NATIONAL QUALITY FORUM

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MEASURE APPLICATIONS PARTNERSHIP
CLINICIAN WORKGROUP

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WEDNESDAY
DECEMBER 9, 2015

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The Workgroup met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., Bruce Bagley and Eric Whitacre, Co-Chairs, presiding.

PRESENT:

BRUCE BAGLEY, MD, Co-Chair
ERIC WHITACRE, MD, FACS, Co-Chair
TERRY ADIRIM, MD, MPH, FAAP, American Academy of Pediatrics*
BETH AVERBECK, MD, Minnesota Community Measurement
MADY CHALK, PhD, MSW, Treatment Research Institute
LUTHER T. CLARK, MD, Individual Subject Matter Expert
STEPHEN FRIEDHOFF, MD, Anthem
SCOTT FRIEDMAN, MD, American Academy of Ophthalmology
SCOTT FURNEY, MD, FACP, Carolina's HealthCare System
LINDA GILLAM, MD, MPH, American College of Cardiology
STEPHANIE GLIER, MPH, Pacific Business Group on Health
RACHEL GROB, PhD, Center for Patient Partnerships

KATE KOPLAN, MD, MPH, Kaiser Permanente*
ROBERT KRUGHOFF, JD, Consumers' CHECKBOOK
BARB LANDRETH, RN, MBA, St. Louis Area Business Health Coalition
AMY MOYER, The Alliance
MARCI NIELSEN, PhD, MPH, Patient-Centered Primary Care Collaborative
JANIS ORLOWSKI, MD, Association of American Medical Colleges
JAMES PACALA, MD, MS, National Center for Interprofessional Practice and Education

DIANE PADDEN, PhD, CRNP, FAANP, American Association of Nurse Practitioners

CYNTHIA PELLEGRINI, March of Dimes

DAVID J. SEIDENWURM, MD, American College of Radiology

WINFRED WU, MD, MPH, Primary Care Information Project

GIRMA ALEMU, MD, MPH, Health Resources and Services Administration (non-voting)

PETER BRISS, MD, MPH, Centers for Disease Control and Prevention (non-voting)

KATE GOODRICH, MD, Centers for Medicare & Medicaid Services (non-voting)

NQF STAFF:

CHRISTINE CASSEL, MD, President and CEO
HELEN BURSTIN, MD, MPH, FACP, Chief Scientific Officer
ANN HAMMERSMITH, JD, General Counsel
ELISA MUNTHALI, MPH, Vice President, Quality Management
MARCIA WILSON, Senior Vice President, Quality Measurement
POONAM BAL, Project Manager
SEVERA CHAVEZ, Project Analyst
ANDREW LYZENGA, Senior Project Manager
REVA WINKLER, MD, PhD, Senior Director

ALSO PRESENT:

SOPHIA AUTREY, CMS
DAN BAROCAS, MD, Vanderbilt University*
CHRISTOPHER BEADLES, MD, RTI International*

SEPHEEN BYRON, MHS, NCQA

STEPHANIE CARTER, American Academy of Dermatology

ALYSSA CRAWFORD, Mathematica Policy Research

REBECCA HANCOCK, American Academy of Ophthalmology

ALESIA HOVATTER, CMS (Physician Compare)

RABIA KHAN, MPH, CMS (MSSP)*

MOLLY MACHARRIS, CMS (MIPS)

KORYN RUBIN, American Medical Association

*** present by teleconference**

CONTENTS

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

9:00 a.m.

DR. WINKLER: Good morning everyone.

To get us started this morning, it's my pleasure to introduce NQF's President and CEO, Dr. Chris Cassel.

DR. CASSEL: Beautiful, Reva, thank you.

So, I'm going to keep this short and sweet because I know you have a very busy day ahead of you.

And, I first want to thank Bruce and Eric for co-chairing this really important component of MAP and important part, actually, of American health care.

And, to welcome you all to the National Qualify Forum, particularly those of you who have not been part of an NQF committee before. I think, as I look around the room, I think most of you have.

But, I also particularly want to thank Reva and the just amazing NQF staff who get this

task every year. Some people refer to this time of year as holiday season. Here at NQF, we refer to it as MAP season.

And so, it's a very intense period of very, very important work and none of it could happen without the excellent staff that we have.

So, I also -- none of it could happen without you, without the input and careful work and deliberation of these committees. So, we really appreciate you taking the time to provide this valuable input from all the different stakeholder perspectives.

Eric was just commenting about what an unusual dialogue this is for most of us in health care who go to meetings of doctors or hospitals or health plans or consumer groups.

And, this is the only place, really, where all of those perspectives come together around one table and really commit to the serious work of consensus building which is not easy, and yet, vitally, vitally important.

Last year, the staff, I want to call

out our staff developed a more streamlined and manageable process for the MAP work that you're doing. And, we got rave reviews from the committee for the much better way the materials were brought together, the background was presented, et cetera.

And, I think you'll find this year that that has even improved more. So, we really -- but, we always like health care, like everything else, we can always improve. So, we welcome your input and feedback.

So, let me just say that something that you all know which is this is particularly this year a challenging and important time for clinician quality measurement. That's perhaps evidenced by the more than 200 public comments that we got just on this issue alone, over 550 overall in MAP which is a significant increase from last year and the year before.

So, increasingly, more and more people are paying attention and offering their input.

And, of course, this year, we have a

whole new set of really important work in helping CMS to meet the goals of the MACRA legislation and, in particular, the Merit-Based Incentive Payment System, or the MIPS, to consolidate a line and strengthen the clinician incentive programs and the measures that are used there.

So, you are playing actually a very important part to help this program meet those goals.

And, with that, I think I'm just going to stop and let the work begin.

Thank you.

CO-CHAIR BAGLEY: I think, Ann, you're next.

MS. HAMMERSMITH: Thank you.

For those of you who have served on MAP committees before, what I'm going to say is familiar to you, but I always like to remind everyone before you do the oral disclosures.

The MAP disclosures are done in two steps because we have subject matter experts who sit on the committee and we have organizational

members. This group is -- primarily consists of organizational members.

That disclosure is very simple and you got a form from us that is so short, you may not remember it.

So, we'll start with the organizational member disclosures, because those are the simplest. If you're on the phone, I will call on you.

Just to remind you, the only thing that you need to disclose if you're an organizational member is if you have an interest of $10,000.00 or more that is relevant to the work of this committee. That's the only disclosure you have to make.

The $10,000.00 or more is personal to you, not your spouse, not your children, not your parents, just you.

So, I'll remind you of who the subject matter experts are. Your Chair, Bruce Bagley, and your Vice Chair, Eric Whitacre, are both subject matter experts. And, Luther Clark and

Constance Dahlin, or Dahlin, are subject matter experts.

So, with that, I'm just looking around the table, start with Beth Averbeck. Tell us who you're with and if you have anything to disclose.

MEMBER AVERBECK: Beth Averbeck with Minnesota Community Measurement, nothing to disclose.

Thank you.

MEMBER MOYER: Amy Moyer with The Alliance and I have nothing to disclose.

DR. CLARK: Luther Clark.

MS. HAMMERSMITH: You're a subject matter expert.

DR. CLARK: Oh, sorry, okay.

MEMBER PADDEN: Good morning. Diane Padden, American Association of Nurse Practitioners and I have nothing to disclose.

MEMBER GROB: Hi, I'm Rachel Grob with the Center for Patient Partnerships at the University of Wisconsin Madison. I have nothing to disclose.

MEMBER FRIEDMAN: Good morning. Scott Friedman, American Academy of Ophthalmology. I have nothing to disclose.

MEMBER WU: Winfred Wu from the Primary Care Information Project and I have nothing to disclose.

MEMBER ORLOWSKI: Good morning. Janis Orlowski with the Association of American Medical Colleges. I have nothing to disclose.

MEMBER NIELSEN: Marci Nielsen with the Patient-Centered Primary Care Collaborative and I have nothing to disclose.

MEMBER KRUGHOFF: Robert Krughoff, Consumer's CHECKBOOK Center for the Study of Services. I have nothing to disclose.

MS. HAMMERSMITH: Peter, we'll have you introduce yourself later.

DR. CHALK: I'm Mady Chalk from Treatment Research Institute. I'm representing the Duals Work Group here as a liaison. Nothing to disclose.

MEMBER GILLAM: Linda Gillam

representing the American College of Cardiology and I have nothing to disclose.

MEMBER GLIER: Stephanie Glier with the Pacific Business Group on Health. I have nothing to disclose.

MEMBER FURNEY: Scott Furney with Carolina's HealthCare System. I have nothing to disclose.

MEMBER SEIDENWURM: David Seidenwurm, American College of Radiology. I have a consulting contract with The Alliance for Radiology Quality that's a conflict, potentially.

MEMBER LANDRETH: Barb Landreth with the St. Louis Area Business Health Coalition. I have nothing to disclose.

MEMBER FRIEDHOFF: Steven Friedhoff representing Anthem. I have nothing to disclose.

MEMBER PACALA: Jim Pacala representing the National Center for Interprofessional Education and Collaborative Practice. I have nothing to disclose.

MS. HAMMERSMITH: Okay, thank you.

Is Kate Koplan on the phone?

MEMBER KOPLAN: Yes, this is Kate Koplan, actually, and I'm representing Kaiser Permanente. I'm from the Georgia Region and I have nothing to disclose.

MS. HAMMERSMITH: Thank you.

Now, we'll move on to the subject matter experts who got a much longer form.

MEMBER ADIRIM: Wait, wait. This is Terry Adirim from the American Academy of Pediatrics.

MS. HAMMERSMITH: Oh, okay.

MEMBER ADIRIM: Sorry about that. I have nothing to disclose.

MS. HAMMERSMITH: Thanks, Terry.

So, we'll go on to the subject matter experts. The subject matter experts sit as individuals, unlike those of you who just disclosed.

Many of you said your name and said I'm here representing such and such organization which is exactly what you are doing.

So, with organizational members, we expect you to bring a certain point of view to the table, that's why you're on this committee.

Subject matter experts are not representing their employer, anyone who may have nominated you, any professional society with which you're associated. You're sitting as an expert, as an individual.

Because of that, we ask you for a more detailed disclosure akin to what we do for standing committees and the CSAC.

So, we are looking for you to disclose anything that you think is relevant to the work of this committee. Please don't summarize your resume. We're particularly interested in consulting, speaking, grants, research that you may have.

So, with that, I'll start with the Chair and Co-chair.

CO-CHAIR BAGLEY: Good morning. I'm Bruce Bagley and I come with a boatload of biases but no conflicts. But, let me tell you about a

couple of things that I do.

I am on the NCQA CPM Committee which oversees the HEDIS measures, so that certainly is something you should know about. It's obviously it's not a paid position.

I'm also on the Board of Directors of HCI3 with oversees both the PROMETHEUS Payment System and Bridges to Excellence. And, that also is a volunteer position.

In addition to that, I serve as a Senior Consultant to the AMA, but not anything to do with their financial, you know, revenue type things.

And, I also work with the American Association of Physician Leadership which does not really deal with this type thing.

Thank you.

CO-CHAIR WHITACRE: My name is Eric Whitacre. I'm a surgeon in private practice in Tucson, Arizona. I have no conflicts, but I should disclose that I am a member both of the American College of Surgeons as well as the

American Society of Breast Surgeons.

Have been on a number of committees and I'm currently on the Coding and Reimbursement Committee at the American College of Surgeons as well as the Performance Measures Committee of the College of Surgeons.

I've also been on the Board of the American Society of Breast Surgeons and represent that society at the AMA RUC.

DR. CLARK: Good morning. I'm Luther Clark. I'm the Global Director for Scientific, Medical and Patient Perspective in the Office of the Chief Medical Officer at Merck Pharmaceuticals. Other than that, I have no conflicts.

MS. HAMMERSMITH: Thank you.

Is Constance Dahlin on the phone? Constance Dahlin?

Okay, and finally, we'll ask our Federal Representatives to introduce themselves.

So, Kate?

DR. BRISS: I'm Peter Briss, I'm with

the Centers for Disease Control and Prevention and I have nothing to disclose.

DR. GOODRICH: I'm Kate Goodrich with CMS, nothing to disclose.

MS. HAMMERSMITH: I can't see all of you. Oh, yes.

DR. ALEMU: Girma Alemu with HRSA. I have nothing to disclose.

MS. HAMMERSMITH: Okay. Thank you for making those disclosures.

Do you have anything you would like to discuss with each other or questions for me?

Okay. And, just a final reminder, if, during the meeting, you think you have a conflict, you think someone else has a conflict, if you think someone is behaving in a biased manner, please speak up in real time.

We want to know that. We rely on you to let us know. If you are not comfortable bringing it up openly in the meeting, please approach your co-chairs who will work with NQF staff or you can approach NQF staff and we will

deal with it.

Thank you.

CO-CHAIR BAGLEY: A couple of housekeeping things at the start of the meeting.

I've already noticed microphone problems and the microphones aren't as much for us around the table as they are for the people on the phone. And, all of you have been on a phone call like this, right? And you know how hard it is sometimes. So, please get your mouth fairly close to the microphone, make sure the red light is going and I think we'll do better.

The other thing I want to talk about is these cards. It helps me if you would kind of turn them this way so I can see them. And, I know it's popular in this town to stand up your card when you want to talk. We're not going to do that this way because that doesn't work very well for us.

And, if you just catch our eye, we'll get your name on a list and we'll get you up. And, if it looks like we don't have your eye, try

it again and I'll read off the list of 39 people that are before you and then you'll know that you're still on the list.

But, I think we can make that work a little bit better than this business because people drop them off the table and forget to put them down and then who knows which one went up first and all that kind of stuff.

So, I think it just works better, certainly for us.

So, with that, I think we probably should start with the opening.

Eric, did you have anything else that you wanted to say at the outset?

CO-CHAIR WHITACRE: Only to add, if it's okay with everyone, if we can be on a first name basis, if that works. We've done that previously and that's no disrespect, it's just a small group and we're going to roll up our sleeves and get into it.

CO-CHAIR BAGLEY: Okay. Kate, you're at the top of the agenda here. Help us out.

DR. GOODRICH: Okay, thanks.

So, I wanted to take a moment to talk a little bit through a few things including sort of the process related to how we -- and, I know on previous calls, you've heard the measures under consideration process, so I'm just going to touch on that very briefly.

A little bit about from more of a process standpoint, our approach to MIPS because that's really the big program we're going to be mostly focused on for the next two days. We'll also be talking about the Medicare Shared Savings Program.

And then, what I see as, and what CMS sees as, the role of the MAP in helping us develop our policies and selecting measures for that program.

So, a little bit first, this is going to be a little bit more MIPS focused because I know that's what we're really -- the program we're all thinking about for the most part for the next couple of days.

So, obviously, the MACRA legislation passed on I believe it was April 16th of this year. Since that time, we've put out a Request for Information. Thank you to those of you who personally or your organizations responded to us. We got a lot of comments on that that have been very helpful to us.

We did solicit comments specifically on measurement and received quite a bit of input on not only so much specific measures but measurement policy. So, I think that's been very helpful.

We are in the process and have been in the process for several months now of designing the initial policies and standing up the operational tactical approaches to the MIPS program.

We anticipate that we'll have a proposed regulation. Our goal is to get it by the end of March. We hope to do that. We'll see how that goes.

And, the reason for that and instead

of putting it in the Physician Fee Schedule Rule, was really to give people more time to comment. We know there's a great deal of interest nationally from all stakeholders in this program.

And, we felt like with the Physician Fee Schedule Rule which comes out July 1st and is finalized in November, that that may not be enough time. And, quite frankly, it would put a lot of pressure on us to get the final rule out in time given that it's going to be a pretty large rule for a brand new program.

We also have to set the parameters for alternative payment models, eligible alternative payment models. So, a lot of work's going to go into it.

So, we're hoping to finalize it sometime in, you know, if we can, September or October. But, that will give folks, I think, more time to be able to comment on it.

So, just sort of that sort of a time line that we're looking at now.

You know, with the law passing in

April, you know, as regards to the measures, it does say in the legislation that we should use the measures that are in existing programs, at least to begin.

But, it also requires that CMS develop a measure development plan or strategy and that we seek comment on that to inform measure development that we would actually do ourselves or measures that we would want to use and that are most appropriate for the MIPS program and also for alternative payment models.

So, that measure development plan which many of you, by the way, already have given us some input on what should be in there, is to be -- by law, has to be posted for comment by January 1st and we are on track to do that.

It will actually not be in the Federal Register, it'll be on our website, so we will send out links to our LISTSERVs including NQF so that they can also send it to partner organizations. And, we definitely want your comment on that.

And, we have to finalize the plan, I believe it's by May. And we have to do this every year.

So, you know, MACRA outlines some parameters for us for the types of measures that should be in the MIPS program. It's very clear about the direction of measurement for the MIPS program.

And, I'll be honest, I think that, you know, at least at the high level parameters that are outlined that they got it right.

There's a focus on outcome measures, focus on patient reported outcome measures, appropriate use, patient safety, care coordination which, you know, as you all know from having sat around this table and in the world that you work in, is the direction that we've been wanting to go for transformation of the health care system anyway.

But, it certainly is helpful to have that defined in legislation for this program.

So, obviously, our measure development

plan is going to be very focused on those areas.

But, like with everything else, the devil's in the details and how that executed. So, that's where we do think we need very, very specific input.

As we have been talking through the four categories of MIPS, of quality measurement, resource use measurement, meaningful use of EHRs and clinical practice and proven activities, we've been working on all four of those categories as well as, of course, scoring methodology.

The law also asks us to engage stakeholders early and often throughout the process. And so, we have been trying very hard to do that.

We've had numerous meetings with a variety of stakeholders. We actually last week had a Design LEAN session for about four days including at our National Quality Conference in Baltimore to help us think through some of the more actually operational issues around how

physicians interface with CMS to get feedback reports to report measures and so forth.

So, and that really involved many different stakeholders who were a part of that process. It wasn't just CMS folks, it was physicians, physician groups, EHR vendors, registries, lots of other folks.

And, we think we got amazing ideas for how to improve upon the current state.

So, I also think that this -- these two days and what the Coordinating Committee will do are critical for us in -- for the quality measurement and I would say also resource use measurement component of the program.

This is where I think we're going to be getting some of our most meaningful input. And, part of that is because of the regular MAP process that happens every year and we always get great input.

But, I really want us to be thinking about in the context of what MIPS is trying to do which is to set physicians up to be able to make

the transition into alternative payment models.

How do we think about measures? Do we think about measures any differently in that context? And, how does that impact how you think about what measures CMS should include in the program.

So, I think we should be thinking about it or that would be helpful to us to be thinking about it in that frame.

And then, finally, what I want to do is read for you a little bit about the principles that we have defined internally as we have been doing this work over the past several weeks.

When we very first started planning, which was back in the summer, we started off by saying, okay, what does success look like? What have we heard from our stakeholders isn't working? And, where do -- what is the ideal state that we want to get to?

We certainly think in the first few years we're going to get to a better state than where we are now. It's probably not going to be

the ideal state in 2017, but it's going to be better than what we have now.

And, it's going to look, I think, somewhat different from what we have now, which I think is a good thing.

So, we talked about what does success look like? And then, what are our strategic goals that we should be working towards for every policy decision that we're making? What are the goals that we have to keep in front of us at all times? And, what are the principles that are underneath those goals?

So, I'm just going to read for you a little bit what we sort of came up with internally in terms of our strategic goals and some of the principles that you'll have to tell me if you agree or disagree with them.

But, much of this is based upon feedback that we've heard from a variety of different stakeholders.

So, a little bit about what success looks like, just a brief mention there.

So, we say that a successful MIPS program fully equips physicians and other clinicians with the tools and incentives to focus relentlessly on improved care and health outcomes for their patients.

MIPS should also prepare increasing number of clinicians over time for a successful transition into alternative payment models that include acceptance of some greater than nominal risk, and to be held accountable for the health of their patient population while having the time and resources to engage individual patients and families in the care that is best for them.

Our strategic goals include using a patient centered approach to program development that leads to better, smarter and healthier care.

Develop a program that is meaningful, understandable and flexible for participating clinicians, design incentives that drive movement towards delivery system reform principles and alternative payment models and ensure close attention to excellence and implementation,

operational feasibility and effective communication with stakeholders.

And so, some of our high -- I'm not going to read all of our principles, but some of our high level principles that I think are important for this group, obviously, number one is to improve the health of patients.

Number two is meaningful measurement, so including measures that are meaningful to patients and clinicians together.

Engaging patients, caregivers and health care professionals in quality improvement. So, establishing policies that incentivize that team approach that includes the patients in improvement.

Driving rapid cycle quality improvement.

Minimizing provider burden, or as one at our LEAN session, one of the providers who was there said to me, yes, you want to minimize burden, but it shouldn't be no burden. You just want the burden to be in the right place. You

want the burden to be on what it takes to actually improve. And, that's exactly right. Right?

Balance simplicity with flexibility. I think one of the lessons we've learned from the existing program is that when we think we're providing a lot of flexibility, we actually make it more complicated. I know that's not a shock to people here. So, we're very mindful of that.

Advance Health IT with the focus on improved outcomes of care.

And then, align with the National Quality Strategy and the HHS Delivery System Reform Goals.

So, I think those are the main ones that I want to highlight.

So, I do want to be clear that these strategic goals and principles are not just words on paper. They have been right out in front of us. We talk about them a lot. We talk about whether or not the policies we're designing, the in the weeds, nitty gritty policies are actually

speaking to those goals and adhering to the principles. So, we're trying very hard to be true to them.

And so, I wanted you all to hear them so you can see where we're coming from. Let us know if you think those are the right ones, if there's you know, principles or goals that we're not thinking of as you all are giving us the input on the measures over the next couple of days.

So, I'll stop there. Thank you very much.

Or, see if anybody has questions. I don't know if we have time for that or not.

CO-CHAIR BAGLEY: That's great.

And we have a few minutes for questions. Anybody have any questions about, you know, kind of clarifying the program or what we're trying to accomplish today in terms of the MIPS?

Kate, nice summary.

You guys all know this? All right.

Well, you know, I had a couple of comments. You know, I think the hardest part for us, if you look through all the commentary from the staff, many of them were encourage further development. And, if that's the only thing we send to CMS, we will not have done you guys any good.

So, I think that the conversation ought to be around how to enrich that recommendation rather than, you know, just up or down. You know, we're not just here to do this, we're here to try to give some guidance about how that further development should go.

DR. GOODRICH: Yes, if I could respond to that.

So, that's very -- I'm glad you said that. So, you know, our measure under consideration process starts early. It started before or right around the time the legislation passed.

And so, we receive, in particular, from specialty societies, but other developers,

suggestions for measures starting in April or even March of each year.

And, we work with the societies throughout the year and the other developers throughout the year to give them feedback on the measures that they're considering.

And so, a lot of what you see in front of you on the calendar is reflective of a lot of development work that's gone on over the last couple of years by a number of specialty societies and we're very glad for that, that that's happening.

We're actually seeing some measures that you have on the consent calendar that are earlier in development, that are probably relatively solidified in terms of numerator, denominator, but not fully complete.

And, I think one thing I would like to see that would be helpful to us, but I think also helpful to the developers from the MAP is some specific strategic direction on some of those. Because, some of those absolutely, you know,

probably got it right, really great for the MIPS program. Some may be better with some refinements.

And so, that's exactly what I think would be helpful to us to hear, not just, you know, like you said, encourage continued development, but is this generally the right direction or how could it be made better?

What might be, you know, a modification or a slightly different direction that would be helpful for us but also helpful for the developer that would be more appropriate for the MIPS program?

We have a number of societies that submitted measures to us that never have before, which I think is fantastic. And so, I think, I don't want to speak for them, but I would imagine it could be helpful to hear from this, you know, august multi-stakeholder group, again, more specifics around direction, I think would be very helpful.

So, you're right, encourage continued

development has the potential to be less helpful, but I think it's what's underneath that that is much more helpful.

DR. CLARK: Most of the encourage continued development that, at least I saw, either they were in -- the measure was in early development or a field testing was in the process of ongoing.

Are we to assume that these are not yet complete at this point so that's why they're on the continuing development?

DR. GOODRICH: So, we require, for a measure to go on the MUC list, it to be a certain -- at a certain point in development. And, the reason we've decided to include not fully tested and developed measures on this list is because we want that direction from the MAP.

Is this the right direction? Should we continue to invest resources? By the way, testing is expensive, right? So, should we continue to invest resources in the testing of this measure if it's completely the wrong

direction?

So, that's why we go ahead and put those on the list. So, typically, these measures do have what I call sort of stable numerator and denominator definitions. They have been specified, the exclusions have been specified.

But, they may not be fully tested within an EMR system or within a registry or what have you.

But, we think it is incredibly helpful to understand if we're even -- we or the developer is going in the right direction in the first place.

CO-CHAIR BAGLEY: For instance, a couple of measures look to me like it'll be a little hard to objectify the numerator, for instance, if you see that kind of thing. Then that's the kind of comment that would be helpful.

You know, by what criteria are you saying it's low, moderate or high? You know, how you're doing that.

DR. GOODRICH: And, you know, we've

asked the developers whether they be one of ours or a specialty society to either be here or on the phone, if possible, when those measures are being considered because I think that sometimes it may just not be clear and having the developer clarify what the numerator is and how it would be collected would be helpful for the MAP. But, also, again, to hear your feedback. So, hopefully we have or will have people on the phone or in the room who can help answer those questions.

CO-CHAIR WHITACRE: There was some discussion last year about development of a testing center within CMS because one of the big issues here is once the measures are specified, as we've seen, it's getting them tested that really is the hurdle. Is that still on the table?

DR. GOODRICH: So, we weren't really developing a testing center. What we were talking about was something we're calling the National Testing Collaborative.

And so, I think two things to say there.

So, that work is still ongoing. It isn't fully developed yet. But, I would also say, and this is -- I want, you know, Helen or Chris or somebody to speak to this, you know, the measure incubator that NQF has pulled together and is piloting now is another important opportunity for finding test beds for some of these measures.

We've had the NQF folks working with us on the National Testing Collaborative so we're not doing two separate things. But, I think there's been a tremendous recognition by the measurement community of a need for this.

And so, I think what NQF is doing with the incubator is going to really advance that and we want to be able to build upon that or, you know, if there's another niche for it within the National Testing Collaborative, be able to do that as well.

DR. CASSEL: If I could just respond.

If people are not familiar with the measure incubator, this is a piece of work that has been ongoing for the last couple of years and now, really is coming to fruition.

Where NQF is not a measure developer but facilitates bringing together the people with the concept, the people with the data, the people with the resources to try to test.

We have this hypothesis that the process could be more efficient and you could get more rapid testing and maybe even, we hope, less costly. So, we'll see if that works out.

We're in the proof of concept phase and a couple of these, we had -- there was an announcement yesterday of the Robert Wood Johnson funded collaboration. We're engaged with PatientsLikeMe for a novel approach to cloud-based crowdsourcing patient reported outcomes on specific conditions.

So, we're very excited about some of those innovative models.

So, anyone who isn't familiar with it,

my letter to our NQF members this month was about the incubator and we'd be happy, Bruce, to send that to all the members of the committee so they get kind of the basic information about it.

CO-CHAIR BAGLEY: Helen, did you have any additional comments? You've been immersed in this work for a long time.

DR. BURSTIN: Yes, I mean part of it, and Kate had said this, I think what we often hear is the rate limiting step for a lot of developers to get to the next generation of measures is testing and not having the available test beds.

So, we have been working to try to see what to do whatever we can to pull in large data, big data resources that specialty societies and others can use.

So, we've also got an early partnership with OptumLabs where we'll be doing some initial proof of concept testing of a series of different incubator projects.

Again, as Chris pointed out, we are

not developing measures, we are simply helping to facilitate that process, pull together some interesting bedfellows at times, those with funding, those with good ideas, those with data, which I think is really pretty important from the get go of developing a measure.

And finally, those with expertise, pull in the expertise of the measure development community about risk adjustment, et cetera, just to see if, you know, at the start, if you have data and all those resources, can you more rapidly develop and finalize and test the measure and get it to market quicker?

And, finally, to fill those national gaps that MAP has been identifying for years now and we know it's really difficult. It's great that CMS is going to have the ability to put more dollars towards measurement, but we recognize they can't all be done by CMS. So, we'd like to ensure there's some ability to bring private sector funding to those efforts as well.

So, thanks.

CO-CHAIR BAGLEY: I think I might add that you're in such a great position to catalyze harmonization among all the -- everybody comes with the same idea and it doesn't look quite the same when it comes out.

Any other questions for clarification for Kate or Helen or Chris?

Okay, shall we move on? Andrew?

MR. LYZENGA: Thank you.

I'm Andrew Lyzenga with NQF.

That's great, sort of setting the stage of the context within which we're going to be doing this work and the sort of principles and goals and considerations we should be keeping in mind as we do this.

In terms of our more immediate objectives here today, we are going to be reviewing and providing input on the measures under consideration for federal programs applicable to clinician settings through a few different programs that we'll hear about today.

To identify high priority measure gaps

for each program measure set and we set aside a bit of time toward the end of this meeting to do that.

And, overall, to finalize our input as a work group to the MAP Coordinating Committee who will be making the final decisions on recommendations for use of measures in the federal programs.

So, just to talk about our approach here a little bit. This is probably going to be a little bit of a refresher from what you heard at our October web meeting.

But, just as a reminder, we've revised our approach a bit. The approach to analysis and selection of measures is a three step process.

First, we developed a program measure set framework. And, again, that's something that we did at our October meeting. We reviewed and finalized the framework.

What we'll be doing today is these second two steps, evaluating the measures under consideration for what they would add to the

program measure sets given that framework, given the objectives and goals and priorities for each program.

And, to finally identify and prioritize measure gaps for programs and settings.

We've set out sort of a framework for making these decisions. We are asking that you make a decision for each of the measures under consideration and those decisions categories have been standardized to allow us for some consistency across our decisions.

Each of those decisions should be accompanied by one or more statements of rationale that explains why each decision was reached and this is where we can provide some input and feedback to CMS as Kate was talking about.

If we have any thoughts or feedback on the measures as we make our decisions, we can give that to us and we can incorporate them into our recommendations.

For those measures that are accepted as part of the consent calendar, NQF staff has given some preliminary rationale for those decisions as part of our preliminary analysis. I'll talk about that a little bit more in a moment.

For those that we pull off the consent calendar for individual discussion, we'll ask that you provide a bit of rationale, again, as when we make our decision.

So, just to talk a little bit about these decision categories, we have split them out into two different kinds of sort of categories, those four, fully developed measures, we heard a little bit about those that are fully developed and those that are at an earlier stage of development.

For those measures that are fully developed, we have a few different categories for decisions, support, conditional support and do not support.

We've got some potential examples of

the rationale here. I won't go through each of those.

But, these are the potential decision categories that will be applicable to those measures that are fully developed and tested.

For those measures that are still under development, not fully tested and developed, we're going to restrict ourselves to these three categories.

First, to encourage further development, to not encourage further consideration or to find that we have insufficient information to make a final decision on the measure.

So, as we do this, we'll want to keep these criteria in mind. We have set out these criteria with input from CMS and with input from the Coordinating Committee and the MAP and you as work groups.

Non-endorsed or NQF endorsed measures are required for program measure sets unless no relevant endorsed measures are available to

achieve a critical program objective.

I should note that these are not sort of set in stone. They're just intended to be guidance really and things that you ought to keep in mind as we're making our decisions.

The rest of these are really sort of attributes of the program that you should keep in mind, not necessarily specific to each measure, but consider whether the measure under consideration fulfills the aims and goals of the program, whether it is specific to the goals and requirements, whether it adds to the program measure set, whether it contributes to the program measure set, adequately addressing each of the National Quality Strategy's three aims, whether it is helping the program measure set achieve an appropriate mix of measure types, whether it is helping the program measure set enable measurement of person and family centered care and services, whether it is helping us move toward consideration for health care disparities and cultural competency and whether it is helping

us more toward a program measure set that promotes parsimony and alignment.

So, as I mentioned, before, to facilitate this process, we're working with a consent calendar process. And, as staff at NQF, we have conducted a preliminary analysis of each measure under consideration. We've done that, again, with input from this committee and the Coordinating Committee.

The preliminary analysis is an algorithm. It asks a series of questions about each measure under consideration. This is developed from the selection criteria approved by the Coordinating Committee and is really intended to provide MAP members with a succinct profile of each measure and to serve as a starting point for your discussions.

And, certainly, it is not intended to be a final decision but to, again, serve as a starting point. You can choose to pull any measure off the consent calendar that you would like to discuss further and potentially consider

a different decision than we have recommended as staff.

In terms of the details of the voting process, I will hand it over to my colleague, Poonam, to talk about that a little.

MS. BAL: Thank you.

So, this will be hopefully a refresher for everyone. We did go over it during the November all MAP meeting, but we did want to make sure that everybody understood, it has changed slightly since last year.

So, basically, every measure under consideration is subject to a vote, either individually or as part of a consent calendar.

With that said, unless a measure is pulled, we won't specifically vote on it. The consent calendar, the assumption is that it is -- you are fine with the decisions that were recommended by the staff and you're okay with moving forward with that.

The work group will be expected to reach a decision on every measure under

consideration. There will be no gray zone or pushing the measure to the Coordinating Committee.

We did previously have a category of split decisions, but we will try to avoid that as much as we can.

Again, however the Coordinating Committee, of course, can continue discussion if there is an important matter that needs to be discussed. So, they do still have that option to bring up that measure.

And, staff will provide an overview for establishing consensus which we are doing right now.

At the start is in person, so moving forward.

So, the method will be that we'll do an introductory presentation. Staff will present it and then once you get a quick overview, Chair will give context to each programmatic discussion and the voting will start once we have had a chance to discuss any measures that are pulled.

There will be lead discussants assigned to each group of measures. That list was sent out with the email that I sent earlier this week. I'm sorry, actually, I think that was last week.

And so, everyone should be aware, your role is to really respond to the person that's pulled the measure, give your point of view. It can be that you agreed with staff, you agreed with the person that pulled the measure or you have a completely different view. That's really up to you as the lead discussant to give your opinion.

The discussion guide which is this master -- that's really loud -- master document that we started last year and we've continued this year will really contain all the information you need.

It has all the measures divided into consent calendars or related groups of measures. Those groups will have the preliminary analysis which will have the decision and the rationale

that staff have listed.

And then, it also includes other things such as the comment, the specifications. So, you do have all that background information all in one master document.

So, the voting procedure will go as forward. So, as I mentioned, staff will review the preliminary analysis, consent calendar, present it to the group here.

After that's done, all the work group -- any work group member can pull a measure from the consent calendar and it's basically considered a regular agenda item as if we weren't using the consent calendar system.

So, the co-chairs will ask the work group members to identify them. At that point, we'll ask the work group member to basically provide a rationale for why they would like to either change the preliminary analysis or discuss the measure further.

And then, as long as there's no objections from the remaining measures, that

consent calendar will be considered established.

So, you can pull as many measures as you want from the consent calendar, but if there are measures remaining on the consent calendar, those will be assumed that you're okay with that decision and that will be the established decision.

So, once the measures are pulled, as I mentioned, the work group member pulling the measure will give a rationale. The lead discussants will respond and then all work group members can provide their input as they feel necessary.

We do ask in the interest of time, please refrain from repeating points that have already been made.

After the discussion of each MUC, depending on if it was a fully developed, still under development or if we're discussing Physician Compare, your decisions will be different.

So, for a fully developed one, as

Andrew mentioned, it'll be support, conditional support and do not support.

For Physician Compare, our decision is really should it be on the clinician web page or should it be in a spreadsheet?

And then, for under development, the options are do not -- encourage further development, do not encourage further development or we do not have enough information to provide a rationale.

So, to understand how we're tallying the votes, so, generally, we're not going to -- if the votes are greater than 60 percent for support, the recommendation is support.

However, if the recommendations are greater than 60 percent for support and conditional support, the result is conditional support and then staff will ask to clarify what the conditions are and announce that before we move forward.

If the MUC receives less than 60 percent for the sum of support and conditional

support, the recommendation is do not support.

We are using 60 percent as our majority moving forward. And, while we do not encourage people to, you know, decide not to vote, we will count the denominator in deciding that 60 percent. So, it won't be the full committee, it's whoever is voting will determine that 60 percent.

So, this is, again, just a kind of more of a display of what could the options be. But, I've gone over this so I won't go over it again. Again, I think everyone kind of understands if we have 25 committee members and two abstain from voting or if they're out of the room or what may be, you can see that if we had ten conditional -- I'm sorry, ten support, four conditional support and nine do not support, it would be at 61 percent and we would move forward with conditional support.

So, along with the voting, we do have a change with our commenting procedure. As you're aware, we had early public -- member and

public comment that had closed on the 7th of December. Those comments have been incorporated in the discussion guide for your use.

Along with that, we have a new procedure for commenting during the meeting. Before each discussion on the consent calendar, we will open it up to the general public to see if they have any comments on the consent calendar we're reviewing at that time.

We do want the comments to be really focused on the consent calendar that we are about to speak to. And, there will be a time later on in the meeting where general comments can be made. So, that will go first so that way the full work group can hear any comments that the members have to make and members of the public. And then, we'll do all the lists.

There will be, also, after the meeting, we'll have another public commenting period which will be from December 23rd to January 12th. And those will be given to the Coordinating Committee during their

consideration. And, again, all comments are given to CMS for their consideration. So, with that I'll stop and see if there's any questions. You have lots.

MEMBER FRIEDMAN: So, can you differentiate between measures that aren't fully developed and measures that are fully developed, what is the minimum criteria for a measure to be fully developed?

DR. WINKLER: In general, based on the information we have that the measure is fully tested, fully developed and tested. That actually is one of the questions that's responded to during the submission process when the measures are submitted to CMS for consideration.

MEMBER FRIEDMAN: Yes, and testing is subjective, so is there a minimum criteria for the amount of testing that needs to be done before they're determined to be fully developed?

DR. WINKLER: We don't have that level of detail.

CO-CHAIR BAGLEY: Luther?

DR. CLARK: If there's a measure that is requested to be removed from the calendar, is that voted on, or is that consensus or how, do you --

DR. WINKLER: Yes.

MR. LYZENGA: We'll vote directly on that measure individually, if it's removed from the consent calendar.

CO-CHAIR BAGLEY: Rachel?

MEMBER GROB: Thanks to NQF for the amazing amount of work during MAP season, much appreciated. I am wondering back to, Andrew, your sort of presentation of the MAP process for arriving at your recommendations to us relative to each measure. What role, if any, the previous clinician work group discussions around measure gaps played in your consideration around -- you know, we have a set of criteria and then, every year, we come up with specific measure gap identification processes. So, how do you mesh those together?

DR. WINKLER: Rachel, if you look in

the discussion guide and take the link out to the full preliminary analysis, you'll see that one of the questions is around gaps, and, what we used to address that question is the discussion from previous years for the gaps identified for the MAP previously.

MR. LYZENGA: So, we had sort of protocol that we went through for each measure and it included, among other things, the gaps that have been previously identified. Did it fit into those? Some questions around alignment across programs and a number of other questions that we considered for each measure.

MEMBER FRIEDHOFF: Okay, first meeting, so apologies if my questions reflect that, but, one of the early options was do not encourage further development. Did you distinguish that from do not support? And also, what is the spreadsheet option, versus physician web page?

MR. LYZENGA: So, the do not encourage further development is really only an option for

those that are still under development. So, it's essentially equivalent to do not support for those measures that are still under development. The do not support is really for those measures that are fully developed and tested, in which case we wouldn't be encouraging or discouraging further development, they're already developed. So, that's just a support or do not support.

But, for those that are still in that process of development, sort of your two options are support further development, do not encourage further development and then the third option of we don't have enough information to really make a final decision. Does that make sense?

MEMBER FRIEDHOFF: The spreadsheet?

MR. LYZENGA: Oh, the spreadsheet.

DR. WINKLER: Let me do that one. In terms of all of the measures, we're going to be talking a little bit later about the public reporting vehicle for the clinician measures is through Physician Compare.

And, one of the questions that CMS is

asking of us is for measures that are in this clinician programs, they are all available for public reporting on Physician Compare. But, they are looking for feedback, because the plan is to publically report them in two ways. One is either on the clinician's individual web page, a little bit more publically available, a little bit more out there, if you will, versus a more downloadable spreadsheet that is available, yet probably not as visible.

And so, CMS asked for our MAPS feedback on -- for each individual measure where they think it would be most appropriate. So, we have drafted, you know, a proposed selection of those two options, if you will, just, again, to add to the feedback to CMS on the public reporting vehicle.

CO-CHAIR BAGLEY: Barbara?

DR. GOODRICH: I just want to clarify, why we're -- it seems like two different places. So, pretty much all of our measure data for every program goes in a downloadable database, just,

you know, so that anybody can have access to. So, pretty much everything will go there.

I think the question is, does it only belong there, or is this something that would be really meaningful consumers, that we want to have publically reported on Physician Compare that a patient could use to, you know, choose providers or what have you? So, that's really -- and, by the way, on Physician Compare, they get displayed as both a percent as well as a star rating, so just to be clear that that's how that's done.

CO-CHAIR BAGLEY: Barb?

MEMBER LANDRETH: I think that really leads to my question and confusion, and I'm new to the MAP also. When I was going through this, it seemed like there were quite a few measures that were very, very clinically detailed that the average consumer would not be able to use, to make decisions on the basis of, and yet, there were some that were very pertinent to the average purchaser.

And so I was a little confused as to

should we look at this tool as a QI tool for clinical practice, as well as a reporting tool, for patients who are trying to make decisions? Because I think that's going to really impact how we vote. There will be very few patients who will ever download a spreadsheet and make any sense of it, but, I can certainly understand how a clinician group would want to do that for their own QI, internal QI. So, could you help guide me in that way?

DR. GOODRICH: So, Physician Compare, the primary audience for Physician Compare is patients and consumers. So, we actually -- the measures that are up there now which is small subset of measures, we've been taking sort of an incremental approach to displaying performance data for clinicians on Physician Compare. So, right now, there is our data for ACOs and large group practices, and that's going to be expanding over the next year to include individual clinicians as well.

As we decide what goes on there, the

number one thing we keep in mind is, is this measure going to be meaningful to a consumer? And, of course, we ask consumers and patients. We have that as part of our testing and our focus groups, et cetera.

So, I agree with you, there are clearly measures on the MUC list that are important because there's a performance gap and it, you know, may be an outcome or appropriate use or what have you, but that really isn't going to be very meaningful to a patient, but it's really important to drive quality improvement. And, it may even be appropriate for accountability purposes.

But, for Physician Compare, specifically, what we want input from the MAP on is for each measure, is this something that's going to be meaningful to consumers and is important for improvement? Because, you know, another major purpose of public reporting is an incentive to drive improvement.

But, I do want to be clear that the

patient and consumer is really the primary audience for Physician Compare. But, we do strongly believe that we should have transparency in all measure information, which is why we have a downloadable database that others can take and, you know, analyze and so forth.

CO-CHAIR BAGLEY: Other comments or questions? If not, Reva, can we go on to the next?

MS. BAL: Reva, actually, if you don't mind, I'll do a quick demo of the voting.

CO-CHAIR BAGLEY: Yes, we're going to give you a test, a trial run of your voting machine.

MS. BAL: So, everyone should have a blue little clicker. Please let us know if you don't. If you're, obviously, a government liaison, you will not be having a voting one, because you're a non-voting member, and Mady also will not be voting. We do have two people on the phone that will be voting through chat. And, Andrew, I will be voting for them as a proxy.

With that said, you'll notice that most of the screens have those committee guidelines and we'll be posting discussion guidelines. But, if you look towards the back of the room, the ones to the sides have the voting slides on them. Those are just for your knowledge so you can see them. It'll show you what the different options are, what measure you're voting for, what program it is and that'll be listed there for you.

There's no need to point at that screen. These should work no matter where you point. But, if you feel extra cautious, you can always point towards Severa, but it should work towards -- if you point any way. So, the way that you know the voting is happening is if you click one of the options that's a valid option, so, in this case, one, two or three, if you click it, you should get a number show up on your screen.

So, if you see the number, that means you're good to go, if you see anything else, that

means you're not good to go. So, with the screen there, we'll be having 35 seconds to vote. We'll tell you when it's open. Please vote then. And, we'll be looking for a certain number of votes at that time. Once we get -- either hit the number of votes or hit the time, we'll stop it and then we'll let you know the results.

On the screen, the percentage will show, so you'll be able to easily see if we've hit that 60 percent mark. So, if you guys want, we can all do a quick test run. So, Severa, I'll give it to you.

MS. CHAVEZ: So, good morning everyone. So, this is the voting slide for a measure that would be fully tested and these are our options. So, this is just an example. Let's do a test run and I will announce that we are now voting.

And, I guess for the benefit of the people on the phone, I should read what we are currently voting on and the options because the people on the phone would be sending their votes

in via chat that only NQF can see. And Poonam and Andrew here would vote for them with their own clickers so they are counted, too. Okay?

All right, so, this is one of the measures recommended for the Medicare Shared Savings Program, MUC ID 15-576, Prevention Quality Indicators 92 Prevention Quality Chronic Composite. The voting options are one for support, two, conditional support and three, do not support. And we can start voting.

MS. BAL: This is only a trial. Please make sure that when you hit -- you get some sort -- whatever your number you selected shows up.

MS. CHAVEZ: Right now, I'm seeing 19 responses. I think we have 23 -- 20 in the room, three on the phone. Oh, okay, all right. So, okay, so we have 22, and I'm going to stop the timer.

MR. LYZENGA: And, you should be able to hit it multiple times. It won't register multiple votes.

MS. CHAVEZ: Right.

CO-CHAIR BAGLEY: Any questions about that? That's pretty straightforward.

MS. BAL: Okay, go ahead, Reva. We're going to -- oh, sorry.

DR. WINKLER: Okay, I think it's time to get started on the actual measures under consideration. We are going to be looking at two programs primarily. And so, we're going to start off with the Medicare Shared Savings Program.

Because each of these programs have all of their unique characteristics, we've asked CMS to provide an introductory presentation on the program to give you an opportunity to get yourself in the familiar with the program, its goals, how it's structured, how it's organized and how the measures are incorporated into the program. And so, to start off, Rabia, are you on the phone?

MS. KHAN: Yes, can you hear me?

DR. WINKLER: Yes, thank you. Rabia Khan from CMS is going to give you an overview of

the Medicare Shared Savings Program.

MS. KHAN: Thank you, Reva. I'm not sure if everyone can see the slides in the room, but I'll indicate which slide I'm on if that's fine.

DR. WINKLER: Thank you, Rabia, we do have the slides projected in the room.

MS. KHAN: Great, thanks. So, yes, I'm Rabia Khan within our Division of Shared Savings Program, and I'll go over the statutory authority for the Shared Savings Program as well as an overview of the program and Performance Year 2014 results.

And then, with a focus on our quality measurement approach, we'll review our quality measures, our data collection mechanisms and our scoring. And then, finally, talk about alignment of the Medicare Shared Savings Program with other programs such as PQRS, the value modifier and the Medicare EHR incentive program.

So, on slide three, the Affordable Care Act Section 3022 mandated the Medicare

Shared Savings Program. Program requirements and policies have been further defined through various regulations. Largely, the requirements and updates have been made to the Shared Savings Program in the 2011 and 2015 Shared Savings Program rules. We also make annual updates for quality, and also now assignment updates, in the annual Physician Fee Schedule Rule.

On the next slide, an overview for the Shared Savings Program, so participation in an ACO creates incentives for health care providers to work together voluntarily to coordinate care and improve quality for their patient population. ACOs submit an application to CMS to join the Shared Savings Program. And, if accepted, they voluntarily enter a three year agreement with CMS.

Each year, the total number of ACOs do change, due to new ACOs joining the program and the few who chose to terminate their agreement. ACOs can enter one of three program tracks, which are based on their opportunities for savings and

the risk of losses. So, most ACOs are in track one, which provides them with the opportunity to share in savings, if earned. And tracks two and three are two sided, so these ACOs also bear the risk of shared losses, but can earn a higher percentage of savings if earned. Track three is a new program track and will begin in 2016.

On slide five, we assess ACO performance annually on their quality performance and against a financial benchmark to determine shared savings or losses. In order for ACOs to be eligible to share in savings, if earned, they must meet our program's quality performance standards. And, I'll provide an overview of our quality performance standards in later slides here.

So, on slide six, we have 423 ACOs who have been established in the Shared Savings Program and Pioneer ACO Model. And the number of ACOs continues to increase. There are 7.9 million ACO assigned beneficiaries, and, the map here shows that we have Medicare ACO assigned

beneficiaries in 49 states, plus Washington, D.C. and Puerto Rico.

For 2015, there are 89 new ACOs covering 1.6 million beneficiaries assigned to the program. There continues to be a strong interest from new and renewing ACOs. And, in terms of shared savings ACO composition, more than a half of providers participating in ACOs are networks of individual practices and group practices. Approximately a third of ACOs include hospitals or professional partnerships.

So, on slide seven, and in the few years of the Shared Savings Program, we have promising results in quality and finance. In quality, the ACOs who reported in both 2013 and 2014 improved average performance on 27 of 33 measures. ACOs also achieved higher performance than other fee for service providers on 18 of the 22 Group Practice Reporting Option, or GPRO, web interface measures.

ACOs demonstrated quality improvement on measures such as patients ratings of

clinicians communication, beneficiaries rating of their doctor, grading for tobacco use and cessation, and screening for high blood pressure. Because of alignment between the Shared Savings Program and PQRS, knowledgeable professionals participating in ACOs qualified for PQRS incentives and avoided the 2016 PQRS payment adjustment when their ACO satisfactorily reported quality measures on their behalf for the 2014 reporting year.

And, on the next slide, in terms of financial results, in Performance Year 2014, there was a total net savings of $383 million. Twenty-eight percent of ACOs held their spending of $806 million below their targets and earned performance payments of more than $341 million. An additional 89 ACOs reduced health care costs compared to their benchmark, but did not end up meeting the minimum savings threshold.

We note that ACOs with more experience in the program were more likely to generate shared savings. 37 percent of ACOs who started in

2012 compared, to the 27 percent of those who started in 2013, and 19 percent of those who started in 2014. In the first Performance Year, 26 percent of ACOs health spending at $705 million below their targets and earned performance payments of more than $315 million.

And on slide nine, so now I'm going to focus on the quality side of the program or quality measurement approach. And, the quality measurement approach for our program is intended to improve individual and the health of populations, address quality aims such as prevention, care of chronic illness, high prevalence conditions, patient safety, patient care giver engagement and care coordination, and these align with our National Quality Strategy and CMS Quality Strategy goals.

We also use our quality measurement approach to support the Shared Savings Program goals of better care, better health and lower growth in expenditures while also aligning with other quality reporting and incentive programs

like PQRS, BM and the Medicare EHR Incentive Program.

And on slide ten, currently we have -- well, for 2015 and in prior years, we have had 33 quality measures that have been separated across four domains that we use as our basis for assessing, benchmarking, rewarding and improving ACO quality performance.

So, we have our four domains which are equally weighted and they are patient care/care giver experience, care coordination and patient safety, preventive health, and at-risk populations. Now, we recently finalized in the 2016 Physician Fee Schedule Final Rule that we were adding a new measure beginning with 2016 reporting year. So, we will be moving to 34 measures.

And then, on slide 11, I'll just briefly go over the high level -- the measures within each domain. So, as you can see in our first domain which is patient care giver experience, we have eight measures and they come

from the Clinician/Group CAHPS Survey and we used the CAHPS for ACOs survey and it does align with the CAHPS for PQRS survey.

So, these are some eight measures that we assessed performance for ACOs in terms of patient and care giver experience. And then, moving on to slide 12, here's our domain for care coordination and patient safety. I won't go through all of the measures in detail or anything, but these are largely claims based measures that we have here.

We do have other measures in this domain that are also reported through the GPRO web interface, but, we have a total of ten measures within this domain. And, on the next slide is our preventive health domain. We have a total of eight measures and this also meets our aim of better health for a population.

There are a lot of screening measures within this measure set and all of these measures are reported through the web interface. And then, on slide 14, this is our clinical care for

at-risk population domain. It is five individually scored measures and a two component diabetes composite. So, you'll see that ACO-27 and 41 make up for diabetes composite. And, these are all also reported within the -- through the GPRO web interface.

So, on slide 15, I'll just sort of briefly go over the mechanisms that we use for data collection. So, we do use the CAHPS for ACO survey, which is a patient survey. We also use claims for our claims based measures. And then, the EHR Incentive Program attestation data since we do have a measure which looks at the percent of primary care physicians who successfully meet meaningful use requirements.

And then, we also use GPRO web interface in alignment with PQRS. And, on slide 16, so just to go over the quality performance standard and how ACOs can be eligible to share in saving when they're meeting that, it changes based on which performance year an ACO is in in terms of their agreement.

So, we, at CMS, designate the quality performance depending on their performance year. So, if you're new to the program, it's their first year as ACO, we often refer to that as your pay-for-reporting year. And to be eligible to share in savings, if earned, the ACO must completely and accurately report all quality measures and that qualifies them to share in the maximum available sharing rate for payment.

Now, we phase in performance measures beginning with their second and ongoing through their third and subsequent years as part of the program. And, we often refer to that as their pay-for-performance years. So, when they're under a pay-for-performance reporting year, they have to meet complete and accurate reporting for all quality measures similar to the pay-for-reporting year, but they also need to meet minimum attainment on at least one pay-for-performance measure in each domain.

And, we are encountering ACOs who will be entering into their second agreement and we

are -- oh, in terms of ACOs who are in their second agreement, we treat them as an ACO in their third performance year here. So, they would fall under pay-for-performance.

And, on slide 17, when we do introduce new measures into the program for the quality measure set, we finalize that we'll be setting them a pay-for-reporting two years before phasing them into pay-for-performance unless we finalize a measure as pay-for-reporting for all years.

We feel maintaining new measures as pay-for-reporting for two years will help to ensure that ACOs have adequate time to phase in their own care processes and infrastructure before they're held accountable for performance and that we at CMS also have adequate data to set benchmarks for these new measures.

And, under pay-for-performance which, again, is the ACO's second or subsequent performance year, we do phase in an increasing number of measures into performance.

And, you can see at the table below,

you can see from those who are just starting within, you know, with the 2015 reporting year versus those who started in 2014 or in 2012 and 2013, you'll see the number of pay-for-reporting measures declines while there's an increase in the number of performance measures.

So, when we talk about ACOs having to meet the minimum attainment level to receive points for these pay-for-performance measures, we define minimum attainment as meeting performance at 30 percent or the 30th percentile of the performance benchmark that we establish.

Shared savings payments are linked to their quality performance as compared to benchmarks based on a sliding scale for scoring. And, we set our benchmarks for two years to support ACO quality improvement efforts.

And, high performing ACOs receive higher sharing rates for payment.

Next slide?

I won't go into this in detail, but here is -- this shows how we use our sliding

scale measures scoring approach where you can see that the 90th percentile is if an ACO meets that performance level in the measure, they would get full points which is two points for that measure in terms of scoring.

We do have one difference for the ACO-11 EHR measure where it's double weighted. So, ACOs can earn up to four points for that measure.

And, if an ACO falls below the 30th percentile, it will not earn any points for that measure.

And then, on slide 19, here's an overview of our 2015 performance year scoring. So, as you can see, the total number of measures and those that are used for scoring as well as the total possible points an ACO can earn for each domain. And, each domain is equally weighted.

And, beginning with the 2015 performance year, ACOs can earn up to four quality improvement points in each domain. However, the total number of points an ACO earns

per domain cannot exceed the total possible points in that domain.

So, for instance, an ACO receives four points for quality improvement in their patient care giver experience and they had an original score of 14 points in that domain, they can't get to 18 points since that exceeds the total possible points, 16 points, in that domain.

So, on the next slide, just an overview on how the Shared Savings Program interacts with other programs.

When an ACO meets the Shared Savings Program requirements for quality reporting and performance, the eligible professional who participate within the ACO will meet reporting requirements for other CMS programs, specifically, PQRS, the Value Modifier and Medicare EHR Incentive Program.

So, on slide 21, in terms of PQRS, and we'll use 2015 as sort of the standard for how we align, but if the ACO satisfactorily reports the quality measures through the GPRO web interface

for the 2015 Performance Year, then ACO participant TINs with PQRS eligible professionals will not be subject to the 2017 PQRS payment adjustment.

In addition, beginning in 2017, CMS is applying the VM to physicians in group practices with two or more EPs and to physician solo practitioners.

Groups and solo practitioners as identified by their TINs participating in a Shared Savings Program ACO in 2015 will be subject to the 2017 VM based on their performance in calendar year 2015.

Previously, TINs participating in that Shared Savings Program ACO were exempt.

So, the VM for shared savings -- TINs participating within the Shared Savings Program ACO is determined by calculating a cost and a quality composite.

So, for TINs who are participating in the ACO, their cost composite will be classified as average. But, their quality composite will be

calculated using ACO-level data reported by the ACO through the GPRO web interface and the ACO All-Cause Readmission measure.

ACO participants may be eligible for an upward adjustment based on their ACO's quality performance. And, if an ACO fails to successfully report on quality measures, then the participant TINs under the ACO who are subject to the VM will be subject to the automatic downward adjustment.

In 2017, that automatic downward adjustment is -4 percent for group physicians in groups with ten or more EPs and -2 percent for physicians in groups with between two to nine EPs and physician solo practitioners.

And, on slide 22, in terms of the Medicare EHR Incentive Program, EPs who participate in the Shared Savings Program can satisfy their CQM reporting for the Medicare EHR Incentive Program if EPs use Certified EHR Technology to extract their data and the ACO satisfactorily reports through the web interface.

EPs still, though, have to separately

attest to all other requirements for the Medicare EHR Incentive Program to successfully demonstrate meaningful use and to avoid that program's adjustment.

And, on slide 23, in terms of public reporting, we do at CMS release and publically report all the Performance Year results on data.cms.gov and the link is available there with our 2014 Performance Year results.

And, we do also publically report a subset of measures that align with PQRS on Physician Compare.

And then also ACOs have to publically report their quality performance results on their website according to our Shared Savings Program Public Reporting Guidance.

And then, finally, on slide 24, in this slide, we wanted to share our considerations when we were developing this measures under consideration list and we would like the MAP to provide input on our MUC list as well as potential measures for the future of the program.

So, in terms of what we were considering, we looked at for measures that address National Quality Strategy and CMS Quality Strategy goals and priorities.

We also want to maintain alignment with other Value-Based Purchasing Programs. You'll see in this MUC list, we consider measures that align with PQRS and the Value Modifier and so, we would also like input in the future, if there are other continued alignment as we move towards MIPS and other Value-Based Purchasing Programs like the SNF Value-Based Purchasing Program.

We also need -- we're thinking through measures that address population health across settings of care and -- largely because ACOs vary in composition. So, we need to consider measures that can be reported on by all ACOs.

And then, we also are trying to focus our attention on patient outcomes. But, where we would like input it definitely is around sort of this balance of process intermediate outcome and

outcome measures that exist within our measure set.

If you experts feel we should move some -- remove some of these process measures and replace them with other measures, so really trying to figure out what is the most appropriate balance of measures within our measure set.

And keeping in mind the sensitivity to administrative burden for reporting, a lot -- most of these measures are reported through the GPRO web interface which does require ACOs to submit the data to CMS. Our claims based and administrative based measures, we do calculate and survey vendors that administer the CAHPS for ACO survey.

But, we would like you to keep in mind sort of when thinking through our measure set and future measures, the burden for reporting.

And, in addition, there may be other opportunities for us to share data to ACOs. Are there claims based measures that we could share in our quarterly feedback reports for ACOs?

So, we do provide ACOs with a quarterly expenditure and utilization report where we do provide them with raw data on readmissions in their reports.

But, we do -- our All-Cause Readmission measure is really where we annually assess in quality using the risk-adjusted measure that we have. But, if there is any feedback or suggestions for other claims based measures that we could consider providing in the quarterly report with raw claims data, that's also something we can consider.

All right, Reva, I don't know if there are any questions or just to turn it over to you.

DR. WINKLER: Yes, thank you, Rabia, very much.

And, I ask any of the work group members if you do have any questions for Rabia about the program, I think she provided a very complete context of the program in which you look at the measures under consideration that we'll talk about.

Before we go to break, I just wanted to remind the work group that, last year, discussion around the gaps for the Shared Savings Program recommendations on the types of measures, and if you will see that, you know, composite measures, care coordination, outcome measures, measures using patient reported data, prevention in population heath that, in fact, that the recommendations from the MAP last year aligned fairly well with, again, CMS's considerations for the future.

So, again, we will have the opportunity to think about and provide more feedback to CMS around this particular program.

But, at this point, we're just a slight bit ahead of schedule, Bruce, and I think would be time to go to break.

CO-CHAIR BAGLEY: Yes, sure. Thanks, Reva.

And, before we go to break, two things.

First, Cindy Pellegrini has joined us

late and Cindy is from the March of Dimes. And, do you have an organizational disclosure?

MEMBER PELLEGRINI: Thank you.

I apologize for having a call early this morning.

Cindy Pellegrini and I have no disclosures.

CO-CHAIR BAGLEY: Thank you.

I also think it would be appropriate to ask if there's any public comment questions I guess might be around the material that's been presented thus far this morning, any questions for clarification about the programs or the procedure.

Barbara and then we'll go to public comment.

MEMBER LANDRETH: You mentioned that many of these measures have been pulled. How do we know which measures have been pulled and how do we know who will be addressing those?

CO-CHAIR BAGLEY: Okay, the measures that have been pulled should be on your agenda

that was on your table in red. Does everybody have that?

MS. BAL: Actually, that was only given to you.

CO-CHAIR BAGLEY: Oh, I'm the only one that has that, oh, okay.

MS. BAL: So, we will --

CO-CHAIR BAGLEY: We'll talk about that when we're going through the individual -- sorry about that.

MS. BAL: Yes, so measures were pulled in advance.

CO-CHAIR BAGLEY: It's right here.

MS. BAL: So, we will announce that measures have been pulled when we go over the consent calendar and we'll state who was the person that pulled them as well.

CO-CHAIR BAGLEY: For those of you not familiar with the consent calendar idea, it really makes you do your homework. In other words, if you -- you can't kind of wait until it comes up to have a comment.

If it's still on a consent calendar, you don't get to talk about it. So, just keep that in mind, if there's something you want to hear some discussion about, you've got to get it off the consent calendar.

So, that's sort of why we do this.

Now, this was very valuable, I think, last year when we had a lot more measures. And, I think it's still valuable, but you still have to pull them off if you want to hear the discussion.

Whether you're for or against it, if you want to hear discussion around a topic that might enrich our recommendations to CMS which is really why we're here, then pull it off and we'll talk about it.

So, let's go -- is there any other public comment? Yes, go ahead.

MS. HANCOCK: Hello, I'm Rebecca Hancock with the American Academy of Ophthalmology and my question -- is this working? Okay.

Rebecca Hancock with the American Academy of Ophthalmology and my question, Andrew, is on your presentation, you had a slide I think about guidelines and the first bullet said that NQF endorsement is required for use of measures in the program.

But, I don't think that's the case, so I was hoping you could clarify that.

MR. LYZENGA: So, they are -- it's required -- recommended would be a better word maybe looking to see what the language was exactly.

Required unless no relevant endorsed measures are available that would fit -- that would meet the program objectives as part of the measure set.

MS. HANCOCK: I'm not certain that that's true. Dr. Goodrich, can you speak to that?

DR. GOODRICH: It's more -- well, you mean statutorily?

MS. HANCOCK: Right. Because I know

there's a --

DR. GOODRICH: Statutorily, yes, for most programs, the way the statutes are written is that we should be using NQF measures, endorsed measures unless there is not an endorsed measure for a particular topic area that we want to use for the program.

Now, the MAP has also separately come up with its own criteria. I think that's what Andrew -- I think that may be what you were speaking to, but I don't want to speak for the MAP on that.

But, it's -- you guys should clarify that, I think.

MR. LYZENGA: Yes, so typically as part of our preliminary evaluation and analysis, we will not recommend support of a measure unless it is NQF endorsed. We'll typically make our recommendation of conditional support with that condition being NQF review and endorsement.

MS. HANCOCK: Okay, thanks. I just wanted to clarify that that wasn't a requirement

for use in one of the programs because I know there's lots of measures that aren't endorsed.

Thanks.

MS. RUBIN: Just a clarification with Physician Compare because I didn't recall seeing as part of the preliminary analysis the ability to comment on individual measures related to Physician Compare. I only saw the ability for MIPS or Shared Savings Program.

MS. BAL: So, that is correct because the MUC list was not under review for Physician Compare. What recommendations we're providing now is on the request of CMS. It was more of just we would like the feedback of the clinician work group and we thought it would be better --

MEMBER ORLOWSKI: Actually, we can't hear you with your head turned.

MS. BAL: Oh, I'm sorry. I'm going to bring this closer to me.

So, what I was saying was that the MUC list is not formally under review for Physician Compare. The list that was provided, CMS

requested that we, you know, get feedback from the clinician work group to help them as they further develop that program.

And so, we as a -- at NQF decided to make it a little more of a formal procedure where it was put on the consent calendars and everybody have a chance to look over it and change the decision.

So, that's why there was no commenting because it's not officially part of the MUC list.

CO-CHAIR BAGLEY: I see no further questions. Anybody on the phone have a question?

All right, we've earned a 15 minute break.

All right, thank you.

(Whereupon, the above-entitled matter went off the record at 10:31 a.m. and resumed at 10:45 a.m.)

DR. WINKLER: Okay, I think that we're going to get started into the work at hand, beginning with the Medicare Shared Savings Program. My slide went away.

Okay, we've just had a discussion of that program. And so on this year's measures under consideration list, there are five measures for you to consider. There are two process measures that are NQF endorsed and already in the PQRS, MIPS measure set -- clinician measure set and that is the Falls measure and the Advanced Care measure. There are also two composite measures that use the ARHQ PQIs, Prevention Quality Indicators, for admissions for various conditions, one for acute and one for chronic. These two measures have been around for a while, but they are being revised significantly as well as additional risk adjustment is being developed for both of those measures. So these measures are still kind of in their developing phase.

And then there is one measure for -- composite measure for ischemic vascular disease. All three of the composite measures are also on the list for MIPS. So with that, as an introduction to the five measures under consideration, Eric, back to you.

CO-CHAIR WHITACRE: Thank you, Reva. We'd like to begin by asking for any public comment on this measure set as part of the consent calendar. So either members in the room or people on the phone and we'd ask that the individuals limit their comments to two minutes or less.

MS. RUBIN: Hi, Koryn Rubin, American Medical Association. First, we seek clarification in terms of with the two PQI composite measures. Whether this is a replacement to the existing Shared Savings Program, kind of modified composite measures given that they are already accountable to a form of these measures due to the use within the value modifier because currently it's sending mixed signals to the ACOs, given that they're being measured on similar things, but differently. So that would be helpful and something hopefully the clinician work group could dive into.

But, in general -- so all the measures that comprise the composite of PQI 91 and 92 are

intended to be measured at the metropolitan area of county level per 100,000 beneficiaries. Depending on the composition and size of the ACO, this measure may not be feasible to implement in the Medicare Shared Savings Program due to the minimum threshold required for the measure to be considered valid and reliable. If you are an ACO and you are accountable for costs which they are per the Shared Savings Program formula, then using measures of admissions and readmissions is inappropriate.

The ACO has a natural incentive to reduce avoidable admissions and readmissions already and we are aware of physician practices that are part of ACOs telling us that this is putting them in a weird place in terms of doing what's best for the patient in terms of treating them, given that they're held to another -- to these admission and readmission measures when they already have that incentive to control costs.

In some cases, the ACO may decide the

patient should be hospitalized or readmitted because that's more efficient than forcing them to pursue office visits or to provide home care, but the ACO doesn't have the flexibility to do that because of a measure that declares hospitalizations and readmissions bad in all cases.

In addition, information on how the measures perform at the ACO level has never been provided for existing measures in the Shared Savings Program or the value-based modifier. Nor have they been submitted to NQF for review. We recommend that the MAP does not support these measures. And if you look in the Discussion Guide, you can see some more detailed comments the AMA provided in terms of the variation of use with the measure and the level of testing and analysis that's been performed. Thank you.

CO-CHAIR WHITACRE: Thank you. Other comments? Comments from the phone?

OPERATOR: If you'd like to make a public comment, please press star 1. No, no

public comments at this time.

CO-CHAIR WHITACRE: Thank you very much. That means we move on then to the work of the committee. First, I'd like to remind everyone of the availability of the Electronic Discussion Guide. We're working from Version 2.5. It's at the very top left of the Discussion Guide. You also have available to you the framework documents, tremendous work by the NQF staff which helps us look at and review existing measures for the Shared Savings Program as well as for MIPS. So two measures have been pulled so far for discussion.

Stephanie, you have pulled two, the last two, Prevention Quality Indicator 92, quality chronic composite as well as the ischemic vascular disease all or none.

And Winfred, you also had wished to pull that last one.

Are there other members who would like to extract measures for discussion? If not, then the work group would agree to accept staff

recommendations for the first three measures. That would be specifically if you review to support the first two measures and to encourage further development of the third measure.

Yes, Jim?

MEMBER PACALA: Does this give us opportunity to comment on them as well, or once we vote we're moving on?

CO-CHAIR WHITACRE: Well, the purpose of the consent calendar is to vote and move on. It doesn't -- did you wish to pull a measure to comment?

MEMBER PACALA: I would like to make a brief comment on measure 3, the PQI 91.

CO-CHAIR WHITACRE: Okay, so that means we're voting on the first two measures where there has been recommendations for support by the staff. If there is no disagreement, then as part of the consent calendar we will accept those with a recommendation of support.

Terrific. Let's move on to the pulled measures.

Stephanie, we can do this in order of the measure or we can do it in the order in which the measure was pulled, but I think Stephanie, you had some overarching comments and concerns.

MEMBER GLIER: Sure, so actually I have a question for the NQF staff which is why I pulled PQI 92. And I'd really appreciate a little more clarification about why you assessed it as a measure still under development rather than as a measure that was done, tested, that sort of was going through modifications. So if you guys could clarify that for me.

DR. WINKLER: Sure. Again, discussion with CMS and their contractors about these measures and the information that was provided to us was that these measures, even though they've been around, are undergoing substantial change and the new development of risk models that have not previously existed. So those elements of the newness, if you will, is the rationale.

MEMBER GLIER: So related, is there something in the recommendation that I've missed

in the Discussion Guide about how we would encourage further development in a particular direction that is different from how we would make a conditional support recommendation pending these measures coming back to an endorsement committee and being pre-endorsed, given the new information?

DR. WINKLER: We can certainly add any of those things that you feel can be put in. If you noticed the commentary is listed under -- in the Discussion Guide under the two bullets, the potential impact of quality of care and contribution to the measure set, and we can add whatever you would like in there as well.

MEMBER GLIER: I don't have anything else to add. My recommendation was actually going to be to move it to conditional support for these measures pending them coming back after having been reclassified at the ACO level and tested at that level with the risk adjustment model. So I think that the comments that are included in the Discussion Guide fit. I was just

wondering about the specifics of the recommendation itself.

CO-CHAIR WHITACRE: You would be in agreement for continued -- encourage continued development for both the third and fourth measure, the composites. And do not support for the ischemic vascular because that was pulled as well.

MEMBER GLIER: I thought we could maybe talk about that one after Jim had a chance to talk about it.

CO-CHAIR WHITACRE: Okay, terrific, perfect. If you'd like to focus on the quality indicator.

Jim?

MEMBER PACALA: I just wanted to make a comment about the PQI 91. I'm fine with continued development, but does continued development mean that the three conditions listed, dehydration, bacterial pneumonia, or urinary tract infection will be continued to be developed? Or would those be under further

consideration for perhaps deletion or modification?

I'm concerned about rates of bacterial pneumonia and urinary tract infection, particularly in complicated elderly patients. Bacterial pneumonia, there are frequent cases of aspiration pneumonia that are really -- I'm worried about antibiotic over-usage. That's my bottom line.

There are cases of aspiration pneumonia where antibiotic coverage is not indicated and they are -- particularly in patients residing in nursing homes. And I'd be worried about urinary tract infection rates being a stimulus for unnecessary treatment of asymptomatic bacteriuria.

So I could just see an inter-professional team or a group of providers now reviewing any case of bacteria -- of pneumonia that's presenting or any possible symptom that might be a UTI and saying okay, we've got to check these things and those conditions being

overtreated. So I guess I would like that comment registered if it's under continued development and I would support for continued development if that comment was considered and there would be the option for deletion of certain conditions such as those two that I mentioned.

CO-CHAIR WHITACRE: Thank you. Janis?

MEMBER ORLOWSKI: First of all, I'd like to echo the comments on PQI 91 and I think in particular the urinary tract infection in an elderly population you have asymptomatic bacteremia. And so I do think that we need to be cautious of that.

In regards to number four which is Prevention Quality Indicator 92, I have three comments in regards to the encouraged continued development. The first is that there is continuing evidence amassing regarding social demographic factors affecting these quality indicators of which neither the healthcare organization or physicians individually can control. And so I just want to continue to

support SES risk adjustment.

The second two issues I'd like to bring up is that they've not -- these measures have not been tested for a smaller population. They are listed as an event per 100,000, but most ACOs do not have 100,000 participants. And so the question is how does this test in a smaller population which is more akin to the ACOs that we're seeing?

And then finally we need to have information on the endorsement for provider level compare sets and that has not been done yet. So those are my comments regarding PQI 92. Thank you.

CO-CHAIR WHITACRE: Thank you. A couple different ways to proceed here. One would be -- because these are very closely related measures and we've heard comments on the PQI measures together, both the acute and chronic, would be if the committee wishes to vote on those while the discussion is fresh in our mind and then move on to the vascular measure which I

think is totally separate.

CO-CHAIR BAGLEY: Just a process comment and Stephanie, you kind of reminded me of this. I suppose probably we were supposed to say this earlier, but when we vote on a measure, we'll always have all three options available to us. So for instance, if you really felt that this should be conditional support, rather than -- then your commentary needs to convince the rest of us that it should be conditional support rather than just say if I were doing it, I'd -- so somehow that's really what we're looking for is guidance around how we all should be thinking about the measure.

CO-CHAIR WHITACRE: Yes, Janis?

MEMBER ORLOWSKI: If that is available to all of the committee members, then I would encourage us to oppose that because these measures are not ready for use.

DR. BRISS: Just some clarification. You can't -- this measure is under development, so you only have the under development options.

You wouldn't be able to do conditional support because it's not a fully developed measure, so we cannot vote in that fashion.

However, if this was a fully-developed measure, you would have the option of support, conditional support -- so, and do not support. So unfortunately for these, since they are not fully developed, we can only have encourage further development, do not encourage further development or insufficient information.

CO-CHAIR WHITACRE: Thank you. David?

MEMBER SEIDENWURM: I had a question about 92. I don't know if the staff people have had a chance to think about how this type of a measure interacts with some of the hospital-acquired conditions, measures, because you're sort of putting people a little bit between a rock and a hard place about identifying the condition at the time of admission and having that be part of the admission diagnosis versus getting blamed for it if it's a hospital-acquired condition. And it just kind of puts people in a

bit of a bind, a little bit along the lines of the antibiotic overuse concern. So I wonder if that could be taken into account as development progresses.

CO-CHAIR WHITACRE: Thank you. We still have to hear from the lead discussants and if we could perhaps focus on the two issues under discussion, and I'll leave the vascular separately.

Marci, did you have anything you wanted to add to the discussion or respond to what's been said?

MEMBER NIELSEN: I did not. I was waiting for my big opportunity to redeem myself from last year and the dog ate my homework and I had prepared a lengthy statement, but all of these clinicians beat me to punch.

(Laughter.)

CO-CHAIR WHITACRE: Thank you. That's terrific. And Kate, I understand is not available unless she's still on the phone. She was earlier. Kate? Not there. Terrific.

MEMBER KOPLAN: I'm here. I don't know if you can hear me. And I am listening intently to everybody's comments. This is my first meeting. I'm taking the opportunity just to listen and learn how the conversations proceed. But I have heard well what everybody else's comments are and won't add anything right now. Thank you.

CO-CHAIR WHITACRE: Yes, Luther?

DR. CLARK: Yes, could you clarify the distinction between principal diagnosis on admission and maybe one that's not principal?

DR. WINKLER: We do have the folks from CMS.

Rabia, are you still on the phone and would some of your folks that are working with these measures that could respond to some of these more technical questions?

MS. KHAN: Hi, this is Rabia. Yes, I'm still on the line and I believe we also have our ACO program analysis contractors on as well to help support this conversation. I don't know if

Chris or Rosita, if you're on.

DR. BEADLES: Yes, this is Chris with RTI. The principal diagnosis is usually taken to be the first diagnosis code for principal diagnosis. Other diagnosis codes and the claims data that are 2 through 25 are considered secondary diagnoses.

DR. CLARK: So if this is not the first diagnosis, one of these diagnoses, then it would not be part of the measure, is that correct?

DR. BEADLES: Yes. Your understanding is correct. And these specifications are exactly the same as what the AHRQ specifications currently are. So for instance I believe it's -- the COPD and asthma, there are a few places where it requires a principal diagnosis of COPD and then a secondary diagnosis of another accompanying factor that I'm blanking on at the moment. But there are a few cases where the specification, as detailed by AHRQ, will also look at a secondary diagnosis in order to count

that admission as COPD admission. I'm just blanking on what they are at the moment. And I believe it's the same thing for dehydration. So if the first diagnosis is for hyponatremia or hypernatremia, a sodium imbalance, then the secondary diagnosis somewhere has to also contain a dehydration to get them into that bucket. But the specifications are not -- the specifications for the conditions, be it dehydration, bacterial pneumonia or a UTI, as well as the chronic conditions, are not changed at all from what AHRQ definitions are -- they were originally specified. I hope that provides some clarification.

CO-CHAIR WHITACRE: Yes. Thank you.

DR. WINKLER: Also, Rabia, there were a couple of comments that Janis made about ACOs having smaller populations than the measure is specified for, the population level. And whether there's been any consideration for the interaction with the healthcare acquired conditions measures, I think you may have heard

those from David. If you have any comments about those?

MS. KHAN: Yes. This is Rabia. In terms of the population level that's used for these measures, both PQI composites are already used in the Physician Value Modifier Program. And we feel that since it's been applied at least and tested and used at a group level for the value modifier that's appropriate for use at an ACO level.

And in terms of I believe your second question, interaction with HACs? I am less familiar with sort of HACs -- I believe it's like the HAC Reduction Program, but we don't have -- the PSIs that are using that program, so I'm a little unsure on what's being asked there.

DR. BEADLES: This is Chris again. I can add sort of a brief comment to it. Most of the time there's a present on admission indicator in the claims database now. That won't be there prior to I think it's 2011 or some year. I'm not exactly sure. But for all of the acute PQIs that

would have to be an admitting diagnosis, so it should not interfere or interact with any of the hospital-acquired conditions. Most of the time that we look at -- when we look at data analysis for admissions for these three conditions, pneumonia, UTI, the present on admission indicator is always filled in. I would say 99.9999 percent. In other words, it's indicating that it's not hospital-acquired condition. And data analysis, we could look at that and see if that's something that needs to be taken into account. But when I look at the claims data, we haven't seen that.

And for the chronic conditions, because it's an admission for COPD or for asthma or for heart failure, I don't think that there's any way that could be misconstrued to be acquired on admission. I think that comment was mostly directed at the acute PQIs. Does that add some clarification for that one?

CO-CHAIR WHITACRE: Yes. Thank you. It does. This is a little confusing because the

same indicator measures are being considered later, tomorrow afternoon, as part of the MIPS program, so we're balancing between what should be used to measure individual performance as well as what should be incorporated into the ACO. So these are all really very helpful clarifications. Thank you.

Yes, Janis.

MEMBER ORLOWSKI: I do want to go back to the concepts that were present on admission, that there are times when -- where there is a net cast to try and capture things present on admission that may lead to inappropriate decisions being made. And pneumonia and UTI are two of those. So the concern is does this set up behavior that would increase the use of antibiotics for conditions on admission, for example, heart failure that is confused. Do we have a touch of heart failure or do we have a pneumonia? Do I have asymptomatic bacteremia or do I have a UTI? And I'm concerned and I think the comment was made earlier that we want to make

sure that we do not put in criteria that leads us to behaviors and screening that is inappropriate.

CO-CHAIR WHITACRE: Thank you. Other comments? So the staff has recommended for both the Prevention Quality Indicator measures, both the acute and chronic measures, encourage future development. We've heard, I think, one comment saying that perhaps they should not be considered. I think if there's no further discussion, perhaps -- and we need to vote on these separately because they're in different phases of development. Perhaps we can proceed to a vote on those two measures before we proceed with the vascular measure. That to me is totally separate.

So can we -- this is our first assay here. Oh please, Jim.

MEMBER PACALA: I'm sorry, Eric, but I did ask a question before and that is if we were to vote for encourage further development, does that mean that we're endorsing looking at pneumonia and UTI or would further development

mean that perhaps the designers of the measure would reconsider those conditions?

DR. WINKLER: Jim, essentially the recommendations from the MAP are the feedback to CMS measure. You heard Kate say this morning one of the values of the feedback is to take under consideration these things. I don't think we can at this point know where that will take us. Or take CMS, anyway.

CO-CHAIR WHITACRE: Thank you. That's very helpful. So basically, we're encouraging further development. This discussion can be a basis for how the measure developer takes that back and refines it, but we're not tweaking the measure on the table.

So if we can show -- this will be our first assay here and using our clickers, if we can show measure PQI 91 prevention quality acute composite on the screen. It's slowly coming up. This will be MUC ID: MUC15-577 for those on the phone. Our options for this -- remember, this is the one that sort of fell in between the cracks.

It was already being utilized and it was considered a fully-developed measure for the purposes of our analysis.

DR. BRISS: Sorry, I think we had some miscommunication. We'll combine them. We'll vote on the second one while we get that slide ready. Will that be okay? Give us two seconds to get that slide ready.

CO-CHAIR WHITACRE: I would be in favor of separating these so there's no ambiguity later when we review the data. Because one of these does fall into a somewhat unusual situation. So the vote would be first, for PQI 91, prevention quality acute composite. MUC15-577. And our choices are encourage further development, do not encourage further development, or insufficient information. Are we ready to vote?

MS. CHAVEZ: Voting is open.

DR. BRISS: Terry and Kate, please put your vote in through the tab feature.

MS. CHAVEZ: Okay, 95 percent voted

encourage for further development; five percent did not encourage further consideration.

CO-CHAIR WHITACRE: Terrific. Thank you. If we can move to the next measure, PQI 92.

MS. CHAVEZ: Voting is open.

CO-CHAIR WHITACRE: This is a vote on Prevention Quality Indicator 92, prevention quality chronic composite MUC ID MUC15-576.

MS. CHAVEZ: Okay, 95 percent voted encourage for continued development; five percent did not encourage further consideration.

CO-CHAIR WHITACRE: Great. Thank you. So if we could move on to discussion to the last measure which is ischemic vascular disease all or none outcome measure. This was pulled by Stephanie and Winfred.

Any discussion as to why the measure was pulled or your concerns?

MEMBER GLIER: Sure, I'm happy to start, unless you'd rather start, either way.

DR. WU: Well first off, I just have a question with respect to NQF 0076 which was cited

as a measure that's currently endorsed and overlaps with this measure. Can you confirm whether or not statin therapies was included as one of the requirements to meet the numerator for that measure?

DR. WINKLER: Actually, this measure is coming up for its maintenance review in the coming cycle and they have -- and Beth can probably add to this, but the indication is that it will have the statin review -- it will have the statin component at that time.

DR. WU: Okay. I mean that was just my major question. And if, in fact, with NQF 0076 coming up for re-review and the statin therapy is included, I'm in support of this recommendation to do not support given that we want to, you know, utilize existing measures. So that's reasonable. However, if that is not the case, I would advise otherwise.

MEMBER AVERBECK: This is Beth Averbeck, Minnesota Community Measurement. Yes, statin therapy is included. There are some

exclusions based on underlying causes, but otherwise statin therapy is in the revised measure.

CO-CHAIR WHITACRE: Stephanie.

MEMBER GLIER: I have a question that may be best posed for either for Sophia or for Rabia if they're able to answer it which is about why 0076 is being pulled from PQRS. I understand that there are some concerns about duplication with components of 0076 as well as with the measure that's actually on the MUC list that we're actually talking about with the Million Hearts set. I'm wondering if you guys could say a little bit more about the thinking behind pulling the measure -- pulling the composite measures in favor of the separate measures.

MS. AUTREY: I didn't know if Rabia wanted to speak first.

MS. KHAN: Sophia, yes. 0076, my understanding is the optimal vascular care measure is not in the Chair's program set, so I'll just turn it over to you.

MS. AUTREY: Okay. So the reason why we initially proposed to pull it was because it did not have the statin component included in it and we did have another measure that was going to have that statin component. So from our standpoint, that would be duplicative so we did want to actually remove it.

MEMBER GLIER: So I'm sorry, you were talking about the decision was to pull the Minnesota Community Measurement optimal vascular care measure which is 0076 referenced in the Discussion Guide, but not actually on the MUC list, because it did not have a statin component. And you had a duplicative statin measure already in the --

MS. AUTREY: Well, the reason was because it didn't have the statin component, but then it actually was not consistent with the guidelines. So that's the reason why we wanted to actually pull it.

CO-CHAIR WHITACRE: Amy, you were next.

MEMBER MOYER: I was initially excited to see this measure because I thought it was the Minnesota Community measure which is endorsed and then I was very confused that we would be considered an overlapping measure that's not endorsed when we have one that is. And I know we probably can't submit measures from the floor, but I was also frustrated to not see the corresponding Minnesota Community Measurement diabetes all or nothing outcome composite, especially since that was a gap area that was identified. And in looking at existing measures in this program, I see two for diabetes. And there's some real gaps there that aren't being measured. I probably can't change that now, but just wanted to point that out.

CO-CHAIR WHITACRE: Beth and then Janis.

MEMBER AVERBECK: So maybe I'll just give some background, the history of the optimal vascular measure because previously it had an LDL target and then when the guidelines changed it

was pulled and went into kind of a year where it wasn't reported while the group got together and looked at the revised guidelines and then made a new measure that had -- a revised measure that then had the statin component in it. So it was on hiatus for a bit while the guidelines were being reviewed and the measurement group got back together again. So that's just the history of why the vascular measure didn't have a statin in because it had the previous LDL target and then it was revised.

CO-CHAIR WHITACRE: Janis.

MEMBER ORLOWSKI: So I'm going to make a general statement about outcomes measures and I'll just say ditto as we roll through them. I think that when we take a look at outcomes measures, we need to take a look at our risk adjustments, specifically, we need to look at the social demographic factors. And if there's not a comment in them, then we have to understand if -- is there the ability for the physician, for the providers, or for the hospital to impact that

outcome or are there factors beyond their control?

So as we take a look at outcomes -- and again, there's amassing literature that there are SDS factors that cannot be ameliorated by the provider. And so we can't hold people accountable for outcomes measures if they cannot affect specific -- if they cannot affect the factors that lead to that outcome.

So again, I support -- let me say this this way, I do not support this measure which is the staff recommendation, but for a different reason.

CO-CHAIR WHITACRE: Peter, did you have a comment?

DR. BRISS: Just to tie up the previous discussion on the optimal diabetes care. Maybe Beth can clarify on that one, too. I think it's a substantially similar story to the optimal vascular care one. The statin component also needed to be updated on that one, too, right?

MEMBER AVERBECK: Yes, so there was a

peer with optimal diabetes that had LDL targets and that on a revision went to statin resource specific LDL values based on age and recommendations.

CO-CHAIR WHITACRE: Amy.

MEMBER MOYER: I just had one additional thing. We looked at alignment across pairs, both at optimal diabetes and the optimal vascular care measure from Minnesota Community Measurement. They are part of the priority list that was put together from the catalyst for payment reform for purchasers. I know we used these in our pay for performance program. We used them in a lot of our other programs. So there's an opportunity for some real alignment there and asking the same thing from providers. We're all asking for that same measure.

MEMBER PELLEGRINI: So cardiovascular isn't something where I spend a lot of time. Can someone explain what the overlap is, if it is exact with the Million Hearts measure and which of the programs, if any, that measure is

incorporated into already? Because we're saying it's duplicative. Part of the reason for the do not support is that it's duplicative of the Million Hearts measure?

DR. WINKLER: That was actually taken as the rationale for removing it from PQRS by CMS this year in the most recent final rule.

MEMBER PELLEGRINI: But is that because that Million Hearts measure is also in PQRS?

DR. WINKLER: Correct.

MEMBER PELLEGRINI: Okay. But that would not disqualify it from being in the Shared Savings Program.

MS. AUTREY: So one of the things that we tried to do with Shared Savings Program and PQRS is align the measure set. And so the reason why when we removed it from PQRS, we wanted to make sure that we aligned with ACO. And that's why.

MEMBER PELLEGRINI: Thank you.

CO-CHAIR WHITACRE: Any comments from

the -- oh, excuse me. Barbara?

MEMBER LANDRETH: Just a quick comment on the statins. I'm assuming the reason that statins were -- or the LDL target was replaced was simply the documentation that a person was on statins was based on the new guidelines. But if you look carefully at the new guidelines, they have very clear indications for high intensity, medium intensity, low intensity statins. And I want to make sure because that is truly an approximation for an LDL target. High intensity statins will reduce your LDL by 50 percent or more. So I think that that's really important that we look at -- if we're taking away the LDL target, I think it's really important that we look at which statins are actually being given. Because if you're giving Pravachol 20 milligrams to somebody with an LDL of 200, is that going to meet your target?

CO-CHAIR WHITACRE: Peter?

DR. BRISS: If I understand it, so two things. A Million Hearts has relevant measures

that HHS has been working really hard at and aligning across programs on hypertension, tobacco use cessation, appropriate aspirin use, and cholesterol management. So all of those issues are addressed currently in Million Hearts measures.

About the last point about cholesterol measures, it's actually harder than one would expect to know what those statins people are actually on from current EHR, so my understanding is you can get a reasonable -- you can know what size pill a person is on, but you can't actually know what dose of statin somebody is on easily. And so I think most of the current statin measures aren't trying to determine intensity of statin use because it's hard to pull out of an EHR.

CO-CHAIR WHITACRE: Beth?

MEMBER AVERBECK: I'll make a comment. We did discuss whether or not we would try and do dosing of statins, but there are a number of initiatives around pill splitting for cost

savings and other things. So it was ideal, averse, and feasibility and so after the discussion it was around statin use. But to try to get to the, I think, hugest point, absolute dosing was really hard through an EHR.

CO-CHAIR WHITACRE: I think this is a great discussion for developers of other measures.

Stephanie?

MEMBER GLIER: To go back to my -- the reason I originally pulled this measure which was actually sort of related to the conversation we've been having here. I think generally -- I'm not sure what the right recommendation is for the MAP work group to make to have this outcome. But in general, it would be really lovely to have high quality outcome measures, composite measures to the extent possible.

I like the Million Hearts measures. I think Million Hearts is doing great things. Keep doing it. But I'm not sure that having those components of the Million Hearts measures

is worth getting rid of a really high value composite measure. And so I would like to encourage CMS to consider using composite measures wherever possible, especially for things like optimal care when we have this kind of a robust set of information together. So whether we decide that the Wisconsin IVD all or none measure or the Minnesota Community Measurement measure when it's done going through the guidelines review or some other approach is the best approach, I think my message -- and I hope that the work group members will support me on this. We'd really like to have this type of a composite outcome measure that can tell us a lot of information easily.

CO-CHAIR WHITACRE: Thank you. We'll be voting specifically on this measure, but I appreciate your comments.

Bruce.

CO-CHAIR BAGLEY: My comments are similar. I think the rationale used by the staff is that if it's part of the Million Hearts, then

we don't have to have another measure. However, what's the mechanism to make sure that measure is in the set I guess is what I want to know, just to say we don't support it because it's done somewhere else is not addressing the fact of whether it should be here or not, to me.

DR. WINKLER: Just to comment. If you look at the measures that are currently in the Shared Savings Program, the aspirin component and the statin component are already individual measures in the Shared Savings Program.

CO-CHAIR BAGLEY: My second comment is about composite measures. I agree. Composite measures are very high leverage for improvement because they force you to have a systematic approach to all four things as opposed to -- so if your organization does 75 percent on each of four measures, that's your average, then if you multiply those all together, you get 32 percent. And that makes providers very nervous. They get twitchy like this, they go what? Thirty-five percent? I'm used to getting 100 percent. So

they're very good for quality improvement. They're a little tough on the troops for payment and judgement.

So I agree that this is the kind of thing that's going to make the most difference for improvement. So I hope we're not going to abandon composite measures because they're not popular.

CO-CHAIR WHITACRE: Thank you. Any discussant contributions? Marci or Kate?

MEMBER NIELSEN: No comments on this end. I do think it's worthwhile to point out two things though that would underscore some of the concerns that have been addressed. One is the shift toward outcomes measures which is a balancing act with some of these performance measures, acknowledging that the goal is going to be outcome measures, but recognizing until we have solid measures, it's difficult to get there and I think that's the sort of needle that we're trying to thread. Yes, that's it. I'm not mixing metaphors.

The other point around risk adjustment for SES is another important one, not just from the provider perspective who may be in an academic medical center taking care of a lot of very sick --- and folks who are high risk, but from the perspective of patients. As we start to report patient-reported outcomes, I think it's important for us to realize that patients want to know who's taking good care of high-risk populations. And so we just want to go on the record underscoring the same kinds of concerns, but maybe from a different angle.

CO-CHAIR WHITACRE: Kate, did you have a comment?

MEMBER KOPLAN: This is Kate also. I am still trying to figure out the redundancy issue. And so it's a little bit -- you know, you can't tell from this analysis and none of us can probably memorize all of the different places where we see the measures. So in the future if, for example, redundancy is one of the concerns, it may be helpful to sort of list it out.

Million Hearts -- and these are the kind of people that participate there. What is currently in different kinds of ACOs you see in -- and that's the PQRS and other places for some of the composites, if that's the group's concern.

But I do also support that the composite measures represent how well we're doing for each individual patient, even though for the separate measures we do well. So we also like composite measures and KP uses a lot of them. So I do agree generally with the concept of them. And I do -- whoever mentioned the statin concern, it kind of does become a process measure if you're just on a statin rather than if you're on an effective statin. So whereas the hypertension control is really a quote unquote outcomer, it's a more robust measure, just the fact whether or not you're on a statin makes me a little bit nervous because it doesn't represent clinical effectiveness. So that would be my concern with that one part, as opposed to the aspirin and blood pressure and the tobacco-free pieces feel

really good.

CO-CHAIR WHITACRE: Thank you. Yes?

DR. ALEMU: My concern is about one of the components of the measure about statin use. And as you know, after the new guideline, I'm not aware of any measure which speaks to that guideline. And the HHS is trying to develop a measure which is simple and can be used for Million Hearts initiative, but in this case I am really not aware of a measure that is currently developed related to the new guidelines. So I just want to point out that concern.

CO-CHAIR WHITACRE: Thank you. Any other discussion? This is just a great example of how we can take one measure which in the end we may not feel very strongly about, generate this great discussion about composite measures, outcomes, patient-reported experience, risk adjustment, and try to refine some other measures which aren't even on the table. So that's really wonderful. That's the value, I think, of this committee.

So I think if there are no other comments, it would be time to vote and it looks like -- oh, excuse me, Barbara.

MEMBER LANDRETH: Please clarify for me again if we do not support this, does this mean that there will not be a composite cardiovascular initiative in this round?

DR. WINKLER: You're making a singular decision on this particular measure for the Medicare Shared Savings Program.

MEMBER LANDRETH: So the fact that it's in Million Hearts doesn't really matter?

DR. WINKLER: The way they talk about Million Hearts measures are the measures themselves which as Peter said were the aspirin, smoking, blood pressure, and statin use. There are -- there's already a measure of aspirin and statin use in the Shared Savings Program.

CO-CHAIR WHITACRE: Yes, Winfred.

DR. WU: Could I just make one suggestion? Since this is going to come up to be one of these re-options, maybe the conditional

support could be one whereby if NQF 0075 does not have its re-review completed with statin therapy listed in the revised measure that we might conditionally support this Wisconsin proposed measure otherwise?

DR. WINKLER: I was going to say just realize 0076 is not in the Shared Savings Program either. It previously was in the PQRS program.

CO-CHAIR WHITACRE: Yes, Peter.

DR. BRISS: I thought when we looked at the Shared Savings Program's measures this morning that, in addition to the two that you said, that blood pressure and smoking measures were also in Shared Savings.

DR. WINKLER: I think you may be right, but was the blood pressure just for hypertensive patients or was it for everybody?

DR. BRISS: It's both a screening measure that essentially applies to everyone and a controlled measure that applies to people who need to be controlled. So all four of the components -- I guess it depends on -- some of

you have said that you feel strongly about a composite measure, but at least all four of the components that are reflected in this composite are already reflected in the program as it stands.

DR. WINKLER: Thanks for the correction, Peter.

CO-CHAIR WHITACRE: Janis.

MEMBER ORLOWSKI: A comment regarding the politics of voting. I am concerned about disagreeing with the measure, but holding it open for further work, like a placeholder to dump other bills into so to speak.

I think that we should say yes or no on this measure or it needs more work, but we also have the opportunity to send strong messages back. We want a measure that does X, Y, or Z. So rather than holding a bad measure open, we should vote on the measure, but then send strong messages about what we want to come forward.

CO-CHAIR WHITACRE: Thank you. That's my understanding as well. We're voting on this

specific measure, not the concept, not other relevant measures that could be very applicable. Thank you.

Yes?

MEMBER KOPLAN: Can you clarify what the choices are?

CO-CHAIR WHITACRE: We're not quite ready to vote. Our choices we'll go over. There's still a comment.

Stephanie?

MEMBER GLIER: It's another clarifying question for CMS. Since we are not, in fact, talking about 0076, but 0076 has been in PQRS before, would that measure need to come back to the MAP on the MUC list in the future for inclusion in the future program or would it be okay as is?

MS. AUTREY: If there were changes to 0076, then yes, it would need to come back through the MAP.

CO-CHAIR WHITACRE: Jim.

MEMBER PACALA: Quick and philosophical

retort to Bruce's endorsement of composite measures. I do think we need to be careful because it would be great to pair -- and I know this is very difficult logistically, but to pair a composite measure with a patient-centered, goal-oriented outcome or process measure.

I've got a lot of patients who don't like to take drugs. And if we start going whole hog on this, and I've got 75 percent of each of the -- and that's what they want. They don't want to take a statin. And if we start doing SPRINT -- if we start following SPRINT, we're going to be pushing blood pressure medicines on these people like crazy. I mean the average SPRINT subject needed three anti-hypertensives to get down to 120.

So just a philosophical comment for general purposes that I do think we need to balance the rigor of the composite measure with some kind of patient or goal-oriented outcome as well. And with some kind of waiver if the patient doesn't want to take all those drugs.

CO-CHAIR WHITACRE: Please.

CO-CHAIR BAGLEY: I think that's a classic physician retort in the sense that 100 percent must be the best. And we don't even know really what optimal -- you guys are beginning to know what optimal performance is and it might be 50 percent that might be optimal performance. And that's perfectly okay. So it's not the composite that makes that a problem, it's the individual measures and patients and stuff that make that a problem. But everybody will be measured on the same approach. And a composite measure makes you have a checklist. If you want to do well on a composite measure, you've got to have a checklist. So it makes you put some process in place that's going to get better outcomes on that, regardless of the patient population by the way.

MEMBER PACALA: I know that. I live in Minnesota and you know, I get together with my panels -- with my team and panels and we've got now statin. That's one of the -- you know, so

who's on a statin, who's not? And we get after them. We force the statins on them to get our composite up.

CO-CHAIR WHITACRE: Barbara.

MEMBER LANDRETH: Jim, I think you're lucky to live in Minnesota. I live in Oklahoma. So we have some of that worst health statistics --

MEMBER PACALA: Better football team.

MEMBER LANDRETH: Well, that's true, but that's all we can do. So unfortunately, it's very true, patient compliance is nowhere factored into any of these measures and I'd like to see future measures being developed that would have in your checklist, Bruce, the physician or the provider has the opportunity to say patient is not compliant. Or patient refuses to exercise. I've counseled until I'm blue in the face. They will not change their diet. So I think that those kinds of things need to be factored in because patient compliance -- we're not acting on widgets. We're not acting on inert subjects.

They have free will.

CO-CHAIR WHITACRE: Cindy and then Janis.

MEMBER PELLEGRINI: Barbara, I really actually agree with you. And I think that there are a lot of cases -- the only place I'm going to disagree is that we shouldn't just be classifying patients as a recalcitrant because in some cases they're actually making very carefully considered decisions.

And I think it's one thing to talk about cardiovascular care, but in the maternal and child health world, we put a lot of choices in front of people and we may encourage one, but we accept others, whether it's things like C-section or scheduled deliveries and things like that. So I'd love to see us all get into that and say either -- how can we quantify the kinds of choices that patients are making because there have been a couple of cases in my own medical history where my doctor said I think you should do this. And I said thank you very much, but you

know what, I'm not going to. And here are my reasons why and we're just going to agree to disagree. Teasing that out is, of course, incredibly difficult, but I'd love to see us go in that direction.

CO-CHAIR WHITACRE: Janis.

MEMBER ORLOWSKI: Not to prolong this too long, but since we're being philosophical, I completely agree. I think that we need to have an opportunity to indicate patients' preference, whether it's the preference or noncompliance. But I also think that when we take a look at certain measures that we need to first of all understand those people who choose not to be compliant, but then we need to compel providers to try to push that percentage. And I'll give you an example.

I recently visited a hospital where I'm sure they had 100 percent compliance with the influenza vaccine documentation on admission to the hospital. Ninety percent of people chose to refuse the vaccine. I don't believe that. And

so I think that what they have is they have 100 percent compliance with the measure. And I would say since we know from a public health point of view, it's probably one of the most important things that we can do is to vaccinate. And once we have the measure and they drive it in there 100 percent, the next thing is that if you're at 90 percent refused, that there has to be some target of improvement so that the next year you're at 80 percent improvement or 70 or whatever, so that I do believe that there should be patients' indication of choice. But it is also our responsibility as physicians is to educate our patients and their families to what is absolutely rock solid, scientific information regarding vaccination. And that is the responsibility we have.

So again, I'm speaking philosophically of where you go from process measures to outcomes or whatever. And there will be patients who refuse vaccinations. That's fine. But we have some role to play in that.

CO-CHAIR WHITACRE: Thank you. We're going vascular to vaccination. That's terrific.

Peter.

DR. BRISS: I want to support that general thrust, too. I don't want to give a sort of too uniform view of us needing to endorse blaming the patient, so think about -- one of my hats is I'm still a working stiff internist and so I know how hard this can be. But you know, think about smoking cessation is still always the right thing. And think about how many times you have to talk to somebody 16 times before they actually quit, but they eventually do quit. And so I'm real reluctant to give providers the patient just won't go there on the first time you say it. And we know that you won't bat a thousand all the time, but it's still -- there are still some things that are the right thing and we ought to be trying to do better.

CO-CHAIR WHITACRE: Marci.

MEMBER NIELSEN: I'm so sorry. I can't help but listen to this conversation and of

course, we all know that language matters. So I'm a little sensitized to compliance language. In many, many cases when patients are making decisions about care they don't want that we believe as clinicians is in there better interest, it's because there are other issues at play, often behavioral health.

And so I recognize this is a measures conversation, but given that we've got a public record here, I would just want to point out that engaging patients in real and substantive ways often gets us the improvements in those measures that are critically important and so behavioral health, absolutely critical, often left out.

CO-CHAIR WHITACRE: Yes, Rachel.

MEMBER GROB: I just wanted to throw out a not very well considered yet by me, idea that we sort of marry the idea of the composite measures and the idea that when we look at outcomes related to specific kinds of recommendations and want to also take into account the behavioral health issues and the

patient's own decision making and autonomy that we think about composites that measure sort of patient experience and shared decision making along with some of these outcomes. I don't really know how that's done because I'm not a technical measure developer, but I know that we have these issues kind of in the field with does patient experience -- high patient experience scores actually potentially indicate poorer clinical quality. And I think it's a good debate to follow further with evidence and measure developments.

CO-CHAIR WHITACRE: Beth.

MEMBER AVERBECK: So good suggestion. Actually, when we looked at the optimal vascular and optimal diabetes, there was a lot of discussion around could we incorporate a shared decision metric in there and then there was more discussion on how there weren't really good definitions nor metrics around shared decision making, so I wonder if with that thought we might want to consider that as a measurement gap in the

discussion tomorrow around shared decision making. It's hard to put a -- when it's not yet fully developed into a composite, although over time that would be ideal and then maybe some steps to get there.

CO-CHAIR WHITACRE: Very nice. We'll start to keep a check list for that. Mady?

DR. CHALK: Those issues of shared decision making out of behavioral health issues have been a particular focus on the Duals Work Group in thinking about measures and assuring that those were included as factors in how these measures are applied. So I think we really need to keep that in mind.

CO-CHAIR WHITACRE: Well, this has been a great discussion. If there's nothing further about this measure.

MEMBER KOPLAN: I have one more comment. This is Kate on the phone.

CO-CHAIR WHITACRE: Yes.

MEMBER KOPLAN: Just about the medication adherence conversation and so I don't

see medication adherence as part of this, although that was obviously part of the previous conversation. And obviously, in CMS stars, for the stars quality measurement, there are at least three med. adherence measures if not more and there are other adherence measures. But in CMS stars, those are weighted very heavily, so they're obviously recognizing the importance of those measures.

It would be nice if that is something that we wanted to proceed with. Those are kind of like standalone med. adherence measures with different specs than what we're used to. If we were to sort of help develop some similar kind of things along those lines to help speak to the patient side, non-adherence, and a real outcomes-based approach. So those are things we're pursuing in KP. Thanks.

CO-CHAIR WHITACRE: Thank you. Rachel?

MEMBER GROB: I'll be quick, but I just -- Mady, thank you for that comment and I

wonder if there's a time that would be appropriate for us to hear more about how your work group coped with these discussions or specific recommendations that you made. I realize that we have to vote now and it's not the time, but that was a very intriguing introduction and I just wanted to acknowledge it and ask for follow up.

CO-CHAIR WHITACRE: Thank you. If there are no other comments, we'll proceed to vote on the measure which is on the screen, ischemic vascular disease, all or none outcome measure, optimal control, MUC ID: MUC 15275. Our choices are support, conditional support, or do not support.

MS. CHAVEZ: Voting is open.

DR. BRISS: Kate, Terry, please enter your votes.

MS. CHAVEZ: We had 20 votes, 10 percent voted support, 40 percent voted conditional support, 50 percent voted do not support. So this measure does not pass.

CO-CHAIR WHITACRE: Thank you. Great discussion. I hope we will continue through lunch.

DR. WINKLER: Okay, I think we're pretty much ready for lunch at this point.

CO-CHAIR BAGLEY: We have another housekeeping item. How many people might be interested in a dinner this evening, especially for those who are out of town? Could you raise your hand so we can get a count? It's yet to be determined where and when, but --

MEMBER NIELSEN: Are you cooking, Bruce? That sounded like you were cooking.

CO-CHAIR BAGLEY: No.

MEMBER NIELSEN: Okay, just checking.

CO-CHAIR BAGLEY: I'm too far from my kitchen.

DR. WINKLER: Okay. We'll reconvene at 12:30. Lunch. Be back here, as you can hear. And we reconvene at 12:30. Thanks a lot.

(Whereupon, the above-entitled matter went off the record at 11:51 a.m. and resumed at

12:29 p.m.)

CO-CHAIR BAGLEY: All right. It's 12:30, so we're going to go ahead and get started. And we're starting out the afternoon talking about the MIPS Program, and sort of the context by which we're supposed to be thinking about these measures. So, Reva, do you want to do the intro?

DR. WINKLER: Sure. Thanks, everybody. I'd like to introduce Molly MacHarris from CMS who is going to introduce and describe the MIPS Program, particularly to set the context for the work that this workgroup is going to do over the next day and a half. Molly.

MS. MACHARRIS: Thank you, Reva, and thank you for having me here today.

So, my role within CMS, I will be leading the new MIPS Program, so we are busily working on everything we need to do over the next few months and years to come. So, thank you all for your input today.

Okay. So, I know that when Dr.

Goodrich spoke this morning she talked at a high level on some of the principles and goals that we have for the Merit Based Incentive Payment System, or MIPS Program. So, these are some of the principles that we have developed so far. These are not final. These are draft principles, so if folks have any comments or feedback related to these, we'd be more than happy to take those. But before I go over these in more detail, I did just want to set the stage a little bit for the MIPS Program.

So MACRA, the Medicare Access and CHIP Reauthorization Act passed this year in April. It did a couple of things. Most importantly for the conversations today and tomorrow are that it repealed the sustainable growth rate, and it authorized two new programs. The first is the MIPS Program, and the second is incentives for participation in an alternative payment model.

Additionally, what MACRA did was that it really tied nicely into some of the delivery system reform goals that the Secretary issued

earlier this year. And just for those of you who may not have those memorized, the two delivery system reform goals that the Secretary issued were that, for the first is that in 2016 we would like to see 30 percent of all of Medicare payments tied to quality or value through participation in an alternative payment model. We hope to see that increase to 50 percent by the end of 2018. And that goal ties really specifically into the alternative payment models.

The second goal which ties into the MIPS Program, is that we want to have Medicare fee-for-service tied to quality or value having 85 percent of those payments associated with that by the end of 2016, and then to have 90 percent of those payments tied to quality or value by the end of 2018.

So, these goals really set the stage for what MACRA did. And I did just want to level set with everyone on those, because while that sets internal goals for HHS, we know that we cannot do this alone. We have to work with the

private payers to actually get us there.

So, just to look at some of the principles that we have. Again, I know that Kate went over these today, but some of the ones I do just want to highlight are that we are really trying to focus on policies that remove as much administrative burden as possible from eligible professionals and their offices. Most importantly, we really want to be using a patient-centered approach. We want to develop a program that is meaningful to professionals, and that we have metrics and activities that are meaningful to providers. And then we also really want to insure that we have excellence in implementation.

Let's see. Okay. So, MIPS is a new program. MIPS will begin in 2019. That is when professionals adjustments will start to be addressed under MIPS. The first year of MIPS there will be a 4 percent payment adjustment. MIPS also sunsets the three existing programs that providers typically deal with, so that

includes the PQRS Program, the Physician Value Modifier, and the Medicare EHR Incentive Program for Eligible Professionals. Those adjustments will end in 2018.

And what MACRA does under MIPS is it consolidates and aligns those programs, and now we have four performance categories. Those include quality, which for the first year will account for a provider's -- of their total composite performance score it will account for 50 percent of their score. Resource use, which in the first year will account for 10 percent of their score; clinical practice in proven activities, this is a new area for us. This will account for 15 percent of their total composite performance score. And then, lastly, the Meaningful Use of certified EHR technology that will account for 25 percent of their total composite performance score. And the concept over total composite performance score we will be assigning to each provider this specific score, and it will be based on a zero to 100 point

scale.

Some of the other things that MIPS does specifically related to the quality component and specifically related to measures, so we're not required to actually go through the MAP process, but as Kate mentioned earlier this morning, we have found through the past years that the feedback we receive through the MAP process is particularly valuable, so that's why we have presented our measures here today and tomorrow.

The other thing that we have to do specifically related to the quality measures is that we are required by law to submit all of the measures to a peer review journal. The law doesn't say that they have to be published, but they have to be submitted to a peer review journal prior to the final measure list being posted. So, that's a process that we're still working through. We're really excited about it. That's a joke.

So, who is MIPS -- who can participate

in this? So, under MIPS there's going to be three main ways that people can participate. The first is as an individual eligible professional. The second is as part of a group practice. And the third is as part of a virtual group. Virtual groups, that's another new concept that we have under MIPS. This is an area where providers that are either solo practitioners or practices of up to 10 provides, they can band together and form a virtual group.

And then who can actually within those areas, who is actually eligible? So, for the first two years, it's a little bit narrower than who can currently participate in the PQRS program, and it's a little broader than who can participate in the Meaningful Use program. So, we have our physicians, PAs, Nurse Practitioners, CNSs, and CRNAs. For the third year forward we can expand that list to those that are currently eligible to participate in the PQRS program.

One thing to note is that on the APM side of things, for the first year of APMs, those

that can participate is the entire list, so what I have covered in those two bubbles, the physicians, PAs, Nurse Practitioners, and then as well as the occupational therapists, et cetera.

We do have a couple of exclusions from MIPS. The first is if you are part of a qualifying APM, you are completely excluded from MIPS. You would be receiving the 5 percent lump sum incentive payment that is associated with APMs.

Additionally, an exclusion is if you are part of a partially qualified APM. The statute gets into a level of detail that talks about different thresholds of whether you are a QP, a Qualified Participant, or if you're a partial QP. If you are a partial QP, you can either elect to participate in MIPS, or you can choose to be excluded.

And then the last exclusion we have is based off of low volume thresholds, which we will establish through rulemaking. They can be based either on number of patients, number of

encounters, or volume of services, or potentially a hybrid of those.

The one other exclusion that we have which isn't noted on the slide is that if you are a newly enrolled Medicare doc, you are excluded from MIPS for the first year.

Okay, so some of the adjustments. I mentioned earlier that we have the concept of a composite performance score. We've abbreviated it as CPS. We love to abbreviate things at CMS. That covers the four domains of performance. Again, it's quality, resource use, clinical practice improvement activities, and meaningful use.

I touched on earlier the percentage amounts for the first year. Please note that those do change over time. In 2020, quality gets reduced to 45 percent and resource use gets raised to 15 percent. And then in 2021 and future years, quality will account for 30 percent, and resource use will account for 30 percent. The adjustments under MIPS must be budget-neutral, similar to the Physician Value Modifier program.

So, when we are assigning the performance score, it gets a little complicated, but at a high level we will be assigning to each EP regardless of how they participate, whether it's as an individual, a group, or a virtual group, a composite performance score which will be based off of a scale of zero to 100. We will then compare that composite performance score to an overall MIPS performance threshold that we will define through rulemaking.

Depending upon where that provider compares to that performance threshold, they will receive either a positive, neutral, or negative adjustment. So, if they are above or at the performance threshold, they would either receive a positive adjustment, or a neutral adjustment. If they are below that threshold they would receive a negative adjustment.

One other thing to note related to MIPS is that by law we must develop the payment methodology using a linear sliding scale, so we're still working through exactly what that

means. But what we anticipate is that we will not be seeing quite as much bunching at the neutral point that we see today under the Physician Value Modifier. Rather, we would see a broader range of scores that could be applied.

In future years when the data is available, we will also need to take into consideration the assessment for achievement and improvement. And then, also, for the first five or six years of MIPS, we have to establish an exceptional performance threshold. And there is a separate pool of money outside of the budget neutrality for those providers who have met exceptional performance. And this is just a brief timeline that talks about the SGR updates for MIPS, and then the APM side of things.

The last thing I'll note is just some process pieces. We do anticipate going through rulemaking in the spring to summer of next year, and then publishing a final rule towards late summer/early fall of next year. We did issue an RFI earlier this fall. We received a lot of

comments on that. Thank you for everyone who commented, and we are still working through those comments and applying those, as much as possible.

So, at this point I'll pause and I guess turn it back over to you, Reva.

DR. WINKLER: I think at this point, if there are any questions from the workgroup to clarify, it is a new program. There are a lot of changes in terms of perhaps the way to think about measures to be recommended by the MAP. And we just want to be sure that you have all the clarity that we can provide as you move through the rest of the agenda.

CO-CHAIR BAGLEY: Janis, go ahead.

MEMBER ORLOWSKI: Thanks very much for the overview. I have three specific questions. The first not a question, it's a comment. It regards this particular slide which reviews the Physician Fee Schedule. And just a note that this is not the Physician Fee Schedule. This is the part that comes from MIPS, but there's another law on the books. And the physician update this

year is actually a negative, so I think we have to be careful about presenting that this is the current Physician Fee Schedule, because it's not what has been proposed.

The second is -- my question is regarding threshold. What are your thoughts currently regarding a threshold, either time in practice, number of patients, or some other threshold for these measurements?

And then the third question that I have, and I understand that you need to get this program in place, so this is probably a minor point. But I was wondering what the thoughts were for new in practice, so someone who is graduating from a residency program new to practice who is just in what I would call a couple of ramp-up years? If there's been any thoughts about those individuals?

CO-CHAIR BAGLEY: Before you answer, is there somebody on the phone that could put their phone on mute so we don't have to listen to the background? Thank you.

MS. MACHARRIS: Sure. So, thank you for the comments and the questions. I'll address the last one first. So, as I noted just briefly, we do have the ability under MIPS similar to what exists today under the Medicare EHR Incentive program, that if are a brand new doc, if you're brand newly enrolled to Medicare, you are excluded for the first year.

MEMBER ORLOWSKI: For just one year. But no ramp-up after that?

MS. MACHARRIS: So, by law you're excluded for the first year. The ramp-up for new docs, that is a concept that we are still working through internally of any policies we would potentially want to institute related to that. So, thank you for the feedback.

For the second question related to the performance thresholds. So, under MIPS, and it gets a little complicated because there's a lot of terminology that we use, and we will try to clarify this as much as possible through rulemaking and then through future

communications.

So for MIPS overall for the entire program, we will establish one performance threshold, in addition to -- well, we have one performance threshold, and then we will also have an exceptional performance threshold. And then within each of the categories, we have the ability to establish benchmarks related to specific measures or activities as much as we have data available to them. But we will have one performance threshold which we will then be comparing all providers against.

MEMBER ORLOWSKI: And I'm sorry, I did use the word "threshold." That probably was confusing. I was referring to minimum volume of patients seen by a physician, is there a threshold below which -- and I'll try to use a different word. Is there a barrier below which you would not be measured in this program?

MS. MACHARRIS: Yes. So, that is an exclusion that we have the ability of implementing. That's another area we're still

working through, what the policy will be. But we do have the ability to set a certain low volume threshold that if you bill, or if you see less patients or less encounters, or any hybrids of those, that you would be completely excluded from the MIPS program.

MEMBER ORLOWSKI: Okay. So, working on that still.

MS. MACHARRIS: Yes.

MEMBER ORLOWSKI: Thank you.

CO-CHAIR WHITACRE: I would like to ask just as a practicing surgeon, is where the QRURs would come in in terms of the feedback reports?

MS. MACHARRIS: Yes, great question. And I apologize that I didn't talk about feedback reports, which is another important component of the MIPS program. So, additionally what MACRA does, is it sunsetted a lot of things, and we use the term "sunsetting," but it could be equated to ending. So, the Physician Feedback program, the QRURs, that separate piece as an existing outside of MIPS will end. Those feedback reports, we're

required by law to issue feedback reports to eligible professionals. The first feedback report has to be issued July 1st, 2017, and then we -- the next feedback report by law we are required to issue is July 1st, 2018. And in that second report we have to provide information on items and services related to your patients for other physicians.

The other piece related to the feedback reports is that while there are those two statutory dates we have to meet, there is a clear intent that we need to provide feedback timely, and Congress went ahead and defined that for us a little bit in more detail, such as quarterly. So, it's an area that we know, we have been working on for years of trying to provide feedback in a more timely fashion. So, we do anticipate that the QRUR reports as a separate concept will end, and the aspects of the QRUR reports that we feel are meaningful we would want to continue under the MIPS program.

DR. CLARK: You mentioned that the

program is patient centric. I was wondering, was there patient input into development and how you may have incorporated patient values?

MS. MACHARRIS: So, I can't speak to whether or not patient input was developed in the actual constructing of the law, but we have been trying to work with as many patients and providers as possible as we have been developing the MIPS program. Some of the things that we have done and we will continue to do is, we issued the RFI which we know not really most patients will be reviewing that. But one of the things we did have is, just last week we held a LEAN event that correlated with the QualityNet conference, and we were able to receive some feedback from patients and providers there. We also have been working closely with the QIOs and QINs that CMS has in our regional offices to try to engage as many patients as possible to work through what would really be meaningful to them.

CO-CHAIR BAGLEY: Cindy, you're next.

MEMBER PELLEGRINI: So, coincidentally,

I spent half the day yesterday in a meeting on potential changes to maintenance of certification. So, that's top of mind for me, and I'm looking at the clinical practice improvement activities element. Just curious, obviously, this is still in the developmental stages, but are you thinking about harmonizing some of that with those kind of maintenance of certification activities to reduce burden on providers?

MS. MACHARRIS: Short answer, yes. I probably won't get into more detail than that because it kinds of starts talking about what our potential policies will be, but that is an area specifically in the clinical practice improvement activities that we are exploring, working with the Boards of what that could potentially look like.

CO-CHAIR BAGLEY: David.

MEMBER SEIDENWURM: Well, having just sat for MOC that was top of mind for me, as well. So, I was wondering if you were going to harmonize some of the practice improvement

activities with some of the other measurement domains?

MS. MACHARRIS: So, for the clinical practice improvement activities, since this is a new area for us, we've been really trying to work through what is the existing landscape for quality improvement activities. We know that quality improvement has been occurring for years and years, but really more at either a regional level or within specific practices. So, we'll talk about this more through future meetings, and through the regulation, but we've been working through what is the current landscape for quality improvement? And which activities that local practices have been doing, or activities that have been occurring at the local level could really be implemented at the national level?

So with all that being said, that's kind of our initial process of trying to create an inventory of what all of these QI activities could be. We do foresee that in the future there would be harmonization potentially across the

QIs, so the clinical practice improvement activities and then also potentially across some of the quality measures, so that is an area that we are definitely looking at and hoping to explore further in future years.

CO-CHAIR BAGLEY: Stephanie.

MEMBER GLIER: This is probably a clarification from NQF. Is the MIPS framework spreadsheet the current physician piece, the fee schedule measures that were finalized for 2016?

MR. LYZENGA: Yes. I believe that's the finalized -- the most recent rule in July or September, whatever it was.

MEMBER GLIER: Okay. So, then a question for Molly or Sophia that you may not actually be able to answer since I know this is getting into policy making. To what extent are you considering rolling over or streamlining the measures that are currently used in PQRS into the MIPS program?

MS. MACHARRIS: So, we are taking a hard look at all of the measures that we have in

existence in the PQRS program and, you know, looking -- let me go back to our principles. So, we're taking a hard look at all of those measures and really trying to work through based off of, you know, some of our draft principles which measures really make sense for us to continue under the MIPS program.

One of the key things that we want to try to do under the MIPS program is not just have a PQRS 2.0, a VM 2.0, or an EHR Incentive program 2.0. I know I said this numerous times at other presentations, and I'm sure for those of you that hear presentations from other CMS staff, you will hear that as a common theme. We do not want to just repackage those existing programs, stick a new label on it and say this is MIPS. So with that, we are really trying to take a look at those measures and work through which of those are really quality quality measures, and which of those are measures that we feel can really be meaningful to the various specialties.

So, I'll pause there. And, Sophia, if

you want to add anything, feel free.

MS. AUTREY: I completely agree, which actually brings us back to one of the additional requests that Kate had earlier today when we received feedback from the MAP and looking at the measures that we have on the table on the calendar, not just the blanket recommendation or support, but actually give us some type of substantive information so that if there are additional requests or additional development that needs to happen for those measures, you're more specific in that guidance. So, that would help us a lot, because we are specifically looking at making sure that the measure set for MIPS is more robust.

CO-CHAIR BAGLEY: Robert, you're next.

MEMBER KRUGHOFF: This is a little tangential to what we're supposed to be focusing on here, but could you give us a little sense of what's happening to Meaningful Use, the sort of trajectory of requirements, standards, et cetera, and incentives for Meaningful Use from now

through, you know, the long-term development of these -- long-term implementation into 20222 and beyond?

MS. MACHARRIS: Sure. So, I'm sure that all of you are aware we recently -- CMS recently issued the Stage 3 final rule I think a month or so ago, which laid out the remaining groundwork for Meaningful Use, the program as a whole. So, that includes the Medicare side for both EPs, and then EHs for hospitals. And then also for Medicaid. So, we have that kind of groundwork already laid out.

What MIPS does specifically is, it folds in the Medicare side for professionals into the MIPS framework. So, it also -- let me think of how I want to frame this. MIPS also does provide to us more flexibility than we feel exists today in the Meaningful Use program. So, without getting into policy, which I, unfortunately, can't talk about right now, we are taking a hard look at the Meaningful Use program, the policies we set forward in the Stage 3 rule.

And then also how we want to implement MIPS as a whole where it really comes across to professionals as a complete program, not four disparate categories, and what changes we would potentially need to make to the Meaningful Use component. So, I hope that helped answer somewhat. I know it was a little vague.

CO-CHAIR BAGLEY: Marci.

MEMBER NIELSEN: I might just offer one example where CMS isn't, in fact, recreating the four programs and rolling them up to be, you know, Meaningful Use. I guess this would be the equivalent of 4.0, and that is under the clinical activities, and as an example of a new way in which you're going to recognize quality improvement is that patient-centered medical homes for those practices that are certified patient-centered medical homes. Right off the bat, you get the full score, that full 15 percent is rated on behalf of that clinician and their practice as meeting all of those requirements. So, that was in statute, but it's a terrific

opportunity, I think, to look to primary care to help drive what you're trying to do systemwide for those practices that have embraced that model.

MS. MACHARRIS: Thank you.

CO-CHAIR BAGLEY: Jim, go ahead.

MEMBER PACALA: Thanks for your presentation. Could you just talk a little bit more about clinical practice improvement? Do you envision the measures to be mostly process measures, or if there are outcome measures envisioned, how are they -- how will they be distinct from quality and resource use measures?

MS. MACHARRIS: Sure. So, the clinical practice improvement activities performance category, within the law it calls out six specific subcategories. Those include patient safety, patient experience, care coordination, and a couple of others. Within that, there are some examples of what some of those activities could look like. We also, additionally, have the ability to expand beyond those six subcategories,

if we so chose to do so. That was an area we specifically sought comment on, on the most recent RFI that we issued, and we're still working through those comments and trying to determine are there activities that could fit into any of the additional subcategories.

So, when we -- as we've been working through our inventory process of the existing QI work that has been done to date, we have been categorizing the measures and activities into different areas, you know, kind of looking at areas that are more process as in, you know, was there after-hours care available, versus other areas where it could be more outcomes-based.

Since we know this will be new under MIPS, we are still working through exactly what that category should look like. So, I think I'll pause there. Does that help answer?

CO-CHAIR WHITACRE: If I could ask again as this is -- not as a co-chair, but practicing surgeon. Would there be thresholds for reporting quality? Right now among the different

programs those thresholds very widely in the various PQRS registries, via claims, via QCDRs. Do you have that envisaged or proposed threshold?

MS. MACHARRIS: So, we do anticipate that in the various categories we will have to set forward some sort of criteria of what success looks like. We're still working through what that should be. Again, kind of taking into consideration all of the feedback we've received over the years, and then also through the RFI of, you know, what should be the appropriate number of measures? Should we still allow providers to select from a broad set of measures? Could we introduce a core set of measures which we know is something that we have struggled with to a certain extent really looking at the physician realm because trying to define a distinct set of core measures that would apply to all physicians is a little bit more difficult on the provider side than on the hospital side. So, we do anticipate specifically calling out per category what success will look like, and what you would

need to do to get either the full percentage points allowable, or a portion of those percentage points. And we'll, of course, talk about that in more detail in the reg.

DR. WINKLER: Yes. Just to clarify, the measures that are under consideration that we have before us, are those all for the quality portion of the MIPS program?

MS. MACHARRIS: Yes.

CO-CHAIR BAGLEY: Any other questions from the workgroup about the MIPS program, in general? Okay. Seeing none, I think we'll move on. And what I'd like to do is open up for public comment.

No? Reva, you're going to lead us through the Physician Compare?

DR. WINKLER: Because public reporting is an important part of quality measurement, and Physician Compare is truly ramping up for the publication of measure results for clinicians, we don't want to overlook, I'm just going to skip through these, the Physician Compare aspect and

the fact that CMS is asking for some feedback. So, we've asked -- again, this is Alesia Hovatter from CMS, and she's just going to go over what's happening with public reporting of physician measures for Physician Compare.

MS. HOVATTER: Great. Thanks so much, Reva. This is Alesia Hovatter. So, at CMS, I am the Physician Compare lead, and thank you so much for having me today. So, I wanted to provide a bit of background on where we are with Physician Compare and our goals, so that could help inform you as you go through this process the rest of today and tomorrow.

Okay. So, for Physician Compare, you know, we think about public reporting and how can we help consumers make informed decisions when making health care decisions, and motivate health care professionals to improve their performance? So, this is really the two-fold purpose that we have displaying on the screen now for Physician Compare.

As most of you are aware, CMS was

required by Section 10.3.3.1 of the Affordable Care Act, also known as ACA, to establish the Physician Compare website. So, this two-fold purpose is really to provide more information for consumers to encourage informed health care decisions, and to create explicit incentives for physicians to maximize their performance. The site was launched on December 30th of 2010, and based on consumer testing and stakeholder input, the site was redesigned in 2013.

So what is Physician Compare? Most of you have probably been on our website, and this is a screenshot from the website, so this is on Medicare.gov. Physician Compare allows consumers to search physicians and other health care professionals who are actively participating in Medicare and Fee-for-Service. At this moment in time, the site includes general information about physicians, health care professionals, group practices including name, address, specialty, hospital affiliation, and clinical training information.

All eligible professionals which we like acronyms, so that's known as EPs, currently provide Fee-for-Service, Medicare services are included. This includes physicians, advanced practice nurses such as nurse practitioners, and physician assistants and other health care professionals, such as physical therapists and social workers. A complete list of those who are included on Physician Compare can be found under the Physician Compare resources pages under "Specialty Definitions," if you all wanted to have any questions about that. Information about physicians and other health care professionals who satisfactorily participate in CMS quality programs, and quality measures for group practices and ACOs.

So as you know, for Physician Compare we've really used a phased approach, so we started with a small set of measures and we are growing that over time. So, this slide represents in February of 2014, the first quality measures were publicly reported on Physician Compare. So,

as a quick synopsis of this slide, that was a subset of the 2012 Physician Quality Reporting System, also known as PQRS, Group Practice Reporting Option, also known as GPRO, measures collected by the web interface for groups of 25 or more EPs and accountable care organizations. So, that's what was available for public reporting.

There was -- also a subset of these measures was published for 66 group practices, and 141 ACOs that successfully reported the measures. So, that's where we started.

So then last year in December of 2014, the second subset of group practice and ACO measures were reported for 2013 data. And that was a subset of diabetes and heart disease measures that were reported for 139 group practices of 25 or more EPs, and 214 shared savings program, and 23 Pioneer ACOs. So now in the current state where we are right now in late December of 2015, Physician Compare will continue the phased approach in additional quality

measures over future years. We will continue to report group practice-level measures reported by the web interface. This year we are reporting measures for approximately 275 group practices.

The first individual EP data will be reported on Physician Compare very soon, which will be right now in December of 2015 by the end of the year. That will include a subset of six measures reported via claims, and that will be for approximately 40,000 eligible professionals.

Also, the first patient experience measures for group practices will be publicly reported. This will include a subset of eight CAHPS for PQRS measures. It will also again be including data for ACOs, approximately 333 shared savings program ACOs, and 20 Pioneer ACOs. And they will have clinical quality of care and patient experience data publicly reported. So, this is an exciting year since we have a bunch of new things going up this year.

So, as Molly indicated, MACRA was recently passed on April 16th of 2015. So, Molly

went over the first couple of bullets that are listed here. What I really want to put emphasis on now is that this increases the data available for public reporting on Physician Compare, so there will be a lot more data that is available which will provide opportunities to give consumers even more information to enhance their decision making.

So, here's where I really want to focus on the presentation today; the challenges to public reporting individual-level measures. Consumers really want individual EP measure data, but it is important that public reporting accurately reflects individual health care professionals' performance. Physician Compare will only publicly report valid, reliable, and comparable quality data that resonates well with consumers. Those are our public reporting standards that we have now. We have stated those each year that we have put something in rulemaking in the Physician Fee Schedule rule, so that still holds true now.

A particular challenge is the small sample sizes that are associated with individual EPs. Analysis to date show that data are reliable, though, and individual EP reporting is viable. So, we really want to engage consumers throughout this process.

Public reporting can serve many purposes. On Physician Compare, public reporting is for the public. It is for consumers. The goal is to, again, help consumers make informed decisions about their health care so they need data that means something to them, and they need data that they can understand.

Not every measure is a good measure for public reporting. Data are collected for a variety of reasons, and some very clinically sound measures are wonderful for informing clinical practice, but other measures are best for aiding consumers. The perfect measure, ideally, would have something on both categories.

To start, what do consumers want? Consumers want data from other consumers.

Ideally, they'd like narrative reviews, something like Yelp; however, these data present many challenges. Consumers do really value the CAHPS data and regularly request this type of patient experience data on the individual EP level. Understanding the concerns of small sample sizes and measure attribution it would be valuable to evaluate the opportunities in this area.

Consumers also really value clinical quality of care measures, the types of measures generally part of PQRS as valuable when they resonate with them, and make sense to them.

Consumer engagement with quality starts with measure development. We need to develop measures that better meet the needs of consumers and can help them make informed decisions about the care that they receive. Physician Compare is actively working with the measure development contractor to build more engagement options and information into the measures blueprint. To help facilitate this, the goal is to get consumers more meaningfully

involved early and often, but this group has a lot more intermediate role to play. We can look to include measures in existing programs and programs soon to come on line that are meaningful to consumers. We can think about the kinds of measures consumers are looking for, we can think about the types of information most important to consumers, and we can work to include measures that focus on things that matter most to consumers and present data in a way that is most easy to understand and interpret. That will be things like outcome measures, composite measures, and are measures being risk-adjusted?

Through consumer informed measure development and measure selection, ultimately, we can work together to insure that Physician Compare is a resource for sound quality data that helps consumers make those informed decisions about the care they receive through Medicare.

That's all I have today. Here's my information, and as many of you know, we have a Physician Compare Support Team, so if you have

any questions in the future, you can either direct them to me, Alesia Hovatter, or the Physician Compare Support Team at PhysicianCompare@Westat.com. So, I know we're running short on time, but I'll take any questions.

MEMBER MOYER: Related to what is going to be reported on Physician Compare, I thought I had heard that not all groups that submitted data were going to have results reported, that there were some where there were questions about comparability of results. Could you talk a little bit about what will actually be out there, and what will not?

MS. HOVATTER: Sure. So, where we are now, again, those public reporting standards are still going to resonate. So just for instance this year for December of 2015 when the measures go up, there were -- what we had stated and you all had probably received information on, the registry and EHR will not be available. And we do have specific information on which measures we

met our public reporting standards, resonate well with consumers. And that information is actually available on the Physician Compare Initiative page, and we have helpful documents that actually list out those exact measures. So I can show you where those are, if that would be helpful.

CO-CHAIR BAGLEY: Any other questions? Janice.

MEMBER ORLOWSKI: Just a comment. I think that -- I do understand that the public wants to see an individual physician, and that's understandable. And I do understand the logic behind that, but there's very good information out there that we should be looking at people within care teams. And there are highly -- high-quality care teams, and if you take a physician out of a high-functioning care team and put him or her into another situation, that quality does not always follow them without the development of a team.

Secondly, we are spending a lot of time talking about and developing the concept of

inner professional teams. So, I just want to note that this big ramp-up in physician-specific data is contrary to what is a trend that is moving us away from physician-specific, captain of the team type work, and moving us towards care teams that are more effective. And I know in many of the places that I visit when you take a look at let's say primary care. Primary care now is -- primary care is given within care teams. Teams become responsible for panels with patients, and so I'm concerned that we have this ramp-up at CMS when the rest of the field is moving in a different direction.

CO-CHAIR BAGLEY: Robert.

MEMBER ORLOWSKI: If you have a comment on that?

MS. HOVATTER: No. Thank you for that, but --

MEMBER KRUGHOFF: I guess I have a counter point to that, and I think what makes sense at the individual physician level really depends on the measure -- the type of measure

itself. There's a whole lot of evidence then on communication skills, or communication performance. Most of the variation takes place and still takes place at the individual physician level. You can have groups and some do much better than others, also, and that's a patient experience-type measure. Also, patient experience measures you don't have the kind of sample size issue that you have with a lot of clinical measures. So, I think you need to have a nuanced approach to which measures you focus at which level on. And I think you will find that there are some measures patient -- for instance, we've just done something on surgeon ratings and the surgeons are not greatly excited about what we've done, but we actually have found a lot of variation among surgeons in terms of outcomes even at the individual surgeon level, but faced with real sample size issues there. So, I just think that has to be nuanced, and I do think that consumers do care that, you know -- rightly or wrongly they care about variation at the

individual physician level. And beyond that I would say in many cases it's rightly. Okay? They really are right to focus at that level. Okay, I'll stop for now.

CO-CHAIR BAGLEY: Other comments or questions? Did you have anything to add to that?

MS. HOVATTER: No, no. Thank you for that, and thank you, Reva.

CO-CHAIR BAGLEY: Alesia, thank you very much.

MS. HOVATTER: Yes.

CO-CHAIR BAGLEY: So, now we will move on.

(Pause.)

CO-CHAIR BAGLEY: Yes. We're going to move on to the derm measures, and invite public comment before we have the lead discussers talk.

DR. WINKLER: Let me just -- yes, on the measures under consideration list we have five process measures that we've grouped together in the first consent calendar. These measures were submitted by the American Academy of

Dermatology, and they address non-melanoma skin cancers. All five of those measures are still in development. The testing results are expected in the summer or fall of 2016. They've indicated that the data source will be claims and registry, and the registry that they are intended for is their -- is AAD's clinical data registry that will be launched in January of 2016.

So, I'd also just want to call your attention to the spreadsheet that we shared with you over the last several months of the current measures in the clinician measure set. There are over 300 of those measures. We've tried to categorize them in a way that would be easy for you to look at them to ask what's currently available for dermatology as you look at the new set. So, there are five existing measures for melanoma and psoriasis, but none for the non-melanoma skin cancers, so these are a new topic area. There is one related measure around biopsy follow-up, though it is not the same measures that you see on these measures under

consideration. So, Bruce, I think --

CO-CHAIR BAGLEY: Now I'm going to open it up to the public comment. Introduce yourselves.

MS. CARTER: Thank you. Can everyone hear me?

CO-CHAIR BAGLEY: Stay close to the mic.

MS. CARTER: I'm going to be close to the mic. So, hello, everyone. My name is Stephanie Carter. I'm with the American Academy of Dermatology.

I just wanted to say that we're pleased that five measures of the skin cancer measures are under consideration. Including these measures in this would help to fill two gaps primarily with having measures that address patient care, as well as providing more measures for dermatologists to be able to report.

These measures focus primarily or all on non-melanoma skin cancer which are basal cell carcinoma and squamous cell carcinoma, which 4

million new cases are diagnosed each year in the U.S. So, including with these five measures, two of them address appropriate use criteria for --

I'm sorry. Of these five measures, two of them address appropriate use criteria for most surgery, two for timely reporting of skin cancers and receiving biopsy results, and one with skin cancer prevention measure. All of these measures are part of a long term effect for the Academy to build a portfolio of performance measures that will be important to dermatology care topics of skin cancer. These measures have been specified and they are currently in field testing, and have been specified for the clinical registry data derm that the Academy will be launching next month. So, thank you for your consideration.

CO-CHAIR BAGLEY: All right. I don't see any other public commentary. Can we go on -- anybody on the phone? Sorry, thank you.

OPERATOR: If you want to make a public comment, please press star 1.

CO-CHAIR BAGLEY: Please go ahead.

OPERATOR: There are no public comments at this time.

CO-CHAIR BAGLEY: Okay. We have lead discussants. We're going to go to Scott and Steve. We'll have the discussion first? Okay. I'm getting direction from my partners up here. Okay. So far we have -- there's -- let me just point out. There's five bullets on your agenda, and there's 10 items on your discussion list, so each one of the bullets is for consideration under MIPS and under Physician Compare. That's why there's two times as many discussion points.

So, so far we have had extractions on the first, second, and fifth bullet, so that would be those corresponding discussion items.

DR. WINKLER: And those are for MIPS.

CO-CHAIR BAGLEY: Right. Are there any additional extractions at this time? Steve?

MEMBER FRIEDHOFF: Four.

CO-CHAIR BAGLEY: Okay.

MEMBER FRIEDHOFF: For 9 and 10, the preventive screening for transplant patients.

CO-CHAIR BAGLEY: Okay. So, the only one that's not been extracted is 3. Is that right?

MEMBER PACALA: I'm confused. When you say 1, 2, and 5, do you mean --

CO-CHAIR BAGLEY: I'm talking about the bullets on your agenda.

MEMBER PACALA: So, that's --

CO-CHAIR BAGLEY: Right.

MEMBER PACALA: Right. So, that's 1-4 and 9 and 10.

CO-CHAIR BAGLEY: Correct.

MEMBER PACALA: Thank you. Okay. So, we have -- the only one we have left is the third bullet which would be 5 and 6. Okay.

CO-CHAIR BAGLEY: Okay, thank you. Sorry for that. I think we can go ahead, and if there's no objection to accepting what would be bullets 3 and 4, which would correspond to discussion items 6-10, 6-8. We'll go ahead and accept them.

5-8.

Right, that's really -- that's the best way to look at it. They have not been pulled. Any objection to accepting the Staff recommendation? I don't see any, so let's go ahead. Now, Scott and Steve.

MEMBER FRIEDHOFF: So, for the clinician reporting time, just a couple of comments, and I think my ultimate conclusion is recommendation is encourage continued development with a few caveats.

I think that most would agree that we want to insure that biopsy results are communicated in a timely fashion, but by communicating an average I'm not sure, do we have an understanding of what the patient as a consumer expects when they're looking at this kind of data? And is it meaningful for a patient to compare whether they get results back in two weeks, three weeks, or four weeks as long as it's communicated, you know, within a reasonable time frame, whatever that might be?

So, for that reason, I was thinking

that maybe average isn't necessarily the best way to measure this. That can mean a lot of good and a lot of bad, whatever that means, with the average being somewhere in the middle, that could suggest a lot of variation. So, one thing perhaps to consider might be a targeted time frame and the percentage that meet that time frame, as opposed to an average as part of the continued development.

And then my third comment is that the core of this measure is communicating critical results back to the patient. And I guess I was questioning why would we isolate this to pathology, as opposed to other critical lab results, PAP smears, mammograms, other imaging. It feels a little myopic in that way.

MEMBER FURNEY: I would echo that, and just add, what causes the patient the most anxiety is the fear of the unknown. So, the fact that we're specifying certain pathology types to be reported instead of all biopsy reports, I think we could simplify as we develop the

measure, simplify that all results need to be communicated within a period of time, whether we decide it is more practical to do it based on median and standard deviation or a critical time frame. But if we're focusing on the patient communication, it is knowing when the result is back regardless of pathology that's important to the patients.

CO-CHAIR BAGLEY: Go ahead, David.

MEMBER SEIDENWURM: One thing I was concerned about, and I think this applies more broadly to just, you know, the current clinical situation is, I don't think that we want to encourage the dissemination of the wrong information quickly. I think we'd rather also have some measurement that would get at the accuracy of the information or standards around the performance of the test that we're reporting. So, I think if we're going to have a standard like this, it ought to be married with some other richer data sources about the actual accuracy of the biopsy, whether appropriate standards for --

and that's just in this one example. It would apply to other procedures, as well; you know, whether the procedure was done in the correct way, whether the biopsy was necessary in the first place. You know, and you could go on from there.

CO-CHAIR BAGLEY: Stephanie, did you have a comment since you're the one who extracted these?

MEMBER GLIER: I did, and I actually want to respond first to Steve. I think -- maybe I misunderstood the specs, but it looks to me like the numerators have a specific number of days in which the response has to get back either to the patient or to the biopsying clinician. Is that -- did you read it differently than I did?

MEMBER FRIEDHOFF: I think I was focused more on, you know, the length of time taken. It's -- maybe I was reading that incorrectly, simply implying an average rather than a threshold.

MEMBER GLIER: In the measure

specifications for both of them? So, for the biopsying time, biopsy reporting time, clinician which is the first -- measures 1 and 2, or bullet 1, depending on how we're counting these, it's -- the number of cutaneous biopsies where the final biopsy pathology findings were communicated within 15 business days from when the biopsy was performed, and for the pathology measure it's within 5 business days from when the biopsy was submitted from the clinician to the pathologist.

I'm okay with those as a general threshold. I don't have any evidence to suggest that that's the wrong number of days. My concern with these measures is that I don't see value in separating the pathologist measure from the clinician measure overall. I think what we're trying to measure here is how well a clinician who performs the test is able to get those test results back to a patient who is concerned about a finding. Back to this question about fear of the unknown. I think we want to make sure that patients are being informed about their health

conditions as quickly and as accurately, but as quickly as we can to alleviate the fear of the unknown in the meantime. And I don't see a lot of value for an accountability program to separate the what happens behind the scenes from a patient. So, if a patient gets a biopsy and the clinician takes that sample and sends it to a pathologist, and the pathologist does whatever the pathologist does, and then sends something back to the clinician, before the clinician can get back to the patient, that's fine. The workflow is fine, but I don't think that the measure of what happens behind the scenes is useful for us as an accountability measure. I think it would be great to have that as a QI measure. If the dermatologists want to include it in their registry more power to them, but I think I have some concerns about having it as a separate measure for use in MIPS.

CO-CHAIR BAGLEY: Amy next.

MEMBER MOYER: I guess I don't know what the evidence is behind the 15 business days

notification. That felt a little generous to me. It doesn't really feel like we're pushing the envelope there. I mean, at a minimum that's three weeks to let a patient know about a result. And the other thing that I'd like to see that I didn't see at least called out in the specs attached was, what do we mean by communication? Did you drop a letter in the mail? You had a conversation with the patient? You know they received the results, just maybe a little bit -- something a little bit more definitive about what does it mean to communicate those results to a patient.

CO-CHAIR WHITACRE: If I could just take off my co-chair hat for a minute and speak as a practicing breast surgeon. I deal with this every day, so if I could just add a level of granularity to some of these points, because they're all important, but there's really more behind the scenes.

First of all, we may not control the length of time it takes for a pathologist to get

us a printed report, and the final printed report is what matters because if you get a preliminary verbal report that says it's benign, but they don't tell you about the atypia, the discussion you're having with a patient much later is completely different, it really results in a lack of confidence, and disruption of flow, and disappointment, not good care.

What happens is, in terms of reporting the pathology reports, local takeover by another group, the hospital now, the secretaries can't do overtime. This is happening in Tucson right now. I don't get printed reports. It can take two weeks for things that used to take five days, so I tell the patients five days and it's coming back in two weeks. So, while I agree that in a systems environment where the system controls everything, that's fine, but where you're dealing with independent contractors, which is still a good part of medicine, separating the pathology time generated report versus the clinician time allows you to separate where the flaw may be. And

how the data is communicated is also very important, but it's going to vary based on pathology type, patient. I don't know how that can be better specified in the measure.

CO-CHAIR BAGLEY: Jim, you're next.

MEMBER PACALA: Well, I wanted to pick up on Amy's point. I mean, does notify mean that you've attempted to notify, or that you have actually spoken to the patient? And those are -- I think those are important. We have a number of patients in our own clinic who you try to get a hold of them and you have to send in the Marines, basically, to eventually -- you know, or tackle them on the street to be able to talk to them. Even with serious news, so that's one issue. And I don't know if somebody who's an expert in communication quality measures would care to address that and enlighten us.

The second thing is, was there consideration of an allowance for interpreters? We have sometimes difficulty lining up an interpreter to convey complicated news to

patients.

CO-CHAIR BAGLEY: Janis.

MEMBER ORLOWSKI: Just to --

CO-CHAIR BAGLEY: Janis, hold on.

MEMBER ORLOWSKI: Yes.

CO-CHAIR BAGLEY: There's a direct response.

MS. AUTREY: So, we did receive actual substantive changes to this measure maybe a week or so ago, so we were not able to provide them to the Committee. But it actually addressed some of the concerns regarding how to communicate, and they specifically identify directly speaking with the patient as one of those criteria. Another one, documenting a telephone message or voicemail regarding availability of the lab results, and mail fax sent to the patient indicating availability of lab results. And then any HIPAA secure electronic communication with the patient discussing the diagnosis.

CO-CHAIR BAGLEY: Thank you for that. Janis.

MEMBER ORLOWSKI: I was going to comment on notifying, but I think it's been handled in regards to that. The second thing is just to add on to Eric's comments.

There are some specimens where the pathologic manipulation and review of it takes more than that amount of time. And I'm a nephrologist, and I can tell you that we can get -- for those who are not doctors, I apologize, but we can get light microscopies with the initial reading within a couple of days, but electron microscopy will easily take three weeks for processing and for it to be done in a final report. So, I think that what we have to do in this is we have to take a look at when the treating physician receives the final report and put timeliness around that, rather than starting the clock at a pathologist time that -- where it actually may take more than two weeks for the pathology work to be completed, especially as we look sort at some of the new markers and the gene sequencing, and the PCI that we're doing on some

of this tissue, I think we have to use the final report as the clock-setting event.

CO-CHAIR BAGLEY: Are there other questions? Yes, go ahead, Stephanie.

MEMBER GLIER: I'm actually wondering if there's somebody here who is a dermatologist who can speak to these tests, because I think your points are totally valid. If there are pathology tests that are going to take longer than the five days that are in the pathology measure, that will affect the 15 day total window that is currently in the measure. Yes, please.

MEMBER ORLOWSKI: Well, I can tell you melanoma is one of those tests. And there is atypia in cells.

No, I understand that but I'm giving an example. I'm giving an example that there are a number of dermatologic lesions that are difficult because you're looking at atypia, and it needs to go through a sequence and review.

CO-CHAIR BAGLEY: So, I'm hearing that -- by the way, Staff recommendation is encourage

continued development. I'm hearing that it should -- CMS should work to make it more patient centered, I think would be the first thing. And, secondly, maybe more generalizable, because if you stop and think about this, if you have one measure for each different diagnosis, you have 1,000 measures for every diagnosis. So, can we have a measure that's just about, you know, reporting to patients that would apply to, you know, a whole raft of diagnoses. Amy, go ahead.

MEMBER MOYER: Recognizing this was submitted by a specialty society for measurement of their members, I guess really hearing this sounds like a -- like one of those measures where it is the system, and the totality of the team. I mean, it's one thing if we're measuring from okay, the physician got the measure and didn't -- or got the results and didn't do anything with them. I'm okay with holding the physician accountable for that, but it really feels like this is one of those interactive, you know, how does everything get handed off, how does

everything play well together? I mean, I'd be interested in doing this for a system, but I would find it challenging to, I think, hold a physician accountable for this, I'm not a physician, but --

CO-CHAIR BAGLEY: It certainly does get to clinical integration, doesn't it? Peter, you were next.

DR. BRISS: Yes, I was thinking about -- maybe this is piling on, but I'm inclined to say that this kind of a measure is never going to move the system in an important way. It's too narrow. And, you know, the truth is, I'd like to see them make one measure -- to the extent that timeliness is a problem, I'd like to see one measure that said -- that was patient centered that said did you get all your relevant results in some reasonable amount of time? And you could do that with one measure, and that would incent the system to solve some of the problems that Eric was talking about.

CO-CHAIR BAGLEY: Comments?

DR. WINKLER: We actually wanted to invite the measure developer to sit at the table to discuss and answering questions that the Committee had.

MS. CARTER: If anybody had a question they would like me to address as a developer on the measure, they're more than welcome. If anybody wants to repeat -- I said if anybody has a question about the measures that they would like answered, and would like to repeat, then I'll be more than happy to answer.

CO-CHAIR WHITACRE: I have a question. Do you have adequate measures for your members to report to participate in quality reporting programs, or is this necessary to complete that set?

MS. CARTER: It would be -- currently we only have six measures on PQRS.

CO-CHAIR BAGLEY: Other questions? Are we ready to vote? Okay, it looks like the answer is yes. Do we have a voting option ready for that?

MEMBER GLIER: Are we voting on just the clinician measure, or are we voting on both the clinician and the pathologist measures?

CO-CHAIR BAGLEY: They're two separate ones.

MEMBER SEIDENWURM: Are we voting for both programs, or --

CO-CHAIR BAGLEY: You're only voting for MIPS.

MS. CHAVEZ: Okay. Now getting ready to vote on MCU15-215. The voting options are 1, encourage for continued development; 2, do not encourage further consideration; 3, insufficient information. Voting is open.

CO-CHAIR BAGLEY: Go.

MS. CHAVEZ: For those on the phone, please submit your votes via chat. Thank you. Okay, 77 percent encourage for continued development, 23 percent do not encourage further consideration, zero insufficient information. The vote is for encourage for continued development.

CO-CHAIR BAGLEY: Okay, let's go on to

the pathologist. You want to read it?

MS. CHAVEZ: Okay. Now voting on MCU15-216. Same options, 1 encourage for continued development; 2 do not encourage further consideration; 3 insufficient information. Voting is open. Okay, 59 percent encourage for continued development, 41 percent do not encourage further consideration, zero insufficient information.

CO-CHAIR BAGLEY: You'll note that that's 1 percent lower than 60 percent.

MS. CHAVEZ: Yes.

CO-CHAIR BAGLEY: Did you get votes from the phone?

MR. LYZENGA: We did, so that -- just to clarify, Reva, that means do not encourage further consideration, the final decision?

CO-CHAIR BAGLEY: Cindy.

MEMBER PELLEGRINI: Just a quick question for our guest from EED. Just -- it just occurred to me as we're looking at this, did EED develop the pathology measure in consultation or partnership with pathologists?

MS. CARTER: So, it was in consultation -- well, we have workgroups that we work with to help develop the measures, so on those we have dermatologists and most surgeons that in some cases they could -- most surgeons do do their own pathology, but we didn't have like a pathologist.

CO-CHAIR BAGLEY: Go ahead, Scott.

MEMBER FURNEY: There were a couple of comments submitted on this measure. One was from the College of American Pathologists, and they were not supportive of this for many of the reasons we've already discussed. Interestingly, the American Society of Dermatopathology was in support. Both of them commenting that the number of measures for pathologists is very limited, which is what I believe was behind part of the development of this. So, if we don't continue with this, we'll have a continued gap to close as we recommend new measures. Pathologists having very few, unfortunately, at this point will have to consider others.

CO-CHAIR BAGLEY: CMS has heard your

comments. Okay. Are we ready to go on to the next one? So, the next -- the last one is the use of preventive screening protocol for transplant patients. Go ahead.

MEMBER GLIER: Me again?

CO-CHAIR BAGLEY: Yes, please.

MEMBER GLIER: So, my concern with this measure is that it is a documentation measure, and it seems very unlikely to me to actually achieve the stated goals which are to insure health promotion using three tiers to increase knowledge screenings and protective methods to limit the morbidity and mortality that can result from non-melanoma skin cancer. So, I find it hard to believe that documentation is going to achieve that. If there is a way to develop the measure further to be more closely tied to those outcomes, it would be great to see that, but I'm skeptical about its current format.

CO-CHAIR BAGLEY: Steve, go ahead.

MEMBER FRIEDHOFF: This is a little bit of a picky point, but if we're thinking of this

in the context of dermatology measures it seemed to me that this was more of a transplant measure. I mean, the analogy might be, you know, a dilated retinal exam being considered an ophthalmology quality metric as opposed to a diabetes care quality metric. So, it seemed a stretch to include this in dermatology for that reason.

CO-CHAIR BAGLEY: Are there other comments? It would seem -- to your point, it would seem like there's a whole raft of things that a transplant patient should have, and this ought to be on it, as opposed to the other way around. Right? Other comments or -- do you have comments about the measure?

MS. CARTER: So, for this measure it was looking to -- or sun protection or prevention -- or skin cancer prevention for transplant patients who are at a higher risk of getting cancer, skin cancers because of transplant and lower immunity. So, we did think this was important. We were not -- I think by making a measure that would encourage the education of

skin cancer, to be more hyper vigilant in, you know, doing some protective activities, clothing, or sunscreen, or things like that, and just making that a part of practice for dermatologists would help to lower that risk of skin cancer. So, we did -- but we did want to --- we did support the measure in the hopes that it would lower skin cancers for transplant patients who are just at higher risk of getting them. So, were there any specific questions?

CO-CHAIR BAGLEY: Beth, why don't you go ahead.

MEMBER AVERBECK: Was an intended group to be measured dermatologists, or anyone seeing a patient who is a transplant patient?

MS. CARTER: With the measure as written, it was for dermatologists, so they're more likely to -- I guess they would be more the specialty that would be looking at skin cancers, or be doing this, but it could be for any provider, actually. So, as long as they, you know, know that the patient is a transplant

patient they can give them education about sun protection since they are high risks.

CO-CHAIR BAGLEY: Scott.

MEMBER FURNEY: If the denominator is all transplant patients there would be no way to hold dermatologists who haven't been consulted to that metric, so it would have to be a transplant team metric to work, has already been discussed. There would have to be a checklist.

As far as a measure, I think as a process measure it is reasonable, but the attribution will have to be to their transplant surgeon.

CO-CHAIR BAGLEY: Other comments? Yes, Peter.

DR. BRISS: If you were going to address this issue, I agree with Bruce, it ought to be a component of a composite measure about what are the most important things to do for transplant patients? It doesn't seem to make sense as a standalone measure.

CO-CHAIR WHITACRE: And surgeon comment

just in terms of knowledge, I was not aware how important this was. But when I touched base with my transplant colleagues, this is apparently a big deal. And they do address it as a team, so I'm not -- I can't speak to the measure, but clinically this is actually very important, and it needs to be assessed in the system.

CO-CHAIR BAGLEY: I don't see any other comments. Anybody else? Okay. Are we ready to vote? Okay, let's do it.

MS. CHAVEZ: Okay. Now voting on MCU15-177 for MIPS. So, options are 1 encourage for continued development; 2 do not encourage further consideration; 3 insufficient information. Voting is open. For those on the phone, please submit your votes via chat. The results for MCU ID MCU15-177, 50 percent encouraged for continued development; 45 percent do not encourage further consideration; 5 percent insufficient information. So, vote is for do not encourage further consideration.

CO-CHAIR BAGLEY: Okay. That concludes

the dermatology section. Now, we have an option to go for a break, or press on. How many want to press on? Okay. You're late voters, huh? Okay. Looks like we ought to press on, so let's do that.

DR. WINKLER: Okay. Our next topic area is in eye care. And what we have are 12 new outcome measures for various eye conditions submitted by the American Academy of Ophthalmology. These measures are still in development, they're still undergoing testing which is expected to be completed in the spring of 2016.

These measures are currently specified for registry-based reporting and electronic capture from EHRs for use in AAO's IRIS registry. And these measures are included in their QCDR for PQRS reporting in 2015 for eye care. So, there are currently about 14 measures for eye care in the clinician set, five of them address some of the conditions that you see here, both diabetic retinopathy, glaucoma, and macular degeneration,

but those others were process measures, so this provides some new outcome measures. But in addition, seven of the measures address new eye care conditions that are not in the existing set. So, with that --

MEMBER GLIER: Oh, right. I was going to say, we're on to public comment.

MS. HANCOCK: Hi, Rebecca Hancock with the American Academy of Ophthalmology. I just wanted to share a few points on the eye care measures that are up for discussion now. All of these measures were developed by the Academy in conjunction with the major sub-specialty societies. They're fully specified and were submitted to and accepted by CMS as qualified clinical data registry measures, and they are currently in use this year by physicians using the Academy's registry, IRIS registry, qualified clinical data registry option, QCDR option to participate in PQRS.

At the end of this calendar year, we will have a full year's worth of data, and are

hoping to wrap-up testing and have the measures fully completed by early spring next year, so they will be ready for use in MIPS in 2017. These are all important patient outcome measures, and we encourage MAP to offer their support for them. Thanks.

CO-CHAIR WHITACRE: Are there any other -- is this questioning for the --

MEMBER GLIER: Sorry. Amy, would you stay for a second? My question is if these are already accepted by the QCDR program and being reported that way, and you're hoping to finalize testing in the spring, if we offer recommendations for encouraging continued development in a particular direction, is the Academy open to those suggestions?

MS. HANCOCK: Yes.

CO-CHAIR WHITACRE: Are there other comments, other public comments either on the floor or on the phone?

OPERATOR: At this time, to make a comment please press star 1. There are no public

comments from the phone line.

CO-CHAIR WHITACRE: Great. Thank you very much. So, a couple of measures have already been pulled, and I think the simplest way to do this is probably to use the agenda with the bullet points because it's really unwieldy in the discussion document because of the public reporting issues.

So, I went ahead and in my mind and on paper went every third measure, so the first number 3 was Exudative Age-Related Macular Degeneration. If I counted correctly, six was Corneal Graft Surgery - Postoperative Improvement. Number 9 was Acute Anterior Uveitis - Post-treatment visual acuity. This is just for reference later. And number 12 is Chronic Anterior Uveitis. Saying each one of these each time is going to be difficult, so I thought going through these -- so, the measures that have been pulled are number 3, which is Exudative Age-Related Macular Degeneration, loss of visual acuity. Stephanie, that's you. Then number 7,

which is Surgery for Acquired Involutional Ptosis: Patients with an improvement of marginal reflex distance. And that's pulled by Bruce. And then the one following that, Acquired Involutional Entropion: Normalized lid position after surgical repair. Again, I think, Bruce, you pulled these as a pair. And then number 10, which is Acute Anterior Uveitis: Post-treatment Grade 0 anterior chamber cells, by Stephanie. And number 12, Chronic Anterior Uveitis: Post-treatment Grade 0 anterior chamber cells. I think I'm ready to sit for my ophthalmology boards after doing this. Holy smokes! I would either have pulled none or all of them, but anyway. So, are there any other measures which the members would like to extract from this group? Yes, David.

MEMBER SEIDENWURM: In the new taxonomy, number 12, intra ocular Pressure Reduction following Laser Trabeculoplasty. Number 2, I mean. Did I say 12?

CO-CHAIR WHITACRE: Number 2? Oh, that helps. Okay.

MEMBER SEIDENWURM: Sorry.

CO-CHAIR WHITACRE: Okay, David. All right. Any other measures to extract? Terrific. Stephanie, shall we start with you? I assume you had a method here.

Oh, sorry. I guess we should -- we can accept the consent calendar which would include Measures 1, Glaucoma, Intra ocular Pressure Reduction; number 4, Non-Exudative Age-Related Macular Degeneration loss of visual acuity; the one following that, Diabetic Macular Edema, loss of visual acuity; number 6, Corneal Graft Surgery Post-operative Improvement in visual acuity; then number 10, no, excuse me, number 11, Chronic Anterior Uveitis: Post-treatment visual acuity. Sorry. And number 9, Acute Anterior Uveitis: Post-treatment visual acuity. Gosh, yes.

MEMBER KRUGHOFF: Can you give us some sense of the implications and the reasons to care about knocking anything off this list? I mean, the reasons I could imagine wanting to knock things off a list would be that they're -- well,

one would be that they don't seem to be valid, but beyond that, you know, if they're too burdensome and the number of patients impacted are too small, you might not want to do these things. On the other hand, if the society has already built these things into its registry program and stuff, you know, that wouldn't -- it wouldn't be very compelling to me as a reason to get rid of it. It might be compelling to not put the results on the Physician Compare website, but even then to have it in the database doesn't seem like a bad idea, because somebody else who's really focusing on this particular field could make it available to patients in a patient forum setting or something like that, drawing on the, what you call the spreadsheet, what we call the spreadsheet here. So, I don't have a very good way of deciding why to get rid of any of these things if the society is doing it, and the data are coming in.

CO-CHAIR WHITACRE: Well, we think alike and this is the challenge for the members

who extracted the measures. Stephanie, go ahead.

MEMBER GLIER: I have two comments, one is a logistics, which is really that I meant to pull 3 and 4 together as a pair. So, before we do the consent calendar, I didn't tell you that, so there's no way you could have known. That was on me, not on you.

My second comment is sort of a response to Robert, and I'm wondering if instead of pulling up the discussion guide on the screen that we're all seeing, if we could go back to the slide with CMS' principles for MIPS, because I think it would be helpful for everyone to be looking at what it is that CMS is trying to build in this program as we're thinking about the measures that are currently proposed, and using that as a bar to say are these measures -- do the measures we're looking at here, even if the ophthalmologists are already using them in their registry, they can use them in their registry for many purposes, including quality improvement, including benchmarking, including peer

comparisons, but are they a fit for MIPS? Are they going to add meaningful information for this accountability program? And if the answer is no, then I would urge us to use our judgment and take a little bit more of a conservative approach about recommending more time and money put into developing these measures for accountability purposes if they don't seem like they're going to be useful for that purpose.

CO-CHAIR WHITACRE: If we can first agree on the consent calendar with the slight change of Measure 4 being pulled, as well. Is everyone in agreement that we can accept the other measures? Beautiful. Please, Stephanie. You'd like to go through where specifically the MIPS principles you think these measures do not satisfy, or may not satisfy those?

MEMBER GLIER: Oh, and I did not actually mean to do a crosswalk specifically to that.

CO-CHAIR WHITACRE: Oh, okay.

MEMBER GLIER: I just thought this

would be a good reference point for people to be able to look at --

CO-CHAIR WHITACRE: Okay.

MEMBER GLIER: -- as we're going through the discussion.

I think I'd like to take more of a questioning approach for the measures that I pulled. Your name is Amy. Right?

MS. HANCOCK: No, my name is Rebecca.

MEMBER GLIER: Rebecca. I'm sorry.

MS. HANCOCK: And Dr. Friedman is an ophthalmologist, and he's representing the Academy, so he hopefully can help me in answering any of the clinical-type questions.

MEMBER GLIER: Thank you. Well, then a question to both of you is, is there a reason to separate the wet and dry macular degeneration measures from each other?

MEMBER FRIEDMAN: Okay, my area of expertise. So, the answer is yes. We -- macular degeneration is the most common cause of vision loss in Medicare patients and patients over 75.

And, basically, we generically categorize it wet versus dry. Wet is more common, wet turns into dry, dry is more serious. We have more treatments for wet.

So, basically, we do have some -- there is some evidence that giving AREDS2, giving patients with dry macular degeneration, which is very, very common, if you treat them with vitamins and it's level 1 evidence, you can slow down the progression of wet macular degeneration and save vision. So, we have separate measures for dry because there is a treatment for dry. And then once they develop wet, we have different treatments for wet. We give them injections, typically. So, they're two slightly -- although it's the same area of pathology, we can separate them out basically into wet and dry, and they do have different treatments; therefore, we have two different measures to accomplish that.

MEMBER GLIER: And perhaps this is not as nuanced a question as I meant it to be, but

would it be possible to consider essentially like an optimal macular degeneration measure that included both treatment courses appropriate for the type of patient you were looking at? So, sort of a compound measure to say for both of these are you doing the appropriate care as determined by the guidelines that the Academy uses?

MEMBER FRIEDMAN: I suppose you do, but I think there's enough difference between the two disease processes and the treatments to separate them out.

CO-CHAIR WHITACRE: Yes?

MEMBER KRUGHOFF: Could somebody explain a little more what the implications are from MIPS of having a whole lot of measures in one field of medicine and a smaller number of measures in another field of medicine? It would -- my understanding is that the MIPS people would still be able in some way to weight those different -- maybe I'm wrong. Could they still weight those measures in the overall MIPS scoring and say well, these are more significant, affect

more people; therefore, we're really going to put priority on that. And so it's the MIPS people who, you know -- CMS who decides how to use all these measures and the weighting of all those measures, but not something that we really need to worry much about except that that's another thing that they might want to get some feedback on when they do it. But it's not -- I'm not -- it's not clear to me what the advantage is in getting rid of some of this information that CMS could have in scoring people.

CO-CHAIR WHITACRE: David.

MS. AUTREY: We had a large number for the larger specialties, but some of the sub-specialties, some of those measures aren't relevant for them. So, you will see in some aspects where there are a large number, but not all of the people in the sub-specialty actually can report all of those measures, so we do have a larger number. But then there are some specialties in which we just have fewer measures because fewer measures have been submitted. So,

it is not as if we have actually said that's how we want it, but that's just how it has occurred. So, we are looking for more measures so that more providers can have a plethora of measures that are relevant for their specialty, and sometimes their sub-specialties.

CO-CHAIR WHITACRE: David was, I think, first.

MEMBER SEIDENWURM: Sure. So, it's great to have an ophthalmologist here to answer these questions because we're getting into some highly technical areas.

My questions were around the questions regarding separating the glaucoma measures into the surgical and the non-surgical. Why not just have a general measure for how well you're doing with the intra ocular pressure? You know, why would those be -- why would those need to be separate? And then the other family of questions that I had, had to do with why one would select an intermediate metric other than visual acuity? I understand for intra ocular pressure it takes,

you know, quite a while for the visual acuity to deteriorate, so that makes sense. But I didn't have the knowledge base to judge the inflammatory cells in the other examples, so if you could address some of those questions in a way that some of us non-ophthalmologists could understand, that would be great.

MEMBER FRIEDMAN: Sure. So, one quick comment on the last thing that was stated, ophthalmology. So, there's some ophthalmologists -- there's a lot of specials in ophthalmology. For example, some ophthalmologists maybe limit their practice to retina, which is what I do. So, a lot of these measures wouldn't be applicable to me. For example, I don't treat glaucoma, so I couldn't report any of the glaucoma measures. There are some ophthalmologists that just limit their practice to uveitis, so we need to have a large group of measures that traverses the whole practice of ophthalmology, so for people that don't do glaucoma, don't do retina, there needs to be measures if they just limit their practice

to uveitis, for example, so they can report on that particular disease set.

Glaucoma, so the first question about glaucoma. Glaucoma, again, you can differentiate from a very common cause of vision loss, most common cause of vision loss in older age Americans, the Medicare population. You can separate that into medical versus surgical. And I think there's enough distinction between those two, if you -- that you can take the patients that are doing well, and you want to certainly have some guidelines or criteria for looking at treatment outcomes based on medical treatment. And then once they advance to that, we do procedures, surgical procedures or invasive procedures. And then at that point you can look at treatment outcomes based on surgery, so they get Procedure A. What was the result of that? So, we're looking at outcome measures now which we didn't before. We looked at -- our initial measure was reduction in LP, but now we're looking at -- we have more robust measures

looking at outcome measures seeing that now the patients that do have to go to surgery, what percent of those eyes do well? And I think there's enough -- you could, again, lump them in together, but I think there's enough distinction between the medical and the surgical to have separate measures for that.

And the other thing is that we do have -- general ophthalmologists treat a lot of early glaucoma, and so they can report on the -- most of the eyes that they're being treated with drops, but then we have glaucoma specialists, and they get the eyes that are doing poorly. And maybe they're doing surgery on the majority of the patients, and they're not seeing the easy glaucoma patients. And they need outcomes that they can actually report on, because they're specializing, they're limiting their eyes to the eyes that aren't doing well. And they get referrals from general ophthalmologists that are seeing the simple eyes, so they need measures that they can report on, because their patient

population is somewhat biased, because they have the worst cases.

CO-CHAIR WHITACRE: Barbara.

MEMBER LANDRETH: What this seems to me is that you may be risk-adjusting patients by developing additional measures, whereas in some other measures risk-adjustment is part of the measure. Do you see what I mean? In other words, is there a way that we can risk-adjust these patients so that you can look maybe not at so many measures, but look at the people who have -- you know, can easily be medically managed and their glaucoma is not at a severe level in the same bucket as you look at the more severe cases, but risk-adjust them.

CO-CHAIR WHITACRE: Robert.

MEMBER KRUGHOFF: Yes, I think that's a very good point. In a sense, you know, I'm -- without knowing what would happen, I'm prepared to sort of send all these measures to CMS to do whatever scoring it wants to do. But that does require some sort of weighting, and it requires

both risk-adjustment, which I assume they would do. But once you've risk-adjusted, you then have to weigh the measures and decide, you know, what the overall aggregate measure is in terms of, you know, quality and reimbursement, et cetera. And somebody is going to have to do that, and I don't have a picture of how that's done. On the other hand, I don't mind having a lot of them to work with. I'd like to have more confidence that they'll do a good job doing that part putting these measures together into some composite thing. But, you know, that's sort of a -- and one could combine them all with every procedure and every type of case being risk-adjusters, and have one overall measure for quality. And, of course, you'd have a lot more clinical information if you did it at that level rather than sending them off as end measures to CMS. But can anybody give us any feedback? Maybe nobody else needs the feedback. I need the feedback as to how CMS is going to behave with this stuff.

CO-CHAIR WHITACRE: Peter, and then

Cindy, and then Beth.

DR. BRISS: It seems to me that the strong format that Robert sort of -- I mean, if you really pushed that to its logical conclusion, then there's no sense of having a MAP. Right? So, it seems to me that our reason for being is to give CMS some advice about what things are relatively higher, and what things are relatively less high priority. And CMS can always take it or leave it. Right? They've been good historically about taking advice from the MAP, but it hasn't been 100 percent, so they can still do their internal decision making, but we can at least give them some advice about priority.

And the rest of your argument is that part of the problem is that we have an embarrassment of riches. Part of the problem is that it's impossible for even technically skilled people to sort through hundreds of measures and make any sense out of them. So, I would generally say having a smaller set of higher value measures would be a good thing. And it's not universally

true that more information is always better.

CO-CHAIR WHITACRE: Cindy.

MEMBER PELLEGRINI: I hope this isn't going to sound like I'm getting into semantics here, but I think we've got a nuance between what I'm going to call risk versus relevance. And there is that issue if the patients have different risk levels, which may refer to their degree of health, their capacity, their resources, their health literacy, et cetera, but then we've got the relevance of the measures to the physicians. And this came up at the certification meeting I mentioned I was at. In that context where they're saying, you know, if you're an orthopedic surgeon you may be an orthopedic surgeon who says, you know, I only do knees. Don't test me on elbows, don't test me on spines because I don't touch them. Right? So, I think we're running into that kind of problem here, and it's a very tempting thing to conflate those risk and relevance things looking at these measures. And we have to look at it from both the

patient side, and the physician side. This may be something that CMS has already kind of parsed out for themselves, I'm not sure.

CO-CHAIR WHITACRE: Beth.

MEMBER AVERBECK: Thanks. I was one of the reactors on this group, and so I think as a physician but not as an ophthalmologist, I was very encouraged that we were moving in the direction of outcome measures from the Academy, so thank you for that. And these are -- and I think, David, to your point earlier, these are new topics, new areas, moving some measures more towards outcomes. I'm encouraged that they're being field tested and that, hopefully, once they're field tested that they might be able to go through the NQF endorsement process, and continue to move down that path. So, that's just a general comment on the measurement set.

DR. GOODRICH: Well, since CMS has been referenced about what we'll do so often, I feel like I should respond. So, a couple of points to make.

I think what I was hearing was the issue of combining some of these measures and the need possibly for risk-adjustment. So, just as generally how this works, we didn't develop these measures, so I think AAO would take this feedback, and should they decide that it makes sense for some of these measures for them to be a composite, which is what you're talking about, I think, and risk-adjust them, they can do that. And then that measure would come to CMS to be implemented in that way. We don't risk-adjust on the back end or anything like that within CMS. We don't combine measures that don't come to us as composites. The developer really has the stewardship over those measures. We might encourage that as we work with the developers to do exactly that. They're getting that encouragement from you now, so that will be up to AAO as to whether or not they want to do that. We'll have ongoing conversations with AAO.

Around the issue of, you know, a plethora of measures because there's such a

variation in scope of practice, and all of that. That is a true thing that we are definitely seeing reflected here. I'll be honest. I do worry about some of the societies that haven't had many measures that are just getting into the measurement game that need measures that are relevant for them, and relevant for their patients for them to be evaluated on for accountability purposes for these programs.

Many of them want to participate these programs. They see a lot of Medicare patients, and so having measures that are relevant to them is really important. And I think it's a balance between having some measures that -- and having the right measures, and maybe over time getting to better measures. It is a balance definitely because, you know, you don't want to have -- as this group has worked hard with us over the past four years to get us to a place where we're seeing more outcome-based appropriate use measures and so forth, and we've made a lot of progress in that direction, not enough, but we've

made a lot of progress in that direction. So, we continue, especially as we see these specialty societies that are starting to get into the measurement development world sending measures to us to try to encourage moving in that direction. I think some have moved further than others, is essentially what I'll say.

CO-CHAIR WHITACRE: Thank you very much. Stephanie, I hope that helped address some of the concerns you have with the measures you pulled, because I know Bruce had pulled some measures, as well. So, if we could perhaps --- oh, other -- I'm sorry, I missed. Yes.

DR. ALEMU: Yes. When you have a large number of measures, I mean, we have to be selective. We know that there are a large number of measures out there, but there are different conditions which need to be looked at, the pre-balance of the condition is, you know, one of the most important factors in addition to relevance and other issues. But when it comes to, you know, these measures which we are talking about, there

are cases where you cannot make composite measures. The individuals will not -- you know, we cannot get them together in order to have one composite measure. So, we have to see it case by case and, you know, we have to look at in order to make it shorter, composite measures are not always the solution. So, it's -- you have to look at them case by case. And in this case, I don't see that making a composite measure solves the problem.

CO-CHAIR WHITACRE: Thank you. Scott, did you have a comment?

MEMBER FURNEY: I would encourage as these measures are further developed, the closer we can get to measuring patient-specific outcomes being visual preservation, visual acuity or preservation. It sounds like just in reading the measures we have intermediate outcome measures that should lead to that, and I think barring a -- to Janis' point earlier, barring a really good risk-adjustment system that would potentially be a bias against those that do secondary referrals

or tertiary referrals. So, I think the measures make sense to me now that they've been explained.

CO-CHAIR WHITACRE: Okay, thank you. Luther.

DR. CLARK: Was my understanding correct that these measures were developed by the Academy in conjunction with CMS, in consultation? Right? They were just submitted.

DR. GOODRICH: The Academy developed them. As we have with other specialty societies, along the way of development we'll connect and talk about it, and all that, but we were not involved in the development at all.

DR. CLARK: But you've had conversations as they developed.

DR. GOODRICH: Yes, and we talk with AAO a lot, gladly so.

CO-CHAIR WHITACRE: Scott.

MEMBER FRIEDMAN: I appreciate that point. So, some of these measures look at surrogates for visual function, so ultimately we're trying to prevent patients from going blind

and improve their vision. So, for example, the cell and flare, if we have one has persistent cells, if left untreated that will lead, ultimately, to vision loss, so we do have two measures and they kind of say the same thing, looking different ways of saying the same thing. Obviously, ultimately, we want to preserve vision. If you have persistent cells and if left untreated, you're probably going to lose -- there's a reasonable chance you're going to lose vision. Intra ocular pressure, if it remains high you're going to lose peripheral vision, eventually, and go completely blind, so that is somewhat of a surrogate for visual function. But I do agree with you. I appreciate that point.

CO-CHAIR WHITACRE: Yes, Robert.

MEMBER KRUGHOFF: Okay, I'll stop after this one. The -- I guess I'm wondering if we say encourage further development, could there be a way to amplify that a little bit and say see if you can come up with something that is more of a composite out of these things, because that

message doesn't get across by just saying don't encourage further development. If there's a potential for a composite, we might want to get that across, but also say encourage further development means to try and get a composite.

The other thing I guess I'd like to express is that I can imagine that consumers who have one of these conditions might be very interested in a rather narrow measure that really has to do with the particular condition I have, unless we know that there's a very high correlation between success in one versus another. But from a Physician Compare database website, the spreadsheet website level, why not make that information available? If the society is moving forward with this anyway, why not make that available so I could actually find out how this doctor does with my particular condition assuming there's adequate sample size. And sample size, you know, has to be a test here.

CO-CHAIR WHITACRE: Peter, and then Steve.

DR. BRISS: Scott, I'm another specialty that needs an education. So, I think I get the logic model for this, so the Uveitis will sometimes lead to vision loss. And what I can't get my mind around is why we need both measures. So, it might be that Uveitis is -- if you mean that they're both getting essentially the same conceptual thing and we might be able to choose one or the other, so you might -- if Uveitis isn't something you really want to treat, and vision loss is relatively rare or far in the future, you might choose the one. If vision loss happens commonly enough that what you're going to treat is the Uveitis, but what you really care about is the vision loss, you might be able to get away with the vision loss. I can't quite get my head around why we need both measures, and why we couldn't choose one as preferable over the other.

MEMBER FRIEDMAN: Sure. I think when you look at them -- so, again, Uveitis, inflammation cells, if you get rid of the cells

in theory you prevent vision loss. The other one looked at baseline visual acuity prior to the onset, so it's slightly different. So, if someone has developed Uveitis and they develop vision loss, you want to make sure they get their baseline vision back, so they're slightly different looking at the same thing, looking at it from two slightly different approaches. And I think there's enough difference between the two that we should probably include both of them.

CO-CHAIR WHITACRE: Well, thank you very much. That's a great discussion. Steve?

MEMBER FRIEDHOFF: Thanks. You know, I think when I first saw the list, I had similar concerns about the sheer volume, but as I heard your feedback, I think it all -- you know, it started to make sense as to why that they were separated both for, you have different clinical presentations to be in some specialization, et cetera. And I think as I think about it, again, I'm not sure what CMS' perspective is on this, but I would think that it's actually perfectly

fine for some specialties to have a lot more measures than others based on the volume of Medicare beneficiaries being seen, the potential for, you know, very good or very bad outcomes, the cost to the system. So, I feel like I'm a little bit less hung up on whether we have a lot for one specialty and few for another, especially if they're meaningful, they meet the MIPS principles. And, particularly, they're things that I think patients are going to be looking for. And if you think about if a patient may be looking -- I don't know that they would necessarily be shopping for a pathologist, and they might have a much narrower scope if they're searching for a dermatologist, but they had a very discrete ophthalmologic concern they might want this level of granularity.

MEMBER ORLOWSKI: So, the 50,000-foot view, it's been interesting to listen to the conversation. The way I view it is the ophthalmologists came forward and said measure us on these because they're important. You know

what? Measure them. And I think the rule is now is to link for the public why these measures are important. So, what we have to do is have verbiage that says the ophthalmologists know about cells and inflammation, and all this other stuff, but in the end, this links to loss of vision. And so I would say measure the ophthalmologists on these parameters. They're well thought out, they have, you know, sort of national association that's backed behind, and they're raising their hands and saying measure us on this. And they're not easy, they're not nonsense. And then what CMS needs to do is translate that into something that becomes understandable to the public of why you would want to know about these measures with your ophthalmologist.

CO-CHAIR WHITACRE: Great, thank you. Bruce, would you like to mention why you extracted the measures, I think 7 and 8. One more hand. Sorry, gosh.

MEMBER SEIDENWURM: So, the

conversation that's been going on here has been great, and I think that several of the physicians who sat around the table in previous years have made analogous statements that have not carried the day. So, I'm very glad that this perspective is seen as valuable as we move forward in these programs. And I think that was very well expressed, and thank you.

CO-CHAIR BAGLEY: Okay. I extracted these measures, this would be 7 and 8, because I wanted to hear -- I don't want to focus too much on the measures themselves. I want to hear some discussion from the workgroup about what I might call expected outcome measures. So, let me take it away from ophthalmology for a minute. If you have a measure about an appendectomy, and the measure is that the thing that goes to the pathology lab ought to be an appendix. That seems like that's an expected outcome, and unless there's some pretty big gap that we don't identify it every time, it's kind of a ludicrous measure.

So, Scott, forgive me. I'm going to oversimplify this, but for ptosis, that means lid hangs down, gets in the way of your vision, and if you do an operation the marginal distance should be greater. In other words, it ought to get farther away from the center of the cornea. So, that's kind of an expected outcome, so unless there's a failure rate of, you know, 80 percent, or 20 percent, or something like that, it doesn't seem like a reasonable outcome.

And I applaud the fact we're trying to get to outcome -- please bear with me for a minute. The other one, Entropion, for those of you -- that means that the lower lid, usually in older people tips in. And the patient-oriented problem is that tears run down their face all day long, any time they're upright. So, the measure, if you really want an outcome measure, not whether we put the lid back where it belongs, is do the tears no longer run down my face. You know, that's the better approach to a patient-oriented outcome. So, I don't want to focus too

much on these two measures because I want to applaud the idea that we're trying to move towards outcome measures. But I want to hear a general discussion about what is an expected outcome versus a gap in care that measures might drive a reduction of?

CO-CHAIR WHITACRE: Yes.

DR. WINKLER: Can I make a comment? Yes, and when we were going through these in the preliminary analysis, one of the challenges we had was exactly this question, because what we did not have was really any information, any data on what current performance is. And that made it very challenging to understand really, you know, is this going to have an impact on patients, because if performance is currently wide-eyed, well, there's not much this measure is going to do to improve that. And that lack of information, I think, underpins some of the comments that you're making right now, and is problematic not with just these measures, but we found it pervasive through a lot of the measures. So, just

to tell you, I found that extremely challenging in looking at the measures.

CO-CHAIR WHITACRE: Luther.

DR. CLARK: Yes. Bruce, I think that's actually a really great point, and it goes back to a couple of the questions I asked earlier, because one can have a clinical outcome which is a measure of success, but then when you think about, you know, what's important to the patient, it may be something different, although related. And I think those two examples you gave are really excellent ones. And maybe an approach to that is just thinking about them in terms of outcomes that really patients value versus outcomes that reflect a clinical success. And I think when we say that measures are patient centric or in that category, it's an important distinction.

CO-CHAIR WHITACRE: Robert.

MEMBER KRUGHOFF: I promised I was finished, but I think when you look at all these things you're wondering about the incidents and

the variability in outcomes. These may all be topped out measures, which is the reason we get rid of measures all the time here, so we really do need to know that kind of thing. This is just an uncomfortable sort of voting situation for us here because we don't know those things, and to say -- to not vote in favor of further development seems to me to be kind of too bad, because I really want to know more. Right? And so I'm just not quite sure what our -- whether there's some way to supplement a negative vote on some of these things by saying but yes, if there's big variation and there's a high incidence of this thing, we'd like you to go on.

My attitude has been, hey, this sounds like a freebie. The doctors want to do it, so I'm all in favor of all the data you can get out there, and then anybody who's going to end up reporting on it -- yes, I wouldn't put -- we have a choice. Should we put it on the visible Physician Compare website, or should we put it in a downloadable database, and if it's not very

important, we only put it on the downloadable database. And if anybody wants to take it and use it, I think that's the best role for the government, anyway, in all of these measures, is to make more data available so that the patient group that's trying to figure out what they want to do with a particular kind of eye condition, can go in and look at it. So, it's all good to have this stuff, unless it's too big a burden on the doctors to do it, relative to the benefit.

MEMBER FRIEDMAN: So a couple of things. So with the question of the ptosis, I agree. You hope the patients are getting better and not staying the same or even more importantly, getting worse; but unfortunately, you'd be surprised. So we think this is significant enough to where we'd like to measure it, and if 99 percent of them are getting better, then maybe we can do away with this measure. But again, it's what Rebecca said, we don't have the data yes for this and the other measures, if our other measures are also topped out, we certainly

don't want to use those, but until we get the data and have a reasonable amount of data to look at what's going on, we think that we shouldn't move forward.

And again, the analysis is encourage continued development, so the measures, at least our particular measures aren't done, they're not ready for prime time, but we're working forward with them and we think we should continue to move forward. Stephanie?

MEMBER GLIER: Yes, I guess I want to respond to Robert's point here a little bit, which is a little philosophical and it maybe goes back to a question he was sort of asking earlier, which I think is to CMS, about whether it's possible in the mixed program to weight measures differently so that people could get a higher score for a more important measure or the equivalent. So if there are measures that we think are just sort of okay, but we need them to fill gaps or we need them to make sure that all subspecialists are able to report something that

is very relevant to their practice, maybe CMS is able to do some program design to weight them more heavily or less heavily based on their relevance to these principles, based on how important they are to consumers. And Kate, you can weigh in on that if you want. Do you want to? I have one other comment to make, but--okay.

But I think we--I agree with you that more information is going to be useful, but I think our role here at the MAP is to tell CMS what measures we think are going to be valuable for accountability. NIPS is going to be a--is an incentive program, it's a 4 percent bonus or 4 percent ding based on your performance, and if we say yes to every measure that comes in, and I'm not--this is not about the ophthalmology measures; I think actually you guys have done an incredible job moving towards outcomes, and I really appreciate all the work you've done thinking about what is important to patients and their function and trying to turn those into

things that are related to care. But in some of the other measures, you guys are going to hear from me a lot today--it's going to be just The Stephanie Show for most of the afternoon too--I think there's some places where the measures are really--they really are standard of care; they really are did you do a surgery and did the surgery do the thing that you were supposed to be doing the surgery for?

That's not useful information in terms of an accountability. We shouldn't be rewarding you for succeeding at the very basic function that you were trying to do. If it is very high quality, great, and maybe we can talk about performance gaps then. But without that data, I think we have to be a little bit more critical of the measures we're looking at. So that's--

CO-CHAIR WHITACRE: So Kate, then Scott, then Jim, then Rachel.

DR. GOODRICH: So on MIPS, we do have the flexibility within the parameters of the MACRA statute to do that kind thing. I will tell

you in our request for information, we got comments from some who said we should weight measures differently, and some who said we shouldn't, so there's obviously a variety of opinion on that. I would also like to say that when we develop measures at CMS, part of our initial process is to do something called building the business case for the measure, which has a number of criteria to it, but a big one is performance variation; that goes for process or outcome. And so I will say with a lot of the measures on here, as we were reviewing them when they came in to us, you know, I just want to sort of re-emphasize what Reva said, we had the same bit of a frustration of, you know, this looks like a great outcome measure, but is there a variation? Is it--we didn't know, and sometimes people don't know; you don't really have good data, so you have to talk to the professionals who really know the world better than you do to understand it, but I will say that has been a frustration.

But one of our core principles--those of you who have heard me talk about our core principles for measure development at CMS--is that there be performance variation. So that is something I think we would want to know before implementing a measure, and we don't always know it, quite frankly, in time for the MAP; sometimes we know it a little bit later, so to the extent we can get that information, that'll be helpful for us as well.

MS. HANCOCK: Yes, and I think we could get you some information after we get data when the year concludes.

MEMBER FURNEY: Just a quick comment as a non-ophthalmologist about these two measures, the surgical measures for both ptosis and entropion. It seems like we're really looking, we're trying to define an outcome from the surgeon's perspective; it would be interesting as the measure is developed to have a patient outcome. So patient satisfaction obviously, most physicians do not want to be

measured by that, but that's ultimately, have you satisfied the patient's need with the surgery is probably better than the anatomic outcome..

MEMBER FURNEY: I'll just react quickly by saying that we have plans to continue measured development efforts in the future and patient reported outcomes and outcomes around what patients want is definitely something that we plan to focus on.

MEMBER PACALA: Yes, just adding on or continuing Bruce's point about really the distinguishing ability of a measure. I'd like to ask Scott, Dr. Friedman, about the macular degeneration measure. So from your experience, the outcome is being defined as a loss of less than .3logMAR of visual acuity; I don't know what that is, but first of all, is that a good distinguishing cut point? That would be number one; two is it clinically meaningful, and then I guess the third question would be is there a potential downside to this, of setting up adverse selection? In other words, would a patient who

perhaps should be operated on for macular degeneration or get VGF agents perhaps could there be a disincentive for the practitioner to say oh boy, this person is likely to lose than .3logMAR because of other features, and so if I actually do what I think should be done, I'm going to get dinged for it.

MEMBER FRIEDMAN: Sure, so to address your first thing, I believe we were told to go by our first names, so you can call me Scott and I'll call you Jim. So logMAR is, you know, not to belabor the point or waste time, is a way to convert the known acuity, 20/30, 20/200, to a way you can do statistical analysis. So basically-- yes, basically it doesn't mean anything to you; don't worry about it. It's just a way that we can look at change in visual acuity. So if you're talking about the wet AMD, we give shots to not only to prevent vision loss, but also to improve it; on average, about a third of the patients see two lines better, significantly better after treatments. So we certainly want to

test whether patients are--making sure the patients aren't getting worse, and again, if your patients are getting worse being treated, probably not doing something correctly; you need to do something else. And then with all these, at least with ophthalmology and presumably with all measures, there's going to be some issues with risk adjustment. In other words, we're going to have patients who are going to have a worse prognosis not only with acute macular degeneration or with glaucoma, for example, so they need to be risk adjusted. Are the people, I guess in my opinion the people that have the worst--they have a worse macular degeneration, and we can separate out eyes that maybe are going to have a poorer prognosis, and do you want to go ahead and refer those out so you don't get dinged for that. But I think if your N is large enough, that's going to be sorted out, and if enough people want to have enough patients, they're still going to have a favorable outcome doing the worst cases, but I think the savvy

ophthalmologist and maybe the savvy physician is going to consider I'm not treating that patient and sending that patient off somewhere else because it's going to adversely affect them, presumably financially.

CO-CHAIR WHITACRE: Rachel, I think you were on the list.

MEMBER GROB: I wanted to go back to the question of what is useful to patients to have reported versus being able to do that drill down, and although I can read through what NQF recommended with respect to what's on the spreadsheet and what's reported on Physician Compare, I'm wondering if you could give us an explanation of how as a group you considered these measures and then the patient's perspective and made your recommendations for one or the other.

DR. WINKLER: I didn't--I skipped through the slides; in fact, I might be able to--no, it's not set up. Actually, the Clinician Work Group had established their guiding

principles for the various clinician programs, including Physician Compare, and there were listed a group of measures that--the types of measures, if you will, that you had established as the type of measures you wanted to see on Physician Compare. We use that as the guidance; we tried to match that with the type of measure that we saw here, again realizing that these were drafts and your feedback on did we get it right or did we get it wrong is appropriate discussion for us today, but if you look--let's see--no, we need to go farther--yes, it's under Physician Compare--it's going to be after Alicia's presentation. Yes. Those were the work group guiding principles, so we tried to match that, so that's where the draft came from.

MEMBER GROB: Thanks for that reminder. I'm just wondering if you had any concerns about the number that are there, because I think we do know that there's sort of a cognitive information overload that can happen sometimes; some people are looking at it, and I

don't know which ones that I might say this shouldn't be reported, but because we're talking about sort of balancing parsimony and this particular measure set with comprehensiveness and the kind of granularity that we've heard so well described here, it seems to me that in addition to these, there's sort of a question about what it would be like from the patient's perspective, because the majority of them I think there's 20--you know, we're reporting--we're recommending to report a lot of them on Physician Compare. So I'm just wondering if anybody has thoughts about that. I don't have a recommendation of a particular one that should be on the spreadsheet versus not, but I do have sort of a concern about Physician Compare getting so big that you know, people looking for an ophthalmologist look at it and go like oh my God I have no idea what to focus on here.

CO-CHAIR WHITACRE: Mady, did you have a comment?

DR. CHALK: I just wanted to follow up

on Rachel's comment. I don't know how a patient sitting there looking at those particular measures would use them. Now, if somebody is going to take these measures, if they're there, and CMS is going to take them or somebody else is, NQF, and translate them into language that a consumer might understand so that they could say okay, if my ophthalmologist measures well on X, here's what it means to me, I should go to that ophthalmologist, I should not, you know, he's a specialist in, or she is in something in particular. But just looking at the measure as a measure that is going to be out in public, I just don't understand how a consumer would use it.

CO-CHAIR WHITACRE: Would you like to respond to that? Sure.

DR. GOODRICH: So yes, so for the measures that we currently have on Physician Compare, they've been translated into English. So--and we've worked with patients to make sure that they can understand what is the way we've translated and have modified wording; so that's

called consumer testing, right? But it's work with actual patients to try to help--to make sure that we actually display a measure and what the measure means in a way that a lay person could understand. We also, you know, I think we try for the seventh grade reading levels, I think that's a yes; I'm getting the thumbs up from Alisa. So we can always make it better, but some of these I also think would be very difficult to translate, so I want to acknowledge that. So that's part of the input we're looking for, is you know, they're all going to go on the spreadsheet; let me just be clear about that again. Everything goes in the spreadsheet; that's just for total transparency. But how do we prioritize the ones that are translatable and meaningful to patients? That's what we really want to know from you all.

CO-CHAIR WHITACRE: David?

MEMBER SEIDENWURM: Well, I think that CMS has done a good job in translating the metrics out there now into English, and so I

think we can rely on them to do a good job going forward. So I think that's one point, but I think that each patient is going to look at this in their own way for the conditions that are relevant to them. So if there does seem to be a proliferation of metrics out there, the people are only going to look at the ones that are relevant to them, just like one doesn't look at the whole array of cars out there on the consumer things, you know, you kind of know if you want a SUV or a sports car or whatever, so you're just going to look at the ones--you know what your budget is, for example, in that analogy. So I think that we can trust the patients; the other thing is remember a big consumer of this information is the doctors themselves, and I think that if the doctors are going to be looking at this and motivating themselves. So again, the wide variety of metrics that are relevant to the physicians I think also drives the quality of care. So you know, I don't think we want to necessarily mush it up and dumb it down too much.

And so I think that we're going in the right direction today, so let's not lose momentum.

CO-CHAIR WHITACRE: Scott, then Robert, then Marcy.

MEMBER FURNEY: Just a very quick point, and just an analogy from my world. We might have said 15 years ago that patients won't understand an HIV viral load in CD4, yet all of my patients that I see can quote that. So I think we need to be careful; there will be a process of patient education and there will only be a subset that will use the site, but I think if we're being careful about translating these, that patients who care about looking for information will actually know what to do with it.

MEMBER KRUGHOFF: I think this is sort of highlighting our problem, and it may come up with the other measures also, that it really does make a difference if you're talking about what measures we'd like to see go forward in the Physician Compare spreadsheet as opposed to what

measures we'd like to go forward on the Physician Compare website itself, where you're only going to, you know, you maybe only want to see a few of them, versus what you want to have go forward for MIPS purposes. They really are different uses, and I can--and they would affect patients at different times in their lives. If I were choosing an ophthalmologist, I might want to have something that was at quite a summary level, and would make it fairly simple to choose--I don't have anything wrong with my eyes, but I want to choose one who's going to be a good ophthalmologist.

On the other hand, if I have a particular condition and I'm looking for somebody to do a particular therapy for me, I might be very interested in having it drilled down later. And trying to put all these things in this same process that we have here, I don't know how I'd solve the process problem, but I do think the process doesn't sort of fit all of those objectives very well.

CO-CHAIR WHITACRE: Reva, would you like to respond?

DR. WINKLER: Yes, I just want to respond to Robert, just to be sure everyone's clear. All of the measures in MIPS are the measures that are our primary agenda items because they are on the measures under consideration given to us by CMS. Realize though that any of those measures that are used in those programs become available for Physician Compare. So it's the downstream, so then it can bifurcate spreadsheet versus--so it's not three choices, all right. Your choice around the measure around MIPS is the primary choice; it's the secondary how is the vehicle for public reporting carried out secondarily. So keep--just--it's not three independent choices.

MEMBER NIELSEN: Although I have worked around clinicians my entire career, it always makes me nervous because I was never good enough at math to go to medical school, so let me own that right up front before I ask my friends

at NQF if this is what we're really trying to do. Dr. Cassel told us this morning that this is one of the rare occasions in Washington, D.C. where we have truly different stakeholders come together and have to collaborate, and I do think that that's true. But one other place would be right down the street at the Patient-Centered Primary Care Collaborative, where everything we do goes into a Venn diagram, and it's just three circles, which is why I can understand it. It's patients, and then it's providers or clinicians, and it's payers. And everything we work on really, if it doesn't fit in the middle of that circle, we can't really work on it because then it's quickly lopsided, and suddenly we're not the Patient-Centered Primary Care Collaborative.

I recognize that you all have to color outside of the middle of the Venn diagram for the purposes of Congress told you to, CMS has told you to, all the advocacy groups are telling you to, but isn't our job to help you shrink what is a huge universe of possible things to consider,

using data, using advocacy groups and other professional associations' advice, to shrink the number of things we're focused on, and in reality, although I think we think not everyone else understands our perspective, we're all basically in agreement. I mean, we've got to shrink the number of measures, and the measures need to be more valuable. The end. Like, that's all we're doing here.

So I guess I share people starting to sound like they're having philosophical disagreements with one another, and we really aren't. Like I think, in my opinion, some of this stuff is mandated that CMS review. Congress told them to; they don't have a choice, Kate sits and smiles nicely at us, and pretends like it was her idea. It wasn't her idea. She doesn't measure this any more than I want to measure it, but you know what I mean? Like, we're all on the same team.

So I think if we took a deep cleansing breath, and thought about we all want a smaller

set of measures, but they need to be valuable and downstream, they have to have meaning to patients. Upstream, I wish they could all have meaning to patients, but that is unrealistic given where we are in the world of measurement and in the world of process shifting to outcomes. Nobody would like outcomes more than me. So anyway, I say go team, we're all on the same team, and do a little yoga, and have a snack, and then we'll get all the rest of this work done.

CO-CHAIR WHITACRE: Helen, please.

DR. BURSTIN: It's hard to follow that. The snack sounds really good actually; I'm not sure about the yoga. You know I think in principle, you're right, Marcy. I do think though that for a lot of specialties, there are subspecialties and again, I'm not sure that the number of measures is really the issue. I think it's not every measure is used for every purpose. Actually at our recent board meeting, one of our consumer members said you know, does anybody complain when the library has too many books? I

mean at some level, if these measures are not all going to be used at the same time for every purpose, but they serve a purpose and they in fact meet the needs of clinicians and patients, so be it. I just don't think--and again, this is to advise CMS on their selection. So make your recommendations, Kate will ultimately take those and CMS and make their final determinations. But I wouldn't get so hung up on the numbers thing I guess.

CO-CHAIR WHITACRE: Rachel.

MEMBER GROB: I would never complain that there are too many books in the library or too many notes in a Mozart concerto, though he was once told there were. But I do think that to some degree, consumers are sort of voting with their feet with respect to things like the Physician Compare website, and that they are going to other places in the private sector, you know, something that's more like Yelp or like Trip Advisor or Amazon where it is sort of boiled down, it speaks to them more loudly. So I'm here

representing patients, I'm the last one who wants to be condescending towards them, but I think there's a concern there that we should take seriously as a work group when it comes to that part of the decision about which things in MIPS show up on Physician Compare and give this feedback to CMS because I know nobody more than CMS wants Physician Compare to actually be really, really useful, and it's that validated data scientifically generated in a way that a lot of the anecdotal stuff out in the public domain doesn't have. But I think we have a job here to make sure that what we represent is as meaningful as possible to as many consumers as possible, and I love the post it on Physician Compare, you know, versus spreadsheet because some consumers-- I couldn't agree more with you, Robert--will want to drill down because they have macular degeneration that is dry, and they need that information, and other people are going to be like hey, I need to pick an ophthalmologist, and they're going to look at it and just go like

whoa, I'm going to look on Yelp. We don't want that to happen.

CO-CHAIR WHITACRE: Well this has been just a brilliant discussion as before, and I would like to pick up on the deep cleansing breath motif, and make a proposal to the group. We're ahead of schedule, but it's been a great discussion and we haven't yet voted, so I'm proposing that we take a brief break now, let everyone refresh, think of what they want to think, any additional final comments, and then work our way through the five measures that have been pulled. Before I do that, however, David I did quickly move over, and apparently you had pulled Measure 2, if I understood correctly? I wanted to make sure I wasn't mistaken, and did we address any concerns in the course of the discussion if it was Measure 3.

MEMBER SEIDENWURM: I did, and they were well addressed.

CO-CHAIR WHITACRE: Is everyone agreeable to that? I think it would give us a

chance all to refresh, rethink. This is such a great discussion; we may have final comments before the vote, we'll still have time for that. Well if everyone is in agreement, let's do that, 15-minute break and we'll meet back here.

(Whereupon, the above-entitled matter went off the record at 2:54 p.m. and resumed at 3:14 p.m.)

CO-CHAIR WHITACRE: So I thought because this discussion--and I'm sure you've heard this before--has been a real eye-opener, had to say it, this--I thought we would take any last comments or thoughts. This has been such an important discussion, not just obviously about the ophthalmology measures, which honestly I admit I don't completely understand at a medical or surgical level, but it's been important in our understanding of balancing parsimony of measures versus granularity and where that balance lies; it's been very important in understanding how we evaluate measures for MIPS versus Physician Compare and how there the translation not just of

language but of scoring needs to occur to be meaningful to patients. So we have a number of measures which have been pulled, and my thought is that we'd have any final discussion, thoughts, before we proceed and then sequentially go through each measure. We've had some close votes, so I wanted to make sure every measure receives an individual vote, and then we'll move on to the next section. And if that's agreeable, I'd open the floor to any last comments, observations, concerns. Wow. That's great. Okay, let's go through measure by measure.

So measure number one, just while we're voting, we voted on the consent, so it's just--I'm sorry, we begin with measure number two, which was the first pulled measure, Glaucoma - Intraocular Pressure Reduction following Laser Trabeculoplasty; MUC ID MUC15-374, which is on the screen. Our choices for all of these measures that have been pulled will be the same; encourage for continued development, do not encourage for further consideration, and

insufficient information.

MS. CHAVEZ: Now voting for MUC15-374; voting is open. And for those on the phone, please submit your votes via chat. Thank you. Okay, the results for MUC15-374 for MIPS are 95 percent encourage for continued development; 5 percent do not encourage further consideration; zero for insufficient information. So vote is for encourage for continued development.

CO-CHAIR WHITACRE: So the next measure for vote is measure number three, Exudative Age Related Macular Degeneration: Loss of Visual Acuity. So this is MUC ID MUC15-379.

MS. CHAVEZ: And same options, one, encourage for continued development; two, do not encourage further consideration; three, insufficient information. Voting is open. For those on the phone, please submit your votes via chat. Okay, and the results for MUC15-379 for MIPS are 100 percent encourage for continued development; zero do not encourage further consideration; zero insufficient information.

CO-CHAIR WHITACRE: So the next measure is number 4, Nonexudative Age Related Macular Degeneration: Loss of Visual Acuity. This is MUC ID MUC15-392.

MS. CHAVEZ: Voting is open. Okay, the results for MUC15-392 for MIPS are 100 percent encourage for continued development; zero do not encourage further consideration; zero for insufficient information.

CO-CHAIR WHITACRE: The next measure is number seven, Surgery for Acquired Involutional Ptosis: Patients with an improvement of marginal reflex distance. This is MUC ID MUC15-375.

MS. CHAVEZ: Voting is open. Okay the results for MUC ID 375 for MIPS are 95 percent encourage for continued development; 5 percent do not encourage further consideration; zero insufficient information.

CO-CHAIR WHITACRE: Number eight, Acquired Involutional Entropion: Normalized lid position after surgical repair.

MS. CHAVEZ: Voting is open.

CO-CHAIR WHITACRE: This is for MUC ID MUC15-377.

MS. CHAVEZ: Okay, the results for MUC15-377 for MIPS, 95 percent encourage for continued development; 5 percent do not encourage further consideration; zero insufficient information.

CO-CHAIR WHITACRE: The next measure is number 10, Acute Anterior Uveitis: Post-treatment Grade 0 anterior chamber cells; it's MUC ID MUC15-396.

MS. CHAVEZ: Okay, voting is open. Okay the results for MUC15-396 for MIPS, 91 percent encourage for continued development; 9 percent do not encourage further consideration; zero percent insufficient information.

CO-CHAIR WHITACRE: And the last measure, Chronic Anterior Uveitis: Post-treatment Grade 0 anterior chamber cells, MUC ID MUC15-399.

MS. CHAVEZ: Voting is open. MUC ID

15-399. Okay, the results for MUC15-399 for MIPS, 86 percent encourage for continued development; 14 percent do not encourage further consideration; zero insufficient information.

CO-CHAIR WHITACRE: Thank you everyone; great discussion.

DR. WINKLER: Okay. Take a deep breath. All right, we're going to move on to our next and last topic area for today, and that's the topic area for cancer. We have a group of 10 process managers that have been submitted pertaining to cancer. We have one new eMeasure from CMS that is still under development around PSA screening; this measure received a large number of comments, so we don't--make sure everyone notices those. There is one NQF endorsed end of life measure, and I will point out that this was a--end of life care was a gap identified by the MAP last year. And then we have eight measures that are in development that were submitted by the Society of Gynecologic Oncology, which introduces the first measures for

endometrial, cervical and ovarian cancers that we've seen. These are also some of the first measures for that particular specialty as well; these measures are still being developed with testing expected to be completed in 2016, and they are being collected in the SGO clinical outcomes registry. So, opportunity for public comment?

CO-CHAIR BAGLEY: Okay. Let's ask for public comment about these measures, this would be the cancer set. Is there anybody who would like to make any public comments? Well I see no one in the room, how about the phone?

MR. LYZENGA: Operator, could you ask for public comment?

OPERATOR: At this time, to make a public comment, please press star one. We do have a public comment from Dan Barocas.

CO-CHAIR BAGLEY: Dan, please go ahead.

DR. BAROCAS: I'm Dan Barocas, I'm an associate professor of urologic surgery at

Vanderbilt University and a member of the American Urological Association. I'm a prostate cancer doctor, a researcher, and a patient advocate. Regarding the PSA testing measures, the key point is that the USPSTF Grade D recommendation against PSA screening is highly controversial. Other prominent national organizations, including the American College of Physicians, the American Society of Clinical Oncology, The American Cancer Society, the National Comprehensive Care Network, and our own organization advocate for some form of shared decision-making to guide screening practices at the individual level. In order for a national measure on over-use to have value, there should be wide agreement on the recommendation, and this is not the case in PSA-based screening for prostate cancer, which in some studies has reduced prostate cancer mortality by over 20 percent.

There were over 350 comments submitted during the CMS public comment period from a

variety of stakeholders; only one comment stood in favor of the measure, and this was from an EMR vendor that sells a product to collect data for such measures. The remainder were uniformly against the measure, and cited data regarding the mortality benefits of screening, alternative methods for reducing the harms of screening, and the potential harms of halting screening for all men in terms of delayed diagnoses and missed diagnoses, which is of particular concern for African-American men and those with a family history who are at higher risk for prostate cancer diagnosis and mortality.

In summary, many view the USPSTF recommendations against prostate cancer screening as severely flawed; at best, they are highly controversial and should not be the basis of a quality measure. Indeed, the measure is currently under review and possible revision, and the USPSTF process itself is under scrutiny, as a bill to expand oversight and stakeholder input has been introduced into Congress. We strongly

urge MAP not to encourage further consideration of this controversial measure.

CO-CHAIR BAGLEY: Thank you, Dan. Any other comment, public comment from the phone.

OPERATOR: There are no further comments.

CO-CHAIR BAGLEY: Reva, do you want to give an overview, and then we'll hear from--well, okay, then we're ready to hear from our lead--well, I'll take Eric's lead and ask you to number your bullets if you didn't do that already, and forget about the numbers on the discussion guide because that was just more confusing than it was worth. I have number one pulled, number two, number five, number seven, eight, nine, 10 and 11. It might be easier to name the ones that weren't, but that's okay. So that--are there any additional requests for--Janice? I'll do it one more time, and then I'll do the ones that are still on the consent calendar; that might be easier. So I have number one, number two, number five, number seven, number eight, number nine, 10

and 11. I my view, that leaves only three and four still on the consent calendar. It's going to be a good afternoon here. Ah, thank you for that. I can't hear you.

MEMBER GLIER: I meant to pull six if you didn't pull six. I pulled five through 11 as a block.

CO-CHAIR BAGLEY: Okay. Do we have commentary from the lead discussants? Yes, there's been a suggestion that we think about separating out number one and number two, right, and then consider the rest as sort of en bloc. So that might be a little easier to manage in terms of the discussion, so let's try to do that. Amy, go ahead.

MEMBER MOYER: Okay. Well generally speaking, in looking at the number of measures that were in here for the different kinds of cancer, I found myself wondering, you know, I know we've had this philosophical discussion about lumping versus splitting out, and one of the concerns that I'm not sure we specifically

raised yet is the ability to have a large enough denominator to end up with reliable measurement that, you know, you can trust. And so you know the more we split things out, the more difficult that becomes. And so in general, I--when we're talking about individual physician level or eligible provider level measures, where we can lump it and where we can increase reliability is useful, and I think that's also useful from a patient perspective to not be looking at all these little minutiae, but instead to have a broader picture.

MEMBER ORLOWSKI: Yes, as a discussant. So as we talked about--first of all, it's the PSA, it's the hospice, and then it's the urogynae issues. In regards to the PSA, I am--I would suggest that when we pick a measure to measure everyone, that we should not be picking those that are in the midst of a widespread medical controversy. And I would say that this falls within it; for years there was a recommendation for screening, there's been a

recent change within, just within the last 18 months, two years, I don't know how long it's been, and what I would say is that there's been much discussion, both publicly as well as within the academic community, regarding the recommendation. And just on the basis of that alone, whether we fall on one side or the other of the debate, I would say that it is unwise to choose it as a measure until the standard of care in the community has been established. And I would suggest that the standard of care has not been established. And--so that's my comment on number one, and I do have an opinion on which side of the debate, but I don't think that that's relevant.

In regards to the hospice, I was going to say it seems like a pretty straightforward, so I'll be interested in the discussion; I have no further comments about the hospice. In the last, which I'll bunch into the urogynae group, urogynae, I would have two comments. There are I believe three measures that have a non-response

from ACOG where they have responded to all of the other measures, and I am looking for a reason for the non-response. I can tell you that personally, I am reading that there's either controversy within their community for the support of that measure, or they're not supporting it but they chose only to make positive comments. But I would, rather than having me guess, I would like to have further information about why there's a non-response.

The second question, or the second issue that I would like to address, when we have specific days, which are 42 days, a very unusual number, 42 days for something, 60 days for something else, that I believe that when we have looked at measures previously in other programs, that the absolute number of hours or absolute number of days sometimes moves people to make decisions that are not appropriate. And I would tell you that having practiced my life in two large cities and with an urban and socioeconomically--low socioeconomic group of

individuals, that helping individuals arrive at specific days, 42 days or whatever, is difficult and it should be done, and there should efforts made to stay within certain days. But unless there's a specific scientific reason why 43 days is worse than 42, I think that we have to be careful about aligning the number of days.

And so as I take a look at it, if the recommendation is for radiation to occur in the first four weeks, then I would suggest that for a national measure, five weeks or six weeks would be the outer limit, unless we're going to risk adjust it in some way. And so I think by the days, what we're trying to do is to link sequentially different treatments, where you have a hysterectomy followed by brachytherapy or something like that. And I, unless someone can explain a scientific reason for being as precise as they are with the days, I think that we need to say that this care needs to occur timely, but have that timeliness be within a reasonable period.

DR. WINKLER: I just want to respond, Janice, because I actually looked up all of the treatment protocols for all these different types of cancers. I am a gynecologist by training, so at least I could understand what they were saying. But the--it's actually the evidence that states those specific days, and those are actually specified, those treatment time frames are specified in the treatment guideline protocols. So based on the evidence--

MEMBER ORLOWSKI: I understand.

DR. WINKLER: --so that's where they're coming from, so I can tell you that part.

MEMBER ORLOWSKI: I believe that, I believe that the guideline says 42 days; what I'm asking is a slightly different question. Is there a reason to suspect that it's poor care if it's at 45 days?

DR. WINKLER: I think you'd have to go back and read the studies, because actually, they really were fairly discriminating on some of these time frames.

MEMBER ORLOWSKI: So again, I think that--again, based on experience, these time frames push people sometimes to make decisions to hit specific times, and I would be cautious is my only comment about that.

CO-CHAIR BAGLEY: Okay, before we dive in, I think we have to vote on, or at least if anybody wants to take number three off the consent calendar; if not, we'll accept that one, and then we can move on. Do I hear any appetite for--number four has been withdrawn apparently; that's no longer on the list. Okay, so number three is the only one we have to do, then. I don't see any rousing--okay. So let's go back to number one, and try to talk about that as a standalone before we move on to some of the other controversy, and Janice and Amy, thanks for the set up on this one. So do we have any comments from the work group about number one? That would be the non-recommended PSA based screening. I'm looking for--pardon? Yes, please do. Why don't you start it off. Thank you.

MEMBER LANDRETH: I think that everything that needs to be said about this measure probably already has been said, and the number of public comments is really very clear, and I agree with all of them except perhaps the physician who wanted to take this to the Supreme Court if we passed it. But I can talk--I'm talking today from a purchaser perspective, and a patient perspective. My husband is 56 years old right now; at age 50, his PSA, which his physician was monitoring, this was back when the guidelines were lower than the four that they currently are for a threshold, he was having serial PSAs every year that were going up just minimally, and his physician said you know, you can have a biopsy, it really doesn't matter, but if you want to, that would be great.

I took him in for a biopsy--he had 20 milligrams of Valium so he needed me there--they biopsied; his Gleason score came back on all biopsy sites as an eight. He had a Gleason score eight malignancy, and he's 50 years old. So at

that point, we're starting to try to determine what do we do. Robotic surgery was really what was recommended; he had the robotic surgery, he went through serial PSA screenings after that point, and his PSA for six years now has been 0.01. So the fact that the physician who was his primary care doc didn't even really recommend that he have the biopsy, but was smart enough to at least measure and give him that option saved his life. And I think it would be criminal if we were to disincentivize providers of any kind from doing the only test that we have that's available right now to prevent the second most leading cause of death, of cancer death, in men. So that's why I pulled it.

CO-CHAIR BAGLEY: Other comments? Sepheen, do you have a comment or do you want to introduce yourself and--

DR. BYRON: Hi, I'm Sepheen Byron, I'm with the Measure Development Team that developed this measure, and I do want to thank you for sharing that story, I think it is very important

for us to hear. I recognize that this is a very controversial topic, and I recognize that there are some issues with disagreements with the U.S. Preventative Services Task Force. So just to explain a little bit about the rationale, this measure is based on that U.S. Preventative Services Task Force recommendation that is actually pretty squarely in the D recommendation space, and I think that for the stories that show that it is a useful test, there are also stories to remember that show that there were harms from the test, and that is where the task force was looking at the bulk of the evidence across all of the studies that were done, and it is a systematic evidence review that we do base our measure on.

Now, this is just to explain our process, so we wanted to make it clear that we are basing the measure on an evidence review that was done in a way that is recommended by the Institute of Medicine in terms of a trustworthy guideline. You know it is a very rigorous

process; I actually attend all of the discussions and I know that there are hard choices to make in medicine, and it is difficult. And so you know, whether or not the Committee feels this is a good measure for this purpose, I think we are very interested in hearing. One thing that was pointed out is that we are still in development, and in terms of where we place the age ranges for this measure, we still have some play around; we wanted to make it more inclusive versus less because we wanted to be able to put it through testing in that way, and because the recommendation does say that, you know, the issue of over-diagnosis and the issue of harms from treatment that didn't need to happen are very real.

I do not want to diminish your story in any way, and I do think that there are many cases where it turned out to be helpful, but when we look at the bulk of the evidence and look at it in a systematic way, that is where the guidelines emerged, and that is what we're basing

the measure on, and the intent is really to make sure that a screening test is not applied to a general population in a way that could inadvertently result in more harm than good. And so you know I think we're very lucky to have the task force stepping in on controversial issues like this and trying to give guidance around where it makes sense from a general population perspective, and if doing something like specifying the age range in a different way might make this measure more palatable, then this is something that, you know, as I said, we have just seen our public comment, there were 350 comments, we have read every single comment, and we want to make sure we do the right thing in terms of this measure. So thank you.

CO-CHAIR BAGLEY: David, go ahead.

MEMBER SEIDENWURM: Well I'll start the ball rolling because I'm too dumb to keep my mouth shut, but I'm going to speak strongly in favor of this measure, and I'd like to disagree slightly with what Janice said earlier, and I

think it's precisely in some areas where there might be some controversy where we might need some leadership from payer groups to help move the ball, because sometimes the physician community is a little bit high bound sometimes in the way we practice. You know, we know it takes 17 or some number like that years for something new that works to work its way into the system and we don't know how to measure how long it takes for something that doesn't work to leave the system because it never happens. So I think that this is exactly the type of leadership that we do need from consensus groups like the task force, and from payer groups like CMS, and I think that adjusting the age range and being very, very careful about the parameters is going to be critical, and I'm not going to want to be sitting in Kate's chair when this--if this is promulgated as a formal policy, but I'd like to encourage people to stand up for the scientific method here and really try to encourage the practice of evidence-based medicine in our

country.

MEMBER PELLEGRINI: David I really appreciate those comments, because I was thinking along the same lines, you know, what--we're talking about measures as a tool to drive change in practice, and this is I think a classic case of driving it really hard really fast, right? So this is a case where we've had a dramatic change in the recommendations, and now this measure is being developed to say all right, we're going to do all in on that change in the recommendations, we're going to try to push everybody to take that up as quickly as possible. And so what I'm turning over in my mind is what is the role of a group like ours in deciding does there need to be a kind of cooling off period of some kind, where--and it's not just the physicians who are resistant; a lot of times, it's the patients too, right? Does society, does the patient community, does the physician community need a little time to process this before we ought to start measuring everybody on it, and I don't think I've

got an answer right off the top of my head, and that's just why we get paid the big bucks here.

CO-CHAIR BAGLEY: Introduce yourself.

MS. CRAWFORD: Sure. So my name is Alyssa Crawford, I'm from Mathematica Policy Research, and I'm part of the team that Sepheen is on developing this measure. So I just want to thank you for bringing that up, because I want to emphasize that this measure is actually very early in the development process. So what I mean by that is that there's still a lot of work we have to do before it's a measure that's ready for use in a program, and I want to emphasize that the guidance you give us, regardless of your decision, is something we'll take into consideration not only in terms of whether we move this measure forward for development, but how we move this measure forward for development. So we're very aware of the work that's going on with USPSTF to update their guidelines, we're very aware that there's a lot of ongoing work in the evidence for this measure, and so I don't

think necessarily--I just wanted to emphasize it--continuing development of this measure does not necessarily mean developing it in the absence of taking that information into account; it's saying that this information and that this concept is worth potentially measuring, and it's worth spending some time thinking about how to measure right so that CMS can make a decision about whether or not it's worth measuring in a few years when the measure is ready. So just wanted to emphasize that aspect and that sense of where the measure is in the general development process.

CO-CHAIR WHITACRE: I'm taking off my co-chair hat again. This is breast surgeon speaking, and I can't help compare this to the mammography controversy. Now the mammography controversy happened sort of as a two-step thing. The first time USPSTF recommendations came out, revolt, act of Congress, yadda yadda said no you can't do that; that's the cooling off period. I mean, that's what happened, and so when the

recommendations came a second time, and now we actually have three different sets of recommendations of screening the average risk woman, it helped to have the cooling off, it helped to have the multiplicity of recommendations because it made clear it's not all black and white. I mean, it's not one truth; this is not written in stone.

The thing that helped us in breast is that during the time that this controversy first started to where we are today, they developed and validated, at least partially, some very powerful statistical risk assessment tools. We have a number of risk models that allow us to stratify lifetime and five-year risk of developing breast cancer. So individualizing recommendations suddenly made sense, not just for mammography. Whether or not it's still real, I don't know, but at least it makes sense.

We have some sense of the scientific method saying we are applying specific screening tools according to relative risk. Do those tools

exist for assessing risk of prostate cancer? Something--the Gail model, Tyrer-Cuzick model, Claus model, I mean BRCAPRO, we can go on and on with the risk models we use. So these are recommendations that are across the board for everyone.

DR. BYRON: Well the recommendations focus on a general non at risk population, and that's for across all of U.S. Preventative Services Task Force.

CO-CHAIR WHITACRE: Risk being family history?

DR. BYRON: Whether or not--family history gets taken into account, but if somebody is considered part of the general population, then the recommendation--

CO-CHAIR WHITACRE: We used to screen --in women, it was male versus female. All women were the same. We know that's not true; we screen differently. The reason I bring that up is because you know, I just--it's hard to believe with the presentations we've seen that reality is

black or white, but it's also hard to believe that this is not, because of a controversy, a somewhat useful tool. We could go the route of Switzerland and not do any mammography, but that doesn't make sense to anyone either. So it may be a timing issue, not just in terms of cooling off, because you don't want something to damage the value of the program that we're interested in making recommendations for. At the same time, it may require further science to stratify risks to know how to use this tool best. Just analogy.

CO-CHAIR BAGLEY: Beth, you're next, and then you.

MEMBER AVERBECK: Yes, I would be supportive of looking into the measure, and part of it might be what's our opportunity to pace the change given the current conversation. Is there an age range that could be considered as sort of a first step where there's general agreement that screening beyond a certain age does not provide benefit and we get more consensus around that? I mean, like diabetes, you know, having an A1C

below 7, below 8 in someone who's 85 is no longer clinically appropriate and so is there some way that we might be able to take a look at age ranges as a way to start down this path of a potential measure where we're trying to prevent harm by doing a screening test?

CO-CHAIR BAGLEY: Barbara, you're next.

DR. BYRON: And that is actually built into our testing plan, because we are aware that the age range is a question for this.

MS. CRAWFORD: This is Alyssa again from Mathematica. I think you're right that we can probably try to identify some ways to measure this; it may not cover all of the scenarios in which it is appropriate to recommend or to work with a patient to decide whether a PSA test is appropriate, but I think we can try to--there is going to be a way that we can measure whether certain types of patients are getting tests that are supported by evidence, and I think that's something that we would be interested in doing

and are looking for your feedback in terms of whether that's an appropriate next step.

MEMBER LANDRETH: I think probably part of the reason that you had so many outraged people responding was the way that the measure was written. It was looking at all patients regardless of age. High risk, low risk didn't really matter, and also I think that it was basically saying you can't do a PSA, you're going to be penalized if you do a PSA rather than if your patient asks for a PSA or if you have a collaborative discussion with your patient recommending or not recommending a PSA, regardless, you are going to be dinged if you ordered a PSA. So I think that's the real reason that you're seeing so much outrage right now, and my concern is that if we as a committee, understanding your good intentions of moving forward and doing the right thing, what's going to happen to the physician who's going to take us to the Supreme Court? I mean, I think there has to be some kind of an explanation or caveat that

says we support the concept, we know you've got a lot of work to do, so we don't get individually sued.

CO-CHAIR BAGLEY: Peter, you're next.

DR. BRISS: So I agree. As a guideline develop our work agendas with the Preventative Services Task Force, I'm generally sympathetic--

CO-CHAIR BAGLEY: Closer to the microphone, please.

DR. BRISS: --sorry. I'm generally sympathetic--my read of the evidence is like theirs personally and professionally. Now having said that, I tend to agree with Janice about given the level of controversy in the field and given the extent to which informed decision making is a very important fact of life in this subject matter, I think a quality--I feel like a quality measure that generally dings people for ordering one of these tests is premature, even for somebody like me who generally agrees with the direction that they're trying to go.

CO-CHAIR BAGLEY: Rachel, you're next.

MEMBER GROB: Even though I know we're not talking about the public reporting side yet, I want to bookmark that for a measure like this, were it to be brought all the way forward, and for low value care measures in general, we need more evidence about how consumers comprehend those, and what kind of action they take, because the goal of CMS and the measure developer and the MAP and us is to help consumers make quality decisions. I'm concerned that given controversy, public awareness and so on, that public reporting of a measure like this will actually drive people in the opposite direction, and I think we just need a strategy for that. I don't think we can withhold information, but I really think that that's a conversation for CMS and eventually for the MAP when we look at public reporting, what does it mean to interpret this for consumers who are going to have their own interpretation, otherwise--

CO-CHAIR BAGLEY: Go ahead.

MEMBER FURNEY: So the consumers will

certainly have their opinions, but to some degree I think it is our responsibility to help them form them. So in this measure, the intent is to not uniformly screen average risk individuals routinely with the test. And I agree that's-- part of my concern about it is how it's written; we don't have the same level of evidence and risk prediction to be able to say who--which of the high risk candidates might benefit. So race, family history, history of prostatitis, and then honestly what we need is actuarial tables. How long will this person live? It's likely if there is benefit it is 15 years after their found and intervened, if there is benefit. And so I agree there's enough uncertainly in the science; I think what we need to do is encourage the development of the measure to discourage, but not prohibit, the use of testing in the average risk patient.

And the idea of a cooling off period, having lived as chair of a quality committee through the breast cancer thing for the last few

years, I'm finally--my armor is dented, but I'm okay. I'm not sure that we can realistically take forward a do not test measure, but I so think we can say that the evidence does not suggest that the routine screening of average risk individuals is a good idea in general, and the absence of evidence does not mean that there is not evidence of harm; there's clearly evidence of over-testing and over-treatment, and we have to weight that in our decision-making.

MEMBER FRIEDMAN: For those of us that are not urologists, so basically you're saying is that any screening is unnecessary at this point, because aren't--don't the specialty societies recommend screening at this point, and you're saying that that's unnecessary?

DR. BYRON: So I do want to point out that the measure does exclude people--it pulls out people who are higher risk, so anyone who has a diagnosis of prostate cancer or a history of a diagnosis of prostate cancer, those taking certain medications that are associated with that

there the 5-alpha reductase inhibitors, and also--I can't remember the last one--

MEMBER FRIEDMAN: So if you already know that you have prostate cancer, one does need to be screened for it. That goes without saying.

DR. BYRON: Right, and those with an elevated PSA test are also pulled out of the measure.

MEMBER FRIEDMAN: Again, if one already knows your PSA is elevated, you don't need to be screened for that as well. So we're looking at people that are asymptomatic that reach a certain age, and you're suggesting that they don't need to be screened at this point?

DR. BYRON: So the recommendation from the U.S. Preventative Services Task Force that the harms outweigh the benefits for screening in the general population for those who are not at risk. There are--the American Urological Association does encourage shared decision making and potentially screening at a younger age. So--but the Task Force recommends against it for all

ages, so that is the recommendation.

MS. CRAWFORD: And can I just add on to that. So this measure as you've heard is based on USPSTF guidelines, and it is the starting point for our development process. So the exclusions that Tina's mentioning are the exclusions that are there currently; that doesn't necessarily mean that we can't consider other exclusions to, as you've said, make sure that the right patients are --that providers are incentivized to have the conversations with patients for whom PSA testing is appropriate, and some of that is talking about the age range; we've already mentioned that that's part of our testing process and something that we're exploring. Part of that is continuing to talk with stakeholders like you and the American Urological Association and others to get their input about other exclusions and new evidence that would help to support other instances in which it's appropriate for patients to be screened. So that's the current state of the

measure; that doesn't mean that we can't take additional feedback and reconsider those exclusions and identify whether there are other ones that are appropriate and evidence based to add.

But I did want to just quickly note that the--just for the reference to the exclusion for patients with a prior elevated PSA, this was put in because we obviously do not want to expect that providers would ignore a prior high result, and to speak to the situation earlier, if three was a decision earlier to test, even though the evidence according to the USPSTF guidelines do not support it, if there was a shared decision making process, and the provider works with the patient, and the patient and the provider together come to the decision to screen that patient, if there is an elevated test, we want to recognize that that is appropriate in that situation for the providers to continue to follow up and make sure the PSA levels, to monitor them over time. So that's the reason for that

particular exclusion, but the exclusions themselves are still very much under development and can definitely be further expanded or refined based on the information we get throughout the testing process.

CO-CHAIR BAGLEY: Peter, you were next.

DR. BRISS: To try to clarify, so all task force recommendations, their chapter and verse says these apply to asymptomatic people at average risk, right? And so the exclusions that you were talking about was trying to operationally define what those word strings mean. There's some things that might happen in the interaction, like I don't know what the answer is to Eric's question about does a family history take you out of the average risk category in this context. There's all kinds of complexity about what average risk might--does being African-American take you out of the average risk category? There are all kinds of things that would be operationally complicated, and so

there's--you know, and the other thing that given the frequency about--at which people still come in asking for a PSA, right? You know, I think you might think about how do we define patient preferences and shared decision-making in this subject matter as you're thinking forward about this; I think it's really hard.

CO-CHAIR BAGLEY: Robert.

MEMBER KRUGHOFF: I'm afraid I've missed something; what does encourage continued development mean? What are the implications if we say that? Does it mean that--

DR. WINKLER: The words speak for themselves; the implication is whatever the--whoever is listening takes them.

MEMBER KRUGHOFF: Will it always have to come back through this process again before it gets supported? So is it just a matter of saying, you know, keep thinking about this; is that what it is?

DR. GOODRICH: So this is Kate. So if the measure undergoes significant changes from

where it is now, which I suspect that it's likely to do, then yes it comes back through this process.

MEMBER KRUGHOFF: So it is to say re-evaluate in a sense. I mean that's what I'm-- that doesn't seem so problematic.

MEMBER KRUGHOFF: Kate caveated it, so I wouldn't assume that all of your recommendations are exactly that. In this particular case, we're talking about some significant issues around the measure, and in this particular measure, that may apply. But I don't think that's how you should interpret that across the board.

CO-CHAIR BAGLEY: I have my own name on the list, and then you Janice. So you know, stepping aside from my chair role for a minute, I just want to make some observations. I think this is very complex as we can tell because there doesn't seem to be any agreement, but it actually is very parallel to the DCIS discussion in breast cancer. You know the pathologists don't really

think that's cancer, and that has led to a fair amount of over treatment, which is part of what's caused the harm that makes the risk, you know the harm benefit balance out of balance. And I think we have exactly the same phenomenon here. It's not so much that the test is the problem, it's what we do with the test result that's the problem, and we're attacking it at the wrong place. So I would suggest we consider re-framing this whole discussion around finding a measure that would address over treatment and not over testing. So I really think that, to you point Robert, and if we are truly are kind of headed down the wrong direction, somebody's got to say halt, and I think this might be a case where we're actually attacking a systematic thing at the wrong place in the system in my view. So maybe to rethink how we might approach this is one thing.

Another thing is, and this comes from a long history of sitting at these kinds of tables is that this is basically a consensus

group, and this entire discussion screams lack of consensus. So for us to decide there's a consensus around something where the entire discussion screams lack of consensus is a little bit over-reaching in my view. So now I'm the chairman again; Janice.

MEMBER ORLOWSKI: Just a point of information. I went and Googled the recommendations, just so that I was very comfortable, and on the U.S. Preventative Service Task Force website, under prostate cancer screening, was a big note saying that the topic is in the process of being updated, and they do have an update section with a new research. And so I think it's a different--I agree with you that we don't have a standard of care, that's the term that I would use. There's not a standard of care. I think that this is different than people who order a test that leads to a lot of over-utilization; that I believe we need to stop. From my point of view, that may or may not be what's going on here once we have an agreed-upon

recommendation, and I think that it is something that needs to be studied, I think there's a lot of concern that there is over-utilization in this area, and overutilization often leads to patient harm, unintended patient harm.

We don't know even from USPSTF, you know, from the task force, we don't have a recommendation they're standing by. Their website says hold on, don't use this information, we're going to be updating it. And so they may come out with an even stronger message that says yes, we're standing by our original recommendation, or they may have involved a whole group of people and they may have some modification. So again, I think that you can't hold physicians, providers--I hate that word--but you can't hold them accountable for something that is going to be measured and which will affect a certain validation score of them on a public website, and will end up affecting the payment that they receive with the measure that is right now going through, you know, a standard

of care assessment of whether the United States Preventative Services and the community at large will stand by this recommendation.

MEMBER FURNEY: I think we'd be doing a disservice if we didn't encourage CMS to continue to address this important topic, to develop data, to refine the models, to look at what can be seen, and then perhaps if the task force changes its recommendations or if it re-affirms its recommendations or if it doesn't, that the data can be interpreted, the metric can be refined, can be brought back for further review. I assume that a topic like this would go through extensive review, both through this type of a process, internal processes performed in good faith at CMS, and you know doubtless with some political guidance as well, depending upon whatever's happening at that moment in history.

So I think that to say that we can't talk about this would be kind of anti-science, and just like every article you ever read says, you know, we need more research on the topic,

yes, and let's keep doing it.

CO-CHAIR BAGLEY: You know the absence of hands means it's time for a vote; is that right? Any other final comments?

DR. WINKLER: I just want to say that we have captured and, you know, we have both recording and transcript to capture all the richness of your conversation. All the caveats, all the input. So even though your votes seem to have, you know, just a couple of little words, they will be modified with all of the richness of the conversation that you've just had. So it isn't just that, there is another section that goes with it that explains the discussion.

MS. CHAVEZ: Okay. We are now voting on MUC15-1019 for MIPS, and for those on the phone, the options are one, encourage for continued development; two, do not encourage further consideration; and three, insufficient information. Voting is open. Okay, the voting results for MUC15-1019 for MIPS are 52 percent encourage for continued development; 33 percent

do not encourage further consideration; 14 percent insufficient information.

CO-CHAIR BAGLEY: So it doesn't pass our 60 percent threshold.

MS. CHAVEZ: Yes, so the vote is for do not encourage further consideration.

CO-CHAIR BAGLEY: All right, let's move on to number two.

MR. LYZENGA: And just for my own curiosity, it's for CMS, does a vote like that mean that--Kate, does a vote like that mean that you will not bring it back through the MAP process, or is there still a prospect that you may? Just curious. A vote to not encourage further consideration, for example, I'm just curious how CMS interprets that, and if that means that you will not bring a revised measure, should such a thing occur, back through the process.

DR. GOODRICH: If we continue to revise it, it would definitely come back. I mean this is a little odd, right? A majority of

people voted encourage continued development, it just doesn't meet the 60 percent threshold. So I'm not sure what message that sends us about what we should do. So we're going to obviously have to talk through it, but if we do decide to continue developing it with all the input and everything, then yes, it would come back through. Yes.

CO-CHAIR BAGLEY: Okay, we're going to move on to the hospice measure. I actually was the one that pulled this because I wanted to hear some conversation around the three-day stipulation and hospice. I know that a lot of the lightning rod issues around people being in hospice right in the last few days of life is really what drew attention to this; I'll buy that. But if we're really going to try to improve that situation, we have to measure far sooner than three days. So why aren't we doing, you know, two weeks, six weeks, five months, I mean, why aren't we looking at maybe multiple dates so then we could study later to see which

one made a difference, you know, instead of three days as just sort of well, we've obviously waited too long, let's not do that anymore. So I guess I'm interested in the conversation about that. Peter?

DR. BRISS: I suspect that I guess it would be good to have more data. This isn't an actual data question, but I suspect that there are a lot of people that are currently dropped into hospice in their last six hours of life, and three days would be a significant improvement. So for the purposes of the quality measure, if we could figure out something that was an improvement from wherever we are.

CO-CHAIR BAGLEY: No Jim, you were next.

MEMBER PACALA: Yes Bruce, my recollection of this is that Peter's right, that three days, there's a huge bimodal distribution of hospice enrollment and less than three days is a huge spike, and then it tails off, and then it sort of is a very broad, normal distribution. So

I think that--I suspect that that's what's behind the three-day.

CO-CHAIR BAGLEY: But let me ask for a clarification; is that just sort of an observational bell-shaped curve or is that an effectiveness bell-shaped curve?

MEMBER PACALA: Observational.

CO-CHAIR BAGLEY: Answer the question. Let's answer the question.

MEMBER PACALA: But I'm answering the question.

CO-CHAIR BAGLEY: Why do you think they chose three days? If this were a medicine, and you know applying it at three days is useless, you wouldn't be doing it.

DR. WINKLER: Bruce?

CO-CHAIR BAGLEY: So I guess that's really what the genesis of my question was, is how do we sort of get this--if we're going to really look for improvement, what's a better way to examine this than just the ones that clearly aren't going to work?

DR. WINKLER: Bruce, I'd just point out that this actually is an endorsed measure, and the summary of the endorsement review is available in your discussion guide, and this was a question that was raised by the committee that evaluated the measure during its last review, and as it says that members question why three days was selected as the numerator; the developer responded that three days was really their minimum; that perhaps seven days might be a better indicator of quality, but that the current reality was such that there were so many patients that weren't getting to hospice at all. But anyway, the summary of the endorsement review is available in your discussion guide; I just wanted to be able to make that out to you.

CO-CHAIR BAGLEY: Beth, you were next. Go ahead, please.

MEMBER PACALA: So I think also this deals with the trajectory of a malignancy, and so you know, there are different trajectories of death, and the trajectory of advanced malignancy

is probably the most predictable, and that is when you lose ADL function, I think about 90 percent of people with cancer, end stage cancer, when they lose ADL function, are dead within two months. And so maybe two months is the right number for looking at cancer, but I would support this measure particularly as a starting point for looking at appropriate hospice enrollment in a special population, or in a sub population in which the outcome and the trajectory is much more predictable.

MEMBER MOYER: I will preface this comment with I was voted most cynical at the NQF Conference last year by my table. This really short term, hey we're really, really sure this patient is dying, let's trip them on to hospice so they don't hit our mortality care measure, I think this could be a balancing against that as well, avoiding, you know, exclusion of those patients because you've managed to get them on hospice even though it's, you know, more than two days out.

CO-CHAIR BAGLEY: Go ahead.

MEMBER FURNEY: One concern that I had, I would favor a longer interval of time just as been mentioned, but I think you know, we should stick with the three days if that's what the society gave us, and it certainly would move the ball somewhere. But is there any chance that we would deny people the supportive services of hospice type care in their last days of life by doing this, and I'm wondering if that could be-- it's probably a small number, but could that be an unintended consequence?

CO-CHAIR BAGLEY: Other comments? What do people think about having multiple time periods as--multiple numerators if you will?

MEMBER AVERBECK: So I wonder if there's an opportunity in the comments because since it is NQF endorsed or NQF staff just said, some of those comments around the timing could go back to the developers for the next time that it's due for review, since it is NQF endorsed. I'm just curious, because it seems like that's

the conversation around what are the intervals and could we get that feedback back.

DR. WINKLER: Absolutely. In fact, one of our biggest pushes right now at NQF is integrating all the information flow between MAP and the endorsement process, and feedback from MAP will definitely feed into the next evaluation of this measure, and so we definitely are taking note and we'll do that.

CO-CHAIR BAGLEY: Peter, go ahead.

DR. BRISS: And I'd love to, especially if we're talking about lengthening the time, if we could have the developer think about the unintended consequences, the possibility which may be the most repulsive example of gaming I've ever heard of actually.

DR. CLARK: Yes, this would seem to be one of those situations where you really would benefit from some input from patient care giver. I mean, they're--as I mean we'll all recognize, these are very difficult decisions and the dynamic as to when one decides to go to hospice

is not an easy one on the part of the family as well as perhaps the provider; certainly on the part of the care givers.

CO-CHAIR BAGLEY: I don't see any hands, so--oh okay, go ahead Sam.

MEMBER FURNEY: I have just a question; in looking at the measure, the attribution of the measure is the provider making the referral, so presuming this is likely an oncologist? Okay. I think three days seems very, very short, and I'm not sure how to revise the measure to reflect what I think this group--it sounds like the consensus is longer is better, and if three days is considered too short of a threshold, then we want to measure that initially and just hopefully, we'll move that number, and over time if the optimal--I don't know if the optimal is 30 days or 60 days, but I think we should eventually move that number as we hopefully top out the measure, that three days is a rare occurrence, because longer than three days is certainly beneficial

DR. WINKLER: From just a timing perspective, actually NQF has an upcoming cancer project that's starting for the spring, and we can certainly bring this subject to be discussed for them on this NQF endorsed measure as part of the feedback from the MAP.

CO-CHAIR BAGLEY: Barbara, go ahead.

MEMBER LANDRETH: Just a quick comment. My personal experience has been that the oncologists are often the last ones to refer to hospice, and I don't know why that is. I suspect that it might be because they want to continue some sort of treatment or give them some hope that additional treatment will work, but from a primary care perspective, I think you're going to see hospice being referred to much, much sooner than three days. So although this is a cancer measure, it would also apply across the board to other providers as well.

CO-CHAIR BAGLEY: But you have both brought back to mind one of the other reasons I wanted to see this pulled out; is there any

reason that this shouldn't apply to all hospice referrals rather than only cancer patients?

DR. GOODRICH: So we'd have to ask the developer, I don't know if ASCO is here on the phone, but typically with these measures, the way they're coded, they're not necessarily coded for a specific specialist, but they are intended for, you know, I'm sure ASCO is developing it primarily for oncologists, but it is likely that it would be possible for primary care physicians or pathologists or whoever else to use this measure if they could select the measure. We'd have to confirm that with ASCO, but it's likely.

CO-CHAIR BAGLEY: It's just an opportunity to point out that there are other things that you die from, you know? Go ahead, Steve.

MEMBER FRIEDHOFF: As I started thinking about the length of stay discussion, I've done some part time hospice and palliative care in the past, and I was trying to pull up some of the numbers that the NHPCO organization

utilizes for their own patient-oriented outcomes, and it's things like you know, pain control, symptom control within 48 hours, family self-reported, knowing what to do at the time of death and other similar types of measures. What I was trying to do is find out if there's any correlation between, you know, length of time in hospice versus those measures, and I couldn't find anything public, but I have to believe that there's probably some information out there so if it's something that's being reconsidered in another work group, that may be worth bringing into this dialogue, because three does seem short, I mean I agree with Jim's statement that you've got to start somewhere, but if there really is an optimal patient oriented outcome driven length of stay, it's something we should probably understand.

DR. BRISS: You know, we've had several conversations today that were sort of about could a measure be generalized beyond the population for whom it was initially specified;

and so if we did that more systematically, you know we would solve some of our problems about small numbers and about lack of measures for certain specialties and about signal to noise ratio and proliferation of measures. If there were a way to feed back general guidance that said every measure ought to be specified as broadly as it can be, if patient populations and provider groups I think that would help a lot of our problems.

CO-CHAIR BAGLEY: Great. Great point. Jim.

MEMBER PACALA: I still think this is at the right spot, and it's the right target population and the right parameters. I think we need to start at a point where we have the most solid data and the most predictability of the trajectory of the patient. And so while it is a low ceiling--is it a low floor--whatever the rate metaphor is, I think this is the correct one. Even with hospice referral criteria out there for dementia, you know, stage 7 and advanced multi-

morbidity and advanced severity of chronic illness, all of those criteria are not nearly as predictable as an end-stage malignancy is. And so I think that does muddy up the precision of the instrument, and I think this would be a good place to start, and I'm endorsing--I'm going to vote yes.

MEMBER FRIEDMAN: So if this measure is NQF-endorsed, is there data showing the results of it, and I suspect it's very, very high.

DR. WINKLER: The information that's available at the time was limited to the testing that they'd one, so it was a very small amount of information provided during the last review. Let's just say we're going to have a lot more information on it coming up in its next review in the spring, and so the question is where the measure is potentially being used right now, and are they collecting data.

MEMBER FRIEDMAN: So if the number is 50 percent or something obscene like that, maybe

it is a good measure the way it's written right now, so maybe we just need more data on it.

DR. GOODRICH: I expect ASCO has this measure in their registry, so they--it's a QCDR? Okay. Yes, so they probably do have that, so.

CO-CHAIR BAGLEY: Stephanie?

MEMBER GLIER: Just to add a quick comment that in NQF's review of this measure in the endorsement summary materials, it does note that the measure is of use; ASCO's quality improvement initiative actually using a modified version of the measure with a seven-day window. So I'm certain that you will have a lot more data when this comes back in the spring. I agree with Jim; I think we should support this measure as it is now and ASCA will be updating the measure. If they see a different data guided number of days, then I'm sure they will update the measure accordingly.

CO-CHAIR BAGLEY: Thank you for that; I see a lot of heads shaking, so maybe we should vote. Let's vote.

MS. CHAVEZ: Okay, now voting on MUC15-415 for MIPS. The options are one, support; two, conditional support; three, do not support. Voting is open. Okay. So the results for MUC15-415 for MIPS are 90 percent support; 10 percent conditional support; zero percent do not support. So the vote is support.

CO-CHAIR BAGLEY: Okay, we'll go on to number five, bullet number five. Stephanie, do you want to have the first whack at this, since you pulled it?

MEMBER GLIER: Sure. So as I mentioned at the beginning of this consent calendar, I actually pulled five through the rest of the consent calendar as a bloc. I don't want to talk about any one of them in particular; if other people have specific comments on an individual measure, I'm happy to defer to that. My concern about these--and it is a concern--is that these appear to me to be standard of care measures and it's unclear that there's much of a performance gap in this space, and I am not

excited about the prospect of having an accountability program run by CMS where we're just asking people to do the very basic expectation of their practice.

Back to sort of the comment that Bruce had made earlier about--I'm not sure what--if I remember the exact example you used, but I think standard of care is too low a bar here, and I think I'd like to see these measures either combined into a single composite that says yes, we are meeting the standard of care on all of these measures, or we're not, or improved individually to be more closely tied to the outcomes that patients need. These are--I think actually one of the things that really caught my eye was that against recommendation on the second listing for each of these measures for the Physician Compare spreadsheet or webpage was spreadsheet for all of them because they are so technical as to be fairly meaningless to most patients. If you are a cancer patient undergoing one of these treatments, perhaps you do want to

know that your doctor is doing this, but again, if it's standard of care measure, I'm not sure that that's telling you what you need to know, either to choose a doctor or to help you guide your treatment. So I was pretty underwhelmed by this whole bloc; I would very much like to see good measures in this space, and if these measures can be improved, I'd love to have them improved and come back. If they are going to stay this way, I am not as excited about moving them forward.

CO-CHAIR BAGLEY: And I also was wanting to ask these to be extracted for a similar reason. I mean, this comes under maybe the heading of compliance with treatment protocols, and is that an appropriate level to set, you know, national standards about. So that's kind of the nature of the discussion I wanted to hear, similar to what Stephanie asked. I have Beth and David, so Beth you're next.

MEMBER AVERBECK: So I'm going to direct my question to Reva, because I know this

is some of your clinical background. Is part of the measure related to the type of hysterectomy, though as to try and have choice of hysterectomy where there are less complications? So some vaginal instead of abdominal; maybe I was misreading the specs--

DR. WINKLER: If you're talking about the specific measure that's minimally invasive surgery performed for endometrial cancer, you know the studies have basically showed that it's perfectly fine to use minimally invasive techniques to get the same outcomes for cervical cancer of a certain stage and grade, which is defined in this measure. And so that's what--the measure would encourage the use of the more minimally invasive surgeries because the outcomes are similar.

MEMBER AVERBECK: So just to clarify, I wasn't--I haven't pulled that minimally invasive surgery. I think we had actually already--that was the only measure on the set that we did not pull.

MEMBER GLIER: So Beth if you wanted to talk about it, I didn't want to stop you, but just to clarify, my concerns are with performance of radical hysterectomy in patients with 1B1-IIA cervical cancer on down.

DR. WINKLER: Okay.

CO-CHAIR BAGLEY: David, you were next.

MEMBER SEIDENWURM: Yes, I'm not sure that we really know what proportion of cancer patients with these diagnoses received the standard of care, and I think that that is something that we ought to encourage inquiry into. I also think that if I understand the way that these programs are going to function, there's going to be sort of a gradation on this, you know, linear scale that was explained to us earlier, so that the people who excel and are able to achieve higher rates might be rewarded compared to the people who weren't able to achieve higher rates or had practice patterns that were otherwise aberrant. So I think it's

kind of self-scaling, and I think that if we're going to look at these metrics as quality improvement tools, you know first you've got to make all your Toyotas the same, you know, then you can make a Lexus, but you've got to even find out if you're even making a Toyota, and I'm not sure that we know that yet. So for those reasons, and also for the reasons that we talked about earlier today about some practitioners who restrict their practice to some of these narrower areas, again, we'll have a greater participation and a greater ability to influence their practices in a positive way.

CO-CHAIR BAGLEY: Peter, you're next.

DR. BRISS: Yes, I was going to say I wish it were otherwise, but ever since Beth McGlynn, you know people only do the right things about 50 percent of the time. Every time I look at another area, it's another--the batting average is always 50 percent, and even on stuff that I know the most about, like blood pressure control, which I think is a completely simple

clinical problem, you know, for which we have easily used effective medications, it's still 50 percent. So I--this isn't my area, and so if everybody's batting 1,000 in this area, I'll be delighted but surprised.

CO-CHAIR BAGLEY: Winfred.

DR. WU: Yes, I just wanted to clarify my understanding. I mean, out of all the measures, I thought the brachytherapy measure, there was some documentation of a pretty significant performance gap, so I just wanted to clarify that. I think on the order of 40 percent of women who should get brachytherapy aren't, so.

DR. WINKLER: Yes, that was the only measure for which we had any hard data on current performance, and it was really disappointing I've got to say.

CO-CHAIR BAGLEY: I don't see any other hands. Now we're kind of talking about this whole set at the same time, so if you stop talking or raising your hands, we're going to vote on them all if that's okay with you guys.

Anybody object to that approach? We might make it. Okay. We're going to start with--that was number five, right? And that's the radical hysterectomy? No, I don't think--we can't do that.

MS. CHAVEZ: Okay, so we'll start with MUC15-465. The options: one, encourage for continued development; two, do not encourage further consideration; three, insufficient information. Voting is open. For those on the phone, oh we have one left voting via phone--okay we got it, thank you.

CO-CHAIR BAGLEY: Next.

MS. CHAVEZ: The results for MUC15-465 for MIPS are 76 percent encourage for continued development; 24 percent do not encourage further consideration; zero insufficient information. So vote is for encourage for continued development. Next.

Okay, sorry about that. Now voting for MUC15-460 for MIPS. Options: one, encourage for continued development; two, do not encourage

further consideration; three, insufficient information. Voting is open. Okay, the voting results for MUC15-460 for MIPS are 95 percent encourage for continued development; 5 percent do not encourage further consideration; zero insufficient information, so vote is for continued development.

CO-CHAIR BAGLEY: I would, after seeing these, I'd entertain a motion to vote for the rest of them as a bloc. Does anybody object to that? Any single person can object to that. All right, so let's do that; I don't know how you're going to do that with. Just put up the next one, and we'll say it applies to all of them.

MS. CHAVEZ: Here's the list of MIPS.

CO-CHAIR BAGLEY: Okay that's perfect. Okay, that'll make it official. It may just take a little time, but we'll get it.

MS. CHAVEZ: Okay, yes. So now we're voting en bloc for MUC IDs 15-461, 15-466, 15-463, 15-454, 15-450 for MIPs. Options are one,

encourage for continued development; two, do not encourage further consideration; three, insufficient information. Voting is open. Okay, we have the results for MUC15-461, 466, 463, 454, 450 for MIPS, and the voting results are 86 percent encourage for continued development; 14 percent do not encourage further consideration; zero percent insufficient information. So the vote for all of these are continued development.

CO-CHAIR BAGLEY: Okay, we have one more item, and that is the opportunity for public comment. Is there any--I'm not sure there's anything to comment on, but is there any additional public comment? Anybody on the phone?

OPERATOR: Once again, to make a comment, please press star one.

CO-CHAIR BAGLEY: We of course will have public comment on the individual measures; that's tomorrow.

OPERATOR: And at this time there are no public comments from the phone line.

CO-CHAIR BAGLEY: Okay, you've done

great work; we're finished ahead of schedule. Dinner, for those of you who are attending, that's going to be at 5:30 at Mio. Are we going to just meet there, or are we going to go en bloc?

MS. BAL: So it's up to all of you to decide; it is only a block up, so not very far at all. You can choose to walk over there together, or you can choose to meet people there. It's up to you.

CO-CHAIR BAGLEY: Okay, what's the address?

MS. BAL: I will announce it shortly.

CO-CHAIR BAGLEY: Okay great. Thank you. Thank you all for your patience and your lively conversation. We'll see you tomorrow.

(Whereupon, the above-entitled matter went off the record at 4:39 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Measure Applications Partnership Clinicians Workgroup

Before: NQF

Date: 12-09-15

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R. Gross

Court Reporter