NATIONAL QUALITY FORUM

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CARDIOVASCULAR ENDORSEMENT
MAINTENANCE STEERING COMMITTEE

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TUESDAY,
FEBRUARY 15, 2011

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

PRESENT:

MARY GEORGE, Co-Chair, MD, MSPH Centers for Disease Control and Prevention
RAYMOND GIBBONS, Co-Chair, MD Mayo Clinic
CAROL ALLRED, RN, National Coalition for Women of Heart Disease
ROCHELLE AYALA, MD, FACP, Memorial Healthcare System
SUNG HEE LESLIE CHO, MD, Cleveland Clinic
ANN DE VELASCO, RN, National Coalition for Women of Heart Disease
DIANNE JEWELL, PT, DPT, PhD, CCS, American Physical Therapy Association
DANA KING, MD, MPH, Medical University of South Carolina
BRUCE KOPLAN, MD, MPH, Brigham and Woman's Hospital
THOMAS KOTTKE, MD, MSPH, Health Partners
DAVID MAGID, MD, MPH, Colorado Permanente Medical Group

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

NQF STAFF:

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

KATHRYN STREETER
REVA WINKLER, MD, MPH

ALSO PRESENT:

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

ANNE SNOWDEN, MPH, CPHQ, Minnesota Community Measurement*

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

SAMANTHA TIERNEY, MPH, American Medical Association

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

*Present via telephone

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

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

9:02 a.m.

Welcome and Introductions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. HAMMERSMITH: Thank you.

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

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

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

Minnesota. No disclosures.

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

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

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

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

MR. SANZ: Mark Sanz. I'm an

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

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

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

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

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

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

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

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

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

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

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

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

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

disclosures.

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

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

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

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

(No response.)

MS. HAMMERSMITH: Do you have any

questions of each other regarding the disclosures?

(No response.)

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

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

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

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

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

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

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

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

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

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

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

than introducing everybody at this time.

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

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

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

on all of the fine points here.

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

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

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

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

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

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

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

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

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

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

(No response.)

DR. WINKLER: My turn?

CO-CHAIR GIBBONS: Yes, your turn.

Project Introduction/Overview

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

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

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

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

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

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

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

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

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

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

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

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

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

They don't see their experience in

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

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

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

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

care for this particular condition.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

in NQF's measure evaluation criteria?

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

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

Next. Scientific acceptability of the measure properties looks at the specificity and the precision of specifications.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

prevention for coronary artery disease or ischemic vascular disease.

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

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

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

DR. SNOW: Point of clarification

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

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

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

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

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

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

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

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

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

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

(No response.)

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

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

CAD - Secondary Prevention

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

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

Just to explain a little bit about

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

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

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

even when we reevaluate measures.

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

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

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

measure maintenance that we provide throughout the year.

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

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

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

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

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

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

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

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

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

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

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

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

management measure, which is new; anti-platelet therapy, a maintenance measure; beta blockers for patients with myocardial infarction or systolic dysfunction, also a maintenance measure; and ACE inhibitors for diabetes for a left ventricular systolic dysfunction, which is also a maintenance measure.

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

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

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

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

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

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

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

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

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

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

chairs of the Writing Committee.

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

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

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

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

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

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

CO-CHAIR GIBBONS: Thank you.

DR. WINKLER: Is someone on the

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

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

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

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

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

Health Partners -- we have moved

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

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

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

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

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

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

So in 2010, we analyzed the rates

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

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

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

Our Measurement Reporting

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

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

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

So we recognize this limitation

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

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

MS. SNOWDEN: Yes.

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

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

Measure 0073

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

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

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

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

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

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

(No response.)

CO-CHAIR GIBBONS: Anybody want to add anything?

(No response.)

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

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

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

CO-CHAIR GIBBONS: Yes.

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

CO-CHAIR GIBBONS: Correct.

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

CO-CHAIR GIBBONS: Correct.

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

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

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

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

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

DR. SANZ: Ray?

CO-CHAIR GIBBONS: Mark.

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

CO-CHAIR GIBBONS: I agree. That's a challenge. Ashley, can you assist us with that? Looks like we've completed the vote. I don't think we took a minute. This is good.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR GIBBONS: Are there other

comments or concerns? Mark.

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

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

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

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

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

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

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

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

And until we could test the

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

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

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

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

MS. TIRODKAR: Yes, absolutely.

CO-CHAIR GIBBONS: Next question.

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

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR GIBBONS: Sid.

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

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

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

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

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

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

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

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

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

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

MS. PACE: Right. But I'm just

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

CO-CHAIR GIBBONS: Mary?

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

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

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

CO-CHAIR GIBBONS: Well, they have

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

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

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

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

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

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

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

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

DR. RASMUSSEN: If I could make a comment.

CO-CHAIR GIBBONS: Certainly.

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

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

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

MS. TIRODKAR: This is a hybrid specification actually.

DR. RASMUSSEN: This is hybrid?

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

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

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

MS. TIRODKAR: Yes, I do. Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR GIBBONS: Mark.

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

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

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

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

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

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

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

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

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

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

MS. PACE: Don't blame Florida.

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

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

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

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

incorporate that?

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

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

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

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

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

later on.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR GIBBONS: Okay, yes, Helen.

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

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

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

DR. BURSTIN: Yes, right, and I

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

CO-CHAIR GIBBONS: Sid.

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

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

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

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

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

DR. MASOUDI: Just very briefly.

MS. PACE: Microphone.

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

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

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

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

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

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

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

Measure 1486

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

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

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

listen to the primary reviewer.

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

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

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

CO-CHAIR GIBBONS: People are up now.

MS. PACE: Okay.

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

clearly defined.

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

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

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

DR. RASMUSSEN: Could you comment

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR GIBBONS: David?

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

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

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

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

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

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

CO-CHAIR GIBBONS: Yes Joe, we can.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

and four medications, putting the patient at some jeopardy.

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

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

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

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

Well, the Chair is happy to report

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

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

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

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

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

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

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

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

DR. MASOUDI: It is.

CO-CHAIR GIBBONS: Okay.

DR. DROZDA: This is Joe Drozda. Can I make a comment about harmonization?

CO-CHAIR GIBBONS: Yes.

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

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

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

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

CO-CHAIR GIBBONS: Okay, and but

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

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

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

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

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

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

DR. DROZDA: I understand.

CO-CHAIR GIBBONS: All right. It's perhaps a technical nuance but an important one for this committee. The Minnesota Community Measurement Project submission has a different number.

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

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

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

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

(No response.)

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

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

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

that standpoint. Other comments? Yes.

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

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

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

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

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

CO-CHAIR GIBBONS: Sure, Joe.

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

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

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

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

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

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

DR. DROZDA: They would?

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

(No response.)

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

Feasibility. I seem to have a mental block.

MS. PACE: Did everybody vote? Everybody vote?

(Off record comments.)

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

(Off record comments.)

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

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

(No response.)

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

(Off record comments.)

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

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

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

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

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

Measure 0068

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

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

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

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

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

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

(No response.)

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

early; you'll be missed.

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

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

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

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

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

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

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

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

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

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

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

All right, that's pretty clear. Bruce, number two, Scientific Acceptability.

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

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

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

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

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

(No response.)

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

MS. PACE: Does everybody think they voted?

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

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

deferred.

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

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

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

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

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

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

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

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

there's documentation of counseling.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. KOPLAN: Yes.

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

(No response.)

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

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

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

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

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

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

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

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

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

already been retooled for EHRS as well.

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

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

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

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

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

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

CO-CHAIR GIBBONS: Sure, Tom.

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

(Laughter.)

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

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

(Laughter.)

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

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

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

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

CO-CHAIR GIBBONS: David.

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

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

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

cessation counseling.

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

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

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

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

CO-CHAIR GIBBONS: Helen.

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

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

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

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

CO-CHAIR GIBBONS: That's

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

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

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

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

Measure 0067

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

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

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

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

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

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

(No response.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(No response.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR GIBBONS: Yes. Sure, Joe.

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

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

So in that context, you know, as

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

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

(No response.)

CO-CHAIR GIBBONS: Helen.

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

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

against each other, and pick best in class.

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

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

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

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

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

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

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

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

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

CO-CHAIR GIBBONS: Other comments before --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR GIBBONS: All right. Other comments on Feasibility?

(No response.)

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

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

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

me feel just wonderful. Learning guinea pigs. I feel better already. Comments or --

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

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

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

Our agenda's ambitious enough on

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

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

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

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

Measure 0075

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

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

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

CO-CHAIR GEORGE: So any questions on this?

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

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

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

CO-CHAIR GEORGE: Right.

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

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

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

DR. KING: True, but not everybody

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

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

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

a challenge.

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

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

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

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

(Off record comments.)

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

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

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

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

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

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

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

CO-CHAIR GIBBONS: Comments.

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

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

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

CO-CHAIR GEORGE: Right.

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

CO-CHAIR GEORGE: That is correct.

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

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

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

(Off record comments.)

CO-CHAIR GIBBONS: Other

questions?

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

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

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

statin. That was just my thought.

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

DR. THOMAS: Okay.

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

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

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

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

DR. SANZ: With a diabetes group?

DR. WINKLER: For diabetes.

CO-CHAIR GIBBONS: Other questions about Scientific Acceptability?

(No response.)

CO-CHAIR GIBBONS: If not, I

suggest we vote on this.

(Pause.)

CO-CHAIR GIBBONS: Moving on to usability.

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

CO-CHAIR GIBBONS: Comments or questions?

(No response.)

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

(Pause.)

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

CO-CHAIR GEORGE: So they've

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

(No response.)

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

(Pause.)

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

(No response.)

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

(Pause.)

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

minutes and 45 seconds.

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

Measure 0074

CO-CHAIR GEORGE: All right. Well, we'll give it a try. 0074, again, was in Group 4. A brief description. This is the percentage of patients aged 18 and older with a diagnosis of coronary artery disease seen within a 12 month period, who have an LDL less than 100, or who have an LDL greater than or equal to 100, and a documented care plan to achieve an LDL less than 100, including at a minimum the prescription of a statin.

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

CO-CHAIR GIBBONS: Yes.

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

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

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

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

(Pause.)

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

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

DR. DROZDA: This is Joe Drozda. I would confirm that as a typo.

CO-CHAIR GEORGE: Okay, thank you. Target population age 18 and older. In terms of denominator exclusions, there are exclusions in this measure for documentation of patient reasons for not prescribing a statin, such as patient declined or other patient reasons, and also documentation of reasons for not prescribing due to financial reasons, other system reasons.

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

I think in terms of the group that

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

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

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

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

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

DR. DROZDA: This is Joe Drozda.

CO-CHAIR GIBBONS: Joe, go ahead.

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

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

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

DR. JEWELL: Okay. So that makes

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

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

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

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

DR. JEWELL: Okay.

CO-CHAIR GIBBONS: Sure, George?

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

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

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

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

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

CO-CHAIR GIBBONS: Comment from the developer?

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

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

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

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

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

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

go ahead and vote.

DR. KING: Yes, I have a comment.

CO-CHAIR GIBBONS: Sorry, Dave.

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

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

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

DR. DROZDA: One of the, and I

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Pause.)

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

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

CO-CHAIR GIBBONS: Comments or questions?

(No response.)

CO-CHAIR GIBBONS: All right. Let's go ahead and vote on usability.

(Pause.)

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

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

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

(No response.)

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

(Pause.)

CO-CHAIR GIBBONS: 8 completely,

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

(Pause.)

CO-CHAIR GIBBONS: 17 yes, 4 no. So at this point, we're going to be -- we'll pause for a moment to allow for comments from other NQF or from NQF members and the public, either people who are in the room or on the phone. Are there comments? Dr. Masoudi.

Public Comment

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

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

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

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

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

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

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

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

which way to lean and how mushy we should be?

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

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

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

That's what we're really at. That's what the criteria are aiming, to help

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

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

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

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

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

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

We're in a little bit different situation for some of the new measures, that they really don't have much of a track record. They may have been tested in a limited way, but not perhaps widely used that we can answer those questions as thoroughly as you would like.

But nonetheless, I think they are valid questions to consider and ask the developers how they plan on addressing potential issues. But for the maintenance measures, I think we really want to look at our experience and our track record for the use of the measures.

CO-CHAIR GIBBONS: Karen?

MS. PACE: Just to go back to Dana's question, I think this gets at, you know, as Reva was saying, we want measures, we're endorsing measures that are useful for both public reporting and quality improvement.

So the question that you're posing that has arisen before, when you have a measure that kind of mixes the target with the plan, is if you have two providers with the exact same score, but one is actually achieving those target levels more, it's invisible.

So you don't really have that information to look at comparisons. So that has been a question that's been raised about those types of measures.

The other thing about intermediate clinical outcome measures such as the target level is that you don't really expect 100 percent, because of some of these issues that we've talked about. The question is whether

you do need risk adjustment for -- certainly for health outcome measures we do.

Perhaps at some, for some of these intermediate clinical outcome measures, there should be some discussion of that or at least thought about that, whether that's relevant or not.

Typically, we have a lot of intermediate clinical outcome measures without risk adjustment. But then the question is, you know, is there really a variation across practices of these people that should not get, reach that level.

Because if it's fairly consistent or random across practices, then it's not really disadvantaging any one practice for performance measurement. So it's a lot of intricate things to consider and, you know, we don't have one right way. You know, we appreciate you grappling with these kinds of questions and issues.

CO-CHAIR GIBBONS: Are there

people on the phone who want to comment from the public? The phone line's open, I believe. Is there anyone else at the back of the room, other than Committee members, who want to comment further?

DR. JEWELL: So the issue of adherence has permeated every conversation I've been involved with in NQF, having now served on a number of panels, and I vacillate between having a blanket statement in the exclusion criteria of every single measure that comes along, that says those patients who don't cooperate aren't counted.

The point that you made, which is that it's potentially an easy out. I can't remember either, Helen. Has the CSAC given any guidance on this? I can't remember, and I just -- because it is something we wrestle with relative to attribution, and I know it's not a solvable problem completely.

But I just, I want to acknowledge that it pretty much hits us everywhere we go

with this, with measure development and application.

MS. PACE: I think it's something that they do question, and as I said, the most guidance we have is the footnotes in the evaluation criteria about patient preference really should be included in measures judiciously, and hopefully in a way that their impact is transparent.

The other side of adherence is that adherence is influenced by the health care provider. So, you know, where do you draw the line, you know? If some providers are more effective in communicating; I don't know. But that's hard to, you know.

So to say that they should definitely be excluded, I mean those are the trade-offs and the balances that have been discussed. But I can't say that there's been one directive up to this point. We may see that in the future, but --

DR. AYALA: I have a question

about that. Is this something that NQF could maybe take up, and that is to get a better definition of non-compliance on the part of the patient?

Because it's almost like risk adjustment in the hospital setting is very well-defined, but in the outpatient setting, where a lot of these measures are going to be used, there is that risk to the physician being graded on their performance if they have a significant part of their population that are either transient or have other socioeconomic situations that interfere with their adherence.

So if there could be some specific definition of non-compliance or non-adherence, where the provider shows that they have done X, Y and Z, and the patient still is not complying, that that might help to balance out that concern that, you know, if you just say the patient didn't take it the first time and that's it; the patient just said they didn't

want it, that you're being too easy on the provider.

DR. BURSTIN: One thing I'll mention is that's part of our medication management project. A couple of years ago, our committee spent a lot of time looking at pharmacy data, relevant measures of adherence, and actually did come up with what I thought were some pretty good ways of describing it.

It's more from the pharmacy data perspective, but this issue of, you know, patients' ability to get their medicines always comes up.

If somebody's always practiced in the safety net, it's always one of those ones that makes me very uncomfortable, because I feel like I can try and do my best, and I feel badly when I feel like we're held to a different standard. But obviously that's something to keep that in mind.

CO-CHAIR GIBBONS: I would just point out that the science in this area is

certainly in evolution, because there's now a variety of efforts at patient education tools, which on the surface to most physicians look sort of like Mickey Mouse revisited. They're trying to remember when they've seen anything so primitive, but now actually have been demonstrated to work in improving compliance.

There's an enormous track record of fairly simple things. So and boy, it's moving before us forward right now at warp speed in a variety of ways, the sort of shared decision-making concept among others. But in pure medicine compliance, there are a bunch of things that have now been shown to clearly work.

DR. KING: Not just educational interventions, but ones that reduce the barriers to refills. So simple reminders or, you know, letting patients have their medications mailed to them as opposed to coming to the pharmacy. These are actually very effective, make sense.

CO-CHAIR GIBBONS: Okay. So I think we'd better break for lunch. We are a little bit behind, so I'd ask everybody if they could to try to shorten lunch to 20 minutes, so we start at five after one please.

(Whereupon, at 12:45 p.m., a lunch recess was taken.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:06 p.m.

CO-CHAIR GIBBONS: So our next measure is 0066, ACE and ARB therapy, and Jon Rasmussen will be the primary reviewer. Jon? Measure 0066

DR. RASMUSSEN: The brief description of this measure is the percentage of patients, aged 18 and older, with a diagnosis of CAD, that are seen by a provider in the last 12 months, who also have either diabetes or an ejection fraction of less than 40 percent.

Impact is very high. We've talked a lot about the impact of coronary artery disease, and the evidence is quite strong on this measure. Any comments?

CO-CHAIR GIBBONS: So comments or questions about importance?

(No response.)

CO-CHAIR GIBBONS: If not, let's go ahead and vote on importance in between

mouthfuls of food.

(Pause.)

CO-CHAIR GIBBONS: Okay. So we have 18 yeses and no no votes. We have a few people who aren't yet back. So we'll move on to scientific acceptability. Jon?

DR. RASMUSSEN: In terms of scientific acceptability, the data is quite strong for using an ACE as a first-line agent or an ARB as a second-line agent, in those patients who have CAD and CAD with diabetes or CAD with ejection fraction less than 40 percent.

The recommendation is that they should be started and continued indefinitely in all of these patients. One point of consideration for the group may be that there are two other cohorts that could potentially be included in this group, and those are patients with CAD and hypertension, and patients with CAD and chronic kidney disease.

The group that submitted this

measure did some work through the PCPI, and they talk about reliability and validity, and they've looked at different medical groups to assess some of those, with no outstanding issues.

With respect to exclusions in this population, they have very similar exclusion criteria that they've described in the past, and actually why don't we get -- I'll get into that a little bit more in the second categorization.

As far as meaningful differences, also in the addendum that they presented with the PCPI data, they show that there are some differences between groups. Not hugely significant; however, enough that focusing on this measure could show some improvement.

Disparities, they did not note any. This is a measure that is not currently used widely, so they had limited data on that.

CO-CHAIR GIBBONS: Questions or issues with scientific acceptability?

DR. JEWELL: I just have a question.

CO-CHAIR GIBBONS: Yes.

DR. JEWELL: And I'm realizing this was similar on the measure before lunch. For the patients who were counted as coming in already on the medication, if the physician makes a decision to discontinue the use of that medication for whatever reason, is that patient counted as positive in the numerator because they showed up on the statin at the beginning of the visit, or are they put into an exclusion category because they were pulled off the statin at the end of the visit?

DR. RASMUSSEN: So the way that the measure is written, a single fill of an ACE or ARB would count them in the numerator.

DR. JEWELL: Okay.

DR. RASMUSSEN: That said, if there's an identifiable reason that the patient should not be taking the medication, this measure, as written, would catch them in

the exclusion criteria. So it could go -- frankly, it could go either way.

CO-CHAIR GIBBONS: Bruce.

DR. KOPLAN: Just one -- I should have asked this question when you were discussing number one. But so if I understand this correctly, this measure is for ACE inhibitors or ARBs in people with coronary disease, and either diabetes or left ventricular dysfunction, is that correct?

DR. RASMUSSEN: Correct. They must have CAD and then one or the other.

DR. KOPLAN: So I know we talked about harmonizing, not splitting. But sometimes the implications of ACE inhibitors or the settings of ACE inhibitors or how you measure who's on, or how you think about putting people on these things is for me a little different.

It's like sometimes a different situation if somebody's diabetic, versus doing it for left ventricular dysfunction. Is this

something -- you hate to divide a measure into two or something. But it just seems like there's a little bit of lumping going on here that might create some, putting some people together that are little different.

DR. RASMUSSEN: The way the recommendations are written, there are four potential disease states in those who have CAD, that could benefit from ACE and ARB therapy.

Now we'll talk about another measure later that they actually specified the exact type of beta blocker that someone with a certain disease may have. So it's not the whole, every beta blocker under the sun. It's a specific amount.

As written, it seems that if there's a patient, a patient with diabetes, for example, that clinically shouldn't be taking it or may have a different threshold, they could be excluded in the exclusion criteria. I'm not, I don't have a good sense

of how we could exclude them immediately in the denominator.

CO-CHAIR GIBBONS: Sid?

DR. SMITH: This may be a little bit of wordsmithing, but I'm wondering if it would be more accurate to say "most recent left ventricular ejection fraction, rather than prior. You've got a patient that comes in, they may have had an injection fraction. Someone's looking at the records if they grab from 18 months ago, that was low.

But after whatever it was, infarct, whatever treatment, they now have an ejection fraction of 48 percent that was done three months before their current visit, are we saying that it's not the same patient as -- I'm just wondering if most recent ejection fraction is more accurate than prior.

Prior could be any one of a number of ejection fractions along the way, and might not reflect the true state of left ventricular function, particularly in recovery from a

STEMI, although we do say with a STEMI they should all be on ACE inhibitors if they have--

CO-CHAIR GIBBONS: Did the measure developers want to comment on that issue?

DR. DROZDA: Joe Drozda. Can you hear me?

CO-CHAIR GIBBONS: Yes, Joe. We're having difficulties.

DR. DROZDA: Yes. Here's what I would say to that. Again, we're not creating a guideline here; we're trying to track the guidelines. Again, the guideline, you know, states that when patients who have an ejection fraction of less than or equal to 40 percent, you know, should be placed on an ACE inhibitor indefinitely.

So there's nothing in the guideline of which I'm aware of, and I'm going to have to go back and look at it again. But I'm not aware of that, that the guideline states that if the ejection fraction then comes back up over 40 percent, it can be

discontinued.

But so we're kind of looking at it from that standpoint, and the situation where someone comes in with a 48 percent. It's the first time you've seen them. They're not on ACE. They had a 40 percent two years ago. I can't, you know, I hear what's being said, but I can't believe that that's a very common situation.

DR. AYALA: I have a question. The definition prescribed, it says that it could include just that the patient was given a prescription, not necessarily that it had been filled, and this is only required one time in the 12 month period.

So for me, the validity of this measure, in trying to capture, you know, get to an outcome that requires more persistent use of an ACE inhibitor or ARB makes me concerned, and I have the similar concern with the measure I'm going to look at for heart failure, beta blockers for heart failure. So

just if we could clarify that definition.

DR. RASMUSSEN: This actually may be a good opportunity, because I think we'll come across this issue again and again when we're talking about adherence measures. I think in the next category is where we'll probably vote on it, with inclusion and exclusion criteria.

But this is a -- this particular measure is a single point estimate of adherence. One time in that time frame that they pick up a medication. That is not a particularly, in my eyes, a great way to measure adherence.

We've got some examples of another HEDIS measure, beta blocker post-MI, where they set a time frame of 180 days, and expect a medication possession ratio of at least 75 percent.

To me, that's a more accurate representation of appropriate clinical care than a single medication fill.

DR. SPERTUS: The challenge is that one will fall down on its feasibility. I mean it's going to be exceedingly difficult to calculate that in a large number of settings. While it may be feasible in some health plan's perspectives, in lots of others it won't be.

DR. DROZDA: This is Joe Drozda. Again, I want to be clear about the measure. This is not a patient adherence measure. We're not putting it forth as that. This is a provider adherence measure, that the provider understands that ACE/ARB are indicated in this situation and prescribes it.

So that's really what we're measuring. Adherence is important to measure. I think we still have a lot of issues around it, including something that Dr. Spertus just said, and that is the feasibility, especially at a physician level.

Right now, I'm personally involved in some work, trying to get information back

from pharmacies through the e-Prescription mechanism, about fills and refills, so the physician even knows what the refill data are.

I think we're seeing some challenges even to PBM data, with the $4 prescriptions that are being floated out, prescriptions without going through the insurance benefit. So it's becoming more and more difficult, even with PBM, Pharmacy Benefit Manager data, to really fully understand adherence.

So there's a lot of challenges in measuring adherence, let alone the other issues I mentioned earlier about attributing it to physicians, when actually probably a system level or a plan level or employer level measure may actually be more useful in terms of it helping us with adherence.

CO-CHAIR GIBBONS: Other comments or questions about scientific acceptability?

(No response.)

CO-CHAIR GIBBONS: If not, I think

we should go ahead and vote.

(Pause.)

CO-CHAIR GIBBONS: Okay. So we have 12 completely, 8 partially and 1 minimally. Can we move on the third criterion, usability? Microphone, Jon.

DR. RASMUSSEN: I keep turning it off to keep it from squealing, and neglect to turn it back on. For the Usability data, this measure is not yet publicly reported. However, it does have a significant amount of value if the measure were approved as it relates to clinical care.

Adding values to existing measures, now we're back to the harmonization question again. There's another measure that I'll be presenting that's looking at a very similar outcome, but immediately post-discharge from hospital.

CO-CHAIR GIBBONS: Okay. Questions or issues regarding Usability?

(No response.)

CO-CHAIR GIBBONS: Okay. I don't see any lights on, so let's go ahead and vote on Usability, please.

12 completely, 9 partially. Let's move on to Feasibility.

DR. RASMUSSEN: Similar to other medication-related measures, the information could be extractable. The information regarding ICD-9 codes also should be extractable without too much difficulty. One comment that I would make, and this is looking at it from the stance of an abstractor, is the exclusion criteria, very similar to other ones that have been reported in the past. So it's not a lot of difference there.

I wonder if the Committee would consider if it's reasonable to have some explicit exclusion criteria. So for an ACE inhibitor, for example, angioedema or renal artery stenosis, so that the abstractor can eliminate those administratively --

(Telephonic interruption.)

DR. RASMUSSEN: So I'm wondering if the --

DR. BURSTIN: If the folks on the call could just please go on mute while you're not speaking? Thank you.

DR. RASMUSSEN: So I wonder if there's some advantage in spelling out some specific exclusion criteria that would make it easier for the abstractor to take patients out of the denominator if they felt that was important.

The converse of that and the authors discussed this, is that some of these may relative contraindications. So if you have a patient who has hypotension, it's not unreasonable to rechallenge, perhaps, with another agent.

So the balance is do you make it easier to eliminate patients from the denominator, mostly appropriately, or do you leave it more to a manual review, to determine whether or not the patient should be taking

the medication?

CO-CHAIR GIBBONS: Dr. Masoudi.

DR. MASOUDI: Yes. We've struggled with this at the ACC-AHA in the development of all of our measures, is this issue of whether or not to have a very clear, explicit list of contraindications, versus those, you know, versus a more permissive list, that allows for absolute contraindications.

I think what we found from an acceptability perspective is that having a very prescriptive list does two things. One is that it increases the abstraction burden, in terms of having to look for specific issues throughout the chart, rather than looking more broadly for just saying an ACE inhibitor's not indicated for this reason or that.

The other issue is from a clinical acceptability situation. I've worked a lot with the CMS measures and we'll talk about those later too, is the -- you know, because

of this issue of the nuances of clinical care and the vast, you know, different types of exclusions that are possible, it's really hard to come up with sort of an acceptable and reasonably exhaustive list of contraindications, and draw bright lines about say what's the right reason for withholding an ACE inhibitor for hyperkalemia or for hypotension, like you say.

CO-CHAIR GIBBONS: I'm just a little concerned, because the mic in the room is a little soft. Joe and John, could you hear Fred's answer?

DR. SPERTUS: Yes. To just add to what he said, in terms of the kind of experience that we've seen with these measures in some of the testing we've done, it's actually kind of to what was said earlier. There are patients that apparently had some of these examples of denominator exceptions like for ACEs and ARBs, but who nevertheless were on the ACEs and ARBs, and for just the reasons

that were said.

These are relative sort of contraindications. The patient may have had a problem, was rechallenged. Anyway, the physician decided it was in the best interest to be back on the medicine. We found that, you know, we want to include those patients in both numerator and denominator.

So I think we're finding in what we're seeing so far that physicians are using these exceptions in a clinically appropriate way, as they manage patients over time.

DR. DROZDA: I would just agree with that. I think it's really, the issue about relative contraindications is an important one, and we wanted to give credit to those physicians where they chose to go ahead with the therapy, and it would be in the numerator and the patient would be counted.

Those who couldn't tolerate the therapy, for whatever reason, they were then excluded, and so that's what the exclusions

are used for.

CO-CHAIR GIBBONS: Okay. I think it's important to point out that I for one can hear the two of you better from wherever you are, than I can hear Fred from the other end of the room. Your voices are coming like God out of the ceiling. So --

DR. MASOUDI: And what would mine be coming out like?

(Laughter.)

DR. SPERTUS: By the way, he's right here with me.

(Laughter.)

DR. MASOUDI: So there, Dr. Gibbons.

CO-CHAIR GIBBONS: All right. I think we're ready for a vote on Feasibility.

Okay. 13 completely, 8 partially. All right. I think we're going to now move on to the final key question, does the measure meet NQF criteria for endorsement. Comments or questions before we vote?

(No response.)

CO-CHAIR GIBBONS: It looks like we're ready for a vote, if you could open that up.

It would appear we had a technical glitch there, so I think we're probably going to have to revote in a second.

(Pause.)

CO-CHAIR GIBBONS: Oh, we are? Have we opened it? All right. We're going to open for revoting.

Okay. Another unanimous yes vote. All right. We're now going to move to the next measure, which is on 0070, beta blockers in patients with prior MI, and Rochelle is our primary reviewer.

Measure 0070

DR. AYALA: Yes, and I'm glad we had that discussion before, because now that I'm focusing on this measure from the perspective of physicians' compliance, as opposed to adherence, that might change some

of my comments from what I submitted in the spreadsheet.

So this is -- the measure title is "Chronic Stable Coronary Artery Disease, Beta Blocker Therapy, Prior MI or Left Ventricular Systolic Dysfunction, Ejection Fraction Less Than 40 Percent."

The description is percentage of patients, aged 18 years or older, with a diagnosis of coronary artery disease, seen within a 12 month period, who also have a prior MI or current or prior left ventricular, ejection fraction of less than 40 percent, who were prescribed beta blocker therapy.

Again, this is whether the physician gave the prescription or if the patient filled it at the time that it was tested during that 12 month period. The importance to measure, lots of data here for this measure and the other one that I'm going to review next, that gives the clinical importance of treating patients with acute MI

or with prior QMI and left ventricular ejection fraction less than 40 percent, with beta blockers.

This indicator actually takes into account the exact type of beta blocker for the patients with the ejection fraction less than 40 percent, and that's different from the other one. For those, it should be the bisoprolol, carbetalol, or sustained release metoprolol.

Are there any questions regarding the, or anyone take exception with the fact that it's important to measure, based on the data?

(No response.)

DR. AYALA: No. Then can we --

CO-CHAIR GIBBONS: Let's vote on Importance.

DR. SANZ: I have a question.

CO-CHAIR GIBBONS: Sure, go.

DR. SANZ: Too late

DR. AYALA: No, that's all right.

Go ahead.

DR. SANZ: I've never seen a measure yet this morning where we have to actually use a specific medication, and I have a problem with this, because basically I send all my patients home on BID metoprolol. That wouldn't be allowed under this. I don't think that's appropriate.

CO-CHAIR GIBBONS: Maybe the measure developers. Fred, you want to comment.

DR. MASOUDI: Well, this is an outpatient measure. The beta blockers specified are those specifically mentioned in the guidelines for patients with left ventricular systolic dysfunction, namely carbetalol or long-acting metoprolol. The other beta blockers are not specified in the guidelines as efficacious in patients with systolic dysfunction.

CO-CHAIR GIBBONS: Sid.

DR. SMITH: The data on beta

blocker therapy with normal LV function, more than three years after a myocardial infarction I'd like to see. There are data saying that patients with myocardial infarction benefit from beta blockers, and generally they're followed about two to three years.

But there are no data that I've seen, taking patients with myocardial infarction more than three or four years ago, placing them on a beta blocker, showing that they benefit. We've gotten into this in the current guidelines. So it's just a matter of the people who put this together, coming up with an evidence-based study showing that that happened.

CO-CHAIR GIBBONS: Okay. So we're sort of moved into Scientific Acceptability. We've already voted on Importance.

DR. SMITH: So I'm disclosing. I voted for this. I have a little trouble, and if I don't think the science is exactly right, do I vote? Yes. All the other stuff is

pretty good.

CO-CHAIR GIBBONS: That's the way it's supposed to be.

DR. AYALA: The only other comment in that regard too is so although we have studies showing certain beta blockers are beneficial, the absence of studies showing that other ones aren't is what? I would suggest considering maybe --

DR. MASOUDI: The issue is that it's responsive to the guidelines. There is specific guidance in the guidelines with respect to the beta blockers that should be used in patients with systolic dysfunction. So this is responsive to explicit recommendation in the guidelines.

I agree with you, that it's true that propranolol has not been studied in patients with systolic dysfunction. But again, to the extent that the Performance measures need to follow the guidelines, we're following that recommendation.

With respect to the issue of longer treatment after MI, the current ACC-AHA secondary prevention guidelines suggest indefinite therapy in patients with MI. So again, it's really more following the guidelines and some of these admittedly important nuances in the interpretation of the existing data.

DR. KING: Those guidelines are being revised. I'm looking up the women's guidelines, because I think they may have -- we may have it already, the ones that came out yesterday. I know the secondary prevention ones have --

CO-CHAIR GIBBONS: Anybody on the phone want to weigh in on this.

DR. DROZDA: Yes, this is Joe Drozda. Again, we have to go with what we have, and right now the guidelines are what they are. Again, we will, if we need to modify it based on new guideline recommendations, we will do that, and we have

a plan for accomplishing it.

DR. SNOW: But this goes to what may be a core and fundamental problem. The measure developer has to go with the guidelines. The guidelines want to be "evidence-based." Where does the evidence come from?

Drugs that the pharmaceutical industry will pull out a sweet little randomized control trial for, but nobody's studying atenolol or propranolol or the other beta blockers because they're generic. So this thing that is kind of in the room, not what we want to be driving the discussion, has a major impact on it, and I don't know how to solve that problem.

CO-CHAIR GIBBONS: Well, at least for this one let me reiterate what Fred said, and just qualify it. In patients with symptomatic systolic heart failure, these are the three drugs that have been studied and been efficacious.

Other beta blockers have been studied. Bucindolol was studied, was not efficacious. Metoprolol tartrate, ordinary metoprolol, was studied, was not efficacious. So that's why these three are singled out, because in randomized trials in symptomatic heart failure.

Now these patients would not require symptomatic heart failure. They're officially Stage B heart failure by the guidelines, and beta blockers are recommended on the basis of expert opinion, and basically chose to extrapolate from the symptomatic data with respect to the drugs.

Does that help? I mean other drugs have been studied and didn't work. That's why the differentiation here.

DR. SNOW: Yes, I appreciate that.

DR. AYALA: Okay. Back to the Scientific Acceptability. The numerator we already discussed. The denominator, all patients aged 18 years and older with a

diagnosis of coronary artery disease, seen within a 12 month period, who also have prior MI or current or prior EF less than 40 percent.

They also list a good summary of exclusions, including medical reasons. For example, allergy intolerant, bradycardia, so on and so forth, and documentation of patient reasons for not taking, for example, that the patient declined or other patient reasons. Then also for documentation of system reasons for not prescribing the beta blocker therapy, and they also have an "other" category there.

DR. RUSSO: Can I just ask one question?

DR. AYALA: Go ahead.

DR. RUSSO: Is it supposed to be symptomatic heart failure, because at least the way it's described, it's coronary disease?

CO-CHAIR GIBBONS: No, no. But the science, that's what I was trying to establish, where the scientific evidence for

the drugs comes from. It's from trials in symptomatic heart failure.

DR. RUSSO: But can we extrapolate --

CO-CHAIR GIBBONS: The guidelines have. The guideline process has.

DR. RUSSO: Because that, I think we would not even question that. But if it were a heart failure measure, at least I wouldn't think twice, because we all put them on carvedilol. But if it's -- I understand, that we have to be consistent with the guidelines.

But it's a little harder, because I guess we could see how it works. I have a little problem, because it's not in the heart failure group.

CO-CHAIR GIBBONS: Well, I don't want to sort of delve too much into the process, but you can see the problem from a guideline developer's standpoint, if what you're suggesting means the moment the patient

develops symptomatic heart failure on metoprolol tartrate, then the clinician is supposed to change the drug. The chances of that happening are --

DR. AYALA: Zero. That makes sense.

DR. RASMUSSEN: Can I ask a question about systems issues. What does that mean exactly?

DR. AYALA: Developer?

DR. SPERTUS: Yes, systems issues deal with factors outside of the locus of control of the patient or the physician, that have an impact on whether or not, you know, therapy can be prescribed. For instance, insurance and medication availability, et cetera, et cetera.

DR. DROZDA: Another good example would be cardiac rehabilitation, when there just is no local cardiac rehabilitation program.

DR. MASOUDI: And the extent to

which these exclusions are relevant to any one of the measures, there is -- so this is, relatively speaking, boilerplate in terms of the ACC-AHA-PCPI put together their exclusions. But certainly these systems reasons are vanishingly irrelevant or close to irrelevant for something like the prescription of medication, are highly relevant to something like the provision of cardiac rehabilitation, or the provision of say primary PCI, where that's not available.

So this is just -- this is a boilerplate exclusion language that's used for all of the measures.

DR. DROZDA: And quite frankly, we don't see this cited, these sorts of things cited very often. It's just extremely rare for almost any measure.

CO-CHAIR GIBBONS: And somebody else can help me out, but this actually did occur for this one a few years ago, when both generic manufacturers for extended release

metoprolol were on FDA sanction, and there was this great tendency in Pharmacy Benefit Programs to switch all the patients to tartrate. If this measure had been done during that six month time frame, there would have been big problems.

DR. MASOUDI: Although that would have been a system --

CO-CHAIR GIBBONS: That's what I mean. It would have been a --

DR. DROZDA: A great example, yes.

CO-CHAIR GIBBONS: That would have been a system issue that nobody had any control over, that would have needed to be factored into the measure.

DR. AYALA: Okay.

CO-CHAIR GIBBONS: Okay. I think we need to vote on Scientific Acceptability.

DR. SMITH: We can go ahead and vote. I just want to be sure that it's understood that this beta blocker thing will be revised, because although they may not have

had it when they wrote it, it is a fact now and this Committee has to deal with the fact that the existing guideline is not consistent with this. I'm working, I'm trying to bring it up right now. It was published yesterday.

DR. MASOUDI: Right. So the women's guideline does in fact specify a one-year time frame.

DR. SMITH: Exactly. That's what I'm saying.

DR. MASOUDI: So right.

DR. SMITH: You're in touch with reality.

DR. MASOUDI: I try to be. What are those green things? So that's right. But so the in fairness, the measure was written before the release of the women's guideline, which just came out last week or something like that, and we have -- the ACC-AHA-PCPI have in place a mechanism whereby we can be responsive and are responsive in relatively short time frames to changes in the

guidelines.

Of course, the timeliness in which that can occur depends on the nature of the change. But it seems to me that this exclusion would be something that would relatively easy to work into the measure, as you know, MI within a year or whatever the new guideline ends up specifying.

DR. DROZDA: And I would agree, and that's because we were aware that things were in development, and we already had gone through the process of saying yes, we'll change if there are changes in the recommendations.

DR. SMITH: I'm not being critical of the people who wrote this. I'm trying to be sure that the Committee approves something that's consistent with what's going to be out there.

CO-CHAIR GIBBONS: Okay. Well, I think we understand the importance of that, and Joe has reflected and Fred has reflected

the PCPI process taking that into account. So this vote was 4 completely, 9 partially, 2 minimally. We need to move on now to Usability.

DR. AYALA: Yes. I might need some help from the developers on this one, because it says it's currently in use, but then it says this measure is not yet used in a public reporting initiative. Is that because you're referring to the pilot groups that you're using in there?

MS. TIERNEY: Sorry about. Sam with the AMA PCPI. The reason we have that distinction is yes, the measures are in use in a number of programs like PQRS and meaningful use and things like that. However they have not at this point been used to report public physician data, make available performance data.

So we kind of draw a distinction between public reporting and just the use of the measures in implementation programs or

things like that. Hopefully that --

DR. DROZDA: So they are being used in accountability sort of programs, without going to the extent of public reporting.

DR. SPERTUS: This is John Spertus. Sid, I'm not sure that the beta blocker recommendations can be inconsistent with the stable ischemic heart disease guidelines, that would be quite relevant to this particular performance measurement set.

DR. SMITH: Yes, I'll take a look. My guess is it will be. The argument has been triggered, does everybody with coronary disease need to be on a beta blocker? That's where it starts. People start rummaging around, saying you know, we really don't have the evidence that people with normal left ventricular function and coronary disease should be on a beta blocker, and they don't have hypertension.

So then well where did this

evidence comes from? Oh, it's the Miami trials. So going back into these trials with acute myocardial infarction, where it was clear that patients started on beta blockers benefitted. The benefit seemed to occur early on, within the first year, and the trials went out for about three years.

And frequently, the benefits were associated with arrhythmic deaths. So that's led to a, what's going to be a revision, what is a revision that now being reviewed and one guideline's out, that beta blocker -- all patients with coronary disease do not need to be on beta blockers, that the subset of patients where they are a proven value are those who have congestive heart failure or systolic dysfunction, and those who have had a recent acute coronary syndrome.

So if you get somebody into your office who had an MI six years ago, who has normal LV function, no hypertension, the evidence to start a beta blocker right there

is not strong.

If you take somebody into the cath lab and do an angioplasty for an 80, 90 percent left anterior descending lesion, they have normal LV function and no hypertension, have not had a recent infarct, the evidence that they need to be on a beta blocker is not strong.

So if we've tried to focus in on where is the evidence that patients with coronary disease will really benefit from beta blockers, and the evidence is really strong for heart failure and for acute coronary syndromes.

Now that's why they've written in this thing, beta blockers should be used for up to 12 months, or up to three years. The level of evidence A, is for 12 months for three years, B, and all women after MI or acute coronary syndrome with normal LV function unless contraindicated.

It doesn't say anything about

extending them beyond that if they have normal LV function.

DR. DROZDA: So the statements, updated statements from the heart disease guidelines may change, but it's currently written for the post-ACS MI group, and those with LV dysfunction. It's explicitly said indefinitely, and then, you know, it's a much lower recommendation for all other patients with coronary disease. So it may change a lot.

DR. SMITH: I have a coop coming up on that, so I need to -- that the lipids that we're discussing. It will be harmonized, and I think Fred, I mean as long as it's made consistent with what's out there, that's the important thing.

DR. DROZDA: We definitely have that mechanism in place, to update these very promptly when evidence changes.

DR. SMITH: But the origin of it, of you know, the whole thing has been should

we be putting everybody on beta blockade that has coronary disease, if they have normal LV function, normal LV gram and haven't had a recent acute event. That's where the --

DR. DROZDA: Right.

DR. SMITH: And trying to see what the evidence, and the evidence is not strong there. I don't know how existent it is really. But I don't -- I think this is a good measure, and if as Fred says and as you say, Joe, it can be revised to be consistent, then it's a reasonable thing to look at.

DR. DROZDA: Yes.

CO-CHAIR GIBBONS: Okay. I think we need to vote on Usability.

9 completely, 10 partially, 2 minimally. Now on to Feasibility.

DR. AYALA: The data is generated as a byproduct of the care processes, and is also electronically collected. In terms of susceptibility to inaccuracies, there was one question I had regarding the supplement that

was provided with this, and it talks about the CMS PCQRI 2008 claims data.

It says that for the beta blocker therapy indicator, 63.67 percent of the submissions were rejected due to an inaccurate diagnosis code. I was hoping the developers could talk about that.

MS. TIERNEY: Yes. So in that instance, some --

CO-CHAIR GIBBONS: Is your mic on?

MS. TIERNEY: Sorry. Is it on? Okay. In that instance, someone or several people, obviously 63.67 percent of people submitted a CPT-2 code saying they prescribed a beta blocker, but there was no diagnosis to correctly identify patients with CAD. So they submitted a CPT-2 code that seemed like they were reporting on this measure, but then they didn't have the diagnosis data that matched with that.

It's kind of a nuance of the PQRI program and probably related to some of the

challenges with that, because this is some of the data from the early implementation of the PQRI program, before maybe they worked out some of these challenges. Does that make sense?

DR. AYALA: So are the challenges worked out, because that's a big part of the population that we'd be testing?

MS. TIERNEY: Right. So well part of the problem is with the PQRI program. But yes, I do believe they've tried to clarify some of that in terms of reporting instructions for people who are going to be using the PQRI program and trying to report data for PQRI. But I think that's part of the problem.

DR. MASOUDI: Right. So the issue is not with the measure itself; it's really with the program that is trying to use these specifications to drive a measure in their way.

It turns out that the way it was

being, you know, for a group of people that were initially reporting in this program that was just being begun, there were a proportion of patients that didn't belong in there, because they actually didn't have the underlying diagnosis to support their inclusion in the measure.

DR. AYALA: So it sounds like you're confident that that's fixed now?

DR. MASOUDI: I think we have to turn to CMS to ask them whether or not they've fixed -- you know, again, it's not -- it's not so much an issue with the measure per se, as the implementation by one program of the measure. So I would have to let them speak to that.

DR. DROZDA: So what PQRI was a self-reported system. So it depended on physicians putting down codes on claim forms, and you know, anybody who's done a, filled out a claim before knows how that -- there can be issues with respect to the accuracy of the

reporter.

So you know, I think this is something that would be generic to any self-reported measure. We'll hopefully over time be extracting these things out of the medical record with, you know, I said the electronic medical record, without user involvement, so that we wouldn't have those sorts of issues.

CO-CHAIR GIBBONS: Okay. Are there other questions or concerns about Feasibility?

(No response.)

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

So we have 9 completely, 8 partially and 2 minimally. All right. Let's move on now to the final, important question, does the measure meet NQF criteria for endorsement. Discussion or comments or questions before we vote?

(No response.)

CO-CHAIR GIBBONS: If not, let's

go ahead and vote.

17 yeses, 4 no's. So thank you. We're going to move on to the next measure, 0071, on persistence of beta blocker therapy. Many of the comments we've made on the previous measure probably apply here, and Rochelle, you're still on.

Measure 0071

DR. AYALA: Okay. This one is more of an adherence, because it's persistence, 75 percent of the time in the 180 degree period after discharge, that the patient was on a beta blocker.

Just for your information, our group voted very strongly for this one, and it's acute myocardial infarction, persistence of beta blocker treatment after a heart attack, and it's the percentage of patients 35 years and older during the measurement year, who were hospitalized and discharged alive July 1st of the year prior to the measurement year through June 3rd of the measurement year,

with a diagnosis of acute MI and who received persistent beta blocker treatment for six months after discharge.

Again, the same discussion that we had before about persistence of beta blocker therapy apply here. So we can probably go to that Importance to Measure vote.

CO-CHAIR GIBBONS: Thank you. I agree. Let's go ahead and vote on Importance.

Okay, unanimous, 21 to 0. Let's go to Scientific Acceptance.

DR. AYALA: Okay. So the numerator statement is 180 day course of treatment with beta blockers. Identify all members in the denominator population whose dispense days supply is 135 days in the 180 day period following discharge, which will give you at least 75 percent of the day supply filled. So it's filled.

The numerator, I'm sorry, and the denominator is patients age 18 years and older as of December the 31st of the measurement

year, and the discharge date, the continuous enrollment is discharge date through the 180 day after discharge.

They had to be discharged alive from an acute inpatient setting, with an AMI from July 1st of the year prior to the measurement year, through June 30th of the measurement year.

If the member has more than one episode of acute MI from July 1st of the year prior to the measurement year through June 30th of the measurement year, the organization should only include the first discharge and must use the codes listed in the table, and there are lots of codes listed.

In the exclusions, you have to look back as far as possible in patients with the history, through either administrative data or medical record review, and they list the codes for that. There's no risk adjustment necessary.

CO-CHAIR GIBBONS: Questions or

issues about Scientific Acceptability?

DR. RASMUSSEN: So this measure actually provides actually provides a good contrast between some of the other medication measurements that we looked at. In terms of exclusion criteria, there's very specific codes in which patients can be excluded from the denominator.

Also, there's a lack of a clinician option to exclude patients from this denominator. So to make this one more robust, I would like to see at least a clinician option to exclude patients.

The one that jumps to mind is fatigue. That's not a listed accepted contraindication. But it's not uncommon for a patient to try rechallenge on a beta blocker, and not be able to take it.

Also another contrast is that this is truly an adherence measure post-MI, measuring a possession ratio for a patient. So I'd be curious to hear the authors'

explanation as to, you know, hearing the other explanation about being a provider measure, and this one is more of a patient measure, if you will, looking at adherence long term, 180 days long term.

Sorry, I put a lot in there. So the first part was just a statement about opening up to exclusion. The second is we've heard about some other medication measures. This one truly measures adherence, 180 days post-MI.

Why did you choose -- hearing the comments about the other measure being more of a physician, we want to make sure the physicians are doing the right job, versus patients doing the right job. What was the decision that went into that in designing this measure?

MS. TIRODKAR: Unfortunately, I cannot answer that question, because I was not --this was developed before I started working in NCQA. But I can get back to you on the

rationale for the 180 days definitely. But right now --

DR. RASMUSSEN: But it's not so much the 180 days. I think that's a reasonable surrogate for adherence. So maybe I'd reformat my question a little bit. Has this -- this measure's been public for a few years now. Have people been able to abstract the medication data successfully across a wide range of health care organizations?

MS. TIRODKAR: Yes, they have, and we have this measure both at the health plan level as well as the physician level, and we have not had, at least recently heard any issues with feasibility for extracting the prescription data.

DR. RUSSO: Just a general question. So the other side of having all the specific exclusions listed are that they may have been a transient type of thing. So if we're say transient second degree block with an inferior infarct or something like that,

but you want to put them on a beta blocker.

So if you're listed as an exclusion and you're on a beta blocker, we still count that as not an exclusion? Just a logistically, how is that counted? So you might want -- or even asthma. It may be mild asthma or a history of asthma.

So are we excluding that patient totally, or do we still include them if they're on the beta blocker? So do we -- are we overly-excluding patients that shouldn't be excluded is the question.

DR. KOTTKE: Yes. I don't know the answer to your specific question, but it came up in one of the measures that I'm going to talk about, which is aspirin use, and in that case, they counted the patient in both the numerator and denominator, if they were receiving it, even if they met criteria for exclusion.

They felt that there were too many people being excluded. So I think that's sort

of -- that's how they chose to do it in the aspirin measure, which seems like a very reasonable approach to me.

DR. RUSSO: You wouldn't want to exclude them --

DR. KOTTKE: Give them credit where you can, but give them -- let them off the hook as well.

DR. RASMUSSEN: I don't know that this would necessarily fall into the harmonization discussion, because we're looking at different medications.

But the discussion around strict exclusion criteria or more open exclusion criteria. I think arguments can be made on both sides, and I wonder if we would benefit from taking a stance either way.

If we're going to have strict exclusion criteria for one measure, should we do it for all, or if we're going to keep them more open, should we do it for all as well?

DR. RUSSO: It just seems to me if

you're going to -- that we would want to say excluded because of asthma. And then but if you have, if you exclude all these patients just by the code. So that whoever's going through the charts would be excluding all those patients that shouldn't be excluded perhaps.

CO-CHAIR GEORGE: I have one comment for the developers in the measure description. It says this applies to ages 35 and older, and your denominator says it applies to age 18 and older. Can you clarify that?

MS. TIRODKAR: Yes. That is a mistake. It should be 18 and older.

DR. AYALA: Ready to vote?

DR. KING: I have a question. Is there any thought to, on this one, specific beta blockers, like we said before, because there are beta blockers that are less specific for the lungs, and one of the exclusions here is asthma and COPD.

There are, of course, different beta blockers affect the lungs to a different degree. Did the developers consider being more specific about lung-sparing beta blockers, or was that not an issue?

MS. TIRODKAR: Again, I don't know the exact answer to that question, but that's definitely something I can bring back as an issue, to perhaps deal with the issue of the exclusion for asthma.

CO-CHAIR GIBBONS: Okay. I think we want to go ahead and vote on Scientific Acceptability.

DR. KOTTKE: Ray, while people are voting, in a fairly large cohort, the addition or subtraction of one over one to a fraction would be decimal-best, and so I don't think that it's a particularly bothersome question.

CO-CHAIR GIBBONS: That's a very good point. Okay. The vote is 8 completely, 11 partially, 2 minimally. Do we still have anybody on the phone?

DR. DROZDA: Yes, but not with regard to this measure.

CO-CHAIR GIBBONS: That's fine. I'm just making sure I'm not sort of speaking into the wilderness with my recording of the votes.

DR. AYALA: Okay, so now Usability. It's in use. It's a HEDIS measure, and our developer said that they're not having any issues with the reporting on that.

CO-CHAIR GIBBONS: Any comments or questions about the Usability?

(No response.)

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

17 completely, 2 minimally and 1 not at all. Let's move on now to Feasibility.

DR. AYALA: Okay. The data's generated as a byproduct of care processes during care delivery, and the data elements are all collected electronically, and they did

not list any difficulties with Feasibility.

DR. RASMUSSEN: I had a thought, and this falls into susceptibility to inaccuracies, regarding a patient who meets one of the exclusion criteria that is actually on the medication. Depending upon how the abstractor pulls the data, once you define your denominator, if the first pass is are these patients on medication, you should catch them.

Then in the hierarchy, if the last thing you do is exclusion, you should be able to count them in the numerator and not lose them in the measure.

CO-CHAIR GIBBONS: Mark.

DR. SANZ: I have a question about how one would gather this data if you don't have an electronic source for -- even if you do have an electronic medical record. So an MI patient goes home.

He's seen maybe, he or she at one month. They're doing okay. So maybe I see

them at three months, and then after that, it's eight months to a year and yearly thereafter. How do I get this 135 days out of 180 day information?

DR. RASMUSSEN: So in my experience, one of the ways that you can get that is if a patient is going to a pharmacy, and that claim is adjudicated through their insurance company, they will have a record of that refill.

Not an inconsequential point though, even more so and Roger alluded to it, is an increasing number of organizations that are offering $4 prescriptions.

Those claims are not adjudicated. So they essentially never hit the electronic record, and those patients are increasingly being lost in measures like this, because there is truly no record of that prescription ever being filled. If it is adjudicated, however, that data would be able to be abstracted.

DR. SANZ: We need to look at the universe of patients outside of those who have insurance, which increasingly is larger and larger, given the environment. In my world, a third of the patients or higher don't have insurance. So let's not assume that as the source for data collection.

DR. SNOW: In Massachusetts, 98 percent of the patients have insurance. Well, maybe it's time. It's interesting. The people who are offering $4 prescriptions are large corporations that have those data. They're just not sharing them, and I think that it is worthwhile for somebody to say come on guys, 'fess up.

DR. KOTTKE: I have a question about feasibility for the doc who has paper and cardboard records. I mean I have a hard enough time in EPIC trying to figure out what, you know.

(Laughter.)

DR. KOTTKE: Yes. I mean, you

know, I still have practice in some places with those records, and I have really no idea what my patients are taking from the record. I'm sure that's true. My paper records I couldn't read anyway. But in the Medicaid world, Medicaid patients don't pay co-pays.

They don't pay $4. They use the benefit, and the point that was being made as that where the pharmacies are involved, they do have real time documentation of the use of the prescription. So you can, fairly reliably, much of the time, get adherence data with some of the limitations that we've discussed.

DR. SNOW: So are doctor's offices that use paper records expected to call pharmacies and ask? Is that what the implication is?

DR. RASMUSSEN: Maybe the author could describe that. This is an NCQA measure, which is generally looking at health maintenance organizations. So patients who

have, have coverage. So it does self-select the population. But I guess I'm not certain how they, to your question, who chases down that data.

MS. TIRODKAR: Okay. Physician level, for the physician level specification, and it's sort of in the guidelines to the HEDIS volume, the requirement is to submit data on 30 consecutive patients. So you have to pull 30 charts, okay. It's not --

DR. KOTTKE: So I have a medication list in there, and that's either what I've prescribed, or it's what the nurse got from the patient when she did the medication reconciliation.

But I have really no idea what the bills were, and I think one thing that's important is HEDIS is for managed care organizations, right? And so -- or health plans, health plans.

And so the feasibility of this for a doctor with a cardboard record is

questionable.

DR. BURSTIN: Just one comment. Much of this is based on pharmacy claims data, I would assume. So again, you're not -- it's fill rates, correct me if I'm wrong. But it's based on supply fill rates.

You wouldn't know that even in your paper record or your EPIC. Right. So that's why it's outside the purview of -- I think, correct me if I'm wrong. This is really mainly based on pharmacy claims.

DR. DROZDA: This is Joe Drozda. Can I make a comment? I'm bringing it back to something I said earlier about, you know, physician level adherence measures, in terms of patient adherence, are really something we're going to have to evolve to.

You're just getting into what we're struggling with, and by "we," I mean in my own work here at Sisters of Mercy Health System. We're trying to get our fill data from -- directly from the pharmacy back

through the same type that we prescribe through.

That is technically possible, but where a provider of the prescription services is saying they don't have a business model yet, which means they're trying to figure out how to make money out of the return information. All we're asking for is every time any prescription gets filled, that the attending or the prescribing physician get a ping back.

That can be done, and the reason I'm bringing it up is I would like to have other people on my side, as we start pushing to have this sort of information flow.

CO-CHAIR GIBBONS: Well, I think one of the practicalities that's been mentioned is the increasing use of the multiple available mass retailer quarterly programs for $10 a generic prescription or thereabouts.

I know I see an increasing number

of patients who are availing themselves of that, when they realize that that's cheaper than their co-pay, under whatever insurance they have.

Those records, as mentioned, are not available. In principle they could be made available, but given the competitive nature of that retail world, I think our chances of seeing that any time soon are small. Yes. I think we want to vote on Feasibility.

Okay. 4 completely, 11 partially, 5 minimally and 1 not at all. All right. Now to the critical question, does the measure meet all the NQF criteria for endorsement, yes or no.

Sorry, start again. Vote again, please.

(Laughter.)

CO-CHAIR GIBBONS: We have two very fast fingers here. That's very obvious. Very fast fingers. Okay. We're going to

start again.

(Laughter.)

This is sort of like an early exit poll in New Hampshire, in the presidential elections. Okay. 13 yes, 8 no. We will move on to 0065, which is Symptoms and Assessment in CAD, and this is Christine's.

Measure 0065

DR. STEARNS: Thank you. This measure would look at medical records to determine if the patient had been evaluated for their level of activity, and also for the presence or absence of angina symptoms and if that's in their medical record.

The developers indicated that the measure is important to reduce mortality, and also to reduce symptoms, and that it is a patient-centered measure. This had been put, I think, down to the bottom of the list, because unfortunately we don't have reliability or validity data submitted.

So I don't know if that has come

in, but I think as of, and someone can help me if there's anything that has been submitted. So I think that that makes our evaluation process a little bit more challenging.

DR. DROZDA: These data have been published on this, and you know, I think PCPI really got caught unawares on the reliability and validity data requirement. But there are published results from the Pinnacle on the fact that this was assessable in about 89 percent of records. That's on 14,000 patients.

DR. WINKLER: We received information from PCPI last night, and the testing information, similar to the ones earlier, describes the process, but provides no actual data on the reliability of the measurements, either at the data element level or at the level of the measure score.

The only data that was submitted is a single result, and for reliability testing, we are looking for something more

data-driven.

DR. DROZDA: And could you just expand on that? What would qualify as good reliability data, the feasibility or ability to collect the data, or the fact that it was independently adjudicated by another source and was collected accurately?

DR. STEARNS: Yes. In this case, we're talking about reliability and not feasibility data, and reliability at the measure score will depend on how the data is collected.

If it's an abstraction, this is your classic inter-rater reliability type situation. For other types of data abstraction, there are other ways of evaluating the reliability of that data, so that you know that the information you're getting is accurate.

There are also reliability assessments that can be done at the level of the measure score, such as signal to noise and

other similar techniques. So we're looking for something in those realms, to give us a sense that is the information you're collecting reliable.

DR. MAGID: Hey John? Just a question. So I guess people should know that you developed the SAQ, the Seattle Angina Questionnaire. So can you tell us what --so we often use the Seattle Angina Questionnaire in outcomes studies. But what is the evidence to support using it in the performance measure?

DR. DROZDA: So the domain that -- this is, unlike everything else we've essentially talked about, which is either a process measure or a surrogate outcome measure, this is a directly relevant patient outcome measure in that this describes the health status, the symptoms, function and quality of life of patients.

It has been used in all of our, in 207 general practitioner clinics in Australia,

to look at potential under-use of treatment in patients with coronary disease, by documenting extraordinary variability in the patients having weekly angina or greater. I know that appropriateness is something that this group at NQF is very interested in understanding.

In the application of the pool of patients with chronic coronary disease, it would really be an opportunity to look at the quality of symptom control of patients with a symptomatic disease, and an indicator of potential under-use.

There were clinics in Australia where none of the patients had weekly angina, and there were another ten percent -- about 20 percent of clinics where over half the patients had weekly angina, and about ten percent where all the patients had weekly angina.

That would indicate a great variability in the control of patients' angina, and there was sort of a remarkable

sense by the doctors that the patients were optimally managed. So it is a direct patient assessment of the quality of their symptomatic control. I don't know if that's sort of what you're getting at, or you want to understand the reliability, reproducibility or the sensitivity of the instrument itself.

DR. MAGID: No. I think the qualities of the instrument are well-developed. But I think it's one thing to say that we're going to measure anginal symptoms and report that as an outcome, which is kind of what you were alluding to in your response.

But in fact that's not what this is at all. This is just saying that it's documented and done, and that there's nothing that says that it's acted or that it's really being truly used as an outcome. So --

DR. DROZDA: So we had that. Yes, it's a great point. So we had a second measure that looks at the control of angina. So the first step is, you know, is it even

reproducibly assessed. This emerged in the very first set of performance measures, because of the absence of documentation.

A lot of times what would be documented in the record was just stable coronary disease, or angina-stable. Another doctor picking up that chart would have no idea if they talked to the patient and they're having angina climbing a flight of stairs, whether that's a worsening or an exacerbation or not.

So the measure was first introduced as a means to make sure that there was explicit documentation of the system burden and the activity that precipitated those symptoms.

We are now getting more comfortable, and now in the next measure, you'll be discussing in a few minutes, looking at management, similar to the way we did with blood pressure, that it was, you know, either asymptomatic, which is the therapeutical, or

you know, there was a plan of action or at least two anti-angina medicines prescribed, to try and maximally control the angina.

So you know, the first step before you can look at it as an outcome is to make sure it's being reproducibly collected in each visit and each clinic where patients with coronary disease are treated.

DR. MASOUDI: And I would just add that actually the symptom management measure, which was submitted for approval, has actually been removed from the agenda because there is no testing data, and the reason there's no testing data is because symptom assessments are not routinely present in a lot of clinical documentation.

So this would certainly be the first step to getting towards a measure that would actually assess an action plan to address symptom status. Without this, it's hard to imagine how you could meaningfully test a measure that is really what we want to

get at, which is the optimal outcomes for patients.

DR. DROZDA: Yes. I didn't realize that was removed. That's unfortunate.

DR. SPERTUS: Yes. We really wanted these two measures to be used as paired measures for obvious reasons, and John's just gone through them. We're getting at the nubbin of what you do when you take care of a patient with coronary disease.

You're looking number one, to prevent mortality and extend life. But number two, and maybe it should be number one, you're looking at optimizing management of their anginal symptoms.

So actually number three, the symptom assessment and level of activity assessment, is indeed a very patient-centered outcome measure. Again, I find it frustrating not to be able to use it and the measure on management, because this is really getting to what patients are looking for.

DR. WINKLER: Just I'll clarify what has transpired vis-a-vis these measures. These two measures on symptom management, assessment and management, as well as the new blood pressure control measures, on their initial submissions, I think most of you have read that they checked the box saying the measures haven't been tested.

We questioned that, because that just is not one of the conditions we're accepting in this evaluation process. So we went back to PCPI and said really, we got nothing?

So they basically told us that, you know, for the blood pressure control and the symptom assessment, they had some, you know, some information, which is what we saw come in very late last night.

But for the management, they out and out said there's nothing. So that was the communication that transpired, to put us in the position we are in terms of evaluating

those measures.

DR. DROZDA: And it does create a leap of faith in this group, but you know, we have documented in the past, when we had a hypertension measure, our plan for control, the ability to capture that in one of the very early PCPI initiatives.

I think the cardio-hit project demonstrated that, and now you're taking the extrapolation that you will take the results from the symptom assessment and the physical activity assessment, and then be able to also marry to it the capacity to collect, that they're either on two anti-anginal meds or that they're --

You know, you're taking those results and then interpreting them and collecting the other additional data. While we haven't tested that, there's a certain cycle here where if NQF were to approve it, it would create much more support for collecting and generating that data, and you've gotten

rid of that sort of provisional acceptance, so that we could have that.

But you know, and I guess we've now removed that measure. But the hope was that you would find these to be very patient-centered oriented measures that resonated with your goals, to look at meaningful outcomes and to lay the foundations for looking at appropriateness and efficiency, and that you would take on, you know, faith that we'd be able to collect data and that we've collected in other performance measures in other settings.

Then with that, we would be able to generate more data as this moves forward. We've just proposed these measures; they were just approved, and we just haven't had the time to generate all of that data for you.

DR. RUSSO: Just a quick question. Is it possible to create a composite measure of the two, if part of it's been tested and part hasn't? Would that be a way that -- is

there any history for doing something like that?

DR. WINKLER: Well as yet, we haven't received any appropriate really testing data about either measure. So that's still an open question, in terms of the reliability of even the measure that's being discussed right now.

DR. AYALA: I'm sorry, did I miss it? Is there a gap? Did we say that there is an identified gap in this, that physicians taking care of patients with coronary artery disease are not asking questions about symptoms?

DR. MASOUDI: Well, they're certainly not documenting it. I mean this is -- talk about a place where there's an enormous gap. Again, one of the reasons why it's been so difficult to try and test a measure looking at say, symptom relief, be that in heart failure or be that in coronary disease, it's so sparsely documented that it's

difficult to even test that.

So whether or not physicians are asking about it is hard to say. I think some of them are, and they're saying, "well how are you? I'm well," to "when did you get angina" and putting down a CCS class or at least thinking about it, to a more sophisticated approach, like using a more detailed instrument.

But in terms of documentation, it's not known or my suspicion is there's a huge gap just in terms of really asking patients in any sort of meaningful way how they're doing. That's -- you know, if you take the documentation as any guide to that, it would suggest that there's an enormous gap here.

DR. SMITH: You have to look -- I mean you may want to -- I think there are physicians, Fred, that when they see the patient with coronary disease, ask if they've had angina, that's included in the dictated

report, electronic medical record. They then ask what, how much physical activity do you get? Do you get it daily, do you get a half an hour every day a week?

So there are people that are interested in this, and it may vary, depending upon where it's a primary care visit, where the physician has multiple issues on the table, and doesn't pursue each one of the diagnoses.

But it is important, and so I suppose anything that would enhance that activity among physicians and make it closer to 100 percent would be a good thing.

CO-CHAIR GEORGE: Have there been other efforts, in terms of physician education, prior to going straight to a measure?

DR. SMITH: Are there other efforts?

DR. MASOUDI: I don't know, and I don't know that that's a standard we would

hold any other measure to as well. I mean I think the -- I mean historically, that hasn't been the approach that has been used, in terms of determining whether or not a measure is reasonable.

You know, you demonstrate a gap in care. This is something that's meaningful to patients. It satisfies all these other criteria. But again, I'm not off the top of my head aware of specific interventions to try and improve this particular aspect of care. I don't know if anyone else is aware of them out there, but --

DR. DROZDA: I think it's a, you know, I mean it's an enormous gap. We've done a lot of research in this area. I mean, you know, many of the people on the panel are cardiologists. Go pull ten random charts and see how well it's documented. I mean it's not even documented at the time of angioplasty in over half the cases.

So you know, I just -- there's a

tension here between having exhaustive data on something that has just not been measured, and the desire of this organization and the entire U.S. health care system to try and start getting to patient-centered outcomes that are meaningful to patients and to society.

And, you know, the symptoms is the number one goal that most of our interventions are directed for in the management of stable ischemic heart disease.

DR. SPERTUS: So, this is Joe. We're going to ultimately have to work our way to the point where we can say, in a risk-adjusted way, what percent of our patients have optimal control of their symptoms. We're not going to be able to get there unless we're actually measuring it.

In other words, that we're measuring that we're asking, and we're measuring that we're looking at not only symptoms but the level of activity, so that we can come up with that ultimate outcome measure

that I'm sure everyone's looking for. I don't know how you get there without this.

CO-CHAIR GIBBONS: Helen.

DR. BURSTIN: Hi, it's Helen Burstin. I just want to point out again, it's really just been an evolution over the last couple of years that's gotten to the point where very clearly the appetite for untested measures has really reduced significantly.

There's a lot of concern about untested measures being out there. The Board of Directors has given us clear direction to move towards tested measures, unless there are three criteria. Unless there's an obvious gap in the portfolio, or there's a legislative mandate for that measure, or the measure is not complex. All those are "ands."

So this one doesn't really qualify in a way. But I guess the question I would have for John and Joe is on the submission form, you talk about the ACCF Registry Pinnacle having data from 47 practices. Is

there no way to use the data already in hand, collected electronically, to test these measures?

DR. DROZDA: Well, we do know that the symptom activity was recorded in those practices about 89 percent of the time. What those results are, which is the symptom management measure, are not known, and the sort of re-abstraction or the interrelated reliability, you know, was not available and not conducted as part of that.

But we know that it was reported on the vast majority of patients. So it's feasible to collect, you know. There is a tremendous challenge. You know, there are lots of articles in the clinical trials arena that show that two different doctors assessing the same patients have much less agreement in the same patient over time using the Seattle Angina Questionnaire.

So you know, the accuracy of the Canadian Cardiovascular Society

classification, I just think it's very, you know, that's a very tall bar for us, and you're not going to see 100 percent concordance. You're not going to know what's right.

So it's a very challenging bar for this kind of measure, to try and provide some of the reliability data you're demanding.

MS. ALLRED: I would like to add something, just from a patient point of view on quality. If I'm having symptoms, I don't really care whether my physician is actually asking me at a visit whether the symptoms are there or not. I care whether when I tell him that I'm having symptoms, he's doing something to help me alleviate it. That's quality in my book.

DR. MASOUDI: Absolutely.

DR. DROZDA: And that's a management measure.

DR. MASOUDI: I absolutely agree, and that was what the other measure was all

about, was the management of symptoms, this paired measure of symptom assessment and symptom management. I agree completely.

DR. DROZDA: And what this current measure is looking at is did the doctor then record it in a way that is sufficiently descriptive, that if a doctor had to fill in for him while he was on vacation, he would know how you were doing when you last saw him.

So this is the first step of ultimately the control measure that you're advocating for, that we too are advocating for.

DR. SANZ: It just seems like this should have some data. Before we mandate this nationwide to every doctor, we need some data that either the patient will be more satisfied, the outcomes will be better, there will be less angioplasty or more angioplasty or less MIs.

There has to be something to justify adding to the routine of a physician

and patient during the visit, before we mandate it to everybody nationwide. It's a good research theory.

DR. JEWELL: Well, but there's even a more fundamental issue here. We're talking about using a patient level measure. This is the world where physical therapy struggles in measure development.

We have lots of outcome measures that are well validated at the patient level, but have been never tested at the provider or organizational level, as a way to successfully distinguish quality among providers.

That's the data we're really looking for, not even whether it -- I mean yes, we want to know if it means something in real life too. But even more fundamentally, we have to understand whether any of the measures we consider are successful at distinguishing quality among the providers, because otherwise we have all those unintended consequences all over again.

That's really the data that we're looking for here I believe, not whether in fact it will rock anybody's world, in terms of patient management, although we hope it will and we want to see that too. But first and foremost, we need reliability and validity data that we can distinguish quality at the physician level with this measure, and we don't have it.

DR. DROZDA: Well first of all, this is part and parcel of quality, right. I mean, if you think that a good quality physician is doing a better job controlling a patient's symptoms, then this is a relevant outcome. It's like saying is mortality a good measure of quality? I don't know. I mean it depends, you know. But I think that that's one important point we're trying to make.

There is a terrific report in the Archives of Internal Medicine by John Beltrame, B-E-L-T-R-A-M-E, that shows extraordinary variability from, you know,

across a random sample of population-weighted GP clinics in Australia.

And you can look, you know, to that data to show there's enormous variability. Now that was generated with the Seattle Angina Questionnaire, not the Canadian Cardiovascular Study classification, which also qualifies in this measure. But I think that merely measuring this and documenting that variability will show marked differences in the ability of different providers to control their patients' angina.

Of those patients who, you know, if all of the patients at a practitioner's clinic are having weekly angina, how many of them are seeing a cardiologist or getting reevaluated for different treatment options?

You know, this is the foundation upon which great quality improvement could occur if the goal is to minimize patient symptoms and burden of coronary disease.

DR. PHILIPPIDES: Just one brief

note in your defense, John, wherever you are. I think that we, as physicians, do a terrible job of assessing activity. We give a lot of lip service about the obesity epidemic and the diabetes epidemic, and how 90 percent of the diabetes is all about lifestyle and moving.

Yet I'll bet you if I went into my own medical record, and it's electronic, I wouldn't have any idea as to who's active and who's not, and how active they are. You know, I don't think I even ask most of the time. So I think it is actually a big deficiency in the health care system.

I don't know if this is the best tool to get at it, but anything that gets at it is probably a good start. So I think we should look at it in that light as well.

CO-CHAIR GIBBONS: Okay. I think we have to call the question, and we're going to vote on whether the measure meets criteria for Importance, yes or no.

So the vote 8 yes, 13 no. So we

have finished our consideration of this measure.

DR. WINKLER: Right.

DR. DROZDA: Thirteen people said angina was not important, symptoms and activity level are not important? I just don't understand that.

DR. WINKLER: That's not the question. The question is according to our criteria, was there a demonstrated performance gap, evidence of effectiveness of the particular measure focus. Those were the key issues of our criteria under importance, not that angina is not important.

I mean I think everyone here in the room is agreeing that topic's important, that in practice people should be assessing these things. We're just talking about the measure, as specified in meeting our criteria.

CO-CHAIR GIBBONS: Okay. We're going to now move on to 0076, which is optimal vascular care, and hope that Anne from the

Minnesota Community Measurement Project has given us a lot of flexibility in the original one o'clock estimate that is now 2:40. Anne, are you by any chance out there?

Measure 0076

MS. SNOWDEN: Yes, I am.

CO-CHAIR GIBBONS: There's a lot of support here in the room, recognizing that you were very patient with us. Okay. So I'm the primary discussant on this one, and I just have to get my folder open to the right place.

So this measure, 0076, is the percentage of adult patients ages 18 to 75 who have ischemic vascular disease, and per the previous discussion, that's defined broadly in terms of coronary disease, renal artery disease, carotid disease, peripheral vascular disease, with optimally managed modifiable risk factors.

Those are LDL, blood pressure, tobacco-free status and daily aspirin use. It's an all or none performance measure. For

those who recall the IOM report on performance measures a while back, the IOM report advocated for composite measures, rather than individual measures, the strategy basically being if you're being taken care of and your LDL was good and you weren't smoking and you were on aspirin but your blood pressure was 220 over 120, maybe you weren't really getting good care.

So this has been in existence in the state of Minnesota, and been publicly reported for a number of years. So as far as Importance goes, I think we'll all agree that taken care of blood pressure, cholesterol, smoking and aspirin use in patients with established coronary disease or vascular disease is important. So I didn't have any concerns whatsoever about Importance. Are there questions about Importance?

(No response.)

CO-CHAIR GIBBONS: If not, we'll proceed to the vote. Is this important to

measure?

DR. WINKLER: Somebody on the phone, we're getting a lot of your background noise. If you're not speaking, please put yourself on mute.

CO-CHAIR GIBBONS: Okay, we have 20 yeses. So we're going to move on now to Scientific Acceptability. So the numerator is important to understand. Some of the provisions are pretty straightforward. Aspirin or contraindications to aspirin, tobacco-free, and an LDL of less than 100. I think those are pretty straightforward.

The one that's not straightforward is blood pressure. Now this measure is based on the state-wide organization responsible for guidelines in the state of Minnesota, ICSI, and I should declare my conflict, in that I have served on ICSI committees, and was part of the ICSI process pretty heavily for a number of years.

So ICSI is responsible for

reviewing the scientific evidence, and defines basically standards for the state of Minnesota, and has a long history of doing so. The history of the blood pressure measurement is complex.

At one point in time, as part of this measure, it was less than 140 over 90 unless you had diabetes, in which case it was less than 130 over 80, reflecting JNC 7. Subsequently, ICSI changed that for consistency to be less than 130 over 80 in everyone.

That was largely on the basis of the epidemiologic evidence and the one paper from the Heart Association about coronary disease and blood pressure control. That was not patient data, but epidemiologic data. Then Accord came out. So now ICSI has revisited that, and now the standard is less than 140 over 90, if you have diabetes, and less than 130 over 80 for everyone else.

So it is the flip of JNC 7, and I

personally think that that's going to be an issue from the standpoint of the scientific acceptability of this measure. The rest of the specifications are very well done.

I would urge those of you who have raised a bunch of questions to look at them. They've been time-tested over a long time, help me, ten years? Anne on the phone can help me. Quite a while in the state of Minnesota. So the specifications, as far as ICD-9 codes, exclusions, particularly vis-a-vis the issues we discussed earlier on aspirin, they are very carefully detailed in here.

But I was concerned about the scientific acceptability of the blood pressure measurement. Anne, would you like to comment?

MS. SNOWDEN: Sure. I guess we ran this by our Measurement and Reporting Committee, and they believed that it was important for the measure to follow the guidelines, not for the measure to drive the

guidelines.

So we felt it was important to wait until the JNC 8 weighed in on a blood pressure control for all IVD patients, before changing it and assuming that we should move everybody to 140 over 90 -- less than 140 over 90.

CO-CHAIR GIBBONS: So if I understand that correctly, you are going to change the specifications once JNC 8 is released?

MS. SNOWDEN: Correct.

CO-CHAIR GIBBONS: Sid, I know you can't share any inside information, but do we have a potential target for when that release will occur?

DR. SMITH: Yes. We're hoping that they'll be released in January of 2012, with a preliminary report at AHA in November. The other evidence that I mentioned from the European guidelines, if you look at randomized trials quoted by them for coronary disease,

there are eight.

Only two of them showed a benefit for lowering blood pressure with a goal of 130. One of them had actually reached 123, with a control at 133. The other reached 135. Four of the trials showed actually no benefit and two showed partial benefit.

So the evidence for lowering blood pressure to less than 130 in coronary disease is questionable right now. So I think Minnesota should be complimented on their decision to stay with 140 over 90, and hopefully -- I mean, the JNC and ATP-4 are just challenging all of these targets.

CO-CHAIR GIBBONS: It's important to us they haven't. It's 130 over 80, except if you have diabetes. That's when it's 140 over 90.

DR. SMITH: I thought I heard the report from Minnesota on the phone say that they decided to stay with 140 over 90.

CO-CHAIR GIBBONS: They're still

there. Anne, clarify that. As I read this, you're staying with the existing Minnesota guideline, which is 130 over 80 unless you have diabetes?

MS. SNOWDEN: Correct.

DR. SMITH: I think that's potentially a problem, unless there's evidence, I mean, to support it. That would be -- but it's an opportunity for Minnesota to actually split it up and look at whether patients at 130, less than 130 over 80 actually do better than those held at 140 over 90, and report back on this.

But in the absence of evidence, one thing that's good is that they've got a cut point of 75. So they're not applying this to really older patients. I think that's good. But I would have concern about holding folks' feet to the fire.

You know, to get less than 130 as opposed to 140 may mean additional medicine with more side effects. It may mean higher

cost. So I think there's some considerations about --

CO-CHAIR GIBBONS: So NQF staff, we need some guidance here. The measure developer is expressing a willingness to change to JNC-8 when available, but that won't likely be before January 2012. At this point, we should look at the measure as submitted. Is this correct?

DR. BURSTIN: Yes. Look at the measure as submitted, and look at the current evidence and guidelines, I'm afraid.

DR. SMITH: But I think the current AHA guidelines don't recommend 130 either. We don't have -- I think it's --

CO-CHAIR GIBBONS: We have one paper that I have to admit is a bit of an embarrassment, because it actually came through the AHA system while I was a member of the leadership group, and I couldn't read the thousands of pages coming through my email at that point in time, so I missed it.

That paper was on coronary disease, and actually favored a goal of less than 130 over 80.

DR. SMITH: But it was a scientific statement, and it did not make it in -- the guideline committees did not act on that.

DR. KOTTKE: So Sid, what's the current position of AHA on blood pressure targeted?

DR. SMITH: 140, as stated most recently today in the women's guidelines. They were just released.

CO-CHAIR GIBBONS: 140 over 90. Okay. So with that discussion, Karen, did you want to comment?

MS. PACE: Yes. I'm just saying all of this, it sounds like, is a lot of concern about the evidence of the target that's specified, and if that's a concern, we probably need to go back and vote on Importance, which is where we talk about the

clinical evidence that supports a measure.

CO-CHAIR GIBBONS: I would respectfully suggest that we move forward, because if we move forward and this is the only issue, the measure developer then has an opportunity to change. Whereas if we downgrade it on the basis of Importance, it's going to be much more difficult. So that's why I put it this way.

So this is under Scientific Acceptability. Any other questions before we vote?

(No response.)

CO-CHAIR GIBBONS: Please vote.

So 1 completely, 13 partially, 5 minimally and 2 not at all. So now we're going to move on to Feasibility.

PARTICIPANT: Usability.

CO-CHAIR GIBBONS: I'm sorry. Made the error again. It's a clear indication that we need a break, when the Chair starts to get those out of order again.

So the measure is clearly in use. It's in use in the state of Minnesota, reported by a large number of practices, and a large number of patients. There's data in the submission that goes over, you know, vast numbers; 2010, 96,000 patients, that kind of thing.

So there's plenty of data on use. But it's important to point out that that use reflects a commitment that's occurred gradually over time.

As Anne stated earlier, in the introduction and her comments, this started out as administrative data and then it evolved to be clinical data, and I think the groups who have undertaken this have generally done a very good job, and there's a large number, large penetration in the state.

I think there is a concern, from my standpoint, from the standpoint of that use, will others be as adept at doing it? Obviously, there's issues of harmonization

vis-a-vis some of the standards that are set in here, some of the definitions, for example, for aspirin, which I've alluded to, and the contraindications to aspirin, that overlap heavily with some of our other measures. Likewise, some of the issues regarding LDL.

But certainly in the state of Minnesota, this is alive and well and very much usable. Yes?

DR. MAGID: So we were just talking about the fact that we generally like this, because it's saying these are all things that need to be addressed for the same group of patients. So that's good. So if we like -- and, as George pointed out, there's lots of room for improvement, because not that many people are doing everything.

So all those things are really good. So if we have just -- if we're picking at this one issue, like you know, maybe the blood pressure target, how do you -- we may not say that we think we want to endorse this,

but we want to give feedback that we like this a lot, and if you just change one or two things, we would really like it a lot. How do we do that? What's the -- Karen, what's the way to give that message?

MS. PACE: Okay. A couple of things. Number one, you've given the message by stating so. But we can make it be even a little bit more. If indeed you don't feel you can support the measure as is and you would vote against it under its current state, you could potentially offer the condition that if the, you know, blood pressure target value was changed to X, then you would support the measure.

That sends a very powerful message, then puts it in the developer's hand to either act, respond or not, and they can tell you what they think and you've made it real clear what you will accept and what you won't.

CO-CHAIR GIBBONS: Yes.

DR. RUSSO: One other comment. I think this is one of the measures that are probably to have some. They do talk about risk adjustment, but I could see if this has been tested in a certain area, that really I could think of certain areas that may be very difficult to achieve all of those goals in certain patient groups or socioeconomic status.

They do comment about that. But I think this might be an important one to look at risk adjustment down the line.

CO-CHAIR GIBBONS: Well, there is data in the submission on risk adjustment, because that has been a concern in the state, and the bottom line is that the risk adjustment model, after it was carefully established and applied, created fairly modest changes in the data.

So they do provide the risk-adjusted data to the physicians. I think I have that right, but the publicly reported

data is unadjusted. Is that right, Anne?

MS. SNOWDEN: That's correct.

CO-CHAIR GIBBONS: Now by the way, Minnesota is not as lily white as everybody thinks. I know it was popular during the health care reform debate for that frequently to be stated.

I would like to point out that the latest census data is not out. But as of the previous census, in terms of percent Caucasian population, Minnesota did not rank in the top quintile of the country. It was actually number 13, and it was more diverse than Kentucky, which most people don't realize. We are becoming more diverse. So I'm quite happy in telling you we'll be lower than 13 on that ranking.

And contrary to what people on the Hill said, we do have poor people, and Tom can attest to that, as well, being from the Twin Cities area.

DR. SMITH: I like this measure,

though. You know, I think health care systems that achieve this type of control and prevention should be recognized. So my only concern is just with the discriminatory factors, the goals.

MS. PITZEN: This is Collette from Minnesota Community Measurement. May I add a comment?

CO-CHAIR GIBBONS: Certainly.

MS. PITZEN: I just wanted to reassure the group. We went through something similar with our diabetes composite. When that measure was being presented at NQF, the Accord study on blood pressure came out two days earlier. We did work through our processes. The ICSI guideline were changed, and we turned that around really rapidly.

So as soon as we had the support to do that, we went forward and did that. So I would imagine this measure would be the same.

DR. SMITH: It would be

interesting to look at the data for those that did have control of less than 130 over 80, as opposed to those that were 140 under 90. I mean it's not randomized, but there might be some interesting findings here, whether the outcomes are different.

MS. SNOWDEN: Yes, we can do that.

DR. KOTTKE: Yes, it is. I think it -- this is Tom Kottke. Don't you report on your website both levels, 130 over 80 and 140 over 90, optimal vascular care?

MS. SNOWDEN: No. Actually, optimal vascular care measure only includes the one blood pressure currently. But what you may be referring to is the HEDIS measure, which is controlling high blood pressure of less than 140 over 90 for people who are hypertensive.

DR. KOTTKE: Okay. Health Partners used the report.

MS. SNOWDEN: We do have the actual individual values of all the patients.

So we could do some analysis on 140 over 90 versus 130 over 80.

CO-CHAIR GIBBONS: That's a small sample size at 90,000.

DR. SMITH: I think there's a paper there, yes.

CO-CHAIR GIBBONS: Okay. I think we've had enough discussion. Usability.

14 completely, 7 partially. Finally, Feasibility. All of this information is generated from the process of care, and simply needs to be extracted. It is amenable to EMRs. There are very few exclusions, because the contraindications have been rolled into the definitions, as I mentioned, for aspirin, for example, and as far as inaccuracies and errors and unintended consequences, there's quite a long description in here where basically the data's been carefully audited.

Groups have to have a 90 percent accuracy rate, and they get re-reviewed if

they haven't. So it's a well-established, well-oiled process, which I think has learned a lot over the course of time as to revisions in the definitions and the data abstraction.

I think it should be pointed out again that this has a long history. It started out as administrative data, then became clinical data, and it's not entirely clear to me from the standpoint of the national rollout, just how many groups would be able to take up that challenge right off the bat. So any other questions or comments about Feasibility?

(No response.)

CO-CHAIR GIBBONS: Okay. If not, let's vote.

18 completely, 3 partially. Okay. So, finally, we get to the issue does the measure meet all the NQF criteria, and I think in light of the previous discussion, it's with -- as submitted with the current blood pressure targets, which I think multiple

Committee members are already expressing support for the measure in general, but concern about that specific item, and the potential for let's say a rollout prior to JNC 8, which would have a different target included in it.

So let's vote on this final question at this point.

DR. KOTTKE: Ray, while you're voting, in 2006, which is the last reported year with both, the higher blood pressure -- the optimal CAD care measure with 140 over 90, with 73.5 percent of patients who are members of Health Partners. With the more stringent, it was 55 percent. So it's almost -- that's an 18 percent difference, 18 percentage points difference in people meeting the optimal.

CO-CHAIR GIBBONS: That's very helpful, Tom. So the measure is approved, with a vote of 13 to 7.

DR. WINKLER: I need to clarify, because you've just approved this measure with

a blood pressure target of 130 over 80. Yes, that's what you just did. So that's why I want to be sure we're all on the same page.

CO-CHAIR GIBBONS: Maybe we should vote again.

DR. RICH: I thought that we were approving it with that modification?

DR. WINKLER: That was the first vote.

CO-CHAIR GIBBONS: Oh, I'm sorry. Then the Chair takes full responsibility for that, if that wasn't clear. We have to vote on the measure as submitted, and as submitted is 130 over 80, unless you have diabetes, and then it's 140 over 90. We can send them a message, but they have to then come back into the system.

DR. RICH: Could we revote on that?

DR. WINKLER: We could do two votes.

CO-CHAIR GIBBONS: We could do two

votes. Well, that's a good idea. David, that's a good point, and we can do that. So let's vote first on the measure as submitted, yes or no.

So now, and there's been quite a shift. We have 5 yeses and 16 no's, based on the measure as submitted. So now, I think in light of David's question, I think we -- right, we have the prerogative to do this. So David, what blood pressure would you like to see?

DR. MAGID: 140.

CO-CHAIR GIBBONS: 140 over 90, for everyone.

MS. PITZEN: Can I ask for clarification? Do you mean less than 140 over 90?

CO-CHAIR GIBBONS: Sid or somebody else help us? How exactly is it worded in the current guidelines?

DR. SMITH: I'll check. I believe it's less than 140 over 90.

CO-CHAIR GIBBONS: Okay. So less than 140 over 90 for everyone, regardless of diabetes. Is that right, David?

DR. MAGID: Yes.

CO-CHAIR GIBBONS: Are there any comments or discussion about that modification?

(No response.)

CO-CHAIR GIBBONS: Now I would point out, just so we're clear, that existing AHA guidelines are in line with JNC 7, so that they still have a stricter target of less than 130 over 80 for -- help me Sid, diabetics --

DR. SMITH: CKD.

CO-CHAIR GIBBONS: CKD.

DR. SMITH: The secondary prevention ones that you and I are working on are probably still being reviewed.

CO-CHAIR GIBBONS: I wasn't going to go there, Sid. So, okay. So with that modification, any questions or suggestions or comments? We're now going to revote, to send

this message to the measure developer. Can we put up the last question?

DR. WINKLER: Just revote it.

CO-CHAIR GIBBONS: Okay. So we're now going to revote with that change.

All right. So the vote with that modification, which obviously Minnesota Community Measurement would have to accept, is 19 yeses and 1 no. So Anne, is there any other information we can provide you besides that feedback?

MS. SNOWDEN: It would just be helpful to get the actual evidence that you're referring to, to justify that change, and we would be happy to change the measure accordingly.

CO-CHAIR GIBBONS: Sure.

DR. SMITH: Yes. The best place to look would be the 2009 European Hypertension Update. If you send me an email or if you give me your email address, or maybe I can get it from staff --

CO-CHAIR GIBBONS: We'll get it to you from staff, Anne.

DR. SMITH: I've sent that to Ray today, so it's in there.

CO-CHAIR GIBBONS: All right. I think at this point the -- yes, anybody else on the phone?

MS. SNOWDEN: I was just saying thank you for that.

CO-CHAIR GIBBONS: Okay. At this point, we're going to take a break. Let's see. We'll need everybody back. We'll take a 15 minute break. So we'll need everybody back at 3:25.

(Whereupon, the above-entitled matter went off the record at 3:12 p.m., and resumed at 3:32 p.m.)

CO-CHAIR GIBBONS: I've been assured that the ventilation system is working. Okay. I want to assure people, I've been assured that the ventilation system is working. All I can tell you, it could be

worse.

There was a famous meeting of the AHA Program Committee in Dallas, Texas. The outside temperature was 108 degrees, I kid you not, and the air conditioning in the building failed.

So by the end of that meeting, there were people who were down to the bare essentials, in terms of clothes. So we are -- we're not going to get there, I'm told.

We're going to be fine, but we've got to move now to Key Myocardial Infarction Measures in the Emergency Department, and I believe these are all CMS measures. So we're going to allow somebody, hopefully representing CMS, somewhere in the back there, to comment for three to five minutes, to open up this section.

DR. WINKLER: Probably not here, but on the phone. Is somebody from either CMS or Oklahoma on the phone to introduce your measures?

DR. BRATZLER: Yes. This is Dale Bratzler. I'm here.

DR. WINKLER: Hi Dale, thank you. Go right ahead.

CO-CHAIR GIBBONS: Thanks for being with us. We are, as you can see, are a little bit behind the planned two o'clock start on these, but we appreciate you introducing them.

DR. BRATZLER: Okay. So I'm going to give very, very brief introductory comments. I apologize, I'm driving. I have a flight to catch. So very briefly, the Emergency Department AMI measures that were initially developed, there are two different sets of measures.

One set are those measures that were initially developed for hospital inpatients. Those patients are identified by a principal diagnosis of acute myocardial infarction. The second group of measures were developed as part of a process related to

rural-sensitive measures.

In other words, there was an entire separate round of measure development that was looking at measures that primarily applied to hospitals that typically did not admit acute myocardial infarction patients, so they were considered rural-sensitive measures. I'm sorry. Can you guys hear me okay?

CO-CHAIR GIBBONS: You are loud and clear.

DR. BRATZLER: Okay, very good. I'm getting a lot of feedback, so I can't tell. So you're going to see that there's some overlap of the measures. I talked briefly with NQF about this.

There for instance is a measure on a use of aspirin for acute myocardial infarctions, and there's a long-standing ACC-supported measure that Dr. Fred Masoudi can talk about, that focuses on patients who are admitted to the hospital with an acute MI.

But since most small hospitals

don't admit patients with acute MI, they transfer them. There is a similar measure that focuses on patients with acute MI or chest pains, who are then subsequently transferred to another facility for ongoing acute cardiac care.

So that just gives you a brief background on the development of the measures. The measures, there is some overlap. Dr. Masoudi really is the champion for the inpatient measures and can speak to those better than I.

The outpatient or the Emergency Department measures that focus on small hospitals were developed initially as a part of our program, looking at rural-sensitive measures, and then subsequently when the Tax Relief Act was passed and CMS had to develop performance metrics for hospital outpatient departments, it made sense to include some of these rural-sensitive measures to evaluate care that was given in hospital emergency

departments for patients who are then subsequently not admitted to the hospital but transferred somewhere else for care.

I'll be happy to answer questions about the individual measures as we go.

CO-CHAIR GIBBONS: Thank you very much. We're going to go --

MS. ALLRED: Can I just ask a question?

CO-CHAIR GIBBONS: Sure. Go ahead.

MS. ALLRED: So is it Dale, is that right? Dale, that's really interesting background, and it makes sense for some measures. I'm specifically talking about the issue of rural hospitals and transfers. So a measure that looked at how quickly you transfer a patient for, say, primary PCI, if you're a non-PCI capable hospital. That makes a lot of sense.

But some of these measures are really intended to apply to the broad spectrum

of Emergency Department patients, and not specifically this situation where you're transferring the patient. They're measures where you broaden the population beyond MI, to a broader class of patients.

So can you explain the thinking on that, because it's a little different from -- the way it's going to be applied is a little different from what you presented?

DR. BRATZLER: Yes. So I think I can explain, and so we've had this conversation. I'm going to use the aspirin measure as the example. Since there are two separate aspirin measures, one that applies to inpatients who are admitted with acute myocardial infarction.

That measure has actually been in use by CMS for many, many years. It was initially developed literally years ago under the Cooperative Cardiovascular Project, and has been used for the inpatient population of acute MI patients ever since.

It's one of the measures that hospitals submit as a part of the hospital reporting system for the annual payment updates, and the cases are identified based on a principle discharge diagnosis of acute myocardial infarction. So we never see a case if they don't an acute MI discharge diagnosis.

The other measure on aspirin was developed, again, when we started the rural-sensitive project, and we were looking for performance metrics that would apply to hospitals, to rural hospitals that we knew were not routinely admitting MIs.

So rural hospitals never had patients eligible for the aspirin measure before, because it only looked at inpatients. So we were looking for measures that applied in the outpatient setting.

And then, as I mentioned, the Tax Relief Act required the identification of new measures that focused on hospital outpatient departments, and so those rural-sensitive

measures made a lot of sense for rural hospitals that were transferring.

So the denominator population that's identified for the aspirin measure in rural hospitals includes patients who come in with suspected chest pain or acute MI that's felt to be cardiac in origin. So chest pain that's cardiac in origin or acute MI.

So the denominator population is different, and we identify the cases through different mechanisms. Since there is no inpatient admission, we don't have any discharge diagnosis claims by which to identify the cases.

So I guess you could argue that that aspirin measure should be expanded in the inpatient setting, to look at a patient that came into a large hospital that does admit MIs. But that's how the measures were developed over time.

It's important because of legislation, different legislative

requirements for measures that focus on different settings of care, and in part based on a different track for development of the two different measures. I hope I've explained it.

DR. MAGID: Oh, we'll talk more about it later. Thanks.

CO-CHAIR GIBBONS: Okay. We're going to then start down the list of the Emergency Department measures. 289, Median to ECG, and this is Carol.

DR. WINKLER: Microphone.

CO-CHAIR GIBBONS: Mic.

Measure 0289

MS. ALLRED: Okay. Can you hear me now? The title of the measure is Median Time to ECG. The description is median time from emergency department arrival to ECG, performed in the ED prior to transfer, for acute myocardial infarction, AMI, or chest pain patients with probably cardiac chest pains.

That seems to be fairly self-explanatory. Of course, it's important. It's a definite step in the process, and it's a diagnostic tool and it impacts a large number of people. There is a gap in performance that is identified, and part of that has to do with getting everybody to ECG. Part of it has to do with the median time of performance. So there is some room for improvement. With that, I think the rest of it's pretty self-explanatory, and I will be happy to ask questions, answer questions.

CO-CHAIR GIBBONS: Okay. Questions about Importance?

DR. KING: Excuse me. What did you cite as the gap, where there was a need for improvement?

MS. ALLRED: Well, they cite the gap in the people being seen and identified early on. So the improvement in quality.

But I also was looking at the summary of the median time to ECG, and if you

look at the difference between the maximum and the median, the maximum is like 540 minutes and that's capped. So there's obviously a big disparity in performance in emergency departments until time of ECG.

DR. KING: I think it's a little misleading. I don't have that -- I meant to bring that sheet. I printed it out. But if you actually look at the difference by quartiles or quintiles, there isn't huge differences. They're on the order of one to two minutes between them, and --

MS. ALLRED: Actually, even with the quintiles, there's a difference for the most part between, you know, if you go to the middle of it, of course it's pretty close. But the rest of them, there is a disparity there, a gap in the time.

DR. WINKLER: What page are you on?

MS. ALLRED: I'm on page three.

DR. WINKLER: It's 1B.2.

DR. MAGID: There are going to be some measurement issues for which this becomes a real issue, but I don't think that's what we talk about at this point.

MS. ALLRED: Right.

CO-CHAIR GIBBONS: So the 25th percentile, for example, is 14 minutes and the 75th percentile is five.

MS. ALLRED: Right.

PARTICIPANT: So that's a little more than three minutes.

CO-CHAIR GIBBONS: Yes. So I think there's opportunity for improvement. Other questions on this?

DR. WINKLER: Yes, I have one question. Really two questions to the group. This applies to patients who are going to be transferred. Is this the kind of measure that applies to anyone who comes into an emergency room with chest pain or whatever?

I mean I don't understand the limitation for this particular measure, as

perhaps a measure of performance in the emergency room around time. Then my second question is, is using the measure of median time useful and meaningful to people, compared to perhaps a percent of patients within a certain, you know, what the appropriate time frame is? Is that a readily understood kind of concept for understanding the performance of an emergency room?

CO-CHAIR GIBBONS: Dale, do you want to comment on how this one got going? It looks to me like maybe it had to do with the origin of this.

DR. BRATZLER: Yes, I will. So the conversation about median time versus proportion has been discussed many times before, and I think, you know, from a consumer perspective, proportion may be a better measure.

But I think where we came down on this particular measure was sooner was better than later. We weren't sure that there was an

exact number within which we should set a proportion limit, so we went with median measure as a measure of performance improvement.

You know, I can't argue the point that a measure could be applied to any emergency department setting. I certainly can't argue that.

I simply highlight that measure was developed as a part of a process of developing performance measures for real hospitals and then subsequently hospital outpatient departments, and you could make the case to expand the denominator population to patients who are subsequently admitted to the hospital also.

DR. MAGID: Well, I mean, for the purposes of NQF, this would not be limited to transfer patients alone. We're being asked to consider this for all comers to the emergency department.

DR. WINKLER: Well, one problem is

how it's specified. If the specifications include those limits, then it is limited.

DR. MAGID: Is that how it's specified?

DR. BRATZLER: Yes, and that --

MS. ALLRED: It is specified. Patients who were transferred.

DR. BRATZLER: Yes, that is correct.

DR. KOTTKE: But isn't that because the patients who are transferred aren't admitted?

DR. SNOW: Yes. This is a measure that can be applied to people who are going to be transferred, as distinguished from all those other things for people who are going to go upstairs, and those measures are timed to initial insertion of catheter.

That kind of stuff applies to people who are staying, but they don't apply to rural, small hospitals, whose job is to get the people out of there and to do that, you

need an EKG. How quickly can you get the EKG? That's the concept here. But how quickly can you get the EKG and the big hospital is equally true. It's just that we're not looking at this that way.

DR. AYALA: But can I mention that in the hospital, they're also timed for how fast they're going to get to PCI or thrombolytics. So that EKG is sort of rolled up into the operationalization of the process, to get to that end point.

So for the inpatients, I think it's less important to separate this part of the process out, as opposed to the ones that are going to be transferred, because the hospitals that are transferring the patient aren't under the gun for the time to PCI time, for example.

DR. SNOW: Exactly. But the PCI patients will have had an EKG done. It's just we don't document it, because we're doing the other. But for the guys who are going

elsewhere, this is the measure.

DR. SMITH: I'm not sure I understand. It seems to me, first of all, we are looking at rural hospitals, is that right?

CO-CHAIR GIBBONS: Well, we're just looking at hospitals at transfer.

DR. SNOW: Transferring hospitals, not specifically rural.

DR. SMITH: Doing the EKG, whether they're going to be transferred or not, seems to me is important, and a timely EKG, and that reflects quality. In fact, the decision about transferring right now is dependent upon some EKG findings, our latest update on the PCI guidelines, which I chaired.

So criteria are diffuse, ST segment elevation from two studies and early congestive heart failure, they should go soon after fibrolysis. But is the idea that we're only looking at patients that we think -- part of knowing that a patient's going to need to be transferred is having the EKG.

So I don't know how we limit the population to only those that we're going to transfer, before we know we're going to transfer them.

DR. KOPLAN: Well, if it's going to be a measure, it will be patients who were transferred, and then they'll go back and look at it, right? It's not going to be prospective. It will be after the fact.

DR. RUSSO: I would agree too. Why not expand it? I think it's fine this way, but it might be useful for each center, you know, the time to thrombolytic therapy, to PCI, to be able to look back and say where their time delay was. So why not expand it, or is there a reason?

DR. KOPLAN: And also maybe on a small level, the patients who had a big delay might be less likely to get transferred, because they might not be candidates anymore or something like that. So there might be a selection bias issue.

MS. ALLRED: The guidelines that they quote in here state that the EKGs should be done within ten minutes and seen by a qualified emergency physician.

DR. SMITH: You're absolutely right, and the level of evidence for those guidelines is C, opinion. We don't have any randomized trials comparing 12 to 8 to 15 to 20.

But you're absolutely right. The guidelines recommend doing the EKG within ten minutes, and in many -- and we actually are doing them in the field, when EMS arrives and getting them transmitted.

So I think being sure that our hospitals that are seeing patients with myocardial infarction do EKG quickly is something we ought to be very certain about. How we get from that down into a group that they suspect may need to be transferred, without looking at the EKG, I'm uncertain about.

DR. SNOW: No, their cart's before the horse.

DR. BRATZLER: Again, I just want to highlight, that the denominator population here is limited to patients who are transferred. So I hear the argument. I understand the discussion, but you could make the case to apply it to any patient that showed up in any ED with chest pains. But for the purposes of this group of measures, they're looking at patients who are transferred for cardiac therapy.

DR. SNOW: And looking retrospectively at how long it took to get that EKG.

DR. SMITH: What about the patients that weren't transferred and died in the hospital who didn't get an EKG in time and might have benefitted from being transferred?

DR. BRATZLER: Yes. That group is missed, clearly. I will tell you, without question, that when we first rolled out this

measure, there were a number of hospitals that still had to call somebody in to do an EKG. They actually did not have staff trained in the hospital to do an EKG.

DR. RUSSO: And how would you take -- you bring up we're doing EKGs in the field, so is that time zero to the ER? Because they might not get it in the ER; they'll get it -- do we count that EKG?

DR. SMITH: It would be repeated right when they arrive. They should again. But by that time --

DR. BRATZLER: If it's done in the field --

DR. MAGID: If it's a STEMI, you'd just go right to the cath lab.

DR. SMITH: Well, we activate the lab, but then -- I guess about cath, that they're coming into Siler City or a hospital that doesn't have a cath lab, they alert us about transfer having that information. So it's very helpful to get the EKG promptly.

DR. JEWELL: So if I could ask the measure developer, the data that you have about the gaps, where you have the percentiles, that was looking only at patients as defined in the denominator?

So the 41,000 eligible cases that you used, those were only patients who were transferred, or those were just the population of patients in the ED with chest pain? Can you hear me?

CO-CHAIR GIBBONS: Are you still there, Dale? I think we lost him.

DR. JEWELL: Well, so the reason I asked the question was that if in fact that data is not just patients who were transferred, then that's a further argument to expand the measure.

DR. MASOUDI: These data are based on the measure, as specified.

DR. JEWELL: Okay. That's what I wanted to know. Okay, thank you.

MS. JONES: This is Rebecca from

the Oklahoma Foundation for Medical Quality, and I would comment that it is based on the population of patients who are transferred.

DR. JEWELL: Thank you.

DR. MAGID: And that makes sense, in the sense that, I mean I've seen the Action data on time to ECG and it doesn't have this kind of distribution.

CO-CHAIR GIBBONS: I would just point out that for a hospital receiving STEMIs, although it's important obviously to do an ECG, the measure is rolled into time to thrombolysis or time to PCI.

So it's irrelevant. I mean what you want is the end product, and anybody looking at the end product is going to look at the components and figure out where the problems are.

So to have two measures out there, for example, and your time to ECG is great, but your time to PCI or time to thrombolysis is poor, well, that's doesn't make any sense,

because the measure that really matters is the time to reperfusion.

So I really don't know that we want to expand this to STEMI-receiving hospitals, because I really think it's irrelevant.

DR. MAGID: The other thing that's a little bit confusing, and it's a shame that Dale's not on the phone, but when he describes -- he says it's the patients who are being transferred.

Well, the patients who are being transferred are patients with STEMI. Yet the denominator is this much broader classifications with chest pains. So it doesn't make sense why it's not --

CO-CHAIR GIBBONS: At least in our region, it's not just patients with STEMI being transferred. I don't know. Others can comment, but it's a broader group of patients being transferred, where they get an initial ECG and say "Whoops, this looks like a problem

with their heart. Out of here."

DR. BRATZLER: Yes, this is Dale. I'm back on. I'm sorry. I'm in transit. Rebecca, I know you're on the call. I am correct, that this measure only applies to patients who are actually transferred?

MS. JONES: Right. Now the chest pain and the ECG measures will apply to any patient that is seen in the ED and discharged and transferred to another facility.

The only one that is track-specific or specifically for patients who are transferred for PCI is the timing measure for transfers for acute coronary syndrome, or acute coronary intervention.

DR. BRATZLER: So the point is is that if a patient came in with severe heart failure and chest pain and were transferred, they would be in this measure.

DR. SNOW: Chest pain patients with probable cardiac chest pains. So it could be from any potential cardiac source.

Congestive heart failure would count.

DR. MAGID: Dale, another question. Could someone else -- another question for you. Since I reviewed some measures that have this denominator of patients with probable cardiac chest pain, you know, they always refer back to Appendix A, Table 1.0, and I could never find that in any of the documents we had.

So you know, I think when you've got, you know, when you've got patients being admitted to the hospital for MI or for ACS or for angina, that all makes sense. But there's this broader class of codes of just chest pain, and you could have trauma and have a primary diagnosis of chest pain.

So I found it very hard to understand really what the validity of that denominator was, since we weren't really provided that data.

The only information that I did find was in this report that was sent from a

Health Services Advisory Group, and in that report, it said that for all the data measures that we're about to talk about, and all the data elements that were in it, it said the highest mismatched data element on an individual measure was probable cardiac chest pain.

So it was identified as the least valid of all of the things in this larger set. Can you speak to that?

DR. BRATZLER: Yes. So the appendix I think that you're referring to is just a list of possible ICD-9 codes that reflect chest pain codes. But we then have a data element, a chart of extracted data element, to see whether or not there are terms in the chart that would exclude the case.

So the example of trauma. If we find somebody where the physician documented trauma to the chest or chest wall pain, other things that suggest that it wasn't cardiac of origin, the hospital is expected to answer no

on that data element and exclude that case from this particular measure.

So it is a chart-abstracted measure, and you know, with all of our chart-abstracted measures, we have some degree of mismatch between the abstractors and secondary review, and that's why we continuously update the data dictionary, to try to address those issues.

But there is no ICD-9 code that is strict enough that we can rule out, you know, the non-cardiac chest pains. So we have the data element.

DR. MAGID: So that's very helpful. But this report is dated January 2011, the one that says that the highest mismatched data element was probable cardiac chest pain.

DR. BRATZLER: Did it mention --

DR. MAGID: It was a mismatch 20 percent of the time.

DR. BRATZLER: I honestly didn't

think it was mismatched that frequently, but again, we -- and in fact within the past few weeks, have made some additional updates to the data element, to try to address some of these discrepancies in chart review.

MS. JONES: Right, and this is Rebecca. I would point out that that report is one on initial validation of measures, and consequently, since then we've provided numerous educational conference calls to providers, and we've got our Q and A system that's up and running.

So we've definitely seen a significant decrease in the number of questions related to that measure. So we really expect the trends, as the newer monthly reports come out, trending down on that.

DR. MAGID: Okay. The report's dated last month.

MS. JONES: Right, and that was the first time that they had compiled the data for the entire measure set, and these measures

have been implemented for three years.

DR. PHILIPPIDES: Basic question. I'm assuming patients who die in the first emergency room, who are not transferred out, would not count in this measure? You could argue that that's a failure of therapy, especially if there's a delayed EKG. But that would actually not count against the initial hospital.

DR. BRATZLER: Well, I guess you could make that point, and you know, what we've done is identified a sample of patients that are transferred, and you know, that population of patients simply isn't in the denominator, because we'd have to figure out a way to identify all of the patients that might have been seen in a ED.

DR. MAGID: Can I ask a question just slightly out of order, but I think it's related. You know, when you think of something like the arrival time at the hospital, that's pretty standardized. There's

someone who always records it in a specific way. The same thing with the time when you leave the emergency department.

There's no one who ever records -- or I shouldn't say no one ever, but typically we're relying on the time stamp of the ECG, as opposed to a time that's recorded by the technician who takes the ECG. Right. So yes. So we have four ECGs in my ED, and I actually went and looked at them.

I put them all next to each other, and two of the four actually read the same time, the other two were off by, one by a minute and the other by three minutes. So I'm just wondering what kind of standardization, and this is, you know, maybe it's a high volume center that has four ECG machines.

But the point is that obviously they weren't all reading the same time, and they couldn't possibly all be reading the correct time. So I'm just wondering what kind of standardization and validation that you've

done of that specific data element, since it's so key to this measure?

DR. BRATZLER: Rebecca, do you want to speak to the specifications about how the hospital has to abstract this data?

MS. JONES: Right, and that was one of the ones that also was a higher mismatch rate on the data element. But on that, we specifically provide instructions and guidance on scenarios, such as if they have multiple times for an ECG. We actually have them default to the time on the ECG strip, unless there's clear documentation that it was an error.

We also provide instructions on if there are multiple ECGs done, which one to take first. Likewise, we also include the timing as we accept pre-arrival ECG in the field.

That was something that we saw questions on, is that their times were off or that they knew that they were off, and once

again, we just provided guidance in the specifications on which time to select, and encouraged them to try to make that a routine part of their operations and their ED.

If they had four ECG machines, you know, put that in part of maybe a checklist of when they do their crash cart checks, to go by and make sure all the ECG machines are timed together.

DR. AYALA: You know, we worked on this at the institution where I'm from, and it's about synchronizing the clocks at every step of the way, from door to balloon, for example. We actually ended up getting atomic clocks, because you really cannot -- you cannot rely on what you're recommending here, to default to a particular machine time.

You really have to have the clock synchronized, and I didn't think of that in this situation. But that's really critical.

MS. ALLRED: You should be able to calibrate each of those machines and know that

they're fairly accurate. I would expect that that would be a requirement, that they were done frequently.

DR. AYALA: But it's not just the machine itself. It's how the machines are timed compared to the timing of the entrance of the patient into the ED. It's the synchronization of the clocks along the whole process.

MS. ALLRED: The other thing that jumped out at me when I was going through this, it talks about the time to ECG, but it does not mention in the measure the ECG time to when it's read. You know, it's going to have to be read by somebody for it to go into effect.

MS. JONES: Right, and I think the reason why we don't have that is it's a lot more difficult to capture the time of interpretation by a physician, and we, I think, had the presumption that at least if we were tracking the time to the test, and could

encourage facilities to get as close to that zero time as possible, the report was there, ready for someone to interpret it, and therefore use it in the diagnosis and plan of care and treatment for the transfer.

CO-CHAIR GIBBONS: So I would just point out in light of this discussion that Table 2, which I'm looking at in one of the reports we were sent, from Quarter 2 of 2009 to Quarter 1 of 2010, said that the top-ranked mismatched data element was the documented date and time of the earliest ECG.

That was wrong 23.4 percent of the time, and the earliest documented time the patient arrived at the emergency department was number two, in terms of mismatched elements, and that was wrong 19 percent of the time.

MS. JONES: Right, and I think that part of the --

(Simultaneous speaking.)

CO-CHAIR GIBBONS: So if I

understand correctly, were you hoping that's better?

MS. JONES: -- new measures that have rolled out with, you know, new data elements. These hospitals have never been required before to track and to trace, and so getting them to consistently get their practitioners and providers to, you know, document this has been a challenge.

But I think once again that we've provided, you know, instructions on what's acceptable to meet the criteria, and you could see hospitals indicating the things that they're doing to try to change practices or change documentation to become more consistent in their practice.

DR. BRATZLER: This is Dale. I apologize, I'm going to go through airport security and then I'll call back in.

CO-CHAIR GIBBONS: All right, thank you Dale. We're all smiling, because we've all been there.

DR. BRATZLER: Yes.

DR. MAGID: I wonder if, you know, to summarize a couple of the issues that have come up. One is is that the evidences for time to reperfusion, not time to ECG, and that we've got major problems with many aspects of this measure, both the time of arrival, the time of ECG and the denominator of patients with probable cardiac chest pains. So it seems like there are a lot of problems with this measure.

DR. AYALA: I just want to add to that, and I think what we really want from this -- I think what they're trying to get at this measure is how fast does the patient get out of that ED? How fast is he transferred? So it's almost like they really want to check not time to EKG, but time to transfer, which is really getting closer to that intervention.

DR. SNOW: But in defense of the measure, that's not the goal of this measure. If you're talking about care, it's time to

reperfusion. That's not a question. But that's not what this is looking at, because the small hospital is not going to be doing the reperfusion and they don't control it.

This is a measure for small hospitals and how soon they can process that patient, and yes, it's really time to get him back in the other ambulance. But they're not measuring that. They're measuring something before that, and perhaps they can be criticized if you think from the care perspective.

But, gee, these are cardiac measurements, and this is the one that they can get, and it's one that yes, indeed, there are problems with the accuracy of the timing and all this and this.

But those are things that can be fixed, and they can make it a reliable measure of one point in the care spectrum. That's what the goal is here, I think, of the developers.

DR. AYALA: But I would argue with that, because like when you look at time to PCI, for example, time to EKG is really important. I mean you really can't make your 90 minutes if you don't get that first EKG within ten minutes, or about that. You can make up for it later.

But the point there is that the outcome you're looking for is the intervention. In this same case, you will push these hospitals to get that EKG really quickly, if you tell them you have this many minutes to get the patient out of your ED.

It's the same thing. You're getting them closer to the intervention, and they will, by default, have to get that EKG done really quickly. But you want to make sure that you're going after the right end point.

DR. MAGID: And Roger, there is a measure. I'm sorry. There is a measure coming up, specifically looking at the time to

transfer. So to the extent that this is a process along the way to that --

DR. SNOW: You're saying it's redundant?

DR. MAGID: I think so, yes.

DR. SANZ: You know, I come from Montana. Much of this discussion here -- and maybe I'm the hick in this -- is irrelevant. I mean we are talking about critical access hospitals that have perhaps eight beds that are inpatient on a given day, and they fudge it because they have another eight that are at their nursing home.

So they move them back and forth in order to obtain the minimal or the maximum Medicare benefit. They have one EKG machine in the hospital. They have no emergency room physician. They have a PA most of the time that they contract with.

If they can get them out of there, it's all because of what the main hospital that is sending the transport can do based on

weather this time of the year. I mean, you don't have -- you're not understanding what this is aimed at. This is not the inner-city hospital that has the Mecca, and there's a lot of people around this room that come from Meccas, that are getting transports from 20 minutes away.

These are three and four hours away, with major winter storms in between, where the patient may or may not frankly be better transferred. If they have a small inferoposterior MI, they may have a higher risk of dying on the road than coming to the hospital.

You've got to be careful. I think this is a great place to start. If you can get some of these hospitals to get an EKG machine that first of all has 12 leads, has a timer that prints out, because the EKGs I get don't all have timers.

I mean you are not talking about a group that I deal with, and let them start

with something simple. You cannot make them start talking about time to reperfusion when they're in a different age.

They don't have a lot of money, you know. They get Medicare plus, I don't know. Somebody around here probably knows. Medicare plus five percent, somewhere in that range. So they're living on a thread, and what they can do is not the same as what you're used to. That's all I'll say.

DR. AYALA: Thank you. I'm from Florida, so we don't have the snowstorms, and I appreciate your comments on that.

CO-CHAIR GIBBONS: Well, I do think it's worth pointing out, since Mark has spoken so eloquently on this point, that we tend to lose track of the fact that 25 percent of Americans live in areas that are "rural" as defined in various ways by access to a hospital that in fact does PCI.

There are papers on that, and it's a pretty astonishing percentage of the

population that we tend to forget about. So thank you, Mark, for your insights from rural America. We appreciate them. I think we're going to have to start taking some votes. We're going to start to take some votes. First, Importance.

17 to 4; yes 17, no 4 for those on the phone. Next, Scientific Acceptability.

MS. ALLRED: Okay. Scientific Acceptability, I think we've touched a lot of the different areas already. The one thing that I would like to go back to and point out is there's a lot of disparity information in this, and I know we haven't talked about disparities anyplace.

But I would love to see the numerator and denominator include some information about sex, gender, ethnicity, because it's all there, and it might explain some of the gaps in timing for some of it. So I thought that was an important issue that was just not addressed.

In terms of exclusions, I mean we already heard the exclusions. If you die, you probably don't get in the measure. So I would say we could vote on that, based on what we've been through.

DR. PHILIPPIDES: Not to beat the inclusion population to death, but I can understand the scientific data behind getting STEMIs, getting EKGs quickly there.

But the other group of possible or probable cardiac chest pain that are transferred out, is there data supporting that there's an urgency in getting those guys in EKG?

I guess I'm asking, why don't they just say that it's an acute coronary syndrome, and make that the sort of backdrop for getting a rapid-fire EKG?

CO-CHAIR GIBBONS: Dale or anybody else from CMS on the phone, do you want to answer that?

DR. PHILIPPIDES: I think that

there's some data in getting a rapid EKG. But probable cardiac chest pain -- if somebody happens to decide needs to be transferred out, I'm not sure there's data supporting it.

DR. BRATZLER: So here's my pushback there. I think when a patient hits the door of an emergency room with chest pain, and there's not an obvious non-cardiac cause, it makes sense to do an electrocardiogram. So that's why we've never limited to what would be seen as the diagnosis after the evaluation.

What we're asking is if somebody when the patient hits the door, the patient was complaining of chest pain, and there are none of the exclusions noted with an EKG done and how quickly, that's what we look at.

DR. PHILIPPIDES: So I agree with that, and I think that's a different measure. Now you're basically saying how fast when somebody comes in with the same -- if they have chest pain as their primary complaint, will they get an EKG? Also a valid measure.

I think it's a slightly different thing than what I thought you were getting at here with this measure.

DR. BRATZLER: Well, I think we get at the same thing. The problem is that, I mean if there's a problem, it's because we -- currently, because of the construct of the measure, we're limited to the denominator population of those patients that had either chest pain or AMI and were transferred.

But we've been reluctant to limit the denominator population to just ACS or AMI, because we're looking at did they complain of chest pain when they hit the door, and did somebody not say that it obviously was not cardiac? If they thought it was cardiac chest pain, they ought to do an EKG.

DR. PHILIPPIDES: And the reason for requiring that they be cardiac -- probable cardiac chest pain with transfer, is it connotes that someone took this chest pain more seriously?

DR. BRATZLER: If you look at all five of the EDAs in my measures, they are limited to patients who are transferred. It's a population of patients that's usually identified through the claims process.

So the measures that we're looking at today are transfer measures, again developed initially out of the rural-sensitive group, which focused mainly on performance measures for patients transferred from one emergency department to another hospital.

DR. MAGID: Thank you. Dale, do you think that you can improve significantly on the problems with documentation? So 32 percent of the time, the ECG date and time was found to be invalid. Twenty-five percent of the time the arrival time was felt to be invalid, and as I mentioned before, just short of 20 percent of the time, the denominator of patients was felt to be invalid.

DR. BRATZLER: So I would bet -- I'd have to look at the data. But I will bet

that the vast majority of time discrepancies are a matter of minutes, if that much.

So you know, for arrival time, we see the exact same thing for the current inpatient ACC measures, because there are different times recorded in the chart, and it depends on who looks at the chart and when they look at it.

So I'm betting that the majority of those time discrepancies are very, very small discrepancies. But absolutely. We're constantly making updates to all of the performance measures for documentation, to improve documentation.

You know, this has taken on even greater significance as we convert to e-specifications for measures where, you know, we have to depend on one of the times that's entered into the electronic medical record, which may or may not be valid. But it's what's going to end up being in the performance measure.

DR. RUSSO: I thought this was like the simplest measure of them all, but I guess not. You know, I would love to see, and I don't know if you -- I think it's fine the way it is.

But is there a way, could we request, the disparities, I think you hit upon, is I really wonder if there would be some real gender differences or other differences. I think that would be fascinating to look at. I don't know if we could request that.

DR. WINKLER: We can ask.

MS. JONES: And this is Rebecca. I can check on that. I think we may have been requested to run some sort of disparity report, but I'm going to look through my files real quickly here and see if -- what those disparities were.

MS. ALLRED: Yes. In the measure, we don't have any disparity data, in the measure we looked at.

CO-CHAIR GIBBONS: Okay. I think we're going to have to vote on Scientific Acceptability. For those who have nine o'clock dinner reservations, we want to get them out on time.

MS. JONES: This is Rebecca again. I did find data on gender and racial disparities for these measures. So if CMS would approve, we could get those sent on.

CO-CHAIR GIBBONS: That would be much appreciated. Thank you. We're still waiting on the vote here. 7 completely, 10 partially, 4 minimally. Moving on to Usability.

MS. ALLRED: Okay, Usability. I think it is usable. It's being currently used in outpatient data, quality data programs. It does not have any harmonization. I suspect that this is a measure that could possibly at some point in time be put into a group.

DR. SMITH: So I just want to be sure I understand. We're going to be looking

at EKGs only on those people that are transferred, and what might come out of this is if you want to transfer a patient, you should do the EKG sooner. You've got to do a better job of that, get new machines, get new people, whatever.

We're not going to learn anything about the people they didn't want to transfer. Maybe they should have transferred them if they had gotten the EKG sooner. Maybe there's a real problem there. It's a very --

DR. BRATZLER: Okay, but I would argue how often when the patient hits the door, in that first ten minutes, do you know you're going to transfer the patient? I would argue that you usually don't know.

DR. SMITH: Yes, and the EKG is what helps me make up my mind. So from my standpoint, if I had responsibility in one of those hospitals, I would want an EKG on all patients admitted with a suspicion of STEMI, so that I could quickly identify those that

would do best for transfer. So that's where I'm having, I'm still having trouble working my way through. I'm hoping that --

DR. BRATZLER: Well again, I think that's what the hospitals are doing. They are setting in place programs to ensure timely electrocardiograms in patients who present with chest pain that may be cardiac, and then we happen to sample a subpopulation of that group that subsequently gets transferred to another institution.

DR. KOTTKE: I may be sort of dense here, but isn't the issue that these patients are not actually admitted to the hospital, so they don't show up as a hospital discharge. So you have to look for them, you have to look for them as a transfer, and that's the only way you can find them.

DR. BRATZLER: Yes.

DR. SMITH: Well, that's interesting. So you are getting data on that other group of patients? I mean, you're not

discriminating against them because they didn't get transferred, are you? I hope that wouldn't be the case.

DR. BRATZLER: No. We do not see those patients.

DR. KOTTKE: One corollary condition. If you're looking at mortality, you can't just look at inpatient mortality and out of patient mortality. You also have to look at emergency room mortality, because that's a third distinct class here. Your numbers would be wacko unless you do that.

CO-CHAIR GIBBONS: I think we need to keep moving. We need to vote on Usability.

7 completely, 12 partially, 2 minimally. Now we're going to move to Feasibility.

MS. ALLRED: Okay. I think Feasibility, the data's readily available. It's also a byproduct of care, so there should be no problem with Feasibility.

CO-CHAIR GIBBONS: Discussion

about feasibility?

(No response.)

CO-CHAIR GIBBONS: All right. We're now going to vote on Feasibility.

11 completely, 8 partially, 2 minimally. Now we're going to move to the final key vote, does the measurement meet all the NQF criteria for endorsement? Is there any additional discussion? Sid.

DR. SMITH: One quick question, because I think Tom has helped me, that there -- do I understand correctly now that there are a group of patients that are being transferred, that are falling out of the system, that we don't have data on?

That we have data on people that stay at that hospital, and we have it on people they get to the hospital, to major hospitals. But there's a group that are being transferred where we don't have information on how they're managed.

That doesn't come out -- in our

system, I think we get that from the transferring hospital, but it's because they're part of the RACE program and it's a bigger state.

But around the country, there are hospitals where they get transferred and nobody's made to look at or looking at the data on how those patients are managed. In that case, it seems like a very important measure.

DR. KOTTKE: Yes, that's correct, because the receiving hospital like us or Ray's, you know what you're doing. But if you would look at the transferring hospital for discharges, you would not see that, because they're just discharged --

DR. SMITH: Yes. But in our situation, we know because we work together with those hospitals. There's a state-wide initiative, where we work with hospitals that don't have, and everybody's part of the team. We discuss outcomes. But that should -- I

think that's just a model, you know, one small program.

DR. MAGID: There are actually two other measures in the packet, one that we'll discuss today and one tomorrow that do focus on that population. So there's a measure that looks at, for those people being transferred, the time from their arrival to when they're transferred, and this is just a subset of that larger time interval.

Then there's, for those being transferred for PCI, there's time from arrival to the first hospital to balloon inflation. So there are two other measures for that group.

DR. SMITH: While you're focusing on this, this is an important thing, if this happening and it's not being looked at in other systems.

DR. KOTTKE: Yes.

MS. De VELASCO: I'd like to say something as both a nurse and a consumer.

Having gone to many seminars where we listen to basically horror stories of women who have gone to emergency rooms and not been rapidly diagnosed, from a consumer point of view I think this sends a loud message, that we are trying to develop things that are to them, at their level of understanding, means better access to care.

So if they actually realize that there are guidelines now of when they can have an EKG, and then may need to be transferred, because a lot of our people do come from rural areas, I think this sends a loud message to patients, that there is a commitment on our part to get them diagnosed early and to get them to proper treatment.

CO-CHAIR GIBBONS: Thank you. Let's go ahead and vote.

The Chair is concerned someone's fallen asleep.

MS. PACE: If everybody thinks they voted? Okay, go ahead and do it.

CO-CHAIR GIBBONS: The vote is 17 yes, 2 no. We're now going to move on to aspirin, and the first is 0132, Aspirin at Arrival for AMI. David.

Measure 0132

DR. MAGID: Okay. So in terms of impact, early aspirin in the first 24 hours has the same -- some feedback -- the same -- Carol, could you flip yours off. Carol? There's the same benefit from early aspirin as you get from reperfusion therapy. So I think clearly strong impact, and there's very strong evidence for this, and that's cited.

There's not a large performance gap, but I think this is, as talked to a couple of people, important enough that even in the absence of a large performance gap, I would recommend that we vote yes for this.

CO-CHAIR GIBBONS: Other discussion about Importance?

(No response.)

CO-CHAIR GIBBONS: We will vote on

Importance.

The group is pulling together as the day moves along. All right. Scientific Acceptability.

DR. MAGID: I think it is well-specified and there's excellent data on reliability and validity. The exclusions are reasonable. There's no risk adjustment, and you can gather this data either electronically or through chart review. There is not any significant disparities. I would recommend this as -- that we move forward, score this well.

CO-CHAIR GIBBONS: Any questions or comments?

DR. KING: Is this one of those -- I mean, don't 90 or 105 percent of the people get aspirin?

DR. MAGID: Yes.

CO-CHAIR GIBBONS: 98.5.

DR. MAGID: There's no question that there's not a great deal of variability.

I talked about that in the first -- it was an issue at the first level. But I think it's an important enough, the impact is high enough that it's worth continuing, despite the lack of variability.

DR. SNOW: Whenever I'm in a meeting such as this, and I'm the only physician and somebody gets chest pain, of course, I always go down, and I assign somebody to go get some aspirin. The guy always says the same thing. He says, "I took one this morning." I tell him you're going to take another one, and he does.

Then of course, the EMTs come and they throw me away and they take over. Then he gets to the hospital. Does he get a third one?

DR. MAGID: No.

DR. SNOW: If you interrogate him and he says he just got one --

DR. MAGID: I wouldn't give him another one, no.

DR. SNOW: I've never asked that before.

CO-CHAIR GIBBONS: All right. We're going to go ahead and vote on the Scientific Acceptability.

19 to 2. Okay. We're going to move on to Usability.

DR. MAGID: I think it's meaningful and useful for public reporting. It is an existing measure, so it doesn't have to add value.

CO-CHAIR GIBBONS: Other comments?

(No response.)

CO-CHAIR GIBBONS: David, you are going for a record here. You are going for the record, clearly. We're now going to vote on Usability.

18 completely, 2 partially, 1 minimally. Now Feasibility.

DR. MAGID: So this is data that is generated in care. The time from arrival is there, the time when aspirin is

administered is there. It could be obtained from either electronic sources or from chart review.

The exclusions don't require any additional data sources. I don't think it's susceptible to significant inaccuracies or unintended consequences, and I think that the data collection can be readily implemented.

CO-CHAIR GIBBONS: Are there any additional comments?

(No response.)

CO-CHAIR GIBBONS: All right. We're going to vote on Feasibility.

19 completely, 1 partially. Okay. Now the final question, does the measure meet all the NQF criteria for endorsement?

DR. MAGID: And I recommend that it does.

CO-CHAIR GIBBONS: All right. We'll go ahead and call the question and vote on this one.

18 yes, 1 no for those on the

phone. All right. We did indeed set a new record on that one.

DR. SMITH: One question, Ray. The thing that sort of lingers, it bothers me a little bit, we're saying aspirin should be given within 24 hours of presenting with a STEMI? We have guidelines that say it should be chewed in the field. Did I read that correctly?

PARTICIPANT: I think it says before, before or at arrival.

DR. SMITH: Before? At arrival, okay.

CO-CHAIR GIBBONS: Okay. So we're going to move on to 0286, Aspirin at Arrival. David.

Measure 0286

DR. MAGID: So I didn't quite understand this until Dale explained it to us, but I assume, Dale, this is the same thing, where we're looking at these critical access hospitals that transfer patients, and that

this is looking at aspirin being delivered in the emergency department before transfer, in patients who are transferred? Is that correct?

DR. BRATZLER: That is correct. So the denominator population again is -- I would point out on the last measure that the denominator population is only those patients who are discharged from the hospital, that ended up with a principle diagnosis of acute myocardial infarction.

This measure looks at patients with either cardiac chest pain or acute myocardial infarction, and asks whether or not they received aspirin either prior to arrival or in the emergency department prior to the transfer.

DR. MAGID: Okay. So I would say that there is strong evidence in support of aspirin in the setting of acute MI, that this patient population is a little bit larger than that, and there's not necessarily strong

evidence in support of aspirin in the entire population, but clearly those who have MI.

We don't really know what proportion of these people end up getting aspirin anyhow, and whether the difference between getting it in the ED versus getting it, you know, a few hours later. We don't know. We don't have good evidence to say what the incremental benefit.

But there's reason to think that it might be beneficial, and there is some data on the performance gap that's quite a bit larger than what we saw for aspirin within 24 hours. So I would say that it probably meets the importance of a measure to report.

CO-CHAIR GIBBONS: Okay. Additional comments or questions?

DR. SANZ: My only question is do we need both? If you believe this one's important, then why do the other one? If you don't believe that probable chest pain needs immediate aspirin, then you don't need this

one, because the AMI part's the same, right?

DR. MAGID: So I think the only reason, you know, I'm on the fence on this one, to be clear. So I think -- so first of all, I don't think there's clear evidence to say that people outside of those having an MI benefit. So that, we just don't know one way or the other. I think the issue is that these patients -- I mean this came up in the sort of time to ECG discussion too.

These patients are likely to fall out of the -- so when you've got these receiving hospitals getting these transfer patients, Mark, they will fall out of the denominator for those patients. So they won't be counted in the quality metrics of those hospitals, because they didn't show up initially at that hospital.

So that's the only potential reason, is that they kind of fall out. But the strength of evidence and strength of impact is not what it is for the other

measurement.

DR. BRATZLER: So this is Dale. A couple of points. One is that in a lot of these small hospitals, the differentiation of non-STEMI, where I think there is good evidence of aspirin benefit, is not that easy. I mean so we all agree that if you have ST segment elevation MI, you ought to get an aspirin, and those are usually reasonably easy to identify.

But I think one of the issues that came up was that in a lot of the small hospitals that may not have access to rapid testing for troponin or other things, they're making a decision based on whether the patient presents with something that looks like probable cardiac chest pain, and should you give an aspirin to that population.

I would argue that that's what we have emergency -- we have a lot of ambulance services all over the country doing, is delivering aspirin to chest pain patients if

there's no obvious contraindications before diagnosis was made.

DR. MAGID: No, I think that's reasonable.

CO-CHAIR GIBBONS: Okay. I think we should vote on Importance.

18 yes, 3 no. Let's move on to Scientific Acceptability.

DR. MAGID: So I think that the specifications are clear, and the reliability is reasonable. Oops, can you go back to that?

The validity suffers from some of the same issues that we discussed about with the time to ECG, and just recalling that about 20 percent or 19.5 percent of those patients who were initially deemed to meet criteria were then found to be invalid.

So there are some issues about validity. They're not any major issues around exclusions. Risk adjustment is not an issue. There were some meaningful differences across sites. It is, I think, the comparability

around just data sources is not an issue, and we don't have any data on disparities.

CO-CHAIR GIBBONS: Maybe I can ask this question of Dale, and probably should have asked it on the Median to ECG measure as well. Dale, as I looked at this, it didn't look to me like there was any low-end cutoff for very low volumes. Is there?

DR. BRATZLER: So there is for reporting on Hospital Compare. I don't have that information. I mean for the inpatient measures, it's 25 cases per year. Rebecca, do you know what the lower limit is?

MS. JONES: It's five cases.

DR. BRATZLER: Five cases what, per quarter?

MS. JONES: I believe it's per quarter.

DR. BRATZLER: So a hospital can submit their data, regardless of their volume. But there's a cutoff that CMS uses for public display.

MS. JONES: And that's if they do not have more than five cases that make it into the denominator.

CO-CHAIR GIBBONS: That seems pretty sparse to me. I don't know what others think, but that seems awfully low to -- in other words, if a hospital has 21 cases a year, they're going to report this measure? I'm going back to Mark's six bed place.

CO-CHAIR GEORGE: I'd say for meaningful use, there is absolutely no lower number. If you have even zero cases, you report with meaningful use for the hospital measures.

DR. BRATZLER: You know, to a certain extent, I think we're highlighting one of the issues that we have around measuring performance in small and rural hospitals, where volume is always an issue, and I think this is part of the attempt to get smaller rural hospitals participating in quality measurement and reporting.

But you know, I can argue about the thresholds that are reported, that are published in the value-based purchasing rule, about a lower limit. I think any number is going to be somewhat arbitrary.

DR. JEWELL: So on the measure submission form, it says under reliability and validity that the measure is undergoing validation through the CMS Clinical Data Abstraction Center?

DR. WINKLER: We sent you the results.

DR. JEWELL: Did you? I don't have it.

DR. MAGID: That's what I've been quoting you guys.

DR. JEWELL: So okay. I apologize. I didn't see it.

DR. RUSSO: Wait. Can you just clarify? So if you have -- so whatever number of patients, they're not -- if you have a large number of patients, you're not sampling

patients. Shouldn't you just report all the patients you have that meet, or how is that working? We're not allowing --

DR. MAGID: I thought it said that if there were less that 80 patients, you reported all your patients, and then if it was greater than 80, you could sample. That was what I recall, at least.

DR. RUSSO: I worry more about the sampling kind of thing or how that's done, in terms of gaming the system, than the lower, I guess there should be a minimum number.

DR. MAGID: Yes. Dale, do you -- I don't know how many of them have more than 80. But can you comment on the sampling approach?

DR. BRATZLER: Yes. The sampling approach is supposed to be random sampling. That's actually developed by the Iowa -- or the Florida QI. I think it's the Florida QI who actually runs that contract. But I don't

know if Rebecca has that in front of her. But they do have the sampling scheme. It's supposed to be random.

MS. JONES: It does, and if there's less than 80 cases per quarter, that they're required to sample 100 percent of their cases. So once it rises to greater than 80, it starts leveling off.

DR. SMITH: Ray, could you or someone clarify for me. Does this mean that a patient that comes in with a STEMI and gets transferred, and took low-dose aspirin 24 hours before they came to the emergency room and got transferred. Let's say they're there and, geez, I realize it's a baby dose low-dose aspirin's good probably, because I'm having this chest pain.

They come to the emergency room and do not get 325 adult dose, do not get that and are transferred away. They are -- under the way I read this, they've gotten acceptable therapy. It still bothers me. I don't know

of any evidence that supports low-dose aspirin 24 hours before arriving at a hospital with symptoms of STEMI is efficacious.

In most of the studies I've seen, it's been adult dose aspirin given at the time of STEMI.

DR. BRATZLER: No, I think you're correct about the evidence. The question is, did those studies include patients that took daily aspirin?

DR. SMITH: No, we don't know. Do we know whether they were taking it chronically, or whether they just took one?

DR. MAGID: I think that there's another issue related to that, which is that you're going to find out that the documentation in the chart will say, you know, aspirin taken prior to arrival. It's not going to give you that time stamp about how long ago it was.

So that's kind of why you probably just need to give them credit, because you

won't be able to sort that out in that level of detail.

CO-CHAIR GIBBONS: Are there other questions?

DR. BRATZLER: No, I would just highlight that, you know, this is something that certainly can be discussed and the measure specifications can be changed, if we think the evidence requires that they be redosed if they just take it chronically. So I have no problem with reevaluating that.

CO-CHAIR GIBBONS: Okay. Let's go ahead and vote on Scientific Acceptability.

We have 7 completely, 11 partially, 3 minimally. Now we can go to Usability.

DR. MAGID: So I think it does meet the criteria for meaningful and useful public reporting, and because it will focus on these hospitals that are not otherwise captured in the existing measure, it would meet the criteria for adding some value to our

existing measure.

CO-CHAIR GIBBONS: Are there other questions about Usability?

(No response.)

CO-CHAIR GIBBONS: Okay. I propose we vote on Usability.

14 completely, 4 partially, 1 minimally. Okay. We're going to move on now to Feasibility.

DR. MAGID: So the data elements that you need, the time of arrival and whether aspirin was given by the emergency department I think will be easily generated as part of routine care. You can either use electronic data sources or chart review.

The exclusions are, I think, appropriately specified, and there's good data, at least, from the prior aspirin measure to say that they're not deployed that often. I don't think they'll be -- I talked to you already about some of the susceptibility to inaccuracies that's already been reported, and

that data collection can be implemented.

CO-CHAIR GIBBONS: Questions or comments?

(No response.)

CO-CHAIR GIBBONS: Okay. I think we'll go ahead and vote on Feasibility, please.

16 completely, 4 partially. And then finally does the measure meet NQF criteria for endorsement? Any additional discussion?

(No response.)

CO-CHAIR GIBBONS: Okay. Let's go ahead and vote on this.

19 yes, 1 no. Okay. So we are approaching five o'clock. We are well behind schedule, so I need to get a sense of everybody. At this point in time there are in fact eight measures that we were scheduled to get through today.

That's conservatively two hours' work. So I propose that we at least try to do

a few more today, if that's acceptable to everybody, especially since several of these fall within the same framework of acute therapy. So if -- I would suggest that we try to see if we can do 163, 164 and 288, depending on the length of discussion.

I guess there's no way to vote on this, other than to ask whether that seems acceptable to people. Probably take us to 5:30 or a little bit beyond, as opposed to delaying two hours' worth of work into tomorrow.

In which case, we'd all just start at 6:00 a.m. I'm glad everybody's still paying attention. This is good. You laugh at my jokes, too. That's even better. All right, good.

DR. SMITH: Carpe diem, push on.

CO-CHAIR GIBBONS: All right. So we'll do 163, Primary PCI Within 90 Minutes of Arrival.

Measure 0163

DR. PHILIPPIDES: And that's a good description of this project. There's some key elements. That's 90 minutes. That's no transfers. They have to arrive there first. But I think we can discuss that in Part 2.

Overall high impact area of health care, very good data that early PCI is very important. I think we should support it on a scientific basis.

CO-CHAIR GIBBONS: Questions or comments?

(No response.)

CO-CHAIR GIBBONS: All right. Let's go ahead and vote on Importance.

Oh, everybody's awake. That's good. Unanimous vote. All right. Scientific Acceptability.

DR. PHILIPPIDES: So I think the measure, as outlined, we can discuss the 90 minutes, is precise and specified. The reliability testing, there's not much there,

but what is offered as far as CDAC comparison to hospital data, it seems like there's reasonable reliability, an it's valid as far as the measure goes.

One of the other people that reviewed this on my group had a question as to 90 minutes versus 60 minutes. I think what they're getting at here, and I might be off on this, those who do primary intervention can chime in.

I think if somebody goes to an outside hospital and they're being transferred in, you want to get them through this in about 90 minutes. Meaning 30 minutes travel, roughly, 60 minutes to now your a new door to balloon time. The theory is that as they're sending them in, your team is getting up and running.

This, I think, is a different animal. I see you shaking your head. I know. Here they're saying they show up at your place without having been at another institution.

What should the clock be? There's a big issue here. They're saying 90 minutes. There's some who think it should be 60. So I'll leave that as the open discussion now.

DR. MASOUDI: Well again, this is responsive to the guideline. I mean I think ideally, it would be five minutes or ten minutes.

DR. PHILIPPIDES: The guidelines say 90.

DR. MASOUDI: Yes.

DR. BRATZLER: And this is Dale. I'll also just point out that the measure currently excludes patients transferred from another facility.

DR. PHILIPPIDES: Yes, that's correct. That's exactly the point I was trying to make. Right. Okay. Other issues, the exclusions. One thing to mention, they added an exclusion which I think is very important, that if somebody was so unstable but they had to be stabilized before going to

PCI, that was a reasonable exclusion.

So somebody comes in and they're in shock, and they have to get pressure started and the balloon pumped. That's okay. Somebody might have had a stroke concomitantly. They can get that dealt with. So that was added on.

There was a concern that this might lead to false exclusions, but so far from preliminary data, that seems to be a low percentage. So those of you who know the data better than I do, please confirm that that's the case, and therefore, I don't think that that's a deal-breaker.

I think the exclusions as changed to the present duration are reasonable and better than before. There are disparities, which I think are important and we should talk about. There was roughly a seven percent difference in rates for Caucasians, going for a PCI in a timely fashion, compared to African-Americans, and there was a gradation

with other groups within that.

It was not further stratified in any way. We can't say anything more about those populations. But as Carol and Anne and others have said, I think that moving forward, it would be great if we could have a particular focus on these disparities going forward, to see what we can learn from that. I think it's an important issue.

Those are sort of the main issues as far as the scientific evidence goes.

DR. SMITH: I'm assuming that in exclusions, we also include the usual end of life issues, someone that may have severe Alzheimer's disease or has indicated a preference that no further invasive procedures. I mean, that's sort of standard. I just --

DR. MASOUDI: The measure only applies to those patients who actually get primary PCI. So if you're going to -- the presumption is if you're going to perform PCI,

you should do it in a timely manner. But if you're not doing it, for instance, in someone who has -- in other words, and it doesn't apply, and they don't get PCI, they're actually not in the measure at all.

DR. SMITH: That's what I would -- yes, that's an exclusion criteria.

CO-CHAIR GIBBONS: Okay. I think we should vote on Scientific Acceptability.

Okay, 19 completely, 2 partially. Moving on to Usability.

DR. PHILIPPIDES: The information produced is meaningful and understandable. It's been used in different registries in the past. I think that there's added value clearly of knowing what the door to balloon time is in patients being treated with a STEMI.

So I don't have any major problems, and even for harmonization, it seems like this is a different measure that fits in nicely with some of the other ones we've

described going into the acute MI realm. So overall, I think it's usable and reasonable.

CO-CHAIR GIBBONS: Comments?

(No response.)

CO-CHAIR GIBBONS: Okay. I think we go ahead and vote on Usability.

Unanimous. All right, Feasibility.

DR. PHILIPPIDES: The clinical measures to date are obtainable through routine care processes. As the electronic records become more widespread, that will become even easier.

In regards to the exclusions, I think they're also reasonable, and again, they are mostly derived from the usual care processes documentation. So I don't think those represent an undue burden.

There is a susceptibility to inaccuracies, and there can be some gaming. If too much is made of that one out card, that a physician or nurse can document a non-system

reason for delay.

But again, to date, there's no reason to believe that that's going to be a significant issue. So what else? Yes. So I think that it's feasible and it's worked well in the past.

CO-CHAIR GIBBONS: Okay. We're going to go ahead and vote on Feasibility.

Another unanimous vote. All right. So we're moving on. Does the measure meet the NQF criteria for endorsement? Keep your eyes out. I'm going to throw in a dummy question here, just to make sure people aren't just voting yes on everything.

All right. I think it's a virtual tie between you and David. Well done. All right. Unanimous, 21 to 0 for endorsement. All right. Now we're going to move to the Fibrinolytic Therapy Measures, 0164, within 30 minutes, and then it's pair right after that, which is 0288, and Andrea.

Measure 0164

DR. RUSSO: Yes. Both of those are relatively, are pretty similar. But basically, the measure is receiving, you know, fibrinolytic therapy within 30 minutes of hospital arrival in the 0164 measure, and described as the percentage of acute MI patients with ST elevation or left bundle on the ECG closest to arrival time, receiving thrombolytic therapy during the hospital stay and having a time from arrival to the hospital to fibrinolysis by 30 minutes or less. This is backed up by lots of literature.

Although we're doing, you know, there's more PCI being done, so there are probably less patients, at least in urban areas or around areas that have access to PCI. There's less of it going on, but it doesn't diminish the significance of delivering fibrinolytic therapy within a good period of time.

So I think it has a high level of evidence in terms of lots of randomized

studies, and would certainly not question the importance of this measure.

CO-CHAIR GIBBONS: Questions or comments? Yes.

DR. SNOW: Thank you. New left bundle branch block on ECG closest to arrival time, or do you really need a bracket on that? Could it have been an old left bundle branch block?

DR. RUSSO: The new isn't listed under the description, but under the --

DR. MASOUDI: In the specification, in the detailed specifications of these measures, it's left bundle branch block that's either new or not known to be old. That's the way it's specified, if you look. The new are presumably newer.

DR. SNOW: That is, you don't have a year-old EKG that has to go on there. You don't have that; correct. So it's new presumably, new or presumed new.

CO-CHAIR GEORGE: This measure

seems very interested, because it has a huge disparities analysis with it.

DR. RUSSO: Yes. I didn't mention that for this section, but I agree. And actually, the performance was actually not, it's only in the 50 -- it's really not as good as you would expect, I guess because the time period's relatively short.

You may take 30 minutes to get your EKG, I guess, in some places. But the disparities are very interesting. So I think it's important.

The Caucasians, I think, came out way above, although some of the N's in the denominator are relatively small in some of the other groups. Caucasians met this more than non-Caucasians.

CO-CHAIR GIBBONS: Importance to measure. I suggest we vote.

All right. A lot of agreement here late in the day. Scientific Acceptability.

DR. RUSSO: So we started talking a little bit about some of the measurement specifications in the numerator, patients whose time from hospital arrival to fibrinolysis is 30 minutes or less. And then, you know, the denominator, all the different denominators are in 2A.4. Greater than 18 years, male or female.

The only thing -- and there must be some basis to this but I'm not aware -- but the only thing in terms of exclusions, is patients who have had a length of stay greater than 120 days. It didn't seem to be relevant, but I wasn't sure why that's in there particularly.

DR. MASOUDI: It has to do with some nuances around sort of when the data is available and collected, based on lengths of stays. I don't even totally understand it. But it just have to do with the ease of collecting data on these patients who have extraordinarily long lengths of stay in a

hospital, and how it overlaps quarters. So Dale, maybe you can speak to that.

CO-CHAIR GIBBONS: Dale?

DR. BRATZLER: Yes, you're absolutely correct. That's correct. So if the patient has a very, very long length of stay, it's possible that they're -- these data are submitted quarterly to CMS.

So if it's more, if they're in the hospital for more than a quarter, it's unclear where you attribute that stay. So those patients are excluded from all the measures.

DR. MASOUDI: It's fortunately a vanishingly small proportion of patients.

DR. RUSSO: Yes, and we talked already a bit about the disparities that were also well-described.

DR. AYALA: Can I ask a question about the comments that were made about measuring disparities? We've talked about the time to ECG, the time to PCI and now this one. What happens with those comments that we make,

where we request the stratification of the patients by race, ethnicity, gender going forward?

DR. WINKLER: A couple of things. I mean first, we'll pose the question and your comments to the measure developers for their response. But also as part of the recommendations that accompanies the endorsement of the measure, you can also recommend that the measure be stratified when it's implemented.

DR. SANZ: Is there a size cutoff, either sample size or institution size? Because I can tell you, some of these critical access hospitals, in fact I doubt any of them have a pharmacist on hand to make up the TPA or whatever they're going to use, TNK.

And that's going to be where a lot of disparities are. You ought to be looking at true rural versus large inner city hospital without a PCI capability.

DR. BRATZLER: So I'll make a

point, and I'm going to have to go soon. They're going to close the door on my plane. But this measure only applies to patients who are admitted and have a discharge diagnosis of acute myocardial infarction.

So most of those small hospitals, even if they gave a fibrinolytic therapy, are transferring the patients anyway. So this really is a large hospital or a medium to large hospital measure.

CO-CHAIR GIBBONS: But Dale, is there a low-end cutoff, because I'm actually thinking of the reverse? That is, hospitals that are set up to be primary PCI hospitals, and give fibrinolytic therapy very, very infrequently, as in single digits per year. Are they still reported?

DR. BRATZLER: Only if they have 25 cases per year that are eligible. But yes, it would be Fred, because I think yes, because it's 25 AMI cases a year. So if they had one case that was eligible for fibrinolytic

therapy and they gave it, then the case would then -- the case would be reported.

DR. MASOUDI: So it's a minimum case volume, but it's total AMIs. It's sort of irrespective of the family of measures. So if there are 25 or more cases per year reported, they do get reported one way or another. There's going to be variability in the patients who qualify for each of the measures within those 25.

CO-CHAIR GIBBONS: Okay. I think we should vote on scientific acceptability.

(Pause.)

CO-CHAIR GIBBONS: 19 completely, 1 partially. Let's move on now to usability.

DR. RUSSO: This, I think, is important and meaningful for public reporting. There is the next measure that's on there, you know, I guess harmonization or duplication even. I'm not sure how we deal with that. But I think this would be a positive response in my mind.

CO-CHAIR GIBBONS: Other comments?

(No response.)

CO-CHAIR GIBBONS: All right. I suggest we vote now on usability.

(Pause.)

CO-CHAIR GIBBONS: 19 complete, 2 partial. And now moving on to feasibility.

DR. RUSSO: Feasibility, the data can be collected either from electronic health records or review of -- chart review. The report is here. Actually, there's a really nice section on looking at susceptibility to inaccuracies, errors or unintended consequences on this particular measure.

Just to outline some of those, in terms of false inclusions, they revised the measure to exclude cases where fibrinolytic therapy was given during PCI, because obviously that's not what you're looking at, or given after PCI. This is just as initial therapy.

They also looked at -- you had to

previously, I guess, document that if the patient had a cardiac arrest or some other explanation, why you didn't give fibrinolytic therapy within a 30 minute period of time. You had to document.

They had cardiogenic shock now. You can just -- you don't need to write that in the chart. It can be implicit, that if they had shock or they had balloon pumps, you could extract that as the reason.

Then there was, I think, even a comment about false exclusions, the type of reason for delay in giving therapy. They made some comments of how discharge is no longer counted toward such reasons. I mean they went through a really nice discussion on how they revised and the reasons for revising that. So I think they did a nice job with this.

CO-CHAIR GIBBONS: All right. We're going to vote on feasibility.

(Pause.)

CO-CHAIR GIBBONS: 20 completely,

1 partially. And then finally the key
2 question, does the measure meet the NQF
3 criteria for endorsement. Any comments before
4 we vote?
5 (No response.)
6 CO-CHAIR GIBBONS: All right.
7 Let's go ahead and vote on that.
8 (Pause.)
9 MS. PACE: Has everybody clicked
10 in? Go ahead.
11 CO-CHAIR GIBBONS: 20 yes and 0
12 no, and one clicker that didn't work, I think.
13 All right. So we're going to move on to the
14 related measure, 288, Fibrinolytic Therapy
15 Within 30 Minutes of ED Arrival.
16 Measure 288
17 DR. RUSSO: So this is really, you
18 know, pretty much the same, a lot less
19 description in there. But basically,
20 fibrinolytic therapy, and they used emergency
21 room. So I guess the question is can you
22 arrive anywhere else other than the emergency

room? Would you arrive, if you're not a transfer, you wouldn't arrive directly to a unit. So I don't know if that's a relevant distinguishing characteristic there.

But again, receiving fibrinolysis with time to arrival from the ED, to fibrinolysis of 30 minutes or less. Again, you know, important. It's guideline-based or based on multiple trials. So I think it certainly meets the importance to measure like the last one. But it's really -- I don't know how we deal with duplication.

(Off record comments.)

CO-CHAIR GIBBONS: Microphone.

DR. MAGID: Just the difference between the percentage versus the median time? Is that what we're looking at?

DR. RUSSO: It says "time of 30 minutes or less," but then the spec.

DR. MASOUDI: So 164 and I believe 287 are sort of the same measure. One is a proportion and one is the median time. So

it's sort of the same, it's almost the same measure. Well, it is the same measure, but it's just a different reporting mechanism.

I believe that middle one is the critical access hospital measure. So that's sort of out of that separate set. So that's why there are three of them.

DR. RUSSO: Do we need all three?

DR. WINKLER: These last three measures, 288, 287 and 290 are all part of measures that apply to that group of patients that are transferred for therapy. This is more those small rural hospitals, if you will, or so they aren't going to be capturing the same patients that were captured in the hospital measure, who were admitted to the same hospital and discharged with a diagnosis of AMI.

DR. RUSSO: Is there a way to write it so that you would capture all of them in one measure?

DR. MASOUDI: Well I mean to be

honest, the proportion within 30 minutes and the median time are essentially exactly the same measure, with the exception of the fact that they report it somewhat differently.

DR. MAGID: But so do you guys have a preferred one versus the other?

DR. MASOUDI: Well, I think that there's been an appeal to both sides of it. So and that's why it's reported. This is how it's been reported publicly in Hospital Compare for quite some time.

DR. MAGID: Okay.

DR. MASOUDI: So to me, it's sort of -- it's almost like a distinction without a difference with respect to those two measures. The third one, and again that's a group that I'm not as familiar with, but that's the group that applies more to the critical access hospitals, and that's why it's a separate measure.

DR. MASOUDI: And are the critical access hospitals transferring people for

fibrinolysis, because that doesn't make a whole lot of sense, does it?

DR. MASOUDI: Not transferring patients, but giving fibrinolysis and then typically transferring them. So it's something that you can measure, the care provided there.

DR. MAGID: Well, wouldn't they be captured in the regular. In other words, is it because they're not admitted to that hospital that they're not captured --

DR. MASOUDI: Right. So it's the same factor that Dale was talking about before. Because they're not admissions, they don't get counted. You don't measure them. They fall through the cracks.

DR. MAGID: And is there a measurement of percentage or a median?

DR. MASOUDI: It looks as if it's a proportion, and I'm not sure why. I can't speak to why they didn't do both.

DR. MAGID: Right, but I wonder if

we could just -- I mean what do we do first, the median or the proportion? I'm confused now. What did we do already just now?

DR. WINKLER: What we were just talking about was --

DR. MASOUDI: Proportion.

DR. MAGID: The proportion. So it seems like maybe we should do the critical access proportion.

DR. WINKLER: That's what's next.

DR. MAGID: Okay, and then is there any reason not to vote the exact same way as we did? In other words, we've got our votes recorded. I would propose that we just do the exact same votes.

(Simultaneous speaking.)

DR. MAGID: I think we want to have dinner before nine o'clock. All right, all in favor, click one.

DR. KOPLAN: But these are clearly going to be harmonized later, right?

DR. WINKLER: These were created

by the same developer. To the degree that they're harmonized right now, we can -- if you can identify elements that require additional harmonization, please do.

DR. MASOUDI: The numerator/denominator times, everything are identical for the first and the third measure. So they're entirely harmonized, with the exception of the fact that one reports the proportion of patients who get it within 30 minutes, and the other reports a median time.

DR. KOPLAN: How many patients -- let's say that all of the patients who potentially could fall into this measure fall into the measure, like 100 percent capture across the United States for both of them.

DR. MASOUDI: Yes, yes.

DR. KOPLAN: How many patients would be in both?

DR. MASOUDI: The same number.

DR. RUSSO: All. It's the same group.

DR. MASOUDI: It's exactly the same group.

(Simultaneous speaking.)

CO-CHAIR GIBBONS: There's two issues. So wait, wait, wait, stop. I think -- let's stick on just 164 and 288. I think we're getting confused by branching out to 287. So let's just stick right now on 164 and 288. We just voted on 164, and now 288 is the patients being transferred.

So they would not be captured in 164. They would not be, and it gets back to the point David asked earlier, because one group is admitted to the hospital and treated there, and their numbers do not include patients who are transferred in. The other group are patients who are treated there and transferred out.

DR. MAGID: Right. But it's the same measure; it's just to a different population. So I'm sort of suggesting that since all the other things are the same, it's

just two different populations. If we liked it in the first group, we should like it just as much in the second group.

So I'm just saying that we don't need to go -- we should be able to apply our voting results to this second population. Same measure, just a different population, because the reason why they're not in the first one is because they don't get admitted to that initial hospital. So that's what I'm proposing.

DR. SANZ: All I can say is just looking at the document, you would never get that. 2A never talks about a patient who is not admitted. It just says that any time discharged or transferred to a --

DR. MAGID: Well, that was true of every one of the measures that Dale gave us, because we were all assigned -- several of us were assigned to them, and we could not -- until he gave us the preamble, we didn't know that. But as soon as he gave us the preamble,

then we--

(Simultaneous speaking.)

DR. SANZ: But there's no way --

DR. RUSSO: You can't tell, you can't tell.

DR. SANZ: I agree with what you're saying. I don't disagree with what you're saying. You can't tell that from here.

(Simultaneous speaking.)

DR. RUSSO: It needs to be included in the measure. Somehow they need to write that in.

DR. MAGID: Right. Well, that would be true of every one of his measures then. That's true of every one of his measures. It isn't clear.

DR. SANZ: It should say "patient transferred out of the emergency room without admission."

DR. MAGID: Yes.

DR. RUSSO: Right.

DR. MAGID: The time to ECG, the

aspirin, none of that was in the document, yes.

DR. RUSSO: Right, exactly.

DR. JEWELL: And that information isn't included in the measure specifications. In the overall manual that's produced, that vendors and hospitals use to track this data, it's made clear that it applies to their OPP as providers in emergency departments and patients that are not admitted.

We can certainly go through and make those recommendations to update, but I think that that might be something that NQF would recommend for every single measure that they approve, because I know that CMS does have multiple measures, but the measure specifications themselves don't specifically delineate that information, although it's given in the overall manual that provides all of the specifications.

DR. RUSSO: I think that would be worthwhile including in each measure, so other

groups don't go through this again.

CO-CHAIR GIBBONS: Okay. So David has suggested we should vote the same way on this one, as on the last one, in essence without revoting.

Does anyone object to that? Is anyone going to vote any differently than they just did on the other measure on this one, now that they understand this nuance, which was not readily apparent from reading these?

(No response.)

CO-CHAIR GIBBONS: Everybody's nodding yes. So can I have anybody who's objecting to David's plan raise their hand? If not, we will assume that we're just going to record the votes as the same on this one as on the other one, and avoid voting, given the hour of the day.

I think we're all tired. So we are going to quit at this point. But when we come back tomorrow, I would point out that the first thing we're going to do is address

Measure 287, which is the median time to fibrinolysis, which is the companion to 164, which is the proportion of people treated within 30 minutes.

We are going to have to decide whether we want to report both of those out or how we're going to deal with that. It's a sort of very basic duplication, just a slight difference in the way they're reported out. What's the start time?

DR. WINKLER: Yes. In terms of starting tomorrow, the agenda calls for eight o'clock. We have access to this room shortly after 7:30. So we'll need a little time to set up. But if everybody could be here before eight o'clock, so that if you could grab your coffee and something to eat, sit down at eight o'clock, we go. All right. If we can get agreement for that, that would be helpful.

CO-CHAIR GIBBONS: Everybody think they manage to swing in here at 7:45, grab some coffee or thereabouts and get plunked

down so we can start work? All right. Well, I thank everybody for their perseverance through a long day.

DR. WINKLER: Thank you.

CO-CHAIR GIBBONS: And I think we accomplished a lot. It's a difficult process, and we knew from the outset looking at this, that this would be a challenge to get through everything. I think we've had good discussion and probably, as you know, had a longer discussion on those things that we turned down, than the things that we accepted.

But I think that was important to be fair to the measure developers.

DR. WINKLER: A couple of logistical things. Your voting gizmo, please leave. We'll get them back to you tomorrow. The flash drives you may take with you and load them onto your computers as you wish. We'll ask for them back tomorrow. Any other questions on sort of logistics?

CO-CHAIR GIBBONS: Do we have to

open anything for public comment right now?

DR. WINKLER: That would be a good idea.

CO-CHAIR GIBBONS: Any members of the public in the back wish to comment, or anybody on the phone?

(No response.)

CO-CHAIR GIBBONS: I think our diligence has exceeded the public diligence. All right. I think we're adjourned.

(Whereupon, at 5:32 p.m., the above-entitled matter went off the record.)

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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 Endorsement Maintenance Steering Committee

Before: National Quality Forum

Date: 02-15-11

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