NATIONAL QUALITY FORUM

+ + + + +

CARE COORDINATION STEERING COMMITTEE

+ + + + +

TUESDAY
FEBRUARY 28, 2012

+ + + + +

The Steering Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:30 a.m., Donald Casey, Jr. and Gerri Lamb, Co-Chairs, presiding.

PRESENT:
DONALD CASEY, JR., MD, MPH, MBA, Co-Chair
GERRI LAMB, PhD, RN, FAAN, Co-Chair
DANA ALEXANDER, RN, MSN, MBA, GE Healthcare
KATHLEEN ALLER, MBA, McKesson Enterprise Intelligence
ANNE-MARIE AUDET, MD, MSc, The Commonwealth Fund
J. EMILIO CARRILLO, MD, MPH, New York-Presbyterian Hospital and Weill Medical College of Cornell University
JANN DORMAN, MA, PT, MBA, Kaiser Permanente
KAREN FARRIS, RPh, PhD, University of Michigan College of Pharmacy
PAMELA FOSTER, LCSW, MBA/HCM, ACM, Mayo Clinic Health System
WILLIAM FROHNA, MD, FACEP, Washington Hospital Center
JEFFREY GREENBERG, MD, MBA, Brigham and Women's Hospital
THOMAS HOWE, MD, Aetna
SUZANNE HEURTIN-ROBERTS, PhD, MSW, HRSA
CHRISTINE KLOTZ, MS, Community Health Foundation of Western and Central New York

JAMES LEE, MD, The Everett Clinic
RUSSELL LEFTWICH, MD, State of Tennessee
MARC L. LEIB, MD, JD, Arizona Health Care Cost Containment System (AHCCCS), Arizona's Medicaid System
JULIE L. LEWIS, MBA, Amedisys, Inc.
LINDA LINDEKE, PhD, RN, CNP, University of Minnesota School of Nursing and Amplatz University of Minnesota Children's Hospital
DENISE LOVE, MBA, National Association of Health Data Organizations
LORNA LYNN, MD, American Board of Internal Medicine
JEAN MALOUIN, MD, MPH, University of Michigan
MATTHEW McNABNEY, MD, Hopkins ElderPlus and Johns Hopkins University
EVA M. POWELL, MSW, National Partnership for Women & Families (by teleconference)
BONNIE WAKEFIELD, PhD, RN, FAAN, University of Missouri and Iowa City VA Medical Center
ALONZO WHITE, MD, MBA, Anthem Care Management

MEASURE DEVELOPERS:

DAWN ALAYON, National Committee for Quality Assurance

MARK ANTMAN, Physician Consortium for Performance Improvement

KATHERINE AST, American Medical Association

KERI CHRISTENSEN, American Medical Association
KEZIAH COOK, Acumen, LLC (by teleconference)
DEBORAH DEITZ, Abt Associates, Inc. (by teleconference)
KENDRA HANLEY, American Medical Association
DIEDRA JOSEPH, American Medical Association (by teleconference)

RABIA KHAN, Centers for Medicare & Medicaid Services
LINDA KLINGENSMITH, Centers for Medicare & Medicaid Services
EUGENE NUCCIO, University of Colorado, Denver (by teleconference)
ALISON SHIPPY, American Academy of Dermatology
OLIVER WISCO, American Academy of Dermatology
LAURA YODICE, American Medical Association

CONSULTANTS:

ARJUN VENKATESH, MD, Brigham and Women's Hospital-Massachusetts General Hospital

NQF STAFF:

HELEN BURSTIN, MD, MPH, Senior Vice President, Performance Measures
KAREN JOHNSON, Senior Director, Performance Measures
KAREN PACE, Senior Director, Performance Measures
LAURALEI DORIAN, Project Manager, Performance Measures
NICOLE McELVEEN, Project Manager, Performance Measures

ALSO PRESENT:

SUE ABREU, Society of Nuclear Medicine (by teleconference)
ERIC HOWELL, Johns Hopkins University

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

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

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

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

(8:37 a.m.)

CO-CHAIR CASEY: So good morning, everyone and welcome to sunny Washington. We are roughly about four weeks away from cherry blossom time. So I hope you are all hanging in there. Welcome to our second meeting of the NQF Care Coordination Steering Committee. We have got a lot of work to do and I know you are all ready to roll up your sleeves and get all this work done in the next couple of days. So I want to say thank you on behalf of my Co-Chair, Gerri Lamb and myself and the staff to really working hard. The amount of information here is daunting and I know the time you spent going through all this with a fine tune comb and the feedback you have given on the conference calls has been incredibly valuable. In fact, this is the first such meeting that I have been through with the steering committee where the pre-work really is done much more aggressively on the front

end. So hopefully, hopefully today there will be interesting and useful discussion. The measure developers will be here to help us answer any questions but I think that based upon the preliminary work this should go well.

I'm Don Casey. I'm the Chief Medical Officer of Atlantic Health System. I'm going to ask Gerri make some comments as well. And then what we want to do is just go around the room again and remind each other who we are and just reintroduce ourselves. So, Gerri.

CO-CHAIR LAMB: Let me add my welcome to all of you. It's good to see you all again. I'm Gerri Lamb and, as Don said, I'm co-chairing with him and we really, really appreciate all of the background work that you have done. We know a lot has gone into getting prepared for today's meeting, not only in the measure review but in the preferred practices. And like Don was saying, it is a pretty ambitious agenda but a huge opportunity

to have lots of good dialogue about care coordination, where we are going, measurement, where the gaps are, and to make some, you know, to have discussion about where we should be going with this.

So we welcome you all and really look forward to talking with you, interacting with you. We will be going through kind of the process for today and, by all means, as we go through it you will have an opportunity ask questions. And let's make sure we can kind of move through the day smoothly. And I look forward to working with all of you.

CO-CHAIR CASEY: So why don't we start, Bonnie, with you and just reintroduce yourself briefly, where you are from, and what you do, and then we will move forward.

Good point. We were going to do that generally but if you feel like you have anything to disclose, say that. If not, say nothing to disclose.

MS. DORIAN: And can I just say if

you have anything to disclose, particularly in light of the measures, because we did do disclosures during phase one but that was before the measures. We knew which measures we were looking at.

CO-CHAIR LAMB: And just a reminder for those of you who haven't been here in a while. Please put your speak on when you speak, because everything is being recorded, and then turn it off so that the next person can go.

MEMBER WAKEFIELD: Bonnie Wakefield, Associate Research Professor at the University of Missouri School of Nursing and an investigator in the Health Services Research Center at the Iowa City VA Medical Center.

MEMBER CARRILLO: Good morning. Emilio Carrillo, Vice President for Community Health Development at New York Presbyterian Hospital and Associate Professor of Medicine and Public Health at Cornell.

MEMBER ALLER: Kathleen Aller with McKesson Enterprise Intelligence Systems. I deploy and implement measures but I don't develop them.

MEMBER FROHNA: Hi. Bill Frohna, Chairman, Department of Emergency Medicine here at Washington Hospital Center in Washington, D.C. I actually don't know much about Washington, D.C. as I'm from Rockville but I make that trip in every day. No, nothing else to disclose.

MEMBER LYNN: I'm Lorna Lynn. I'm the Director of Practice Improvement Module Research at the American Board of Internal Medicine, where I work on developing ways of assessing the quality of care that physicians provide.

MEMBER FOSTER: Good morning, I'm Pam Foster. I'm the Director of Care Coordination at the Mayo Clinic Health System and I have nothing new to disclose.

MEMBER LEIB: I'm Mark Leib. I'm

the Chief Medical Officer for the state Medicaid program in Arizona and I have no disclosures.

MEMBER HOWE: Tom Howe, Medical Director with Aetna in New Jersey, internist by training. I use measures but don't develop them.

MEMBER FARRIS: Karen Farris, University of Michigan College of Pharmacy. I'm a researcher.

MEMBER AUDET: Anne-Marie Audet, Vice President at The Commonwealth Fund for the Health System Quality and Efficiency Program and I have nothing to disclose.

MEMBER DORMAN: I'm Jann Dorman. I'm from Kaiser Permanente. I work in the care management institute where we work to develop care delivery improvements for all of Kaiser Permanente members.

MEMBER LEE: I'm James Lee. I'm an internist at the Everett Clinic near Seattle Washington and part of my role is to

work with care coordination between the hospital and the clinic developing programs.

MEMBER MC NABNEY: My name is Matt McNabney. I'm a geriatrician at Johns Hopkins and I work closely with the American Geriatric Society in their evaluation of quality measures.

MEMBER LOVE: Denise Love, National Association of Health Data Organizations. I have nothing to disclose. I just work with all payer claims databases and no very little else lately.

(Laughter.)

MEMBER WHITE: Alonzo White, Managing Medical Director, Anthem Care Management for WellPoint. My wife is in charge of EMR and Meaningful Use for Morehouse Medical School.

MEMBER LEFTWICH: Russ Leftwich, I'm the Chief Medical Informatics Officer for the State of Tennessee Office of eHealth Initiatives. I have nothing to disclose.

MEMBER ALEXANDER: Good morning, Dana Alexander. I'm the Vice President of Integrated Care Delivery and Chief Nursing Officer with GE Healthcare IT and I have nothing else to disclose.

MEMBER MALOUIN: Good morning, Jean Malouin. I'm a family physician with the University of Michigan, Associate Chair for Clinical Programs in Family Medicine and Medical Director for the Michigan Primary Care Transformation Project.

MEMBER KLOTZ: Good morning. I'm Chris Klotz. I'm Program Advisor to the Community Health Foundation of Western and Central New York. and have been responsible for an initiative on improving care transitions for the last five years or so.

MS. MC ELVEEN: Good morning, everyone. Nicole McElveen. I'm a Senior Project Manager with the National Quality Forum.

MS. DORIAN: Good morning. I'm Lauralei Dorian, Project Manager for Care Coordination.

MS. JOHNSON: Hi, I'm Karen Johnson. I'm the new Senior Director for this project.

MS. ALAYON: Good morning. I am Dawn Alayon. I am the Senior Healthcare Analyst at National Committee for Quality Assurance.

MS. HANLEY: Kendra Hanley, I'm a Project Manager with the American Medical Association, representing the measures on behalf of the PCPA.

MS. AST: Good morning, Katherine Ast. I'm Policy Analyst at the American Medical Association in Measure Development.

MS. CHRISTENSEN: Keri Christensen, also with the AMA PCPI in Measure Testing.

MS. YODICE: Good morning. I'm Laura Yodice with Measure Testing at the AMA

PCPI.

DR. ANTMAN: And Mark Antman, Director of Measure Development Operations for the AMA PCPI.

MS. DORIAN: And then Arjun.

DR. VENKATESH: Arjun Venkatesh. I'm the Chief Resident, Emergency medicine at Mass General and Brigham and Women's.

MS. DORIAN: Great. Thank you very much, everyone.

I wanted to just echo what Don and Gerri said and say how excited we are about spending the next two days with you.

Before we get started with any measure talk, I just wanted to go over a few quick housekeeping notes that I have.

First of all, our meeting staff will be out these doors for the whole two days. So if you have any questions about travel or anything like that, they will be there for you. They can also direct you to the bathrooms which are out these doors and

through the glass doors. But if you get lost, just ask them.

Just a reminder that this conference call or this meeting is being recorded. So please, as Don said, use your mikes. Turn them on when you are speaking and off when you are not speaking.

The call is also open to the public both days so we will be taking comments from the public twice today.

Also I think Don and Gerri we decided last time that it worked well to turn the name tents on their sides.

CO-CHAIR CASEY: So in other words, if you want to speak, turn your name up this way. And since I'm not so good with names, if you could just slightly tweak your names towards us. You don't have to drown out your others. That would be good. Because I think I know everyone's name but I'm not perfect. Gerri's perfect.

(Laughter.)

MS. DORIAN: We also have flash drives with any materials you might need. So just kind of waive your hand if you want us to bring that over to you. And you also should have received your voting device. So if you haven't, also waive your hand and Nicole can bring that over to you because she will running the voting portion of the day.

And we also wanted to note that dinner reservations have been made for this group at D.C. Coast, which is just a couple blocks away. So you are more than welcome to come if you want to. It will be around 6:30 p.m. And during lunch, we will put a sign-up sheet with the menu and the directions and everything so you can decide whether you wanted to come.

So are there any questions?

CO-CHAIR CASEY: And that will be Dutch treat on your per diem. Oh, Hi, Helen!

MS. DORIAN: Are there any questions about sort of the logistics of the

day or anything?

Okay, So we are just going to briefly give you an update on the progress of what you worked on in phase one. It's hard to believe that it has been over four months, I guess, since we met during phase one and did some of the strategic work. As you recall, Arjun, who we were lucky to have here for two days, presented the environmental scan to you. And then you also fed back on the first outline of the commission paper and then again met via conference call to feedback on the first draft of the Commission paper. And that paper is now open for public comment through March 6th. So it is on our website. It is also on the SharePoint site. So you, of course, are more than welcome to comment on that final draft as well.

And then you also importantly contributed to the development of the call for measures and the pathway for it and understanding what we wanted to see moving

forward in the area of the measurement of care coordination.

And unfortunately, as you know, we didn't receive any new measures but that call for measures still stands. It is a very important area of work. So moving forward, we will be keeping those concepts in mind that you developed and worked on.

And because we have 15 maintenance measures but we have two days, we really wanted to capitalize on that extra time that we have. So that is when we are going to be doing the discussion of revisiting the 25 preferred practices that were endorsed in 2010 as part of Nicole's project. So we will be having that discussion tomorrow and we will be talking about the measures today and tomorrow morning.

So with that, I will hand it over to Karen.

CO-CHAIR CASEY: Well, let me ask Dr. Burstin if she would like to make any

introductory comments.

DR. BURSTIN: Hi, everybody. Helen Burstin. I just wanted to say welcome. I'm the Senior VP for Performance Measures, except today I am the mother of two children with science fair projects.

(Laughter.)

DR. BURSTIN: So I couldn't take the Metro because I was late. And then I drove and L Street was completely stuck. So my apologies for being late.

But thank you for all your hard work. It's obvious you have finished all those evaluations on time and I think this will be a great discussion. I am especially excited, I think, about tomorrow because measures are great but I do think the fact that we got nothing in that was new really tells us that either the field isn't ready or we are not being clear enough on what those gaps really are. So I think our hope is to take those practices and really think hard and

actually try to get to some detail about what are those measures that need to be developed, rather than a lot of similar measures that we tend to see over and over again.

So these guys, you are in great hands and looking forward to a couple of days with you.

CO-CHAIR CASEY: Well we might the science project experts to be tie breakers if we need to.

DR. BURSTIN: They are seven and nine.

(Laughter.)

CO-CHAIR CASEY: Well you know, maybe that is good. They may know something about care coordination we don't.

So we talked a little bit about the flow of this. We have a list of measures and I want to be, Gerri and I met last night. We have our infamous pre-meeting chat that we do as a tradition. So we got it all down.

But seriously, we want to be

mindful and respectful of the measure developer who are here on a schedule and we know that Mark and his group are here today for PCPI. We have, by my count, three other measure development groups. One is NCQA, who I think is here today but predominantly going to be here tomorrow. And then CMS is here and then we have the AAD here for one of the measures.

So we thought that what we would try to do is without jumbling it up too much, maybe slightly reorder our approach to this, rather than from the top. So what we hoped to do perhaps maybe was in the beginning look at the PCPI measures but start with 0647, 0648, and 0649. I was on the conference call workgroup that discussed those measures and they seem to fit together in terms of the discussion around a transition record. And I think those of you who were on that call recall that that was pointed out that while they are not a composite, they fit together.

And so we thought that we start with that.

We also recognized that there are, in essence, four medication reconciliation style measures; one with PCPI and three with NCQA. And we also know that there is a CMS drug education on meds which may or may not be related. So those things sort of harmonize into one theme but we will discuss the med rec PCPI measure this morning.

And then the last is the, for PCPI, that sort of pairs up with the 0511, which is the imaging study for bone scintigraphy pairs up with biopsy follow-up of AAD to some extent. So if AAD is here today we might want to try to put those things together. But if that is okay with you, what we would like to do is focus on, for the next period, 0647, 0648, and 0649.

The process is we are going to ask each of the Steering Committee members who was the lead on discussing the measure on the call to start off with giving us a summary of the

results of the call as well as any nuances of the initial evaluation and just step through the components of each of the measures.

Then perhaps maybe I will ask Karen and Lauralei to just recount our voting process, if you could quickly.

So we will have a presentation. We will have a discussion. If there are questions, we will ask the measure developers to step up to the plate. We don't want to get into long drawn-out comments because those were hopefully dealt with. Obviously, if there was a to-do where we needed more information, we are going to ask the measure developers to provide any additional follow-up that was asked for and then we will vote on some of the categories in sequence.

And so do you just want to review that for us in terms of what we are going to be voting on?

MS. JOHNSON: Okay. As you recall, there are four major criteria. So

what we are going to do today is the first two criteria, importance and then scientific acceptability, those are must pass criteria. So how we are going to vote today is we are going to ask you to vote on each of the three sub-criteria under criteria one, importance to measure. Okay, so you will vote on each sub-criteria separately. And then we will use the decision logic to come up with the pass or not pass for importance so you don't have to vote on importance. Does that make sense?

We will do basically the same thing for scientific acceptability. So you will be voting on reliability, and then separately voting on validity.

And then again we will use decision logic to see if it passed scientific acceptability. Okay?

Then you will vote for usability, then for feasibility, and then overall for pass/not pass overall. Okay? Does that make sense? And we will go through this again as

we start the voting process. Okay?

CO-CHAIR CASEY: Does everyone get the general flavor? I think when we get into it, if there is confusion we will stop the train and be sure but I think the goal is to try to get as much quantitative evaluation of each of these subcomponents, knowing that they will be thresholds to proceed, importance obviously being the first one.

So let's move ahead then. Let me ask before we do that are there any -- Oh, I'm sorry. But before Karen does that, are there any general questions about what we have said so far?

Okay, Karen.

MS. JOHNSON: Thank you, Don. He's excited. He really wants to get into these but I am going to bore you with a few details first.

I just wanted to go over very quickly the evaluation criteria. I know you have done it before now with the workgroup

calls and doing the online tool. But I just wanted to hit a couple of high points. Again, all of our measures today are measures that have already been endorsed once. So these are not new measures. But just to remind you of some of the things that we are looking for is when we ask for things like gap analysis, that sort of thing, if the measure has been in use, then we expect data from the measure. So that is one of the things.

Reliability and validity, unless it has already gotten a high rating, then we are hoping that they have done even more testing so that we feel even more comfortable about reliability and validity.

For usability, we are looking for hopefully actually use in public reporting or accountability. Or if not that, then at least plans on how it would be used. And then finally with feasibility, we are really interested in hearing about problems with implementation, lessons learned, that sort of

thing.

As we go through, I know you guys know and love these rating scales but we will be flashing these scales up when it comes time to vote, just to remind you of things. So there is the generic rating scale for the first two sub-criteria of importance and then for usability. And again, there is a difference between giving something a low rating versus insufficient evidence. So I just wanted to remind you of that again. You have seen all these slides before but these are kind of things to keep in mind as you are doing your voting. So remember low rating is not the same as insufficient evidence. If you don't see what you need to make a determination, then you need to call it insufficient.

Okay, next slide. Importance to measure and report. Again, we have three sub-criteria under that criterion. And all three are must pass. And again, we are going to

vote on those separately. So again, all three are must pass.

This is just -- I'm not going to talk about this much but we do have an option that if a measure hits everything else but it has high performance level already. So if there is not a whole lot more room for improvement, we do have something that we can use called reserved status that we keep that measure alive. I don't think we are going to need that on these measures but if we do, we can come back to these slides and I will remind you of what that is.

Sub-criterion 1(c): submitted versus existing evidence. And many of you understood this from the workgroup discussion. I think some of the measures, as we have discussed, have fairly thin evidence. But again, we want you to think about this criterion in terms of what has been presented and remembering also that the developers have potentially added some things to their

submission since you saw it after the workgroups. So they did have a chance to add some stuff to that.

Again, the three scales for quantity, quality and consistency for high and moderate -- well, for all of these, really. For quantity, it is the number of studies in the body of evidence and again, body of evidence is the whole body of literature related to a measure, not just particular articles or selected articles.

Quality has more to do with the type of study that it was. So we all know our CTs are the gold standard. So if there is data from our CTs that will probably rate a high rating and then on down to not very well designed observational studies and such.

And then consistency, we are looking for consistency.

And then just to remind you, this is the decision logic table that we will use to see if something has passed criterion 1(c).

And you can see that basically you need to have moderate or high consistency to pass. And that is one of the main things. And insufficient evidence, if there is not enough evidence for these, then it may not pass 1(c), okay? But that said, this is something that I really wanted to point out because it did come up on the workgroup calls and it is going to be important today. We have a couple of potential exceptions to that evidence criterion. So even though the last slide just said if there is insufficient evidence it wouldn't pass it, we have an exception for other types of measures that are not outcome measures. And basically what that is is if there is not enough evidence, you guys can decide amongst yourselves if you think that the benefits would outweigh the potential harms. And if you can say that, then you could go ahead and pass criterion 1(c), even if there is not a full body of evidence with the great RCTs and that sort of thing. Does

that make sense? Everybody clear on that one?

The other exception has to do with health outcomes. We do have two outcome measures in the set of 15. And the exception for evidence there is you don't have to look at quantity, quality and consistency for the two outcome measures. What you are looking for there is just a rationale that you can link an outcome to some kind of process or structure, that sort of thing. Okay?

Again, scientific acceptability. The two sub-criteria are reliability and validity. And again, both of those must pass. And these are the rating scales for reliability and validity. Again, you have seen these before but I do want to point out we did some capitals and some underlinings here to just to really emphasize the difference between high and moderate ratings that you would potentially give here.

For reliability in both cases for high and moderate, you need precise

specifications. The difference between the two ratings has to do with the levels of testing that they did. If they tested at both the data element level and the score level, then you could give it a high. But if they did only one or the other, that would be a moderate. Okay? And validity is similar. In both cases you need good specifications that are consistent with the evidence. But to give it a rating of high validity, you need to have testing at both the data element level and the measure score level and you also need to feel confident that the threats to validity have been addressed. Okay, so that is when it needs to have a high rating.

To give it a moderate rating, if they have done testing at either data element level or score level or they have only done face validity, then that would be a moderate level. And of course again, threats need to be assessed. So that, I think the differences between those two, I'm not sure that we

pointed out well enough early on. So I wanted to make sure that you understood that.

These are the rest of the scales with the low and the insufficient.

And then you have seen this decision table and what this is telling you again is that basically you have to have high or moderate on both validity and reliability in order to pass the scientific acceptability criteria.

Okay, usability. Basically what we are looking for is is it useful for both public reporting and for quality improvement. And then feasibility, the extent to which data are regularly available.

This one is a little bit different. I want to gloss over this right now. We may want to come back to these slides later but we do have one composite measure in your list of measures that we are going to be looking at. And the main idea is that the composite measures, the way they are set up is

each piece of the measure, each composite that makes up the measure needs to either be endorsed by NQF or meet the individual criteria, just like a single stand-alone measure would. Okay? So that is the gist of these slides here.

I don't think I need to go over this right now. If we need to come back to these slides tomorrow when we discuss the composite measure, which is the NCQA Health Home Measure, these slides may be more important for us tomorrow. So go ahead to the next one and the next one.

And also I am going to put off this set of slides until tomorrow. But basically once you have gone through and you have evaluated, today and tomorrow morning, all of the measures, give them a thumbs up or a thumbs down, then we need to talk about whether there are related or competing measures. And when we do that, there are a few that we will have to look at and I will go

through those slides tomorrow. There is no point in doing it. We will have to do it tomorrow again anyway. Keep going. This is just the decision logic.

And now I am going to hand it over to Nicole who is going to tell us how we are going to do electronic voting.

MS. MC ELVEEN: Great. So as was previously mentioned, everyone should have a small device. We have specifically assigned a certain device to you. So please make sure that you hold on to the one that you are using. It is already on. You will have about 60 seconds to cast your vote. What we need you to do is you will cast your vote using the numbers here and each number will correspond to what you are voting for. So for example, as you see on the screen, if the voting measures are yes and no, you would push one for yes, two for no. High, moderate, low, insufficient it is one, two, three, four.

We do ask that you sort of point

towards me because I have the system here on the computer that will log in the numbers. You also must know that if for some reason you push the wrong the first time, the number that you push last is the number that will register. Okay? If we have any problems, we can easily redo our vote, if that is the case.

So we are going to go through just two quick test slides so you guys make sure you know what you are doing. So let's see here. So the first question we have for you is did you have any difficulties traveling to Washington, D.C.? You push one for yes and two for no. And you can start.

UNIDENTIFIED SPEAKER: Do we need to press send?

MS. MC ELVEEN: No, just push the number.

All right, good. Most of you didn't have any difficulties traveling. That's great.

So the second question we have for

you is how much snow covers the ground where you live. One for completely, two for partially, three for minimally, and four for none at all. And you can start.

And did everyone vote on the second question? I just want to make sure all the clickers are working. We have 21 responses but I think we have 23 people at the table.

MS. JOHNSON: You can keep trying. It won't count it twice.

MS. MC ELVEEN: A small green light will appear towards the top of the remote. Okay, I have all 23 now.

So this is the process that we will take again, throughout each of the measures that we vote on.

CO-CHAIR CASEY: So any questions? I know things may come up in the process but are there any questions about what Karen has presented or the process of voting? Yes, Helen?

DR. BURSTIN: Just one clarification of what Karen said that I was little confusing to me. I want to make sure people understand. So all these measures are maintenance obviously. They are previously endorsed. They have been tested. While we love if they have done additional testing, it is not an absolute requirement that it go up a level of testing at maintenance. It is often difficult for developers to do so I don't want to set that expectation up-front. It hasn't been something we have clearly shared with the developers. We would love that but we understand that is pretty difficult to do.

CO-CHAIR LAMB: Helen, could you just clarify they are endorsed -- if they are time-limited and there is any questions about any of the must pass criterion, how do you suggest we handle that?

DR. BURSTIN: If they were time-limited, meaning they hadn't yet been tested, then scientific acceptability is where testing

comes into play. And if they are not adequately tested, they will go down and the evaluation will stop at scientific acceptability.

CO-CHAIR CASEY: Any questions? It is all crystal clear?

CO-CHAIR LAMB: I have another question.

CO-CHAIR CASEY: Sure.

CO-CHAIR LAMB: Just in terms of order, there are measures that cluster in terms of what they are trying to capture, in terms of care coordination like transitional care, med rec. My understanding, I just want to clarify this, is that we look at them individually but that we would have an opportunity to look at them as a group in terms of making recommendations related to consistency for harmonization. Is that correct?

DR. BURSTIN: Yes, definitely. As much as possible. We know how difficult it is

in the course of our project to harmonize but any of those recommendations would be very welcome.

CO-CHAIR CASEY: So that won't actually be part of the vote but it will be a CODA to our discussion.

DR. BURSTIN: Right. So you would vote on the measure as is and then part of your discussion tomorrow is when you discuss what needs harmonization or which are competing. We could specifically give additional comments back to the developers, see what they can do and come back to us.

CO-CHAIR CASEY: We had a couple of other late arrivals down at the end of the table there. And we had done some introductions. So would you mind reintroducing yourself to the group and also we are asking if you have anything pertinent to disclose relative to today's work.

MEMBER HEURTIN-ROBERTS: I'm Suzanne Heurtin-Roberts. I'm from HRSA and

I'm one of the persons who voted yes, I had trouble getting to Washington, D.C. today. Metro was crazy. And 15th Street breaks up and doesn't just follow where it is supposed to.

No, I have nothing to disclose. Thanks.

MEMBER GREENBERG: Hi, Jeff Greenberg from Brigham and Women's Hospital. Sorry I was late. Nothing to disclose.

CO-CHAIR CASEY: No sweat.

MS. DORIAN: And I'm also just going to take this opportunity to see if we have anybody on the phone.

CO-CHAIR CASEY: Anyone on the phone?

(No response.)

CO-CHAIR CASEY: Not at present. We would just ask you to, if you want to speak, turn your card this way so we know that you have got your hand up. And also if you could just tweak your card just a little bit

towards us because I am not perfect with names and this would be great to just remind us.

All right, we are ready to jump in to the first part of this. And if everyone can get out our list, we are going to focus first of all on the PCPI Measures 0646, 0647, and 0648 -- I'm sorry, 0647, 0648, and 0649. We will deal with those three first, the transition record, the timely transmission of transition record, and the transition record with specified elements.

We don't have our full group here. I know Eva was the lead for 0648. So we may ask someone else on the workgroup to take the lead and I will ask for a volunteer in a moment.

But why don't we kick this off Russell with you, if you don't mind, walking us through the summary of the discussion and what the recommendations were for 0647.

MEMBER LEFTWICH: The discussion was that the evidence studies supported this

as a scientifically appropriate and valid measure. There was some discussion about the meaning of the setting of care that the inpatient facility and whether that was limited to acute care hospitals or not and it was, I think, a consensus that it should not be. And the majority of the workgroup felt that the measure rated highly and that it should be endorsed. I don't think there was any significant dissenting discussion, really.

CO-CHAIR CASEY: So this is page four of your Care Coordination Maintenance Project Summary that we sent out to you just in case you are missing that. Do you want to step through each of the segments of this, Russ, just real quickly? Do you have it? I know it is --

We are trying to match the leadership on each of the calls in terms of who covered what on the call from a kickoff standpoint so that you will be, as we move forward, those of you who were the lead on the

discussions will be on the hook to take us through this. We will also try to capture the information on the screen here so that you can read it up here to follow along so we don't get lost because I know there is a lot of stuff that we have to wade through.

So this is the description of the measure. And again, we are not going to dwell a long time on this.

MS. JOHNSON: In case this is too difficult for you to look at on the screen or if you don't have it on your computer, we have a few printed copies of this document and we can make more, if you would like some. Does anybody want a hard copy of this?

Okay. All right.

MEMBER LEFTWICH: The importance was felt to be high. My analogy was the importance of treating a severed femoral artery is fairly obvious.

And the scientific acceptability was considered either high or moderate by all

of the voters. The only issue that I recall raised was the measure says all ages but the evidence is really based on studies of older adult populations.

There was some concern about the chart abstraction to obtain the data for the measure versus electronic and that the chart abstraction might be prohibitive in terms of practicality.

CO-CHAIR CASEY: You want to show usability and feasibility? Why don't we go through the whole summary and then we will take comments and questions.

MEMBER LEFTWICH: Usability-wise, it was felt to be fairly overtly usable by both the patient population and other stakeholders. And because the data elements are captured in the course of care, the feasibility was felt to be high in general.

And as I mentioned earlier, there was some discussion about the clarity of what an inpatient facility represented, whether

that was only acute care hospitals or other inpatient facilities as well.

CO-CHAIR CASEY: And then these are some of the other discussion points here. The preliminary assessment was pretty unanimous on the small number of folks who were on the call, I think Russell, that this was suitable for endorsement.

MEMBER LEFTWICH: Right.

CO-CHAIR CASEY: But that these other issues were raised to AMA PCPI in terms of additional points to work on over the time period that this gets used.

In essence, I think one of the themes that came up was that it is much harder for organizations that don't have electronic systems, for lack of a better phrase, to collect some of this by hand than it would be if there was a well-oiled machine to sort of coordinate this. And I think that is technically important feedback. And I think we heard that consistently through a lot of

these measures so that is kind of a theme here. So in spite of that I think we, as you said, felt that this was the prize we were after.

MEMBER LEFTWICH: Yes, and my personal opinion is that we should be building to the future anyway and certainly there are many setting sin which electronic data collection is not yet in place but coming soon we hope.

CO-CHAIR CASEY: Right. Any other comments, Russell, that you want to make?

MEMBER LEFTWICH: It occurred to me after our discussion that the issue of what an inpatient facility is is I think it is appropriate to interpret that broadly but not to mix the data, I would think, in any single reporting of the measure that it should be segregated as to what the setting, inpatient setting is. It would seem usable to me to have a mixture of settings.

So we will take some questions or

comments. And again the rule is if you want to ask or say something, put your card up like that. So, Kathleen.

MEMBER ALLER: Yes, I don't disagree with anything that was stated. So, just up-front.

But this particular measure that is looking at do you have the right elements of the transition of care record, particularly as I look at it from the standpoint of an inpatient setting is very tightly aligned with the whole EHR Incentive Program and I look at it and say well you know, I don't have any objection to endorsing the measure but it would make more sense to just say did you in fact get a transition of care record from a system that is certified to produce this, rather than having to go through and assess in fact whether all the elements were there. Because if it is a certified system to produce this, they ought to be there.

And I guess I wonder how things of

that type, does that play more into how the measure would be used or implemented, rather than the endorsement process?

CO-CHAIR CASEY: Yes, it is kind of, in my estimation, kind of a chicken and egg question. In other words, does this then inform a certification process, for lack of a better word? And I mean that with a small c not a big C.

But I think that in essence this would evolve into potentially a standard set of data elements that would be part of the care transition communication.

MEMBER LEFTWICH: I mean I'm all about the meaningful use incentive program and what is in it but I think there is, in the incentive program, the thresholds are set fairly low. And I would worry that if we just relied on that to be sure that those data elements are transmitted, that might not be sufficient and wouldn't really be the equivalent of a quality measure that the

number of transition documents that have to be sent in stage one is only 50 percent and in stage two it is 65 percent. So true that a certified system should capture those elements but not that it would allow to measure the absolute number of those transitions where that data is being sent.

CO-CHAIR CASEY: Yes, but I just want to be sure we understand our goal here isn't to set certification standards. It is to decide about the measure.

MEMBER LEFTWICH: Right.

CO-CHAIR CASEY: So I think your point is well-taken about future usability, Kathleen and I think PCPI probably appreciates that feedback. So let me ask Karen, then.

MEMBER FARRIS: So I have a difficult question, guys. Because this is a process measure, the validity and reliability are really important. And as I read through the information about the measure, I am unclear what data are available to establish

the validity. I'm not questioning on its face that it is the right thing to do. I think that is kind of like med rec. We all think it is the right thing to do but there is not an RCT that says handing a person a transition record improved outcome. Well I don't think there is, maybe there is, but there is not one that says oh, we did a med rec, ADEs went way down. There is not an RCT that says that.

So I am just a little confused about what we are supposed to do around these kinds of process measures where it is a specific process and I really doubt that we have done the RCT to say this single step produced this outcome. So there is my concern.

CO-CHAIR CASEY: So Karen, let me -- It is a great, great point and one that comes up all the time. And I think the question you are raising is what would make this a really good measure, in terms of validity. And the answer is, something that

may not ever be done. So in the context of what we have to do today, you have to take the best guess in terms of your estimation of where the evidence lies and vote that against the sub-criteria that we are putting forward, knowing that many of these don't have level of evidence.

So I'm just trying to point out that in the voting, it would help to sort of think through that question and apply the sub-criteria in terms of what you think would be most appropriate in terms of how to judge this measure.

Does that make sense?

MEMBER FARRIS: Not really, as you can tell by my face. Because I thought that the criterion around validity and reliability are very straightforward and very, you know we got to have an RCT to link this to an outcome and we have got to have four or five of them to be high, okay, now she is saying no, that is not right. I mean, to get high you would

have to do that, to have a high rating you would have to have that.

So I'm sensing that we are moving to a lot of exceptions around the process measure. But I could just be interpreting this reliability and validity thing inappropriately.

DR. BURSTIN: I think we need to separate out what is evidence, which is actually under importance to measure and report, which is where the quality, quantity and consistency comes in. First was the reliability and validity of the measure. And many of these measures still tend to rely on the process in terms of face validity.

Requiring RCT evidence, I mean that gets to the quality of the evidence. You are not going to get an RCT, of course, that says you can deny somebody a transition record to show that they did poorly. That is an obvious on.

So it is going to be difficult to

find studies, I think, to do that. And I think that is why we did specifically put in to our criterion that there is an exception for areas like this. We will see if we can get the quick guide to share with you all but it just very clearly indicates that in areas where the evidence just isn't there but it is so obvious in some ways, intuitively obvious, and clearly the committee believes the benefits to patients significantly outweigh the risks, then there could be more of a pass on it.

But I do think there is a fair amount of evidence around patients having information resulting in improvement but probably not to this level of specificity.

MEMBER FARRIS: Thank you. Yes, I was confusing the terminology around importance and validity. So you are correct. The importance is what evidence is there that this is meaningful and that is where the RCTs and things come in. So thank you for the

exception opportunity.

CO-CHAIR CASEY: Well I am glad you are bringing this issue up on the first go-round because it is a thread through many of the rest of the measures that we are going to look at. So it is good to have this discussion.

CO-CHAIR LAMB: I think that the point is a really important one for the rest of the measures, which is in some cases the support, the evidence. We may not be able to get the RCTs but we are still dealing with when we get to scientific merit and reliability and validity, what we are dealing with is face validity. And so that the guideline related to where this face validity fit in this and some of you may have issues with stopping at face validity and not having construct or criterion validity but the guidelines specify that in the absence of higher levels of validity, that is a moderate. And so hopefully, we can tease that out as we

go through. But I am really glad you brought that up early.

CO-CHAIR CASEY: So Matthew.

MEMBER MC NABNEY: I think this was discussed on the call but I don't recall what was actually discussed. In the numerator it says that the patient or caregiver received it. What documentation that wasn't just given but it was actually received and what standard does that require of the person to get into the numerator? I don't know.

CO-CHAIR CASEY: Yes, I wonder if the AMA has any insight into that question.

CO-CHAIR LAMB: While you're thinking about the answer, can I add to yours Matthew? Because I had a similar question. In the numerator, it looks like it has three components. Did they receive it? Was it reviewed? And then did it include all the data elements? And it wasn't clear to me how the first two were met and whether it was an all or none.

If you had the data elements but there was some question that a patient received it or it was reviewed, what is the scoring?

CO-CHAIR CASEY: Do we have a mike over there for you? Do you want to answer that? I think the request was, Matthew, to repeat the question.

MEMBER MC NABNEY: The question, and Gerri elaborated on it as well is to be included in the numerator it sounds like in the description of the measure that the instruction, the discharge through the transition record needs to be given to the patient, to the caregiver but it is not clear to me how that is documented it was received and hopefully then acted upon. But just simply the act that it was received and somehow signed off on or signed for.

MS. AST: The way the measure is written right now it is just that the provider documents that they have given it to the

patient.

MEMBER MC NABNEY: That seems -- In my opinion that seems a fairly low threshold to dispense information as opposed to confirming that the information impacted care through the transition.

CO-CHAIR CASEY: It's one side of the handshake.

Okay, Jeff.

MEMBER GREENBERG: So I have a question on randomized controlled trials. I mean, I certainly think we need to have good evidence but for most of these, I don't think it is realistic to have randomized controlled trials. I have seen studies recently of researchers who follow around physicians and look at all clinical decisions made and what percent are based on randomized controlled trials and some are under five percent. So we really don't use randomized controlled trials in taking care of the patients in the vast majority of times.

So I just think if we limit ourselves to where there are randomized controlled trials, while I want there to be evidence, we are going to have nothing to do here. But that being said, for this particular measure, 0647, I think there is, there are good randomized controlled trials. Actually I think the Project RED Study at BMC, it was one site, granted, but it was a pretty good study of if you give patients a very sort of colorful, glossy, transition record, it does prevent readmissions. So I actually thought the evidence for this one was better than most of the process measures we have.

CO-CHAIR CASEY: Thank you. Tom?

MEMBER HOWE: Yes, this is a slightly different area question.

In this document, there is a reference to the measure actually being used with a high mark quality blue hospital Pay for Performance Program. A question about the inclusion of the information about measure use

and is this inclusive or is this -- How does this information get in here? And it is useful to know. Is the measure feasible and usable by some third-party but is this an example or is this the only group that used it? What are to think about the information that somebody used it?

CO-CHAIR CASEY: Yes, my gut is that it adds to the evidence that it actually has been implemented in some sort of standardized way. I don't know that that requires publication but I think the question maybe is for AMA PCPI to give us some feedback about that question.

UNIDENTIFIED SPEAKER: I'm sorry. It's really hard to here from over here.

CO-CHAIR CASEY: It is hard to hear. The question I think Dr. Howe is asking -- and actually if you could speak into your microphone a little more directly it might be helpful.

The question Dr. Howe is asking is

related to the use of this measure in a Pay for Performance insurance product and how that informs the reliability, validity and evidence around effectiveness of the measure. Tom, is that what you are asking?

MEMBER HOWE: Yes, what are we to think about the examples that we are given where it has been used.

MS. CHRISTENSEN: So this program, to give just a little bit of background, Highmark actually came to us when they heard that NQF had given the measures time-limited endorsement and they were very eager to include them. And they actually included them in two different programs, one for their inpatient transition of care measures and one for their emergency department transition of care measures. And their findings were really very interesting and very encouraging. Their experience was that at the beginning of the program year, very, very few of the organizations were able to meet the measure.

And through implementing different quality improvement projects, they were actually able to get that number up very significantly by the end of the year. I can't quote the numbers off the top of my head but over 20 percent of them reached the threshold that they were looking for within one program year, which they thought was really great. And they do publicly report those numbers in their annual report that is available online.

CO-CHAIR CASEY: Tom, does that help?

MEMBER HOWE: Yes, I guess I'm asking a more general question, though. What is the process for including measure use? Is that at the discretion of the measure designer or is that the discretion of NQF? What leads to somebody giving us an example of the measure that is being used in these documents?

CO-CHAIR CASEY: Let's ask Helen to give us some insight.

DR. BURSTIN: So it speaks

directly to the usability of the measures. So the usability criterion is really all about use, has it been meaningful. Actually it is interesting that the Board just approved the change to this criterion that will start in a few months, which I think will make it even more clear, which is really about use and usefulness as being one of the criterion. So I think the high market example gives you a flavor of that one particular group using it in an accountability application found it useful.

It isn't so much about evidence. It isn't so much about science acceptability. It is really about the third criterion of usability.

CO-CHAIR CASEY: Well, the way I view it is it is implementation evidence. It is sort of an additional key to informed use usability in terms of how it has been used in the field. So think of it that way as helping to inform your decision.

Yes, Dana?

MEMBER ALEXANDER: I don't know if I'm still clear on I heard the question asked and the answer for the threshold of meeting the intent that the transition record was given to the patient. But Gerri, one of her add-on question was what about the validation that the necessary data elements, required data elements were included in that transition record, in terms of information. Is that being evaluated as a part of this?

CO-CHAIR CASEY: I think your question is to PCPI.

MEMBER ALEXANDER: Yes.

CO-CHAIR CASEY: Yes. Did you hear that?

MS. HANLEY: Yes. I think that is really going to depend on who or what program is implementing the measure.

So for example in the Highmark Program, they would be responsible or take on the responsibility to make sure that the

information included in the transition records accurately reflected the care that was provided. If this measure was picked up by CMS in one of their programs, for example, CMS would have some of that responsibility to audit or verify that the information reported is representative of what is in the medical record.

So we as the measure developer actually don't receive that data. You know, we develop the measures. We trust the measures. We maintain the measures but we don't receive data back.

CO-CHAIR CASEY: I have Anne-Marie and then James.

MEMBER AUDET: This is the same following up on the same theme because in the way you specify your numerator, it says patients who receive a care transition record and with whom a review of all included information was document. From your definition, I assumed that your testing of the

measure was actually looking that the patient had received the record plus all of the documented elements were there, too.

So I just want to clarify because that is where I assume and from this discussion now I am hearing something else. But I may again, I just want to make sure I really want to understand how the measure was tested because how it is defined is very much along the line that all of the content was there.

And Lauralei is putting up the numerator statement just so that the Steering Committee can see what she is referring to. So any comments from AMA on that?

MS. CHRISTENSEN: So the Highmark Program implemented the measure but PCPI did our own testing project with an organization who did have an electronic health record and they actually went through and set up their electronic health record in a very clever way so that it would pull all the information into

a screen for the provider to review with the patient. They would then indicate in that record that they have reviewed all of that information with the patient and then it would print out a copy for the patient to take home. And the auditing that we did during that project to calculate the liability score that you see so that that was from that project.

CO-CHAIR CASEY: Does that help, Anne-Marie? Yes, James.

MEMBER LEE: Yes, I have a question about the sort of broad intent of these measures. There is a bundle. If you take a look at a sort of real high level, we will never quite have the clear evidence and trials on this.

So then the question is, is the intent to standardize care or cost with some measurement for better or worse this is how we do business type of question and that we have some standard format for healthcare to deliver transition and then asking the question is

this effective.

So one thing is are we think this will steer us to the right place or are we 180 degrees off in terms of course? I would like to sort of ask the developers this question and help us visualize this. Because for right or wrong, at least we are heading in the right direction if the bundle makes sense and is standardized.

CO-CHAIR CASEY: It's Russell's femoral artery analogy. Comments?

DR. ANTMAN: So forgive me. Restate the question, if you would, please doctor.

MEMBER LEE: Is part of the intent for this bundle measure to develop sort of a standardization nationally towards transitions so at least we have a platform to begin the quality improvement journey?

CO-CHAIR CASEY: Mark, can I just jump in here and clarify?

They are presented as three

measures and theoretically they fit together as a bundle. Our goal here is not to decide on the bundle. Okay? So I think the answer is yes but for today's work we are going to still have to vote separately on each measure.

So does that make sense? In other words, they fit together. So Mark, I don't know if you have anything to add.

DR. ANTMAN: Yes, thank you. Absolutely that is the intent. One might wonder, I will add, why we didn't develop these measures and present them as a composite from the very beginning. The reason for that is when we initially, when they were initially presented to NQF and implemented to the extent that my colleagues have described, they have not yet been tested and the PCPI policy is that we can't put forth a composite measure unless the individual components have been individually tested.

Now that they have been, it might be possible to consider putting them forth as

a composite. But at any rate, to go back to you question, absolutely the intent is to move the field and advance the state of what is being done at transitions.

MEMBER ALLER: I'm just concerned. There have been several questions about the numerator and the denominator and how this is calculated. And the responses have been kind of well it depends on how it was implemented at that organization and that leaves me with some concerns about the reliability/validity components of the evaluation. Can you comment a little more on that?

CO-CHAIR CASEY: Well maybe I can just help clarify what I think I heard and that is in the pilot that was done by the payer they sort of determined their own approach. But when the AMA actually tested it, they stuck to the numerator criteria in terms of evaluation. I think that is what I heard. Right?

MS. CHRISTENSEN: Obviously I was

not part of the implementation but we did have several conversations with them about the intent of the measures. And as far as I know, they followed it exactly.

CO-CHAIR CASEY: James do you still want to say something? Put your card down, then.

(Laughter.)

CO-CHAIR CASEY: Jeffrey.

MEMBER GREENBERG: It's great to know that this was used. I just think in general do we want to know anything more than that it was used about how it went? I mean, we've probably all seen payers at times use measures; some are great and some end up doing terribly.

So it would just be nice to have a sense okay you used it and what happened. Like, did docs revolt? Did patients revolt? Was it helpful? Was it not helpful?

CO-CHAIR CASEY: Any insights?

MEMBER GREENBERG: Yes, was there

any impact on any outcomes?

MS. CHRISTENSEN: So in the Highmark Program, I've got the numbers up here, the first year they used it as a pilot program for their top, top tier of performers. And it went well enough with that top, top tier, very small Tier 3 hospitals that they rolled it out to the full fan the next year for the Quality Blue program is an option opt-in for additional payment.

And the numbers for 2011, and this was somewhere around 60 hospital organizations, I'm not sure of the exact number, for quarter one 27 percent of the organizations met the measure; for quarter two 30 percent of the organizations met the measure; and 94 percent met it in quarter three. So like I said, it did take some time for them to ramp up to get into that level of performance but they were able to do a really good job. That was the transition record at discharge measure.

CO-CHAIR CASEY: Dr. Carrillo.

MEMBER CARRILLO: Actually, the numerator there is about maybe 12, 13 elements that are required. If a particular record lacks two of the elements, does that mean the measure is negative?

CO-CHAIR CASEY: In other words, it is not included in the numerator, Emilio. Right?

MEMBER CARRILLO: Right.

CO-CHAIR CASEY: And the answer is yes. The answer is yes.

Dr. White.

MEMBER WHITE: I want to go back to Dr. Greenberg's question. Excuse me. You gave information about what percentage of people participating actually were able to accomplish this but you didn't give us any outcome information. Is there any outcome information available?

CO-CHAIR CASEY: That is the PCPI. Right?

MEMBER WHITE: Yes.

MS. CHRISTENSEN: They are looking at that but with it only being in the program for one year, they don't have -- it just hasn't been enough time since 2011 for them to have that statistical power yet.

CO-CHAIR CASEY: Dr. Frohna, did you want to --

MEMBER FROHNA: I was going to comment on the same thing. Basically that you can take a passport to surgery and have six people check a box and the wrong patient can still have the wrong procedure done. So that was the outcome that we were looking for.

CO-CHAIR CASEY: Okay. So good discussion. Good clarifications and good review. Thank you, Russell for kicking this off. Hopefully some of these questions I think will be generic questions as we move forward. So we will keep these in mind.

But I think we should get ready now to move into our vote. And Nicole, do you

just want to remind us sort of what that step-wise is going to be briefly so that we get that fresh in everyone's mind and you get your handy dandy voters ready?

Everyone has a voting device. Right? And we all have used it before. So Nicole, do you want to --

MS. MC ELVEEN: Yes. So, everyone should have your voting device. Again, we are going to vote on the three sub-criteria for importance first. So you will see on the two screens on the left and right of the larger screen is the first is impact. And again, impact addresses a specific national health goal priority or that the data demonstrated a high-impact aspect of healthcare.

So your voting options are one for high; two for moderate; three for low; and four for insufficient. And you may begin your voting now.

CO-CHAIR CASEY: And point to

Nicole.

MS. MC ELVEEN: Okay.

CO-CHAIR CASEY: Do we have everyone?

MS. MC ELVEEN: Yes, we have everyone. We have 16 high; six moderate; zero votes for low; and zero for insufficient.

CO-CHAIR CASEY: Okay. Our next vote.

MS. MC ELVEEN: Next is going to be performance gap. The data demonstrated considerable variation or overall less than optimal performance across providers and/or population groups.

Again, one for high; two for moderate; three for low; and four insufficient. And you may begin.

CO-CHAIR CASEY: While we are doing that, is there any committee member that joined us on the phone since this time?

No one, okay.

MEMBER POWELL: Actually this is

Eva Powell with National Partnership for Women and Families.

CO-CHAIR CASEY: Oh hi, Eva.

MEMBER POWELL: Hi.

CO-CHAIR CASEY: What should we do, ask Eva to record her vote verbally?

Eva are you following along with our discussion?

MEMBER POWELL: Yes, I am.

CO-CHAIR CASEY: So you can let Nicole and Lauralei know what your vote is, your numerical vote on this one. One is high; two is moderate; three is low; four is insufficient.

MEMBER POWELL: Okay. Should I just do that by email or verbally?

CO-CHAIR CASEY: Why don't you do it verbally?

MEMBER POWELL: Verbal, okay. I'll vote two.

CO-CHAIR CASEY: Moderate. And what was your vote on the first one?

MEMBER POWELL: I missed the discussion on that one so I won't vote.

CO-CHAIR CASEY: Is this on the webcast or not? No. We'll go back and get that to you. All right, thanks.

Okay, so it looks like it is about split down the middle here, ten to nine with one low and two insufficient. And Eva has moderate.

MS. MC ELVEEN: And it is really ten high and three moderate.

CO-CHAIR CASEY: Okay.

MS. MC ELVEEN: And the last under evidence is going -- I'm sorry. The last under importance is going to be evidence. Again, looking at the quantity, quality, and consistency of the body of evidence. And one is for yes and two is for no. And you may begin your votes.

CO-CHAIR CASEY: And Eva if you want to just record your vote over the phone for us.

MEMBER POWELL: Okay. I'll vote yes.

CO-CHAIR CASEY: Thank you. We are using voting devices so we won't attribute your vote.

MEMBER POWELL: Thank you.

MS. MC ELVEEN: We're still waiting for a few more people.

CO-CHAIR CASEY: We're still?

MS. MC ELVEEN: One more.

CO-CHAIR CASEY: One more. Oh, Kathleen stepped out.

MS. MC ELVEEN: Good.

CO-CHAIR CASEY: So we had 17 plus one yes and four no, with one abstention.

MS. MC ELVEEN: So we are skipping the empirical and we are skipping overall for importance?

CO-CHAIR CASEY: Right.

MS. MC ELVEEN: All right, our next is going to be on the scientific acceptability of the measure properties. So

first reliability.

CO-CHAIR CASEY: So we are on 2(a), reliability, Eva. One is high; two, moderate; three, low; four, insufficient evidence. This includes precise specifications and testing with appropriate method and scope with adequate results.

MS. MC ELVEEN: Okay, you may begin voting.

CO-CHAIR CASEY: Eva, do you want to --

MEMBER POWELL: Yes, you can record me as having the fourth option, inadequate evidence.

CO-CHAIR CASEY: Four, okay. Thank you.

So two high; 14 moderate; four low; and three for four, with Kathleen out of the room.

CO-CHAIR CASEY: Okay, next. Validity.

MS. MC ELVEEN: Next is validity.

So again looking at several elements including whether the specifications were consistent with the evidence, looking at the testing, risk adjustment, stratification, and your voting options are one for high; two for moderate; three for low; and four for insufficient evidence. And you may begin your votes.

CO-CHAIR CASEY: Eva do you want to --

MEMBER POWELL: Yes, I'll do four again.

CO-CHAIR CASEY: Four. Thank you.

MS. MC ELVEEN: All right.

CO-CHAIR CASEY: So one high; 12 moderate; five low; and five insufficient evidence with Kathleen abstaining.

MS. MC ELVEEN: So, so far we pass on importance and scientific properties.

CO-CHAIR CASEY: So the measure passes on the first two major criteria.

MS. MC ELVEEN: Yes.

CO-CHAIR CASEY: Now usability.

MS. MC ELVEEN: Yes. So usability. Again, same voting options. One for high; two for moderate; three for low; and four for insufficient information. You may begin your voting.

CO-CHAIR CASEY: Eva?

MEMBER POWELL: I will go with one.

CO-CHAIR CASEY: Okay.

MS. MC ELVEEN: Two more responses we are waiting for. Okay.

CO-CHAIR CASEY: Fourteen high; six moderate; three low; and zero insufficient. Great.

MS. MC ELVEEN: The next is going to be feasibility. Same voting options. One for high; two for moderate; three for low; and four for insufficient information. You may begin voting.

MEMBER POWELL: This is Eva. I'll go with two.

MS. MC ELVEEN: And we're waiting on two more responses. Okay.

CO-CHAIR CASEY: We have eight high; ten moderate; three low; and one insufficient.

MS. MC ELVEEN: And what was Eva's vote?

CO-CHAIR CASEY: And Eva was moderate?

MEMBER POWELL: Yes.

CO-CHAIR CASEY: Eleven.

MS. MC ELVEEN: Okay, and the last is overall suitability for endorsement. And you vote one for yes, two for no. You may begin your voting.

CO-CHAIR CASEY: Eva?

MEMBER POWELL: One.

CO-CHAIR CASEY: Yes.

MS. MC ELVEEN: All right.

CO-CHAIR CASEY: So I haven't gotten the formula memorized but I think this one passes.

MS. MC ELVEEN: Yes. We have 23 for yes and zero for no.

CO-CHAIR CASEY: Great. Well, that's good. This was the first time I have used the criteria. I think this is really an enhancement. I hope you do, too. And I think the discussion is helping to also inform the measure developers.

So knowing that many of the themes that you have brought up today are going to be probably repeated, why don't we see if since it is 10:00, do you want to move -- shall we move to one more and then take a break? Does that seem reasonable?

MS. DORIAN: Also, we have made copies of this document that summarizes the workgroup discussions. So if anybody wants one.

CO-CHAIR CASEY: Matthew, do you --

MEMBER MC NABNEY: Since we are all kind of learning this process, in the

discussion if we can have help which of these components we are talking about so we can sort of mentally take notes for ourselves that this is going to impact our vote on this or that. Because I have thought about it as I was voting I should have paid more attention to the discussion of what was actually being discussed so that might be helpful.

CO-CHAIR CASEY: So I think the point is we are trying to make sort of a Robert's Rules of Order for NQF and that is good point which is when you are addressing something, say I am addressing this or that in the sub-criteria so that we can just be sure we are all on the same page. And it may be that you have two issues but I do think that is very important, Matthew, to help us with our process. It also helps the measure developers as well because I just think we are going to -- Yes, Gerri?

CO-CHAIR LAMB: While we pass this, question in terms of follow-up is that I

thought the discussion was very rich and had many important points. How does that go to the developers like PCPI in terms of improvement in measure specification, the encouragement to do more validity testing? Are those just basically recommendations? Are those expectations for the next time it comes up to maintenance? Just some clarification of what happens to these excellent recommendations.

DR. BURSTIN: I'll start and certainly the developers can chime in. I mean usually the developers are always interested in finding opportunities to improve the measures. So I think you are giving them a lot of good thoughts. These are measures that are so important that have actually been retooled, etcetera. So I think they are going to get a good bit of actual use in the coming years and I think that as the measures come up for either annual updates to NQF or certainly by the three-year review that there would be

an expectation that all these comments would be considered and the measure would be improved.

We also can do an ad hoc review at any point in time, just to remind folks. So that if the evidence base changes or if there is new information or the developers learn from implementation more broadly that there is a better way to make this measure, they can bring back those changes at any time and we can review them. So it isn't static for three years but certainly the last point would be by the three year maintenance we would expect some of these changes to be incorporated.

CO-CHAIR CASEY: Well let me also point out that in the consensus development process, after we are done, then staff will be creating a summary document which will include our recommendations that will go to public comment and then come back to us for review, followed by then the final document for vote.

So there are still steps along the

way and they will try as best they can to reflect in summary format what the rich discussion is in terms of key points, just so that the end user understands that we are addressing a lot of these issues from a technical standpoint. And obviously I know that AMA PCPI staff well enough that they will always take any good feedback to heart and take that back to the shop. And I believe that is true pretty much with all the measure developers I worked with. So I think we are in good shape but it is a good point, Gerri, to just remind us about.

Anne-Marie?

MEMBER AUDET: Yes, this is the perfect point. So Helen, does that mean that for instance in three years when a new committee comes along there would be some new in order to judge this we need this additional information?

DR. BURSTIN: Yes, there is always an expectation by the next maintenance you

would consider whatever the maintenance committee had said previously.

CO-CHAIR CASEY: Okay, so -- Oh, I'm sorry. Jean.

MEMBER MALOUIN: Yes, I just wanted to speak to the feasibility piece of this. It seems like with a lot of these measures, the feasibility of moving these forward in a uniform way really depends a lot on EHR vendors being able -- us being able to have a voice with EHR vendors to say this is the direction we need to head in. Because without the ability to do this standardized along a lot of different EHRs or across a lot of different EHRs, these things will never get the momentum that I think they need.

So I think I would just put out a plea for that to be sort of the next step with this is to really try to influence the vendors of those electronic systems.

CO-CHAIR CASEY: Well, I think that is one level Jean. And just hearken back

to all the times you have worked diligently on reviewing the preferred practices to also think about how they fit together with the other components of care coordination. And I think, obviously, we are not going to just bring these out as individual items. We need to fit them together.

But at this point what we are lacking is a standard framework and so I think your point is well taken that this is really the foundation for getting that into a more direct conversation and decision about what the future looks like as far as how these things appear in the general practice of daily care coordination.

Yes, Dana?

MEMBER ALEXANDER: So I will just add on to that from a vendor perspective that I think there are so many initiatives that are in flight right now in the industry and that there is some really forcing functions. So I think that will help to achieve what you have

just described, Jean. And that whether through the standards and the operability framework, through the quality data model, the meaningful use, you know, EHR incentives.

So again I think there are initiatives in place that will help to really create those forcing functions for this change to create the standardization that we all are seeking.

CO-CHAIR CASEY: Yes, and I think when we get into the discussion of preferred practices, we will have a chance to talk more about this as one component of what we need to do.

I think what we want to do now is move into the next measure. And Eva, I don't know if you were here in the beginning but we are going to ask each of the folks who were on the subcommittee calls is I will call them to start by kicking off the summary of the information that was sent around by staff around the results of those calls. And we

have you on next for 0648. And I don't know if you knew that or not. But would you feel comfortable sort of walking us through the next measure, which would be 0648, transition record with specified elements transmitted to the facility? This would just be a high-level overview of what we discussed on our conference call and what the results were in terms of our overall assessment in the subgroup of these domains.

MEMBER POWELL: I guess I don't have what was sent around. Is it on the SharePoint site?

MS. DORIAN: It is on the SharePoint site, yes.

CO-CHAIR CASEY: It is on the SharePoint site. So perhaps maybe what I might do is ask if any of the other members, since I don't want to put her at a disadvantage, any of the other members would volunteer to lead that. And if there are no volunteers, I will. Does anyone want to take

that, since Eva is a little disadvantaged?

Okay. Well since I was on the call, let me just walk through this. I think actually, as I said before, the discussion was along the same lines as the measure that we just talked in terms of some of the issues around usability and feasibility.

Obviously, this fits into the same paradigm that we talked about about the quality of evidence being more on an observational/retrospective basis. Clearly, the group felt that it was important for the most part and that the evidence in terms of importance for health outcomes was based on decision logic. There was no available evidence at the time we discussed this to decide if the health outcome was rationally supported by this. You can see the sub-voting on quantity, quality, and consistency was about two-thirds high, one-third medium.

The acceptability of the measure was fairly unanimous overall. The reliability

had high to medium. There were some discussions, as I recall, about the reliability and validity by members of this subgroup. People thought that this was, for the most part, a highly usable measure and that feasibility again was somewhat of a challenge, although not an insurmountable challenge. There was again the ever present discussion of the difference between how this works in the paper record versus the electronic health record but people generally felt that this met suitable criteria for endorsement.

And as you can see, PCPI was on the phone. There were some feedback points about terminology and whether there was any validation as to whether in the transmission of the record, whether the correct information was actually ensured at the other end, in terms of documents and documentation.

We did, you know, to James' previous point, highlight this is a bundle,

although it is not being presented as a bundle, that these kind of fit together with the one voted on and also 0649.

And that in general, there was positive feelings about this in the context of some of the limitations that occur around measures like this.

So let me ask the subgroup, did I get that right? Is there anything you want to add?

So let me see, first of all if there are general comments and then if you want to deal with specifics, let's go ahead and deal with those. Russell, you are reaching for your card.

MEMBER LEFTWICH: Well I guess you implied it and we talked about it before. The measure states it correctly that the information was transmitted but what is missing is some confirmation that it was received, which is going to apply -- did apply to the last measure. And it is just a comment

that I guess we all need to carry forward to the rest of the community that that is a data element that we need to enable.

CO-CHAIR CASEY: Yes, the intent of all of these transition issues is that both sides of the handshake are working, so to speak.

Other questions? James.

MEMBER LEE: You know, I would like to raise a question to PCPI and also everyone else. It is interesting when we talk about the sort of quality measures as studies really look at subpopulations in this after these trials worked. Vulnerable patients this worked. Heart failure patients, this works well.

Now looking at electronic records, though, it is hard to turn it on for certain subpopulation only. You know, there is some technical elements that are structurally different about the world we live in today as opposed to in the past. And the question that

I sort of bring forth that as we endorse these measures in a larger population, are we comfortable with that sort of raw concept and saying it worked for subpopulations and the health records generally is for the whole population you are managing.

And that is a big switch. And how do we understand the implications? And I don't know how to answer that. And I seek for expert advice on this matter.

CO-CHAIR CASEY: So let me ask. Does PCPI want to -- do they understand sort of the general question? I think what James is asking about is sort of how do we get more specific with certain subpopulations and ensure that we are not just dealing with the bare bones issues. Right?

MEMBER LEE: Right. And in day-to-day practice and speaking as a medical director, once we turn that thing on, it is on. You know? It is hard to turn on for heart failure patients over 65 on three meds.

Generally, that is not how these electronic health records work. And so I would just like to pose that question. We are making a big leap here in terms of acknowledging the next level. Do we all feel good about making that leap? Is that the right leap to jump?

CO-CHAIR CASEY: Mark?

DR. ANTMAN: Thank you. Mark Antman for the PCPI.

So I think unquestionably the development group considered when this measure is being developed if it should be focused on certain populations, heart failure patients or others. And I think the feeling of the group was that given that the technology should be available to make that transmission, rather, of the transition record within 24 hours possible, the feeling was that it should be applicable to across all patients, all discharge patients that is. And they absolutely recognized the potential data collection burden being created but I don't

think the group felt that there was any -- that there was sufficient evidence to justify focusing the measure on any one more multiple particular subpopulations.

CO-CHAIR CASEY: Does that help, James?

MEMBER LEE: It definitely gives me a little more confidence looking at this as a broad measure.

CO-CHAIR CASEY: Pamela?

MEMBER FOSTER: My question related to the numerator. And you may have just answered it but I was not clear whether it was all patients who had a written record transmitted and I was wondering if this included any type of a verbal handoff from provider to provider would that be included in the numerator?

CO-CHAIR CASEY: Lauralei is putting that up on the screen here.

So Pamela, do you want to -- do we -- Can you specify here?

MEMBER FOSTER: In the numerator, would that include any patient who was discharged who had a verbal handoff from the provider to provider or is this strictly a written record that was transmitted to another provider?

DR. ANTMAN: I'm looking for the specific language that excludes verbal transmission but I believe somewhere in here it does say the intent was to be clear that it must be written. It may be electronic but verbal is not acceptable.

CO-CHAIR CASEY: I wish I could get credit for all the things I said but didn't write down. Never mind.

Matthew.

MEMBER MC NABNEY: I think from the standpoint of --

MEMBER FOSTER: Well I think it is important because at Mayo Clinic we do capture that electronically, that verbal handoff. And the handoff sometimes the written record is

not always prepared in the way that the receiving provider needs it to be at the time the patient is discharged. So I just, I think there is an opportunity there that could be looked at.

CO-CHAIR CASEY: Yes, I think Pamela your point is that it is one thing to say here is a piece of paper, here is an electronic health record. It is another to actually have a conversation between providers about what is important and that gets back to our tradition of being sure that we communicate directly rather than just saying, well didn't you get the facts or the piece of paper or the e-message. Right? Didn't you get my email?

Matthew.

MEMBER MC NABNEY: I think that last measure and this measure and the handshake analogy, I really -- Independent of the actual exchange, whether it is the med list or the summary, I think the process of

ensuring receipt as well as delivery, it is almost a cluster measure within all these measures is finding better ways to do that, whether it is electronically, fax, verbally, and how to document that. I mean, that would really move a lot of these forward.

CO-CHAIR CASEY: Gerri?

CO-CHAIR LAMB: I would just encourage everyone as we are having this discussion to go back to the plans for tomorrow, which is where are the priorities and gaps and maybe jot some things down. So Matt like your comment there about making sure we get that handshake, what is it that we really think is central to capture in care coordination that we don't have right now? I think we can agree that this is really a beginning set and that we have an opportunity here to suggest some future direction. So please jot down notes for the discussion tomorrow.

Mark, I have question for you.

You mentioned before that PCPI looks at individual measures, before taking a look at the opportunity for bringing them together. It would just help me as we kind of go through some of the other transitional care measures in that just to think of where PCPI is going because the ones we are looking at right now either go to the patient or they go across providers. But they differ in the data set. What is the components of them in terms of receipt. You know, sent received, reviewed, and so forth.

What is PCPI's thinking about next steps down the road? I know we will get to harmonization but before you are not here with us, I really would like to think about what is next steps. Because I am struck by we are seeing one measure at a time and there is opportunity, it looks like, for building consistency not only within the measures but across. So where is PCPI on that?

DR. ANTMAN: So thanks for that

question, Dr. Lamb. Unquestionably, this workgroup, this development group, many members of the group express the opinion when these measures were being developed that that next step, the confirmation of the receipt of the transition record and action taken by the next provider should be included in the measure set. And certainly we are all hearing this again today, of course.

The feeling at the time that the measures were developed was that the burden of assembling the data from multiple sources to include in either a single bundled or composite measure.

At that time, the feeling that would be too burdensome to try to collect all that information. But unquestionably, things have advanced and we have not had the opportunity to reconvene this workgroup. But certainly when we reconvene this group, I'm sure that that will be one of the first topics of discussion. Have things progressed far

enough that we can now add a measure or integrate a measure related to the receipt of the information and action taken by those providers?

So I can assure you we have taken that to heart and that will absolutely be part of the discussion going forward.

CO-CHAIR CASEY: Jean and then Emilio.

MEMBER MALOUIN: Yes, this may be something that is sort of implied in the language here but it says the process of providing it within 24 hours of discharge. And I just wondered if we needed to clarify that it is not enough, I mean from a recipient point of view, it is not enough to produce it within 24 hours. If you stick it in the mail and then the recipient doesn't get it for a week or something, it is really not useful. But to actually have the receipt of it within 24 hours of discharge, I think is the critical point.

CO-CHAIR CASEY: Yes, be sure that the handshake occurs within 24 hours. Right? Good. Emilio.

MEMBER CARRILLO: Yes, what is the rationale for not including more specified requirements for the numerator statement? Why is there -- whereas in the other measure we do.

CO-CHAIR CASEY: I think it is because this is kind of a transactional measure. Did the transaction occur? This is my read but I will ask AMA to clarify.

MS. HANLEY: Yes, that is correct. This measure is really looking at whether or not the transition record from the prior measure that we discussed was transmitted within the appropriate time frame. So we are not actually -- This measure is focused on the timing of that transmission.

MEMBER CARRILLO: That linkage is not clear outside of this room.

MS. CHRISTENSEN: So I had the

opportunity to go out to seven different hospitals as part of a base validity survey that we went out and talked to different organizations. And the way we explained it was that measures are set up as a group. So you could send a really bad record out in a short amount of time and do well on this measure or you could send a really good record out in a really long amount of time and do good on the other measure, or you could do good on both measures and send a good record quickly, if that makes sense.

CO-CHAIR CASEY: Yes, and I think it fits back into the paradigm that while these are testing individual parts of the transaction, their intent is to fit them all together over time. So does that make sense?

MEMBER CARRILLO: Right because the importance of having those elements for the next provider I think is perhaps more relevant than the importance for the patient who may have no health literacy to have those

elements in their hands. So I see a need to make that more clear.

CO-CHAIR CASEY: That they don't understand.

MEMBER CARRILLO: Well, that there will be elements also applied to the provider record.

CO-CHAIR CASEY: Chris?

MEMBER KLOTZ: Well you are talking about these two as fitting together but in the 0647, it is saying that this record is going to the patient or their caregiver. And then in the one we are just talking about, it is saying it is going to the next facility and the primary care physician.

So I don't see that the 0647 more detailed description is necessarily applied to the 0648. I don't see that you have made that connection.

CO-CHAIR CASEY: Yes, let me -- Maybe I misspoke. I think their intent is ultimately to make these things to fit better

together. But I think we are just voting on this measure right now, in terms of whether the transaction is important, knowing that they do intend to evolve into a composite.

MEMBER KLOTZ: So it is just the transaction, not necessarily what it includes.

CO-CHAIR CASEY: That's all we're voting on. Right. That's all we are voting on is the importance, the evidence, the feasibility of achieving the numerator.

DR. BURSTIN: I guess one question would be and this came up I remember the last time this measure came forward, that the term transition record isn't really a term of art. It is one you clearly defined in the first measure. It is being used in the second measure.

So as I read it, my understanding is, you are in fact transmitting within 24 hours the transition record, which you have defined in the first measure.

CO-CHAIR CASEY: Yes, okay.

DR. BURSTIN: So the question is, should these actually be paired I guess would be the question that you should really be looking at them together.

CO-CHAIR CASEY: Yes, and I think that is why we are considering them together. I think though if we make the assumption, which I think is Chris' point, it is implied but let's get clear on what we need, for example, by a transition record in a standardized set of data elements. And I think that trying to connect this with the other measure is going to be sort of the work of the AMA in terms of implementation.

But I just want to point out that again this is mainly about being sure that whatever is sent is standardized and done in a timely fashion and sent and received in a way that is validated.

So I think that is the important intend of this measure. Lorna?

MEMBER LYNN: So there is a data

collection flow sheet that was included in the materials that looks identical to the previous measure. So I assumed that it was looking at those same elements as Helen was just saying.

CO-CHAIR CASEY: Good point. Any other -- Yes, Anne-Marie?

MEMBER AUDET: That's what I assumed to. The only thing is when you did your reliability testing, whether you looked at what was being transmitted or if it just was the record and the record could have been missing half of the elements. So again, we are coming back to this thing.

So the question I think is really how you tested it.

CO-CHAIR CASEY: Yes, and I think Mark said before they did not get to testing these as a composite. That is their next intent. So if we endorse the three of them, then that will give them the ground to then move to designing it so that it is put together, which I what I think we are trying

to get at.

Right Mark?

MS. CHRISTENSEN: So the data collection form, if you guys have that, that is actually great, that was very, very similar to what we did as a data collection form for the reliability testing which we did. So we did go through and look at each of the elements specifically as well as the time frame. So if it is listed as a data collection element there, it was assessed in the record.

CO-CHAIR CASEY: So this is just to show you how they did it. We are not voting on the data collection form, though. Right? This is just to give you background information about the technical specifications about what was transmitted, which I assume was closely harmonized with the other measure.

CO-CHAIR LAMB: Again, I think there is a common theme that we should just come back to as we review other measures that

look like they have some similarities is the alignment. And I think we are raising that in so many different ways.

I have a question about the reliability. In looking at the tests and these were done across these measures in I guess the same or similar sites, the CAPA for 0648, for this one, the timely transmission of the transition record is much lower than the others. Can you speak to that, what you think is going on there? It is really not a strong support for reliability.

MEMBER KLOTZ: So this one in particular, for those of you who are familiar with electronic health records, the system, the way they were doing it, had it set up to automatically fax. It is, unfortunately, very, very difficult in some systems for a human being to go in and find that date and time that it was faxed. And the records don't necessarily stick around for a long time. So if some of that was based on our sampling, it

went past the amount of time that it was stored in the record. So that would be a definite recommendation to vendors to keep that information around longer if it is something that we consider important.

MS. YODICE: I was going to mention also that our sample was 100 patients and that there is actually 95 of those cases did agree in our reliability testing, only five did not. And the low CAPA is just probably a result of the lower sample of 100.

CO-CHAIR CASEY: Thank you. So, Eva, do you have any questions or comments? We hate to not have you here. But I'm sure you have been listening in with great enthusiasm here.

MEMBER POWELL: Yes. no, I don't have any questions. Thanks.

CO-CHAIR CASEY: Okay, so no cards -- Russell.

MEMBER LEFTWICH: Just a quick -- on the last measure, I was surprised that

people didn't see a performance gap. In this measure, I just wanted to preempt that by saying people think this is happening. I don't.

CO-CHAIR CASEY: Good point.

So, Nicole, I think we are getting fired up here to vote. So everyone get their votes. Eva get your voice ready and we will turn it over to Nicole.

MS. MC ELVEEN: Okay. So we are voting again on the three sub-criteria under importance. The first is impact. Your voting options are one for high; two for moderate; three for low; and four for insufficient. And you may begin your voting.

And Eva, if you can hear me, just let us know when you are ready what your vote is for impact.

MEMBER POWELL: Okay, I would say one.

CO-CHAIR CASEY: Twenty-three ones, zeros for the rest.

MS. MC ELVEEN: Okay, the next is going to be performance gap. Again, voting options One for high; two for moderate; three for low; and four for insufficient. You may begin your voting.

MEMBER POWELL: This is Eva. I vote one.

MS. MC ELVEEN: We're waiting on -- Okay.

CO-CHAIR CASEY: So we have 15 to eight, high to moderate with zero low and zero insufficient.

MS. MC ELVEEN: The next is on evidence. And this is one for yes and two for no. You may begin your voting.

And Eva, your vote on evidence?

MEMBER POWELL: The choices are one for yes and two for no?

MS. MC ELVEEN: Yes.

MEMBER POWELL: Two.

CO-CHAIR CASEY: We have 18 yes and five no. So I think we are moving ahead

here.

MS. MC ELVEEN: Okay, we are moving on to the scientific acceptability of the measure properties. The first question is around reliability. The voting options are one for high; two for moderate; three for low; and four, insufficient evidence. You may begin your voting.

And Eva your vote on reliability?

MEMBER POWELL: Moderate.

CO-CHAIR CASEY: Two high; 16 moderate; three low; two insufficient evidence.

MS. MC ELVEEN: Next is validity and the same voting options. One for high; two, moderate; three for low; and four for insufficient evidence. And you may begin your voting.

And Eva your vote on validity?

MEMBER POWELL: I will say moderate again.

MS. MC ELVEEN: And we are missing

one vote from the members here.

CO-CHAIR CASEY: Two high; 15 moderate; three low; two insufficient evidence.

MS. MC ELVEEN: So we are passed on the scientific acceptability.

CO-CHAIR CASEY: Yes.

MS. MC ELVEEN: Next is usability. The same voting options. One for high; two for moderate; three for low; and four for insufficient information. You may begin your voting.

MEMBER POWELL: This is Eva. I will say moderate.

MS. MC ELVEEN: We're missing one more. Let me make sure.

CO-CHAIR CASEY: I feel like I am in Chicago. Vote early and often. Right? Unlike Chicago, we hope.

So ten high; eight moderate; two low; two insufficient.

MS. MC ELVEEN: The last is going

to be feasibility. The voting options: one, high; two, moderate; three, low; four, insufficient information. You may begin your voting.

MEMBER POWELL: This is Eva. I will vote moderate.

CO-CHAIR CASEY: Five high; 15 moderate; two low; one insufficient.

MS. MC ELVEEN: All right. And last is overall suitability for endorsement. One for yes, two for no. You may begin your voting.

MEMBER POWELL: Eva votes yes.

CO-CHAIR CASEY: Twenty-two yes; zero no. The measure, I think passes for endorsement.

MS. MC ELVEEN: Yes.

CO-CHAIR CASEY: So good work everyone. We are off to a good start. We are going to take a break. I would like to ask Denise to be ready to get in position for 0649. And then for AMA's edification, we

would like to do 0511 and then go back to 0646, if that is okay with you.

So let's take a -- my watch -- What time do we want to synchronize our watches to, Karen? We want to be back at five of -- five 'til eleven. Okay? Thank you.

MEMBER POWELL: And this is Eva. I'm going to have to sign off now but I will see you tomorrow.

MS. MC ELVEEN: Thanks Eva. See you tomorrow.

CO-CHAIR CASEY: Great.

(Whereupon, the above-entitled matter went off the record at 10:41 a.m. and resumed at 11:01 a.m.)

CO-CHAIR CASEY: Okay, so we now are without Eva on the phone but I think everyone else is here. And I am going to ask that we reconvene and let's move to 0649. We are going to do, just to remind you, we are going to do 0649 and then we will do 0511 after that. So mark, we will ask you to get

in position until 0511. And then we will end with, we will go back to 0646, who I think James had. So James isn't here but I will remind him.

But in keeping with the transition record theme, we thought it would be useful -- James you are going to be the fifth one when we do med rec -- to move toward the last of the transition record measures, 0649, which is transition record with specified elements received by patients discharged from the emergency department. This was, again, the same discussion group that dealt with the others. And Denise, we are going to turn it over to you to sort of help us run through the discussion points and what was decided on that call.

MEMBER LOVE: And I will apologize ahead of time that I was not on the call. I was --

CO-CHAIR CASEY: I'm sorry.

MEMBER LOVE: That's okay. I was

actually skiing at Big Sky that week. So, apologies.

CO-CHAIR CASEY: So you had snow on the ground.

MEMBER LOVE: But I did read the measure and I think the discussion really for 0647 is relevant to this one in 0648 because it seems like the same measure except for it is specified for patients discharged from the emergency department. And I think that the group felt that this also is high impact.

The evidence in some of the comments were mixed because I think the testing was done on inpatients, and that is my assumption, and not really on the ED. So we are just assuming that the similar results would occur as for inpatient with the emergency department. So the performance gap has some mixed reviews.

Again, the scientific acceptability could just be carried over from the previous discussion. I won't go into that

and the nuances but the sub-scores were derived based on the inpatient testing of the measure. The group felt usability was high, feasibility is mixed, and I think the receipt and confirmation issues are identical.

I did note, I mean and this is where I come into the NQF process a little handicapped because I just noted there are some other overlapping measures in NQF's suite of measures but I don't know that that is relevant at this point for this measure. And then my own thinking was the harmonization of the inpatient and the ED numerators. I think they are quite similar but maybe a little different. But from a feasibility standpoint, I just had a question to the developers. I mean, would it not be more streamlined to do the numerator for the ED and the inpatient or any site of care the same? And then the sampling would differ, you know whether it is an ED or an AM surge, you know, not to have numerators specific to the site of care

because I think the issues are the same. And then that is more of just my question as I read through this.

But I think the group had almost identical scores between 0647 and 0649.

CO-CHAIR CASEY: So, AMA, do you want to give us some feedback about that question of the --

MEMBER LOVE: Yes, so importance was high. Let me go back. Let's see. The scientific acceptability was mixed but mostly yes. Usability was mostly high with some spread between medium and insufficient. And feasibility mostly high. So and importance, everyone felt or most of the people felt that it was important. There are some feasibility questions because the EHR doesn't really exist in a global sense and so there is some abstraction involved. So you know, the cost burden and all of that I'm not getting into because that is outside the scope of this discussion as well.

CO-CHAIR CASEY: Great. Why don't I, before we ask AMA to comment, ask if any of the other members of this subgroup who were on the call or not have any other items to add to and elegant summary by Denise?

So the AMA PCPI folks I think have a question before them about some of the minor discrepancies between the numerators, Denise.

DR. ANTMAN: Right. This is Mark Antman for the PCPI. Yes, this was raised I think in the conference call a couple of weeks ago. And as I think we may have noted then, there was some consideration by our development group of exactly duplicating the requirements of the other measure that you have already looked at, the transition record for inpatient discharges in the measure for the ED setting. But the feeling, frankly, was that and this was with considerable input from emergency physicians participating in the work, the feeling was that it was, frankly, unrealistic to construct a measure with the

bar set as high as it was for inpatient discharges for the ED setting as well, given the various differences in the nature of the ED setting and discharges from the ED setting. The feeling was that the requirements of the measure, the numerator elements should be restated to be absolutely raising the bar for what is currently done in ED discharges but not requiring the level of detail and quite the number of elements that were specified in the other measure.

CO-CHAIR CASEY: Gerri.

CO-CHAIR LAMB: This is another question for you, Mark. That makes sense in terms of being reasonable about the setting. Was there any discussion in terms of within that standardizing the components so that they were similarly defined across these kinds of measures or is that next step kind of work?

MS. CHRISTENSEN: Operationally, again those of you who might be familiar with processes and EHRs, typically the discharge

process for inpatients is different than the discharge process for an emergency room patient, simply because of the length of stay and the complexity of the stay. So this was thought to be more in line with that when we actually went to implement it in organizations.

CO-CHAIR LAMB: I have another question also related to the evidence. I noticed that much of the citations in this one are pretty much the same as the other ones and there really aren't any here specific to transfer of information in the ER. Is that because there is no data out there on that?

MS. AST: Hi. Yes, there certainly is not as much data and I spoke with one of the emergency physicians on the group prior to this meeting and he was pointing to a few things that are similar but again, not directly related to this. And I wanted to just read you another thing that he said that there is no evidence supporting the idea that

the inclusion of specified elements in the transition leads to better outcome. But there is some indirect evidence that because of the emergency situation and the sorts of problems people are being transitioned are highly variable that the points in the trajectory of care when a tradition occurs are similarly highly variable that prescribing a standard set of data points would likely be wasteful or even potentially harmful.

So he was saying that the attention would be directed to some irrelevant data and away from what is really important and he pointed to a couple of books that he has done with Emily Patterson. This is Dr. Robert Wears. So just part of the evidence is still in the works but there is just not as much for the emergency department as there is for inpatient.

CO-CHAIR CASEY: Dr. Frohna.

MEMBER FROHNA: I would agree. As far as I am aware here is a paucity of

information out there with regard to discharge instructions in the transition of care. Intuitively this makes sense and I think we should be doing something about this. And I think these data elements in the workflow and in the time crunch that we experience in the EDDs, these elements are, I think, obtainable, achievable and transmissible into the document for the patient in the follow-up that we need.

So I think both of those things are very reasonable.

CO-CHAIR CASEY: You know, one place to look potentially is in the greater Cincinnati area where they have instituted something called HealthBridge which has been in play for many years that actually creates a transition record and makes it easily, quickly communicable across settings to all providers who participate in that. So it might be, if you haven't looked, a place to consider. And I know that just by virtue of the fact that I have been in Cincinnati for part of my career.

So whether they publish that or not, I don't know, but it may actually be a good place to look.

So, Jean?

MEMBER MALOUIN: So I apologize if I missed something here but it looks like 0647 and 0649 are sort of paired in a sense that they are ED and inpatient. But it doesn't look like there is a paired one for 0648, which is that the facility gets a record from the ED facility. And that seems like that would be very important as well.

CO-CHAIR CASEY: So you are pointing to, let's say, a nursing home patient or --

MEMBER MALOUIN: Well, no, even an -- My understanding of 0649 is that it is the patient gets the record. And what I am thinking of is when a patient of mine is in the ED, that my clinic receives a record of their discharge as well.

CO-CHAIR CASEY: Yes, I'm honestly

getting confused about the term facility because I think in some worlds that means a hospital only. So that is just my own bias. But I think you are talking about the next point of care that is responsible for the care delivery.

MEMBER MALOUIN: Right, exactly. Yes.

CO-CHAIR CASEY: Sometimes facility isn't the right word, in my opinion.

MEMBER MALOUIN: But is that addressed under 0649?

CO-CHAIR CASEY: So Mark, I think that is a confusing issue and maybe you have thought through that but I wonder if you have any insights.

DR. ANTMAN: I'm sorry, specifically the use of the word facility in this context for the ED?

CO-CHAIR CASEY: Well I think Jean is a bit confused about what that means in terms of what that universe is.

MEMBER MALOUIN: Yes, I guess what I am thinking about is does this 0649 refer to the ED giving just the patients the transition record or does this also include the ED sending to the recipient facility, like where the patient's primary care home is? Do they get a copy of the discharge record?

DR. ANTMAN: So it is specific to the former, the transmission of the information to the patient and not the latter, not the transmission to another setting.

That was certainly considered by the development group but again the feeling at that time was that this was a starting point, to standardize what the transition record must include at ED settings. This certainly is an opportunity for enhancement of this set of measures as we go forward.

MEMBER MALOUIN: Thank you.

CO-CHAIR CASEY: Yes, certainly my own experience in rural Arizona as a primary care physician taking full risk Medicaid

capitation is that we wanted to know every patient was in the ED whenever they were 24/7 and we wanted some information about it. So I think in the context of things like accountable care, global capitation, this is going to be really important to sort of be sure we connect those dots, Jean, in the future. So thank you for bringing that up.

Yes, Mark?

DR. ANTMAN: May I just add? The group has hopefully noticed how we defined the plan for follow-up care, which is an element of the transition record for the ED setting where the intent there was to provide that connection with the PCP or specialist or whoever will be caring for the patient after the ED discharge, although it is not an attempt to say that that information must go to that other site of care within a certain period of time. It was an attempt to include in the transition record given to the patient at least an indication of what needs to be

done with your PCP or whoever will be seeing you next.

CO-CHAIR CASEY: Bill.

MEMBER FROHNA: I was going to say I agree with that because it is kind of, what Jean had brought up, a baby step. And eventually getting to the point where patients know their doctors in their healthcare home and from that way we can kind of tie in information systems that send the autofax or email or whatever to the provider. But the reality is there is pockets of success, whether it is Cincinnati or some places around the country but overall those pockets are few and far between and in the minority of situations.

And so I think just kind of getting to this point of agreement for a discharge transition to the patient or care provider and say take this with you to your doctor. I've tried to call, I can't get ahold of him. It is 2:00 a.m. on a Saturday. That

type of thing. So I think putting the onus on the patient a little bit is part of it but I think getting the emergency providers to put the information out there is an important step. And then ultimately closing the loop downstream at some point will be important as well.

CO-CHAIR CASEY: Well and just to finish the thought, sometimes it is very unclear to the patient who that person should be. So having that information readily available at the point of care for the ED to say this is who I am talking about, also helps. So I think it sort of connects the dots both ways. That is really where we want to go.

In rural Arizona it is easy because I was next door to the ED and I almost camped out there.

Denise?

MEMBER LOVE: As someone who has measured emergency department reports, data,

for many, many years, we struggle over defining emergency department. I mean, I have been through meetings that have lasted two days and we have not resolved how to define an ED.

So that was one question here. And I don't know how the measure is constructed and how rigid the ED. But I am a health system using it in one setting and another health system another, you could have very different results if you count your urgent care or you count observation, which observation is this black hole that nobody knows what to do with.

CO-CHAIR CASEY: Well I think that is a really good point and I don't know if you have gotten that far in terms of parsing this out but operationally, I think that is going to be important. Do you have any insights?

DR. ANTMAN: I would say that is certainly a consideration for us going forward. I would say we have not, the initial

thinking was to -- I don't even recall any discussion of attempting to parse it out at that point.

MEMBER LOVE: Well I would recommend, you know, I think in here somewhere I read in the longer one the definition with the 450, the Revenue Codes, but I would be quite limited to those settings and not just open it up because you are going to get different rates because of the observation care issue and urgent care issue.

CO-CHAIR CASEY: That's a great question. In the age where we are trying to avoid sending people or having them show up in the ED for care and providing them with alternative sites where they are going to sort of a caregiver that they don't really have a therapeutic or personal relationship with, I think this is going to become a bigger and bigger issue going forward. So I really appreciate your bringing that up in the context of this. For now I think we are

talking about the ED in terms of how it is defined on the UB-04.

MS. HANLEY: And just to add to that, we have not included urgent care or observation in this measure.

CO-CHAIR CASEY: Lorna?

MEMBER LYNN: So something I am struggling with a little bit this morning is thinking with all of these measures, but especially this one in 0647, this could be done well or could be done not so well and you could still check the boxes off. So it is different than a lot of process measures where either the cholesterol is obtained or it is not. I wonder about that in terms of what we will learn going forward with these measures in terms of this being done preventing another ED visit or not, depending on how it is done. I guess this is mostly for the NQF staff if they have any advice on how we should consider in our rating or just in comments for the future.

DR. BURSTIN: It's a good point, much more so for the future. I'm not sure really how much can be applicable right now but it is worth discussion.

CO-CHAIR CASEY: Well I think this one is very high stakes because it is kind of a chicken and egg. Right? Presumably some of these patients are in the ED because care coordination wasn't good. So, are we just putting them back into the system that sent them there? I don't know. But I think that is what you are getting at is how do we get more global in terms of our thinking. So that can come out in our day two discussion about what we need to inform the future.

CO-CHAIR LAMB: And going back to what Will was saying, which is what is essential for baby steps. What are we missing for baby steps and what do you envision for the next step so that we can keep moving the measurement forward? And I think that is going to be the crux of tomorrow. But you

know, Will's baby steps is really important. We are probably missing a lot of baby steps. So what else needs to be there? But a lot of this discussion on the transitional care measures is really kind of establishing that foundation and infrastructure. Where do we want to build it?

CO-CHAIR CASEY: So no cards are up, which means we are getting in position to call again to vote. So why don't we go ahead and do that?

We have Kathleen and Eva who are absent so we will mark that. But let's proceed with our process here.

MS. MC ELVEEN: All right. So, let's get started. If everyone can view the screens, I am just going to announce what we are voting on. If you feel it is still necessary for me to announce the voting options, I can do that as well. But I think everyone has gone through the two exercises so you are probably comfortable with it.

So the first we are voting on is impact and this is under importance sub-criteria. And you have your four voting options shown on the screen and you may begin your voting now.

CO-CHAIR CASEY: Kathleen, we are voting on 0649, which is the transition of the ED. I know you were on a call but you are eligible still to vote, if you still wish.

MS. MC ELVEEN: Okay, so we have 16 high; six moderate; zero for low; and zero for insufficient.

CO-CHAIR CASEY: Okay.

MS. MC ELVEEN: The next is performance gap. And you may begin your voting.

Okay, we have 14 for high; seven for moderate; one for low; and zero for insufficient.

The next criteria we are voting on is evidence. And this is a yes or no. One for yes and two for no. And you may begin

your voting. One more person.

Okay, we have 15 for yes and seven for no.

CO-CHAIR CASEY: So we move forward.

MS. MC ELVEEN: Yes. The next is the scientific acceptability of the measure properties in reliability. You have the four voting options showing on the screen and you may begin your voting.

Okay. We have one for high; 14 for moderate; seven low; and one insufficient evidence.

The next criteria is validity. And you have the four voting options. And you may begin your votes.

Okay we have two high; 14 moderate; six low; and one insufficient.

The next criteria is -- So we passed on the measure properties. So we are moving on to the next. It is going to be usability and you have four voting options

shown. And you may begin your vote.

We have 11 high; nine moderate; three low; and zero insufficient.

The next criteria is going to be feasibility and you have four voting options as shown on the screen. You may begin your votes.

All right, 12 high; eight moderate; three low; and zero insufficient.

And lastly we are going to vote on overall suitability for endorsement and the voting options are one for yes; two for no. You may begin your votes.

All right, 23 yes.

CO-CHAIR CASEY: So we are three for zero, batting one thousand on yes. So I think that was really good work and Gerri and I thought hard about putting these three measures forward first because we think it got to discussing them together kind of got to the heart of some of the issues that are generic throughout the work we have to do.

We would like to shift because we have the PCPI staff here to the other two measures, which are released but somewhat different. And I am going to ask Marc if he would step up to discussing the 0511, which is correlation with existing imaging studies for bone scintigraphy. Marc you were on that call, I hope.

MEMBER LEIB: Actually I was not but I wasn't doing anything fun like skiing. But I have reviewed the data that was presented here.

CO-CHAIR CASEY: You are in the group.

MEMBER LEIB: I will try to present it fairly and if I get off because of words here don't reflect what was discussed in the group, someone else please jump in.

CO-CHAIR CASEY: No problem. Thank you.

MEMBER LEIB: I'm going to start with of course the description of the measure

and the numerator and denominator. So I am not going to go through what that has been -- what is already there.

In the group call, there was some discussion about the importance to measure and report. And surprisingly while they said that there is a high and that the impact can be high and the quantity and quality of the evidence is high, the importance to measure, one person said yes and two reported no on the overall numbers. So again, I wasn't part of the call and can't tell you why but the numbers speak for themselves.

The accessibility of the measure properties, though, everyone voted yes on that. So we have concurrence of that, although most were in the moderate range.

I don't know if you want me to go through all the measures individually or just --

CO-CHAIR CASEY: Well I think just highlight the sub-criteria in terms of what

was discussed and what the decisions were.

MEMBER LEIB: The sub-criteria on the evidence based on decision logic, there was one yes and two nos. And it is not a health outcome so that was not applicable there.

The quantity and the equality of the measures were mostly no votes. There was one high vote on quality, two lows; all lows on quantity; and on consistency, two lows and one high. Again, it seems to be one way or another by when the results were looked at in the studies.

And the acceptability of the measures was again yes three; no zero. But they were all in the moderate range. The reliability and validity were moderates for the most part with one low vote on the validity.

And the usability, it was moderate and high for all three participants and the feasibility was moderate or high for all three

performance events.

And the preliminary assessment whether criteria is met or suitable for endorsement, yes were two and no was one.

CO-CHAIR CASEY: And I think the discussion points.

MEMBER LEIB: The discussion points, there was a lot of concern expressed here in the written report regarding that some of the exclusions were not well defined. It was talked about the correlation whether or not the reporter, the nuclear medicine doc who dictates the report correlates the findings of the bone scan to other studies, whether it be a CT, an x-ray, an MRI, or something else had used reasonable efforts to obtain those other reports and other studies. And there is no definition of what a reasonable effort is. There is no definition of how much trouble they are expected to go to obtain those other studies to then correlate it or I didn't have it in my fingertips and therefore I couldn't

compare it and that was enough to exclude it from the denominator.

And I think because there was a lot of that, my favorite terms I squishiness in the denominator, that there would be a lot of variability in the measures on how often it was successful or not successful or appropriately reported in the correlation provided on the bone scan report to the other studies that I was trying to get out over here.

And if I am misunderstanding or misstating it again, please jump in.

CO-CHAIR CASEY: So any comments or questions from the participants of the group or others? Jean.

MEMBER MALOUIN: Yes, I just wanted some clarification. This is just looking at, correlating with previously done studies. This isn't advocating for doing additional studies to correlate.

MEMBER LEIB: Correct.

MEMBER MALOUIN: Okay, thank you.

MEMBER LEIB: Looking at a previously performed study, again whatever it was, an x-ray, MRI, or CT, and you are looking at bone scan, bone scans, I know the clinicians here all know this, but they can be nonspecific. You can have a hot spot on a bone scan for a number of different reasons. In order to correlate it, especially in say a patient with cancer and know if it is a metastatic disease or something, you might want to look at another study to see what that other study looks like also. So I think that is where they are trying to get the measure to improve overall quality but it is not to advocate for new studies or additional studies being done at the time.

CO-CHAIR CASEY: Lorna?

MEMBER LYNN: I've thought about this measure a lot since the phone call and thinking it basically excludes the studies that weren't able to be obtained were not --

coordination. We won't know what percentage of -- can't be correlated with study. And although I understood from one of the developers on the call who was a physician, she doesn't want to be blamed for that. She says maybe instead the institution.

I'm worried if we are just not going to understand what the reality is if we allow that.

CO-CHAIR CASEY: Good point. Gerri?

CO-CHAIR LAMB: Question for the workgroup. Did you have any discussion about the fit with this particular measure in care coordination and the fit of looking at the correlation between different tests before any given population? Was that part of your discussion?

I'm just interested in conceptually if you saw this as a fit with care coordination.

CO-CHAIR CASEY: Any thoughts? I

have the same question. Tom?

MEMBER HOWE: We didn't discuss that at the workgroup but I think this is marginal in terms of its relevance to care coordination, particularly if we leave this denominator this way.

I share Lorna's concern about the denominator. It really defeats the purpose of the measure.

CO-CHAIR CASEY: Tom you had your card up. Did you want to add anything else or that was it? Anne-Marie.

MEMBER AUDET: So I reiterate I had the same concern about the denominator exclusion. And also really much what Gerri was picking up on, this is just looking at whether there is other radiological confirmation. But what about the history of the patient, the course of the patient's illness, laboratory data? So I felt this was a very narrow definition of care coordination that perhaps would not benefit us as we were

really looking at a much more comprehensive definition of coordination.

CO-CHAIR CASEY: Alonzo?

MEMBER WHITE: My concern is that this may actually generate additional studies because if the test, the x-ray is not readily available, what are you going to do if you know you are being measured? You are going to order another one, rather than make that reasonable effort. So I am concerned it is actually going to increase the amount of utilization you are going to see --

CO-CHAIR CASEY: James.

MEMBER WHITE: Without improving health outcomes.

MEMBER LEE: Looking at this measure at another level, in the trenches when we see patients, we are asked to call 800 numbers often to see if a certain study should be done. That is care coordination.

But you know, if you are stepping back to looking at another level, really what

we are asking is was the test appropriate. Is there any clinical evidence that if we go through a set of guidelines that this is appropriate? And embed that as sort of a quality measure on ordering tests.

So I do see a connection between imaging and quality but you know, this funnel is getting real small with this particular measure. So we start opening up this area to blend the two, looking at imaging utilization as a quality issue and I think that is an important question to ask. There is a lot of care coordination done day to day for imaging.

CO-CHAIR CASEY: Jeffrey?

MEMBER GREENBERG: Well, I agree with what Anne-Marie and others have been saying. This just seems like a very narrow and somewhat random measure. The first three we dealt with were sort of major issues. Right, going home from the hospital or the ED with any problems. And now we are talking about nuclear medicine which is a big deal but

it not the major problem facing healthcare. And I can see if this measure applied to all radiology studies. You know, any radiology study should incorporate other films that are relevant. This just seems sort of too small and I agree with the sort of methodological issues that others have brought up as well.

CO-CHAIR CASEY: Yes.

MEMBER HEURTIN-ROBERTS: It seems to me that really this is more a question of best practices in imaging, than it is a question of best practices in coordination, measuring best practices in care coordination.

I think that it is probably a very good thing to measure. Certainly it seems to be a good thing to do but I'm not sure it is really relevant to care coordination. As we said, it is narrow but I think it is in the wrong --

CO-CHAIR CASEY: Suzanne, would standard of care be a better phrase than best practice?

MEMBER HEURTIN-ROBERTS: Sure. Sure.

CO-CHAIR CASEY: Yes, I thought the same thing. Emilio.

MEMBER CARRILLO: Would focusing on this particular item give the impression to the world that this is more important than the one thousand other measures that are more relevant to care coordination that are not here?

CO-CHAIR CASEY: Yes, let me -- I am speaking for myself now. And I am thinking back to when we voted on this because I think Helen we approved this in the original steering committee.

We want to be sure we have got a space for everyone, that every care giver recognizes that there is some importance of care coordination in their domain. And at the time this was just about average in terms of the types of things we had two or three years ago. So I don't remember the specifics but I

think this was along that vein that it was, it could be argued within that domain it was important for that particular microsystem. Your larger system about where does it fit into the grand scheme I think is still relevant. So Helen, did you want to --

DR. BURSTIN: I think you are right. I don't think it was in this project in particular but there was another one. I think there is still a desire to make sure there are measures that reflect care coordination in different fields. And so I think the issue, probably the reason this measure has gone forward to date has been the fact that frankly there aren't a lot of measures for radiologists around care coordination yet they play a role.

So I'm not sure every measure has to kind of be the big tent, Jeffrey, but at the same time the question is does this one fit in that sort of grand scheme of being applicable to a certain population where there

are coordination issues at stake, and does the measure meet the criteria.

CO-CHAIR CASEY: I mean, you could back out of that any of the women in the room have gone through the issues around imaging for other reasons know this, that getting people to at least talk to you and tell you what is going on is, I think the biggest challenge. And my sense was that was the general intent of this measure was not in our previous steering committee. I misspoke but I think that is really why this was brought forward. But that is up to the committee to decide at this point.

So I am going to see if -- Yes, Lorna?

MS. DORIAN: I just wanted to let you know this measure was originally in the outpatient imaging efficiency project.

CO-CHAIR CASEY: Thank you.

So any comment from our AMA counterparts?

DR. ANTMAN: So I believe we have another staff member and a clinical expert that may be on the line. So I'm hoping they may be able to comment on some of the issues.

CO-CHAIR CASEY: Who would that be?

MS. JOSEPH: Hi.

CO-CHAIR CASEY: Okay, there we go.

MS. JOSEPH: This is Diedra Joseph. Can everyone hear me?

CO-CHAIR CASEY: We can hear you great.

MS. JOSEPH: Okay, thank you. Thanks for the opportunity to respond and thank you for your review.

So if I may, I would like to address a couple of different issues that the committee has highlighted and then I will defer to the clinical expert, Dr. Sue Abreu who is on the line to add more.

So with regards to, I know that on

the pre-call there was a lot of discussion about the denominator exception. So after the pre-call with the subgroup, the society of nuclear medicine and AMA PCPI nuclear medicine workgroup co-chairs revisited the idea of removing the exception from the measure but they still believed that the system reason exclusion should remain in the measure.

So the intent of the measure is really to encourage correlation with existing imaging studies. However, expert clinicians in this field confirm that there are frequent instances in which existing studies are not available. Just as an example, patients frequently visit multiple institutions for different studies, especially when referred for advanced therapy. So given the variability in accessing a patient's existing studies, the co-chairs thought that the system exclusion should not be removed in order to allow for accurate capture of those instances in which the study is not available, hoping

that this will help inform the quality improvement gaps that may exist between providers and also support the notion that it would be unfair to penalize clinicians for not being able to obtain a previous study if reasonable efforts were made.

So to that point, I also wanted to address the reasonable effort kind of issue. And we also did discuss after the pre-call possibly editing the measure in that we could add a definition for reasonable effort. And so we did try and draft a possible definition, in order to see if that might help to further clarify for the committee. And I will just read the draft that we came up with.

So for the purposes of this measure, reasonable effort is defined as an attempt to obtain copies of any relevant imaging studies or reports performed within the preceding 12 months to include requesting that the patient bring the images and reports, if possible, and contacting the referring

provider, the prior ordering provider, or the facility at which the imaging study was performed prior to the finalization of the current bone scintigraphy report. When such studies are not available, the reason for lack of availability should be recorded.

So that is kind of how we attempted to address the issue about how to define reasonable efforts. And then I think that I will defer to Sue Abreu, if there is anything she wanted to add about the importance of the measure.

CO-CHAIR CASEY: Please.

DR. ABREU: Hi, this is Sue Abreu. Thank you for letting me address the committee.

As was mentioned, we are a very small specialty. Nuclear medicine is a separate board, although much nuclear medicine is performed by radiologists, there are many of us who practice full-time nuclear medicine. This is our only measure. Because we are a

referral, primarily imaging specialty, we don't control the outcomes directly by the results of what we do. So it is a great challenge to come up with a measure that works and that reflects the work of the nuclear medicine physician. That's why we included the exclusion, since thing outside of our control can impact what we do, even though we are doing the best we can.

So since this is a very small area, we realize that it won't have the rigorous randomized clinical trials and some of the other evidence that are available for other measures. But nonetheless, it is an important measure to us.

CO-CHAIR CASEY: Thank you and I believe we appreciate that. I think that there is no doubt that in your world, as I will call it, that this is a big deal. So I think people, I see some heads nodding here that they understand it.

Jeffrey.

MEMBER GREENBERG: I guess I'm concerned that there seem to be two criteria that are almost in opposition here. If this meets criteria one that this is truly important to patients, then I don't think trying is good enough. You have got to get the records. And I think it would be unfair to perhaps judge docs on this specifically but you can judge an institution on it that if you are an institution, you do nuclear medicine, you need to do whatever it takes to get these records if it is truly important to patients, whether it is hiring a guy with a car to drive around and get them.

If it isn't that important then, okay, you try. You hope you get it. If you don't, you just do it anyway. But then you failed on the first one.

So I mean, I don't see how we reconcile those two. If this is really important, then you need to get the records. If I were a patient, that is what I would

expect.

CO-CHAIR CASEY: Sounds good. Thank you. Jean?

MEMBER MALOUIN: Well I guess one thing that occurs to me is that if it is really important, then maybe you actually do need to order the study to correlate it. Because it is kind of like if this -- I guess I am trying to figure out what we are trying to prevent here. If we are trying to prevent unnecessary chemotherapy or treatment because there is something that hasn't been validated because if it is not enough to diagnose a MET on this particular study, then maybe you should get whatever study is valid.

I don't know. It just seems like this is a little bit fuzzy in terms of its importance to the care of patients, to me anyway.

DR. ABREU: This is Dr. Abreu again. Could I address the committee again?

CO-CHAIR CASEY: Please.

DR. ABREU: We as imaging providers would love to be able to order all of the tests we would like to do but it is actually the referring healthcare provider that does that. Otherwise, you start to get into some interesting self-referral issues and whatnot. So generally the format is the referring provider sends the patient to us. Sometimes as the result of previous imaging study that recommended it or it may be the primary imaging study done. For example, a patient with what seems to be bone pain who already has known prostate cancer.

So even though we would always like to have the images, it is not always up to us to order them. And so that is why that passed back and forth between the referring provider and us becomes a coordination issue.

We would also love to have, always have those images with us. And until everyone has electronic imaging, though, sometimes there is just physical films and reports that

you don't get. Plus you have facilities that won't release them without the patient's permission and the patient doesn't get around to it. So there is times we just physically cannot get hold of the items we need.

CO-CHAIR CASEY: Matthew.

MEMBER MC NABNEY: Yes, getting back to if it is really important we should measure it, if it is consistently difficult in all parts of the country, then the rates will reflect that and practices or hospitals or systems will be revealing that it is only possible in 70 percent and that is consistent. But if it is possible to drive up quality by expecting that, then higher performing places will do better. So I mean, the difficulty of reaching 100 percent or a high score shouldn't be the reason to use it or not because it is difficult to achieve a high score. But whether certain practices and systems do it better than others and that will drive up quality by comparing it to each other. So I

mean, just the fact that it would be difficult for a practice, as it was suggested, to do this because it is hard, I think that it would be hard for all.

CO-CHAIR CASEY: Alonzo.

MEMBER WHITE: I just wanted to point out there may be a misperception here that this is just primarily cancer care. This isn't just primarily cancer care. I'm a pulmonologist by training and we use nuclear studies a lot for pulmonary embolism. We also use it to decide how much lung to remove from someone who may have his lung resected. I can tell you we use it for things to determine how much liver disease may be present or what is called orthodeoxia and things like that, where you are trying to determine if there is a physiologic shunt present. There are lots of other uses besides just straight cancer sort of treatment. And I want people to make sure that they understand that maybe the correlation isn't necessarily even with the

film. It could be with other studies. It could be with spirometry or pulmonary function testing. So there are other things.

CO-CHAIR CASEY: So let me put a circle around this conversation a little more tightly. I think we are creeping into the diagnostic imaging, sensitivity specificity, positive predictive value world, when we really should be talking about care coordination and how this measure performs relative to that topic. That doesn't mean that we think this is a useful measure elsewhere. But I just want to be sure the committee stays focused on this because I appreciate what you are saying but I want to be sure we stay focused on the price.

So I'm going to ask Mark, Suzanne and then Jean.

MEMBER LEIB: Well I just want make sure that I'm not misreading this. Because while nuclear medicine scans are done for a variety of reasons, this measure is

specific to bone scintigraphy, which I think I'm not a nuclear medicine doctor and I don't even play one on TV, but I think the primary use of bone scintigraphy is for cancer; although certainly other things could cause a bone abnormality, including osteomyelitis or other issues. I think it is mostly for the serious ones are for --

CO-CHAIR CASEY: Right. And the diagnostic capabilities are important but let's focus on care coordination.

MEMBER LEIB: Right but there are clearly other uses for nuclear medicine besides bone scintigraphy.

CO-CHAIR CASEY: Suzanne.

MEMBER HEURTIN-ROBERTS: It seems to me that this is a measure of the entire system. I think part of the problem is we are thinking of it in terms of a measure of a particular specialty. And I don't think that is the intention. I think what you said about it being, it should be consistent whether the

data is good or bad, the outcome is good or bad, it should be consistent.

This is really a measure of how well the system is working in terms of coordinating care. And obviously, the radiologist -- not the radiologist -- the nuclear medicine docs are struggling with that system. So I don't think we should see it as reflecting upon a particular discipline.

CO-CHAIR CASEY: Jean.

MEMBER MALOUIN: So my comment is sort of along those lines as well. I think that ideally the measure would be all tests are correlated with available tests when possible. And I guess this is more of a philosophical question for the NQF folks is that, is that how you start this by picking one particular area where you can measure and saying okay we will put this one forward and then maybe next time it will be a measure of some other test that needs to be correlated with another test. Because this is sort of

very specific and narrow focus but it is a subset of a much more important and bigger area. I don't know if that is a clear question.

CO-CHAIR CASEY: Helen, let me give my eye and then you can tell us the truth.

I think when we started this, since there was sort of nothing out there, our goal was to at least populate some space where we could put a footprint in. As we get into evolving our criteria and our approach to evaluating measures becoming a lot more sophisticated, that may change. But I think that is probably how, my guess is, this ended up where it ended up. So am I getting that right, Helen?

DR. BURSTIN: Yes, I think so. I think for many areas where there aren't a lot of measures, you have got to start somewhere. And the question is, is this a good place to start for particularly to be able to assess

the quality of nuclear medicine for which there are no measures. It won't, you know, you can't boil the ocean on care coordination on this one, certainly. But is it a reasonable starting place? Does it meet our criteria I think is really the decision. It certainly wouldn't rise to the occasion of being something used across all systems across all providers, but it might be very useful for a subset for whom measurement has been really lacking. I think that is how you have to sort of factor that in.

CO-CHAIR CASEY: Anne-Marie, your card went down.

MEMBER AUDET: I'm struggling because what is the intent? What is the impact of this measure? And really when you look at it, it is based on the guideline that is premised on bone scans are very sensitive but specificity of finding is low and requires all this additional information such as history, physical exam. But I think we are

getting into the characteristic of a test, as opposed to really care coordination. And what does it mean for patients? Well maybe they won't get a repeat test but on the other hand, they could get a repeat test as was pointed out before. So I am really struggling with that right now. And I am saying I am not sure and that is more of a process issue. I'm not sure that if we decide this is not in care coordination but more in quality of radiological studies, are we allowed not to vote on this? Because you know, --

CO-CHAIR CASEY: No, we're going to vote on it. Sorry.

MEMBER AUDET: Okay but we would vote on another on a measure but based on the fact that it is looking at the quality of imaging study or gold standard scintigraphy as opposed to coordination of care.

CO-CHAIR CASEY: It can still be -- The measure isn't dead in the water.

CO-CHAIR LAMB: I just want to

share, Anne-Marie, I struggled with that, too. Because I go back to the domains of care coordination. And while those domains may not be fully representative, full scope, I struggle with where does the bringing together of different tests come? Is that in the quality of the diagnostics or is that really care coordination? Because it doesn't fit easily within the domains of communication transitional care, medical home, or plan of care. And maybe this is a dialogue. Clearly as Don is saying, we need to vote on it, but what are those domains? And do we need to expand our thinking about how the data come together across different providers. And whether this is one kind of like what Will was saying before, is this a baby step in terms of a new domain or is it totally off the table in terms of what is relevant to care coordination? And I don't have an answer to that. I am struggling with it and I think probably just need to vote and figure out

where we are at.

CO-CHAIR CASEY: Russell.

MEMBER LEFTWICH: On feasibility, I ream reading the final report documents that there is correlation of existing relevant imaging. I'm afraid that documentation may show up somewhere else in the patient's record and wouldn't be captured in the final report.

CO-CHAIR CASEY: Good point.

So I think -- Emilio.

MEMBER CARRILLO: I am also asking in terms of preferred practices, what preferred practice would this align to, although we haven't asked that about the other measures and perhaps we will talk about that tomorrow. And certainly I would also echo what Jerry just said. I mean, it seems somehow that it is not connected at this point in time.

CO-CHAIR CASEY: Yes, and that is not, I think your point is excellent and perhaps we should try to, if we haven't done

it before, retrofit the measures that we vote on into preferred practices which I know has already been done to some extent. But I think it is an important point.

DR. BURSTIN: Just one process point. We really just needed to find a home for all of our measures. So we looked at this and saw it was about communication of results. And we put it in here. It is not as if the developer came to us and said we think this is a care coordination measurement necessarily. So I just want to be clear that it was our decision not theirs that they are putting this forward as the premiere measure of care coordination. We found a home and we thought this fit reasonably well.

CO-CHAIR CASEY: Anne-Marie?

MEMBER AUDET: So then I have a question for the physician on the call because if we are truly looking at the impact that this measure would have on improving specificity of the testing, then do you have

any data or studies that show that? Because again I come back to my earlier comment that we are focusing on other radiological imaging, not history, physical exam, other test results. So do you have any data to support the improvement and specificity just from that additional data for this measure?

DR. ABREU: This is Sue Abreu again. I do not have any data to address that specific point. I would turn to our AMA colleagues to see if they have any, if their bank of studies happens to have anything with that data. But I honestly I guess it falls into one of those things where it is like, yes, it does this. I mean, I'm not sure anybody has ever studied it because to us it seems obvious, although I realize it would be much better to have a study to prove that. But I do not have a specific study that can give you numbers on that point.

CO-CHAIR CASEY: Does the AMA PCPI staff are to comment on that? Do you have any

data? Use your mike, please. The answer is no. Mark?

DR. ANTMAN: May I add to that, please? But before -- If I may, I would like to talk a little bit about the earlier questions about the context meaning the value of this measure related to nuclear medicine and bone scintigraphy specifically, rather than imaging in general. But before I do so, may I ask if our staff member, Diedra on the phone, if she had anything additional to say with regard to the previous question about studies.

MS. JOSEPH: Hi, this is Diedra. Can you hear me?

CO-CHAIR CASEY: Yes.

MS. JOSEPH: Okay. Sorry, I was talking. I don't think anyone can hear me there.

So we did try and perform a search of the medical literature and there were no studied identified. There was basically no

data.

CO-CHAIR CASEY: Thank you. Tom?

MEMBER HOWE: Yes, we are going to get into this with another measure but it really seems like we are sort of defining standard of care here. I mean, if you are doing an imaging study that has low specificity, you need to get supporting imaging that has better specificity, which is sort of the obvious. And how would you measure that something improved? I guess looking at the imaging reports of the bone scintigraphy, you know, from the group with better correlations versus not better. I don't know. I don't think we have thought through how this measure would even be, how you would identify that something beneficial happened.

CO-CHAIR CASEY: I'm going to take the prerogative of the Chair here because I think we are spending a lot of time on this measure and we are ending up in sort of some

black holes here.

So maybe two more questions or comments before we bring this to a close because I think we could debate this for a lot of time and I think it is going to apply to another measure, Tom, as you pointed out, the breast biopsy measure as well.

So James, briefly.

MEMBER LEE: Just a quick comment. I agree that perhaps this really is a topic for tomorrow afternoon, abnormal labs, imaging, should they be available across. Is that a domain or not? Those are the questions I think we will take at another time on another day.

CO-CHAIR CASEY: Thank you. Jean?

MEMBER MALOUIN: Yes, well I have been thinking about this and I think a couple of observations. The first is that I like the idea of putting measures like this under care coordination because I think what it does is we usually think of care coordination as being

the responsibility of PCPs and ED and in-patient facilities. But this really illustrates that it is really everybody's responsibility and so that everybody has to sort of say I have a horse in this race or whatever they say.

But the second thing is that I do think that because this particular measure is not as intuitive as some of the other ones like saying I think it is important to communicate in transitions of care, it is not as intuitive. So I think that there really does need to be some evidence behind it that yes, indeed that there is a lot of unnecessary treatment going on because these results aren't correlated, things like that. So just an observation.

CO-CHAIR CASEY: Okay, last comment Suzanne.

MEMBER HEURTIN-ROBERTS: Well I just want to go on record. I think this can be seen as standard of care or as care

coordination. I think we can and we have been arguing both sides. But if we choose to see it as care coordination, I really think we should think about framing the denominator in terms of the entire population, rather than the exclusions. Because if we think of it as care coordination, that is the only way it is going to be useful to care coordination.

CO-CHAIR CASEY: Well put. Okay. So we are going to call the question here, Nicole, and get ready to vote now on this. So everyone get their voters ready. And we will proceed.

MS. MC ELVEEN: Okay. We are first voting on impact. You have four voting options. One for high; two for moderate; three for low; and four for insufficient. And you may begin your votes.

I'm waiting for one more.

One high; nine moderate; seven low; and six insufficient.

Okay, the next is going to be on

performance gaps. Again, you can see the four voting options on the screen. And you may begin your vote.

Okay. Four high; nine moderate; one low; and nine insufficient.

And last under importance is evidence. And two voting options, one for yes, two for no. You may begin your votes.

I'm missing two or waiting for two. Okay, there we go. Five yes, eighteen no.

So the measure doesn't pass importance.

CO-CHAIR CASEY: So we are not going to proceed with further vote.

The measure, I think to summarize this, I think there was a lot of good discussion about the relevance of the issues raised by this measure. And I don't think this committee is saying it is unimportant to the nuclear medicine community. I think the challenge was trying to reconcile with care

coordination versus standard of care, as it was so eloquently put by Suzanne. So I think we are not trying to say bad things about this measure, we are just simply evaluating it in the criteria that we put forward.

DR. BURSTIN: To be clear, the criteria are the criteria. They are not criteria for care coordination measures. I want to be clear the committee truly voted it as stands based on those three criteria because it is not really whether it meets the criteria for care coordination measure. It is does it meet criteria for an NQF-endorsed measures. So I want to make sure we are all in the same place there.

CO-CHAIR CASEY: Okay, so we have one more PCPI measure to consider and why don't we try to do that before lunch. Was that in accordance or are we breaking now? What do you want to do? Do you want to try to get through some of this? Do we have a working lunch?

So how about if we present the measure and then we can break for lunch and then come back and have a dialogue. Does that seem reasonable so we at least get that out in front?

I think the reason we regrouped them for the PCPI staff is that we have a number of other measures with the NCQA group on medication reconciliation. So we wanted to kind of use 0646 as a theme knowing that we probably won't get to the NCQA discussion tomorrow but that there are going to be a number of sort of hematic issues across all of them that we want to consider much in the same way we did with the transition records.

So I am going to ask that James take the lead on summarizing the 0646 measure and then we will break for lunch.

MEMBER LEE: So many of the relevant points have been discussed in other measures so PCPI will try to keep it succinct.

I think overall in terms of

importance the workgroup discussion of this measure we felt that this is a very important area clinically and has significant cost and safety implications. There is much evidence, based on the submission of the literature that medication errors are common after discharge and leading to readmissions.

I think one of the concerns raised by some of the members is this whole idea of target of population versus a broad everyone should have a reconciled medication list and we had that discussion already.

In terms of scientific acceptability, we ask the PCPI folks to clarify the denominator. Is it based on hospitalization or patient? And then there is also some concern about testing that was done for this particular measure because it was done through one EHR. And some members expressed concern about whether we can reproduce validity, reliability through this methodology. And chart abstraction may be a

method but it wasn't tested with the submission of this measure.

And then lastly in regards to usability and feasibility, I think we have that same, we struggle with the same idea that we are making an assumption that the medication list is correct when patient or family gets it. And how would they verify that piece? And that is a very tough area.

So with that, we will open for other comments.

CO-CHAIR CASEY: So any questions or additions that the workgroup wanted to add to James before we break for lunch that he didn't cover that you think is important before we move into the global discussion?

I can see people are hungry.

MS. DORIAN: Actually before we break, just because we have it scheduled on the agenda for this time, I am just going to ask Nicole, who is our operator, to see if there are any members of the public on the

line, please.

OPERATOR: Yes, we do. And for any public comment, please press *1.

We have no comment at this time.

MS. DORIAN: Okay, thank you.

CO-CHAIR CASEY: So Lauralei, what is our process? Should we break for a period of time and then reconvene or how do you want to work this?

MS. DORIAN: I have it scheduled for half an hour.

CO-CHAIR CASEY: Half an hour? So roughly about 20 of one we will be back. And if you want to bring your lunch, we will continue to work through that. But why don't we take a 30 minute break and we will try to ring the bell at about 25 of just to get you warmed up to getting back to your seats. Okay?

MS. DORIAN: And I will have the sign-up sheet for dinner in the other room as well.

(Whereupon, the above-entitled matter went off the record at 12:15 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(12:53 p.m.)

CO-CHAIR CASEY: I see we have some new friends who have joined us. So one of the things we want to do is reintroduce yourself to the group and also declare whether you have any concerns or conflicts relative to the work we are going to do.

So I see Jann and Linda. Jann? Yes, can you use -- You just joined us. Right? I'm sorry. I'm sorry. Linda. I apologize.

MEMBER LINDEKE: Hello, I'm Linda Lindeke. I am here representing NAPNAP, the National Association of Pediatric Nurse Practitioners. I was at the Institute of Madison best practices group this morning talking about teen care. So I have a good excuse for missing it but I am glad to be with you for the next day and a half.

CO-CHAIR CASEY: Thank you, Jean.

And yes? Yes, Julie?

MEMBER LEWIS: Sorry. Good morning. My apologies for not being able to join this morning. Julie Lewis. I am here, I guess not really representing anybody but I work with Amedisys which is a home care and hospice company and I don't have anything to disclose.

CO-CHAIR CASEY: Thank you. So is there any member that is back on the phone? I know Eva was on in the morning but said she probably was going to drop off. Any steering committee members that we are missing on the telephone?

So for Julie and Linda, let's just recapitulate the findings of the morning. We covered four measures. And those measures are PCPI measures 0647, 0648, 0649 that were all recommended by the steering committee. We also discussed before lunch 0511, which is correlation with existing imaging studies for bone scintigraphy. That did not get approved

by the committee. We just presented the first part of 0646. So we are trying to manage all of the AMA PCPI measures as a bunch because we have the benefit of having a great team here from Mark Antman's group to help clarify and give feedback about the measures.

The goal here is to review the conversations that you had a part of your subgroups and I believe that I don't see any of you on the hook here but we do have -- we are asking members of the initial workgroups to lead the first discussion that is presenting the findings of the work group. And then we will go into discussion. We also have a specific process that we are now using in the NQF consensus developments process that requires us to document our votes in the key domains. We have a format that Nicole McElveen has used. You should have a voting machine. Do you have that? And it should be pretty self-explanatory to you when we get into the voting how this will work. But the

good news is we are getting real-time feedback on all of this.

So, and those are important because they will be calculated and submitted as a part of the report that goes out for public comment as well. So they will actually see the summary votes for each of the categories here so that they can understand how we reached our decisions.

So do you two have any questions for us? Ready to go.

James had presented the first part. James Lee had presented the first part of 0646, which is reconciled medication list received by discharged patients. We purposely moved that from the top of our list for PCPI to the fifth because we know that will dovetail into the NCQA discussion that I think will probably be tomorrow.

So we are at the point of discussion. So if you can all get that in front of you, let's proceed.

Matthew?

MEMBER MC NABNEY: I was talking with James before the break about the definition of a reconciled medication list. Because that is used repeatedly and we know what it is but it could be define differently by reconciled with what and how completely and other things. So for discussion.

CO-CHAIR CASEY: Do you have an opinion?

MEMBER MC NABNEY: Well I mean I think presumably we mean the changes made from the pre-admission but there is a lot of -- well there are some assumptions that the inpatient facility had the correct pre-admission medication list with which to reconcile. There is the assumption that the changes that were made were accurate and that the reconciliation from the hospital side is. So as far as like what steps were taken and what were they compared to.

Because I think it also sounds

like it is the nursing administration record they are comparing it to.

CO-CHAIR CASEY: Other comments or questions? I'm sure we are not ready to vote on this one. And I know you are still recovering from a nice lunch.

Yes, Karen?

MEMBER FARRIS: I apologize I didn't read the whole thing as well as I should have. Were all of these data obtained from EMR or was there a mix of chart audit and EMR? I will be presenting tomorrow the NCQA measure related to this and they are calling it a hybrid measure. And I just wanted your perspective on that.

CO-CHAIR CASEY: That is to the AMA folks. Right?

MEMBER FARRIS: Yes, because that is what we are doing now is 0646. Right?

CO-CHAIR CASEY: I didn't know when you were pointing who you were pointing at.

MEMBER FARRIS: I am pointing over this lovely row of people right here.

CO-CHAIR CASEY: Okay, great.

MS. YODICE: So in the testing project that we did, it was tested in an EHR and we also did a visual inspection of the medical record and compared the two for reliability testing.

MEMBER FARRIS: Checking if it was done or not done. Correct?

MS. YODICE: It was done. In the testing project?

MEMBER FARRIS: No. The outcome variable was it was reconciled or not.

MS. CHRISTENSEN: Can you bring up the measure specs again?

CO-CHAIR CASEY: Right here on the screen.

MS. CHRISTENSEN: Before there was that -- Someone help me with the word. Yes, the data elements that it looks for. That might clarify.

CO-CHAIR CASEY: So Karen, does that --

MEMBER FARRIS: I think it still gets back to Matthew's point about how do you really know that list is the right list. I mean, this is just a tough, tough one to know the gold standard because it is really a compilation of starting with the list, asking the patient, going to all the sources where you know they are getting their meds, and finding out what they are really doing. It is just a tough one.

CO-CHAIR CASEY: Yes, Dana.

MEMBER ALEXANDER: So, I think the reality is the accuracy of the list continued to be a challenge. You know, thinking about when a patient is admitted into an inpatient setting, even if you have the list of their current medications from the outpatient setting and then you are trying to verify that with the patient. Are they actually taking those medications? Are they taking them the

way that they were prescribed? I mean all of those I think remain variables and factors that we as an industry are struggling with.

But that said, I think that this measure in terms of the construct of this measure and the data elements and the approach I think is good and probably the best that we can achieve right now in terms of as we are still struggling with all the accuracy and some of those variables, which some of that may always be with us because again the integrity and the accuracy really is sometimes dependent upon what the patient is telling us.

CO-CHAIR CASEY: So Julie picked up on it. Linda, just so you know, in order to raise your hand, you put your card on the end.

Julie? Don? We are having a little trouble with that mike.

MEMBER LEWIS: Oh wait. There we go. We got it. Okay, sorry.

So I just wanted to follow-up on

both of those points from the post-acute provider perspective. So in the home we are going to come up with a list that is going to look very different than whatever we get from the hospital. And that is just by definition of being there and looking at the bottles and all that kind of stuff. But I think even though that being said and that this isn't complete, it would still be great if this happened. Right? I mean, so it is still kind of one step in the right direction, even though it is not going to be everything or certainly everything we need, to me it is still we are progressing so to speak.

CO-CHAIR CASEY: Christine.

MEMBER KLOTZ: I would agree with Julie's comment and that maybe this gives us an idea for discussion tomorrow. This is the first step to make sure this happens and then the next step is to find out what is the patient understanding? What is their current actions? Of course that is really hard to

measure but something we can talk about tomorrow.

CO-CHAIR CASEY: And I know Anne-Marie has her card up. But let me just say I think on one level it is I am point A and you are point B and the patient is in the middle. And I am telling you at point A that when the patient arrives at point B, this is the list of medications that the patient is on at point A. So I just want you to know that. And then the second level is more patient-centered and related to things like is that the right list and does it jibe with what I was taking and things like that. And you are saying for that first level, this is useful.

Anne-Marie?

MEMBER AUDET: This is a question for the PCPI colleagues. You mentioned that this measure is specified for discharges from all inpatient facilities, skilled nursing, home health. I think it came up actually in the discussion of the subgroup if I recall

reading in the summary. But your testing was only on inpatient. Right? You didn't look at med rec from skilled nursing facilities or home health.

So I just wonder why you specify -- you could have narrowed your specification for the measure, if you haven't tested it in all settings.

MS. CHRISTENSEN: One thing I will share, although we didn't do a chart review from those types of organizations, we did include them when we went to talk about face validity and usability. So that is included in those testing data. We went to rehab facilities and long-term care and other organizations like that.

CO-CHAIR CASEY: Russ?

MEMBER LEFTWICH: Two things. The medication reconciliation as it is defined in EHR functionality is the comparison of two lists of medications. Clinically, I think most would agree that it should involve the

patient or caregiver in the process. And certainly some EHR systems have developed a much more complex and robust process for medication reconciliation.

The second point, the document that was up before, I was going to comment on the --

CO-CHAIR CASEY: You mean the -- Yes, that.

MEMBER LEFTWICH: Yes, if you could scroll down to number seven, I wanted to point out that there is some misalignment of terminology in the description, the numerator statement and I think reflected here. The usual, the requirement for exchange of a list about medication allergies specifies allergies and intolerances. This document introduces instead adverse, well, in one place it says adverse reaction and in another place it says adverse events, which gets very convoluted because for one thing, the adverse event is an event. The list of allergies and intolerances

is a list of conditions.

Secondly, adverse events would include things like overdoses, extravasation of an IV, things that aren't generally considered a reaction to the medication. So I think there is some potential problem in data collection with this and there might be some medications that were discontinued because of an adverse event that should not in fact be further withheld because it was an overdose or it was some other. And I have a little concern that this should be defined more clearly.

CO-CHAIR CASEY: Do you want to see if the AMA staff has any insight into that?

MEMBER LEFTWICH: I would be glad to, yes.

DR. ANTMAN: So I am certain that this language was considered very carefully by the group but we did feel that by saying that caused an allergic reaction or adverse event

would be sufficiently clear. We would be happy to consider revising that language if necessary but we felt that we were covering what needed to be covered with that language.

MEMBER LEFTWICH: Yes, I don't think it is sufficiently clear at all because it is ambiguous.

CO-CHAIR CASEY: And as I think and Karen may know this, I think there are, at least from FDA's standpoint explicit definitions for ADRs versus ADEs. Right? So I think we just have to warn our colleagues here.

I think allergic reaction seems specific enough but I think your point is elsewhere we have got this issue of adverse reaction. Right?

MEMBER LEFTWICH: Right. Being different from an adverse event, although a subcategory of an adverse event.

CO-CHAIR CASEY: Right. Karen, did you want to say anything or not? No,

okay.

DR. HOWELL: Some of the literature describes adverse drug events though as ADEs. So that is, some of the definitions are out there in the literature, at least that I am using as an academic. I am from Johns Hopkins. I'm Eric Howell.

MEMBER LEFTWICH: Yes, I don't disagree that definitions are out there but in this summary document, both terms are used as if they were interchangeable and they are not. I don't disagree that that has a definition. I am just concerned about the way it is used in this measure or at least in the description. And adverse event does cover a lot of, if you have done clinical studies, if the light turns yellow while you are in the intersection on investigational drug, that is an adverse event.

CO-CHAIR CASEY: Let me ask Karen to help us.

MEMBER FARRIS: I think the point

is well made that if you are taking NSAIDs and you have an ulcer, that is not an allergic reaction. That is an adverse drug event. You know, it is a rising from exposure to the drug without, for whatever reason. So there is definitely a difference between allergies and adverse drug event. And that is Russ' point in the EHR that you have this field called allergies. And typically we don't see ADEs put in there. We see allergies. That is your point. Correct? Yes.

CO-CHAIR CASEY: Denise.

MEMBER LOVE: Maybe I am over thinking this but I am thinking of the 20 or so states that have patient safety reporting systems. I mean, how they are defining it, how they are collecting it, are there implications for this abstracted measure or are they, too, just separate things?

CO-CHAIR CASEY: So well I am going to look at my old friend, Karen Pace who is here subbing for Helen for a while. But I

think -- Do the Common Formats deal with this issue at all, do you recall?

DR. PACE: I'm not sure if they did deal with this or not. I imagine it was one of the things they addressed.

CO-CHAIR CASEY: AMA, are you familiar with that Common Formats paradigm in the patient safety organization? I think this is just a nuance that I think Russell and Karen are raising for us to just be sure we get the language sort of harmonized correctly and used correctly. I mean, my other pet peeve, you know this is I don't think nursing homes call themselves in-patient facilities. So I am just saying that that is not what they are deemed to be by themselves.

Karen? So Denise, does that help get at --

MEMBER LOVE: Well I think as far as measure harmonization but then as a policymaker, my wheels is turning that if this is being measured by a facility and they are

in a patient or an adverse event reporting system, you know, I might want to compare those rates. But this is a bigger issue that is not specific to measurement. I think the original thought was the harmonization.

CO-CHAIR CASEY: Well and that may actually apply to the FDA, too, since theoretically we are supposed to be reporting all these things in when they are severe enough. Right? So I think harmonization from that reporting is maybe a nuance beyond the way this measure was initially designed that we could think about futuristically because I think it may actually help, especially if, for example, this is done in the context of patient safety improvement identification of events and an attempt to provide safe harbor so that these things can be analyzed by root cause analysis and the like. And this is a place where we find these things by intent or accidently, just in terms of the way it is documented. So Denise, that is an excellent

point.

MEMBER LOVE: Well and it would reduce burden on the facilities that are reporting to all these various streams.

CO-CHAIR CASEY: Other comments here?

Well are we ready to vote, Dana?

MEMBER ALEXANDER: Almost. So to go back to your comment, Don, then are we suggesting because this measure is to cover patients in the hospitals, you know SNFs, rehab facilities, that we change the term inpatient facility?

CO-CHAIR CASEY: I'm just giving feedback to AMA. I mean, from my perspective it is a nuance that I think could be confusing.

MEMBER ALEXANDER: I agree. I think it could be confusing. I think it is confusing because I think when I first read it I was thinking inpatient hospital and now I see that is much broader, as it should be.

But to change the terminology.

CO-CHAIR CASEY: Right. Karen?

MEMBER FARRIS: Yes, now I do have one more question. Could I get folks from that workgroup to talk about your perception around the quality, quantity of evidence or where we are talking about an exception here because we think it is the right thing to do and we are not going to harm people? Or if you think the quality, quantity and what was the other word, consistency -- thank you -- is there, could I just get your perception in the workgroup or whoever led this measure?

CO-CHAIR CASEY: Karen can I help you a little bit with your question?

MEMBER FARRIS: Sure.

CO-CHAIR CASEY: Evidence towards what question? Could you just double clarify what you mean by that?

MEMBER FARRIS: The first one. It is 1(c), the 1(c) question. Right? That is what I am asking about.

CO-CHAIR CASEY: Thank you.

MEMBER FARRIS: Not reliability and validity of the measure did they do the med rec, but 1(c).

CO-CHAIR CASEY: Any thoughts about this? This is kind of the -- I know this question has been looming large nationally. Jann?

MEMBER DORMAN: I guess I have the same question because to me this seems to be a measure of patient experience. Did I get a list of my medications and was it accurate seems to be valid in itself, whether or not it drives anything. If I am in the hospital and I need to take medications and nobody tells me what they are or they tell me what they are and they are wrong, I need a list and I need it to be accurate. So how does that impact the standard for evidence?

CO-CHAIR CASEY: This is kind of I think back to Russell's femoral artery, my it's a wonderful life. If he hadn't been born

at all, what would life be like without him, so to speak. So I think it is still worthwhile to discuss this but I think my sense is that is where people are coming from. It is like before we had nothing and now at least we are trying to get on the same page.

So that doesn't answer your question, Jann but it, I think, provides a context for why this was invented in the first place, as I view it. Karen?

MEMBER FARRIS: So I can let it go and vote moderate. I just want it to move forward, honestly because again I think it is the right thing to do. And I think most people around the table think it is the right thing to do. So just in terms of process, are we thinking about it is an exception or we move it forward with that 1(c) moderate or that is -- Okay.

CO-CHAIR CASEY: Yes, Gerri.

CO-CHAIR LAMB: Karen, what I did was go through on the document in terms of

which of the references directly spoke to outcomes. Now we can't interpret the quality of the studies but there were five of them that specifically spoke to med rec and outcomes. And so giving it the benefit of the doubt and I don't know whether folks from AMA want to speak to that, that there are studies that link the med rec to patient outcomes.

CO-CHAIR CASEY: Yes?

DR. HOWELL: Yes, I just wanted to absolutely support what you said. There is actually a lot of evidence to show that if you do appropriate medication reconciliation and patient education so all the studies related to these bundles, no study looks at an individual intervention and there probably won't ever be studies to look at individual interventions. So I don't think you are going to get a randomized controlled trial on this alone ever but the studies that are out there strongly show that when you encompass this medication reconciliation with other

components of the bundle, and this is an important component, that you reduce harm, adverse drug events, and also reduce readmission rates.

So I think for all we have discussed today, this is very strong evidence.

CO-CHAIR CASEY: If I liken this to scaling Mount Everest, which I think this is like, we are at base camp with this. But what we really need is critical thinking, harmonization with prior medications, patient understanding, lots of critical thinking, decision support about whether the drugs have unintended consequences, perhaps maybe undetected or unanticipated drug-drug interactions or other types of things. And I think this should then create the platform for moving into this larger scale question of whether these more systematic approaches to decision-making can actually then improve outcomes. I think that is what this is intended to do is to create that base for

getting to, yes. Russ, did you want to say anything? Okay.

James.

MEMBER LEE: Yes, I just want to make one comment, that the title of this measure reconciled medication received by discharged patients, this measure is really intended for a patient to receive a passive role. I think some of the arguments we have about what is a good medication reconciliation involves active patient role, it has to do more with patient-centeredness. And there are many things in the clinical arena that should be discussed whether a patient should be front and center, benefit and risk analysis of a procedure, you know, many other things.

And to me, that may be a separate issue that will come up as part of the overall improvement, what constitutes good patient care and patient-centeredness. So I support this measure.

CO-CHAIR CASEY: So I think that

is good. And I think one of the things Gerri and I highlighted in our discussion last night is that if you look at the list of the other measures, for example, theoretically at least the 0520 drug education on all meds provided to patient/caregiver could be a potential nice hybrid. So somehow or another I think when we get through all these measures, we are going to see more nuance in some of the other measure descriptions that will then take us back to how could we harmonize. But in the meantime, we are still sort of voting on the individual measures at this point. And that is what our goal is in day two with NCQA.

So think about it in those terms.

So, Christine, are you raising your hand? You are getting ready to go. All right. So if Chris is ready. I'm sorry, Pam.

MEMBER FOSTER: Thank you. I just had one question for the measure developers. Was there a particular reason that indication wasn't included? Is it just because that is

not the practice? I know that we struggled with that with the other measures. And I just wondered if you had any facts on that, why the indication for the drug was not included on the med rec.

CO-CHAIR CASEY: Great point.

DR. ANTMAN: Right and I am going back to the language of the different categories of medications that are to be included in the list. And yes, I recognize that indications for the individual medications is not mentioned as a separate element. I think our development group probably felt that that was more or less implicit in the list being made. But I recognize that that is --

MEMBER FOSTER: And I think that is an unfortunate misperception that is out there. A lot of drugs are taken for off-label and patients don't know what conditions they are taking their drugs for. So this may be more of a discussion for tomorrow but I think

it is something to think about for the future about trying to capture that. And it is required, ironically, it is required for nursing homes. When a patient goes to a nursing home you have to indicate what the drug is for but not for a patient going home.

CO-CHAIR CASEY: Yes, Russell?

MEMBER LEFTWICH: I guess I would be concerned that we are creating an impractical because the reconciler at that point may not be aware of the indication and it is not captured anywhere in that record.

CO-CHAIR CASEY: Yes, Mark?

DR. ANTMAN: So if I may, the language in the detailed explanation of the components of the numerator requirements, I think the workgroup felt that this does speak to the indications in being continued medications. It says medications prescribed before the inpatient stay that patient should continue to take after discharge, etcetera. And new medications patients started during

the inpatient that are to be continued after discharge.

CO-CHAIR CASEY: We have that language up there that Mark is referring to. Sorry, Mark. I didn't mean to interrupt.

DR. ANTMAN: I'm sorry. So I recognize that doesn't specifically say the indications. I think that speaks to the an earlier point about this measure, which is our development group recognized that in order for this measure to be implemented, it does require input from a lot of different sources. And that is part of the challenge in having structured it in this patient-centered way that we did. It is not a measure of the medication reconciliation process. It is a measure of what did the patient receive and did the patient receive the complete list. But it also, it is intended to also promote the consideration of what in fact should be the list that the patient gets. And because it involves a multitude of healthcare

providers in the hospital or other inpatient setting, we didn't use more specific language to refer to the discharging physician or someone else should specify the indications because that information is coming from multiple sources, I think it was our thinking that by saying medications that the patient should continue or medications that should be discontinued, that implied that one clinician or another was clear about the indications.

I hope that helps.

CO-CHAIR CASEY: Matthew.

MEMBER MC NABNEY: Yes, that comment just made me think again about the reconciliation at discharge. The wording of this, which I understand and as people pointed out, it is a step towards the ultimate goal of a better measure but it is very hospital-centric. So the list at discharge from the hospital's perspective which the reconciliation might in fact be more accurately shifted back towards the ambulatory

perspective and the way this is worded it is all -- and I am not saying that is not still beneficial compared to not doing it, but that the hospital perceives the patient should be on and reconciling it towards that.

As opposed to reconciling it with the primary care physicians and where do we meet in the middle and how do we come to the proper --

CO-CHAIR CASEY: And I think, I am speaking off the top of my head but I think some of the NCQA measures get to your question, Matthew.

Karen? Two of them do. You are not giving us the peace sign.

Anne-Marie.

MEMBER AUDET: Well hearing this conversation makes me a bit nervous because again we are setting standards of care here in some ways. You know, we are saying that all these elements are fine and if really I hear from my colleagues that are experts in this

area that the indication is really important and it should be here. And I am looking at some of the NPSG so the National Patient Safety Goals. And there it says as item two, that to find the type of medication information to be collected including purpose of the medication.

So I am just raising the question whether this itself is missing a few elements that really are recognized as national standards.

CO-CHAIR CASEY: And that I believe is an NQF safe practice, I believe, if I am not mistaken.

But I think there is a safe practices statement about this that we probably ought to look at.

So Kathleen?

MEMBER ALLER: I don't claim to be qualified to speak to what should be in the med reconciliation but we are talking about a fairly complex process and I missed some of

the discussion this morning. But it seems as though this was tested on a fairly small data sample. Is there wider usage than is stated here? Because trying this out on 100 patients in a single organizations raises questions to me about how feasible it is, given all the comments about how complex this process is.

CO-CHAIR CASEY: Is that a question to AMA?

MEMBER ALLER: Yes, it is really a question to the AMA.

MS. CHRISTENSEN: Sorry our batteries are running a little low over here.

So this measure was also included in the Highmark Program. So we can look up the number of organizations but it should be somewhere in your information. We did provide that. And Laura is whispering 32 or 33 organizations used this.

And the performance on this was not as good as one might expect because this is a very difficult thing to get at. The

quarter one, two, and three data for 2011 were 35.5, 41.3, and 54.2 percent respectively. So we are seeing improvement there but not as rapidly as some of the other measures.

Does that kind of answer that?

CO-CHAIR CASEY: Lauralei, do you have some information up here? Is that what you are trying to show us? Oh, I'm sorry.

Is that you, Nicole, who has got that up there? That's Lauralei, okay. So I think I saw something about 81 sites in there.

MS. DORIAN: It's got 63.

CO-CHAIR CASEY: Sixty-three? Okay.

MS. DORIAN: Whatever is in there.

CO-CHAIR CASEY: All right. Does that help to clarify what is in there, Kathleen?

MEMBER ALLER: Yes, I mean for this whole bundle, it seemed like a fairly low number of participants working with a complex measure.

CO-CHAIR CASEY: Dr. Carrillo.

MEMBER CARRILLO: Yes, a measure reconciliation issue that most likely tomorrow we can address but I just wanted to point out that 0646 and 0647 both are measures something received by the discharged patient. And in 0647, as we discussed this morning, one of the elements is a current medication list. So if we have a transitional care tool that the patient gets with their current medicine and then you get another piece of paper we do reconcile med, which is different, it is going to make a lot of confusion. But maybe that is probably something for tomorrow.

CO-CHAIR CASEY: Dana?

MEMBER ALEXANDER: So I need to jump back to the indications discussion because I just needed to close out a comment there that I see this now as kind of a big miss if it is not called out into the measure. Whether it is the clinician reconciling and understanding the indications for use or with

the patient and particularly, too, because it is part of the national patient safety goals, I just think that it really needs to be clearly called out in the measure.

CO-CHAIR CASEY: Okay. Mark?

DR. ANTMAN: Thank you. Hearing this discussion, which I think is very useful for us to hear and thinking back on the discussion of the development group, I believe that this truly was a feasibility of measurement issue for this group.

If the requirement for the measure were to document each medication to be taken or not to be taken but for those to be taken to require that the documentation include the purpose of the medication and to pass the measure, that would be an element that would need to be identified and verified for each and every medication. That, I think in our view, would add up to probably an infeasible measure.

The group took the direction that

it did to land on, reconcile what we refer to what we refer to as a reconciled medication list is because it was felt that this is something that could be achieved, could be found, could be verified as something that included all of the required elements but without adding additional burden to the documentation. No question whatsoever that the elements, the indications and the purpose of each medication are unquestionably important. And it is, in part, for that reason that we cited the national patient safety goals. I think the feeling of the group was that this measure was supportive of those goals. And if I may add, the joint commission, the developer of those national patient safety goals, was supportive of this measure as constructed.

So absolutely those elements are important but they would result in a measure that would be very, very challenging to collect the data for and to then score.

CO-CHAIR CASEY: Dana are you still raising your card?

So Chris has had here clicker in her hand for several minutes.

(Laughter.)

CO-CHAIR CASEY: Are there any last comments before we move on to vote? I think we will revisit this over and over again tomorrow. But I think this was a good discussion and I think the PCPI got really good feedback. So it is with pleasure that we move forward, Nicole, into the vote.

And just you will get directions, in terms of Julie and Linda about how to do this. It will be pretty straightforward. Point your voter at Nicole, though to be sure it beams. Okay?

MS. MC ELVEEN: And the other point of importance for voting is the last number that you push is the number that will register.

CO-CHAIR CASEY: Yes, you still

have about a minute and if you change your mind or you felt like you did, but we are not going to finish until everyone votes. So you can't abstain.

MS. MC ELVEEN: So we are starting with the first sub-criteria under the importance to measure and report. And the first is impact. And you have four voting options. You push one for high; two for moderate; three for low; and four for insufficient. And you may begin your votes now.

So we have 23 for high; one for moderate; and no votes for low or insufficient.

Next is going to be performance gap. Again, you have the same voting options. One for high; two for moderate; three for low; and four for insufficient. Begin your votes.

Eighteen high; six moderate; no votes for low or insufficient.

The next sub-criteria, again under importance to measure and report as evidence. And you have two voting options; one for yes, two for no. And begin your vote.

Okay, 21 yes and 23 no. I'm sorry, three no. Excuse me. Sorry. So we will pass on importance.

Moving on to the second major criteria, scientific acceptability. We are voting on reliability first. Four voting options as shown on the screen. One for high; two for moderate; three for low; and four for insufficient. Begin voting.

Two high; 17 moderate; four for low; and one for insufficient evidence.

Next sub-criteria is validity. Again the four voting options are shown on the screen. You can begin voting. We need two more votes.

One high; 17 moderate; four low; and two insufficient.

So we pass on scientific

acceptability. The next is usability. And you see the four voting options as shown on the screen. You may begin votes.

Ten for high; 13 for moderate; no votes for low; and one for insufficient information.

Next criteria is feasibility. The four voting options are shown on the screen. You may begin voting.

Five for high; 16 votes for moderate; two votes for low; and one for insufficient information.

And last we are voting on overall suitability for endorsement. One for yes, two for no and you may vote now.

We are short two people. Okay.

Twenty-four yes.

CO-CHAIR CASEY: Very good. We are on a roll. I am going to turn the MC responsibilities over to Dr. Lamb at this point.

CO-CHAIR LAMB: We're going to

move on now to Measure 0645. And let me just check. Are the measure developers from American Academy of dermatology here? Welcome. Glad to have you.

CO-CHAIR CASEY: Thank you to the PCPI. You are welcome to stay. We appreciate your input. And we are very happy you were here.

DR. ANTMAN: And thank you very much for the feedback from the committee.

CO-CHAIR LAMB: Measure 0645 biopsy follow-up. Bonnie is going to give us an overview and then we will open it up for questions.

MEMBER WAKEFIELD: Okay, so this measure looks at patients who have had a biopsy and whether those results have been reviewed by the biopsying physician and communicated to referring physician and the patient.

So in our group there were a couple of areas of concern. One was the

evidence base for this measure, although we did discuss it is one of a common sense measure. If you have a biopsy, it should be communicated to you and to your referring physician. So we weren't -- we didn't dwell on that a lot.

One of the other concerns was a specification for a time element and there was a suggestion that that result be communicated within 30 days unless there were valid reasons for not doing that.

One of the other concerns is it is suggested in the measure under feasibility that the biopsying physician or facility keep a log of contacts. And we kind of questioned whether that was the way to go within an environment of an electronic record. And after I have done some thinking about that it also seems somewhat prescriptive to have people keep a log and it would seem that people could look at creative ways to keep track of that and that wouldn't be in the

measure.

Other discussion focused on whether the referring physician or the biopsying physician should communicate the results to the patient.

At the time that we discussed it, there was no evidence on the reliability and validity data but some have been submitted since. In the interrater reliability was using percent agreement was pretty good except for a few of the elements and those focused on documentation on whether or if the results weren't communicated, the rationale for not communicating those results. That reliability estimate was low. And they felt the validity was good because all of the details could be extracted from the medical record.

That's it.

CO-CHAIR LAMB: Thanks, Bonnie. Comments, discussion? Jean.

MEMBER MALOUIN: So this is kind of an interesting one. Because first of all,

I guess I am not sure of the scope of this because biopsy you think of like a dermatologist or a family physician doing a skin biopsy. But then does it also apply to a gastroenterologist doing a colonoscopy with a biopsy? So that is my first question.

And the second question is relating to the comment about whose responsibility is it? Is it the referring physician or is it the biopsying physician? And it is kind of a slippery slope because when you think about if I order a Pap smear on a patient, it is not the responsibility of the pathologist who diagnoses the CIN I to report to the patient. It is my responsibility as the ordering physician. And we discussed this at the University of Michigan with gastroenterology and their take on this, their stand on this for a long time was that they were acting as a technologist and that I, as the ordering physician who ordered the colonoscopy was the one that was responsible

for conveying the results of the biopsy to the patient and their job was similar to a pathologist with a Pap smear to convey that result to me. And so I think some clarification on what this exactly was applying to and if it was applying to both of those types of situations, skin biopsy and colon biopsy, just two examples of many, then can we set a standard for that that would apply to all of them?

CO-CHAIR LAMB: Jean would you like to ask that of measure developers? Do you want them to respond to that?

MEMBER MALOUIN: That would be wonderful.

CO-CHAIR LAMB: Could we get a response related to the questions of scope and your thinking about accountability?

DR. WISCO: Hi. This is Oliver Wisco. I am the director of dermatologic surgery at Keesler Air Force Base. I was one of the people that came in to propose this

measure originally.

And yes, this does apply to anybody essentially doing biopsies and excisions. If you look at the inclusion criteria for the biopsy or excision codes, it does allow for people doing excisions and biopsies.

In terms of reporting to the patient, this responsibility we didn't specify because there is multiple avenues in which this can occur. So if for example for your case, the reporting of a coon polyp inherent to the measure because of the care coordination, that agreement is made between the physicians and what is really important is that the patient has been notified. Specifically who does it, as long as it is documented that it is occurring by somebody, that was what was required to meet the specifications of the measure.

For example, if I biopsied a melanoma for another dermatologist who has a

very close relationship but doesn't like doing biopsies, that referring provider to me may say to me let me talk to the patient, I have the relationship. If we specify that the biopsy provider has to do that, then they potentially would not qualify for that measure for something that is very simple where they should qualify, because once again, the patient was notified.

MEMBER WAKEFIELD: So I would just like to comment on that because the way we read it was that the biopsying physician reports it directly to the patient. In all cases, that is kind of how we read that. So it may need, the language may need clarification then.

MEMBER MALOUIN: And I actually like your definition that it is based on a predefined relationship between the two physicians because that is kind of the way most of us are approaching this whole accountable care organization model is that

you really need to talk to the people that you work with and come up with relationships that work for both of you. And they may be very different, depending on the setting.

CO-CHAIR LAMB: Other questions, comments?

DR. PACE: I was just reading the numerator instructions specifically say that the biopsying physician must do this. It is just black and white.

MEMBER MALOUIN: But I guess maybe that does need clarification then because that isn't always the way it has worked out. I don't know. Unless we want to say that it should always being the biopsying physician.

In a case I mentioned at U of M with the gastroenterologist, we actually pushed back on them and said no you should, you know, if you are getting the money for it, you should be notifying the patient. But that was our agreement. But it could very well have been that the gastroenterologist said no,

we think you should do it and we agreed to that. I don't know. Maybe there isn't --

I think the important point, which is what you mentioned back there, is that the patient gets notified.

MEMBER WAKEFIELD: Although I think the patients aren't always sure who is going to tell them, though. I mean, am I going to get that from my primary care physician or am I going to get it from this specialist?

MEMBER MALOUIN: Yes, and that should probably be part of it is that the patient understands the process from the beginning.

CO-CHAIR LAMB: Anne-Marie?

MEMBER AUDET: Just a few questions. One is continuing on that line of thinking. I know for radiology there are some state laws that prevent radiology to disclose results to patients. So I don't know if it is the same for biopsy but that could prevent

someone from disclosing directly and it has to go through the primary care or the referring physician. So that is one thing.

The other things is I think it is really important to have this communication with the trio because what if the biopsying physician says one thing to the patient and then in consultation with the primary care getting more historical perspective on what is happening to the patient, the diagnosis of the biopsy changes. So then you have two different messages that go to a patient and then you are in a worse situation.

And then the other, the last one is I was not sure how you scored this sheet to come up with your numerator, a yes or no, because you have a number of yes, no. So what was your scoring on the abstraction tool?

MS. SHIPPY: Hi, I'm from the Academy of Dermatology. I'm Allison Shippy.

So you are --

CO-CHAIR LAMB: Do you have the

mike on?

MS. SHIPPY: Yes.

CO-CHAIR LAMB: Please.

MS. SHIPPY: Can you hear me now?

So you are referencing this chart abstraction. So I am curious what are -- I'm confused by the scoring.

MEMBER AUDET: So in order to have your numerator you have to have done this or not. So it is a yes or no. There are many different questions on this.

And so there are multiple questions --

MS. SHIPPY: All of them would have to be yes, essentially.

MEMBER AUDET: Oh, okay.

MS. SHIPPY: I think this was from just a user standpoint that it was a little bit easier to kind of, you know, if I am the physician entering or answering these questions about the particular patients, we tried to kind of break it up a little bit more

so it could just be digested a little bit easier for the user standpoint. So that is why we broke them up so all of them would have to be a yes.

CO-CHAIR LAMB: Suzanne and Jeff, do you have your card up down there?

MEMBER GREENBERG: I do. A couple things. One I agree with her saying that it has to be the doctor who does the biopsy has the ultimate responsibility, I think to communicate, or to make sure they communicate, communication happens. That doc is most familiar with what the condition is that they are finding.

So with all due respect if you are a gastroenterologist, if they see themselves as technologists then perhaps they should be paid as technologists.

MEMBER AUDET: That was my take on it.

(Laughter.)

MEMBER GREENBERG: No, I mean I

concur that our gastroenterologists would never do that and the primary doctor would just not be as familiar with what the polyp means and what the biopsy means.

So to me anything, you know, a system can have a system to make sure it gets done but it is really an abdication of responsibility for doing a biopsy saying I am not going to be responsible for relaying that to the patient.

I am a little bothered by this one and I think reading the comments folks in the workgroup were as well, that this really shouldn't need to be a performance measure. It is a little embarrassing that we have biopsies going on that aren't being communicated potentially malignant or otherwise harmful conditions not being communicated. I mean, I am fine with it but it is just a little concerning that I would hope our performance measures are a little more aspirational than saying okay, you didn't

completely screw up and, therefore, you get credit. I'm just curious what other people think.

And also the time limit thing. I mean, this should be within a certain amount of time, not in the calendar year there was communication done. But it needs to be done in some reasonable amount of time, a couple weeks or a month, I would say.

CO-CHAIR LAMB: Matt?

MEMBER MC NABNEY: I just wanted to clarify the excision versus biopsy and that might just be a terminology. And I assume because you said the codes capture it but are there, I assume there are not all biopsies -- Not all excisions are biopsies necessarily and how does that work in the denominator?

DR. WISCO: Correct. Basically, it does specify biopsy and it should say biopsy or excision. You are correct.

MEMBER MC NABNEY: So it is an excisional biopsy?

DR. WISCO: Well if you think -- So an excision to me, if I was to biopsy a suspicious lesion for melanoma, I am simply taking a piece and the way it is gross by the pathologist, it is looked at with less sections histologically.

If this is an excision, they then look for clearance versus biopsy they are looking for diagnosis. Now, both of them should be reported to the patient and to the referring physician.

And you are correct in that the title should say biopsy or excision.

CO-CHAIR LAMB: Russ?

MEMBER LEFTWICH: As I listen to some of these comments, I'm not sure we can be prescriptive about how notifies the patient. I think it does fall under state law in some cases. And you know, unless the measure reads and/or in some places, and I do think sometimes the biopsying physician is acting only as a technician, radiologically or

ultrasound guided biopsy, that physician may not really be involved at all except to do the biopsy.

CO-CHAIR LAMB: Russ do you want a response from the measure developers on that, in terms of state law and whether that was taken into account?

DR. WISCO: We did not take that into account, into state law who needs to notify the patient.

I would like to look at that, the numerator statement, if you can pull it up.

Okay, so patients who are undergoing a biopsy results have been reviewed by the biopsying physician, that is requirement number one; communicated with the primary care physician, requirement number two -- primary care/referring physician; and requirement being communicated to the patient. I agree completely the and/or statement needs to be there but I don't believe that it specifically says that the biopsying physician

has to be the one that notifies the patient.

In the details? All right, I stand completely corrected.

May I address the gentleman's question about or statement about the utility of this measure, the importance of this measure?

So the comment was that we want to aspire for higher quality measures to look at whether we are truly doing what is best for the patient in terms of exceeding standards of care. I completely agree with that statement. I completely agree that it should be no question that if you have a malignancy that malignancy should be communicated to you by the biopsying referring physician and to the primary care physician. That should be inherent to the system in what we do. I can tell you without statistical data but more empiric data that it does occur that we don't always notify. And you see this in the care coordination with patients leaving the

hospital, going to the primary care physician for things as simple as a CBC that was drawn and then whether the CBC was normal or abnormal, the patient doesn't know. You see the next physician who needs that data but doesn't have that data. So it is redone.

So one of the reasons that this biopsy measure was created, number one being a dermatologist we wanted to look at something that can impact us with other specialties as well. So we wanted to make sure that this whole process was being held accountable, meaning I don't want rebiopsies being done. Does that occur very often? No.

Now what about the patient that has a normal biopsy? So have you ever heard the statement no news is good news? And that happens a lot. And what we are trying to achieve is best scare scenario where everything is communicated. So this isn't just bad biopsies. This is good biopsies. So if I had a biopsy a mildly dysplastic nevus,

meaning it is not melanoma but it looked bad clinically, I want you to know that and I want the physician to be held accountable for that information of getting to both the provider and to the patient. That is best care. So minimal care, absolutely. That should happen but this also reaches the other aspect of it.

In terms of us creating this measure, this is not simply for dermatology. And actually in terms if you look at the feasibility for us to do this, this probably isn't the best measure for us because if I measure looking at it from the PQRS side, if do 2,000 biopsies and I have to report on 80 percent of them, say 50 percent of them are Medicare, this is actually difficult for us. But in terms of the physician that does 50 breast biopsies and 25 of them are Medicare patients, this is a really good measure for PQRS.

Taking that aside, the medical standpoint for best care for patients, this is

something that we should be doing. This is something that does reach above and beyond the standards of care.

MEMBER CARRILLO: I think it is going to be really problematic, difficult to vote for this measure, unless there is some clarification in the writing. I agree with a lot of the points that have been made, Russell's in particular. And from the perspective of the primary care physician, it is practically axiomatic that presenting a biopsy to a patient is a skill set that has cultural meanings, that has behavioral meanings, etcetera. So this would be a very, very confusing measure to put out there to the world of primary care medicine.

CO-CHAIR CASEY: I just wanted to point out for the steering committee that while I can appreciate the passion and the interest, I want to be sure we stick to the criteria that we are going to vote on and frame our discussion around which criteria we

are debating or discussing so that we can help to sort of inform the discussion that leads to the vote. So just a housekeeping reminder to sort of stick to the knitting a little bit more.

MEMBER LYNN: I wonder of the measure developers could comment on two things, the tracking communication and the log and on the timing.

MS. SHIPPY: So after the steering group call last week we did add the time specification and we added a 30-day measurement piece. So I think that that should be reflected in the updated paperwork that we had submitted to NQF. I think we did add a disclaimer that there would be kind of an exclusion or an exception that would be in place if there was kind of a process that prohibited that reporting physician from reporting that within the 30 days.

MEMBER LYNN: And then do you have a particular question about the biopsy

tracking log?

MS. SHIPPY: I think the point about that had come up in the call to prep for this in person was that it wasn't as -- I didn't link enough to the EHR aspect and that this really lent itself to a paper-based chart. So I think that as it is written we definitely do have kind of a hard chart or a hard log that is suggested but I think that it is not as set that it has to be something like that, that it has to be a paper chart. Is that what you are referencing?

MEMBER LYNN: I think if you want this to be something that would be used by all physicians to do all kinds of biopsies, --

MS. SHIPPY: Add more elements to the log book.

MEMBER LYNN: -- I'm not sure that the old-style log book is --

MS. SHIPPY: Yes, I think that point is a point taken.

MEMBER MALOUIN: I guess I'm just

wondering if there is a way that we could just put a statement in here that says -- because the language says whose biopsy results have been reviewed by the biopsying physician and communicated to the PCP and the patient. If we could say the communication to the patient about that particular piece of it, unless some kind of little clause that says unless there has been an explicitly defined -- Unless it has been explicitly defined to the patient or to all involved that the primary care physician would do the communication or something. Or unless some other arrangement for communication has been defined and explicitly communicated to the patient. Because I think that would cover a variety of situations where perhaps that is the kind of relationship that has evolved in that community.

CO-CHAIR LAMB: Karen's next. Let me just ask point of clarification here. We are talking about measure specification and

switching from who is going to -- giving an or statement but it is not here and it hasn't been submitted. How do we handle that?

MS. JOHNSON: I think what we need to do, generally we would vote on as written. With these changes, I think maybe the or statement might be a minor thing. And if the developers are willing to say that they would do that, then we could vote with that agreement in there.

So I guess it depends on whether the developers are willing to say that they would change it in that way.

DR. WISCO: Absolutely, yes we would make that change.

MS. JOHNSON: Okay, so let me make sure I understand. You are talking about basically getting rid of the language where it says it is the biopsying physician communicating to the patient. You are saying the important thing is the patient receives that and it doesn't have to be, just as long

as that happens.

MEMBER MALOUIN: I mean and we could even leave the language as but just put a clause that says this is also a viable alternative or something, as long as there has been an established communication pattern that the patient is aware of. I think that would just cover more basis than this does.

MS. JOHNSON: Right. I think that that one section in the detailed numerator where it says by the biopsying physician also would have to be tweaked a little bit.

CO-CHAIR LAMB: Dana?

MEMBER ALEXANDER: So I am curious on the time, the 30-day time frame that was established to communicate with the patient about the biopsy. Because I have already put myself in the shoes of if I were a patient, having a biopsy to think that it was going to take 30 days to get my result information, I would find that unacceptable.

CO-CHAIR LAMB: Dana, do you want

to hear the measure developers speak to the time frame?

MEMBER ALEXANDER: Yes, please.

DR. WISCO: Just to make sure I understand your question, your statement was that we shouldn't be breaking 30 days or that --

MEMBER ALEXANDER: It's too long.

DR. WISCO: Every so often from the dermatologic standpoint I will do a biopsy for what looks like melanoma. And the biopsy itself has to go through several levels for the official diagnosis. Thirty days is not unreasonable on the off chance that it is a severely dysplastic questionable whether it is melanoma.

What typically would happen, and this is more of the rare instance would be that we would do a biopsy. It would say in the community, it is sent to the pathologist. The pathologist is not comfortable making the diagnosis, which is then sent to the

dermatopathologist in the local area, who then says okay, this is severely dysplastic. I can't tell that this is melanoma. It is then sent to the academic center and sent to the melanoma specialist, which then has several immunostains that would take sometimes a week or so to get the official read because then they present it in path conference.

MEMBER ALEXANDER: So I would assume that what you just described there, which I can see those situations happening is why you put the language in here with an exception allowance for processing and/or interpretation delays outside of the reporting clinician's control.

DR. WISCO: Right.

MEMBER ALEXANDER: So it seems to me that I just need to better understand why we couldn't tighten up that time frame to shorten the time frame and then keep your allowance clause in there.

DR. WISCO: So typically two weeks

is essentially reasonable. To say on a high volume center that does this all the time, which there is plenty of academic centers that have very atypical tumors, extending that additional two weeks would make a lesser burdensome on them for reporting for this measure.

So it is the excessive above 30 days where the exceptions we felt really was needed below 30 days completely reasonable. And I understand your question. We should be getting biopsy results back in two weeks but to --

MEMBER LEFTWICH: Why aren't we starting the clock when the biopsy film report is available?

CO-CHAIR LAMB: I'm going to take co-chair privilege here because I think what we are doing here is massaging the measure specification as we are going along and we are making some fairly substantial changes in it.

What I would like to ask is

because most of us have not seen the reliability and validity testing and that it was just received, if we could get a brief overview of that because we have got to make a decision here about whether to move forward in voting.

MS. SHIPPY: So after the steering group call we did also -- Prior to the steering group call we had included some reliability testing that had been done by an outside group. So I think that that should be included now. That was on the data element level. And from a validity standpoint, we did have, so we had a chart abstractor. So we had testing sites essentially and that was a mix of EHR users as well as paper chart users. We asked them to send us their copies of their charts that they had input for the testing project and they sent that to our chart abstractor or our medical abstractor and they looked at, they did a visualization so they looked at it and filled out the tool that we

had sent.

So when I spoke with Karen Johnson, I think that she and I had talked about that being kind of a way that we can prove validity testing.

MS. JOHNSON: And just let me clarify on that, usually when we think about validity testing what we would say is if you could take the results of an EHR or a registry or something like that and compare it to the full medical record, then we would count that as data element validity.

I think a little bit of the unknown is that you didn't get the full chart. You got sections of the chart. So I think you would have to convince the steering committee that that is good enough to be able to call it good validity testing.

MS. SHIPPY: So I think our thinking in how it is good enough is that we felt like we were explicit enough with kind of which charts or what pieces of the chart or of

the medical record the measure reporter had to be looking at. So specific to that biopsying date. But we recognize that we don't have, I wish we kind of had some seat fillers like we could look like we are an AMA level but we don't have the resources to provide any more information other than that.

CO-CHAIR LAMB: Additional comments, based on what we just heard? Lorna?

MEMBER LYNN: These are all dermatology practices? So you don't have any information about how this would perform for a gastroenterologist or a gynecologist, etcetera?

MS. SHIPPY: Right.

MEMBER GREENBERG: A couple things, and Don to your point, I think two things relating to validity and then feasibility I guess.

There has been talk of the and/or issue. I think we need to be clear. If this measure is supposed to be at the institution

level, then I think it is fine to say the patient has to receive the results by somebody. But if it is meant to be a doctor-level measure, and if you say well it could be either the referring doc or the biopsying doc, that is a recipe for no one doing it. That is just sort of saying somebody should do it, one of you guys should do it. That only works if we are talking at the institution-level.

So if it is meant to be a physician-level measure, we need to put our stake in the ground and say it is that doc.

The second thing is people mention state laws. Is there really any state law that says a doctor who has treated a patient is not allowed to talk to the patient about his or her treatment of that patient? I have never heard that.

MEMBER AUDET: That's why I asked. I just said I know for radiology, if you go and get radiology procedures or whatever, there are some state laws that prevent if you

call up and say I want my results, they will not allow it. You have to get those results from your referring physician.

MEMBER GREENBERG: That sounds hard to believe that if I am a radiologist and I do a biopsy and I find the results I am not allowed to tell the patient what it is.

MEMBER AUDET: I did not mention biopsy. That is why I am saying I am asking the question. I did not state. I said could this be also an issue that needs to be taken into consideration.

MEMBER GREENBERG: Obviously we don't want people violating state law so that gets to the feasibility. But it is hard for me to believe that if you do a biopsy on a patient as a physician you can't talk to the patient about it. But if I am wrong, I would love to know.

CO-CHAIR LAMB: Other comments? Anne-Marie -- Sorry. I didn't see that yours was up. Please, Suzanne.

MEMBER HEURTIN-ROBERTS: I just wanted to say to get back to the time I don't want to beat a dead horse but this may work for dermatology but for other cancers, you really want to know what is going on very soon because that is time you could be beginning chemo. You could be performing surgery. I mean for breast tumor or something like that, I think that you really need to have a much briefer timeline. And that is not just for the patient's comfort. It is for medical reasons.

CO-CHAIR LAMB: Anne-Marie?

MEMBER AUDET: Yes, well all this discussion should be maybe also based on evidence. Are there any studies about the impact on prognosis of delays? And that would be, of course, very different from different types of conditions. So if you are talking about dermatology, it is very different than talking about other biopsies.

And then just again my previous

question about the chart abstraction. On your chart abstraction if everything has to be yes, then it means that the primary care physician has to tell the patient and the biopsying physician has to tell the patient. So it is not an either or on the way you scored. So I just, I think there is a lot of issues of questions about how this is done that may need clarification.

CO-CHAIR LAMB: Jeff is yours still up? Matt.

MEMBER MC NABNEY: I wonder if one way to get around this either or is to say that it is the biopsy, and this may not be our position to say this, but the biopsying physician either informs the patient or delegates that responsibility and documents it as such, so that it is at least clear and there is not this who does it. Well that would be up to them but they would do the primary care physician, presumably but they would be on record as taking responsibility

for informing the patient either directly or indirectly.

Or like Jeff said, nobody is going to do it or are they are going to assume the other person is doing it. But if the buck stops with the biopsying physician in some fashion, then it would at least be done.

MEMBER GREENBERG: But then you get situations where you know, noted PCP. You need to make sure that PCP is willing to take on that responsibility and not just that a page was sent or an email was sent. So I mean that is --

CO-CHAIR LAMB: You need the mike, please.

MEMBER AUDET: Sorry. You see that is where I am kind of struggling with the fact that this is dermatology versus broader because dermatology you can have a lot of self-referral people walking in, getting biopsies and their primary care physicians never know. So then of course it is very

important that the biopsying dermatologists make the conversation.

But if we broaden it to other types of biopsies, then it is a very different type of setting, I think.

CO-CHAIR LAMB: It seems that we are re-looking at the same issues and going back to them over and over again, which is about the scope and who tells the patient, as well as data support.

I am wondering, I think we need to base this on the criteria that we are using and data. And I think the measure developers have told us what they have data-wise and what they don't have.

I wonder, Helen, do you want to weigh in on this before we move to vote?

DR. BURSTIN: I think you have had your discussion. Just go ahead.

CO-CHAIR LAMB: Okay. Is everybody ready to vote based on what we have and the current measure as it exists?

MEMBER WHITE: With no modifications?

CO-CHAIR LAMB: We have discussed lots of variations on the theme. So we will stay with current measure. Current measure.

So, Nicole.

MS. MC ELVEEN: Yes, so we are first voting on impact. You have the four voting options shown on the screen. And if everyone is ready, you can begin your vote.

We have nine for high; ten votes for moderate; four for low; and two for insufficient.

The next is performance gap and the four voting options are shown on the screen. You may begin your vote.

Two votes for high; ten votes for moderate; four for low; and nine for insufficient.

And last under importance is evidence. And the voting options are one for yes, two for no. You can begin your votes.

One more. We are waiting on one more response. And this could be a close one so I would like to make sure I get them all. I'm still missing one response.

CO-CHAIR CASEY: Point them towards Nicole again.

MS. MC ELVEEN: Someone has chosen not to vote. Okay, we'll see. Okay. So we have ten yes, 14 no. So the measure will not pass.

So it does not pass importance so we will not continue voting on it further.

CO-CHAIR LAMB: Thank you all for a very thoughtful discussion and thanks to the measure developers for engaging in that discussion with us.

We are going to move on now to Measure 0171 and the measure developers from CMS are here? They are calling in.

MS. DORIAN: Do we have any developers from CMS or Acumen on the phone?

MS. DEITZ: Can you hear me? This

is Deborah Deitz from Abt Associates.

MS. DORIAN: We can hear you, Deborah, yes.

MS. DEITZ: Good.

CO-CHAIR LAMB: Before we turn it over to a summary by, let's see, who is doing this, this is Alonzo, we have received additional information related to risk adjustment and reliability and validity. So we would like CMS to give us an overview of that before we move into the measure development.

MS. DEITZ: The new risk adjustment that was, the analysis that was conducted was conducted by our team but primarily by Keziah Cook and the folks at Acumen. And my understanding is that they are on the line but perhaps they are not able to -- Yes, I just got an email from Keziah that she is on the line but no one can hear her. So is it possible to --

OPERATOR: Her line is open.

DR. COOK: Hello, can anyone hear me?

CO-CHAIR LAMB: Yes, we can.

DR. COOK: All right. You couldn't earlier.

MS. DEITZ: There is an echo, though.

DR. COOK: Yes, I am hearing that, too.

CO-CHAIR CASEY: I think your volume is a little high. I think it might help to turn that down a little bit. That might help.

DR. COOK: Is that better?

CO-CHAIR CASEY: No.

DR. COOK: I think maybe the feedback is in the room.

CO-CHAIR CASEY: Yes, I think your voice is loud and that is causing potential feedback. So just try to talk a little softer.

DR. COOK: Okay, so the questions

were about the reliability and validity testing to begin?

CO-CHAIR LAMB: The questions were related to the risk adjustment methodology and reliability and validity, yes.

DR. COOK: Okay, great. Well I'm happy to start briefly with the risk adjustment. I think the first thing to note is that the two measures that you are considering today, the acute care hospitalization and the emergency department use without hospitalization are very similar measures. They are both capturing utilization by home health patients of acute care services. And these measures are specified so that they are mutually exclusive. A patient who has an acute care hospital visit will not be counted toward the emergency department use without hospitalization.

So the risk adjustment model used a multinomial logit that an capture both of those outcomes. The multinomial logit has

three potential outcomes, no acute care use, emergency department use without hospitalization, and acute care hospitalization.

The risk factors for the model include several broad categories. The main ones are prior care setting valuables. So this captures where the patient receives care immediately prior to entering home health. Some patients enter home health directly from the community, so they did not receive any care either in an inpatient setting or in a skilled nursing facility prior to home health. Then we also have measures of acute care use in the 30 days preceding home health. And these include outpatient emergency room use, inpatient acute care hospitalization, long-term care, rehab, and skilled nursing use. And then we further divide the inpatient acute care use into five different categories, based on the reason for that hospitalization that immediately preceded home health care.

In addition to those prior care variables that capture the 30 days prior to home health care, we also include condition categories that capture the patient's health status in the six months prior to home health care. These categories are groups of diagnostic codes and they have been defined originally for the Medicare Advantage risk adjustment model but they are sort of clinically consistent groupings of ICD-9 diagnostic codes.

And then in addition to this information about the patient's diagnostic history, we also include demographic variables, namely age and gender indicator for ESRD status, indicator for disability status. So these are patients who originally became eligible for Medicare either due to ESRD or to disability prior to age 65.

So those are sort of the categories of our potential risk factors. And then after defining that set of potential risk

factors, we used a variable selection method to choose only those variables that were specifically significant predictors of either outpatient emergency department use or acute care hospitalization.

So questions?

CO-CHAIR LAMB: Any questions before we move into reliability and validity? James, you want to wait until we get a review?

If you would, move into reliability and validity and then we will ask our questions after that. Thanks.

DR. COOK: Okay. So we present -- So the reliability testing that we presented was at the measure level and what we looked at was to what extent can providers be distinguished, based on their performance on acute care hospitalization or ED use without hospitalization.

And the analysis, it is a beta binomial technique and basically we fit a beta

distribution across the agencies. So this is a distribution of -- I mean, I guess we could say true agency performance. And then we used the number of patients that each agency saw to further account for the variability in the measure due to potentially small numbers of patients.

And so you know, at the end of the day what this allows us to do is to calculate a reliability statistic for each provider and then we present those stratified by agency size. And what we find is for the agencies with 100 or more home health stays at the median and really even at the 25th percentile, the agency reliability scores are quite high. Sort of a typical rule of thumb for interpreting these scores is above about a 0.7 or so, it is quite good. So for the larger agencies, there is enough variation across agencies to distinguish between agencies, based upon performance on these measures.

For the agencies between 20 and

100, you know, a number of those agencies actually do have quite high reliability scores but it will be harder to distinguish those agencies who have smaller differences in their score from the average agency performance, just because of their small numbers of patients.

And then for validity, you know, these measures we re-specified them using claims data and we presented evidence that was gathered in other settings that validate the elements of the claims data used to calculate these measures but we have not yet had the opportunity to do -- so that is data element validity and we have not done validity of the measure as specified.

I will say the earlier versions of these measures that was specified using OASIS data were reviewed by a technical expert panel prior to the previous NQF evaluation. And these measures were reviewed by our clinical team and by various folks at CMS.

CO-CHAIR LAMB: Thank you. I think what we will do is have Alonzo give an overview and then we will go into questions. Will you stay on the phone with us if there are questions related to what you just covered?

DR. COOK: Yes, we'll be here.

CO-CHAIR LAMB: Thank you.

MEMBER WHITE: Okay, this measure looks at the percentage of home health stays in which the patients were admitted to an acute care hospital setting during the 60 days following the start of a home health stay.

The numerator is the number of home health stays for the patients who have a Medicare claim for an admission to an acute care hospital in the 60 days following the start of the home health stay.

Some of the exclusions are patients who are not continuously enrolled in fee for service Medicare during the numerator. People who die, home health stays which begin

with the low utilization payment adjustment, and those who actually care for by multiple home health agencies. As she stated, this was submitted by CMS.

And this is an outcome measure. There were some questions. Do you actually want me to go through each one of the -- Okay.

CO-CHAIR LAMB: If you would briefly summarize them, thanks.

MEMBER WHITE: Okay. If we look at importance, there were eight yes and one no. And the questions that came up, the first was that will not address outcomes -- Will address outcomes but will not address disparities and it does not actually link the home health treatment to the actual cause of the admission. So in other words, if there is a breakdown in the treatment, is it reflected in the actual cause of the admission or could they have been admitted for some other reason? And it doesn't really address that.

Under impact, there are eight

high; one medium; and under the performance gap there is seven high and two medium. Under 1(a), evidence, there were eight yes and one no. Under outcome there were six yes, one no. Under acceptability there were nine yes and zero no; reliability, nine high; under validity, nine high.

There was a question about scheduled admissions and are they accounted for in this process.

Under usability, there was somewhat of a split between five high and four moderate. Under feasibility, there were eight high and one moderate. And there was also a question that asked about what about claims lags.

The preliminary assessment was there were eight yes and zero no and there were questions that asked about what is this actually measuring. It this actually a measure of home health or can this be used to assess care coordination from the inpatient

setting. Could this be used to assess the effectiveness of case management? Could this actually look at the effectiveness of alternative care settings, assuming the member came from somewhere else.

CO-CHAIR LAMB: Thank you. Don?

CO-CHAIR CASEY: Yes, my question is to the measure developers. This is Don Casey, the Co-Chair.

This is a pretty complicated measure and I appreciate Alonzo's summary because I tend to agree with the decisions or the opinions of the workgroup. But one of the things I have become particularly sensitized to in our own health system plus analytically some work I have done on claims in aggregate myself has to do with how the present on admission indicators applied both in terms of the descriptions of the population and then the sort of interpellation of the model vis-a-vis the effect of this. For example, a patient develops, comes out of an acute care

hospital into a long-term care facility or a post-acute unit with an orthopedic procedure and goes home and ends up with an osteomyelitis and then gets home care and then ends up back in the hospital receiving IV antibiotics and perhaps bouncing around in that sense, versus the obvious issue that we are trying to deal with, which is issues that are preventable to begin with.

So can you talk a little bit? Because I didn't have a chance to wade through all the analytics on this about how the POA indicator gets applied, if at all, in terms of parsing out the analysis into something that provides us with a little more richness of the description of what is going on. I don't have a black and white answer to how it happens but I know it is mixed in here and provides, in my sense, some significant potential for distraction of validity, for example. So, can you comment on that?

DR. COOK: Sure. So, we don't

make use of the present on admission flag from the inpatient prior care setting flags. I think to some extent all of the information that we are capturing is risk factors. So the prior care setting variables and also the condition categories are capturing -- It seems that we are present on admission to home health care. So these are all measures of the period prior to the beginning of home health care.

In terms of the relationship between, in some sense, what we think the patient was receiving home health care for and what the hospital admission was for, we are taking a broad view of the impact that home health care potentially can have on patient outcomes.

You know, of course home health care can't prevent all hospitalizations and we, honestly, would be very skeptical if agencies were consistently reporting, you know, had zero percent hospitalization rates

among their patients.

So, there is noise in this measure. You know, it is capturing both those hospitalizations that the home health agency can impact and also some that would occur regardless.

We do make exclusions, and this was at the advice of the workgroup that reviewed the measure earlier. We do exclude planned hospitalizations. So these are hospitalizations for procedures that would be sort of consistent with standard types of treatment for various conditions. But yes, there is noise in this but we think that the variability between agencies and agencies prior success in adopting quality improvement targeted at reducing hospitalization suggests that there are ways that agencies can work to reduce their hospitalization rates.

CO-CHAIR CASEY: I mean, I have our own empiric data that we have published showing that, for example, two-thirds of

clostridium difficile infections, three-quarters of patients with sepsis septicemia and almost 85 percent of patients with MRSA have that coded across the University Health System Consortium 200 hospitals as being present on admission. So I'm just trying to get at this attribution back to the hospital for all the problems as being one of the sensitivities we have on the hospital side.

We end up, I think my opinion is that at the least majority but maybe a lot more than the majority of care we provide is for issues that are present on admission to begin with, not that we don't have internal issues about care ourselves.

So I am just trying to balance this out in terms of the accountability that will drift from this into the public domain.

DR. COOK: Right. And I guess just to clarify, it is the home health agency here that is sort of being held responsible and information from a hospitalization that

preceded home health care has been included as a risk adjustment factor.

So a patient who had a diagnoses for recurrent UTI or for sepsis or for various types of persistent infections, you know, we would expect them to have an elevated rate of acute care hospitalization following or during home health care due to the information that they had that condition prior to home health care.

CO-CHAIR CASEY: You know, my point is that several, well many health systems have their own home health care agencies. So I am just trying to let people know that perceptually there may be that nuance.

CO-CHAIR LAMB: Important point. Thanks for that discussion.

Julie, is yours up?

MEMBER LEWIS: It is. So probably no surprise, I have a couple of comments on this and a question.

So to start off, let me say that I

think ACH rates for home care, great measure. No problem with it. I think the one we currently have, not so great. Would love to improve it. No problem with that either. But you know, if you sit with the home care care center and nurses and therapists and you see enough times that what they have when that patient arrives says discharged to home care, you don't have a discharge summary. You don't know why they are there. You are trying to track that down. You are calling the physician. They won't answer. So can they do care coordination without anybody else? I don't think so. So to me, I have trouble with this as a care coordination measure.

I feel like some of the other measures you really see that link and I am not seeing that here. So, I guess if this was a measure where both the hospital and the home health or the physician and the home health were both held accountable, I think I would be all for it as a care coordination measure.

And again, I think ACH rates is a great measure and I would love to improve the one we have. I just am not getting the care coordination, I guess component of this, the way it is currently worded.

And then I have one technical question for the measure developers and that is how are recertifications handled in this? Are they a new admission? If I have a patient for 200 days, is that counted the same way as a patient that is there for 30 days?

DR. COOK: Well I'm happy to speak to the second point. The measure is specified for the first 60 days of a home health stay. And home health stays are defined as sort of a continuous period of home health care. It could represent multiple payment episodes by Medicare and there could be multiple recertifications for continued eligibility within the same home health stay. But we are only measuring acute care hospitalization during the first 60 days of that stay.

We chose to use a fixed window, rather than measuring acute care hospitalization across the entire period because among the home health elderly population, the probability of hospitalization pretty much linearly increases as you increase the time period you are observing.

So if you observe someone for 120 days instead of 60 days, you expect them to have a substantially higher rate of acute care hospitalization. So by using that fixed window, we actually avoid penalizing those home health agencies that have longer length of stays for their patients.

MEMBER LEWIS: So I think that is great. I think that is much, much better than the measure we currently publicly report. But again, I am just having trouble on the care coordination aspect. So I would love other people's thoughts.

CO-CHAIR LAMB: Would anybody like to respond to that before we move to

discussions? Denise.

MEMBER LOVE: I'm not sure mine hits that directly. I mean, I rather like this measure. I see it as a screening measure and a measure that starts getting at the issue that there may be a problem. And maybe there is other measures that get at the attribution and the care coordination part. I'm seeing this as a very important measure at some level, be it care coordination or just part of the dashboard might need to drill down and then find out why these measures vary. I mean, it could be a whole bunch of other sub-measures, if that helps.

CO-CHAIR LAMB: Julie I think that you have gotten to a crux of the challenges of measuring care coordination because it exists that at the interfaces between providers and settings. So that the attribution issue becomes an important thing of can we really control this. And I think virtually every provider who is involved in some piece of the

care coordination work has that same question, whether it be home care or long-term care or primary care providers. And I think that is part of the baby steps of this is it is chicken or egg. Where do we start with this? How do we begin to parse a very integrated delivery system. And I think that we could go around the room and probably have different perspectives on the extent to which hospitalization is parsable but it is a key outcome indicator and it is one, of course, that is tremendously focused on nationally. I don't know that there is easy answers to that. That is my perspective on that.

Let's go to some of the comments. Pam?

MEMBER FOSTER: Thank you. I was on this workgroup and I reviewed this measure. And I think I was the one who probably screamed the loudest about the related piece, the related readmission piece. And looking at it from the acute hospital side, we are

measured by 30-day all-cause readmission. So kind of applying that same thinking here trying to determine how does that then really truly reflect the quality care or the care coordination at home health.

But I really commend the measure developers because we talked about that a lot on the call and I think the refinement of the risk adjustment really helps. And then excluding the planned admissions is getting us more to a true number. And so I hope the same thing happens with the hospital readmissions at some point. But I just want to say that I find that moving us forward in the right direction.

And then the other side is kind of getting back to the whole care coordination piece. We did talk about that on the call-in and I think CMS addressed that in that it is a little difficult to tell whether this is a care coordination measure for the home care or for the hospital or both. And I think it is

probably both because one could argue if you had good care coordination in the hospital and you are in the right setting post-discharge, you shouldn't come back if things are being managed well. And so that is that piece of it.

But then the home care side of it, if you identify someone in the home setting who isn't in the right setting, then our presumption is you are getting them to the right setting.

So I do see it as an important care coordination measure and maybe I am just looking at it from a different perspective but those are my thoughts.

CO-CHAIR LAMB: Thanks, Pam. I think --

MEMBER LEE: Just a quick question for the developer. The HCC model has shown positive benefits in terms of predicting costs a year ahead. Meaning, we know this patient had this profile of diseases, their likelihood

of costing XYZ is in this probability range.

In the material that CMS submitted has a probability of acute hospitalization with that particular condition. And so conceptually, in a way it is measuring system effectiveness very broadly, including whether health plans respond to the needs of the home health, primary care, and specialist, hospital. It is an all-inclusive measure.

And I am curious as to application of the HCC model looking at this and what is CMS' perspective about measuring the system versus accountability, such as in this case, home health.

DR. COOK: I can speak just briefly to the choice of using the HCC model and as you mentioned, that model was developed for predicting costs in advance for properly paying the Medicare Advantage plans.

And you know, because we are aware that the predictors of costs are not necessarily the same as the predictors of

utilization, we actually included the whole set of hierarchical categories used in the Medicare Advantage predictive model and also the additional condition categories that were shown to not be related with future costs because we figured there certainly would be some disease categories that would be related with hospital use but overall just wouldn't be related with cost. You know, perhaps those patients spent more on hospitals and less on something else so the impacts on costs just wouldn't show up.

So we did include a broader set of potential risk factors than the HCC model that is applied to predicting costs.

In terms of your comments about sort of measuring the system, I think that actually gets to some of the other discussion of care coordination. And you know yes, we are measuring something at the home health agency level but the tools home health agencies have to prevent hospitalization will

likely involve coordination with the patients other care givers, their doctor, their family, and the other resources available within that community to try to treat patients within their home or to move them to a more appropriate care setting if they are not stable in their home, rather than bouncing them in and out of the hospital.

But you know, I think the way we are using the HCC model is really as a convenient grouping of diagnostic codes into clinically coherent categories.

CO-CHAIR LAMB: Thank you. Denise?

MEMBER LOVE: I just had a question because of, I think the policy potential of this measure, how the duals are handled. Is that just a risk stratifier? They are not excluded, right, the dual eligibles?

DR. COOK: Yes, dual eligibles are included in the measure but at advice both

from the workgroup and from CMS we did not include an indicator of dual eligibility as a risk factor. And the concern there is that if we were to risk adjust for dual eligibility, we would be sort of holding agencies to a lower standard for the dual eligible patients then for their other patients. And that doesn't seem to be something we would like to do. But the duals are included in this population but we don't adjust explicitly for their dual status in the risk model.

CO-CHAIR LAMB: Julie is yours up again?

MEMBER LEWIS: It is. I'll be quick. I probably wasn't very clear. The attribution doesn't bother me. I mean, we could use this today. It is good. That is not the issue here. And if it is between having no measure or having this measure, then I would say we have this measure.

But I guess more what I am saying is we are moving forward. Some of these

measures I can really see how you are forcing that coordination to happen and you are measuring it. And I just don't see that here. So I would love for CMS to think about you know, what is that next step.

The other thing, too, is I think having a 30-day measure would also be interesting because I can tell you hospitals would become very interested in coordinating care for 30 days. At 31, not so much. So you know, I think there is just more work to be done. I'm not saying we should kill the measure and I'm not worried about attribution. I just think there is so much more that could happen in this space. So that was all.

CO-CHAIR LAMB: Thank you. Don?

CO-CHAIR CASEY: Julie, I'm sorry but we are interested a lot and, you know, so I just want to go on record as saying I don't agree with that. I think we are very interested across the continuum, otherwise we wouldn't be in all the other businesses we are

in, including ambulatory care.

So let me just back up and ask the measure developer a couple of other related issues which again I probably might have found in detail. One is the inclusion or exclusion of patients that end up in inpatient hospice, who then don't die. And the second is and again this is not in the HCC, I understand but you know, Medicare does permit the use of a palliative care code V66.7, which I think is a useful but underused marker for assessing whether patients have been identified to have been eligible for palliative care. And I always remind people that palliative care is not what your DNR status and whether you have advanced directives but how you want to live with an advance care plan.

So I am just wondering if there is room to consider, maybe not in this go around but in the future, parsing that out, since it is such a prevalent issue in this population. And again, I don't know how to analyze it but

I do know that we, it is something we track on the internal side, on the inpatient side because we are trying to raise that number. We think that palliative care is woefully underused. And it seems as though there is an opportunity here to call out something. I don't know whether it affects your risk adjustment or not. I know it is not in the HCC but could you comment on that issue in this context?

DR. COOK: Sure. So for this measure, we are not explicitly considering a patient's palliative care status. I will note the inpatient admissions that we count toward the acute care hospitalization measure are only short-stay acute care hospital admissions. So if a patient is transferred to an inpatient hospice, they would not, you know they would not -- the agency would not be penalized for that. That wouldn't look like a hospitalization for this measure. But I think it is actually a very interesting idea to

think of other ways to measure the transition from home health to hospice because that certainly is a very important transition that some of these patients are making. I don't quite see how to do it in the context of the acute care hospitalization measure but that is a really interesting idea and we will definitely be thinking about that as we work towards other measures.

CO-CHAIR CASEY: Just to clarify, palliative care is not hospice. I'm not talking about that. I'm talking specifically about palliative care. So just think about that, please.

DR. COOK: Okay, yes.

MEMBER LYNN: Is it correct that this includes only fee for service Medicare patients and not Medicare Advantage patients?

DR. COOK: Yes, that is correct. And unfortunately, that is a limitation with the data at this time. I know CMS has made some moves toward requiring encounter

information from the Medicare Advantage patients so down the road it may be possible to extend this measure to include the Medicare Advantage population but right now, it is just fee for service.

MEMBER LYNN: My other question is there anything that helps you know whether or not patients are discharged prematurely from a hospital, which could be another reason why the agency maybe correctly sent him back to a hospital?

DR. COOK: Right now we are not using any information of that sort. You know, we are only using the information from the prior hospital stay as a risk adjuster. We are not using it as a way to exclude patients from the measure population.

CO-CHAIR LAMB: Denise, did you have another question? Any other comments, discussion? Alonzo.

MEMBER WHITE: What about patients that come from alternative settings; people

who come out of SNFs, come out of long-term care, maybe are sent from home to home health? Are we looking at apples and oranges here? That is what I am really asking.

DR. COOK: Right. So, we do include the sort of a whole gambit of the prior care setting indicators as risk adjusters. So in the risk adjustment model, we are accounting for differences in outcomes among patients entering home health from the community from another long-term care setting such as a SNF or a long-term care hospital, versus those from an acute care setting.

You know, and by including both the information from the sort of most recent inpatient discharge and also information sort of from the whole six-month look back, we do have some information about patient health status, even among those patients who enter home health directly from the community or from another care setting, rather than from the hospital.

CO-CHAIR LAMB: Thank you. Any other comments, questions? Are you ready to take your --

MS. JOHNSON: Normally as NQF staff, we would not be asking you questions but because the submissions came in kind of late, we did have a chance to look at this maybe a little bit more in detail than the rest of you guys did.

So that being said, I have just three fairly quick questions that I think it would be useful to have some clarification on. So I will just tell you the three questions and then I will let you answer them, if you will.

First of all, your reliability measures, and this is kind of just out of curiosity but we were unclear about it. You did use the signal to noise analysis for that and you used the beta binomial model. We were unclear. Did you use the risk adjusted right on that? And if so, why was beta binomial the

appropriate methodology there? We were a little confused. So that is the first question.

The second question has to do with validity. And as I understand it, what you did is you talked about the payment error, patient record audits, if you will, and use that as your validity testing. But we were curious as to how you might talk about those people in that sample, those hospitalized patients, and are they the same as home health patients who might be hospitalized and would that affect your validity testing in any way?

And then finally, the third question, we noticed that you exclude stays or episodes that started out as LUPAs, which is four or fewer visits. And I just wanted you to comment a little bit on that exclusion. That was a fairly large chunk of stays that are getting excluded and we wondered if perhaps they are going back to the hospital within the four visits and is that a quality

issue?

DR. COOK: Okay, so let me actually start with your last question first, if you don't mind.

The exclusion for LUPAs, you know there were really two reasons for that exclusion. First, I think there was a sense that when a home health agency sees a patient four or fewer times, they haven't had much of an opportunity to impact that patient's health status. So it would, in some sense, unfair to hold them accountable for a hospitalization.

And I think the second reason for that exclusion is actually exactly what you said and I think what came up in one of the earlier questions, which is there are cases where a home health agency visits a patient for an initial visit and they clearly determined that that patient is not stable in their home and needs to be transferred back to the hospital or to another more appropriate care setting. And again, you know, it would

be unfair to penalize a home health agency for making that clinically appropriate decision.

So yes, there probably are some cases where a home health agency with a LUPA probably ought to have been held accountable for a hospitalization that ended the home health stay but there was definitely a sense among our development team and among CMS that in a lot of cases, LUPAs occurred due to appropriate decisions on the part of the home health agency and that it would be unfair to include them in this measure.

So I guess to move on to the question about reliability, we conducted the reliability testing on the observed rates. And you know, a primary reason for this is we actually conducted reliability prior to fully developing the risk adjustment model. And basically if the observed measure did not have sufficient variation to distinguish between high and low performing agencies, a risk adjustment isn't going to fix that in some

magical way. You know, risk adjustment reduces the variation somewhat between agencies. So had the reliability numbers seemed unpromising at the observed rate level, we would then really have had to consider should we, for instance, only include very large agencies in this measure or are there other changes we need to make to the measures specification so that it has better ability to distinguish prior to moving forward to risk adjustment.

And second as you mentioned, the beta binomial really would not be appropriate for determining signal to noise ratio of a risk adjusted measure. We would need to make some pretty significant modifications to that measure for it to actually count full for the pattern of variation we expect to see in a risk adjusted measure.

So I would say that the reliability statistics, that they are sort of necessary but maybe not completely sufficient.

Had they looked poor, it may have not even been worthwhile moving forward with our development of this measure, but they were quite promising on the observed measure. So we did move forward.

And then I guess your final question about validity, you know, CMS has a variety of ways of validating the claims data. The specific reports we cited, which were the errors in inpatient payment, those analyses are looking at among patients for whom Medicare paid for an inpatient hospitalization, you know, how often can that hospitalization be validated through medical chart reviews. And I think the thing to consider there in terms of is this sort of broad portfolio of hospitalization similar to home health patients getting hospitalized, you know, from the very specific diagnoses, reason for treatment in the hospital, I would suspect there probably are significant differences among the populations.

However, just at the level of if Medicare is charged for hospitalization, can we document that that hospitalization occurred? I don't think there is really significant reason to believe that hospitals would be worse at record keeping or more likely to submit erroneous claims for home health patients than for other patients.

CO-CHAIR LAMB: Thank you. Don?

CO-CHAIR CASEY: One last quick question. Just remind me how many positions on the claims ICD-9 code submissions do you use for this calculation. How many lines is it, 10, 25? Is it all?

DR. COOK: We are actually using all of the diagnoses listed on the claims in constructing the HCCs.

CO-CHAIR CASEY: Thank you.

MS. MC ELVEEN: Okay, if everyone's ready we are going to start with importance to measure and report sub-criteria impact. The four voting options are shown on

the screen. You may begin your votes.

We are short one vote. I know someone stepped out. I'm not including her. Oh, okay. Fourteen high; nine moderate; and zero votes for low or insufficient.

And next is going to be performance gap. You may begin your votes. Okay. Thirteen high; nine moderate; zero votes for low; and one for insufficient.

Lastly under importance is evidence. And we are not voting on overall importance?

DR. BURSTIN: Right. So in general, if it is an outcome measure, a rationale is sufficient. If they have gone ahead and provided data on evidence, great but it is not a requirement. But one or the other is required.

MS. MC ELVEEN: Okay.

CO-CHAIR CASEY: So then we determine importance just by the first two. Got it.

MS. MC ELVEEN: Okay, so next we are going to then move on to the scientific acceptability of the measure properties. The first sub-criteria is reliability. The four voting options are shown on the screen and you can begin votes.

Okay, 14 high; ten moderate and no votes for low or insufficient evidence.

Next is validity. You can begin your votes. One more. Okay, got it. Eleven high; 12 moderate; one low; and no votes for insufficient evidence.

And moving on to usability, you can see your four voting options for usability. I'm sorry, is there a question? Okay. You can begin your votes. Waiting on one more.

Okay, we have 11 votes for high; 13 for moderate; and no votes for low or insufficient evidence or information.

Moving on, feasibility. You can begin voting. Okay, 17 for high and seven for

moderate, and no votes for low or insufficient information.

And then finally, overall suitability for endorsement, one for yes, two for no. You can begin voting.

Twenty-four for yes.

CO-CHAIR LAMB: And it passes. We are going to take a quick break. How long? Ten minutes. And we are going to come back and do 0173 and Anne-Marie, you are going to be on.

(Whereupon, the above-entitled matter went off the record at 3:15 p.m. and resumed at 3:27 p.m.)

CO-CHAIR LAMB: We're going to move into Measure 0173, emergency department use without hospitalization. It is another CMS measure. And before Anne-Marie gives us an overview, just to point out that we had similar questions related to risk adjustment and reliability and validity and the same things that we learned for the last measure

hold here. So it is same risk adjustment, same reliability and validity metrics.

Anne-Marie are you ready?

MEMBER AUDET: Yes, I am and actually this is pretty simple because this is a very similar measure. This is looking at the percentage of home health stays in which patients use the emergency department but are not admitted to the hospital within the 60-day period of their home health stay. So the numerator and denominator are pretty straight forward.

So I am just going to review some of the comments that were made during our small group call. One related to the impact and you can read some of -- one of our colleagues was wondering whether if you really count the number of people that this affects that it turns out to be pretty small but otherwise, the performance gap did quite well. Everyone was pretty much in agreement that this was high.

In terms of scientific, the reliability and validity, those ratings were also quite high. We had some questions but I think we just got some new data about the risk adjustment methodology.

The usability was split between high and medium. Basically on the basis that although they do present methods used to assess usability such as focus groups, consumer representatives, external advisory groups, they do not really talk much about the results of these focus groups and this information. So they did it but they didn't report on the results.

In terms of feasibility, there were seven highs and two mediums. And in terms of preliminary assessment of endorsement most favored, yes there was one no. Although the reason for that, no I don't think we got to discuss.

So I think that is all that I want to say at this point.

CO-CHAIR LAMB: Thank you. Any other members of the workgroup who worked on this have any comments before we open it up?

Okay, general discussion, comments? Will are you about to put yours up? Go for it.

MEMBER FROHNA: All right, thanks. I was part of the group as well and so I kind of crunched some of the numbers and that is where I was kind of thinking about the impact that this would have and the big picture and that is why I was a little hesitant about the value of the measure.

But having said that, a couple of questions. One has to do with not a hospitalization, you know an ED visit and again with observation. And so this observation status admissions, they are still in the hospital but under observation kind of outpatient status. I think that counts as the ED visit without hospitalization. I may need to kind of get that clarified. Just realizing

that it is not an insignificant proportion of all patients who stay in the hospital. For example, at our high acuity adult-only ED, almost 35 percent of those patients who stay additionally in the hospital besides the ED visit are in the observation status. So that is a significant number, especially if you lump that into what is an outpatient visit versus an admission visit.

And then what I did is actually look at and refer folks to the national hospital ambulatory medical care survey, the last being done in 2008. And that is where a lot of information comes back at utilization rates for different populations and especially the elder care in general, looking at the utilization rate there of 52 visits per 100 person years in that patient population. So it is not an insignificant utilization that those have and obviously a higher acuity mix there with 30 to 40 percent of those patients being admitted to the hospital.

I guess this points out that elderly folks, high acuity, they utilize resource but I think you have really got to look in close to see is it considered an appropriate utilization of the ED or not. We are just talking briefly a patient who spikes a fever at a home health unit and has cancer diagnosis receiving some kind of treatment. It may be a short work-up to look at blood and urine and go home but that is an appropriate utilization. And so there is many different flavors of what is appropriate and not. And so you just have to be careful saying just because they didn't get admitted, even though they may be observation or whatever, doesn't mean it wasn't completely appropriate utilization.

CO-CHAIR LAMB: Will, would you like to ask that to the CMS folks in terms of observation --

MEMBER FROHNA: Yes.

CO-CHAIR LAMB: -- as well as any

kind of correction for appropriateness?

MEMBER FROHNA: Yes.

CO-CHAIR LAMB: Can you respond to that?

MS. MC ELVEEN: Operator, are the lines open?

OPERATOR: Yes, they are.

MS. DORIAN: Keziah are you there?

DR. COOK: Can you guys year me?

CO-CHAIR LAMB: Now we can. Yes, thank you.

DR. COOK: Okay.

CO-CHAIR LAMB: Did you hear the question?

DR. COOK: Yes, I did.

CO-CHAIR LAMB: Thank you. If you could respond.

DR. COOK: Sure. So regarding observation stays, we are including emergency department visits that also include observation. And that again was a decision from CMS. We actually analyzed observation

stays separately from outpatient emergency department visits and there certainly are a number of outpatient emergency department visits that also involve observation. And CMS felt it was more appropriate to group emergency department visits that include observation with the outpatient emergency department measure, rather than measuring them separately or considering those to be similar to hospital admissions. So it does include observation stays.

I guess in terms of the second comment, I think like acute care hospitalization, we certainly don't take the view that a home health agency can prevent all outpatient emergency department use and that certainly there are cases where outpatient emergency department use is the most appropriate response to the patient condition. But again, there is variability amongst agencies in what fraction of their patients are receiving outpatient emergency department

care. And there is evidence that sort of through better coordination with a patient's doctors and also just more prompt response to patient or family member concerns that home health agencies can have some impact on reducing outpatient emergency department utilization.

CO-CHAIR LAMB: Thank you. Matt, did you have yours up?

Other -- Oh, Don.

CO-CHAIR CASEY: Don Casey, Co-Chair. Two questions that I think are related specifically about the characteristics of the emergency departments. For example, Washington Hospital Center is a level one trauma center with lots of other services that go on. We are a level one trauma center regionally that has a helicopter. We are a primary stroke center that receives intracerebral hemorrhage patients from the field. The radius is, you know, potentially 50 to 75 miles. We also have a training

program. So that is one question is how or if you adjust for the characteristics of the ED department in terms of its availability of resources. You know, my expectation is we would probably not have as much of a problem with inpatient mortality if we didn't have these services.

Secondly, a related question and I know this has been analyzed and Anne-Marie may have the data on it but there has been concern about the relative socioeconomic status of the neighborhood, as I will call it, having an influence on ED utilization. I know that I believe there has been studies that that has a particular impact, though you may be familiar with others. But I know that is in people's minds.

So it gets back to in the Medicare data knowing that you don't have much looking at dual eligible populations and things like that. So, what say you about those two general questions here?

DR. COOK: So in terms of taking into account characteristics of the emergency department, we did not do that. And I think given that our unit of analysis is the home health agency, you know, the decision to take a patient to an emergency room. I mean, yes, it probably has some relationship with is there an emergency room available. But in terms of the specific treatments that emergency room can offer, you know, I think it is maybe less relevant.

One thing to keep in mind is that if a patient goes to an emergency department, you know, perhaps attached to a hospital that doesn't have the ability to really treat their condition, and then they are admitted to a different hospital. Those patients would not be included in this measure denominator. They would be in the acute care hospitalization measure. So that may speak some to concern that the different emergency rooms have different resources.

Just in terms of socioeconomic status, you know, again CMS advised us not to include dual eligibility as a risk factor. You know, I think there is evidence that there are differences across socioeconomic groups either as determined by race or as determined by dual eligibility that do impact emergency department use but we did not consider that to be an appropriate risk adjustment factor.

CO-CHAIR CASEY: I will just say that in New Jersey, the common theme, and I'm not from New Jersey but I live there now, the common theme is that the lawyers made them send the patient to the ED, even though they didn't need to have that happen. So again, that is not for this measure. I am just trying to state that there are some systematic issues here that relate to inappropriate utilization of the ED. And if you don't believe me, Bill I'm sure could tell you a few stories.

MEMBER FROHNA: Well, I was going

to say you live in the United States.

(Laughter.)

CO-CHAIR LAMB: Emilio?

MEMBER CARRILLO: Yes, we have good characterization of ambulatory-care-sensitive conditions that also related to the Prevention Quality Indicators, PQIs, all of which are part of an NQF certified or recommended. Is there any thinking about qualifying the type of the CPTs and the ICD-9s and -10s of the patients of the visits that are being seen in the ED as a way to maybe get at this a little bit more directly?

DR. COOK: Right. So for this measure, you know, this is an all-cause measure. So this is capturing all patients who use the emergency department as outpatients. You know, we are considering further measures that would look specifically at preventable conditions either for ED use or for hospital admission. But this measure is really for the all-cause measure that is a

baseline.

CO-CHAIR LAMB: Julie?

MEMBER LEWIS: Yes, I will just really quickly second some of Don's comments.

So I appreciated the measure developer's response but the thing that caught me is you know, when the decision is made to send the patient to the ED and the problem is the culturally relevant part is that that is not often a decision. They go when you are not there, when the physician doesn't know. It is just, that is their primary care source.

And so I just kind of second that that is a legitimate problem and something to think about. You know, other than that, it is the same thing. There are 150 things that affect this measure that have nothing to do with the home health group, not that it not a -- it is not a bad measure. But again, you know, the more measures that actually get at what is the actionable thing that they could do. So here you are kind of telling them well

you are bad. You know, this isn't very actionable. It is similar to the ACH measure. So just again a plea to get to more, you know, tell them what to do and then incent other providers to help them get there.

CO-CHAIR LAMB: Julie, I would like to provide an alternative way to think about that. Is that when I think about care coordination, it reminds of those of you who have been around a while, the mantra of managed care, which is right service, right time, right place, right cost. And in my thinking ER use and hospital use is, I think as James was saying in my view, a system indicator of our ability to get people to the right place at the right time. And for those folks who don't need to be in the hospital in the ED, it is the wrong place. And so it gives, as an outcome indicator, in my thinking, it gives us a clue that says how can we assist people to use appropriate settings more effectively, which then drives process

indicators for home care, in terms of what are the obstacles. Because I think if we went around the room, we could probably list about 100 obstacles to getting people to the right place at the right time at the right cost. But it gives us a flag, a general flag and it is a place the ER and the hospital that unless you need to be there, you don't want to be there. So just a thought of how I think about those outcome indicators.

MEMBER LEWIS: I completely agree. And especially you know, I do think it is a system problem but I think the measure is in a system measure really. So I agree with you completely, though.

CO-CHAIR LAMB: Other comments? Yes.

MS. KLINGENSMITH: Hi, I'm Linda from CMS. I am fairly new to CMS so I appreciate the opportunity to be here. I had my first exposure to the workgroup and I appreciate that. This is giving me a lot of

insight into things. I do want to respond to Julie's two comments and to Gerri, yours as well. I do agree wholeheartedly with all of your comments and I think one of the things that we are kind of getting there, I think one of the things, that is one of the reasons why we changed our data source is because we were always saying for using the OASIS tool in terms of with the ER visits, again, half the time, whether it be, I don't want say fault of the clinician or information not being shared by the caregiver or the patient that they went to the ER, we are not capturing that information. We are only capturing about 25 percent of the actual visits that do occur to the ER without hospitalization. That is significant.

That is kind of one of the reasons why we changed this claim source because again, it is happening all the time. So I think our goal for this is to get this in place and then looking at that data, working

from a surveyor perspective, in terms of double checking and looking at the raw data, going back and getting these improvement plans and identifying why are these patients going to these ERs and what can we do from a provider standpoint to limit those reasons.

Because you are right, I mean, that is just what they do. The ER is their care. They know that the nurse is coming. They know that the therapist is coming to the home. But you know, what? Just they don't feel good or maybe their caregiver is not at home, the first thing they do is get into the car and go to the ER, which is a homebound issue, number one. But I do appreciate the feedback. And I just kind of wanted to give you an idea of where we were going and really one of the reasons why we are changing to this data source. We are looking for something more valid and reliable from a reporting perspective and then taking it that next step.

CO-CHAIR LAMB: Thank you. I

can't tell if it is Suzanne or Jeff down there. It's Jeff.

MEMBER GREENBERG: We've got a quirky mike down here.

So you know, we have been dealing most of the day with process measures and it is sort of refreshing to me to finally have some outcome measures to look at. Unfortunately, they both fall on Julie and our home healthcare colleagues, and just unfortunately because they are hard, the nice thing about a process measure is you do know exactly what you are supposed to do. The downside is it may not be that meaningful. This is really meaningful but it is vague and you are not sure what to do.

And I would ask you, Julie, it seems like it would allow sort of well-enlightened home health agencies to try to take action and devote resources to areas that would change the culture, would put alternatives to ship them to the ED as soon as

anything happens, which I sort of see is culturally entrenched in a lot of places. But could this measure, you know, promote some kind of cultural change or is it a resource allocation or a sort of leadership imperative that we need to do it differently in a creative way that isn't going to be prescribed by this measure?

MEMBER LEWIS: So absolutely, yes, it is my answer. And so I loved your comments because they were directly related to what I was saying. It is a good measure and I support the measure. It is just like you are always like okay but give me a little bit more. And I know that we are working there.

So yes, I do think that it will really start to draw attention to a good place, which is an area we need to focus on, which is an ED visit. So yes, it is a good measure. It is just like give me more. So that is all it is.

CO-CHAIR LAMB: I would just

really urge you to do the give me more tomorrow and let's get it down so we can talk about it. So think about your give me mores. It sounds like s'mores. Doesn't it? Emilio.

MEMBER CARRILLO: Yes, just a check. What definition are we using for process versus outcome measure? Because this seems to me to be a process measure. Maybe I am just using a different way of thinking about it.

MS. JOHNSON: Wow, you're putting me on the spot and I should know this. When I think of process measure, I guess I think of some kind of intervention that is done. So I am thinking of the intervention as opposed to the outcome of the intervention. So I don't know that I have answered your question very well but that is what I am thinking of. Process would be intervention kind of thing and outcome would not. And then I think Gerri can help me.

CO-CHAIR LAMB: I think you know

the way that CMS looks at it is very Donabedian-like, which is structure-process-outcome. Process if your actionable steps and your outcome is your impact. So hospitalization, functional status. In some cases, your outcome measures could be intermediate variables. But in this case, it is what is the goal and how do we get there. And I think that is Julie's what she is speaking to is let's have some meaningful processes that I can ultimately change that outcome. Right, Julie?

MEMBER LEWIS: Correct.

CO-CHAIR LAMB: Does that help, Emilio?

Kathleen.

MEMBER ALLER: This is just kind of a follow-up to Julie's give me more comment and to the whole issue of usability for process improvement and that is that while I support the risk adjustment for this in the previous measure and I understand why we do

it, I have also spent my whole career in sort of provider-level analytics. And one of the challenges is if you have this risk adjustment methodology that has to go to CMS and you get the data months later, etcetera, you can't really use the data as well internally to do those drill down answer the questions what is going on internally. So there is a real trade-off there in terms of usability when we do that kind of risk adjustment.

CO-CHAIR LAMB: That's a good point. Alonzo?

MEMBER WHITE: Could one of the unintended consequences of this measure and the last one be if your scores are too low it means you aren't taking the right patients? So in other words, are you avoiding the sick people so that your numbers look good?

CO-CHAIR LAMB: Is it Keziah? Keziah, can you speak to the cherry picking factor?

DR. COOK: Sure. So in fact risk

adjusting this measure, while it does make it more complicated to implement, you know, I think the primary purpose for doing the risk adjustment is to avoid cherry picking.

So a provider that had a very healthy mix of patients would actually have an expected rate of emergency department use that would be quite low. And if their actual rate exceeds that, even if their actual rate is also quite low, so let's say their expected rate was two percent and the actual rate was four percent, then because this measure is risk-adjusted, it would be evident that that agency was performing worse than expected.

So I think the risk adjustment is really to avoid creating incentives for cherry picking patients.

MEMBER WHITE: Well okay, say the expected rate is six percent and they come in at two percent. Is that really cherry picking? I mean, I'm just asking.

DR. COOK: Well to the extent that

there is something the agency can observe that we can't observe in our data, there is always a chance of cherry picking. And maybe we would be suspicious. But we hope that if an agency is able to have substantially lower rates than their predicted rate, it would be due to appropriate care or prophecies that they adopted. So perhaps if they instituted remote monitoring or if they had 24-hour nurses on call or something along those lines, they may legitimately have decreased their rates substantially below their expected rate.

MEMBER WHITE: Okay but if they know that that rate is going to be posted on some website and that people are going to go look at it, including the payers and the patients, could that have an adverse effect?

DR. COOK: I mean again, I think that is a risk and I think again that is the main reason why it is important to risk adjust these rather than to just post the observed rates.

CO-CHAIR LAMB: Anne-Marie.

MEMBER AUDET: That is, of course, an excellent point and I think that is why we need balancing measures. So you need to be looking at other things, so as your admission rate for ambulatory-care-sensitive conditions or readmission rate or is your mortality rate. So you really have to have balanced score card of what is going on in your community to look at balancing measures and make sure you are not getting these unintended consequences. That is for sure.

MS. KLINGENSMITH: Hi. Can I actually respond to that? I do agree, there is always that potential for cherry picking. But one of the things also is again processes, having processes put in place with the ideal process measures, again to look at the whole process and to do an analysis of that.

But also on the other end with providers, I don't want to keep throwing that in, but we do have surveyors and they get

these reports and those are the kinds of things that they are looking for, those kind of anomalies, supposedly if you will. If they are expected to have a certain rate and all of a sudden their percentage is a lot lower than it should be, that is where they are being trained to target upon that. That is not a catch-all. That is not 100 percent okay this is going to solve the problem but at least it is another form of check and balance that is currently in place right now.

CO-CHAIR LAMB: Thank you. Jean?

MEMBER MALOUIN: I guess I kind of wondered, since there was a willingness to look at risk adjusting for this measure, I wondered about the ambulatory-care-sensitive condition adjustment and why that wasn't also being willing to be applied. Somebody asked that question and I think you just said because we didn't. And it seems to me like that would be a more fair assessment of performance.

DR. COOK: So again, I think that is the thing to keep in mind with both this measure and the acute care hospitalization measures you considered earlier, in that they are all-cause measures. And that they are, they are based off these older measures that were specified with the OASIS data that were NQF-endorsed previously and have been publicly reported for a while.

We have also and we are also looking at other measures that would capture only avoidable hospitalizations or only avoidable EDUs or only ambulatory-care-sensitive conditions for instance. But it did seem to be useful to have this all-cause measure.

So again, this doesn't have to be the only measure of emergency department use but it was sort of the first one we fully developed with the claims data. You know, but we certainly are considering further refinements to ambulatory-care-sensitive

admissions or to other says of targeting admissions that we think are particularly sensitive to care processes.

MEMBER MALOUIN: I think that would be really helpful because what I kind of hear you say, with all due respect, is we are doing it that way because we have always done it that way. And we want to hopefully take this a step further than that. So, thank you.

CO-CHAIR LAMB: Other comments?

Ready to vote? Remember this is an outcome measure. So we won't be doing 1(c).

MS. MC ELVEEN: Okay, if everyone is ready, the first criteria we will be voting on is impact. And you may begin your votes.

We have 14 votes for high on impact, ten for moderate, no votes for low or insufficient.

Next is going to be performance gap. And you may begin your votes. And we have 12 votes for high; 11 for moderate; one

for low; and no votes for insufficient. So the measure will pass on importance.

The next criterion is going to be reliability. And you may begin your votes. We're waiting for one more. Oh, there we go. Okay.

Thirteen votes for high; ten for moderate; and one for low; and no votes for insufficient.

Next is going to be validity. You can begin voting. Okay, eight votes for high; 14 for moderate; two for low; no votes for insufficient.

So the measure will pass on scientific acceptability.

Next is usability. And you may begin your vote. We are waiting for one more vote to come in. There we go. Five for high; 18 for moderate; and one for low.

The next criterion is feasibility. You can begin your vote.

Fourteen for high; nine for

moderate; one for low; and no votes for insufficient information. And lastly, overall suitability for endorsement, one for yes, two for no. You can begin your vote.

Twenty-three yes, one no.

CO-CHAIR LAMB: So it passes.

MS. MC ELVEEN: So the measure will pass.

CO-CHAIR LAMB: And we are going to move on to Measure 0520, drug education on all medications provided to patient/caregiver during short-term episodes of care. And Dana.

MEMBER ALEXANDER: Okay. So the description of this measure is the percentage of short-term home health episodes of care during which patient/caregiver was instructed on how to monitor the effectiveness of drug therapy, how to recognize potential adverse effects, and how and when to report problems.

There are three denominator exclusions that I will make mention. Episodes in which the patient was not on any

medications since the last OASIS assessment, episodes ending in patient death, and long-term episodes as defined at greater than 60 days under home health services.

So then, through our workgroup, the importance to measure and report we had five yeses and one no. The impact for high and two medium, performance gap five voted high and one voted insufficient. The evidence we had six yes and zero no.

And then on the quantity, three high, two medium; quality three high, moderate three; and consistency five for high and one moderate.

It was made mention that they felt there was excellent rationale that they had provided evidence regarding health disparities.

Scientific accessibility of the measure properties; again, five yes, one no. The reliability was four for high, moderate one. Validity high for three and two medium.

There was discussion that while feeling that this is an important topic, very critical, but some concern that the measure as defined how it really, that it maybe does not really indicate the performance or driving towards truly the process that we are trying to get to in terms of measurement.

And specifically what we were talking about there that checking a code or checking a box that says drug education has occurred does not necessarily mean that the education was thorough or effective. So I can teach you about an education but have you truly, as a patient, understood that? Have you really been able to consume that and can you also retain that information as well, too? So that was some of the discussions within our group.

Usability. The vote was two for high and moderate there were four; feasibility the same as well. Our preliminary assessment of criteria is that we felt that it was

suitable for endorsement by the majority and again, as I think I mentioned, the majority of the conversation was around again just checking a box is actually going to measure a patient's understanding and being able to report out or recognize adverse or potential problems with their medication.

CO-CHAIR LAMB: Great summary. Comments? Discussion from other members of the group or generally?

MEMBER LEFTWICH: Yes, a couple of points. Although it seemed obvious that like the femoral artery that this was important and some of these studies cited were of nurse pharmacist teams doing medication education, which certainly is not likely the setting in the home care. I guess the other point is that this not really bundled but sort of sequential with other, I made the point that the success of this process is really dependent on getting accurate medication reconciled medication lists from a facility

upstream and that a very good job could be done on education but it is the wrong medicine. So it is dependent and along the same lines, the outcome that this process presumably affects may be affected uncontrollably by other factors like the medication education that takes place in an inpatient facility or a primary care practice.

CO-CHAIR LAMB: Other comments? I wonder if some members of the group could talk a little bit about Dana about what you were mentioning is the concern about kind of the causal sequence, which is if you educate, it doesn't necessarily relate to outcome. Because I noticed that the predictability was not supported in the data that were submitted.

What was the discussion about that?

MEMBER ALEXANDER: Well any member of the workgroup can surely chime in here but as I best recall, and again I can't really -- I don't really recall specific conversation

that the validity was not supported. So again, if somebody else can to speak to that, fine. But as related to the education piece for the patient that there needed to be some type of mechanism in place or should be hopefully already is an expectation is that there is some type of demonstration back from the patient verbally of their understanding of their education.

So I don't know if that helped to answer your question or not.

MEMBER GREENBERG: So I think I was the guy that called out and had the issue with the validity. And it was as you described, Dana. More though this is checking a box. And my understanding of validity, and this is new to me is that we need to be sure that if the measure is done, that it actually accurately reflects that the act we care about was in fact done.

So I just want, I wanted to see data that said yes, if that box is checked it

actually does indicate that in fact something was taught and something was learned and not just that a box was checked. That is my concern. So that is where I was coming from on that.

CO-CHAIR LAMB: Julie?

MEMBER LEWIS: So I have similar concerns and my comment is just kind of, I suppose, the kind of real world operational perspective on this hopefully and that is that this is in the middle of about a three-hour intake appointment where they are answering what about 200, 100 questions. I fear that it will become a checkbox, like a lot of things, unfortunately I think in the OASIS, not that it is not highly important. It is, you know, just as a little piece of information.

So we are in the middle of a randomized controlled trial on a pharmacist intervention during the home health episode. That seems to have a big impact on this. So you know, we love things like that and I would

so much rather put our clinician's time and effort into coordinating that pharmacist phone call than check. Just a thought.

CO-CHAIR LAMB: Karen, you are grooving in that one. Did you want to make a comment?

CO-CHAIR CASEY: Come on, Karen!

MEMBER FARRIS: Well I of course support what Julie just said, get more pharmacists everywhere.

But I think the predictability analysis if they report this huge bar for a one-time patient education intervention. You know, to think that that one instance is going to change what was it -- anyway, the two outcomes they assess. I was just like really? Probably not.

So you know, I hear what you are saying but I'm not sure it was the right outcome. And I'm just not convinced that one-time medication education with no follow-up, with no focus on particular medications that

are impacting symptomatology, which is really what is going to drive a readmission or something. I'm just not sure that is the best analytic approach.

CO-CHAIR LAMB: That's a good point. James.

MEMBER LEE: Personally, I sort of like this measure for three reasons. In a conversation with Dr. Coleman, Eric Coleman about sort of care transition issues, you know, I think there is good data suggesting that medication reconciliation as opposed to education in patient's home setting clarifies many of the issues. And so delegating the accountability towards a home setting seemed to be in line with the current thinking around care transition. I think that this thing that -- Something now what is interesting is that with the previous measure, having a reasonable list from inpatient, reasonable and then go in an educate and look in some of the cabinets. What is in there? It seems to make a lot of

sense and consistent with the care model.

So for that reason, I like this measure but we know home health is a very challenging job and we all wanted you guys to be in there yesterday.

CO-CHAIR LAMB: Emilio?

MEMBER CARRILLO: Yes, a question to the CMS folks. Why not or will you be thinking about introducing teachback as a measure, which is an NQF-endorsed measure and which is, I think, tells us a little bit more about what we want to know and doesn't have some of the concerns that we see in this measure.

MS. KLINGENSMITH: Hi, is Deb on the phone? Deb Deitz? Is her line open?

OPERATOR: It's open.

MS. DEITZ: All right. Hopefully you can all hear me.

So this measure is actually based on an OASIS item that is done at the time of is charge in terms of whether or not during

the episode all the medications the patient or caregiver received education on all those medications. So it is not something that is collected actually during the initial intake. We actually have a measure related to that but we haven't -- it's not publicly reported. It is just feedback to the agency.

And then the second question. I'm sorry, could you repeat the second question that you were asking?

MEMBER CARRILLO: The teachback tells us, cuts across issues of proper education, cultural competency, health literacy, and tells us if the patient understands what has been transmitted. And that outcome measure, I think, cuts across several of the concerns that we have, with measures such as this one. My question is, is this teachback NQF-endorsed measure something that CMS is looking at in these types of settings.

MS. DEITZ: And I just would note

that there are the item that collects this measure has a manual that is provided to all the clinicians working in home health and there are instructions in that manual as to what is an appropriate level of education, at what time, in what way you would assess the evaluation and in terms of whether or not the patient had understood the education.

So I guess my question is would you want that level of detail specified in the measure so that it said with teach back or is that level of detail more than you would want to see in this measure?

MEMBER CARRILLO: Well, perhaps not in this measure but as a separate measure. I think that I'm not quite sure how you would integrate it into the way this particular measure is done.

MS. DEITZ: Okay, so you are saying something like this measure would be whether it was provided and then another measure would be related to whether or not

that teaching was effective.

MEMBER CARRILLO: Correct.

MS. DEITZ: Well that is certainly something for us to think about as we are thinking about additional measures.

CO-CHAIR LAMB: Thank you. Kathleen?

MEMBER ALLER: Yes, just a brief follow-up on a similar theme. I do think it would be helpful given the clarification you just gave us to state in here that this instruction occurs at discharge because I think it would have eliminated a lot of our questions. It would help other people use the measure.

MS. DEITZ: Again, just to clarify, it is not at discharge. It is whether or not it occurred during the home health episode. The first, you know, this is for short-term.

MEMBER ALLER: Okay. So at some point during the entire episode of care, that

still helps to clarify it wasn't just during an intake assessment.

MS. DEITZ: So perhaps re-titling it to include the words during the home health episode.

DR. COOK: I think we actually already have the word during the home health episode in the measure title and in the short description.

CO-CHAIR LAMB: Dana?

DR. COOK: Drug education on all medication, provided the patient/caregiver during short-term episodes of care. We would be very open to rephrasing it if something else would be clearer.

MEMBER ALEXANDER: So just to tag on with what Kathleen was just talking about and the person from CMS is that might be worth considering maybe even to thinking about a little bit more clarification on the during because I don't think that the majority of us caught that; that it was during the home

health episode of care, which brings me a greater sense of comfort about that. That it is not during the initial intake when the patient is getting asked his 150 questions but actually then maybe as the medications are even being ordered during their home health episode of care and being given the right education and so forth at the right time, right place. And then at the very least then, make sure that there is some type of validation by discharge that this is done but hopefully has occurred earlier in the process.

So, to go back though that I think whether or not the feedback, the teach feedback could be incorporated as a separate measure or within this measure maybe for consideration if not now maybe at some point later in time. Like you said, we are talking some baby steps here but it would be nice to have that component as a part of the composite measure sometime in the future that we would move towards.

CO-CHAIR LAMB: Don?

CO-CHAIR CASEY: Well I am struggling with this one for the reasons given and you know, the issues of things like health literacy, cognitive function, socioeconomic status, which quite frankly has more to do with medication adherence than it does medication education. You know, the presence of multiple comorbidities, the number of drugs, all these factors just seem to me to be weighing over my decision. I certainly agree that letting people be reminded of what it is that the doctor told them to do and take is important. But I am just struggling with this one a little bit.

CO-CHAIR LAMB: Would it be fair to say you are struggling then with impact and importance, just to kind of categorize the struggle?

CO-CHAIR CASEY: Yes. Yes, I am.

CO-CHAIR LAMB: Okay, good. And I will just add the thing I am struggling with

and I don't know if this was discussed is while education is an important part of care delivery, is it reflective of care coordination? Is it in the right pew? Is it an antecedent to care coordination? Because when I think about care coordination, I am thinking about connects. And this is patient/provider education which, again, is important but is it contained within care coordination? Just a struggle point for me.

Karen?

MEMBER FARRIS: Yes, I hear you, Gerri. That is a very good point. And to Don's point, because it included caregiver, I wasn't as concerned about cognitive status and multiple chronic conditions because I thought it may be education to the patient and/or the caregiver and both are there. So that was my perspective.

CO-CHAIR LAMB: Anne-Marie?

MEMBER AUDET: The other thing that I am struggling with is just the time

period. Because this is that there was education within a 60-day time period and according to all of our discussion about cognitive function, one time in the 60 day may not be worth anything whatsoever. So it doesn't surprise me that the validity testing which, -- And that was one question is when did you do the validity testing? Was it at the end of the 60 days of the home health?

But in any case, wherever you do this, and that is where the teachback, knowing the teachback because there are some, I know some sites are using teachback in the hospital stay and clearly patients have to go through multiple iterations of education.

So I am struggling with, I guess, the validity of this measure in terms of what we are measuring in terms of one-time education having your relationship with the outcomes we are seeking.

CO-CHAIR LAMB: Do you want to ask that to the measure developer, Anne-Marie?

MEMBER AUDET: Yes.

DR. COOK: This is Keziah from Acumen. Can you guys hear me?

CO-CHAIR LAMB: Yes, thank you.

DR. COOK: Okay. Just to speak to the predictive validity analysis that we ran, we were considering outcome measures that were also measured on short stay episodes, so on the 60-day period. And the two measures, again sort of measuring something that occurred during the home health, during the 60-day period.

So I think this was part of the reason why we and our technical expert panel were not that surprised that education during the 60 days wasn't immediately able to impact an improvement and management of oral medications or emergent care for medication mishaps.

You know, and I mean I think if we had found a strong relationship that would have been very interesting but we and our

experts were not particularly surprised that the education was not able to have an impact on those sort of big outcomes in a brief time period.

I think it is also important to note that those two measures are also reported to the agencies. So they do also have information about how their patients are improving on their drug-related outcomes. And as Deb mentioned earlier, you know, there is guidance provided to the agencies about what constitutes appropriate education on medications.

CO-CHAIR LAMB: We have several up. Russ, and then Marc, and then Dana.

MEMBER LEFTWICH: Yes, I just, I struggled with this as well but I do think it is care coordination because of that sequential nature of you have got to have the reconciled list to do this. And maybe there is an unintended consequence or potential unintended consequence in a good way that if

this process discovers issues like there isn't a reconciled medication list or that doesn't reconcile with what is in the cabinet at home, maybe it is a good thing in that respect.

CO-CHAIR LAMB: So what you are suggesting, Russ, is that if nothing else, it gives us insight into the cascade that will require care coordination. And I think that is what I struggle with is do we measure the antecedents or do we try and get into the heart of what does coordination look like?

Marc?

MEMBER LEIB: I've been struggling. I'm new at this so I am really trying to get my arms around some of these measures. This measure, the 0511 measure and the biopsy measure, whatever that one was which really appear to me to be more a measure of what a single practitioner, physician or whoever is doing, rather than coordinating and continuity of care across broad aspects of the system.

And I know when I am sitting here, I am looking at this for a care coordination to that narrow focus and the measure doesn't measure up. So we sort of vote yeah or nay on that, when it doesn't seem to meet what we are supposed to be looking at. But at the same time, each of the specialties has to come up with measures for PQRI and then measures with CMS and all these other things, that once we reject it because it doesn't meet our narrow focus, leaves them in a lurch. And I am wondering if some of these things might be better bucketed in other places, of which I have no expertise to know what they are yet. So I can't begin to tell you.

MEMBER HOWE: Yes, I'm less concerned about whether this is in the right bucket but I do share Jeff's concern that I'm not sure that this measure can measure what it says it is measuring. Unless there is an access or an acquisition tool that can really confirm and validate that the teaching that is

supposed to be going on here actually happens. Because there is really too much potential for these two boxes to get checked off and you are not really capturing the event that you want to capture.

MEMBER GREENBERG: Yes, I thought it was interesting. The validity testing to me wasn't actually testing the validity of the measure. It was testing it to link to the outcome. It really was testing the importance of the measure and it didn't pass. And I'm willing to agree that perhaps it didn't have the statistical power or whatever to confirm that it didn't pass.

But yes, the validity is just are you actually measuring what you want to measure? And surveying 50 patients saying did you actually receive education about your medicines would do that. I would be convinced if we just do that, yes, patients received the education that the checkbox said they did. And that is what I am not seeing.

So you could argue that both the importance and the validity are questionable in my mind.

DR. COOK: Could I just interrupt for one minute? I did want to note this measure actually had received time-limited endorsement from NQF a couple years ago. So the goal of our submission this time was to provide the new evidence about the additional reliability and validity testing that was conducted after data collection began across all approximately home health agencies in the country.

There was some earlier data collection on a subset of agencies that may have gotten at more sort of what your questions are. Deb, could you just briefly describe that earlier work?

MS. DEITZ: Well, we did exactly what you are talking about. We went and looked at the -- We compared the response on the OASIS to what actually we were able to

find in the medical record to determine whether or not we saw evidence of the teaching had occurred. And I don't know if Keziah if you have that. That was in our original submission and I'm not sure that I have that testing result in front of me right now but we did do that testing. And perhaps in a minute, we will have answers about what that testing said but we did do the testing that you are describing. And we did it on a smaller sample and then once we were collecting data nationally, we moved on to looking at what we could see from the national perspective.

CO-CHAIR CASEY: Linda, did you want to say something?

DR. PACE: I did except for I am new too, so my head is spinning right now.

To the point about, and I understand about checking the box, there is a lot more to it. You are right. We are not positioned yet to capture all of that. We are capturing on the instrument itself and on care

plans. For instance, when staff go in, clinicians go in to teach a patient, again to Julie's point a lot of times they are coming from some kind of facility. Excuse me, we don't have med sheet. We are asking for one but we don't have one. So we have to go over the meds of what the patient or the caregiver say the meds are. Then we have to coordinate with the physician. We have to put it on the plan of care, which the physician has to sign and the test that these are indeed the meds, the dosage, route, etcetera. Then also we put on the plan of care that we are going to be teaching an educating the family and the patient regarding all these medications.

So I do think to sum it up, I do think there is a lot of care coordination involved. In fact, there is a lot of coordinating with pharmacies from the clinician perspective, coordinating with the medications and making sure there is allotment.

We do also capture re-demonstration on infusion of medications, injections, etcetera. We are not capturing that obviously in this measure but it is something that we need to look at. How can we capture that in some sort of a measure?

But I just wanted to kind of put your mind at ease, that is going on in the provider world, in the home health world we are doing that.

Also again I am just trying to get my hands around it from a knowledge perspective, but all Medicare patients receive a survey at the end of their episode or at the end of their care. And it does have three or four pointed questions about medication. Did your clinician review the medications with you? Do you have knowledge of your medication? Do you know the side effects of your medication? So we are capturing it there. We just have to find a way to pull this all together.

CO-CHAIR LAMB: Suzanne, is yours up>

MEMBER HEURTIN-ROBERTS: I guess this sort of follows up on it. This may be asking too much of a measure but we are talking about teaching but we have no idea whether there is any learning going on, whether that teaching is effective. And I'm not sure how you would go about this but if you could have some sense that in fact the information was received and understood and not just the patient checking off the box, that would make this a much stronger measure, I think.

MS. KLINGENSMITH: And as I mentioned, we are capturing that. In fact, I believe in April there is going to be first public posting of the survey results for the Medicare patients. And so that data is going to be put public. It is going to be in April. We are going to start seeing some of that.

And you said something else, in

terms of capturing it. It will come back to me.

CO-CHAIR LAMB: Emilio, did you want to say more about it?

MEMBER CARRILLO: Yes, just to answer your question, that is a teachback, which is an NQF measure. I mean, it has been around for a long time. And the CAHPS just tells you that it was done. It doesn't tell you that it was properly learned.

CO-CHAIR LAMB: Julie?

MEMBER LEWIS: So I'm sorry. I keep putting my card up and down. I did it like four times.

So I guess this is a question for CMS. So you have the things around medication that are mandatory. Right? They are required for payment, etcetera. You have to have them. And you have the things in the survey that we have kind of talked about. Could you maybe just, and maybe this is too general and everybody else but me is there, but could you

tell me what this measure -- What does this get you? So is it your hope that this is something that isn't currently captured or focused on? I don't mean to demean it by calling it the checkbox, but that that is going to change the behavior.

Because it seems like you are collecting a lot around medications right now. So could you just maybe put this measure into that broader scope?

MS. KLINGENSMITH: I think that is exactly it. And I don't want to say this too loud but that is what we are looking at with the next measure as well. We are looking at putting attention on a deficit. Because one of the number one reasons for emergency room visits or hospitalization is regarding medications, whether it be not adhering to them, not taking them correctly, reaction, due to improper teaching, whatever. We are trying to focus performance and change behavior on the clinician's perspective and also by making

this a public reported measure bringing it out to the public, saying this is what you should be expecting. You are supposed to be receiving education on all of these medications for the families, for the caregivers and that is what we are finding on this HCAHPS what we call it for the consumer testing that we are doing on the consumer surveys, that is what we are also looking at.

In our consumer testing groups that we have had, we have had different caregivers from the community. We have had professionals. We have had a variety out there. And one of the things that this measure such as this bringing to light is oh, okay, it is kind of giving me an idea of what my expectations are supposed to be, what training we are supposed to be receiving, what kind of care we are supposed to be getting and what we are looking at as being valid services that we should be receiving and should be provided to us.

MEMBER LEWIS: Okay. No, I'm totally 100 percent with you on that. And I guess my concern here is we are just going to see 99 percents across the boards on this.

MS. KLINGENSMITH: I tell you we are not.

MEMBER LEWIS: You know, if I am -- I don't know.

MEMBER AUDET: That was going to be my next comment because you're telling us somehow that is 70 percent.

MS. DEITZ: Do you understanding that this measure is currently, this is the measure that is being currently collected and reported on Home Health Compare? That is what you are looking at now. So it is not a new measure.

CO-CHAIR LAMB: Well unless there is something pressing, we may stop after this.

MEMBER FARRIS: Okay. I appreciate your clarification on the process and linking to HCAHPS and to the surveys and

all that. But I guess my concern, and I think it has been stated but I just want to clarify, my concern with the outcomes, linking it with the outcomes like you have, is that there are a lot of interventions going on right now around this and the medication list that we talked about this morning, there is transition coaches going on to the home that are doing med rec, the hospital is doing teachback. I mean with all the focus on preventing readmissions, we have so many initiatives around this that I am not sure that you can fairly link the home health teaching with the outcome and that is my concern.

CO-CHAIR LAMB: Any last pressing comments before we move into a vote? Okay, Nicole, you are up.

MS. MC ELVEEN: Okay. If everyone is ready --

MS. DEITZ: Actually, Deborah Deitz, if you want it, I could give you the results of the field testing which we just dug

up for the validity that we were able to corroborate with the medical record documentation supported the testing in 94.29 percent. That's it.

CO-CHAIR LAMB: Any questions about that? Okay, thank you.

MS. DEITZ: You're welcome.

MS. MC ELVEEN: Okay, impact under the importance criterion. You can begin your votes. We are awaiting one more response. Okay.

Five voted high; 13 moderate; five low; and one insufficient.

Next is performance gap. You can begin your votes.

Okay, six high; nine moderate; eight low; and one insufficient.

Next is on evidence. Yes, we are doing evidence. And again to remind the group, on evidence you are voting one for yes and two for no. And you can begin your vote.

We are still awaiting one last

response on evidence. Okay. Just one more time because we are missing one response. Okay.

So we have seven yes and 16 no. So it is not going to pass.

CO-CHAIR LAMB: This one does not pass. Okay, thanks for the thoughtful discussion.

Now I'll ask the question. We have one more for CMS. Is CMS going to be here tomorrow or do we need to do that one?

They are not planning. Okay, one more.

CO-CHAIR CASEY: So do you all have your five hour energy drink?

CO-CHAIR LAMB: Okay, we're going to move on to 0526. And Suzanne?

MEMBER HEURTIN-ROBERTS: James, this is the measure of --

CO-CHAIR LAMB: Is your mike on?

MEMBER HEURTIN-ROBERTS: Oh, I'm sorry.

James this is the measure of whether home health got there yesterday or not. This is measure 0526, CMS, it is a CMS measure on timely initiation of care.

The definition is percentage of home health episodes of care in which the start or resumption of care date was either on the physician's specified date or within two days of the referral date or inpatient discharge date, whichever is later.

Okay, we all thought pretty much that this was a high impact measure. And the performance step was a little less obvious. I think that the -- I forget what the gap was. I think it was 70 percent were already meeting this standard, 70 percent of episodes were meeting this standard. But in terms of the criteria where this obviously does no harm to anyone but probably does good, I think we performed well.

So anyway, the impact -- the importance was determined to be a yes for one

but three people said no, importance to measure and report. Impact was high four, all four of us. And then the performance gap, one person high, two persons medium, one person low.

Okay and moving on to evidence, the evidence was the real sticking point for this measure. There was only one study that was given as the body of evidence. So in terms of quantity, it was very low. All of us said it was four. And the quality, however, was very good. It is based on OASIS data. In terms of consistency, it is hard to evaluate that. What do you say when you have one study?

Now on our phone call, it was pointed out to us that there is really very, very little research done on this, that this is pretty much it. So it is not a question of them not providing the evidence. This is all there is.

We were pretty wary of moving

forward with this. You can see that two of us thought it did meet the evidence requirements. Two said no. And I don't remember the logic model but I'm not sure that it passed for evidence. However, it was pointed out to us by staff that an exception can be made if we think the circumstances warrant it so that we can certainly talk about that.

In terms of scientific acceptability, yes, we all thought it was acceptable. It was very high reliability. The reliability tests were done as beta binomial tests. And I believe the reliability coefficient was around in the 90s consistently.

Let's see where am I? Validity. There was some question about validity, however, because one measure of validity they measured this timely initiation of care against some other measures and timely initiation of care was shown to be associated with improvement in daily function but it was

also shown to be associated with increased acute hospitalizations. So it seemed to us that that was sort of across purposes.

And I am going to let CMS people, because they convinced me that maybe this wasn't the issue, that this was really okay, that there ways to explain this, so I will let them do that.

The other source of the idea that this was a valid measure was face validity. And I have no problem. We all thought that face validity was fine but there was very little information given as to how face validity was reached.

Now on the call it was pointed out to us that there was a very involved well-established procedure that they used to establish consensus about face validity. So knowing that, we would say yes, this is valid, however, based on the information we were given in the application that validity was in question.

Usability, we all thought it was well-described. It was a good measure. It was highly usable.

And in terms of feasibility, yes, this is data that has to be turned into CMS by home health services anyway. so this is data that is readily available.

So in terms of whether the criteria, whether the measure met the criteria to be endorsed, three of us said yes, one of us said no, and that was based on the question of how do we evaluate a measure on just the one study. And we were going to wait until this discussion to talk about exceptions and how to address that.

CO-CHAIR LAMB: Would you like to, Karen, would you just fill us in on exceptions and the situation under which we would consider that?

MS. JOHNSON: Just a reminder that if the body of evidence is lacking, we can go back to this exception here on the bottom

left-hand side for non-outcome measures. If there isn't really a body of evidence, you can decide if you think that the benefits outweigh the harms. And if you do, that would allow you to go ahead and pass on 1(c). So again, just a reminder of that.

CO-CHAIR LAMB: Comments? Go ahead, Jann.

MEMBER DORMAN: I can't believe I am going to get the chance to tell a joke in a group like this but I only know one joke related to transitions. And it goes: How do you raise the 30-day readmission rate? And the answer is: Send in a home health nurse.

So this relationship between starting home health and increasing readmission rates, we have seen this at Kaiser. And you know, I would submit that it is not a reason to discount the validity of the measure that there is so much work to do and in helping people to stay safely at home and that the timely start of home health is

one of them. So I would just put that out.

CO-CHAIR LAMB: Dana?

MEMBER ALEXANDER: Yes. Kind of from my kind of clarification here, maybe for others, too, as related to kind of the scope and importance of this. I see that it is reported that 11.4 percent of patients do not receive their first home healthcare visit within this required time frame that is being described. I guess my next question would be, and it may be in here and I missed it, is that in that of that 11.4 percent of patients that falls into that category, what is the percentage then of that population group then that gets readmitted back into the hospital, you know, as a readmission.

CO-CHAIR LAMB: Is that a question to the CMS developers?

MEMBER ALEXANDER: Yes.

CO-CHAIR LAMB: Do we have that data?

DR. COOK: I don't think that is

something we included on our submissions and I frankly can't recall. We may have done that stratification internally when we were looking at the predictive validity but I don't recall the results.

I think Jean or Liz or both are on the phone and their earlier published paper again doesn't exactly address that question but sort of gets at something similar.

CO-CHAIR LAMB: Yes, and I ask it because 11.4 percent of the patients did not get seen within the time requirement so not good but also what was the untoward outcomes or what happened as a result of that. And you know, in the lineup and overall scope of priorities of care coordination is that really important. That is where my thinking is in my head. Maybe it is. I just -- I don't know.

MEMBER LYNN: So I appreciate Jann's comment. I also appreciate that CMS has put forward some of this data that maybe looks like it is not the most supportive of

the measure because it helps us to understand more questions to ask.

In terms of the study that was done, it was a really, really big study that seemed to be a well done study. And someone who was on our workgroup call pointed out how hard it is to do this kind of research and that we may never have a lot of it. I think in terms of the information, Karen, you reminded us about in terms of exceptions, I can't see how any harm could be done to a patient by having a timely initiation of care.

Another comment that came through with the workgroup call was that patients who don't get that visit, aren't going to be in this denominator. So they may actually have been readmitted to a hospital and we would not know it in terms of this measure because they didn't have that visit.

CO-CHAIR LAMB: Thanks, Lorna.

Who has got their sign up down there? Suzanne?

MEMBER HEURTIN-ROBERTS: Yes. The flipside of that also is that they only included patients for whom home healthcare was provided, which implies that that patient was sick enough to need home healthcare. And we had no idea of how many patients were released without home health care and didn't need them. So there is no comparison and there is no way to get that data. I understand.

CO-CHAIR LAMB: Julie?

MEMBER LEWIS: So I am mostly just going to agree I think with the other comments. I actually really like this measure. I think it is a very important measure. As we think about being a good care transitions partner, I think it is a wonderful measure for you to internally, this is one of those you could actually know what you are doing. Right? And you can say oh, okay, it is very concrete.

And I wasn't surprised to see the ACH rate going up but the way it was worded

anyways because another way to look at that, and we don't know that this is what is going on, but another way to look at that is in those two days, ten of them are going to the hospital regardless and maybe if you brought a home health nurse in, only eight went. You know, you just don't know. I mean, I wasn't surprised but I think it is a very important measure.

CO-CHAIR LAMB: I'd like to say a couple of comments about that as well. In the spirit of baby steps, okay, we have very few measures that look at are services delivered when they are expected to be delivered. And this may be one that is really critical to the patient experience, which we don't have a lot of.

The one question that I did have though is in the study that was done, it looked like there was a difference in the experience where it was a start of home health versus a post-acute resumption of home health.

And I was wondering why not separate that in the measure rather than lumping them?

Can the developers respond to that?

DR. COOK: Are Liz and Gene on the phone? They were actually the authors of that earlier study.

DR. NUCCIO: I'm on the phone but I don't know if it is muted.

DR. COOK: We can hear you now, Gene.

DR. NUCCIO: Oh, great. Actually, Liz was not part of the study. Angelo Richard was.

But we identified -- the question is we did identify different rates of hospitalization for the startup care patients versus the patients who were resumption of care. And that was sort of new information or the first time that it has actually been empirically established. When we developed the measure, the limited endorsement of the

measure occurred before the study was completed.

So, I think the answer to your question had we decided to split and create two measures, one for patients who are returning to home health care versus those who are starting home health care, I think the answer is no we had not considered it because we were trying to deal with the time limited endorsed measure only.

MS. DEITZ: Can I just say and also because I think that we think that it is critically important for both populations.

DR. NUCCIO: And I also might want to point out that we are in the process of redoing that analysis with newer data. The data that we used were data from 2001 and now we have, obviously, some newer data available to us and so we are going to be looking at it with a newer data set.

We can look at what it might take to have an additional measure or a separate

measure.

CO-CHAIR LAMB: I guess the alternative too is that if you find, you know, if it is consistent and the new data set is to look at whether this might be a risk adjuster, given that the folks that are -- You know, if the pattern looks different in its resumption, are those patients more likely to be readmitted to the hospital?

DR. NUCCIO: Right. The resumption of care is indeed a dichotomous variable in several of the OASIS outcome measures. I don't know whether or not it is with the measure that Keziah had presented previously but I know that it is for several other measures.

DR. COOK: The measure we discussed previously is just for the first 60 days of home health care. So it actually, the folks have a brief hospital visit and then return to home care are not captured in that 60-day measure.

CO-CHAIR CASEY: Yes, I think all of our intuitive natures would expect this to be a no-brainer. But in fact, we ran into the same issue when we tried to define an appropriate time interval post-discharge for evaluation of patients with acute decompensated heat failure and came up with nothing, no difference between whether it was two, seven, or 30. So I think we just need to be careful and I don't have an obvious explanation for that. It seems like there may be issues about the care in the hospital, the transition of care, the infrastructure around the home care delivery process that may probably factor into this. So I am just a little uncertain about it. I still think that intuitively, though, it is important.

CO-CHAIR LAMB: Jean?

MEMBER MALOUIN: Yes, I think though the difference between what you are describing and this particular measure is that this is really just about the efficiency of

when a service is ordered having that service delivered, as opposed to what is the right interval of care following an event. It seems a little bit different.

CO-CHAIR CASEY: Yes, I think what I am trying to get at is that it is unclear as to the impact on real outcomes, which would be re-hospitalization. So that is the point.

CO-CHAIR LAMB: Suzanne?

MEMBER HEURTIN-ROBERTS: This may be something we want to talk about tomorrow morning -- and I apologize, I have a cough that won't go away -- but I wanted to raise the issue now.

For me this measure illustrated a problem that I think all of us had as to whether to interpret the evaluation criteria very strictly and literally and follow the algorithm that was given us, or use intuition here and there. I was pretty harsh on this measure, even though I liked it but I was trying to follow the algorithm strictly.

And just for this group and for NQF in the future, that might be something you want to address up-front in orientations.

CO-CHAIR LAMB: Any other comments? James.

MEMBER LEE: Yes, just a quick comment. We look at timely initiation of home health services as a way to address acute hospitalization. Are we thinking in the right direction? Is timely initiation really about improved function? If so, does the data that we have here support that?

And this is a delivery model issue, as we pointed out. And so from that perspective, I guess I should send more people to home health but not thinking about avoiding hospitalization within short-run because the evidence doesn't support that clinical approach.

So it's just a thought.

CO-CHAIR CASEY: Well I have an n-of-1 trial. I am not a Medicare beneficiary

but I did have a hip replacement four years ago. I did not go to post-acute rehab and I was real happy on day one that home care showed up. And my wife was really happy. She was the one because she had to take care of grumpy old me.

CO-CHAIR LAMB: I told you it was a patient experience measure.

DR. NUCCIO: This is Gene Nuccio speaking again. Indeed the data, the analysis does show that functional outcomes do benefit significantly when you come into the patient's home early. And in another analysis that I have done with hip and knee replacement, that is corroborated but with an n greater than 1.

CO-CHAIR LAMB: Thank you for that. Any other comments? Are you ready? Get your clickers out.

MEMBER ALLER: So did we get clarity on how to answer the evidence question? I understand the slide. But if we are saying we believe we should override, then

we say yes to the evidence, even though -- Okay.

CO-CHAIR LAMB: So you are asking a logistical as how do I answer the question. Okay. The answer is yes, you would say yes.

MS. MC ELVEEN: Okay, everyone ready? Okay, we are voting on impact first. Okay. Again, you know the four voting options and you can start your vote.

We are awaiting two more responses. Okay, 13 high; 11 moderate; no votes for low or insufficient.

Next is -- Oh, sorry.

MEMBER HEURTIN-ROBERTS: May I ask a question, just to clarify the exception before we move on? So I understand that we would say yes, it meets the body of evidence. Will it be noted somewhere that we did that because an exception was made and not to suggest that we thought the body of evidence really met the criteria?

CO-CHAIR CASEY: Yes. Staff is

very good at capturing that nuance.

MEMBER HEURTIN-ROBERTS: Okay.

MS. MC ELVEEN: Okay, the next criteria performance gap. You can begin your vote.

Okay. Six high; 14 moderate; three low; and one insufficient.

The next is going to be on evidence and we are doing a -- So this is the slide for our potential exception to evidence and it is one for yes, two for no. Let me start the clock. You can start voting.

Okay, that was quick. Okay, so 23 responses for yes and one for no.

CO-CHAIR LAMB: Nicole?

MS. MC ELVEEN: Yes?

CO-CHAIR LAMB: For the purposes of just documentation, does it matter if we -- do we need to say whether we are voting to override versus evidence or it doesn't matter?

CO-CHAIR CASEY: Well that is probably a lower, higher threshold. So I

would say we met the higher threshold.

MS. MC ELVEEN: Was that the last number you hit? You hit two? The one that you counted as the vote. You meant it be one. Okay.

So I will just -- So just for the record on evidence, we have 24 yes and zero no.

Okay, so we will move on.

MEMBER AUDET: Those criteria we had all along. I just I'm not sure why we are specifically focusing on this for this measure because I voted according to that criteria for other measures during the course of the day.

So if we are calling out this measure that we -- You know, I don't think it is fair because I have been doing this for other measures, too. So just a clarification.

MS. JOHNSON: Part of that I think is my fault because I am a little bit new at how this process goes. But we have been keeping notes. So we will definitely be

saying in the report that the body of evidence was thin and that we can invoke and some did invoke this exception. So I think they are still going to be okay.

MEMBER AUDET: I did that for other measures, not only for this one.

MS. JOHNSON: Right. I understand.

MEMBER AUDET: And we did not have this discussion for all the other measures.

CO-CHAIR CASEY: Well the ones we didn't approve, I mean the ones we voted down. So I see the point.

MS. DORIAN: And ultimately, it is still a yes or no vote.

MEMBER HEURTIN-ROBERTS: And those passed anyway.

MS. DORIAN: Exactly. So we will be capturing in the summary more than anything.

MEMBER HEURTIN-ROBERTS: May I? In our workgroup, in our call, this question

was raised about whether we should do that or not and we were told to hold any decisions about exceptions until we got to this group.

MS. MC ELVEEN: Okay, so we are going to continue with the vote. We are now voting on the scientific acceptability of the measure properties. First on reliability. You can begin your vote.

One more response. There we go. Fifteen high; eight moderate; one low; and no votes for insufficient

Next is going to be validity. You can begin voting.

We have eight votes for high; 15 for moderate; no votes for low; and one for insufficient evidence.

Okay, moving on. So that means the measure will pass the scientific acceptability of the measure properties.

Next is usability. You can begin your votes.

We are missing one person. There

we go. We have 18 for high and six for moderate. No votes for low or insufficient.

And moving on to feasibility. You can begin voting.

Twenty-three high and one moderate. No votes for low or insufficient.

And then finally overall suitability for endorsement. One for yes, two for no. You can begin voting.

One last vote -- oh, there we go. Twenty-four yes, zero no.

CO-CHAIR LAMB: And that's a pass. Thank you for hanging in there. And also thanks so much to the measure developers and CMS. And thank you for your very thorough and thoughtful responses to our many questions.

MS. DORIAN: Nicole, we are just going to check to see if there are any members of the public on the phone.

OPERATOR: Yes, we do.

MS. DORIAN: Would you please open up those lines?

OPERATOR: Certainly. For public comment, please press *1.

And there appears to be none at this time.

MS. DORIAN: Okay, thank you. Would everybody please remember to leave your voting device at your station? It will be there for you tomorrow.

CO-CHAIR CASEY: Yes. So one more housekeeping point for tomorrow. Just so we understand, we are meeting at 8:30 here again. And we will have NCQA. We will have five measures. Three of them will be related to medication review and medication reconciliation. So we will actually since we have talked about this already, move those up in the rank of our discussion. So we will talk about those first and then we can flip a coin about the Advance Care Plan, which I think may be more robust than medical home system survey. So those two.

We hope to then have about a half

an hour discussion around related and competing measures, which staff will lead. And then we have the working lunch and afternoon session around preferred practices. And I think we just need to think a little bit more about how we want to frame that discussion. But I think again, please just review those tonight when you are sitting around with your glass of wine or your slippers or both and we will be done by tomorrow at four.

So thanks to everyone for great work. We made great progress today.

(Whereupon, the above-entitled matter went off the record at 5:10 p.m.)