NATIONAL QUALITY FORUM
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CARDIOVASCULAR STEERING COMMITTEE

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FRIDAY,
APRIL 8, 2011
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The Steering Committee met at the Venable Conference Center, the Capital Room, 575 7th Street, N.W., Washington, D.C., at 8:00 a.m., Raymond Gibbons, Chair, presiding.

PRESENT:

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

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

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

Benefits Trust
ANDREA RUSSO, MD, Cooper University Hospital

PRESENT: (Continued)
MARK SANZ, MD, The International Heart Institute of Montana
SIDNEY C. SMITH, JR., MD, University of North Carolina at Chapel Hill
ROGER SNOW, MD, MPH, Commonwealth of Massachusetts
CHRISTINE STEARNS, MS, 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
KAREN PACE, PhD, RN
ASHLEY MORSELL, MPH
KATHRYN STREETER, MS
REVA WINKLER, MD, MPH
ALSO PRESENT:
SUSANNAH BERNHEIM, MD, Yale/YNHH Center for Outcomes Research and Evaluation (CORE)*
ROBERT O. BONOW, MD, American Heart Association
LEIN HAN, PhD, Centers for Medicare & Medicaid Services*
MAI HUBBARD, PhD, Mathematica Policy Research*
ROBERT J. SCHMITZ, PhD, Mathematica Policy Research*
SAMANTHA TIERNEY, MPH, American Medical Association

*Present via telephone

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

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

8:06 a.m.

CHAIR GIBBONS: I think what we're going to do this morning is -- and for the benefit of everybody on the phone, we did not quite finish yesterday's agenda. We have two measures yet to consider in the inpatient heart failure measures from yesterday before we move on this morning to the outpatient heart failure measures.

So, our task is to complete yesterday, then complete the outpatient heart failure measures before we move on to some of the important follow-up issues dealing with disparities and with the retirement of measures that we referred to several times yesterday. And then the real task, which is competing measures, which Jon asked about yesterday right near the close. We're going to face the biggest challenges. And I hope all of you looked at the grid from Phase I and gave this a lot of thought because that's when

it's going to take a lot of collective wisdom.

Are there any questions about what we're going to do today before we get started? This is all a holding action to get David organized.

MEMBER MAGID: You know, Ray, I have a present for you here -- Fauxpology is your word and it -- I don't know if you've heard of it before; I'm hoping you haven't, it says when a person makes it sound like they are apologizing when in fact they are just shifting the blame or using twisted logic to argue their way out of responsibility for their actions. You said you wanted a new word.

CHAIR GIBBONS: That is a great one. I think we'll get the staff to put that on a slide for us so we all get it spelled correctly.

MEMBER MAGID: F-A-U-X-P-O-L-O-G-Y. I'll take care of that, too.

CHAIR GIBBONS: All right. I do

think that it's going to be hard to top that in the course of today. So, thank you for starting us off in a positive direction.

So, David, are you ready to start on Measure 330?

MEMBER MAGID: I am. I am. You know, I was really kind of hoping that we would do this measure at the end of the day because with all the energy drained out of us we moved so quickly through Ray's measure, but he wisely said no we have to wait until this morning.

So, let me just give you a little bit of the background on this measure.

So, heart failure is the number one cause of hospitalization among Medicare members, which I think Ray mentioned, but it's also the number one cause of readmission. So it's both the number one cause of hospitalization and readmission. Readmission following hospital discharge for heart failure occurs in over 20 percent of Medicare patients

within 30 days and in half of patients in the coming year. So it's very common. So, readmissions and adverse outcome from a cost perspective and a patient perspective, because readmission is typically driven by symptoms and that typically represents worsening quality of life.

Now, I think it's important to acknowledge that many readmissions are appropriate, particularly when the alternative to readmission is worse.

So, the key question for this outcome measure is not whether any individual readmission may be unavoidable or beneficial, okay, because clearly a bunch of them are, but whether hospital-level variations and readmission rate are driven by preventable events. That is the key thing we have to keep in mind.

So, while truly unavoidable readmissions may be common, they are also by nature invariable. I mean, the proportion of

patients who get readmitted for appropriate reasons should be about the same so they shouldn't contribute to differences in risk standardized readmission rates. So, the goal of this readmission measure is to reward processes of care that decrease preventable events and therefore reduce overall readmission rates.

So, there's a more than a twofold variability in risk standardized readmission rates between institutions so on face value that's a strong argument that many readmissions are preventable. Moreover, studies have consistently identified a high proportion of readmissions that are attributable to modifiable factors such as medication errors, non-adherence with recommended therapies and failure to obtain timely outpatient follow up. So, in a variety of existing interventions to improve the process of hospital transitions, right; so the transition from hospital to home, including

interventions like medication reconciliation, transition coaches and early follow up have been shown to decrease overall readmission rates.

So, just to summarize, some readmissions are unavoidable, but that should be pretty much the same across institutions. We see high variation in readmission rates; over twofold. We know that certain readmissions are due to modifiable factors and that interventions to reduce readmission rates have been a success.

So, that's sort of the background for the measure. So, in terms of the -- this is clearly a high-impact thing. Number one cause of hospitalization, number one cause of hospital readmission. There's clearly a performance gap, there is over a twofold variation, there is outcome for the fact that readmissions are due to modifiable factors, and there are interventions that have been shown that can reduce readmission rates. So

I would say the answer to this is yes.

CHAIR GIBBONS: Okay. And I think you've really nicely summarized the whole issue of hospital variation, the fact that some individual patient readmissions are clearly beneficial. We mentioned several points in yesterday's discussion, the way some of the measures, although their intent is very different, get misinterpreted and applied to individual patient situations, and that's part of the push back from the clinical community. I think we somehow need to be mindful of that and the NQF needs to be mindful of that because certainly for this particular measure, as there's more and more attention on readmission, I at least hear a lot of misstatements, both at a private level by clinicians and at a public level as people comment on them.

Now, I erred already this morning. I made my first error because I didn't allow the folks from Yale who are on the phone as

the developers here to comment. So, now that they've listened to your summary, I'll ask them whether they want to add anything in terms of their overview of the measure.

So, anybody on the phone from Yale want to add anything at this point?

DR. BERNHEIM: Hi, Susannah Bernheim. We are here at Yale and I think we -- David did a beautiful job.

CHAIR GIBBONS: All right. Thank you. So, obviously we have some folks from Yale if anybody has any questions for the developers.

Are there any further comments or questions or discussion about the importance of this measure?

OPERATOR: And again, for the phone audience, that's star 1 if you would like an open line.

CHAIR GIBBONS: We don't need questions just yet from the public.

All right. If there are no

questions or discussion, we're going to go ahead and vote on the importance.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Okay. Devorah?

MEMBER RICH: Yes.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So, the vote is unanimous; 19 yes, no no, or no zero.

So, we'll move on now to scientific acceptability. David?

MEMBER MAGID: So, the application -- I think did a excellent job with this area. I think that it is well-specified. The data about -- all of the factors that are described here I thought are well-described. The one thing I would comment on; maybe two things -- one is that there doesn't appear to be significant disparities in the same way that we saw for the hospital mortality measure. So, they look at disparities in this case, not so much at the individual patient level, but

they looked at hospitals and they looked at the characteristics of those hospitals in terms of the demographics of the patient populations that come to those hospitals. So for instance, hospitals that had higher proportion of minorities might have had slightly higher rates of readmission, but the confidence intervals were such that they overlapped, so there weren't any statistically significant differences.

The other thing that came up in the comments that George had about socioeconomic status, that is not built into the risk models, but that is done on purpose and Reva clarified that instead of actually controlling for socioeconomic status, they do stratified analyses. So, I think that across all of the measurement properties the folks who filled out this application did a nice job.

CHAIR GIBBONS: Thank you. Are there other comments at this point about

scientific acceptability?

(No audible response.)

CHAIR GIBBONS: I hope everybody's awake.

(Laughter.)

CHAIR GIBBONS: At least got a laugh on the phone. That's good.

All right. We will go ahead and vote on scientific acceptability.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Devorah?

MEMBER RICH: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So, the responses are 18 completely; 1 partially.

So, we'll move on now to usability. David?

MEMBER MAGID: So, I think the measure does meet the criteria for usability. It's been in place now for a short time, but I don't think people are having any troubles

with it. So, I feel it meets the criteria for usability and also adds value to existing measures. I think there's a important domain of quality that's not captured in the mortality measure or any other measures we're looking at.

CHAIR GIBBONS: And the application did include as a supplemental document the publication and circulation outcome.

Are there other comments, concerns, questions about usability?

(No audible response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you. Devorah?

MEMBER RICH: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So, the summary responses is completely 18; partially 1.

And now feasibility. David?

MEMBER MAGID: So, the data is generated during care. It could be obtained from electronic health records or paper. I think that the -- it's not particular susceptible to inaccuracies and the data can be implemented. So, I do feel like it's feasible.

CHAIR GIBBONS: Discussion or questions about feasibility?

(No audible response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Thank you. Devorah?

MEMBER RICH: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So, the summary of responses is 18 completely and 1 partially.

Now, before we have the final vote on this measure, I just want to make sure --

there was some discussion with the previous mortality measure and then some offline discussion at the end of the meeting about this issue of racial disparities and socioeconomic status. As people thought about this issue overnight; and Reva did clarify what the issues were offline from an NQF standpoint, are there additional thoughts or questions about this that we can discuss with the developer as a committee before we take the final vote on this? George?

MEMBER PHILIPPIDES: I just have a question. How will socioeconomic status be dealt with moving forward or reported?

CHAIR GIBBONS: Okay. So, can I direct that question to developers? Did you hear George's question? How will socioeconomic status be dealt with from the standpoint of reporting going forward in the future for this measure?

DR. BERNHEIM: Yes, hi, this is Susannah Bernheim from Yale. So, as was

mentioned, socioeconomic status is not built into the measure. We, as part of our work with CMS, have ongoing surveillance of the measure. So the way that this is primarily handled from our standpoint; and I think Lein Han may be on the call and can speak more from CMS' perspective, is from a surveillance perspective. We each year look at how hospitals that have high proportions of African-American patients or high proportions of low-SES patients and spacing at hospitals are preforming on the measure, so it is a way to surveil for concerns about disparities.

CHAIR GIBBONS: And is that surveillance publicly reported anywhere?

DR. BERNHEIM: It is not currently, but my understanding is that CMS' intention is to make that public.

DR. HAN: This is Lein Han. I think it's on our website, cms.gov. I can provide the URL of the website later.

CHAIR GIBBONS: Okay. That would

be great. Now, when you say on your website, is it on Hospital Compare.

DR. HAN: Oh, no, no, no. It's a separate site. I mean, it's surveillance system. Actually we put the analysis together and put -- published in what we call a chart book. So, it's a chart book. In this chart book we monitor several measures; performance, hospital performance by disparity, but at the national level. So, this is how -- I think Susannah describe one of the analysis that we have done. That's about safety net hospitals, right, Susannah?

DR. BERNHEIM: Right.

DR. HAN: Yes. And we have also -- can you tell a little bit more? We have also monitor in addition to the safety net hospital and also what else you're in?

DR. BERNHEIM: So, there are a number of things we look at in there. We look at hospitals based on the socioeconomic status of the patients based on where they live,

based on proportions of African-American patients in the hospital space, on safety net status. We also look at teaching hospitals versus non-teaching hospitals. We look at geographic regions.

You know, the idea here is that we don't want to stratify the measure, but CMS does want to be aware if there are indications of changes from what we're currently seeing in terms of how well sub-groups of hospitals are able to perform on the measure.

CHAIR GIBBONS: Well, I'm going to ask for any comments or any other comments from the Committee. Sid?

MEMBER SMITH: Yes, Sid Smith. I think the data that you described would be -- are important and very helpful. I'm a little concerned about -- it seems to be obscure in terms of how to find them. Is there a link on the Hospital Compare website, or is there any way that the public could have -- or we even would know how to take a look at it?

DR. HAN: Oh, yes. This is a public information. The Hospital Compare, we -- mostly is to publish these information for the consumers. So this is a type of analysis to monitor, you know, the effect of our implementation of our program initiative and the measures. So, it's a separate analysis.

MEMBER SMITH: Yes.

DR. HAN: If your question is whether you can have access to it, definitely.

CHAIR GIBBONS: No, I think the real question is not -- I mean, and I think Sid's trying to bring this out, is we sort of think of this as intrinsically linked to the data that you're showing on Hospital Compare so that it shouldn't require a whole separate effort on the Internet to locate a separate body of publicly-available knowledge. If the group at Yale has got to go to all this trouble, it would seem that I think we're trying to convey a sense that it should be easier for people to find it either through a

direct link from Hospital Compare or actually by putting it on Hospital Compare, because I think it would be of equivalent public interest.

Is that the sense of the Committee? I see a lot of nods yes.

So, I think we want to kind of convey back as our sense that it's great that these analyses are being done and they should be more visible to the public if we're ever going to effectively deal with the issue of disparities in the country and maybe consider a simple thing like a direct link from Hospital Compare to this alternative site.

DR. HAN: Yes, this request is reasonable. We will consider that. I just never thought about that because this -- I think it was -- this year was the first time that we put together the chart book.

CHAIR GIBBONS: Okay.

DR. HAN: So, yes.

CHAIR GIBBONS: Well, we just

offer that as a quality improvement suggestion.

DR. HAN: Yes.

CHAIR GIBBONS: All right. Are there any other questions or comments from the Committee before we take this vote?

(No audible response.)

CHAIR GIBBONS: If not, let's go ahead and vote on whether the measure meets criteria for endorsement.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Devorah?

MEMBER RICH: Yes.

CHAIR GIBBONS: So the vote is unanimous, 20 votes yes in favor of endorsement.

Before we move onto the next measure, I did want to reflect the fact that, as David said, we went through the mortality measure relatively quickly yesterday. We spent a little bit more time here this

morning, but not a whole lot of time more. And I don't want anybody to misinterpret that as being a lack of attention to these particularly important measures. I think instead it reflects how completely the application was submitted. When submitted all the data was there to answer any particular concern so there really wasn't much discussion. I think we reflected at the last meeting for the previous AMI mortality measure how well that submission was completed, and these two were in the same category. David and I had an offline discussion about what more we were going to have to say because it was all there.

So, I thank the folks at Yale for being available again this morning and sorry we had to inconvenience them over two days. And thank you for your effort in completing the application so well.

So, we're going to move on to now the next measure. Andrea?

(No audible response.)

CHAIR GIBBONS: Developer on the phone for the next measure?

Give me the number.

PARTICIPANT: Nine-sixty-two.

CHAIR GIBBONS: Nine-six-two.

DR. HUBBARD: Yes, we're here for Mathematica Policy Research.

CHAIR GIBBONS: You want to make any brief comments before we start consideration of the measure?

DR. HUBBARD: I think we'll have Sophia Chan from CMS speak first.

Sophia, are you on the line?

MS. CHAN: Yes, I'm on the line. Good morning. This is Sophia Chan from the Office of Clinical Standards and Quality of CMS. Let me explain the purpose of CMS developing this heart failure composite measure and also the major characteristics of the methodology of the measure.

CMS developed this heart failure

composite measure because we feel that it is important for consumers to have a summary measure that helps them evaluate the overall quality of inpatient care for heart failure. And the primary objective of this measure is to summarize measures for the heart failure focus area into a single composite that's useful, understandable and acceptable to a wide range of stakeholders. So as a result, it's a so-called formative measure and CMS hopes to publish composite measures of inpatient hospital quality on Hospital Compare together with the underlying process and outcome indicators which are already publicly reported. And we believe that providers in addition to consumers will find the composite useful as they can examine the values of each component indicator to understand how they can improve future performance.

And also, based on feedback from the NQF Steering Committee meeting on the CMS AMI composite measure back in February, we

have made two important changes to the heart failure composite. But firstly, the measure was redefined in a manner that makes it easier to understand. And secondly, we implemented a requirement that every hospital for which a composite is computed have observations for each of the component indicators.

So, the measure we present here contains no imputation. And in addition, imputing the measure we have tried to balance the need to have a composite available for as many hospitals as possible and at the same time a need to ensure accuracy by setting an appropriate minimum number of observations.

So, overall the composite measures compute entirely from information already available on Hospital Compare and we at CMS believe that the reporting of this measure will add a valuable dimension of hospital quality for consumers and providers without adding any additional reporting further.

So, I would now let Mai Hubbard

from Mathematica present some additional remarks about the measure.

DR. HUBBARD: Thanks, Sophia. Hi, I'm Mai Hubbard from Mathematica Policy Research. I'm actually one of the developers of this project, along with Bob Schmitz, Marian Wrobel and Jessica Roth also from Mathematica, and Jim Burgess and Gary Young from Boston University.

And as Sophia mentioned, we've revised our composite methodology following the issues that were raised in February regarding our AMI composite measure. And overall we've computed the composite as a simple average of the process and the outcome domain scores at the hospital level. And each domain score is computed then at a rate of some of the actual to expected scores.

And we've made three significant changes. The first is the minimum sample size for the possible care indicators that we've increased. Previously we had that hospitals

were included in the composite as long as they had one patient. Now we've increased that to a minimum of at least five cases.

And second, to address the Committee's concerns regarding imputation of the measure, we have eliminated all need to impute by requiring that hospitals have all four of the process of care indicators, as well as two of the outcome of care indicators.

And lastly, we combined the indicators in such a way that the final composite scores actually centered around one. This makes it easier for stakeholders to actually see what -- to rate the performance of their own hospital. Furthermore, this mitigates the issue regarding the very tight distribution that the committee members raised concern about previously during the meeting.

So, in summary, testing of our measures showed quite strong reliability across year. And furthermore, although we have not argued for an actual reflective

composite but rather a formative one, our analysis indicates that there is positive correlation across the constituent indicators. And furthermore the office showed that there was one single underlying construct.

And so, we'd like to thank you so much for taking the time to look at our measure. And at this time we'd be very happy to accept any questions that you may have about our composite.

CHAIR GIBBONS: All right. Thank you very much. We'll go on.

Andrea?

MEMBER RUSSO: You know, unfortunately all the changes that they're talking about -- actually when I -- the one that I had reviewed; I'm pulling up the newest one on the disc, is reflective of the changes for this, but unfortunately my initial reviews of it, they made some significant improvements. So, I'm going to run through as I'm discussing this -- the changes, because

it's a completely different application than the one I reviewed as I see here.

So, basically starting with the first importance of the measure to report, it's -- you know, clearly the whole concept of this composite measure is an important one. This particular measure combines the hospital process and outcome of care measures for heart failure patients, so it's, you know, a disease. And looking at, you know, the composite measure for the disease similar to the MI-1 that was previously reviewed. I think this is, you know, important. I think the whole concept of having a single composite measure for all different stakeholders to look at, for patients to be able to look up on the website is a good concept. I did have some major consideration, major problems with the initial version, but I see that there are very significant changes on the subsequent revision here.

So, this would be used for public

reporting and, you know, all of the important things. All the individual measures were NQF-endorsed, however, two of those measures were ones that we did review yesterday. One and two that we either -- were retired for two different reasons. One was the particular measure related to discharge instructions. So, the reason that we thought that wasn't such a great measure is that it doesn't say the quality -- as our patient representative here told us yesterday, the quality of discharge instructions is not at all reflected with a piece of paper handed to a patient. So, I would question use of that particular measure in the formula here.

And the second one was the left ventricular ejection fraction -- systolic function evaluation. Those were two of the process measures that were being included. Now, we retired that, and this might be a good thing that it's actually incorporated into this composite measure.

Then the other two are ACE inhibitor, ARB for left ventricular systolic dysfunction, which is, you know, a good one we reviewed yesterday also. And then the other one was smoking cessation advice and counseling.

So, for the process measures I would question, you know, whether or not we would want to consider recommendation of something different for the discharge instructions or perhaps elimination of that one.

CHAIR GIBBONS: Can I ask Reva to comment on the smoking cessation?

DR. WINKLER: As we mentioned the last time we looked at the AMI composite, the smoking cessation measure was originally endorsed by NQF, but the endorsement was removed several years ago because the measure was found to be invalid. So it is no longer an NQF-endorsed measure. None of the smoking cessation measures are.

MEMBER RUSSO: Okay. So, that's an important point to be taken. So, there's two of the four process measures really shouldn't be in there anymore. So, you know, we'd have to ask the measure developers if -- you know, how they would deal with that and, you know, would they be willing to eliminate those. I think, at least from my impression, I'm interested to hear what the group says, but the evaluation of LV systolic dysfunction isn't such a bad thing to keep in there. But, you know, because it's retired, but it wasn't -- the reason for retirement was just because everyone was doing so well on it. So, that would be a significant change.

And then the outcome measures were -- the one wonderful measure that we just heard about with the -- well, the two with the 30-day risk standardized mortality and the 30-day risk standardized readmission, and those seem to certainly be relevant and well-developed, you know, measures that would be

included in the formula. And we can go -- I don't know if you want me to go into -- so now there are some changes to the formula.

But I think in terms of the first question --

CHAIR GIBBONS: Let's not go into the formula just yet. Let's just vote on importance for the measure as submitted. So the measure as submitted which had smoking cessation, discharge instructions, LVEF and ACE or ARB as the four process measures and the two outcome measures. So can we vote on importance of the measure as submitted at this point.

MEMBER KOTTKE: Can I ask a question at this point?

CHAIR GIBBONS: Yes, Tom. Sure.

MEMBER KOTTKE: It's my understanding that composite measures need to comprise NQF-endorsed measures. No? Okay.

DR. WINKLER: They don't have to comprise endorsed measures. They need to be

-- the components need to have been evaluated need criteria. But they may not be deemed to stand on their own as an individual measure, but they need to meet the criteria, however.

MEMBER RUSSO: And before people vote, just so it's clear that in some of the weighting; and again, I'll have to compare the differences between the two, but the weighting can depend on -- the denominator weighting is dependent on the number of patients. So it's weighted -- so you're going to have -- if you have a lot of smoking cessation, that may take more weight. And if you have a lot of, you know, discharge instruction patients in there, that's going to take a lot of weight in the formula.

MEMBER MAGID: Yes, I just think it's important before we vote just to make sure everyone understood, because I thought Andrea did a good job, but one of the components is discharge instructions, which we uniformly voted down at this level.

And the second component is smoking cessation, which Reva is just telling us in invalid. So, two of the four are ones either we said are bad or are found to be invalid. So, before we maybe go on and spend a lot --

CHAIR GIBBONS: Tom?

MEMBER KOTTKE: I guess, where is beta blockers in this? And then, and also there's a paper by Piepoli back in BMJ 2004, "Exercise Training Meta-Analysis of Trials in Patients With Chronic Heart Failure," which concludes that for patients with chronic heart failure who CHAIRpate in cardiac rehab, their mortality rates and readmission rates are 0.72 compared to those who don't participate. And so, this gets to the issue of, you know, you send them home with an unopened envelope of instructions versus, you know, here's a way of -- here's a randomized trial evidence way of reducing both readmission and that. And I know it's sort of sneaking up on CMS, but

perhaps they want to think about that as a part of their measure; did the patient participate in cardiac rehab after their hospitalization?

MEMBER SANZ: Ray?

CHAIR GIBBONS: Yes, Mark?

MEMBER SANZ: So, if we voted no in the past, that means we're done.

CHAIR GIBBONS: We're done with the measure as submitted and then we can make suggestions and --

MEMBER SANZ: So, we can make suggestions?

CHAIR GIBBONS: Yes. Oh, yes.

MEMBER SANZ: Because last time we --

CHAIR GIBBONS: Well, we'll make conditional suggestions, but we will, you know --

MEMBER AYALA: I wanted to ask Reva to define the difference between meeting criteria and being NQF-endorsed. When you say

the components only have to meet criteria, you mean just for the first question?

DR. WINKLER: No, all four of the components. If you recall yesterday, I think there's a pretty example in the PCI composite, you at the first meeting evaluated all of the components and said they all met criteria. Yesterday you looked at a all or none composite measure. It met criteria. Then the question was do you want to endorse all of them and you said, no, the composite is fine. We don't need to individually endorse as stand alone measures the various components. But all of those meet criteria, but instead of just adding five measures to the portfolio, your decision was to add one. So, that's the difference. They meet the criteria, but they don't have to be individually endorsed --

MEMBER RUSSO: And again, remember --

DR. WINKLER: -- as standalones.

MEMBER RUSSO: -- with this

measure if you say yes, then a lot of the weight could be towards measures that we don't think -- or at least from previous voting we do not think are important.

CHAIR GIBBONS: Additional discussion here? This is very key.

(No audible response.)

CHAIR GIBBONS: Okay. So we're now going to go ahead and vote on importance of the measure as submitted.

DR. WINKLER: Dianne?

MEMBER JEWELL: No.

DR. WINKLER: Devorah?

MEMBER RICH: No.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So, the summary is 1 yes and 19 no's.

So, we will at this point not consider the measure as submitted, but rather try to I think provide guidance to the developer in terms of what we think would be an important measure.

So, let me ask Andrea to lead off with that.

MEMBER RUSSO: Okay. So, I think the first part of the recommendation would be to include measures which we think are clinically important. So the concept of beta-blocker therapy for our standard therapy for heart failure patients. And the measures that we already have present, beta-blockers should be in there. I would suggest that -- elimination completely of the discharge instructions and then also the smoking cessation.

And then, the consideration -- I think I was happy to hear actually that you did change -- there was a formula in there to -- if you are missing data. I guess, let's just talk about the general concept of -- and we didn't review what's in there now, but what to do with patients who are missing data. I have some issues with including hospitals that are missing either numerator -- that are

missing some of the numerator. And there was a way to take the average of the overall data in the -- I think you eliminated that into the formula. But I would say that if you're missing data, you shouldn't be included in this measure. And I know you're trying to get as many places as possible.

DR. HUBBARD: As developers can we make a comment on that?

CHAIR GIBBONS: Yes, absolutely.

MEMBER RUSSO: Sure.

DR. HUBBARD: So, we have no -- we do not have any hospitals at this point with missing data, so we're not calculating any score whatsoever for a hospital if they're missing data.

MEMBER RUSSO: So, then I think you need to just state it and just write it as is then and just say that only hospitals who have all of however many measures -- if it turns out to be the six, for a process to outcome measures -- only hospitals that have

all of those measures will be included in this.

DR. HUBBARD: And I think we did mention that in our final package that we sent to the NQF.

MEMBER RUSSO: Okay. And that was the issue, yes, because we just -- we didn't --

DR. HUBBARD: Okay.

MEMBER RUSSO: -- have all that. Okay. So and then the question is how to weight it. And I don't know; I'm interested to hear what other people think, but if you weight it more heavily to the measures that have more patients, you could say, well, that's good, but then that might lead to more gaming maybe, you know? So why not figure out -- at least to me, weighting should be how -- if we're going to weight them all differently; and maybe want to and maybe we don't, but if we're going to do that -- or we should think of what's clinically the most important

perhaps, or just say weight them all equally or weight the process equal to the outcome measures. But weighting it by the number of patients, to me, would be the least favorable option. I'm not sure what other people would recommend there.

MEMBER KOTTKE: The impact on mortality is the reduction when you provide times the proportion in your population who are not currently receiving it. And so, it does make -- to make it makes sense to weight on the number of patients and the impact of the intervention, that combination.

CHAIR GIBBONS: Sid?

MEMBER SMITH: Mine is on -- I suppose we ought to deal with this topic first, then I have another --

CHAIR GIBBONS: Okay. So, other comments in terms of direction we can provide or thoughts we can provide about weighting?

MEMBER RUSSO: Oh, and the other concept in there, too, just is -- and this may

be the only way to do it right now, but the outcome measures were on the Medicare-only patients, is that correct? Because that's the way the data's available --

CHAIR GIBBONS: Yes.

MEMBER RUSSO: -- and the process on both. Is that okay with everyone? I think maybe -- so the process measures -- oh, I guess they're all -- well, that's --

CHAIR GIBBONS: They're all --

MEMBER RUSSO: They must be all Medicare-only. Is that correct?

CHAIR GIBBONS: Yes, I would think so. Dana?

MEMBER RUSSO: But there was a comment in there that process indicators will report on all patients and I'm wondering why you divided that out.

CHAIR GIBBONS: Maybe I can ask a developer to comment on that.

DR. HUBBARD: I think the problem is that given that there are concerns that we

have we're unable to distinguish between Medicare patients and non-Medicare patients at this point. So what we are using is what's available on Hospital Compare, which is Medicare patients for outcome and all patients above the age of 18 for process of care measures.

MEMBER RUSSO: So they're different?

CHAIR GIBBONS: So, now actually that has direct impact on this weighting issue. So, does the weighting of the process measures therefore reflect the larger patient sample?

DR. SCHMITZ: Well, the --

MEMBER RUSSO: That's what it sounds like.

DR. SCHMITZ: -- process measures as a group are weighted equally to the outcome measures as a group, so they have the same weight.

CHAIR GIBBONS: Okay. That's

helpful. Dana, you had a comment?

MEMBER KING: Yes, this was not about weighting.

CHAIR GIBBONS: We'll move onto another topic.

MEMBER KING: All right. The discharge instruction thing, we shouldn't lose that concept altogether. In other words, it may be important to track perhaps a new thing that's better than just handing them a sheet of paper with six things on it. Like do they have coordination of care or some kind of transition program from inpatient to outpatient, or cardiac rehab specifically for congestive heart failure patients, something that's a little more interactive? So, we're not saying that the whole concept of giving people instructions is bad. What we're saying is to measure it a different way. And if it was measured a different way, like coordination of care, for example, I think it would be a worthy addition to a composite

quality measure.

CHAIR GIBBONS: Tom?

MEMBER KOTTKE: Yes, I agree with that comment, and then want to express my existential angst about tobacco. There are three studies in the literature that basically show that people who quit smoking at the time of an acute cardiac event double their life expectancy compared to those who don't. And the principle of what gets measured gets done. I realize that the tobacco measure is invalid and people game it and we game it in our hospital, too, because everybody gets advice, you know? Like quit smoking, idiot, you know? But if somebody could come up with a valid measure, I'd be grateful.

MEMBER MAGID: I don't think you double your life expectancy. I think you double the number of additional years of life you have left.

MEMBER KOTTKE: You double your subsequent life expectancy.

MEMBER MAGID: Yes, there you go.

CHAIR GIBBONS: Yes, the word there is "subsequent."

Okay. Sid, you wanted to make another comment?

MEMBER SMITH: Just are these all patients with systolic failure or heart failure in -- are we -- I'm confused about -- are we adding beta-blockers? And if so, are we addressing patients with systolic failure? What's the population?

DR. HUBBARD: This is all patients with heart failure.

MEMBER SMITH: So it can be non-systolic failure? It can be diastolic failure, right?

PARTICIPANT: Presumably, yes.

MEMBER RUSSO: It's just that one of the component process measures looks just at the systolic dysfunction. I guess unless you're restricted to just those with systolic dysfunction for the whole -- all the process

measures.

MEMBER SMITH: I'm trying to figure out how the therapy that we are measuring relates to the group that we are including.

MEMBER RUSSO: Yes, that's a good point. So then you would just -- so you would only have two things in the numerator. You'd have only two process measures and then two outcome measures. That's one way to construct it.

MEMBER SMITH: Unless we define the groups based on the ejection fraction. And then ICDs potentially are in there if they have significant systolic dysfunction. I mean, if you want to get a marker for mortality and things that are not being done --

MEMBER RUSSO: It needs a lot --

CHAIR GIBBONS: I don't think we have time here to create an entire new measure. I think we've kind of given a fair

bit of input and had a sufficient discussion of the measure as submitted and I think we are going to need to move on to today's outpatient measures.

So thank you to the developers for being available and I hope that that discussion and the guidance is useful to you.

MEMBER SANZ: I would just like to say I think that the concept of a composite heart failure measurement is very important. Is this the end of this measure or can they come back before we're done as a committee?

CHAIR GIBBONS: I think that's totally up to the developer. If they want to --

MEMBER SANZ: Do you want to comment on that at this time?

DR. SCHMITZ: The question is is there an opportunity to come back?

CHAIR GIBBONS: Ask NQF staff to comment on that.

DR. WINKLER: We're willing to

talk with the developers and see what their potential timelines are, you know, in this phase. Obviously there's interest from the committee, so within the time constraints of project we could see how flexible we can be.

MEMBER RUSSO: And I would second that. I think it's a really important thing to do if done right.

CHAIR GIBBONS: All right. So, I think I see a lot of nods around the table, so I think we can convey a sense of the Committee that the concept of a properly designed composite measure is felt to be very worthwhile.

So, let --

DR. HUBBARD: May I make one point to the Committee about where we have to start? We have to start with the measures that are on Hospital Compare. We do not have opportunities to reconfigure those measures. We can pick and choose what goes into the composite, we can reconsider how they're

weighted, but we can't go under the hood of the measures that are there. And I just want folks to understand that as we deal with --

CHAIR GIBBONS: So, let me just -- isn't beta-blockers on Hospital Compare?

It's not a measure? Okay.

All right. We need to move on. We've got to move on to the first outpatient heart failure measure, which is 0077, heart failure symptom and activity assessment, but we first need some brief comments by the developers who are present. Dr. Bonow?

DR. BONOW: Thanks. Is the microphone on? I'm sorry.

So, would you like me to discuss the background for all four measures or --

CHAIR GIBBONS: Sort of three to five months, the general background kind of --

DR. BONOW: For all four?

CHAIR GIBBONS: For all four.

DR. BONOW: For all four. Yes, thank you.

CHAIR GIBBONS: Is his mic on? Can you double check so people on the phone can hear?

DR. BERNHEIM: It's coming in and out, Ray.

CHAIR GIBBONS: It's coming in and out?

DR. BERNHEIM: Yes.

CHAIR GIBBONS: So, Bob, testing, testing?

DR. BONOW: Testing, testing, one, two, three. Can you hear me?

CHAIR GIBBONS: Can you hear him, Dianne?

MEMBER JEWELL: I can hear you. Yes

DR. BONOW: I'll hold it very close.

MEMBER JEWELL: Thank you.

DR. BONOW: Thank you, Mr. Chairman. My name is Robert Bonow, professor of cardiology at Northwestern University

representing the ACC/AHA/PCPI for these four measures which are for continuing endorsement of NQF.

I will not add to the groundswell of the discussion already about the impact of heart failure in the United States other than to reiterate the 5.7 million patients, the greater than 1 million hospitalizations per year, the fact that an individual at age 40 has a 1 in 5 chance of developing heart failure during his or her life span and the annual cost in excess of $37 billion.

The work group consisted of myself as co-chair, but also a family practitioner as co-chair. And we had a multi-disciplinary cross-specialty force including internal medicine, family medicine, hospital medicine, advance practice nursing, palliative care and patient consumer representatives as well, and one payer representative.

We reviewed the updated ACC/AHA 2009 Guidelines, which has some new Class 1

recommendations. We reevaluated and updated data regarding gaps in care, which persist, especially on the outpatient side. We reviewed data regarding feasibility, reliability and exception reporting and made every effort to harmonize our measures with those developed by others, including CMS and Joint Commission. These measures went through a period of 30-day public comment, extensive peer review and are now being presented to you.

We believe these measures have broad applicability, can be reported via claims but are also easily integrated into electronic medical records. Our exception methodology supports clinical judgment regarding appropriateness of care for given patients. Our measures have been tested in a variety of settings, a variety of data sources and our measures are in wide use already in many settings including PQRS and meaningful use Phase I.

The testing has included outpatient data derived from PQRI, the Doc Project, Cardio Hit and the PINNACLE Registry, a large registry from the American College of Cardiology. We have data regarding disparities in addition to the paper in your submission from Chan and coworkers in Journal of the American College of Cardiology last year. There's a paper in the current American Heart Journal by Thomas and coworkers looking at inpatient use of these measures. And both the outpatient PINNACLE data by Chan and the inpatient data from Thomas indicate that these measures actually provide good data regarding equal access to care and quite good care across the disparity spectrum.

In addition, there was a paper published online two days ago in circulation from the improved Heart Failure Registry, which is an outpatient registry involving 167 outpatient practices nationwide involving over 11,000 patients looking at 24-month outcomes

and the use of the ACE/ARB and beta-blocker measure led to a significant reduction in mortality. This is among the first if not the only paper demonstrating a connection in heart failure between process measures and a heart outcome such as mortality. The hazard ratio for ACE inhibitor was 0.4; for beta-blockers, 0.44.

The measures. Specifically for left ventricular ejection fraction we actually considered retiring this measure because it's not the ejection fraction itself which leads to an outcome, but it's the identification of the patient who needs therapy. However, in doing so, by retiring that, we have the concern that this is inexorably linked to the drug therapy. And if we retire the measure, then the drug therapy has to be re-specified to include only those patients with low ejection fractions. How do we identify those patients? And/or we would have a measure in which would be a large number of exclusions

because of the large number of patients with normal ejection fractions.

So, we did maintain the ejection fraction measure.

We made it clear that the ejection fraction does not have to be measured every year. Once the low ejection fraction is demonstrated, it could be a prior echo from several years ago. As long as it is mentioned within a 12-month period the echo itself does not have to be repeated.

The concern about overuse was addressed. We can go into details if you'd like, but we actually found that in a large sample of Medicare claims data only 2.5 percent of Medicare patients with heart failure received three or more echocardiograms per year. So there does not appear to be overuse of echocardiograms in the outpatient setting.

Regarding the symptom and activity assessment, we modified that to become much

more quantitative. We believe that we should be either including a New York Heart Association functional class or some more quantitative quality of life measure to allow clinicians to determine whether their patients are improving or not. So it's not satisfactory just to say the patient still has symptoms. We should be more quantitative and that could drive the team, physicians and nurses, to develop a different care plan to try to improve the patient.

Regarding the beta-blocker measure, which now includes a discharge recommendation as well, which was not previously in our measures -- and that's based upon the updated 2009 ACC/AHA Guidelines, which now include beta-blockers at discharge for appropriate patients.

We believe that these measures focus on accurate and appropriate evaluations in monitoring of disease to guide treatment including a patient-focused measure to improve

symptoms and improve function. And thank you for this consideration.

CHAIR GIBBONS: All right. Are there questions at all for the developer? David?

MEMBER MAGID: Yes, thank you. That was a very nice presentation. I just wanted to ask you a question about one of the things you said. I feel a little uncomfortable --

DR. BONOW: Sorry, right behind you.

MEMBER MAGID: You said that there was no data to suggest overuse of outpatient echocardiography? I may have misheard you, but --

DR. BONOW: In Medicare claims data we actually looked to see whether we could identify evidence for overuse of echocardiography. It's obviously a concern. And in fact, we thought we were going to develop an overuse measure and felt that the

data supporting that would be hard to justify based upon the Medicare data we had available.

MEMBER MAGID: Doesn't the Dartmouth Atlas suggest variations approaching threefold in echocardiography use?

DR. BONOW: There's clearly a variation.

MEMBER MAGID: Yes. So either that's --

CHAIR GIBBONS: So --

DR. BONOW: But I'm not sure you can demonstrate that for heart failure per se --

CHAIR GIBBONS: Right.

DR. BONOW: -- or just for the use of echocardiography.

CHAIR GIBBONS: Right. I think we have to be careful what the universe is of that data, whether it's inpatient or outpatient. There is an existing AHRQ grant to Yale to revisit some of the imaging analysis from Dartmouth that is now 15 years

old, because the only previous data on stress imaging was based on 1996 data.

Sid?

MEMBER SMITH: So, if I heard you correctly, Bob, you looked at a Medicare database. And using a criteria of three or more echos for overuse it was somewhere around 2 to 3 percent. And your conclusion was that there was not a great deal of evidence from this database that overuse was occurring in the outpatient setting. Is that correct?

DR. BONOW: Based upon that sample from Medicare.

MEMBER SMITH: Yes.

DR. BONOW: And realizing that in some patients three or more echos may be appropriate. We don't know the appropriateness of those echocardiograms. It's just a sample. But there did not appear to be a large signal of overuse in outpatient heart failure treatment.

MEMBER SMITH: I mean, I think it

all resides in how you -- maybe Dartmouth is saying two or more a year is overuse. So it depends on how you set your standards for --

DR. BONOW: We could spend a lot of time on this discussion.

MEMBER SMITH: Yes, so my question though is with the assessment of symptoms and how easy it's going to be how well we are putting forth for the clinician what they're supposed to do. You say no change in some -- when folks are going to be in the records looking for were symptoms assessed, what are they going to be --

DR. BONOW: New York Heart Association functional class would suffice.

MEMBER SMITH: So they just want some for every visit?

DR. BONOW: Something more quantitative than the patient has dyspnea.

MEMBER SMITH: Okay. Just put in whatever the New York Heart Association classification is?

DR. BONOW: That --

CHAIR GIBBONS: I think we want to defer this discussion until the details of that measure. So, Dianne?

MEMBER JEWELL: Yes?

CHAIR GIBBONS: Could you hear Dr. Bonow?

MEMBER JEWELL: I did, thank you. And I apologize to him that I'm not present to have the conversation face-to-face. So, I am definitely having one of those existential angst moments with this measure because, you know, somebody who's responsible for overseeing an implementing exercise with patients like this. I absolutely want the medical community to be checking on functional capacity, whether it's with New York Heart Association class or a standardized questionnaire.

My struggle is that we had a similar challenge with the measure that AAC/DPR presented in their last meeting

regarding the assessment of risk. And the issue that we had with that measure was that we weren't clear what the information would lead to because it was only the process of asking the question.

Having said that, I think the testing data indicated that there are some gaps in how frequently the medical community asks patients about their functional status, so I have to say that I voted no on the importance criteria when I did my first review more to prompt a conversation and hear what others on the Committee had to say about this. Because if I'm putting my hat on as a physical therapist, I'm all for this measure. If I'm putting my hat on as an NQF participant in some of the things that we've decided, I'm not convinced that it meets the criteria for importance.

MEMBER RUSSO: I would like to comment. I think actually it's a very important thing to assess at each visit, is

the way I think it's specified even, because not only does it have ramifications regarding how the patient's feeling, it has ramifications regarding what other therapy may be appropriate, whether it be drug or device therapy for the patient. So I think it's really important and we should document it in some quantitative manner, which is I think what the measure here does, which I think is actually very nicely done.

CHAIR GIBBONS: All right. Others who want to comment on importance of this symptom measure? David?

MEMBER MAGID: Just, what's -- I'm sure there's a performance gap, but I'm wondering about 1C. Where's the outcome or evidence?

MEMBER RUSSO: So, that may be a harder part of it and maybe the developers could give us some data. But I think if you don't have this information, then you can't assess the patient for other therapies. So,

1 although it's two steps away -- so if the
2 patient needs an ICD, there's outcome data
3 with ICDs. But if you don't even get to that
4 step, where are we?
5 MEMBER JEWELL: This is Dianne
6 again. I completely appreciate that
7 perspective. My struggle again is with the
8 consistency of our decision making. I could
9 make the same argument that cardiac
10 rehabilitation programs absolutely need to ask
11 the questions that lead to better risk
12 stratification so they can safely implement
13 whatever program has been prescribed. But at
14 that time our decision making was exactly the
15 question that was just raised. "Where is the
16 link to the outcome relative to the activity
17 in question with the measure?", so hence my
18 angst.
19 CHAIR GIBBONS: Tom?
20 MEMBER KOTTKE: This is just a
21 point of information that I need clarification
22 again, and I think Dr. Bonow mentioned this,

but what exactly does quantitative results of an evaluation of both current level of activity and clinical symptoms document? Does that mean a six-minute walk or -- in 77, or am I --

CHAIR GIBBONS: Bob, you want to comment on that?

DR. BONOW: No, believe me, our committee had many of the discussions I'm hearing right now as well, and that actually came up; should we be forcing more quantitative objective evidence? And we decided this would be really undue extra work for a busy practitioner. The idea though is to move the field forward beyond just a simple statement that I have a symptomatic patient with heart failure. How does the more quantitative measure of the patient's symptom status this month compare to how it looked six months ago? Is the patient improving? Is the patient getting worse? Because that could drive, as we've heard, more therapies.

I think the way to put this is let's bring the patient into the discussion here. This is a patient-centered measure. Otherwise, we're talking about tests and drugs based on tests and we're not talking about what really matters for the patient. So we thought that moving a patient-centered measure into a more quantitative field to allow one to assess efficacy of therapy or to move patients toward more advanced therapies would be quite helpful.

MEMBER SANZ: Mr. Chair, to your right.

CHAIR GIBBONS: Yes, Mark? Sorry. We were trying to discuss the appendix. Go ahead.

MEMBER SANZ: I have concerns about this in the same way we had that discussion last time about a study in Australia and asking about chest pain. I can't imagine as a clinician -- I just can't imagine not asking about symptoms of

congestive heart failure and how this --

CHAIR GIBBONS: Okay. So, our off-line discussion is actually pertinent. I would urge you to look at the attachment that came in with the application, which is a summary of the PCPI performance measure testing, and the median for heart failure assessment was 73 percent in the sample. The median of the spread, whether it was adequately documented, 73 percent. So as David said, there's clear evidence of a gap. Now the question is --

MEMBER SANZ: Is that a gap in documentation or a gap in clinically asking? There's a big difference.

CHAIR GIBBONS: Well, we don't know. I think we can just look at the documentation. So it is in the --

MEMBER JEWELL: This is Dianne again. I guess I'm curious, for the measure developers, if the conversation came up around this measure specifying it to relate to the

action that's been described, which is that you've asked the question and documented it in a quantitative way, but it's linked to a response by the clinician, a plan of care of some kind, whether that conversation came up around measure development.

DR. BONOW: Yes, actually in our actual document there's a link to this driving a plan of care if symptom status, quantitatively defined, is not improving or is worsening.

MEMBER JEWELL: And so that was in the application for the measure? I'm sorry if I missed it.

DR. BONOW: I don't believe it's in the application, but it's in the document that the PCPI has endorsed.

CHAIR GIBBONS: Tom?

MEMBER KOTTKE: Yes, I'm just, you know, one of those general cardiologists, but every patient I see I ask, you know, "Do you have PND orthopnea, edema, dyspnea on

exertion, chest pain on exertion? Are you better? Are you worse? How are you limited?" But I don't write down class. And I think for me those other words are more descriptive than class. And I'm not -- we're talking about a lot of primary care docs treating heart failure and, I mean, that's where heart failure is treated. And I don't know if -- I mean, I have a couple of issues. One is, you know, expecting them to start -- we tried this in our practice to get people to stage in class of heart failure and we worked like hell. And then when -- stopped, you know, beating people up over it, I think it evaporated.

CHAIR GIBBONS: So, that really dovetails onto Mark's comment. Part of it is documentation and part of it is how you document.

Andrea?

MEMBER RUSSO: I think that in terms of -- it is somewhat important to be

somewhat quantitative. I think we all do that. When we first talk to the patient, we ask them how they're feeling. But then -- maybe this will be eventually a composite measure that might make a lot more, you know, clinical sense to tie it to outcome, but in terms of -- again, I don't want to reiterate, but other therapies. So if they have a left bundle and they're class 1 heart failure, you're probably not going to be thinking of other therapies such as, you know, CRT, ICD or pacemaker.

So I think quantifying it; and the way they did it I thought was a reasonable thing either by Heart Association class or by other valid tools, which I don't know how many people use, but so I think it is important to not only put all the pieces together and say, yes, you're short of breath, but are you short of breath after walking a mile or short of breath walking, you know, across the room? That's clinically relevant to other therapies

that you might consider.

CHAIR GIBBONS: Okay. Mary?

VICE CHAIR GEORGE: You know, as I was just reading the numerators, it says patient-reported health status as assessed by a structured survey questionnaire offers another more patient-centric approach, but it doesn't say anything about being a valid survey. So, you know, I think the way I read it, it could be interpreted to do exactly what Tom is asking. That's his survey, which is valid in his practice. Then I would ask the measure developer if that would meet the measure.

DR. BONOW: The measure really would require a more -- and I suppose you can come up with your own grading system. So, I think the answer is yes if you then put a number on that from 1 to 10. But I'm not sure how tested or valid that may be beyond the single practice. So, the measure really specifies either a New York Heart Association

functional class or one of the existing validated tested surveys.

CHAIR GIBBONS: Okay. Tom?

MEMBER KOTTKE: I hate to be an anti-ACC grinch here, but I'm not sure this is patient-oriented. I mean, I think patient-oriented is "Are you dissatisfied with what you can do in your life right now if you're on the right therapy?" You know, "Do you want me to do more for you?" And if they say no, then the obligation is to not do any more. I mean, it's -- nobody's asking the patient are you satisfied or dissatisfied with how you're doing?

CHAIR GIBBONS: Carol? I could see you were just itching to comment.

MEMBER ALLRED: That's right. Absolutely.

CHAIR GIBBONS: The moment he said that --

MEMBER ALLRED: Absolutely.

CHAIR GIBBONS: -- you were just

jumping out of your chair. Go ahead.

MEMBER ALLRED: Yes. Yes. You know, I have to comment on this on several levels, not only my own experience with heart failure, but also being in charge of a patient organization and listening to lots and lots of stories.

I'd have to say, Mark, that not everyone out there asks the questions. There are a lot of people out there that are just left hanging and they don't know where they're at in their prognosis. I have that exception. I have a good relationship with my cardiologist, but it took time for us to get to that point where we could take the time to discuss everything. In fact, I had a meeting with him where I actually put my chair in front of the door and said, "Sit down; we're not finished."

CHAIR GIBBONS: Do they do that in Montana, Mark?

MEMBER ALLRED: We do it in Texas.

But I get my questions answered. And I think it's important to have those discussions because it does make a difference to me if I get discouraged because I can't walk a mile without being short of breath. But last week or the last visit I could only walk upstairs and I was short of breath, and now I can walk for 10 minutes. Obviously I'm making progress. So, I think it's an important patient measure.

CHAIR GIBBONS: Okay. Thank you. David?

MEMBER MAGID: I have one last comment, which is -- well, first of all, I absolutely agree with what you're saying. I think the issue is still 1C. And we had a similar measure that was brought to us by Dr. Spertus when we were at our last meeting, and we had this same discussion. And in that discussion we came to the conclusion that we -- well, we stopped at this point because we felt like there was no evidence for what you

requested. So, I just want to make sure we're being consistent across how we handle the --

CHAIR GIBBONS: Right, but to be fair, there wasn't the volume of data in that application which there is here, and that's why the appendix I specifically mentioned.

MEMBER MAGID: Right.

CHAIR GIBBONS: There is an appendix and then the one publication from Fontero is actually in the application. So demonstration of a performance gap is --

MEMBER MAGID: Right, it's not 1B; it's 1C.

CHAIR GIBBONS: Yes, it's 1C.

MEMBER MAGID: Yes.

CHAIR GIBBONS: So, it's a little bit of a different discussion for that reason, because the evidence was lacking from the other one.

So, I think we've gotten everybody who wanted to comment to comment. And now we have to take the vote on importance of this

measure.

MEMBER RICH: Ray, if I could just add one more piece of evidence --

CHAIR GIBBONS: Sure, sorry.

DR. RICH: -- to the conversation before we take the vote. There is a study. It's limited in its design, but there is a study in Heart in 2007 that does speak to some inconsistencies in a cardiologist's ability to consistently classify patients in the NYHA class system. So, I just want to make sure that we're -- for the sake of completeness recognize that there is some contrary evidence out there about the utility of that particular aspect of the measure.

CHAIR GIBBONS: Maybe I could as the developer to respond to that.

DR. BONOW: Oh, no, I agree. I think if you had -- I mean, essentially it's what Tom suggested, that we first talk with the patient. That's how you come up with the New York Heart Association functional class.

And I might differ from Tom with the same patient whether it was a 2 or a 3, but I would be internally consistent in my own judge of this patient, whether the patient is now improving or not improving, going from a 2 to a 3, or a 2 to a 1. So, I think within in a single practitioner there's probably internal consistency.

CHAIR GIBBONS: Okay. Any other comments before we vote?

(No audible response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: No.

DR. WINKLER: Devorah?

MEMBER RICH: No.

CHAIR GIBBONS: To summarize the votes, we have 8 yeses and 12 nos. So we are done with the evaluation of this measure and I think it's pretty evident that the stumbling block was item 1C.

All right.

MEMBER RICH: So, if I could at least offer the suggestion that it would have helped me tremendously to have the measure specified with a more -- the measure itself specified with a link to the plan of care because I fully recognize that that is in fact how the information is being used when it's being collected. And I also appreciate that there is a gap in performance, so for what it's worth, that's one person's perspective on how that measure could come back around.

CHAIR GIBBONS: Okay. Thank you, Dianne, and thank you for your time in reviewing this.

Now, we're going to move onto 0079, which is heart failure, left ventricular ejection fraction assessment in the outpatient setting.

Rochelle?

MEMBER AYALA: Yes. I'm going to read what the description is, but then I'm

going to ask for some clarification on the definition. And it says the percentage of patients 18 years or older with a diagnosis of heart failure for whom the quantitative or qualitative results of a recent or prior or any time in the past left ventricular ejection fraction assessment is documented within a 12-month period.

So, I wanted to just clarify, is it that the patient was newly diagnosed with heart failure, or is it a patient that's been carrying the diagnosis of heart failure for a long time? And so, I'm concerned about the situation, for example, where a patient's been carrying the diagnosis for a long time. The physician has documented a couple years ago what the most recent ejection fraction they have for the patient. The patient hasn't changed at all with their symptomatology and now we're in this 12-month period of measurement and the physician has not documented in the progress note the result of

that older EF.

DR. BONOW: I think you described it. It's both types of patients; the newly diagnosed patient and the patient who's been carrying. So it's every patient you're seeing within that 12-month period. Do you have documentation of an ejection fraction either this year or a prior ejection fraction that was performed years ago demonstrating an ejection fraction in the abnormal range?

MEMBER AYALA: Okay. Just, you know, for logistical purposes, I guess the way that the physicians would comply with this is that every time they list the diagnosis in their record, that progress of heart failure, they should put in parentheses what the ejection fraction was just to make sure that they're documenting in a way that whenever that 12-month period hits that they're compliant.

DR. BONOW: Well, and I guess you could interpret it -- but sometime in that 12-

month period, yes. So, if it's easier for the clinician or the team to be sure that they're going to be, you know, within that window whenever it starts and ends, yes. So, it could be every visit.

MEMBER AYALA: Okay. So that's I think important because when I first looked at the information about the performance, the information that's in their main packet actually cites data from 2003 and it wasn't clear whether or not that was inpatient and outpatient or only inpatient, but it was like 35 percent compliance. But your more recent data that you have in the appendix shows that for this measure the performance on the DOQ was 85 percent, on the PCPI hit was 23 percent, and in the PINNACLE Registry it was 64.7 percent. And when I first saw that, I thought, "Oh, there's a big performance gap here. Then we really should be considering this measure."

But then after consideration of

what we just discussed, I'm wondering how much of this gap that the physician is not documenting every visit what the older EF was and therefore it appears that they never did it. But in actuality they may actually have done it and it would be appropriate for them not to mention it.

DR. BONOW: I believe that could explain some of the variation you're seeing. This may drive people to report it.

MEMBER AYALA: Okay. In terms of the importance to measure, I think we had this discussion a couple times; we had yesterday and today, and I think everybody agrees that it's important for the physician to know the ejection fraction of the patient to choose the appropriate care for the patient. And as you said, this measure is important because you're using it to base some of your other measures.

So, I'm a little bit torn here because I understand the intent of the measure; and I think it's correct, the intent.

I'm just concerned that, you know, it may not be so valid because what are we really testing? You know, are we capturing the physician's non-compliance accurately? So, that's the part about this that bothers me. And it just occurred to me when we were talking, when you were giving your presentation, because I had interpreted it that the patient was just newly diagnosed and within one year of diagnosis the ejection fraction had been documented. But after listening to your opening remarks, I was concerned that it may be the situation that we described.

CHAIR GIBBONS: Okay. We need to get input from others. Mark or Andrea; I'm not sure who's --

MEMBER RUSSO: Yes, I guess I'm starting to have a little bit of concern, because I think, you know, we could talk specifically about how it's measured, you know, when we get to that, but the importance

is clear. You need to know -- you see a patient and you're a cardiologist; you need to know what their ejection fraction is.

So, and maybe we can make recommendations. You might combine some of these things, this with the last measure. And, you know, there's ramifications in terms of therapy. When you measure it, how you document it. We could talk specifically in the measure, but it's an important thing to know regarding other therapy. And whether -- you know, there's for example under-utilizations of ICDs in the United States. Improve heart failure. One of the earlier studies showed that -- and these are highly-motivated practices. Enrolling patients. Fifty percent of these highly motivated practices did not -- fifty percent were not identified or not, you know -- did not have ICDs where they would be indicated based on clinical measures. So we know despite the recent media that there's under-utilization of

ICDs.

If we don't know their ejection fraction, we don't know their heart association class, we're not going to be able to fix that and there may be some issues with medicines, too. So, how we specify it's one thing, but this is important.

CHAIR GIBBONS: Okay. Bruce, you've been dutifully waiting over there, or somebody's dutifully waiting over there. They're not waiting over there. Tom?

MEMBER KOTTKE: I know nobody else forgets what the ejection fraction is in their patients they only see once a year in follow up, but I think this is a very important measure to have the physician write it down once a year so they remember whether there's systolic or diastolic heart failure, how bad it is. Have they overlooked -- do they need to have another discussion about a device, all those kind of things. So I think this is a very important measure.

MEMBER CHO: I just want to make a comment.

CHAIR GIBBONS: Yes, Leslie?

MEMBER CHO: The way this reads right now, you know, I appreciate the intent of this measure, but I'm afraid that when somebody reads this, they're going to get an echo on a stable patient every 12 months. And so, I share Rochelle's concern that the way this currently reads in a stable patient with EF of 35 percent, this to me reads like you have to get an echo every 12 months.

CHAIR GIBBONS: Okay. All right. We can't have a lot of off lines. Use the mics in fairness to the people on the phone and everybody else. Rochelle?

MEMBER AYALA: I understand what you're saying. It is written that you just have to have documented within the last 12 months, but I understand what you're saying, that people might misinterpret that.

In terms of the importance though,

I just wanted to reiterate that it is listed as evidence C, level C, but then there's like a disclaimer about that at the bottom saying that it shouldn't be construed as implying that the recommendation is weak because many important clinical questions are addressed and the guidelines may not lend to study. And it's also a recommendation class 1, so again it is important.

My other question that's kind of related to this though is there a guideline that actually says what is the appropriate interval to check, because that's kind of related to this, too. So if you only had it done once, and that was 10 years ago, is there any guideline to say when you're supposed to repeat it?

CHAIR GIBBONS: I think the answer is no because there's no evidence. Bruce?

MEMBER KOPLAN: Yes, I would actually agree with Leslie that when I -- I understand that it does not tell you to do an

echo every 12 months. But when I first read the title of this, that was my first take and I had to think about it.

And I would agree that it is absolutely essential to know what somebody's ejection fraction is when they come to a cardiology clinic, when they come to see a consultant. If somebody has a history of congestive heart failure and they show up in an emergency room, it's a very important and helpful thing to know, you know, whether it's diastolic dysfunction, systolic dysfunction, if they're being referred for consideration for a defibrillator, et cetera.

So, I wonder if -- it seems like there's a lot of agreement on that. If there was some way we -- you know, sometimes we suggest wording to make things seem more along the intent of what you're trying to achieve, because I do think that there's a concern. And it seems to be one of the future themes that we're going to deal with in medicine,

over-utilization of care, and we want to be care not to do something that might create more imaging especially.

CHAIR GIBBONS: So, if I can ask the developer, friendly amendment documentation of prior LV function assessment in the title, would that be acceptable?

DR. BONOW: Yes, we could change the title, but I'm not sure how to change --

CHAIR GIBBONS: Change the title, but none of the specs. It's all in the specs. It's just about the title. Is that correct, Bruce?

MEMBER KOPLAN: Yes, that would be -- and I would ask Leslie also, because she brought the issue up. But I would like that better personally.

CHAIR GIBBONS: Okay. So, with that friendly amendment, we must move ahead if we're going to get you on your planes, unless you're going to walk home.

We now need to vote on importance

to measure.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Devorah?

MEMBER RICH: Yes.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So, we have a vote of 19 yeses and 1 no.

We're going to now move on to scientific acceptability. I think some of the discussion has already been about that. Rochelle?1

MEMBER AYALA: Yes, it's pretty straightforward. It's just a documentation in the progress note of an LVEF assessment, which is pretty easy if you just do it every time. And the numerator is -- they specify how they get it from the electronic medical record or claims data. And the denominator is all patients age 18 years or older with a diagnosis of heart failure.

As I mentioned, the data source is

the paper medical record, or electronic medical record, or claims data, or registry data, and they have information for all the different pilot tests that they did.

In terms of reliability and validity, we talked about that a little bit in the data that they submitted in the appendix. As I mentioned, there was a variation in the compliance among the three different pilot studies; 23 percent, 64 percent and 85 percent. And in the reliability testing it did pretty well where they had two different reviewers reviewing the data.

I had a question. I didn't understand what this said. In the DOQ project there was mention that ICD-9 coding was not sufficient in identifying -- patients with left ventricular systolic dysfunction was one of the questions under feasibility testing. But that was in the small study that DOQ -- I didn't know how significant that was.

DR. BONOW: Yes, and I just had an

off-line conversation with Sam Tierney. It's not clear that the ICD-9 code differentiates inpatient/outpatient.

MEMBER AYALA: I'm sorry?

DR. BONOW: It's not clear that it differentiates between inpatients and outpatients. Is that correct?

MS. TIERNEY: Yes, I think that the ICD-9 code --

CHAIR GIBBONS: Closer to the mic, please.

MS. TIERNEY: Sorry. The ICD-9 codes are very general, so it's just general for heart failure. Maybe that was what that Doc Project was mentioning, that in order -- that you need more in order to identify whether they have systolic or diastolic dysfunction.

MEMBER AYALA: Okay. So, I thought that -- and there's no exclusions and no risk adjustments, so I thought that it was statistically sound. They didn't really

mention much about disparities specifically, but I know you mentioned that you had some disparities data. Did you see any disparities in this indicator?

DR. BONOW: No, neither in the inpatient or outpatient side in the data that are our there.

CHAIR GIBBONS: It's actually up in section 1 of the submission as well. It deals with a point we're going to deal with later on when we discuss disparities. The forms are confusing in terms of where to put that data and that's why several times yesterday everybody was struggling to find the data. Of course, we have the same problem that the submitters have.

Are there any other comments or questions about scientific acceptability?

MEMBER RUSSO: I just have one question --

CHAIR GIBBONS: Yes?

MEMBER RUSSO: -- for either other

people on the table here or for the developer. So, does everyone use the mild, moderate, severe designations with the same exact -- is there an echo document that says this is what it is? Because some people say, you know, maybe moderate might be it for -- is that a clearly delineated cutoff for everyone?

DR. BONOW: That's a very good question. I mean, the current echo documents indicate one should measure this and report an ejection fraction. Our concern is that not every echo laboratory nationwide does that at the current time. And so what does the clinician do when he or she receives a report with no ejection fraction, which often occurs. Hopefully the field will evolve to a higher level. In fact, there's going to be performance measures on imaging sooner or later, which might drive it faster. But at the current time the poor clinician many times does not have that data and therefore we try to become much more semi-quantitative.

And I certainly agree that even though echo ejection fractions are also highly variable, the qualitative assessment of mild, moderate, severe could vary according to the eye of the beholder, but it was an attempt to guide the clinician. If it says severe dysfunction, moderate dysfunction, good, this person is now a candidate for therapies. If it's normal or mildly dysfunctional, probably not.

CHAIR GIBBONS: And it's worth pointing out that those particular categories actually have traced through a series of guideline documents extending back to 1998. So, they've been around for awhile. Whether everybody follows them exactly remains to be seen. But moderate, being below 40, you can find an ACC/AHA Guidelines back in 1998.

David?

MEMBER MAGID: Yes, I was going to say we have a seven-site NHLBI heart failure study and if we couldn't use the qualitative,

we would have to drop a lot of patients. So, I think it's really important that you included both.

CHAIR GIBBONS: All right. We're going to go ahead. Any questions on the phone?

(No audible response.)

CHAIR GIBBONS: If not, we're going to go ahead and vote on scientific acceptability.

MEMBER JEWELL: No questions.

DR. WINKLER: Dianne?

MEMBER JEWELL: Partially.

DR. WINKLER: Devorah.

MEMBER RICH: Partially.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So, the vote is 12 completely, 6 partially and 1 minimally.

We'll move on now to usability.

MEMBER AYALA: Yes, it's in use with these pilot studies and it doesn't seem like it's causing any difficulty to collect

the data. And I think going forward for people to comply, they just would have to make mention of the ejection fraction or the left ventricular systolic function along with their diagnosis, and that wouldn't be too difficult to do.

MEMBER SANZ: I have a question.

CHAIR GIBBONS: Yes, Mark?

MEMBER SANZ: In the pilot studies was there any look at the use of echo or imaging compared to patient, or compared to groups that didn't have to -- did you look at the appropriate versus inappropriate use of imaging after implementing this type of requirement?

CHAIR GIBBONS: Tough question.

DR. BONOW: No.

MEMBER SANZ: If I would guess, echo went way up.

DR. BONOW: Oh, I don't -- well, we can look at that. I would bet the other way. I'm not sure, because I think people are

already doing this. They may be doing more echos already and this may reduce utilization once they realize they don't have to do it every year.

MEMBER SANZ: We're both guessing, right?

DR. BONOW: We are.

CHAIR GIBBONS: All right. Other questions? Comments?

(No audible response.)

CHAIR GIBBONS: If not, let's vote on usability.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Devorah?

MEMBER RICH: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So, the tally is 12 completely, 6 partially, 2 minimally.

And let's move on now to feasibility.

MEMBER AYALA: It's the same

thing. It's feasible the data can be generated as a byproduct of the care processes and you can collect the data electronically. No exclusions and no inaccuracies documented.

CHAIR GIBBONS: Okay. Are there comments or questions?

MEMBER JEWELL: This is Dianne. The mics are still popping in and out and I actually think it might be because people need to speak right into the mic the whole time.

So, I say that only to preface that I don't know where we landed with the unintended consequences over utilization of echos based on the earlier conservation, part of this meeting, clarity --

CHAIR GIBBONS: Okay. So, sorry if you didn't hear that. The --

MEMBER JEWELL: -- about what the consensus was on that.

CHAIR GIBBONS: Right. The discussion was basically a concern over whether collecting this data lead to an

increase in the use of echo or a decrease in the use of echo. And there was speculations on both sides, but everybody agreed they didn't have the data to support their speculations. Is that an accurate summary?

MEMBER JEWELL: Thank you.

CHAIR GIBBONS: I think that's an accurate summary. I'm sorry, we will all try to speak directly into the mic rather than looking down at our notes as we speak, which is what the problem is.

All right. So are there other comments or questions about feasibility?

CHAIR GIBBONS: Yes, Dana?

MEMBER KING: Question? Because this has to be documented and it's annual and now it's in the progress note in our electronic medical record, even though it's electronic. So, now you're saying that the extractors do a text search for the word "ejection fraction," or for the word "fraction," or for the initials "EF," or for

the word "heart failure assessment?"

In other words, that doesn't sound that easy to me and because I could have looked at it. I could have looked at tab B, which says here's the reports. I looked at it and I said, "Oh, yes, the EF's 48. Yes, that sounds good. They're not having any problem. They're here for a diabetes checkup anyway, not this. They seem to be doing fine. They're not short of breath."' Boom. I looked at it. I didn't write down EF in that note. Or some people write down EF. Some people put ejection fraction. Some might put echo 48 percent.

This actually seems like a problem to me and there would be multiple ways of documenting it, even if we were so obsessive that we did so every time.

CHAIR GIBBONS: All right. That's a good --

MEMBER MAGID: I can comment on this.

CHAIR GIBBONS: David?

MEMBER MAGID: Yes, so, you know, there's a small universe of tests that you do to measure EF, right? I mean, there's echo, there's nuclear stress tests, there's ventriculography, cardiac MRI. I mean, there's not a large number of tests. And so, in our project all the sites have electronic health records and we essentially review the imaging and cardiovascular tabs and find that we can find the EF of well over 90 percent of the patients in those tabs.

We do do natural language processing. And the way we did it, we sort of backed into it; and I imagine the developers have thought of this, but we actually looked at about 100 to 200 charts to see all the different ways the text showed up. And then using that we actually did run text searches.

We found that we weren't able to really find the information all the time just from the search, but they would point to us

where in the record it was, so we could then quickly find it. So, you know, we haven't had trouble finding EF data in our electronic record across the seven sites that are in our project.

MEMBER RUSSO: And the other comment is also if you have a registry, obviously the registry I assume would have -- this particular PINNACLE Registry has probably a spot for that.

DR. BONOW: Well, I think moving into EMRs this will be much easier to capture than going through charts. But, I mean, it has some of its hurdles, but I think they can be overcome.

CHAIR GIBBONS: Okay. I think we need to move ahead and vote, please.

DR. WINKLER: Dianne?

MEMBER JEWELL: Partially.

DR. WINKLER: Devorah?

MEMBER RICH: Completely.

CHAIR GIBBONS: So, the final

tally is 7 completely, 11 partially, 1 minimally.

And now we're going to vote on the final key question, does it meet criteria for endorsement?

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Devorah?

MEMBER RICH: Yes.

CHAIR GIBBONS: And the vote is 18 yes and 1 no.

So, we're going to move on to the next measure, 0081, heart failure, ACE and ARB therapy for LV systolic dysfunction.

And Jon has been just sitting there quietly on the far side of the room just waiting his turn here for the last day-plus. So, he's now --

MEMBER RASMUSSEN: I'm closing out with the last two.

CHAIR GIBBONS: He's still awake and we're going to let him spring into action.

Jon?

MEMBER RASMUSSEN: Well, first I'm gratified that the last measure was approved, because that increases the denominator for the next two measures. The title is, Heart failure: ACE or ARB Therapy in Left Ventricular Systolic Dysfunction. A brief description is the percentage of patients 18 and older with a diagnosis of heart failure with a current or prior EF of less than 40 who received an ACE or ARB therapy within a 12-month period outpatient, or at hospital discharge inpatient.

So, the importance of this measure. The impact is high. The developer did a nice job introducing all four of the measures.

As far as performance gap, on the outpatient side there's a significant gap. When a recent review was done, the average compliance was 80 percent, but a gap between 6 and 96 percent. So pretty significant. On

the inpatient side it's much better. The average is 92 percent. Outcome in evidence is very strong, 1A.

CHAIR GIBBONS: Okay. Any other comments about importance to measure?

(No response.)

CHAIR GIBBONS: I would just point out that if Tom did one of his little calculations here and you started talking about outpatient heart failure in the United States with that kind of performance gap, there are a lot of lives here.

MEMBER KOTTKE: Our calculations are that if we can just improve care by 10 percent that we would have the equivalent impact on mortality as perfecting care for STEMI.

CHAIR GIBBONS: I'm the set up man.

MEMBER KOTTKE: Yes.

CHAIR GIBBONS: You know, STEMI's the gold standard for cardiology.

(Off mic comments.)

CHAIR GIBBONS: Microphone. You got to be careful.

All right. So for those on the phone, the discussion was why we always compare to STEMI, and it's basically because that's been well worked on and is a great systems care issue. So, we're going to go ahead and vote.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Devorah?

MEMBER RICH: Yes.

CHAIR GIBBONS: So, the vote is 18 yes, 1 no.

We're going to move on to scientific acceptability. Jon?

MEMBER RASMUSSEN: For the specifications, very nicely specified. Numerator is for a patient who meets a denominator, have an ARB or ACE fill once within 12 months, or if it's inpatient, at

discharge. For the denominator, it's an office visit with that code or a principle diagnosis of heart failure as an inpatient.

Reliability and validity are both very extensively discussed in the PCPI review, but just in short in the Doc Quality Project there was 94 to 100 percent agreement on reliability. The exclusions are justified and are consistent with the other ACE and ARB measures. Meaningful differences I discussed a little bit earlier. Disparities, black patients are significantly less likely to receive this therapy, but the absolute spread is only 0.5 percent. So it's significant but small. And then men versus women, women were slightly more likely to receive the therapy; 2.6 percent.

CHAIR GIBBONS: Other comments or discussion about scientific acceptability?

(No response.)

CHAIR GIBBONS: And we'll come back to the disparities issues in the

disparities discussion.

I think we'll go ahead and vote then, please.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Devorah?

MEMBER RICH: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: Vote is 19 completely and 1 partially.

Moving on now to usability. Jon?

MEMBER RASMUSSEN: So, here's where the quick review slow downs a little bit. For meaningful use, certainly appropriate. Adding value to existing measures. This is where I think it gets a little bit interesting.

And before I get into my comments, I'd like to ask the developer, when talking about harmonization you mentioned 0162, and that this measure, to avoid duplication, you're requesting endorsement of this measure

at an individual clinician level of measurement. Can you explain that, please?

DR. BONOW: The intent here, with help from my colleagues, is really to enhance care on the outpatient side. So, we're really looking at individual clinicians on the outpatient performance. So that we're were not competing or duplicating the CMS measure for inpatient discharge.

MEMBER RASMUSSEN: So, why did you include the inpatient in the denominator?

MS. TIERNEY: I think I can speak to that. And so, I apologize; I think I misled Dr. Bonow just a little bit.

So, the measure that we submitted is for the clinical level both inpatient and outpatient, because we do have that piece about at discharge and there are discharge codes for physicians. So I apologize, Dr. Bonow.

But we didn't submit the -- we do have a companion measure. It's kind of all

one measure that addresses clinician and facility level. But because of the CMS measure and not wanting to compete with that measure, we're not submitting the facility level specifications and not submitting that for your consideration for endorsement, because of that competing measure. Does that help clarify?

MEMBER RASMUSSEN: It does, but in fact I'd almost encourage you to put the facility level in there, because in just our group alone over our last two visits this is the 5th ACE/ARB measure that we've reviewed for LVSD. And now, there are different components to that. It's patients who had ICDs, LVSD at discharge, post-MI, chronic stable CAD on an outpatient level and now this measure.

Now, this doesn't exactly -- this isn't harmonization, but maybe there should be one to rule them all. And that is, if a patient has documented ejection fraction of

less than 40, then we determine an index date.

Now, whether that index date is a hospitalization or an outpatient code, that's the date at which we start looking at ACE or ARB therapy. And that can include -- because Fred Masoudi's comments yesterday were well taken. There are some of these measures that may have excluded patients with ICDs. If we can make the measure general enough that all of these patients; post-MI, post-ICD -- we know they're supposed to receive the therapy if they have an ejection fraction less than 40 percent. We have one measure, inpatient and outpatient, and we're good.

DR. WINKLER: I can respond to that.

CHAIR GIBBONS: Okay. We're going to ask NQF to respond to that.

DR. WINKLER: Yes. Jon, I think you are very clearly describing what a great many people in the NQF world are asking for and looking for. There are some realities in

the world at this point, but I think that that would certainly be the goal.

One of the issues when we talk to the measure developers is again broadening the concept and asking them to accept that challenge to figure it out, because there are different data platforms that are used for measures. There are different focuses on why different developers develop measures, you know, whatever their original interest is.

And so, your points are absolutely well-taken. I could get you 100 people lined up behind you with a brass band.

The reality is moving people along. And so, for whatever recommendations you can make to encourage the development of that kind of a measure, because NQF CEO Janet Corrigan says over and over and over the best measures are one measure addressing a single topic applicable to all settings and all levels of measurement. So, I mean, that's where we want to go.

Any recommendations you all can make to help us move towards that would be very, very useful and I would pose the challenge to measure developers that moving in that direction is actually going to benefit everybody.

MEMBER SMITH: I'd support what you and Jon have said. Is there any other class of medications that has so many indications as ACE/ARB right now? I mean, really it's interesting to think about the focus that we have on those meds.

DR. WINKLER: Later, when we look at some of the competing and related issues, the same issue comes up with multiple measures around aspirin and antithrombotics, statin use, beta-blockers.

So any of these -- there's a whole group of things because the denominator populations are very related and they may be subsets or setting-specific or some aspect of it, but it's all really talking about the same

sort of secondary prevention for this large group of patients at risk. So, I think it's challenging methodologically, but absolutely the direction everybody needs to go in.

CHAIR GIBBONS: And, you know, I think we've had several people comment as we've gone through these; Dana in particular, about this issue. I think we want to come back to it when we talk about competing measures later on. And for the moment, unless there's more discussion here, let's --

MEMBER RASMUSSEN: Well, I just want to say I want to make sure I'm not picking on this measure. In fact, I think this is the best of the five that we've reviewed and comes closest to that ideal.

CHAIR GIBBONS: All right. That's a comment for the record and for the developer.

Let's move ahead to vote on usability.

DR. WINKLER: Dianne?

MEMBER JEWELL: Partially.

DR. WINKLER: Devorah?

MEMBER RICH: Partially.

CHAIR GIBBONS: The vote is 13 completely, 7 partially.

And moving on now to feasibility.

MEMBER RASMUSSEN: For feasibility, data generated during care, yes. Electronic sources, yes. Exclusions require no additional data sources. Susceptibility to error or inaccuracies, not anticipated. Data collection can be implemented as written, yes. I would place my standard comment when speaking about medication adherence measures that -- hope that you would consider in the future looking at a persistence measure rather than simply a one-time medication use.

CHAIR GIBBONS: Other comments?

(No response.)

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

DR. WINKLER: Diane?

MEMBER JEWELL: Completely.

DR. WINKLER: Devorah?

MEMBER RICH: Completely.

CHAIR GIBBONS: So, the vote is 16 completely and 3 partially.

And we're going to move on now to our final vote, does it meet criteria for endorsement?

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Devorah?

MEMBER RICH: Yes.

CHAIR GIBBONS: The vote is unanimous, 19 yeses. There are no recorded nos. So we've completed that one. And we're moving on; drum roll in the background, to our final measure consideration -- gotten at least some smiles. People are indeed awake -- 0083 heart failure, beta-blocker therapy.

Jon, you're on again.

MEMBER RASMUSSEN: So, this measure is paired with the ACE/ARB measure we

just did, so there are some sections that I'll move through quickly because a lot of the information is the same.

The measure title is "Heart Failure: Beta-blocker Therapy for Left Ventricular Systolic Dysfunction." Description of the measure: Percentage of patients 18 years or older with a diagnosis of heart failure with a current or prior EF of less than 40 percent who are prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting or at hospital discharge.

Impact is high. The performance gap between white patient and black patients, only 0.1 percent. Between men and women, 0.5 percent with women having a higher percentage. Very low spread between the groups. Evidence is 1A.

CHAIR GIBBONS: Other discussion about the importance of the measure?

(No response.)

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

MEMBER RUSSO: I mean, it's impressive the variation between the practices from -- you know, the improved the heart failure trial, too, so clearly important.

MEMBER RASMUSSEN: I actually jumped ahead in my notes and talked about disparities too soon. In inpatient care the average is 78 percent at discharge and outpatient it's 86 percent average, but the spread is 9 percent to 100 percent. So, I apologize. I had my notes flipped.

DR. WINKLER: Hold on just a sec. For importance, Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Devorah?

MEMBER RICH: Yes.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So, the vote is unanimous; 19 yeses.

So, Jon, scientific acceptability?

MEMBER RASMUSSEN: Very similar information for the prior measure. The PCPI data was quite extensive. I mentioned disparities in the previous vote.

CHAIR GIBBONS: We're going to come back to that. It again reflects the form. It's not your --

MEMBER RASMUSSEN: It's not me?

CHAIR GIBBONS: It's not you. It's the form.

So, other comments or questions about scientific acceptability?

(No response.)

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

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Devorah?

MEMBER RICH: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: Okay. So, the summary of responses is unanimous; 18 votes

for completely and no votes for anything else.

Moving on now to usability. Jon?

MEMBER RASMUSSEN: Meaningful use, clearly would be useful to the public to be reported. Adds value to existing measures. As a tangent to my previous comments, this is the third beta-blocker measure that this group has reviewed, so same comments about that.

CHAIR GIBBONS: Other comments on this?

(No response.)

CHAIR GIBBONS: Okay. I think we'll go ahead and vote.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Devorah?

MEMBER RICH: Completely.

CHAIR GIBBONS: The vote is 18 completely; 2 partially.

And then finally, feasibility?

MEMBER RASMUSSEN: Data generated during care, yes. From electronic sources,

yes. No additional data sources required for exclusions. Susceptibility to inaccuracies. None are expected. And data collection can be implemented, yes.

CHAIR GIBBONS: Comments or questions?

(No response.)

MEMBER SZUMANSKI: I have one question.

CHAIR GIBBONS: Yes?

MEMBER SZUMANSKI: Or just one clarification. You indicate in exclusions that there may be systemic reasons or organizational reasons for excluding someone. Can you tell me what those might be? Those would not be routinely documented in the chart. Is this we don't have enough beta-blockers to go around, or why?

DR. BONOW: I think in general we have to talk about patient reasons for exclusion as well as system reasons. And system reasons could be something like that or

unaffordability. But I mean, if it's documented, I guess we can hypothesize or speculate as to why there could be a system reason. I'm not sure I can come up with a great example for that, but there certainly could be one related to resources.

MEMBER SZUMANSKI: I would just be curious as to where you would look for that information in the medical record.

DR. BONOW: I think you would look for that the way you would look for other exclusions, a reason why the patient is not receiving a beta-blocker. Has to be indicated somewhere in the record as to why that patient is not receiving a beta-blocker. So, that person would then be excluded because of valid reasons.

MEMBER SZUMANSKI: Thank you.

CHAIR GIBBONS: Roger?

MEMBER SNOW: Yes, I have a question for the developer that actually goes back a little bit. It has to do with the

specific beta-blockers. You specify particular beta-blockers and don't mention the one that is probably the most used one, which is atenolol. And my question is why? It probably reflects my ignorance, but is it because of demonstrated lack of efficacy or because of lack of evidence?

DR. BONOW: Lack of evidence for atenolol, but evidence from other beta-blockers that they are not effective and therefore the three drugs which have been shown in clinical trials to be effective and are in the guidelines are metoprolol succinate, carbetalol and bisoprolol, whereas bucindolol, salmeterol, propranolol and metoprolol tartrate have been tested and have not been found to be successful and therefore this probably not a class effect.

MEMBER RASMUSSEN: So Roger, when I was reviewing this measure, that numerator is consistent with a previous measure that we approved, 070, the best randomized control

trials, looking at mortality, were those three drugs. You can find a meta-analysis that suggests a class effect, but the clearest strongest data is for those three drugs.

MEMBER SNOW: I thought that was probably the reason, but I wanted to learn something here. That's why I came here is to learn, and for the coffee.

CHAIR GIBBONS: And I would point out parenthetically that at least with respect to disparities issues this did raise a sort of initial confusion because the bucindolol trial which was NHLBI-sponsored had a higher percentage of African-American participants than other trials. So there was a misperception, at least at one point, with regard to potential racial differences in response to the class of drugs, which I think has been largely dissolved given the disparities data we've seen, but nevertheless, did exist for one period of time.

All right. I think we need to

vote on feasibility.

DR. WINKLER: Dianne?

MEMBER JEWELL: Completely.

DR. WINKLER: Devorah?

MEMBER RICH: Completely.

DR. WINKLER: Thank you.

CHAIR GIBBONS: The vote is 19 completely; 1 partially.

And then our final vote whether it meets criteria for endorsement.

DR. WINKLER: Dianne?

MEMBER JEWELL: Yes.

DR. WINKLER: Devorah?

MEMBER RICH: Yes.

DR. WINKLER: Thank you.

CHAIR GIBBONS: So, the vote is unanimous; 17 in favor of endorsement and no recorded votes against.

MEMBER THOMAS: May --

CHAIR GIBBONS: So, I want to thank at this point -- oh, sorry?

MEMBER THOMAS: Oh, I just want to

make one comment, and part of it may be that I'm not sure about something. In terms of beta-blocker and the other measures that NQF and others have endorsed, are some of the measures specifying those specific beta-blockers and other measures not?

And then in terms of that I feel as if that's confusing for clinicians and that we should move towards consistency, either accepting that those three are what we need to think about. But I know that we can't change everything now, but that we should move towards that because it really does affect clinicians. Because once they think that they don't need to have those specified, then they will assume that for the other measures and then not necessarily make that measure.

CHAIR GIBBONS: So I think we're going to come back to that in the discussion of harmonization and Jon already referred to it with respect to one other measure with this same spectrum. It is a recurrent theme and

one that we have to think about and devote some time to in the subsequent discussion.

At this point I want to thank the developers for their participation in consideration of these measures. I also want to point out that we may actually at least for the moment be done voting, so I think we should thank the staff at least for their diligence in making everything work for the votes. Barring yesterday's failure, we would have had perfect performance. And things certainly worked better this time than the last time, and that was not an accident. There are people who are actually plugging away as we go through this process, and we thank them for that.

At this point what we're going to do is we're going to first talk about the issue of retirement of measures; which we have alluded to, and Reva's going to discuss that for us. And that will probably take us up to the break. We are a little bit behind

schedule, but not terribly. And Jon got us back on schedule; thank you, Jon, or at least closer to schedule, so I think we'll have time to do due diligence for these other important issues.

Reva?

DR. WINKLER: Thank you. Thanks to everybody for doing the sort of first step of the work that we've done over these last two meetings. As always, there are follow-up activities. Since this is the first approach that NQF has taken towards looking at both maintenance of measures and endorsement of measures at the same time, we are encountering any number of new questions or new challenges. The first one that you all brought to us last time was the issue of measures that have been long in use and that have been topped out, if you will. The current performance is very, very high.

And so, you all kind of have this concept of retirement of measures. Well,

given that we were a public meeting, I'm sure you can imagine we did get a certain amount of feedback on that discussion. However, it was certainly something that's been discussed conceptually previously in other settings within NQF.

And so, we needed to think internally about how we look at these measures because there is -- it's felt to be that the measures that are topped out but are otherwise good measures are different than measures who have issues and no longer meet the criteria. So, we want to be able to make a distinction between those measures that in maintenance we remove the endorsement because there's a problem with the measure as opposed to measures that are good, valid, reliable and still fine. It's just that because usually as a result of their own success there are just such high levels of performance there's very little opportunity for future improvement and so to be able to designate those differently.

So, what is currently happening is we took this discussion in a proposal back to CSAC last month and it is not a finalized proposal. It is currently out for NQF member and public comment. And this is a proposal around designation of inactive endorsement. Now, a lot of people have said I'm not sure I like the name. Fine. The name may change. But for right now this is where it's going.

So, what we're going to ask you to do is sort of pilot this for us. We're going to do the field test, if you will, to see if using the criteria that we've embedded in the policy speaks to the issues that you've raised and feel are applicable.

Now, the two measures that you indicated this for in the last meeting was the 160, which is beta-blocker prescribed at discharge after AMI; and the other was 142, aspirin prescribed at discharge for AMI. And so, we'll use those two and then if we want we can talk about perhaps the ejection fraction

measure that we talked about yesterday.

But in thinking about the concept of topped out, when you looked at your data, you had one data point. What you had was the national mean. And so, when you look at opportunity for improvement, perhaps not on a national level looked at that way, but perhaps there may be opportunities for improvement if you look at the data more differently, if it will.

So, what we were thinking about is looking at the data more completely, one for representativeness. I mean, is the data we're looking at that shows very high performance representing, you know, a large spectrum of providers? I think that if we were looking only at data from one state; say from the State of Minnesota, it really wouldn't necessarily reflect what was going on in the rest of the country, even if their performance was very, very high.

In this particular case we're

looking at national data, we're looking at a large number of participant hospitals. So, I would ask you the question: Do you feel that that data is a representative to say that the opportunity for improvement is limited?

The other questions that we asked in terms of data was the range. We know the median may be at 98, 99 percent, but what do we know about the decile, the lowest decile, the lowest quartile? What's the range? And so, I was able to ask CMS's contractor and they provided the data in terms of how it breaks down in deciles for these two measures after AMI. And in the memo that I gave you on inactive endorsement, if you go down to the attachment, the first attachment actually is their spreadsheet where they talk about -- this is in your -- it's on your thumb drive. It was sent to you. I don't know. It's the memo on inactive measures.

And if you scroll past four pages of actual words, you'll get to the first

spreadsheet. And what this is is the broken down by -- or, well, different percentiles. We see the 5th, the 10th, the 25th, 50th, 75th. So, for the measure for aspirin at discharge, the 10th percentile is 90 percent. The 25th percentile is 96 percent. And the beta-blocker, it' similar.

MEMBER RUSSO: Can I just ask a simple question that's even a step back from this, and this is just maybe me and it's clear to everyone else. So although there's a lot of hospitals who obviously this represents, there are hospitals that are not included in this, correct? Because this is all -- right now is not required? Correct me if I'm wrong. Are we still thinking of making these inactive? Once this is required for everyone, are we still seeing right now the best people who did this voluntarily and might we even want to even take a step back and wait because we're taking the more highly-motivated. Granted, there are a lot of hospitals, but

still more highly motivated. And when we get it out to everyone, we may see even more variations.

DR. WINKLER: I think these are exactly the questions we're asking you to help us think through, because the criteria 1B, opportunity for improvement, given that limited data that you had, you know, yes, it looked great, nothing more to do. But I think we need to probably look at that criteria more completely or with sort of a different lens for this particular concept of topped out. What do we mean? And the questions you're asking I think are exactly the things we'd like you to help us think through in terms of that.

So, given the conversations we may want to revisit those recommendations. And today gives you an opportunity to do that as we think about this maybe a little bit more broadly in terms of what does it mean when we say there's no opportunity for improvement?

Aside from this data on the percentile so that you can look at the range, the other question was the disparities data. Is there data that demonstrates an issue among certain disparities population that could demonstrate an opportunity for improvement? And I think that that kind of data, all of these pieces I think are important to consider when you are thinking about whether a measure truly has very limited or minimal opportunity for further improvement.

So, your thoughts would be helpful as we're trying to put this kind of together to help guide steering committees in making these decisions.

MEMBER KOTTKE: Yes, I'm concerned that -- say that an n of 1, terror of the numerator, you know -- say I'm out in a small hospital and I'm arguing, you know, you have to -- beta-blockers, you have to measure ejection fraction, you have to -- and it doesn't show up on the active list. And they

say, well, you know, they misinterpret it.

And so, and I know that the beta-blocker story came from NCQA retiring it, and individual organizations I think can retire it. Mayo can decide they're not going to measure something because they know they do very well, but a particular organization may not. And I think if there are measures that we know are strongly associated with outcomes, that somehow we have to preserve that information for the casual reader who may misread the intent of the retirement.

MEMBER RUSSO: And in addition, in terms of, you know, my passion for beta-blockers, I think just looking at what you're showing us here is a minimum of 28 percent. I mean, and then even the 5th percentile -- again, granted that's a lower -- but 85 percent -- beta-blockers are standard therapy. And these are -- to me that's not acceptable, 85 percent, without saying what you're -- you know, exclusions you can include. So to me,

85 percent, even for 5 percent or the 5th percentile would be unacceptable.

MEMBER SNOW: Which raises the point that somewhere we need to provide guidance to users as to when they can pull the trigger on use of a measure that in some places such as the Mayo or like that may have been topped out and have little utility.

I mean, up until somewhat recently most people that I've talked to haven't really thought of that issue, that you -- you know, it doesn't make much sense to worry about mammograms because everybody gets one, or that kind of thing. Everybody's getting Pap smears. So, now we should put our energy someplace else, but when and what's the line? And being able to talk and think about that so that when it gets out into the community hospitals, the folks working on it have guidance. That's what we really, really need.

MEMBER CHO: Reva, is there a data on beta-blocker use throughout the last three

years? Has it stayed this way?

DR. WINKLER: I probably could have asked for it, but didn't, so I don't have it at hand. I'm going to guess they've got it, but I don't have it to give you.

MEMBER CHO: The second question is, is you guys have retired other measures in the past?

DR. WINKLER: Not in this way. This was kind of a first because it's part of the maintenance activity and we've really done maintenance in a very casual way in the past, more if there were issues around a measure, as opposed to really systematically, like you've done, look at it against the criteria. Many of these measures have been endorsed for many years and have not undergone that kind of a thorough review. You know, time moves on. Sometimes, you know, measures just are no longer particularly useful in the portfolio.

So, this truly is our first go at this. So, not really. So, that's why this

whole concept about retirement, if you will; although that won't be the term that's used, but acknowledging that measures may be topped out is the sort of term people talk about. But the question is what do we mean by that? What does it take to be that? And then do we want to somehow designate them differently than just saying, oh, keep it on the endorsed list versus -- because it really doesn't meet that criteria for opportunity for improvement perhaps.

MEMBER CHO: Right. I guess all of us are struggling that when we retire or when these become legacy measures or whatever, that we would fall off, the standard of care will fall off.

DR. WINKLER: Well --

MEMBER CHO: But I think the other way to look at it is, is for years the U.S. has recommended vaccination. And at certain point the vaccination has been steady; and Mary could speak for this from the CDC point

of view, mainly because some people don't want to get vaccinated or whatever, but the level has been steady. The recommendation is there. So, I wonder in the light of measure fatigue the amount of measures coming down the true impact that you want to make. I mean, it's difficult I think.

DR. WINKLER: The tension is, you know, measures that are good -- if it's a good measure, what's the problem keeping it in the portfolio? The issue is resources, and as you say, measure fatigue or just how many can anyone cope with, as well as maintain them, or have the expectation that people will use resources to collect data for the limited information that's going to drive further improvement. So these are the tensions that are involved. But I think we have to look in a world where we don't want an endless library of measures that aren't looked at carefully against, you know, the criteria, the usefulness, the value added, you know, the

opportunities associated with them.

Karen, did you want to say something? Karen helped develop this with Helen and the rest of us.

DR. PACE: Yes, I just wanted to mention the evidence task force also addressed this a little bit last year. And one of the things that keeps coming up is, well, what's the threshold? What's the definition of being topped out or no opportunity for improvement, et cetera? And they really -- it kind of revolves around some of the discussions you've made, that there is no one threshold. It kind of depends on the population at risk, the consequences involved in the particular quality topic in terms of impact on patients, and that's what we need. So we can't just say, you know, if it hits this number it's gone. We need you as the people with expertise to help weigh those factors.

But I think the other thing is in terms of, you know the discussion about when

should providers stop using a measure, we're talking about measures that have NQF endorsement. So, these are often used in public programs, in required reporting programs. And so, individual providers may not have that particular choice if it continues to be an active NQF-endorsed measure.

And just one other thing about the percentile chart that you have. Just keep in mind that that's the percentile on the hospitals, so we don't know exactly how many patients are represented in each of those percentiles. So, that's another kind of slice of the data that we don't have for you right now.

MEMBER SNOW: One thing that might get at a little bit of this; not completely, but might make it more manageable, is if you could for topped out good measures, in light of the concern that if they sort of go away that performance will fade; we don't know that

will happen, but everyone will worry about it -- if you have a protocol for rotating some of these measures. So, put them in the background with the understanding that they will come back after some period of time, you know, on a schedule. That won't solve it, but it might make it more malleable.

VICE CHAIR GEORGE: Reva, you know, I think in terms of our voting, and particularly on this issue, if this first question were split so that we could actually vote on performance gap, that might provide some additional information as we go through this process.

MEMBER KOPLAN: Have you actually come up with a way to express the designation? Would that be helpful to come up with something like that?

DR. WINKLER: Well, that's what the proposal around the term inactive endorsement is. It remains endorsed, but again it's sort of in an inactive way.

Because NQF doesn't implement the measures, Roger, the idea is that it's still sitting on our shelf and should. Programs that do a lot of measurement want to rotate them every couple of years to maintain surveillance and all that. They're still using an endorsed measure, though. It's not one we're advocating being actively used on a regular basis.

MEMBER KOPLAN: Right. And would it be reasonable to use something along the lines of like reflecting what some of the comments were, like legacy due to high compliance achieved, or something like that? Because then it tells you why -- this designation -- it sounds like is clearly only because of high compliance achieved. It's not because of anything else. So this just implies that we think it's important, but that's why.

DR. WINKLER: That's correct.

MEMBER RUSSO: And I think what

Leslie was alluding; or maybe I don't want to put words, but when do you do that? Is it after just one year of good performance? Do you need five years? Maybe the duration of great performance should be in that formula somehow.

MEMBER KOTTKE: Can I make a comment? Minnesota has had 12 cases of measles in the last week after years of none at all. At ICSI in Minnesota we had this issue of guideline fatigue, where we kept on -- we got the important guidelines and started getting down. And I think what we recognized is at some point you don't need guidelines on trivial stuff. And I know NQF has thought about this, but making sure that if there are measures, they're measures about important things. And I think that's why we rejected the amiodarone ALT thing yesterday.

I would personally like to see that all of the guidelines stay in the list of endorsed, but perhaps you just asterisk it and

at the bottom say, you know, think -- you know, there's very high performance with this measure. You know, one should think carefully before asking people to collect data on it or something. But I'm worried that they don't look at a second list and there are some very important things on this second list that people don't look at. They just look at endorsed measures.

CHAIR GIBBONS: Yes, I agree. I'm a little concerned about the separate list concept and whatever you call them. I would rather see them flagged as, you know, no longer active. And I guess I want to put on the table something that I think is inherent in some of the comments, which is there's an opportunity cost here regardless of the cost of actually collecting the data. And I think Tom referenced this in some of his comments yesterday.

The reality is there's just so much energy and so much focus that a given

practice, physician, hospital, system, whatever can put on quality improvement. And really it boils down to where is all that energy best directed? And I really doubt that it's best directed getting aspirin from 98.5 percent to 100 percent because most of that's actually going to turn out to be a documentation problem.

So, I think we want to be mindful of that and somehow flag it. And I like Tom's idea, which is I think individual systems should decide to some degree what they're going to retire, quote/unquote, but it should still be on the same list with some sort of flag saying we think overall performance is well enough that the healthcare system ought to move onto other things.

DR. WINKLER: We can take that as sort of an implementation feedback on how we would designate, portray, title or whatever. We're still talking more the concept as opposed to how exactly we're going to call it.

MEMBER RASMUSSEN: Reva, you made a comment that worries me just a little bit, and that is that NQF endorses a measure and that's as far as their influence goes. So that CMS could say this is an endorsed measure and require organizations to report it, even though that they may be in the 99th percentile. So they have to spend some of that energy reviewing that data. Even though they're very good and we've said it's endorsed, CMS can do whatever they want with it.

DR. WINKLER: That actually is pretty much always the case with the endorsed measures.

MEMBER RASMUSSEN: Right.

DR. WINKLER: Okay?

MEMBER RASMUSSEN: Yes.

DR. WINKLER: I mean, it's guidance, but it's something that's taken very seriously, which is why this is a very significant issue. There are considerable

concerns mentioned both here and elsewhere that these are good measures. They measure important things. And the only issue we've got is the opportunity for improvement, the high current levels of performance.

So, the question is what do we do with this kind of a measure? If you take it off the list, is it going to be interpreted that this is a bad measure such as -- because we're going to take off, you know, five others off the list because they do have problems.

So, that seems to be an uncomfortable place. I see you guys express discomfort with doing that. But essentially your votes heretofore have done exactly that. What we're trying to do is open the door up to considering another way of looking at these measures as opposed to either a yes/no. It's kind of like the third way, if you will.

MEMBER RASMUSSEN: How about an NQF hall of fame?

CHAIR GIBBONS: Yes, right.

Carol?

MEMBER ALLRED: I was just going to suggest how about just leaving it on the list but with a designation of high compliance?

DR. WINKLER: Again, I think that that kind of feedback are the suggestions in terms of how we might implement it. But the issue at hand for this group right now is currently you've taken those measures off the list. So, the question I've got to come back to now is do you want them back on the list with some designation?

I mean, so far because these two measures, very rightfully, reading the criteria, you've voted them not to meet the importance criteria, but that takes them off the list. Clearly that poses a relatively new problem that we're trying to work our way through at NQF. You're the pilot study. You're helping us figure this one out.

MEMBER SNOW: Yes, but there's

something that's a little unclear to me. Have you created and identified another place for us to put them?

DR. WINKLER: Well, this is the proposed policy that we talked about, inactive. That's the proposal that's currently -- you know, that NQF currently has. It's out for comment. It's been, you know, gone through CSAC. It will go to the Board. You're helping us by giving us the feedback and we're also looking about how it might actually be applied with some real measures.

MEMBER SNOW: So, could we vote this morning to use that bucket?

DR. WINKLER: Yes, that's exactly what is on the table right now is to --

MEMBER SNOW: So, I move it.

CHAIR GIBBONS: Okay. So, and it gets back to Mary's point earlier. We never voted 1B separately, but we would have I think voted. You know, had we had that separated out, it would have been clear what the issue

was. Rochelle?

MEMBER AYALA: Well, I just wonder if we had a designation like that should we be more specific than saying high performance? Should we have like a quantitative cutoff point beyond which we said it's --

MEMBER KOPLAN: The problem with that is that you're going to have to individualize, you know, in terms of -- some things are more important at certain levels than others, I would think. So I think one of the problems sometimes, as happened this week and the last time, or these last two days, is that sometimes people say, oh, we're inconsistent. We did this on this measure and that on this measure, but I do think you kind of have to individualize sometimes.

MEMBER AYALA: Well, my concern with that is that if we don't put it very, very high, like 98 percent, for example, then the next question we have to say is at a certain level we have to look at disparities

because if you get it really, really high, by definition you're eradicating disparities. But if you start having a gap between where you think it's acceptable and 100 percent, then you're opening yourself up to disparities, like a gap.

VICE CHAIR GEORGE: No, but I think it also depends not just on what that mean or median is, but what your range is. So, two measures could be 98 percent for the median, but have still a different lower end.

MEMBER AYALA: Oh, I didn't realize that we were talking about median here for the --

CHAIR GIBBONS: Well, you know, to get back to the question Leslie asked, for example, you know, the medians for these measures have been persistently high for years. We're looking at at least three years and maybe five years the medians have been particularly high, or have been consistently high, because that's what's shown in most of

the data sets. But I don't know that I've ever seen the 10th percentile applied over time to see what's happened to that during the same time frame.

MEMBER RASMUSSEN: As a point of clarification, I'll --

MEMBER JEWELL: This is Dianne. It's a little hard to know how to participate in the conversation since I can't see the slides, but I would offer this: It seems to me that part of what we do when we consider a measure the first time -- well, consider a measure is we ask about importance.

And so, if we have an inactive class of measures and there's some regular schedule that's enacted for revisiting them, rather than waiting for a trigger, like an arbitrary sort of drop below a certain performance level -- but maybe there could be criteria for reactivating that could be developed and those criteria could fall along the lines of, you know, this issue of how much

of a drop in performance are we seeing, but also what impact that translates into along the lines of some of the calculations that have been offered up in our discussions. So, I guess I would just offer that.

MEMBER RASMUSSEN: So, a question: For example, if CMS is using this measure, how do they grade an organization? Is it based on median? Is it based on percentile? The reason I ask; with this beta-blocker measure, if we get credit, if we're in the 90th percentile and I miss one patient, I'm in the 50th percentile. That's not existential angst, that's just plain angst. You know, if you're chasing one person. So, it's a clarification question more than anything.

DR. WINKLER: And honestly, I don't want to speak for CMS because they actually make the rules of their implementation and their payment programs, and I just don't know the details.

MEMBER RASMUSSEN: So, it may vary

by accrediting organization.

DR. WINKLER: The implementation programs are -- you know, use these measures, but the rules on how they do it and whatever incentives that may go along with it are really specific to that program.

CHAIR GIBBONS: And obviously that's a numbers issue. And I'll just reflect that in the discussion of imaging efficiency measures that loomed very large because at least one of the developers was going to put in something that would be a major problem at the low end of numbers with respect to whether the performance changes were due to chance alone, and it was a major struggle in the process.

Yes, Karen?

DR. PACE: Just one other comment on the disparities issue; and it kind of relates to why we've asked that question under importance, is that if there is data that there are disparities issues, we would kind of

consider it doesn't matter what the median and mean and percentile rankings are, that that would be justification that there are opportunities for improvement and in eradicating disparities. So --

CHAIR GIBBONS: Yes, and I think as we -- we should though reflect that that's in itself a complex issue.

DR. PACE: Right.

CHAIR GIBBONS: Because what is the socioeconomic group that you're looking at? Is it left-handed Finnish-Americans that have a disparity? And because it came up in part of our discussion yesterday, you can get into an awfully small sector of the population and is it worth the opportunity cost in the other 99.85 percent of the population?

So, okay. I think we've had a good discussion on this. Reva, anything else we can provide?

DR. WINKLER: Yes, in fact I need some action from you because --

CHAIR GIBBONS: Action? Well, Roger has moved that we're going to put these two measures in the inactive category.

DR. WINKLER: Okay. Hold on. I need a couple other things. Because you stopped your evaluation at importance and it failed on your first vote, we didn't do the evaluation of the other criteria. And in order to keep them on the endorsed list, they've got to meet all the criteria. So, yes, it's a process issue, but it's one we want to keep nice and crisp and clear.

CHAIR GIBBONS: Okay. So, let me try and take a stab at a suggestion. We figure out who the original reviewers were and ask them to re-consult that particular application with the notion that their scoring will be distributed to the committee for either an email ballot or a telephone ballot subsequently regarding the criteria so that we move the process along here today. And we probably I think should do the same thing for

EF.

DR. WINKLER: Okay. That's what I was going to ask, do you want to include the EF in that?

CHAIR GIBBONS: Yes.

DR. WINKLER: That's fine. We can do that. We did --

CHAIR GIBBONS: I think EF boiled down to performance gap versus unintended consequences in the discussion.

DR. WINKLER: Given the discussion, I think that what we've learned is we're going to have to ask the questions of the committee somewhat differently, particularly in this topic area. So certainly we can approach it differently. And I think we'll parse that out in the questions we ask you as we do this final evaluation on these three measures.

Are there any others that seem to fall into that category?

CHAIR GIBBONS: Roger?

MEMBER SNOW: List the three measures for me again so that --

DR. WINKLER: It was aspirin after discharge for AMI --

MEMBER SNOW: One-forty-two, one-sixty and what's the other one?

DR. WINKLER: Oh, let me look at -- it was yesterday's. One-thirty-five.

MEMBER SNOW: Thank you.

CHAIR GIBBONS: So, Kathleen, you're not done yet with 135.

DR. WINKLER: But I would recommend that we have outlined the proposal in this memo. You have received it. Before you do register your final votes, we'll send around the survey to do that. Just please look this over because it does have the details in it.

MEMBER SZUMANSKI: Reva, I just have one comment --

CHAIR GIBBONS: Yes?

MEMBER SZUMANSKI: -- on this, if

I can.

DR. WINKLER: Yes.

MEMBER SZUMANSKI: I would ask from the application standpoint and the hospital end it would be extremely helpful if NQF could create some recommendations or guidelines for a quality department to say, you know, you're falling for the last rolling 12 months or quarters. You're in the 100th percentile. Please consider, as Tom indicated, selecting other measures that might be on your dashboard. I don't know that people know how to do this out there and it just might be helpful if you can give them some overall general guidance on how to retire a measure or how to bring a new measure into their dashboard.

And secondly, these measures that reach that top level of performance are used routinely by hospitals for public relations reasons. And I think it would be very much of a challenge for them to say, well, we're going

to now not give you as much information as you had. They need this to maintain their day-to-day operations from a public satisfaction perspective unfortunately.

MEMBER SNOW: I hear that, but the concept that I will point to is not giving them less information, but giving them different information. If the total effort remains the same, then they'll just be talking about different things are being improved. And I would avoid the term "retire." I would use the term "rotate," if we think of it as something that can come back when needed. If it's a good measure; that is, the structure of the thing is good, it measures something that's real, then it won't get bad. It's not like cheese.

MEMBER SANZ: The other thing is you shouldn't be -- you're right that a lot of this is used for public marketing, but marketing and measure where everybody has 99 percent I would argue is not a useful use of

this tool and all the effort required to capture it. You ought to be marketing your congestive heart failure composite score if you're that good.

MEMBER SZUMANSKI: And I don't disagree with that, but I'm not sure they know how to do that. And by giving them some structured guidelines on measurement -- and that might be helpful, because they always fall into, well, we're looking really good. Here's our number. So, and I don't disagree with what you just said.

CHAIR GIBBONS: Christine?

MEMBER STEARNS: But and that I think though that we should also think about trying to find something other than inactive perhaps to call high performers that have been rotated out or something so that -- to express because that will better communicate.

DR. WINKLER: As I mentioned, this is out for public comment. I'm sure we're going to get all sorts of suggestions. We'll

add yours to the list.

CHAIR GIBBONS: Okay. We're going to take a 20-minute break right now and then come back for a discussion of disparities.

(Whereupon, the above-entitled matter went off the record at 10:50 a.m. and resumed at 11:11 a.m.)

CHAIR GIBBONS: So, we're going to take a little time discussing and reviewing the data which we requested on disparities. And NQF went back to developers, and in particular CMS. And there are two separate documents and the one that I propose that we discuss is just entitled, "Disparities, CMS." It's an Excel spreadsheet and it's now up on the screen. Disparities analysis for 26 performance measures.

The other one is the emergency department measures, which, you know, we did also discuss the last time, but are far smaller numbers because they largely reflect smaller hospitals that are then transferring

the patient on. And we went through a discussion of those. It's not to say they're not important, but simply in terms of the overall numbers and impact I think we'd be best to focus on this analysis.

And I mentioned that this issue surfaced because several of you mentioned it to me at the break the last time, that it was obvious that the disparities blank in part 2 of the form was not being taken seriously and expressing concern over that. So, that's why we then had a discussion about the issue and asked the staff to revisit it with the developers.

So, I think I'd ask everybody -- make sure everybody gets the right spreadsheet open. And one of the people who did discuss it with me at the break last time was George. So, I've asked George to just take a look at what's here and make a few comments and inspire some comments from everybody else to this important issue. And then we'll discuss

what other guidance we might give NQF going forward. George?

MEMBER RICH: Yes, this is Devorah. Can I just ask a question? On the thumb drive I don't see the spreadsheet. I'm not sure where I'm supposed to be finding it. I just don't see it.

DR. WINKLER: It's a PDF file on your thumb drive.

MEMBER RICH: Under -- okay. That's helpful. But -- and it's under --

DR. WINKLER: Do you have a disparities slide?

MEMBER RICH: Under the competing measures form?

DR. WINKLER: There should be a disparities folder.

MEMBER RICH: Oh, fine. Okay. Thanks. Thank you so much.

CHAIR GIBBONS: Okay. So, has everybody found it?

(No audible response.)

CHAIR GIBBONS: I see a bunch of nods yes. I don't see any nos.

So, George, you want to make a few comments?

MEMBER PHILIPPIDES: Yes, just a few comments. So, this is in fact some of the data that we had requested. It's CMS data from a 2009 clinical data warehouse, and depending on the parameter, they have up to have 400,000-plus patients they've looked at. And they break them down by race, ethnicity in the first few pages, and later on there's also some data on gender. And I think broad strokes, there still are small differences, but they're small in many, many cases. Okay? So, not as problematic as, you know, we initially had been thinking.

There are a few things that you might want to sort of focus on. One is, if you look at PCI and time to reperfusion, there is still a small but significant difference between Caucasians versus Hispanics or versus

Native Americans in some of those parameters that I think sort of jump out. Similarly, on page 4 there are some differences as far as flu vaccination at discharge. And I'll give you guys a moment.

DR. WINKLER: CMS has included measures on pretty much everything they put up on Hospital Compare, so they gave us data beyond the cardiovascular measures that you guys discussed. They were bountiful in their response.

MEMBER PHILIPPIDES: And then again, you should probably peruse this in your own time period, but on page 7 there are also some small but again significant differences in regards to reperfusion therapy, both PCI and fibrinolysis between males and females.

So, overall I think this is helpful. This is the kind of data that in the future we'd like to have sort of up front imbedded in our paperwork so we can comment on these at the appropriate time. It really is

very, very helpful in helping us guide the developers as to what we want.

And we also should discuss, as Ray brought up, when in our future discussions, you know, time 1 or item 3 or 4, do we want to sort of bring this up. And that sort of gets at the issue of what do we think the valence is for this kind of data. Should it be something that's discussed up front as part of the initial impact and scientific importance?

CHAIR GIBBONS: Sure, Tom?

MEMBER KOTTKE: You know, we were having this discussion with Bob Bonow at the break about, you know, what part of town you live in in Chicago depends on whether you get PCI and not looking at -- I mean, the disparities may be hidden in the ZIP code of residents rather than in race or ethnicity.

CHAIR GIBBONS: Yes, for sure. David?

MEMBER MAGID: Yes, so I think that it's important to do that -- the sort of

hierarchical modeling that helps you separate out what's going on. So, you mentioned the reperfusion work, George, and I've alluded a couple times to the -- I think a seminal paper by Betsy Bradley that was in JAMA that looked at -- it basically -- first it showed that African-Americans were -- had significantly longer door-to-balloon times than non-African-Americans. But then it said, okay, well, how can we sort of apportion this disparity in a way? What is it about -- is it that providers take care of these patients differently, or is it that the hospitals where these patients receive care are of lower quality?

And what she found was is that the majority, probably about two-thirds of the longer door-to-balloon time could be apportioned to the fact that African-Americans receive care in hospitals that overall had worse door-to-balloon times. So, I think if we're going to, you know, look at these measures, we need that type of hierarchical

analysis that helps us understand what's better than just sort of saying it's worse in African-Americans than whites.

CHAIR GIBBONS: So, I certainly wholeheartedly agree. And now the question is now that that analysis has been done and published, is anybody doing anything about it?

MEMBER MAGID: Yes, that's a good question. That's a good question. Yes, how are they acting on it?

CHAIR GIBBONS: Is the world -- you got to use your microphone, Tom.

MEMBER MAGID: I don't think he wants that recorded.

CHAIR GIBBONS: So, I mean, you know, I think there's a message there. If we're going to collect these data and look at them and then, as in that case, extensively analyze them. All right? And what?

MEMBER MAGID: Well, I mean, I think the thing about the disparities literature is largely study after study after

study that shows that, you know, certain groups of patients; be they, you know, women compared to men, or African-Americans compared to non-African-Americans, have worse outcomes. But we really have very little understanding as to why that occurs. And so, this was sort of one of the first studies that began to help us understand that. I mean, to the extent that, you know, CMS and other agencies report out, you know, their results by hospital and hospitals see how they do compared to others, that's one way that you can affect change. I'm not sure exactly beyond that, you know, what we're suggesting. Did you have some specific ideas?

CHAIR GIBBONS: Well, I mean, for example, I happen to know that there's a leadership group meeting today as we're meeting for a mission lifeline for the American Heart Association. It would seem to me that hopefully within the context of that QI project that someone's looking at this

specific issue and saying, okay, what can we do? And likewise, I would hope within the ACC efforts at QI that somebody's thinking about it, because I don't think there's any issue about which physicians feel more consistently together about than the fact that people ought to receive the same care regardless of their ethnicity, or gender, or anything else. I mean, I think there's a uniform commitment to that concept and we ought to try to figure out from a system standpoint what we can do.

Mary?

VICE CHAIR GEORGE: Yes, just a couple of things. Actually, HHS today released two new initiatives, "HHS Action Plan to Reduce Health Disparities." Second one is the "National Stakeholder Strategy for Achieving Health Equity." And I think, you know, it clearly emphasizes how important this is on a national level.

In terms of what level of data we have here as we go through our meetings may be

different than all that is needed to do the fine research, but we can certainly keep a certain level of maybe high-level disparity data in what we do and it should be there to stimulate others to look further.

MEMBER MAGID: I mean, the folks from Yale gave us that information on both the mortality and readmission rate, so maybe asking for that kind of data across all the measures would be good.

MEMBER RICH: Hi, this is Devorah. I see that there's also opportunities here to collaborate with Robert Wood Johnson. I know they just put out a parcel of proposals mostly looking at the county health statistics and how to do some work there. But they're very interested in this and this could be the area that they'd want to do some piloting profiling around.

MEMBER SMITH: Ray?

CHAIR GIBBONS: Yes?

MEMBER SMITH: To answer your

question, we published a paper just a few months ago in circulation that Mauricio Cohen is the first author on; Bob Bonow and I are co-authors, looking at close to 450 hospitals, 150,000 patients in AHA "Get With the Guidelines" for acute myocardial infarction showing that the racial differences exist, that when patients were entered into these quality improvement programs, that those differences improved. So there are people doing something about it. Specifically, the American Heart Association in "Get With the Guidelines" and the use of quality improvement programs has been shown at least in 150,000 patients, 450 hospitals to narrow these differences.

MEMBER AYALA: One other --

CHAIR GIBBONS: Yes, other comments? Rochelle?

MEMBER AYALA: Yes, that just echos what I mentioned in the first phase, and that is that when you put quality and

eliminating disparities together, it's very powerful because you first have to collect the data and look at it and analyze it before you can actually do anything about it. And then you create your own quality improvement program to eliminate any existing disparities. But if you don't know you have them there, then you're not going to do it. And a lot of times institutions are not going to collect this data unless it's a part of a mandated, you know, indicator, quality measure. And you're looking at it at multiple levels.

So you're right, there may be hospitals where all the care is bad and they happen to have a lot of minorities there. And you might not have any disparities within that hospital's data, but that hospital's contributing to a higher level of data. So, if you're combining the quality part, that hospital's goal is going to be just get our quality up because we have to report that. And it may in the future actually be tied to

reimbursement.

So, if you link them together this way, you're getting a lot of data, you're having a lot of incentives for improving quality which will ultimately narrow the gap and eliminate disparities or decrease disparities.

MEMBER RUSSO: And similar to that the data was also for improvement. Linking the two with improved heart failure showed the same thing.

The other thing, and related to the last discussion right before the break, you know, I'm wondering if somehow the formula to put some of the measures aside might also incorporate some of the disparity issues such as, for example, the beta-blocker one. So, if you look in here, although most of them I -- George summarized, most of them do not look that different. But on the beta-blocker acute MI measure there is, you know, 96 versus 98 percent. I mean, we're talking about, you

know, Hispanic patients, you know, whether it's hospital-related or whether it's related -- you know, whatever the reason for it is, there clearly is this disparity in care, you know, identified with beta-blocker use, some with gender, too. But, so, should that be in the formula maybe before -- or should -- as long as beta-blockers are in a composite measure, maybe that's enough. But those two things in the formula for retirement.

DR. WINKLER: Actually, it's in there.

CHAIR GIBBONS: So, other -- I guess I'm going to put the interventionalist on the spot. Mark, any discussion in the interventional community about this issue of door-to-balloon time differences?

MEMBER SANZ: First of all, I don't know any specifics on disparities. But as someone has already pointed out, we are rapidly reaching the limits of what we can do from the standpoint of infrastructure. People

are pretty much down to less than 90. Some are down to less than 60. If you're inner city, you're -- or if you're in a city, you know, you're pretty much there and it's dependent on, as I think Bob Bonow said, something like where your ambulance is going to take you, and that's more of the disparity issue than anything that providers have control over. If you're in a rural environment, there are simply limits to what you can do. I don't think that there's a lot of room within the medical community to effect change. It's now an infrastructure issue.

CHAIR GIBBONS: Right, it's a systems of care issue probably.

Well, I think we can at least make sure that the necessary -- I guess one question in my mind is we're seeing these data and obviously CMS went through a process before they agreed to release them to us. Are they posted publicly anywhere?

DR. WINKLER: We actually have

them posted on the Web site for this project with the meeting materials. So, but I'm not sure that they actually post them anywhere on CMS' world.

CHAIR GIBBONS: I mean, I --

DR. PACE: What was Lein talking -- were these data in the chart book she was referring to, or was that just specific --

DR. WINKLER: Lein was talking I think about more of the analysis they did. So, I don't know to what degree there may be some of this data replicated. It's possible.

CHAIR GIBBONS: So, it would seem to me to be helpful, period, if these were more widely disseminated and more widely available for people interested in quality improvement to see. So, if the committee agrees with that, I think we could give CMS some feedback to encourage them to release them more than just on our committee Web site, which to be honest people aren't going to find or look at, because I do think there would be

broader interest. We can direct people to our Web site from efforts like Mission Lifeline and ACC, similar efforts, to try to make them aware of this as far as the systems issues.

Moving forward, I think we had a sense the last time that we wanted to make certain that disparities data was required for the submissions, and I think clearly conveyed that message to the staff and the staff will convey that to the developers.

But we did have this confusion repeatedly, I think, about where the data appears in the form, because there's a section in section 1 and then there's another section in section 2. Can I get a sense of people as they reviewed this where do they think it should be so we can give the staff some guidance moving forward as to where this should be on the form? George alluded to it; should it be, you know, fundamentally considered as part of the importance rather than the scientific acceptability?

Others want to comment? Roger?

MEMBER SNOW: Yes, I just want to vote for importance. And we talk about rotating or retiring measures. I don't think we should consider a measure for rotation if there's a significant problem of disparities. It's just too important an issue broadly and in terms of care. So I think it belongs at least in one.

MEMBER AYALA: I agree with that. I think it should be close to the performance gap. And I like what Reva had put together in that document we looked at just now, where you had those different levels of the total number of patients, the range; because that came to me when we were talking just now. We don't want to look at just the median; we want to see the range of the data and the disparities in terms of opportunities for improvement.

CHAIR GIBBONS: Other thoughts about this issue? Mary?

VICE CHAIR GEORGE: Yes, I guess

this really pertains to maintenance measures, but in looking at the disparity data with a maintenance measure, it would be helpful to know what the previous -- when it was previously up for review what the disparities data showed in the past compared to where it is with the current submission.

CHAIR GIBBONS: In other words, to specifically ask the measure developer to indicate whether they're tracking disparities so that the updated submission; be it three years or five years or in yesterday's case twenty years later, we'll be able to provide data in terms of this important issue. Does that sound reasonable to everybody?

MEMBER AYALA: Just thinking about the types of information that the developers gave us under the disparities. A lot of times it was just a simple statement or a little paragraph that really didn't give us data, but rather said that they didn't have any evidence of it. Is it too hard or too much to ask of

the developers to actually in their pilots when they're giving us their information back how they developed the measure and what their reliability, validity and all that was, to actually ask them to include disparities, include race, ethnicity, language, whatever we decide on and that they report those back to us as well?

DR. WINKLER: We can certainly communicate that as an important aspect of information in part of the testing, you know, to what degree it's feasible and doable for the different types of measures on different data platforms. But we can certainly add that to guidance. And we certainly get questions all the time about, well, what kind of testing? What all do we need to do to, you know, provide a good solid testing basis. And so, we can add that and be sure that that's emphasized as well.

Karen?

DR. PACE: And I would just add --

and your comments are great and we need to do some more clarification, but that actually is the intent of having disparities information in both places. The one is kind of is there a problem whether you know it from your measure or from research or whatever? And in section 2 it was about testing that -- you know, part of the testing, but that definitely needs more work. And appreciate your comments.

CHAIR GIBBONS: Any other thoughts of those who have looked at these data that we as a committee want to convey back to either CMS or NQF?

DR. WINKLER: Or other developers.

CHAIR GIBBONS: Or others. By the way, you realize now, since this is posted on the committee proceedings, if you are discussing this issue with any other group, you can at least point them to that location for these data. They're in the public domain, so there's nothing confidential here.

MEMBER PHILIPPIDES: I have one other small tweak.

CHAIR GIBBONS: Yes, George?

MEMBER PHILIPPIDES: Just looking at this now that they have age, region, urban versus rural. There's no mention; it's probably a difficult parameter, of socioeconomic status, which is probably moving forward going to be an important thing to look at. So, we might ask whenever there is such data to include that and have the details in true detail so we can look at it.

DR. WINKLER: Yes, George, just to tell you that disparities is a conversation that happens at NQF on a regular basis. In fact, we have an upcoming project that's going to address disparities. One of the real challenges that's constantly discussed is how do you describe these elements? What do you mean by socioeconomic status? What data do you use to classify, you know, patients into whatever strata it is you think is important?

And there's huge discussions around the proper classification for some of these issues. So, and it's certainly not in any way standardized. So, those are huge issues, but they're being discussed and certainly we can push for more.

MEMBER PHILIPPIDES: Well, certainly to have something like Medicaid versus not, or ZIP code, that kind of thing, it might be helpful.

CHAIR GIBBONS: Yes, I think as we pointed out; Tom and others pointed out, you know, you can get a fair bit of data from ZIP code. And the Yale folks mentioned that yesterday you can model socioeconomic status. But that data is fairly static because it's only updated by the census process and I don't know actually whether it's updated in between the 10 years.

Tom, you may know.

MEMBER KOTTKE: There is an ongoing survey; what is it, American Community

Survey, yes, which is ongoing and there's a little better -- but I mean, people are mobile, but they're not all that mobile.

CHAIR GIBBONS: So, I pointed out in an off-line discussion yesterday that if you look at a particular ZIP code that might actually change quite a bit over a 10-year period of time. There's a problem in terms of updating that and that's why it's only a surrogate because it's a moving target in some areas of the country, more so than others.

But I think, George, that's a good suggestion as well.

Are there any other thoughts? Rochelle?

MEMBER AYALA: Just a follow up to that. When we first came in, I was thinking about disparities more along the lines of race, ethnicity, gender. But then as we talked around the room, these other issues came up, these other areas that are worthy of analysis, including rural versus urban and

then socioeconomics. And so, when we ask the developers to give us disparities data, are we going to specify what type of data we would like to get back, like which categories and maybe prioritize them, or, you know, to help people in the future instead of having a fragmented set of data to look at it?

DR. WINKLER: Well, you know, what we're trying to do is standardize the requests for everyone so it won't be so much topic or measure-dependent. And we have to look at the -- you know, what's reasonable. That's a lot of the work that Karen does. And so, we'll take all of your feedback in terms of what's desirable. Again, a lot of the push back we get from developers is they don't have data like that and things like that. And there are limitations. But again, constantly asking, constantly pushing, constantly requesting can you know, make progress.

CHAIR GIBBONS: Okay. I think this has been worthwhile. I think it was

certainly worthwhile to request the data. Hopefully the process will be improved moving forward with respect to this important issue. But I for one was heartened by the data. It was not nearly as bad as I thought it might be except for the PCI issue that we pointed out, which by the way has a long, long history going back into, oh my goodness, the 1980s when Herman Taylor was at the University of Alabama at Birmingham and actually first studying this issue in the Great State of Alabama. So, there have been people pursuing this particular goal for a long, long time in the scientific community.

So, let's move on then. There are a few follow ups from our last meeting that we need to deal with before we broach the whole issue of competing measures.

So, the first one I think is fairly straightforward. It is that, if you recall, we considered a composite measure for chronic coronary or vascular disease from the

Minnesota Community Measurement Project where we all liked the notion of this composite. It was the measure that's been in use in the State of Minnesota. So to remind everybody: Smoking cessation, aspirin, blood pressure control, lipid control. All four. It's an all-or-none measure. But we did not like their threshold for blood pressure control, which had a whole unique history and was not aligned with the national blood pressure -- existing blood pressure guidelines.

So, we had two separate series of votes. One was that literally rejected the measure as it was, but the second was that we would entertain -- or we did vote approval of the measure if they changed the blood pressure criteria.

DR. WINKLER: You know, I'd like to just point -- direct the committee to -- this is the memo that's called "Follow Up From Phase I." And we asked the measure developers a large number of questions based on your

discussion for follow up. And it's a fairly meaty document, so you can certainly look at it at your leisure. But in those follow up, we can go and look at the one from Minnesota. And basically they agreed to make the change. They went to their committee on March 9 and they approved the change. So, they have adopted the 140/90 threshold and agreed to align with JNC 8 when it becomes available. And if we need to review all the blood pressure measures, that's -- you know, everybody's sort of aware of the desire to align around a single national guideline as opposed to kind of having guideline confusion. So, Minnesota did come back favorably.

So, I will interpret your vote to say that you have approved the revised measure. I just want to be sure everybody's aware of that and you're okay with that.

CHAIR GIBBONS: Yes, so this is to be transparent. They've come back. They have changed. We told them to change. They did

it. We actually voted on this, but just to make everybody aware that this is now -- unless somebody has some additional concerns, this is approved with the different blood pressure target. And personally I think it's a big deal, because it's a national composite outpatient measure.

Any other discussion or comments about that?

DR. WINKLER: Okay. There was one --

CHAIR GIBBONS: Now, Reva, you want to take on the other one?

DR. WINKLER: Yes, the other one. The other measure was the measure from NCQA on blood pressure management that there were a couple of issues around. And in the follow-up document you'll see their responses. One was -- if you recall, it had two blood pressure targets. It was the less than 140/90 and less than 140/80. And your question was what's the evidence for the 140/80? What's the deal?

And so, basically they've removed it. So, there is no second target.

The other question I think was the significant issue, was the lack of an upper age limit with concerns about blood pressure control in the elderly or patients without tolerance. We had very similar conversation yesterday on the hypertension measure, so this is not a new issue.

I can tell you that their responses, that their advisory committee talked about it, didn't -- hasn't come to any agreement, although they are certainly willing to discuss it, particularly in the realm of harmonization, because this measure is essentially a component of the Minnesota composite and the Minnesota composite has an age limit, an upper age limit of age 75. So we've got a harmonization issue that it think is the way we could tackle this. And NCQA has indicated that they'll also align with JNC 8 going forward. And given some of Dr. Smith's

comments over the two meetings, it seems likely there might be some additional guidance coming forward from there on some of these issues as well that we will revisit.

All of the measures that are endorsed go through annual updates. We look at new ones, and any measures that need to be seriously reconfigured because of new evidence, new guidelines, whatever, we just review them at that time. So, all of these blood -- knowing JNC 8 is out there in less than a year, we know that we'll have to take a serious look at all the blood pressure measures, and we've got several once they're available.

So, in terms of this measure from NCQA, it was one of those where we didn't vote it conditionally. We voted it that we didn't like it as submitted. But now that we have these changes, we did not do the second vote like we did with the Minnesota measure. So the question is does the committee want to

revote the revised measure from NCQA?

CHAIR GIBBONS: Yes, and I would suggest that what it would then take was again identifying somebody to be the reviewer and hopefully the same person who was the original reviewer re-looking at the application in light of these responses and then providing advice to us that would be the basis for a future vote either by email or conference call. And so, the real question is do we feel that these responses are satisfactory to merit that additional work?

MEMBER SNOW: Well, we asked them to do a particular thing and they've done the particular thing.

CHAIR GIBBONS: No, we didn't actually -- it was not as direct here. We just raised in our -- they were here.

MEMBER SNOW: Yes.

CHAIR GIBBONS: And they heard all our concerns. And then they came back with these responses. We never got to the details

of the measure.

MEMBER RUSSO: What is this add -- what's the value added of this measurement compared to the hypertension measurements from yesterday?

DR. WINKLER: Essentially the denominator populations are different. Yesterday's measure was patients with hypertension. This measure is patients with ischemic vascular disease. So, I think that given that's where we are today, it prompts the bigger question that I think Dr. Gibbons mentioned at the last meeting; why isn't there one measure for blood pressure control for everybody who needs their blood pressure controlled? Excellent question, but I don't think we're quite there yet, though it's definitely a worthy goal. But they are different patient populations.

MEMBER KOTTKE: I guess, I mean, people probably know this, but it's a matter of, you know, how the patient gets in the door

and how they get identified. That's why there's so many different --

DR. WINKLER: So, when we do the follow up, which is likely to be probably by email, would you like to include this as a follow up to revote?

(No audible response.)

DR. WINKLER: I'm seeing nodding around.

CHAIR GIBBONS: You know, is it worth the effort in light of these responses from the developer, is the question? I just need a sense.

MEMBER KING: I have a question about that would relate to that. In other words, yesterday we said that everybody's blood pressure should be less than 140/90 and these people should have their blood pressure -- and now they agree that it should be 140/90. Aren't they included in that?

DR. WINKLER: No, not necessarily. If the patient -- well, you tell me: How many

patients carry both the diagnosis of coronary artery disease or ischemic vascular disease and hypertension such that they would be captured in the hypertension measure. That's the difference. Unless you carry a diagnosis of hypertension, you won't get captured.

MEMBER MAGID: I'm not really sure that you're going to capture more people. So there are a significant number of people in the United States who have hypertension for which it's not recognized and they don't carry a diagnosis, that's true. But this measure doesn't really address that.

DR. WINKLER: No, I guess the question I would ask you, are there patients who have coronary artery -- or ischemic vascular disease primarily --

MEMBER MAGID: Right.

DR. WINKLER: -- coronary disease that don't carry a diagnosis of hypertension also?

MEMBER KING: Not those that don't

have their blood pressure -- you would carry that diagnosis if your blood pressure two or more times in a row was over 140/90. If it was below, you already meet this and we don't need to monitor you, judge you and do anything. I would still maintain that now that they have harmonized, this measure may not be necessary at all.

DR. WINKLER: That's a different question.

MEMBER MAGID: Yes, I mean, I think that you're not going to capture a significant proportion of the people. In other words, those people with known coronary artery disease are the ones we focus on a lot. The people that are largely unrecognized are not in this group.

MEMBER KOTTKE: Because they've done the work I think we ought to give them a response. I think that's polite.

MEMBER SNOW: I agree with that.

CHAIR GIBBONS: No, no. I think

we want to -- all we're going to do -- vote today is whether it's worth the effort to have this re-reviewed and fully revoted. That's what this vote is about. Is it worth the effort? Because we can't do it properly without a re-review, etcetera. So, can we use our automated system for this?

DR. WINKLER: As long as you -- if you ignore the meet criteria and just use it as a yes/no.

CHAIR GIBBONS: Yes/no.

MEMBER RUSSO: Can I ask one other question?

CHAIR GIBBONS: Yes.

MEMBER RUSSO: So, would this open the door; and I'm not saying it's good or bad, for all the other measures that we stopped at that first step for people to come back in the next month or --

DR. WINKLER: You didn't stop at the first step. You did the complete evaluation, but during your discussion you

talked about being open to revisions to the measures. You didn't do that with all the rest of the measures.

MEMBER RUSSO: Okay.

DR. WINKLER: And so the follow up of --

MEMBER RUSSO: And so we did this for the one we just talked about, so why wouldn't we do it for this person then?

DR. WINKLER: Because we did this one first and didn't think about it.

MEMBER RUSSO: Okay. No, no, I'm saying, but we should give them -- no, no, I know that we didn't do it that day, but we should --

CHAIR GIBBONS: We became more proactive as the day went on the last time.

MEMBER RUSSO: That's right. Yes, okay. Give them the same chance, I mean.

DR. WINKLER: Yes, that's essentially it.

CHAIR GIBBONS: And you could

potentially just, as Tom said, just say this is a matter of politeness. They came back, blah, blah, blah.

So, is the voting clear as to what we're voting on? It's whether we're going to go to the trouble of re-reviewing this particular blood pressure measure that we rejected the last time?

(No audible response.)

CHAIR GIBBONS: So, if the vote is now clear, we're going to go ahead and vote.

DR. WINKLER: Dianne and Devorah, are you clear with this?

MEMBER JEWELL: I think so.

DR. WINKLER: Okay. Good.

MEMBER RICH: I think so as well.

DR. WINKLER: Dianne, Devorah, what do you think? Dianne?

MEMBER JEWELL: Yes for me.

DR. WINKLER: Devorah?

MEMBER RICH: Yes for me as well.

DR. WINKLER: Okay. So, okay.

CHAIR GIBBONS: So, the vote is 17 yes; 3 no. So, we will re-review this and just the same way we're going to re-review those measures slated for rotation the way we said earlier. Okay? All right. Good.

Now, we're going to move onto competing measures. Oh, boy.

DR. WINKLER: Okay.

CHAIR GIBBONS: So first of all, we've got to find the right grid.

DR. WINKLER: Right. Okay. Again, it's the third of the other memos that says "Memo to Steering Committee: Competing Related, Final." And I believe on your jump drives it's a PDF and the side-by-sides that go with it are attached. Okay?

Okay. And essentially we identified based on where were at before this meeting measures that seem to be competing, topic areas. Some of those have been eliminated by the decisions you've made over the last couple of days, but I think that what

we can do is start with the first side-by-side around aspirin use because it brings the whole problem to bear all in one fell swoop.

This is not all measures that had aspirin in its title. Aspirin on arrival I did not include. These are more the secondary prevention measures. As you can see --

CHAIR GIBBONS: So, let's make sure first before we start, has everybody found the right grid?

DR. WINKLER: Right.

CHAIR GIBBONS: Or they can see it on the screen, but hopefully the right grid on their computer.

DR. WINKLER: Has everybody got the side-by-side for secondary prevention, anti-platelet agents? There are six measures on this side-by-side.

MEMBER RICH: I'm sorry, I'm --

CHAIR GIBBONS: And it is page 7.

DR. WINKLER: Yes.

MEMBER RICH: Okay. Fine.

Thanks.

DR. WINKLER: Okay? Now --

CHAIR GIBBONS: Wait a minute. Whoa, whoa, whoa. I really think we need to just make sure we're literally all on the same page.

DR. WINKLER: Yes. Are we all on the same page?

CHAIR GIBBONS: Do I have nods? Do I have nos? I got a lot of nods. Thumbs up. Far side of the table? Christine?

MEMBER RICH: You're talking about the PDF file --

CHAIR GIBBONS: She's looking.

MEMBER RICH: -- that is in landscape format?

DR. WINKLER: That's correct.

CHAIR GIBBONS: Christine is looking.

MEMBER RICH: Yes?

DR. WINKLER: Correct.

CHAIR GIBBONS: Suma? Okay. So,

we'll give a few more seconds to make sure, because I think it's really -- otherwise it's so hard to catch up on these discussions.

DR. WINKLER: Dianne and Devorah, do you have the --

MEMBER JEWELL: I'm good.

MEMBER RICH: Yes, I got it. Thank you.

DR. WINKLER: Great. Thanks.

CHAIR GIBBONS: All right.

DR. WINKLER: Okay.

CHAIR GIBBONS: All right. We will proceed.

DR. WINKLER: All right. What I've included here; and six seemed to be about the limit of what we could put on a single page, is the first two measures are measures you reviewed at the first meeting. And the first one is the chronic stable coronary artery disease anti-platelet therapy, and that's from PCPI. You also looked at ischemic vascular disease, use of aspirin or other

antithrombotic.

Now, we also have in the portfolio another measure that came out of our clinically-enriched administrative data project of secondary prevention of cardiovascular events, use of aspirin or anti-platelet therapy. That project was looking at measures that can be generated primarily with administrative data, primarily claims data with -- enriched by either EHRs or PHRs. So, you will see measures from that project peppered in here.

Under related measures I included the Minnesota composite because one component is the same thing. And when you're talking about harmonization -- now, the last two, the 142 is the aspirin prescribed at discharge for AMI, and this is the measure you sort of are discussing about its status. So, it's still kind of to be determined, I guess.

The last one is the aspirin at discharge for patients with PCI, which was a

measure you evaluated last time, but it became a component in the new composite yesterday and you recommended the composite but not the individual measure.

So, can't tell the players without a score card.

CHAIR GIBBONS: Is everybody tracking that? So in other words, the last column on this grid is the individual measure that yesterday we said because it was rolled into the composite we were no longer going to recommend for endorsement?

DR. WINKLER: Right.

PARTICIPANT: That's 1493.

CHAIR GIBBONS: Because of very high compliance, 1493. So, in essence the last column to some degree has already been wiped

off --

DR. WINKLER: Yes, right.

CHAIR GIBBONS: -- by us yesterday.

DR. WINKLER: So, anyway. So, and not all of these measures are on our list for maintenance review. Now, earlier in this memo -- and if you recall at the end of the last meeting, Helen started walking you through the proposed kind of algorithm, policy, whatever you want to call it, that talks about how to evaluate competing and related measures. And I think one of the first things is definitional, and that is which measures are competing and which measures are related? And frankly, I found that difficult because if you look at them, I think that if you look -- the biggest target population is patients with ischemic vascular disease.

Now, they may be subset because they either just had an AMI, just had a PCI or they're just the CAD subset, but the target population is still this group. But yet they all kind of look at a different piece of that big pie. And I think this is where Jon and a lot of other people's suggestion that is there

some way we can move to, you know, sort of one way of looking at this concept of secondary prevention with the appropriate medications? So, there are -- this just gets, you know, extremely complicated.

And the question I would ask you is, given that we can't roll it up into one measure yet, do we need all of them that are here? And I think that's sort of the fundamental question. If you look at the first two measures, you're talking about aspirin and anti-platelet agents in CAD. Essentially the next one, 68, is use of aspirin and antithrombotics in ischemic vascular disease. That's a slightly larger denominator. CAD is the largest portion of it, but it does include peripheral arterial disease and cerebrovascular disease and some other ischemic vascular diseases so that, you know, 67 is a subset of 68. Is there a need, a benefit, a value or does it just add confusion and chaos to have both measures?

Since those are both up for maintenance review, that's a fundamental question for this committee in terms of your final recommendations going forward.

MEMBER SMITH: Are you saying, Reva, that the Venn diagram for 67 lies entirely within 68? I would wonder about that.

DR. WINKLER: Well, the way --

MEMBER SMITH: I mean, I'm sure there's overlap, but --

DR. WINKLER: Well, ischemic vascular disease is defined as --

MEMBER SMITH: -- disease is included in the definition of ischemic vascular --

DR. WINKLER: Yes. I mean, it's defined as CAD plus PAD plus CVD. So, I mean, just by purely the definition of the ischemic vascular disease.

MEMBER RUSSO: As a separate question moving forward, is there a way as a

measure developer that you can query to see -- you must have spent a lot of -- or you know the measures, but someone from the outside developing new measures so we don't get three more of these next year that you can query by keywords? Or should we consider requiring the submitters add some keywords so we can use a query search so that new people don't make up the same measures again?

DR. WINKLER: Well, we've actually done that, and it's actually a requirement on the submission is that they look to see what other measures may be similar. I think it would be beneficial to be able to make it so obvious about what measures exist so that people don't even bother investing in development of similar measures going forward. That becomes a communication issue. But you're absolutely right, Andrea, that that is something that is, you know, highly desirable. And in our communications with measure developers, which we do on a regular basis,

these are the issues that get discussed, because there isn't a point in committing more resources to redevelop the same measure.

MEMBER KING: I am a proponent of the BBT, the big basket theory. And 0068 appears to be the big basket and it include 67. In fact, if I read it right, I think it includes 0142 and 1493. It includes people with a PCI, people with an AMI, people with a reason for aspirin. And our discussion around harmonization was who needs this medicine to prevent cardiovascular disease, just the same kind of conversation we had about, you know, who needs beta-blockers and who needs ACE/ARBs? This is who needs aspirin? And 68 seems to be pretty close to what we've been asking for all meeting long.

CHAIR GIBBONS: Okay. So, now let's point out that 68 is in fact a component of 76. So, I mean, it does get complicated, but 68 is a component. It's the aspirin component of 76 with slight differences in the

denominator because 76 is capped at 875.

DR. WINKLER: Right. Although we are -- once we kind of figure out which ones we need to work on the harmonization, those issues become very serious.

CHAIR GIBBONS: Moot. Yes. So, and then, Dana, I think the one thing everybody should look at, because this certainly came to mind as we were considering these the last time, are the exclusions. Because both 67 and 76 allow for clinically-important exclusions and 68 does not allow any exclusions. So, everybody should scroll down and look at exclusions because that is really -- aside from the denominator, overall broadly cast, is in defining compliance are there exclusions?

DR. WINKLER: Just keep going. Scroll down.

CHAIR GIBBONS: They're on there. You just got to keep scrolling on this form.

MEMBER JEWELL: Is it listed in

the exclusions or just on numerator description?

DR. WINKLER: It's a long scroll. It's on page 18 of the -- there it is.

Yes, these are complicated analyses to try and present.

CHAIR GIBBONS: Okay. So, you have to use the microphone, but I think if you scroll down to the exclusions, you'll see that there's another fundamental concern here.

MEMBER MAGID: Yes, so in terms of the exclusions, you know, because one's a hospital-based measure, it has sort of hospital-based-type exclusions. One's an ambulatory measure. It has ambulatory-type exclusions, right? So --

CHAIR GIBBONS: Well, whoa. I'm not sure which one you're looking at for hospital-based. Which one are you --

MEMBER MAGID: Oh, I'm sorry. Wait a second. I'm looking at the blue ones. Never mind. But I'm looking on the right

page.

CHAIR GIBBONS: You got to be on the right --

MEMBER MAGID: I'm on the right page.

CHAIR GIBBONS: Now you got to look for the right column.

MEMBER KOPLAN: I think one thing is you do have -- when you talked about, you know, lumping 67, 68, 142 and maybe 76, that you have to be a little careful about over lumping because it's very -- I think one of the things maybe we haven't done that needs to be done more is more outpatient kinds of quality things. A lot of the hospital stuff gets tracked a little bit more it seems like. And so, you know, looking at a measure that's after QMI at discharge is very different in my mind than in an ambulatory setting. And I don't know if I'd want to lump those two because there are so many different issues that come into play there.

I would agree that it does seem like 67 and 68, at least the first block that describes them, you can put them together, but then there's the issue also one of them has clopidogrel incorporated and one just has aspirin.

DR. WINKLER: That's the next harmonization question I was going to pose to you. If you notice all six, the actual inclusions for the medications are all different. There are six different unique inclusion criteria.

MEMBER RUSSO: I think it may be hard to eliminate these up front now, I hate to say. But as moving forward again, when developers come up with the measures, they need to say that they looked, but what are the differences and outline the differences for us why their measure should be approved in the future, because I think we're going to continue to see this if we don't.

CHAIR GIBBONS: Well, I would

predict; and NQF staff can help, that they will all have a case for their measure going forward. So, that will be it. They'll make the case and you'll have a grid with six measures unless we, you know, swing into action here. Suma?

MEMBER THOMAS: Could in the future -- just throwing this out there. Could they send a measure to you just with like their title and purpose and then you guys sort of pose the question to the staff in the future rather than the whole -- you know, just their purpose and then you could pose those questions to them?

DR. WINKLER: Well, I mean, I think the purpose -- one of the things we hope to do to have our enhanced database is expect measure developers to go check and see. I mean, you can just do the search, find the measures and then, hello, do you need to add to this?

But, yes, that dialogue is

something we would encourage and be happy to participate in if indeed folks, you know, contacted us.

MEMBER RUSSO: Is there any way we could put this back? It's hard to say one is better than the other. You know, is there any way we could say, hey, you two look at it together and, you know, harmonize, or is that not going to work?

CHAIR GIBBONS: Well, how do I politely put this? Something came up in imaging last year -- Helen's not here, so -- which was -- at least from Committee's standpoint looked like it was straightforward harmonization. I would defer to Helen to try to describe to you how difficult this became in the negotiating process. And it took six months?

At least six months. And that, believe me, on the surface was -- I mean, the Committee thought it was straightforward. This is not nearly as straightforward. So, I

mean, I can imagine that one of these negotiations might well take two to three years. Mark?

MEMBER SANZ: Looking through this, I just don't see why we can't vote. As you look at the numerator for 0076, it lists pretty much everything you would want as far -- there are other exclusions in the numerator separate from the exclusions on page 18, if you go to page 12 and 13.

CHAIR GIBBONS: Right.

MEMBER SANZ: But I personally would be ready to vote today. I don't really want to do this again in one month, three months, six months as these people go back and forth and resubmit their versions of how they want to -- you know, one side says I want this or that. I'm pretty comfortable with 0076.

DR. WINKLER: Just a differentiation between what we would call competing measures, and that's the multiplicity; do we need them all, that's

really a competing measures discussion. That really is a steering committee decision.

The harmonization of the measures that are left with a similar topic is something we get into with the developers.

DR. PACE: But it's something that you have the ability to only recommend measures on the condition that they harmonize on a particular --

MEMBER KOPLAN: So, were you then proposing to take 67, 68 and 631 and just roll them all into 76?

MEMBER SANZ: That would be my proposal.

MEMBER RUSSO: And then how would you handle --

MEMBER SANZ: I don't see the down side, so --

MEMBER RUSSO: -- the exclusions? Would we say -- how are you -- well, because they're different.

MEMBER SANZ: Look at the

exclusions in the -- the exclusions in 0076 are not complete in the exclusion section. There's actually several in the numerator section. You got to look up above on page 12 and 13.

CHAIR GIBBONS: And that's historical reflecting the experience with the measure over time as a composite. There were adjustments in both numerator and denominator. And that was all spelled out in the original application.

MEMBER KING: I would agree with Mark. The question, we can't make all the 65s and the 75 and the 18 and overs and the -- they mention six drugs. They only mention five. We can't wave a magic wand and make those equal, but what we can say is that it's doesn't supply us with meaningful additional information to justify another measure.

And so, if I understand Mark correctly, he's saying that 67, 68 and 631 don't really supply anything meaningful added

to 0076, and actually I would agree.

CHAIR GIBBONS: Okay. So, we have two bold statements in favor of 0076. Others want to comment?

I'd point out we have several different options. One is we could actually vote today. Mark has expressed a clear preference in doing that. We could as a group say everybody wants to ponder this grid a bit more carefully, and we'll then take a subsequent vote.

Bruce?

MEMBER KOPLAN: Rather than vote right now, I would -- because the only thing we have all these bold statements, which I'm not sure if I agree or disagree, but it would be nice to just hear someone's opinion about maybe like the dangers of over-lumping or some -- one of the educated members of the group or -- like what -- there must be some downside to doing this.

MEMBER RUSSO: And the only other

question too is what do you do with the age? Do we just arbitrarily say there's no age cutoff now? And then what do we say about the tobacco-free status, that we don't have that one anymore? Like do we have to modify the measure?

DR. WINKLER: No, you don't need to do anything with the measures. If you weed out and make the group smaller, then we'll really hammer hard on the harmonization issues around ages and things like that.

In terms of the smoking measure, NQF has specifically gone away from having disease-specific smoking measures. What we have is a measure of smoking cessation for everybody, and that is sort of your component here that has been subsetted for this population.

CHAIR GIBBONS: Tom?

MEMBER KOTTKE: Yes, and the tobacco measure we declared -- or that was declared invalid was advice to quit smoking,

not smoking status. This is smoking status.

CHAIR GIBBONS: This is smoking status. This is the outcome. This is the outcome. It's a component. And so, that's why as multiple clinicians who in the State of Minnesota quickly realized they'd never get to 100 percent because they'll always have smokers in their practice and just points out that we always still have a ways to go.

Suma?

MEMBER THOMAS: This measure also includes that blood pressure goal of 130/80. Does -- or --

CHAIR GIBBONS: Oh, no, no. No, no. This is the revised measure that they came back and changed. That's what we just alerted everybody to. It's 140/90 and they have agreed to change the blood pressure when JNC comes out.

MEMBER THOMAS: If needed, right.

CHAIR GIBBONS: If it's needed.

MEMBER RASMUSSEN: So, Mark, is

what you're proposing lumping or a death match for 76?

MEMBER SANZ: You're talking to an interventional cardiologist, so --

MEMBER RASMUSSEN: Yes.

MEMBER SANZ: Typically I would approach it with a death match.

MEMBER RASMUSSEN: Okay.

MEMBER SANZ: But why don't you explain? I don't understand the difference.

MEMBER RASMUSSEN: So, is it combining pieces of the other measures into 76, or just saying we like 76 enough that we would vote on that? All the other ones yes?

DR. WINKLER: Yes, let me just make it real clear --

MEMBER SANZ: I don't know what the real difference --

DR. WINKLER: Yes.

MEMBER SANZ: I mean, seems like it's --

DR. WINKLER: Let me just make it

real clear: What you need to pick from is what's available up there. You're not making new measures.

MEMBER SANZ: Seventy-six seems more detailed than the other ones as far as I can tell.

MEMBER RUSSO: I guess I'd just have to look at the particular -- are all the drugs included? I mean, it just takes a little, you know, extra looking here because --

MEMBER KOPLAN: Well, clopidogrel or -- those types of things are not included in 76, right?

DR. WINKLER: Well, here it is. There it is, yes.

CHAIR GIBBONS: Yes, they actually are. They're folded into the definitions. It's very --

MEMBER KOPLAN: Okay.

CHAIR GIBBONS: You really have to go through --

DR. WINKLER: It's on a different page.

CHAIR GIBBONS: Yes, it's on a different page.

MEMBER KOPLAN: Okay.

DR. WINKLER: Page 11 versus page 10, so it's just hard to see side-by-side.

MEMBER KOPLAN: They came up with Pravigard, which is good, because I'd never even heard of that before.

CHAIR GIBBONS: This side of the table's getting a little punchy here. They're getting hungry. We're going to have to break for lunch shortly. Their glucose levels are starting to fall.

MEMBER AYALA: I just wanted to remind everyone, we need to also look at the level and the setting. I don't know if that makes a difference here.

CHAIR GIBBONS: Say that again.

MEMBER AYALA: The level and setting. Has everybody considered those

differences?

DR. WINKLER: Just to summarize, 67 and 68 and 76 are really clinician level, group level kinds of measures, so they're similar. The 631 is a measure that can be measured at the clinician level. It can also be measured at higher levels of system or plan, or whatever. So, they are comparable in that respect.

MEMBER RASMUSSEN: On page 12 for 76 under contraindications, anticoagulant use, Lovenox, Coumadin, we would need to add dabigatran presumably.

DR. WINKLER: Right.

CHAIR GIBBONS: I suspect that anything of that sort; a friendly amendment, we can bounce back to the developers. I don't know this for a fact, Jon, but I suspect that internal discussion is already ongoing in the State of Minnesota because there's a fairly good process to try to update these whenever individual clinicians call up. I mean,

really, it's pretty -- tries to be responsive.

VICE CHAIR GEORGE: Since this relates to the entire population of ischemic vascular disease, do they also note for individual populations where certain drugs are contraindicated as opposed to the rest of the population considered?

CHAIR GIBBONS: I'm sorry, I'm not following. Which group?

DR. WINKLER: For instance, if Proxigel were added to this list, it's contraindicated in stroke. And would that just be noted with an asterisk?

(Simultaneous speaking.)

CHAIR GIBBONS: That I think we'd have to ask the developer. I don't know how they're handling that. We could easily ask.

All right. Before we go to lunch, I need a sense. Do people want to vote on this now, or do they want to postpone it under further consideration?

Dana and Mark have already said

they want to vote on this. Now I need to sort of get a sense from people.

I have questioned their glucose level, on least on this side of the table, given some of the comments that are going on off line. There's a serious blood glucose issue.

I don't sense a wave of enthusiasm for voting now, so I think what I'm going to suggest that we do moving forward is that everybody ponder the basically choosing 76 as in essence best in class. It's a composite. It rolls the other things in. And if that is our perspective, then we can have a vote on it subsequently. But in the meantime, if people have any questions or concerns, we can certainly reflect them back to the developer, just the one that Mary just asked, for example. We can easily ask. And dabigatran we can easily ask so that we're making certain that we do due diligence on this before we vote.

Does that sound like a reasonable plan to everybody? We're going to have to put a time frame on that. Any comments from those on the phone?

MEMBER JEWELL: No, that works for me.

MEMBER RICH: Sounds fine.

CHAIR GIBBONS: So, I think that's how we will approach this. Right now we're going to break for lunch. And then realize, we've only looked at the first example of competing measures.

MEMBER JEWELL: So, Ray and the group, I'm actually going to be saying goodbye to you now.

CHAIR GIBBONS: Okay.

MEMBER JEWELL: I've got another meeting which is commencing shortly, so I need to go attend to that. But thank you for --

CHAIR GIBBONS: Okay. Thank you and we --

MEMBER JEWELL: -- so attentive to

me on the phone out here in the virtual world.

CHAIR GIBBONS: Okay. All right. Take care.

MEMBER JEWELL: Thanks. You, too. Bye-bye.

CHAIR GIBBONS: Bye-bye.

All right. We're going to break for lunch, and we will reconvene at 1:00.

(Whereupon, the above-entitled matter went off the record at 12:20 p.m. and resumed at 1:00 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:01 p.m.

CHAIR GIBBONS: So, my sense is that we have gone as far as we can go today on the anti-platelet agent issue.

We will plan moving forward to redistribute the Minnesota Community Measurement Project application to everybody so that everybody can see that and all the details.

We can then entertain questions for the developer before we subsequently take a vote. Now, I think you're going to realize how important that vote is in the context of the next discussion, because if you'll keep scrolling down that same document regarding competing measures you will come to this page on lipid control. And we now have a very similar paradigm. We don't have six; we have five. But we have 0074, chronic stable CAD from the AMA and PCPI. We have 0075 on vascular disease and LDL control less than 100

from the National Committee for Quality Insurance. And we have our newly-endorsed measure, 0076, on optimal vascular car.

And I think you can quickly appreciate that there are a lot of similarities, and some of the differences are actually along the same line as the last discussion of anti-platelet therapy. They all have the same target, LDL of less than 100. All three of these have undergone review by this Committee.

If you look carefully, there will be minor differences I think in the numerator for sure. The universe of 0058 and 0631 being pretty similar, but 0067 being in a narrower population. But then I would sort of remind you, if you page down far enough, you're going to get to the exclusions and you'll discover in the first column and the third column there are going to be exclusions. There aren't going to be any exclusions in the second column. So, in part, some of our discussion

of the anti-platelet issue is also going to apply here.

So, I'll open it up at this point for additional comments from anyone who has looked over these and wants to comment or make a suggestion. Leslie?

MEMBER CHO: Can we take 0611 out of there, only because it's a primary prevention and all the other ones are secondary prevention?

DR. WINKLER: Okay.

MEMBER CHO: So just to make one thing easier?

DR. WINKLER: Sure. Again, I was looking for things that might be related. You may not consider it a competing measure and drop that out. So, fine. Can certainly do that.

MEMBER KOTTKE: Ray?

CHAIR GIBBONS: I see a lot of nods around the table, so I think there's a consensus we should do that.

Tom?

MEMBER KOTTKE: So, going back to Mark's question of -- is this what, near death experience or something, so --

CHAIR GIBBONS: No, I think it was Jon's question.

MEMBER KOTTKE: So, would we be saying that if you're going to have some sort of measure for risk factor -- secondary prevention, you do this bundled measure or you don't get anything from NQF? Is that what sort of is on the table?

CHAIR GIBBONS: Well, remember the votes we took yesterday where we could endorse individual measures. We could endorse the composite or we could endorse both.

Helen?

DR. BURSTIN: Hi, everybody. The only difference here would be that we actually don't have the individual measures from Minnesota Community Measurement. We actually have only ever endorsed the composite. So you

would be left without individual level --

MEMBER KOTTKE: No, but I'm talking about 0074, 0075 and 636. But we do have 74 and 75.

DR. BURSTIN: Yes, we have 74 and 75.

MEMBER KOTTKE: But would we be dis-endorsing those?

DR. BURSTIN: Yes.

MEMBER KOTTKE: And we'd basically say if you want -- an organization that wants to claim that they are using an endorsed measure would have to include all of the components, which -- in 76? Is that --

DR. WINKLER: Tom, I think what you're saying is if you do for a lipid control what you are thinking you might do for the aspirin measure and focus everything in on 76, then that's effectively what you're saying.

MEMBER KOTTKE: Right.

DR. WINKLER: If you're picking 76 and saying the others should go away from an

ambulatory care measure.

MEMBER KOTTKE: Which may be -- I mean, it's quite reasonable that outside of exclusions, I mean, anybody who has vascular disease and needs lipid control also needs aspirin and they need, you know --

CHAIR GIBBONS: Need to stop smoking and they need their blood pressure controlled.

MEMBER KOTTKE: Yes. Yes, they need that. Then you have interventions.

VICE CHAIR GEORGE: So, and I don't know whether you can answer this: On 76, looking at the exclusion, since we don't have the individual measures, is there anything in there that would allow for documented reasons for not prescribing --

CHAIR GIBBONS: Yes.

VICE CHAIR GEORGE: Okay.

CHAIR GIBBONS: Since I was the primary reviewer, yes. That's part of their constellation of exclusions. Physician

judgment. That's document.

Yes, Helen?

DR. BURSTIN: Just to follow up one more time, there are multiple -- somebody had asked -- I guess I was told by staff, one of the questions was are there any down sides to not having the individual measures? And I think it's just at least important to consider the fact that there are multiple uses of NQF endorsed measures. Some are for payment. Some are in PQRS. Some are public reporting. And the question would be at the end of the day would this one all-or-none composite be one-size-fits-all for all potential uses? Because you would essentially be saying none of the other measures on their own can stand alone. And as I mentioned, we don't have the individual components submitted, reviewed or endorsed from Minnesota, so it's not as if we have that option.

MEMBER KOPLAN: Also, is there --

CHAIR GIBBONS: Yes, Bruce?

MEMBER KOPLAN: This kind of alludes to something that was said before, but the fact that one of them deals with discharge after MI and the other one is more -- it sounds like an ambulatory thing, is there some difference in how these things -- am I wrong?

DR. WINKLER: No, it's just the way they are identifying the denominator. Seventy-five is an outpatient measure, but one of the ways you could get included is if on claims you have had a hospitalization --

MEMBER KOPLAN: Oh, yes. Okay.

DR. WINKLER: -- for something, you know, CABG, AMI, something.

CHAIR GIBBONS: So, all three are meant to be outpatient measures.

DR. WINKLER: They're all outpatient measures.

MEMBER PHILIPPIDES: And in both cases with a composite you have to hit all four targets to get -- credit the numerator. So, for better or for worse, it seems to me;

at least the way this one's written, tobacco-free status for many folks will be the killer. And it almost becomes what is your tobacco-free status rate? Because if you have one of the composites that's so much lower than the other ones, that's what it sort of devolves to.

CHAIR GIBBONS: So, Tom, might want to comment because I think his organization is the highest rated in the State of Minnesota right now on this composite. And as I recall about half of your non-100 percent values is due to tobacco. Is that pretty much it?

MEMBER KOTTKE: Yes, that's probably not too inaccurate. There are very considerable discussions going on about this; certainly around the diabetes composite measure, and I think around here of, you know, if you -- I mean, if you have something where patients will not move, do you discourage physicians from -- and are they punished for

-- you know, they're doing everything they can, but they feel that the measure is unfair because it's out of their control.

MEMBER SNOW: Well, it's also really not a composite anymore because the rate-limiting step is tobacco so it's, as you said, I mean, just --

MEMBER PHILIPPIDES: Well, that's my concern. And if you wanted to actually get a glimpse at one of the other three things, this might be --

CHAIR GIBBONS: So, let me just chime in and point out that although you might think that, when the data on these composites were first compiled the rate of compliance with both the blood pressure and the lipid control were less than with tobacco. Yes, they were less than 85 percent. Each one of those was less than 85 percent. Tobacco is going to be about 85 percent because you got about 15 percent smokers. And those other components were less. So, don't misunderstand

from what we're saying. We could show you the data, and I don't have it currently, but they're still less. They are less at the Mayo Clinic for sure. I can tell you that one. We're not doing as well with getting LDLs less than 100 as 85 percent; we're not there, in people with known vascular disease. Think about it. I mean, it's pretty amazing when you look at the actual data.

So, other comments or questions about lipid control? I think we're going to have the same potential dilemma here, and we may want to have the same process of looking carefully at the specifications of 0076 before we vote. And in the meantime, getting some sense I think of the downside; again, as stated by Helen, of doing away with the others. But, you know, we propose something. It goes out for public comment. And this will inspire a lot of comments.

And Tom has suggested I need to change my phone number. I'm not sure of that

yet, but --

MEMBER KOTTKE: You know, you could just go to minnesotahealthscores.org. And in fact, they report the composite for vascular disease, but then also independently report performance for blood pressure, bad cholesterol and LDL for tobacco-free and aspirin use daily. And so, it's not as if it's bundled and opaque. And so, there is that composite, but also there's ranking. And so, we're not saying that you can't see behind the curtain of the composite.

DR. WINKLER: Tom, just to clarify, this is a question that comes up a lot about composites -- is one of NQF's guidance in the framework for composites is that the measure can be deconstructed into its component parts, certainly for feedback to providers on the QI side. But, you know, I think it becomes ambiguous if the specifications don't say that they will report out the sub-components if it's not specified.

So, and it's not in this evaluation form that it would be. So, if indeed that were the expectation, I think we would want to be sure that Minnesota would want to specify it that way, because that would be an important aspect.

MEMBER KOTTKE: Yes, I would agree.

DR. BURSTIN: And the other issue is that at least for some of the programs like PQRI, soon to be PQRS, the payment -- you know, the programs for physicians to report on performance, they would lose the ability to use the individual measures as measures to assess performance.

CHAIR GIBBONS: So, I can't easily show it, but on my computer in front of me right now is the slide from the 2007 data of the composite. Of course now I've lost it. I'm going to bring it up again.

MEMBER KOTTKE: While Ray's chatting, in fact many of the clinics have

reporting 96 percent to 90 percent tobacco free and lipid control is down around 80 in others, so --

CHAIR GIBBONS: Right. Yes, I'm looking at 2007. So you've got the current one up?

MEMBER KOTTKE: Yes, I'm on the live Web site.

CHAIR GIBBONS: Yes, okay.

MEMBER KOTTKE: And the 96 percent is Edina Sports Health and Wellness. I mean, you know, like what do you expect?

CHAIR GIBBONS: So, blood pressure less than 140/90 is what?

MEMBER KOTTKE: Best clinic is 80 percent. Best clinic for LDL is 83 percent. Aspirin use daily, best clinic -- well, there's a bunch that are -- you know, you got to scroll way down to get down as low as 95 percent, but there's some 100 percents.

CHAIR GIBBONS: So at least in 2007 the mean data for both blood pressure and

LDL cholesterol was less than the mean data for tobacco-free. So, the drivers were in fact those two in terms of the composite for many, many more places than the tobacco-free. But obviously you'll never get to 100 overall because you're going to have a certain percentage.

And do you have the state average there for the composite? You know it for your place. It's 70 isn't it, for your place?

(Off-mic comments.)

CHAIR GIBBONS: What's that? I ask you these embarrassing questions?

MEMBER KOTTKE: Yes, I actually don't know that. And I -- let me --

CHAIR GIBBONS: This is for the public record. Maybe you should turn your microphone off.

MEMBER KOTTKE: Yes, right.

CHAIR GIBBONS: So the statewide average in 2007 for the composite was 40 percent. Think about what that means. Less

than half of the people, less than a flip of the coin that the people with vascular disease get those four things.

MEMBER KOTTKE: Well, Mayo Clinic and HealthPartners Clinics were tied at 44 percent.

CHAIR GIBBONS: In what year?

MEMBER KOTTKE: This is current posted year, whatever that is. Must have been last year.

CHAIR GIBBONS: So, there's clearly more room for improvement than tobacco cessation?

Okay. I think we've got a path moving forward at least for lipid control. And then we need to keep scrolling, right? There's another one on here, isn't there? Got to get to it.

DR. WINKLER: Okay. Page 39 is the beginning of the side-by-side for beta-blockers. I'll point out that the third, measure 160, is again this hospital measure

that you all still need to act on in terms of the fact that it's one of those topped out measures. Great measure, topped out.

MEMBER RUSSO: And it seems like there are some differences, too. I mean, 71 looks at persistence of beta-blocker treatment six months after discharge. Do we really want to eliminate -- well, other -- because that's persistence. And the first one includes an ejection fraction with a low EF. The fourth one looks redundant. I don't see what -- but that's actually not under review anyway. I don't know we can eliminate something not under review.

DR. WINKLER: Well, what we'll do is just take your input in terms of those. The issue with that measure is actually that it's a purely claims-based measure and there is a constituency that does want and demand clinics-based measures.

MEMBER RUSSO: Well, that would mean to at least to eliminate it, but --

MEMBER RICH: Regarding 71 and 160, I mean, doesn't 160 -- it's sort of an implied subset of 71, although it could happen that maybe it wasn't prescribed but the person is taking it. You know, it just seems that 71 is the more outcomes-based measure.

CHAIR GIBBONS: Certainly 71 requires, as I recall, persistence for six months, right?

MEMBER RASMUSSEN: Seventy-five percent compliance over 180 days post MI.

MEMBER KOTTKE: Ray, can I make a --

MEMBER RICH: I mean, 160 is really just a process measure, did they get the prescription? But 71 is are they actually following through?

CHAIR GIBBONS: Okay. Tom?

MEMBER KOTTKE: Oh, no, I was just thinking sort of a stray thought about composite measures again. We did a very large randomized trial of 44 clinics for

preventative services and found that docs tend to -- they'll start on one thing and want to perfect it before they go onto the second. And so, they get -- like they'll work their entire lives on hypertension alone or smoking alone. And we found that getting them to bundle the idea of preventive services, this package of preventive services. And so, I think there's value in a composite measure so they don't get stuck on, well, I'll work on hypertension after I get all my smokers to quit, you know? And because, you know -- so they think of it as a group of behaviors or interventions.

CHAIR GIBBONS: So, other thoughts on the beta-blocker issue, because this is much more in the category of competing measures? They're all in the same sphere. I mean, three of them have a denominator that's based on an MI. The first one has a broader denominator that's based on prior MI or LV systolic dysfunction.

And remember, we can't redesign a measure, but our challenge here is to look and say, okay, has one of these trumped the others? Do we want to attempt to harmonize some of the criteria if we're going to have four beta-blocker measures out there? And obviously you've got four different developers. So, you know, we can calculate out her remaining life span and see whether this is feasible, that she attempt to get the four of them to harmonize. She's young enough. I think it's still feasible. In my case, maybe not. Tom's definitely not. So, I --

DR. WINKLER: You know, doing the harmonizational always sort of lands in my lap. And I'm just going to say that there isn't harmonization to be had among measures. Like for instance, in 71 and 613, which is, you know, beta-blocker after heart attack, use of -- I mean, there isn't harmonization at the same measure. So, pick one. That's really

the tough stuff we're asking you to do, because harmonization can occur afterwards. On the measures you think that the measure concepts are unique and important. And if there are little variations in how the definitions that will make the whole thing line up better, great, we'll work on that. But what's the point of making three measures that say the same thing say the same thing?

CHAIR GIBBONS: So, let me take a stab at it and sort of point out that, as I've said already, 70 is a broader measure. It actually includes people -- 70. It includes people with LV dysfunction. So, you don't have to have a prior heart attack. You just have to have LV dysfunction and you're in that one as well. And it's chronic, so that it will capture people whose heart attack was three years ago. Are they still taking a beta-blocker at this time? If they have LV dysfunction, are they still taking a beta-blocker at this time?

So, it seemed to be a broader measure that is going to capture over time most of the patients who enter the other things.

Jon?

MEMBER RASMUSSEN: So, a thought about that measure: One of the measures that we discussed today will get those patients with LVSD. This is one of the measures, when we're looking at beta-blockers, any beta-blocker will do because it combines MI patients who really any beta-blocker has been shown to help. LVSD, it's a more narrow group. So, I think there's other measures that will touch on that LVSD portion. If you look at 160, that's our inactive/hall of fame measure that we were talking about earlier today that is already pretty high. Seventy-one then takes the piece of 70 that takes the MI piece and it's also a medication persistent-measure, which we've talked about being the goal long term.

MEMBER RUSSO: The only other comment, although that's -- I agree with everything said, is just that there were specific beta-blockers that might be appropriate according to the guidelines for those with heart failure and systolic dysfunction. Although this doesn't say heart failure, it says LV systolic dysfunction. So there's a little disconnect there because we want to use the ones that are in the guidelines, I think. So, we want long-acting, you know, metoprolol or carvedilol. So, it's the specification for the type of beta-blocker that might be in question with that.

MEMBER RASMUSSEN: But the way 70 is written I believe that any beta-blocker will meet that measure because they combined the MI, in which case, you know, really any beta-blocker would be okay, but that would also be okay for the patient with LVSD. The standalone measure for LVSD requires one of the three specific beta-blockers.

MEMBER RUSSO: But it says "or," right, "or left ventricular?" So, prior MI or left ventricular systolic dysfunction.

MEMBER RASMUSSEN: Yes, so that creates the denominator. The numerator allows for any beta-blocker, I believe.

MEMBER KING: No, the numerator says bisoprolol, carvedilol or sustained-release metoprolol.

MEMBER RASMUSSEN: Okay.

MEMBER KING: So, it does --

MEMBER RASMUSSEN: My mistake.

MEMBER KING: -- restrict it to --

MEMBER RUSSO: But is that appropriate.

MEMBER RASMUSSEN: Yes, I had the measures mixed up.

MEMBER RUSSO: So, let me think now. So, for the prior MI that doesn't have -- is it appropriate to restrict that? I don't know. It's not.

CHAIR GIBBONS: Well, Dana can

comment. I think that one of the things you run into here is again if you've got to parse out multiple measures, then you have different beta-blockers that qualify in each one. And is that helpful to practicing physicians? Isn't it better that they actually get in the habit of using the more restrictive beta-blockers and then they can not have to -- they don't have to think about it. They just know I'll use one of these three and it's going to be okay no matter what the patient's problem is.

And cost, now TOPROL-XL is -- or metoprolol succinate is available on most of the drug programs, so cost is no longer an issue. And so is carvedilol. It's available on a couple of them for 10 bucks a quarter. So, cost for those three is no longer an issue.

MEMBER RUSSO: The only one that stands out are these four that doesn't seem to add anything without all these questions in

mind is the 613, I think. Or what does that add except the claims data.

DR. WINKLER: Yes, it added the data platform, which was the original issue, you know, several years ago.

MEMBER RUSSO: But we should be shifting towards, you know, clinical data to -- I think, right? Or do we want to -- why do we want that in there? I know someone wants it in there, but I don't even know who. So, but I'm just being naive about this. I don't think that's valuable, as valuable as the other ones.

DR. WINKLER: Well, certainly a lot of our audience members and stakeholders who do a lot of data crunching using claims data are really constantly asking for data or measures based on claims data. So, there is a huge audience out there.

Now, I think that as we transition into electronic health records, that is likely to change; may not totally go away. But there

is a significant stakeholder group who very specifically is always asking us, always asking us for which of your measures can be done with claims.

MEMBER RUSSO: Okay. Sorry, I didn't mean to insult anyone in the room. I'm just asking the question.

MEMBER SNOW: No, but that's important transition and it's probably valuable for them to hear that they need to be getting ready to think about something else rather than just embed that backward thinking.

MEMBER KING: Well, excuse me, but I'm not so sure in this particular case. In other words, when you're talking about lipid control or blood pressure, you have to have a clinical measurement. And so, someone needs to take their blood pressure or measure their cholesterol. If you want to know if someone had a heart attack and if someone got a drug, an extremely reliable way of doing that is looking at diagnosis codes from hospitals and

offices and pharmacy codes, because that means they really went to the pharmacy and picked it up. That is not an irrelevant -- that is an extremely relevant and perhaps superior way, looking at data and say I gave it to them or I meant to, or I said it in my note but they didn't get the prescription is another way of measuring that. But I wouldn't call it superior for this particular measure. If you want to know if they got it, claims data is actually superior in this particular case because there's no clinical thing that you have to measure.

MEMBER RUSSO: And to add to that, too, I think and to clarify, certainly things like claims data for mortality post-discharge is invaluable. There's no other way to get at that data. But the clinical data clearly is better for this kind of measurement; at least for us clinically.

MEMBER PHILIPPIDES: Can I circle back to 70 for a second?

CHAIR GIBBONS: Absolutely.

MEMBER PHILIPPIDES: So, I'm going to express some angst. I don't think it's existential angst; it's just plain angst. And in the composites that we looked at before, we had a disease process that affected a patient and then we said what are the treatments that have been shown to give them benefit? And that's how a clinician thinks, I think, and that's what we should be ranking. That's what you guys did in Minnesota so well.

This is slightly different. This basically looks at several different conditions; two in this case, and says when should give beta-blocker? You know, it's not exactly like clinicians think. You know, it would be strange to just list all of the conditions that required beta-blocker and then ranked on that.

So, it doesn't sort of feel like the way the clinician would think of it.

CHAIR GIBBONS: We're retiring

160, or at least that -- so we have three other measures. So, you know, the rubber hits the road here. We've got three measures dealing with the use of beta-blockers post-MI. And do we want three different measures out there to contribute to the confusion, or do we want to make a case for one of these as best in class and trumps the others? We cannot sit and fiddle with them. We have to either say, okay, all of these go out and people look and say, well, why in the world didn't the Committee pick one? Or we pick one and then they'll say why in the world did they pick that one?

Bruce?

MEMBER RICH: I think we should definitely pick best in class, otherwise I think that we're not really being responsible as a committee.

MEMBER KOPLAN: Can you put two together? And then you'd have two instead of three, you know what I mean?

CHAIR GIBBONS: You can pick two out of three and make one go away; I think that's feasible, but you'll have two different platforms.

MEMBER KOPLAN: Are 71 and 613 more are alike than -- because the other one's chronic stable --

MEMBER SNOW: No.

MEMBER KOPLAN: No?

MEMBER SNOW: I don't think so.

CHAIR GIBBONS: Doesn't sound like you have a ground support for that particular combination of two. All right.

MEMBER SNOW: Does 70 have the key features of 71 in fact? I mean, there's this issue about disease process, but the thing about 71 is that it's about persistence adherence. Because I'll tell you, there's plenty of data out there that show that people get a prescription for a beta-blocker and then they don't fill the second one. And knowing about that is very important. And that's a

key care issue. And that's what 71 is about.

And my question really is whether 70 can take care of that, because it's partly about the wording. It says they may have had an MI in the remote past. Are they still on the beta-blocker? That's an argument for persistence. And so, maybe it's going to take care of 71.

Now, what it won't do is if they just had the MI -- because -- but in time --

CHAIR GIBBONS: Well, Jon can comment. I think the difference here is 70 is based on prescriptions -- prescribing. So in essence, it just says two years later, after their infarc, did the physician prescribe the beta-blocker? Now, does that mean they ever got it filled? That's the point that Dana raised earlier; we really don't know. So it's not a perfect measure from that standpoint, but it will capture over time whether the doc thinks they're persistent.

Now as a doc, I was recently

chagrined to find that somebody I'd dutifully written, you know, statin prescriptions for for the last eight years had never gotten any of them filled. I mean, any of them. And sat there and sort of smiled and said, well, I didn't have the heart to tell you.

And unless you think this was somebody who wasn't pretty sophisticated, they have Ph.D. after their name.

MEMBER SNOW: Right. So, you wrote for 10, then went for 20, then went for 40.

MEMBER KOTTKE: Seventy-one is just for six months. I mean, do we believe that? I mean, I think --

CHAIR GIBBONS: And that's the point I think Jon made when he reviewed it.

MEMBER RASMUSSEN: And to Roger's point, we sort of run out of evidence-base after a couple of years with beta-blocker post-MI. So, we get it the first six months, which is a pretty acute period, or we

potentially run out of data on the back end with the 70.

MEMBER SNOW: We don't know what they're doing at a year.

CHAIR GIBBONS: Come on, group. We got to be bold here.

MEMBER RUSSO: The harder part -- I think what we're -- maybe not just me, but it's hard because when we reviewed them and we're looking at the voting, you could see here that, you know, everyone wasn't uniform; maybe more uniform for some than others, but there must have been something in the original performance of the measure that we had some differences in opinion. So, we're looking at this and trying to remember all the details of how it performed. So, which is better? You know, there may be pluses and minuses of both, but are we assuming they both -- they obviously must have had a good gap, otherwise we wouldn't have approved it. It's hard to make the decision between the two.

MEMBER AYALA: Can we just say 70 and 71 together? I mean, two separate ones, but just say just choose those two out of the four?

CHAIR GIBBONS: Well, we've already -- remember there's three, because we've already rotated 160. So, it really is three: 70, 71 and 613.

DR. KING: I'm not so sure I would have voted for 70 or 71 if I'd realized that 613 existed.

DR. WINKLER: See, this is the opportunity. You looked at each of those as individual. That was the reason we did it in a step-wise approach. So, now that's why your final vote was whether it met criteria. And we still have yet to make your final recommendations for endorsement, and that's because we have all of these secondary questions to approve.

Now, just to be clear, 613 is really not on the table, but your feedback and

your discussion certainly is going to influence where we go with it in the future.

DR. PACE: So as Reva's saying, your prior vote was preliminary because you still had to look at the comparison to see if any of these are superior. And as you were talking about, you can recommend more than one. I mean, our ideal situation is that one is clearly best. If you recommend more than one, we're going to want the steering committee's justification for that. What added value does it have? What additional group of entities will actually be included in performance measurement? What is the value of having the more than one measure?

DR. KOTTKE: That raises the stakes, if we have to justify ourselves. I mean, the conflict bit is about how much do we want to be purely data-driven, sort of USPSTF level, you know, like going beyond a year. I mean, my personal feeling is 613 is the -- you know, the probably the EF can be subsumed

under a heart failure composite. And 613 otherwise, it's simple. You know, you had a heart attack, a myocardial infarction, you ought to be on a beta-blocker.

CHAIR GIBBONS: Okay. So there's an argument for 613. And Dana, I think, was arguing for 613. So I consider the straw vote has already been taken, that there are two votes for 613. Are there others who want to stand up for 613?

Yes. Sorry. Sorry. Yes. George, 613. Three. There's a growing groundswell. Bruce, 613. Four.

MEMBER MAGID: Is the difference between 613 and 71 the point that Roger brought up about the fact that with 613, you could have filled your prescription once and then we have no information about --

MEMBER KING: On the measurement date. When they're measuring it that year, you had to be on it then.

CHAIR GIBBONS: Right.

MEMBER SNOW: It says prescribe. I don't know if it was prescription --

MEMBER KING: No, at the pharmacy.

MEMBER SNOW: Is that --

MEMBER KING: It's pharmacy data.

MEMBER SNOW: Okay.

MEMBER KING: So you're on it when they do this thing.

MEMBER MAGID: And it's not tied to any time period then. So, anyone who's had an MI, this is for the rest of their life.

Whereas 71 is tied to an event. And so, I see sort of two advantages of 71. One is it looks at therapy over a longer period of time. But the other thing is is that it's focused on the time that's most evidence-based, right? I mean, the first year after an MI is where we have the evidence. We don't have any evidence to say that if you had an MI 10 years ago you should be on a beta-blocker. We don't have any evidence to say five years ago if you had an MI you should be

on a beta-blocker. I don't even think we have evidence to say if you were on MI two years ago you should be on a beta-blocker. So, the problem with 613 is it's certainly a lot less evidence-based than 71.

MEMBER KOTTKE: Of course we do have evidence that people who have a second MI and are on a beta-blocker have higher survival rates.

MEMBER MAGID: Right, but we're talking about -- you know, right? I mean, if you've had MI -- my dad had an MI --

CHAIR GIBBONS: We want to get comments from the public.

MEMBER MAGID: Okay.

DR. BONOW: Well, sorry, but Mr. Public was wondering if Dr. Smith is coming back, because he and I have been dealing with this in the secondary prevention guidelines update, and we did look at what the evidence was for beta-blockers after an MI, after the first year. And that's why some of the other

-- besides 613, some of the other measures might be more pertinent to the fact that -- I agree with David that the evidence after a year, it gets pretty weak, and maybe you can out to three years and find some data, but it's not very strong. Whereas if you have a low ejection fraction, then you want to be on it forever, which is I think what the left column is about.

CHAIR GIBBONS: I'm going to try to move this along. Okay. So, here's what we're going to do. We're going to have a vote where there are four options.

MEMBER RUSSO: Could I ask one quick question --

CHAIR GIBBONS: Yes.

MEMBER RUSSO: -- because I want to make sure? So, the last column, is there -- so, we're holding the practice or the physician responsible. So, is there something in there for adjustment for -- because it's the prescription for the beta-blocker, so low

SES. Is there an adjustment in there, too? So, the patient not filling the prescription, how is that dealt with? So, are we going to have adverse -- so, people who take care of patients in an indigent area might look worse because of that, because there's no adjustment, is that right? Because this is filling a prescription.

CHAIR GIBBONS: Six-thirteen.

MEMBER RUSSO: Six-thirteen is the claims data one.

DR. WINKLER: I was going to say, typically --

MEMBER RUSSO: Good point.

DR. WINKLER: -- these are when they have to --

MEMBER RUSSO: Yes, have the benefit. Yes, but there's still no adjustment, I guess. Those are any other -- okay.

CHAIR GIBBONS: There are exclusions for contraindications, which you

can find on the form.

Okay. So, here's going to -- I'm going to try to force some sense of where everybody is. All right?

So, you get to vote once and you can vote for preserving all three measures. Okay? Preserve all three measures. That's option No. 1. Option No. 2 is you got to preserve a single measure, which is going to be 0070. Option No. 3 is 0071. And option No. 4 is 0613.

And I need everybody to vote. There can be no abstentions. This is not like the U.N. So, I need everybody to vote to find out where everybody stands. So, option No. 1 is to hold them all; and then option No. 2 is 0070 alone; option No. 3 is 0071 alone; and option No. 4 is 0613 alone. And we're going to have to do this by show of hands. We couldn't have possibly foreseen how complicated this discussion would get, so --

PARTICIPANT: (Off microphone.)

CHAIR GIBBONS: Oh, we did? Okay. We did, but we didn't anticipate this chairman trying to force the issue with this vote.

All right. So, option No. 1, preserve all three measures. Show of hands?

There's a groundswell of opinion for that one.

Okay.

DR. WINKLER: Devorah? Are you still with us, Devorah?

MEMBER RICH: I'm still here. (Telephonic interference.)

DR. WINKLER: We lost you a bit.

MEMBER RICH: What?

DR. WINKLER: We can hardly hear you.

MEMBER RICH: Okay. My vote is for the third option, 0071.

DR. WINKLER: Okay. We'll record it.

CHAIR GIBBONS: Okay. All right. Option No. 2, 0070. Show of hands?

(A show of hands.)

Two.

(A show of hands.)

Option No. 3: 0071?

(A show of hands.)

And option No. 4 is 0613.

(A show of hands.)

CHAIR GIBBONS: Okay. So, I think that's pretty clear. What was the final tally for 0071?

DR. WINKLER: 0071 was 13.

CHAIR GIBBONS: There it is. Okay. So, operationally, staff, what does this mean?

DR. WINKLER: Well, what it means is going forward, if indeed you all feel comfortable that is your final vote among the beta-blocker measures, is that 70 will not be endorsed, 71 -- or recommended for -- not be endorsed. Seventy-one is recommended for endorsement. One-sixty is the one that's still in the hall of fame. And 613, even

though it's not on the table, the recommendation we will carry forward associated with this is this committee doesn't feel it's needed in view of the other measure. Does that summarize what we did? Is everybody comfortable with that?

MEMBER RICH: Could you just explain, where does that leave us at this point with 160? I mean, what --

CHAIR GIBBONS: We got -- 160 we're still going to have a separate review as we indicated earlier with respect to its installation in the hall of fame.

DR. WINKLER: Right.

MEMBER RICH: Okay. Thanks.

MEMBER SANZ: Mr. Chairman?

CHAIR GIBBONS: Baseball analogies work. I mean, baseball analogies work. Mark?

MEMBER SANZ: Mr. Chairman, I believe your glucose levels are risen highly.

(Laughter.)

Prior to lunch, I can't see a

whole of difference between forcing through this vote and one on the vascular disease vote. Could you explain to me why we did this and not that?

CHAIR GIBBONS: I think these are more clearly competing measures rather than the composite versus individual measure. That would be one sense.

And secondly, 0076 is really a sea change and I didn't sense that everybody was comfortable yet voting for the sea change. I want everybody to think that through, because we're voting for a sea change with that one. It will change the playing field. It might not change it right away, but it will change the playing field.

So, let us move forward, now that we're making such intense progress, to the next -- we have to keep scrolling down. ACE/ARB.

DR. WINKLER: Now, one of the things that -- these are only the measures

that are ACE/ARB associated more with the coronary artery disease realm and don't include the ones we were talking about today that include those in the heart failure realm.

CHAIR GIBBONS: So these are only from phase I?

DR. WINKLER: Yes.

CHAIR GIBBONS: So, we again have four measures.

DR. RASMUSSEN: Only two of these were on phase I.

CHAIR GIBBONS: Two of them are phase I. One is endorsed and not under review and I don't know what --

DR. WINKLER: Yes, the --

CHAIR GIBBONS: Tell me about the last column.

DR. WINKLER: Same thing. It should say endorsed, not under review. They're the same kind of measures we've been talking about, these clins-based measures, for the most part.

One-thirty-seven is the hospital measure you've already evaluated in the first phase, but it doesn't fall into the legacy hall of fame inactive bucket.

MEMBER SANZ: Given our votes in the last two days, what is not subsumed under the votes we've already done since most of these involve -- in fact, not all of them involve LV dysfunction?

DR. WINKLER: Well --

MEMBER SANZ: Have we already subsumed these?

DR. WINKLER: Well, I think one of the issues that I think demands a little more thinking is for the hospital measures what gets you into the denominator is your primary discharge diagnosis. And if it's AMI, you're in the AMI measure. If it's heart failure, you're in the heart failure measure.

MEMBER SANZ: Is that a choice of the developer, or does it have to be that way?

DR. WINKLER: Well, I think that's

the way that CMS has developed those measures because they're groups. There's the group of AMI measures that will apply to all patients with a primary discharge diagnosis of AMI. They did a similar set of measures for heart failure.

CHAIR GIBBONS: They're a different section of Hospital Compare. If you go on Hospital Compare, they're in different places.

All right. So, we're in the same --

DR. KOPLAN: Does it look like everything goes in the 51?

CHAIR GIBBONS: I'm trying to find the numerator statement. It's here. I'm just scrolling down and seeing.

DR. RICH: For 551 the numerator details are blank. Why is that?

DR. WINKLER: Well, the way we make these is based on what's input into those fields in that submission form. And depending

on how -- Yes, I think they're there, but -- yes, sometimes they end up in the wrong fields. But the measure developers, when they make their submissions are actually doing the data entry into our database. So we end up with things being --

DR. RICH: It's under the numerator statement? Okay.

DR. WINKLER: Yes.

DR. RICH: I'm sorry. My apology.

DR. WINKLER: Yes, it's under the numerator statement.

CHAIR GIBBONS: So, at least I don't see a mention here of ejection fraction. Have I missed something? On 51 Bruce raised the question, did that encompass everything. So, that encompasses quote high-risk co-morbidities: heart failure, hypertension, diabetes or chronic kidney disease, but I don't see any mention of LV systolic dysfunction.

MEMBER SANZ: Could I ask what is

the --

CHAIR GIBBONS: Sorry. It's claims-based, so they don't have it.

MEMBER SANZ: Could I ask; you probably know, Ray, what is the data on ACE inhibitors for things like carotid artery disease, without LV dysfunction of MI or -- I just don't remember seeing it, but you may be able to point to it.

CHAIR GIBBONS: Yes, I think we would have to look at the AHRQ Evidence-Based Practice Center Meta-Analysis that was published in Annals, November of 2009. And it's on the AHRQ web site, but of course it's impossible to find. Because they go through the inclusion criteria for all the trials and I don't honestly remember whether cerebral vascular disease was included. Peripheral vascular disease was because the HOPE trial enrolled a lot of patients whose sole manifestation of presumed vascular disease was peripheral.

Does anybody else in the room want to take a stab at that, or know whether cerebral vascular disease was included? I don't remember.

I'm pretty sure it was November 2009 Annals of Internal Medicine. I can't remember the authors, but it's from the AHRQ Evidence-Based Practice Center review of ACE inhibitors that concluded that for coronary disease or coronary disease equivalents that ACE inhibitors reduced total mortality.

MEMBER RUSSO: Can I make just a general statement about the four? The two that do not include an ejection fraction to me have much less value, or little value, because really the limitations of claims data and guideline compliance is really the EF number on those. So, I would say that out of the four, two of them are easy to say are much less valuable. But I think actually they're not under review anyway.

CHAIR GIBBONS: But we can provide

guidance. Helen?

DR. BURSTIN: (Off microphone) added complexity of these as well as the data source. We talked about the fact that 0551 is completely claims-based, so of course it doesn't have EF, at least at this point. But 0066 is currently specified for multiple platforms including its been re-tooled for EHRs, which is how the LVEF could be brought to bear.

So one other consideration for the Committee is if you think they're equivalent, is that something you want to consider as well to have the option of having an EHR-based measure in addition to a pure claims-based measure, which you're right, could not get an EF.

CHAIR GIBBONS: Does 0066 encompass 0137?

MEMBER RUSSO: I think the hospital -- the level -- let me think here. So, the 0137 is at hospital --

CHAIR GIBBONS: Discharge.

MEMBER RUSSO: -- discharge.

CHAIR GIBBONS: But that person's got to have a diagnosis of coronary disease, so they're going to fall in 0066. Well, their MI will give them a diagnosis of coronary disease and their systolic dysfunction will qualify under 0066.

DR. WINKLER: Yes, from a patient level, you're right, they'll overlap. But the 0137 is a hospital-level measure of hospital performance and it's measured and reported that way, whereas 66 is a clinician-level measure and it's measured and reported that way.

MEMBER MAGID: So, I've been wondering about that, Reva. Can we ever really combine a hospital measure and an ambulatory measure, because they're really targeting different organizations.

MEMBER SNOW: And if so, maybe it would be better not to put them -- it would be

a little easier if we didn't --

DR. WINKLER: Well, I think since you mentioned -- this is sort of the first time we've ever actually had to do this as explicitly as we're asking you to do today. These are the questions, is do we include, do we not include, you know?

MEMBER MAGID: So I would suggest for the Committee's consideration that when you do this in the future that you set up tables that compare hospital measures and you set up tables that compare ambulatory measures because they're really targeting different organizations.

DR. WINKLER: But we still will have the harmonization issues.

MEMBER MAGID: That may be, but in terms of saying we're going to get rid of something or not, I'm not sure we can --

DR. WINKLER: That's a fair comment.

MEMBER MAGID: Yes.

DR. PACE: But that's for discussion. I mean, it depends again on the data. I mean, at this point in time that's a realistic issue because of the different data platforms. In the future that may not be as much of an issue, but definitely, you know, we can put them together that way.

CHAIR GIBBONS: I'm going to try to move this along because I think I've heard some worthwhile comments that can drive votes.

So, the point's already been made that 551 and 594, because they use administrative data, do not have LVEF and we therefore consider them inferior to the other two.

So, I'm going to ask you to vote yes or no and whether you agree with that statement; are 551 and 594 inferior to the other two? Yes, raise your hand?

MEMBER RICH: Yes.

DR. WINKLER: Okay. Thanks.

CHAIR GIBBONS: No?

DR. WINKLER: Thanks, Devorah.

CHAIR GIBBONS: No?

DR. WINKLER: Are there any note votes?

DR. WINKLER: Okay. So it was --

CHAIR GIBBONS: There are no votes? So, that was a unanimous vote.

So, now let's attack 0066 and 0137, both of which were reviewed here. And I think David has already made the point: one is an inpatient measure reported as a measure of hospital performance; the other is an outpatient measure reporting on clinician behavior.

Do we believe -- I mean, do we -- I think there's a fair argument just from that that both of them should be preserved. If you're in favor of preserving both of them, please vote yes at this time.

MEMBER RICH: Yes.

DR. WINKLER: Thank you, Devorah.

CHAIR GIBBONS: Is anybody

opposed?

Okay. Now, I think the only remaining issue is is there any harmonization to be done across these two?

DR. WINKLER: I think if you guys can point anything out, it would be helpful. What we will do is a much more careful look at them. But if you can point anything out, it would be useful.

MEMBER PHILIPPIDES: Do both look at diabetes or just the one?

CHAIR GIBBONS: Just the one. Just the one. The outpatient measure uses some other parameter, LV systolic dysfunction or diabetes, to make the case for using an ACE inhibitor. So that's gotten on base. That goes back to stable angina or the MI guidelines.

MEMBER KOTTKE: Ray.

CHAIR GIBBONS: Yes, did you find the paper?

MEMBER KOTTKE: Yes, and basically

it -- I mean, I just only have the abstract, but it's in patients. It appears to be just patients with ischemic heart disease and they don't talk -- the title doesn't say ischemic heart disease or equivalents. It says ischemic heart disease.

CHAIR GIBBONS: Okay. So, we'll have to actually pull the full paper and the AHRQ to answer the question about cerebral vascular disease, because HOPE certainly had people with peripheral heart artery disease and that's a major component with a meta-analysis.

Okay. Well, we at least tried on that front. Harmonization issues. Any other harmonization issues that people can see?

DR. WINKLER: Just as information for me, when we use the term ACE/ARBs, we're talking about the class of drugs, correct? We don't need to parse out individual drugs?

CHAIR GIBBONS: Correct.

DR. WINKLER: I didn't think so.

Just checking.

MEMBER KOTTKE: Well, that's -- there's some debate about that in the literature, but I think most people would say there are ARB for people who can't take an ACE.

DR. BURSTIN: Any issue with the fact that one has AMI in it and one doesn't? I mean, they both have LVSD based on EF, but one is specific to having been post-MI.

CHAIR GIBBONS: Well, that's the hospital part. Once that person leaves the hospital, they're in the purview of the second measure.

DR. BURSTIN: Although wouldn't it make sense potentially -- I mean, again, it's not all about the first measure; it's also about the hospital measure. One potential thing would be, shouldn't the hospital measure be potentially broader to be ischemic vascular disease or LVSD without a specific focus on AMI? Just a consideration.

CHAIR GIBBONS: Well, it would require certainly a rethinking on CMS' part, because that would cover about six different DRGs.

Tom?

MEMBER KOTTKE: So, I have the article here and on the table it's baseline risk, quality of the evidence as -- I think that's what it says. Strength of evidence is low. ACE inhibitors; perindopril, ramipril, reduced composite efficacy and endpoint cardiovascular death, non-fatal, da-da-da-da, for the -- or one of the following depending on the trial. Stroke -- oh, maybe non-fatal stroke -- sorry. I'm reading the wrong thing. So, that wasn't about entrance criteria, but was about outcome.

CHAIR GIBBONS: Yes, that's the endpoints. Yes, the actual meta-analysis covered just every endpoint in excruciating detail. It was a very hard go at reading. It was a table with 18 or 20 entries. It

required endurance.

I don't see any other issues for harmonization. Unless somebody else does, I think we may have done all we could with this issue.

It hasn't been a big deal. Okay. So --

DR. BURSTIN: But just in terms of the evidence, I guess just one question back to CMS; maybe not for this moment, but perhaps for the next iteration these measures are obviously undergoing change. It may be a whole lot of DRGs, but if the evidence suggests somebody's in there with unstable angina and they had LVSD, wouldn't you kind of want to do the same thing even if they're not there for an AMI? I'm just trying to think. Again, you guys are the smart evidence-based guys, but they're in the AMI bucket because that's how they've done it. And I guess the question would be going forward should they consider a broader bucket?

CHAIR GIBBONS: Thoughts about that? It's a good question. Personally I think they should. How in the world they would ever report it I think defies imagination, but the evidence will certainly -- because there are seven different -- all these different DRGs. So what are they going to put down on Hospital Compare?

DR. BURSTIN: Call it, you know, unstable coronary, you know --

CHAIR GIBBONS: Ah, it's not necessarily even unstable.

MEMBER RASMUSSEN: Do we just leave it as LVSD, make that the overriding criteria and then let everything else fall beneath an MI, if they had ICD?

DR. BURSTIN: It's not urgent for today. Just as you talk about recommendations for their future consideration, it would be nice if they kind of tracked with the evidence.

CHAIR GIBBONS: So, have we

finished off the competing measures table from phase 1?

DR. WINKLER: Yes, and given the discussions we've had and the fact that we've talked about measures, I think we need to redo the side-by-sides for phase 2 and save that for another day.

But I think that we've learned a lot from listening to you struggle with this. This discussion is not over. I think that Ray's asked you something fairly considerable, and that's to think of the ramifications and think about, you know, the support for just doing the composite measure versus any component measures and we will get your feedback off -- you know, down the road when you've had a chance to really review and look at those more carefully.

At this point, I mean, you've done an enormous amount of work for us, you know, over the last two days.

We need to kind of regroup a lot

of what it is you've brought us to. We do need to do some follow up with you.

As I mentioned at the beginning, we're going to be putting these recommendations and reports out for public comment. And so, phase 1 goes before phase 2. They're going separately. So, we are going to be, you know, wanting to wrap up and focus on phase 1. So, we need to wrap back with you with these final decisions.

Also, if you noticed, as we were going through the evaluation, your last vote was on, does the measure meet criteria. And that's because of all these subsequent decisions about competing measures and the hall and fame, and all these other things that are potential caveats. So, what we're going to ultimately want to do is a final tally of what you thought met criteria, but what may fall out from recommendation for final endorsement because of all of these other issues, secondary issues that we've talked

about. And then end up with a list of final recommendations for you to approve before we take this out for public comment.

So, we do need to do some ongoing work. I think it can be done a great deal by email. I do envision we're going to need at least one conference call to be able just to talk through it so that everybody's comfortable.

These are thorny issues. You are the first group that we've posed a lot of these questions to. You're helping us learn. You're the pilot test. If it's felt a little uncomfortable and messy, I think that's somewhat the nature of the beast. It's your expertise we're really drawing on to help us figure out the best way to approach this.

This is the first of 25 endorsement maintenance committees -- 22, sorry -- going forward and approaching our work in this way is different than the way we've done it before. Clearly you've brought

up issues we had not anticipated. We're having to regroup a few things. That's the nature of continuous learning, which we cannot thank you enough for helping us do. So, I think that -- I'm not going to ask you to do anything more today.

CHAIR GIBBONS: I am.

DR. WINKLER: Okay.

CHAIR GIBBONS: So, we're not done yet. I want to just remind people of what's going to happen, okay, so that no one's terribly shocked. One is, for retirement in the hall of fame, we're going to ask the original reviewers of three different measures; aspirin, beta-blockers; and, Kathleen, you've already identified for LVEF, to revisit that measure in light of our discussion, provide a score for all four criteria. And overall that will then be distributed to everybody prior to the conference call for their review and consideration. And we will then take a final

vote on the conference call following a brief presentation by each of those three people.

We are going to redistribute to everybody 0076, given the magnitude of the discussion we've had about that measure as a composite. And we've already voted on that with the only concern being the blood pressure. But now that we're looking at it as a possible at least replacement of individual measures, I think everybody has expressed appropriate concern about proceeding too hastily.

So, we need everybody to review that and we need them to review that, not just for the conference call, well in advance, because we would like to flush out any questions that are relevant with the developers. And we could conceivably try to have them on the call.

DR. WINKLER: Yes, definitely.

CHAIR GIBBONS: Okay. But I think it would be nice if we tried to flush out as

many of those things beforehand as we could so that we can then basically -- and we'll ask the staff to present a grid of pros and cons. I think Helen has already done that verbally, but we want a grid of pros and cons, because in essence we're going to be voting on the same sort of issues: preserving these individuals versus the composite. It's not quite the same as the previous vote because the individuals are from different groups, but I think we want to have that well flushed out for everybody in advance.

So, that's going to take place.

And then lastly, we're going to have a grid of competing measures from phase 2, which some of you highlighted already as we were going through that process. And as Reva said, I think staff will have the guidance from this exercise today to create a grid that will basically hopefully facilitate the discussion. And that for sure we will need people to take a look at prior to the call

because just from the discussion we've had today, that would totally consume a conference call unless we are more efficient.

So now, lastly, I would like to suggest to the NQF staff and to all of you that it would be best if this conference call takes place when the constructive dialogue we've had here is still fresh in everybody's minds. And I know it seems like a long way away, but summer is coming. So we need to do it before everybody departs for parts unknown for their summer vacation.

So, I'm now going to just do a little informal ballot. Okay? How many of you have planned summer vacation -- and I sort of tend to define that as a week away -- planned summer vacation before June 1? Two.

How many have planned summer vacation during the month of June? Two more. Okay.

So, as a target we certainly want to have it before June 30th, and it would be

nice the sooner the better since we have people departing. We'll distribute a grid to try to figure out when the most people are available, but I think as a target, unless I hear otherwise, certainly before the end of June.

DR. WINKLER: In fact for phase 1 we really need to have it done by the middle of May, which kind of goes along with you. We may need to do like the phase 2 competing measures later, but we need to get the phase 1 stuff finalized for going out for public comment in June. So, it kind of dovetails with that timeline you talked about.

MEMBER RUSSO: Just a quick question. When things go out for public comment on the things we discussed today, does the measure developer have a heads-up before the -- that they know that this is something that might be retired, or how do you deal with that?

DR. WINKLER: Remember, they've

all been here.

MEMBER RUSSO: That's true. Good point.

DR. WINKLER: They definitely are quite interested in the discussion and your recommendations. But as a caveat to everyone, we're continuing to, you know, progress towards your final recommendations as we're going through these subsequent steps. And the measure developers will be invited to join your conference call. Your conference call actually will be the equivalent of a meeting. Anybody can listen in. It will be a public call.

CHAIR GIBBONS: So, and we will be happy to give them your phone number and email if you wish.

MEMBER RUSSO. No, I don't. Well, we're from phase 1, so I'd have to look if they were all here today hearing this, I guess. Okay.

CHAIR GIBBONS: Is there any other

business, staff? We never did solicit public comment today.

MEMBER ALLRED: I have one question before we --

CHAIR GIBBONS: Yes. Please, Carol?

MEMBER ALLRED: Before we do 0076, don't we have to vote on the blood pressure portion of that?

CHAIR GIBBONS: We voted conditionally the last time that if they made that blood pressure change, we would approve it. So, that's why I just registered for everybody.

MEMBER ALLRED: Okay. So, we're okay on that?

CHAIR GIBBONS: Yes, we're okay from a process standpoint. For transparency, I pointed out that they had responded and met our request. So, we've had that vote and, you know, we actually scored -- I was the primary reviewer. It was scored reflecting the old blood pressure criteria, but that was the

single deficiency that everybody identified. So, we have had that vote.

Public comments from the room?

Look forward to the conference call. Okay.

Any on the phone, are there any public comments or questions?

DR. WINKLER: Operator?

OPERATOR: Star 1 for a comment or question.

(No response.)

OPERATOR: There are not, sir.

DR. WINKLER: Okay.

CHAIR GIBBONS: Thank you very much, operator.

OPERATOR: You're welcome.

CHAIR GIBBONS: I hesitate to say this, but I think we're actually done for this meeting. Thank you, everybody, as always for your cooperation.

(Applause.)

MEMBER RICH: I just want to say

that I really have enjoyed participating in this. I look forward to having more of those measures that I have to present to you again. But I've really enjoyed working with all of you. It's really been a fabulous learning experience and very rewarding. So thank you, and thank you for including me.

CHAIR GIBBONS: Thank you, Devorah. And I will just reflect as the chair my thanks to all of you for your diligence. This is hard work. As you slough through 10 or 15 or 20 of these in a day, it gets pretty demanding. I do think that this group excelled from the standpoint of treating each other with mutual respect and of trying to mold together different viewpoints, different backgrounds in the cause of advancing this particular effort and quality overall. And obviously we had some jokes along the way and a lot of good interaction, but I personally had the feeling that everybody was trying to work together towards the goal and not

pursuing any particular personal or professional agenda, and that's why I think the work went well. And I thank you all for your cooperation and the effort.

MEMBER SNOW: Well, I know that I speak for many others in saying that you and Mary have given us great leadership, and we thank you for that. It kept us going, kept us honest, and frequently kept us laughing.

DR. WINKLER: Thank you, all. You will definitely be hearing from us.

CHAIR GIBBONS: Travel safely.

DR. WINKLER: Our work is not done. Although we're unlikely to meet face-to-face again, I think we can anticipate at least one if not two conference calls and emails. So, we'll see you in virtual space. Travel safely.

(Whereupon, the above-entitled matter went off the record at 2:19 p.m.)

M

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Cardiovascular Steering Committee

Before: NQF

Date: 04-08-11

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