NATIONAL QUALITY FORUM

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CARDIOVASCULAR MEASURE ENDORSEMENT PROJECT 2014 STANDING COMMITTEE

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FRIDAY
DECEMBER 5, 2014

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

PRESENT:
MARY GEORGE, MD, MSPH, FACS, FAHA, Co-Chair
THOMAS KOTTKE, MD, MSPH, Co-Chair
CAROL ALLRED, Immediate Past Chair, WomenHeart: The National Coalition of Women with Heart Disease
LINDA BRIGGS, DNP, George Washington University School of Nursing
LESLIE CHO, MD, Cleveland Clinic*
JOSEPH CLEVELAND, MD, University of Colorado-Denver
MICHAEL CROUCH, MD, MSPH, FAAFP, Texas A&M School of Medicine
ELIZABETH DeLONG, PhD, Duke University Medical Center
TED GIBBONS, MD, FACC, FACP, FASE, Harborview Medical Center; University of Washington Medical Center*
ELLEN HILLEGASS, PT, EdD, CCS, FAACVPR, FAPTA, American Physical Therapy Association
JUDD HOLLANDER, MD, FACEP, Sidney Kimmell Medical College; Thomas Jefferson

University
THOMAS JAMES, MD, AmeriHealth Caritas Family of Companies
GERARD MARTIN, MD, Children's National Health System
KRISTI MITCHELL, MPH, Avalere Health
GEORGE PHILIPPIDES, MD, Newton-Wellesley Hospital
JASON SPANGLER, MD, MPH, FACPM, Amgen, Inc.
HENRY TING, MD, MBA, New York-Presbyterian Hospital and Health System*
MLADEN VIDOVICH, MD, Jesse Brown VA Medical Center; University of Illinois at Chicago

NQF STAFF:
HELEN BURSTIN, MD, MPH, Chief Scientific Officer
SHARON HIBAY, RN, DNP, Senior Director
WUNMI ISIJOLA, MPH, Project Manager
KAREN JOHNSON, Senior Director

VY LUONG, Project Analyst

ALSO PRESENT:

ILEANA PINA, MD, MPH, The Joint Commission

ELVIRA RYAN, RN, The Joint Commission

STEVE SCHMATLZ, PhD, The Joint Commission*

ANN WATT, MBA, The Joint Commission

* present by teleconference

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

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

(9:04 a.m.)

MS. ISIJOLA: Good morning, everyone, and thank you again for joining us for Day 2 of the Cardiovascular Project. Again, my name is Wunmi Isijola, and I'm joined here by Sharon Hibay, Karen Johnson, and Vy Luong.

We have a host of measures that we'll be considering today really being presented by the Joint Commission, and I will turn it over to our co-chairs, Dr. Kottke, and Dr. George to give us a recap.

CO-CHAIR KOTTKE: Good morning, thanks. Yes, I think yesterday was very successful. We've just had a chat with ACCF on 1524 CHADS2 and they realized that there's a couple of problems that they have, and so they are not going to put the measure forward at this time. They're going to reconsider whether to propose a totally new measure around anticoagulation rather than have us debate, and debate, and debate and still say not quite adequate.

That's all. Otherwise - yes, Judd?

MEMBER HOLLANDER: You know, I'm just thinking again that we went through a lot, and that's a perfect example of something where we could give them really good feedback, and they could make the measure much better. And it makes me wonder whether this whole Committee shouldn't function a little more in the journal model, where there's sort of a revise and reconsider. Can we get the stuff earlier before it's finalized? Like now we're voting yay or nay, and that's a bummer because there's some really great ideas that aren't getting through. And if we saw it and had input and could help shape it via a discussion like this earlier, I think the quality in the country would be a lot better. We'd be able to come out with a lot stronger measures. So, I don't know. Again, it's something we can't decide, but it's something that just, you know, to throw back for NQF to think about.

CO-CHAIR KOTTKE: I guess, I mean, I would say NQF has been working with them, and

this is - I mean, we see it at some point. You can only see it the first time for the first time. And I think they are doing the revise and reconsider, but they're just - we're on this sort of HAS-BLED and CHA2DS2-VASc, and is CHADS2 the state of the art anticoagulation decision calculator at this time? And they're going to have to think that through. I think there will still be plenty of people pushing anticoagulation and use of scores, it just won't be an endorsed measure.

CO-CHAIR GEORGE: Basically, we'll see this again in a slightly different version later on.

MS. HIBAY: Right, and just to be clear, we also just offered, and I know they will take up, ACC Group will meet with the staff from NQF to review. And just in general, as we continue to, you know, being the quality improvement experts that we all are at the table, as we continue to make sure our processes are up to what they need to be, and we're tweaking them.

That's the point of the preliminary analysis; we're also encouraging those measure developers to be coming to us as early as possible so we can be successful in getting good measures endorsed. There is a lot of positive energy around this measure so, you know, we'll do our best to work through those details.

MS. JOHNSON: And if you don't mind me adding a little bit to it, your role as a Standing Committee is a new role for us. And we have you down as the overseer of the portfolio, and that role, to tell you the truth, is new for us. And we're still trying to learn and figure out what that really means, but I think what you're talking about, Judd, is what we're thinking about in terms of that, being able to offer that advice early on. And developers, I think, are paying attention to that, so when we write that section in the report of, you know, suggestions for future development, we mean that. We put that in there for a reason, so that sort of feedback we definitely want to get documented

and get down.

MEMBER HILLEGASS: Can I ask about the other measures that were the stress testing, imaging, and all that?

CO-CHAIR GEORGE: We have two measures that we are deferring until after public comment.

MS. HIBAY: Correct. And 670, if I remember the number correctly, 670 is the measure that we're going to allow because of 671 and 672, we're going to allow the measure developers to bring back information, as well, at the post-comment call, because they're all so intertwined. The concepts are all so intertwined, so we said we would offer reconsideration at that time.

MEMBER HILLEGASS: But there was also a discussion about sending this to possibly another committee, like Resource and Cost, and you supposedly told us that Helen was going to tell us whether we could do that or not.

MS. HIBAY: Yes. We are going to address that after this meeting is over, after the two days are over, so I don't want you to

think that that's fallen by the wayside. We understand that request is still there. Helen is in and out over two days, and so to really give her a substantive review of the concepts that we discussed, we want to be fair to the discussion and the decision, if that's okay.

MEMBER JAMES: And just to that point, this is - it's the element of the three legs of the Triple Aim, and some of these measures hit multiple legs. So, that's why we're happier going down another leg than another, but I can understand why it -

MS. HIBAY: Yes, correct. Just for full disclosure, so my role before I came to NQF was working with the American Board of Internal Medicine, so I'm really familiar with the concepts of Choosing Wisely. And in my role, there were lots of societies who approached us and asked for measures that fit along the themes of Choosing Wisely. And I guess my head sees, and I think we mentioned in yesterday's conversation that the AUC measures were in part

done because of the Choosing Wisely, or to reflect Choosing Wisely.

So, you know, that's - these measures may come to many, many condition or disease-specific committees in the future, so I also wonder if there's an opportunity for us to provide additional guidance on how we can improve the - because we're all kind of learning as we go, but try to understand how we can review these consistently across committees, so this will be something that we bring back to Helen as well.

CO-CHAIR GEORGE: I just have one question. Are there any concerns or questions about the insufficient with exception option for voting? Okay. Just want to make sure everybody was clear on that.

MEMBER CHO: This is Leslie Cho. I just have a quick question. Sorry I couldn't join you afternoon -- yesterday afternoon. Did 1524, the measure developers, are they going to provide CHA2DS2-VASc2 score in the next revision?

CO-CHAIR KOTTKE: They'll probably -

they have to go back and decide what they're going to do. They will probably come in for round 4. Round 3 is in June; round 4 will be later. They don't think they can meet June, so they'll be back. They have to decide whether to retire CHADS2 and just go with CHA2DS2-VASc2 and HAS-BLED. They haven't quite decided exactly what they're going to do, so they have to regroup.

So, we'll start this morning with 2438. Do we have the developers, this is Joint Commission. Do we have the developers - and the discussants are Henry Ting on the phone, and Kristi Mitchell.

While the developers are joining us, who's on the phone? Henry, you're on the phone?

MEMBER TING: Yes, I'm here and prepared to present the measure.

CO-CHAIR KOTTKE: Leslie Cho is on the phone, and Ted Gibbons is on the phone. Anybody else on the phone?

DR. SCHMALTZ: Yes, this is Steve Schmaltz from the Joint Commission. I'm also

listening in.

CO-CHAIR KOTTKE: Oh, thank you. Okay, developers?

MS. WATT: Good morning. I just want to introduce ourselves. My name is Ann Watt, and I'm an Associate Director in the Department of Quality Measurement at the Joint Commission. Turn this one off then. Thank you.

Next to me is Elvira Ryan. She is our Clinical Lead for the Advanced Certification for Heart Failure and a member of our technical advisory panel. Ileana Pina, who I think is not a stranger to many of you, worked with the advisory panel that helped us to develop these measures. So thank you for having us.

MS. RYAN: Good morning.

MS. WATT: Do you want to start with the -

MS. RYAN: The introduction.

MS. WATT: Okay.

MS. RYAN: Okay. Good morning. Thank you for the opportunity for us to be here today.

This is a set of six standardized performance measures that were developed to support the Joint Commission's Certification Program in Advanced Heart Failure Care. The measure set was developed with an emphasis on the transitions of care, specifically the transition from inpatient to outpatient.

The Joint Commission's standardized systematic process for measure development was employed and initiated for the development of this measure set. And as a part of this process, as Ann mentioned, the technical advisory panel was established to define the scope of the measures and to recommend measures which would address key aspects of care.

The Advanced Certification Program was actually implemented in January of this year, and to date we have 58 participating organizations. And in order to participate for the certification process, it is mandatory that they collect all six of these measures and submit data to the Joint Commission.

CO-CHAIR KOTTKE: Okay, thank you. Who is - Henry or Kristi?

MEMBER TING: Yes, I think we agreed that I would lead the discussion and certainly Kristi would chime in.

So, this is Measure 2438, beta blocker therapy, specifically three long-acting beta blockers, bisoprolol, carvedilol, or sustained-release metoprolol for left ventricular systolic dysfunction prescribed at discharge.

I just want to make sure everybody can actually hear me okay through the phone.

CO-CHAIR KOTTKE: Sounds good.

MEMBER TING: The measure steward is the Joint Commission. The level analysis is a hospital facility. I'll start with the evidence. This is a process measure. I felt that the evidence was low to moderate, and the rationale being this is a Class 1 Level of Evidence A Guideline Recommendation from the heart failure recommendations. There is no systematic review provided in the - developed from the measure

developers.

Also, it's not explicitly stated in the - and it was admitted that this - the empirical evidence includes all studies in the body of the evidence. If we look at the guidelines, which sort of recommended this as Class 1 Level Evidence A Recommendation, there were six trials quoted in the guidelines from 1990 to 2003. In the proposal we were given from the measure developers, they quoted four different studies.

I would note that these studies are all from 2003 or older, and much has changed in heart failure therapy since that time.

The only other concern I had about the evidence is that although this is a Class 1 recommendation, the Class 1 recommendation is not for prescription of these three medications at the time of discharge. The benefits of these drugs are actually from long-term therapy and compliance, not for prescribing these medications at the time of discharge.

CO-CHAIR KOTTKE: So, Tom here. I guess I have a couple of questions. You imply that maybe by saying that a lot has changed in the last 12 years, so are you suggesting that the prescription of these drugs is no longer -

MEMBER TING: I'm suggesting that the studies being used to justify the evidence is from 1999 to 2003, and we all know much has changed since that time. I don't think we know if these drugs have the same relative benefits in the setting of the other medications and therapies we're using for heart failure patients.

CO-CHAIR KOTTKE: Are you aware of trials that have been done since 2003?

MEMBER TING: I have not done that analyses myself, but that was not provided by the measure steward either.

CO-CHAIR KOTTKE: Okay. And the other question is if it's long-term, when would you suggest the drugs be started?

MEMBER TING: Well, you know, when these patients are discharged, I could imagine a

situation where they're sick enough that you might start them on a short-acting drug so that you can titrate and escalate them, and then convert them over to these long-acting beta blockers. I'm not questioning the benefit of a long-term beta blocker, both for compliance and benefit, but at the time of discharge I could imagine patients potentially being discharged on a short-term beta blocker because you're going to be escalating other therapies and eventually converting them in the next 30 days, two months, or three months to a long-acting beta blocker. Again, this measure is looking at beta blocker prescription of these three long-acting agents at the time of discharge.

CO-CHAIR KOTTKE: Okay. Mladen and then Judd.

MEMBER VIDOVICH: Well, I probably would want to add to this that I think the evidence is quite strong. Maybe it may not have been presented in the measure, but I think there is - I probably can't quote because I'm not

specifically a heart failure specialist, but I mean there's good evidence that if medications are not started in the hospital, they may not be continued. And I think the escalation of medication in the hospital and then continuation has also been shown, I think more than once, to be associated with compliance and good outcomes. So, while perhaps it might have not been presented, I think the data for this is quite overbearingly strong to suggest that this would be an appropriate measure, I think.

CO-CHAIR KOTTKE: Okay, thanks. Judd, can I have Ileana make a comment or offer something?

DR. PINA: Thank you. Thank you for asking me to come. I really appreciate it. So, first of all, we haven't needed new mortality trials since 2003-2004 because beta blockers are entrenched as part of what we now call GDMT or Guideline Directed Medical Therapy. However, having said that, there's been an evolution in the way that the guidelines have looked at this.

There are two studies, one is called IMPROVE HF, and one is called OPTIMIZE, that showed very clearly that if the beta blockers are not started in the hospital there is a high likelihood that at six months the patients will not be on it.

In addition, these new guidelines published in 2013 clearly state that the beta blockers and the ACE inhibitors should not be stopped at the time the patient is admitted, so I see this measure as both reinforcing the fact that stopping the beta blockers is not indicated and that most decompensations have nothing to do with the beta blocker. But, again, getting the clinicians thinking that they need to - if they haven't been on it, they need to start it because of that high likelihood.

The drugs are lifesaving: 34 percent mortality reduction, reduction in rehospitalizations, and ventricular improvement. I mean, we reverse about a third of our patients with beta blockers, so I think that adding this

to the sort of the thinking at the time of discharge to me is like really critical and keeping right with the guidelines.

CO-CHAIR KOTTKE: So, are ready to vote on evidence?

MEMBER TING: So, just -

CO-CHAIR KOTTKE: Go ahead.

MEMBER TING: This measure has nothing to do with stopping beta blockers. And the issues that have been brought up about sort of compliance and prescribing this medication at the time of discharge, and compliance of patients afterwards was not anywhere in the proposal. And I'd like to see some evidence about compliance rates on patients who are prescribed at the time of discharge because most studies looking at medications prescribed at the time of discharge and looking at long-term compliance at one year, and two year indicate that close to half of our patients have stopped Guidelines Directed Medical Therapy for most cardiovascular conditions at one year despite being prescribed for them at the

time of discharge.

We note that the primary non-compliance rate with these medications is probably 20 percent primary, means they never fill it, and about 50 percent at one to two years, meaning they stopped it themselves.

CO-CHAIR KOTTKE: Are we ready to - Judd, oh?

MEMBER HOLLANDER: Just one question. This - my reading of this and, you know, I haven't read every word. I wasn't one of the primary reviewers. It's just beta blocker therapy. It's not limited to these three long-acting beta blockers. Is that correct?

MEMBER TING: No, it's for these three specific long-acting beta blockers at the time of discharge, Judd.

MEMBER HOLLANDER: Oh, okay. Thank you for clarifying.

CO-CHAIR KOTTKE: Okay. Are we ready - George?

MEMBER PHILIPPIDES: I can - let's

vote.

CO-CHAIR KOTTKE: Okay. Are we ready to vote? Oh, no, sorry, Liz.

MEMBER DeLONG: I guess not being a physician treating heart failure, I'm totally confused. I mean, we have Henry saying there's no evidence. We have other people saying there is, but apparently evidence was not presented sufficiently within this application.

CO-CHAIR KOTTKE: No. Henry is not saying there's no evidence; Henry is saying there's no evidence since 2003. Ileana says the reason there's no evidence since 2003 is that the evidence before 2003 is so clear that there have been no subsequent trials. The reason that it's long-acting beta blockers is that's what was used in the trials, and so it's specific to the evidence. And there's - I'm not a heart failureologist either, but there's a difference between short-acting and long-acting beta blockers in efficacy for the treatment of heart failure.

DR. PINA: Actually, carvedilol is a short-acting form that's being recommended; it is not the long-acting form. The only long-acting form here happens to be metoprolol succinate because the short-acting form had a negative trial versus carvedilol, which is why we use succinate which is what was done in the trial MERIT-HF. Bisoprolol happens to be a long-acting just pharmacologically, has a long half-life, that's all.

MEMBER TING: Let me try again. Maybe I wasn't as clear or effective in my communication. I think the evidence is clear that if you take these three medications long term and stay compliant to them, there is benefit in terms of heart failure mortality. There's no disagreement on my end or with Ileana on that issue.

The question that's at issue is, at the time of discharge prescribing these three specific beta blockers, calling them out, is that associated with long-term survival benefit?

There's not a single study that says prescribing these three specific medications at the time of discharge improves survival -- no randomized trial. It would be assumptions that prescribing these medications at the time of discharge would correlate to what was done in the trials, which is randomized trials of patients taking these medications long term. I think that's the evidence.

CO-CHAIR KOTTKE: Okay, other - seeing nobody sneaking toward their name tag, let's vote on evidence.

MS. LUONG: Polling for evidence starts now, one for high, two for moderate, three for low, four for insufficient evidence, and five for insufficient evidence with exception. Evidence passes with 25 percent voting high, 69 percent voting moderate, and 6 percent voting low.

CO-CHAIR KOTTKE: Thank you. Henry, performance gap?

MEMBER TING: So, the opportunity for improvement was provided by the developers. The

data and the literature from 2003 to 2004 found that 78 percent of patients with heart failure were discharged on beta blockers. I don't know whether they mean any beta blocker, or these three beta blockers. That's not specified.

During pilot testing of this measure at nine sites involving 878 patients total, the performance varied from 61.5 percent to 100 percent. No data was provided by the developers on any disparities in the application.

CO-CHAIR KOTTKE: Thank you. Any discussion, any - are we ready to vote on performance gap? I believe we are.

MS. LUONG: Polling for performance gap starts now, one for high, two for moderate, three for low, four for insufficient. Performance gap passes with 37 percent voting high, 58 percent voting moderate, and 5 percent voting insufficient.

CO-CHAIR KOTTKE: Thank you. Priority?

MEMBER TING: So, for priority there's no question congestive heart failure is a

national health priority, and it's something that cardiovascular professionals must focus on. My concern is that I'm not sure that this specific measure is a national health priority, and this is a measure using one of these three beta blockers at the time of discharge.

Again, I just want to express that my concern is that I don't think there's a body of evidence that measuring this measure prescribing of these three medications at the time of discharge has been correlated or linked to any desired health care outcome.

CO-CHAIR KOTTKE: Sure.

DR. PINA: So, in both IMPROVE and in OPTIMIZE, the patients who were not on beta blocker at the six-month level and had not, therefore, been started early had a greater number of rehospitalizations, so we do have some link to outcomes by the absence.

I also want to point out that there are other beta blockers that have actually had negative trials in heart failure, including

bucindolol and metoprolol tartrate, so you really can't expand this and say beta blockers. And the others really haven't been studied.

CO-CHAIR KOTTKE: Thank you.

MEMBER TING: So, Ileana, that's at six months. Right? That's not at the time of discharge.

DR. PINA: Right, right, but the study -

MEMBER TING: I mean the measure --

DR. PINA: Yes, the study looked at patients being discharged on the drug, and then were they subsequently - that was the question that the Registry asked, is if they were -

MEMBER TING: Yes. And I'm just questioning the time - I'm not questioning at all that these drugs are helpful and beneficial if patients take them long term. The question is whether prescribing just these three medications at the time of discharge is an issue for me, because I don't think there's evidence, and I have yet to hear any evidence quoted that

discharge for the - on these three medications correlates to any health outcomes.

CO-CHAIR KOTTKE: Okay. Gerard, and then Judd.

MEMBER MARTIN: I think a question for you. Are you getting at the whole idea that who is - who would be more likely to prescribe this, whether it's the hospital-based physician, or the primary care physician, or outpatient cardiologist? Is that the issue?

MEMBER TING: Are you asking me?

MEMBER MARTIN: Yes.

MEMBER TING: Yes. No, I'm getting at, I think - I want a measure that we're going to hold people accountable for, for improvement for endorsed by NQF to actually reflect actually what the evidence says, which is are you taking these three beneficial medications long term? And creating sort of these interim surrogate measures which we think may be correlated, but we have no evidence thereof, is creating sort of clerical checklists for people to do. And if these

patients are just simply discharged on it and never fill it, and there's no mechanism to keep them on it at six months or a year, there's no benefit.

CO-CHAIR KOTTKE: Judd?

MEMBER HOLLANDER: I'm wrestling with this because I think Henry is right, but I think Ileana is right. I mean, the best time to start the medication is the time of discharge; there's no doubt about that. Every time it's ever been looked at, if you don't start it at discharge, it doesn't get started.

On the other hand I talked yesterday about something I feel passionate about, that you can't take data from the outpatient setting over the long term and appl it to the acute care setting. It doesn't work. And, in fact, the ACCHA guidelines on heart failure basically say nothing about the acute management of heart failure. There's not a single therapeutic Class 1A Level of Evidence A recommendation in those guidelines, not one. There's two pages in the 8 million pages

of the document effectively that focus on acute care. And I'm afraid of the slippery slope here, and the slippery slope is taking what we know chronic and now applying it to the tail end of the acute care setting, and that's dangerous. The next step would be: everybody needs to get this when they get into the hospital, so it's not - and I agree with you, Tom, it's not exactly the same, but it's getting closer to that.

So, I think what we need from an evidence-based point of view is more research in the acute care of heart failure patients and what the right therapies are, and then we could develop the guidelines. So, I'm just saying this is in a funny area where somewhere between what Ileana and what Henry say is at least the way I feel about it.

DR. PINA: So, we just reviewed the literature and we have a paper in the American Journal of Cardiology actually this month as a commentary to exactly what you're saying. Most of the acute heart failure trials have only really

looked at the first 48-72 hours, and they will really take you to what you do later, but it's a problem because if you don't give the diuretics, if you don't give the ACE, if you don't give the beta blockers, they'll be back, two weeks I guarantee. So, we went through the literature, and actually the paper we are recommending that we need more research into that transition from the very, very acute to sending them home, which is an element of four and a half days. That's all you've got, is four and a half days. And we're encouraging, you know, sponsors of acute trials to really not to stop at their drug, but to take the clinicians to the next step.

So I was just looking at the improved data. There's actually a 10 percent improvement in ejection fraction in IMPROVE, which looked at the earlier adoption of beta blockades.

CO-CHAIR KOTTKE: Ted, you have the floor.

MEMBER GIBBONS: Yes, thanks. This reminds me of an earlier core measure for

measuring ejection fraction where although there wasn't any evidence, you have to measure it in the hospital. It was quite efficient to do so, or you had to state that you had a plan to measure the ejection fraction in follow-up. So, it seems that many of the subtleties here may be that there is a plan to begin beta blocker, and if the patient is stable enough from a hemodynamic standpoint you can begin it in the hospital, or make a statement that you will begin it with the first week or two of post-discharge follow-up based on the patient's recovery.

So it seems that in terms of how people actually practice, that it makes sense to have it optimal to have it prescribed at discharge, but to have a plan to begin it when the patient is a candidate for it.

MEMBER TING: I think that's a great summary of it. This is Henry, again. I think we've seen both sides, and again it's not the evidence that long-term therapy with these three beta blockers improves survival. I don't dispute

that at all. It's when you start in when the patient is stable, because we've seen the other side, as well, where, you know, previously we know that with spironolactone/Aldactone that those are beneficial for heart failure, and there's studies that show that they were beneficial for heart failure. And we started them at the time of discharge because everybody thought that's when you had to do it, and then we had more readmissions because of hyperkalemia. So, you know, ideally all of us who are taking care of these type of patients would want to make sure that we're starting the medications that are evidence-based when the patient is able to take them, even acute or subacute outpatient setting, and escalating them, and not just putting them on a single standard dose.

So, my only quibble with this is the fact that you're creating a measure that's going to be held for accountability or quality improvement, and it's at the time of discharge as opposed to what has been described as optimally

getting these patients on it for the next 12 months, or 24 months.

CO-CHAIR KOTTKE: So -

DR. PINA: Let me just say - I'm sorry.

CO-CHAIR KOTTKE: I've been asked to redirect the -

DR. PINA: Okay.

CO-CHAIR KOTTKE: We voted on evidence already. It's passed evidence. We're discussing priority. Anybody have anything to say about priority? Linda does.

MEMBER BRIGGS: So, I think that we all agree that priority of heart failure and heart failure treatment is a very high priority across the nation. There's a large number of patients, it's like the number one reason for admission in the hospital, very high readmission rate, there's 20 percent I think or more that was quoted as a statistic in here. It's a high cost, so in terms of priority I think we have good evidence that there's high priority.

MEMBER TING: High priority for heart failure which I agree with. Is there high priority for this specific measure, which is what we're being asked to vote on?

CO-CHAIR KOTTKE: Right, so that's been raised. Gerard, are you - okay, everybody has their - are we ready to vote?

MS. JOHNSON: Can you let me just add in a little bit? I know high priority is a confusing criterion, and as a matter of fact we are seriously thinking about what we're going to do with this, but what we really want you to think about is the priority of the - what the measure addresses overall, so not the details of the measure per se, but basically this is a heart failure measure that is a high priority. So, it's a little bit of a higher level think about priority.

(Simultaneous speaking.)

MEMBER VIDOVICH: Priority of heart failure, priority of beta blocker are we voting, or priority of those specific beta blockers?

Right? I mean, you can split this in several components. Right? Because I think we just dissected this into multiple pieces. Right? It almost seems that yes, giving these beta blockers in setting of heart failure patients makes sense, but are we splitting this into specific beta blockers that we are voting for, or -

CO-CHAIR KOTTKE: My understanding from Karen is that it's priority of heart failure, that it's priority of the condition.

MEMBER VIDOVICH: Priority of the condition. Okay.

CO-CHAIR KOTTKE: Carol, did you have something?

MEMBER VIDOVICH: So, not - we're not voting on bisoprolol. Okay.

MEMBER ALLRED: Yes. I would just like to add from the patient standpoint, I would consider these a high priority for quality of life.

CO-CHAIR KOTTKE: Thank you. Are we ready to vote? It looks like we're ready to vote.

MS. LUONG: Polling starts now for high priority, one for high, two for moderate, three for low, and four for insufficient. High priority passes with 58 voting high, 37 voting - 58 percent voting high, 37 percent voting moderate, and 5 percent voting low.

CO-CHAIR KOTTKE: Thank you. Scientific acceptability and reliability. Henry?

MEMBER TING: Sure. So, the numerator statement is patients who are prescribed on one of these three beta blockers for LV dysfunction at the time of hospital discharge. The denominator statement is patients with heart failure with current or prior documentation of ejection fraction of less than 40 percent. There's quite a long list of exclusions from the denominator which is provided by the measure developers. The data source includes electronic clinical data, electronic health records, paper medical records, and pharmacy.

With regards to - I'll stop there, that's the scientific acceptability.

CO-CHAIR KOTTKE: Issues or concerns, then reliability. Kristi?

MEMBER MITCHELL: For the measure developers, I notice that there is quite a bit of detail around particularly the ICD-9 and a crosswalk to ICD-10, but not as much detail around the - the data elements that were captured in the Registry or in electronic medical records. Is there an implementation manual of some sort that could be submitted in addition to this application?

DR. PINA: So, Get With The Guidelines, HA has a very large registry, adopted this as a measure even before the guidelines. We had a lot of discussions about this and we adopted it even before the guidelines, so we now have data in there that needs to be mined to see what there is. And I can certainly suggest that to the scientific committee of Get With The Guidelines for us to take a fresh look because we have now thousands, and thousands, and thousands of patients. And now we have a 30-day form that we

didn't have before, so we are going to know what happens to those patients at 30 days. And I think that's a great idea.

CO-CHAIR KOTTKE: Other issues with reliability?

MEMBER TING: Oh, reliability?

CO-CHAIR KOTTKE: Yes.

MEMBER TING: I thought we stopped with scientific acceptability.

CO-CHAIR KOTTKE: No.

MEMBER TING: The reliability I have several comments.

CO-CHAIR KOTTKE: Okay, fire away.

MEMBER TING: Okay. So, reliability testing was done at the nine participating pilot sites. The Joint Commission actually went to visit these hospitals from April to July of 2012, and actually re-abstracted 201 medical records, so reliability was actually tested by what was reported versus what the Joint Commission saw when they sort of re-abstracted the charts.

There inter-reader analysis

reliability had a kappa ranging from .31 to .77, so with the specific data elements that were extracted the prescription of the three beta blockers at the time of discharge actually had a kappa of 0.72 which indicates substantial agreement. For documentation LV systolic dysfunction less than 40 percent, the kappa was 0.77, again, demonstrating substantial agreement.

The documentation of reasons why the patient was not prescribed one of these, so exclusions, or documentation why a patient couldn't take one had a kappa of 0.33, which is quite low, and only shows a fair agreement. So, that is a concern specifically with the documentation of why patients had a contraindication or were not discharged on it. And there was quite a bit of disagreement between what was reported from the sample size versus what the Joint Commission found. In fact there was in that sample 25 mismatches for what was abstracted versus what the Joint Commission found on manual review of the charts.

CO-CHAIR KOTTKE: Linda?

MEMBER BRIGGS: Looking at that section, there is a bullet point that says no reason for the bisoprolol and other drugs that we've been talking about. The sites didn't realize that the documentation of a reason for administering beta blockers was not required for patients with an LV, or systolic dysfunction greater than 40. So, it's, I guess, again, education around the particular measure that was maybe the issue there based on what's reported, anyway.

CO-CHAIR KOTTKE: I, frankly, myself am not too concerned about the reason. With multiple providers entering opinions into the chart, it's easy for one abstracter to choose one, and one to choose another. You know, I think the crucial is the ejection fraction and whether or not they were on the drug.

MEMBER TING: Well, I think that's an assumption, Tom. I would agree with you if that was the reason. I don't think we were provided

that level of detailed granularity as to why. Was it just they chose different ones, or whether there was documentation of exclusions when none existed. You know, because you can imagine patients being documented as being exclusions when they should have been on this beta blocker at the time of discharge. So, I was not given in the proposal the reasons for this low kappa, and where the disagreements occurred, so from a pure reliability perspective I didn't feel like it was sufficient, or it was quite low for that specific reason. Because there's a very long list of exclusions, and I don't know whether it was just because they picked different ones, or whether it wasn't done when it should have been done.

CO-CHAIR KOTTKE: Ileana, or anybody have any -

MS. WATT: This is Ann. As noted, a large part of the reason for the disagreement was because the abstracters in the hospitals did not have a clear understanding of the specifications with regard to the ejection fraction, so they

were looking for reasons where they didn't exist. That's one.

The other thing is that what we find is that sometimes the hospitals who are doing the abstraction for these pilots tests, they have -- they're clinically savvy people because generally it's done in that service, and a lot of times we find that they infer that, oh, well, obviously it wasn't done because of this, but there is no direct documented link the medical record. And our instructions are that unless there is a link in the documentation between the condition and not doing something that it doesn't count.

DR. PINA: There's been some back and forth about the level of 40, 35, and some trials have used 40, and some trials have used 35. There really isn't a heck of a lot of difference between 35 and 40. And if you go even higher up a little bit, 40 to 45, that's really like the gray zone. So, I think that a lot of people interpret 40, or interpret 35. I don't think there's that much.

MEMBER DeLONG: I'm a little bit concerned that if there is a long list of exclusions that must be because there's potential harm. Is that right? I mean, why a long list of exclusions if it's perfectly fine to give it to all of these people? Are we not worried at all about downside risk of promoting measures that could have an impact on the wrong patients?

DR. PINA: I can answer that clinically. It is very rare the day that I can't start a beta blocker. And, for example, below 18 we need to exclude because the data in the pediatric population is not as robust as it is in the adult population. And you have to tell them about worsening heart failure. You have to do that because that's part of the labeling of those drugs. But like I said, it's a rare day that I can't start a beta blocker in the hospital.

CO-CHAIR KOTTKE: George?

MEMBER PHILIPPIDES: This is mostly to educate myself, Ileana. I've seen cases where patients get started on metoprolol, not the long-

acting form, not succinate with the intention that when they get to the next visit outpatient they'll be switched over. By this metric, that would be a bad performance. Is that correct? And I understand there's a comparison between short-acting metoprolol, I believe, and carvedilol, but are saying that metoprolol short-acting is worse than not starting it all in the hospital?

DR. PINA: You bring up a great point. So, the true metoprolol tartrate dose for heart failure is actually TID, if you look at the pharmacology of the drug. And we don't have any data on that because even the COMET trial was done on BID, and I think it was obviously stacked up so the carvedilol would look good. And the mortality really wasn't that different, but the hospitalizations rate were.

I don't know that I would penalize anybody for starting metoprolol tartrate with the plans to switch them over to succinate at the first visit, but there are side effects to the tartrate, like a drop in heart rate that may be,

you know, when the drug peaks, a drop in blood pressure when the drug peaks, and succinate just gives you such a nice even keel absorption and blood level that the patients tolerate it extremely well, and even the blood pressure doesn't drop much.

I mean, in our place where I am fighting constantly Guideline Derived Medical Care, patients are going home on like 90 percent beta blocker which is pretty darned good.

MEMBER TING: So, Ileana, or maybe the measure developers, since we're discussing the exclusions and Liz brought it up, one of the listed exclusions from the denominator is, and I quote, "Patients with a documented reason for no bisoprolol, carvedilol, or sustained-release metoprolol at the time of discharge." That's it, so there's no further indication that you just have to document a reason, but it doesn't give you the clinically appropriate reasons.

MS. WATT: That's correct.

MEMBER TING: So what is a clinically

valid versus invalid reason to give the checkbox and exclude that patient from the denominator of this measure?

MS. WATT: The measure doesn't address what is a clinically valid versus a clinically invalid reason because we - the Joint Commission generally speaking does not establish goodness or badness of reasons because we understand the physicians have a stronger understanding of a patient's particular case. So, if a doctor or nurse practitioner, advanced physician's assistant and so on documents a reason and links it, that counts. I'm doing air quotes here for the purpose of that measure.

CO-CHAIR KOTTKE: Yes, this is inferential, but it's - I think it's the reason ACC Guidelines say strongly recommended versus must, just that it's always defer to the individual physician's judgment that they may know something about the patient that we can't predict into the future, but that's inferential.

Are we ready to vote on reliability?

MEMBER TING: But, Tom, doesn't that become sort of a potential issue of gaming and just documentation, because if my reason is because I want to start short-acting metoprolol with a plan to convert to long acting at, you know, the first medical visit. Ileana pointed out that is an inappropriate reason, I don't want to start the long-acting metoprolol. So, this measure theoretically with any appropriate documentation become 100 percent for everyone.

CO-CHAIR KOTTKE: Sure, sure. Yes, any guideline can be gamed. Any time you leave it up to professional judgment can be gamed, but if you eliminate professional judgment you won't get any guidelines.

Are we ready - yes?

MEMBER MITCHELL: Yes, but I just have to comment. We're talking about measures now and not guidelines, so the concept of gaming the system is incredibly important in this context. So, to Henry's point, I do think we need to better understand what that exclusion criteria -

what is it, because I don't think we want to put forth a measure in which we're setting it up to game the system.

CO-CHAIR KOTTKE: Anybody else have a comment in response to that? Seeing none, let's vote on reliability.

MS. LUONG: Polling for reliability starts now, one for high, two for moderate, three for low, and four for insufficient. Reliability passes with 11 percent voting high, 68 percent voting moderate, 16 percent voting low, and 5 percent voting insufficient.

CO-CHAIR KOTTKE: Henry, would you like to talk about validity?

MEMBER TING: Yes. So, when I looked at validity, the statistics that were done for reliability testing and validity included just nine hospitals. The overall rate was 87 percent with a minimum of 61, and maximum of 100 percent.

Because of this rather small sample size, beta blocker therapy was correlated but did not reach any statistical significance in

correlating with other measures of heart failure, including discussion of advance directives, as well as post-discharge evaluation of heart failure patients. So, there isn't really I felt sufficient evidence that this measure was - has enough data for validity testing with other measures of heart failure performance measures based on what was provided.

CO-CHAIR KOTTKE: Any other discussion? Seeing no action, are we ready to vote on validity and threats? Any other - Henry, do you have any other comments on threats to validity?

MEMBER TING: Other than I didn't find evidence of -

CO-CHAIR KOTTKE: Okay, let's vote on validity.

MS. LUONG: Polling starts now for validity, one for high, two for moderate, three for low, and four for insufficient. Measure 2438 passes with 11 percent voting high for validity, 58 percent voting moderate, 26 percent voting low, and 5 percent voting insufficient.

CO-CHAIR KOTTKE: Henry, would you like to talk about feasibility?

MEMBER TING: I'm not sure that I have anything else to say other than what's been stated about feasibility.

MEMBER MITCHELL: So, it stated in the proposal that five sites dropped out, but the reason wasn't as clear as to - I think they started with 15 sites in total and they ended up with nine that comprised the sample. What were some of the reasons for the drop out?

MS. RYAN: The pilot actually was conducted during the summer months, and that's a time when a lot of the facilities are lower on staff because of vacations. And at the time of the pilot it was more or less having the resources to do the abstraction. Sometimes when the staff turns over they start out with a project with certain lead staff, and the staff turns over mid-project, and then that creates some conflict for the organizations.

CO-CHAIR KOTTKE: I have a question. Do

you compensate the sites for - you do not compensate the sites for participation.

MS. WATT: No, we do not.

CO-CHAIR KOTTKE: Okay, thank you.

MS. WATT: No, we don't.

CO-CHAIR KOTTKE: Okay, yes. So, that - I mean you can tell your Health Partners eager to jump in, you know, we think twice.

MS. WATT: We'll remember that.

CO-CHAIR KOTTKE: We do do some testing, but it - I mean, it's real, it's a real burden on the organizations to participate and collect these data.

Okay. Feasibility, seeing no - oh, I do. Linda?

MEMBER BRIGGS: So, I did have a question again about the five sites dropping out. And the other piece is in the feasibility it talks about how much time and cost was computed, 30 minutes per measure, $10.34 to take care of this, but these same statistics are listed for several measures. And while they may have all

been done in the same sort of batch, I would kind of posit that different measures require different amounts of time for you to collect that data, particularly since you had developed a tool for a pilot or whatever, but yet said that sites were free to do whatever they want going forward in terms of how - if they want to design their own tool, blah, blah, blah. So, I don't think we have a really good feel for how much each individual measure actually did cost per site, and so I'd ask you to clarify that.

MS. WATT: I don't know, is the short answer. The longer answer is because, as Elvira noted, all six of these measures are required to be collected in real life, there's one data collection tool that collects all of the data elements for all of the measures, and it was that whole collection period that you see, you know, the 30 minutes and the $10 or whatever it was. And I really can't break it out by individual measure because that's just not the way that they abstract. And that's why you see the same number

reported because it's for the entire set.

CO-CHAIR KOTTKE: Okay. Let's vote on - oh, Judd, sorry.

MEMBER HOLLANDER: So, I see this as a reasonably burdensome measure because you can't do it electronically. You need to go into the record to see why somebody did or did not give a drug. I mean, if they give one of these three drugs it's easy, you could probably get that from your EMR, or figure that out easily from coding stuff. But if they didn't get it, then someone really actually has to dig into the chart to see what the documentation is. So, this is a little more complex.

I mean, on the opposite side of my argument people managing care transitions for heart failure patients, and there may be somebody that this would be tagged to, but it's actually a real cost. It's not an easy thing to do.

CO-CHAIR GEORGE: It's stated in the - I think for all of these measures that they are planning to retool them as e-measures. Is that

correct?

MS. WATT: This is Ann. That is correct. You know, the problem is, and we've been doing - and I'm sure that you all are involved with this, too, have been doing significant work in trying to re-engineer measures for the medical record, or the electronic medical record. And what we're finding is unless you have these data in standardized fields that you're using structured vocabularies, you can't collect the data. So, unfortunately, at this point anyway, it's very difficult to get complex clinical measures reported via the EHR. We're working on it, we're trying, and that is the goal down the road.

DR. PINA: The hospitals have become very aware of this 30-day readmission rate, and the penalties that they're paying which are pretty high this year because it's of the total Medicare charges. So, they've come up with committees and groups to try to do this, so I think a lot of the hospitals are doing this, and

they are spending the time. They have a set of abstracters that are actually going into the records to try to find out what is driving the 30-day.

CO-CHAIR KOTTKE: Okay, seeing no further action, let's vote on feasibility.

MS. LUONG: Polling starts now for feasibility, one for high, two for moderate, three for low, and four for insufficient. For feasibility 5 percent voted high, 58 percent voted moderate, 32 percent voted low, and 5 percent voted insufficient.

CO-CHAIR KOTTKE: Usability and use, Henry?

MEMBER TING: So you use and usability is the extent to which potential audiences, consumers, purchasers, providers, policy makers are using or could use these performance results for both accountability and performance improvement to achieve high-quality efficient care for patients of populations.

Again, I think the concern as I've

already expressed with sort of you can document any reason to exclude them from the denominator, and this is just a prescription of these three medications at the time of discharge, so I felt that was low.

CO-CHAIR KOTTKE: Anybody else have - seeing no name tags, let's vote on usability and use.

MS. LUONG: Polling starts now for usability and use, one for high, two for moderate, three for low, and four for insufficient information. For usability and use, 11 percent voted high, 47 percent voted moderate, 42 percent voted low.

MS. JOHNSON: This is not a must-pass criteria so we don't really talk about present for this one.

CO-CHAIR KOTTKE: So, we're ready for overall up or down.

MS. LUONG: For overall suitability for endorsement, one for yes, and two for no. Polling starts now. For measure 2438, 89 percent

voted for overall suitability for endorsement of the measure, and 11 percent voted no.

CO-CHAIR KOTTKE: Okay, thank you very much. Thank you for your comments, Henry. we appreciate -

MEMBER TING: There's actually an issue of competing measures, Tom.

CO-CHAIR KOTTKE: Oh, okay, go ahead.

MEMBER TING: There are actually two competing measures which are actually more than competing. Measure 0083 for heart failure is beta blocker therapy for left ventricular systolic dysfunction, measure 0615 heart failure is use of beta blocker therapy. So, I think these are actually not just competing, they're conflicting.

MS. HIBAY: So, the measure for - the competing measure 0083. Henry, I think that's what you're speaking to.

MEMBER TING: And 0615. They both refer to beta blocker therapy for heart failure.

MS. HIBAY: Okay. So, 0083 is at that point anticipated to be reviewed the next phase,

the next phase of the project, and we will do the competing conversation at that time. It might get delayed to the next one. We're still not totally sure on the phasing because we have so many measures already for the next phase. So, we are - we would like to defer the conversation of competing until the time when 0083 comes up.

MEMBER TING: And 0615?

MS. HIBAY: I need to look into when the phase comes up for that one, Henry.

MEMBER TING: Just in our library that you sent us, so I'm just trying to pick those out.

MS. HIBAY: Very good.

MEMBER BRIGGS: Is the 0083 an existing measure?

MS. HIBAY: I'm sorry, can you ask the question again?

MEMBER BRIGGS: Is 0083 heart failure beta blocker therapy for left systolic dysfunction, is that an existing that would be up for renewal rather than a new measure?

MS. HIBAY: 0083 is up for maintenance at this point in time for the next phase. We still have to -

MEMBER DeLONG: So, it seems as though we should be packaging competing measures together, and that competing measures should have been rolled into the discussion before we got to suitability for use. I'm - I feel not competent enough to vote against this measure, but I do think it creates a slippery slope of gaming the system and imposing a convention on practice that isn't fully specific enough.

MS. JOHNSON: So, let me at least address your first question about why aren't we discussing these things in tandem? And, actually, that was our plan originally, and what happened with Phase 1, you guys may not have realized it, but we ended up getting a whole lot more new measures in Phase 1, so these were actually - we were initially planning on talking about these in Phase 1 and all of these together. And we've had to move them because new ones came in the door,

so we did try but, unfortunately, we just had too many to be able to do it. So, that's why we're actually going to push the competing of these measures to the next phase so that you guys will be able to look at both in depth, and then make a decision if you need to on best in class or superior.

MEMBER DeLONG: But we've already decided on this one.

MS. JOHNSON: Right. So, this one -- what this one means is is that for now if all goes through, it would be endorsed, you know, again if all goes through. The next time when you do the next one in Phase 3 or 4, wherever it lands, you'll have that discussion for that measure, and then we'll decide then at that point if they really are competing. We would ask you to select the best in class, if you can, or else provide some rationale and justification of why it's appropriate to have more than one measure at that point.

MEMBER HOLLANDER: Let's say we have a

competing measure that comes up in Phase 3 or Phase 4, but this measure is not there, and we like the competing measure better, what happens?

MS. JOHNSON: If you had one in Phase 3 or 4 that points back to this one? We will be looking at those, just like we'll be looking - or we'll actually be looking back, so as a matter of fact on your post-meeting call we actually will be seeing that scenario, and we're going to be doing that. So, there was something that was passed in Phase 1 that is directly competing to something that you're looking at right now in Phase 2, so we're actually going to do that scenario in your post-meeting call.

CO-CHAIR KOTTKE: Tom?

MEMBER JAMES: My understanding had been that the roles of the work groups is to be able to judge the suitability and scientific appropriateness of individual measures, not to make determinations as to prioritization. And I think you're hearing is - and that that body then falls to CSAC and to other users to make

determinations and come up with that infamous reduction in - the P word for a small number of measures. Parsimony, yes. Keep thinking of a church mouse, but anyway, but what I think you're hearing is a sense from this body is that we would like to be included in at least previous and prioritization of competing measures.

MS. JOHNSON: Yes. And, again, that kind of goes back to your role as overseer of the portfolio, so this kind of feedback is helpful for us as we try to make that more clear.

MS. HIBAY: And, Henry, to provide update on 0615, that measure was previously in front of this Committee, and it looks like endorsement was removed from that measure in February of 2014, so that should not be a competing measure unless they would bring that measure again forward at a subsequent phase.

But in addition, just to let you know, we do hear the rub there, that you want to be talking about similar measures at the same time, and we're working very hard, and we will take

into consideration, you know, hearing the priorities from the Committee. But I think you understand if we don't have it, it's silly to have the conversation right now because we don't even know when 0083 is going to be presented so, you know, if that comes to us in the next phase, we can go through this activity now, but -

MEMBER TING: Yes, but if we're the overseers of the measures, you know, all I have is actually a document that lists all the measures in the portfolio, and I can't recall which ones was endorsed, coming up for maintenance, or -

MS. HIBAY: That's fine. Yes, that's fine, Henry.

MEMBER TING: It's hard for me to -

MS. HIBAY: Yes, I just went on the fly right now right into our database to see what was active, and what was up to date. So, when you get a list of the measures in the inventory depending upon what list you're looking at, you're looking at all measures, measures that are

not endorsed, and measures that are endorsed, you know. So, you can filter it by those three areas, so you may have the all measure one.

CO-CHAIR KOTTKE: Okay. So, Carol has to leave somewhat earlier, so we're going to go to Measure 2440.

CO-CHAIR GEORGE: Carol, did you want to start, or do you want me to start? Okay, great.

MEMBER ALLRED: Do the developers have anything?

MS. RYAN: Hi. This measure looks to see was the care transition record transmitted to a next level of care provider within seven days. And within that, there's also consideration given that the care transition record includes discharge medications, reason - I'm sorry, follow-up treatments and services needed, procedures performed during the hospitalization, reason for hospitalization, and treatments and services provided during the hospitalization.

MEMBER ALLRED: Okay. This is a measure

that is very closely related to the one Henry just presented. It's the same group, the same hospitals, pretty much the same evidence that we presented in the other one. The nine hospitals, 858 patients involved.

The measure itself I think is a very good measure because the whole purpose of it is to set up a follow-up appointment transferring the information from the hospital record to the attending physician, and there are five data points that have to be included in that. And it needs to be done within seven days of discharge, the reason for hospitalization, the procedures performed during the hospitalization, treatment and services provided during the hospitalization, discharge medicines including dose and indication for use, and any follow-up treatment or services needed, so it looks to me like that's a wonderful way to transition that care from the hospital back to the private physician.

In terms of evidence, I think the evidence is okay. It may be a little bit shy in

places, but I don't see anything wrong with it all. So, I would say let's go ahead and vote on evidence.

CO-CHAIR KOTTKE: Mary would like to add a little bit.

MEMBER ALLRED: Okay.

CO-CHAIR GEORGE: So, I will say that the developers did perform a literature review resulting in about 35 different references with evidence-based guidelines, cohort studies, other references. And I think while this process itself is not specifically unique or needs to be unique to heart failure patients, the timing referenced in the measure is probably very specific for heart failure patients.

They cited evidence from five citations, rather than empiric studies, and 17 references for this pilot measure. So, I thought the evidence was fairly good.

MEMBER HILLEGASS: I kind of disagree about the evidence. I don't feel that the evidence is that strong for this whole group of

measures specifically. So if you want to go back to Henry talking about the specific beta blockers, if we carry that discussion over here, these are specific things that need to be measured for all patients. It shouldn't be just for heart failure. So I really think it's a valuable measure, but I don't think the evidence supports it, in my opinion.

CO-CHAIR GEORGE: I think - and I agree with you to a certain extent on this whole package of transition measures. One of the things that CDC commissioned a study of transition of care for heart failure, for MI specifically, and stroke specifically in 2011 from AHRQ with their evidence-based review process, and there was basically nothing in terms of evidence in the literature. It's because it hasn't been done; people haven't studied it. So, you know, it's one of those things, how - so we fault and absence of the literature?

DR. PINA: May I? I think that what's been happening and why there are no more data on

the evidence for here is because heart failure care, all care has become so fragmented. And we have seen such a drastic increase in hospitalists taking care of all these patients, and they'll never be seen by that same person in the outpatient. And the outpatient doctor most of the times don't even know that the patient has been in the hospital. And I think some of this may get better as we're moving - I sit on the Electronic Health Initiative, as we're moving with the Office of the National Coordinator to get the EMRs in better shape so that the outpatient EMR talks to the inpatient EMR. And I think that that's what's happened; it's why we don't have any more evidence, because it's been so fast that the fragmentation of care. The Commonwealth calls it a cottage industry, that's what they call health care.

CO-CHAIR KOTTKE: So, let's see, Linda, then down the line, Tom, Mladen, Judd, and then George. We'll go around this way. Oh, sorry, I missed -

MEMBER DeLONG: Could I just interject that evidence - I'm going to go all the way opposite from what I usually say. Evidence in this kind of a thing where you're looking at care processes is very difficult to get. We have tried to analyze things like a follow-up appointment, and it is so totally confounded with the site that it is very difficult to have firm evidence regarding some of these things. So I wonder about that criterion for something like this. You can't do a trial.

MEMBER BRIGGS: I would agree that it's difficult for this type of measure, but the one thing that concerns me about this measure is that there are so many pieces of it. And because of that, trying to make any one piece of evidence match it is difficult in and of itself. So, there's one study that we were given with the packets. Yes, there may be other data, but given the complexity of this measure, I don't think that the evidence really is there to support the full complexity of this measure.

CO-CHAIR KOTTKE: Tom?

MEMBER JAMES: This week's issue of the New England Journal of Medicine has an article on the handoff, on a standardized handoff process between residents, showing a significant reduction in adverse events at that level. But the question I have has to do with the seven-day.

In my past employer, we did a study looking at readmissions with heart failure and several other significant diseases and found that you maximize at three days, 72 hours, and that - to make contact. If you went out to seven days there was a much higher readmission rate, so I'm questioning the seven days as opposed to an earlier time frame for handing off. And goodness knows, we all got our hand slapped if we didn't dictate as hospitalists right away.

DR. PINA: I think that what has never come through with our seven-day and our three-day is that there are physiologic reasons why the patients get worse at about seven days. And it has to do with neurohormones. When they get

excessively diuresed in the hospital, which is what we all do, there is a rise in aldosterone levels that happen at about a week to 10 days where then they become avid sodium absorbers. And if you don't see the patients then and try to adjust their diuretic and go up on the other drugs, I assure you a readmission. I mean, I can even put the Good Housekeeping Seal on it that they'll be back. So, there are physiologic reasons that I don't think have ever come out in any of these papers, but that's the reason why we have always thought of that seven-day, or that seven to ten day.

(Off-microphone comment.)

DR. PINA: Right, but if the clinician who's taking over the patient sees the - knows that the patient has been in the hospital they're more likely to act on it. And, obviously, that's the extension that we can't always measure; you're right.

MS. RYAN: I think another thing to explain is that this measure correlates with a

measure that we haven't yet discussed with respect to the appointment within the seven days. And we're not saying, you know, seven days, but within that seven-day time frame, and the expectation being that by the time the patient has the appointment, the -

(Off-microphone comment.)

MEMBER HOLLANDER: I'm questioning whether those should be paired measures. And I'm - you know, we're doing an Epic implementation, so automatically we meet this if it's referred to somebody in our system. Right? But that's not really good care; it just means somewhere in some electronic cloud void the record exists. So, it's - you know, I agree with the philosophy. I frankly think it should be the day of discharge; I don't see why we tolerate things going on for weeks. You have to do the damn work anyway; do it when it's best for the patient rather than when it's best for the doctor. But I do question whether we're going to get what we want. We're just going to have it go into a void somewhere;

they're going to meet the measure. We're going to sell more EMRs to deal with this because it's going to fit into the ROI on doing that, but it's not entirely clear to me it's going to improve care unless there's an appointment that comes with it. So, if part of the other measure was having an appointment with the care record in hand, that would be really good.

CO-CHAIR KOTTKE: Gerard and then Mladen.

MEMBER VIDOVICH: First just make a comment, it may sound stupid. But I think it's like, you know, do we need a clinical trial? You know, the famous thing for jumping out with a parachute. Right? This completely makes sense, everybody needs a discharge summary. Right? This is - I mean, this is in your genome. Right? So, I have no problems with evidence here. This essentially says please write a discharge summary, so that's great. No problems there. I don't think anybody needs evidence for this, but I have some problems with - you know, again, the

devil is in the detail.

Care transition record, what is a record? And I think this is what Judd mentioned, is everybody is going to EMR. Right? You know, the Affordable Care Act talked about EMR integration so maybe one day our EMRs will talk together. What is a record, is it paper, is it electronic, is it implied in some sort of - I think that's a problem that records at this time.

Then definition of next level of care. What is next level of care? Is this a nurse practitioner, is this an internist, is it a heart failure specialist? Within seven days. Right? You know, it should be instantaneous. Right? You know, again, if you look at these pure definitions, just semantically I have a problem with that. And then is this a double standard? Right? You know, are we treating heart failure patients with this, and then if you don't have heart failure then you don't get a discharge summary, or you could wait two weeks. Right? That's a question for Joint Commission. Right?

The Joint Commission does a great job in standardizing care across many, many hospitals. Right? Is this cool to do this for heart failure and not for pneumonia? I mean, do you have a similar measure for a zillion other conditions that also need a discharge summary?

MS. WATT: This is Ann from the Joint Commission, and we have - there is a Joint Commission standard that says that the medical record needs to be completed within 30 days, and that all medical records need to have a discharge summary.

I think the reason why, you know, that's a standard, and that's what every -

MEMBER VIDOVICH: Thirty days?

MS. WATT: - hospital is looked at, or that's actually two standards, but every hospital in the country is looked at those things. I think the reason why we pulled this out for this particular performance measure set was because of the issues related to readmissions and so forth. It seems to have a higher resonance, I

think, would be the thing.

In answer to your question about what is a care transition record? We have a detailed implementation guide that we've prepared, and there are data element definitions for every one of these things. And in here we state that a care transition record may consist of one document or several documents, which could be considered a care transition packet. The hospital must be able to identify which documents make up the care transition record, and the hospital must identify what specific documents are transmitted to the next level of care provider. It could be in the form of continuing care plan, discharge instruction form, or another patient-specific document contained in the medical record. So we do try to describe very clearly what we're looking for.

MEMBER ALLRED: We're still on evidence.

MEMBER PHILIPPIDES: So this is just a general question. There are specific things we're

asked to look for in regards to ranking the evidence. Did the developer present data supporting the idea that instituting this metric leads to better patient outcomes. Is that right? But sometimes it feels to me that if we like the metric enough, or it feels right, we're willing to forego that threshold and say well, we don't need the evidence.

I'm actually okay with that because I like this transition care things. I think they're really important, I think that's where we're moving into the next phase of good health care, but I'm just concerned as to whether that would really - do we need to hold ourselves to what's written there as far as evidence. Because to my knowledge, and correct me if I'm wrong, Mary, that the data suggesting that if we do this, it will lead to fewer admissions or better outcomes is not that robust. I mean, it makes sense. I think it has face validity to all of us, but I don't think there's been data presented. Am I wrong about that?

(Off-microphone comment.)

MEMBER PHILIPPIDES: So then I'm lost. I don't know whether to follow the guidelines as written and look for that evidence, or to say well, in this particular case we all have a good feeling about it. We think it makes sense logically, let's just pass it. I don't know what to do with that.

CO-CHAIR KOTTKE: Ted is on the phone.

MEMBER GIBBONS: It strikes me that we're - when we're looking at these six measures that we are at risk of falling into the same trap as yesterday with 670, 71, and 72 where it seemed to me since I was going to present 672 and didn't have the opportunity, that that should have gone first because it was the broadest measure. And then 671 and 672 would have followed thereafter because 672 had the strongest evidence for asymptomatic individuals in general.

So, I wonder if what we're doing here is criticizing the limited nature of one measure and hoping that it will follow to the next

measure such that if someone gets an appointment, then they get the 72-hour phone call, then they show up to their appointment and they have their discharge summary with the provider. So I wonder if part of this is the way we're presenting the measures, and in what order.

CO-CHAIR KOTTKE: I have a rhetorical question. How many people could get that study through the IRB -- the usual care arm of sending the patient home without a discharge summary?

MEMBER HOLLANDER: I could guarantee at the two institutions I've been at, that would go through the IRB. It's usual care versus expedited transition. One is the doctor does whatever the doctor normally does. We don't slow it down, but -

CO-CHAIR KOTTKE: We normally send a discharge - the patient does not leave a hospital on our system without a discharge summary.

MEMBER HOLLANDER: That's a system I want to go to, so move to Philly.

(Off-microphone comment.)

MEMBER HOLLANDER: Right, so you can't but, you know, I think a lot of the world - I mean, I ask the question now: if the Joint Commission standard is 30 days to send a note, but yet the Joint Commission says we shouldn't have readmissions within 30 days, there's a bit of a problem there.

MEMBER VIDOVICH: That's the double standard. You can't have 30-day and a 7-day same for different conditions. That concerns me.

MS. WATT: Just a clarification. Number one, the Joint Commission doesn't say anything about readmissions within 30 days; that's CMS. But secondly, what we say is that a discharge summary has to be completed within 30 days. We don't say anything about transmitted or anything else. What we are saying in this measure is that we need to have a care transition record created and transmitted within seven days of discharge for heart failure patients.

And in terms of the paired measure,

you know, the way - because, as you know, all six of these measures are required for organizations that have the Advanced Certification for Heart Failure, they are in effect paired measures; they don't have a choice. And the intent - the reason why we do measures in sets like that is so that when you look at the results as a whole, it gives you a pretty good indication of the care presented or given to the patient, and that's why we do it.

DR. BURSTIN: I'll just make a comment, I'm sorry, just briefly. So we've gone through this a lot in our care coordination projects where most of these transition measures reside. There actually is a fair amount of evidence about transitions. You know, I don't know about the specificity of the seven days, but at times that committee, in particular, and it is certainly within your purview, can go ahead and put forward a measure with the - using the evidence exception if the benefits significantly outweigh the risks. And that's certainly within your

purview, to Liz's point earlier. I will point out, though, although it's not in this project, but care transition group also did endorse a measure of a transition record within 24 hours for all patients, so I just want to put that in context.

MEMBER ALLRED: The measure also does state that it could be transferred by phone, by email, by various other things, so if you just pick up the phone and calling the attending physician and tell him what's going on, I think that suffices.

MEMBER DeLONG: Then there's no record of that.

CO-CHAIR KOTTKE: Helen and then --

MEMBER HILLEGASS: But for clarification, I think we need to set a bar like we talked yesterday. And we need to make a decision: are we going to constantly bypass our algorithm and do insufficient, you know, with whatever exceptions, or are we going to stick to what we were given, which is look at the

evidence, decide on the evidence, rate the evidence. And maybe an exceptional case, and I'm saying this as a devil's advocate because there are five measures that are very similar. We're going to be addressing the same issues because I read all of them. I couldn't just read one; I read all of them. And they're all very similar in lack of evidence, so we need to decide now: are we going to bypass the evidence which is bypassing what we've been told to do, go through our algorithm, or are we going to actually rate the evidence?

The reason I say we need to set the bar is there are other groups that these measures could go to. And maybe we need to make a standard as to what comes here and what doesn't come here. And I don't know, maybe I'm talking out of school here, but I do believe that we need to make a decision. Are we going to go by the rules, or are we going to constantly bypass and do five, insufficient, you know, with exceptions. And where do we make that decision as a group,

because it's silly to keep arguing this on the next four issues that might have similar lack of evidence. So, I think we need to make some kind of decision here where we go with the evidence, how often we bypass it.

We all think these are quality issues. We think these are - we all believe in 24 hours you should have this care transition. Where do we set the bar with this group?

MEMBER DeLONG: Helen hit the nail on the head. Is there any risk - I mean, if it's hard to get evidence and you've got a measure that you can't imagine a risk does the evidence criterion have to really be strict? I mean, I would say on the first one I had doubts about risk. On this one, I'm having trouble imagining any risk.

MEMBER HILLEGASS: And you're talking about bypassing our algorithm and writing a new algorithm. Correct?

(Simultaneous speaking.)

MEMBER HILLEGASS: Making a lot of

these fives.

DR. BURSTIN: Except, just to be clear, the exception is part of your algorithm. We put that there intentionally when the evidence tests were submitted several years ago. So, it's not going outside the algorithm. I will say, though, we do view it as an exception. It is not something you want to invoke constantly, but in the right instances for the right kinds of measures where evidence is weak, certainly not so much on the clinical side, but I think more of a crosscutting side we see it more invoked than usual.

MEMBER HILLEGASS: But we have five measures - and you're saying we need five exceptions.

DR. BURSTIN: No, I'm not saying that. I'm just offering to you that that is -

MEMBER HILLEGASS: Just throwing it out there.

DR. BURSTIN: - certainly a possibility, and that you should really be

weighing - this is when your expertise comes into hand. Does the benefit of having that measure in the portfolio significantly outweigh any risks for patients?

CO-CHAIR KOTTKE: Well, I can tell you our primary care docs do not ask rhetorically; they ask how do you expect me to treat this patient when I don't even have an idea they were in the hospital? I mean, you know, does a tree fall when there's no forest?

CO-CHAIR GEORGE: And I was going to bring up what Helen mentioned about the NQF was the preferred practices and performance measures for reporting care coordination. And this is one of the preferred practices in that NQF document. Also recommended in the transitions of care consensus policy statement from American College of Physicians Society of General Internal Medicine, and Society of Hospital Medicine, American Geriatric Society, and the American College of Emergency Physicians, and the Society of Academic Emergency Medicine, so it's evidence

that's recommended from many, many different societies in NQF.

CO-CHAIR KOTTKE: Gerard.

MEMBER MARTIN: So, again, new to NQF, not new to quality improvement, it seems to me that we're arguing over something that's pretty silly. There are two aspects to evidence. There's evidence where you're saying I want to do Drug A, which has this outcome, and a new drug. And we're going to try to impact survival, quality of life, blah, blah, blah, where we say wow, to do that there's a lot of risk involved. And we're going to go for a randomized double blind study.

Someone in the quality improvement realm, and I don't know still what NQF is, I'm learning, there is a - I don't want to say a lower bar, but there is a different risk involved, where you're looking at - and I'm sorry, I think from my hospital we've learned that hand-offs are critically important. And if you don't do hand-off well, even if it's inside the hospital, you're in trouble. So, the idea

that you don't hand-off outside the hospital is unbelievable. Okay?

To Tom's point, I can get this through my IRB. I have through a National Quality Improvement collaborative looking at single ventricle patients, and part of - one of the key drivers was a better handoff to the outpatient world. And we left it blank, because we didn't know what the strategies were going to be, and we looked for best practices within hospitals.

So, if this is about quality, and this is a hand-off, I think the evidence, and whether you want to use the exception thing, then great, use the exception thing because hand-offs are important, and this shouldn't be a randomized double blind study; it should be does this make sense, and is this the right thing to do?

The only point I would take is, you know, with Joint Commission is it probably shouldn't be heart failure; it should be every discharge. And it's only because, you know, this is that whole thing about you're coming to the

cardiac group, that it's with us, but this should be part of Joint Commission telling every hospital to do this within seven days for everyone that leaves.

CO-CHAIR KOTTKE: Thank you. Leslie, on the phone you had a question or comment.

MEMBER CHO: Yes, my comment: I totally agree with the previous speaker. There will never be a randomized controlled study versus, you know, care transition versus no care transition. But I still think this is such a good and important thing, that even if we don't have the randomized controlled study from the New England Journal, it should go forward. And I advise the NQF staff again, evidence the way you guys have put it in that algorithm is very difficult unless it's like a randomized controlled study of drugs. And I really think that for many of these measures where it really makes logical, pragmatic sense, that algorithm is really not that helpful.

CO-CHAIR KOTTKE: Carol, was that you, or is that George?

MEMBER ALLRED: Yes, I was.

CO-CHAIR KOTTKE: Okay.

MEMBER ALLRED: I just wanted to make a comment about the discussion. Yesterday we got hung up on evidence, and we were talking about new measures and the lack of evidence. And it looks to me like this is the same thing. Are we going to say the evidence isn't good because it's not there, or are we going to figure out how to deal with new measures that improve quality?

CO-CHAIR KOTTKE: So, Kristi, Judd, and then back to Liz.

MEMBER MITCHELL: My question isn't so much about the evidence; it's about the bar that we need to establish for accountability. So, I think in the context of quality improvement, this is all good. This is motherhood and apple pie. Right? But I think when we're talking about dollars and cents, and incentivizing hospitals and providers, individual attribution around accountability, then the question becomes clear to me that we have to figure out what we're going

to do around evidence. So, I just put that out there because I think that those concepts get conflated in our discussions. So, quality improvement and accountability are not the same.

MEMBER HOLLANDER: I agree with all these sentiments, and I'm all fine with this going forward. I guess what I'm questioning is, this is a proxy outcome for something where we already have a hard outcome, and we now have a whole series of proxy outcomes for heart failure where we're measuring, you know, the more important thing which is, you know, 30-day readmissions or 30-day quality of care framed as readmissions. So, I wonder if we're not better off having one composite measure that looks at the things that would get us there.

So, I think we can all agree you have to have the record transmitted, but if you just have an institutional-wide electronic medical record you meet this criteria. That really does nothing for care. Okay? You need to have an appointment at some period of time. There's not

great evidence whether it could be seven days, or 14 days, there are some unintended consequences if you get people who don't need an appointment to have an appointment and block people who need it from it, but we all agree at some point in time you need the appointment. And maybe it really should be a composite measure that you do the three, or four, or five things that get you to the likelihood of decreasing 30-day outcomes. There's a great paper in the STEMI world that Elizabeth Bradley wrote years ago that has like seven things that you should be doing at your institution to improve your STEMI outcomes. And we've seen composite measures here, and I'm raising the question. I know it's not the measure in front of us, but we have a whole group of measures. Maybe we should have them come back framed as a composite because this one measure is not going to help anybody on an EMR; it's not going to do anything to their institution that's already being done. It's in the record and may be ignored, but the next step might actually be

really useful at that institution with that patient. And if it's put together that's just one way where I think we're really improving quality rather than layering on a bunch of proxy measures where we already have the outcome measure in the portfolio.

CO-CHAIR KOTTKE: Liz?

MEMBER BRIGGS: I just want to reemphasize - sorry, I'm going in a different direction, but what Leslie said was if it makes sense, the evidence isn't as important. I think there are a lot of things that make sense offhand and have been shown in trials to not work. I think it has to pass a different bar, and that is absolutely minimal risk. And if it feels good, and it's minimal risk, and risk includes cost, then maybe the evidence bar is too high.

CO-CHAIR KOTTKE: Okay. Does anybody have anything new to say, new plus relevant, two attributes. Seeing nothing, let's vote on evidence.

MS. LUONG: Voting for evidence starts

now: one for high, two for moderate, three for low, four for insufficient evidence, five for insufficient evidence with exception. And this is for Measure 2440.

Measure 2440 did not pass with 22 percent voting moderate, 6 percent voting low, and 72 - oh, it did pass. I'm sorry, with exception. So, Measure 2440, 22 percent voted moderate, 6 percent voted low, and 72 percent voted insufficient evidence with exception.

CO-CHAIR KOTTKE: Thank you. Carol, do you want to talk about performance gap?

MEMBER ALLRED: There's definitely a performance gap. I think the statistics were less than 40 percent of the people are actually getting the transmitted record within a timely basis. And that's not within the seven-day time period. So, there's a definite room for improvement there.

CO-CHAIR KOTTKE: Disparities?

MEMBER ALLRED: Disparities, yes. There are disparities in care, but none of the studies

on this particular group of five actually designated the disparities, so they went to the literature and actually are showing that white Anglo Saxons have a better rate of getting that first review out than minorities do.

CO-CHAIR KOTTKE: Does anybody need to dispute what Carol just said? Okay, let's vote on performance gap.

MS. LUONG: Polling for performance gap starts now: one for high, two for moderate, three for low, and four for insufficient. Performance gap passes with 56 percent for high, 44 percent for moderate.

CO-CHAIR Kottke: Priority?

MEMBER ALLRED: Priorities. Obviously, heart failure is a major problem; it's a high-cost, high-risk disease, so I think it is a high priority.

CO-CHAIR KOTTKE: Looks like everybody wants to vote.

MS. LUONG: Polling starts now for high priority: one for high, two for moderate, three

for low, and four for insufficient.

CO-CHAIR KOTTKE: Even I can pick up the subtle bodily motions that -

MS. LUONG: Priority passes with 66 percent voting high, 22 percent voting moderate, and 11 percent voting no.

CO-CHAIR KOTTKE: Scientific acceptability and reliability.

MEMBER ALLRED: Okay. Scientific acceptability, the numerator statement and the denominator statement I think are good. The exceptions there, exclusions from the denominator are limited to left ventricular assist devices and heart failure, which makes perfect sense to me. So, I would say the scientific acceptability is good.

Reliability, the data points are easily extracted from the electronic record or paper record.

CO-CHAIR KOTTKE: I just have a question of why do you exclude patients with LVADs, with transitions?

DR. PINA: They are usually in the hospital a lot longer, and the VAD coordinators are all over them, so it's really part of the expected care of LVADs. But yes, I mean, if you're in a place where nobody has seen you in a few days, you're in trouble.

MEMBER CLEVELAND: I guess I would just - Tom, if I could make I guess a comment as a VAD surgeon; I would actually like to see the VAD patients. I'd advocate that they put into this, too, because particularly the increase in the rate of thromboses with Heart Mate 2 pumps, et cetera, et cetera, INRs that - bleeding, I think that it's critical they be seen within a week and have a proper discharge. So, I actually think that we should include, not exclude, VAD patients. I can understand excluding heart transplant patients. That's a different kettle of fish, but I would ask that the VADs be placed in there.

CO-CHAIR KOTTKE: Have we heard about reliability?

MEMBER ALLRED: Yes. I thought I did reliability, but the data again seems to be accurate data points to have in.

CO-CHAIR KOTTKE: Okay, ready to vote on reliability?

MS. LUONG: Polling starts now for reliability: one for high, two for moderate, three for low, and four for insufficient.

MEMBER ALLRED: Usability? Feasibility, I would say the only thing about feasibility -

MS. LUONG: Reliability passes with 17 percent voting high, 72 percent voting moderate, and 11 percent voting low.

CO-CHAIR KOTTKE: Validity.

MEMBER ALLRED: Validity. I think the data points are valid; I think they're the right ones to use.

CO-CHAIR KOTTKE: Judd?

MEMBER HOLLANDER: I'm just going to reiterate my comment before that if you're in a health system-wide, enterprise-wide electronic medical record then sort of it loses its face

validity of getting it to the primary care provider because there's no evidence that they'll ever see it or put it in a file.

CO-CHAIR KOTTKE: Other comments? Ready to vote on validity?

MS. LUONG: Polling for validity starts now: one for high, two for moderate, three for low, and four for insufficient.

MEMBER ALLRED: Okay, feasibility?

CO-CHAIR KOTTKE: Feasibility?

MS. LUONG: Yes.

MEMBER ALLRED: I think we talked all around feasibility for this particular measure. One of the things I'd like to raise is that there is a part of this that suggests a care coordinator, which would certainly add to the cost of doing the procedure. And as everybody has talked about, can the institution get the records out in the seven-day time frame without it being an undue burden? Other than that, I think it's feasible.

CO-CHAIR KOTTKE: Seeing no action,

let's vote on feasibility.

MS. LUONG: Before we vote on that, the results for validity testing: 83 percent voted moderate, and 17 percent voted low.

CO-CHAIR KOTTKE: Helen noted that it's feasibility of the measure, not feasibility - so feasibility of collecting the data about the measure, not the feasibility of sending out the discharge summary.

MS. LUONG: Voting for feasibility starts now: one for high, two for moderate, three for low, and four for insufficient. For feasibility, 39 percent voted high, 50 percent voted moderate, 6 percent voted low, and 6 percent voted insufficient. It passes for this criteria.

CO-CHAIR KOTTKE: Usability and use?

MEMBER ALLRED: Usability and use, those are suggestions they made was internal use for the hospitals, using it for health care plans, things like that, but this is a new measure so usability is really not proven.

CO-CHAIR KOTTKE: Ready to vote on usability and use?

MS. LUONG: Polling starts now for usability and use: one for high, two for moderate, three for low, and four for insufficient information. Usability and use passes with 22 percent voting high, 56 percent voting moderate, 6 percent voting low, and 17 percent voting insufficient information.

CO-CHAIR KOTTKE: So, overall vote?

MS. LUONG: Polling for overall suitability for endorsement starts now: one for yes and two for no. For Measure 2440, it passes with 89 percent voting yes for endorsement and 11 percent voting no.

CO-CHAIR KOTTKE: So, Sharon or somebody, we're running considerably behind, but we haven't had a morning break. Are we going to competing measures, I - yes.

MEMBER HILLEGASS: Does this new measure add something that's not already measured by 0648?

MS. JOHNSON: So, that is a discussion that we're going to table until the post-meeting call. And, also, Ann brought this to my attention, and I apologize for the confusion, but these measures as a group when they originally put their submission in, they were planned for use in the Joint Commission programs, but those went into play January 1st, 2014. So, these are actually in use at least in the Joint Commission Programs. Do I have that right, Ann?

MS. WATT: That's correct.

CO-CHAIR KOTTKE: Break until 11:15.

(Whereupon, the above-entitled matter went off the record at 10:58 a.m., and resumed at 11:13 a.m.)

CO-CHAIR KOTTKE: We are going to start with 41 and 42 because they're very closely related to 40.

CO-CHAIR GEORGE: We'll be doing them separately beginning with 2441. I'm sorry. We're just taking things all out of order today. Any introductory comments from the developers?

MS. RYAN: Sure. 2441 is for discussion for advance directives and 2442 is for advanced directive executed. We would just like to explain that initially this was a combined measure, but during the pilot process the facilities had indicated that with the measure being combined it was hard for them to tell was the measure passing because they had discussion with the patient as opposed to the advance directives being executed. And the priority for the facilities was to make sure that the directives were executed. So they had actually requested that these two measures be separated out. And that's why it went from one to two.

CO-CHAIR GEORGE: All right. So we have Linda, Tom and George.

MEMBER JAMES: This is the 2441. Make sure I'm on the right page. Let me just do a quick summary for the evidence, because this is another one where the scientific evidence is not fair, in my estimation, for a discussion of advance directives leading to a definitive

outcome. However, as somebody who has spent time in areas working with patient-centered care and patient-focused care, this is one of those measures that gets into the heart of that. Making sure that patients are -- or the intention is the patients are engaged and help direct their care.

Problem for me with this particular measure: It's a discussion by any health care professional. And we all know about the times that a nurse comes in to sign the pre-ops sheet for patients and gets consent. And that counts as a discussion of the operative procedure. This is end-of-life discussions and it should not be passed off. It should be by somebody who's really caring for the patient. And I would like to have seen that rather than just any health care professional.

Secondarily, this is for patients -- an exclusion is patients less than 18 years of age. The portion of me that's a pediatrician recognizes that children and their families

should be very much engaged in this kind of discussion, so I'm a little uncomfortable about that.

I understand why discharge to a hospice. That means that -- the suggestion is it means we've already that discussion, so it would improve your ratio for including it.

So this is one where the balance is lack of scientific evidence, so I would recommend a five on this versus the patient-centered focus that this is still an indirect measure of what the patient should be engaged in a meaningful discussion.

CO-CHAIR GEORGE: Go ahead, Gerard. And then Joe.

MEMBER MARTIN: So as the pediatrician I guess it depends upon the type of heart failure. Ninety percent of our patients with heart failure have a structural heart defect, which is readily amenable to either cardiac surgery or interventional cardiology and with survival rates that are over 98 percent. And so,

if it's advanced heart failure, I couldn't agree more where they're moving on towards heart failure. But if it's -- I mean to having that type of discussion. But just for age itself, it would have to be defined by kind of the -- what type of heart failure.

MEMBER CLEVELAND: I guess if I could ask a point of order, too, and clarification from the developers, because as I understand it our program went through Joint Commission certification for an LVAD center and one of the metrics on that was that there had to be an advance directive discussion to be approved as the Joint Commission over that program. And here we have a denominator exclusion that excludes LVAD patients. So I think that exclusion should probably be moved, otherwise we've got a measure that directly conflicts with something that's a process for Joint Commission certification.

MS. WATT: I think that's the reason for the exclusion, because it is included for the LVAD and we know that everybody who is certified

for LVADs has to have our certification.

MEMBER CLEVELAND: Okay.

MS. WATT: So it's like a mutually exclusive thing.

CO-CHAIR GEORGE: Is that Kristi?

MEMBER MITCHELL: Clarification. When you say "all heart failure," we're including patients who have pulmonary hypertension as well?

(Off-microphone comment.)

MEMBER MITCHELL: So, okay. Just making sure I'm clear on that.

CO-CHAIR GEORGE: George?

MEMBER PHILIPPIDES: And then there's no differentiation between obvious systolic dysfunction inpatients who have heart failure on the basis -- with normal LVEF, is that correct?

DR. PINA: This should include, if I'm correct, half N, half for F, both.

MEMBER PHILIPPIDES: Okay.

DR. PINA: Low EFs and high EFs.

MEMBER PHILIPPIDES: Because I've just generally considered the patients with the very

low EFs -- that this discussion is sort of more urgent than patients who had their first heart failure presentation and their EFs are 65 percent. So this groups them all together?

DR. PINA: Yes, because even those patients are older and they have a lot of comorbidities and many of them we keep doing things to them that really haven't changed much their outcome. So I would include this as a conversation that I have with mine. And they get so edematous and they just -- their pulmonary functions get worse, their kidneys get worse. So whether the mode of death is cardiac or the mode of death is from one of the comorbidities, the discussion I think should be had. I don't know that we specified.

MEMBER PHILIPPIDES: Okay. I'm not sure I understand what you're saying, but I think that could lead to some discussions with some 30-year-old folks that might not be as important as the older folks with bad LVs.

CO-CHAIR GEORGE: Judd?

MEMBER HOLLANDER: Yes, I actually agree 100 percent with what George is saying, but I think I'm a little more afraid of the concept of a one-time discussion with somebody who comes in with A-fib and a little bit of heart failure. The A-fib is totally fixable or it's related to drinking too much the night before and now having a discussion about end-of-life planning with a 32-year-old that is otherwise really fine, that has no difference in mortality as compared to an advanced heart failure patient regardless of the injection fraction.

And so, I think in the end for a lot of these measures we're stuck between low or with exception, and I think the fact that this includes a whole bunch of people that I frankly think might be inappropriate to go near an end-of-life discussion, and it's overly concerning and overly broad, I have trouble in my mind making this with exception. I think it's problematic.

CO-CHAIR GEORGE: I have just a

question for the developers. Did this come up with any of your pilots?

MS. WATT: No. Actually no. I'm -- no, is the short answer.

DR. PINA: I think probably in the context of this is a together measure from Get With the Guidelines, that is in Get With the Guidelines. Get With the Guidelines concentrates more on the low EF patients, because that's where we have the evidence for the care and we don't have great evidence in HEF F as to what to do.

CO-CHAIR GEORGE: Tom?

CO-CHAIR KOTTKE: Yes, I'll take a diametrically opposed position from Judd that any adult should have an advance care directive, and the short form can simply be if you're unable to make a decision about care, who is it that is your proxy? And that's enough. And you don't know when you're going to slip on the stairs here at NQF and -- of course if you take the elevator, you won't slip on the stairs, but you could get stuck and starve to death.

MEMBER PHILIPPIDES: I'd like to be resuscitated, for the record. I just wanted to --

(Laughter.)

MS. HIBAY: Good news, George. That made the transcripts.

MEMBER DeLONG: I think there's a difference between what everybody should do and what we should impose as criteria for endorsing a measure that could cause some psychological distress. I don't know that it's our position to promote that sort of thing.

MEMBER VIDOVICH: My question for developers is again similar to the previous measure. It's how does this compare to other Joint Commission standards in a place for advance directives for all patients admitted to the hospital?

MS. WATT: I'm sorry. I'm not familiar enough with the standards to answer that. I'm sorry.

CO-CHAIR GEORGE: Any other comments

on the evidence? If not, we'll vote.

MEMBER PHILIPPIDES: Actually I have one comment. I think that this is another case where there's not a lot of sort of hard evidence showing that if you have this discussion that down the road there are significantly better outcomes or money saved. I think this is another one that we all know that to be the case. If you have better communication and avoid intubations and all those kind of things that it makes sense.

I just wanted to make sure Tom and that we all agree on that in reading through this protocol.

CO-CHAIR GEORGE: Linda, did you --

MEMBER BRIGGS: I was just going to say that there is again very little evidence there, and what we do have is very old. There was part of a study -- the Krumholtz group in 1998. One of the issues that they found -- they actually interviewed patients at three days and six days, between three and six days of

enrollment in the support study and then two months after discharge, and a large number of those patients actually changed their minds about what they wanted. So I mean, that's a whole other issue to be dealt with.

So when you talk about a one-time discussion, you have that discussion with that setting in the acute care area where the person either does or doesn't think they're going to live, and then quality of life changes again two months out. And what you really want to know is what's going to happen to them in the long run.

So I would agree that there's insufficient evidence, but based on what we've said about the fact that there could be some psychological harm to certain groups because this is in all heart failure rather than our low ejection fraction group of people, that there is some degree of harm that we could consider in this. So I would not consider this insufficient with exception. I would consider it insufficient.

CO-CHAIR GEORGE: Any other comments?

(No response.)

CO-CHAIR GEORGE: All right. We'll vote on the evidence.

MS. LUONG: Polling for evidence starts now. One for high, two for moderate, three for low, four for insufficient evidence, and five for insufficient evidence with exception.

For evidence 6 percent voted high, 17 percent voted low, 33 percent voted insufficient evidence, and 44 percent insufficient evidence with exception. It's in the gray zone.

CO-CHAIR GEORGE: So we'll continue. So comments on the performance gap and disparities?

MEMBER JAMES: If we're looking strictly at the measurement of reported advance directive, there is clearly a performance gap. There is no measurement of what is the person's input, the patient's input into the decision making. That would be a better measure, but

there's no way to get that. This becomes a surrogate measure and this surrogate measure does show a performance gap and significant disparities.

CO-CHAIR GEORGE: Any other comments? George?

MEMBER PHILIPPIDES: I think that what they cited was just sort of low rates of having these discussions in heart failure groups. I don't know that they cited performance gap between commissions or between entities. And as far as disparities, they cite disparities in heart failure care, not in asking or having a discussion about advance directives. So again, it's very little and it really focuses more on heart failure treatment in general and I think less on this particular metric.

Any thoughts, Linda?

MEMBER BRIGGS: I agree with that. I think that there is -- the disparity issue in particular was not really addressed in terms of this indicator. It was related to -- in-patient

care of heart failure patients was the disparity quote that we were given.

CO-CHAIR GEORGE: Any other comments on performance gap disparities?

DR. PINA: So, even though it's not directly related to advance directives, there's an offshoot of this, which is the ICD conversation, whether to put it in ICD or not, which does have to do with dying if you don't have the ICD. There is an NIH study going on right now called WISDOM that is looking at the conversations around the ICD. And hospitals have randomized to either be the conversation or talk to the patients who already have an ICD and see if the conversation was had by someone else about this.

So hopefully we're going to have a little bit more data when the trial is over. It's at least halfway done. I know we're enrolling, and it's a very interesting study.

MEMBER JAMES: Actually, just to that point, there are those studies that have shown

the incidence of discordance between patients wanting the ICD turned off and that doctor's actually doing it. That's another measure that should be --

DR. PINA: It's a scary one.

MEMBER JAMES: Yes, it is.

CO-CHAIR GEORGE: Linda?

MEMBER BRIGGS: Oh, I don't have another comment. I'm sorry.

CO-CHAIR GEORGE: All right. We'll go ahead and vote on performance gap.

MS. LUONG: Polling for performance gap starts now for Measure 2441. One for high, two for moderate, three for low, and four for insufficient.

For performance gap 6 percent voted high, 24 percent voted moderate, 24 percent voted low, and 47 percent voted insufficient. Does not pass.

MS. JOHNSON: And so for this one I'd like to get from the Committee just so that I understand it as we write the report -- can

someone just help me understand why those of you who said insufficient did?

MEMBER JAMES: Let me just throw out what I think may be our view, and that is the intention of the measure is excellent and there is a real need. The issue comes in what is being measured and whether that directly relates to what the need is. And that I think is reflected in this vote.

MS. JOHNSON: Thank you, Tom. I do appreciate that. Go ahead, Linda.

MEMBER BRIGGS: So I would say that also because it really didn't speak to disparity issues directly related to the group of patients that were being potentially asked this one time discussion issue. That was part of my reason for choosing insufficient.

MS. JOHNSON: Okay. So, and, Judd, go ahead and then remind me to come back to that, Linda.

MEMBER HOLLANDER: Oh, go ahead. Go back to that first.

MS. JOHNSON: I just want to make sure that everybody's clear, and maybe everybody isn't. With the disparities question we are interested in disparities, but we think of disparities as helping to inform whether or not there's a gap.

So there's three ways really that you can talk about having a gap in performance. One is if everybody just is doing poorly across the board. Right? Another is that some folks are doing well and maybe some folks aren't, so you have wide variation in practice. And then the other way that you can demonstrate a gap is having certain sub-populations have poor performance.

So having the disparities is a way to demonstrate a gap, but if the developer does not show disparities, that doesn't mean that there's not a gap. There's a couple other ways that a gap may be demonstrated. So hopefully that's more clear now.

But, Judd, go ahead.

MEMBER HOLLANDER: So I was going to say this says less than optimal performance across providers, and I think we just had a pretty robust discussion about what is optimal performance, that not everybody with heart failure should have the discussion. So my vote is that I don't believe it should be 100 percent. I do believe that they documented it's 50 percent. I think 50 percent might actually be the ideal number. I don't know. So it's hard to go forward.

And I'll just add to this just in case the developer is going to resubmit, when you look ahead to reliability, which we haven't gotten to, a kappa of 0.18 is probably kind of a fatal flaw in the whole process, too. So I'd just throw that out there. When people are thinking about the effort, I think we would have gotten stopped there had we not gotten stopped here anyway.

MS. JOHNSON: So with my explanation about disparities not necessarily being able to kill the gap piece, let me ask with a show of

hands does anybody feel like that they would like to re-vote or is everybody happy with where this has landed, that it stops here?

(Show of hands.)

MS. JOHNSON: Okay. I see no hands saying that they want to continue, so the measure stops here, correct?

(No audible response.)

MS. JOHNSON: Thank you.

CO-CHAIR KOTTKE: Okay. 2442. That's Mike and Ellen. And do the measure developers want to offer any preliminary comments?

MS. RYAN: As I mentioned earlier, this one correlates with the 2441, and this measure looks at where the advance directive is executed.

CO-CHAIR KOTTKE: Mike, are you the guy?

MEMBER CROUCH: Ditto.

(Laughter.)

MEMBER CROUCH: It's the same issues. The kappa of 0.18. The reliability is terrible.

I'm in favor of the concept of advance directive for patients with heart disease, which is what this is targeted to. There's good evidence that it's not happening often enough, that a very small percentage of patients have had a chance to express their wishes to the doctor or had a discussion with the doctor. Ten percent are confident that their doctor understands that. It's a problem. I don't think the measure as comprised is likely to fix that with the methodology of the measure.

But the other problem is that they say, well, we have this pilot, too. I looked at the pilot too on the Website and there's no operationalization of what an executed advance directive is and how the chart orders are supposed to know that an advance directive has been executed, what that means to be executed, how much discussion went into the process prior to whatever execution is. It's something that really needs work, but it's a messy area and very difficult to deal with given the state of

searchable data fields and current medical records. So I don't think it's a practicable measure at this time.

CO-CHAIR KOTTKE: Ellen?

MEMBER HILLEGASS: I would totally agree. I think this is going to get stopped along the way if it's not stopped in the beginning because it doesn't have any reliability. It has a lot of red flags throughout it with minimal to no evidence. Same thing with performance gap. We can go through each one and vote as we go along, but I don't think there's any strength in this proposal.

CO-CHAIR KOTTKE: Anybody else care to jump in the water before we vote on evidence?

(No response.)

CO-CHAIR KOTTKE: Okay. Let's vote on evidence.

MS. LUONG: Voting for evidence starts now for Measure 2442. One for high, two for moderate, three for low, four for insufficient evidence, and five for insufficient evidence with

exception.

For evidence 19 voted low, 56 percent voted insufficient evidence, and 25 percent voted insufficient evidence with exception, so this measure does not pass.

CO-CHAIR KOTTKE: Okay. Karen, do you want to ask or inquire?

MS. JOHNSON: Yeah, I think it's probably worth having in the transcript so that we make sure that we write our report accurately. So maybe just make sure that I understand your thinking here a little bit more. Technically we're not supposed to say it would fail on reliability. So this should be the evidence vote.

MEMBER HOLLANDER: I did not see a single piece of evidence in the summary that suggested people do not follow advance directives. Right? That's what this measure was. It was about executing the advance directive. It was silent on that.

MS. WATT: Sorry. I just wanted to

clarify: This measure doesn't have to do with whether or not what the patient asked for in the advance directive was carried out. It has to do with whether or not an advance directive was actually created.

MEMBER HOLLANDER: Then explain to me how that's different than the last one.

CO-CHAIR KOTTKE: One was just a discussion. Was there a one-time discussion about advance directives. This one was that it executed. That is what Sharon pointed out. It's a legal term.

Okay. Oh, Leslie is on the phone and would like to offer a comment.

MEMBER CHO: Yeah, that's exactly what I was going to ask, about the execution part, because that does seem like a -- it's a legal thing, isn't it, that's totally different from the previous measure we voted down. So if a patient brings in an advance directive, it's whether that advance directive got executed at the hospital.

MS. WATT: Okay. So this is Ann from the Joint Commission, and I would love to say yes you're absolutely right, but really the intent of the measure is that whether or not an advance directive was created after the discussion that happened in last measure.

MEMBER CHO: Okay. So that's totally confusing, because to me when I saw this I actually thought what I first said about execution.

My second point is is these are re-endorsed measures. How is it that we are voting all these down when it was initially passed with the same criteria, either the same algorithm, the same thing from the Cardiovascular Committee initially? I'm asking the NQF staff, actually.

MS. JOHNSON: This is actually a new measure, so this has not been looked at before.

MEMBER CHO: Oh, okay. Thank you.

CO-CHAIR KOTTKE: Linda, Ellen and then Mike.

MEMBER BRIGGS: Okay. So we have a

little more clarification from the Joint Commission about what executed means. And if you actually do go back to their documents related to the advanced heart centers, yes, I have that page. So anything -- and there's a whole list of things that qualify for that -- would include an advance care plan, an advance decision making, advance directive. The MOLST form, the POLST form, a personal directive, a power of attorney for health care would all be considered documents that would apply to that. So there is definition in that sense.

That being said, in terms of the evidence to support the particular measure itself, I still think that there's not enough evidence.

CO-CHAIR KOTTKE: Ellen?

MEMBER HILLEGASS: All of the evidence says it should be done. But if you read the evidence, there's no evidence to say it actually has been done. So we're voting on a should versus a -- we're voting on the fact that they

say it should be done, and this is saying that it is done. So I don't think that there is evidence to say that this is done, to show that.

I think it's a valuable measure and I think it should be done. I don't see that there's any evidence saying that one of the outcomes is to decrease anxiety. I'm trying to look at the specific. It was reduces -- it becomes transitioned to focus on palliative care. There's no evidence on that. And there's no evidence that it decreases anxiety, etcetera.

So we could call it insufficient, but I just don't think there's evidence to support it.

CO-CHAIR KOTTKE: Mike?

MEMBER CROUCH: One of the biggest problems is there are 11 different data sources in the record, or potential data sources in the record, all the ones that she enumerated and some others. And that's why the kappa was so low, because the chart order is going through. We're looking through progress notes, HPIs, looking for

evidence of these other -- a power of attorney, an order by the doctor that there was do not resuscitate orders, all these potential things. And the more data sources that you look through to try to find something, and you're not even quite sure what you're looking for, the reliability and validity both are very suspect.

So conceptually I agree that it ought to be done, but there are tremendous problems with it being done this way and holding anybody accountable for whatever this is.

CO-CHAIR KOTTKE: Anybody else care to weigh in?

MS. JOHNSON: So what I'd like to ask you guys to do now that the developer has cleared up whether or not these documents, some of these documents were created, not fulfilled, I would like us to just do this vote one more time so that everybody is extremely clear about what we're voting on. So thank you for humoring me on that.

MS. LUONG: We will re-vote on

evidence for Measure 2442. Polling starts now. One for high, two for moderate, three for low, and four for insufficient.

So for Measure 2442 for evidence 6 percent voted moderate, 41 percent voted low, 41 percent voted insufficient evidence, and 12 percent voted insufficient evidence with exception. So this measure does not pass.

MS. JOHNSON: No, it does not pass.

CO-CHAIR KOTTKE: Okay. So we're back to the last two measures, 2439 and 2443.

CO-CHAIR GEORGE: Any comments from the developers on 2439?

MS. RYAN: 2439 is a measure looking at post-discharge appointment made for the patient before discharge or at hospital discharge, and it basically looks at was there an appointment made within seven days of discharge.

CO-CHAIR GEORGE: And our discussants are Ted and Ellen.

MEMBER GIBBONS: Yeah, I'd be happy to discuss this. And I want to thank the Joint

Commission for putting this forth because I think it really does reflect what the Heart Failure Society of America wants to push forward on the agenda, but I think it still needs some work.

Now, just to clarify with the description, this to my reading was that the appointment for location, date and time for an office or home health visit is scheduled within seven days post-discharge. So it's actually the appointment must be within seven days post-discharge, not that the scheduling was done within seven days. Is that correct?

MS. RYAN: Yes, that's correct.

MEMBER GIBBONS: Good. Okay. Thank you.

So this is a new measure. Its level of analysis is at the facility level. It's a process measure. And if we go to the evidence, the evidence is based primarily not on a systematic review, but quoting some well-written guidelines that come from the ACC from 2013 and the Heart Failure Society of America in 2010,

which are guidelines, as well as the Joint Commission's diagram of optimal care, which by itself is not evidence, but a trajectory for care coordination.

The only study that is relatively pertinent to this is the often-quoted Hernandez study from JAMA in 2010, which was an observational study following up patients after discharge for acute decompensated heart failure where it was demonstrated that there was a reduction of readmissions if the patient actually saw a caregiver within the time period of observation, which was around seven days. So it wasn't the making of the appointment. It was the actual appointment showing up and that there was about, by my recollection, about a 20-percent reduction in readmission for that population.

The time frame for that particular study was 2003 to 2006, so it's fairly old data. And the evidence that making the appointment separate from keeping the appointment is not there. So this is an indirect measure where this

making of the appointment may influence outcomes. Obviously if you make the appointment and show up, the two appear to be linked, but it's not been proven by the evidence.

So in the spirit of our previous discussions, I can I think truncate it to say that I would say that this is a valuable part of the care transition, but it's insufficient evidence with exception from my standpoint.

MEMBER SPANGLER: So, I know we'll get to this later because it's a competing measure, but we had this same discussion with 2455 in Phase I.

MEMBER GIBBONS: Right, yes.

MEMBER SPANGLER: And I don't know if we're going to come out differently or not, because it's the exact same issue that we've discussed previously today, that we discussed in Phase I as well.

MEMBER GIBBONS: Yes, right.

MEMBER SPANGLER: So it doesn't seem to be any different than before.

MEMBER GIBBONS: The only difference in the measures that I saw was that 2455 does not state seven days and this one does, and the 2455 was based on registry data from ACC, and this is a Joint Commission --

MEMBER SPANGLER: Right, and I think you're exactly right. I'm not comparing the two measures. I'm just saying the issue of the evidence with both measures --

MEMBER GIBBONS: Right.

MEMBER SPANGLER: -- is the same issue.

MEMBER GIBBONS: Correct. Correct. Well, and I think you could argue both ways, that it's insufficient evidence overall or it's insufficient evidence with exception. As someone who is a heart failure doctor in a public health hospital I can tell you that each of these six measures from the Joint Commission are ones that we already have in place and which probably account in part for the fact that our readmission rate for our indigent population has fallen from

39 percent to 16 percent.

So I think that there is value in each of these, and the question is whether we support the care coordination measures that are in the spirit or that the measures as they are written don't give correct instruction about -- we give to an institution about how to implement them.

MEMBER SPANGLER: And if I recall correctly, the last time we endorsed this measure, but I thought it was insufficient evidence with exception and we moved on. Is that correct?

MEMBER GIBBONS: Yes. I thought --

(Simultaneous speaking.)

MEMBER GIBBONS: Yeah, it did move on, right.

MEMBER HILLEGASS: I'd like to discuss the evidence a little further. I do think that it's important in this measure to not only put in discharge appointment, but I think that since the evidence supports that the patient actually has a

visit, I think that's a key component of this measure, that it shouldn't be just an appointment. Because your evidence talks about good support when there's a visit and not just the appointment. So I'd like you to re-look at the evidence and really look at the evidence talking about the visit and not the appointment. So my recommendation --

MEMBER GIBBONS: Could you make the distinction what you mean by a visit?

MEMBER HILLEGASS: Well, that the patient --

MEMBER GIBBONS: A face-to-face?

MEMBER HILLEGASS: -- was actually seen by someone. And I'd have to go back and look at the research for -- they looked at a post-op evaluation, so I think an evaluation would be more important than a seven-day appointment. I think the evidence does not support appointment. I think the evidence supports a visit.

MEMBER GIBBONS: Yes.

MEMBER HILLEGASS: And so I think we need to distinguish between the two, because I do think there is evidence to support a visit.

MEMBER GIBBONS: Well, I think we need to be clear about what a visit is, because I think you're absolutely right that the evidence dating back to 2000 would support an interaction within seven days has just as much of an effect as a face-to-face visit. So I think a visit would mean an interaction, whether it's on social media or email or a phone call, but I agree with you that that's where the most compelling evidence is.

MEMBER HILLEGASS: Well, so I think there is sufficient evidence for an evaluation or an interaction.

CO-CHAIR GEORGE: Judd?

MEMBER GIBBONS: That's not what the measure says.

MEMBER HOLLANDER: Yes, so we talked yesterday exactly about the points that are being outlined here. This is actually one of the very

few things where there's evidence that remote monitoring and telemedicine can actually decrease visit and decrease costs. So I would argue that a visit should include that.

But again, as we're rolling out more and more measures, I'm pretty sure you can't actually get a visit without an appointment. And we have another measure coming up that's about evaluation, so to me this seems unnecessary, because if I make an appointment and I don't make arrangements for the patients to get there and they can't access the appointment, this is just silliness.

So I think in the absence of evidence this doesn't rise to the insufficient with exception because although it is the first step in getting an appointment, we need them to have the appointment or the visit or the evaluation. And this is a short-term proxy for a proxy for an outcome. So I could live with skipping this one since there's no great evidence.

CO-CHAIR GEORGE: Mladen and then Tom.

MEMBER VIDOVICH: Yes, the only things I want to say is if the patient -- you know, and working in an inner city hospital with a lot of indigent patients, they may get an appointment, but they don't show up. You can't penalize the hospital for the patient not showing up, although they made every effort of scheduling the appointment, right? So this measure looks at making every best effort to send them home with an appointment and beta blockers and, hey, say if they don't show up because -- I can name a laundry list of reasons, you're penalizing a different entity here, right? So I don't know.

MEMBER HOLLANDER: Can I kick back on that; it's directly related to my comment, before Tom? So we give them an appointment between 9:00 and 5:00. That's what we do now. I think that's unacceptable for some patients. So the question is do we want to have patient-centered measures? There's many other times they can be seen. We could send people to their house if they want. We could give them appointments to come in. We

could do telemedicine. I think just giving an appointment in a non-patient-centered manner probably isn't the best way to decrease 30-day readmissions. So I would kick back on that a little bit.

CO-CHAIR GEORGE: Ileana?

DR. PINA: Yes, let me respond to that. The problem is that if you don't even make the attempt to make that appointment before they go out the door, I assure you that they won't have an appointment if you just hand them a piece of paper that says here's the number to call on Monday. So, yes, it would be best if we could document the appointment, but the appointment may be in their primary care, which may be out of the system. Could be anywhere.

In our numbers, I can tell you that since I've been looking at this; and we just had an abstract at the American Heart, about 50 percent of the patients that are given the appointment do not show up for lots of reasons. Mostly transportation. And now I'm trying to

target those reasons. But if they hadn't gotten that, they wouldn't have been seen. Of the ones that do get seen, my numbers are very similar to the Hernandez paper. The readmission rate is very, very low, if they get seen.

And obviously we need to expand it to a bigger population. But I think it's our attempt to get at that business of at least put it there, because if you don't, then you're totally at the mercy of them calling. And they have been in the hospital for four-and-a-half days where they haven't absorbed much of anything and they're certainly not totally diuresed, as we know how we send them home. So I think this is our attempt to do that. Not perfect.

CO-CHAIR KOTTKE: Yes, I think one of the assumptions we're making here is that the patients are seen in the system. And Ileana mentioned this, that there are patients who are seen in the hospital and they are not -- come from 150, 200 miles away. And we've had other discusses particularly around cardiac rehab where

we just couldn't even -- we were very concerned about double-dinging doctors for little minor -- for being accountable for asking patients if they had been in cardiac rehab. Now we're saying even if the patient is out of system from a long way away, that the hospitalizing organization is responsible to make sure that patient is actually seen.

And I mean, maybe that's right, but I just to point out that -- take May Clinic Rochester. Are they -- patient comes from Dubai. Are they responsible for making sure that patient is seen in Dubai within seven days?

MEMBER HILLEGASS: I want to point out some data. There's a study done by COPD patients, and they knew the patients wouldn't follow up in the seven days. So what they did is is they hired an individual who would go out to the homes and visit the patient within three days and made a huge difference in re-hospitalization. That's a visit. That's a visit.

So I think we need to be looking at

more than an appointment. If you know your patient population is 50 percent not going to show up, then you hire somebody to do that visit for you. I don't think the appointment is well documented for any kind of evidence. And I think outside the heart failure range -- realm we have other evidence that shows that visits make a difference, or interactions. However you want to define that.

CO-CHAIR GEORGE: Ann?

MS. WATT: In our data element definition the question is was a follow-up appointment for an office or home health visit for management of heart failure scheduled within seven days. And it has to have a documented location, date and time. And then in our notes to the abstractors we say a follow-up appointment is an appointment with a physician, APN/PA in a physician office or ambulatory care clinic, or a home health visit with an RN/APN for professional nursing services that occurs within seven days, blah, blah, blah. So we did try to capture that

in the definition for this measure.

MEMBER GIBBONS: This is Ted Gibbons. You know, I agree with Ileana's experience that in order to operationalize this you have to have the subsequent measure, too, 2443, because what happens with our patients is that they are overwhelmed with the ability to take care of themselves and the follow-up telephone call, which we have also instituted, reinforces the fact that they have a visit, however you want to define it, available to them and that the principles of that visit, the reasons and the time and date are reinforced.

Now, how that subsequent one is operationalized is a matter of debate, but the appointment can't exist in isolation from its follow-up. So I guess that is a difficulty in more concepts than the fact that this particular measure doesn't provide value.

CO-CHAIR GEORGE: Tom?

MEMBER JAMES: Well, I think that the next measure answers what Ellen is looking for.

With this particular measure I'd like to be able to refer to a similar measure in the mental health community, and that is the experience with a measure that says a patient discharged from a psych hospital needs an appointment within seven days. That has done a great deal to reduce psychiatric readmissions. I would guess the same would hold here.

CO-CHAIR GEORGE: Any further discussion on the evidence?

(No response.)

CO-CHAIR GEORGE: If not, we'll vote on the evidence.

MS. LUONG: Voting for evidence for Measure 2439 starts now. One for high, two for moderate, three for low, four for insufficient evidence, and five for insufficient evidence with exception.

For evidence, 24 percent voted moderate, 24 percent voted low, 18 percent voted insufficient evidence, and 35 percent insufficient evidence with exception, so the

measure proceeds.

CO-CHAIR GEORGE: We'll move onto a discussion of the gaps.

MEMBER GIBBONS: Just as in the previous discussion the gap is a bit indirect, although the developers do quote the fact that from old billing data there was a 52 percent lack of follow up. So that there's a significant gap there.

I think the same issue arises for the perceived gap in non-white populations in that it may be the gap in heart failure care in general. But I don't think that diminishes the fact that there is a gap and need to fulfill this coordination of care need.

DR. PINA: As a matter of fact, in the Hernandez paper that everybody quotes where the visit actually happened, 34 percent only of the programs had a scheduled visit at 7 days in their planning. In other words, that that was part of their processes of care. So, and we recently re-looked at this in Get With the Guidelines, and

it's gotten a little bit better, but not great.

MEMBER GIBBONS: Right, and that was in 2003 to 2006 from Hernandez. I think people have gotten a little bit better, but it's only with a tremendous amount of effort and clinical decision support data that we review on a monthly basis that allows us to improve. It's a lot of work.

CO-CHAIR GEORGE: Any other comments on performance gap?

MEMBER BRIGGS: I just wanted to say that it's pretty obvious that there is a performance gap because what you see in the rates of re-hospitalization. The problem is the data you present is old, so I would vote it more a moderate level for this rather than high.

CO-CHAIR GEORGE: Shall we vote on gap?

MEMBER GIBBONS: The data is old from Hernandez, but the developers present data from when they did their chart review that was from April to July of 2012, I believe. So even that

showed that there was a significant gap at that point, so I would still as it's high.

MS. LUONG: The polling for performance gap starts now. One for high, two for moderate, three of low, and four for insufficient.

For performance gap, it passes with 18 percent voting high, 71 percent voting moderate, and 12 percent voting low.

CO-CHAIR GEORGE: Priority?

MEMBER GIBBONS: For priority based on the fact that there's a gap in an important management issue, I would list it as high priority.

CO-CHAIR GEORGE: Any discussion about priority?

(No response.)

CO-CHAIR GEORGE: All right. We'll vote on priority.

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

For high priority, 65 voted high, 24 percent moderate, and 12 percent voted low. It passes.

MEMBER HILLEGASS: Do you want to go through the numerator versus denominator?

MEMBER GIBBONS: Sure.

MEMBER HILLEGASS: The numerator is for any patient with a follow-up appointment including location, date and time for an office or home visit for management of heart failure scheduled within seven days post-discharge.

And then the denominator is certain ICD codes, all heart failure discharged from a hospital inpatient setting to home or home care. Those seem appropriate.

MEMBER GIBBONS: Yes, so the data extraction was similar to the previous measure where there are 201 records that were looked at, both paper and EMR. And this was, as mentioned before, a four-month review from April to July of 2012 of nine hospitals after a number of other hospitals dropped out.

The hospitals were small to moderate in size, and in 5 cases greater than 400 beds. Interestingly enough, the re-admission rate even at that point seemed to be fairly high because there were 878 patients with 1,372 admissions. I wonder if Joint Commission could tell us what the re-admission rates were per 30 days.

But the exclusions were still troublesome to me because 37 percent of the patients were excluded based on the listed exclusions including LVED and length of stay greater than 120 days. I would assume, but please correct me if it's not correct, that the exclusions were based on the previous discussion about LVED enrollment. Is that correct?

MS. RYAN: Yes, that's the same.

MEMBER GIBBONS: Okay. One of the other exclusions was that documented patients with no documented reason for no post-discharge appointment within seven days. What's the rationale for that?

MS. RYAN: There are some

circumstances where patients might be from out of state or even out of country, so it is not within the purview of the caring provider to be able to make that appointment. So there was consideration given for that.

MEMBER GIBBONS: Okay. But it's less than optimal, but that's a reasonable exclusion. Okay.

So the specifications seemed reasonable and it was done by direct JCAHO extraction of records from the sample of records taken. So it seems an acceptable approach.

CO-CHAIR GEORGE: Ellen?

MEMBER HILLEGASS: So with the specifications though they only looked at whether there was a documented appointment. So again, I want to go back to talking about they only documented an appointment and not whether the patient was seen by someone.

MEMBER GIBBONS: Right, but that's not within this measure.

CO-CHAIR GEORGE: George?

MEMBER PHILIPPIDES: Do we know how often they use the patients with a documented reason for no post-discharge appointment within seven days? Was it used often or was it mostly the other exclusionary criteria that dinged them?

MEMBER GIBBONS: It's mostly the others.

MEMBER PHILIPPIDES: Okay.

MEMBER GIBBONS: I think it was less than three percent that was no post-discharge appointment. It was uncommon.

MEMBER HILLEGASS: And I wanted to talk to the reliability testing. It was a little concerning to me that five hospitals withdrew from testing due to lack of resources to complete the project.

MS. RYAN: That was commented on earlier with respect to the timing of the pilot testing, and some of the hospital leads for the project had some turnover.

CO-CHAIR GEORGE: Judd?

MEMBER HOLLANDER: I actually hadn't

picked this up the first time through, but I have real concerns about the exclusion and being somewhat subjective and not contained where you could just say I can't get an appointment done. I understand that out-of-the-country thing. I kind of get that. I don't really get the I-live-200-miles-away. Someone could get on the phone and make that appointment. That's something we should be able to do.

I would also like to see; just and sort of a friendly amendment; doesn't impact my voting, that telehealth is clearly defined as a visit, because a telephone call is. And so I can easily imagine some payer saying, oh, telehealth doesn't count as a reason to ding people because it's not considered a phone call and has an entirely different regulatory structure. So I would like to see as this goes forward that that gets built into the measure.

But one can imagine today that if this is a pay-for-performance measure somebody has a note saying they were discharged at night. The

office was closed. Couldn't make an appointment. And that's not acceptable to me, but it would fall as an acceptable exclusion criteria here.

CO-CHAIR KOTTKE: Yes, I'll change my prior comment. I mean, I think wherever in the world you ought to be able to pick up the phone and call somebody and say this patient needs to be seen. Being responsible for them being seen is a different story.

MEMBER HOLLANDER: But don't you think that's the whole point of the measure? I mean, I get calling Dubai may be a little more difficult, but if somebody refers somebody to the Mayo Clinic, then the Mayo Clinic has a obligation, I believe, to get them an appointment. And I would say that the Mayo Clinic should then set them up for a telemedicine visit or a telephone consult, which would meet the criteria, to tide them over to the time that they could get that appointment.

So I think within the language of this there's plenty of opportunities for people to provide care during that care transition period

if they can't get an appointment. And I think that that's going to improve the care of these patients.

CO-CHAIR GEORGE: Any other comments on reliability? If not, we'll vote.

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

For reliability it passes with 76 percent voting moderate, 18 percent voting low, and 6 percent voting insufficient.

CO-CHAIR GEORGE: Okay. We'll move on to validity.

MEMBER GIBBONS: In terms of validity the same type of analysis was done and appealed to comparison to other heart failure transition measures, but they found that the overall percentage of patients who had a follow-up appointment was only 14.9 percent with some -- one center I think approaching 90 percent.

And the correlation that didn't meet statistical significance was that medical record

transmission was 56 percent and a post-discharge call was 35.5 percent. So I think this accentuates the gap, but it still appeals to what we consider to be an appropriate definition of appointment as has been discussed before. But certainly the extraction method seemed to support the fact that this was reasonably valid.

CO-CHAIR GEORGE: Comments on validity?

MEMBER HILLEGASS: I'm just going to say for the record again that this is only measuring appointment. And so, I think it would be a much stronger valid testing done and valid information if we were looking at some sort of interaction with a health care provider, a visit or something.

CO-CHAIR GEORGE: Other comments?

(No response.)

CO-CHAIR GEORGE: We'll vote on validity.

MS. LUONG: Polling for validity opens now. One for high, two for moderate, three for

low, and four for insufficient.

Validity passes with 71 percent voting moderate and 29 percent voting low.

CO-CHAIR GEORGE: All right. We'll move on to feasibility.

MEMBER GIBBONS: Again, I think that feasibility was questioned by the fact that several hospitals dropped out, but I think we had a reasonable explanation for that that over four months that there were perhaps under-staffing, but I don't know that we've completely understood why that should be the case. But nonetheless, the simplicity of just documenting whether there's an appointment does not seem to be burdensome, so I would say it's feasible.

MEMBER DeLONG: This is basically a check box, right?

MS. WATT: The measure requires that the appointment be made. That requires an action on the part of the hospital staff to get that appointment made.

MEMBER DeLONG: How does JCAHO find

the data?

MS. WATT: In the medical record. Chart abstraction.

MEMBER DeLONG: Chart abstraction?

MS. WATT: Correct.

MEMBER DeLONG: So this involves a fair amount of work to determine whether somebody actually wrote make a follow-up appointment, or whatever?

MS. WATT: All of these measures are chart abstracted. And as we discussed earlier, all of the data elements for all of the measures are generally abstracted at the same time, yes.

CO-CHAIR GEORGE: Linda?

MEMBER BRIGGS: I just wanted to point out that in this chart abstraction for the appointment made, it's actually three components to say yes. They actually have to a location, they have to have the date and the time. So in order to say yes there's three different pieces that have to go in that. I just wanted to add that.

CO-CHAIR KOTTKE: Well, it actually should be pretty easy to find this in the discharge summary if a hospital has its act together. It's not like looking for family history or some other things that could be anywhere.

CO-CHAIR GEORGE: Other comments on feasibility?

(No response.)

CO-CHAIR GEORGE: We'll vote on feasibility.

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

For feasibility it passes with 6 percent voting high, 88 percent voting moderate, and 6 voting low.

CO-CHAIR GEORGE: Usability?

MEMBER GIBBONS: Based on the comment before, it sounds like the Joint Commission has enacted this part of the advance certification on heart failure beginning in January. So at some

point I suppose it will be reported. It's intended as an e-measure. And I was wondering if the developers could tell how that is going.

MS. WATT: We're breathlessly awaiting the endorsement decision before we move forward with the e-specifications.

MEMBER GIBBONS: But as far as the advance certification are people reporting this in a usable number?

MS. WATT: Oh. Oh, yes. Sorry. It's a requirement. There are close to 100 hospitals now reporting for the advance certification for heart failure and every one of them is reporting on this measure. They have not rebelled yet.

MEMBER GIBBONS: Okay. Thank you. So I would say that if there's feasibility, then usability would allow the follow-up that would then inform 2443.

CO-CHAIR GEORGE: Any comments on usability? If not, we'll vote.

MS. LUONG: Polling starts now for usability and use. One for high, two for

moderate, three for low, and four for insufficient information.

For usability and use, 24 percent voted high, 65 percent moderate, and 12 percent voted low. It passes.

CO-CHAIR GEORGE: So we'll move on to the overall vote.

MS. LUONG: Polling starts now for overall suitability for endorsement. One for yes, and two for no.

For Measure 2439 for overall suitability for endorsement 82 percent voted yes, and 18 percent voted no. It passes.

CO-CHAIR GEORGE: Any competing measures?

MEMBER GIBBONS: We've talked about that before. 2455 presented by ACC and voted on before doesn't specify that the appointment be within seven days. And it's a registry rather than an EMR. Interestingly, if you look at their submission, again they actually presented data showing an improvement that was significant

between 2011 and 2012 based on the registry. So it would be interesting to see what happens with this from JCAHO.

MS. HIBAY: This is a measure that the related and competing discussion will be hosted at our post-call meeting on the 19th of December.

CO-CHAIR GEORGE: Okay. And I believe we're going to do public comment.

MS. ISIJOLA: Operator, can you open the lines and see if there are any public or member comments?

OPERATOR: Okay. At this time if you'd like to make a comment, please press star then the number one on your telephone keypad.

(Pause.)

OPERATOR: At this time there are no comments.

MS. ISIJOLA: Okay. So, having no comments, we have one additional measure left. And I see people that need to catch their flights and travel, so we'll table this last measure, Measure 2439 for our post-meeting call and we'll

work with the Joint Commission to ensure that they're available for that call. Oh, is it? Measure 2443, we'll make sure that that's available for the post-meeting call.

MS. JOHNSON: Can we just get a show of hands? We're a little confused here. How many people could stay another half hour, 45 minutes to finish this up? Half hour at most.

MS. HIBAY: How about the developers? Okay.

MS. JOHNSON: This is the Joint Commission. Okay. So how many has to leave?

MS. HIBAY: How about on the telephone as well? Are you able to hang for a half hour?

MEMBER CHO: Yes.

MEMBER GIBBONS: Yes.

MS. HIBAY: Okay. We'll proceed with reviewing measure 2443.

CO-CHAIR KOTTKE: Okay. Developers, anything you need to say?

MS. RYAN: Sure. This measure looks at a post-discharge evaluation for heart failure

patients within 72 hours. And within this evaluation we're looking for an evaluation of symptoms or if the symptoms are worsening, if the patients are able to adhere to their medication regimen and also how they're doing with their activity levels.

CO-CHAIR KOTTKE: Okay. Linda, you're the discussant.

MEMBER BRIGGS: Okay. So the measure is patients who received this evaluation in 72 hours. And so that would be the numerator for this.

And then the denominator is very similar to others that we've looked at. The denominator being that it's heart failure discharged. This time it is patients going to home, home care or leaving against medical advice. There are exceptions that we had again as before. So in the evidence the same evidence was cited as previously for the appointment, which is the one non-randomized observational study from Hernandez. And the discordance here

is that the time interval is seven days there, and in the measure it's three days.

Now, there are two clinical guidelines that the developer cites and both of those say preferably within three days is reasonable, reasonable from the American Heart Association, and that's a Class 2-A recommendation with a level of evidence being B. And that was just citing the Hernandez study. And the Heart Failure Association is recommending a visit in three days, and that strength of evidence was C, which was expert opinion only.

So I would say the evidence for this particular measure is insufficient. But it doesn't cause harm to anyone, so I would say it's insufficient with exception.

CO-CHAIR GEORGE: And I would just add I think some of the evidence -- there was a 2012 Cochrane review of 25 clinical trials on post-hospital interventions that was cited when we reviewed the measure in Phase I about making the appointment, but it covered various interventions

including early post-hospital follow-up to reduce readmissions. And I think that evidence is somewhat relevant to this discussion, but it wasn't cited by the developers.

MEMBER JAMES: I think the practical experience that that's been held by many health plans is that for those people who are discharged with higher level degrees of heart failure; New York Class 3 and 4, that this has been a game changer as far as the ability to reduce readmission rates. Right? I think that's the only issue, is it's separation as to those people who have mild failure, first time systolic dysfunction versus somebody who's got known disease.

CO-CHAIR KOTTKE: Okay. Anybody else urged to comment?

(No response.)

CO-CHAIR KOTTKE: Ready to vote on evidence?

MS. LUONG: Polling for evidence starts now. One for high, two for moderate,

three for low, four for insufficient evidence, and five for insufficient evidence with exception for Measure 2443.

For Measure 2443 on evidence, 7 percent voted high, 36 percent moderate, 7 percent voted low, and 50 percent insufficient evidence with exception. This measure passes.

CO-CHAIR KOTTKE: Performance gap?

MEMBER BRIGGS: So, there is a gap. The performance gap cited by the developers is that of the nine test centers that reported the minimum group of folks that complied with this measure was actually 0 and the maximum was 37.8. So there's a huge, huge area where there could be improvement in having this evaluation done.

CO-CHAIR KOTTKE: Anybody urged to comment?

(No response.)

CO-CHAIR KOTTKE: Let's vote on performance gap.

MS. LUONG: Polling for performance gap starts now. One for high, two for moderate,

three for low, and four for insufficient.

For performance gap, 71 percent voted high, and 21 percent voted moderate. It passes this criteria.

CO-CHAIR KOTTKE: Priority?

MEMBER BRIGGS: I think we've discussed this a number of times, that heart failure is a high priority.

CO-CHAIR KOTTKE: Seeing no motion, let's vote on priority.

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

High priority passes with 93 percent for high, and 7 percent for moderate.

CO-CHAIR KOTTKE: Scientific acceptability and reliability. Linda?

MEMBER BRIGGS: Okay. So, they did inter-rater reliability. They only reported on one data element itself, which was the actual conducting of the evaluation. There was 95 percent agreement and the kappa was 0.75. So

that's strong agreement. Usually again numerator, denominator and exclusions are what the Committee wants, but they did report on the one.

CO-CHAIR KOTTKE: Thank you. Judd?

MEMBER HOLLANDER: Just one comment, and I'm not sure where the right place to say this is, but I think every time we hear heart failure and admission or discharge, we need to think admission and observation. We're seeing a huge shift to put these patients in observation. And I can kind of interpret the language either way, but it says inpatient somewhere, and observation is strictly outpatient in terminology. And I think it should be included. So I don't know if there's a way to amend it.

Ileana and this group discussed that on the last round. I think it's really important. Otherwise, we're taking patients who really -- we all know this. We're taking patients who warrant inpatient admissions, squeezing them into observation. Their inpatient

stay is less quality care. And now we're going to send them without the same transition mechanisms. That's a really bad thing to be doing.

CO-CHAIR KOTTKE: Mladen?

MEMBER VIDOVICH: Yes, fantastic point, because at the VA we have like a chest pain unit. Fantastic point.

CO-CHAIR KOTTKE: Okay. So ready to vote on reliability?

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

Reliability passes with 14 percent voting high, and 86 percent voting moderate.

CO-CHAIR KOTTKE: Validity?

MEMBER BRIGGS: This is the section where I think this measure stumbles a little bit, and it might be easily rectified by changing the evaluation time frame to that within seven days. Because the evidence that is cited from the very beginning is the study that has to do with

evaluation within 7 days, not the 72 hours, even though there are clinical guideline recommendations for shorter time periods. So again, I would say that that's a validity issue that those things don't reflect the same information.

Do you want me to speak to the validity as well? Okay. In this case they used comparison or correlations with similar types of sampling that they were doing with other indicators within the center's data set and they did beta blocker and post-discharge appointment. Interestingly enough, the correlation with the post-discharge appointment was poor. So even though they might have had an appointment, maybe the re-evaluation never occurred. Who knows?

Neither one of these actually reached statistical significance. The beta blocker therapy one was -- the correlation was 0.512. The sample sizes were relatively small even though we're talking about 800 patients that were actually in the sample that they looked at.

CO-CHAIR KOTTKE: Mladen, do you still -- No? Okay. Ready to vote on validity.

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

Validity passes with 7 percent voting high, 64 percent voting moderate, 21 percent voting low, and 7 percent voting insufficient.

CO-CHAIR KOTTKE: Usability and use? Did I miss feasibility? Sorry.

MEMBER BRIGGS: No, we're good. So feasibility, we were quoted the same statistics as before, because it's the same data set basically.

CO-CHAIR KOTTKE: Okay. No other comments?

(No response.)

CO-CHAIR KOTTKE: Let's vote on feasibility.

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

For feasibility, 14 percent voted high, 79 percent voted moderate, and 7 percent voted low. It passes this criteria.

CO-CHAIR KOTTKE: Now usability and use.

MEMBER BRIGGS: Okay. So this is a new measure. There is a desire to use it in the data set. And you say you're actually implementing that as we speak, essentially.

CO-CHAIR KOTTKE: Okay. Seeing no cards up, we'll vote on usability and use.

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

For usability and use it passes with 29 percent voting high, 71 percent voting moderate.

CO-CHAIR KOTTKE: Overall?

MS. LUONG: Polling starts now for overall suitability for endorsement for Measure 2443. One for yes, and two for no.

For overall suitability for endorsement of Measure 2443 100 percent voted yes for endorsement. This measure passes.

CO-CHAIR KOTTKE: Competing measures?

MEMBER BRIGGS: I would say the main ones were discussed.

CO-CHAIR KOTTKE: Okay. So that's it. Oh, we'll open it one more time for public comment.

MEMBER BRIGGS: For Judd this one does say telemedicine.

CO-CHAIR KOTTKE: Minor victories.

MS. ISIJOLA: Operator, can you open the lines again for public and member commenting once more?

OPERATOR: Okay. Once again, to make a comment please press star, then the number one.

(Pause.)

OPERATOR: Okay. There are still no comments at this time.

DR. BURSTIN: And just one comment. I know you had a discussion about some of those

overused measures yesterday. So those typically do go to the clinical committees if they're clinically-related to overuse. We're happy to get input if you'd like from the Cost Resource Use Committee chairs, but they are really dealing with cost measures. We very much consider these within your purview, so you'll have an opportunity to get back to those at a later date.

MS. HIBAY: I just want to make one more comment related to any competing measures of the measure we just did, which is 2443. They will be held on the post-call meeting on December 19th.

CO-CHAIR GEORGE: I'd just like to thank everybody for all your hard work and great comments. Thank you.

CO-CHAIR KOTTKE: Same. It's obvious you've given a lot of serious thought and the developers appreciate it, and I think we're improving care in America. Thank you. And happy travels.

DR. BURSTIN: And thanks to our Co-

chairs as well, and all of you.

MS. ISIJOLA: Thank you all again for attending. We'll definitely send you information for next steps, particularly for the post-meeting call. And please have lunch on your way out.

Thank you everyone who joined us online as well.

(Whereupon, the above-entitled matter was concluded at 12:43 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Cardiovascular Measure Endorsement Project 2014 Standing Committee

Before: NQF

Date: 12-05-2014

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