NATIONAL QUALITY FORUM
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CARDIOVASCULAR STEERING COMMITTEE

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

PRESENT:

RAYMOND GIBBONS, Chair, MD Mayo Clinic
MARY GEORGE, Vice Chair, MD, MSPH Centers for Disease Control and Prevention
CAROL ALLRED, RN, National Coalition for Women with Heart Disease
ROCHELLE AYALA, MD, FACP, Memorial Healthcare System
SUNG HEE LESLIE CHO, MD, Cleveland Clinic

DIANNE JEWELL, PT, DPT, PhD, CCS, American Physical Therapy Association*
DANA KING, MD, MS, Medical University of South Carolina
BRUCE KOPLAN, MD, MPH, Brigham and Woman's Hospital
THOMAS KOTTKE, MD, MSPH, HealthPartners

DAVID MAGID, MD, MPH, Colorado Permanente Medical Group
GEORGE J. PHILIPPIDES, MD, FACC, Boston Medical Center
JON RASMUSSEN, PharmD, Kaiser Permanente - Colorado
DEVORAH RICH, PhD, UAW Retiree Medical

Benefits Trust

ANDREA RUSSO, MD, Cooper University Hospital
MARK SANZ, MD, The International Heart Institute of Montana
SIDNEY C. SMITH, JR., MD, University of North Carolina at Chapel Hill
ROGER SNOW, MD, MPH, Commonwealth of Massachusetts
CHRISTINE STEARNS, JD, MS, New Jersey Business and Industry Association
KATHLEEN SZUMANSKI, MSN, RN, NE-BC, Emergency Nurses Association
SUMA THOMAS, MD, FACC, Lahey Clinic Medical Center
NQF STAFF:
HEIDI BOSSLEY, MSN, MBA
HELEN BURSTIN, MD, MPH
ASHLEY MORSELL, MPH
KATHRYN STREETER, MS
REVA WINKLER, MD, MPH
ALSO PRESENT:
SANA AL-KHATIB, MD, MHS, Duke Clinical Research Institute
SUSANNAH BERNHEIM, MD, Yale/YNHH Center for Outcomes Research and Evaluation (CORE)*
LAURA BLUM, Heart Rhythm Society

JOHN BOTT, MSSW, MBA, Agency for Healthcare Research and Quality*
JENSEN CHIU, MHA, American College of Cardiology Foundation
DEL CONYERS, Heart Rhythm Society
SHERYL DAVIES, MA, Stanford University - AHRQ QI Development Team*

JOSEPH P. DROZDA, JR., MD, American College of Cardiology*
N.A. MARK ESTES III, MD, FACC, Tufts Medical Center/Tufts University School of Medicine
SUSAN FITZGERALD, RN, MBA, American College of Cardiology

JEFFREY GEPPERT, EdM, JD, Battelle Memorial Institute*

JONATHAN HALPERIN, MD, Mount Sinai Medical Center*

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

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

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

KAY SCHWEBKE, MD, Ingenix*

MELANIE SHAHRIARY, RN, BSN American Heart Association

*Present via telephone

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

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

8:35 a.m.

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

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

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

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

you when you're speaking.

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

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

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

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

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

disclosures.

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

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

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

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

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

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

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

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

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

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

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

Boston Medical Center, and I have no additional disclosures.

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

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

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

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

(Laughter.)

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

MEMBER JEWELL: Absolutely.

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

themselves, please.

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

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

DR. BURSTIN: Helen Burstin, NQF.

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

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

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

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

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

Development Task Force at the Heart Rhythm Society.

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

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

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

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

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

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

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

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

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

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

failure, atrial fibrillation, hypertension and ICD use.

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

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

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

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

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

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

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

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

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

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

recommendations you've made.

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

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

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

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

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

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

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

Well, just a couple of just

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

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

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

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

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

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

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

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

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

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

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

Are there any questions before we get going?

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

CHAIR GIBBONS: This is above my

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

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

MEMBER JEWELL: Thank you.

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

MEMBER JEWELL: Not at all.

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

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

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

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

(No response.)

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

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

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

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

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

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

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

OPERATOR: Yes, we can hear you.

CHAIR GIBBONS: Okay. So thank

you, Rochelle.

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, there's not that

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

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

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

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

moment.

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

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

(No response.)

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

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

CHAIR GIBBONS: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MEMBER SMITH: Yes.

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

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

MEMBER JEWELL: My vote is yes.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So in fairness to

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

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

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

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

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

MEMBER SNOW: CHA2, S2.

MEMBER RICH: Right, which --

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

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

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

able to clarify even further.

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

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

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

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

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

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

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

performance.

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

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

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

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

CHAIR GIBBONS: Yes, Leslie.

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

CHAIR GIBBONS: So developers want

to comment on that difficult question?

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

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

(Laughter.)

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

CHAIR GIBBONS: Yes, David.

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

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

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

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

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

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

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

MEMBER MAGID: 400 million.

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

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

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

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

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

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

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

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

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

CHAIR GIBBONS: That is correct. Rochelle.

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

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

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

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

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

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

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

it in this document.

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

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

CHAIR GIBBONS: Sid.

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

MEMBER RICH: Okay.

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

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

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

did you hear the question? Jon?

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

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

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

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

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

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

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

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

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

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

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

CHAIR GIBBONS: Other comments from anybody on the committee?

MEMBER SNOW: Well, I'd just make

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

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Partially.

DR. WINKLER: Thank you.

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

CHAIR GIBBONS: I don't recall

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

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

MEMBER RICH: No, Feasibility.

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

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

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

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

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

CHAIR GIBBONS: Jon, do you know?

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

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

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

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

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

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

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

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

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

MEMBER KING: Ray, I have a comment.

CHAIR GIBBONS: Yes, Dana.

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

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

atrial fibrillation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIR GIBBONS: Helen.

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

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

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

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

CHAIR GIBBONS: Other comments before we vote?

MEMBER RUSSO: I do.

CHAIR GIBBONS: Yes.

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

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

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

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

that.

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

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

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

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

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

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So the vote is

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

MEMBER JEWELL: You're welcome.

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

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

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

discussed by Dr. Estes and Devorah.

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

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

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

discussed before.

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

CHAIR GIBBONS: Other questions about Importance?

(No response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

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

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

The denominator is patients with

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

These have to be not only internally consistent but harmonized.

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

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

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

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

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

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

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

CHAIR GIBBONS: Jon?

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

I would also advocate for putting

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

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

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

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

submitted, for those on the phone.

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

(No response.)

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

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

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

CHAIR GIBBONS: Helen?

DR. BURSTIN: One more point about

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

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

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

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

welcome those additions.

DR. HALPERIN: I agree.

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

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

CHAIR GIBBONS: Yes, Dana.

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

CHAIR GIBBONS: No, to anticoagulation.

MEMBER KING: Okay.

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

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

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

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

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

In the interim, you know, I think

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

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

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

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

CHAIR GIBBONS: Okay, Devorah.

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

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

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

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

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

because they're on another agent.

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

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

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

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

CHAIR GIBBONS: Bruce?

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

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

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

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

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

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

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

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

CHAIR GIBBONS: Okay, Sid?

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

another FDA-approved medication for this indication?

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

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

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

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

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

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

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

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

CHAIR GIBBONS: That's an exclusion.

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

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

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

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

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

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

Vote again, please.

DR. WINKLER: Dianne?

MEMBER JEWELL: Partially.

DR. WINKLER: Okay.

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

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

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

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

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

MEMBER PHILIPPIDES: Ray, I have a question.

CHAIR GIBBONS: Yes.

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

CHAIR GIBBONS: Right, FDA.

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

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

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

CHAIR GIBBONS: Mark, developers?

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

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

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

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

of the numerator.

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

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

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

he appropriately treating to the CHADS2 score.

CHAIR GIBBONS: I want others to comment. David?

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

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

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

threshold should be FDA approval?

(Show of hands.)

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

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

DR. WINKLER: Dianne?

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

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

(Show of hands.)

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

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

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

DR. WINKLER: Dianne.

MEMBER JEWELL: Not at all.

DR. WINKLER: Okay.

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

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

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

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

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

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

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

CHAIR GIBBONS: Are there other

comments or questions?

(No response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

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

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

CHAIR GIBBONS: Other comments or questions?

(No response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

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

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

MEMBER SNOW: What's the other

vote?

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

MEMBER JEWELL: Could I ask a clarifying question please?

CHAIR GIBBONS: Sure.

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

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

MEMBER JEWELL: Okay, thank you.

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

MEMBER JEWELL: Okay, thanks.

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

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

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

baseline.

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

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

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

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

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

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

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

CHAIR GIBBONS: Yes.

DR. WINKLER: Dianne?

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

DR. WINKLER: Dianne?

MEMBER JEWELL: No.

DR. WINKLER: Okay.

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

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

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

CHAIR GIBBONS: Correct.

MEMBER RUSSO: Okay.

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

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

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

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

DR. SCHWEBKE: You hear me okay?

DR. WINKLER: Yes Kay.

DR. SCHWEBKE: Great, thank you.

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

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

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

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

Now based on our test results,

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

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

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

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

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

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

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

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

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

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

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

MEMBER SNOW: Okay, I have one.

CHAIR GIBBONS: Roger Snow.

MEMBER SNOW: I'm supposed to talk

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

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

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

I think your point is well-taken,

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

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

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

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

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

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

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

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

(Off mic comment.)

CHAIR GIBBONS: No comment, okay. So --

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

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

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

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

than evidence-based.

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

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

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

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

MEMBER SNOW: The other side of

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

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

CHAIR GIBBONS: Okay. Other comments? Tom.

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

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

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

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

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

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

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

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

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

MEMBER KOPLAN: Okay.

(Laughter.)

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

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

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

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

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

CHAIR GIBBONS: Okay. Other comments?

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

CHAIR GIBBONS: Certainly.

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

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

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

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

(Simultaneous speaking.)

MEMBER RUSSO: No, the comments.

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

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

MEMBER RUSSO: Right, PFTs, exactly.

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

CHAIR GIBBONS: Rochelle.

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

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

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

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

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

So again, in the spirit that it

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

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

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

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

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

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

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

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

DR. WINKLER: Dianne.

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

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

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

(Whereupon, the above-entitled

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

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

DR. MASOUDI: Dr. Gibbons?

CHAIR GIBBONS: Yes.

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

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

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

CHAIR GIBBONS: Absolutely. Fred,

that's perfectly fine.

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

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

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

who have received implantable cardioverter defibrillators.

The use of this expensive therapy has increased substantially over the last several years, in large part because of the expansion of ICD therapy for primary prevention of sudden cardiac death in patients with left ventricular systolic dysfunction. In fact, left ventricular systolic dysfunction is one of the most common reasons for which implantable defibrillators are placed, and as many of you know, coronary artery disease, myocardial infarction is a very common cause of left ventricular systolic dysfunction.

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

as a second measure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

committee for you.

(No response.)

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

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

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

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

CHAIR GIBBONS: No, I'm sorry.

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

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

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

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

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

the data in the submission.

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

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

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

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

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

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

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

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

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

Other comments about scientific acceptability?

(No response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Partially.

DR. WINKLER: Thank you.

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

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

MEMBER KOPLAN: Can I make a silly comment?

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

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

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

CHAIR GIBBONS: No.

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

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

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

CHAIR GIBBONS: She voted partially on the phone.

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

(Off mic comments.)

CHAIR GIBBONS: Are we keeping score?

MEMBER KOPLAN: That was a

mistake.

(Laughter.)

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

MEMBER KOPLAN: I apologize.

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

(No response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

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

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

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

CHAIR GIBBONS: Other comments or questions here?

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

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

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

MEMBER SANZ: Ray, I have a question.

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

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

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

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

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

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

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

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

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

DR. MASOUDI: Yes, that could

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

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

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

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

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

MEMBER SANZ: I agree.

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

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

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

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

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

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

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

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

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

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

CHAIR GIBBONS: Well, I think --

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

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

MEMBER KING: Okay.

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

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

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

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

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

substantial risk for sudden cardiac death.

CHAIR GIBBONS: Devorah.

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

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

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

MEMBER RICH: So it should be 100 percent.

MEMBER PHILIPPIDES: It should be

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

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

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

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

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

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

working towards --

(Simultaneous speaking.)

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

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

(No response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

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

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

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

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

DR. MASOUDI: Can I interject on that issue?

MEMBER PHILIPPIDES: Sure, please.

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

MEMBER KOPLAN: Can I ask a

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

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

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

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

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

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

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

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

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

(Simultaneous speaking.)

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

MEMBER SANZ: But Ray, on your

right.

CHAIR GIBBONS: Yes. Thank you, Mark.

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

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

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

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

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

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

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

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

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

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

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

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

Not because it doesn't happen, but

because it happens quite rarely.

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

DR. MASOUDI: That's correct.

MEMBER SANZ: As they're going home.

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

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

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

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

MEMBER PHILIPPIDES: Okay, and then we --

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

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

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

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

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

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

CHAIR GIBBONS: Roger.

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

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

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

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

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

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

They're the accessory documents with --

MEMBER PHILIPPIDES: Okay, okay. I guess I was looking more for race and ethnicity, but I did see that, and there were no differences between safety net and the other hospitals. That's correct. Okay.

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

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

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

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

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

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

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

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

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

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

MEMBER RICH: I'm sorry.

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

CHAIR GIBBONS: So 160 is an acute MI discharge.

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

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

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

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

CHAIR GIBBONS: Yes, Rochelle.

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

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

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

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

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

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

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

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

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

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

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

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

CHAIR GIBBONS: Other comments or questions?

(No response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

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

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

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

DR. MASOUDI: Oh yes, I apologize.

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

have a discussant.

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

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

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

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

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

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

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

MEMBER CHO: I have a question.

MEMBER KOPLAN: Yes.

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

improves outcome?

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

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

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

ACE inhibitor, according to this composite.

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

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

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

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

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

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

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

But when you combine two different

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

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

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

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

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

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

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

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

CHAIR GIBBONS: David.

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

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

DR. MASOUDI: Yes.

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

(Simultaneous speaking.)

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

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

nothing composite measure, for PCI.

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

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

That's the spirit, and if you go

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

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

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

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

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

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

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

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

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

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

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

MEMBER MAGID: Okay.

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

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

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

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

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

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

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

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

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

MEMBER KOPLAN: So that would

involve taking out the word "all?"

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

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

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

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

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

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

(No response.)

CHAIR GIBBONS: All right. Let's

go ahead and vote on this one.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

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

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

CHAIR GIBBONS: Additional comments or questions?

(No response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

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

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

CHAIR GIBBONS: Any other comments or questions?

(No response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

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

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

CHAIR GIBBONS: Yes.

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

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

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

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

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

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

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

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

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

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

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

DR. WINKLER: Bruce is volunteering.

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

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

(Laughter.)

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

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

MEMBER KOPLAN: It shouldn't be hard.

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

MEMBER PHILIPPIDES: I am.

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

DR. MASOUDI: I'm present.

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

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

CHAIR GIBBONS: Not a big deal either way.

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

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

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

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

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

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

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

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

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

at acute MI.

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

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

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

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

(Simultaneous speaking.)

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

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

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

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

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

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

MEMBER PHILIPPIDES: And this is just this measure.

CHAIR GIBBONS: We are just voting on this measure, because we have to basically make certain that we've evaluated separately each of the components of the composite, because that's been an issue for other composite measures that have come forth through the NQF system, and this one should

not be subject to that criticism.

You don't need to know the whole history of that over the last two years, but it's an enormous history. So we must vote on this component.

MEMBER PHILIPPIDES: Made very clear, Mr. Chairman.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

MEMBER JEWELL: Yes.

CHAIR GIBBONS: 18 to 0. Now Feasibility?

MEMBER PHILIPPIDES: So I'm hungry. All of the things that I said 20 minutes ago apply. I think it's feasible. Let's vote.

(Laughter.)

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: 19 to 0, and then

the final vote, does this measure, this individual measure, meet the NQF criteria for endorsement?

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

CHAIR GIBBONS: Okay. That's a unanimous vote of 20 to 0. I agree. George should lead all of these. So now we have had, I'm going to get all my numbers right. So we've had, and let me look at the sheet with my bifocals. We have had individual votes on Measures 1522, 1528 and 1529, approving them.

They are incorporated in the composite 0965. That composite, as we said, reflects a longer-term trend, a recommendation from the Institute of Medicine, some real world experience, and our own direction to the developers at the last meeting.

So we're now going to take a vote on whether, in our view, 965 trumps the others. In other words, that the others go

away because there's a single measure that counts, and it's 965. So that is a yes or no vote.

DR. WINKLER: No, that's not --

CHAIR GIBBONS: No?

MEMBER RUSSO: Could we discuss this further or ask a question? So two questions actually. One is, is there a standard in NQF for the process?

Do you need to have measures, single individual measures out there before you make a composite measure, and then the second question would be if, for some reason, and not so much in this measure, but I'm thinking of a subsequent measure we have to review later today, and we reviewed one last time that has a very complex kind of mathematical formula, to come up with a measurement for that particular composite measure.

If for some reason we find out that this composite measure turns out to be

something that was a mistake in something we created, are we allowed to go back and divide that measure up into the individual measures, without having the individual measures to give, you know, sites credit for them?

So would it be -- what's a disadvantage, an advantage if we approve the individual measures and leave them as such, if we go back and there's something wrong with the way we've created the composite measure formula, and again I don't think it's going to be in this case.

But are we allowed, you know, does that give us the ability to give people credit for the individual measures? If we excluded those individual measures and subsequently when we go out to get this and look at it again prospectively now in real life, are we allowed to divide it up after the fact?

So I don't know what the precedence is and --

DR. BURSTIN: I'll start. So

essentially, our requirements for our composite framework is that each measure needs to be individually evaluated as a stand-alone measure, and its role within a composite. Then you need to make a decision whether those individual components have worth on their own for accountability purposes.

Would you want to see, for example, just beta blocker without ACE/ARB? Would you want to see any one of those individually, or is the composite, because it's all or none, is it a stronger measure overall, and therefore well of course you would want to be able to divide this up for quality improvement purposes internally, to say hey, we're really failing on ACE/ARBs, but we're great on beta blockers.

But the question is would you want to use that for an accountability function or public reporting, or would the composite really suffice? The issue of whether the composite's wrong, that can always be

addressed and fixed. That's not really something I would get too concerned about right now.

CHAIR GIBBONS: And I would second that, just from, you know, and Tom can chime in, because he probably knows the details of this. But certainly in terms of the Minnesota experience using composites, you can correct the deficiencies on, you know, once you sort of recognize, oh, we didn't quite get this numerator or this denominator or whatever.

If the overall spirit is correct, you can correct the deficiencies. That's not the issue, and it's just that from a public reporting standpoint, you now have a single number, and that number really counts more than the individual components. You do tend to, on an operational level internally, as Helen just said, look at what, where are we fouling up here, when you don't do well on the composite.

But Tom, do you want to comment at

all on that? He must be hungry. All right. So I am told now that I misstated the vote, so especially for the people on the phone, the vote is supposed to be as follows:

One, we recommend the composite and the individual measures. Two, we recommend just the composite, or three, we recommend the individual measures. So further discussion on this before we vote, for those three options? Mark.

MEMBER SANZ: I'm just confused what this means. If we vote number one, does that mean people will have to report to both?

DR. WINKLER: It means you will have recommended for endorsement four measures, the three individual plus the composite.

CHAIR GIBBONS: So conceivably, yes. People would then conceivably have to report four things.

MEMBER SANZ: I see.

DR. MASOUDI: At the risk of

alienating the group, Ray, could I make a brief comment?

CHAIR GIBBONS: Absolutely.

DR. MASOUDI: And I apologize, because I know that you're waiting for lunch. But I would just say that it seems to me that based on many of the other measures that are out there and currently endorsed, that the individual components of this seem, including levels of performance, to conform to those criteria that have been used for endorsement elsewhere.

Also, I would suggest that having the endorsement of the entire group of measures will not involve duplicative data collection on the one hand, and provides us as implementers with more flexibility in terms of how to use the measures.

MEMBER SMITH: How does the composite measure work again? If we say we want the composite measure, then it's an all or none. Either you're managing your patient

correctly or you're not.

CHAIR GIBBONS: Right, correct. So for example, you know, just pulling numbers out of the air, you might be 90 percent on Measure 1, 90 percent on Measure 2, 90 percent on Measure 3. But where you really are is 78 percent.

MEMBER SMITH: Yes, I resonate. I think we ought to look at the total approach.

CHAIR GIBBONS: Rochelle.

MEMBER AYALA: Just an option for the title of the composite, which I think goes to a lot of what you've been talking about, and that is some -- I've seen it before, where sometimes they refer to these as the measure of ideal care, the MIC, the measure of ideal care, and then you define what is ideal care.

So like if you're looking at composite for the AMI indicators and you take out the ones that you think should be in that composite. From what you said before about anyone placing an ICD in a patient should have

these anyway, kind of sort of brings it to that level, as opposed to just is the patient on an ACE or a beta blocker.

CHAIR GIBBONS: We had a discussion on that for the composite measure. People didn't like the word all. I have no idea whether they like the word ideal. But there was a feeling that we should have the specific components listed in the title for clarity, and I think the measure developers indicated a willingness to do that. Is there other discussion on this vote before we vote?

MEMBER JEWELL: Ray, am I choosing one, two or three, or we're taking three separate votes?

CHAIR GIBBONS: No, no. The vote is, one, the composite and the individual measures; two, just the composite measure; or three, just the individual measures.

MEMBER JEWELL: Thank you.

CHAIR GIBBONS: And the question being asked is what is your recommendation for

overall endorsement?

MEMBER JEWELL: Thank you.

CHAIR GIBBONS: Yes, and that's fine. I'm glad you asked, so that we're all clear on that.

MEMBER RUSSO: And just one other question, because I wonder -- so the developers created the composite measure up front this time, which is, I think, a little different than what's been done in the past.

So if this were a yearly process and the group that developed this didn't have to wait three years, would they have -- I'm curious as to would you have just put out the individual measures first, or does it, you know.

If it wasn't waiting three years, as I'm getting the feeling that, you know, obviously they want, you know, us to consider all the measures separately plus a composite. But if there were a different process in NQF, maybe it would have been submitted

differently? Is that correct or --

DR. MASOUDI: Well originally this was submitted at the original call as the three individual measures. Again, the composite was submitted in response to the discussion at the last meeting around the PCI measure.

So this was an attempt to be responsive to the request for a composite measure for these processes of care for patients with ICDs.

CHAIR GIBBONS: And just for clarity, Fred, so we're entirely transparent, the developers would like to see everything approved, or just the composite?

DR. MASOUDI: Well, I think our preference would be that they all be approved, for the purposes of allowing us flexibility in terms of implementation. Again, I think the individual component measures seem to be on par with a variety of others. That of course is -- that final judgment is up to you.

But our preference would be, if it's possible, to have each of the measures endorsed, if it's possible.

MEMBER RUSSO: Just to clarify --

CHAIR GIBBONS: Tom.

MEMBER KOTTKE: Yes, if I could just make one comment about the composite used by Minnesota Community Measurement, for example, the diabetes measurement, which includes tobacco use, and the question has arisen, if you have tobacco in there and you have just smokers who aren't going to quit, does this mean that the doc gives up on the patient, the patient's other measures, because they'll never achieve the composite?

So I think this speaks for the composite plus the individual measures for that flexibility, if the proposers learn that there's something in there that may have an unintended consequence.

CHAIR GIBBONS: Other discussion before we vote?

(No response.)

CHAIR GIBBONS: All right. We're going to go ahead and vote.

DR. WINKLER: Dianne?

MEMBER JEWELL: One.

DR. WINKLER: Okay.

CHAIR GIBBONS: So there are 12 votes one, that is the composite and the individual measures, and 8 votes two, just the composite measure. So we have approved the composite and the individual measures, and let me ask for help here, staff. Okay.

Since George is on a roll, and we have a feeling this will go faster before lunch than after lunch, we're going to do Measure 1530 at this time, prophylactic antibiotics prior to ICD.

MEMBER PHILIPPIDES: This measure looks at the proportion of patients who receive an ICD implant or lead procedure, that receive antibiotics within one hour. For some reason, if it's a fluoroquinolone or

vancomycin, two hours, Bruce, maybe you can help me with that one, prior to the procedure.

The impact, I think, has had about 120-140,000 ICDs placed per year. Infection rates vary between about .7 percent and 3.28 percent, and when these get infected, they're a huge cost and it's a high-morbidity situation for the patient. So I think the impact is high.

I could not find evidence of a performance gap data, but I've been bad at finding data it seems. Can we ask if there is such data? They mentioned that in the next registry, it will become available. But I didn't see any, as far as the performance gap. Can I get some clarification on that?

DR. MASOUDI: Yes. We do -- Krystine McGuinn, are you there?

MS. McGUINN: (off mic)

MEMBER KOPLAN: What is the gap, because at my institution, if anyone doesn't get antibiotics, it's a mistake, and also I

think the last time like JCAHO came through, that was one of their requirements, that they had -- that every patient had to have antibiotics. So I would think the percentage is very high.

DR. MASOUDI: Yes. The Joint Commission focuses on, I think, general surgical procedures, if I'm not mistaken. So this is an area that I don't believe is actually captured in the Joint Commission -- and skip the surgical measures.

I'm finding the data that we have, again because this is worked into the more recent version of the registry, we don't have the same level of experience with this particular measure as we do the others. I'm just looking for the numbers here. I believe they were supplied, but it was probably as an appendix. Are ACC staff there?

CHAIR GIBBONS: Yes, they are, and we're all looking for the data as we speak.

DR. MASOUDI: Okay.

MEMBER KOPLAN: The three electrophysiologists in the room, is it like 100 percent at each of our --

MEMBER RUSSO: A hundred percent, I agree, but I don't know what the data is. Is that on the ICD registry form or is that --

CHAIR GIBBONS: You must use the mic.

MEMBER RUSSO: But we should know that data, right? Maybe it's not 100 percent.

DR. MASOUDI: Yes. So here's the data that I have here.

MEMBER PHILIPPIDES: I think I just found the document that you were looking for, Distribution of Prophylactic Antibiotics, and I think, if I'm reading this correctly, the median was at about 100 percent, and the 25th percentile was .9889.

DR. MASOUDI: That's what I have as well. So again, it's sort of like one of these -- rather than many of the process measures, this is almost like as much a never

event as I think you were alluding to before.

MEMBER PHILIPPIDES: Okay. Shall I proceed?

CHAIR GIBBONS: Yes. Yes, please.

MEMBER PHILIPPIDES: So there is some evidence in the form of prospective trial, looking at antibiotics versus not, and there's no question. It was actually stopped early, that trial, because the people who didn't get prophylactic antibiotics had a high risk of infection.

So I think overall, there's a high risk population. This does matter, this administration of antibiotics, but I'm a little bit concerned about the very, very, very small impact gap across the country.

CHAIR GIBBONS: Other discussion on this point?

MEMBER SNOW: Well, if everybody's getting it, then it's kind of topped out, isn't it? Of course, it's important. I don't think, you know, the antibiotics, implanting

a device like that. That's almost a no-brainer. But if everybody's getting it and it's under a registry and the reporting's 100 percent, there's not going to be any gain from separately reporting it, is there?

MEMBER PHILIPPIDES: Also as a general rule, there's so much onus now placed on avoiding hospital infections, that I think this is just going to take care of itself, without having to adopt this particular measure. I mean everybody is on top of hospital infection rates.

CHAIR GIBBONS: It would seem as if 1(b) is not met.

MEMBER PHILIPPIDES: Yes.

CHAIR GIBBONS: Is there other discussion before we vote? Helen?

DR. BURSTIN: I was just going to say, we are in the midst of our surgery endorsement maintenance project, just like you guys, and they are reviewing those skip measures. So one other possibility is to

ensure that ICDs are included in the list of procedures covered by the skip measure.

CHAIR GIBBONS: Now there's a provocative suggestion. The staff are, they may be hungry, but they're still thinking. All right.

MEMBER RUSSO: Out of curiosity, do they have a gap or are they up to 100 percent also for other pre-op antibiotics? Doesn't everyone do that everywhere all the time? How could you not?

DR. BURSTIN: It's dramatically increased over time. There are still some areas where there's a gap. But again, it's one of those interesting areas. We're starting to look at some of the population differences. It's not uniform.

CHAIR GIBBONS: Okay. I think we should vote on importance.

DR. WINKLER: Dianne?

MEMBER JEWELL: No.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So the vote is 3 yes and 17 no. So per our protocol, we are through discussing this, but we will urge the staff to carry the message to the surgical committee, to try to make sure that ICD implants are included as a procedure in their measures.

We now want to make sure we make available time for any other members of the public present, or present by phone, to comment.

DR. WINKLER: Operator, is there anyone who'd like to ask a question or make a comment on the phone?

OPERATOR: If you do have a question or comment over the phone, please press *1 at this time. We do have a question. Christopher, your line is open.

MR. DEZII: Great, thank you. My name is Christopher Dezii from the Bristol-Myers Squibb Company. We are the makers of coumadin, as well as having a direct factor

10(a) inhibitor in a full development program, and I am a member of the NQF Supplier and Industry Council.

Just a brief question on 1525, chronic anticoagulation measure. Just to confirm, did the steering committee recommend the measure to include other anticoagulants with an FDA-approval threshold?

CHAIR GIBBONS: That was a recommendation that we made back to the developer.

MR. DEZII: Thank you, and now here's a follow-up to that, but this is probably an NQF question, and it's around harmonization. If and when the signed measure approaches, is approved, will that prompt a review to update all measures containing exclusive reference to warfarin?

DR. BURSTIN: Chris, this is Helen. All of the VTE measures are going through currently our processes in safety later this year, and I'm sure this issue will

likely come up. I can't make assurances that it will be a uniform process.

MEMBER SMITH: Wait a minute, though. Have there, I don't know that warfarin has been tested in all circumstances. So I think it would be highly illogical to broadly include this for all mention of warfarin. I don't, I'm not sure the basis for your question.

MR. DEZII: Well, the basis of my question is that there are a number of different measures, and one that comes to mind, I believe it's a heart failure measure, for patients with afib with warfarin utilization. I just assumed it might be more reasonable, based on the discussion going forward and allowing for innovation, that it would be updated to include other, or you know, or just anticoagulants, oral anticoagulants.

MEMBER SMITH: Warfarin is used for patients with prosthetic valves. It may

have normal sinus rhythm. Can you quote an RCT there?

MR. DEZII: For what, the measure?

MEMBER SMITH: Yes.

MEMBER RUSSO: It's the level of evidence for the other anticoagulant, which is only one that's in that focused update guideline. But it's a large randomized clinical trial, compared to -- it's for a specific indication, and they excluded patients with valvular, you know, prosthetic valves.

MR. DEZII: Non-valvular, yes.

MEMBER RUSSO: So it's a specific study looking at a specific indication that caused it to be approved by the FDA. That was what they were studying, is it a non-valvular, atrial fibrillation group that did not have -- you were excluded if you had renal failure, excluded if you had a metal valve. So in that group is what the guideline came out with.

MR. DEZII: Right, right. Yes.

I'm not looking for answers; Helen pretty much answered it, that there is a prompt to review these. That's all. But thank you.

CHAIR GIBBONS: And you probably didn't hear that comment, but it is hopefully based on the evidence, and that is, I think, what the committee had just kind of --

DR. WINKLER: Reinforced.

CHAIR GIBBONS: Reinforced, that's right. That's a good word. Reinforced with several comments here.

MR. DEZII: Great, thank you.

MEMBER SANZ: I think the actual stated vote was on use of FDA-approved drug for non-valvular atrial fibrillation. It was not for all warfarin indications.

CHAIR GIBBONS: Correct.

MR. DEZII: Yes, agreed.

DR. WINKLER: Are there any other --

MEMBER SANZ: By the way, it is a Class 1 indication for dabigatran. We found

out later after that vote. So there is no disharmony between FDA and the guidelines.

MR. DEZII: Okay.

DR. WINKLER: Okay. Are there any other questions from the phone?

OPERATOR: Not at this time.

DR. WINKLER: Thank you. Anybody in the room?

(No response.)

CHAIR GIBBONS: All right. We're going to break for lunch, and we're going to hope that we can be back and starting to work at 1:15, please.

(Whereupon, the above-entitled matter went off the record at 12:29 p.m. and resumed at 1:17 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:17 p.m.

CHAIR GIBBONS: So we're now going to move on to another sort of composite measure, 0964, which is on PCI. It reflects our discussion at the previous meeting. Fred, do you want to make a comment?

DR. MASOUDI: Yes sure, Ray. Thank you again for having me back. This measure is in direct response to the committee's request for an all or nothing composite for the clopidogrel class. Aspirin and statin after PCI measures that were considered and were viewed as individually scientifically sound during the last meeting.

There were some issues around the level of performance for the two anti-platelet drugs. The data, so this composite is quite similar to the composite that has been discussed before, so I'm sure the issues around the naming would apply to this measure.

This measure differs in that

rather than focusing on two medications, it's three medications. Again, two different anti-platelet agents and statins. The testing results should be included in your packages. The overall performance on this measure, is about, I believe it's -- I'm sorry.

It's 86 percent at the median. So it's certainly a reasonable gap at the median level, and around 90 percent below the highest quartile.

The values with respect to safety net versus non-safety net, the proportion of patients within a hospital that are white, the male versus female at the individual level, the age greater than 65 and race data are all included in your packets, as requested by the committee at the last meeting.

Again, I believe that conceptually this is quite similar to the previous measure. It's just in a different population and using different processes of care.

CHAIR GIBBONS: Okay. Thank you,

Fred, and this, the discussion of this measure will be led by Mark Sanz. Mark, you're on.

MEMBER SANZ: Thank you. I'd like to thank Fred and the ACC for coming up with this composite measure, because this was highly asked for at the last meeting. I think this is very well done. The gap is -- well, the first thing would be the impact is high, since this is every PCI in the United States.

The performance gap actually is much higher when you have a composite measure than with any of the individuals. So previously, we had been up in the 95 percent range, but now the mean is down in the 85 percent range, and the evidence is high.

CHAIR GIBBONS: Are there other comments or questions before we vote on importance?

(No response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So the vote is 19 to 0. Scientific Acceptability, Mark?

MEMBER SANZ: The specifications are good. My only concern was the, again getting back to, not that I want to bring it up again, but the warfarin and so on. Do we want to strictly limit it to these three drugs?

There are newer P2Y12 agents coming, Ticagrelor and some others, or do we want to just say P2Y12 approved agent, because does it say in here, list those three drugs, Tica, Plavix and Prasugrel.

DR. MASOUDI: And could I respond to that by saying that's an excellent point? These, the measure is intended to be designed to be responsive to changes in FDA approval for medications that might substitute for these. So should Ticagrelor be approved by the FDA, the measure can and will be changed

to reflect that.

MEMBER SANZ: Okay. The other thing would be, and maybe you can help me with this, Fred, would be the statin. So it's pretty obvious if your LDL is over 100, it's probably obvious if your LDL is over 70. Do you get dinged if your LDL is 50 and you don't put someone on a statin, and what if you have the main problem being a low HDL and you choose to use niacin and Lopid, something like that?

DR. MASOUDI: Yes. My recollection -- I'm sorry. I need to find the submission for the statin measure. My recollection is is that this only applies, for the purpose of accountability, to patients with LDLs that are at or above 100, but allow me to recheck the specifications.

MEMBER SMITH: Are you looking for data to support the use of statins with LDLs less than 100?

DR. MASOUDI: That's not the issue,

the specification.

MEMBER SMITH: I can easily give you the data on that one.

DR. MASOUDI: Yes.

MS. FITZGERALD: So Fred, this is Susan from the ACC, and we had originally required the LDL greater than 100, and the committees that reviewed this actually took that requirement off.

DR. MASOUDI: Okay.

MS. FITZGERALD: Do you remember that, Fred?

DR. MASOUDI: So at this point, there's no LDL restriction. But if one were to write that one was not going to prescribe a statin because of an LDL that they felt was in the clinical target range, although there is some debate about that, that patient would be excluded.

CHAIR GIBBONS: There's flexibility for physician judgment.

MEMBER SANZ: All right, and then

my only other concern would be 2(a)(8), the exclusions. We've had a discussion about hospice already. I really don't want to relive that. But transfer to an acute facility. If someone's doing free-standing cath lab PCI and transfers to another facility, that would be excluded here and I don't think that should be.

DR. MASOUDI: Yes. This is again -- this issue was discussed with respect to the individual component measures. Now there was some debate about that. Again, this is an issue of -- you know, again, this just reflects the specifications of the component measures, and to that extent, that exclusion applies across each one of them.

This again reflects back to the conversation that was had at the last time, when this issue was raised and the measures were moved forward, but I hear what you're saying.

MEMBER SANZ: Okay. There is a

whole thing on disparities separate from the guidelines. It's nice what they do. So I don't want to go into it at length.

CHAIR GIBBONS: Yes, and we'll be looking over that data tomorrow. It's pretty interesting.

MEMBER SANZ: It's interesting --

CHAIR GIBBONS: It really is interesting.

MEMBER SANZ: Yes.

CHAIR GIBBONS: I think we'll be glad we made that request. Are there other comments or questions before we vote on the Scientific Acceptability?

(No response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: Sixteen completely, 4 partially. We'll now move on to Usability.

MEMBER SANZ: So, you know, I think this has all been discussed before. It's very usable. It's been used in most cath labs in the United States already. Unlike a lot of other areas, most cath labs already submit to NCDR, and more are coming all the time, and it clearly adds value to existing measures now that it's a composite.

CHAIR GIBBONS: Other comments or discussion?

(No response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So completely, 19; partially, 1, and now finally, Feasibility.

MEMBER SANZ: The data is generated during care. You can get it either on paper or electronically, although I think you have to submit electronically. Exclusions we've

talked about, and there aren't a whole lot of reasons for inaccuracy.

CHAIR GIBBONS: Other comments or questions?

(No response.)

CHAIR GIBBONS: All right. Let's go ahead and vote on Feasibility.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: 19 completely, 1 partially, and then finally, we're going to vote now. This is just to endorse this composite, the first vote.

MEMBER SMITH: Ray, can I ask a question about -- I've already voted, no major hang-ups here, but are we, when we do this composite, will the single measures be included like we did with the heart failure one, where we had -- we're going to look at the whole thing, and then --

CHAIR GIBBONS: We're going to have

a subsequent vote right now.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So the vote is 18 yes, 1 no. So we've approved this composite. So in terms of your question, Sid, we're now going to have the same discussion that we had about the earlier composite and the individual measures.

MEMBER SMITH: Okay. So I just think that we would be well served if there were some criteria about composite measures. We said that all composite measures we'll do one way, whether there are certain concepts that govern whether or not the individual measure should be reported.

Otherwise, it could be termed capricious, sort of, you know, have we had lunch yet? How was the decision -- what is the basis for the committee to make this decision? I just think that the process would

be well served by some criteria.

CHAIR GIBBONS: Okay, staff. Helen, you're on.

DR. BURSTIN: Actually, I think would we'd like to do is actually share with the committee the composite framework that we adopted last year.

I think just very much in a quick summary, the idea would be to determine, for the sake of NQF endorsement, if the end goal really is its purpose to be used for accountability and quality improvement, but not just QI internally, but really some external-facing function around accountability and public reporting.

Do you need to continue -- I'm sorry. I'll take that back. Is there additive value beyond the composite, in having the individual measures individually reported on for one of those accountability functions, and I'll pull up the exact language for you. But essentially, it's really a value metric,

that if you have the overall comprehensive nature of care, is there a need for the individual elements, or can it -- or is the value really fully subsumed in that composite?

MEMBER SMITH: Well, my reaction from a quality-improvement standpoint is there is value. It would be very important to know --

DR. BURSTIN: Let me just finish with that, because again, all measures that are out there for QI, there's no reason the individual components couldn't be used for QI at every one of your institutions. The issue is NQF doesn't endorse measures for only QI.

So certainly individual components, continue to use them, you know, as you see fit, to improve care. The issue is for accountability. Is there value in having the individual measures?

MEMBER SNOW: All right. The idea that I see here is that the best use of the composite measure is the public use. The

individual QI issues remain and they'll still be available. But for the public, and the composite is really more like looking at an episode of care, where the individual ones are looking at elements of care. So that's where that comes in, I think, the accountability piece.

CHAIR GIBBONS: Devorah.

MEMBER RICH: I want to agree with Roger. I'm sorry, I want to agree with Roger. What I was thinking from a public-reporting standpoint, Mark said that the measures are relatively high in and of themselves. It's only when you get to the composite that you see where the gaps are.

The last time we did this vote, I actually voted for number one, because I felt that there was an opportunity for the public to learn more. But I think in this case, there's not that much of an opportunity, and we don't want to overwhelm people.

So I think from a public-reporting

point of view, it makes sense for this measure only to focus on the composite.

CHAIR GIBBONS: David.

MEMBER MAGID: Fred, we should probably -- I don't know, Fred. Are you still on?

DR. MASOUDI: Yes, I'm present.

MEMBER MAGID: Fred, you had a reason why you wanted the individual measures. Could you just remind us what that was?

DR. MASOUDI: Ideally, from the perspective of implementation, I think that just having the availability of the capacity to use for the purposes of reporting the individual components is useful, because oftentimes in the reporting, you know, you'd like to report the overall rate of a composite, and then provide some insights into where the deficiency comes from, because of course, you know, that's the downside of composites is that you lose some of the granularity.

So from our perspective, ideally we would have the flexibility to use those things for public reporting purposes. I do understand how, particularly for -- I mean I would say for the statin measure for sure, levels of performance for the statin measure are on par with the ACE inhibitor measure for systolic dysfunction in ICD patients.

There actually is still a fairly substantial persistent gap in care there. Obviously, not as much so for the aspirin and clopidogrel. So I understand, you know, the concerns about the issue of those two measures in particular being topped out.

But again, that's why I was, you know, hopeful for the possibility of having the individual component measures used for the purposes of public reporting. But we certainly understand with respect to the latter two measures about the anti-platelet agents. Their performance is obviously high. That's apparent.

MEMBER SANZ: Fred, this is Mark. As far as QI goes, even if we voted this was only composite measure, you could report through the NCDR all the individual members to the group.

DR. MASOUDI: Yes. There's no doubt about that. I think that was Helen who made that point, which is a good one. Again, I think sometimes in the context of public reporting, you know, while composites are extremely useful to provide an overall picture of care, in many cases, I think experience has shown that, you know, for the purpose of transparency, it's nice to have the individual components reportable, so that there can be an understanding of where the composite came from, you know, where the performance in the composite came from.

MEMBER RUSSO: I guess is there any situation we might want, since the individual composites might include, not for this example we're looking at now, if there was any

disparities within, say, you know ACE or ARBs. Maybe your hospital has a lot of renal failure patients and maybe if you divided it out -- well, I guess that would be an exclusion.

I'm trying to think is there any situation where we might want to know about the performance of the individual measure related to disparities or any other features that we wouldn't be able to get out of the whole group of measures together, and the second part is also do -- it was different with the previous one, the composite measure.

The individual ones really haven't been out there a while. This would be a little different. So we already know there's high performance, or we have a suggestion that there's probably high performance also on the one we looked at earlier today. Might we want to consider those type of things too?

For this one, I don't -- it doesn't, since they're high -- I don't know that there's much benefit, because they're

high performing already, and we know that, for the public, and even for the individual.

CHAIR GIBBONS: Christine?

MEMBER STEARNS: Can I just ask how much more of a burden it is for providers to provide the individual measures versus the composite?

(Simultaneous speaking.)

CHAIR GIBBONS: I think the answer's none.

DR. MASOUDI: Yes. There's no additional burden, in that public data that are submitted for the purposes of computing the individual measures are those that are used to compute the composite. So that the onus is basically on the reporter to compile the data in a different manner. But no additional onus on the provider.

CHAIR GIBBONS: So the only potential burden is on somebody looking at the public report being that provider or the public, to say which one of these four numbers

is really important.

MEMBER MAGID: Well, and is there a risk that they won't then report the composite?

MEMBER RUSSO: The only other part of that is not again, in a subsequent measure later today, is how they're weighted. In this one, you know, they may have equal weight or how are they weighted in the individual. How is that whole formula calculated? So I think, I still think there's some value to the individual measures in many instances. Probably not this one here, but --

MEMBER SMITH: So before, with failure, we voted for the composite plus the individual measures. Why is this, and actually I voted just for the composite before, and after discussing with Helen, I understand. I'm actually beginning to come around. I don't understand why this is any different from what we did before.

I mean if it was correct to say

composite plus individual before, why isn't it correct to say that now, and who are we to say what the public is interested in? Maybe the public is a little more interested in than just a simplified number. Pretty intelligent people out there.

MEMBER KOTTKE: Let, if I can --

CHAIR GIBBONS: Tom.

MEMBER KOTTKE: And I don't know how much this has a relationship here, but we have -- we report a composite lifestyle metric, physical activity, nutrition, alcohol and smoking. While I think the lie rates are very high for alcohol and physical activity, it's very clear that we can't do anything to our composite measure unless we improve nutrition, because only about ten percent of people say they get five fruits and vegetables.

So there's some advantage. I mean that really tells us how, what we have to do to change. So I think there is some advantage

at least to knowing the rates of the individual measures, and I'm still not clear in my own mind whether we ought to report, because you can get numbers after numbers after numbers, you know, page after page after page of these.

MEMBER RUSSO: And I think we should --

CHAIR GIBBONS: They've got to be in the context of all of the growing number of measures that are, you know, publicly reported. Can the public actually find what is important in these big lists? That's the downside.

MEMBER RUSSO: And I think we shouldn't assume that the public doesn't want to know. If you have something combining outcome measures like mortality with process measures, depending on how it's weighted, the public may want to know the mortality is high. But meanwhile they're using, you know, beta blockers.

MEMBER PHILIPPIDES: So let's say that public knew that at your hospital, after the patient was discharged after a procedure, there was a 99 percent rate of aspirin use. Does that tell them anything?

It tells them part of the story. I mean really what you want to know is, does somebody who goes to this hospital get all of the medications they're supposed to after their intervention, so that they've gotten adequate care.

So I would argue that if sometimes like giving -- as intelligent as the public might be, that's debatable, sometimes giving them part of the story when they've haven't gone to medical school, it's not that helpful. Whereas I think this composite measure is more helpful.

Internally, I like the individual measures. But as far as reporting out to the public and rating our performance, I think the composite makes more sense to me.

CHAIR GIBBONS: Dana.

MEMBER KING: As I recall, that's exactly the rationale for why we wanted the composite measures. We want them to reflect proper care in situation X. You had a PCI, proper care and proper discharge medications or ICD placement, and that's what we want you to get.

In these instances, we were told by the people around the table that it should be 100 percent, not in the lifestyle thing, where it's obviously a little unrealistic, to expect everyone to be, you know, eating fruit all day long.

(Laughter.)

MEMBER KING: I mean some -- I mean but I don't think that I was alone in thinking that the composite was a way to reduce the total number of measures and measure burden, and also capture the proper care.

The individual things that make up

the composite are not lost when we do it this way, because that's the way they're calculated, and that can be fed back to any group or hospital or whatever that wants to focus on it for QI or other purposes, is my understanding.

So I don't think the information is lost in the composite when we do it this way.

MEMBER JEWELL: This is Dianne. You know, my sense is that the public wants to know what is the best way to identify quality, and when we produce measures or vet measures and say these measures reflect good quality, if there are a lot of them that seem to be talking about the same thing, then the public's next question is okay, but which one of these helps me do that best.

And it's true that they might be curious about other things, but I feel like our obligation is to be as clear as we can when we know which is the best way to reflect the good care that was just described. So I'm

leaning more towards composite. If the composite is as good as the sum of its parts, why do we need the parts?

DR. MASOUDI: May I just make an additional comment, Ray, if I may?

CHAIR GIBBONS: Sure, Fred, sure.

DR. MASOUDI: I mean, you know, I wonder though, if to some extent this couldn't be in the purview of the developer, and what I mean by that is that, you know, FTS has engaged in a voluntary public reporting system whereby they report an overall composite. It's actually a rollup of processes of care and outcomes of care. It's a very nice system that they have.

But they also, so when they report that, they report it out as a one-two-three star system. It's a very nice composite. It's extremely rigorous. But they have found in their experience that people, some people, and I think it's probably inappropriate to generalize to the public in general, but some

people are interested in understanding what's under the hood, and which components of that people are doing well and not.

So when I talk about having more flexibility to use this in the context of a public reporting program, that's really what I'm talking about, is you know, again, some people won't want to know that, and some people may not be sophisticated enough to understand it.

But I think the public is fairly heterogeneous, different levels of sophistication, different levels of desiring to know, you know, what makes up a composite. So that's sort of my perspective from the developer's point of view.

CHAIR GIBBONS: Okay, Sid.

MEMBER SMITH: So it gets back to my original question. If we're going to tell them what's under the hood when they have heart failure, why aren't we telling them what's under the hood when a stent's put in?

Shouldn't there be criteria that could uniformly be applied?

DR. BURSTIN: Yes, and let me just weigh in. Again, I think there's lots of additional. These meetings are always very helpful for us, because it does identify additional areas where we need guidance, and I think you've identified a clear one.

What we've said to date is that the determination the committees need to make is whether the component measure, meaning of the composite, is important enough in its own right as an individual measure. So that, sure, the composite, you're all agreeing, is completely -- but should those individual measures, can they stand alone? Are they important enough on their own for a measure of quality, and that's really the determination you need to make. I think there are two related issues that we've heard a lot about over the last year that I think we need to address, one of which is there are different

kinds of composites.

So sometimes there are things where the individual elements within a composite are somewhat co-dependent on each other, and you've kind of got to do the whole package to really affect the outcome. One question should be, is this an example of that.

In that instance, those should be the kind of bundles that we've already endorsed, like the prevention of VAP or the prevention of CLAB. Do we need to do all four or five of those elements to actually get the desired outcome? This would be a question for you.

Again, we haven't given that level of guidance, and I think that's -- I think those are the kind of things I'd be happy to try to get more guidance for you. But I think, and I'm sorry. The last point is it's not exactly clear whether, if you endorse the composite, it necessarily means you can't look at the individual components of the composite.

But it doesn't mean you would necessarily want to look at one of these in isolation.

MEMBER RUSSO: Or would one other way to look at it is is when the individual components no longer have any value. So if they're out there and everything is 99 percent, get rid of it, as opposed to what we saw earlier today, with the one we voted down as individual measures. It really hasn't been out there showing that it's useless to look at individuals. So I mean there's different ways to do it. I don't know which is the best.

CHAIR GIBBONS: Okay. I think this has been a healthy discussion about an evolving issue. Let's all agree it's an evolving issue. So I am usually the one who's responsible for those sorts of things.

We'll ask two important questions. Has anybody's voting gadget been compromised?

(Laughter.)

CHAIR GIBBONS: Two? Do we need to

test them? Yes. Let's, maybe we can set up a question. We'll use this question as our set-up test. It doesn't look like anybody was hurt, and then the third question is, is anybody's computer hurt?

All right. So before the rest of us vote, let's have the two of you test your gadgets and see if they still work, by just voting on this one right now. Both are working. The meeting can continue.

Okay, there we go. All right. So I think we'll go ahead, then, and wait a minute. We'll just wait a second and let Roger fully recover here. Okay. We'll go ahead and vote, and just to remind everybody, it's one is the composite and the individual measures. Two is just the composite. Three is just the individual measures.

He gave me the high sign. I think he's going to be back momentarily. We voted for him. No.

(Laughter.)

DR. WINKLER: Dianne?

MEMBER JEWELL: Two please.

DR. WINKLER: Okay.

CHAIR GIBBONS: Wow. So the oohs and aahs you hear on the phone is because there were 8 votes for the composite and the individual measures, and 10 for just the -- 11. Sorry, 11 for the composite.

MEMBER KOTTKE: See, I knew I'd get you one time for this.

CHAIR GIBBONS: All right.

DR. BURSTIN: And Ray, we're happy to come back at a subsequent conference call and try to give you a little more guidance if you want to revisit this, because obviously it's split.

CHAIR GIBBONS: Okay. So we have just approved the composite. So I do want to sort of reflect that this is an incredible effort on the part of the ACC and all the other, all the team there that were involved in responding with these two composites in

very short order, in response to our earlier meeting and suggestions.

So we thank them and recognize them for all of that effort in doing that.

DR. MASOUDI: And just to speak on behalf of the people who were involved in doing that, I would say first thank you, and thank you also for the flexibility and being willing to hear about these measures during this meeting. So we very much appreciate it.

CHAIR GIBBONS: All right. Thank you to the others on the phone. So now we're going to move and shift to a different arena, which is hypertension, and Mary has conveyed to me that she believes I've sufficiently tamed this committee, so that she can now take over and run the discussion of these measures, which are actually more in her area of expertise in terms of public health than mine. So Mary, you've got to take over.

VICE CHAIR GEORGE: All right. So we'll be moving on to Measure 0018 first, and

any comments from the developer.

DR. MASOUDI: Is Measure 0018 the ARQI hypertension?

VICE CHAIR GEORGE: It's the NCQA hypertension.

DR. MASOUDI: Oh sorry.

DR. PAWLSON: Okay, got it. Thank you. I'm Greg Pawlson. I'm an internist geriatrician by background and Executive Vice President of NCQA, and I think the staff sent me here to be the old war horse to introduce the old war horse measure.

This is a straightforward blood pressure control measure. It actually first got into general use in HEDIS in 1999, and has been revisited at three intervals since then. The pluses of it are that it is very widely used. It is understandable to consumers, patients and clinicians.

It can be readily and reliably extracted from paper or electronic charts, with relatively low error rate and relatively

straightforward ability to extract the data. It has not certainly topped out in terms of performance.

The exclusions are relatively straightforward, and I would add that it has been reviewed every three years since 1999, and each year, we have tried to introduce changes to it, including concerns such as home blood pressure measurements and some risk adjustment and some other things.

Each time, our technical measurement expert panel, our technical advisory panels and our Committee on Performance Measurement, as well as public comment, have ended up going back to pretty much the CORE measure as being, for the present time at least and the present data systems we have, the appropriate trade-off between sort of sophistication of the measure and measurability.

We certainly would be open to and glad to take back on suggested further changes

to the measure. We'll update in a resubmission, I think, some of the areas that were not addressed in the original submission, that was asked for. So with that, if there's any questions.

MEMBER MAGID: When was the last time it was reviewed?

DR. PAWLSON: Two years ago, three years ago.

MEMBER MAGID: Three years ago.

MEMBER KOPLAN: On the numerator, is it the most recent blood pressure or any blood pressure?

DR. PAWLSON: Yes, no. It's the most recent. We looked at all different options. It's one of the reasons why the home blood pressure, groups couldn't decide on how to bring that in. We looked at trying to do averages; we looked at, you know, multiple blood pressures. There's some reasonable data that shows the last blood pressure is a reasonable compromise, again, mostly from

measurability viewpoints.

We're working on, as are others, a lot more sophisticated measures that you can use in electronic data systems, by time intensity of control over large periods of time. But that's where we are now.

MEMBER MAGID: Just sort of speaking to that, there was a paper published in the last year that looked at several different ways of assessing last blood pressure, average of the last blood pressure, the mean of all the blood pressures in a given period of time.

I think at the aggregate level by which this kind of quality measure is reported, that the results were comparable. There really wasn't, you know, when you looked at how organizations would be ranked form, you know, best to worse and so forth, that really didn't change the rankings. So I think there is good data to support the approach.

MEMBER RASMUSSEN: David, did that

include home blood pressures, or were those office?

MEMBER MAGID: Well, that's a separate issue, and that is something I want to discuss, but I don't know if this is the time to discuss it, or whether someone's going to go through it and we just -- is someone leading the discussion of this measure?

VICE CHAIR GEORGE: Yes. I think Leslie, why don't you go ahead and start, and then we can pick that up.

MEMBER CHO: So this is Measure 0018, which is controlling high blood pressure, and it's important, I think, to distinguish the three blood pressure measurements that we're going to be talking about this afternoon.

So this is percentage of patients who have diagnosis of hypertension and are under control, and the control is defined differently this time as less than 140 over 90.

As you recall, we had long discussions at the last meeting about 140 over 80, and in certain populations even lower than that, and the developers have changed that to 140 over 90 during the measurement year. So the impact, all of us agree that hypertension is a leading cause of cardiovascular disease.

Performance gap, as you know, exists. Outcome of evidence in terms of -- and we can debate about the outcomes of evidence in particular, subset of patients in the second part, I think. But I think the importance of measure, all of us agree.

VICE CHAIR GEORGE: And I think it's important to realize that this measure is the percentage 18 to 85 years old, adequately controlled. Are there any comments on the Scientific Acceptability, I mean the Importance?

(No response.)

VICE CHAIR GEORGE: Okay. We'll go to a vote.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

VICE CHAIR GEORGE: 20 yes, no no's. Moving on to the Scientific Acceptability.

MEMBER SNOW: Just one second, to make sure that I've got it right. It looks to me as if on the paper it says that it's number 0018. That document there says it's number 0013. Is one of them a typo or --

MEMBER CHO: No, no. There's a 0013 and an 0018.

MEMBER SNOW: There's both.

MEMBER CHO: We discussed -- yes. We're discussing 0018 first.

MEMBER SNOW: Okay, thank you. I'll look some more.

VICE CHAIR GEORGE: Leslie.

MEMBER CHO: So the second is Scientific Acceptability of Measure Properties, and I have some questions for the

developers, if I may, and that is is one of the concerns that I had, looking at this measurement, is that if a patient gets diagnosed with hypertension, and you're titrating up the dose of medications, especially in the elderly, how, when is the time frame for control defined? How is that defined?

Then the second is I know this is a hybrid measure, which is a CPT code and a clinical chart. So if a patient comes to multiple different physicians, a primary care doctor or endocrinologist or cardiologist, is just the last measurement of that quarter taken or year taken? How is it measured?

DR. PAWLSON: It's year, right.

MEMBER CHO: Year. If a patient gets diagnosed with hypertension, let's say, in July of this year, and in by -- or let's say he gets diagnosed with hypertension in October of this year and in December he's not controlled because we're titrating, is that

dinged against me or against the clinician?

DR. PAWLSON: Yes. That's the problem with sending an old war horse to the -- - I'm not sure, but I know that the way we use it in the health claim populations, that it requires the diagnosis in the year before.

So I don't know whether that applies to -- so there's a continuous enrollment. I don't know that that applies to the -- I'll have to check whether that applies to the clinician.

MEMBER CHO: Okay. So the measurement year is -- from the onset of diagnosis to the following 12 month period hopefully.

DR. PAWLSON: Yes.

MEMBER MAGID: You have to carry the diagnosis. So those people wouldn't be in the denominator, because they wouldn't have carried the diagnosis.

MEMBER CHO: Diagnosis for -- okay. And then the second question I had is for

these measurements, when you -- to test the validity of these measurements, I notice that you have the product line separated by insurance, and is the N the number of companies or is the N the number of -- I hope it's not the number of patents, because there's only like 269. Is the N the number of companies?

DR. PAWLSON: Companies, and we choose -- and again, obviously we can't control how this measure is used outside of our own environs, any more than any other measure developer can. But we believe that it's important to stratify by insurance status. But again, it's not a requirement of the measure.

MEMBER CHO: I don't know if this is a setting to bring this up, but in terms of the disparities, or a couple of things. The measure developer said to withhold or they want to go with the 140 over 90 until the new JNC-8 guidelines are published, which I think

is totally reasonable and acceptable. The age of 85, how was that chosen?

DR. PAWLSON: Helen will remember. We had a lot of discussion about whether there should be an age cutoff and how that sort of harkens back to my own experience as a geriatrician. We actually took this to our GMAP.

We had discussions with NQF, and the general consensus was, and it's not an exact science at all, is that by 85, there's enough admixture of other issues and problems, and enough potential exclusions that could be applied, that the measure becomes much less precise.

So you would potentially have to put in a whole bunch of other codicils on patients over 85, even though, you know, there's at least some evidence from some systolic measures at least, that that age group is not immune, obviously, to the consequences of high blood pressure. But it

was really the presence of multiple comorbidities and functional status issues.

MEMBER THOMAS: I had a question. Is white coat hypertension in the exclusions?

DR. PAWLSON: No. This is an office-based and it's again, the last measurement recorded. So that it would be, you know, hopefully clinicians who are aware of that would do multiple blood pressures, and it would be last recorded for that visit.

But you know, obviously all the, as far as I'm aware, virtually all of the data on blood pressure control is based on clinical trials that were done using office-based measurements. There's a few studies of home-based, but not much.

MEMBER THOMAS: White coat hypertension is an office-based phenomenon. I guess it's real too. It's real, I mean, and people who get ambulatory blood pressure monitors, who have white coat hypertension and it's demonstrated by that, you can write it in

your chart as a diagnosis. I mean as more people are using ambulatory blood pressure monitors, as many of us are doing, we can document that, because they say that their blood pressures are normal at home.

Anyway, I see it as a real phenomenon myself, but I don't know if others disagree.

MEMBER RUSSO: One other question too, and it may be in here, I just can't find it. So is there a minimum, is there a requirement for more than one visit in the measurement period to be included in the measure. For example, if you see a patient for a one-time visit for evaluation of something else, their blood pressure is high and it's a one-time consult and you never see them again, you may refer back to the primary care doctor or something for the blood pressure.

So is there, or should there be a consideration of more than one visit in the

measurement period to be included in the measure?

DR. PAWLSON: I believe it's one visit in the measurement period.

MEMBER MAGID: It's an interesting issue because one of the drivers of therapeutic inertia is when physicians don't address the hypertension, and they refer them back to someone else. We've seen that, particularly when clinical and non-primary care specialists do that.

So rates of blood pressure control in young women are about half what they are when, like say an OB/GYN doc is the primary care doctor, and they refer patients to like a family doc or an internist, that ends up with blood pressure control rates half what they are when the doc, when the primary care doc is the -- when, I'm sorry, an internist or a family physician. So I think that that would be a really bad exclusion.

MEMBER RUSSO: No, no, not to the

point, but to say that you've made a plan of action. So you've called the -- and this happens.

You call the doc and you increase their blood pressure medicine, say they're going to come to you in a week to get their blood pressure checked again. You may do an intervention, but the last recorded blood pressure that you have in the office is high.

You talk to them on the phone and say I've just increased it, doubling the beta blocker dose. They're going to see you next week. But you've only seen that patient once.

MEMBER MAGID: Well, but it's not the last time you've seen them. It's their last visit in the year. So that shouldn't be an issue.

MEMBER RUSSO: Or it may be outside the practice somewhat.

VICE CHAIR GEORGE: Isn't this measured at the health plan level, not at the physician level?

DR. PAWLSON: Well, it ultimately is measured at the physician level, because health plans don't take care of people; clinicians do. So it's done by chart review in a clinician's office, and obviously it depends on what --

MEMBER MAGID: It's in the health plan, so it's -- yes.

DR. WINKLER: Greg, just to clarify. In the submission, it says the level of measurement or analysis is the individual clinician or group of clinicians. It does not indicate health plan level.

DR. PAWLSON: Yes. We obviously omitted that. It should be both.

MEMBER AYALA: I have a question about exclusions. We talked about this in Phase 1, especially elderly patients who don't tolerate blood pressures less than 140 over 90. Is there an exclusion for that if the physician documents the patient didn't tolerated it?

DR. PAWLSON: No.

MEMBER CHO: Actually, there's a -- okay. So according to this form, this is the -- I know we've had millions of forms, but this is the response from the developers to us, based on 0073, which is the blood pressure management that we discussed at last meeting.

DR. WINKLER: Remember, that's a different measure for patients of coronary artery disease.

MEMBER CHO: Right. But it does address this issue about lowering the blood pressure with multiple different medication, and according to them it says that they fully support development and testing of risk adjustment. Now are you guys the same measurer that developed or are these different? These are different?

DR. PAWLSON: They're different measures.

MEMBER CHO: Okay, nice.

MEMBER MAGID: So the issue that I

want to discuss, and I'd like our group to consider, I don't know what it is, an amendment or a request back to the developers, is around home blood pressure monitoring. So I think, you know, three years ago, there was -- the evidence base around home blood pressure monitoring was just evolving.

But today, we have dramatic evidence in support of home blood pressure monitoring. Just in the last three years, there have been publications in JAMA and Circulation and several others, and there have been reviews.

And all of those studies have shown very large differences or very large improvements associated with home blood pressure monitoring, on the order of about 10 millimeters of mercury systolic.

So remember, at a public health perspective, people get excited about two or three millimeter mercury. That's a lot of MIs, a lot of prevented cases of heart

failure, stroke and chronic kidney disease, and a lot of -- fewer cases of, a lot of lives saved.

So 10 is just huge. I mean and I know Tom is always talking to us about public health impact. Hypertension is responsible, is the second leading cause of preventable deaths in this country after smoking. So I think it's really time that home blood pressure monitoring be included in this measure.

I think some of the concerns about home blood pressure monitoring probably three years ago was well, what's the evidence base? There may be some concerns about the validity of blood pressure, home blood pressure monitoring cuffs and it might require a different cutoff, because home blood pressure measurements tend to be about five millimeters of mercury.

But I mean if we're going to be up to date, and this measure doesn't include home

blood pressure monitoring, you're really not up to date with where current practice is. We know that one of the big barriers to hypertension control for patients is a focus on office-based care.

When you do focus groups with patients, to say look, you know, we understand this disease. You understand you're at risk. We have relatively inexpensive effective medications, but we can't get you to keep coming back to the office.

The patients say well, it takes a half a day out of my life every time I have to come into the office. I have to travel to your office, I have to sit around in your waiting room. I see you for only five minutes. Then you change my medicines. I have to go to the pharmacy. I can't take a half a day off from work.

But if you give me an opportunity to measure my blood pressure at home and telemonitor them to you over the Internet or

by the phone lines, I'll do that. So I think this, the way the measure is currently structured, with the absence of home blood pressure monitoring, really is doing patients a disservice, and it's time to change the measure, to allow it to incorporate that.

DR. PAWLSON: Could I ask a question? Are you -- is this both for a measure of whether home blood pressure monitoring is done or not, because that seems to me --

MEMBER MAGID: No. It's for inclusion of those measures in the outcome, because more and more there are patients who are saying "I'm not coming into the office anymore. This is how I'm going to manage."

DR. PAWLSON: So I think -- I mean this is a huge issue, and I think the ACC has also tackled this to some degree. I think it deserves, as you're suggesting, very careful attention. I'm aware of the discussion the last time, and it ended up not so much that

there wasn't really great evidence that home blood pressure monitoring is important, and that there should be ways of encouraging it.

It was how practically to incorporate it into this kind of a blood pressure measure. So that would it override the office thing? Would it only be if it was the last one recorded? How would it -- so there's a lot of practical issues to be worked out, which is not, doesn't mean that we shouldn't address those.

But it would fundamentally alter the measure. So and it may be important to do that, but I'm just putting that out there.

MEMBER MAGID: It is. It's very important to do that.

DR. BURSTIN: Just one process point. Again, keep in mind that the measure's not been tested at all to incorporate home monitoring. So one possibility would be to ask the developer, and I know Greg's waiting to update this measure, as new guidelines come

out, to consider the inclusion of home monitoring to follow. I'd be curious to hear Dr. Smith's perspective.

MEMBER SMITH: Somehow, I think we need to be aware that JNC-8 is going to be presented in November, a large database. Unfortunately, I cannot talk about it.

But one thing to point out with regard to home blood pressure monitoring, which I think is really very good, all of our RCTs available showing the benefits of lowering blood pressure come from office-based. They didn't use home.

So when you begin to talk about cut points, the cut points are derived from office-based measurement, not from home. So how you make that comparison and weave it into a performance measure becomes very difficult, and even the treatment of hypertension can find strong data support initiating treatment at systolic blood pressure of 160.

Many of the trials which show an

improvement in outcomes do not lower the blood pressure to less than 140, especially in the elderly, which gets back to a question that came up about how hard do you push to get less.

You should treat over 160 in the elderly, but the data that pushing them down to 140, particularly in the presence of multiple drugs, is going to have improve end points over 148 or whatever is not as strong.

I'm not able to comment, other than to say that there will be an important report coming in November.

VICE CHAIR GEORGE: Thank you for that.

MEMBER MAGID: Yes. I would just say that I think we know we have a lot of studies that talk about the relationship between office and home base, and I think we know that home blood pressure measurements tend to be a little bit lower, but not dramatically lower.

I guess at a minimum, I mean my hope would be that, you know, because what we're doing here is for three years, right? So are we going to be having this same discussion three years from now? I mean that would be really terrible. So we need to do something about this issue.

MEMBER SMITH: Home blood pressure's important, and the issue about peripheral versus central blood pressure and differential response to medical therapy is important.

MEMBER AYALA: Can we ask for the developer to consider adding the exclusion of patients who don't tolerate the blood pressure less than 140 over 90?

VICE CHAIR GEORGE: Is the developer willing to consider that?

DR. PAWLSON: What's the exact? You want to have an exclusion for patients who are white coat hypertension, or who don't tolerate --

VICE CHAIR GEORGE: Patients who do not tolerate.

DR. PAWLSON: Okay, and that would be some entry, a note entry or some judgment of the clinician that that was the case?

VICE CHAIR GEORGE: That would have to be noted in the record.

DR. PAWLSON: Yes. We could certainly look at that. But again, it would probably require retesting of the measure.

MEMBER MAGID: I would like to ask the developer to conduct, at a minimum to conduct validity studies on home blood pressure measurement.

DR. BURSTIN: Just as a process point, given that these blood pressure measures are in flux, we are anxiously awaiting this seminal report in November. It just seems like perhaps, you know, the reality is they're not going to change the measure between now and November.

It would be illogical to do so, and

I think what we'd want to do is potentially suggest that as they update the measures to reflect JNC-8, they consider the issues raised here and test them, as David pointed out, for the next go-round.

VICE CHAIR GEORGE: So our committee would make those recommendations to the developer, and any other comments before we vote on Scientific Acceptability?

DR. WINKLER: You're in an interesting situation, because your vote for Scientific Acceptability will have to be on the measure as submitted.

Dianne?

MEMBER JEWELL: Partially.

DR. WINKLER: Thank you.

VICE CHAIR GEORGE: 4 completely, 12 partially, 3 minimally. Moving on to Usability?

MEMBER CHO: Okay, moving on to Usability, this has been in use since 1999. It's clearly been tested. I think it's very

usable, minus this point about home blood pressure monitoring. So I think it's pretty self-evident.

VICE CHAIR GEORGE: Any comments or questions? Move to a vote on Usability.

DR. WINKLER: Dianne?

MEMBER JEWELL: Sorry, partially.

DR. WINKLER: Thank you.

VICE CHAIR GEORGE: We have 12 completely, 6 partially, 1 minimally.

MEMBER CHO: Before we go on to Feasibility, I just have a question for the NQF people and those of you who have sat on NQF boards before.

If a measure like this over time has really a penetrance that's kind of leveled off, which this measure seems to have leveled off, what is the, you know, in terms of the 90th percentile or whatever? It's still 54 or 70 percent or so, pretty much stable.

What's the feeling to hold on to measures like this? Indefinitely, until -- I

mean we all agree hypertension is important, but what is the sort of philosophical overview?

VICE CHAIR GEORGE: I think they're more than -- it's not a simple question. The question you might want to ask is, is there a characteristic about the measure that causes it to not perform real well as a reflection? Is there something going on in the care of patients that causes that plateauing or something going on elsewhere?

So I think to each circumstance it is unique. This is an outcome measure, and for the most part, I guess the question is philosophically can outcome measures be topped off? Not really, if your goal is to, you know, get the entire population to the optimal levels.

MEMBER CHO: I just asked that because of these new measurements, or new blood pressure monitoring mechanisms that are coming into place, and maybe incorporating

those in a more dynamic manner is better suited than holding onto older measures. But anyway, moving on to Feasibility.

MEMBER MAGID: Well, I mean I think that one of the issues is that if patients, as I understand it, you'll have to correct me, if patients are doing home blood pressure monitoring, and they're not coming in to the office, their blood pressure is likely under control.

Yet but in this measure, they're counted as being out of control, because they don't have a measure, and if you don't have a measure, you're in the denominator but not in the numerator.

DR. PAWLSON: If they don't have a visit all year. No visits, that's right. If you have no visits. I think that at least up until now, the issues about an office-based measurement at least once a year have been fairly strong. I wouldn't also characterize it as not -- it's showing the same level of

slow improvement that virtually all the outcome measures do.

They don't, there's no magic formula to suddenly, you know, demanding that everybody record a beta blocker prescription at discharge, which is one time, easy. This is tough, this is a tough measure.

MEMBER KOTTKE: Also, yes. Hypertension's very interesting, because it's been so hard to improve, and Whisnant down in Rochester, two surveys, identical methodologies, ten years apart, identified treated and controlled dropped from 29 percent to 19 percent in Medical Tone USA, and it was -- I will blame that it was, the cause was an emphasis on a novel risk factors, and an urgent care unit, where people stopped going to their primary care physician, and just walked in and this was before the EMR and they were seen without records.

So then, like somebody mentioned over here, the big problem is oh yes, go back

to your primary and get your blood pressure treated. They have since closed the UCC.

MEMBER RICH: In thinking about this conversation, it strikes me that it's a great idea to use home monitoring, but patients should show up at least once a year. So I would say since your measure is once a year, they don't need to come in quarterly.

That's really taxing. But if they're not even showing up in your office once a year, it means not having any kind of physical, and that doesn't seem to be good medicine.

MEMBER MAGID: It's interesting. I mean I think for most of the measures that we've looked at so far, we've had people with ischemic heart disease or heart failure, and those patients do come in a lot. People with isolated hypertension, particularly men of a certain age, don't make -- it's not uncommon to find.

I mean when you look at the sort of

preventative recommendations for men, there aren't very many, if any, for men who are, you know, 20, 30, 40, you know, colonoscopy at age 50 or a colon cancer screening. So it's not uncommon to find men with isolated hypertension not making regular visits, particularly if they're doing something like home blood pressure monitoring.

MEMBER KOTTKE: I would say in my patient population, they've got a blood pressure cup at home, but they're not using it.

DR. BURSTIN: One more point on Feasibility. This measure has been retooled already for EHRs, just FYI.

VICE CHAIR GEORGE: Okay. So we'll vote on Feasibility.

DR. WINKLER: Dianne?

MEMBER JEWELL: Partially.

DR. WINKLER: Thank you.

VICE CHAIR GEORGE: 12 completely, 8 partially. Now we move on to the final vote

on endorsement. Any other last comments?

(No response.)

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

VICE CHAIR GEORGE: Unanimous, 19 yes. Okay. Next, we're moving on to another blood pressure measure, number 0013. Any comments from the developer?

DR. DROZDA: Yes. This is Dr. Joe Drozda. I'm on the phone. I take pleasure in presenting this measure from the American Heart Association, the ACC and the AMA's PCPI.

The measure is a percentage of patients age 18 years and older with a diagnosis of hypertension, with a blood pressure of less than 140 over 90 millimeters of mercury, or patients with a blood pressure of greater than or equal to 140 over 90 millimeters of mercury and prescribed two or more anti-hypertensive medications during the most recent office visit within a 12 month period.

This measure is actually very similar to the blood pressure measure that we presented as part of the coronary artery disease set that you considered in February. It is, was put together by the same writing group, made up of specialists, primary care physicians, advanced practice nurses, even patient consumers and a payor were represented on this committee.

It was broadly vetted in the usual fashion through PCPI and its member organizations, as well as ACC/AHA, and underwent a 30-day public comment period. It replaces two measures, hypertension measures that were published in 2005.

Those were separate measures of blood pressure control and management. Those measures actually were tested in the CMS doc project and are in use in PTRS and meaningful use Stage 1. The new measure actually combines these parameters into intermediate outcome measures, in which we have included

patients whose blood pressures are less than 140 over 90, as well as those who have blood pressures higher than that.

The target, I think, reflects the most recent data out of trials like Accord, that sort of gives us some caution about lower blood pressures. The measure also addresses the complexities of hypertension management, some of which have been discussed today.

It allows the physicians to choose the blood pressure used for decision-making, and to identify that blood pressure on the chart. That blood pressure can be derived from blood pressures taken in the office, from home blood pressures, from 24 hour blood pressure monitoring. It can even be an average of blood pressure.

It also has an exception methodology to address issues like the elderly and those patients who might not be able to tolerate blood pressures of less than 140 over 90. Again, it's based on JNC-7 and we do have

provisions made for readdressing the measures based on the release of JNC-8.

There is also, I would advise you, another panel, NCQA, AMA/PCPI has put together, to address diabetes, and diabetes control in the diabetic population will again be addressed by that group. So this measure is really focused on the -- it's a clinician level measure. It's focused on the electronic health record, although we have specifications for claims-based administrative data as well.

But we would like to see this utilized in the electronic health record going forward, as a QI tool, as well as for public reporting and accountability.

VICE CHAIR GEORGE: Okay, and Dana, I think you're presenting this.

MEMBER KING: Well, I couldn't have said it better myself actually. So the first one, I guess, number 0018 that we talk about was kind of like the soil sample of the United States, and how we're doing on high

blood pressure.

This one is a little more directed at what happens on the ground, because of the exceptions, because of the allowance, to not be controlled if you're taking two or more medications.

So it's not just the blood pressure. There are some other qualifications as well as exceptions. So otherwise, those are very similar measures. The data that was just presented for the importance and the prevalence of hypertension and the gap all apply to this measure as well.

DR. WINKLER: Do we have current performance data for this particular measure?

DR. DROZDA: This measure, as a combination, is brand new. So we really don't have current numbers based on it. We have numbers on the two separate measures that were approved previously. But I don't have those right at my fingertips. Maybe others at the meeting do have that.

VICE CHAIR GEORGE: Okay. Any further comments on this?

MEMBER JEWELL: This is Dianne. This isn't really an important question, because my answer to that vote is yes, this is important. It's really more we had discussions this morning about the way measures are labeled, and so it feels a little counter-intuitive to me to call something blood pressure control, but have as a part of the measure a situation in which the person is not controlled.

So whenever the appropriate time is to discuss that, I just want to put that in the queue.

MEMBER KOTTKE: I have one question. Maybe Sid wants to address this, that the two or more, and it seems to me that it would be three or more, because many of my patients are on a beta blocker, an ACE and a diuretic, and sometimes they're on a calcium blocker too. It seems to me that two or more

is a little bit alligator arms for attempts to control.

DR. DROZDA: This is Joe Drozda. To respond to that, this was a topic of some discussion at the work group, and I think we settled on two or more primarily from a patient safety perspective, especially considering that this was going to be a publicly reported measure.

We were most concerned about patients who a provider might try to either overly-aggressively try to get a blood pressure under 140 over 90 or would pile on three medications just to meet a measure, and might put the patient at some jeopardy. So that was -- it was a safety concern that led us to choose two, rather than three.

MEMBER SMITH: So I don't know of any good data to support this discussion. The guidelines for renovascular hypertension, one of the criteria for looking at renal artery stenosis would be failure to respond to three

or more. This whole area would benefit from a little more evidence, I think, in terms of what would be the best measure for us to use even.

VICE CHAIR GEORGE: Any other comments on the importance? If not, we'll go to a vote.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

VICE CHAIR GEORGE: 19 yes, 1 no. We'll move on, Scientific Acceptability.

MEMBER KING: So the specifications we talked about. It's adults 18 and older. The reliability and validity is not known for this because it's new.

Some of the exclusions we talked about. The denominator will be people who have been under care for a year or more, or it says 12 consecutive months. This information is obtained from electronic, mostly from electronic health records.

MEMBER RUSSO: I think this one, correct me if I'm wrong, the way I read it is different than the other one, in that two things. One is that you need to have, it's specified in the medical record for more than one value. So you had to be seen, I am assuming that means within the measurement period, more than once. I'm not sure if that's correct or not.

Then the other thing is this does include the home review, review of home blood pressure monitoring. So that would address the other issue that was brought up earlier.

MEMBER KING: Right. It says you have to have greater than one value.

MEMBER RUSSO: So that means two or more, right? But I don't know if that's in the same visit or if that's, you know. I like it better for the scenario that I outlined before, is that you may truly address it with more than one period. It's not just a one-time person who lives two hours away, that's

going to get their follow-up blood pressure checked somewhere else.

MEMBER KING: I believe that didn't say more than one visit, because it could be one visit in the office and then a visit from a home blood pressure. So that's two measures.

MEMBER RUSSO: True. That could be true. That would follow.

MEMBER KING: So that's why they didn't specify two visits. So they just said greater than one value.

MEMBER RUSSO: Yes, that would make sense.

MEMBER CHO: What is the added value of this measure on top of the measure we talked about previously?

MEMBER KING: That is a good question.

DR. DROZDA: Yes. This is Joe Drozda. Let me take a crack at it. By the way, I'd first like to thank Greg Pawlson for

breaking the ice on this section of the discussion. He did so admirably, and I don't think that I'm, in trying to -- I don't want to diss the NCQA measure. It has been around for a while, as Greg said, and has had significant utility.

But I think this one addresses a number of issues that I think NQCA is still struggling with, and that is those patients whose blood pressures are over 140 over 90. You know, to say that 70 percent of patients have blood pressures over 140 over 90, to say that that means that we're not at our target yet, I think, is probably not correct, because I don't think the number for control that we are shooting for is 70 percent.

I'm not sure what it is, but it's not 100 percent either. Because of what we talked about earlier, there are patients who do not tolerate blood pressures of 140 over 90, and shouldn't be driven to that level. They very well could be under, should be

considered under control, along with those who are doing well under 140 over 90.

We're not clear on exactly where that cutoff is above 140 over 90, and how that should be quantitated. But this is an effort to kind of get at that, without setting another blood pressure cut point. So I think this again addresses these sorts of complexities that are very difficult to do when you take an arbitrary cutoff at any point, like 140 over 90.

So I think we're doing that, and we're also addressing the issues of how the blood pressure is taken, and it's not in the NCQA measure, which depends on the last blood pressure in the office.

We are allowing blood pressure readings from ambulatory blood pressure monitoring, blood pressures at home and blood pressures in the office, and reflecting the way physicians practice, because those of us who treat hypertension actually take all those

numbers into consideration when we have them, and make decisions based on treatment, not on the arbitrary last one we took in the office.

So I think this is a little bit, an attempt to be a little bit more, I don't know, sophisticated in our approach to measurement.

MEMBER JEWELL: So this is Dianne again. I appreciate the methodology enhancements that you just described. But the comments you made prior to that about the patients who aren't under control but are getting two or more meds, I'm still stuck with why we call it a measure of blood pressure control then.

I don't see how the public would ever understand the difference between what's controlled and what's not controlled if they think that 140 over 90 on multiple meds is controlled, or even not, you know, and they are having ongoing problems. I think we potentially lead them astray.

So I'm not so sure it's a problem

with the measure as what you call it that I'm wrestling with here.

DR. DROZDA: I guess what I said earlier was that I think it's leading them astray to say that 140 over 90 is the gold standard. You're either there or you're not controlled.

Because quite frankly, if you're 75 years old and you get possible hypotension as soon as your blood pressure is over 150, is under 150 over 80, you shouldn't be driven to 140 over 90. That's actually poor quality care. So that was really that paradigm we were working on.

MEMBER JEWELL: And I hear you. I think it's, I'm really thinking about the group of patients for whom that is not the issue, and the physician and the patient are working very hard together to find the best combination of interventions to reduce their risk of adverse events as a result of hypertension.

Maybe it's semantics to everybody and I don't know everybody else. But if you call it "control," it sounds like it should have a label. Because you include in the numerator people who actually are below a certain threshold that you've defined, to me it feels like it's two measures that don't match bundled into one, and that there should be two separate things, or call it something else.

VICE CHAIR GEORGE: Clearly, the devil's in the details of any of these measures that we look at. David.

MEMBER MAGID: Yes. I'm just a little bit concerned. I understand the example that you gave, and I wouldn't disagree with the assertion that not everyone should have their blood pressure driven below 140 over 90.

I'm just wondering whether you're going to cause more harm than good, because if you took the universe of people whose blood

pressure -- who are on two blood pressure medications, whose blood pressure was above 140 over 90, I think the vast majority of those people would benefit from being on a third medication, and having their blood pressure less than 140 over 90.

So I'm just wondering whether there is a better way to address the issue that you have, than the way you've constructed this measure, which may do more harm than good.

MEMBER RASMUSSEN: Is a percent reduction in blood pressure a more appropriate target?

MEMBER MAGID: I don't know about that.

DR. DROZDA: I think you'd still run into the problems we talked about earlier, and this is a great discussion, and it reflects actually the discussion in the work group, as we were balancing off all of these very important issues, including patient safety. We obviously came down on the patient

safety side.

But I don't know that I can argue with the assertion that a good percentage of patients who have blood pressures over 140 over 90 need to be on three drugs or more. I don't think I can argue with that. But these are just sort of the exigencies of a publicly reported metric.

Now we do believe that by having this measure out there, that we will now be drawing attention to that group of patients that may have not been particularly well cared-for in the past, and that we think we will drive improvement, even in that group of patients.

I think we'll find, by the way, that a number, a great percentage of them will be African-American, and we do want -- by the way, I did mention -- I did mean to mention this earlier.

We would like to see this measure stratified by age, sex and ethnicity, race and

ethnicity, so that we can look at the very important areas of disparities in hypertension treatment.

VICE CHAIR GEORGE: Tom.

MEMBER KOTTKE: Yes. This is just a semantic argument, but I think you've grabbed the "first, do no harm" cell and not necessarily the patient safety cell, to argue that not treating blood pressure increases patient safety. I don't think there's evidence for that.

I think there is a legitimate argument not to do harm when in doubt, but to categorize it as safety --.

MEMBER CHO: I think the way this currently reads, that all of us are having difficulty with, is if your blood pressure is greater than 170 over 100, and you're on two anti-hypertensives, you get a pass based on this measure. I know that the intention of the measure developer is not that.

So that's, I think, what all of us

are having such difficulty, you know, coming to grasp.

MEMBER KOPLAN: I would agree. I don't think it reflects what's trying to be achieved. I think it's kind of convoluted and it would be confusing.

MEMBER RUSSO: I think it also, you could potentially be on subtherapeutic doses, two very low doses of two different drugs and not capture it. Is there some other way to capture the intent or a plan to control, to be -- so you're at the visit and it's high, and you're still trying to adjust it. It doesn't capture that either.

I guess that wouldn't be intermediate outcome, but I'm just trying to think. It's not capturing, although the intent's really there, it's not definitely capturing what I think the intent is.

DR. DROZDA: If you look at the previous two measures that this replaces, actually the one was a plan of care measure,

which sort of approached it just the way that you view, you describe.

We thought it would be more useful for public reporting to have a single measure, and then when we got into the details, we ran into the kinds of issues that you're describing, and realized that there might not be ideal care for people included in the measure, and for which you get credit.

But on the whole, we thought that this would actually move the ball down the field a little further.

VICE CHAIR GEORGE: Thank you, and we're going to need to move ahead. So we're going to, if there's no other objections, go on to voting on Scientific Acceptability.

MEMBER KING: This is with two meds, right?

DR. WINKLER: Dianne?

MEMBER JEWELL: Minimally.

DR. WINKLER: Thank you.

VICE CHAIR GEORGE: Three

completely, five partially, seven minimally, five not at all. Usability?

MEMBER KING: Would this measure be usable, meaningful and useful for public reporting? I think that there has been some discussion about that. The previous components were used.

VICE CHAIR GEORGE: Any additional comments? Okay. We will vote on Usability.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

VICE CHAIR GEORGE: Four completely, nine partially, six minimally, one not at all.

MEMBER KING: The next issue is Feasibility. The data are generated during care. Blood pressure measurements are obviously freely available through electronic sources. There are exclusions. This one has more exclusions, but more relevant ones according to our discussion. Data collection has been and certainly could be implemented.

VICE CHAIR GEORGE: Any discussion

on Feasibility?

(No response.)

VICE CHAIR GEORGE: We'll move to a vote.

DR. WINKLER: Dianne?

MEMBER JEWELL: Minimally.

VICE CHAIR GEORGE: Nine completely, six partially, five minimally. Now we move, if there's no further discussion, move to a vote on the measure as it stands. Any discussion?

(No response.)

DR. WINKLER: Dianne?

MEMBER JEWELL: No.

VICE CHAIR GEORGE: Six yes, 14 no. Now we move on to another hypertension measure. Any comments from the developer? This is Measure 0276.

MR. BOTT: Yes. This is John Bott with AHRQ. Just very, very briefly, this is an AHRQ quality indicator. It's an area level measure, so we're measuring care at a

population level being typically a state or a county. It's looking at potentially preventable admissions, in this case for hypertension with high quality care in the community.

It's a measure that uses electronic inpatient administrative data sets to compute the measure, and it was a measure that was initially endorsed by the National Quality Forum in 2007. That's all I'll note for introductory comments.

VICE CHAIR GEORGE: Okay. Christine.

MEMBER STEARNS: Hopefully, we'll be able to move through this one quickly. This is a high impact measure, and I think as it was introduced, the evidence suggests that there's a wide variation in admissions for hypertension, which may well relate to income and access to care. So this measure would be useful in looking at the health care delivery system generally. So I don't know if you have

any questions or if you want to move forward.

VICE CHAIR GEORGE: I had one question for the developer. Under the notes for Opportunity for Improvement, the developer said little evidence exists regarding the validity of the indicator. Can the developer respond to that?

MS. DAVIES: Yes. This is Sheryl Davies. So the issue here is that these indicators are measures of ambulatory care -- hospitalizations, and these indicators were originally conceptualized and developed by a couple of groups independently in the 1990's.

At that time, most of the work surrounding the validation of the indicators really focused on validating the entire set of conditions that were identified as ambulatory care sensitive conditions. So that includes other things such as COPD and CHF, and some acute conditions as well.

So we have quite a bit of evidence, you know, showing that either the proxies for

access to care or direct measures of access to care certainly impact the hospitalization rate for these conditions as a whole. But for this particular one, there's been, from a published study point of view, there's been relatively little additional work looking at hypertension individually.

So we don't have any reason to believe that hypertension would be particularly different, and but we don't have the literature-based evidence for that. We have taken this particular indicator to a clinical panel. The clinical panel did discuss, you know, certainly that hypertension is an important complication or chronic disease, and that admission for hypertension would be important.

They did note, as you probably will discuss, you know, the primary concern with the indicator was that it was really missing other manifestations of hypertension, such as cerebral vascular disease or kidney disease,

that would show up. So that was the main concern about the indicator, and we took it from a face validity point of view.

VICE CHAIR GEORGE: Any other questions or comments?

CHAIR GIBBONS: I'd just make the comment, to expand on that last point, that in my practice, the overwhelming majority of people who come in to the hospital with heart failure, with normal left ventricular function, have uncontrolled hypertension.

So there's a huge population, huge public health problem. This doesn't come close to capturing that.

VICE CHAIR GEORGE: Dana?

MEMBER KING: I don't also see any data about the correlation between the measure we just talked about, blood pressure control, and admission for it. In other words, it seems that one would definitely follow the other. If we were controlling blood pressure in the community and the public

health arena, we would have much fewer admissions for hypertension, for a variety of reasons, as Dr. Gibbons said.

So having this as a separate measure and saying there's all these things that contribute to it, such as socioeconomic status, minority status, access to care, etcetera, those are all the things. That's all the reason why we're only controlling half the hypertensives, and why half of them get admitted to the hospital every couple of years.

So it seems like it's just another way of measuring the same thing, and I'm not sure what it adds to our already subpar, suboptimal control of hypertension. It's just another reflection of that, but I don't think it really adds a lot of additional data.

It seems like it would reflect the local population with kidney disease, heart failure, hypertension and poor socioeconomic status, and it would be at addition.

VICE CHAIR GEORGE: Roger.

MEMBER SNOW: You know, the PQIs, in several instances, seem to have this problem that they've kind of missed the mark. But the issues are -- a lot of people, people who have uncontrolled hypertension usually don't get admitted at the hospital for that. They get admitted to the hospital for something else.

So you're not capturing what you're looking for for that reason, just as Dana previously said, and that when you want to identify what's causing that, on the other hand, it's all these other co-morbidities or other things. So not unlike the PQI around the angina, we're looking at --

We're trying to measure something by looking at a proxy that doesn't really capture it.

VICE CHAIR GEORGE: Christine.

MEMBER STEARNS: I guess I approached reviewing this, and I don't have a

clinical background. So I was looking at it from the perspective of someone who might be engaged in the dialogue about wellness in the community, that in some of the recent data in a report that just came out that did look county by county, that came out across the nation.

So in looking at it from the perspective of those who may be involved in other sort of state-based initiatives, giving a basis of comparison to how different regions of the state are doing and as compared to how other states are doing. But there are a lot of initiatives that are going on in the community, and this gives a basis for comparison of how the community is doing.

But I don't know if folks are looking at it from that perspective, of being sort of a useful measure. I'm also not aware of all the other measures that currently exist out there.

But that, you know, for folks that

are engaged in, you know, sort of wellness initiatives at the employer level or the community level, having information to be able to judge your region is useful data, and that was -- and it does seem that this does measure something that is accurate and measurable, and there does seem to be a disparity.

But and some of those factors are things that you perhaps don't need a measure to tell you socioeconomic status in sort of different regions of the state. But there are initiatives sometimes that are going on in a local area that may be making an impact, and so that that you would need.

MEMBER MAGID: I guess I'd like to know, I have one general question and then a specific question. The general question is how is this information more helpful than the data we already get from NHANES, which gives us a great deal of, you know, level, not just the people with diagnosed but also undiagnosed hypertension, at I believe the county level.

The second question I have was about the ICD-9 codes, and whether this is limited just to primary hospital diagnosis versus whether, or whether it includes secondary?

VICE CHAIR GEORGE: NHANES is not geographically localizable.

MEMBER MAGID: Well, it's reported that way.

VICE CHAIR GEORGE: That's a different survey. BRFSS is state-based, but NHANES is not. It's generalizable to the entire population.

MEMBER MAGID: But so they don't report data at smaller geographical levels?

VICE CHAIR GEORGE: Not for NHANES.

MEMBER MAGID: No, okay.

VICE CHAIR GEORGE: We have a few states that have done some sort of state level kind of mini-NHANES, but --

MEMBER MAGID: And the answer to the question about whether it's primary versus

primary and secondary diagnoses?

MR. ROMANO: I could address those questions.

VICE CHAIR GEORGE: Thank you.

MR. ROMANO: Hello?

VICE CHAIR GEORGE: Go ahead.

MR. ROMANO: This is Patrick Romano. I'm the clinical leader of the AHRQ quality indicator support team. So just to address a couple of these questions. So yes, the specification is based on the principle diagnosis or the principle reason that a patient is admitted to the hospital.

Now we of course recognize that many patients with hypertension are admitted for heart failure or for other related conditions. There is a separate PQI for heart failure, and that would capture those patients who are admitted with acute heart failure, secondary to hypertension.

There are also, of course, other Prevention Quality Indicators that may overlap

with hypertension, that may capture patients as well, such as the PQI related to diabetes, because diabetic patients sometimes are --

MEMBER MAGID: If I could just interrupt you --

DR. ROMANO: -- admitted to the hospital as a complication of diabetes and hypertension.

MEMBER MAGID: Okay. I was only concerned if you were going to include secondary, so that I'm glad to learn that it's just primary.

DR. ROMANO: Yes. One other point is just that this indicator is really intended to describe population health. It's an area level indicator.

It's designed for use at the geographic area level, and so as has been pointed out, it doesn't really overlap with NHANES in that sense, and the added value comes from local public health agencies and local coalitions that are interested in

tracking the performance of the health care system as it relates to population health.

We know, of course, that healthy people and healthy communities are one of the three national aims that are part of the new National Quality Strategy that's been established or promulgated under the Affordable Care Act.

VICE CHAIR GEORGE: Any other major comments on the importance of this measure?

(No response.)

VICE CHAIR GEORGE: Okay. We'll move to a vote.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

VICE CHAIR GEORGE: Seven yes, 11 no. Okay. We are going to keep going forward and transition into three heart failure measures, 0135, 0162 and 0136. Any brief comments from the measure developers?

DR. MASOUDI: Yes hi. This is Fred Masoudi again. I'll speak on behalf of these

measures, which are three or the measures that have been used by the CMS and Joint Commission over the last several years, as part of the Hospital Compare public reporting program.

The three measures under consideration are the evaluation of left ventricular systolic function, first. The second is ACE or ARB for patients with left ventricular systolic dysfunction. It looks like the title's cut off in the agenda, and then finally detailed discharge instructions at the time of discharge for patients with heart failure.

Again, these three measures have been used for quite some time in the context of a national public reporting program currently in use on the Hospital Compare website. I think of the measures that you've seen today. They're probably three that you're perhaps most familiar with. I'll leave it at that for the time being, unless there are specific questions.

VICE CHAIR GEORGE: Kathleen.

MEMBER SZUMANSKI: I have Measure 0135, which is on the evaluation of left ventricular systolic function in patients with heart failure. This is a measure that really does not stand alone as determining outcome, but it's a building block of the treatment protocol that's going to be designed for the particular patient.

Obviously, the documentation of the 2D echo result in a medical record is fairly easily obtained. Some of the issues with this measure, I think, in terms of importance, is, comes a little bit further in the discussion.

But obviously this is a major health problem in the U.S., and that we have to have a jumping off place, and the jumping off place for this measure is evaluation of left ventricular systolic function. So I would suggest that this is probably an important thing to measure.

VICE CHAIR GEORGE: Any comments or

discussion on Importance?

MEMBER JEWELL: This is Dianne. I see a lot of P's in our Excel spreadsheet for this measure, meaning partially by the other reviewers in the review group. I'm just curious what some of the hesitation was.

VICE CHAIR GEORGE: Not sure.

MEMBER SZUMANSKI: Not under Importance. It's under performance --

MEMBER JEWELL: We're looking at 0135, are we not --

MEMBER SZUMANSKI: -- evidence. It's further down in the discussion. I don't believe it's on the importance of the measure.

DR. BURSTIN: It's actually on the measure gap, because it's actually pretty small.

MEMBER SZUMANSKI: Oh, I'm sorry. Obviously, you know, the more we focus on this, the closer we get to achieving the performance levels that we want.

There continues to be a measure gap

in some settings, and certainly from a disparity standpoint, it is identified that in the Native American population, there is probably a more significant gap than in other populations. So it is closing in some areas, but in others, the gap still exists.

MEMBER JEWELL: Thank you.

VICE CHAIR GEORGE: Any other questions?

(No response.)

VICE CHAIR GEORGE: Okay. We'll vote on the importance.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

VICE CHAIR GEORGE: Fifteen yes, three no.

MEMBER MAGID: I have just a general question, and this may apply to a number of measures. But I just thought about it in light of this. So we did some validation of primary discharge diagnosis of heart failure, and its high positive

predictive value. But it was part of a multi-center study.

One of the things we found was though that there can be upcoding with this diagnosis, and that sometimes you see situations where the physician caring for the patient might, on initial admission of a patient with shortness of breath, put "heart failure" in the differential diagnosis, but by the end of the hospitalization, it was clear that the patient had pneumonia and not really heart failure.

But for some reason these specialized coders that the hospitals hire to enhance reimbursement go through and actually change the discharge diagnosis to maximize reimbursement.

So we did, one of the studies was in this, we were looking at cases in which EF wasn't measured in people with a discharge diagnosis, and we found that, you know, a small, not large, but a small number of people

really didn't have heart failure on careful review.

Was there a way to get those people out of the denominator, and have you guys seen this is other quality measures? That was really a NQF question, not -- well, it sounds like Fred's going to respond to it.

DR. MASOUDI: I can do that. I can tell you that you're right, there's a small amount of misclassification, some of which may involve miscoding.

I would say that in general, any time this has been looked at within the Medicare population, and it's not done systematically with these measures, because you can imagine the burden of abstraction involved in corroborating a clinical diagnosis of heart failure would be prohibitive.

We have found that the positive predictive value of this family of codes as a principle discharge diagnosis tends to be extremely high, north of usually 95 percent.

Of course that's not 100 percent, and that work has not been done in a while.

But speaking directly to the issue of is there separate corroboration of a clinical discharge diagnosis? Well unfortunately the answer is no, and I think from a practicality standpoint, that's really not feasible.

MEMBER RUSSO: Although just on a broad level, many of these measures, particularly those from CMS, have had validation sampling, and this one actually reference that as well. They're small numbers, but they do do a cross-reference to an audited sample.

MEMBER MAGID: Yes, no, and I agree. It has a very high -- I was just more curious as to the people that go through and collect this data, if they were going through a chart and they realized hey, this patient really doesn't have heart failure, it's tough. It's just reported. Okay, and that makes

sense, why it should probably never be 100 percent.

VICE CHAIR GEORGE: Is that situation likely to be improved with electronic records?

MEMBER MAGID: I doubt it.

MEMBER PHILIPPIDES: Can I ask a question about one part of the definition in there? Plan to check LVF post-discharge. How do we assess if someone is going to -- it's planned that they're going to have an echo after they're discharged?

DR. MASOUDI: Yes. This is an attempt to sort of level the playing field, for those institutions that don't have the capacity internally to assess left ventricular systolic function. As you can imagine, a small rural hospital may not have the capacity, say even over a weekend or something like that, to do that.

So what this has done is through chart documentation, it has to be documented

there's a specific plan for it to be assessed as an outpatient.

MEMBER SZUMANSKI: I think under Scientific Acceptability, there are some challenges, and I think David has pointed out one of them, from a documentation standpoint. Obviously, if there is a test result in the medical record, it's easy to say okay, the 2D echo shows.

The other two that are difficult, however, was it done before arrival and if it was, is it documented somewhere in that record. Lastly, is it planned after discharge and when is it going to get done, or does the report actually get back to the record.

So an abstractor is a bit challenged by trying to find the documentation if it's not a test that was done during that hospitalization period.

As a result, as again David pointed out, there is upcoding on this, to say we assume that the physician has ordered or it's

coming, or we don't quite have it but we're assuming that it's going to be there. Therefore, this is a patient with heart failure.

That's an unfortunate thing that happens, but abstractors do this as a rule of thumb, I think in general, to give the benefit of the doubt in those measures that are somewhat difficult to collect. We know with this one, the numerator and denominator is fairly clearly defined. Exclusions are identified, and in the --

So from a scientific acceptability standpoint, I think it does meet the criteria, even though we know that perhaps there is some gaming that goes on with this measure that does not happen with some of the others.

MEMBER THOMAS: I have a quick question with the numerator. In terms of the time before arrival, is there any limitation on the amount of time? Is it ten years, you know? Can it be at any time?

MEMBER SZUMANSKI: From the numerator time window is from hospital arrival to the time of hospital discharge.

MEMBER THOMAS: No. I mean that testing of LV function before arrival? I just wondered if there was a time limit.

DR. MASOUDI: Yes, there's not, and this has been a topic of substantial debate. I think the -- and after a huge amount of going back and forth on this, the decision has been not to put a time window around it for several reasons.

One is that putting a time window around the variable increases the burden of abstraction. But perhaps more importantly, that it's -- that in some cases, a direction for action obtained a year or two ago may be adequate, and we don't want to necessarily stimulate over-use of imaging.

Further, there's not explicit guideline recommendations as to what an appropriate time interval is. Sort of the

three of those things conspiring together have led the measure in the direction of not using an explicit time window around the documentation.

The idea here is for the clinician to document the EF that they are using to help guide the management of the patient, and direct the use of other evidence-based therapies. So that's sort of the approach that's been taken here.

MEMBER SZUMANSKI: I think the one thing that this measure may bear scrutiny in the future on is the use of imaging, and how many times do you image the same patient in a given period of time, especially if they're frequent flyers and admitted regularly.

DR. MASOUDI: Right, absolutely, and the one thing to emphasize about this measure is that it does not suggest that a patient who is admitted with heart failure necessarily needs a new assessment of left ventricular systolic function. That is to say

if a patient had one several months ago and they say this is a patient with a known ejection fraction of 20 to 25 percent, that gets credit.

So this is not designed to stimulate repeat imagining in frequent flyers, as per the concern you raised.

MEMBER THOMAS: I mean I totally respect that. But just, as we all know, there is a lot of imaging done, and maybe an unintended consequence of this. But, you know, I think it's a good measure overall.

DR. MASOUDI: I'm sorry. Could you clarify the unintended consequence part of it?

CHAIR GIBBONS: Fred, this is Ray. I think Suma's actually correct, because I've had this discussion with multiple physicians. They do not realize, people do not actually realize.

They are under the misimpression that they have to do the EF during the hospitalization, and use that for

justification for doing something that's clinically actually unnecessary. It's a misstatement of the specifications in the measure.

DR. MASOUDI: Right. I see, okay. No, I think that's -- I understand what you're saying. Thank you for the clarification.

MEMBER KING: I have a question about the meaningful differences. I understand about the Native American patients, but nevertheless the national performance rates for this measure in the first quarter of 2010 were 98 percent.

Native American patients were 3,400 of the 773,000 in the data warehouse, which is well under -- well, one percent. Am I right? Yes, thank you. Well under one percent, and we're talking about their performance was only 94-95 percent, versus the 98 of others.

When you put that on the front page of the Arizona news, does everybody really get upset about it and get motivated to -- I don't

know if it's a meaningful difference for a national guideline from NQF, to keep doing this, and it is getting near to our, what we call our retirement warehouse, and we should, you know, think about that.

VICE CHAIR GEORGE: I think we had some other measures in this. Can you comment Reva?

DR. WINKLER: Well, we need to have a further discussion about the concept of retirement, which you all brought up last time, and prompted a great deal of internal discussion at NQF, because we really hadn't a process or criteria, which you also asked for, for doing that.

Since that time, we have developed those, and it's on the agenda to discuss tomorrow. If this is a measure that may fall into that category, we can flow these all together, if you'd like.

MEMBER KOPLAN: Was this raised when we were talking about number one, because

we're already on number two, and this applies to number one?

MEMBER SZUMANSKI: I think the struggle that I have with this measure is that it is a starting point for therapy, and if you eliminate this one, it has impact on the measures that come below this. So it serves as a foundational measure.

To me, this would be better served in a composite format, and I know you hate to hear that word, but it really doesn't stand alone without what are you going to do for this patient whose EF is this?

DR. BURSTIN: And there's a composite measure you're going to review later today, on exactly that point. Just one comment on the EF alone issue. This comes up all the time with assessment measures. So in general, you know, assessment measures have a place.

But the question would be since you also have therapy measures that depend on the

assessment, is the assessment alone important enough as a stand-alone? The LV, the other measures about beta blockers and ACE/ARBs depend on demonstration of low EF. So just a question about that.

MEMBER SANZ: The problem is that you end up losing all of your -- you only know then that the patients who got the EF were treated appropriately. You don't know that the patients who should have been on treatment didn't get the test. So they're not mutually independent.

Having said that, if 99 percent of people are getting the test, what's the value here?

MEMBER PHILIPPIDES: That the impact is very, very small, almost nothing. Is that right?

MEMBER SANZ: Wasn't that 1(b) performance gap? We kind of missed it.

MEMBER SMITH: Maybe if the impact is small, my question is not important. I am

concerned about what Ray says. The way it's written now, it would appear that every time a patient's admitted, you need to get a systolic ejection fraction.

DR. MASOUDI: Well again, just to speak to the -- and it's quite possible, and Ray, as you've alluded to it, it is in fact the case that in some circumstances, this has been misconstrued.

But the measure specifications themselves, I think, are quite clear, that this doesn't require actually a repeat imaging, but rather the documentation of a left ventricular systolic function, which can be from before the hospitalization.

So and again, these are the specifications that have been in place over the last eight to ten years or however long that CMS and the Joint Commission have been using these measures for the purpose of the public reporting program.

MEMBER RUSSO: Yes. So it clearly

states, I mean, you can have it prior to admission, and I guess with the comments made today, we don't know how long before. So maybe there should just be something saying that it -- just a little asterisk saying it does not need to be during this hospitalization or immediately before.

It could be within something clinically -- a little asterisk saying that you don't need to repeat it every time you come in, you know, reflecting the comments that were made, with that mantra. Just if there's some clarification needed for overuse. I don't know if there is overuse or not.

VICE CHAIR GEORGE: We have one option, whether people want to go back and revote on the Importance, based on the discussions we've had on scientific validity.

MEMBER KOPLAN: I second the motion.

DR. MASOUDI: I have a question.

VICE CHAIR GEORGE: Yes.

DR. MASOUDI: A process question about something that I believe NQF staff mentioned, which was that it was, there was a plan to circle back to a group of measures, and decide whether or not about the issue of topping out. Is that, was that an accurate? Did I hear that right?

DR. WINKLER: It will depend on what the decision is of the discussion currently on the table. We will be circling back for the ones that were previously discussed, but I think the committee's still discussing how they feel about this measure right now.

VICE CHAIR GEORGE: Right --

DR. MASOUDI: Is that in the performance level though, or does that include the performance level?

DR. BURSTIN: Right. So let me just take a moment, because I think we're operating a little bit in the dark, although I think you shared the inactive memo with

them, is that right, inactive endorsement? So you've seen what we've proposed. It's going out for public comment this week. It will then go to our board.

But essentially what we proposed is that for measures that are otherwise important, valid, reliable but incredibly high levels of performance, the idea would be should we at least keep them somehow in an inactive status, so people could use them for periodic surveillance, to make sure that when you take your eyes off the prize and they're not being perhaps front and center as the way they have been for years, which is probably why they're at 98 percent, because we paid on them and looked at them constantly, to make sure that the performance doesn't deteriorate.

We can maintain them in an active status, so that if there was a decrement in performance over time, that measure wouldn't need to come back through the process. It would still already be in this inactive mode.

VICE CHAIR GEORGE: So we would need to endorse a measure in order to have it considered for inactive status?

DR. BURSTIN: This is a little complicated, because these measures are endorsed. They're up for maintenance. So I think this might be one of the ones if you want to put it as a parking lot. I think the issue would be how important is this measure on its merits, if you take away the issue of the percent performance, all the issues still notwithstanding that you've already talked about around the EF.

But still just this issue of it being at 98, 97-98 performance consistently for years, with really very little variation across hospitals. If you take that out of the mix, is this -- does it otherwise meet the NQF criteria for evaluation.

MEMBER SZUMANSKI: Can I just ask a clarifying question? If the issue comes up that imaging is being overused in patients

with heart failure, and we are not monitoring the use of imaging in heart failure, and we're moving directly to treatment, does that have an impact on whether or not this measure remains in existence?

I don't know if I'm making myself clear, but I see this measure coming under fire from the imaging standpoint and the cost. So I'm just asking if, do we need to continue to measure it, to see are they actually over-imaging heart failure patients?

MEMBER KOPLAN: You won't get it.

MEMBER SZUMANSKI: Okay.

MEMBER THOMAS: There are many ways that that's already being addressed, and so -- no, no. It's a good question, but there are many other ways that's being addressed on a national level, that we unfortunately know the answers, that there's just an increase, a huge increase in imaging. So I think we do need to take that into consideration as we are.

MEMBER SZUMANSKI: Okay, that's

good.

MEMBER RUSSO: Is there is any way to -- so we still know measures are important and we want to retire it. Is there something on that last thing that we vote on? Could it be inactive then, that's going to -- you know, is there some way that we could specify that it's still important, all these things are good to do, but we want to -- we don't really need to use it still? How would we do that?

DR. WINKLER: You need to evaluate the measure as it is, because we still -- those measures still have to meet all the criteria. The only one they could maybe fall off on is the opportunity for improvement. So they still have to pass everything else solidly.

So some of these other issues you're raising make me wonder how you feel about the other criteria. So that conversation is very important, because it is a prerequisite to moving them into that

inactive category.

VICE CHAIR GEORGE: Bruce.

MEMBER KOPLAN: Isn't it just better to have a yes/no, and not like an in limbo kind of thing, because then it gets confusing. Like is there, has this been established as a precedent already? So if it hasn't yet been established, then what you just said, just evaluate?

DR. BURSTIN: Yes.

VICE CHAIR GEORGE: Any more comments on Scientific Acceptability?

MEMBER SZUMANSKI: I heard that we're going to go back and vote on Importance again. Are we not doing that?

VICE CHAIR GEORGE: A show of hands?

MEMBER AYALA: Can you clarify first though, because I'm confused. If we did go back, are we supposed to ignore the performance part?

VICE CHAIR GEORGE: No.

DR. WINKLER: No. One of the issues is it's important to capture the rationale behind your vote, and if your discussion focuses strictly on the lack of opportunity for improvement, and no other issue such as evidence base or any of the other concerns, and you think that it won't meet the importance criteria. That's fine as a special case.

But if there are issues, particularly around the evidence base, that means you're kind of failing on that criteria. We're trying to sort out how to walk you through these options that are branching, frankly.

VICE CHAIR GEORGE: Right, and it sounds like we've had a lot of discussion about other issues outside of the topping out on performance. So that's fine. We'll just, we will proceed to evaluate the entire measure, and vote on Scientific Acceptability.

Tom's gone. Everybody voted?

DR. WINKLER: Dianne?

MEMBER JEWELL: I'm sorry. People were popping in and out. So which vote are we taking?

DR. WINKLER: Scientific Acceptability.

MEMBER JEWELL: Acceptability, partially. Thank you.

VICE CHAIR GEORGE: So that's seven completely, six partially, five minimally. And moving on to Usability?

MEMBER THOMAS: I think the question of does it add value would be based on some of our prior conversation here, in terms of is this an important measure to be used as a stepping stone to other clinical decisions, or can we gather this information in another way, or have we proven that there is no performance gap that is significant enough?

I think the only thing that I would note under Usability is the issue of imaging,

which we've already talked about, and in the CDAC trial with the audits that were done on this measure, there was a 4.6 performance deficiency noted in charts that were reviewed, and they were all related to documentation of a note indicating that EF was done, will be done, had been done in the past. So the issues were documentation-related, not performance-related.

VICE CHAIR GEORGE: Any further discussion on Usability?

MEMBER SNOW: We were talking about upcoding and those issues, gaming. They impact this. I'm not sure exactly how much they impact it, but it affects the Usability, apart from can people understand the number, which is the usual way that usability is described. Because its ability to be used if the reliability, going back to scientific acceptability. If that is poorer, then its usability is less.

VICE CHAIR GEORGE: Any further

discussion?

(No response.)

VICE CHAIR GEORGE: We'll vote on Usability.

DR. WINKLER: Dianne?

MEMBER JEWELL: Partially.

VICE CHAIR GEORGE: 5 completely, 10 partially, 4 minimally, and Feasibility.

MEMBER SZUMANSKI: I think the measure is feasible to collect. I think the issue again rests with the documentation, and the upcoding that does occur we know that it happens unfortunately. That really is the bulk of what I can say about feasibility. It can be collected.

MEMBER PHILIPPIDES: But we still have some concern about the unintended consequence of perhaps over-ordering imaging studies; is that correct?

MEMBER SZUMANSKI: I believe that's a concern with this measure. Maybe not now, but it will be in the future.

VICE CHAIR GEORGE: Any other -- David?

MEMBER MAGID: Did we have any suggestions for addressing that issue? I thought Ray, you might have brought up -- you brought up some specific language, and I wonder if we could help with that.

CHAIR GIBBONS: Actually, others have suggested the language. I think the measure specs are pretty clear. The problem is how the clinical practice community has chosen, usually without any knowledge, to interpret them.

So I'm quite serious. I've had fairly ferocious arguments with other staff physicians at the Mayo Clinic, where they say "no, no, I have to do an echo with this admission."

I say "no, no, you don't," and you know, it's really quite fascinating to see how people, and they will all quote, by the way, some meeting that they've just gone to, where

somebody who was allegedly a, quote, quality guru in their organization or whatever, stood up and made that statement, and it's flat-out wrong.

MEMBER MAGID: Right, and the fact that the financial incentives line up so nicely doesn't have any impact, right?

MEMBER SANZ: Couldn't much of this be resolved with an explanatory one sentence. "This measure does not mandate an echo at the time of admission."

CHAIR GIBBONS: You're assuming somebody would actually read that. They will not.

MEMBER THOMAS: The problem is --

MEMBER SANZ: But you will remind them, on your right or left side. Read the sentence.

MEMBER THOMAS: The problem is, as all of you are probably aware, those who are reporting on PQRI for example right now, we get a short little blip, you know, as an

indicator. Are you doing this, are you doing that? It doesn't have any of the description of the measure.

So this, unless it was changed a lot, it really would probably continue to be an issue.

VICE CHAIR GEORGE: Any other comments on Feasibility?

(No response.)

VICE CHAIR GEORGE: Okay. We will vote.

DR. WINKLER: Dianne?

MEMBER JEWELL: Minimally.

DR. WINKLER: Thank you.

VICE CHAIR GEORGE: 5 completely, 8 partially, 6 minimally.

MEMBER MAGID: Just I just ask Mary then, this is really a question for NQF staff, have you had a situation like this, where you think that, you know, on the one hand you have this measure which you think is fairly evidence-based in terms of quality, but the

introduction of the measure actually had the negative unintended consequences of driving up utilization where it might not have been necessary? Is that a problem you've had before?

DR. WINKLER: Well, not in this specific thing. But it's certainly not unusual for us to get the feedback that the on the ground implementation has issues that weren't necessarily anticipated or grow with the implementation of it. We try and solicit that information from folks, but as yet it isn't -- it's one of those things that kind of comes in randomly.

DR. BURSTIN: It is. There was one very prominent example when we had the initial pneumonia measure, that you had to have antibiotics in within four hours of coming to an EDE with presumptive pneumonia. Everybody walked in, the little old ladies with CHF, everybody was getting shot up with antibiotics, from what we heard, instead of

getting their CHF managed.

And so the measure, and that's an example of somebody asks well, what do we do when we hear about that? We did ad hoc review. The measure was re-reviewed. The measure was subsequently changed to be either presumptive diagnosis of pneumonia on the chest X-ray, as well a six hour window.

But again, there are examples like that, and it's the kind of thing you oftentimes you don't know about for initial endorsement, for a measure like this that's been out for years and years and years. I think it's an interesting question of how you would begin to assess whether in fact it's driven up imaging because of a perception you need to do it every time.

MEMBER PHILIPPIDES: I have this feeling that in three years, we'll be in the same room, and we'll have one measure in front of us getting too many echos in one year period. Should that be a quality measure of

bad quality, and then we'll harken back to this discussion, and think we didn't get it right exactly. But it's a tough one, it's a tough one.

MEMBER SNOW: Well, that's because everything you do drives up imaging. I mean going to the store drives up imaging, everywhere.

MEMBER PHILIPPIDES: Right. But lowering reimbursement drives it down.

VICE CHAIR GEORGE: Well I mean certainly, this is an opportunity to take our comments back to the measure developers, and you bring up the interesting point of the complexity of measures, and the education that needs to be done by developers about the complexity and exactly what these measures mean.

So any further comments before we vote on endorsement of the measure as it stands?

MEMBER STEARNS: So will a no vote,

how will -- where are we on the -- we've topped out on performance. Is that, are we back to that question again, that voting no is not a reflection on the quality of the measure, but rather on the topping out on performance, or are we not considering that point at this point?

VICE CHAIR GEORGE: At this point, it would be a totality of all of the factors that we consider.

MEMBER KOPLAN: And it also sounds like it's not just the topping out on performance issues, from our discussions.

VICE CHAIR GEORGE: Any further questions?

(No response.)

VICE CHAIR GEORGE: All right. We'll vote on endorsing the measure.

DR. WINKLER: Dianne?

MEMBER JEWELL: No.

DR. WINKLER: Okay.

VICE CHAIR GEORGE: 5 yes, 13 no.

So we are proposing to take a 15 minutes break, bring us back at five minutes to 4:00.

DR. WINKLER: This is Reva. To our measure developers on the phone, as you can see, we're running a bit behind schedule.

At this point, we're uncertain as to whether we're going to be able to get to all of the measures that are in the last group. It would be good for us to know if any of you would be able to let us push your measure until first thing tomorrow morning, if time runs out on us.

So if you're on the phone and can tell me right now. If not, if you can email Katie Streeter, or somehow just let us know what our options might be.

(Whereupon, the above-entitled matter went off the record at 3:39 p.m. and resumed at 3:56 p.m.)

VICE CHAIR GEORGE: Okay. Our next measure is Measure 0162. Andrea?

MEMBER RUSSO: Okay. So this is

0162, which I thought ahead of time it would be easy, but now I'm not sure. So this is ACE or ARB for LV systolic dysfunction in heart failure patients, and basically, the description of the measure is the percentage of heart failure patients with LV systolic dysfunction who are prescribed ACE or ARB therapy at hospital discharge.

So it's an inpatient measure, right, at the time of possible discharge. For the purposes of this particular measure, systolic dysfunction is described as an ejection fraction of less than 40 percent, as we've seen, or a narrative description of moderate to severe systolic dysfunction. So the quantification for that description would be equivalent, you know, clinically to less than 40 percent. It's a process measure.

The importance of the measure is just, you know, it's clear. It affects large numbers of patients. It's important in both quality improvement and public reporting.

This has a high impact. There is, you know, we know lots of data, as everyone here knows, that the therapy reduces mortality and it improves morbidity also.

There are some disparities also that were mentioned, namely in African-Americans, who had a lower rate on this measure of 91.8 percent. Lots of data. Again, randomized control studies, meta-analyses. So I don't think there's any question that this is an important measure.

MEMBER RUSSO: There is no concern, just because based on the earlier discussion, some of the other ones, I thought, were easy also. Yes. No concerns, no.

VICE CHAIR GEORGE: Any discussion about this importance of this measure?

MEMBER KING: At the risk of violence, I do have a question. It seems that we've had several of these ACE or ARB in the treatment of something, and it seems to me that the "something" was left ventricular

function, 49 or 50 times.

I guess we had in the setting of coronary disease and then we had it in the setting of an MI, and then we had in the setting of atrial fibrillation, and now we have it in the setting of nothing, right?

MEMBER RUSSO: They do actually have a nice --

MEMBER KING: Just coming in the hospital and then leaving, then we have it again. I don't know. It just seems to be crying out for harmonization.

MEMBER RUSSO: And they do actually describe that.

MEMBER KING: And that doesn't mean it's not important; what it means is just a consolidation. So you know, just a little asterisk for later, that's all.

MEMBER RUSSO: I don't know if you want to discuss that now. They do describe it later in the application, really nicely actually, looking at -- they talk about

harmonization and comparison and come up with this particular measure. They said that there's no NQF endorsed measure with the same topic and the same target population. That means the hospital discharge.

So I don't know if that's true or not, but you know, we can clarify that, but it's -- and they go through some specifics that it's not harmonized in other settings by specifications. We can go through that later. But this is at discharge with not just coronary disease patients; it could be non-ischemic cardiomyopathy patients. It's the time of discharge, so it's not post-MI.

MEMBER KING: A follow-up. It seems like no, that's right. In fact, it seems like this one -- it's not the other ones cover this one; it's that this one covers the other ones.

MEMBER RUSSO: A good point.

MEMBER JEWELL: So this is Dianne. I thought that one of our objectives was to

vet measures on their own merits, and then pick best in class, and I realize that if we already think we know what the one is that's best in class, that seem like some redundancy. But I guess that's where I thought this was.

CHAIR GIBBONS: Just to clarify though, this is principle diagnosis of heart failure, DRG heart failure. But that's --

MEMBER RUSSO: So not MI.

MEMBER KING: Not just --

MEMBER RUSSO: Not CAD.

CHAIR GIBBONS: Not an MI, not CAD. You've got to be in the DRG for heart failure.

MEMBER KING: Even if it was due to coronary disease, even if it was due to --

CHAIR GIBBONS: It doesn't matter what it's due to. It's in your --

MEMBER KING: It doesn't matter.

CHAIR GIBBONS: No. That's your principle diagnosis.

VICE CHAIR GEORGE: Any further discussion on the importance of this measure?

(No response.)

VICE CHAIR GEORGE: All right. We'll move to a vote.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

VICE CHAIR GEORGE: Unanimous, 18 yes. All right. Moving on to Scientific Acceptability.

MEMBER RUSSO: I think in terms of this category, the things look pretty good here. The specification again is those who have ACE or ARB therapy at discharge, and have the diagnosis of heart failure, as was mentioned. The exclusions, you know, certainly are reasonable ones.

They did do some reliability testing, which they outline regarding, you know, and the only question I would have for the measure developers, the one where they validated with a sample of five cases per quarter across all topics, they came up -- the

percentage was only like 77 percent for, you know, validating the reason for no ACE inhibitor or ARB at discharge.

To me, that seemed low, but I don't know what's considered -- no. Does everyone -- the other things were 86 or 98 percent, you know, for validation there. But other than that, I mean I think I didn't have any other, you know, difficulties in this category.

Disparities, there was the race disparity that was identified still. So I think, you know, it looked good to me in this category. They did say the race disparity, although they didn't adjust for all others. It was a univariate analysis. They didn't adjust for everything else yet, but they did address disparity.

DR. WINKLER: Just a question, because you had a similar one with the MI measure, is how is a missing value for a left ventricular systolic dysfunction handled in this measure?

DR. MASOUDI: If the LVF is not known, the patient can't be assessed for compliance on this measure.

DR. WINKLER: So you're saying they're excluded for a missing value?

DR. MASOUDI: Yes, which is in part the reason why the previous measure is, was intertwined with this particular one.

MEMBER SNOW: I have a question about validity testing. It says here 2(c), "Face validity is regularly assessed with the technical expert panel responsible for reviewing and supporting the measured topic." My understanding of face validity is that it is something that you get with people who are not experts, that content validity is done with experts, and I mean it's sort of almost, maybe it's being used in a jargony way.

But I don't think it necessarily changes outcomes here, but am I the only one who thinks that, or does it matter? I want to see who responds. Shut up and move on, I

guess.

MEMBER RUSSO: Point well-taken.

VICE CHAIR GEORGE: Any other concerns or comments on the scientific acceptability?

(No response.)

VICE CHAIR GEORGE: Hearing none, we'll move to a vote.

DR. WINKLER: Dianne?

MEMBER JEWELL: Partially.

DR. WINKLER: Thank you.

VICE CHAIR GEORGE: 11 completely, 7 partially. Moving on to Usability.

MEMBER RUSSO: This measure is currently in use, and they actually, you know, go through some discussion on -- I don't know if harmonization is under this or not. Is it? Yes, I think it is, you know, as how it's something I guess we're talking about more tomorrow.

But they go through a very nice discussion on how this measure, you know,

compares to other measures, and they bring up that even though some of the specifications may be a little bit different, this is again, you know, measured at the time of discharge and compared to another measure, 610, was an outpatient measure that had a three-year time window, based on administrative data.

Again, they're totally different. They're looking at something totally different in that case, with regard to the setting of care and the type of data there. So you know, I think this is fine for this measure.

VICE CHAIR GEORGE: Any discussion about the Usability?

(No response.)

VICE CHAIR GEORGE: All right. We'll move to a vote.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

VICE CHAIR GEORGE: 14 completely, 4 partially, 1 minimally, and Feasibility.

MEMBER RUSSO: The one question I

had on a comment they made on feasibility, are all data elements available electronically, they say "no," and I think, I'm assuming, is the only thing that's not available, the comment about moderate or severe LV systolic dysfunction? Is that what was meant by that?

DR. MASOUDI: Yes. There's, I think currently, this is going to change over time, I think undoubtedly. Currently, the actual value of left ventricular systolic function can be challenging to ascertain electronically. It's really a function of the robustness of the underlying system in which the measurement occurs.

Again, I think with more widespread adoption of EMRs, the answer to this question will certainly change.

MEMBER RUSSO: So you know, I think, okay. That answers the question, because I guess the one difference here obviously is not just using the EF number, but it's allowing the moderate or severe systolic

dysfunction. I don't know how other people feel about that. I was fine with it the way it is, but something to think ahead about in terms of harmonizing with other measures.

I think -- oh, the other thing, exclusions. They make a comment on what have you learned from this before. If you're excluding certain patients from use of an ACE inhibitor, before they look back and found that, you know, some of the same contraindications to ACE inhibitor therapy are similar for ARBs.

So rather than some people may not repeat it, because it's intrinsically obvious to everyone that reasons like hyperkalemia or other renal dysfunction issues. So for the going forward, that would be included. You wouldn't have to reabstract that data. You wouldn't have to redocument the same reason if you're already documented it for the ACE inhibitors.

So I think, I didn't have any other

issues in this category. I think that's fine.

VICE CHAIR GEORGE: Any discussion on Feasibility?

(No response.)

VICE CHAIR GEORGE: Okay. We'll take a vote on this.

DR. WINKLER: Dianne?

MEMBER JEWELL: Partially.

DR. WINKLER: Thank you.

MEMBER JEWELL: You're welcome.

VICE CHAIR GEORGE: 13 completely, 5 partially. And any further discussion on this before we move to a vote on endorsement?

MEMBER RUSSO: I guess the only other question I alluded to before is I'd just like to, and this may be just a minor point, just the thoughts of the developers. You know, talking about potential overuse for the exclusion criteria for potentially distorting the performance rates.

Can you just make a comment on the difference in terms of that 77 percent that

came out in that, you know, random sample of whatever it was, five. Let me see what page that was on, but is that considered an acceptable number?

DR. MASOUDI: Yes, I think those are both important but slightly different questions, vis-a-vis the 77 percent issue. A lot of the sort of reproducibility of these things depends upon the complexity of the -- sort of the data element itself and sort of the variety of sources where that might be captured.

I would say, you know, for this specific data element, an approximately 80 percent, you know, rate of reproducibility is actually, I think, quite acceptable. That's obviously just -- that's a subjective estimate.

With respect to this issue of the, you know, the exclusions, I think that any measure with an exclusion, you know, this is a philosophical that pertains to any measure

where exclusions are allowed.

And many such measures don't have a clearly delineated list of exclusions for a variety of reasons. This construction is the result of years upon years of field testing, and responsiveness to the community that uses these measures. So I think it's always, you know, a possibility that any exclusion could lead to gaming.

But I think as was suggested before at the prior meeting, if one is going to write down why one didn't give an ACE inhibitor, it's just as easy to give it when you're thinking about it. So I think the likelihood, the concern about gaming of this sort of exclusion is, you know, to the extent that you have to think about giving a medication in order to write a reason not to give it down, sort of minimizes concerns about that.

MEMBER RUSSO: Okay, thanks. That makes sense.

VICE CHAIR GEORGE: Any other

comments or questions on this?

(No response.)

VICE CHAIR GEORGE: All right. We'll vote on the endorsement.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

VICE CHAIR GEORGE: It's unanimous, 20 yes. Okay, and we'll move on to the last one in this set, number 0136. Carol?

MEMBER ALLRED: The title of this measure is heart failure, discharge and detailed discharge instructions. The brief description is percentage of heart failure patients discharged home with written instructions or educational materials given to patients or caregiver at discharge or during hospital stay, addressing all the following: activity level, diet, discharge medication, follow-up appointment, weight monitoring and what to do if things worsen.

Now I have to stop right here and tell you that this measure gave me a great

deal of existential angst. Sorry Ray. I could not come up with a better word, and this is where my patient side comes out. I am a patient. I have been hospitalized with heart failure, and when I read this, it looks to me like the importance of this measure is: did someone in the hospital document whether or not written instructions were given to the patient?

In my outlook, it is not whether written instructions were given to me; it is what is the quality of those instructions? Was I as a patient able to understand those instructions, and can I then take them home with me and apply them to improve the outcome of my condition.

MEMBER SMITH: You're absolutely right. As a physician, I'll join you.

MEMBER ALLRED: All right. That was my synopsis up front. I don't think that during a hospital stay, any patient could be totally educated about what they to know about

heart failure. I think the measure misses its point from that standpoint.

But if you back off and look at it just from written instructions, obviously that's an important thing. So I'll throw it out for discussion and let you all decide where I go from here.

MEMBER SZUMANSKI: I think the other point with this, in conjunction with it, is we have national standards on health literacy. It is not spoken to in this measure at all, and it ties in with what you're saying. If they can't understand it, it wasn't explained and they can't even read it, they're coming back to the hospital with their instructions still in the sealed envelope and saying "Somebody gave this to me, but I can't read them or understand them."

MEMBER MAGID: Right. I guess -- I don't know who's supposed to call on me, but I think that in each of the packets where they talk about process measures, they talk about

the strength of association with outcomes. The mere, you know, provision of discharge instructions, I don't know that that in and of itself is related to outcomes.

MEMBER MAGID: Well, about ten years ago --

MEMBER JEWELL: This is Dianne. It sounds like what, the outcome comments aside for a moment, it sounds like what this measure needs to read like is verification, that there's documentation of verification of understanding or something along those lines. Clearly, if there's not understanding, any link to outcome is luck, not follow-through.

MEMBER MAGID: Yes. I was going to say that I know, I can think of several examples where the patient was given a discharge sheet with their medications, and told to take coumadin, and they went ahead and continued to take that warfarin they used to be on and came in with an INR-12, you know. So they got a written piece of paper. That

didn't help them at all.

MEMBER SANZ: To go to the other side, I agree completely with what you're saying. However, measuring that is not so simple. It has been shown in Kim Eagle and the Michigan experience, that just having a measure saying "Did you provide detailed discharge guideline change rehospitalization?"

So there is evidence for this in the gap project, gap CHF. There was a gap MI project too. However, it's not as good as what you're describing. I just don't know how you measure that.

MEMBER ALLRED: Yes. I don't know how you measure that either, but there's an article that came along with this, that was published in March of last year, and basically it talked about the change in outcomes being less than one percent when it was documented in the record that the discharge instructions were given.

But there's also another one that

documented when there was a follow-up with a nurse, there was a much greater change. So that's kind of combining what's missing in this one, is that this is hospital-only, and the follow-up has got to be important to the care of the patient too.

MEMBER SMITH: So I agreed with what you said in the beginning, and I know the way, you know, living in this. What happens is people will document that they gave their patient instructions.

But there is a baby here, and if all we say is get an ejection fraction, give the meds, open the door and send them home, we're really missing a very important aspect of care, and that is patient education.

Time and time again, the better educated the patient, the better the outcomes. It's a confounding variable in many studies, and a direct relative variable. So the question is how do we form a recommendation about the need to educate the patient that

will really work? I think that's the issue.

MEMBER ALLRED: I found I struggled with this, because I found that really hard. If was going to make that recommendation as the patient that it missed the mark, how do you actually measure the fact that the patient understood, and I don't know. I think it would have to be a follow-up with someone, who could sit down and take the time to go over those instructions. How do you document that?

VICE CHAIR GEORGE: Yes. We've certainly struggled with this in stroke in providing discharge instructions.

But I think, you know, one of the things that we found was more helpful was including in the measure instructions were given to the patient or the patient's caregiver, which is perhaps someone that may be more receptive, at the time of hospital discharge, to getting the message.

MEMBER JEWELL: This is Dianne. I guess I'm perhaps not understanding a

logistical area here. Is the issue that phrasing "verification of understanding" or some other follow-up, as was described, is not currently in medical records or not easily added to a medical record, so that it's still a check that it occurred?

Is that the problem? It sounds like we're defining, and we have a recommendation for how to redefine the measure. What I thought I heard was it's difficult to capture. So I guess I don't know enough about the logistical barriers in that regard.

MEMBER SZUMANSKI: I think what I heard is that it is documented in the record that it's given, but the patient, no one sits down with the patient and says "let's go through your discharge instructions. These are important things you need to know. This is when you need to call your doctor, and this is when you need to come back to the hospital."

Nobody says that to the patient or explores their understanding of that. They're just given a packet of information that they're expected to take home and read, and they don't understand it.

MEMBER JEWELL: And so it sounds like, if I understand what you're saying, is that if a measure were created that specified verification of understanding, which would require the behaviors that you just described, that perhaps people would game the system and just check it without still really doing it. Is that the worry?

MEMBER SNOW: No, I don't think so. I think the problem is that it doesn't do that, that in some venues, there's resource put to nurses and others sitting down with patients, and actually verifying that they understand what's going on to at least some degree.

But from this measure, I don't think -- if all you're measuring is that you

gave them something, you can't differentiate that excellent care from just giving them a piece of paper with nothing on it, except a problem list.

MEMBER JEWELL: Yes, I'm sorry. I totally see the point of the problem with the current measure. I was trying to respond to this issue of how do we give the measure developer a recommendation that would improve the measure. So thank you. That helps.

MEMBER SANZ: I question whether this is even needed anymore. We have two 30-day readmission measures about to be discussed. This is an upstream measured that was designed fairly long ago, like I said. Does it really matter? What counts is the downstream. Are they readmitted or die in the next 30 days? So I don't care how you do it if you have good results.

MEMBER KOTTKE: Yes. I guess I would jump in with Mark and not be too harsh on the measure, because historically, people

were sent home without anything, and this was good. I mean, you know, this looked good a long time ago.

But now that we have 30 day readmission and 30 day death, do we really need this measure, because people are going to have to do whatever it takes, and we know that a, particularly for heart failure, a visit within a week with the clinician is -- changes.

Yes, I mean, you know, and so maybe we just, you know, we've got the stick there, which is 30- day readmission and 30-day mortality, and people just tough it out, figure out what works for them.

MEMBER SNOW: So that means that the creation of those has ripped importance from this admission, from this measure?

MEMBER KOTTKE: Yes.

MEMBER ALLRED: Maybe if this measure was harmonized with outpatient care, that would be helpful too, so that the

instructions were followed up in an outpatient setting.

MEMBER KOTTKE: Well we, from our experience, I mean as trying to reduce readmissions at Regents Hospital, we're trying to figure everything out and talking to people in Boston and here and there, and this measure really would be quite superfluous and I think Mark's idea of just tossing it out and saying it was great in its day, rather historically. It's pass,.

MEMBER PHILIPPIDES: Perhaps another view on the 30-day admission rate and how it pertains to this measure, this is going to be on the other side. I actually hate that measure. I think -- no. I think there are certain things that nurses and physicians in hospitals and advocates can control. You can speak to your patients.

You can give them the right medicines. You can check an echo. You can check 20 echos. But I don't think -- I think

it's a degree of arrogance to think that we can control 30-day death rate or readmission rate to a real degree.

I think some of that stuff, a lot of it, more than we care to admit, is out of our control. Yes, we should strive to make those numbers zero. What we can control are more of these measures, right? You can control that you speak to a patient and give them the right medications.

It seems to me that we should be graded sometimes on the things that we have some control over, not on some pie in the sky, we will pay you or not pay you parameter. So if we're saying that in order to get to 30-day readmission this is being totally taken care of, it's 100 percent, then I would agree that there's no role for any kind of measure like this.

But if we're not at 100 percent on this, I actually don't think it's a bad thing to look at, because it's one of the few things

that we can control. Now this measure is imperfect, for all the reasons you stated. I don't like it for the same reason. I don't think it's effective.

But it doesn't mean that we shouldn't think about getting another reality-based parameter, things that we really can impact on, and look at that as a measure down the road. I'm just concerned that in going for 30-day mortality and 30-day admission rate, we're missing the boat a little bit, and I don't think that those are really feasible personally.

MEMBER AYALA: Can I talk about the health care administrators now being focused on the threat, that they will actually lose funding or reimbursement for the readmission. So I've already started seeing like a whole aggressive approach from the administrators' side, in terms of developing care coordination and investment in nurses to do exactly what you're talking about.

That goes along with something very much more intensive than just giving patients the discharge planning. they actually start with the education in the hospital, having classes, multiple classes with the patients while they're still in the hospital, and following up with them for, you know, a couple of weeks after they get discharged, and then handing them off to a disease management team that follows them in the outpatient setting.

This is being driven rapidly by the threat that if the health care systems can't control those readmissions, they're going to lose a lot of money down the road. So I see a lot of scrambling to take care of this issue in a much more thorough way than what's described in this indicator.

MEMBER MAGID: I wonder if we could vote on this.

VICE CHAIR GEORGE: Any last minute comments before we vote on the importance?

(No response.)

VICE CHAIR GEORGE: Okay.

DR. WINKLER: Dianne?

MEMBER JEWELL: No.

DR. WINKLER: Thank you.

VICE CHAIR GEORGE: 4 yes and 15 no.

CHAIR GIBBONS: You were flawless until that last vote.

VICE CHAIR GEORGE: 16 no.

CHAIR GIBBONS: All right. I am going to relieve Mary at this point, as we move forward to the other heart failure measures. So the next one is 0358, heart failure inpatient mortality. It was originally supposed to be Tom.

Then he was supposed to have a conference call, so it was going to be Suma. So now I don't know who it's going to be, and I'm waiting for a signal from the far side of the room.

MEMBER KOTTKE: This is heart failure 0358. It's AHRQ, heart failure

mortality in-hospital. Let me say that yes, Suma kindly agreed to do this for me, and then she started really looking at the documentation, and Ray wanted to learn a new word, and that's -- there's a new word in here, gastrointestinal congestive heart failure.

It's in the document, gastrointestinal congestive heart failure. A lot of the documentation here appears to be just stray ball insertion. Like they compare in patients with and without Alzheimer's disease and outcomes, and I don't know what happened.

But let me say that that being said, that the information provided by the measure is useful and meaningful. The measure uses the same specifications as the CMS measure, but CMS uses 30 day mortality rather than in hospital mortality. The data are routinely generated. Exclusions do not require additional data, and many states

report the measure and it's operational.

So I think it meets, despite all the random documentation. It meets the criteria of importance.

MEMBER THOMAS: I had one comment on this just, which I had mentioned to Reva, that under citations for evidence of high impact, the citations are 20 years old, and I think that as a maintenance measure, I would expect that there would be more recent citations. Twenty years old to me seems -- we would expect more than that.

CHAIR GIBBONS: Okay. Can I ask the developer, if you're still on the line, to respond to that concern?

MR. BOTT: This is John Bott with ARHQ. Yes, I definitely acknowledge the citations are pretty old. It wasn't brought up in the submission process. There's an opportunity for NQF to push back and say could you update this, and it wasn't brought to our attention. But we -- yes, we were negligent

in providing a more recent citation.

I don't know if any of the other folks are on the call, the IQI team that want to respond with any comment at this point.

DR. MASOUDI: Part of that reflects the history of the measure, since this was originally included in the IQI module that was released in 2001. So there's been sort of an accumulation of evidence over that time period. So part of that is sort of reflected in these submission document.

MEMBER THOMAS: But I guess to me, just this is me just not understanding the process exactly. When a measure is brought up -- a maintenance measure is brought up, so isn't there an expectation that there is some update to that information, throughout the document, which I have a problem with some other things in the document as well.

DR. WINKLER: I think that there's sort of an obligation and expectation on everybody's part that in order to maintain the

measure, you need the most current and up-to-date information to be able to make an assessment and an evaluation on that.

So I don't think that's unreasonable to expect more up-to-date measures than something 20, or information more than 20 years old.

CHAIR GIBBONS: Okay. I think we'll go ahead and vote on importance.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So we have 12 yeses and 7 nos.

DR. WINKLER: Just because there are a substantial number of nos, to be able to explain that in the document, could somebody just give me your reason for no? Oh, there are seven of you out there. Give me two, something.

MEMBER RICH: For me, it's the lack of keeping it current. So I don't even know

what's happened over the time.

MEMBER SNOW: The currency question is partly for me, although sometimes you can look at the literature and see that there's nothing new there. So I have decided in a venue or other not to put things in a literature list just to have a recent date.

But the more I thought about this, I just -- I started off saying yes and then decided no, because the mortality rate in the hospital from heart failure, it didn't seem to have a unique benefit to know about, to make a measure.

CHAIR GIBBONS: Scientific Acceptability.

MEMBER KOTTKE: Well, it's well-defined. It's valid, it's reliable. Risk adjustment algorithms are available in scoring and an analysis to allow for identification of disparities and outcome.

I can't really tell you whether the document gave us rates of disparities, but you

know, there's a certain sort of, to respond to Roger, I guess I'm relying on my sort of general knowledge of heart failure, that it's not a good thing to have, and it kills a lot of people.

There's disparities that certainly we see heart failure in young African-Americans, where we do not see heart failure in Caucasians in their 30's. There's very definite differences in disease. I would say that it's scientifically acceptable.

CHAIR GIBBONS: Other questions or comments about this criteria?

VICE CHAIR GEORGE: I just, I have a question, which I would say it's probably a stupid question, but we decided there weren't any. But in terms of in-hospital mortality measures, how do advanced care directives, how are they taken into account?

MEMBER KOTTKE: If I'm understanding, if they're at comfort care, they're out of the denominator.

CHAIR GIBBONS: The developer want to comment on that?

DR. MASOUDI: There was no specific exclusion for, you know, do not resuscitate or for care indications. The general consensus has been that that type of -- is too subjective and prone to gaming type behavior, not objective enough to include in the model.

CHAIR GIBBONS: So there is no exclusion for that?

DR. MASOUDI: Right, yes.

CHAIR GIBBONS: Thank you.

DR. MASOUDI: I would just add that if the patient is admitted specifically for palliative care, then they would be excluded, because they wouldn't be considered an acute care hospitalization.

But if at some point during the course of an acute stay the patient is converted to palliative care, that would not be excluded, because that decision can be made at any time during the hospitalization, even

after a month of unsuccessful care.

MEMBER RUSSO: I think you need to exclude, you know, if you intentionally aren't going to be treating, you need to have that as an exclusion if you -- how could you fault? You may have certain hospitals might be transplant centers or transferred there and they're very sick patients, and they won't -- you know, they're being resuscitated.

I think you need to have some exclusion in there, because there will be patients who'd get admitted and are DNRs. So I don't know why we wouldn't add that.

MEMBER KOTTKE: I guess if, you know, you actually are trying to save them, but they're DNR from the start, you know, they'd be in the numerator and denominator of this. But if they were just admitted for palliative care, they wouldn't be --

CHAIR GIBBONS: But the question is if somebody, you know, this is their 14th admission for heart failure in the last two

years, and somebody finally has the frank discussion that says maybe we should stop trying to do things, and just keep you comfortable, they're counted.

MEMBER KOTTKE: Right, right. If the patient changes, the patient is not allowed to change their own mind. You know, say that you're treating the patient and finally he says "Look doc, enough's enough. I mean stop," you know.

DR. MASOUDI: Right. Ideally, we would want to exclude patients who were DNR at admission to the hospital. But there's no data element currently available that would allow us, or CMS for that matter, to exclude such patients.

There is a lot of concern and there's empirical evidence of this, that if you include, if you exclude patients who are made DNR after a week or so in the hospital, then it leads to gaming, in that all you have to do before somebody looks like they're going

to die is to write a DNR order and they get excluded.

So it's undesirable, from a methodologic perspective, to exclude patients based on an aspect of treatment that occurs well into the hospitalization. But ideally, we would certainly want to exclude, based on DNR at admission or in the first 24 hours, if that were available.

MEMBER SANZ: Did I understand you to say that DNR is equivalent to palliative care?

DR. MASOUDI: I did not say that.

MEMBER SANZ: I thought you just said that if they're admitted with DNR, that they'll be excluded?

CHAIR GIBBONS: No.

MEMBER SANZ: No?

DR. MASOUDI: No. What I said is if they were admitted for palliative care, they would be excluded. If that was the reason why they were admitted to the hospital,

they would be excluded, because they would not be counted as an acute care hospitalization.

We might also want to exclude patients who were DNR at admission, but not on palliative care, but we don't have any mechanism for excluding such patients.

CHAIR GIBBONS: So you know, the dilemma is, as he pointed out, if somebody has received intensive treatment and then everybody gives up, they should be counted, because otherwise the system can be gamed.

But on the other hand, if it's clear within the first few hours of admission that this is all futile, and that's a joint decision or a patient decision or whoever, they have no means of excluding. That would not be gaming. That would just be reflecting the patient's situation and, in some cases, their decision.

VICE CHAIR GEORGE: And the mortality rate is risk-adjusted?

MEMBER KOTTKE: Yes. There's the

capability of risk adjustment.

CHAIR GIBBONS: So let's go ahead and vote on Scientific Acceptability.

DR. WINKLER: Dianne?

MEMBER JEWELL: Partially.

CHAIR GIBBONS: So 1 completely, 14 partially, 3 minimally and 1 not at all. Moving on to Usability, Tom?

MEMBER KOTTKE: The information provided by the measure is useful and meaningful. The measure uses the same specifications as the CMS measure, but the CMS measure uses 30-day mortality. So I would say that it's usable.

CHAIR GIBBONS: Other comments or questions?

(No response.)

CHAIR GIBBONS: If not, let's vote.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Okay.

CHAIR GIBBONS: Completely, 8;

partially, 7; minimally, 3; not at all, 1. Feasibility.

MEMBER KOTTKE: The data are routinely generated. Exclusions do not require additional data. Many states report the measure. It is operational already. So it is feasible.

CHAIR GIBBONS: Any other comments, questions?

(No response.)

CHAIR GIBBONS: All right. Let's vote.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

CHAIR GIBBONS: So 15 completely, 5 partially. And now the final vote, does it meet all the criteria for endorsement, yes or no.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

CHAIR GIBBONS: Yes, 13; no, 7. So

we'll move on to the next measure, 277, CHF admission. Mary.

VICE CHAIR GEORGE: So this is similar to one of the hypertension measures that we looked at earlier. 0277 is congestive heart failure admission rate, the percent of county population with admissions for congestive heart failure.

The measure addresses population health, timely and effective care, and it's been in use, I think, for the past decade. It's an outcome measure. It was actually an objective in Healthy People 2010. It's, as far as I know, it's not in Healthy People 2020.

The impact of the measure, according to the data presented, is that low income zip codes in New York City in 1995 were found to have 4.6 times more heart failure admissions than those from high income zip codes. It was noted that this original study was described as a surrogate for access to

care.

In terms of opportunities for improvement, the developer states that the indicator is measured with high precision, and most the variants reflects true differences across areas. It's risk adjusted for age and gender, and the developer states that this measure may reflect poor care, poor patient compliance or lack of access to care.

They showed demonstrated gaps by age, gender, income level and variations on metropolitan, micropolitan size. They say that the measure is not supported by a guideline, and according to the developer's website, the literature review found no benchmark for this measure.

They suggested some concern that the measure does not measure outcomes, but an aspect of care associated with an outcome, and that it is best used with indicators that measure similar aspects of care, and I'm not quite clear what they meant by that.

They also suggested concern that the use of the indicator may create perverse incentives to improve performance on the indicator without truly improving quality of care.

CHAIR GIBBONS: Other comments or questions about Importance?

VICE CHAIR GEORGE: I think from what, a very small literature review that I did on some of these ambulatory care sensitive conditions, I guess I was struggling with the fact that they're sometimes meant to imply accessibility issues or quality of care issues, or social determinants of health issues, or poverty.

There's, you know, there's just so much overlap in terms of what the measure is actually measuring.

MEMBER RUSSO: I'm having a hard time with this, and I guess just trying to figure out the importance. So not that it's not an important concept in general, but what

does this have to do -- doesn't it just have to do -- it's nothing that is intrinsically or necessarily, you know. It could be a first admission for heart failure, that hasn't seen a provider, right?

Is this what's measured? I don't know how this really measures quality in any way.

VICE CHAIR GEORGE: It's measuring heart failure admissions at the hospital, but it's not a hospital measure. It's a geographic area measure.

MEMBER MAGID: I think these ambulatory- sensitive conditions are, the thought is that there are a certain number of admissions for, like we talked earlier about the hypertension, you know. If hypertension is properly treated in the ambulatory setting, then patients presumably won't be coming to the hospital very often for malignant hypertension, you know, 240 over 130 or something like that.

You shouldn't see people very often having to come to the hospital without a control of hypertension and requiring admission. I think that's the idea behind these things, in that somehow it reflects the quality of ambulatory care in the community.

There might be issues around -- but I think what Mary's saying is that these things are multifactoral. It could be issues around access, it could be issues around quality of care, and maybe that's why we struggle with them, because we're not-- it doesn't clearly indicate what the solution to the problem should be. Is that what you were saying Mary?

VICE CHAIR GEORGE: Dana or Carol, sorry.

MEMBER ALLRED: Yes. I was going to ask, if this was part of the 2010 Healthy People, do they have some outcome data on that? I mean in other words, by concentrating on this as one of the issues, did they

decrease the poor outcomes or --

VICE CHAIR GEORGE: I'm not sure exactly how Healthy People was measuring this. There are a number of different states that post this information on their websites, on maps. You can go to the state of Hawaii and each island has their rate posted online, and a number of other states do as well.

MEMBER ALLRED: So I guess I'm trying to understand what's the benefit of the measure, and measuring it by county or by geographic area, if you're not going to do something with it to improve the plight of the people.

MEMBER KOTTKE: That's exactly the reason for publishing it. For example, the University of Wisconsin county health rankings have countyhealthrankings.org, publishes, and it kicks people in the butt.

I mean it creates a tremendous amount of interest, and while there's nobody to blame for, you know, you can't really nail

a single particular doctor or hospital or whatever, it is one of the ten ambulatory-sensitive --

I think there's ten: diabetes, preforative appendicitis, long-term complications diabetes, chronic lung disease, etcetera, that are consideration ambulatory care-sensitive conditions. So it's just sort of a public shaming kind of thing, I think.

MEMBER KING: Well, I don't think we're trying to just publicly shame when you say there wasn't any improvement in it. But like you say, it doesn't mean it's not a relevant measure. We didn't address the underlying problem. It's ambulatory-sensitive.

There's no greater ratio of primary care physicians to population now than it was ten years ago, and consequently in my mind, there have been no improvement in this condition, because there's no one out there to address the risk factors for congestive heart

failure that ends you up in the hospital, and so there's no improvement.

Maybe, I don't know why they didn't put it on the 2020, because they may actually be doing something about it. We're trying to increase the ratio. There's after a decade of having zero or one or two more medical schools, now there's eight more and we're going to have more doctors and hopefully more primary care doctors and more people in the community addressing the risk factors that lead to ambulatory-sensitive admissions.

So this is not the time to take the foot off the gas pedal, it would seem.

MEMBER RUSSO: I think it's interesting and would it be possible to even construct a measure to look at, to include a change over time? I guess you'll have that data, but what you really want to do is to say you're looking at it. You find the areas you need to improve and then improve in those areas, to show you've done better.

I guess you'll have that after you look at it over years.

CHAIR GIBBONS: Well so in light of this discussion, let me just sort of go to one section of the application, which is 1(c)(4), Summary of the Evidence, which says "As the causes for admission may include poor quality care, lack of patient compliance or problems accessing care, areas may wish to review CHF patient records to identify precipitating causes and potential targets for intervention."

So this measure has been in existence for a number of years. Do we have examples that the developer can cite where that's happened?

MR. BOTT: I can't personally cite an example. We don't really closely track the end results with the use of the measures, given software and the measures are freely available for people to download and use. We're focused on developing and maintaining

measures. But perhaps other members of the ARQI team have some examples. I'm not sure.

DR. ROMANO: We're certainly aware of county and state health departments that have implemented this and used this as a tool to allocate resources toward primary care workforce development in communities that are felt to have a disproportionate burden of -- avoidable hospitalizations.

But in terms of the success of those interventions, whether those efforts have actually reduced disparities, we're not sure. There is longitudinal research evidence showing that in general, when primary care physicians supply increases, that the rates of these indicators decrease, and of course, CHF is probably the highest prevalence of these indicators.

But typically, when people do this in a research context, they look at all the PQIs together, rather than looking at them individually.

VICE CHAIR GEORGE: I could imagine where this would be really useful if you were using it to look at where you need to put more federally qualified health centers, and if the Affordable Care Act sticks around, it would provide some measure of accessibility to care pre- and post.

MEMBER AYALA: I think if it's used correctly, that way you're actually looking at planning for the community, then that's appropriate.

But what I've started to see is non-clinical administrative people who are looking at these results and they hear the word "preventable," and what they start doing is they start seeing every single admission with this diagnosis as preventable.

They don't really understand that preventable is like a broad topic, meaning that some of these admissions are preventable, not every one is preventable, and that there are patients that have gotten great care and

still end up in the hospital, just because, you know, the prognosis of their condition or where they are in the course of their disease.

So I think there is a little bit of a danger there, that there's a lot of pressure on individual physicians, when they have patients admitted with these diagnoses, because there's this concept that every one of these admissions is preventable individually.

MEMBER SNOW: I keep coming back to the problem here, that the proxy is too far from what you're trying to do something about, and I understand that this got started when there was a concern, understandably, about ambulatory care quality and no real good way to get a handle on it. These were seen as a way to get at that issue, and I think it's a very clever idea, if you go back to 1993.

But we've seen some others where it was just clear that there were unanticipated reasons why it didn't work, and the -- if you think about this, there are circumstances in

which an admission to the hospital for congestive heart failure is in fact a proxy of care and the quality of care. That's not hard to imagine.

But what about someone who's had the fifth and sixth and seventh hospital? It doesn't matter what kind of care they're getting -- well, it matters. But the hospital admissions are not going to be a proxy for their care, because they're on the way out, and no matter what you do for them, they're going to be having hospital admissions for congestive heart failure, quite apart --

And then apart from that, of course they do mention in there other issues, such as patient compliance and, you know, how much salt he's got on the table and stuff like that, beyond the care purview for the most part. I just find it hard to see this measure as doing what it's trying to do.

CHAIR GIBBONS: Okay, Tom?

MEMBER KOTTKE: Yes. You know, we

talk a lot about disparities, and I think this is a measure that really gets us to the heart of disparities. If we take this off the table, you mentioned, Mary, for the federally qualified health centers, I mean that we point that even in Washington, D.C. here, going from Southeast to Northwest, that life difference and life expectancy is like 20 years.

I mean, you know, that we have phenomenal, we have more disparities in this country in life expectancy than we do between here and Bangladesh. I just, I hope we don't take this off the table.

MEMBER CHO: I have a question. So at the Cleveland Clinic we draw from, just like Mayo, from large proportion of patient populations. So I would say six county -- we're located in a very poor county. We draw from 14 counties, but 20 to 30 percent of our patients come from out of state.

So some of them come for heart failure. They get transferred. We have

ambulatory systems. So how is that counted? What is counted? Our rate of CHF admission, which does not adequately reflect Cuyahoga County, or does it count where the patients come from?

VICE CHAIR GEORGE: This measure specifically excludes transfers from other hospitals and health care facilities, SNFs, any intermediate care facilities, admissions with certain cardiac procedure codes and pregnancy.

DR. MASOUDI: And I might add also that the measure is based on a population. So it's based on where patients reside, not where they seek hospital care.

So it's intended as a measure of population health, and again it's allied with the concept that as we're trying to improve our health care system, the fundamental goal is to improve population health, recognizing, of course, that some of these individual hospitalizations are unavoidable.

But I think AHRQ is very clear in its guidance, that this is intended as a measure of potentially preventable or ambulatory care-sensitive hospitalizations. There's no implication intended that all of these hospitalizations are in fact preventable.

MEMBER AYALA: You know, I know this sounds kind of crazy, but if you just say that, if you make it instead of preventable, you know, instead of PQI, call it PPQI, a potentially preventable quality indicator, I'm telling you that really could shift the focus of people who are making decisions about how to respond to the results they're getting.

DR. ROMANO: Well, the term "prevention quality indicators" is only meant to apply, that they are sensitive to preventive efforts, however those preventive efforts may be organized and delivered within the community. But we appreciate your concern, that there might be an overt

implication from that term.

CHAIR GIBBONS: Okay. I think we need to go ahead and vote on the importance of this measure.

DR. WINKLER: Dianne?

MEMBER JEWELL: No.

CHAIR GIBBONS: 15 yeses and 5 no's. Moving on to Scientific Acceptability.

VICE CHAIR GEORGE: Okay. This measure is precisely defined. The numerator is all discharges 18 and older with an ICD-9 diagnosis of heart failure. It quantifies the number of admissions for 100,000 population, and the denominator is those in the area 18 and older.

I went through the exclusions just a few minutes ago. Risk adjustment is by age and gender only, and results show that areas with high rates of admission also have high rates of admissions for other ambulatory care-sensitive conditions.

The reliability testing used a

signal ratio which was 93 percent. Validity testing was done with expert panels and empirical analysis from HCUP data, and disparities, as I said, have been identified, certainly by age, gender and income level of zip codes.

CHAIR GIBBONS: Other comments or questions on Scientific Acceptability?

MEMBER SNOW: Well now I'm concerned about the, we're talking about disparities, and they're risk-adjusting for age and gender only. Yet a lot of our concern, and I share that concern, goes to race and ethnicity, and it isn't broken out.

Now I guess you're saying the area is a proxy for that, but that's also not a solid proxy. I think it's a concern.

DR. GEPPERT: Just to clarify that, sorry. This is Jeff Geppert.

CHAIR GIBBONS: Thank you.

DR. GEPPERT: Again, the software allows you to report by race and ethnicity,

and states vary in terms of the quality of that data and their ability to do so.

But AHRQ creates what are called state snapshots that include these measures, where they've gone through and sort of improved the quality of their race ethnicity data or use only data that have high quality race ethnicity data. That includes stratifications by race.

We've done some of that analyses ourselves, and we can provide that to the steering committee. There's definitely a racial disparity that's evident in the data.

MEMBER SNOW: Given the other discussion, it would be important to do that.

CHAIR GIBBONS: I think I hear a clear sense that we'd like to see that data subsequently. Are there other comments on scientific acceptability? We're hoping we get power back in time to vote.

(No response.)

CHAIR GIBBONS: Keep your fingers

crossed. Yes. Well, we might have to do that. We're just going to give it about a minute here to hope.

MEMBER JEWELL: Are you all sitting there in the dark?

CHAIR GIBBONS: Well, our projectors are dark. There are lights in the room, but our projectors are dark.

MEMBER JEWELL: It's quite an image to hear the conversation and not be able to see.

CHAIR GIBBONS: Okay. So I think we are going to have a hand vote on this. Completely?

(Show of hands.)

DR. WINKLER: Raise them and keep them raised.

CHAIR GIBBONS: Scientific Acceptability, Scientific Acceptability.

DR. WINKLER: One, two, three, completely. Completely.

CHAIR GIBBONS: I mean partially?

(Show of hands.)

Minimally? Not at all? People may vote twice. Can't trust them.

DR. WINKLER: Dianne?

CHAIR GIBBONS: Dianne.

MEMBER JEWELL: My hand is up for partially.

CHAIR GIBBONS: We couldn't see it. All right. So we're going to move on now to Usability.

VICE CHAIR GEORGE: This measure has been in use for about ten years. Certainly, the literature shows that it's a little bit difficult to understand, in that it could be measuring access to care, availability of care, quality of care, appropriateness of care, etcetera, etcetera.

Studies in countries with universal health care have found similar associations in relation to poverty for this particular measure. There's no competing measures.

CHAIR GIBBONS: Questions or

comments?

MEMBER AYALA: Yes. Can we ask for it to be require to be stratified by race, ethnicity, language, gender? Can we ask for that, to make it more usable?

CHAIR GIBBONS: I think we just heard from the measure developer that the data on that point is not always reliable, depending on the location.

MEMBER KOTTKE: But the data by zip code are -- the Ginnie index are quite reliable, and in fact if you adjust for poverty and race, you're going to erase exactly what you're looking for, is the differences because of those factors.

Those are causative factors and you don't want to adjust for them. You may want to identify for them, but certainly not statistically adjust for them.

CHAIR GIBBONS: Other comments?

MS. DAVIES: This is Sheryl Davies from the development team, and just to add to

that point, we did take these through a clinical panel process, where we were actually looking at different types of uses, so not the uses being considered today.

You know, just as a face validity, our clinical panel felt like SES, socioeconomic status-related risk adjustment was extremely important when you were using this, perhaps at a large provider group, but agreed that when looking at it as an area level, that it's important not to adjust away what you're, you know, hoping to measure. So that's why the stratification is optional in the software, so that folks look at it as they see fit.

CHAIR GIBBONS: Okay. So in other words, that users can do it if they want, if it's going to serve their purpose. Okay. Other questions? Thank you for that clarification. We're going to now vote on Usability, and we still don't have power, so we're going to do it -- you're going to have

to put your hands up another time.

So those who feel completely, please raise their hands?

(Show of hands.)

DR. WINKLER: One. Okay.

CHAIR GIBBONS: Partially?

(Show of hands.)

DR. WINKLER: I think everybody's voted.

CHAIR GIBBONS: Phone.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Okay.

CHAIR GIBBONS: Okay, and then finally Feasibility.

PARTICIPANT: What was the vote?

DR. WINKLER: I'm sorry. Completely was 2, partially was 18.

VICE CHAIR GEORGE: Okay. In terms of Feasibility, this relies on administrative data. Exclusions, there are none, so no required additional resources. In terms of

susceptibility to inaccuracy, errors or unintended consequences, the developers noted that providers may reduce admissions without improving quality of care. It does not include ED admission data; only hospital admission data.

CHAIR GIBBONS: Other comments or questions? Carol.

MEMBER ALLRED: I just have one comment I'd like to make, because I heard the term earlier in this, non-compliant patients, and I would hope if we're looking at stratifying by race and ethnicity and socioeconomic, that we would not use the term "non-compliant" but perhaps "uneducated."

VICE CHAIR GEORGE: I think that was in terms of some of the things that the measure might actually be measuring. That was straight from their documentation.

CHAIR GIBBONS: Sorry. Other comments, questions?

(No response.)

CHAIR GIBBONS: All right. We're going to go ahead and vote on Feasibility, again by hand. Completely?

(Show of hands.)

Partially?

DR. WINKLER: Dianne?

MEMBER JEWELL: Partially.

DR. WINKLER: Thank you. So it's 9 complete and 11 partial.

CHAIR GIBBONS: And then the final vote, does it meet criteria for endorsement by NQF. All who say yes, please raise their hand?

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Okay.

CHAIR GIBBONS: So that's a unanimous -- no, I'm sorry. One no vote. Okay, sorry.

DR. WINKLER: 19 yes, 1 no.

CHAIR GIBBONS: One no. We have lost the bulb, all right. Is there a former

chief resident in the room? I thought they were always supposed to carry bulbs.

All right. While we're doing that, we're going to start on the next measure while we're switching. The next measure is 0229, which is hospital, 30-day, all cause, risk standardized mortality rate, otherwise known as RSMR, for those who are into initials, which I wasn't familiar with, following heart failure hospitalization.

It is the CMS measure that's posted on Hospital Compare. Dr. Masoudi or CMS, representatives on the phone, do you wish to comment at all at this point, before we start?

DR. WINKLER: Is anybody on the phone?

MS. BERNHEIM: Hi. Susannah Bernheim is here from Yale CORE. I don't know if Dr. Masoudi was going to speak about the measure.

DR. WINKLER: Well, whoever.

CHAIR GIBBONS: All right. Well,

that's fine. I think you can just be available for questions. That would be great. So I think everybody is probably familiar with this measure. It's been publicly reported on the Hospital Compare website. It's obviously of major public health importance.

Heart failure is an enormous problem from a public health standpoint and from a care delivery standpoint, and we're managing to take care of people, so that they live long enough to develop heart failure, and seeing more and more. It's the most common, I think this is right, it's the most common admission under Medicare and CMS, and it's the second most costly total bill under CMS.

So I think it's pretty straightforward and it's important to measure, and there are clearly gaps and differences across the country. I welcome any other comments or issues.

MEMBER MAGID: I'll speak up in favor of this measure because it's an outcome,

right. Almost all the time we're talking about a process that we think might be related to mortality, and this is an outcome measure.

CHAIR GIBBONS: So I'll call 0229. This is the 30-day mortality after heart failure. Can we please vote on Importance. Oh, we're there. Look at that. We're ready to go. So we can once again use our gadgets.

Missing one.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So the vote is 19 to 0 unanimous for Importance. For Scientific Acceptability, this application is noteworthy for the detail and comprehensiveness of the way all the entries are completed. It includes, as an addendum an accompanying technical report.

Just from the standpoint of what you might say is the ultimate test of scientific acceptability, the data has

actually been published in a manuscript last year, looking at long term trends in cardiovascular quality and outcomes.

So that the measure specifications are very carefully delineated. The modeling is very carefully outlined and defended in the application, and I really didn't have any concerns. But I'm welcome to other comments from anybody.

MEMBER MAGID: Can you comment on the risk adjustment that's included --

CHAIR GIBBONS: So the risk adjustment used is administrative data, but it is previously validated against clinical data, and the overall C index for that comparison exceeded .7. So that they were able to demonstrate that the results they get using administrative data are highly comparable to clinical data, in terms of the risk adjustment.

It follows a similar pattern to what was done in the MI validation that we

went through at the last meeting.

MEMBER MAGID: Yes. It's a pretty sophisticated hierarchical modeling approach that what's her name, Normand's her last name, she's a statistician from Harvard, developed.

CHAIR GIBBONS: Sharon-Lise Normand. Other questions or comments?

(No response.)

CHAIR GIBBONS: Okay. If not, let's vote on Scientific Acceptability.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: The vote is 19 completely and 1 partially. Now moving on to Usability, it's obviously in use and I think most hospital administrators and cardiology chiefs in the country are certainly aware of their own numbers and paying attention to them, which is the ultimate test of usability.

I think my only sense is that the public probably doesn't go to this website as

often as was hoped originally, but certainly the doctors and the administrators and other health care providers are certainly aware of the data and using the data. So I think it passes the test for usability.

DR. WINKLER: One comment is this measure is written and submitted and currently in use for the Medicare population age 65. Just we've been in conversations with the developers. There is a very strong interest on their part, and they're working diligently towards being able to expand it to all ages ultimately, with the AMI measure and the heart failure.

But there are methodologic issues around combining data sets. But they are actively working on it, and we can expect to see that going forward.

MEMBER SNOW: I'll agree that the general public probably don't go looking for this, but they sure do notice it when it pops up in the newspaper.

CHAIR GIBBONS: Yes, which it has in a variety of cities in a variety of stories around the country. I actually personally thought there would be more of those within the very first week, and was surprised at how limited they were. But all right. So we'll vote on Usability.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

MEMBER JEWELL: Yes.

CHAIR GIBBONS: Responses are 17 completely and 2 partially. And now moving on to Feasibility, it's clearly feasible. It's being done. There really, I think, were minimal problems from the start.

There was this one year sort of trial period roll-in before the actual numbers were released, when hospital administrators only saw the numbers before the public saw the numbers.

But it's certainly feasible, and I

didn't see any concerns with respect to that. And again, the application is very complete with respect to all of those issues. Any other comments or questions? If not, I suggest we vote on this, Feasibility.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So 19 completely, 1 partially and now we'll move on to the final vote, does the measure meet all the criteria for endorsement. Sorry.

MEMBER PHILIPPIDES: I'm sorry. I should have brought this up before. Can I ask something about the disparities issue?

CHAIR GIBBONS: Sure, sure.

MEMBER PHILIPPIDES: I apologize for not getting it in the right order. Here, it states that disparities in race and socioeconomic status have been reported at the patient level, but not at the hospital level. They say that "Hospitals with many lower

socioeconomic patient populations are able to do well on this, and therefore CMS does not plan to stratify the measure."

Is there -- it sounds like sure, those hospitals can do better, but if they have more of those patients and they tend to do poorly, are they at a disadvantage? Are hospitals that have these patients at a disadvantage? And why not include race and socioeconomic status, I guess, is my final question?

CHAIR GIBBONS: Can the developer answer that question?

DR. BERNHEIM: Sure, I'm happy to. Hi, this is Susannah Bernheim from the Yale CORE team. It was sort of a two-part question, and I think the first one, let me just explain the analysis we did a little bit more clearly.

For both the proportion of patients at a hospital that were African-American, and then in a subsequent analysis in a similar

fashion, looking at the proportion of patients who come from a low income areas, we looked at hospitals by deciles of that measurement, to see whether or not those hospitals that had higher proportions of patients that were African-American, consistently performed worse on the measure.

If you look at the median, there are slight differences from the lowest decile to the highest decile. But the important piece of information is that the ranges and the inner quartile ranges of the hospitals on the lowest decile, on the highest decile, again divided into deciles by the percentage of their patients that are African-American, are entirely overlapping. There's very little different in the ranges.

So our take on that is that the proportion of patients in your hospital who are African-American is in no way determinative of performance. So there are high performers with high percentages of

African-American patients, and low performers with high percentages of African-American patients, and similarly, for the socioeconomic status.

So there's really not an indication that those hospitals are consistently doing worse on this measure. So that's the rationale. I think the phrase that you used was that "can perform well."

What we mean by that is frequently do perform well in a similar range performance as the hospitals with much lower percentages of those patients. So we really don't see significant evidence of disparities at the hospital level.

MEMBER PHILIPPIDES: Could a different take on that be that those hospitals are actually performing better? They're doing the same with a more difficult patient population? Wouldn't that be an equally reasonable way of looking at that data?

DR. BERNHEIM: Right. I mean we,

we can't answer that question absolutely. But I think that you can similarly argue that there is in this a measure of a quality of care. If those hospitals can perform well, then the benchmark should be the same for them.

We don't think that it makes sense to stratify, which essentially condones saying we expect hospitals with higher proportions of minority patients to do worse on this measure, when we know that they can do equally well.

MEMBER PHILIPPIDES: If I bat .300 against Sandy Koufax and .300 against a minor league pitcher, it's certainly reasonable to say that when I bat against Sandy Koufax I could be a .300 hitter, but I'm doing a better job of it. If there were no disparities at the individual level, I think you'd have a case. But there are.

DR. BERNHEIM: Right, and I think again the question is what the alternative is, and I think that we think that -- you're

absolutely right. I think what you're trying to say is that we may actually be hiding even better performance, right.

For those hospitals that have higher percentages of African-American patients who do well are probably -- are not probably, potentially we can't know, even better performers than they appear to be, because they're doing this in a population that at a patient may have worse outcomes. But we don't know that. But again --

MEMBER PHILIPPIDES: And that's the argument in favor of including socioeconomic status and race in stratification.

CHAIR GIBBONS: Ahh, but see I'll do the counter, which is you would then conceivably justify poorer performance at the other end of the spectrum, when the data would suggest that it's not actually justifiable.

MEMBER PHILIPPIDES: That's correct, or you would discern better performance.

CHAIR GIBBONS: So I think it's a mixed, would not necessarily be a good thing overall.

DR. BERNHEIM: Right. It would certainly look as if CMS was condoning that if you have a poorer population, we expect you to do worse in the outcomes of those patients, and I think that's not where CMS wants to fall on this measure, and that the evidence doesn't, really doesn't support that that's consistently true at all.

I mean these distributions are strongly overlapping. Hospitals are really doing similarly across the deciles.

CHAIR GIBBONS: David.

MEMBER MAGID: This is really a comment that applies both to this measure and the next measure, which we might be able to get through.

But your answer to this question has to do with how hospitals perform, and we do know that in certain cases, hospitals

sometimes the association between poor outcomes for say African-Americans compared to non-African Americans has been explained by the fact that sometimes hospitals that have a high proportion of minority patients often provide poorer quality care.

That was a paper from your institution by Betsy Bradley. My question is really not focused on the hospital but in your risk model, you do not include any socioeconomic factors.

It may be that the reason why you don't have that is you don't have access to that data. That would be one thing, versus saying that socioeconomic factors do not, are not related to these potential outcomes of readmission or mortality.

If you don't have socioeconomic data, then just tell us you don't have it, and I'll be fine with it. If you do have it, I'd really like to know at the individual level whether it's associated with the outcomes, and

if so, why it's not in the models.

DR. BERNHEIM: So there are ways to look at socioeconomic status with Medicare claims data. They're not perfect, but there are certainly ways that we can do that and that we did for these analyses. You know, I probably should have said this first, but you know, the NQF guidance is, you know, to not risk-adjust.

MEMBER MAGID: Okay, that's fine. You don't need to say anymore.

CHAIR GIBBONS: Are there other comments, noteworthy for the intensity and quality of the discussion?

(No response.)

CHAIR GIBBONS: All right. So we're going to go ahead and vote on does the measure meet the criteria for endorsement.

DR. WINKLER: To the folks on the phone, we're hearing you. Dianne?

MEMBER JEWELL: I'm sorry. All I could hear was whoever's cell phone that was.

What are we doing?

DR. WINKLER: We're voting whether the measure meets criteria, yes or no.

MEMBER JEWELL: Okay, thank you. Yes.

CHAIR GIBBONS: Okay. So the vote is 17 yes and 1 no. So I think at this point, we're going to conclude our work for the day, but first ask for any public comment from anyone on the line, or there's no public left in the room.

So I guess Casper can't comment in the room. So anybody from the public on the line? Do we need to check with the operator?

DR. WINKLER: Operator, is there anybody --

MEMBER MAGID: Ray, if there's no public comment, since this next measure is so closely related -- no.

CHAIR GIBBONS: No. I don't think we want to rush.

MEMBER MAGID: Okay.

DR. WINKLER: Operator.

OPERATOR: This is the conference operator.

DR. WINKLER: Yes. Is there anybody on the line who wants to ask a question or make a comment?

OPERATOR: We currently have no one. Just another reminder folks, touch *1 to ask a question.

DR. WINKLER: Okay. And if, while we're waiting, just for the folks at CMS and Yale, you had said that you would be available to be with us tomorrow morning to start this conversation, and we really thank you for bearing with us, for not getting through them today.

So we will be starting at eight o'clock in the morning. Operator, is there anybody who wanted to say anything?

OPERATOR: Still no one has queued up.

DR. WINKLER: Great. Then we'll

assume there's no one out there. To everybody in the room, we will be meeting in the same room. We'll be starting at eight o'clock. Access to the building is about no earlier than 7:30, I believe. So yes. I believe so, yes.

CHAIR GIBBONS: Continental breakfast at approximately 7:30.

DR. WINKLER: 7:40.

CHAIR GIBBONS: 7:40, 7:35, whatever. Don't break down the door. Just wait for the doors to open.

MEMBER RASMUSSEN: Just a question. We were going to discuss competing and related measures tomorrow. I haven't seen the Phase 2 comparisons.

DR. WINKLER: Actually, a couple of things. We're probably only going to be able to look at the Phase 1, although on your jump drive is the Phase 2 side-by-sides. We put them on there. But frankly, we were throwing so much stuff at you that, you know, it

starting we were getting embarrassed.

So you know, I think that in terms of follow-up, we can do the Phase 1. We can talk about the implications for Phase 2. But just as we've had to do it on a two-step version, I think we'll probably have to do something similar on the Phase 2 measures too. But you do have the side-by-sides in there.

MEMBER RASMUSSEN: Okay. No arguments here.

DR. WINKLER: Yes. You can keep the jump drives for tomorrow, load them onto your laptop, whatever. Ultimately tomorrow before you leave, we'll ask for them back. Thank you all very much, and have a good evening.

CHAIR GIBBONS: Yes. Thank you all for all the extended effort and discussion today.

MEMBER JEWELL: Talk to you tomorrow.

(Whereupon, the above-entitled matter went off the record at 5:36 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Cardiovascular Steering Committee

Before: NQF

Date: 04-07-11

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter