fib treatment algorithm.  
12 This is looking at people with a documented, by  
13 electronic medical record a documented high CHADS  
14 score of one or above, people who should be on  
15 anticoagulation in the world of nonvalvular AF.

16 As far as evidence, as heard before,  
17 there were a lot of clinical trials citing the  
18 importance of anticoagulating high-risk A-fib  
19 patients. They relied heavily on the ACCF and  
20 AHA guidelines and ACCP guidelines. And I think  
21 the evidence is strong for this concept.

22 We then looked at, again, PINNACLE

1 Registry data from 2012 and I think one other  
2 year to look for opportunities for improvement  
3 and performance gaps. And that was cited, they  
4 estimated that roughly 59 percent -- pardon me?

5 CO-CHAIR KOTTKE: We're going to vote  
6 on evidence first.

7 MEMBER PHILIPPIDES: There was strong  
8 evidence.

9 CO-CHAIR KOTTKE: Okay. Anybody want  
10 to pile on? Okay, let's vote on evidence.

11 MS. LUONG: Evidence starts now for  
12 Measure 1525; 1 for high, 2 for moderate, 3 for  
13 low, and 4 for insufficient, and 5 for  
14 insufficient evidence with exception.

15 Evidence passes with 89 percent for  
16 high, 11 percent for moderate.

17 CO-CHAIR KOTTKE: It is so impressive  
18 it gets music.

19 (Laughter.)

20 CO-CHAIR KOTTKE: Okay, George,  
21 opportunity for improvement and disparities.

22 MEMBER PHILIPPIDES: So, I will go

1 quickly. So, again, they cited PINNACLE Registry  
2 data from 2012. The mean performance was about  
3 59 percent of these high-risk patients were  
4 appropriately anticoagulated but there is a  
5 wide-range of zero to like 99 percent with an  
6 inter-cohort score of about 22 percent. So,  
7 there was a gap and there was a range.

8           Interesting, there also was some data,  
9 not a lot but some data suggested that there were  
10 disparities of care in different groups. Men  
11 were treated more avidly than women. Non-African  
12 Americans less likely to be treated and patients  
13 with non-private insurance. So, there was a  
14 suggestion there of some disparities that we  
15 should all sort of know about.

16           CO-CHAIR KOTTKE: Are we ready to  
17 vote? It sounds like it.

18           MS. LUONG: Polling starts now for  
19 performance gap: 1 for high, 2 for moderate, 3  
20 for low, and 4 for insufficient.

21           One hundred percent for performance  
22 gap.

1 CO-CHAIR KOTTKE: Priority?

2 MEMBER PHILIPPIDES: High prevalence,  
3 high morbidity, high mortality, high cost, high  
4 priority.

5 MS. LUONG: Polling starts  
6 now for high priority: 1 for high, 2 for  
7 moderate, 3 for low, and 4 for insufficient.

8 One hundred percent for high priority.

9 CO-CHAIR KOTTKE: Scientific  
10 acceptability, numerator/denominator exclusions,  
11 beta source issues/concerns.

12 MEMBER PHILIPPIDES: So, I am not  
13 going to over numerator/denominator again. They  
14 are pretty straightforward I think. It is  
15 basically numerator people on Coumadin.  
16 Denominator, those over 18 with nonvalvular AF or  
17 A-flutter. That is pretty straightforward.

18 I think the exclusions warrant a  
19 little bit of discussion. I would like to hear  
20 what Mladen has to say about this. The medical  
21 exclusions, I think, were fine. Transient or  
22 reversible causes of pneumonia, surgery,  
pregnancy, I think that is right. There is no

1 rush to treat with anticoagulation, we agree.

2 On the appropriate medical exclusions,  
3 bleeding, allergy, absolutely. But I always get  
4 concerned when I see patient reasons in sort of  
5 italics that include economic, social, religious,  
6 noncompliance, and patient refusal and especially  
7 patient refusal as being an appropriate outcome  
8 always bothers me because one could make an  
9 argument, I think we have made this before, in  
10 the area of lipid management, that a system or a  
11 physician who takes time to educate a patient and  
12 goes over the risks and benefits might have less  
13 patient refusal.

14 And put another way, one way to game  
15 the system and not anticoagulate those who should  
16 be is to write the patient refused, when it  
17 really could be that there wasn't as much time  
18 and effort put into educating that patient.

19 They do give some data on this. I  
20 don't know if now is the time to get into that.  
21 Sixty percent of the physicians two years in a  
22 row in the Registry had no exclusions but of

1 those physicians who had exclusions, there is a  
2 wide range. And there were some physicians who  
3 used exclusions a lot and, in those physicians, I  
4 think it was 87 percent of them were patient  
5 exclusions, not medical exclusions.

6 So, again, it doesn't seem like there  
7 are many physicians who are using the exclusions  
8 but of those that do, most of those, the vast  
9 majority are on the patient side and again, that  
10 always worries me because I think that is sort of  
11 hard to document what is really going on there.  
12 So, that could be a source of dirtying up the  
13 data.

14 Mladen, any thoughts on that?

15 MEMBER VIDOVICH: That is always a  
16 problem. We run into this a lot with STEMI, with  
17 patient inclusion and why was I late with door to  
18 balloon time. And you always try to come up with  
19 some things to game the system. I don't know how  
20 to eliminate that. Maybe people have a good  
21 idea. It has to be there somehow because people  
22 do refuse anticoagulation frequently. They don't

1 have money or they don't have transportation.

2 You know how it is in practice.

3 So, I believe it, if it were up to me.

4 MEMBER AL-KHATIB: I want to second  
5 that as well. As a practicing  
6 electrophysiologist, I see a lot of patients with  
7 atrial fibrillation. We have these discussions  
8 about the benefits and risks of anticoagulants.  
9 And I can't tell how many times, after going  
10 through all of those and trying to convince the  
11 patient that should be on one, their answer to me  
12 is no, they we refuse. And they consistently  
13 refuse. We absolutely have to have that there.  
14 We don't have control over it.

15 MEMBER VIDOVICH: It is more common  
16 than not. You know how it is.

17 MR. CHIU: Can I add just really  
18 quickly just to their points, really fast? That  
19 is a good point, I think that he is bringing up.  
20 Some of our sets in terms of patient refusal,  
21 actually, that would be considered a performance  
22 not met, like cardiac rehab and like referrals

1 and things of that sort. Those are recently  
2 updated, those sets.

3 But like for medication we might be  
4 just a little bit more leery. I see your point  
5 about it being other the flip is like  
6 over-medication. And somebody simply doesn't  
7 want it, it is a med, there are some unintended  
8 consequences. So, that is why currently as it  
9 stands it is '08 and 2011 when A-fib gets  
10 updated, that issue will be discussed further  
11 about patient refusal. We still consider that an  
12 exception to the thing realizing you are going to  
13 have a few people that are arguably gaming the  
14 system. I can argue almost any measure can be  
15 gamed to some degree.

16 But that is something that will be  
17 taken up when we visit CHA2DS2-VASc and all the  
18 other things for the next A-fib update.

19 CO-CHAIR KOTTKE: Okay. Yes. Oh,  
20 sorry, Tom.

21 MEMBER JAMES: This kind of issue was  
22 discussed at one of the AQA meetings. And the



1 consensus from that particular meeting, ACC was  
2 involved, was that patient refusal is  
3 appropriate, should be included as an exclusion  
4 but it should be monitored and tracked by a  
5 doctor for public reporting purposes.

6 MR. CHIU: We do track the exception  
7 rates of this. Hence, we have broken them into  
8 the buckets but those are tracked. Or at least  
9 we recommend they are tracked if people use our  
10 measure and other ones.

11 CO-CHAIR KOTTKE: Linda?

12 MEMBER BRIGGS: I just wanted to speak  
13 to the denominator statement because I think it  
14 is not as clear as we would like it to be because  
15 it talks about one or more high-risk factors or  
16 more than one moderate risk factors.

17 For CHADS2, there are no like high or  
18 moderate. It is in CHA2DS2-VASc, there are those  
19 additional things that we added. The high ones  
20 are the stroke, TIA, other thromboembolism. So,  
21 I am just saying that there is a lack of clarity  
22 there that maybe you want to clarify the

1 denominator statement a little better, maybe as a  
2 particular part number of risk factors or what.

3 Right now it says high or moderate.

4 And I know what CHADS is and I had to go look  
5 that up because I had no idea where I would find  
6 that. And it is really when you look at  
7 CHA2DS2-VASc versus CHADS.

8 MR. CHIU: What page are you referring  
9 to? The reason I bring that up is one of our  
10 sections is --

11 MEMBER BRIGGS: Oh, I'm sorry.  
12 Actually, it is on page two, where it has the  
13 numerator and denominator statement and it is  
14 actually in the beginning of the specification as  
15 well.

16 MR. CHIU: Okay. So, it must have  
17 been cut off. So, it is an error, an oversight  
18 in our writing this but the denominator actually  
19 is probably not even here but we actually do  
20 specify it in our published document what  
21 moderate is and what high-risk is delineated.  
22 So, the high-risk being the prior stroke and the

1 moderate being the other.

2 MEMBER BRIGGS: It is delineated  
3 elsewhere. Okay.

4 MR. CHIU: So, I apologize it wasn't  
5 written here.

6 (Simultaneous speaking.)

7 MR. CHIU: Yes, 2006 guidelines.

8 MEMBER BRIGGS: Okay.

9 MR. CHIU: We actually cited directly  
10 to the guidelines and write it down. It is like  
11 a table that I guess I think we maybe tried to  
12 embed and we weren't able to get the table in  
13 there. So, oversight on our part.

14 MEMBER PHILIPPIDES: So, they  
15 performed reliability testing based on the  
16 PINNACLE data and the ICD-9 codes. I think it  
17 was a signal to noise ratio at the level of  
18 performance measure and it had a very high score  
19 of like 0.99.

20 So, it seems like for reliability  
21 testing, it was reliable. And should we vote on  
22 reliability?

1 CO-CHAIR KOTTKE: Yes, let's vote on  
2 reliability.

3 MS. LUONG: Voting for reliability  
4 starts now; 1 for high, 2 for moderate, 3 for  
5 low, and 4 for insufficient.

6 So for, reliability we have 47 for  
7 high; 47 for moderate; and six percent for low.  
8 So, it passes.

9 CO-CHAIR KOTTKE: Validity and threats  
10 to?

11 MEMBER PHILIPPIDES: So, in my  
12 opinion, the specifications outline align with  
13 the evidence. I could not find any formal  
14 validity testing. They basically leaned on face  
15 validity. They cited the fact that they polled  
16 certain ACC and AHA committee members. And there  
17 was a high number of those guys and gals who felt  
18 that this was valid and that it basically  
19 outlined good quality.

20 We talked about the threats to  
21 validity in our discussion about the exceptions  
22 and exclusions. So, I think we sort of went over

1 that and feel okay with that. And as I mentioned  
2 before, the data support the idea that there were  
3 meaningful differences in regards to performance  
4 across a pretty large registry. So, overall, I  
5 had not major problems with validity, as  
6 outlined.

7 CO-CHAIR KOTTKE: Anybody have the  
8 urge? Seeing none, let's vote on validity.

9 MS. LUONG: Voting for validity starts  
10 now; 1 for high, 2 for moderate, 3 for low, and  
11 4 for insufficient.

12 Validity passes with 18 percent for  
13 high and 82 percent for moderate.

14 CO-CHAIR KOTTKE: Feasibility.

15 MEMBER PHILIPPIDES: So, this again  
16 was a review of mostly electronic medical  
17 records. I believe that is correct, guys.

18 And they mentioned that the people of  
19 value in the Registry in the review didn't have  
20 quote, unquote, any major problems or ask to  
21 changing anything. I had a hard time if there  
22 problems in getting specific pieces of the data.

1 I might not have looked in the right place. I  
2 looked in the appendix as well.

3 So, I couldn't find exactly what  
4 percentage of the time they missed certain data  
5 elements, so just the broad statement that there  
6 was no major issues in extracting the data. And  
7 similarly there was no mention of sort of cost of  
8 extraction or time of extraction that I could  
9 find.

10 And I don't know if the developers  
11 want to comment on that.

12 MR. CHIU: I'll comment on the cost  
13 first. We don't really have a hard and fast rule  
14 in terms of the cost. And I will say the  
15 PINNACLE, unlike all the other registries, one  
16 advantage it has is that it is actually free to  
17 physician offices, so there is no cost  
18 associated. Obviously, the real cost is the  
19 nurse or somebody actually pulling the data.  
20 That is the real cost there. We didn't actually  
21 quantify the time it would take for this specific  
22 measure.

1           The thought, obviously it is biased on  
2   our part, we thought that this measure was pretty  
3   much easy to pull because a lot of this stuff you  
4   already pretty much have, the diagnoses and  
5   things of that sort. It should be easy to pull,  
6   like Cerner and Epic and all those others. So,  
7   that is kind of what we think in terms of the  
8   cost.

9           And then your first point, in terms of  
10   the missing data we will probably have to get  
11   back to you. That relates to the earlier  
12   question about assessment on the risk factors.  
13   So we can get back on specific numbers. I don't  
14   think there is a lot of missing data but we can  
15   certainly check, at least on the few key elements  
16   needed for this measure and get to your point, I  
17   think, Dr. DeLong about what we do with the  
18   missing data because there is a little  
19   incongruence in the form.

20           MEMBER PHILIPPIDES: I think in regard  
21   to the missing data, in this metric that makes  
22   sense that if somebody doesn't comment on whether

1 or not they anticoagulated or not, then that is a  
2 no. This one it fits with the classic nursing or  
3 doctor rule, that if you didn't document it, you  
4 didn't do it.

5 So, my suspicion is that 2(b)(7)  
6 pertains to this metric and not to the last one  
7 on an individual element level. I am just  
8 suspicious that that is what you are going to  
9 find.

10 MR. CHIU: Yes, we are going to  
11 confirm it. This one, we are pretty certain that  
12 if you are not document, you are failing. So,  
13 the point is you need to be giving the  
14 anticoagulant.

15 MEMBER PHILIPPIDES: So, those are my  
16 comments in regards to feasibility.

17 CO-CHAIR KOTTKE: Seeing no movement,  
18 let's vote on feasibility.

19 MS. LUONG: Polling for feasibility  
20 starts now; 1 for high, 2 for moderate, 3 for  
21 low, and 4 for insufficient.

22 Feasibility passes with 29 percent for



1 high and 71 percent for moderate.

2 CO-CHAIR KOTTKE: Usability and use.

3 MEMBER PHILIPPIDES: So in regards to  
4 usability, at present, this measure is not being  
5 publicly reported. It is being used in PINNACLE,  
6 I guess in some ACC practice improvement  
7 pathways. It is sort of percolating on that  
8 level.

9 There is mention that this might be  
10 picked up in CMS in the future and it is sort of  
11 a more robust for maybe part of the PQRS complex  
12 of metrics. But that is sort of where it is. It  
13 is a little bit early on, I guess, in its  
14 mention.

15 MR. CHIU: When we wrote this, this  
16 was actually -- just to give you a little  
17 history, this was actually written I think in  
18 December 2013. And it was supposed to be  
19 reviewed last time and it wasn't. So, some of  
20 this are the factors of it being old.

21 So, hence, this is actually, one thing  
22 we can say, I think we wrote this as we weren't

1       sure if it was. Now, we are certain it is in  
2       PQRS. This measure, 1524 is a piece of this.

3               MEMBER PHILIPPIDES: Okay, so I should  
4       have read the more PQRS. It's in there. Thank  
5       you.

6               And overall, I have no major issues  
7       with usability.

8               CO-CHAIR KOTTKE: Unintended  
9       consequences?

10              MEMBER PHILIPPIDES: I don't have any.

11              CO-CHAIR KOTTKE: Let's vote on  
12       usability and use.

13              MS. LUONG: Polling starts now for  
14       usability and use: 1 for high, 2 for moderate, 3  
15       for low, and 4 for insufficient information.

16              Usability and use criteria passes with  
17       41 percent for high and 59 percent for moderate.

18              CO-CHAIR KOTTKE: We will vote on the  
19       overall.

20              MS. LUONG: For overall suitability  
21       for endorsement, polling starts now; 1 for yes  
22       and 2 for no.

1 Measure 1525 passes for overall  
2 suitability for endorsement, with 100 percent.

3 CO-CHAIR KOTTKE: Any issues of  
4 competing measures, George?

5 MEMBER PHILIPPIDES: There are two  
6 competing metrics out there but both of those  
7 have to do with patients who have already  
8 suffered a stroke and they are both, I believe  
9 in-patient to traditional care medicine  
10 out-patient based. So, it really is a slightly  
11 different population. This is primary prevention  
12 trying to stop the first row. So, I don't think  
13 there is a major issue.

14 CO-CHAIR KOTTKE: Than you. It is  
15 break time. Fifteen minutes.

16 (Whereupon, the above-entitled matter  
17 went off the record at 3:21 p.m. and resumed at  
18 3:33 p.m.)

19 CO-CHAIR GEORGE: This is Measure  
20 2461. Our developers are here. I just will let  
21 everyone know that Sana has recused herself from  
22 this measure. And the discussants are Carol,

1 Joseph and Tom James. So, developers, if you  
2 will introduce the measure.

3 DR. KUSUMOTO: Great. Thank you very  
4 much for this opportunity. My name is Fred  
5 Kusumoto. I am from the Mayo Clinic. I am an  
6 electrophysiologist here representing Heart  
7 Rhythm Society. So, thank you again. I  
8 appreciate it and do want to acknowledge that  
9 Sana is one of the principal developers for this  
10 and actually recording some of her work here.

11  
12 So, this first data measure, 2461,  
13 really looks and gets at this sort of first  
14 in-person evaluation of someone with a new  
15 implantable device. Remember that a lot of  
16 people are implanted with devices, 200,000 to  
17 300,000 people and we are really talking about  
18 new devices. And the reason we want to focus on  
19 new devices is once these devices get implanted,  
20 it is important to realize they then shift their  
21 environment of care to an outpatient situation  
22 where the monitoring then and the care of that

1 patient then changes over time because a device  
2 is something that can be prescribable or changed.  
3 In other words, this isn't an inert thing. It is  
4 not like getting a hip or a prosthesis of some  
5 kind. This really is a new tool that then can be  
6 used and taken care of.

7 So, a couple things. So, let's take  
8 a look at the evidence base, briefly, before you  
9 guys speak about it. Remember that the in-person  
10 evaluation has been around since the 1990s. It  
11 has been endorsed not only by Hearth Rhythm  
12 Society but also by the Canadian Society of  
13 Cardiology. The reason for this is because this  
14 first visit is critical first of all for  
15 coordinating care but also because the great  
16 majority of complications occur during this first  
17 month anywhere from two to five to six percent of  
18 lead issues where in fact lead problems get  
19 recognized.

20 This first visit is also very critical  
21 and unfortunately, there is a big gap for care.  
22 Sana has done wonderful work looking at the

1 Medicare sample where there has been 40,000  
2 patients with devices in place where, in fact,  
3 only 40 percent of those patients actually  
4 received the appropriate guideline-directed  
5 follow-up.

6 In addition, there is significant  
7 consequences to not having this appropriate  
8 follow-up for the same group in a group of  
9 patients with ICDs. So, these are devices then  
10 to defibrillate patients when they have sudden  
11 cardiac death or ventricular arrhythmias. In a  
12 group of 70,000, in fact, again, 40 percent of  
13 patients did not get appropriate follow-up and  
14 those patients, when you looked at one-year,  
15 two-year, three-year mortality had a seven  
16 percent increase in mortality.

17 This is not just in isolation. If you  
18 look in the Canadian database, again, 10,000  
19 patients from Ontario, in fact who had ICDs, they  
20 have much better follow-up, 86 percent of those  
21 patients, in fact, got appropriate follow-up  
22 within this time period. But in fact for those

1 patients who did not get follow-up, there is a 30  
2 percent increase in mortality in that group.

3 So, critical, a gap, a lot of  
4 variability and very impactful.

5 CO-CHAIR GEORGE: Thank you. And who  
6 is -- Carol?

7 MEMBER ALLRED: Thank you. Now, can  
8 you hear me? Great. Thank you for that  
9 wonderful introduction. You really set the  
10 stage.

11 Okay, can you hear me now? All right,  
12 very good.

13 I think that was a great introduction  
14 and set the stage well for the measure. I was  
15 particularly struck by the first follow-up visit  
16 being so important because of the complications  
17 and because of the education of the patient and  
18 their family. It is a wonderful time for them to  
19 finally get their act together and ask questions.  
20 This is a personal experience. I do have an ICD  
21 implant and between the time of implant and that  
22 first visit, lots and lots of input from people

1 with things that some were true, some were not  
2 true, but everyone had an opinion about what was  
3 going on and what I needed to know. So, it was  
4 good.

5 I would agree 100 percent with the  
6 numerator statement here. I would disagree with  
7 you on the denominator statement in that I think  
8 the person with a repeat procedure still needs  
9 that follow-up visit because the chances for  
10 infection, the chances for lead movement, the  
11 chances for any number of things, and sometimes  
12 just the reprogramming. I had a different device  
13 put in. I had extra leads put in. I needed that  
14 same follow-up that everybody else did. So, I  
15 would include those people.

16 CO-CHAIR GEORGE: Can you speak to the  
17 evidence right now?

18 MEMBER ALLRED: The evidence really  
19 doesn't address the follow-up person with a  
20 repeat procedure. It is one of the exclusions in  
21 there.

22 The evidence itself is one study with



1 a fairly small number. I thought could have been  
2 a little bit better evidence but it was very good  
3 and I thought what was there was accurate.

4 DR. KUSUMOTO: Great, thank you. And  
5 let's bring up, when we talk about the  
6 denominator statement because your point is  
7 incredibly well taken with regard to thinking  
8 about this problem, about this difficulty because  
9 those patients who have devices in place are an  
10 incredibly important group. The reason, just as  
11 a quick aside, just to acknowledge this important  
12 point, is that it suddenly makes our group very  
13 variable. And so that it makes it somewhat more  
14 difficult.

15 MEMBER ALLRED: Absolutely.

16 CO-CHAIR GEORGE: Tom, do you have a  
17 comment on the evidence?

18 MEMBER JAMES: Yes, and there is  
19 nothing like meeting with the developer to start  
20 changing some of my thoughts but much of it has  
21 to do with definitions. Because when I started  
22 looking at the evidence and started thinking in

1 terms of, from the title, in-person evaluation  
2 and then looking at the EKOS study -- you didn't  
3 mention that one.

4 DR. KUSUMOTO: I didn't. I was going  
5 to let you do it.

6 MEMBER JAMES: Okay, this is where we  
7 had that discussion. But the part where the EKOS  
8 study looked at ambulatory measurement from  
9 remote monitoring, as Fred was pointing out, this  
10 was subsequent to an in-person evaluation.

11 I had gone to the Heart Rhythm Society  
12 and the European version to look at what evidence  
13 they had. Again, so much of this was  
14 definitional, I was convinced from speaking that  
15 if I changed the definitions to something that a  
16 general internist like me could understand, then  
17 I think we have got good solid evidence behind  
18 this one. So, I would be supportive on the  
19 evidence level.

20 CO-CHAIR GEORGE: Tom?

21 CO-CHAIR KOTTKE: So, you have just  
22 confused me. What is the problem you have with

1 the definition?

2 MEMBER JAMES: The definition, it says  
3 in-person and yet it looked like from some of the  
4 studies, it was done by remote monitoring. But  
5 the point was that that study started after the  
6 in-person visit. And secondarily, it is the  
7 definition of who is an appropriately trained  
8 clinician. Because I thought well, heck, I see  
9 people who have had a pacemaker in my office. I  
10 can't do anything about it but I know they are  
11 there.

12 So, if we have the clarification on  
13 the training level, who is the appropriate one,  
14 and then finally what is missing from the  
15 evidence what actually happens during that  
16 meeting, that in-person evaluation. And that is  
17 better defined in this document than it is in the  
18 measure.

19 And I think just adding those as  
20 definitional elements will satisfy this.

21 CO-CHAIR GEORGE: Any other comments  
22 on the evidence? Ellen?

1                   MEMBER HILLEGASS: The only comment I  
2                   had was I was concerned about the two- to  
3                   twelve-week window. I thought twelve weeks was  
4                   too long but I know you base your statement on  
5                   the evidence and the evidence did say two to  
6                   twelve weeks. But I still believe that is too  
7                   long.

8                   DR. KUSUMOTO: I can't help but agree  
9                   with you. So, our practice at the Mayo Clinic is  
10                  ten days, seven to ten days. And so, there is no  
11                  question I absolutely agree with you.

12                  Having said that, the evidence which  
13                  then goes with the consensus statement is two to  
14                  twelve weeks. And because of that, that is where  
15                  our evidence is, that actually Sana's study has  
16                  looked at, as have others, the Ontario database  
17                  and also Hess et al. when they looked at the NCDR  
18                  database and really called that out.

19                  So, when you start to look at evidence  
20                  with large numbers greater than 100,000 patients,  
21                  it really, sadly, is two to twelve weeks, even  
22                  with our personal issues associated with that.

1                   MEMBER HILLEGASS: Yes, I wish there  
2 was evidence to show a shorter amount of time  
3 because I really think you need that.

4                   MEMBER ALLRED: I agree with that,  
5 too, because if you are going to have an  
6 infection, you need to catch it sooner, rather  
7 than later.

8                   DR. KUSUMOTO: And that is the one  
9 thing I wanted to emphasize in this measure. It  
10 is really a care coordination measure. It really  
11 is making sure that we transition and put  
12 responsibility on the implanting physician that  
13 hey, if you are going to implant it, you are  
14 responsible for then making sure that this  
15 patient sees someone at some period of time.

16                   MEMBER ALLRED: I agree.

17                   CO-CHAIR GEORGE: If there are no  
18 other comments, we will vote on the evidence.

19                   MS. LUONG: Polling for evidence  
20 testing starts now. I'm sorry, polling for  
21 evidence starts now: 1 for high, 2 for moderate,  
22 3 for low, and 4 for insufficient, and 5 for

1       insufficient evidence with exception. And this  
2       is for measure 2461.

3               For this measure, 38 percent voted  
4       high and 63 voted for moderate.

5               CO-CHAIR GEORGE: Okay, we will move  
6       on to performance gap and disparities.

7               MEMBER ALLRED: Okay, performance gap.  
8       There is definitely a performance gap. I think  
9       only 42 percent of patients actually received  
10      that first follow-up visit during that period.  
11      So, that is an opportunity to improve.

12              There is some disparities information  
13      that indicates that white Anglo-Saxon people have  
14      a higher incidence of having that follow-up visit  
15      than minorities do. So, that is an important  
16      area. We need to address that disparities gap.

17              MEMBER JAMES: I would corroborate  
18      that from our own data within a Medicaid plan.

19              CO-CHAIR GEORGE: Any other comments  
20      or discussion? If not, we will vote.

21              MS. LUONG: Polling for performance  
22      gap starts now; 1 for high, 2 for moderate, 3

1 for low, and 4 for insufficient.

2 For performance gap, it passes with 81  
3 percent for high and 19 percent for moderate.

4 CO-CHAIR GEORGE: And priority.

5 MEMBER ALLRED: It is a high-priority  
6 item. It is a growing area because there are  
7 like 55 percent more people with implants in the  
8 last ten years. So, currently, there are 2.9  
9 million people in the United States with  
10 implants.

11 I think it is an expensive area and,  
12 obviously, patients without good care aren't  
13 going to do well.

14 CO-CHAIR GEORGE: Comments?

15 MEMBER DELONG: I have a question out  
16 of total ignorance. Are these procedures all  
17 sort of equivalent in their need for follow-up  
18 and their risks?

19 DR. KUSUMOTO: So, I can answer that  
20 with regards to the sort of clinical need. You  
21 know certainly we have sort of one-lead,  
22 two-lead, and three-lead models of devices. In

1 fact, this first follow-up, although you are  
2 going to recognize more lead issues, obviously if  
3 you have more, the more leads you have, the more  
4 likely that you are going to run into issues. As  
5 Ms. Allred pointed out, the big issue here is  
6 this change in care environment. So, I would  
7 make the argument that even though there is some  
8 complexity associated with it, you are more  
9 likely than to find problems let's say with  
10 defibrillators compared to pacemakers because  
11 those are designed, as Janey said to be pacemaker  
12 pluses, right, the plus is the defibrillation  
13 portion.

14 The big issue that comes here that the  
15 importance of this measure really is making sure  
16 that the patient is touched personally and some  
17 of these questions can be answered.

18 MEMBER JAMES: Two responses. First,  
19 as a clinician, the ability to follow-up and  
20 ensure that the questions are answered and that  
21 patients understand, helps to generate that  
22 compliance. We talked about that with drugs



1 previously. The same thing applies with devices  
2 to be used appropriately.

3           Secondarily is a health plan. This is  
4 considered an expensive type of investment in a  
5 patient. you want to make sure, as a health  
6 plan, as a payer, that you are protecting that  
7 investment. Doesn't that sound terrible?

8           MEMBER ALLRED: No, it is not  
9 terrible. I think it is great. Absolutely.

10           CO-CHAIR GEORGE: Any other comments?

11           MEMBER PHILIPPIDES: A very brief  
12 comment. Is there anyone here who places these?  
13 She just left. That's too bad.

14           I think sometimes the payment for  
15 these procedures are bundled. Is that correct?  
16 Such that, if you touch a patient within a  
17 certain amount of time after you place this,  
18 there is no additional income coming in to the  
19 system. So, this is another one of the sort of  
20 many metrics that is sort of going upstream  
21 against sort of the RVU and payment tide and  
22 trying to change behavior in sort of a very

1       difficult time.

2               So, my suspicion is sometimes when  
3       people go outside of these ranges before they  
4       arrange follow-up, that is maybe one of the first  
5       times they can actually start to get reimbursed  
6       again for the work. I know that sounds somewhat  
7       cynical but I think that is the reality.

8               So, I like this measure because it  
9       starts to push back against some of that stuff.

10              CO-CHAIR GEORGE: If I could just add  
11       that as a surgeon I am horrified that we even  
12       have to have a measure like this.

13              MEMBER ALLRED: Absolutely.

14              CO-CHAIR GEORGE: All right, let's go  
15       ahead and -

16              MEMBER HOLLANDER: Actually, I'm going  
17       to raise it. It is not that relevant to the  
18       voting but it will be in two or three years. I'm  
19       just going to throw it out there.

20              (Laughter.)

21              MEMBER HOLLANDER: It is the  
22       definition of a visit. And so my job now is I am

1 running a huge telehealth program for Jefferson  
2 and everybody is looking into doing visits by  
3 telehealth.

4 And so I think as measures like this  
5 roll out, this may be a perfect thing,  
6 particularly if you have a patient traveling 50  
7 miles or 75 miles to get to a referral center and  
8 they have it planted, that you could actually do  
9 this by video conference.

10 So, I just put it out as we start to  
11 think about it in this and other measures,  
12 defining a visit is going to become important in  
13 the near future and we may want to do that.

14 MEMBER ALLRED: I would have to  
15 disagree in that I don't think you could do the  
16 first initial visit by teleconference because it  
17 is the hands-on. It is the looking at the  
18 incision. It is all of the different things  
19 going into it plus the personal interaction  
20 between you and the person who has put it in and  
21 you get your questions answered.

22 MEMBER HOLLANDER: My point is still

1 we should define the visit.

2 MEMBER ALLRED: Yes, you're right.

3 MEMBER HOLLANDER: It may or may not  
4 be appropriate for every condition but we should  
5 at least know what counts and what doesn't count  
6 as we go forward.

7 MEMBER ALLRED: Right.

8 CO-CHAIR GEORGE: All right, let's go  
9 ahead and vote on priority.

10 MS. LUONG: Polling for high priority  
11 starts now; 1 for high, 2 for moderate, 3 for  
12 low, and 4 for insufficient.

13 High priority passes with 69 percent  
14 voting for high and 31 percent voting for  
15 moderate.

16 CO-CHAIR GEORGE: Okay, we will move  
17 on to scientific acceptability, the  
18 specifications and reliability testing.

19 MEMBER ALLRED: Okay, I am going to  
20 throw it to one of my colleagues.

21 MEMBER CLEVELAND: I'm happy to take  
22 over, at least for the reliability.

1                   So, I think the strength of this,  
2                   again, is emphasized. So, the clinician-level  
3                   analysis I think that is a very -- for the  
4                   specifications, I think that is the place where  
5                   this needs to be.

6                   The specifications will include codes.  
7                   I guess, it is going to obviously transition in  
8                   the administrative from ICD to ICD-10 codes. And  
9                   so it is well thought of that way.

10                  There is a fairly sophisticated  
11                  algorithm that is detailed but in looking through  
12                  that algorithm, I think that is a reliability, at  
13                  least for the specifications present.

14                  The validity testing, in terms of --  
15                  I don't know if we want to talk about the specs  
16                  only or talk about the reliability testing, too,  
17                  as well.

18                  Okay, I don't know. Tom, do you have  
19                  another thoughts?

20                  MEMBER JAMES: No, you are summing  
21                  that up right. I think the attribution  
22                  methodology is going to be the key thing because

1 if it is billed out as a group, who is going to  
2 be responsible?

3 CO-CHAIR KOTTKE: We don't have  
4 trouble with attribution at Health Partners. We  
5 have got the algorithms and the algorithms are  
6 there. It is not a big --

7 MEMBER ALLRED: And I think the  
8 measure actually states that the person who  
9 implants the device has primary responsibility.

10 CO-CHAIR GEORGE: Liz?

11 MEMBER DELONG: Okay, that was my  
12 question. Is it the interventionalist or the  
13 PCP? I thought this was a transition, partly a  
14 transition measure, in which case you would  
15 expect the PCP to pick up.

16 DR. KUSUMOTO: So, my apologies for  
17 confusing you with regards to the definition. It  
18 is a transition measure in the sense that it is  
19 transitioning from a hospital situation to an  
20 outpatient situation. But it is the hospital --  
21 so, this is important because it squarely puts  
22 the responsibility of this transition and the

1 correct hand-off into one unequivocal place.

2 That is what is critical. The implanting

3 physician.

4 CO-CHAIR GEORGE: Gerard?

5 MEMBER MARTIN: So, I have been

6 waiting for my first time to do this today and

7 that is, representing children. I know this is

8 described as being for adult patients. This is

9 absolutely one measure that there is no reason

10 why it should be just adults because of the --

11 and this applies to children as well. And I

12 don't know how you all deal with that. It is

13 something that pediatric centers could do. I am

14 sure that we actually do it. I hope. And I

15 don't know why we are keeping this just to the

16 adult age.

17 DR. KUSUMOTO: It is an incredibly

18 important point. So, we will talk about this on

19 the next section.

20 With regards to making sure that the

21 test was done appropriately et cetera, Medicare

22 fee-for-service with critical, just with regard

1 to the billing piece, at least for this, for our  
2 testing.

3 CO-CHAIR GEORGE: Any other comments on  
4 reliability, specifications? If not, we will go  
5 ahead and vote.

6 MS. LUONG: Polling for reliability  
7 starts now: 1 for high, 2 for moderate, 3 for  
8 low, and 4 for insufficient.

9 Reliability passes with 50 percent  
10 high and 50 percent for moderate.

11 CO-CHAIR GEORGE: All right, we will  
12 move on to validity.

13 MEMBER CLEVELAND: So again, validity  
14 for this measure was conducted at the level of  
15 the data element and, again, using Medicare  
16 fee-for-service claims. Essentially, the data  
17 was compared from claims to date in the patient  
18 chart and then computing sensitivity specificity,  
19 positive predicted value, negative predicted  
20 value. Those were all in the 95 to 100 percent  
21 range. So, that implies, again, at least  
22 supports, I think, indirectly the validity of



1       this measure. So, I, personally, did not see any  
2       problems with validity.

3               CO-CHAIR GEORGE: Any questions on  
4       validity? All right, we will vote on validity.

5               MS. LUONG: Polling for validity  
6       starts now: 1 for high, 2 for moderate, 3 for  
7       low, and 4 for insufficient.

8               Validity passes with 75 percent voting  
9       high and 25 percent voting moderate.

10              CO-CHAIR GEORGE: Moving on to  
11      feasibility.

12              MEMBER CLEVELAND: The data is --

13              MEMBER JAMES: It would be  
14      interesting.

15              CO-CHAIR GEORGE: Any other comments  
16      on feasibility? Okay, we will take a vote on  
17      that.

18              MS. LUONG: Polling for feasibility  
19      starts now: 1 for high, 2 for moderate, 3 for  
20      low, and 4 for insufficient.

21              Feasibility passes with 31 percent  
22      voting high and 69 percent voting for moderate.

1 CO-CHAIR GEORGE: Usability?

2 MEMBER CLEVELAND: So, for this  
3 measure, the proposed result is okay, but I think  
4 --

5 MEMBER JAMES: The only parts that I  
6 had any concerns about was thinking in terms of  
7 what public reporting would be. For me, as a  
8 primary care physician, how would I go about  
9 judging a cardiologist based upon having  
10 information on this?

11 So, I think for a cardiologist, it is  
12 great. I'm not sure for the rest of us what we  
13 are going to do with that information.

14 MEMBER CLEVELAND: Send him to  
15 somebody else.

16 CO-CHAIR GEORGE: Kristi?

17 MEMBER MITCHELL: My question to the  
18 developers: have you thought about the  
19 implementation of a measure like this in an ACO  
20 or some other closed system, such that it will  
21 address the issue about the data and be able to  
22 follow Mrs. Jones across time and setting?

1                   PARTICIPANT: So, Kristi, the proposed  
2 rule that came out the other day,  
3 electrophysiologists, so if they were the ones  
4 using this measure, are actually not included in  
5 the one ACO piece; they are actually part of the  
6 exclusivity, they are excluded from exclusivity.  
7 So, obviously, that is in the proposed  
8 rulemaking. It is a three-day old proposed rule.  
9 So, we did -- that is something we looked at  
10 right away. So, to answer your question, the  
11 implications at this point if the proposed rule  
12 looks like the -- if the final rule looks like  
13 the proposed rule that physicians,  
14 electrophysiologists will continue to have the  
15 flexibility to practice in multiple settings.

16                   And then if the patient's primary care  
17 provider is in a particular ACO, then that will  
18 allow them to ensure that the patient is going  
19 back to their hub.

20                   CO-CHAIR GEORGE: Any other discussion  
21 on usability? All right, we will vote.

22                   MS. LUONG: Polling for usability and

1 use starts now: 1 for high, 2 for moderate, 3 for  
2 low, and 4 for insufficient information.

3 For use and usability, both criteria  
4 passes with 31 percent for high and 69 percent  
5 for moderate.

6 CO-CHAIR GEORGE: All right, so we  
7 will vote on the overall suitability for  
8 endorsement.

9 MS. LUONG: Polling starts now for  
10 overall suitability for endorsement: 1 for yes  
11 and 2 for no, please.

12 For Measure 2461, it passes with 100  
13 percent yes for overall suitability for  
14 endorsement.

15 CO-CHAIR GEORGE: And are there any  
16 competing measures? We will move on to Measure  
17 2474.

18 CO-CHAIR KOTTKE: Okay, cardiac  
19 tamponade and/or pericardiocentesis following  
20 atrial fibrillation ablation.

21 DR. KUSUMOTO: Okay, thank you very  
22 much again for the opportunity.

1                   So, 2474 really looks at a procedural  
2 complication, pericardial tamponade during a  
3 procedure that electrophysiologists do. You  
4 heard from Michael from ACC earlier, and you guys  
5 all know AF is everywhere. Right? I mean it is  
6 in the water. I see it in my clinic all the  
7 time. And really a very, very difficult problem.

8                   We had spoken about the stroke issue  
9 earlier with regards to the anticoagulation. The  
10 second issue is symptoms.

11                  So, a fair majority of patients are  
12 asymptomatic with atrial fibrillation, but a  
13 large number of them actually have significant  
14 reductions in quality of life with this. We have  
15 medications and they can be used for this.  
16 Unfortunately, the medications at the end of the  
17 year failed half the time, if not more, and they  
18 are associated with significant risks.

19                  For example, in the affirm trial,  
20 those patients who are on our strongest medicine,  
21 amiodarone, actually had a higher risk of being  
22 hospitalized in the ICU because of pulmonary

1 complications and other issues.

2 So, our alternatives for treatment are  
3 very poor. And for this reason, over the last  
4 ten years, it is really remarkable, I did my  
5 first atrial fibrillation ablation back in 1996  
6 that in fact this has now emerged as one of the  
7 principle procedures that is done for the  
8 management of atrial fibrillation.

9 It is now being done more and more  
10 frequently, and the big issue with this is  
11 complications. As I tell all of my patients,  
12 this is an elective procedure. And what we need  
13 to do is to make sure that we avoid risk -- risk  
14 of stroke, risk of urgent surgery, risk of et  
15 cetera, et cetera, et cetera.

16 When you look at major risks of  
17 pericardial tamponade, where the heart is  
18 inadvertently perforated in the heart wall and,  
19 in fact, you then have fluid going around the  
20 heart is actually a signal important event. This  
21 is really, this event should not happen. You  
22 really think about this as a serious adverse

1 event.

2 I look back on our experience at Mayo  
3 Clinic, again, because we have systems in place  
4 because of this issue, we actually have not had  
5 any of these events over the last ten years at  
6 our place. And this is not trying to spout, et  
7 cetera. This is really because we took great  
8 effort to take a look at this, per se.

9 Now, my colleagues at the Mayo Clinic  
10 Rochester, however, have had some events. Again,  
11 not disparaging, again, different patient  
12 populations, et cetera. And it is anywhere from  
13 one to two, to three percent of patients. And  
14 the clinical outcomes with these problems are  
15 key.

16 So, if the Mayo Clinic Rochester  
17 experience about another 15 percent of those  
18 patients had pericardial tamponade actually went  
19 on to surgery. Those patients who have  
20 pericardial tamponade have longer  
21 hospitalizations. In a 100,000 patient database,  
22 looking at the nationwide hospital inpatient

1 sample, in fact the hospitalization was seven  
2 days for those patients who had pericardial  
3 tamponade versus those patients who did not,  
4 which was about a day to day and a half.

5 In addition, those patients who have  
6 had pericardial tamponade, even if treated, if  
7 you look at Chinese data, in fact 25 percent of  
8 those patients actually developed what we call  
9 postcardiotomy syndrome, where in fact they get  
10 chest pain and so forth. So, this is something  
11 that lives with them.

12 So, this really is an event that  
13 should not happen. And for this reason, we feel  
14 that this is a very important thing to measure,  
15 report, and hopefully minimize.

16 CO-CHAIR KOTTKE: Great. Thanks. Joe,  
17 Jason? Who?

18 MEMBER SPANGLER: Let me turn my  
19 speaker on. Sorry about that.

20 This is a negative or a complication  
21 measure. So, the lower the number, the better  
22 the quality, just so we keep that in mind. We



1 had a few of those earlier to discuss.

2 I had some issues with the evidence  
3 with this, mainly because I didn't feel like  
4 there was any QQC provided. It seemed like it  
5 was only expert opinion, even though it was based  
6 on a guideline, but the expert opinion didn't  
7 seem very specific to me for the actual measure  
8 that we were looking at.

9 So I -- going through the algorithm  
10 that we have, I actually thought the evidence was  
11 not low but actually insufficient; I didn't think  
12 there was evidence that went directly with the  
13 measure that we were looking at. So, that was  
14 kind of my major issue.

15 MS. JOHNSON: So, let me interrupt  
16 here and just make sure everybody understands our  
17 criteria for evidence for outcome measures.

18 So, for outcome measures, we do not  
19 necessarily ask for the QQC. So, what we want  
20 the developers to provide for us is a rationale  
21 for saying that at least something that they can  
22 do can help that outcome. So, that is what you

1 need.

2 MEMBER SPANGLER: Okay, so I apologize  
3 for that. Sorry about that.

4 MS. JOHNSON: No, that's fine.

5 MEMBER SPANGLER: So, then I would say  
6 there is a rationale. I would agree with that,  
7 but I still feel like that the evidence -- there  
8 is a rationale, but it still feels to me that the  
9 evidence that they are providing is not directly  
10 related to the actual measure that we are looking  
11 at.

12 CO-CHAIR KOTTKE: Other comments?  
13 Joe, do you want to talk about why it is bad to  
14 poke a hole in the heart?

15 MEMBER CLEVELAND: Thank you,  
16 Chairman. I think the only other thing I think  
17 that confounds this a little bit -- I mean I  
18 think this is something where I can understand  
19 the rationale and as a cardiac surgeon I agree  
20 this is a bad problem when it occurs. And at our  
21 place, fortunately, I think it has been over five  
22 years since we have had to take anybody to the

1 operating room for this. So it is infrequent but  
2 when it occurs it is disastrous.

3 So, the only question I have, and this  
4 is in our measure worksheet, is the question  
5 about other structures or processes of care. And  
6 I guess I would ask the developers, are there  
7 standards for periprocedural management of  
8 anticoagulation? Because I assume all these  
9 people have -- well, maybe they are not all on  
10 anticoagulation as we learned, but a vast  
11 majority of them are. So, are there standards  
12 for, in terms of target INRs before one proceeds  
13 with this and things like that? So, I could see  
14 if one lab is willing to do a catheter-based  
15 ablation with someone with an INR 23 and  
16 everybody else has to be less than two. How do  
17 we control for that? Because that could affect  
18 the outcome.

19 DR. KUSUMOTO: So, a great point with  
20 that. So, the problem with that is that there is  
21 going to be variability with regards to then you  
22 have introduced variability into that, which

1 makes it somewhat difficult.

2 For example, for patients with  
3 persistent atrial fibrillation, when they leave  
4 the lab, they are going to be in sinus rhythm.  
5 So, in fact, because this is their highest period  
6 for having stroke, in fact we demand now actually  
7 before we used to do low molecular weight  
8 heparin, actually we now do those procedures with  
9 patients on full anticoagulation. And actually  
10 our lab has looked at the, they call them novel,  
11 but the new oral anticoagulation agents. In  
12 fact, it is actually fairly safe. We have not  
13 seen, albeit in small numbers, any change sort of  
14 in our outcomes with regards to pericardial  
15 effusion and tamponade. And that is why we  
16 specifically chose tamponade as opposed to just  
17 the development of effusion.

18 I mean, this is something that is very  
19 definable. This is someone who now has a second  
20 procedure with a needle in their chest or  
21 open-heart surgery, et cetera, which really then  
22 becomes a signal event.

1 CO-CHAIR KOTTKE: Thanks. Henry Ting  
2 online. Welcome Henry. You had a question?

3 MEMBER TING: Yes, not a question.  
4 Just a comment. I thought the evidence was a  
5 pass because this is an outcome measure.

6 CO-CHAIR KOTTKE: Okay, thank you.  
7 Gerard, are you voting? No. Judd is, though.

8 MEMBER HOLLANDER: Yes, so I guess you  
9 are, effectively, trying to make this a never  
10 event. And so then my question concerns  
11 unintended consequences.

12 So, I have no knowledge in this area;  
13 I don't know how much of this is operator error  
14 and how much of this is patient-related factors.  
15 But my question is: are they going to be patients  
16 who might have received an ablation before who  
17 now won't because the operator considers them too  
18 high risk?

19 DR. KUSUMOTO: So an absolutely great  
20 point. But again, and there are some patient  
21 characteristics that are associated with the  
22 development of pericardial effusion that we will

1 obviously go through if this passes this hurdle.  
2 Having said that, the great majority of this,  
3 albeit small, number is really relative to the  
4 physician himself or herself, in fact, in how  
5 they are handling those catheters inside the  
6 atrium. I mean it really is where gentleness is  
7 really critical, no matter how much you are  
8 ablating or not ablating, et cetera. The gentler  
9 the ablation is, the better the catheter  
10 handling, et cetera. So, this really is a  
11 quality piece.

12 CO-CHAIR KOTTKE: Great. George?

13 MEMBER PHILIPPIDES: To follow-up on  
14 the comments you both made: would a practitioner,  
15 after this goes into effect, shy away from doing  
16 this procedure on patients who require  
17 anticoagulation because, by definition, they have  
18 a much higher risk of tamponade and effusion?

19 DR. KUSUMOTO: So again, an  
20 interesting point. And I think this data is  
21 evolving dramatically and quite quickly and  
22 couldn't be included into the application. In

1 fact, I would say that 95 percent of our patients  
2 that we ablations on actually now, over the last  
3 several years, because our mainly persistent  
4 atrial fibrillation are on anticoagulation.

5 So, while I think there is certainly  
6 no question that if you are on anticoagulation  
7 are more likely than to bleed and then have  
8 tamponade. But then what is going to happen, I  
9 will give just a personal anecdote here from a  
10 case from a few days ago, actually. A woman who  
11 actually came to us for an ablation for atrial  
12 fibrillation went and did this transseptally.  
13 You have to go from the right atrium to the left  
14 atrium to sort of get your catheters into place.  
15 Well, as part of our sort of zero tolerance for  
16 this event, we have an intracardiac echo in place  
17 during this procedure. What this is is an  
18 ultrasound so we can monitor the effusion.

19 Well, she had a slight effusion to  
20 begin with, which is common in patients on  
21 anticoagulation. We did this and there was this  
22 question: Was there a slight increase in the

1 effusion?

2 So, because of these sorts of systems  
3 in place, we then stopped the procedure. And  
4 then, because of our zero tolerance, we actually  
5 then woke the patient asking are you having any  
6 chest pain. In fact, she was having a little bit  
7 of chest pain. So, we in fact then stopped the  
8 procedure. And then what?

9 Well, I am not sure whether or not she  
10 would have, if we would have then anticoagulated  
11 her further as we would often do as we do for the  
12 rest of the procedure, would she have then gone  
13 on to develop tamponade. But the point is that  
14 even in these patients who have higher risk for  
15 tamponade and for developing pericardial  
16 effusion, there are ways to monitor this, to make  
17 this still a never event.

18 CO-CHAIR KOTTKE: Let's see. Jason  
19 and then Liz.

20 MEMBER SPANGLER: So, I'm going to go  
21 back on something I earlier said because I am  
22 relooking at this. Obviously, I think I looked



1 at it not as an outcome. So, the evidence is, I  
2 agree with Henry, not as important.

3 The question I have is when we are  
4 looking at a health outcome measure and the  
5 processes and structures of care, you have  
6 mentioned some of the things that can improve. I  
7 guess my question is, you know you talk about  
8 high-quality A-fib ablation and some of the  
9 things you have done. Are those the standards,  
10 the benchmarks?

11 So, what I am trying to figure out is  
12 if we have this type of measure and people don't  
13 score high on this measure, do they know what to  
14 do? Do they know how to improve upon this  
15 measure? So is it because they are not  
16 performing at the standard of care or is this  
17 because this is a complication that happens? I  
18 mean I guess my question is: Can this be a never  
19 event? That is, basically, my question.

20 DR. KUSUMOTO: My personal thought is  
21 yes or certainly pretty darn close to it. I  
22 mean, who knows? But I do think that yes, this

1 can be made a never event with good systems of  
2 care, and good training and teaching, and all of  
3 those kinds of important things.

4 MEMBER SPANGLER: And it doesn't  
5 matter whether it was out there?

6 DR. KUSUMOTO: Yes, I think that they  
7 are, in fact. You know again, that is why I  
8 think this sort of measure is so important. That  
9 is why I feel so passionately about that and you  
10 hear this in my voice. I think this is something  
11 that can be done.

12 We do it in our small system. What do  
13 we do? Well, we have people when they want to  
14 learn AF ablation, they come to our place as  
15 visiting scholars for a week to week and a half.  
16 We go through our systems with them. In fact,  
17 not just the procedural piece of this is how I  
18 move my hands, et cetera. Well, these are the  
19 things that we do. Here is the checklist that I  
20 go through. Once I have done the transseptal, I  
21 am looking at the ST segments. I am doing this.  
22 I am doing this. I am doing this, et cetera.

1 Here are things that can happen.

2 So, we do this sort of in our own sort  
3 of place in a sort of -- in an organized fashion  
4 but, nonetheless, not nationally. If you had a  
5 measure like this, there would be an emphasis, I  
6 think, of moving this ball forward to make this a  
7 never event.

8 CO-CHAIR KOTTKE: Liz and then George.

9 MEMBER DELONG: So, I am a little bit  
10 confused about perverse incentives. Is there not  
11 an ongoing trial of ablation versus is it medical  
12 therapy?

13 DR. KUSUMOTO: Yes.

14 MEMBER DELONG: So, there is an  
15 alternative and the jury is actually out as to  
16 which is better, unless there are pre-specified  
17 patients who are destined for ablation. Is that  
18 the case?

19 DR. KUSUMOTO: So a great point. So,  
20 let me just, again, I don't want to take the  
21 committee's time too much. There have been  
22 trials that have looked at ablation versus

1 medication, both in nuance in atrial fibrillation  
2 and in patients who have actually failed a prior  
3 drug therapy.

4 Let's take the prior drug therapy  
5 first because those were the ones that were done  
6 first. So, these were patients who had failed  
7 one drug; they randomized to another drug, which,  
8 obviously, doesn't work, and then the ablation  
9 does better. It does better in the sense of less  
10 atrial fibrillation and improved quality of life,  
11 those kinds of indices. The study that you are  
12 referring to, CABANA, is looking at hard outcomes  
13 with regards to stroke and hospitalizations.

14 MEMBER DELONG: So, I guess the  
15 perverse outcomes are there are alternative  
16 therapies, potentially, and to avoid doing an  
17 ablation on a patient would mean that you might  
18 be switching the patient to something that is  
19 equally effective, but you do not capture the  
20 revenue from doing that. And I don't know which  
21 one weighs out.

22 DR. KUSUMOTO: But you would capture

1 -- again, these are patients often, at least at  
2 our place, they are drug refracted. I mean, they  
3 really don't have a ton of options. I mean this  
4 is really, it is sort of the last stop. And I do  
5 think that if you make the hurdle a little  
6 higher, with regards to we are going to measure  
7 this and we are going to report it and we are  
8 going to show it off to the world that, in fact,  
9 I think that you would then put the onus on the  
10 provider doing this procedure to in fact do a  
11 high quality job.

12 CO-CHAIR KOTTKE: Okay, are we ready  
13 to vote? Oh, two people. Tom and then Joe.

14 MEMBER JAMES: Mine's a question. And  
15 speaking to the relative importance, what I found  
16 is one article from Sue showing 2.9 percent  
17 incidence of tamponade with this. The paper  
18 talks in terms of two million people with atrial  
19 fibrillation. I am trying to get down to what is  
20 the incidence of all of this to get a relative  
21 importance?

22 DR. KUSUMOTO: Yes, so that is good.

1 We will talk about it, too, hopefully again if we  
2 pass the validity and reliability piece. We in  
3 fact took the large database of 600,000 patients,  
4 a million sort of events, et cetera, and kind of  
5 looked at sort of the incidence.

6 And if you kind of run through those  
7 numbers, you are looking at a couple thousand  
8 sort of patients, which if, in fact, you then  
9 put this on the, what do I want to say, the  
10 people who do the majority of these procedures  
11 who are, in fact, those people who do less than  
12 20 procedures, you would then get rid of, if you  
13 made them zero, 90 percent of the events.

14 Now, I am not saying that it would  
15 potentially be zero but, nonetheless, there is  
16 clearly -- if we again talk about gap and  
17 potentials for benefit from this measure.

18 CO-CHAIR KOTTKE: So, this really begs  
19 the -- you know I think the right denominator is  
20 the patient with the ablation, not the patient  
21 with atrial fibrillation. And this has to do  
22 with 0715, too. It is the denominator is the

1 patient in the cath lab.

2 Joe and then Gerard.

3 MEMBER CLEVELAND: Yes, my only other  
4 comment, I guess, to address at least Judd and  
5 maybe Liz is would people not want to do this or  
6 would people be denied this procedure? As a  
7 cardiac surgeon, there is, actually, we do open  
8 maze procedures still that actually if you are  
9 seeing this growing effusion, I am going to stop  
10 the anticoagulant and maybe this is a person who  
11 should go for a radio-frequency maze.

12 So, there is another alternative  
13 procedure that can be done. Obviously, it is  
14 more invasive and differs from drug therapy, but  
15 it is not as though these people will not be  
16 treated or at least not have that option to.

17 CO-CHAIR KOTTKE: Gerard?

18 MEMBER MARTIN: Then they will really  
19 have chest pain.

20 (Laughter.)

21 MEMBER MARTIN: Sorry, I thought we  
22 would at least laugh a little bit this afternoon.

1                   With the tamponade, how much of it is  
2 due to the transseptal versus the actual  
3 ablation?

4                   DR. KUSUMOTO: So, a little of both.  
5 And it actually, I think, varies depending on the  
6 type of ablation that in fact you do and the  
7 experience of the operators.

8                   I actually believe that when you look  
9 at the low number of operators, is actually from  
10 the transseptal rather than the ablation itself.

11                  MEMBER MARTIN: I mean it does raise  
12 the question of whether the title of this should  
13 be cardiac tamponade during transseptal  
14 procedures in adults.

15                  DR. KUSUMOTO: So, we looked at that  
16 a little bit. So, there is some data to suggest  
17 that in fact there is a higher, and again, from  
18 experienced centers.

19                  So, we do ablations on the right side,  
20 where you don't have to do the transseptal there.  
21 The pericardial tamponade raised very, very low,  
22 vanishingly low. If you add the transseptal it



1 adds an additional sort of half a percent or a  
2 percent. If you then do the atrial fibrillation  
3 ablation, that is when in fact you do have more.

4 The problem is so again when we get to  
5 the measure itself, trying to tease out those  
6 patients with regards to just doing the AF  
7 ablation only.

8 CO-CHAIR KOTTKE: Okay, anybody else  
9 have the urge to -- Tom is here. Okay, shall we  
10 vote?

11 MS. LUONG: Polling starts now for  
12 evidence help outcomes: 1 for yes and 2 for no.

13 CO-CHAIR KOTTKE: While people are  
14 voting, it reminds me of a cartoon we had outside  
15 of our cath lab, where the fellow is standing  
16 there and the catheter is coming out the  
17 patient's mouth and the preceptor says, I told  
18 you not to push.

19 (Laughter.)

20 MS. LUONG: For evidence help  
21 outcomes, 94 percent voted yes and 6 percent  
22 voted no.

1 CO-CHAIR KOTTKE: Okay, opportunity  
2 for improvement in disparities.

3 MEMBER SPANGLER: So, you know the  
4 performance gap is interesting because if you  
5 want it to be a zero event, then there is a  
6 performance gap. But if you look at the  
7 complication rate, and I don't have experience,  
8 obviously, with these patients at all. I mean it  
9 seems pretty low; I mean the numbers they give,  
10 1.2 to 2.4. So, in that respect, there may not  
11 be one but if we truly think there is a zero  
12 event, then there is a gap that there can be  
13 improvement upon.

14 There is no, I didn't see any data  
15 around disparities.

16 CO-CHAIR KOTTKE: Okay, Henry, you  
17 have a comment?

18 MEMBER TING: Yes, I do. I don't  
19 think this can be a never event. I sort of  
20 disagree with the presenter because these are  
21 things that happen at large centers that do a lot  
22 of cases. And the Mayo Clinic Rochester was

1 referenced as one of the best and highest volume  
2 centers that do these procedures. And some of us  
3 do the transseptal, but some of those are also  
4 due to the aggressiveness of the ablation. And  
5 so when you are doing patients who are coming  
6 back with recurrent atrial fibrillation who have  
7 already had an ablation, this can -- if you are  
8 not willing to do the procedure and be successful  
9 and try very, very hard, then you will never have  
10 tamponade or pericardial effusion. But if you  
11 are actually trying to cure the disease and  
12 trying very hard, then you can cause a  
13 pericardial effusion.

14 So, I don't think this is a never  
15 event. I think if you are going to try to do  
16 these in complex patients who have recurrent  
17 atrial fibrillation after several ablations, this  
18 is something where you can have this event.

19 I want to make a few other comments  
20 before actually I need to go to another meeting.  
21 It is probably out of place, but the other thing  
22 I wanted to say is it is now said as and/or. It

1 can't be and/or. It says and/or cardiac  
2 tamponade or pericardiocentesis. It is either  
3 and or it is or. I don't know how to interpret  
4 and/or in a numerator. So, that has to be fixed.

5 And then the other thing I would point  
6 out is that this misses all patients who have a  
7 pericardial effusion caused by the procedure,  
8 which may be moderate to large size, but did not  
9 require pericardiocentesis or cause tamponade.  
10 Not all pericardial effusions cause tamponade.

11 So, when you do these procedures, you  
12 wind up with a moderate to large effusion and you  
13 don't have tamponade, this is completely missed  
14 in the numerator.

15 And I do think the distribution of  
16 evidence, opportunity for improvement is quite  
17 low because if you are talking about 1.2 to 2.4  
18 percent, and that is a range, that is not a big  
19 area for improvement.

20 DR. KUSUMOTO: I'll agree with Henry  
21 in the sense that that is why it is chosen as we  
22 can pick on pericardial tamponade and that

1 physiology because pericardial effusions are  
2 present. And in fact, as I mentioned, you can  
3 see this at baseline in some of our patients. So  
4 I think that that is a point.

5 I will differ a little bit with  
6 regards to the never event, as I mentioned  
7 earlier. Maybe it could never be a never event  
8 but boy, it sure would be nice to have it be a  
9 never event and be, obviously, as close to zero  
10 as possible, even with these complex ablations  
11 that we are doing. I mean that really implies  
12 that maybe the way that we are doing it is not as  
13 good. So, I would make that argument sort of  
14 with that.

15 I do want to note that there is one  
16 study that has come out since this application  
17 went in that in fact did show some disparities  
18 where women were more likely to have pericardial  
19 effusion than men. I don't know if that is just  
20 because of atrial thickness compared to men.  
21 There are a whole host of issues one can think  
22 about but, nonetheless, that data is out there

1 now.

2 CO-CHAIR KOTTKE: Anybody have any  
3 thoughts on Henry's objection to and/or?

4 I mean they are basically saying if it  
5 is just an or, if you have both, you are out.

6 But why would you be out if you had both  
7 pericardial tamponade and a pericardiocentesis?

8 I mean, pericardiocentesis is the treatment of  
9 tamponade, and I mean I think the and/or is fine  
10 myself.

11 MEMBER TING: Is it correct English?  
12 I think it is just or, then. If you have either  
13 one, isn't it or?

14 CO-CHAIR KOTTKE: But then if you have  
15 both, you are out.

16 MEMBER TING: If it is or, you have  
17 both, you are in. It is or.

18 CO-CHAIR KOTTKE: Oh, okay.

19 MEMBER TING: From a medical  
20 perspective, I don't think you are supposed to  
21 use and/or.

22 CO-CHAIR KOTTKE: Oh, we just got an

1 official inspect language. It is "or."

2 Okay, Liz.

3 MEMBER DELONG: So, the conversation  
4 seems to imply the need for risk adjustment. But  
5 clearly, the event rate might not support risk  
6 adjustment. But it is an outcome. I mean it is  
7 a bad outcome.

8 It would seem we are still aiming to  
9 drive it down. I just wonder about ranking sites  
10 according to this outcome if they haven't been  
11 credited with the risk that they are taking on.

12 MEMBER TING: I would agree with that  
13 comment, Liz, because if you only adjust it for  
14 age and gender, which was done for this outcome,  
15 clearly this is not the only thing that  
16 correlates with the outcome.

17 CO-CHAIR KOTTKE: Other comments? Are  
18 we ready to vote?

19 MS. LUONG: Polling starts now for  
20 performance gap: 1 for high, 2 for moderate, 3  
21 for low, and 4 for insufficient.

22 Performance gap has 6 percent high, 47

1 percent moderate, 35 percent low, and 12 percent  
2 insufficient.

3 MS. JOHNSON: So this is in our gray  
4 zone. We do continue.

5 CO-CHAIR KOTTKE: Okay, priority.

6 MEMBER SPANGLER: I would go back on  
7 an earlier comment I made within the National  
8 Quality Strategy just because it mentions  
9 cardiovascular, whether everything here is a high  
10 priority. So I would question whether this is a  
11 high priority or not.

12 Going back to something Tom said, it  
13 seems to be low prevalence overall. I agree  
14 severity can be high. There was no data  
15 presented about severity. You did mention the  
16 hospital stay, but that wasn't in the  
17 application. So that is new information and  
18 there is no cost data.

19 I think the priority is questionable.  
20 It is definitely severe when it happens, but  
21 everything else around priority, I would say  
22 would be low.



1 DR. KUSUMOTO: I would apologize. The  
2 hospitalization data was in the nationwide  
3 sample, which was in the thing, but again, buried  
4 way in the references, et cetera. So my  
5 apologies to the group on that.

6 CO-CHAIR KOTTKE: Other comments?  
7 Joe.

8 MEMBER CLEVELAND: I agree in theory  
9 that, while infrequent, I would still say for an  
10 elective procedure this is a calamitous type  
11 outcome. So, it just depends on how you view it.

12 I mean if there is a surgeon running  
13 up to the EP lab to open somebody's chest, it is  
14 not a good day for you or the patient.

15 CO-CHAIR KOTTKE: My feeling is that  
16 a patient has the right to be safe. And I think  
17 this makes it -- the right denominator is the  
18 patient going to the cath lab. It is not all  
19 patients with AF because it is an elective  
20 procedure.

21 And I disagree somewhat with Henry.  
22 If risk of tamponade is that high, maybe you call

1 Harzell Schaff and have him do the procedure as  
2 an open; it is an open chest procedure instead of  
3 messing around with catheters.

4 MEMBER TING: That is a patient  
5 preference issue. So, if the patient chooses  
6 that --

7 CO-CHAIR KOTTKE: Yes, sometimes you  
8 stop, though.

9 Okay, any other -- yes, Judd and then  
10 --

11 MEMBER HOLLANDER: So, I am trying to  
12 put my patient hat on. This is something I would  
13 love to see publicly reported. If my family  
14 members or I need to go for an ablation, I want  
15 to be able to pick the doctor that has done a lot  
16 of procedures and has a low complication rate.

17 So, I think with A-fib growing, to me  
18 that makes this a high priority. I want to know  
19 the answer to that.

20 MEMBER TING: Judd, what needs to  
21 along with this is success rates from atrial  
22 fibrillation. You know sort of like how many

1 patients have successful ablations with this  
2 operator, as well as recurrence rates at one year  
3 and two years.

4 CO-CHAIR KOTTKE: And tamponades.

5 MEMBER VIDOVICH: I just wanted to say  
6 it is somewhat of a crude measure like  
7 perforation yes or no, but it is a good quality  
8 measure. And again, it may differentiate from  
9 good operators or from centers. And I think it  
10 is not like a publicly reported, I don't know,  
11 CABG outcomes in New York, you know if people  
12 actually went to a different state. I think that  
13 this actually will improve overall quality and  
14 move through it. It is a rare event, but it is a  
15 worthwhile one.

16 CO-CHAIR KOTTKE: George and then Joe.

17 MEMBER PHILIPPIDES: Henry, I think I  
18 missed what you mentioned a moment ago. Are you  
19 saying that looking at this metric without also  
20 knowing how many successful tough ablations  
21 somebody did is incomplete and might not give a  
22 fair picture of a person's quality?

1                   MEMBER TING: Absolutely. So, if this  
2 is equated to angioplasty and stenting, you would  
3 want to know successful procedure without  
4 complications. An equivalent complication would  
5 be coronary artery perforation requiring coronary  
6 artery bypass surgery as an emergency part of the  
7 procedure.

8                   You know you would want sort of a  
9 family of measures that includes -- if you are  
10 truly the patient, you want to know what are the  
11 changes that this operator would be successful,  
12 their experience, as well as their complications;  
13 this is one of the complications. This is not  
14 the only one. And it is probably not the most  
15 common complication from atrial fibrillation  
16 ablation either.

17                  MEMBER PHILIPPIDES: Yes, because I do  
18 think sometimes patients get sent on -- a  
19 physician in the community might send on the  
20 tougher cases into Mecca to be done. And so by  
21 definition, they will do the easier cases but  
22 send the tougher cases on. And I do think there

1 has to be some understanding of the different  
2 patient populations. Surgeons see this all the  
3 time in second opinions for bypass.

4 MEMBER TING: And there is no risk  
5 adjustment with this measure right now, just age  
6 and gender.

7 CO-CHAIR KOTTKE: The point I would  
8 make is what Henry and, I guess, Liz have brought  
9 up previously, is that is where risk adjustment  
10 would help with that type of thing.

11 MEMBER PHILIPPIDES: And that wasn't  
12 done, except what Henry mentioned already.

13 CO-CHAIR KOTTKE: Gerard, are you  
14 voting? I can't see -- oh, that's George. He's  
15 hiding.

16 Okay, we are ready to vote, it looks  
17 like.

18 MS. LUONG: Polling starts now for  
19 high priority: 1 for high, 2 for moderate, 3 for  
20 low, and 4 for insufficient.

21 For high priority, 13 voted high, 56  
22 voted moderate, 25 voted low, and 6 voted

1       insufficient. It passes.

2                   CO-CHAIR KOTTKE: Okay, scientific  
3       acceptability and reliability.

4                   MEMBER SPANGLER: Do you want me to  
5       keep going? Do you want to take over? What do  
6       you want to do? Or Henry, do you want to give it  
7       to Henry?

8                   MEMBER CLEVELAND: I'm out of my  
9       league here. I was going to actually bunt this  
10      or whatever. I will be honest with you. I don't  
11      understand the crosswalk that is done. So, if you  
12      do, you can help me.

13                  MEMBER SPANGLER: So, I mean I think  
14      the measure specifications are clearly defined,  
15      as is the data source. It seems to be  
16      implemented.

17                  There has been discussion about the  
18      denominator, but I didn't have issues with the  
19      denominator. I don't know if other people wanted  
20      to speak to that. And if we want to talk about  
21      that, we can now. I can go on to testing,  
22      reliability testing if you want or if we want to

1 talk about that, we can.

2 CO-CHAIR KOTTKE: Sure. Are we going  
3 to talk about reliability testing?

4 MEMBER SPANGLER: Testing?

5 CO-CHAIR KOTTKE: Yes.

6 MEMBER SPANGLER: All right. So they  
7 did reliability testing through the beta-binomial  
8 model, measuring signal to noise ratio. We  
9 talked a little bit about signal and noise  
10 earlier. And there is also demonstrated, I  
11 thought, high reliability.

12 So, I didn't have any issues with the  
13 reliability.

14 CO-CHAIR KOTTKE: Okay, any -- let's  
15 vote, seeing no dissension.

16 Who had questions? Jason, did you  
17 have questions about the denominator?

18 MEMBER SPANGLER: No, I didn't. I  
19 thought somebody else did but I didn't.

20 MS. LUONG: Polling starts for  
21 reliability: 1 for high, 2 for moderate, 3 for  
22 low, and 4 for insufficient.

1                   For reliability, 38 percent voted  
2                   high, 56 percent for moderate, 6 percent for low.

3                   CO-CHAIR KOTTKE:   Validity.

4                   MEMBER SPANGLER:   It looked like  
5                   empiric and face validity and face validity was  
6                   done in measure development.   They did some  
7                   testing and the results showed ablation was the  
8                   most common procedure and one with the  
9                   complications being measured.   So it seemed to  
10                  correlate.   The validity seemed to correlate with  
11                  what they were looking to measure.   So I thought  
12                  the validity was fine.

13                  CO-CHAIR KOTTKE:   Did you have the  
14                  urge to --

15                  MEMBER PHILIPPIDES:   I have a quick  
16                  question.

17                  So we are proceeding as though that  
18                  says cardiac tamponade or pericardiocentesis.   Is  
19                  that correct?   Okay.

20                  CO-CHAIR KOTTKE:   Joe?

21                  MEMBER CLEVELAND:   I was just going  
22                  ask in terms of the three-year rolling average,



1 the rationale for that. Is it just because of  
2 the infrequent nature of this complication?

3 DR. KUSUMOTO: Correct.

4 MEMBER SPANGLER: Sorry, I didn't know  
5 this was part of this. Again, we multiply have  
6 talked of this but I think it is important that  
7 there isn't really risk adjustment done as much  
8 as should be in this. I think that is an  
9 important point to keep in mind.

10 CO-CHAIR KOTTKE: Tom?

11 MEMBER JAMES: Yes, a question. Do  
12 you think there is sufficient data to create a  
13 differentiation among the measured entities? It  
14 is going to take enough volume in any one place  
15 and will there be sufficient differentiation with  
16 this measure than can help create some  
17 improvement or is this not a comparative measure  
18 but one in which, against each other, that  
19 measure against the absolute.

20 DR. KUSUMOTO: Well, again, I think it  
21 is the absolute that you really want zero. And I  
22 am going to, again, argue the other side of the

1 coin with Henry and agree with my surgical  
2 colleague here. You know we talk about outcomes  
3 in terms of yes, a successful ablation. Well,  
4 that is kind of like well, you know, the patient  
5 survived whatever that line is. I mean you  
6 really want to avoid complications. And this,  
7 again, when you look at all of the evidence from  
8 these large claims databases, et cetera,  
9 pericardial tamponade is the most common serious  
10 complication that occurs. I mean you can make  
11 arguments about stroke and other things having  
12 bigger sort of issues but when you look at  
13 absolute numbers, it is pericardial tamponade.

14 CO-CHAIR KOTTKE: Judd.

15 MEMBER HOLLANDER: Getting at Tom's  
16 point, maybe I am a little redundant. But if we  
17 are comparing across providers and that is sort  
18 of our hopes for this, how many cases does the  
19 typical operator do a year and is there any  
20 statistical difference between them?

21 DR. KUSUMOTO: Yes, that is a great  
22 point. So, in the paper that was included in

1 your piece looking at the nationwide inpatient  
2 sample, in fact there was a dividing point at  
3 about 25. So, if you did less than 25, in fact,  
4 you had a higher complication rate with regards  
5 to pericardial tamponade compared to those  
6 patients who did greater than 25, which was borne  
7 out actually in our data, too.

8 What is important to know that is if  
9 you take those 25 and 90 percent of sort of the  
10 complications, mainly because they have the  
11 higher volume, are in fact in that group of  
12 patients, even given a three-year rolling  
13 average. So, I think the shortcut for these  
14 physicians, I think.

15 You either get into it, you do it, you  
16 do it well and you get publicly reported or you  
17 don't.

18 MEMBER SPANGLER: What are those  
19 numbers, comparing the greater than 25 or less  
20 than 25? Or are they --

21 DR. KUSUMOTO: Oh, so pardon me. So,  
22 it is looking at the ranges are in single

1 percents. So, it is going to be when you go  
2 greater than 25, it is about one to one and a  
3 half percent. And then when you go less than 25,  
4 then it goes to two and a half to three. That is  
5 correct for that data. That's right. Correct.

6 MEMBER HOLLANDER: So, that wasn't  
7 exactly my question but I think that is  
8 interesting to inform volumes better.

9 I am saying if I am trying to choose  
10 between three providers, do they each do 100  
11 cases a year, so if one is two percent and one is  
12 one percent, it is a one-patient difference? Or  
13 are you doing 500 patients a year, where maybe a  
14 two or three percentage is statistically  
15 relevant?

16 DR. KUSUMOTO: Yes, you know this  
17 question is going to be how does this go.  
18 Because I do think that the way that this  
19 procedure should go, as a sort of a personal  
20 editorial, is to sort of large places that do a  
21 lot of them can be very good, particularly if  
22 they are going to be very complicated and have

1 higher risk.

2 CO-CHAIR KOTTKE: Looks like we are  
3 ready to vote.

4 MS. LUONG: Polling starts now for  
5 validity: 1 for high, 2 for moderate, 3 for low,  
6 and 4 for insufficient.

7 For validity, it passes with 6 percent  
8 voting high, 63 percent voting moderate, 25  
9 percent voting low, and 6 percent voting  
10 insufficient.

11 CO-CHAIR KOTTKE: Feasibility.

12 MEMBER SPANGLER: So, the data is  
13 collected through administrative claims and there  
14 is, it looks like, readily available electronic  
15 form for this. There didn't seem to be any  
16 identified areas of concern. So, I thought the  
17 feasibility is pretty good.

18 CO-CHAIR KOTTKE: Seeing no motion,  
19 let's vote.

20 MS. LUONG: Polling starts now for  
21 feasibility: 1 for high, 2 for moderate, 3 for  
22 low, and 4 for insufficient.

1                   Feasibility passes with 56 percent  
2                   voting high and 44 percent voting moderate.

3                   MEMBER DELONG: So, again, a naive  
4                   question and I'm sorry I didn't ask this. If the  
5                   patient does experience one of these  
6                   complications, is it unlikely that they would  
7                   have already been discharged and reporting to a  
8                   different hospital or something? I just don't --

9                   DR. KUSUMOTO: I'm sorry. So, again,  
10                  so the complication happens. You are going to be  
11                  in the hospital for a week because of the  
12                  complication.

13                  MEMBER DELONG: But the complication  
14                  is evident immediately. So, they haven't gone  
15                  somewhere else.

16                  DR. KUSUMOTO: Oh, yes, absolutely.  
17                  No, no, this is procedural.

18                  MEMBER DELONG: Okay, that is all I  
19                  wanted to know. I appreciate it.

20                  CO-CHAIR KOTTKE: Usability and use.

21                  MEMBER SPANGLER: So it is not  
22                  currently publicly reported but it is being

1 considered in the quality programs for CMS for  
2 2015.

3 So, again, I think the comment I made  
4 earlier, just a little red flag, we don't know  
5 because it is not being publicly reported but I  
6 think this probably has moderate to high  
7 usability, depending on implementation but I  
8 don't think there will be any problems.

9 PARTICIPANT: And since we submitted  
10 the application and actually this measure is in  
11 PQRS 2015.

12 MEMBER SPANGLER: So, it was included  
13 in the final rule, I guess.

14 CO-CHAIR KOTTKE: Joe?

15 MEMBER CLEVELAND: I'm just going to  
16 with a comment made earlier today about public  
17 reporting. And I fully submit that I think for  
18 this measure to really have full impact, it is  
19 going to have to be publicly reported. So, I  
20 completely endorse it.

21 CO-CHAIR KOTTKE: Let's vote.  
22

1 MS. LUONG: Polling starts now for  
2 usability and use: 1 for high, 2 for moderate, 3  
3 for low, and 4 for insufficient.

4 Usability and use passes with 44  
5 percent voting high and 56 percent voting  
6 moderate.

7 CO-CHAIR KOTTKE: So, overall?

8  
9 MS. LUONG: Polling starts now for  
10 overall suitability for endorsement: 1 for yes,  
11 and 2 for no.

12 For overall suitability for  
13 endorsement, 81 percent voted yes and 19 percent  
14 voted no.

15 CO-CHAIR KOTTKE: And I assume there  
16 are not competing measures.

17 MEMBER SPANGLER: No.

18 CO-CHAIR KOTTKE: Okay, thank you very  
19 much.

20 If somebody can find Sana. Oh, she  
21 left? Oh.

22 CO-CHAIR GEORGE: All right, we will



1 go on to the least measure of the day, 0715.

2 CO-CHAIR KOTTKE: Unless somebody  
3 rebels, we are going to finish up today, the last  
4 measure.

5 CO-CHAIR GEORGE: Any rebelling?

6 CO-CHAIR KOTTKE: Seeing no rebelling,  
7 we will go.

8 MEMBER SPANGLER: Do we need to let  
9 the -- if people are expecting public comment at  
10 this time, do we need to let them know or that is  
11 just assumed? Only because the schedule says  
12 4:45. So, I am sure they are assuming that we  
13 are not finished, that they have to wait but I  
14 don't know if people are waiting right now for  
15 that.

16 MS. ISIJOLA: Operator, can you open  
17 the line for public and member commenting?

18 OPERATOR: And at this time, if you  
19 have a public comment, would you please press \*1?  
20 Again, for public comment, please press \*1.

21 And there are no public comments at  
22 this time.

1 MS. ISIJOLA: Okay, thank you.

2 CO-CHAIR GEORGE: All right, so  
3 Gerard, Liz, and Tom Kottke are the discussants.  
4 We will hear from the major developer.

5 DR. BERGERSEN: Good evening. Hi. My  
6 name is Lisa Bergersen. I am an interventional  
7 pediatric cardiologist from Boston Children's  
8 Hospital. I am the measure developer sponsored  
9 by Boston Children's Hospital to be here today.

10 First, I will just start by defining  
11 the metric for you, which is the standard adverse  
12 event ratio in patients less than 18 years of age  
13 for the outcome adverse events.

14 The numerator for this metric is the  
15 occurrence of adverse events at an institution  
16 divided by the risk-adjusted expected rate of  
17 adverse events due to the case mix complexity at  
18 the institution.

19 The denominator is derived using CHARM  
20 methodology, which is a risk-adjustment  
21 methodology based on three procedural  
22 characteristics and patient characteristics; one

1 procedural characteristic, two patients.

2 The procedural characteristic is the  
3 procedure type risk group. I will give you a  
4 little bit of background on that. Patient  
5 characteristics being age and the presence of  
6 hemodynamic variables.

7 We have shifted gears considerably  
8 from adult measures. As some background,  
9 congenital heart disease affects one in a hundred  
10 children. And our field of pediatric  
11 interventional cardiology is rather young.

12 Over the past couple of decades, tools  
13 and equipment and procedures have evolved  
14 considerably, such that where it was primarily  
15 diagnostic a couple of decades ago, we are doing  
16 more and more interventional procedures which  
17 either complement or replace some of the surgical  
18 techniques used in congenital heart disease. We  
19 don't do just one type of procedure. There is a  
20 multitude of different types of procedures.

21 About a decade ago, reports of adverse  
22 events came from single institutional

1 experiences. And institutions would contend that  
2 you couldn't compare their adverse events to  
3 others because their case mix complexity might be  
4 different. Thus, there was a need to develop a  
5 way to allow for equitable comparisons among  
6 institutions.

7 Adverse events were agreed to be an  
8 important outcome from these procedures and,  
9 therefore, risk adjustment methodology was  
10 necessary. None existed. Therefore, in 2006, we  
11 put together a small group of institutions which  
12 were put together to have a geographic  
13 distribution, have some variation in case volume,  
14 with the hope that that data set could support a  
15 generalizable risk adjustment methodology for the  
16 field.

17 It was limited to eight institutions  
18 to allow for reliable data capture and assurances  
19 that there wouldn't be biases in attribution and  
20 classification.

21 This data set was collected between  
22 2007 and 2010 and from this dataset, we were able

1 to develop procedure type risk groups.  
2 Ultimately, four categories of the multitude of  
3 different procedures that we performed  
4 categorized into four groups of similar risk;  
5 half of them, being in category one, with  
6 decreasing frequency with increasing risk.

7 This was, by far, the most important  
8 factor in adjusting for the risk of important  
9 adverse events in our population, which range  
10 from two to eight percent across the  
11 institutions.

12 That risk adjustment methodology, the  
13 model, all of the factors were published and the  
14 methods are completely translucent within the  
15 literature. To date, there hasn't been a  
16 publication in a separate dataset that I can cite  
17 for you as a validation dataset for the  
18 methodology.

19 Therefore, in the materials that you  
20 received, we have provided a preliminary analyses  
21 or an analyses on another multi-center database.  
22 So, the C3P0, after achieving our initial aims,

1 our goal was go beyond benchmarking and risk  
2 adjustment methodology and explore quality  
3 improvement initiatives.

4 So, we invited additional sites and  
5 expanded our participation to 15 sites with the  
6 goal to reduce radiation exposure. While that is  
7 the primary goal of our current project, we still  
8 report the standard adverse event ratio to the  
9 institutions for their internal quality  
10 improvement processes, both by actually  
11 institution, as well as provider, which we also  
12 do internally.

13 This metric, although it is put forth  
14 to you as an institution-based metric, internally  
15 we use it for performance reporting, for  
16 providers to the Board of Registration and  
17 Medicine at Boston Children's Hospital, as well  
18 as the Department of Public Health. The measure  
19 put forth to you is at the institutional level.

20 Oh, so the data set that I showed you  
21 has not been published. We put it in a  
22 validation data set from January to September.

1 Our intention is to audit -- actually not our  
2 intention -- we will be auditing 2014 data in  
3 2015 what you have presented before you.

4 I think that is about what I wanted to  
5 say about some of the background on the measure.  
6 Thank you for your time and I will answer more  
7 questions as we go along.

8 CO-CHAIR GEORGE: Thank you and we  
9 will go on to the discussion of the evidence.

10 CO-CHAIR KOTTKE: Measure 0715,  
11 standardized adverse event ratio for children  
12 less than 18 years of age undergoing cardiac  
13 cath. It is the ratio observed to expected  
14 clinical important adverse events, risk adjusted  
15 using the CHARM method. It is facility level.  
16 It is an outcome measure. And I would say the  
17 evidence is high.

18 CO-CHAIR GEORGE: Any discussion on  
19 the evidence? Tom.

20 MEMBER JAMES: First, as a  
21 pediatrician, I am glad to see this. But  
22 secondarily, why the exclusion of those

1 facilities with less than 50? We just had the  
2 discussion about volume-related improvements.

3 DR. BERGERSEN: Yes, so the derivation  
4 data set, as well as any testing data sets thus  
5 far have been in centers that are freestanding  
6 pediatric heart centers. So, it hasn't been  
7 centered in centers that perform a small volume  
8 of cases, as this point.

9 CO-CHAIR GEORGE: Any other comments  
10 on the evidence?

11 If not, we will go to a vote.

12 MS. LUONG: Evidence of outcomes  
13 polling opens now; 1 for yes, and 2 for no for  
14 Measure 0715.

15 One hundred percent voted yes for  
16 evidence of outcomes.

17 CO-CHAIR KOTTKE: Okay, opportunity  
18 for improvement. Observed adverse event rates  
19 from eight pediatric hospitals used in testing  
20 are included in Section 2(b)(5.2). Rates from  
21 these facilities range from 1.71 percent to 7.86  
22 percent. The developer cited several studies



1 that likely include rates of complications  
2 following cardiac cath in children. So, there is  
3 no information on disparities.

4 And some of the data referenced from  
5 58 centers were just reported at AHA, nearly  
6 20,000 procedures, adverse events of 1.9 percent.

7 So, it seems to me there is  
8 opportunity for improvement. And the  
9 denominator, I think the denominator is kids  
10 going into the cath lab, not the total, it is  
11 irrelevant that it is one percent of kids have  
12 congenital anomalies. Kids deserve to be as safe  
13 as possible going into the cath lab.

14 CO-CHAIR GEORGE: Liz?

15 MEMBER DELONG: So, to further  
16 demonstrate my ignorance with respect to  
17 complications but the list of complications that  
18 you are accumulating is pretty long and it wasn't  
19 clear to me that they were all really  
20 significant. And there was no tabulation as to  
21 when you did collect these. What was the  
22 tabulation? What were the complications? And

1 did they fall more in the moderate range or did  
2 they fall in the severe range? I mean I have no  
3 clue.

4 DR. BERGERSEN: So, in some of our  
5 other publications, we have elaborated. The  
6 overall rates of what we are calling clinically  
7 important adverse events is four percent. And of  
8 those, about one percent are going to be these  
9 life-threatening high-severity events. And the  
10 other two to three percent are going to be the  
11 other major adverse events.

12 One of the unique characteristics of  
13 the registry is that we have assigned a severity  
14 level, which has been adopted by the  
15 international pediatric congenital cardiac code  
16 for severity of adverse events. And according to  
17 EKOS, there is definitions for severity levels.  
18 So, clinically important events would come under  
19 level 3, 4, or 5 events and the less important  
20 events were not included in the measure.

21 MEMBER DELONG: I guess my question  
22 would be suppose you have got a site that has a

1 two percent mortality rate versus a site that has  
2 at three percent rate but nobody dies. They have  
3 got a three percent rate of some of these  
4 relatively less severe complications. They are  
5 going to look worse.

6 DR. BERGERSEN: That is a good point.  
7 Fortunately, within cardiac catheterization for  
8 congenital heart disease mortality is exceedingly  
9 rare, which is one of the reasons we couldn't use  
10 that as an outcome measure for the field.

11 MEMBER DELONG: Sometimes we use  
12 composite measures because we don't have enough  
13 events. But once we use composite measures, it  
14 seems that they all have to be serious enough so  
15 that we can compare the event rates.

16 CO-CHAIR GEORGE: Any other comments?  
17 If not, we will vote.

18 MS. LUONG: Polling starts now for  
19 performance gap: 1 for high, 2 for moderate, 3  
20 for low, and 4 for insufficient.

21 For performance gap, it passes with 13  
22 percent voting high, and 80 percent voting

1 moderate, and 7 percent voting insufficient.

2 CO-CHAIR KOTTKE: Priority. The  
3 developers state that congenital heart disease is  
4 the leading cause of morbidity/mortality  
5 affecting one percent of infants and that cardiac  
6 cath has become a common quote interventional  
7 procedure with therapeutic goals complementing  
8 surgical strategies and, at times, eliminating  
9 the need for surgery.

10 Stated like all the others, it is a  
11 National Quality Strategy priority area. Again,  
12 I would say that if you are going to do pediatric  
13 caths, you ought to be good at it and you ought  
14 to have low complication rates. And I think the  
15 appropriate denominator is the child going into  
16 the cath lab. Really the one percent doesn't  
17 have anything to do with that.

18 And so, I think it is high priority.

19 And I think also the fact that it is  
20 internal rather than external, so that pediatric  
21 cardiologists who are doing this or are saying we  
22 need standards for our own practice raises the

1 priority.

2 MEMBER MARTIN: I just wanted to,  
3 again, second your comment about high priority in  
4 congenital heart disease. We have both  
5 surgical-based interventions and catheter-based  
6 interventions. There are now registries tracking  
7 both the surgical-based procedures and the  
8 catheter-based procedures.

9 This registry, the C3PO and the CHARM  
10 methodology has been critical in forming another  
11 registry that is up and running that is available  
12 now in over 90 sites in the United States. And  
13 it is this methodology that is informing that  
14 registry, so that we can start to take this to a  
15 national level. So, this has been a critical  
16 piece of information for us and it something that  
17 we would expect, with broader use, we will see  
18 even greater variation in the outcome results,  
19 whether it is with the adverse events.

20 So, this is a high priority.

21 CO-CHAIR GEORGE: Liz? Any other  
22 comments on priority?

1                   MEMBER TING: Yes, this is Henry. I  
2                   raised my hand on the web links. I don't know if  
3                   it was seen. Just a quick question. Is the  
4                   denominator all children who go to the cath lab  
5                   for diagnostic and therapeutic procedure or are  
6                   those two separated between a diagnostic  
7                   catheterization versus a therapeutic  
8                   catheterization?

9                   DR. BERGERSEN: That is correct, all  
10                  patients who go, including those with diagnostic  
11                  and interventional caths are included.

12                 For diagnostic catheterization  
13                 procedures, in addition to the adjustment for age  
14                 within the model for CHARM, diagnostic  
15                 catheterizations were stratified by age group  
16                 with a higher rate of adverse events observed and  
17                 expected among younger infants, as compared to  
18                 the older children.

19                 So, they are in three different  
20                 groups, based on age groups.

21                 MEMBER TING: So, do you stratify on  
22                 the therapeutic procedures as well? Because I

1       could imagine those could be very, very different  
2       and much higher rates of complications, depending  
3       on what the device is or specific therapies are  
4       done.

5               DR. BERGERSEN:   So, the CHARM risk  
6       adjustment methodology includes age as a patient  
7       factor that is adjusted for in the final model,  
8       after accounting for an independent of the  
9       procedure type risk group.   So, yes.

10              CO-CHAIR KOTTKE:   In fact, the type of  
11       procedure is in the model.   She said yes, Henry.

12              CO-CHAIR GEORGE:   Any other comments  
13       on priority?   All right, we will vote.

14              MS. LUONG:   Polling opens for high  
15       priority; 1 for high, 2 for moderate, 3 for low,  
16       and 4 for insufficient.

17              High priority passes with 63 percent  
18       voting high and 38 percent voting for moderate.

19              CO-CHAIR KOTTKE:   Scientific  
20       acceptability, numerator/denominator exclusions.  
21       Numerator number of diagnostic and interventional  
22       cardiac caths for children under 18 years of age

1 resulting in clinically important adverse events  
2 performed by an institution performing at least  
3 50 cases per year in pediatric patients under 18  
4 years of age. The denominator is the number of  
5 diagnostic and interventional cardiac cath cases  
6 for children less than 18 years of age performed  
7 by institutions performing at least 50 cases per  
8 year in that pediatric population.

9 Exclusions, primary electrophysiology  
10 cases, ablation cases, pericardiocentesis only,  
11 thoracentesis only. The data source is  
12 electronic clinical data, electronic registry,  
13 paper, medical records.

14 I didn't have any concerns there. It  
15 looks like Liz.

16 MEMBER DELONG: I just wonder about  
17 standardization of data elements because if you  
18 are using different kinds of sources like the EHR  
19 and a clinical registry, et cetera, is that  
20 harmonized?

21 DR. BERGERSEN: That is a great point.  
22 And there has been a lot of effort over the past



1 decade to develop common nomenclature in the  
2 field.

3 The procedure types, as defined in the  
4 procedure type risk groups, although you may use  
5 different nomenclature within your own reporting  
6 systems, there is clear one to one mapping. So,  
7 while the C3PO Registry uses a nomenclature for  
8 procedure type risk groups, when we attempted to  
9 map that to data elements within the IMPACT  
10 Registry, which uses the IPCC nomenclature, we  
11 were able to do that in a reliable fashion.

12 MEMBER DELONG: Yes, I guess I am more  
13 concerned about the outcomes, the complications.  
14 I mean one of them is monitoring. Is that  
15 well-defined?

16 DR. BERGERSEN: That is a good point.  
17 Within the registry, which I presented you the  
18 data that has been tested, as I stated earlier,  
19 the adverse events are further classified,  
20 according to severity.

21 So to give you an example which would  
22 illustrate your point, an arrhythmia, just saying

1 an arrhythmia would be an event that would be  
2 included. An arrhythmia that is self-terminating  
3 would not meet the definitions and would be of a  
4 low severity. However, one that required  
5 medication to terminate would be in a severity  
6 level 3. And if you required cardio version, it  
7 would be a severity level 4.

8 We have tried to be as clear as  
9 possible with our definitions.

10 MEMBER DELONG: So, my question is  
11 really would those all be coded the same way  
12 across different databases? Would you pick up  
13 the arrhythmia that required medication  
14 similarly?

15 DR. BERGERSEN: Thus far, it has been  
16 an abstraction from medical records and there has  
17 been limited testing in other data sets. So, I  
18 can't answer your question sufficiently.

19 CO-CHAIR KOTTKE: Okay. Are there  
20 some questions about data elements? Are they are  
21 defined? Developers compared information  
22 recorded in the database with medical record.

1 This is also considered validity and passes  
2 reliability by NQF requirements.

3 Data element testing was done using  
4 data abstractor from the EHRs and paper records  
5 entered into the database registry. A sample of  
6 3,359 pediatric patients from 11 pediatric  
7 hospitals with a total of 784 cases were  
8 examined. No information about the types of  
9 facilities, where they were, size, et cetera, or  
10 patient included in testing.

11 So, it is unclear whether the testing  
12 sample represents the variety of entities whose  
13 performance will be assessed by this measure.

14 The results of the data element  
15 validity testing indicate that 85 percent of the  
16 149 adverse events, including the medical record,  
17 were captured in the registry. All interventions  
18 performed were recorded correctly.

19 The developer states that all major  
20 adverse events were appropriately captured but  
21 that two events related to sedation and airway  
22 management and late identification of a growing

1 fistula requiring surgical repair were not  
2 recorded.

3 So, I think reliability is moderate.

4 CO-CHAIR GEORGE: Other comments on  
5 reliability? All right, we will vote on the  
6 reliability.

7 MS. LUONG: Polling opens now for  
8 reliability: 1 for high, 2 for moderate, 3 for  
9 low, and 4 for insufficient.

10 Reliability passes with 13 percent  
11 voting high, 68 percent voting moderate, 13  
12 percent voting low, and 6 percent voting  
13 insufficient.

14 CO-CHAIR KOTTKE: Validity, the  
15 specifications do align with the evidence. The  
16 validity was tested both at the data element  
17 level and the measure level.

18 Let's see. The risk adjustment model  
19 appeared to be appropriate to me but I am not a  
20 statistician. Specifications, this measure was  
21 risk adjusted using a logistic regression model  
22 with three risk factors. The calculated score is

1 the ratio of observed expected rates of  
2 clinically important adverse events occurring  
3 during or following cardiac cath.

4 The developers do not provide  
5 information on how the risk model is developed.  
6 The C statistic reported for the risk adjustment  
7 model is 0.72. This model discrimination  
8 statistic represents the proportion of all  
9 possible pairs with different observed outcomes  
10 for which the model correctly predicts a higher  
11 probability of observations with the event  
12 outcomes than the probability for non-events.

13 I don't think I want to read all this.  
14 Anyway, when applied to the impact data set, the  
15 AHA abstract reported a C state of 0.70 as well.

16 So, I think it is valid.

17 CO-CHAIR GEORGE: Any threats?

18 CO-CHAIR KOTTKE: No particular  
19 threats.

20 CO-CHAIR GEORGE: Any comments on  
21 validity? All right, we will vote on validity.

22 MS. LUONG: The poll opens for

1 validity voting: 1 for high, 2 for moderate, 3  
2 for low, and 4 for insufficient.

3 Validity passes with 25 percent voting  
4 high, 69 voting moderate, and 6 percent voting  
5 insufficient.

6 CO-CHAIR KOTTKE: Feasibility. It  
7 appears to have -- from the databases in the  
8 hospitals, I would say that it is feasible.

9 CO-CHAIR GEORGE: Any comments on  
10 feasibility? All right, we will vote.

11 MS. LUONG: Voting starts for  
12 feasibility: 1 for high, 2 for moderate, 3 for  
13 low, and 4 for insufficient.

14 Feasibility passes with 38 percent  
15 voting high, 56 percent voting moderate, and 6  
16 percent voting insufficient.

17 CO-CHAIR KOTTKE: Usability and use.  
18 The measure is currently used in the congenital  
19 cardiac catheterization project on outcomes  
20 quality improvement, C3PO QI, program for  
21 internal quality improvement. Public reporting  
22 is planned.

1 Data on improvement over time using  
2 this measure is not provided, although the  
3 developer states that progress is tracked for the  
4 participating institutions and reports are  
5 available on demand.

6 According to the developers, the  
7 vulnerability of the measure is potential lack of  
8 reporting adverse events. However, they note  
9 previous audit results have found a 92 percent  
10 event capture rate among high severity clinically  
11 important adverse events.

12 MEMBER DELONG: So, I have a question  
13 and a comment. The question is I am really  
14 confused because there have been a number of  
15 these categories that have had an insufficient,  
16 except that there were no comments. So, I feel  
17 sort of ignorant in terms of why there was an  
18 insufficient, if there were no comments. I mean  
19 I would like to hear why they were insufficient.

20 But my other comment is there is no  
21 time frame given. So, I don't know how you can  
22 evaluate and compare, if it is not with a

1 consistent time frame.

2 DR. BERGERSEN: I'll address the time  
3 frame. In order to have a sufficient number of  
4 events, at least in institutions performing  
5 between 300 and 600 cases, we need a time frame  
6 of about a year. So, in implementation we report  
7 both locally and within the registry, rolling  
8 four quarter averages.

9 So, each quarter are rolling four  
10 quarter average of the past four quarters. It  
11 wasn't in the materials provided to you. It's a  
12 good question.

13 CO-CHAIR GEORGE: Any other comments  
14 on usability? All right, we will vote.

15 MS. LUONG: Polling starts now for  
16 usability and use: 1 for high, 2 for moderate, 3  
17 for low, and 4 for insufficient information.

18 Usability and use passes with 31  
19 percent voting high, 63 percent voting moderate,  
20 and 6 percent voting low.

21 CO-CHAIR GEORGE: So, any final  
22 comments before we vote on overall measure



1 approval? If not, we will vote.

2  
3 MS. LUONG: Polling starts now for overall  
4 suitability for endorsement for Measure 0715: 1  
5 for yes, and 2 for no.

6 For overall suitability for  
7 endorsement of Measure 0715, 94 percent voted yes  
8 and 6 percent voted no.

9 And that concludes the voting for  
10 today.

11 CO-CHAIR GEORGE: I assume there is no  
12 competing measures.

13 MS. ISIJOLA: Operator, can you open  
14 up the lines once more for member and public  
15 commenting?

16 OPERATOR: Yes, ma'am. At this time,  
17 to make a public comment, please press \* then the  
18 number 1. At this time, there are no comments.

19 MS. ISIJOLA: Thank you.

20 Okay, well today ends today's meeting.  
21 We do have reservations for you at Mio, some of  
22 you are familiar with that, at 6:30. We can try

1 to push that back so you can refresh yourselves  
2 and be a little more comfortable.

3 We will reconvene tomorrow at 9:00  
4 a.m. for the meeting and at 8:30 for the  
5 breakfast. But please let us know if you have  
6 any questions.

7 (Whereupon, the above-entitled matter  
8 went off the record at 5:22 p.m.)  
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A			
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Project 2014 Standing Committee

Before: NQF

Date: 12-04-2014

Place: Washington, D.C.

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