NATIONAL QUALITY FORUM

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CARDIOVASCULAR MEASURE ENDORSEMENT PROJECT
STANDING COMMITTEE MEETING

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TUESDAY
APRIL 22, 2014

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The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:00 a.m., Mary George and Thomas Kottke, Co-Chairs, presiding.

PRESENT:
MARY GEORGE, MD, MSPH, FACS, FAHA (Co-Chair), Centers for Disease Control and Prevention, Division for Heart Disease and Stroke Prevention
THOMAS KOTTKE, MD, MSPH (Co-Chair), Medical Director for Population Health, Consulting Cardiologist, HealthPartners
SANA AL-KHATIB, MD, MHS, Duke University Medical Center
LINDA BRIGGS, DNP, George Washington University, School of Nursing
JEFFREY BURTON, RN, Clinical Performance Improvement Specialist, United Physicians*
LESLIE CHO, MD, Cleveland Clinic
JOSEPH CLEVELAND, MD, University of Colorado Denver
MICHAEL CROUCH, MD, MSPH, FAAFP, Texas A&M University School of Medicine

ELIZABETH DeLONG, PhD, Duke University Medical Center
TED GIBBONS, MD FACC FACP FASE, Harborview Medical Center; University of Washington School of Medicine*
ELLEN HILLEGASS, PT, EdD, CCS, FAACVPR, FAPTA, American Physical Therapy Association
JUDD HOLLANDER, MD, FACEP, The University of Pennsylvania
THOMAS JAMES, MD, AmeriHealth Caritas Family of Companies
JOEL MARRS, PharmD, FNLA, BCPS (AQ Cardiology), CLS, Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado Anschutz Medical Campus; American Society of Health-System Pharmacists
KRISTI MITCHELL, MPH, Senior Vice President, Avalere Health, LLC
GEORGE PHILIPPIDES, MD, Boston University/Boston Medical Center*
NICHOLAS RUGGIERO, II, MD, FACP, FACC, FSCAI, FSVM, FCPP, Thomas Jefferson University Hospital
JASON SPANGLER, MD, MPH, FACPM, Amgen, Inc.
CHRISTINE STEARNS, JD, MS, NJ Business & Industry Association
HENRY TING, MD, MBA, Mayo Clinic
MARK VALENTINE, MBA, The Heart Hospital Baylor Plano, Baylor Health Care System
MLADEN VIDOVICH, MD, Jesse Brown VA Medical Center

NQF STAFF:
WUNMI ISIJOLA, MPH, Project Manager
VY LUONG, Project Analyst
CHRIS MILLET, Senior Project Manager, Health IT
LINDSEY TIGHE, Senior Project Manager, Performance Measurement
REVA WINKLER, MD, MPH, Senior Director

ALSO PRESENT:
SUSANNAH BERNHEIM, MD, MHS, Center for Outcomes
Research & Evaluation
DALE BRATZLER, DO, MPH, University of Oklahoma
Health Sciences Center*
KEZIAH COOK, Acumen LLC*
JEPTHA P. CURTIS, MD, American College of
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ROBERT McNAMARA, MD, MHS, Yale School of
Medicine
ILEANA PINA, MD, MPH, Albert Einstein College of
Medicine
RANDAL THOMAS, MD, FAACVPR, American Association
of Cardiovascular and Pulmonary
Rehabilitation

* present by teleconference

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

8:00 a.m.

DR. KOTTKE: Thank you, everybody, for ending on time yesterday and being very concise in your efforts. It's a beautiful day out there.

We'll start with Measure 0286. Mary George is the first discussant and Joe Cleveland is the secondary.

MS. TIGHE: Do we have our colleagues from CMS for Measure 286?

Operator, is there a Dale Bratzler on the line?

OPERATOR: I don't see that he has joined yet.

MS. TIGHE: Okay.

DR. KOTTKE: Mary will give a recap of yesterday.

DR. GEORGE: So we started the day with a couple of measures that were intended to be harmonized at the facility level and the provider level. These were the two composite

measures for aspirin and statin and P2Y inhibitors following PCI. And we overwhelmingly approved the measure at the facility level and we did not reach consensus at the provider level.

We went on to the measure on medication adherence to antiplatelet therapy. There was some concerns with this measure about applying it to ACO and provider group level, but there was more consensus with it being done at the health plan level, but ultimately there were also concerns about applying this to both types of stents, so that we did not approve that measure.

There was a measure on the appropriate use criteria for PCI. There was some discussion about whether this was a documentation measure or whether the word 'documentation' in the title was actually somewhat of a misnomer, but we did approve that. We discussed the risk-adjusted rate of bleeding following PCI. There was some

concern about lack of excluding for more than just bypass surgery and whether other procedures should also be reason for exclusion.

Then we discussed the three post-PCI mortality measures: the in-hospital mortality, the 30-day mortality for NSTEMI, and 30-day mortality for STEMI. We did approve all of those.

Anything you want to add?

DR. KOTTKE: No, that's very nice. Thank you.

MS. TIGHE: Operator, did Dale Bratzler join us?

OPERATOR: I still don't see him on the line.

MS. TIGHE: Okay, thank you. I guess we'll go ahead and begin discussion of 0286.

DR. GEORGE: So this measure is for aspirin at arrival in the ED or within 24 hours of arrival and prior to transfer. So

this is for patients that show up in the ED and then are then transferred to another facility, but not admitted at the facility where this is being measured. CMS is the measure steward.

The evidence for this was based on ACC/AHA 2012 and 2013 guidelines, Class 1, Level A Recommendations. They cited five RCTs plus two meta-analyses for unstable angina and NSTEMI, as well as two other RCTs for STEMI. So based on that evidence and the systematic reviews, I rated this as high on the evidence.

DR. KOTTKE: Joe, did you want to --

DR. CLEVELAND: Nothing to add.

DR. KOTTKE: Any other comments? Okay. Vote on the evidence.

(Pause.)

MS. LUONG: Timer starts now. One is for high. Two is for moderate. Three is for low. Four is for insufficient evidence with exception, and five is for insufficient

evidence.

(Pause.)

DR. WINKLER: Lindsey is doing three from on the phone.

MS. LUONG: For evidence, 15 voted high and 6 voted for moderate.

DR. KOTTKE: Opportunity for improvement.

DR. GEORGE: This measure had -- even down to the 25th percentile, it was still at 100 percent adherence, then dropped down to 87 percent adherence at the 10th percentile. So there's some, but little, room for improvement.

Data on disparities showed adherence at 97 percent for whites, 96 percent for blacks, and 95 percent for Hispanics. So when I was considering this, I saw this as having little room for improvement and certainly a question of whether this measure is topped out.

DR. KOTTKE: Joe, any --

DR. CLEVELAND: I had the same exact thoughts. In fact, I think that's kind of the crux of this measure is my review.

DR. KOTTKE: Tom?

DR. JAMES: Yes, I thought this one had been retired. If it weren't through NQF, it would have been one of the other agencies.

DR. WINKLER: I'll clarify. There are two measures. One is for patients that are coming in to the -- admitted to the same hospital. Then there is this one that is the transfer.

The other measure, which had been NQF-endorsed, was topped out the last go around and we put it on reserve status. Since then, CMS has suspended it from the IQR and they are not seeking continued endorsement of the measure. So it's fallen out of the portfolio, but that's the one for the patients being admitted to the hospital. This is the companion measure for transfers, so this

measure is in the OQR.

DR. KOTTKE: Judd? Sana?

DR. AL-KHATIB: Do we know how they came up with these numbers in terms of the percentiles? Did they exclude patients who had contraindications to aspirin?

DR. GEORGE: They exclude those with a documented contraindication. They also exclude those that are on anticoagulants.

DR. AL-KHATIB: Thank you.

DR. KOTTKE: Further discussion? Oh yes, Linda.

MS. BRIGGS: I apologize. I can't pull up the measures that we're looking at right now. You were talking about disparities and my question is about women and whether there was any notation for disparities for the women that were in the study so far?

DR. GEORGE: I don't recall that they looked at gender for disparities.

DR. KOTTKE: Further discussion? Time to vote.

MS. LUONG: Timer starts now. One is for high, two for moderate. Three is for low and four is for insufficient.

(Pause.)

So for performance, 2 voted high, 7 voted moderate, and 13 voted low.

DR. WINKLER: We are in a situation which is not unusual in these measures. They've been around for a while and actually are probably victims of their own success, similar to the inpatient measure we're seeing and topping out.

We can either at this point basically you have the choice of not recommending the measure for continued endorsement, or there is the option of putting it in a reserve status which means we finish evaluating the measure, but it would carry that hey guys, you're going to get very little mileage out of using this measure. It's a good measure, but nonetheless it's fairly topped out. That's what reserve status means.

That's the pathway that the companion inpatient measure took and you can probably foresee a similar future for it. So it's truly up to you all if you feel that this is a good measure. It's going to meet all of the other criteria very highly, except for being topped out. That makes it a candidate for reserve status.

MS. DeLONG: I have it on. Can you not hear me? I frequently forget, but this time I haven't. What about when they're wrapped into some other all-or-none type measure? Do we not consider that?

DR. WINKLER: An all-or-none uses the same concept of a measure, but isn't necessarily -- they're not using the results of this measure to calculate the result of that composite, so having concepts alike is not a problem. Also, if indeed there was a composite actually used the results of this exact measure and aggregated it with others and somehow formed the composite, that would

be perfectly fine as part of the composite, but perhaps it doesn't have as much value as a stand-alone.

So those are the types and questions you would be asking.

DR. KOTTKE: So if we have a consensus that it goes to reserve, do we vote on everything else?

DR. WINKLER: Yes.

DR. KOTTKE: Okay. Priority? We have to do all the voting anyway, right?

DR. WINKLER: I think the question is, do you all think that this is a good, strong, solid measure that really its only problem is that it's topped out and then it would be a candidate for a reserve status? If that's the case, then we would proceed. If you feel that really there's very little purpose in that and that it's topped out and you don't want to recommend it go forward, we just stop right now. So I think perhaps we ought to see what the committee thinks about

that.

DR. TING: Can you share more about the tangible value to have a reserve status for one that's not being used?

DR. WINKLER: Well, this measure is being used and the reserve status sends a signal that the measure really has very little opportunity for improvement. It's topped out and as I say, it was this committee, actually the last go around, that created the whole concept of the reserve status because we had so many of these measures topping out.

And so what has happened is frequently those measures over the subsequent years either get retired or suspended from use or ultimately retired. So it really does send a signal saying the value of this measure is not so great because it's topped out, not because it's not a good measure. Some people feel very strongly that you don't want to send the signal it's a bad measure. It's not a bad measure. It's just right now, with being

topped out, you don't have as much value.

DR. AL-KHATIB: I just have a quick question about the data source that they're proposing to use. They list administrative claims and then electronic clinical data, what have you. And I'm not sure how you would capture whether aspirin was given on arrival through administrative claims data and although there's a lot of potential in terms of using EMR to capture those data, we're very far from being able to use EMR to capture this level of detail, if you will. So I'm not sure how this would be put into work.

DR. WINKLER: Do we have anybody from CMS join us? Dale, are you on the line?

MS. JOHNSON: Dale's not on the line, but this is Wanda Johnson.

DR. WINKLER: Oh great, Wanda. Did you hear Sana's question?

MS. JOHNSON: Yes. When we say there's a combination of administrative claims, that means that we use the ICD-9

diagnosis code to put them into the population, but the information really is abstracted from the paper-based medical record.

Some facilities have electronic health records and you could pick up aspirin administration on the EMR. It's a little more difficult to pick up contraindications, but that's what we -- when we select that it's administrative claims and paper medical record plus EHR, it means that it's a combination of the information.

DR. BRATZLER: Wanda, this is Dale. I'm here.

MS. JOHNSON: Thanks, Dale.

DR. KOTTKE: Mladen.

DR. VIDOVICH: Just to clarify, this will continue to be followed, aspirin on arrival, right? We are not recommending we don't want to follow this metric.

DR. WINKLER: What do you mean by following?

DR. VIDOVICH: Meaning measuring this.

DR. WINKLER: This is the kind of reason for the signal is whether people will continue using the measure or not really depends on the value they perceive in it. But this measure, again, has such high performance that it may very well cease to be used going forward because of that. And we certainly have seen that happen with some of the other measures.

DR. VIDOVICH: Because it's a widely accepted and recommended -- okay.

DR. KOTTKE: Judd?

DR. HOLLANDER: You know, I'm sitting here for two days and we're adding a lot of measures and we have one that has done its job. And so I think it's a good signal to the world to say let's stop measuring things that don't need to be measured at the same time.

First of all, this is a subset,

right, because it's only in the transfer patients, so it's a subset of a measure that's already been retired because it was good enough. We see the trend and as we're adding things I think we do a service to everybody if we can eliminate things that no longer need to be measured. And I personally prefer the retirement because it's a real decision.

Like we seem clear on what we think the relevance is here, and it seems to me the reserve is almost a copout for not being willing to say okay, it worked.

DR. KOTTKE: Other comment?

DR. WINKLER: Essentially, your vote on the opportunity for improvement where the lows predominated means it doesn't pass the subcriteria. So if you're comfortable with that, then the measure stops right here because it has to pass all three of these subcriteria to pass the importance criteria.

The question would be is there enough feeling among you all that you would

want to consider a reserve status and we would then continue to be able to qualify it for that. But if not, if you feel that you're content with letting it stop right here, that's all we have to do.

DR. KOTTKE: If you raise your hand, you are voting to put it in reserve. So we could see a show of hands?

If you raise your hand, you are voting to put it in reserve and we would continue to vote on the other elements. If you don't raise your hand now, we will stop. And of course, CMS will get the information that we stopped because we thought there was no room for improvement.

So show of hands, people want to put it in reserve. Three, four. Four. Mary is over here. So, we'll stop. Thank you, Mary.

DR. GEORGE: So we're moving on to 0289, median time to ECG. Judd?

DR. HOLLANDER: So this is

actually an interesting measure that's in existence. It's also only for the transfer patients, but it's a downstream process measure that involves more than the patients it's targeted to get.

So this is time from emergency department arrival to initial EKG. And the evidence here is for STEMI patients. So if you're a patient with an ST segment elevation MI, getting a quicker door to balloon time or door to lytic time has been shown to reduce your mortality. Getting an EKG faster is something in that process, but there is no real evidence that getting the EKG faster in the broad cohort of chest pain patients where it's being measured in that broad cohort here improves your outcome.

So this is a big catchment of all the patients who come in the ED with chest pain so we can find not really the needle in the haystack, but the really important patient who has ST segment elevation MI, where this is

one stop along the pathway to reducing their mortality.

MS. TIGHE: I'm sorry, I'm going to jump in. I just realized we do have Wanda and Dale with us now, so I'd like to give an intro to Measure 0289.

Wanda or Dale, would you like to give an introduce to 0289?

DR. BRATZLER: This is Dale. I think really, the presenter already gave pretty much the background. This was a measure step that was originally developed as part of a rule measure step and then became part of a transfer measure within the hospital outpatient quality reporting program. It looks at the first important time stamp in a patient who may have STEMI that needs to be transferred to another facility for potential intervention or kept at the original facility for fibrinolytic therapy. So I don't have too much other background, but it was part of our original rule measure set.

DR. HOLLANDER: I think I covered the evidence already.

DR. GEORGE: Any discussion on the evidence?

DR. WINKLER: Judd, how would you rate it based on the evidence algorithm?

DR. HOLLANDER: I think the evidence isn't directly applicable and I was going to get to it later on, so I would rate it low. But part of it is a bigger picture concern. And so my bigger picture concern is that chest pain is the second most common thing we see in the emergency department and the inclusion/exclusion criteria here are age greater than 18.

So I can tell you anecdotally, we've all over the last decade because of these types of measures put in really good care processes to get EKGs early. But now like if you fall down and hit your chest and you're 19, you jump ahead of all the septic patients and patients with pneumonia and get

your EKG. So when we would get to the unintended consequences, there's huge unintended consequences because a nurse doing A in the ED means they're not doing B, C, D, and E.

And so my biggest concern with this measure is that we're doing a lot of stuff on 98 percent of patients that it doesn't pertain to. At HUP, we send 30 patients a year to get primary PCI with STEMI. We see 5,000 patients a year with chest pain and we're already measuring the true outcomes. We have door to balloon time. We have door to needle time as a measure and we have mortality as a measure. So this is one early step where we are now expending a lot of energy, but we're already measuring what really happens to those patients.

So to me, if you're measuring the outcome, I don't see why we individually need to measure the process that may or may not be directly related to the outcome. So again,

sticking to the evidence part of the component, there's no evidence that knowing the EKG times after you know the door to needle time makes a difference -- or door to balloon time.

DR. VIDOVICH: I actually like your point. If your door to balloon time is less than 90 minutes or less than 60 minutes and you achieve your goal of early reperfusion, then perhaps you should measure multiple components of the process. In a time to page, or time to ED, time to call the cardiologist perhaps. I actually don't disagree. I think it's a good point.

DR. KOTTKE: So I think, on the other side, is that this measure I think was designed to pick up the clean miss, where somebody never even thought -- now, I don't work in the ER -- my question is, I think you believe those are extremely rare or nonexistence.

DR. HOLLANDER: I can only speak

anectdotally about the clean misses in our ER and we have them. They got their EKG in the time. Someone misread their EKG and so this doesn't do that. But I think most institutions now have a STEMI committee or whatever you want to call it. And when they're not meeting the door to balloon time, they're looking at why and this is one of the seven or eight steps in the process that people talk about. So it's going to be found without this being a measure.

The other thing that's a little unusual here is that it's a transfer measure only, but you get the EKG before you know you're transferring the patient. You might not actually give the aspirin in the last measure before you know you're transferring the patient, but there's no reason to inherently think the EKG time is different in transfer patients and nontransfer patients because it's actually what would determine whether or not a patient got transferred. So

there's a separate carve-out for transfer patients. I realize they get treated differently because they may have an option of thrombolytics at the first hospital and primary PCI at the second hospital, but it's not clear that the EKG is going to drive that decision.

DR. AL-KHATIB: I agree with what Judd said. The other thing that I would add is if you look at the evidence that they provided yesterday, cited the guidelines, but at the same time when you look at the EKG has to be done within ten minutes, this is actually based on expert consensus, expert opinion, rather than any solid data.

If you look at the opportunity for improvement where they provided some data, 75th percentile was 13 minutes. And so the question that I would ask is do we have any data to say that if you do the EKG within 10 minutes versus at 13 minutes, that you actually change outcomes. And I'm not aware

of any data. I actually would suspect that there shouldn't really be any significant difference. And that's why I don't think that the evidence is there.

DR. VIDOVICH: I can't think of it off the top of my head, but I think there was a paper a few years ago that looked at several components how to decrease door to balloon time and one of them was EKG, one was direct paging to the operator sitting there. I think they actually did several components, but there's no direct evidence, I agree.

DR. JAMES: The paper itself says the level of evidence is C. Writing clinical policies for a Medicaid company, I wouldn't accept that level of evidence. Secondarily, we have putting in more and more measures in one area, which is really becoming a process, or an intermediate process measure doesn't get to the outcome. It seems to me diluting our ability to put emphasis on the proper measures. So I'm not happy with this one.

DR. GEORGE: Are we ready to vote on the evidence?

MS. LUONG: The timer starts now. One is for high. Two is for moderate. Three is for low. Four for is for insufficient evidence with exception and five is for insufficient evidence.

(Pause.)

The evidence criteria, two voted moderate. Twelve voted low. One voted insufficient evidence with exception and seven voted for insufficient evidence.

DR. WINKLER: So essentially, the measure stops here because you feel it does not pass the evidence criteria. All agree? Great.

MS. TIGHE: Thank you, Wanda and Dale. We have 2377 up next. Do we have our colleagues from ACC to join us?

DR. KOTTKE: The next measure is 2377, Defect Free Care for AMI.

Welcome. So if you would like to

give a brief discussion of the measure, and then.

DR. CURTIS: Sure. My name is Jeptha Curtis. I'm from Yale University working with the American College of Cardiology to develop and test this measure. I know many people in the room, so good morning to you all.

So this measure is emerging from the action Get With The Guidelines registry which most, if not all, of you are familiar with, but it is the nation's largest registry of acute myocardial infarction. It's a voluntary hospital-based registry which tracks the inpatient care and outcomes of patients admitted with myocardial infarction.

The primary goal of the registry is to improve the quality of care delivered to patients with myocardial infarction. Hospitals that elect to participate in the registry commit by contract to submitting data on all cases admitted with MI. So there's no

cherry-picking of cases for submission. The registry is audited as you've heard, I think extensively, yesterday. And in keeping with the goals of improving quality of care, there are benchmark reports that are provided by the registry on a quarterly basis. And in each of these key elements, process measures, are fed back to hospitals so that they can improve.

One of the process measures that is currently being used and is up for endorsement for today for public reporting is the composite measure, process measure. And in that and I'm not sure what documents you all have, but in that there's a -- this composite consists of 11 different individual processes, all of which have previously been shown to be important and affect the outcome of patients with myocardial infarction. They all have strong recommendations from the current guidelines for the care of patients with MI and on that basis are evidence-based.

What we have shown through our

testing is that if you roll up all these individual process measures together and if you construct it as a perfect care, or defect free care would be the alternative name for it, you're still seeing significant variations.

Now many of the individual components of the measure are topped out as you guys have just been discussing, the aspirin on arrival and aspirin on discharge, for instance, is relatively high; more than 99 percent of patients are getting that. But if you roll up all the individual components, you are seeing variations, such that the median was 66 percent. In the inter-hospital quartiles, I believe it ranged from about 55 percent to 75 percent. So you have meaningful variation in this concept of defect free care.

And when you're considering this, I think it's important to consider that this is really the minimum that we owe the patients who are being treated for myocardial

infarction, right? Every one of these is necessary and if it's not being provided to patients, represents a significant death. I think that's why even though individual components of it are topped out, it is the summary of care, next to outcomes probably, the most comprehensive way we have of evaluating the care of patients with MI.

So I'll stop there, thanks.

DR. KOTTKE: Liz?

MS. DeLONG: Okay. This measure, as he said, has 11 components. I think it might have been very difficult for the developer to substantiate the evidence and validity, et cetera, for all 11. I'm afraid they may have gotten a little confused by repeating something about aspirin after every component. So I got confused when I was reading it. I can tell you what the statement was.

Evidence -- well, I don't have it here. At any rate, the evidence varies, but

it's mostly 1A. I think they've gathered a huge amount of evidence. My one worry is smoking cessation. They claim a high level of evidence for smoking cessation, but their measure is smoking cessation counseling. And I do wonder whether there's a lot of variability in the importance of 11 measures.

And in particular, I would have trouble rating smoking cessation along with statin at discharge. There's no weighting algorithm here. They're all treated with the same weight. So in terms of evidence, I think the evidence is very high for all but smoking cessation counseling.

DR. KOTTKE: Just to note, three Public Health Service Task Forces have concluded that there's Level A evidence that smoking cessation constantly increases smoking cessation.

DR. SPANGLER: That's also specific type of counseling, too. I mean, it's the 5As is what they recommend, so I

didn't see that mentioned here, but yes, it's a pretty specific type of counseling that has that high evidence, so.

MS. DeLONG: So is that embedded in this measure, that counseling has to be specific?

DR. CURTIS: Sorry, could you repeat the question? It's really not -- the information the registry captures is whether or not any smoking cessation counseling which was provided, doesn't specify the type. I do, however, believe this measure, this component to the measure is consistent with other recommendations. And I think there's other NQF-endorsed measures for smoking cessation counseling prior to discharge. So I think it's consistent with that, but to that component, we think it's an important piece of this and may not have the same level of evidence or specificity that the other components do have.

We would note though, that waiving

individual components to a measure always seems to get bogged down in arbitrary decisions, so we have opted not to try to do any weighting, but rather again say in totality, this is a measure that captures important components of care and each of these needs to be addressed in the delivery of care to patients.

DR. KOTTKE: In fact, on the -- looks like page two, where they describe the smoking cessation, it is really the 5As plus prescription of pharmacotherapy. So I would say it's state-of-the-art.

DR. SPANGLER: Yes, I see it on page 96 too, they mention the 5As as well.

DR. KOTTKE: Henry, any comment on evidence? Any further comments before we vote on evidence? So let's vote.

MS. LUONG: The timer starts now. One is for high. Two is for moderate. Three is for low. Four is for insufficient evidence with exception. And five is for insufficient

evidence.

(Pause.)

So the evidence criteria, 11 voted high and 11 voted moderate.

DR. KOTTKE: Liz, opportunity for improvement?

MS. DeLONG: There are a couple of areas where the opportunity for improvement is discussed. I wasn't clear on how many of the hospitals actually participated in their tabulation, but their tabulation gives a mean of around 70 percent and a median that's a little lower, I think. I thought there was a significant gap for improvement.

DR. KOTTKE: Henry?

DR. TING: I think for the all or none measure, there's probably a significant gap. Some of the individual components may be topped out as we discussed.

DR. SPANGLER: I just had a process question for Reva about this type of measure. Because it's so comprehensive as a

composite, do we then look back at -- because there are individual measures here. And do we discuss whether if we think this should be a measure that we eliminate the other -- I mean how do we --

DR. WINKLER: No, these composite measures are measures that need to stand on their own. Because they're components, you want to be sure the components are evidence based. But when it comes to the actual scientific acceptability, reliability, validity, you're talking about how that measure is aggregated and how the data is put together. And this is -- all or none is a commonly used construct for a composite.

So you want to look at that -- the resulting reliability and validity for that way of combining the different components. So you don't need to break it down with the exception of the evidence, you don't need to break it in its bits and pieces, but really you want to see how the whole thing works

together.

DR. SPANGLER: I understand that. My question is there are individual NQF-endorsed measures from these components. Would we ever look at those and say well, we have a composite. We don't need these individual measures any more.

DR. WINKLER: Actually, if you recall the portfolio review I talked about yesterday, we actually do have pretty much all of them as individual measures at some point in time. It's just they're not up for review in this particular meeting. So it will be one of those things to consider when those measures come up in their turn.

DR. KOTTKE: Any further discussion?

DR. JAMES: Yes, I could just comment for Jason. Outside of the government, health plans represents the largest user of measures. So there is utility for health plans and being able to have a composite as

well as having individual ones. And my wife works for a hospital. She doesn't want me to use composites.

DR. WINKLER: Jeptha, if you can clarify Liz's question. How many hospitals are in the registry?

DR. CURTIS: It's a moving target. There are more than 900 hospitals. I think 950 are currently participating. In the sample that we were using for testing, there were 839 hospitals that were available that were actually included in the defect measure after we applied our kind of data quality checks and things like that. 553 were used for the evaluation. So there was a drop off based on whether or not the hospital's submission had past data for this time frame.

DR. KOTTKE: Any other discussion? So vote on opportunity for improvement.

MS. LUONG: Timer starts now. One is for high. Two is for moderate. Three is for low. And four is for insufficient.

(Pause.)

Can everyone just point to me again? Twelve voted for high. Seven voted for moderate. And two voted for low.

DR. KOTTKE: Priority? Liz?

MS. DeLONG: Pardon?

DR. KOTTKE: Priority?

MS. DeLONG: Well, they don't tend to give any estimates of benefit, but MI care is clearly important. I'm not sure whether each one of these elements needs to be included. Whether that creates more burden than is necessary. If you separate out the importance of MI care from the individual components, are they all important to include in the importance, given that there are no estimates of benefit?

And by the way, the sentence that keeps repeating is "estimates of the benefit of aspirin therapy across the body of evidence are not reported." And that's in there several times. You might want to scan that

document.

DR. CURTIS: I will speak candidly about -- I would use the word chaos of trying to get these applications. You said we're trying to pull 11 elements into an application --

MS. DeLONG: I know, I know.

DR. CURTIS: -- with the evidence, with the gaps in care, with the importance. And I think the system did not do the reviewers justice, so my apologies for that.

That said, it's hard to evaluate the importance for each component to it in that we do know, I would say at a high level, we know each of these pieces of the composite are individually important, I would say based on the evidence that we have. I would say for the majority of them there is some evidence that there is variation in care around the individual components to it, but there are ones where the gaps are larger. I'm not sure if I'm answering your question specifically

though.

MS. DeLONG: I'm not sure either.

DR. CURTIS: Repeat the question for me and I'll try to reframe it.

MS. DeLONG: Well, I'm not sure that if you did a marginal look at each of the components over the rest would there actually be benefit there? For example, if they had ten would having the other one make a substantial difference?

DR. CURTIS: I guess it depends on the perspective that you're using. So a difference in what I would ask you?

MS. DeLONG: In an outcome, presumably mortality or survival time.

DR. CURTIS: I think that's a broader question than can really be addressed with the evidence that we have here. I think that's where you sort of started this question. Would it make a difference in the assessment of hospital quality if we change the components of things that were making up

this composite measure? Yes, it would certainly change it. If we took out evaluation of ACE/ARB for patients with left ventricular systolic dysfunction, your hospital estimates would change a little bit. Whether or not -- because we don't have the data for empirical analysis to say okay, this is most strongly associated with one-year outcomes, we don't have that information readily available for us to be able to test whether or not --

MS. DeLONG: You actually do, don't you? I mean you have the data and haven't you merged it with the CMS?

DR. CURTIS: We are working on that. I think the problem that we ran into on those analyses is that the data that we had for analysis for 2011, the 2012 data had not been released and we're still waiting for that. So if you do it at 2011 data, a single year of data and after you merge the data, generally you get about a 60 to 70 percent

merge rate of Medicare fee-for-service patients. So your population at the individual hospital level is shrinking rapidly. And so from that perspective, we thought it would be better to wait for the 2012 so we'd have at least two years of data and get more stable estimates.

But I think that's still missing the point. The point is that each of these is a Level 1 recommendation for the care of patients with MI. I don't care, honestly, if it's not as strongly associated with one-year mortality in our analyses because I know from clinical trials and from task forces and from all the weight of evidence that we have is that every component in here is important and worthy of measurement and I think worthy of reporting.

DR. AL-KHATIB: Actually, what I wanted to say is we had this discussion yesterday, Jeptha. You weren't here where we were talking about the incremental value of

adding one intervention on top of other interventions. But I completely agree. These are all evidence-based guideline recommended interventions for patients with myocardial infarction and yes, maybe we don't know the incremental value of adding the ninth intervention on top of the other eight, but we will never have studies that will look at the incremental value of every intervention. I would hope that this argument that Liz is using won't be taken or perceived as something negative against this measure.

DR. KOTTKE: My feeling is -- let me just make a comment that to tell a patient you got eight, you don't need the ninth.

Leslie?

DR. CHO: There is actually data from the Get With the Guidelines. There's a couple of papers, that if you meet some of their -- as hospitals, as you know, there are hospitals that participate. There are some don't meet Get With the Guidelines as much as

others. And there is a mortality difference. I mean I think that's a well-known, well-accepted, sort of it's published in JACC and there's been a bunch of papers that if you have hospitals and there's like 3,000 hospitals that participate, I think, in Get With the Guidelines. Correct me if I'm wrong.

DR. CURTIS: So not for this particular version of the registry, but I think there are -- there have been analyses that have supported the link between in-hospital process measures and in-hospital mortality. I think what we were trying to do is assess its effect on long-term. Because some of the components, quite frankly, could have no direct effect on in-hospital mortality whether or not you were referred for cardiac rehabilitation, for instance. It may be a marker of quality of care delivered, but it's not directly linked to the outcome and that's why we thought we'd probably have to wait for the longer term outcomes to meet the criteria

of empiric -- the empiric analysis requirement.

DR. KOTTKE: Sir.

DR. SPANGLER: I want to back to Liz' point because my only concern -- there's two issues. One is the weighting, because not all of the evidence here is equal. So there are some that the evidence is stronger than others. The other thing is because it's all or none, if you have consistently a facility that has 7 out of -- let's say 9 out of 11, 10 out of 11, 9 out of 11, 10 out of 11, they're going to get zeros across the board. When you're measuring that, it's the same as a facility that's getting 2 out of 11, 3 out of 11, 2 out of 11. Those are equal in this measure when I would say there's very different quality of care being provided in those two instances. So I'm not sure how -- it's -- I think those are two different issues.

And Reva, correct me if I'm wrong,

but not all composite measures are all or none.

DR. WINKLER: No, they are multiple different types of constructs. This is one type.

DR. SPANGLER: And I am not sure if that was thought of when you guys were developing the measure about not doing it all for none and what the rationale was for doing it all for none versus doing kind of a step-wise approach.

MR. CHIU: I just want to chime in here real quickly here. So thanks for allowing us to be here. So I think to your comment we did ask this group to develop the measure, think about all or none, equal, latent opportunity and all the various ways of composite scoring.

I think actually having used NQF's own composite methodology, we decided all or none, but a fact that I think Jeptha Curtis articulated really well and just emphasizing

again all these things are class 1As. And we realize some of them are kind of topped out individually, some of these are cardiac rehab is one, I think it's 70 percent, kind of one that does bring it down.

But I think to your point, looking at the 12, if someone is missing 10, that is kind of 10 to the measures that they just fail because the idea is you have to get all eligible. You have to get them all to achieve. And so I hear your points, yours and Dr. DeLong's points. I think well taken, but the empirical analysis, unfortunately, we just don't have at this time to really determine which parts and which elements truly are getting to the end point, but we realize overall all of these components make up the whole thing. But not knowing the empirical analysis it's a little hard to start judging which element should be taken out per se, at this juncture, but we are willing to update it as needed.

DR. CURTIS: Let me just follow up on that. As Jensen was alluding to, the ACC has measure developments and all sorts of committees that are evaluating this. Actually in what's reported back to sites that participate in this registry, they get it both ways. And so there is sort of a defect-free care which this is the construct that they elected to submit, but they also get the proportion of opportunities that are met which is another way of constructing -- we thought it would be kind of duplicative to put both of them forward, so we opted to put this one forward, simply because we thought that it set the bar higher and that we should it would really provide a little bit more of an impetus for hospitals to try and be perfect or defect free.

DR. SPANGLER: I like setting the bar high. I guess the issue becomes when -- because measures are being tied to payment and penalties related to payment, a couple of

things are going to happen. Some are going to be penalized similarly to low or much lower quality.

What I'm also concerned about is what sometimes happens because it's tied to payment is people try to fill these measures or try to qualify these measures in not honest ways, let's put it that way, just so that they can meet the criteria because of the payment issues and reimbursement issues that are related to it.

DR. KOTTKE: I don't think that it's isolated to payment. I mean it's bragging rights and other things. I mean any time you have any measures, some people will lie. People lie.

MS. DeLONG: And the more measures you have, the more likely you're going to encounter gaming.

DR. KOTTKE: Yes, but the question is which Class A measure are you going to take out? They're all evidence based.

Henry? Henry has the urge to speak.

DR. TING: I'm listening to all of this and I understand that these are all Class 1A, very important measures. I think part of the problem this committee is having which is maybe the problem I'm having is how do we approach these composite measures? Because each one of these individual measures are important. In fact, some of them are so important they've topped out. We decided to retire the aspirin measure.

And I'm personally not completely, to be honest, sure exactly how we're supposed to evaluate a composite in the setting of these individual measures which are all important and should be done as Jeptha pointed out. No one is going to argue the evidence for any of these measures. These are all Class 1A. We all believe them.

But as far as a composite, what's the right approach for us to say we should do

this composite? And then how does that reflect or how do we harmonize with the others that are stand alone, that are already out there and what time cycle does that get done? It's one thing to say we're going to harmonize, but this is redundant potentially if we don't harmonize today or in the next year.

DR. MASSOUDI: This is Fred Massoudi. Can I make a comment?

DR. KOTTKE: Yes, Fred, go ahead.

DR. MASSOUDI: Thanks. I'm sorry that I can't be there in person today. You know, I appreciate the issues raised about gaming. I don't think that a composite necessarily makes a measure more prone to gaming than anything else necessarily. I think gaming is a concern with any measure at all that could be used for the purposes of accountability. So I don't know that that's necessarily a specific criticism of this measure as much as it is the use of measures

at all for the purposes of accountability.

Secondly, you know, in our experience having worked with NQF, as you recall from the history of the cath-PCI measure which we developed as an all or none composite, we are following the approach that has generally been recommended by NQF in terms of generating an all or none composite that puts together a number of processes of care per the specific conditions. So in some respects this has been responsive to guidance we've received in the past for NQF.

DR. KOTTKE: Thanks, Fred. Kristi just took her thing down.

Tom?

DR. JAMES: This time I am speaking from the perspective of working with the AQA's Public Reporting Work Group. This is a kind of measure that really flies well within the multi-stakeholder group of that particular body in that (1) it represents importance, what we're discussing right now.

Secondarily, it creates a wide variation in reported outcomes. Those measures where there are small differences in results are ones that are really not very useful for the consumer. So this one, I think, is terrific.

DR. KOTTKE: If I were hospitalized and someone said well, that's good enough for the patient, eight out of ten. You've got eight. You don't need the other three. I'd be a little disappointed in the care I were receiving.

Mary?

DR. GEORGE: Yes. I know several years ago when IHI first developed the white paper on bundling measures and composites, they really stressed not putting too many in one bundle and sometimes breaking that big bundle up into things that might happen by one care team in the hospital versus that your discharge measures might be happening with one care team, whereas the ED early care processes may be happening with a different care team

and whether there was any thought in terms of maybe having rather than 11 measures in a composite to maybe breaking that down into something more along the lines of where that care was actually taking place in the hospital.

DR. CURTIS: We have not tried to explore whether or not it's more useful for the other set of consumers, the providers to break it into that. We certainly think that there's added value for the composite versus the individuals.

I will say that the care of MI patients in general is pretty well cordoned off in most places. It's generally a care team that's caring for you once you get out of the emergency room and on the in-patient services. Now you might be switching from the CCU to a step-down floor or something like that, but it's generally a group that's cohesive, that's been working together for a long time that has their patterns of practice

pretty well established.

I will say the other piece of that is that the action Get With the Guidelines registry per se provides the existing community that is used to looking at this and used to evaluating the full component of the measure. So it's not that we're necessarily adding a new burden. What we're really looking for is the endorsement of this organization to say you can use this measure for public reporting sort of the logical extension of the internal quality improvement efforts that the registry has been facilitating for years.

DR. KOTTKE: Linda.

MS. BRIGGS: I was going to reserve my comments for the feasibility section, but since we're talking about the number of indicators within this composite measure, I think that part of the opportunity for improvement piece that we're seeing is the variability that's caused by this very high

bar of 11 things to get to. And while I think it's really important for us to have very holistic care for the MI patient, that measuring these 11 things when maybe 5 of them, at least aspirin we've decided no, we've kind of topped out on.

The burden of actually measuring something that you've already topped out on, you're going to keep topping out on that particular agent probably in most of the high-performing hospitals. So you're really not for most places not measuring anything that's contributing to a change in the quality of care for most institutions. The things that you care about within that 11 are the things that people tend to miss.

So we have apparently other free-standing indicators that have to do with things like fibrinolytics or time to PCI and all the pieces that go in here. I really think that while it would be nice to look at this composite index for all of those things,

that you're creating a lot of work for people in data collection that isn't necessary overall. Yes, people that are doing the Get With the Guidelines registry, they're already collecting that data. But if we approve this measure and it goes forward, then other people are going to be expected to collect that data, too, probably. And while some of that is good, we're also probably creating a lot of work for people that may be unnecessary.

DR. KOTTKE: Judd.

DR. HOLLANDER: So I am wondering if it's possible to not have the best of both worlds on one data form, right? Like why can't the composite be reported with all the individual elements from one place? So -- and then you get everything. Because if you're going to collect all 11 of these things individually, and it's 11 different data forms, well, you're repeating a lot of information and if you're going to collect a composite, you're repeating or people are

filling out other data forms that have a lot of information.

And so if the measure, I'm going to say harmonized, for lack of a better term, or consolidated is probably the right word, if we have multiple measures that get at the same or redundant data, why can't it be consolidated so there's one reporting system that provides all that relevant information? And so in essence, this one is collecting each of the 11 subcategories, but there's another one door to needle or door to lytics and it's all on different data forms, presumably. So unless everything is coming through the same registry for every one of these measures, and so it would behoove us to find the best repository of all that information and have it all completed at once, rather than fill out Form A for this measure, Form B for this measure, and send it to a different place.

DR. WINKLER: Judd, I think you're sort of describing why people would really

truly love to see in an ideal world, but our world is far from ideal. And what we have are multiple implementers. And I think many of these measures are hospital-based measures. They've been in play a long time by CMS. The data collection system are sort of established. This, I think, is -- this registry is a parallel effort as well.

I don't know that just by endorsing measures we're going to have a way of any sort of forcing function to move to a consolidated data collection platform which probably would be really nice, but I think we're not there yet and one of our problems with these measures is we endorse them, but then those various implementing organizations do their thing.

DR. KOTTKE: If I can just make a comment before going on to Joe, our experience abstracting paper records is the cost is getting your hands on the record. It's not the additional data element. It's actually

culling the record.

Joe?

DR. CLEVELAND: I just want to echo as I hear the discussion. I think that I interpret this as really the totality of care for the patient and therefore I realize it's a little unwieldy. I really think that's what we should be about. And again, I'm thinking if I go and do a bypass operation, do seven of ten steps, right but three are not, the outcome may not be great. I mean maybe that's too -- it's not quite the appropriate analogy, but it really says you've got to -- we've got to set bar high. I think that totality is important.

DR. KOTTKE: Sir?

DR. VIDOVICH: I just have a little comment as I was going back and forward in looking. We did some research on the impact of insurance status with Get With the Guidelines and I was looking at the paper. It was a few years ago. And the measure actually

very nicely discriminated between different insurance carriers, Medicare, Medicaid, private insurance and that was refreshing my memory and while all the components were different between various insurances, the measure actually captured it very nicely. And then even after multiple adjustments, it turned out to be a good indicator of differences of care.

So looking back, again, it's been a while since I thought about this paper, but I think it does nicely describe a composite outcome of complete MI care. That would be my take on this. I found it quite valuable.

DR. KOTTKE: Thank you. Liz, did you have another comment?

MS. DeLONG: I just wanted to pick up on what Linda said because it's not only coding whether they did it, there's a lot of overhead in eligibility for each one of these that has to go into the composite because you have to calculate how many of these things was

the patient eligible for in order to calculate whether they got it all right. And that's variable.

DR. KOTTKE: Further comments?

DR. CURTIS: So I guess one of the struggles here that the NQF endorses measures that are agnostic as to who is applying them. In this case, the measure is developed and implemented currently for quality improvement purposes at the level of an individual specific registry. So from that perspective there is no incremental demand on hospitals. They've already made that investment in quality improvement. They've already paying the fees which are minimal compared to the amount of effort it takes for the personnel to abstract these charts so that we can provide this data back to them.

So it gets to the larger point of what if this were applied to a different population or a broader population? I can't speak to whether or not that's feasible and it

probably would be. There would be overhead and expenses associated with that. But for the target population in which this was developed and currently applied, there is minimal incremental efforts required, in fact, none.

MS. DeLONG: I guess my concern would be standardization across all of the different entities that decide to capture.

DR. KOTTKE: Are we ready to vote?

MS. TIGHE: I'll just jump in because we've talked about a lot of things that are not what we're voting on right now.

(Laughter.)

I think the one comment was made related to high priorities that MI care is clearly important. Everything else has really dabbled in the construct of the composite, the validity of that construct, and the feasibility which we'll vote on next.

DR. KOTTKE: So we are voting on priority.

MS. LUONG: The timer starts now. One is for high. Two is for moderate. Three is for low. And four is for insufficient.

(Pause.)

Priority, 15 voted high and 7 voted moderate.

DR. KOTTKE: Thank you. Scientific acceptability --

DR. WINKLER: This is one of the important criteria about composite measures and it really was what you all have been talking about. And that is the construct, how this measure was conceptualized and put together and what's included, what's not, all the things you've been talking about is what's in 1D. So that's the criteria for this composite that you're addressing in your next vote. You can see it talks about the construct, the rationale, and the aggregation and weighting. You've all talked about all of that stuff.

DR. AL-KHATIB: I was actually

reserving these couple of questions until we delved into the specifications of the measure, but my questions are actually directed to the developer.

In terms of, for example, like people -- I know Liz mentioned the issue of patients not being eligible for one of these interventions, so how do you handle contraindications, like if a patient has a contraindication to one of these medicines, for example? That's one.

The second thing that I want to ask is you mentioned evaluation of LV systolic function and we all know that sometimes you have patients where the troponin is just slightly elevated. They just had an echocardiogram done two months ago. Now for this particular encounter, maybe we as clinicians decide that repeating the echocardiogram is really not necessary. So how do you handle that if the patient does not get an LV assessment during this encounter.

And then finally, the issue of time to reperfusion or to PCI is really key. Why is it that we have redundancy? I think at least this is the way I see it when you talk about consideration of reperfusion therapy. I mean aren't those redundant? Why not do away with the consideration of reperfusion if you do have time to either primary PCI or lytic therapy?

DR. CURTIS: So I can try and address those and of course try to keep the way that each of these 11 components are calculated in my head is a little much. But I think the composite was constructed in a way that we tried to be as fair to hospitals as possible. So for each one, we tried to apply sort of a standard of reasonability to say okay, if there is documentation that you considered whether or not to perform an assessment of left ventricular ejection fraction but you had the information or otherwise thought it was unnecessary, as long

as we documented that rationale you would be, I believe, given credit for that. Okay?

For the reperfusion question, it's a component -- there's two components to reperfusion, right? There's the decision of whether or not someone gets reperfused. And then there's the timeliness of the reperfusion.

So the D to B and the D to needle or dirty needle are both assessing the timeliness of that reperfusion. But both of those actually kind of miss the question of whether or not all patients are getting reperfused. So from that standpoint, I think they are capturing distinct domains. One is the speed. One is whether or not they got reperfused at all. It's probably one of the more controversial components of this particular measure, but we find one that's important. Actually, has very little variation at the individual hospital level. Most patients are getting reperfused most of

the time and the ones aren't there, there's usually good justifications for that.

DR. KOTTKE: We are ready to vote unless someone raises their name tag. We're ready to vote on the composite.

MS. LUONG: The timer starts now. One is for high. Two is for moderate. Three is for low. And four is for insufficient.

(Pause.)

Seven voted for high. 11 voted for moderate; two for low and one for insufficient.

DR. KOTTKE: Okay. Acceptability and reliability.

MS. DeLONG: For reliability, they produced one of those plots where they did a split sample and they looked at the percent from one sample versus the percent from the other sample. As I said yesterday, I prefer to see percent agreement when you approach it from two different directions, but the worry about this chart is that there are

discrepancies between one take on the random sample and another take on the random sample. I'll try to find the page that's on.

DR. CURTIS: So I think this reflects sort of the difficulty working with some of these documents. So we have a beautiful figure which shows the correlation of the random split sample; one versus random split sample two. And it is a line. This is the highest correlation I have ever seen for a random split sample. It's .97 something.

So there are differences in any random sample that you choose. There may be a few more defects in one than the other. We only apply a minimum threshold of 25 cases and so if you had one defect in one place, you'll see some variation around it. But it seems to be a pretty consistent, and I would say reliable indicator of the care that's being delivered at these hospitals that is reproducible in two different random samples in the same time frame.

MS. TIGHE: The figure that they are referencing that shows that is figure two. It's on page 117 of the packet that you all have.

MS. DeLONG: So there is a great distinct trend there, but you do have some that are at maybe 45 versus 35; 40 versus 25. I mean that --

DR. CURTIS: Right, but I guess how much of that -- so if we dug in on that, right, I mean 35 versus 45 is pretty good. If you actually look at -- not to sell the outcomes measures short, but if you look at the correlation of random split sample for the outcomes measures, that's much more of a shocker. And what you'll see, some indication that there's a quality signal that the ICCs are acceptable, but much lower level of what I would call reliability in this.

If you dug in on these where there is more difference and we have not done that and maybe we should have, I would speculate

that this would probably be due to hospitals at the lower range of volume. And so that's probably the ones we're seeing a little bit more --

MS. DeLONG: But they're going get dinged, right? I mean where they come out in the spectrum is dependent on this measure and if they're going to be paid based on this measure, and the take on this measure for that site is that variable, that's bothersome for them.

DR. CURTIS: I would argue this is the least amount of noise I've ever seen for any measure that's been evaluated. This is perfect correlation, near perfect, number one. Number two, there's no plan or mechanism that I could see this being turned into financial penalties at this point. I don't see a pathway for that. I can't speak for what the ACC is trying to do in this regard. This is at this point purely a quality improvement effort. And it's trying to leverage the

effect of public reporting of this to further enhance hospitals' quality improvement initiative. So I would try and divorce this from the consideration of possible financial penalties.

If I were a hospital that's 35 in 1, and 45 in the other, I have things that I need to do to improve. It doesn't matter if it's 35 to 100 or 45 to 100. There's an equal opportunity there. I mean there's nobody that's going from zero to 100. There's nobody that's going -- maybe looking at it right now, maybe 10 to 20 at most on the edges of the spectrum here in terms of the performance in sample one versus sample two. But I mean it's a pretty reliable signal of quality in my opinion.

MS. DeLONG: I will say that the components, you did a chart review versus the components and they turned out very well. I think the Get With the Guidelines database itself is capturing those components very

accurately. But that does lead to some concern on my part about this plot and the discrepancy that you can see in the lower volume hospitals.

This didn't -- by the way, you didn't say what time period this is.

DR. CURTIS: This is 2011-2012, we took all the cases --

MS. DeLONG: So two years of data for each site?

DR. CURTIS: Two years of data that were then -- yes, correct. And then split.

DR. KOTTKE: Other comments? So we've had the discussion on reliability. Is that correct? Are we ready to vote? Seeing no -- oh, Sana.

DR. AL-KHATIB: I want to make one comment that I think was not very clearly stated is that when they did the reliability testing, they did it both at the data element level and at the measure of score level. I

think that's something important to keep in mind as we vote, if we have to stick to the algorithm here. So just something to keep in mind.

MS. DeLONG: That's what I was saying, when they did it at the data element, it was very good.

DR. KOTTKE: Let's vote.

MS. LUONG: Timer starts now. One is for high. Two is for moderate. Three is for low. Four is for insufficient.

(Pause.)

For reliability, 16 voted high and 6 voted for moderate.

DR. KOTTKE: Thank you. Validity. Liz?

MS. DeLONG: There is no empiric evidence of validity, but once again, the individual components seem to be accurately constructed. The overall component, there wasn't evidence given.

DR. KOTTKE: Any other comments?

Are we ready to vote on validity? Seeing no objections, we'll vote on validity.

MS. LUONG: The timer starts now. One is for high. Two is for moderate. Three is for low. And four is for insufficient.

(Pause.)

Can everyone just point to me again? Six voted for high; 15 for moderate; and one for low.

DR. KOTTKE: Feasibility. Validity of the composite.

MS. BRIGGS: Under the STEMI population, you have time to fibrinolytic therapy and time to PCI. Is there a choice within those to say not applicable for those particular things?

DR. CURTIS: Yes, I'm sorry, just to clarify. So the denominator of opportunity changes for each patient and changes for whether or not you're a STEMI or a non-STEMI. And certainly if you receive lytic therapy you would not be eligible for a long time.

MS. BRIGGS: That wasn't entirely clear from what the denominator statement was. It was STEMI versus non-STEMI, but nothing in terms of if the patient received fibrinolytic therapy versus PCI.

DR. CURTIS: Right, and the other analogy for that would be for the patients with a low ejection fraction. Not all patients will have a low ejection fraction, so again there's that evaluation of whether or not they're eligible and that's true for every component of measure. Again, for transfers in, they're not being held accountable for whether or not a patient received aspirin at the referring hospital.

MS. DeLONG: So what happens when ejection fraction is missing? My experience is that that is missing a lot in some of these databases.

DR. KOTTKE: You get a zero.

DR. CURTIS: No, in this case, you drop out of the numerator and the denominator

for that particular component of the composite. And so you're still dinged because assessment of left ventricular ejection fraction is still one of the components. So in a defect-free care construction you would be a zero as opposed to a one. Is that clear?

MS. DeLONG: You said drop out of the --

DR. CURTIS: No, you drop out of both if you're not eligible -- for left ventricular ejection fraction specifically refer ACE/ARB, in patients with reduced LVEF, you drop out of numerator and denominator if you don't know what their EF is. You can't be in the denominator if you don't know what their EF is. You can't assume that they have a low EF because 60 percent of patients do not or 75 percent do not have a low EF.

So for that particular component, yes, you have to have an EF that's assessed. It has to be low. You have to have no contraindications to an ACE/ARB and then if

you meet all these conclusion criteria, then you assess whether or not they actually receive this treatment.

MS. DeLONG: By and large, they get a zero anyway.

DR. CURTIS: Correct.

DR. KOTTKE: If they don't measure the EF and document it, they don't meet optimal care. Other comments on the composite validity? Seeing no movement, we'll vote.

MS. LUONG: Timer starts now. One for high. Two for moderate. Three for low. And four for insufficient.

(Pause.)

Can you just point towards me again? Thanks. Thank you. For this, four voted high. 16 voted moderate. One for low and one for insufficient.

DR. KOTTKE: Liz, feasibility.

MS. DeLONG: I think we've trod that ground as well. My worry is the coding that is necessary and the recipe feeling of

this whole thing that is it really something that will actually be implemented given the complexities?

DR. KOTTKE: Sana?

DR. AL-KHATIB: I think within the realm of the action Get With the Guidelines database, this is certainly feasible and doable. Could you give us a sense of what percentage of patients who present with AMI are being captured by this registry?

DR. CURTIS: It is very hard to get a sense of who's not. The auditing that they do and they do do auditing which is where we got the agreement for the individual components, does not address, does not scour hospital records and develop -- did you send us everybody with a MI?

The contract that the hospitals sign when they agree to participate in the registry says that they have to agree to submit every patient with MI. That's very hard beyond sort of assuming that hospitals

are trying to do the right thing and not game things. I don't know why they would be paying these fees and participating if they're not going to plan on participating wholeheartedly. But again, I don't have a response for that.

DR. KOTTKE: Henry.

DR. TING: So this is a question for Tom, actually. Just warning here. Tom, on a personal level, it is my opinion, I like component measures when you think about perfect care for AMI, diabetes, PCI. I think they're a good thing. They tell us about whether the patient got everything we think we should be doing in terms of level 1 the evidence.

And we had the one, the door to ECG. We like door to balloon time, the whole process, not just component to the process.

But you had mentioned that, I think earlier on in this committee meeting, that certain people like individual component measures. And you said something about your

wife or something -- who likes individual component measures as opposed to the entire composite, what we think is perfect care for diabetes or AMI or PCI.

DR. JAMES: This gets right into usability as well opposed to feasibility, but it's -- when we start looking at processes for hospitals or physicians when they're doing transparency work or developing pay-for-performance payment for value programs, there may be times when the bar may be too high for certain elements and so you say let's do it in segments and work our way up.

When I'm dealing with consumers, with the AQA, they want to have something which sounds like Atul Gawande wrote it and that is it's really a checklist they know that a facility is going through every step all the way and that they know the perfect should not be the enemy of the good. But it's how things are being used in different circumstances. That's why it's good to have a tool kit of a

variety of measures.

DR. TING: I'm sorry, so what you're suggesting though is that at the measurement level there is probably a need for both the individual components of the composite as separate measures, is that what you're advocating?

DR. JAMES: That's right. In fact, when you look at what NQF says how measures are being used, two thirds of all measures adopted are being used in some sense or another. Very few of them are being used universally, except the aspirin on arrival. It's because there are different opportunities.

DR. KOTTKE: Liz.

MS. DeLONG: One concern about the usability of this is that unless you have all the individual components as well, a site doesn't really know where they're being dinged. You know you got an 80, let's say. You don't know whether there's a particular

measure you're failing or whether you're across the board, not doing well.

DR. CURTIS: I think that goes to how public reporting and internal quality improvement efforts complement one another and you can't have one without the other, right?

From a consumer standpoint, I think it's useful to have this all or nothing composite defect free care. They know, whoever the consumer is that this hospital, this proportion of patients receive defect free care.

For the site, for the institution, from their perspective, they need to know where they're falling down if they are falling down. The action registry does provide all this information in great deal to the participating hospitals. So again, you can't have one without the other. So there has to be a mechanism by which that information is fed back to sites. However, on a consumer level, I don't necessarily, I wouldn't expect

that I would have the information and expertise to evaluate okay, they're really bad on door to needle, but they're okay on aspirin on arrival. Right? So I think they have to go hand in hand. I completely agree with that. From a public reporting standpoint, I think you really only need the composite.

DR. KOTTKE: Linda, then Judd, then Tom.

MS. BRIGGS: If we're making the leap to public reporting on this, one might also assume that insurance carriers, et cetera, might decide to adopt this measure beyond what the American College of Cardiology is monitoring with the Get With The Guidelines.

So say CMS wanted to pick this up and say all right, you need to give us defect free AMI care. So anybody who is not currently using the Get With The Guidelines database will now have to look and obtain the data for each of those 11 elements as they've

been approved theoretically by us and then be able to report in this very complex algorithm as we've been talking about, if this person meets this contraindication, then they fall out of the numerator, they fall out of the denominator. It becomes very difficult for someone who is not a member of the particular registry if again, this gets applied at another level.

DR. CURTIS: I don't think there's a reason why it could not be adopted by an organization like CMS or another interested party. It would have to be that they use similar comparable definitions and details and attention to fairness and equity as they do so.

MS. BRIGGS: But there are costs with this.

DR. CURTIS: Let me continue. The other piece is that the individual components are already being collected for most measures, right? So aspirin on arrival, aspirin on

discharge, beta blockers on discharge, all these sound familiar because they're JCAHO measures, right? So relatively few of them are new or novel or stand alone as opposed to what hospitals are already doing. So I guess I can't speak beyond that, but I think that it's again, all of them are C, components to the care of this patient population and if an organization wanted to make that investment and they wanted to do it fairly and equitably, I don't see why that should be a barrier.

DR. KOTTKE: Putting my insurance company hat on, I don't see why an insurance company that acts on behalf of a patient shouldn't expect that a hospital provides good care.

Judd?

DR. HOLLANDER: My spine tingles every time I hear the word defect free care. And I almost want to vote against the measure just for its name because you could rupture the heart in a cath. lab. You could get a

groin hematoma. You could actually die and you could be getting defect free care. So I urge the developers to change the name. It's really guideline compliant care and it's really 2014 guideline compliant care because in a year or two there will be new data and something else will be added and you're not even attacking everything. But it is not defect free care. It is just a composite of these 11 measures.

And so I think consumers will totally misinterpret it.

DR. KOTTKE: Tom?

DR. JAMES: Let me just start off by just complimenting your organization. George told me about with composite measures in diabetes that the all or none phenomena with HealthPartners in Minnesota was that very few physicians, internists, were able to achieve all elements of their composite measure until the insurance companies started saying this is what it is. The ACP got behind

it. Other state organizations got behind the quality measures and guess what? Minnesota proved to the rest of us that composite measures really do serve as a lever to improve care. After all, the point of all of this is people. It's caring for people. It's not just an academic exercise.

I have some strong feelings here.

(Laughter.)

DR. KOTTKE: How do you really feel, Tom?

Any other comments or can we vote on feasibility of the composite? Let's vote on feasibility of the composite.

MS. LUONG: Timer starts now. One is for high. Two is for moderate. Three is for low. And four is for insufficient.

Seven voted for high. Twelve for moderate. And two for low.

DR. KOTTKE: Usability and use. Liz?

MS. DeLONG: Well, it is obviously

being used in Get With The Guidelines. As a follow up to Sana's comment, I'm not sure what percent of patients are actually being evaluated under those circumstances. Apparently, there has been an improvement in not only the measure, but an accompanying improvement in mortality. So it apparently works despite the complexity.

DR. CURTIS: Just to clarify. I don't think we have evidence that improving on this measure improves your mortality. What we have is an association between a hospital's performance on this composite measure and their in-hospital mortality. So it's an association. It's not causality, but yes, there is some evidence to suggest that if you do well, your patients do better.

Yes, Christine.

MS. STEARNS: There's been a lot of comments previously about the benefit to consumers who are looking for information, the quality of care at a particular hospital.

Could you just comment about how this might be used for public reporting. It's mentioned that that's something that's planned. Could you just comment a little bit about that?

DR. CURTIS: So I think the American College of Cardiology and again, if I go off track somebody correct me, but they have a true commitment to increasing their investment in public reporting as a lever to get hospitals to focus even more efforts on improving quality of care.

So they are in the process of creating a mechanism, a pathway by which public reporting can be achieved and there has been a pilot and specifically PCI 30-day readmission rates was publicly reported in a voluntary session among hospitals that were participating in the CathPCI Registry and they had the option of opting in or out of voluntary public reporting that was on both hospital compare as well as internal American College of Cardiology website. So I wouldn't

say the pathway is well demarcated at this point, but there is a pathway and I would imagine that this would follow a similar path.

MR. CHIU: The only thing I would add to your comment, Curtis, is that work group is kind of deciding the measures of the public reporting initiative, actually partnered, ACC has partnered with HRS and STI as well, so we have kind of partnerships, it isn't just ACC kind of going at it alone. So you'll see obviously PCI, that's our more robust registry and has been here for over ten years as yesterday we alluded to the 133, the mortality measures that gone through three or four cycles. So hopefully, the actionable ones, hopefully, this gets endorsed. This will be kind of a similar thing. But action, this measures specifically is planned to be potentially in the future, sooner rather than later, we hope in that portfolio. But I can't speak for that committee and jump the gun on that, but they wanted to see it gets endorsed

at NQF first and then get that in the program, in the public reporting initiatives.

DR. KOTTKE: Further comments on usability and use? Seeing no movement, let's vote.

MS. LUONG: Timer starts now. One is for high. Two is for moderate. Three is for low. And four is for insufficient information.

Can everyone just point to me and vote one more time? Thank you. Keep pushing it.

Six voted for high, 14 for moderate; and 1 for insufficient information.

DR. KOTTKE: Okay, now we'll vote on overall.

MS. LUONG: Timer starts now. One is for yes. Two is for no.

Nineteen voted for endorsement. Three voted no.

DR. KOTTKE: Congratulations. Thank you for your time.

Reva, break until 10:00? Okay, we'll break until 10:00. Thank you everybody for your thoughtful comments.

(Whereupon the above-entitled matter went off the record at 9:44 a.m. and resumed at 10:00 a.m.)

DR. KOTTKE: This is for people to draw terms. I'll -- Lindsey will tell us how this is going to work since I don't know.

MS. TIGHE: As you all may recall when you initially signed up for this, there was an option of a two-year or a three-year term for the Standing Committee. So we're going to split it 50-50 just so everybody isn't recycling at the same point in time. But I will caveat that if you are interested and you draw either a two-year or a three-year term, our policy does allow for you to serve two consecutive terms. So even if you draw a two-year term, at the end of the two years you could reapply and nominate yourself again to participate. So you could be on this for a

very long time if you wanted to be. But Wunmi is going to come around and let you draw either a two- or three-year term. And Vy will record the results of that.

DR. GEORGE: Mary George, three-year term.

MS. TIGHE: And I will jump in, Jeff, Ted, and George, I'll be drawing for you as your proxy just like I've been voting for you.

DR. KOTTKE: Tom Kottke, three years.

MS. TIGHE: Jeff Burton, two-year term. George Philippides, two-year term. And Ted Givens, three-year term.

MS. STEARNS: Christine Stearns, two-year term.

DR. HOLLANDER: Judd Hollander, two years.

MS. STEARNS: Two-year term.

DR. HOLLANDER: Judd is two.

DR. CLEVELAND: Joe Cleveland,

three-year sentence.

(Laughter.)

DR. JAMES: Tom James, two-year term.

MS. HILLEGASS: Joe, I'm serving with you for three years.

(Laughter.)

DR. VIDOVICH: Mladen Vidovich, three-year term.

MS. DeLONG: Liz, three-year term.

DR. RUGGIERO: Nick Ruggiero, two-year term.

MS. BRIGGS: Linda Briggs, three-year term.

DR. CROUCH: Michael Crouch, three-year term.

MR. MARRS: Joel Marrs, two-year term.

DR. SPANGLER: Jason Spangler, three-year term.

MS. MITCHELL: Kristi Mitchell, three-year term.

DR. CHO: Leslie Cho, three-year term.

DR. AL-KHATIB: Sana Al-Khatib, two-year term.

DR. TING: Henry Ting, two-year term.

DR. KOTTKE: Thank you, everybody.

MS. ISIOJOLA: Wait, Carol Allred, two-year term.

DR. SPANGLER: Sorry, quick question. The terms started January 1 or before that? I'm trying to remember. November?

DR. WINKLER: Essentially, the beginning of the year.

(Pause.)

DR. GEORGE: We will go ahead with Measure 0642, cardiac rehab. Do we have our measure developer representatives for these measures? Go ahead, yes.

MR. LICHTMAN: Good morning. I am a rookie. Good morning. It's my pleasure to

be here and I thank you for inviting me and my colleagues up above on the telephone. I'm Steve Lichtman. I work at Helen Hayes Hospital in New York and I've been doing cardiac rehab. as the director of the program there for 22 years and I'm also the ex-president of the American Association of Cardiovascular and Pulmonary Rehab., one of the organizations developing this measure.

We also have on my team or on the team, Randy Thomas, a cardiologist from Mayo Clinic; Marge King, a cardiologist from my hospital, Helen Hayes Hospital; and Karen Louie, from GRQ, who is a legislative expert on cardiac rehab and all three of them are also ex-presidents of AACVPR.

So I thank you for looking over this measure that we're presenting. The primary goal of our measure is very simply put. It's to get as many individuals into cardiac rehab with the appropriate diagnoses as possible. And the basis of the measure

looking at referral is that referral is the first step in the process that drives enrollment. And without referral, there's no enrollment. So the committee decided many, many years ago to concentrate on referral as that is the primary driving force to enrollment or the only driving force to enrollment and cardiac rehab.

Just as a quick overview of cardiac rehab, it's a multi-disciplinary approach to the healthcare of a patient with cardiac disease. It's a very low cost, very highly effective method of treating patients with cardiovascular disease. It impacts significantly on the mortality, the morbidity and the quality of life of the patient. There is tremendous amount of literature on the benefits of cardiac rehab. It's rated as a 1A recommendation for most patient populations, so there's an extreme benefit and need for patients post-cardiovascular event to get into cardiac rehabilitation.

However, there's a tremendous gap in referral and enrollment. Despite the numerous and documented benefits of cardiac rehab, back when we started this in 2007, and I jumped in on the committee around 2010, the enrollment rate in cardiac rehab was nationally somewhere, depending on the articles that you read, somewhere between 18 and 35 percent. CC adaptation of this measure by NQF with its endorsement previously that has increased, but it's still short of anything that we would want in the cardiac rehab field. We would look for enrollment and referral rates upwards of 80 and 90 percent is what we would want, probably never reaching 100 percent because not every patient is eligible. There are medical conditions that are exceptions, insurance exceptions, et cetera.

These gaps in referral have been documented in numerous articles, so there's a clear need for a driving force nationally to

get patients referred to cardiac rehabilitation.

We see a clear increase in enrollment in cardiac rehab from increases in referral. There have been studies by Sheri Grace up in Canada and also Phil Ades here in the United States where when they put in automated systems to increase referral, they get a tremendous and dose response and an increase in enrollment.

These measures are what I consider point of contact measures. This measure is a point of contact in the in-patient setting that every patient with an eligible diagnosis should be leaving in-patient settings with the appropriate cardiac diagnosis with a referral to cardiac rehab, and the measure points out it's not just referral. Referral alone is not sufficient. And that's clear in some of the Grace articles where referral systems alone don't work. You also need communication systems.

And the measure states that an appropriate referral includes the referral, but it also includes the communication from the in-patient setting to the cardiac rehab setting such that the cardiac rehab setting receives the referral, but it also receives the referral and patient information so that they can take the ball at that point and enroll the patient.

Physicians have little control over enrollment. They have control over referral. And that's really what this measure is concentrating on. Getting the physicians to refer patients to a low-cost, highly-effective method of treating cardiac patients in terms of mortality, morbidity, and quality of life.

DR. GEORGE: Thank you for that introduction.

Leslie.

DR. CHO: So thank you so much and I think that no one disputes the benefit of

cardiac rehab, the great improvement in patient care when patients are enrolled into a cardiac rehab. Now this is a process measure and I think that one of the key things about this measure that I struggle with is that I know doubt the great benefit of cardiac rehab, but the enrollment referral does not equal in moment and I read through the -- and thank you for providing all the back documentation. I read through the Grace articles and I read through some of the other components that are included in the background for this. And that is one of my biggest problem with this measure.

And I think when we vote for evidence, the evidence that we're voting for is actually the evidence -- what we really want to get at is enrollment. But what we're voting for is referral because you can't get to enrollment until you get -- until you have referral. And I think that if we follow the NQF algorithm for the strength of evidence,

it's moderate because referral is not one-to-one with enrollment, even though it's the first process in the enrollment.

MR. LICHTMAN: I can appreciate that point of view because they are two separate and distinct processes and the committee took a purposeful stance way back when on concentrating on referral because that's really what the physician can control at the point of contact. It's very difficult to control enrollment once it's in the patient's hands. So by concentrating on referral, we felt that we would really have the physician responsible for what they're in control for and they are clearly in control for referral.

DR. CHO: I totally understand. We understand, but based on the algorithm, based on the NQF algorithm, because referral is not one-to-one with enrollment, it is a moderate based on the evidence --

MR. LICHTMAN: I agree, it's

clearly not one-for-one, but also I think if you look at the articles which you did, there is a dose response that there's a relationship between increase -- understood.

DR. GEORGE: Ellen.

MS. HILLEGASS: I, too, am a strong proponent of cardiac rehab. And I have to tell you that I don't think there's a person in this room that doubts the evidence or doubts the indications for cardiac rehab or doubts the outcomes from cardiac rehab. That said, we have to look at the question. And the question is does the evidence show a relationship and the problem is the evidence is related to the outcome of cardiac rehab. And so when we're voting, I think we need to keep that in mind, as Leslie said, because we're not voting on referral. The evidence is on outcome, I'm sorry, long morning. The evidence is on outcome, but it's not on referral. So the weakness is the referral.

And we had this discussion

yesterday when it came to adherence with medications. You can hand the prescription over. You can actually send it in to the Rite-Aid or whatever, and the person can pick it up. But then you don't know if they actually take it. So we did have this similar discussion yesterday of adherence to medication.

But keep in mind that the evidence is really strong for the outcome. So part of my question is that is the evidence strong enough at the level of moderate showing that there's not strong evidence for referral, but there is very strong evidence for outcome.

DR. THOMAS: This is Randy Thomas. I'm on the line. Do you mind if I just say something really quickly?

DR. KOTTKE: Go ahead, Randy.

DR. THOMAS: Can you hear me okay? I apologize. I'm seeing patients and I'm just kind of on for a couple of minutes. I just wanted to make a quick statement.

I can understand the discussion points and concerns about direct evidence on enrollment and completion of rehabilitation and there's -- I guess what I would say is if you look at the strength of the evidence from the perspective of okay, if you take a patient in the hospital and someone is referred to a rehabilitation program and someone is not, where is the strength of evidence showing that the person referred to the rehab program is going to have a better outcome than the patient who is not referred?

And the evidence, I would say, is above moderate that the person who is referred to a program is going to have a much better outcome than the patient who doesn't get referred. And so although if you look for specific studies looking at the correlation between referral and enrollment and completion, and just like you're saying medication is the same thing. You're not going to find a complete correlation. But if

the question is taking a step back at the level of the hospital, if you compare a patient who doesn't get referred the outcome is much, much worse than those who don't get referred. And that's really the key point to this measure. It's the first step. It's the key step. It's probably 70, 80 percent of the battle to get them referred to the program. Now they may not go for various reasons. Sometimes because of the patient or for other reasons, but the referral is the key thing that the provider has control over and that's the reason why the focus of this measure was on referral.

DR. KOTTKE: If I could just jump in and remind people even if it is only moderate evidence that we would still go ahead and can endorse.

DR. GEORGE: Other discussion?

DR. CHO: I say we vote.

DR. GEORGE: We'll vote on the evidence.

MS. LUONG: Timer starts now. One is for high. Two is for moderate. Three is for low. Four is for insufficient evidence with exception. And five is insufficient evidence.

For the evidence criteria, 19 voted moderate and 3 voted low.

DR. CHO: Next is the opportunity aspect and the performance gap in the measure and clearly cardiac rehab is only being utilized in less than 15 percent of our PCI patients and 30 percent of our CABG patients and clearly there's an incredible need for performance gap narrowing. There is a disparity among minorities and among women and I think that in regards to opportunities for improvement it's quite high. I mean we have huge room for improvement.

DR. GEORGE: Liz?

MS. DeLONG: How does that relate to insurance status? Are we talking about improving insurance as well?

DR. CHO: No, no, no. You are absolutely right. There's data out there from the rehab literature saying that patients obviously, insurance is a big factor. Where they live is a big factor. How close they are to a rehab center is a big factor. There's a lot of issues. But I think the problem is is that traditionally if you look at all the rehab studies, women and minorities always have less enrollment even if they have similar insurance. Women, because they are maybe taking care of their family or there is some transportation issue, women tend to be older when they have their MI. There's some other issues and I think regardless of that, I think the performance gap for cardiac rehab is significant.

MS. DeLONG: Just concerned about once again public reporting and if a hospital sees primarily patients who don't have adequate insurance, is that a problem?

DR. CHO: So at the Cleveland

Clinic, I can speak for the Clinic. We give a referral to our cardiac rehab patients regardless of their insurance status. And so they come to the Cleveland Clinic and if they have no insurance, we will provide free cardiac rehab.

MR. LICHTMAN: Just to follow up on that and I wish I could have summarized that as well as you did, the diagnoses included in the measure are almost universally accepted by insurance companies. Medicare covers all of them. The private insurances are rare that won't cover all of the diagnoses. It's more if the hospital participates in the insurance as opposed to the insurance coverage. So as long as the hospital makes contracts with the private insurers, they tend to cover all of these diagnoses.

It's really people with no insurance where the issue would lie and hopefully with healthcare reform that will

become less and less of an issue as we move along and many programs do provide scholarships, as we call them in the business, for patients who are uninsured or under insured. So insurance, while it is one of the documented barriers to cardiac rehab, is really in this instance not a major barrier to cardiac rehab. It's a surmountable barrier in the cases that we see.

DR. GEORGE: Ellen, I didn't know if you had anything to add?

MS. HILLEGASS: I would just say that I agree with what Steve said and that insurance is definitely not a problem. I would say one of the problems is probably distance and location of the cardiac rehab. And so that is a limitation, but that's not in this problem right now.

DR. GEORGE: Any other comments on the gap and disparities? All right, we'll vote.

MS. LUONG: The voting starts now.

One is high. Two is moderate. Three is low. And four is insufficient. For performance gap, 17 voted high and 5 voted for moderate.

DR. CHO: Next is priority. To summarize George who was here yesterday, it's CAD, bypass, PCI, acute MI, cardiac vas. surgery, cardiac transplant, so a very high priority in terms of prevalence and the type of patients that we want to serve using these quality metrics.

DR. GEORGE: Any discussion on the priority?

DR. KOTTKE: I would only add that also change in outcomes is large.

MS. TIGHE: George, thank you for quoting me. He feels honored.

(Laughter.)

DR. GEORGE: If not, we'll vote on the priority.

MS. LUONG: Voting starts now. One is high. Two is moderate. Three is low. And four is insufficient. For priority, 20

voted high and 2 for moderate.

DR. CHO: It's not a composite measure. Yay.

(Laughter.)

So the next comes scientific acceptability. So the measure is -- the numerator of the measure is people who have had MI, unstable angina, we'll talk about some of these components which are a little bit problematic. People who have had bypass, PCI, valve surgery, cardiac transplant, who is referred to cardiac rehab. And the denominator is the -- all of these people.

My three big issues with this besides going through the exclusion criteria, my big three issues is that number one, predominantly this was based on the ACC PCI database as well as Get With The Guidelines database and not with the STS and not with the surgical database. So there is a component of the patient population that is missing. And the small amount of patients with 234 patients

in the ACC/AHA, APCVVR database -- something like that -- probably included the valve surgery and the transplant and what not, but the majority of this data comes to us from a PCI database. That's my number one problem.

Number two problem, is that chronic stable angina is very difficult to get at regardless of which database you use. That's my other sort of big problem. And I think that in terms of the -- how the PCI and the bypass patients or patients with MI, I think the scientific acceptability is quite high because those are easy patients to get. It's the other patients that are a little bit problematic.

MR. LICHTMAN: We actually broke down the data a little bit and looked at that and we saw that we did have significant amounts of PCI in MI patients, but we also had a representative sample of coronary artery bypass graft patients. I think this is somewhat reflecting the national trend where

we're seeing less bypass patients and more PCI patients overall.

I agree, very difficult to get the stable angina patients. That's a very small number of our database. But I think we do have a fairly good representative sample of the CABG patients. Heart transplants are very low because they're very low nationally, so I don't think we could get any more of those.

I really think we have a good, overall view of this with the exception perhaps of the stable angina patients.

DR. CHO: And they're outpatients?

MR. LICHTMAN: They're also less represented, I think, overall in the inpatient setting. You don't see them as often in the inpatient setting.

DR. KOTTKE: Why would you admit somebody with stable angina unless they're having like a hip transplant?

DR. CHO: What about valves?

MR. LICHTMAN: We have far less

valve surgery patients, but still some, far less in this database. I think just because of the nature of the reporting of that. But overall, when you look at the reliability overall, I think it's very good and rates very highly.

DR. CHO: It's a reliability based on the majority of your data is based on the ACC/PCI database and Get With The Guidelines. That's where the majority of your data comes from. So actually there are a huge number of patients actually that do not fall into the ACC/PCI database, nor the Get With The Guidelines database that go for valve surgery and whatnot, you don't get those patients.

MR. LICHTMAN: I think valve is probably the one that's lacking. I don't want to jump ahead to another measure, but stable angina would fall more into another measure than this measure. We really don't see those coming from the inpatient setting. I agree we need more valve.

DR. CHO: In the ideal world, the way this data would be captured is through electronic medical record, maybe CMS or whatever, but the way this is currently stated in the measure is basically to get it at it from the ACC/PCI database and Get With The Guidelines database. Thus, eliminating other set of patient population that would benefit from cardiac rehab as well, but that don't get captured into those two databases.

MR. LICHTMAN: Yes, on the other hand, if you extrapolate from what we have, I don't see a rationale for coming up with a theory that would say valve patients, the reliability for those patients in terms of the measure would be any different from anybody else.

DR. CHO: It's not the reliability. That's what I'm asking. I think reliability is clear for your PCI and your bypass patients. That's clear. I guess my concern is is that who said the unknown

unknown yesterday? Who was it that said it? Anyway -- was it George again? It's the unknown unknown that you don't know how many valve patients that you're missing because the database that you're extrapolating your -- that is being reported to the measure -- to NQF, is using only the two -- two of those databases.

MR. LICHTMAN: All I can comment on is that we're not without them and I really don't see a rationale. I understand the data is on all the patients that you would want, but looking at the reliability of the measure within specific patient populations should be similar.

DR. GEORGE: Ellen and then Liz.

MS. HILLEGASS: The point I wanted to bring is on the phone we discussed this and we also talked about the fact that just because they're given the referral and even though you quote here referral is defined as an official communication between the

healthcare provider and the patient to recommend and carry out a referral order to an early outpatient cardiac rehab program, many of the patients may have their procedures for their admissions in a tertiary center and go home to their private physician and then that physician may not refer them. They may have gotten their referral at the other place, but their primary physician may not refer them. So we're not picking up -- your data hasn't picked up losses in that data.

And I think that's a problem and maybe Kristi can address this as a patient. Patients are more likely to follow a referral from their private physician versus the tertiary center, but the tertiary center may actually give the referral, so you could check that off, they've been referred. And so -- but actually, they aren't by their primary physician, so they don't actually go to cardiac rehab.

And so how reliable is referral

when you're talking about one physician may refer them, but the private physician may not, so the patient wouldn't go. Does that make sense or did I get you all confused?

DR. KOTTKE: I believe that is covered with the next measure 0643 which is referral from an outpatient center.

MR. CHIU: If I can step in real quickly. I think it's a great point you bring up. There are missed opportunities in inpatient settings. So the thought is again not to jump to 0643, but you kind of have to discuss the others in some kind of paired way to the discussion.

I think we discussed yesterday and the pair would be -- I think our thought was the first opportunity, heart attack or CABG procedure you go in as an inpatient 0642. You would hope the doctor would send a referral. If they don't, then we would assume they would go to their private doctor or something in the suburbs or something else.

And 0643 then would actually capture that patient. If they're already referred, then that's captured. They don't have to do it again. They don't have to refer it again, but if they've not been referred there's an opportunity again to then refer.

If I can circle back to Dr. Cho's point real quick about STS. I think that's a really good point. I think that is a limitation because we're kind of -- we're kind of centric to ACC, Get With The Guidelines. I think that's a great point you're bringing up. If I'm correct, I can't speak for STS. I do think STS has this inpatient measure in the registry, so I can't speak to their numbers, but we could as an action item follow up with STS then to see for the valve surgery.

Now the other pieces we would have and they might have that other piece then to get at their liability, I think that's the point that you're trying to bring up. That would be that point.

MS. MITCHELL: Jensen, you stole my thunder. That's exactly what I was going to recommend.

MR. CHIU: I'm sorry about that.

MS. MITCHELL: I mean I'm almost positive that STS has that information in the database. And we know that the TAVR registry has it.

MR. CHIU: Right, right.

MS. MITCHELL: I would presume that it would be in there. So could you, as an action item, taking the calculation algorithm and applying it to a broader set of data.

MR. CHIU: We can take a look at that, yes.

DR. CHO: And Jensen, I just want to ask so I understand the piece of paper that the patient gets for referral, but how do you validate when if the hospital center referral to the cardiac rehab facility, how is that coded in the NCDR? We participate in the

NCDR. And I'm not sure how that circles back.

MR. CHIU: I think, unfortunately, I think the reliability is a little bit weaker. It's just a challenge in trying to connect the dots per se. There's a challenge I think kind of circling back. I think our old kind of 0642 is simply you're referred and there's like no questions asked. That's not really valid. The doctor says well, is the referring site ready to get the paperwork and all that?

Now getting to that next part, we've actually built that into all their data dictionaries about jumping to 0643, the PINNACLE outpatient and action and the path PCI. In terms of auditing that, I do admit that is a weaker element. This is the communication piece. I mean we realize going into this that we constantly get dinged in that. We would rather have not had our original measure. You just simply refer then it's higher rates, but that's kind of

meaningless, because --

DR. CHO: Now that, you know, like Get With The Guidelines has shown us that initially when we started it was 56 percent referral and now you are at 75. Has the enrollment also increased? Is there data for that?

MR. CHIU: I don't believe we have data for that unfortunately. It's hard to -- I guess the point is we prefer to have enrollment.

DR. CHO: Yes, yes. And you know, one of the things I was actually last night I was trying to look through the Internet, Mr. Google, on whether the Get With The Guidelines increase in referral has translated into increase in enrollment and actually all I could find is pretty steady rehab enrollment rate across the country. And I think that would be another sort of interesting thing. ACC has this great amount of information and it would be great, I think to have that in the

measure to sort of validate.

MR. LICHTMAN: I completely agree. The ultimate goal is enrollment. But I don't think it belongs in this measure. I think that may be a separate measure in the future. If you have referral and enrollment in the same measure, there's going to be a lot of confusion on the point of contact, we believe. I agree 100 percent. That's the ultimate measure and we need to move on to that eventually.

MR. CHIU: Like a paired measure. I think what you were trying to bring up is you have one measure and you don't know if they're enrolled they would they even get a referral, so you're dinging the doctor because they never even got referred.

MR. LICHTMAN: Right.

MR. CHIU: That's to Dr. Cho's point, if we have a paired measure, then the doctor knows locus control, referral, enrollment for the payers and purchasers at

the site.

DR. AL-KHATIB: I am actually struggling with the construct of this performance measure for several reasons. The first concern I have is I see this as being somewhat far removed from the outcome that we're hoping to achieve and this is just a check box that somebody says yes, we referred and to me, perhaps coupling that at least, at a minimum I would like to see that being coupled by maybe counseling the patient about the value of rehab. I mean you could refer and you could check a box a say yes, we communicated to the patient the value of rehab, but I don't know that that really gets to core of what you're trying to achieve here because part of the thing and I was looking at the exclusions that you list here and

I completely agree with if the patient died, you can't refer them. But I also think that you really need to probably exclude patients who refuse to go to rehab

because how many times do we talk to the patient and some patients are not motivated to go. And this is not something that I should be penalized if the patient decides after you give them all the information that they need about the value of rehab and everything else, if they decide they don't want to go, it is a commitment, and the patient has to be sold.

MR. CHIU: Refusal exclusion to that point. When this measure was first submitted in the care coordination project, actually that steering committee actually thought patient refusal should not be a way to game the system. So we originally actually had the measure where patient refusal was an exclusion, that we actually just changed because that steering committee felt really strongly that patient refusal should actually not be "an excuse" of that --

We hear your point, so we actually switched our -- we can switch it again back to this -- a few votes on that. But the vote was

that patient refusal was -- it was out of the locus of control. That's, you know, we first argued, then we switched it back. So we figured -- still that's kind of a binding thing and we can switch it back. Care coordination at the time felt strongly that patient refusal, if you have patient refusal you should at very least still refer them. It's up to them if they want to enroll, basically.

DR. KOTTKE: I think that's the point that this is about referral and you can still refer the patient even though the patient says I'm not going.

MR. LICHTMAN: And also when you dig down and you look at why we're doing this, this is really behavior modification. This is to get increased referrals from physicians and if they see nationally eventually when if this measure is accepted, they're on the low end, hopefully that will drive them to do exactly what you're saying. To not only just say

okay, I referred my patient. My job as a physician is done. And we don't want that. We do want people to understand why they're going into cardiac rehab.

I'm not a physician. I an EdD, but I do the intakes for our cardiac rehab patients and when they do come in, I spend --they're there already. They've already committed to one visit. I spend at least 15 or 20 minutes going over the benefits of cardiac rehab. I don't think a physician would have the time to do that, but certainly a little bit of education goes a long way with this patient population.

DR. AL-KHATIB: I completely agree with you. It doesn't have to be done by the physician, but there are many members on the team that could potentially play that and I wonder if this is something that we could request in terms of modifying the performance measure to say referral and counseling.

DR. GEORGE: I'm going to take

them in the order I saw them. I think Ellen and then Liz and Judd.

MS. HILLEGASS: The one thing I did want the group to talk to, we also spoke about the exclusion criteria and particularly where it says the healthcare system factor the program is within 60 minutes. Personally, having run cardiac rehab, 60 minutes is a long time to drive two to three times a week. So I have trouble with that in the denominator. I'd like to know your data on that and your --

DR. CHO: So I read through their data and it comes to us via Canada, I think. Canada has the best data for that. And there is a sharp decline after the 60 minute cutoff to their credit. And I agree with you, practically, because truly the number of patients that were enrolled who live 60 minutes away was like in single digits. But just the way murky statistics worked out, 60 minutes was the cutoff. But I think traditionally, 30 minutes has been used in the

past. And I think that for all intents and purposes I think 30 minutes for patients, especially elderly patients and what not, I think that's a reasonable thing.

I think that just to talk about patient refusal, it's like smoking cessation. We give smoking cessation counseling and they refuse, but we still have to do it. So it's like that.

MS. DeLONG: I am now totally confused. I would have expected absolutely no discussion on this measure because it is exactly one of the measures that was incorporated in what was called defect free care and that generated no discussion.

DR. CHO: Well, the defect free care, if you look at it, it just says referral to a cardiac rehab and it's only for AMI. It's only for patients with MI. Not if you had an elected PCI, not if you had an elected bypass surgery. You know what I mean? Not if you had elected valve surgery. So that is a

small --

MS. DeLONG: That's a small population that is a subset of this.

DR. CHO: Correct.

MS. DeLONG: The issues that are coming up are related to referral versus actually enrolling.

DR. HOLLANDER: I am with Sana and others on the counseling component, not just the referral component because we're in the world of electronic medical records. So what's the first thing that's going to happen? Everybody goes home with a diagnosis of AMI. It's just going to be an automatic pop up that says cardiac rehab. We already have them in the ER. If the nurses check smoking box, it says stop smoking. It meets the criteria. It does nothing. There is really good evidence no one reads their discharge instructions or has any idea what's in them.

So I think the measure where in the EMR world it is so easy to game this as a

single thing. It's really important that there be documentation within the record of counseling or I think we're not accomplishing the really important goals.

MR. LICHTMAN: I agree with that 100 percent. As a small part of that, just to address a small part of that, as opposed to just yes, giving the prescription and checking off that they've been referred, I think it's key for the committee to remember there's also communication involved. And when communication goes to a cardiac rehab center and for those of us who's run them, I think you know this, every patient is a jewel and when you get documented records from an acute care facility that that patient not only has the prescription, but you have their information, the contact then is going to come from the cardiac rehab center. That happens automatically, I can tell you. We call our patients automatically once we have the referral. In our world, that's a given.

DR. KOTTKE: I'd like to ask Judd a philosophical question whether it's tougher to check two boxes than one box. Referred and counseled. I mean is it any tougher to check the counseled box than the referred box?

DR. HOLLANDER: I guess it's a rhetorical question, but the answer is what documentation needs to be there? So if it just says I have counseled the patient, no. If it actually talks about the discussion, then it has some elements that need to be included, then maybe yes. But I'm actually happy with his answer that there's communication going forward in this seminal reach out. I think that's a great closed loop.

MS. MITCHELL: I have a question about this measure and the care coordination measurement set. Is this measure in it? Was it in there? Is it out?

DR. WINKLER: It's in the NQF portfolio, so it really depends on the

opportunities of various NQF projects, how things came through. I think care coordination was the opportunity at the time they were ready to submit it. But as things get sorted through it was more appropriate to say the cardiovascular.

DR. GEORGE: Are we ready to consider reliability? We'll go ahead and vote on reliability.

MS. LUONG: The timer starts now. One for high, two for moderate, three for low, and four for insufficient.

For reliability, 16 voted for moderate; four for low; and two for insufficient.

DR. CHO: Next is the validity and I think we've touched upon the validity, feasibility, and the usability. But the validity, I think because it does not have STS and because it only uses the two databases that are primarily focused on coronary revascularization, I think the validity is

moderate.

DR. GEORGE: Any further comments on validity? All right, we'll go ahead and vote on validity -- oh, Linda.

MS. BRIGGS: I guess I have a concern about the communication piece between the provider and the rehab and exactly how we have some concrete measure of that. Yes, you could make a new check box or whatever, but how are we capturing that necessarily? How reliable is that? How valid is that?

DR. CHO: Jensen, I think, spoke to that point earlier when he said that the PINNACLE registry will include that as a feedback loop and they don't have the data currently because it's something that they're going to start.

And I think that that is critical, clearly. Because I think that's what -- it will be wonderful to see how this measure looks and what the performance improvement is, or what not in a year or two from now.

You know, Reva, can I ask just a hypothetical question? Do you guys routinely, like for measures like this, where there is continuing sort of moving gap and not something simple like aspirin in the ER, do you guys have or does the committee know what the performance is each year?

DR. WINKLER: That is the purpose of asking the question under 1B, opportunity for improvement is we are really looking for data for use of the measure also, alternatively, under whatever section for meaningful differences. So the information we get is from the developer.

DR. CHO: What about -- so let's say we approve a measure, like this measure for instance. And it comes up for review in three years or whenever. But between that time, between when we approve to three years, do we have any --

DR. WINKLER: Not at this point because we're essentially evaluating it for

endorsement. Clearly, one of the most important pieces of information developers can provide to us is how the measure is being used, how it's working, what's the impact, you know. Is it doing what you expect it to do? But we do completely rely on the developer for providing that information to us. It's not something NQF tracks independently.

MR. LICHTMAN: We would clearly keep track of that. That's what we do as a committee. I mean we're constantly updating our databases, looking where it's included and new databases, so that's something that's an on-going continuous process of our committee.

DR. GEORGE: We'll go to a vote on validity.

MS. LUONG: Timer starts now. One for high; two for moderate; three for low; and four for insufficient.

For validity, 16 voted moderate and six voted for low.

DR. CHO: Next is feasibility. I

think it's very feasible also for -- we need to add the STS database component to it. It's a hospital-based system, it's a hospital-based metric, not at the clinician or at the delivery system level, but I think it's very feasible.

DR. GEORGE: Any comments on feasibility? All right. We'll go to a vote on feasibility.

MS. LUONG: Voting starts now. One for high; two for moderate; three for low; and four for insufficient.

Can everyone just point at me again? Seven voted for high; 14 for moderate; and one for low.

DR. CHO: Usability, the accountability, and the improvement and also public reporting, I think it's very usable data. I think that again, the action item, notwithstanding, it's a very usable data.

DR. GEORGE: Any comments on usability?

Henry?

DR. TING: Mary, I just have one comment with regard to what Judd and Linda, I think, have said. It's actually beyond counseling. If you think about all these things about referral, or writing a prescription, it actually goes beyond counseling. It's really moving into the world of shared decision making. None of these interventions that we're talking about will make a patient live forever. And if they don't do it, they'll die. It's not a 1-0 phenomena. It's all sort of relative benefit, relative risk.

At the end of the day, all we can do is discuss with the patients the benefits and risks and have them make a choice. So actually I think what Sana had said, the patient refusal or decline to do this because they don't see the benefit worth whatever it is, the hassle, the risk, and everything else, it's actually within the realm of the patient

choice to say I want to do this because it is something I want to do and it's a choice I want to make or it's something I don't want to do. But we don't have a measure that I've seen yet that involves measuring shared decision making or that it occurred beyond informed consent.

I don't think patient refusal or patient choice is a gaming thing. So just as to usability.

DR. VIDOVICH: I would agree, it's similar to contraindication for statin or contraindication for ACE. That doesn't count, that does count. So I think refusal should be entered.

DR. HOLLANDER: I'd add to that we're taking all of this as dichotomous and there's no reason it can't be got it, refused it, didn't get it and be reported. And if an institution reports an 80 percent refusal rate, well, then there's either a problem with communication or they're lying. And so maybe

the third thing is to peel out refusals because if you're going someplace and no one is listening to the recommendation, I would think consumers want to know that. Either they don't trust the doctors or the doctors are lying.

DR. GEORGE: I was going to say you know another alternative is to record the counseling and we talked about that earlier. We see this all the time in stroke education. Give the education but -- and we've talked about it in smoking as well. But we give it.

MR. LICHTMAN: The reason I am smiling is this is the discussion we had for years as a committee and as Jensen said we have ourselves gone back and forth. So I don't think there's a clear-cut answer here. Either way, we still need to increase referrals. That's how we looked at it as a committee.

DR. GEORGE: All right, we'll vote on usability.

MS. LUONG: Timer starts now. One for high; two for moderate; three for low; and four for insufficient information.

The responses are three for high, 15 for moderate, and three for low.

DR. GEORGE: So any last comments before we move on to an up or down vote? A good discussion already. All right, we'll vote.

MS. LUONG: The timer starts now. One for yes and two for no for endorsement.

Twenty voted yes for endorsement, two for no.

DR. GEORGE: So at this point, we'll be moving on to the sister measure.

DR. KOTTKE: So 0643 is the outpatient measure and it reads percentage of patients evaluated in outpatient setting who in the previous 12 months have experienced an acute myocardial infarction or chronic stable angina or who have undergone cardiac surgery, PTCA, valve surgery, transplantation and who

have not already participated in an early outpatient cardiac rehab program for the qualifying event. And who are referred to an outpatient cardiac rehab intervention program.

And so it's exactly the same as the prior measure, except for it's from the outpatient setting for people who have not -- who have had an event but have not participated. I don't know that we want to revisit exactly the same discussion. I see a no shake over there.

DR. WINKLER: I think there might be some of these criteria that are somewhat different because of the outpatient you may want to talk about. So let's just go through them. But there's some that are identical.

MR. LICHTMAN: Just one quick general statement. The way we looked at these is twofold on why we wanted an outpatient separate measure, but a complementary measure. One is as was stated around the table, people are going to fall through the cracks in the

inpatient setting and we want to make sure everybody gets a referral.

But also, it's a slightly different patient mix as I pointed out earlier. We're going to pick up the chronic stable angina patients who you're not going to pick up from an inpatient setting.

Also, in the future, I would anticipate that my committee, our committee, is going to include heart failure patients because on February 28th, CMS approved heart failure for reimbursement. So I feel the third-party payers are going to fall into step. And they put in an interesting proviso on that, that the patient could not have been hospitalized for the last six weeks, which is not what we wanted in their approval, but you know, that's what they said. So there are going to be heart failure patients who are not hospitalized who are going to be picked up in the outpatient setting. That's all.

DR. KOTTKE: The way this reads is

that somebody with chronic stable angina would need to be referred once a year for cardiac rehab. Is that's what it's intended to read?

MR. LICHTMAN: This says once a year?

DR. KOTTKE: No, it says percentage of patients evaluated in an outpatient setting who in the previous 12 months have experienced chronic stable angina or -- not and -- or who have had a procedure.

MR. LICHTMAN: Correct.

DR. KOTTKE: So basically, that says to me that what you're saying is they have chronic stable angina. They haven't participated in cardiac rehab in the prior 12 months and need to be referred.

MR. LICHTMAN: Chronic stable angina traditionally are referred if it worsens. So I don't think that was our intent to have them come in every year. That would be something that we would not encourage in the cardiac rehab world, even though they

would benefit from it. We know that, but insurance coverage-wise and event coverage-wise, generally physicians are referring when they worsen.

DR. THOMAS: This is Randy Thomas. If I could just state quickly, I agree with what Steve said. For an episode of stable angina, I guess you could say, that's what would be considered an indication for referral. If they've had an episode of stable angina or a worsening of previously more stable angina, then they'd be eligible for an amount of rehabilitation. But that was the intent, like Steve said.

DR. KOTTKE: So I think the evidence is the same, basically the same as --

DR. TING: I would ask you a question about that because a lot of patients have chronic stable angina and are on medical therapy. So to require referral to cardiac rehabilitation every 12 months for those groups of patients, which is what the

denominator states right now. So it's just a numerator statement as you may, Tom. I think that evidence doesn't exist at 12 months versus 11 or 13 months makes any difference at all for referral to cardiac rehabilitation and the denominator.

You would refer someone at 13 months, but you don't need to refer them at 11 months. I don't think there's evidence.

DR. KOTTKE: I guess my objection is to the use of the word chronic stable angina. Is it progressive angina or I don't think you want to say unstable because that implies you're going to hospitalize them, but with that little diddle with the terminology there, I would -- I think the evidence is moderate.

DR. GEORGE: Any other concerns or discussion on that? All right, we'll vote on the evidence.

MS. LUONG: The timer starts now for evidence. One is high; two is moderate;

three is low; four is insufficient evidence with exception; and five is insufficient evidence.

Can everyone just point to me one more time? Thank you. For evidence, one voted for high; 15 for moderate; four for low; and two for insufficient evidence.

DR. KOTTKE: Performance gap, I won't go through the numbers. It's the same. It's a huge performance gap.

DR. GEORGE: Any discussion on the gap? All right, we'll vote on the performance gap.

MS. LUONG: The timer starts now. One is high; three is moderate; three is low; four is insufficient. For performance gap, 19 voted for high; one for moderate; one for low; and one for insufficient.

DR. KOTTKE: Priority, this is on par with -- the impact of cardiac rehabilitation is on par with other procedures and things we do for our patients with heart

disease. So I would say it's high priority.

DR. GEORGE: Any discussion? All right, we'll vote on priority.

MS. LUONG: The timer starts now. One for high; two for moderate; three for low; and four for insufficient. For high priority, 16 voted high; four for moderate; one for low; and one for insufficient.

DR. KOTTKE: For scientific acceptability specifications and reliability, it's exactly like Leslie said. There are some gaps in what they assessed, but with the exception of my objection about the implication that you need to refer chronic stable angina once a year, I think the reliability is moderate.

MS. TIGHE: And just to confirm, that is a change that you're willing to make to the measure to clarify his points about the chronic stable angina that's the change you'd make to the measure.

MR. LICHTMAN: Not only did Dr.

Kottke point that out, but it's something we've missed in seven years in the wording. I think it's just the wording issue and it's not our intent and we will change that. We will clarify that. Thank you for the opportunity.

DR. KOTTKE: So I would say that reliability is moderate.

MS. MITCHELL: So in looking at the scientific acceptability that was actually submitted, it talks about using or the metric calculation was using the PINNACLE registry and it's not clear to me how many sites this represents. And so I think this is different. We're talking about a totally different set of data used to derive measures. I kind of just want to take a moment and just talk a bit more concretely about use of PINNACLE. Just more information about it.

MR. CHIU: I see what you're saying, great. When this was submitted, it was roughly about 150 practices. I think

about 1500 of providers for the PINNACLE side of this measure was being reviewed. We would assume, of course, a description, Dr. Kottke was saying. We're hoping that people reviewed it so you're not coming once every year. That's an issue that we'll have to figure out.

We assume -- our intent was to have everybody come in once a year to be doing the chronic stable angina, but that might be kind of a shortfall there, but we have about 150 practices and I think currently about definitely 2000 to 2500 providers in the PINNACLE registry, so it's still growing. That was originally four or five years ago. You're aware, Kristi, very much so. And I think we have over 800 locations.

DR. CHO: So that was one of my biggest concerns about this measure, that it's different from the previous measure is that the PINNACLE Registry is a very small subset of the American cardiology practices out there. And many of these patients may go back

to their primary care doctor and not to their cardiologist and what not.

Of all those sort of issues, that's my biggest, overwhelming issue with this measure.

MR. CHIU: I agree. That is definitely a shortfall, I mean actions have much bigger market penetration. I think this measure, like the inpatient one, corollary, hypothetically can be used in other -- if there other registries that go live, we can't say that because ACC already has one and we're not going to create another one. But if AHA or others create one, this type of measure we would think would be pretty easy for them to implement and we can't speak for other groups, but this measure is created such that unlike the risk models with the proprietary calculations, simply you see the numerator and denominator, they can then apply it elsewhere and we'd be perfectly -- actually, others use this, unlike the risk models.

DR. CHO: The other thing, this came up in our group discussion is that my fear was and I know Tom disagrees, but if you get dinged twice, so let's say I have a patient, I did a drug-eluting stent. I refer them to cardiac rehab and they whatever, went to cardiac rehab, didn't go to cardiac rehab. They come back and see me in clinic and I didn't put in there that I refer them to cardiac rehab because I had already referred them to inpatient, do I get dinged?

So I refer them to cardiac rehab when they were inpatient. They come back and see me a month later as an outpatient.

MR. CHIU: You wouldn't get dinged.

DR. CHO: I would not get dinged.

MR. CHIU: You would not because you're already in an inpatient setting, it's the same patient.

DR. CHO: It's the same patient.

MR. CHIU: If it's an outpatient

you wouldn't get dinged.

DR. CHO: Okay.

MR. CHIU: So this would make more sense probably as a pair of inpatient outpatient, but we didn't do that because the registries were different so we couldn't capture them longitudinally as the same patient, but yeah, that's a good point.

DR. KOTTKE: That's not what the measure says. It says who have not already participated in an early -- so, in fact, you would get dinged, but the -- the reason -- it's not too tough to refer again and it's like with smoking, asking repeatedly, they may have changed their mind in a month and said yeah, I thought about it and I might as well, I guess I will go.

It's not like doing a second echo or -- and you kind of set up two scenarios there. One is you're the inpatient physician. You refer the patient. They go to cardiac rehab. You will not be dinged if you don't

ask them or refer them again. But when you read the measure, it really requires the physician to ask the simple question when you first see the patient, it requires the physician to say have you attended cardiac rehab? Because it's who have not already participated, not referred, but have not participated in an early outpatient cardiac rehab setting.

So it's really a measure designed to really not just increase referral, but enrollment because you're not asking them if they've been referred. You're asking them if they've participated which is really a key question. And then if they say no, that should lead to further discussion, just like the inpatient measure with the communication. This is communication that we're trying to encourage, behavior modification, we're trying to encourage from the outpatient physician and the patient.

So one scenario, you won't get

dinged. In the other if you refer them to cardiac rehab and they don't participate and then you don't ask them that simple question, you could get dinged for that one.

MS. HILLEGASS: I just wanted you to speak to also the AACVPR/ACCF/AHA/CR3 data. It appears there's only six sites, six outpatient centers that provided data?

MR. CHIU: I can speak to that briefly. So we did that project AACVPR/ACCF/AHA collaborative. There are actually 13 sites. That is correct. So we did actually pretty intense retrospective trans-extraction project, 13 sites both in and outpatient settings. I memorized all the names, but there's a lot of rural settings and large settings as well. We can send that document over, the findings of all that. But that was separate from the testing that we did from the registry itself.

So, as a ACCVPR/ACC/AHA collaborative, those groups weren't

necessarily, you know, were involved in ACC's work or ACPR's work. It was meant to test the reliability of the measure. Is this a reliable measure? Is it a feasible measure?

So, we polled 13 sites. It was pretty intensive, because we basically did the test-retest method, inter-rater reliability and intra-rater reliability with the site itself.

So, that was, I think, easily a nine-month endeavor. And we actually used that testing to move at the care coordination, this was a time-limited endorsed measure. We used that to basically become fully endorsed last year.

MR. LICHTMAN: Yeah, and there were six outpatient, seven inpatient. And we required the facility to do an enormous amount of work or asked them to do an enormous amount of work.

They had to pull 35 charts, there had to be a site supervisor, there had to be

two reviewers to look at intra and inter-rater reliability.

I thought it was a little longer than nine months, actually. I thought it lasted a year.

And this data is actually being published or been published. Excuse me. I keep forgetting it's been published. So, we conducted that like a research study.

And that's why the N on that was so small as opposed to the big, big registries, but that was really an intensive look at different types of reliability and validity that we well, we would have liked to have more, but it was such intensive work that we could only ask a limited number of dedicated sites who really, really wanted to help.

But the data was the outcomes were excellent. They were really high Kappa and percent agreement coefficients on that.

DR. TING: So, just two questions,

Jensen.

So, if we take chronic stable angina out, what are you going to replace it with?

And the second question is on reliability, how reliable is the PINNACLE registry able to detect patients who have had whatever you replace the words "chronic stable angina" with?

Like, someone who has worsening angina, do you have any reliability data about your ability to detect if someone has had worsening angina in the PINNACLE registry?

MR. LICHTMAN: Well, first of all, I don't want this committee to think we're taking angina out, which we're not. We're just going to clarify and redefine it.

In terms of frequency of enrollment, it's not the purpose of any cardiac rehab program to continually enroll any patient. We want to promote patients to the highest level of independence and a

healthy lifestyle, et cetera, et cetera, so that they don't have a reoccurrence.

Our goal with stable angina patients is to raise the anginal threshold, get them more functional, halt disease progress.

And if that's what we accomplish in our patients with angina, we're not going to see them again and we don't want to see them again.

So, we simply have to clarify what are the criteria for referral back into a cardiac rehab program, but everybody with stable chronic angina should come at least once because with the lifestyle modifications, the behavior modifications, the exercise modifications, there are tremendous benefits.

DR. TING: I understand that, but the current measure that's being presented and that we're discussing voting says, patients with chronic stable angina should be referred every 12 months.

And then the comment was made by you and Randy Thomas that only patients with worsening angina or change in anginal status will require referral in the last 12 months.

So, I'm asking for clarification as to what are you going to replace the words "chronic stable angina" with, because that's everybody with coronary artery disease on medical therapy and what's the reliability testing you have in the PINNACLE registry to detect that someone has a change from chronic stable angina?

DR. GEORGE: I think the clarification was that had had an in-episode and that the wording around the 12 months was to be cleared.

MR. LICHTMAN: I agree. The clarification is not around the diagnosis. The insurance companies actually delineate a very, very specific diagnosis. It's not just the patient coming in who complains of chest pain.

You have to have documentation as to a positive stress test supported either by a stress echo or a cath or a nuclear stress test to go along with symptomology.

So, I don't think we're going to change the definition of "chronic stable angina." I just think we need to clarify the frequency of attendance or referral rather referral to a cardiac rehab program.

And I right off the top of my head, I'm not sure.

DR. TING: Well, without clarifying that, I'm not sure that I personally can approve a measure that I'm not sure what I'm voting on, right, with chronic stable angina in there and requirement for referral every 12 months, which is what this measure says.

DR. KOTTKE: My interpretation, either new angina or progressive angina, I mean, I think that would be acceptable to me.

DR. TING: Can't vote on I need clarification about the measure.

DR. GEORGE: I think we have an option where we could ask the developers to go back and clarify this and then delay our vote on it.

Would that be acceptable?

DR. AL-KHATIB: Could I ask a question about feasibility? Because I would hate for them to put too much work into this if we're going to decide not to advance this measure.

Because I am concerned about the fact that this actually uses just PINNACLE and we and that's a major point that was raised here.

And I'm not sure, like, how are you going to overcome that big challenge, because very few practices participate in PINNACLE and, you know, beyond PINNACLE I don't know how this is feasible.

DR. KOTTKE: Well, I don't feasibility is about the measure, not about coverage of the population, right?

DR. AL-KHATIB: Well, no, in terms of feasibility of how practices are going to be able to report on this measure.

DR. KOTTKE: But if some practices can do it, I would assume that all practices

DR. AL-KHATIB: But if they only well, no, it's only the practices that participate in PINNACLE, is what they told us. I'm not sure what

DR. KOTTKE: How are they systematically different from other practices?

DR. AL-KHATIB: Well, because there's a way of an electronic way of capturing what they're doing in other like, unless we have EMR, which again we're very far from EMR at this point, that's the only other way you can capture that electronically.

DR. KOTTKE: Right, but you can capture it manually. So, if the American Academy of Family Physicians decided to do this, they could say you have to riffle your

charts, but this isn't about can we assess this in all patients in the United States with chronic stable angina.

It's about if an organization wants to use this as a measure, can they collect the data?

MR. CHIU: The CR3 initiative actually is your point. So, we agree completely with PINNACLE. That is the shortcoming is that this a lot of data is coming from PINNACLE, but the CR3 Initiative we can send a document around, a published document.

None of those sites use PINNACLE at all and they basically would say we would say, here is the measure, you tell us if we can come back, and then we show the scores that, you know, all the statistic inter-rater and intra-rater and show that we can get the measure both not just referral, but the communication piece and everything.

And those sites use both some of

them used EHR, but some of them did use paper. And not just big centers, but also rural centers as well, geographically across America.

So, we only picked 14, because it was very intensive. We wanted to pick more, I really wanted to pick more, but we basically gave, you know, a small kind of token of appreciation of 200, $300 for all the work they did for, I guess, over a year.

But your point, yeah, I mean, the testing we're showing right here a lot right now for this fold is PINNACLE, but this measure hypothetically could be used in other settings and we can send it around, the CR3 document as well.

DR. WINKLER: If others feel strongly that you really want to see the rewording clarification before you proceed, I think we've got a post-meeting conference call scheduled.

I forget the date exactly, but we

could bring it back and you all could look at the clarification and proceed with your evaluation.

DR. KOTTKE: If I can just jump in once more to make sure that the proposers understand my issue, and I think it's Henry's issue, too, is that the way it reads right now, it suggests than an individual with chronic stable angina has to be referred to cardiac rehab once a year.

And I would accept a new episode of angina or new angina or progressive angina, some of those words, but I it's about those three words, "chronic stable angina."

MR. LICHTMAN: I agree a hundred percent. It reads incorrectly.

DR. HOLLANDER: Can I make the proposal that we take a provisional vote based on the change that clarifies this issue? And that way, you know, we know what we're thinking about it now.

It's easier to me to run through

the process while it's clear in my head than start over in a couple weeks and try and remember the conversation.

And then, you know, by email they can just send us the new wording and we can say, that sounds good. And I just find that easier, personally, for me.

DR. TING: Judd, I'm sorry. I agree with that, but the issue here is going to be what is a change in angina and how are you going to reliably detect that in a registry or any EMR?

Is it a change from Class I to Class II angina? Is it a change from frequency? Duration?

There's a lot of nuances to this, and I'm not sure I can just sort of know what's going to be changed so we can vote yes or no. That's personally.

DR. KOTTKE: Ellen.

MS. HILLEGASS: I just want to say one thing in relation to what Sana talked

about getting the data.

If you look at the CR3 data that you collected and you just said you paid them 200 to $300 to even do this, how are we realistically going to get the data from people who are not on EMR?

You only collected it from six sites. And so, realistically how are we going to get that information if we're not paying people 200 to 300 to collect it and it is very cumbersome when you don't have an EMR?

DR. KOTTKE: Well, PINNACLE and others, they actually pay to participate. I mean, it's feasibility is about can you do it, not what you have to incent them to do or anything else.

In many of these registries, the groups actually pay to participate and not get paid themselves.

MR. LICHTMAN: Yeah. And the only reason there was a gift, I mean, if you worked it out, it was probably two cents an hour.

The only reason we felt we had to do that was because these were sites who were dedicating a lot of resources not just to doing the measure, but rather to doing intra-rater reliability, inter-rater reliability, retesting, percent agreement.

They to do this measure on any one individual patient takes moments. What they did took weeks and weeks and weeks of effort.

And that was just our idea of just giving them something back. That's all. That had nothing to do with the measure.

MS. HILLEGASS: But it's still six out of 45. Only six met the criteria of the 45 that you saw.

According to your data here, only six facilities met the criteria to collect the reliability.

MR. LICHTMAN: No, no, no, they didn't meet the criteria. These were the only six facilities willing to put a year's worth

of effort into something which at the time was not even envisioned as a publication, but rather just as a justification to this measure.

We contacted many, many facilities. We had other facilities that were eligible. We even had facilities overseas contact us.

But when we outlined exactly what we wanted to do, only six centers could put in the time, the effort and the personnel to testing this, not for the measure, but to test the measure. It was really tremendously labor-intensive for a center.

Had I not been on the Committee and been excluded because of that, my center couldn't have done it. We could not have put the personnel to do this testing over a year's time.

DR. KOTTKE: Henry, let me ask you if rather than chronic stable angina if it said "changing anginal symptoms," would that

be acceptable?

DR. TING: I just think that there are a lot of things that are acceptable, but what can be detected in a registry, an outpatient registry that a patient has had a modifiable, measurable, significant change in duration/frequency of angina that would justify a referral to cardiac rehabilitation every 12 months in an outpatient setting.

I mean, I think that's

DR. KOTTKE: Well, I think the word "change," I mean, if the word "change" is in the record, that's what I'd accept.

DR. WINKLER: Guys, I just caution you it's not our job to do this. It's theirs.

DR. TING: Okay.

DR. WINKLER: And so, that's the question is

DR. TING: I'm not trying to what's in front of me I can't vote on.

DR. WINKLER: Okay.

DR. GEORGE: Do we have any sort of

consensus?

Linda.

MS. BRIGGS: I would agree with Henry that we have to vote on what's in front of us. And we can recommend that it come back to us and we can look at the new definition of whatever we're going to put for stable angina, but I also want to make a comment about feasibility.

And feasibility is more than is it possible, period, to do this? Feasibility has to do with is this reasonable for people to do across all the facilities that we're talking about?

You have to yes, you can collect any amount of data anywhere, anytime. It's possible to do that, but is it something that most facilities can accomplish?

That is an important piece of feasibility and usability. So, I just want to caution to say you have to go beyond is it possible. You have to look at the amount of

time, effort, money spent, personnel involved.

And having done data collection for studies, I can tell you that each one of these elements, yes, it's in the paper chart, maybe it's in an electronic health record, but is it in a retrievable format so that you can actually get at it easily?

So, every time you add an element, you add an amount of time that somebody is looking for another piece of data.

If it's actually in a registry like the CathPCI Registry, that makes it much easier. If it's actually in PINNACLE, that's easier, but you only have a certain number of sites in PINNACLE.

And, you know, to say that this is going to be something that potentially could be used beyond PINNACLE means that if we decide on that word change, how do you search for that in a paper chart?

DR. GEORGE: Is there a code that would indicate

MS. BRIGGS: No.

DR. GEORGE: a change or nothing.

DR. KOTTKE: 200 years ago they didn't have sinks in operating rooms. I mean, you know, these the impact of cardiac rehab is on par with other things we do that

MS. BRIGGS: I don't disagree with that. I used to work in a cardiac rehab center. I'm very pro cardiac rehab.

I'm just talking about when you look at the practicality of the measurement and what you're asking people to do and record and be rated upon, pay-for-performance, et cetera, these things we're talking about have impact.

When you look at is there unintentional consequences, they do have unintentional consequences for certain people.

And I'm, like I said, I'm a proponent of cardiac rehab. That's not the issue.

MS. TIGHE: I'm going to jump in, actually. It sounds like you're raising some feasibility concerns that relate to the change that the developers are potentially considering making in the measure.

So, it sounds as though we're going to be unable to vote through the measure at this point.

Just in the interest of time, we do have one more measure we'd like to get to before lunch. If we could wrap this conversation up, I would ask you to vote on the measure in front of us knowing that the developers can use the time during the comment period to address these issues and potentially bring back new information for you to consider.

DR. HOLLANDER: Can I destroy your plea and say one thing first, because I think I have an easy fix.

An acceleration in symptoms from chronic stable angina is unstable angina. And

then if you look at everything else on this list, everything else on this list gets done in a hospital, okay.

You don't get any of this stuff done as an outpatient. And, in fact, if you have unstable angina, you get hospitalized.

So, I'm wondering if the wording, and this is a recommendation to you guys, can't be changed, who have been previously hospitalized in the prior 12 months for one of these things, and change the chronic stable angina to unstable angina, and then you're covered.

I know it can't be changed on the vote now no, no, no, I'm just saying as a recommendation for when they come back, it might clarify

MS. TIGHE: Yeah, and I think at this point they've heard many recommendations. They have a lot to consider.

So, I'm going to, again, insist that we cut this off and vote on the

reliability as the measure is specified now knowing that we can bring it back later.

MS. LUONG: So, voting starts now. One is high, two is moderate, three is low and four is insufficient.

Six voted moderate, 10 voted low and five voted insufficient.

DR. KOTTKE: Okay. Thank you very much. We'll move on to 2473, Hospital 30-day Risk-Standardized Acute Myocardial Infarction Mortality.

CMS is the steward. Discussant is Kristi.

DR. WINKLER: Do we have somebody from CMS on the line?

MS. KHAN: Yes, this is Rabia Khan.

DR. WINKLER: Okay. Hi, Rabia. Hold on. I guess we do have people in the room. Hello there. Hey, how are you?

DR. McNAMARA: Hi. Can you hear me? Yeah, I'm Bob McNamara from Yale. And Susannah Bernheim also from Yale. And Johan

from CMS is here.

So, the overall aim of this measure is to start to realize the potential of EHR data to build in these measures, the rich clinical data that's very difficult to obtain on the current setting and be able to put it into an outcome measure.

So, we're not going to go through the whole thing. There was already a publicly reported NQF-endorsed AMI mortality measure. So, I just want to highlight a few points that are novel to the EHR aspect of this.

First, is we developed this model de novo rather than just starting from the prior model and trying to retool that, the second we looked at this model in terms of the current clinical capabilities and the current EHR environment rather than putting undue burden on clinicians to add onto the measure or to be dependent upon EHR development.

Another thing that I definitely want to emphasize that came up on the call, we

used the action Get With the Guidelines clinical registry, the ARG that you've heard about multiple times, which is a clinical registry. It's not an EHR, but this is intended to be used for EHR.

So, we looked at this, the data elements within the ARG Registry for feasibility. We developed three specific criteria for the feasibility for each of the data elements to ensure that the elements will be able to be retained reliably across sites.

We wanted to stick with the 30-day outcome. So, we linked the data with the CMS. And we ended out with a very parsimonious model of five risk factors for risk adjustment that are very objective. Age; two vital signs, systolic blood pressure and heart rate; and two laboratory values, creatinine and troponin ratio, which is the troponin value on the first troponin obtained divided by the hospital upper limit of normal and came up with a very a model that performed very

well.

Had a C statistic of 0.78, which is well in line with previous mortality measures.

The measure performance using this model showed a variability across hospitals. At least the 280 hospitals within the ARG data set. And we would anticipate the variability even higher once you took that to a larger data set.

We eSpecified it which essentially is just translating from a human readable form to a machine readable form. And we had various levels of feasibility, reliability and validity testing, both traditional for the model, as well as in an EHR environment.

So, with that, we can open it up to any questions.

DR. KOTTKE: Kristi.

MS. MITCHELL: So, as we talked about this yesterday, this is our first eMeasure, if I'm not mistaken.

DR. WINKLER: It's the first outcome eMeasure.

MS. MITCHELL: The measure developers sufficiently stated the rationale supporting the relationship between AMI mortality and at least one healthcare action.

Specifically, developers showcased the link between AMI mortality and complex critical aspects of care such as communication between providers, patient safety and coordinated transitions to the outpatient environment.

I also thought that they provided contemporary which was very helpful for us, contemporary references to further demonstrate the relationship between hospital organizational factors and performance on the MI mortality measure.

And as such using the Algorithm 1, I would submit that this outcome measure passes the evidence criteria.

Any discussion?

DR. KOTTKE: Elizabeth?

MS. DeLONG: Nothing.

DR. KOTTKE: Any other discussion on Linda, on we're ready for the vote.

MS. LUONG: Voting starts now. One for yes. Two for no.

(Voting.)

(Pause in the proceedings.)

MS. LUONG: Can everyone just point to me again? Thank you.

(Pause in the proceedings.)

MS. LUONG: 19 voted yes. One voted no.

MS. MITCHELL: Okay. Moving on to performance gap. The measure developer provided data reflecting performance measurement scores calculated from a cohort MI discharges for patients age 65 and older from January 1 through December 31st, 2009.

They merged that data set with data from Medicare Part A claims data and it resulted in 20,000 admissions from 280

participating hospitals.

The risk-standardized mortality rate derived from this registry data ranged from 9.6 percent to 13.1 percent with a mean of 10.8 percent.

The developer provided other rationale including doing a claims-based MI mortality using publicly reported CMS data for the same time period.

And then they also identified additional studies in the literature that further demonstrate the ability of hospitals to implement strategies to achieve low risk-standardized 30 day mortality rates. And so with that, I think that it's high performance gap.

As it relates to disparities, the developer investigates well, actually did do an analysis looking at race and SES and demonstrates that there was little influence of these factors on the risk-standardized mortality.

DR. KOTTKE: Further discussion?

No further discussion. Let's vote.

MS. LUONG: The timer starts now. One for high, two for moderate, three for low and four for insufficient.

(Voting.)

(Pause in the proceedings.)

MS. LUONG: For performance gap, 16 voted high, three voted moderate, one for low and one for insufficient.

DR. KOTTKE: Priority.

MS. MITCHELL: For the reasons discussed at length yesterday and I guess we can also call upon George thank you very much AMI mortality is high priority in terms of prevalence, severity and cost.

The measure developer provided an extensive list of citations in case you were concerned that there wasn't such priority, to demonstrate that this measure addresses a high-priority need within healthcare.

DR. KOTTKE: Liz, nada?

Any other discussion? Seeing no action, we're ready to vote.

MS. LUONG: Timing starts now. One for high, two for moderate, three for low and four for insufficient.

(Voting.)

(Pause in the proceedings.)

MS. LUONG: For high priority, 19 voted high. Two voted for moderate.

DR. KOTTKE: Acceptability science and reliability.

MS. MITCHELL: Great. So, Bob provided a wonderful overview of the measure in terms of its scientific acceptability.

I would like to ask Reva just to kind of step in for a second around the eMeasure technical review, because I am actually not familiar with that process.

DR. WINKLER: And it's a wonderful thing to see my colleague. Chris is here as our sort of our in-house expert on HIT and

the eMeasure. So, I'm going to let Chris Millet answer that one for you, Kristi.

MR. MILLET: Sure. I can provide us a little overview for the kinds of things we look for when we do this eMeasure technical review.

As the gentleman from Yale mentioned, what's kind of unique about eMeasures for the EHR environment is that they're actually specified to be human readable and machine readable.

So, we wanted to be to consider electronic data sources, but we also want electronic systems to be able to do to interpret the measure so that we can calculate it and get to where it's an automated way of reporting the measure.

So, there are specific things we look for to aid with that. Some of them are technical standards that are used within the format with the measure specification itself.

So, we look at that which was for

this measure it uses acceptable standards that are out there from HL7.

We look for the codes used in the measure. So, we want to make sure that they are vetted to some degree.

And the National Library of Medicine provides pretty robust vetting of codes used in measures. And all measures need their codes to be vetted to some degree, but in eMeasures it's even more important.

So, you know, we talked to the measure developers and they have worked with the National Library of Medicine to utilize some of the resources they have to evaluate the codes that they use and that it follows current best practices and how a code should be used in eMeasure specifications.

Feasibility is really important. I mean, there was a pretty good discussion on feasibility just in the last measure.

So, a lot of these issues impact feasibility. So, we wanted to make sure we

take a really conscious look at feasibility especially for eMeasures.

And, you know, this measure was the feasibility assessment for this measure came before some of the work NQF has done on, you know, kind of relooking at feasibility and how that applies to eMeasures.

But a lot of what the measure developer did in this measure's feasibility assessment, which I guess we'll get into more later when we talk about feasibility, but a lot of that follows a lot of the findings and the things you recommend in our own feasibility assessment.

So, that's kind of an overview for what we look for and what we found.

MS. MITCHELL: The TEP provided a favorable review of this eMeasure as currently drafted?

MR. MILLET: I'm sorry, can you

MS. MITCHELL: The eMeasure Technical Review Panel.

MR. MILLET: So, there's not an eMeasure review panel. We kind of do like a staff technical review, which I have done we worked with the measure developer on any questions that come up during that review. And we were able to talk through any issues there. And we didn't find any issues.

MS. MITCHELL: Okay. I'm going to move on if you don't have any more questions about eMeasures, but I have some more about the specs themselves.

So, what we heard was that this is again an outcomes measure, 30-day all-cause mortality.

Mortality was defined as death from any cause from 30 days of the index admission.

The developer noted that ascertaining mortality would occur by linking to an external data source such as Medicare enrollment database, the National Death Index.

The denominator statement included

inpatient admissions from patients 65 and older who were discharged from short-term acute hospital with a principal diagnosis of AMI. They went through the exclusion criteria.

As it relates to actual specifications, the codes were provided to identify AMI discharge, date of birth and so on and so forth.

What I felt was important was that they also took note that ICD-10 is coming around the corner. And so, they took the necessary means to provide the crosswalk between these measure specifications.

Since this measure is risk-adjusted, the measure developer took the time to describe how the RSMR would be calculated. And this is really, I think, the part that's going to require some discussion.

I know that we talked about in terms of the spirit of parsimony we get down to five different elements, but various other

models that I've seen use, you know, upwards 13 elements to adequately risk adjust for this patient population.

And so, I think that there is room for sort of the discussion in and around how 13 elements or eight or whatever were culled down to five and was it really sort of a reaction to what you can collect in the EMR.

And I'll pause and see if anyone else wants to add something.

DR. KOTTKE: Liz.

MS. DeLONG: That was going to be my main point as well. I would like to know how if you were to apply this model to the same data that different models have been applied to, how would they agree?

I think the harmonization with other more elaborate models should be shown.

DR. BERNHEIM: Hi. This is Susannah. So, a couple of things to that point.

First, just conceptually why be

parsimonious? I think it's obvious, but I want to be really clear.

We didn't know what we would find doing this work, but our first pass was that to get eMeasures out the door, you have to have pretty strict criteria for anything you put in them.

We wanted to be sure that any variable that was in this model, we had a lot of confidence would be defined the same across hospitals, would be in structured fields, would be extractable and that any EHR should feasibly do that.

I mean, when you look at the variables that are in the risk models just by face validity of this group, you can say, you know, I'm pretty confident that systolic blood pressure and heart rate and troponin and creatinine and age are going to be reliably consistently found and we did a bunch of other testing to be sure that they're feasibly extracted from the EHRs.

We then we originally judged the variables and considered a wider set. Things like history of heart failure.

And unfortunately right now when you talk to experts in the field and you look in the EHRs, you can't reliably pull history of heart failure out of an EHR and have confidence in it across all spaces.

So, we had to say if we stick with our original goal, which is to find something that could go out the door, can we do it? Can we build a good model with what is less than other people have?

And here's what sort of made us feel confident in what we found. The first is that the discriminative ability is quite good. It's better than some clinical models that have more variables. So, that made us that took a first step towards making us confident this was going to be useful.

The next thing we did was we have a claims-based model that's been NQF endorsed,

that's been in use for a long time that's showing improvement, continues to show variation, has scientific acceptability and we said, does this tell us something really different about hospitals?

This isn't classic validity testing, but it was very reassuring to us that the performance of hospitals when you match the same when you look at the same group of patients and the same outcome and you use our new EHR-based model and the familiar claims-based model, we find very similar results for hospitals. So, that was reassuring to us.

And then finally, the one advantage of using a data source that was broader than what you could find in the EHR, was that we could test the importance of some variables that people thought were critical.

And so, the final thing we did was we said, let's choose something that the clinicians feel like is really going to make

a big difference that we don't think we can yet get out of an EHR, and ask whether or not it adds so much to this model that the current model isn't viable.

And so, we looked at EKG findings, which I hope we're not too far from being able to pull that out from EHR, but we can't do right now. And we put those in and looked at how much it improved the model, and the answer was not very much.

So, the sum of those three things made us confident in this parsimonious model. Confident enough to bring it forward to all of you, but that was the approach we took to answer those questions.

DR. KOTTKE: Judd.

DR. HOLLANDER: So, I want to sort of hit the problems with troponin, which from a 10,000 foot view seem really obvious. It's just a number and there is an upper limit of normal for your reference lab.

But the IFCC task force says you

should use the 99th percentile and half the labs in the country are using the 95th percentile, which means in some labs their upper limit of normal is falsely elevated.

By the end of the year, there will be more high-sensitivity troponins on the market, which means 50 percent of people by definition will have a measurable troponin.

And using the let's just say the upper limit of my assay right now is 0.04, which it is at Penn, but the 99th percentile of that assay is 0.026. That dramatically changes the ratio.

As we get to high-sensitivity troponins and that drills down to 0.006 as the upper limit of normal, that 0.04 is astronomically elevated.

And in this model as best I can tell, you don't adjust for the assays or standardize what the 99th percentile value for that assay should be. You leave it to a local determination.

So, I think, you know, something that seems incredibly standardized which probably accounts for a large proportion of your model, isn't. And it's going to get more disparate and less reliable over the next year.

And since the ratio of, you know, troponin value to your upper limit probably drives the model, it's one of the things most related to outcomes and acute MI, I see that as being a real problem getting worse over the next year.

So, I agree you can get it easily, but I think you need to know what it is you're getting besides the two numbers.

DR. McNAMARA: Sure. I think that's a great point. And that's one of the reasons that there are as you alluded to, there are many different assays for troponin.

And that's why the troponin ratio is used. Because if you just use a regular troponin value, some troponin I, some troponin

T, high sensitivity, low sensitivity. So, it should be normalized to what your upper limit of normal is.

And as with any, you know, performance measure of deciding, a hospital, yes, can say, oh, our upper limit of normal is something different and can change it, but there should be an upper limit of normal for that assay that they use and that should be standardized.

Whether a hospital uses that standard or not I guess is something that can be assessed in implementation.

But, and as you said, as things change, right, I mean, troponin level changes over or the troponin assays have changed over the last five or ten years and they're probably going to change over the next five or ten years that this ability to normalize it or index it, I think, is very important.

And as far as its value, yes, I'm a cardiologist. The troponin is incredibly

valuable, but it actually was not as valuable as some of the other ones. It was only five.

So, it is important. Each one of the elements are important. So, it's of value, but maybe saying that it's driving the model is overemphasis.

DR. KOTTKE: Sana, and then Tom and then Liz.

DR. AL-KHATIB: So, I appreciate the challenges that you face when you're trying to create an electronically-based performance measure. Because as was pointed out, we have different EHR systems and a lot of the data elements have not been standardized, if you will, across those systems.

But it seems like you use that probably somewhat to your detriment, because you ended up, you know, focusing this model that you're proposing here to things that you felt would be pretty reliable in terms of how standard they are across the different

systems, but excluded several of the other clinical factors that have been proven time and again to be associated with mortality in this patient population.

You know, one very well-vetted and validated model is the one that came, for example, from the GUSTO trial that Kerry Lee actually was the first author on hard to push against that importance of those clinical data.

I also would, you know, would echo what Judd said with regard to some of the accuracy of these factors that you're including in the model. And I would actually even make it simpler than the troponin, heart rate and blood pressure.

I mean, who is measuring those? Are they accurate? What numbers are you looking at? The patient may present in atrial fibrillation and you may have a nurse who's checking the heart rate, you know, using the radial pulse and that's invariably not an

accurate measure unless you go like precordially over one minute in people with atrial fibrillation, which is a common rhythm in these patients.

So, I really would question even the accuracy of the data that you are getting when you are looking at simple things like vital signs.

DR. BERNHEIM: So, these are great and important questions and I'm going to let Bob weigh in as well, but, you know, we face this every time we build an outcome measure.

No data source is perfect, right? I mean, there's no questions that things aren't in. And when we look deeply at the registry data which we've worked with, we find inaccuracies there, too.

So, there's no question this is not a perfect measure. We do think the variables here are about as good as you'll get in a measure in terms of being accurate.

One clarification I think is

important is that throughout these measures it's very important that we're assessing the patient status on arrival, that we don't want to look three days later because the patient who is in atrial fibrillation, it's a very different status and a very different question. So, we do specify that it's the first recorded value.

And that was one of the things we did feasibility testing on was to ensure that hospitals were able to not only identify those first variable, but identify the first on presentation.

And as to sort of there being other good models out there, it's true. I mean, there are also other published models that are quite close to this in terms of being parsimonious and have been found to be successful.

So, there will be important variables on a patient level and important models that exist, but our test was to see how

good a model we could. And we found one that works as well as those models not to disregard, you know, important literature and trials that have shown other variables.

I mean, one thing I will say that we find consistently as we develop outcomes measures is that there is a difference between what it takes to have a good model predicting an individual patient's outcome, in which case we sometimes need more information, than to assess in aggregate the risk of the patients that are entering a hospital.

So, one of the key things about these measures is that we are trying to understand how Hospital A versus Hospital B differ in terms of the aggregate risk of their patients when they present with AMI. And that makes these models a little bit more forgiving than an individual patient predicting model and have found that they can, like this one, perform very strongly even when they don't have as many variables as in other models.

So, again, that's given us confidence in it.

DR. KOTTKE: Tom, and then Leslie.

DR. JAMES: I'm glad to see the movement towards eMeasures. They do have strengths and they do have weaknesses.

One of the issues that I would like to understand a little better in the field of reliability has to do with the impact on the denominator exclusions particularly that about unknown death, Number 5.

It depends on how many deaths, the percentage of unknown deaths versus those that are picked up as to how much that's going to impact the scoring.

What's your experience?

DR. BERNHEIM: So, for this we're using the CMS data, which is pretty comprehensive. I'm just flipping to the page where I have the actual number so I can yeah, we have it in here and I will find it for you if you give me one second.

It's in the testing section. So,

I'm looking in our testing section here where we talk about exclusions.

So, unknown death was zero in this case. We put it in as a because we put it in all of our measures in case there is missing. But as it turns out, we had no unknown deaths in this one.

DR. KOTTKE: Leslie.

DR. CHO: So, we have a measure similar to this. It's the 30-day risk-adjusted mortality that the Yale group has developed.

Have you tested your model with this one and what's the

DR. BERNHEIM: Yeah, sorry. So, we're the same team, same group. And, yeah. So, what we did was we looked both at the performance of the models and this performs better than the claims-based models, but then also at how differently it profiles hospitals.

And that's also in here in it's under the Validity section. We have a scatter

plot that shows how hospitals perform in the final model for the eMeasure versus the current administrative claims model.

DR. KOTTKE: Okay. Any further comments on reliability? Liz has her hand up.

MS. DeLONG: I have a question and a comment. The question being, are you saying that the upper limit of normal will be standardized, or a site can actually change their upper limit of normal?

We talked about this on the phone call, actually, that if a site changes their upper limit of normal at will, they can dramatically change their assessment.

The comment is, all of this comparison is again against administrative data. You haven't, as Sana pointed out, your comparison does not include any model that was developed on clinical characteristics other than what you've captured in the administrative data.

DR. McNAMARA: Right. Well,

regarding the troponin, yes, the troponins will be on the troponin upper limit on normal will be determined based upon the assay that a hospital uses.

Can a hospital report whatever upper limit of troponin they want to? They can, but I suppose anybody could do that on any measure. They could change the blood pressures and everything they want to in a medical record.

But each assay, as you know, should have an upper limit of normal and to be able to apply that to be able to use troponin across the different sites that it should be like that.

As far as the value, as Susannah mentioned, there's been many other models out there certainly on the individual level. And there was one actually on the ARG data set that we used many of the same risk factors involved. And our C statistic is generally very good and is in line with all the other

ones.

We didn't use all the elements that they had due to this criteria, you know, history of peripheral vascular disease, for instance.

On certain levels, it should be an easy thing. You would think the patient either has it or doesn't. But as you probably all know how well that's recorded, how well a physician assesses whether somebody has peripheral vascular disease or not can be done a lot more reliably in a clinical registry where, you know, they have specific criteria, but how much of that works in a day-to-day clinical practice can be very different.

So, the short answer is that it operates reasonably well compared to other risk models. And as Susannah says, the main issue on the hospital level we feel that it we're confident that it's functioning well enough.

DR. KOTTKE: Other discussion.

Tom, are you still Tom James, are you okay. Are we ready to vote on reliability? Looks like we're ready to vote on reliability.

MS. LUONG: The timer starts now for reliability voting. One is high, two is moderate, three is low and four is insufficient.

(Voting.)

MS. LUONG: All right. Two voted for high for reliability, 13 for moderate, four for low and two for insufficient.

DR. KOTTKE: Validity.

MS. MITCHELL: So, in terms of validity testing, the developer indicated both critical data elements and performance measure scores were tested during this process.

We talked a lot about validity already, to be honest with you. It was demonstrated in terms of applying the claims-based model versus the eMeasure-specific model correlation coefficient of 0.86. We saw the pictures on

Page 28, I believe.

And then in terms of the C statistic relative to the five risk factors it was 0.78. And, again, that was considered acceptable. So, any other comments about validity?

DR. KOTTKE: Other comments? Seeing none, let's vote on validity.

MS. LUONG: The timer starts now. One for high, two for moderate, three for low and four for insufficient.

(Voting.)

MS. LUONG: Four voted high, 14 moderate, three low, and one insufficient.

DR. KOTTKE: Feasibility.

MS. MITCHELL: So, we've also been talking about this as well. By and large, all the data that's been discussed today can be routinely collected and delivered through care except for this troponin issue.

Interestingly, the EHR survey that you guys did which we have not talked about

suggested that the data could be captured manually. Just how feasible that is across the board is a whole other question, I think, but it's possible. It's a possibility issue.

And so, I think overall the feasibility of capturing the elements that you described needed for this model seem quite reasonable.

DR. KOTTKE: Other discussion? Seeing no other oh, Reva.

DR. WINKLER: I just want to make a comment about the feasibility assessment that is part of eMeasure evaluation. And that is really looking up front during measure development on the feasibility of collecting data elements and having them be present in a standardized fashion across.

And so, this is sort of one of the earliest uses of it. And, in fact, they got there before NQF did the work we did on feasibility assessment last year, but they essentially ended up in the same place.

And so, that feasibility assessment is something we expect to see as a large part of eMeasure evaluations as we see new eMeasures coming down the road.

DR. KOTTKE: Any further discussion? Seeing no further discussion, let's vote on feasibility.

MS. LUONG: The timer for feasibility starts now. One for high, two for moderate, three for low and four for insufficient.

(Voting.)

MS. LUONG: For feasibility, ten voted high and 12 voted for moderate.

DR. KOTTKE: Usability and use.

MS. MITCHELL: The measure is currently not being publicly reported, but my understanding is that CMS may consider including it in future IQI programs.

DR. KOTTKE: Any further oh, Henry has a comment.

DR. TING: A question. So, you

know, a 30-day RSMR has been publicly reported part of value-based purchasing developed by your team.

Is this measure potentially it's the same measure almost except using different models to adjust clinically adjust for mortality.

Is the intent of this measure to replace the other measure, or are we going to have two measures looking at the exact same thing with different models, one from claims, one from a clinical registry? It's just a question.

MS. HAN: Your question is whether CMS will implement two measure simultaneously, or will select one?

DR. TING: Part of it is NQF. So, we approve this measure.

MS. HAN: Yes.

DR. TING: It's exactly the same measure as the other one, which is a claims-based RSMR that's actually part of

value-based purchasing.

So, we approve this measure. This is the same measure except using a different model clinical registry adjusted.

So, I mean, is the intent to have how do we feel about having two exactly the same measures looking at the same outcome for the same population of patients, and how is, you know, NQF and CMS thinking about this?

MS. HAN: Okay. Well, CMS is developing and continues developing these EHR measures. Especially outcomes in and the goal is that in the future we would like to move from claim-based measure to the EHR measures. And that's our goal.

DR. WINKLER: Yeah, I think we realize that we're in a transitional phase. And so, certainly we are seeing within our portfolio measures that are often pretty much the same measure, one EHR-based and one that's some other data source and we'll live with that duality for a while.

But at some point I think we will want to either, you know, it will be one or the other and I think that we will always have some claims-based measures, some, you know, eMeasures.

But for right now as we're in transition, you know, this is the very first eMeasure that's an outcome measure. And so, we're moving into, you know, relatively unchartered waters to understand, but we certainly, I think, have the support of everyone wanting to continue this development and push forward.

DR. KOTTKE: Thank you. Any further comment? Seeing no further comment, let's vote on oh.

DR. HOLLANDER: So, if we're trying to standardize everything and make it reproducible, then I don't understand why you wouldn't just take what the FDA approved as the manufacturer's 99th percentile for each assay.

There's only, you know, 10 or 15 of them on the market and just plug that in at each institution and do the math rather than let each institution pick a somewhat arbitrary cutoff.

And I know that's not what's proposed right now, but I would urge you to go back and relook at that because I just think it's a more standard, reliable, reproducible way to measure the troponins.

And then as assays change, I mean, right now the FDA testing for troponin is unbelievable to define what the 99th percentile of normal is.

So, it's in the package insert. It seems easy to take that and you know that's the most accurate value you could get to compare across institutions, because it's the same assay across institutions using that assay.

DR. McNAMARA: Right. No, I think that's a great idea. I mean, I would look at

this in terms of the measure says to normalize the troponin obtained to the upper limit of normal at that hospital.

And if you want to define the measure obtained at the upper limit of normal at that hospital, will be the hospital just puts in which assay they use and there will be a standardized set of upper limit of normals from the implementation, I think that's fine.

That, I think, is well within both the spirit and the functionality of this measure. So, I think that that could be a very good idea.

DR. KOTTKE: Further comment? Seeing no further comment, let's vote on usability and use.

MS. LUONG: The timer starts now for voting. One for high, two for moderate, three for low and four for insufficient information.

(Voting.)

(Pause in the proceedings.)

MR. KOTTKE: George, you have 22 seconds.

(Laughter.)

MS. LUONG: For usability and use, eight voted high, 11 for moderate and two for low.

DR. KOTTKE: Any further discussion before we have final vote up or down? Seeing no movement, we'll vote for approval or endorsement or not.

MS. LUONG: The timer starts now. One for yes and two for no for endorsement.

(Voting.)

MS. LUONG: 21 voted yes, and one voted no for endorsement.

DR. WINKLER: Thank you very much.

DR. KOTTKE: Thank you. Thank you. Time for public comment.

MS. TIGHE: Operator, if you can check and see if anyone on the line has a comment and anyone in the room?

THE OPERATOR: Okay. To make a

public comment, please press star then the number one.

There are no public comments from the phone lines.

MS. TIGHE: And none in the room. And we are right at the lunch break, 12:15 exactly.

DR. WINKLER: Just as you're going to lunch, we know Henry is leaving relatively early.

Anybody else? When are you leaving, Michael?

Okay. When you say "after lunch," are you saying 12:30? Because we do have to worry about our quorum.

Okay. All righty. Lunch is ready.

(Whereupon, the proceedings went off the record as 12:13 p.m. for a lunch recess and went back on the record at 12:44 p.m.)

A F T E R N O O N S E S S I O N

12:44 p.m.

DR. KOTTKE: So, we're discussing Measure 2455, Heart Failure: Post-Discharge Appointment for Heart Failure Patients.

Jason Spangler and Tom James are the discussants, but the we will ask the American College of Cardiology representatives to give us a brief description.

(Comment off mic.)

DR. KOTTKE: 2458 has been withdrawn. No? They didn't withdraw it because of you. So, you don't have to apologize.

Okay. Go ahead, please.

DR. PINA: I'm Ileana Pina. I'm a heart failure transplant cardiologist and associate chief of cardiology at Albert Einstein, Montefiore New York.

Hello, Sana. How are you?

And I've been asked by the American College of Cardiology to talk about

the Post-Discharge Appointment for Heart Failure Patients measure. I was on the original Performance Measures Committee for PCPI.

In 2002, Stephen Jencks, which many of you know, published a paper in the New England Journal sort of alerting the country that 20 percent of patients with heart failure who had been admitted for a decompensation of heart failure were coming back within 30 days with tremendous variabilities in states and tremendous variabilities even within a state.

But in that same paper when he linked it to the administrative Medicare data, he reported that almost 50 percent of the patients were never seen by a provider within 30 days. And yet, we continue to lower our length of stay.

If you look at the Europeans, the Europeans who have a much longer length of stay, have a better 30-day readmission. So, whether it's omission or commission, it's

actually a fact.

Get With the Guidelines has been collecting data on this for quite a long time. And we actually had a paper that was chaired by Hernandez from Duke that showed that the hospitals there weren't that many of them there was about 35 percent that actually had a seven to 10-day clinic. But the patients who did attend a seven to 10-day clinic had a significantly lower rate of readmission.

That 20 percent that Stephen Jencks is actually we knew about this earlier from another registry called ADHERE that we had been collecting. So, that's sort of the clinical reasons for it.

DR. KOTTKE: Thank you.

Jason.

DR. SPANGLER: Thanks. I thought that was a great description. I mean, this is basically a readmission measure looking at readmission in a different way. It's a process measure at the facility level.

My biggest issue, and we'll go through obviously everything else, but my biggest issue actually was about the evidence, because of the evidence that's provided and what we're looking at.

And I know and it may be technicalities and this came up, you know, in our workgroup call, but having an actual appointment, scheduling an appointment and what happens at the appointment are very different things.

And what I don't see as evidence that scheduling appointments changes anything, because we don't necessarily know even if they have the appointment.

We know that there is, you know, there is evidence and they provided the Cochrane data around post-discharge, you know, a lot of post-discharge management including scheduling, you know, can change things.

And even the evidence around from the guidelines was not very strong evidence

and it was only based on, you know, basically two studies, but it was kind of I would even that say, you know, but that was actually having a follow-up appointment and it was, you know, even the wording are reasonable things to do.

So, my biggest thing was that was with the evidence. And I know during our workgroup some people kind of disagreed with that and thought, you know, it wasn't strong evidence, but there was evidence for this.

So, you know, I don't know if you want to address that, but that was kind of my biggest concern.

DR. PINA: No, I'd be happy to address that. I can tell you the data around the country is that for every five patients that actually get the appointment, three show up and two do not. And the main reasons at least at our place, is transportation.

But without a measure, what has been going on is that the patients are told,

call this number on Monday, make your appointment.

And if you think that, you know, just putting it in the chart and not making sure that they're there, if you don't even write it in the chart, it's certainly not going to happen.

And, first of all, finding out who is going to do that follow-up? Because that's equally important. Who's going to do that 10-day, seven-day follow-up?

So, I fully agree with you that writing it in the chart is good, but not sufficient. You would want to see the actual schedule and the patient actually attending, but we haven't done much of this at all.

So, this would be, to me, a first step to really get people to think about it and do it before the patient goes home.

DR. KOTTKE: Thanks. Other discussions? Sana.

DR. AL-KHATIB: The only thing that

I would point out is to remind ourselves as a committee of the discussion that we had with regard to referral, you know, for rehab, to a rehab program.

Because the same we raise the same concerns, the same arguments, but then we ended up, you know, agreeing that there is still value in doing that. And I just want to caution us against holding this measure to a higher standard than the referral for rehab.

DR. SPANGLER: Because it's my measure, I want to hold it to a higher standard.

(Laughter.)

DR. SPANGLER: Just kidding. No, I agree, I mean, and not just the rehab. I thought this conversation has come up several times with several measures about, you know.

And that's why I think having the algorithm in the chart that I think NQF calls for about how this leads to the, you know,

sometimes it's not as clear, but I agree with you.

DR. KOTTKE: Tom.

DR. JAMES: As the second on this one, I can say that the concept I believe is a very valid one. And I think the evidence is there for having the readmission or for the follow-up appointment.

This is very similar to what's going the measure that we have in mental health for follow-up efforts. Psychiatric hospitalization that has clearly demonstrated a reduction in readmission.

This is what goes on in the ACOs. That was part of the Brookings ACO development that demonstrated the same kind of anomaly.

The problem here, and this is what I'd like to get your thoughts on this, is that the ACC recommendations indicates that people with heart failure should be seen within seven to 10 days, but there is no time frame listed within this.

This could be an appointment three months from now, and that, I think, is the problem. This is not like a good care coordination measure that NQF is also pushing, until we can input time frames.

DR. PINA: Right. So, again, I can tell you what I've seen in my place is that in the electronic health record you must have the date of the appointment and it must be given to the patient before they walk out the door.

As a matter of fact, if the patient is going home on a Friday, I charge my house staff for them to make the appointment on Monday morning if they can't get into the clinic schedule and call that patient Monday morning.

So, I agree with you, but it has to be documented in the chart with a date so that we can actually calculate.

You're right. Three months from now isn't going to help anybody.

DR. KOTTKE: So, in the measure, is

there a I don't see any okay.

DR. GEORGE: We've looked at this a little bit in the stroke population and several of our stroke hospitals did a small pilot last year. Baseline data really low rates of patients having appointments after they leave the hospital and they did track appointments kept both before and after.

And doing this process really can make a difference in getting the patient to follow up.

It's not easy, it takes a lot of process change at the hospital level with who's in charge of making these appointments, but it does make a difference and I think you have to start somewhere.

DR. KOTTKE: Ellen, and then Judd.

MS. HILLEGASS: And I wanted to reiterate what Tom said. In the COPD population, the same thing. It's actually documented that by seeing the patient within seven days, that made a difference in

rehospitalization.

They actually have a pilot where they are sending RTs paid by the hospital to go out within 48 hours to see the COPD patients.

So, there's some pilots out there for doing -- two. So, there is data in other populations.

I'm not familiar with heart failure whether it's seven days, but it does work the same way.

DR. PINA: I have my own internal data which I have not published yet. In our seven to 10-day clinic, the readmission rate is eight percent for the patients who actually do show up and come back. And there's actually a physiologic reason for the worsening within two weeks.

What happens in a hospitalization with heart failure is usually diuretics are given. And if nothing else is done, I guarantee you that patient will be back

because the neurohormonal cascade just takes off.

In about two weeks they all become avid absorbers and reabsorbers and now their diuretics don't work anymore.

So, there's actually a physiologic reason even for two weeks if they get worse, they get worse within a week. It doesn't take long.

DR. SPANGLER: So, is there a reason why that wasn't put in the measure itself like schedule within two weeks?

DR. PINA: Well, when we did the measure, we weren't thinking necessarily about the physiologic basis, but more of a process of care of having that patient who was sick enough, first of all, sick enough to be in the hospital needs to be seen, you know.

We say seven to 10 days, because we know physiologically that they start to get worse.

DR. SPANGLER: But the measure

doesn't

DR. PINA: The measure doesn't talk about the physiologic

DR. SPANGLER: No, I'm just saying it doesn't talk about a date. Because the guidelines say seven to 14, and you're saying physiologically 14, I'm just wondering, well, that seems to make sense.

DR. PINA: And of course it's going to vary from patient to patient. Not every patient is going to be the same like any COPD or any stroke patient. There's going to be a lot of variability.

DR. HOLLANDER: So, what I love about this is you include observation. So, it's not just hospital discharge. And so, I think that's really important.

And I would say maybe you should even think about including emergency department visits, because we're talking about care transitions for heart failure patients and they only send 10 to 15 percent home from

the emergency department. And the main reason is that we can't do care coordination.

So, if you look at it and reframe it as when they have an acute decompensation which includes the ED, you need to schedule an appointment with their, you know, heart failure specialist or primary care provider that would fit.

I know that's not in the measure before us, but I just throw that out there to think about it.

DR. PINA: As a matter of fact, many of our clinical trials will use not just a calendar date change of an inpatient hospitalization, but a time in the ED where the patient was, say, given an IV diuretic, watched for a few hours and then sent out as an event, as a heart failure event.

DR. KOTTKE: Further discussion? So, are we ready oh, I'm sorry, Linda.

MS. BRIGGS: I just have a question about the definition of "inpatient facility,"

because sometimes patients go to a subacute facility.

And so, that patient would be seen by someone in the subacute facility most likely, but it still would be good to know if that would be considered an inpatient facility or not.

DR. PINA: I would favor considering that, because that would be very similar to an ED visit that doesn't get admitted. That gets treated and gets sent out.

And I think we are going to be seeing more hospitals doing that, not actually admitting the patients, just putting them under the Medicare observation status and sending them home.

MS. BRIGGS: Let me clarify what I meant, actually, because I saw this in I worked for a while as a hospitalist as part of an internal medicine team.

And one of the things that would

happen if someone wasn't able they were admitted for heart failure and we were concerned that they couldn't go home by themselves or whatever.

We would then refer them from the hospital then to subacute care. And they might be there for however long their benefits lasted. Maybe two weeks, maybe four. And then the next thing we would see is they'd be back in the hospital again, that they never actually ended up being seen by somebody on the other side of that.

So, if this is just inpatient facility as in hospital admission or observation status at a hospital, it wouldn't necessarily capture those patients who move then to another level of care and then out to the outpatient area.

DR. KOTTKE: Further discussion on evidence? Are we ready to vote on evidence?

(Pause.)

DR. KOTTKE: I think we're ready to

vote on evidence.

MS. LUONG: The timer starts now. One is for high, two is for moderate, three is for low, four is for insufficient evidence with exception, and five is for insufficient evidence.

(Pause.)

MS. LUONG: Can everyone just point at me again? Okay. We lost one.

(Pause.)

MS. LUONG: So, three voted for high evidence, 13 for moderate, one for low and one for insufficient evidence with exception.

DR. KOTTKE: Opportunity for improvement.

DR. SPANGLER: So I think this is the first time we're talking about heart failure, but similar to our previous discussions, there is a performance gap.

They talk about -- there's a mean of less than even as an improvement from the

data from 2011-2012 that's still less than 50 percent of CHF patients on the post-discharge scheduled follow-up appointments. So, there is a big gap there.

Additionally, there are disparities that exist across races. And interestingly, I found out that there were disparities between Medicare and Medicaid patients as well. So, I think there's a high performance gap.

DR. KOTTKE: Any further discussion on performance gap? Let's vote on performance gap.

MS. LUONG: The timer starts now. And it's one for high, two for moderate, three for low and four for insufficient.

(Pause.)

MS. LUONG: We have 17 for high and one for moderate.

DR. KOTTKE: Priority.

DR. SPANGLER: So again, similar to previous discussions, CHF leading cause of

morbidity and mortality; reducing both of those and readmissions has been a national priority affected by this. And then for data that they provide regarding costs, the costs are pretty substantial. They noted $30 billion annually, so I would say it's a high priority.

DR. KOTTKE: Further discussion? Tom.

DR. JAMES: And just to follow up with what Jason said, yesterday it was reported that heart failure readmissions are the most costly readmission type for Medicaid.

This is also, as I think Jason is saying, is part of the whole national quality strategy on heart disease. This is a priority measure.

DR. KOTTKE: Any further discussion? Seeing no further discussion, let's vote on priority.

MS. LUONG: The timer starts now. One for high, two for moderate, three for low

and four for insufficient.

(Pause.)

MS. LUONG: I think we're supposed to have 19, so we're missing two. Can everyone just point over to me, just to make sure?

Yes, we have 23. 19 for high. That's a hundred percent.

DR. KOTTKE: Scientific acceptability and reliability.

DR. SPANGLER: So, the measure specifications are clearly defined. They have a good calculation algorithm. I thought the exclusions and exceptions were well-detailed. So, I think it's going to be implemented consistently.

Talking about testing here as well? You know, they did empiric reliability testing signal to noise and I thought the results demonstrated high reliability.

DR. KOTTKE: Any further discussion? Seeing none, let's vote on - oh,

sorry, Tom.

DR. JAMES: Again, the issue with reliability has to do with the absence of having a hard time deadline as far as when an appointment should be made.

This means in my estimation, this is a low-bar measure.

DR. KOTTKE: Anybody else care to comment on the open-endedness of the time frame?

Seeing nobody who wants to, let's vote on reliability.

MS. LUONG: The timer for reliability starts now. One for high, two for moderate, three for low and four for insufficient.

(Pause.)

MS. LUONG: Six voted for high, 11 for moderate and one for low.

DR. KOTTKE: Validity.

DR. SPANGLER: So, only face validity was done with three separate

committees. The results showed a 69 percent either agree or strongly agree that you can distinguish between good and poor quality.

So, the highest would be a moderate validity and I think it probably is about moderate, but it could be higher than that. So, that's the recommendation.

They mentioned - sorry. I just want to note, there was a mention and maybe I'm getting confused in terms of - there was a mention of content validity in the application, but they didn't produce any results. They didn't demonstrate what that was, so I didn't know if there was additional validity they had done but didn't give the results, or they were just referring to what they had already done.

MR. CHIU: That was just referring to what we've done. Basically, we considered that, you know, the group experts creating the measure and then reviewing it for the content validity, but I think we already discussed

that. We realize it's probably at best to be moderate.

DR. WINKLER: One comment on criteria for validity is the - whether the specifications are consistent with the evidence. And this is perhaps where your time or lack thereof time and the specifications may enter into criteria.

DR. KOTTKE: Anybody else need to make a comment? Let's vote on validity.

MS. LUONG: The timer starts now for validity. One for high, two for moderate, three for low and four for insufficient.

(Pause.)

MS. LUONG: 15 voted for moderate and four for low.

DR. KOTTKE: Feasibility.

DR. SPANGLER: So the data is collected through a registry, which is the Get With the Guidelines Heart Failure Patient Management Tool. So they describe kind of how much this is used. It seems to - I don't

have any experience with this, but it seems to be something that is used pretty substantially. And there's, you know, it's an electronic form that's readily available.

So, I didn't see any concerns. I thought there was a high feasibility.

DR. KOTTKE: Yes.

DR. PINA: It is the hospitals that have Get With the Guidelines really use it a lot not only to bring up sort of the water rising that everybody is aware that we are collecting this information, but they're giving it back to the staff so that they can see what they're actually doing comparing to other hospitals like us. And then you can actually if you win an award, you can actually use that in advertising in your city as an award for quality.

So, there's a lot of a lot of bonuses for using Get With the Guidelines, which the hospitals use. And by the time they're in there, the numbers do go up.

DR. KOTTKE: Sana.

DR. AL-KHATIB: Just a quick question. I'm actually very familiar with the Get With the Guidelines Heart Failure database, but what is the total number of hospitals participating in this database now?

DR. PINA: I think it's about 541 distributed all over the country. Small hospitals, big hospitals.

MS. MITCHELL: Was the intent for this measure to be applied only to a Get With the Guidelines hospital?

DR. PINA: No, I think this measure should be applied all the way around. It's just that because we've been collecting the data so consistently, it's our best proof of what can be done in a hospital.

If the hospital decides to do quality, they may decide to do it some other way. And we do have literature on this from the H2H program of the ACC, that hospitals that have three or four different tactics to

lower their readmission rates whether a visit or whether working with clinicians, the rates dropped.

So that getting involved, just that alone, works.

MS. MITCHELL: And H2H is hospital to home?

DR. PINA: H2H was hospital to home, which was the ACC initiative with the IHI.

DR. KOTTKE: Anybody have - need any other comment on feasibility? Seeing none, let's vote on feasibility.

MS. LUONG: The timer starts now. One for high, two for moderate, three for low and four for insufficient.

(Pause.)

MS. LUONG: Nine voted high and ten for moderate.

DR. KOTTKE: Usability and use.

DR. SPANGLER: So, the measure is currently used in two programs. Both with Get

With the Guidelines, one the heart failure and I think what you described in the heart failure recognition program.

It's not publicly reported, but there are plans for public reporting incorporation into CMS' PQRS program.

My only concern is that no time frame was given for when that was going to be done. I'd be pretty confident it probably is going to occur within six years, which I think is what is called for, but it would be nice to actually have a time frame.

DR. PINA: So, the Joint Commission has a certification for heart failure for hospitals. And in order to get that certification, the hospital has to prove that they have entered into a quality program like Get With the Guidelines and that they have an award. So already, the bar is raised.

DR. KOTTKE: Further discussion? Seeing no action -- you don't need to feel the need to comment, do you, even though your name

is called.

(Laughter.)

DR. KOTTKE: Let's vote on usability and use.

MS. LUONG: The timer starts now. One for high, two for moderate, three for low and four for insufficient information.

(Pause.)

MS. LUONG: Ten voted for high for usability and use, and nine for moderate.

DR. KOTTKE: Any further discussion before we take a final vote?

Tom.

DR. JAMES: Just to try to reiterate it again that while this may be one that we want to allow in now, this is such a low-bar measure and does need to be harmonized with the care coordination measures and this and normally ACC is out in front, but I think we're lagging on this one. I just don't want you to be embarrassed.

(Laughter.)

DR. KOTTKE: You want to embarrass them up front.

I would agree with Tom that I'm a little surprised about the lack of pace, but I think you'll probably fix that.

DR. SPANGLER: Yes. I would just also kind of reiterate what Tom is saying about the harmonization.

I mean, there's a bunch of competing measures or possibly competing measures here and trying to make sure those are all, you know, harmonized would be ideal.

DR. KOTTKE: So, final vote. Yes or no.

MS. LUONG: The timer starts now. One for yes and two for no for NQF endorsement.

(Pause.)

MS. LUONG: Thank you. 18 voted yes for endorsement. One no.

DR. KOTTKE: Okay. Thank you very much. We do have - you mentioned competing

measures. Do we really have any?

DR. WINKLER: Not -- I mean, there are other measures around heart failure, not so much around appointments.

And so, there are some care coordination measures in terms of follow-up after hospitalization and -

DR. SPANGLER: Not necessarily competing, but definitely kind of harmonization, making sure there's not overlap or anything like that.

DR. PINA: Yes, most of the CMS measures up to recently have included what's done in hospital to the patient. In other words, the EF measure, the ACE inhibitor given, et cetera.

Care coordination is a super important measure, I think. The majority of patients out there with heart failure are unfortunately not seen by us, the heart failure community. They're primarily seen in primary care practices, where the whole team

approach may just not be available to these practitioners. So this is really a whole change in mentality.

DR. SPANGLER: I'm curious, and maybe Jensen, you're the best person to answer this, but has there been a consideration by ACC of a composite heart failure measure similar to like - because it seems, that actually to me seems to be something that would be easier done.

(Laughter.)

DR. PINA: It certainly makes sense because now we have enough of the little pieces that we can probably put a composite together.

When we were doing the performance measures, we didn't think at that point that we had enough information to really go out. And you'll see it in the next one coming out, too.

MS. DeLONG: On this measure, I didn't really hear any killer comments. And

yet, somebody voted against it. It would be helpful to me if I had all the reasons out there before I vote.

MS. HILLEGASS: This is a little bit off the topic, but in the sense of I really liked this because it said prior to discharge and appointment. And the cardiac rehab one talks about referral, and I didn't like referral. I wondered if there's any way - I know we can't change them, if we could have, on the post-inpatient, an appointment.

Instead of checking a box for referral and checking a box for counseling, you will have had to talk to them about cardiac rehab if you've made an appointment with a cardiac rehab. And I that's what I really like about this. I had no problems with this whatsoever, but the referral to me just seems like just out there, but maybe that's just me.

DR. KOTTKE: Thank you. 0521.

DR. WINKLER: Do we have someone

from CMS, a measure developer for 0521?

MS. DEITZ: Yes, this is Deborah Deitz. I'm a nurse researcher with Abt Associates. Hi. And we've been the contractor helping CMS with this measure.

MS. GALLAGHER: Deb, hi. This is Caroline Gallagher. I am the lead at CMS for the Home Health Quality Reporting as well, but I'm going to let Deb take the lead on this discussion.

MR. HITTEL: And David Hittel from University of Colorado is also on the line, or also part of the team.

DR. WINKLER: Great. Thanks very much.

Deb, why don't you give us a brief introduction to the measure?

MS. DEITZ: Okay. This is heart failure symptoms addressed. And it's a process measure designed to reduce the need for urgent care and readmissions for heart failure patients who are in the home health

setting.

And the idea is that by early identification of heart failure symptoms and coordination with physicians and other providers to intervene if the patient is experiencing heart failure exacerbation, we can reduce the readmissions.

This measure has been endorsed by NQF and reported on Medicare's home health compare website since 2011. As it's currently specified, it assesses whether the clinician addressed the patient's symptoms of heart failure, if the patient is exhibiting symptoms of heart failure.

We have proposed to revise this measure at this time so that agencies will now be held accountable for assessing heart failure symptoms in all patients with a diagnosis of heart failure, not just ones who showed symptoms of heart failure and that they address those symptoms when they're present.

In addition, there's one other

change. The measure now applies to both short-term and long-term home healthcare episodes. In the past, the long-term home healthcare episodes were excluded. And now, they're no longer excluded.

I think Acumen, who has been doing the a lot of the statistical analysis conducted some testing to ensure that removing that long-term episode exclusion doesn't distort the results of the measure. The mean agency performance stays pretty much the same as a result of the change. And also, removing that long-term episode exclusion increased the number of agencies eligible for reporting the measure.

So, I think that pretty much gives you an overview of where we're at.

MS. GEORGE: Thank you. Mark.

MR. VALENTINE: Yes. This is an existing process that's been happening for been going on for the last five years. There's 888 or 8,800 home health agencies

that are currently using this.

There are no studies, though, that show the use of this process specifically, that the outcomes are impacted, but the measure ties directly to the consensus-based guidelines. There is no evidence of QCC included. The highest possible rating would most likely be a moderate.

The developer does site guidelines from the Heart Failure Society specific to patients and family education for self-care and the recognition of heart failure symptoms when they call the provider.

And the developer does not include any guidelines for clinical assessment or failure symptoms.

So, you know, the goal is really to provide this assessment using the OASIS tool. But at the same time, making sure that the patients, they'll go into the acute setting.

So, they're being assessed, then

cared for from an outpatient perspective and not into an acute care setting perspective and it's over a long period of time.

DR. GEORGE: Any comments?

Judd.

DR. HOLLANDER: Yeah, maybe I'm missing this, but I'm kind of unenthused about this one.

(Laughter.)

DR. HOLLANDER: I mean, I understand the importance of the problem. Don't get me wrong, but it's a relatively narrow difference between the 75th and 25th percentile.

MR. VALENTINE: Right.

DR. HOLLANDER: And it's about assessing symptoms and then doing appropriate care.

MR. VALENTINE: Doing something about it.

DR. HOLLANDER: I don't know what appropriate care is. To me, if I'm sending a

provider into the home, I want one thing. I want them to keep that patient out of the hospital.

MR. VALENTINE: Right.

DR. HOLLANDER: And so, this is too vague for me. I want to know of the percent of time they go into the home, what percent do they end up sending the patient to the hospital, you know, or can they really keep the patient out of the hospital.

Because if they just go there, record a bunch of symptoms, give somebody a dose of lasix and send them to the hospital, they'll meet this measure, but they haven't done anything for the patient.

And so, I'm not sure I see how this is helpful to measure it. There has to be an intervention that occurs as a result of that home visit that keeps somebody from getting worse. And I don't see that embedded in here.

And I don't see any evidence such

as documenting you have signs and symptoms and giving you an extra dose of lasix or saying, don't eat salt, which might actually meet this improves outcomes.

DR. GEORGE: Liz.

MS. DeLONG: (Speaking off mic.)

THE REPORTER: Microphone, please.

MS. DeLONG: Sorry. It says that the number of home health visits in the numerator statement that were assessed for symptoms of heart failure and appropriate actions were taken when the patient exhibited symptoms or heart failure for heart failure.

I don't I don't understand the denominator, actually, but it claims when appropriate actions were taken. Whether that's specific, I don't know.

MS. COOK: Would you like us to clarify the types of actions that are documented by the OASIS tool?

DR. GEORGE: Please.

MS. COOK: Sure. This is Keziah

Cook from Acumen. The item on the OASIS tool that the numerator of this measure is captured using is called Heart Failure Follow-Up.

And there's a screening question that identifies any patients with symptoms of heart failure.

Patients identified as having symptoms, the home health staff is also asked to indicate what action was taken.

The actions they can choose are no action taken, which would result in failing this measure, or they can indicate the patient's physician or other primary care practitioner was contacted the same day, the patient was advised to get emergency treatment, the home health agency implemented the physician-ordered patient-specific parameters for treatment, they provided patient education or other clinical interventions, or they obtained a change in care plan order.

So, for instance, increased

monitoring, a change in the visit frequency, orders for Telehealth or so forth.

So, those are the that's the level of specificity that the OASIS tool documents the type of action taken by the home health agency.

For the purposes of this measure, taking any of those actions is considered to meet the denominator of the measure, whereas taking no action in response to the symptoms or failing to identify that a patient with heart failure had symptoms at all, failing to assess the patient results in failing the measure.

DR. GEORGE: So, assessment is required, as well as the action; is that right?

MS. COOK: That's right.

DR. GEORGE: Judd.

DR. HOLLANDER: So, it allows both ends of the spectrum to be a positive result. Calling the doctor and then doing nothing

would count, or sending the patient to the emergency department, which is exactly what we're trying to avoid, would count.

So, if all you have to do is like contact somebody and do something at either end of the spectrum, we're not really solving the problem though.

The problem is we want to improve home care, and we're not necessarily doing that because we're sending patients back to the hospital or leaving them at home doing nothing different. And both of those meet the criteria in this measure.

So, you know, I guess my perspective is not changed after hearing what's included in the OASIS tool, because it includes effectively everything besides ignoring the patient.

DR. GEORGE: Sana.

DR. AL-KHATIB: I just have a quick question. I actually share the concerns that Judd just mentioned, but I also have a

question because I'm having difficulty visualizing how this will be, you know, will work in terms of, I mean, is this a database that we're talking about that captures all the home health encounters within a health system or how is this going to work in terms of like what are the who are the participants and how many people are we capturing through the system that you are proposing?

Sorry. I mean, having reviewed all these measures, now some of these measures are blending together especially when it comes to the source of data.

MS. COOK: Sure. This is Keziah from Acumen again. I'm happy to clarify on that point.

This home health measure and is based on the OASIS assessment. OASIS is required for all home health patients who are receiving care covered by Medicare or Medicaid. So, it's part of the conditions of participation in the Medicare program. So,

this is a mandatory assessment.

It's conducted at the start of care and again at patient discharge or transfer.

And specifically for this measure the patient is eligible for the measure in terms of those patients with a diagnosis of heart failure are identified based on the initial assessment, and then whether or not the patient was assessed and interventions appropriate actions taken is assessed based on the end-of-care, the discharge or transfer OASIS assessment.

So, this measure is currently being collected. Has been collected since 2010 for all home health patients whose care is covered by Medicare or Medicaid.

DR. GEORGE: Liz.

MS. DeLONG: So, I still don't understand who the population is in the denominator, because the denominator statement says the number of home health episodes of

care ending with a discharge or transfer to inpatient facility.

Does "discharge" mean discharged from home health care? I don't understand the terminology. Sorry.

MS. COOK: Right. Okay. And our apologies. I know this is not as specific to the setting.

So, a patient can exit home health in a couple of different ways. They can be discharged to the community, which usually means they're either no longer home or they no longer have a need for skilled care in their home. So, they would remain in their home, but they are no longer receiving home health services. So, that's considered a discharge to the community.

They can also be discharged to an inpatient setting such as a skilled nursing facility or a hospital.

And then finally there is an OASIS assessment type for a transfer to an inpatient

facility. And this assessment type is conducted when there's an expectation that the patient will be returning home and will resume home health care once they return home.

So, the patients in the denominator of this measure are all home health patients with a diagnosis of heart failure or symptoms of heart failure whose home health episode ends during a rolling 12-month reporting period.

DR. GEORGE: Tom.

DR. JAMES: Just to put this into some other context, this is a measure that I believe is part of or would be part of the nursing home assessment on the Medicare webpage. Home health, yes.

And, frankly, there are very few measures out there. And yet, patients when they're being discharged from the hospital should be given a choice of three separate home health agencies from which to choose. And having some reliable measures that are

based in evidence could help them make better choices than which one has the highest alphabet letter.

So, there's a real reason for this, but by the same token I am concerned about the level of evidence here. I'd like to see a tighter measure.

DR. GEORGE: Any other comments or discussion on the evidence?

Linda.

MS. BRIGGS: I'm still having trouble as Liz was with the denominator here, because basically it's talking about the episode of home health care ending in either discharge or transfer to an inpatient facility.

So, it kind of, to me, it's like, okay, are these people that ended up in the hospital and now we're looking back at them? Is that what we're looking at?

MS. COOK: And you know what? I'm sorry. I think I think probably our

sentence structure is a little confusing there.

They are episodes that either end in discharge that can be discharged to the community, or can be discharged to an inpatient facility, or they end in transfer.

So, it's actually all home health episodes that end via any means other than the patient's death at home.

DR. VIDOVICH: I'm just asking for clarification. It says "endorsement maintenance." So, this had been previously endorsed, this measure?

MS. COOK: That's right. Yes.

DR. VIDOVICH: So, then so, this has been endorsed as is, right?

DR. WINKLER: Well, not as is. Actually, they've made significant revisions to the measure for this particular evaluation to enlarge the denominator for all patients with heart failure.

Previously it was just the

patients with heart failure with symptoms. So, they are revising as part of the maintenance process. But this measure, yes, has been endorsed by NQF for quite a few years.

DR. VIDOVICH: With the same wording symptoms assessed and addressed, right, which we have a little bit of a problem writing.

DR. WINKLER: I'm sorry?

MS. COOK: The previous title, I believe, was Heart Failure Symptoms Addressed as our denominator expansion was to also require an assessment of symptoms.

DR. VIDOVICH: Okay.

MS. COOK: Previously, if a home health agency failed to identify that a patient had heart failure symptoms, that patient was not included in the measure and we felt that was a shortcoming.

DR. GEORGE: Leslie.

DR. CHO: So, does the measure

developer have any data that doing this measure has improved patients' outcome somehow in the last four years?

MS. COOK: You know what? I think what we can say is that as agencies became more comfortable with the OASIS, the instrument, the overall performance on this measure did increase somewhat.

That was also part of why it seemed important to expand the denominator to include both addressing symptoms and also assessing symptoms.

DR. CHO: I appreciate that the yeah, it was surveyed, but I want to know it improved patients' outcome. Like, were did you have these patients' heart failure symptoms assessed more and did that translate into less rehospitalization or whatever? You know what I mean?

I would like to it's all good and fine for us to assess these symptoms, but I want to know what they led to. And you have

four years of data now.

MS. COOK: Sure. So, that's not something that's really feasible directly with the OASIS data, you know.

What we have seen is that there has been a fairly stable trend in terms of hospitalization and ED use rates.

The other thing we've seen, though, is that the actual rate of patients with heart failure at home health agencies has declined over the time period.

I believe there was and, Deb, Deb Deitz, if you're able to jump in here, I believe there were some changes in the home health payment system that may have changed when home health agencies identified patients as having heart failure.

So, the reason why we're not able to conclusively say that over this time period conducting the assessment and addressing of symptoms led to a change in outcomes, is we don't know that our population of patients has

been stable at that time.

There is some evidence to suggest that the patients identified as having heart failure currently the heart failure likely represents a more significant component of their care needs than patients who could have been identified having heart failure back in 2010.

DR. AL-KHATIB: So, I completely agree with

MS. COOK: Yeah, we see a trend as the number of patients with heart failure in home health drops a bit. We see roughly stability in the rate of emergency room use or in the rate of hospitalization, but it's just hard to determine if we're really comparing apples to apples there.

DR. AL-KHATIB: Well, so I completely agree with the comment that was made by Leslie that, you know, we really need to have some data on the impact of the performance measures.

And if you don't have that in place assuming that this gets endorsed, I don't know what the outcome of this measure will be today, but if it gets endorsed, I think you need to have a plan in place as to how you intend to study the impact of this measure on patient outcomes.

DR. GEORGE: Any further discussion? All right. We'll vote on the evidence.

MS. LUONG: The timer starts now for voting. One is for high, two is for moderate, three is for low, four is for insufficient evidence with exception, and five is for insufficient evidence.

(Voting.)

(Pause in the proceedings.)

MS. LUANG: So, for evidence, four voted moderate, nine for low, one for insufficient evidence with exception, and six for insufficient evidence.

MS. TIGHE: So, the measure did not

meet the importance criteria of the Subcriterion 1a for evidence. Thank you everyone from CMS who joined us for that measure.

And then moving on, it's the last measure of the day, 2450, the ACC measure.

DR. KOTTKE: Okay. While the ACC comes back, it's 2450, Heart Failure: Symptom and Activity Assessment.

Primary Discussant is Joel Marrs and secondary discussant is Mladen Vidovich.

MS. TIGHE: And we did receive an email request. There seems to have been an after-lunch slump. So, if you can just lean in a little bit more and speak up into your microphones, people on the phone are having trouble hearing.

DR. KOTTKE: Okay. Welcome again.

DR. PINA: Thank you again for letting us make this presentation.

So, this measure combines symptom and activity assessment and it's something

that we really pained over.

You heard this when we had our phone conference a couple weeks ago when we were doing the performance measures, because activity is absolutely directly related to prognosis.

And it would be wonderful if we could put everybody on the treadmill and do a cardiopulmonary test and get their actual prognosis right off of their VO2, but nobody is going to do that.

So, we have to ratchet it down some and we said, okay, well, what about a questionnaire?

And we have some wonderful instruments that I use all the time in my clinic, but the primary care practitioners many times don't even know that it exists.

So, we have to start somewhere to get physicians to think about activity level in the heart failure patients, which is directly related to mortality.

And of course the New York Heart class takes into consideration the symptoms and the activity level. The two sort of go together. And it's a classification that everybody is aware of.

They're not writing them down in the charts. I know that for a fact, because I look at charts all the time, but and it is highly subjective.

However, when you look at the literature, there is a breakdown of patients with Class 4 by description who have a 50 percent mortality in six months. Patients who are Class 3 are below that, and one or two are below that.

So, it has value in that it's getting the physician to think about the symptoms as it relates to activity level and then putting that in the prognostic category where it belongs.

And so, we came up without getting again, it's one of these got to start

somewhere, because they're not really thinking about it and they're not documenting it.

MS. MARRS: All right. So, to start off with the evidence assessment, there was no QQC submitted. And so, highest level could be moderate.

And a lot of the evidence background is driven by poor recommendations both in ACCF AHA guidelines, as well as HFSA guidelines was kind of a primary driver for evidence

DR. VIDOVICH: My comment would be this is dissimilar to the measure we discussed yesterday for indications for PCI. I think it's an important part of documentation to have in the chart.

DR. KOTTKE: Judd.

DR. HOLLANDER: So, I guess my question is how this changes anything. So, I think from a patient-centered approach it's nice to address the patient's symptoms and try and improve them, but maybe the last thing I

need is another prognostic tool.

I mean, we have BNP, we have LV function, we have troponin. And now if the sails for this is symptoms helps with prognosis, I don't know that I need it unless you're going to tell me that if I use Drug A or Drug B or do cardiac rehab it's going to change their outcome.

DR. PINA: So, yeah. You're absolutely correct. You don't need another prognostic tool, but you don't have the perfect prognostic tool, because pro BNP in many instances has a lot of prognosis.

But if you're in the clinic, you may not have that pro BNP for prognosis where an activity assessment it's pretty easy to do within your history.

The second thing is that if the patient is truly Class 3 or 4, you would go to another level of drug. You may think about a device where you've now cataloged that patient as a different New York Heart class or refer

that patient earlier to a specialist or to advanced cardiac therapies care.

So, it does much more than just say, oh, okay, here's my other prognostic tool. We haven't got the perfect prognostic tool. But if I could put them on the treadmill, I'd give them the prognostic tool except you can't do that on everybody.

DR. KOTTKE: Yes, Sana.

DR. AL-KHATIB: Yeah, I completely agree with that comment especially as an electrophysiologist looking at patients with heart failure trying to understand what their, you know, level of heart failure symptoms and functional capacity is.

It's very critical for me sometimes to get some more objective data, if you will, to decide do they need a cardiac resynchronization therapy, what, you know, if they get cardiac resynchronization therapy, are they actually responding? Is there anything that we could do to optimize their

response? So, certainly there are a lot of applications there clinically.

The one question that I want to ask you is in terms of like looking at the quantitative evaluation of someone's, you know, level of activity and their symptoms, I didn't see anywhere here, and please correct me if I'm wrong, as to what tests you would count in terms of, you know, what tools, what tests would count or would any test or tool that any clinician, you know, count.

DR. PINA: But as I said, the clinicians normally aren't doing any type of testing in their office.

Certainly if a six-minute walk were documented on the chart, I'd be quite happy with it because it's a simple test done in the office and it's very inexpensive.

If somebody gave the patient a questionnaire like the Minnesota Living With Heart Failure or the Kansas City, which is a very low patient burden, it takes eight

minutes to fill out, that would make me very happy because I would have domains of Leslie, you know this of activity and of symptoms altogether in one questionnaire.

But the physicians are not doing that and we would love for them to do that. So, to me, this is the first step and that's how the Performance Measures Committee discussed it. We have to start somewhere to get people to note down and to think about the activity of that patient.

DR. KOTTKE: Jason, did you have something?

DR. SPANGLER: I just had a follow-up on that. Are you worried though without listing any type of tool that there are going to be poor tools used?

And there may be documentation, but it may not be good documentation.

DR. PINA: So, by it's very nature, New York Heart Class is highly subjective, because it's based on the patient's assessment

of what they think they can do, which is not often, as you know, correct, and our assessment of their assessment.

However, as bad as it is, when you start to look at clinical trials the numbers do kind of break down.

I'm not afraid that they're going to use other tools, because right now they're doing nothing.

And in the eight minutes that they have to see the patients, this may be the best we can expect right now, you know, as the time with the patient keeps shortening, you know.

And again in the care standards, you know, coordinated care measures, this is perfect for the same reason.

MR. CHIU: If I can just add something really quickly, you know, in our measure algorithm this is used in Pinnacle outpatient Hughes and many others, but the New York one is definitely the predominant one if there's anything documented.

But simply any tool currently that's constructed can be so long as it's embedded, but there is another Minnesota one. There's a few others that we've actually listed.

It isn't in this description here, but in the details I believe it is listed as realizing the New York Heart Class is probably the predominant one if anybody documents it.

DR. KOTTKE: Joe, and then Ellen.

DR. CLEVELAND: Yeah, I really just want to make a comment to amplify what Sana said, which I really think that while this may not be perfect to start, as we start looking towards trying to figure out who is going to need advance therapies whether it be transplant beds, other things like that, cardiac resynchronization, we've got to start somewhere with some activity level because it does correlate, I think.

And I think the body of evidence

here suggests that's robust enough. And so, I think that there is precedent for trying to establish at least some marker.

MS. HILLEGASS: And I wanted to say that there's very strong evidence with the six-minute walk for multiple disabilities from COPD, to heart failure, to LVRS, to transplant and there's criteria.

Now, it does take a while. So, the other thing that we're using in therapy is we're using gait speed. And gait speed is highly correlated with function. And gait speed takes a maximum of two minutes.

And we're using gait speed across the board. There's so much data on gait speed out now besides six-minute walk that I would highly recommend you look at these kind of functional tests.

DR. KOTTKE: Yeah, there's a very interesting BMJ paper. The title is something like Outwalking the Grim Reaper. It's very close to that that if you can't walk a mile in

half an hour, you're going to die.

But my question is, I mean, we say, well, a six-minute walk only, you know, but a six-minute walk probably really takes ten minutes in an eight-minute visit.

Is this designed for cardiology groups or is it designed for primary care? My primary care colleagues tell me that on average they have to deal with seven and a half topics in ten minutes. And, you know, you're going two minutes is allotted.

And what about what about patient desire? I mean, I'm just a general cardiologist, but I see a lot of old patients who are pretty satisfied not being able to do much.

And I think a big question is, are you dissatisfied with what you can do? I don't want to ride a double century even if somebody thinks I ought to be able to.

DR. PINA: But that's the difference between quality of life and

functional assessment. So, they may be functioning at a New York Heart Class 3, but be perfectly comfortable with it.

So, that's where, great, if we have the quality of life instrument, we would have that piece of information in there, but we don't.

DR. KOTTKE: Yeah, Ellen.

MS. HILLEGASS: Just to go back to the gait speed or the six-minute walk, the gait speed could be done by another staff personnel.

And Barry Make out of Denver Jewish gave a great presentation to docs at a Chest meeting and said, look, look at your patient. Can they stand up out of the chair? If they can't get up, they're not going to be active, A.

And then he said; B, look at how they walk. How slow are they versus so, you may not have a specific gait speed, but you might say to yourself and that's not going

to take you six minutes or eight minutes.

Just ask them to stand up, and then ask them to just take a little bit of walk and that's what we're talking about basically. That's what the physicians need to be doing.

And if they eyeball that they are not able to stand up, then they aren't going to be active. And if they can stand up, but they're just barely beating the grim reaper, as you said, then that's another one. Then you need to refer these people or realize that these are the people that are going to be rehospitalized.

And there's very good data coming out about this as far as rehospitalization and gait speed.

DR. KOTTKE: Well, that's true, but are they avoidable rehospitalizations?

Tom and Liz.

DR. JAMES: Two things real quickly. One is to follow up on exactly what

you said, and that is ask if there is a parallel patient-reported outcomes measure that's in the works or is being considered.

Second thing just being a country primary doctor, you know, who doesn't have access to all that fancy equipment where you can get your stuff done, I walk patients in the hallway. You get a lot of information while you're doing that.

I learned this from the orthopedists. It's about time I learned it from the cardiologists, too. There is a lot of information just from listening and that is much more of a primary care type of measure that we don't have that much of for heart assessments in primary care cardiologists have a ton of.

DR. PINA: I still walk them in the hallways. Matter of fact, I won't let them go into the exam room so that I can watch them walk into the exam room and get on the table. I find out a lot about that simple yeah.

DR. KOTTKE: Liz.

MS. DeLONG: So, for clarification, is this any patient with existing heart failure? Because my worry has always been unintended consequences.

The patient comes in with an acute problem that is not a heart failure problem. And you're using your ten minutes to have the patient walk instead of treating the problem.

DR. PINA: Right. So, this is for patients either in their initial evaluation for heart failure and in every follow-up appointment for heart failure.

Is that not correct, Jensen?

DR. KOTTKE: Sana.

DR. AL-KHATIB: Just two questions. The first question is for you, Jensen.

Did I hear you correctly that you said that an assessment of the New York Heart Association class would count, would fulfill this measure?

MR. CHIU: That is correct.

DR. AL-KHATIB: Because to me that makes it a bit less appealing because of the very well-stated concerns about how subjective the New York Heart Association Class I would want to shoot higher, you know, for something that's more objective that's going to tell me more than the New York Heart Association Class.

DR. PINA: Sana, we spent about three hours discussing this very thing at the performance measures meeting and we were not very enthusiastic that if we put something else in there they would do it, because even now the New York Heart Class is missing from most of the charts that I see. So, something as basic as that is just not even being recorded.

And the other benefit to this, by the way, is if you're in a multi-specialty group or multiple physicians of the same specialty who see the patient sequentially, if I see a New York Heart Class 3 that a

colleague wrote down, I know what that patient looked like at the last visit.

So, it's important for patient-centered follow-up.

DR. AL-KHATIB: And then the second question I have for you in terms of implementation, are you expecting the healthcare provider to make this assessment every time they see the heart failure patient even if the like they just assessed the patient two weeks ago, nothing has changed.

Could they then document that nothing has changed, or do they need to go through the same especially of like quantitative assessment?

DR. PINA: I expect the same at every single visit. Because most of the times after you've talked to the patient and you do the eyeball test, you know what it is.

MS. TIGHE: Sorry to interrupt. Operator, if you could see if the AMA PCPI staff have an open line, they're colleagues of

the developer, to make a comment.

OPERATOR: So, we have Jamie's line open.

MS. JOUZA: Hi. Thank you. Yes, this is Jamie Jouza. I was part of the developer for the specifications for this measure. And I just wanted to highlight that the specifications actually list the four tools that are included in this measure.

There is not the six-minute walking test option to meet the numerator for this measure.

And I believe you would find within the measure, language of the numerator statement that actually includes this as well.

So, there are a couple different places within the measure documentation specifications that it details what would sufficiently meet an assessment of the symptoms and activities of heart failure.

MS. DeLONG: So, I just want to clarify that, as written, the denominator says

that it's any patient age 18 or older with a diagnosis of heart failure. And it doesn't exclude those who aren't there for a heart failure visit.

Sorry to be nitpicky, but that's what the denominator says.

DR. PINA: No, I appreciate to be nitpicky. I think that's why we're all here. I think if the diagnosis appears anywhere in that patient's history, someone should make that assessment even if it's the fourth or the fifth.

If you're talking to the patient and they come in with a bellyache for something totally different and the New York Heart Class is two, that's fine. It's New York Heart Class 2.

I think it should be documented either way.

DR. KOTTKE: Further discussion? I didn't see where those four what the four acceptable tests were.

Can somebody list those?

MS. JOUZA: Yes. So, it's in the numerator and it includes the New York Heart Association Class or completion of the Kansas City Cardiomyopathy Questionnaire, Minnesota Living with Heart Failure Questionnaire or Chronic Heart Failure Questionnaire.

DR. KOTTKE: My concern with this, it doesn't strike me as being very patient-oriented. I mean, it doesn't ask how satisfied are you with your current situation.

And, I mean, I ask my patients, you know, has anything changed? Are you stable? And if they say nothing has changed, I'm happy.

Even though they are shuffling down the hall with a walker, which they are, I don't I don't stir the pot too deep.

DR. PINA: I think in reality we need another measure somewhere along the way that discusses health status, which is what you're implying including the quality of life.

But a true health status assessment I fully agree, because they are a little bit different.

DR. KOTTKE: Leslie.

DR. CHO: I think, you know, this is kind of like the Afib CHADS score, CHADS Vasc score. You have to have something in the chart to begin with.

And they might be happy with a CHADS score of four. I don't know, but you still need the CHADS score, I think, in the chart.

And I think for that purpose because it's a beginning to the heart-- you know, the way we think about and treat and do quality metrics. I still think it's a good measure.

DR. KOTTKE: Mladen.

DR. VIDOVICH: Yeah, I would add, I mean, simply to what Leslie mentioned is these are these simplified classes like an ASA airway classification or, you know, chest pain

specification, Canadian.

They're not great, but the extremes work really well, you know, one and four work well. Two and three there's always some contention. People may not agree. But as you said, it does help you.

And, you know, as an interventionialist, I ask about angina every time and I document some sort of form, episodes of angina, whatever.

So, I think it has tremendous value. It may be oversimplified, it may be not perfect, but it's withstood the test of time for sure.

DR. KOTTKE: So, are we ready to vote on evidence? Some people think so. Okay.

MS. LUONG: So, the timer for evidence starts now. One for high, two for moderate, three for low, four for insufficient evidence with exception and five for insufficient evidence.

(Voting.)

MS. LUONG: For evidence we have one for high, 14 for moderate, three for low and one for insufficient evidence.

DR. KOTTKE: Okay. Opportunity for improvement.

MR. MARRS: All right. So, like what was mentioned before, they used the PINNACLE registry to evaluate performance gaps.

And based on that, they looked at 2011-2012 data, about 1200 providers in the PINNACLE registry. And just 36 percent one year and 35 percent the second year were actually meeting documentation standards for one of those four either New York Heart Association class, Kansas City, Minnesota or the Heart Failure questionnaire form.

And so, pretty big performance gap standpoint from a documentation standpoint just in that registry itself.

From a disparity standpoint they

did look at different ethnicities and gender and all those and there was no real disparity that stuck out between any of the subpopulations.

DR. KOTTKE: Other comments? We will vote.

MS. LUONG: The voting starts now. One for high, two for moderate, three for low and four for insufficient.

(Voting.)

MS. LUONG: For performance gap, 16 voted high and three for moderate.

DR. KOTTKE: Priority.

MR. MARRS: I think based on the conversation that we've had round this topic, I think it shows that it is a high priority that we do need a better way to assess or better kind of accountability of documenting some sort of assessment of clinical activity or clinical system function.

And so, based on that, evaluate it as a high priority.

DR. KOTTKE: Further discussion? Let's vote.

MS. LUONG: Voting starts now. One for high, two for moderate, three for low and four for insufficient.

(Voting.)

MS. LUONG: So, for high priority, 16 voted high, two for moderate and two for low.

DR. KOTTKE: Scientific acceptability and specifications and reliability.

MR. MARRS: I think it was clarified earlier that it is any visit not necessarily just for heart failure itself. Having a diagnosis of heart failure was in the denominator and so I think that clarified things a bit.

In regards to reliability, the PINNACLE registry that they utilized, it is only 1200 providers, about a half million patients in that.

And so, a fairly decent sample size to evaluate and so felt met reliability standards there, but there was no necessarily empiric testing of performance scores.

DR. KOTTKE: Further discussion?

MS. MITCHELL: I just have a question on

DR. KOTTKE: Yes, ma'am.

MS. MITCHELL: Yes. So, in the improved heart failure study it was made up of 167 offices, right?

So, how many separate practices were looked at using PINNACLE registry? I think you mentioned 1200 physicians, but I don't have a sense of how many practices.

DR. PINA: I know they optimized and improved data very well. I don't know how many practices here.

MR. MARRS: I thought it was in the 150 range, maybe.

DR. PINA: Maybe.

DR. WINKLER: I just wanted to

point out you mentioned no empiric reliability testing, but that's what this is, is a signal to noise results with the reliability testing.

So, there is empiric testing in the measure score.

MR. MARRS: Right. Yeah. Sorry, I misquoted. So, yeah, it was 0.99. So, high reliability score.

DR. KOTTKE: Okay. Any further discussion?

DR. PINA: We're trying to find those numbers for you.

DR. KOTTKE: Seeing nobody who is asking for further discussion, let's vote on reliability.

MS. LUONG: The timer starts now. One for high, two for moderate, three for low and four for insufficient.

(Voting.)

MS. LUONG: For reliability, 11 voted high and nine for moderate.

DR. KOTTKE: Validity.

MR. MARRS: The primary analysis for validity was based on face validity of the data from the PINNACLE registry.

DR. WINKLER: I think just to be fair, you had raised a comment on the previous measure about what do we know about the impact. And that's a validity question.

And so, you know, what information we have on this, because certainly that was a big point I think Sana raised on the previous measure. So, in all fairness, we want to hold all the measures to the same standard.

So, if there's any information about that, that would be important.

DR. KOTTKE: Anybody have any questions? Liz.

MS. DeLONG: Was this measure endorsed so that it's been in, I mean, the other one had been endorsed and should have reliability and validity.

DR. WINKLER: Okay. This one is a new measure.

DR. KOTTKE: Any further comments on validity? Ready to vote? Vote.

MS. LUONG: The timer starts now. One for high, two for moderate, three for low and four for insufficient.

(Voting.)

MS. LUONG: For validity, one voted high, 16 for moderate, two for low and one for insufficient.

DR. KOTTKE: Feasibility.

MR. MARRS: The main issue on feasibility which came up on our conference call as well was kind of just the standard documentation piece in the medical record and kind of standard extraction piece from a consistency standpoint with, you know, many, many different EHRs out there and trying to have a standard process to abstract was the main concern, I think, from a feasibility standpoint.

DR. KOTTKE: Did feasibility of a six-minute walk in an eight-minute visit come

up?

MR. MARRS: I don't remember that specifically being discussed.

DR. KOTTKE: Yes, sir.

DR. HOLLANDER: Along similar lines, some of these surveys are not quick not easy and not for the uneducated. And they can't be done with the physician sitting at the bedside telling them how to do it in that time frame.

Handing it to them in the waiting room, I'm not sure how well that works. And so, I think New York Heart Association Class, you know, it might be nice to have that documented, but I don't think that's changing the world, you know, as far as outcomes.

The other measures that are, I believe, a little more patient-centered and get to what they actually can do and more useful, but I think there are potential feasibility issues and then can you apply it broadly within your practice.

DR. KOTTKE: So, I have a question. How many people would send the patient to the cath lab if you thought they were Class 3, and your colleague had written down Class 2, and you asked the patient if anything had changed and they said no?

Any other discussion? Sana.

DR. AL-KHATIB: Just a quick question. Is there any outpatient-based heart failure database or registry? I mean, PINNACLE is not specific to heart failure and you have wonderful databases capturing inpatients, you know, heart failure patients who are hospitalized.

Are there any databases in existence or that are being plan designed for outpatient heart failure patients?

DR. PINA: Right. So, the optimized and the improved HF databases were mentioned. Some of those have been truncated.

The Get With the Guidelines now collects a 30-day tool to see where that

patient has been within 30 days.

I don't remember if we put in there a six-minute walk or a KCCQ, but it's certainly something I can take back and we may think of modifying it.

Certainly on an EHR it's very easy to put in a place for if a six-minute walk is there, you check it. But it's not only check, you have to have a number, you know. And the same with an exercise test. You have to have a number.

DR. GEORGE: Ileana, do you know if or any if Joint Commission is looking to develop an outpatient measure accreditation?

DR. PINA: As far as I know, no. I mean, years ago CMS, who is here, had thought about some outpatient measures, but it never and the QIOs were handling them internally, but nothing happened.

DR. KOTTKE: Further discussion? Seeing no movement, let's vote on feasibility.

MS. LUONG: The timer starts now

for feasibility. One for high, two for moderate, three for low and four for insufficient.

(Voting.)

MS. LUONG: For feasibility, two voted high, 12 for moderate and five for low.

DR. KOTTKE: Usability and use.

MR. MARRS: The main issues around usability I think came up with the allowing the four different measures to assess activity level and clinical symptoms, I think, came across as flexible, but also kind of a limitation, I think, in usability from kind of standardizing of how you're going to assess patients across multiple providers.

DR. KOTTKE: How about use, prior use, somebody using it outside of heart failure clinics.

MR. MARRS: What was the question?

DR. KOTTKE: Is anybody using it outside of heart failure clinics?

MR. MARRS: Not that I'm aware.

DR. KOTTKE: Is it being used? That's a no.

Further discussions?

DR. SPANGLER: You know, public reporting is also an issue. And this is a little bit different because the assumption, which I think is a good one, but just to keep in mind is that PINNACLE is going to be a qualified clinical data registry, you know, within PQRS. And we'll probably know that in the next few months, but, I mean, it should most likely happen, but it's a possibility it may not happen.

DR. KOTTKE: Further comments. Let's vote on feasibility or usability and use.

MS. LUONG: The timer starts now. One for high, two for moderate, three for low and four for insufficient information.

(Voting.)

MS. LUONG: For usability and use, two voted high, 13 for moderate and five for

a low.

DR. KOTTKE: Any other comments before we vote to approve or endorse?

DR. HOLLANDER: So, I just want to sort of restate my comments from earlier having, you know, tried to step back and listen to the conversation.

So, I agree this is phenomenally important so that we can better understand how to risk stratify patients.

I'm not sure that makes it a measure. That makes it a research project using the PINNACLE database.

And so, my real issue with this, it's hugely important, but it's not time as a measure because we don't know what to do with the information to change care.

And so, I'm, you know, in my head I'm having a hard time getting my hands around what's important information and what actually should be a measure.

And so, I think I fall out on the

scientific side. I'd love to see the publication. I'm not sure I want to report it to get the data.

DR. CHO: Judd, Let me ask you a question. So, let's say you are seeing a patient continuously for heart failure. So, the patient is coming in again and again for heart failure.

You don't get the sort of activity measures or whatnot and so you just kind of, you know, like one day you look like your fluid overloaded, next day you don't, whatever, and you're kind of like, well, maybe we'll give you another diuretic, we'll lower this, we'll lower that without any objective clinical assessment.

I mean, I think that's a measure of poor quality of care, don't you?

DR. HOLLANDER: Well, I wouldn't necessarily agree with that, but remember this is a little bit about documentation.

And I think if the measure said

when I do the assessment, I sort of hate to say it, I respond with something useful to improve the care of the patient based on my activity level assessment.

And if I don't get an activity level assessment, that counts as a zero. Then that would be a measure that ties to something that's an outcome, but right now it's just getting an activity level.

And there's no data that formalizing the activity level leads to a better intervention at that visit than saying, are you doing better or are you doing worse.

DR. CHO: There's data out there that if you have, you know, a poor activity, your morbidity and mortality dramatically changes.

And I agree that New York Heart Association may not be one-to-one linked with that, but currently under the current the way we practice medicine, we don't have that perfect tool.

So, until we get there, things like Kansas City and things like Minnesota Heart and whatever, these are surrogate tools for us to eventually get there.

DR. KOTTKE: Do we know that's cause and effect?

DR. HOLLANDER: Yeah, that's what I'm saying. So, do we know so, one side of the coin, and I'm playing devil's advocate, I'm not saying this is what I believe, is at some point you're doing so crappy your activity level is horrible. Your prognosis is horrible.

Do I know that I can do something to change your prognosis based on that activity level, or is that, as Ileana said, a prognostic tool that says, you know, effectively you have Stage 4 cancer?

DR. PINA: Actually, if you're using it correctly and somebody let's say was Class 2 and now they're a Class 3, you should be thinking about what is the next thing that

you need to do for that patient.

If the patient is an African-American, then they qualify for a vasodilator combination. If they haven't had a CRT and their QRS is widened and they're a Class 3, they definitely are candidates for CRT.

If they are still symptomatic and you haven't started them on an aldosterone blockade, those are all for the Class 3 patients that we know improve symptoms, improve outcomes, including hospitalizations and mortality.

So, there is sort of the next thing to do, which I think what's you're getting to, appropriately so.

DR. HOLLANDER: So, I guess my question summarizing that, I agree with all that, but maybe this should be the next thing that you need to document the care pathway is right based on symptoms and maybe we don't need a measure that's just based on symptoms.

So, I'm just throwing it out there.

DR. KOTTKE: Joe, you're wagging your head about something.

DR. CLEVELAND: Yeah, I think that I support the idea of the measure, but I have to agree with Judd's comments.

I think that maybe we're just not there yet with what are evidence-based, i.e., is this really something that can be of performance, or do we need to collect a little more information first?

DR. AL-KHATIB: I think it would be ideal to have data that show that if you assess and you intervene, you improve patient outcomes. We're not quite there.

But as clinicians, I think we all know how often patients, you know, underplay, if you will, their symptoms and they come to you like, oh, yeah, I'm okay, I'm okay.

But if you have some sort of objective assessment and that's the part that really appeals to me, it makes you think,

well, what else could I be doing in terms of optimizing their medications, in terms of considering procedures like cardiac resynchronization therapy.

And I can't tell you how many times, you know, if I just go by what, you know, the person who saw the patient first who said, oh, the patient is okay, they're doing fine, and I don't take the extra step of saying, well, let me see if I can get a more objective assessment of how fine they are.

I would have just not done anything, but, you know, based on those objective, you know, assessments and interventions, you have the potential to improve the quality of that patient greatly.

Yes, we need evidence, but I definitely see value in this as a first step toward doing that.

DR. WINKLER: I'm just a little bit concerned. We've gotten through the whole evaluation down to the last question and we're

going back and questioning the evidence.

So, I just would like you to, you know, kind of tell me where you're at there.

DR. CHO: Well, I kind of think it's kind of like the cardiac rehab referral and enrollment.

You know how like optimistically I hope that referral will improve enrollment. Like this, I hope that by endorsing this, we will improve patient -- quality of care for heart failure patients.

It may be optimistic. I may just need to go and, you know, go walk around and, you know, have some realism, you know, whatever, but I just hope that, you know, measures like this are a step towards what I hope to see later on, which is, you know, asking the patient's quality assessment and then, you know, rewarding physicians for good quality delivered.

DR. VIDOVICH: See, and the way I look at it is like we talked about the

indication for PCI and AUC criteria.

I could hope also if we do document that the FFR was 0.73, it will more likely end up with appropriate PCI.

Or if you say it was, whatever, daily angina, it's more likely that the patient should receive a stent then if it's really unstable, unchanged angina.

So, again, this indication is not ideal either, but it seems that the PCI world is maybe closer to this at AUC then the heart failure work. So, it's a good step in the right direction, but it's not perfect.

DR. KOTTKE: I don't think it's like cardiac rehab, because it's irrefutable that failure to refer to cardiac rehab is a barrier to cardiac rehab.

And it's not irrefutable that failure to write down class is a barrier to good heart failure care.

And there is potential for harm, you know, if you're taking six minutes of the

eight or ten-minute visit or whatever it is to document this every time and you expect primary care docs to do this, that and patients do object to forms and we can say, why don't you get the nurse to do it, but I don't, I mean, at Health Partners we've got to pay our nurses.

I mean, they're expensive, you know. And they've got a lot of work to do. And they, you know, come and punch you in the eye when you give them too much work, you know. They're not free.

DR. PINA: I disagree that the patients mind doing this. We hand it to them in the waiting room. We have the clerk at the front desk hand it, because we don't want to taint their assessment.

And it takes them eight minutes. And I've been doing this for over ten years. Haven't had anybody refuse, because we tell them very clearly this is all about how you feel. I'm interested in how you feel, period.

And they do it. And they fill it out very well. So, I don't think that the patients and the nurses don't do it. You can't have the nurses do it, actually. It's not the right

DR. HOLLANDER: I echo, you know, that sort of anecdotal experience and have no doubt your patients could do it at Montefiore, but across town at Jacoby they probably can't.

DR. PINA: We actually see those collected at Jacoby. Hate to tell you.

DR. KOTTKE: We have 80 different languages spoken as our first language in St. Paul.

Okay. Are we ready to vote oh, no, no, no. Thomas. This is the last

DR. JAMES: Realizing that Dr. Crouch is not here, I guess I'm the only primary care doctor left and standing.

I just keep wondering what Osler and Cushing would say about this measure. There is a lot to physiology that comes from

this kind of a physical assessment and I don't have the tools that you all as cardiologists have, but I do have this.

So, it may be who's being measured, that definition of "clinician," but I think this is this is something that I could adjust my schedule to when I'm seeing patients.

DR. KOTTKE: Go ahead and vote.

MS. LUONG: All right. The timer starts now. Vote one for yes, and two for no.

(Voting.)

MS. LUONG: 16 voted for yes, and three for no. And that concludes the voting for today. Thank you, everyone.

DR. KOTTKE: Okay. Thank you, everybody. We're done 35 minutes early.

MS. TIGHE: We're not done.

(laughter.)

DR. KOTTKE: If Lindsey talks quickly.

MS. TIGHE: We do need to pause for

public and member comment. Operator, if you could check if anyone on the phone has a comment and

THE OPERATOR: At this time if you would like to ask a question, please press star and the number one.

THE OPERATOR: There are no public comments from the phone.

MS. TIGHE: All right. Thank you, operator.

DR. WINKLER: In terms of follow-up activities, we will be putting these recommendations together for a report to go out for public comment.

We are talking about a follow-up call May 5th to tidy up some of the things that got left over from your conversation the last two days. And that would go that would be prior to this draft report we'll write.

The draft report is scheduled to go out for comment the end of May. It's a 30-day comment period. We get comments from

all sorts of folks and then we will meet with you by conference call in July to respond to those comments before they go to NQF's members for voting and ultimately through CSAC and the Board for final endorsement.

Now, in terms of the fact you're a standing committee and we don't end things at the end of that process, I can't we can't give you time frame, but we have every expectation that we will be reconvening you probably early in 2015 most likely at an in-person meeting.

However, as a standing committee, there may be issues that come up. Requests for ad hoc reviews of existing measures, you know, those sorts of things that we may call on you and need to schedule a call to ask for your input and decision-making.

And that's really one of the from our perspectives, one of the major advantages of having a standing committee. We can always go to you guys. You're there and

so, other things may come up that we just don't know about right now.

So, there will be a series of phone calls to finish this work up, as well as we truly expect that we'll do a similar set of measures early next year and at least annually.

But if you notice, we only got through 18 measures. And, you know, if we did that every three years, we still wouldn't get through the entire portfolio of 80 measures.

So, you know, we're working on the best logistics to get through and keep the portfolio updated and maintained over our three-year time frame.

This one is one of the big portfolios. It does have its challenges. So, we really do appreciate all the effort you have put in, the work and the time, and we definitely will be in touch going forward.

Lindsey, anything from you?

MS. TIGHE: No.

DR. WINKLER: No? Tom, Mary.

DR. KOTTKE: Well, thank you, everybody, for your hard work and your diligent thoughts and paying attention and getting done on time and happy travels.

DR. GEORGE: Right. And I just want to thank you all also. I know it's a big job.

DR. KOTTKE: Good job to our chairs, to our co-chairs.

(Whereupon, at 2:26 o'clock p.m. the meeting was concluded.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

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Before: National Quality Forum

Date: 04-22-2014

Place: Washington, D.C.

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