NATIONAL QUALITY FORUM

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MEASURE APPLICATIONS PARTNERSHIP
CLINICIAN WORKGROUP

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WEDNESDAY
DECEMBER 12, 2018

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The Workgroup met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, NW, Washington, D.C., at 8:30 a.m., Bruce Bagley and Amy Moyer, Co-Chairs, presiding.

WORKGROUP CO-CHAIRS
BRUCE BAGLEY, MD, National Quality Forum
AMY MOYER, The Alliance

ORGANIZATIONAL REPRESENTATIVES
KEVIN BOWMAN, MD, Anthem
HELEN BURSTIN, MD, MPH, FACP, Council of Medical Specialty Societies
DAE CHOI, MBA, MPH, Genetech
ROBERT FIELDS, MD, Mount Sinai Health System
SCOTT FURNEY, MD, FACP, Atrium Health
ANN GREINER, MS, Patient-Centered Primary Care Collaborative
ROBERT KRUGHOFF, JD, Consumers' CHECKBOOK
TRUDY MALLINSON, PhD, OTR/L, FAOTA, The George Washington University*
IRA MOSCOVICE, PhD, MAP Rural Health Workgroup Co-Chair
AMY NGUYEN HOWELL, MD, MBA, FAAFP, America's Physician Groups
DIANE PADDEN, PhD, CRNP, FAANP, American Association of Nurse Practitioners
KIM RITTEN, HealthPartners*

DAVID SEIDENWURM, MD, Sutter Health/American College of Radiology
J. CHAD TEETERS, MD, RPVI, FACC, American College of Cardiology
PATTI WAHL, MS, St. Louis Area Business Health Coalition

SUBJECT MATTER EXPERTS
MICHAEL HASSETT, MD, MPH
DALE SHALLER, MPA
ERIC WHITACRE, MD, FACS

FEDERAL GOVERNMENT LIAISONS
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REENA DUSEJA, MD, Centers for Medicare & Medicaid Services (CMS)

NQF STAFF:
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JOHN BERNOT, MD, Vice President, Quality Initiatives
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VAISHNAVI KOSURI, MPH, Project Analyst

MIRANDA KUWAHARA, MPH, Project Manager

ELISA MUNTHALI, MPH, Senior Vice President

ERIN O'ROURKE, Senior Director

ALSO PRESENT:
JOEL ANDRESS, PhD, CMS
SUSAN ARDAY, CMS
JAYANTI BANDYOPADHYAY, MPH, Mathematica*
CHRIS BEADLES, MD, PhD, RTI International*
HEIDI BOSSLEY, MSN, MBA, Bossley Consulting, LLC
RICHARD DOANE, Premier, Inc.*
STEPHAN DUNNING, OptumLabs
DAN GREEN, MD, CMS
DEANNA HAYES, PT, DPT, MS, Focus on Therapeutic Outcomes, Inc. (FOTO)*
STEPHEN McCOLLAM, MD, American Academy of Orthopaedic Surgeons*
JENNIFER McLAUGHLIN, American Medical Association
SRINIKETH NAGAVARAPU, PhD, Acumen, LLC
COLLEEN PARKER, RN, BSN, CEN, LUGPA and Oregon Urology Institute*
RYAN PEZOLD, American Academy of Orthopaedic Surgeons*
LYNN PEZZULLO, RPh, CPEHR, Pharmacy Quality Alliance (PQA)*
SANDRA POGONES, MPA, CPHQ, American Academy of Family Physicians*
LINDSEY ROTH, MPP, National Committee for Quality Assurance (NCQA)*
DARSHAK SANGHAVI, MD, OptumLabs
MICHELLE SCHREIBER, MD, QMVIG Group Director, CMS
HEATHER SMITH, PT, MPH, American Physical Therapy Association*

KIM SPALDING BUSH, BS, CMS*

JENNA WILLIAMS-BADER, MPH, NCQA*

***Present via telephone**

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

(8:31 a.m.)

CO-CHAIR BAGLEY: Well, welcome to sunny Washington. Those of you who live here, that's fine but for those of you who have traveled, I'm glad you made the trip and I hope you have a good time today.

My name is Bruce Bagley and I'm the co-chair with Amy this morning and I think we'll have some introductory remarks and then we'll talk a little bit more about meeting conduct.

So, John, do you want to start off?

DR. BERNOT: Yes, good morning, everyone. Again, thank you so much for coming out to Washington, D.C. on this early Wednesday morning with holiday season and weather across the country. So we really appreciate that you made the effort to get here.

We have a busy day today. This is Day 3 of MAP. The PAC/LTC group had gone Monday, the hospital group went yesterday, and this is the final, the clinician group today. So we have a

lot on the agenda but we're really happy that you were able to make it.

There's a few minor points I'm going to go over more of the logistics of the meeting.

The first one is we have a new voting software. I think you'll happy to know, fingers crossed, the last few days, it went very well. It's been a big improvement. I think the committees really were pleased with the change. But we do have instructions on everyone's seat about getting onto the Poll Everywhere software. If at some point over the last 10 or 15 you realize you've not been able to get on or you're having a problem, just let one of the staff members know and we will come around and make sure because we will need everyone to be on that for the voting.

The way it works, as you'll be able to see, we're going to do a test, but you will be able to see the votes. We will know who voted but we will not know how you voted. So that's just we have an integrity check that the correct

people are voting but we do not know what the vote will look like.

All of the meeting materials, if you're following on your computer, are on the public.qualityforum.org website. The discussion guide we'll actually be using which has the hyperlinks to move through it.

I think also most of you have been here in the past but if you have not, when you wish to speak, we use the tent cards -- oh sorry, Bruce is going to talk about the tent cards so we're on that one.

The other logistics, restrooms are down the hallways this way and then you make a right.

So other than that, I'd just like to say thanks again for coming. A busy day today, so I will keep the remarks short from the NQF side but a lot of work has gone into it both from the NQF staff and from comments from the chairs. So I think we'll have a good meeting today.

So with that, I will turn it back over

to Bruce.

CO-CHAIR MOYER: I just wanted to welcome everyone today.

And one additional thing I wanted to add very timely, we worked on this with Michelle, if everyone could mute their cell phones.

I'm looking forward to some really robust discussion and thank you all for being here.

CO-CHAIR BAGLEY: And about the tent cards, the tent cards are so we know who you are. So make sure that we can see them. There's a lot of people in this room and it's a long way to the other end of the table.

If you want to speak, all you have to do is catch our eye and we'll put you on a list. So if you will look at -- if I give you the high sign, that means I've seen you and you're on the list. And if at any time you want to know what's going on with the list, we'll read it off to you. But usually that worked pretty well for us and that way, people don't have to worry about

putting their tent cards back down and all of that kind of stuff because that gets confusing after a while for the chair, at least. So I would prefer that you use the other method.

We're going to dive right in here. Do you want to take the first part, Elisa?

MS. MUNTHALI: Yes. Good morning, everyone. My name is Elisa Munthali and I'm the Senior Vice President for Quality Measurements at the National Quality Forum. I welcome and thank you all for being on this workgroup.

So what we're going to do today is to combine introductions of the workgroup with disclosures of interest. We're going to do it in two parts because there are two types of workgroup members. There are organizational reps and there are subject matter experts.

We'll start with our organizational reps. We'll start with the organizational representatives and the room and then go to those that are on the phone. And then we'll go to the subject matter experts; go to those in the room

first and those on the phone.

For the organizational reps, we sent you a questionnaire. It was a short questionnaire. We essentially wanted to know the financial interest and work that you've done where you've been paid $10,000 or in excess of $10,000.

So we will start to the left of me. I think we're starting with I think it's Scott. And if you can introduce yourself, let us know which organization you are with, and let us know if you have any disclosures.

MEMBER FURNEY: So my name is Scott Furney. I am a representative of Atrium Health. That's a new name that used to be Carolinas HealthCare System. So we've expanded to Georgia. The name no longer fit so it's now Atrium Health.

I have no disclosures of any type.

MS. MUNTHALI: Thank you very much. And what I should have done is tell you who is the subject matter experts. There are more organizational representatives on the workgroup

than subject matter experts. So for this first round, everyone with the exception of Michael Hassett, Dale, your co-chairs of course, Eric, and I think that's it.

So we'll continue on.

MEMBER FIELDS: Rob Fields, Senior Vice President, CMO for Pop Health at Sinai. I'm here representing the National Association of ACOs. No disclosures.

MS. MUNTHALI: Thank you.

MEMBER TEETERS: Hi, I'm Chad Teeters. I'm from the American College of Cardiology and I have no disclosures as well.

MEMBER MOSCOVICE: Ira Moscovice, professor at the School of Public Health, University of Minnesota representing the MAP Rural Health Workgroup.

MS. MUNTHALI: And, Girma, we'll wait until we introduce our federal liaisons and then we'll have you introduce yourself then. The same with you, Peter.

MEMBER PADDEN: Good morning. I'm

Diane Padden. I'm representing the American Association of Nurse Practitioners.

In terms of disclosure, I do sit on one of the MAP MACRA episode-based cost measures development, as well as the MIPS outpatient measures as well.

MEMBER SEIDENWURM: Hi, I'm David Seidenwurm, American College of Radiology and I was a co-chair of one of the episodes, the spine fusion episode.

MEMBER WAHL: Good morning. I'm Patti Wahl with the St. Louis Area Business Health Coalition. We represent large self-funded employers. And I have no disclosures.

MEMBER BURSTIN: Good morning. Helen Burstin, CEO of the Council of Medical Specialty Societies. No financial disclosures.

MEMBER CHOI: Hi, Dae Choi with Genetech. Just a general disclosure that I am employed by Genetech. We have portfolios in oncology, ophthalmology, and neuroscience.

MEMBER GREINER: Hi, Ann Greiner,

President and CEO of the Patient-Centered Primary Care Collaborative and no disclosures.

MS. MUNTHALI: Great. Thank you very much.

So Kim Ritten, are you on the phone?

MEMBER RITTEN: Yes, I'm on the phone. This is Kim Ritten from HealthPartners in Minnesota and I have no disclosures. I'm sitting in for Sue Bugel.

MS. MUNTHALI: Thank you very much.

Terry, are you on the phone? Okay, Terry may not have joined us yet.

So thank you to all of our organizational representatives. And so now we'll go through disclosures for the subject matter experts.

For the subject matter experts, you received a lengthier form that asked you to disclose any activities that were relevant to the work in front of you.

Just a couple of reminders. We're interested not just in the paid activities but

also those that are not paid. In addition to that, we wanted you to know that even though you disclosed does not mean that you have a conflict of interest. We do this in the spirit of openness and transparency.

And so in the room, we'll start with Dale.

MEMBER SHALLER: Good morning. Dale Shaller. I am a patient experience subject matter expert. I have no disclosures related to the measures under consideration but do if there were patient experience measures. But since there aren't, I think I'm okay.

MS. MUNTHALI: Thank you.

Eric.

MEMBER WHITACRE: Good morning. My name is Eric Whitacre. I have several disclosures, none financial.

I'm a member of the Performance Measures Committee of the American College of Surgeons that's involved in measure development, none of which are directly related to these.

But I do for the breast measure, the lumpectomy/mastectomy measure. I have been involved with peripheral emails, not in terms of the measure creation but responding to member frustration over the process.

In terms of reimbursements, because I guess that's now part of this committee, I am the ASBS representative to the AMA RUC Committee, alternate to the CPT, and a member of the American College of Surgeons Coding and Reimbursement Committee.

MS. MUNTHALI: Thank you. And I think Michael is the next subject matter expert.

MEMBER HASSETT: My name is Michael Hassett. Thank you. I'm a medical oncologist. I work at Dana-Farber Cancer Institute in Boston, Massachusetts and I sit on ASCO -- a committee that is responsible for developing measures for ASCO, which is the American Society of Clinical Oncology.

MS. MUNTHALI: Thank you, Michael.

And your co-chairs, of course, are

subject matter experts. I'll turn it over to Amy first.

CO-CHAIR MOYER: Hi, I am Amy Moyer and I work for The Alliance. We are a cooperative of self-funded employers. So I am a purchaser.

And I have no disclosures relevant to measures that are before the committee today.

MS. MUNTHALI: Okay, thank you.

CO-CHAIR BAGLEY: Hi, I'm Bruce Bagley. I'm a family physician and at this point in my life, I am independent consultant working less and enjoying it more. And I have no conflicts that are relevant to this.

Like all of you, I come with a boatload of biases but I have no conflicts of interest.

MS. MUNTHALI: Thank you very much.

And we understand that we have another organizational representative on the phone, Trudy from the George Washington University. Trudy, are you on mute by any chance?

Okay, we may come back later in the meeting.

In addition to having our subject matter experts and our organizational reps on the committee, we also have federal liaisons who are part of the committee but they are nonvoting workgroup members. And so I'll start with Michelle Schreiber, who is from CMS, to introduce herself.

DR. SCHREIBER: Thank you. Good morning. I am Michelle Schreiber. I am one month into my job as the new Director of QMVIG, which is the Quality Measures Value-based Incentives Group. It is the group within CMS that owns most of these programs that you love dearly. So, thank you.

MS. MUNTHALI: Thank you.

DR. SCHREIBER: And I have no disclosures.

MS. MUNTHALI: Thank you. Girma?

MEMBER ALEMU: Yes, I am Girma Alemu with the Health Resources and Services

Administration. I have no disclosures to report.

MS. MUNTHALI: Thank you very much, Girma.

Peter?

MEMBER BRISS: Good morning. I'm Peter Briss. I'm with the Centers for Disease Control and Prevention and I have nothing to disclose.

MS. MUNTHALI: Thank you. And Trudy did communicate with us via email and she has no disclosures.

So we've heard all of the disclosures and I thank you all for participating. I just wanted to remind you if at any time during the meeting you remember that you have something to disclose, we want you to do so. You can speak up in real time or you can contact any of us on the NQF staff or your co-chairs.

Likewise, if you feel that one of your workgroup members is acting in a biased way, we want you to speak up or contact us and let us know.

So with that, I thank you again.

CO-CHAIR BAGLEY: John, would you like to introduce your staff?

DR. BERNOT: Sure. One thing we'll do is just introduce the staff. I want to also point this out, not just so who we are but if you have any questions as Elisa mentioned throughout the day, please grab any one of us and just ask the question. We'll do our best to answer it.

But for those of you who I do not know, I'm John Bernot. I'm Vice President of Quality Measure Initiatives with NQF and a member of the Clinician Workgroup.

MS. O'ROURKE: I'm Erin O'Rourke. I'm a Senior Director with NQF and I support the Coordinating Committee.

MS. KUWAHARA: Good morning, everyone. My name is Miranda Kuwahara and I serve as the Project Manager for this work.

MS. KOSURI: I'm Vaishnavi Kosuri and I serve as the Project Analyst on this team.

MR. AMIN: Good morning, everyone.

I'm Taroon Amin. I'm a consultant supporting the MAP Coordinating Committee.

DR. BERNOT: Well, I think that's it. Back to you, Bruce and Amy.

CO-CHAIR BAGLEY: Michelle, we're going to ask you to set this whole thing up.

Before we do that, Amy, do you want to just say who you are and your conflicts?

MEMBER NGUYEN HOWELL: Sure. Hi, good morning, everyone. Amy Nguyen Howell and no conflicts.

CO-CHAIR BAGLEY: Okay, thank you.

DR. SCHREIBER: Thank you to the co-chairs. As you heard, I'm Dr. Michelle Schreiber and, on behalf of CMS, I'd really like to welcome you all to the MAP. This is a wonderful committee with a lot of diverse opinions, which we look forward to hearing. Sincerely, thank you for your participation.

You know your input today is really extremely valuable. As I've been part of this for the last couple of days, the feedback is very

important. We take copious notes but truly CMS does listen to the comments that are here and it does influence and change the way that some of these measures are developed, go forward, and become part of rulemaking. So we want you to know that your opinions really do matter.

We'd like to thank NQF also for convening this work and for your expertise.

I'm joined today by some of my colleagues at CMS, Dr. Reena Duseja, who is the Chief Medical Officer for QMVIG, will be here shortly.

We have a number of people in the audience, including some of our experts and the contractors who actually are measure developers. Please take a moment to interact with them if you have questions. They really are the experts in some of these areas.

The Measure Application Partnership is an important annual process that, frankly, many of you know better than I do but it's where NQF convenes multiple stakeholders to provide input

on measures for use in federal programs, which will become part of rulemaking really almost as soon as these meetings finish.

The committee also helps to provide guidance on future direction and helps identify gaps in measures. And of course, there is the opportunity for important public comment that we appreciate very much.

So you've heard I'm new to CMS, one month into this. This is the group that is responsible for quality measures, for their development, for their stewarding in the programs that many of you are familiar with, the Hospital, Stars, MIPS, meaningful use, a/k/a Promoting Interoperability, post-acute care, inpatient psych. So it's a host of programs and these MAP Committee meetings are very important in providing input to all of them.

So, by way of background, I know a few of you. I don't know many of you. I am a primary care general internal medicine physician and until about a month ago, I was still seeing

patients. So this is something that's near and dear to my heart.

I'm also a caregiver for an elderly mother and hence, the phone calls this morning.

I've worked in healthcare for really many years, always within the healthcare space. This is a new transition to the policy side. It's really very humbling and very exciting to see it from the development of the things that we work with on a daily basis.

I was most recently the Chief Quality Officer of the Henry Ford Health System and was also its lead in their Epic implementation. My particular interest, actually, is the intersection of quality quality measures in the electronic medical record and so it's very exciting to, again, be in this spot of development.

I know that you've heard presentations before on CMS' important initiative of Meaningful Measures. So let me just touch on a couple of things today to keep in mind as you consider your

votes on the measures that are before you.

Meaningful Measures was launched really just last year to improve outcomes for patients and caregivers by empowering them with information that is helpful for them to make decisions. But Meaningful Measures is also about making things better for healthcare systems and certainly more importantly for providers. It is about reducing the reporting burden to clinicians and promoting patients over paperwork.

With this in mind, we actually narrowed down the initial 184 measures submitted to the MUC list down to a very parsimonious list, most of which have fallen on this committee. The prior two MAPs actually had fewer measures to consider, while you have a larger agenda.

You know we do recognize that quality measurement and quality reporting is not a perfect science and that all of the programs that we work with have opportunities for continued refinement.

This past month I've really come to

appreciate how CMS does take these comments seriously and is working all the time on improving both the measures and the process of developing them and again, delighted to hear your feedback.

As part of the effort to reduce burden, last year through Meaningful Measures we removed 79 measures and saved an estimated over $125 million in expense, while continuing to align measures across multiple programs. Meaningful Measures is a commitment to infusing the principles of value, innovation, and flexibility and follows the CMS quality strategy goals, which include making care safer, strengthening the person and family engagement, promoting effective communication and care coordination, promoting the effective prevention and treatment of chronic disease, working with communities to promote best practices of healthy living and, of course, making care affordable.

Meaningful measures is not just about burden reduction, however. The work also calls

for identifying and filling in gaps where there's a lack of important measures, some of which you'll see today, and focusing more on outcome and patient-reported measures, although I want to be clear that process measures have a role as well.

We'll continue to align measures across all programs and payers. I'm really particularly excited about the work that has reinstituted with the partnership of National Quality Forum, AHIP, America's Health Insurance Providers, and CMS called the Core Quality Measures Collaborative, which is a set of committees that is looking to align CMS measures with the major payers in the United States. So if we can have sort of a seamless view of quality measures and programs, I think that would also help reduce burden.

Finally, we recognize that we have to reduce the burden of the measurement systems, including making quality measures more real-time so that they are actionable. There is a great

deal of work and thought going on around multiple registries, as well as significant thought to the future and what it means to have electronic quality measures.

So please, and a couple of final comments, think about these areas as you make your recommendations today:

1) Are we addressing a high impact area?

2) Are the measures meaningful to patients and caregivers and include the patient voice?

3) Is this an outcome or a process measure? They are different and both have a role.

4) What is the burden of the measure, or the burden, or unintended consequence of including the measure in a value-based program?

5) Is there a significant opportunity for improvement in the metric area, or is it really just topped out?

6) And finally, does the measure fit

a population-based payment or alternative payment model and does it align with other programs or payers?

I'd also like to close by saying please always, as we do, think about equity and about advancing interoperability in electronic health records.

I thank you, and, on behalf of CMS, we all thank you for your time, your dedication, and we look forward to your participation, and look forward to working really with each and one of every one of you. Please feel free to come and talk to us or reach out to us anytime.

I turn this back to the chairs. Thank you.

CO-CHAIR BAGLEY: Great. Thank you, Michelle. Any questions for Michelle before we go on? She's going to be here all day. She's chained to the chair and taking notes, copious notes. So she's going to try to take in everything that goes on. But you're going to be here all day to answer questions. So, we're

good.

All right, Miranda, do you want to talk a little bit about the process?

MS. KUWAHARA: Yes, absolutely. So, just to provide an overview of how our low today will work, I will start off by describing our approach.

So, MAP follows a three-step process, which consists of a program overview, followed by a review of the current measures, and an evaluation of the measures under consideration for the next iteration of the program measure set.

Due to the large number of measures under MAP Clinicians purview and in the interest of time, we will not revisit the overview of the MIPS and SSP programs or the current measures, which were reviewed during the orientation web meeting. We did provide you with the measure frameworks, which houses the 2018 and 2019 measure sets for both programs. Those were delivered to you in an email sent out on December

5th.

If you are following along as a member of the public, you can also locate them on the left-hand navigation pane of the web platform.

MAP workgroups must reach a decision about every measure under consideration. Decision categories are standardized for consistency across the measures and programs. And one or more statements of rationale should accompany each decision. Next slide, please.

NQF staff have conducted preliminary analysis of each measure under consideration, which are presented in the discussion guide also sent out in that package of materials. This discussion guide is also linked on the left-hand navigation pane, if you are following along as a member of the public.

Preliminary analyses are intended to provide MAP members with a succinct profile of each measure and serve as a starting point for MAP discussions.

Staff use an algorithm developed from

the MAP Measure Selection Criteria to evaluate each measure.

The preliminary analysis algorithm uses a series of criteria to determine if a measure receives a recommendation of support for rulemaking, conditional support for rulemaking, do not support for rulemaking -- I'm sorry -- do not support with rulemaking for a potential with mitigation, or do not support. And we'll cover those decision categories a little bit later in the presentation.

Reflected on this slide is MAP's measure selection criteria, which serves as a tool used to assess the measure sets used in quality initiative programs. The criteria are not absolute rules, rather they are meant to provide general guidance on measure selection and decisions and to complement program-specific statutory and regulatory requirements. Next slide, please.

Reflected on this slide are those decision categories I mentioned previously.

Please note that do not support for rulemaking with potential for mitigation has newly replaced refine and resubmit. This new category captures measures which are conceptually promising but not yet ready for rulemaking.

And a pause here to see if there are any questions from the workgroup about this new decision category.

Okay, seeing none in the room and none in the chat, I'll continue on.

Sure.

MR. AMIN: Yes, if we can go back one slide.

So I just want to emphasize to the workgroup in the conversations we've had over the last two days with the prior -- with the Hospital and the Post-acute Workgroups, I just want to note the distinction. Really there's a lot of conversations between the difference between conditional support and do not support with mitigation.

I just want to point out the

distinction that seemed to resonate the most with the other workgroups, given that this is new as part of the 2018-19 launch of this cycle. So the first is to say that both represent that there are some changes that are required. The real question is the extent of the changes that are required in the measure. So really conditional support for rulemaking is intended to be that these are conditions that we would want the developer and the program implementers to consider but it is good enough to go ahead.

For do not support with potential for mitigation, these are items that you believe really need to be addressed before the measure is able to be used in the rule. That is obviously a matter of judgment and we would yield to you all as experts as we are going through these measures to weigh the degree that you feel that these changes need to be considered before going to rulemaking.

So that distinction was a topic of conversation among the other two -- the past two

days. And before we get into it -- before we get into any specific examples, risk adjustment, attribution, these are going to come up, obviously, as questions and you'll have to judge how much of a concern you have where it falls in terms of the decision category.

So just to preempt that before we get into any specific examples, that will be a struggle I am sure but part of it is using your own judgment to weigh how big of an issue it is.

CO-CHAIR BAGLEY: Thank you, Taroon, for that.

And just to maybe put a fine point on that, the third category last year was refine and resubmit but, as you all know, there was no mechanism for resubmission for this committee to ever see it again for any kind of decisionmaking. So that's the biggest change.

CMS, I suppose, can do whatever they want with it after it gets through this committee but it's not coming back to this committee.

MEMBER BURSTIN: That's helpful for

both counts. It was, the revise and resubmit, for those of us who have been around the block for a while, that was confusing. And so the word ideally in conditional support is helpful. Because it says that identified conditions or modifications that ideally would be addressed prior to implementation. So there's really no clear expectation those changes will be made. So essentially it is you could live with this, is my sense of how I would handle that, versus do not support for rulemaking with potential for mitigation, a very long term, is really we would really expect some of these changes to be made before the measure is implemented. Okay, thanks.

DR. SCHREIBER: It did. So for the last couple of days, really the groups have kind of struggled with these categories. And I think the way that we are sort of interpreting is if you're willing to consider it, if you are willing to consider it more or less as is, maybe with a few minor modifications but you really support it, vote that way. If you really don't want to

see this move forward, vote on the do not support side of it, the you know not consider the last category.

Obviously, you can say don't support at all with the category before it with major modifications. We would take that as you really don't want it to go forward.

That being said, as the committee chairs pointed out, CMS does have the right to take any of them forward but we really do take these comments under advisement and if you really don't support it, please make it clear.

CO-CHAIR BAGLEY: I think this will become much more clear as we have our discussions as well. So when you start to see what types of things people are concerned about, it will work out.

Any questions or clarification?

Okay, Miranda.

MS. KUWAHARA: All right. So this year we have updated our voting procedures. We've highlighted the new principles in red over

the next several slides to draw your attention to those updates.

We define quorum as 66 percent of the voting members of the workgroup, both in-person and remote. We've defined consensus as greater than or equal to 60 percent of voting participants and a minimum of 60 percent of the quorum figure voting positively.

Next slide, please.

We will begin with a staff introduction of each measure under consideration and lead discussants will present on their findings.

Our co-chairs will ask for any clarifying questions, to which developers may respond to questions about the measure specifications. They have all received invites to join this meeting remotely so they can address any questions you might have for them.

Staff may respond to questions on the preliminary analysis or lead discussants may respond to questions about their analysis.

We will then open for a vote on the acceptance of the preliminary analysis decision. If greater than or equal to 60 percent of the workgroup members vote to accept the preliminary analysis assessment, then the preliminary analysis assessment will move forward as the workgroup's recommendation. If we do not achieve that 60 percent threshold, then we will reopen for discussion.

Next slide, please.

After the discussion concludes, chairs will reopen the measure under consideration for a vote. If the chairs feel that a consensus decision has emerged, then we can vote on that decision category but if the consensus decision has not emerged, we will vote on each potential decision category one at a time, beginning with support, followed by conditional support, then do not support with potential for mitigation, followed by do not support.

Next slide, please.

The decision category that captures

greater than or equal to 60 percent will move forward as the recommendation for that particular measure.

If not decision category achieves greater than or equal to 60 percent, then the preliminary analysis decision will stand and the Coordinating Committee will consider that measure informed by the discussions that come out of this workgroup meeting.

So are there any questions about the voting procedures?

All right, the last and final slide in this section is just an overview of the time line for the cycle. Following this meeting, we will open for a public commenting period between December 21st and January 10th. Then, the Coordinating Committee will finalize the workgroup's input in January and the final report summarizing the measure deliberations will be submitted prior to March 15th.

Before we open for public comment, I just wanted to see if there were any questions on

any of the material I've covered thus far.

Okay.

MS. KOSURI: And before we want to do a test run of voting.

MS. KUWAHARA: We wanted to do a test run of voting. So I can open it up and just make sure that we have all of our members.

So I'm going to unlock it right now and if you could, input yes to submit your vote. And even if you input no, we would know that you have voted.

We've got ten votes so far. So if people can continue to vote, we're looking for 17 votes -- or 18 votes.

MS. O'ROURKE: And if you're having Wi-Fi challenges, we're going to get IT to get you back connected. So apologies and just bear with us one minute while we get IT.

DR. BERNOT: And if anyone's having trouble getting onto Poll Everywhere, just raise your hand and one of us will come around and help out.

MS. KOSURI: So for those of you who have successfully casted your votes, feel free to go up, get a refreshment, a cup of coffee, while we iron out this new voting platform.

(Whereupon, the above-entitled matter went off the record at 9:08 a.m. and resumed at 9:22 a.m.)

CO-CHAIR MOYER: All right, everyone, if you could take your seats, we're going to keep on track and keep on time. We have a lot of measures to get through today.

MS. KOSURI: Hi, everyone. We want to redo the vote again, just to make sure that everyone is able to vote. So could we get everyone back to their seats so we can try that again?

So I'm going to clear the poll again and then hopefully you'll be able to -- yes. We're at 13. We're still at 14 votes. So if people can vote again -- 15. We're at 16.

DR. BERNOT: So we're looking for two more votes -- one more vote now.

MS. KOSURI: One more vote now.

MS. KUWAHARA: All right, thank you all for your patience. We are going to move forward.

We did take an ad hoc break so we're going to skip over the break we had scheduled in our agenda but we will take this opportunity to hear from any members of the public who would like to offer comments. So, we can begin with those in the room.

Seeing no comments in the room, Operator, could you please open the lines for those participating remotely?

OPERATOR: Yes, ma'am. At this time, if you would like to make a comment, please press star and then the number 1 on your telephone keypad.

Okay, and we do have a comment from Richard Doane with Premier, Inc.

MR. DOANE: Yes, good morning, everyone. Thank you so much. It's great to speak with you this morning and I appreciate the

opportunity to make comments.

So the MAP is considering four opioid-related measures for inclusion in the Medicare Shared Savings Program, also known as MSSP, and we ask the committee do not support these measures for inclusion and I'm going to outline some reasons why. Premier is incredibly supportive of measures across -- setting appropriate opioid use, however, these specific measures are not well-suited for MSSP.

As part of MSSP, ACOs receive monthly, unblinded Parts A and B claims data. Unfortunately, ACOs have limited access to Part D information and are unable to monitor this information on an ongoing basis.

Additionally, the ACO model beneficiaries are permitted to see any provider and may see providers that are not affiliated with the ACO. The ACO is, therefore, unaware of prescribing practices for these providers and has less of an opportunity to proactively intervene and help modify their prescribing patterns.

Premier member ACOs are also working to better manage medications for ACO beneficiaries and is encouraged that CMS has sought comments on how to more rapidly provide Part D data and if the Part D data benefit could be incorporated into ACOs.

Additionally, Premier supports and collects three of these measures for PBMs. We just do not support them for ACOs, due to the model constraints that were outlined previously.

So in conclusion, since these are claims-based measures, it would be useful if CMS could provide confidential measure results along with national benchmarks to ACOs, however, the measures should not be formally included in the program because ACOs have limited ability to impact measures and the measures have not been tested for this ACO model.

Thank you so much.

CO-CHAIR MOYER: Thank you.

A couple brief housekeeping items. Kevin has joined us. Kevin, would you introduce

yourself and give us any disclosures that are relevant?

MEMBER BOWMAN: Hi, Kevin Bowman. Nice to meet everyone.

I'm with Anthem and I do not have any disclosures.

CO-CHAIR MOYER: And Reena, I'd like to introduce you as well.

MEMBER DUSEJA: Good morning. Hi, I'm Reena Duseja. I'm the Chief Medical Officer for the Quality Measurement and Value-based Incentives Group so I work with Dr. Schreiber and I have no disclosures.

MS. KUWAHARA: Great, thank you all very much.

So, John, I will pass it to you to introduce our first SSP measure group.

DR. BERNOT: Great, thank you.

So the first group of measures we will all relate to the use of opioids. So I will introduce all four of the preliminary analyses, and then we'll have the lead discussants talk,

and then it will be open for a discussion, a larger discussion.

I want to give a couple of caveats. The preliminary analyses by staff are done through an algorithm that we apply to the best of our ability. that's the one that is used across all of MAP. We work very hard with the other groups to try to strive for consistency. But the take home message: this is the starting point for discussion.

The committee here of experts makes the final ruling. So this is to get us started. Hopefully, you see our logic. We will try to highlight the through process that we went that put it into the category. But again, this is the starting point for discussion and, again, the ultimate vote can go wherever you would like it to, as an expert committee.

So I'm going to go through this first group of measures, starting with MUC2018-077. So I will introduce the number, I will read the title and I will go over the staff preliminary

analysis and give a small snippet of information, if it's relevant.

So this measure, again MUC2018-077 is the Use of Opioids from Multiple Providers in Persons With Cancer. The description of this measure is the rate of individuals without cancer -- excuse me. Sorry, I will go back for the record -- Use of Opioids from Multiple Providers in Persons Without Cancer. And the rate of individuals without cancer receiving prescriptions for opioids from four or more prescribers and four or more pharmacies.

The preliminary analysis for this -- this is an NQF-endorsed process measure. The preliminary analysis was a conditional support for rulemaking with the condition that the duplication/harmonization is considered between this measure and MUC2018-079, which I will get to momentarily. So that's the first measure.

The next measure is MUC2018-078. This is the Use of Opioids at High Dosage in Persons Without Cancer. Similarly, it is the rate of

individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120 milligram morphine-equivalent dose for 90 consecutive days or longer. Also a process measure that is NQF-endorsed. The preliminary analysis for this was similarly, conditional support for rulemaking with the condition that that duplication is considered between this measure and also the next one that I'll talk about, which is MUC2018-079 and I will do that one right now.

I am moving quickly intentionally because I would like the discussion to be from the committee but feel free to stop me if there's any questions or clarifying points on the PA itself.

So the third measure in this group is the Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer. This is, essentially, a combination. It is the rate of individuals without cancer receiving prescriptions for opioids with a daily dosage

greater than 120 morphine-equivalent dose for 90 consecutive days or longer and who received opioid prescriptions from four or more prescribers and four or more pharmacies.

The preliminary analysis -- again, also a process measure that is NQF-endorsed. The preliminary analysis is the reciprocal of the first two. This is a conditional support for rulemaking with the condition of considering this potential duplication now between this and 077 and 078.

So essentially, 077, 078 are two components that make up 079. As the staff preliminary analysis, we're trying to make the committee aware of that and give any guidance to CMS whether this should be individually, the combination, or all put into the Shared Savings Program.

And then one last measure that is not related directly to those measures but also around the opioid topic is MUC2018-106. This is the Initial Opioid Prescription Compliant with

CDC Recommendations. The description of this is a composite score indicating compliance with five measurable CDC opioid prescribing guidelines. The denominator includes new opioid prescriptions in the measurement year and the numerator includes new opioid prescriptions that are compliant on all five CDC indicators. This is a higher is better measure. It's a composite measure.

The preliminary analysis for this was do not support for rulemaking with potential for mitigation. And the mitigation would include specifying the measure at the health plan level.

I'll give just one or two brief sentences on this. If looking at the PA, the preliminary analysis and the specifications there is a lot of information about health plan-level data; however, the only data available to us as staff was a county-to-county comparison, which is why it went into the do not support with mitigation, again, through our algorithmic view of this.

Are there any questions on any of the four?

MEMBER SHALLER: Just a quick question just on the last point. Why would you want to make this contingent on specification at the plan level and not the ACO level, since this is an MSSP measure?

DR. BERNOT: That's really probably more appropriate would be ACO level. The language we used is what NQF-endorsement categories are. NQF does not have an ACO-specific endorsement level.

But you are correct, actually for the record, it would probably go down better saying at the ACO level.

CO-CHAIR MOYER: All right, the lead discussants for these measures, Terry was not able to join us today. So we have a mix of individuals, Ann Greiner, Helen, and Robert. So, is anyone dying to start?

I think, given, you know we used to have the consent calendar approach and we're kind

of viewing these as all relevant to opioids and that the discussion may better lend itself to looking at them together. Are there any objections from the committee for kind of considering and talking about these as a group? I just want to make sure everyone is okay with that.

Not seeing any, Bob, I'm going to start with you.

MEMBER FIELDS: Sure. So at this point, NAACOS is not supportive -- do not support with mitigation for all of the measures, with the exception of 078, which we would support with mitigation as stated in the preliminary analysis result.

The main reasons is, as stated by the gentlemen from Premier, primarily has to do with data and the ones with multiple providers, the two measures that discuss multiple providers. The way we normally assess this at the clinician level is using state controlled substance databases, for instance, and none of those as far

as I am aware, at least none of the ones that I've worked with in North Carolina and New York cross state lines. And so many of our patients in our markets see various providers in multiple states and the data is, essentially invisible to us, at least in anything that would resemble timely and actionable.

And so as a result just operationally, it would be really difficult to measure at the clinician level and take action, most importantly, on behalf of the patient. So just fundamentally, it is flawed operationally.

And then you know certainly in terms of the support, as stated conditional support on 078, we agree with that. I don't have any additional comment on that.

And then I agree with the recommendation of do not support for rulemaking, although the reasons why we don't support the last measure, 106, also includes just the large number of variables in the measure, actually trying to compare the five CDC recommendations

versus prescribing how it's just, again, operational, is pretty challenging for what providers actually do. The EMRs don't support it that way. It would be pretty challenging to report at that level. So and additional reasons for possible mitigation, besides the one that was stated.

CO-CHAIR MOYER: All right, thank you.

Additional comments from other lead discussants?

MEMBER BURSTIN: I'm happy to go.

So echoing some of the other comments as well, I think certainly -- I'll do the PQA ones as a group because I think they are probably more likely linked as to the separate one.

I think just the idea that if they're built off of Part D PBM plans, I think it's a real question how adaptable that is to the MSSP program. We just don't know what that looks like, as you try to move it out of a Part D-specific program, which is what PQA developed them for.

It's also -- it was pointed out by one of the commenters, there's no exclusion for palliative care although there is for hospice and I think that's an important consideration if it does get conditional support.

One of the other commenters also noted the buprenorphine is included as a narcotic and, again in this case, it really doesn't kind of fit if the intent of this is to get at opioid misuse. So one issue there.

And I think you know for some, the high dosage one in particular, again it was pointed out for certain patients chronic illness, serious illness care, there may be needs for higher doses and probably many of you have seen some of the concerns raised about potential unintended consequences in the way some of the -- not so much the CDC guidelines as written but how the CDC guidelines have actually been implemented in regs and by pharmacies have potentially led to unintended consequences for patients.

So I think it's certainly something,

if CDC adopts these, I hope they will continue to look for where there are unintended consequences.

Actually as an aside, I am co-chair with the CDC at the National Academy of Medicine on standardizing the evidence and standards for opioid use. So one of the big issues we're going to take on is this issue of harmonization of guidelines but particularly this issue of unintended consequences, which I think is real. The issue of what level it's been tested at I think is important.

And for the other one, on the initial opioid prescription, I think this is a really interesting measure. I'm glad that Dae Choi is at the table. It's a little hard to understand how that all can be assessed from claims data I think is one of my biggest concerns. Just a lot of those nuances are probably more likely to be in a chart than in a claims data only and I wish we could move beyond. Trying to look at really important measures using only claims, it's time to move beyond that and I think this one screams

for being an e-measure, as opposed to just doing that.

And again, I think similarly, I think the fact that this one has only ever really been, and correct me if I'm wrong, specified and tested at the health plan level using claims data I think is also another question of how easy is that going to be to be adapted to this.

And I would also personally love to get a read from Peter, just a comment just in terms of CDC's read on how well the measure actually is concordant with the CDC guidelines and updates of that are coming out continuously. So it also I think will be somewhat difficult for the measure to keep up with what is a rapidly evolving guideline space.

Thanks.

CO-CHAIR MOYER: Ann, did you have anything that you wanted to add?

MEMBER GREINER: So if those of you sitting around the table don't know, my organization is multi-stakeholder. So we've got

everybody under the tent, clinicians, and patients, and employers. And so you know the views that are represented here are very broad.

I think you know first off we applaud CMS for trying to get to some measures that address what is obviously a huge public health issue. Maybe there are some states that appear to be making progress but I think we all acknowledge that this is a really major public health issue in this country. And so we do want to try to get to some kind of measure.

A number of the comments from respondents was concern about multiple measures and given your desire and I think it's shared by not just clinicians but patients as well that we want to try to reduce the burden of measurement. It would seem that, ideally, we would want to get one of those three measures; 2018-079 because it's broader and encompasses multiple kinds of issues seems to be the one that, if we can address the data issues, would be most attractive to move forward.

The data issues, apparently, are quite considerable but we would encourage continued work to try to address this.

And at the ACO level, given the ability to go across settings of care and the accountability there, it seems very appropriate to really continue to work on this and move it forward.

The exceptions that are in the last measure we thought should be applied to 079 so that you take into account, again if this is possible from a data perspective, you know folks that are in long-term care, or nursing homes, or SNFs, and the like because we know that they are often, frankly, overmedicated and it's problematic. So that is probably something that we would suggest be looked at.

Given the multiple range of stakeholders that are a part of our organization, we don't have a stand at this point. I'm very interested in the conversation and encourage CMS to do the continued work to move this forward.

Thanks.

DR. PEZZULLO: Hi, this is Lynn Pezzullo from PQA, the measure developer for the first three opioid measures.

I just wanted to make a point of clarification. I believe one of the comments was that buprenorphine was included in the measures. And to clarify, the measures do exclude buprenorphine.

CO-CHAIR MOYER: Thank you for that.

Ira, I see you have your card up.

MEMBER MOSCOVICE: I just wanted to put a rural perspective on this. The MAP Rural Health Group looked through these measures and felt that 077 was -- all of these measures -- the whole issue of opioid prescribing obviously is a huge issue in the rural environment but that they supported 077.

And the reason they didn't support 078 and 079 was really the high dosage issue and the fact that there aren't pain management specialists in rural areas and so this would fall

on the shoulders, generally, in terms of primary care providers and it's a real challenge for them. And they felt the much more reasonable comparison across all providers would be through using 077.

CO-CHAIR MOYER: Okay, I'm going to take a brief pause for Rob Krughoff to introduce himself and let us know if he has any disclosures, since he's joined us.

MEMBER KRUGHOFF: Hello. I'm with Consumers' CHECKBOOK Center for the Study of Services. And I'm sorry I had things that messed up my schedule this morning but I'm really glad to be with this group on very important work. Thank you.

MS. MUNTHALI: Do you have any disclosures? Any disclosures of interest financial?

MEMBER KRUGHOFF: Oh, no, I have nothing to disclose.

MS. MUNTHALI: Thank you.

MEMBER KRUGHOFF: I keep doing that

again, and again every year. So, yes.

CO-CHAIR MOYER: All right. So I believe our next step in the process would be to vote on accepting or rejecting the preliminary analysis of NQF. I feel like I'm hearing a desire to change -- oh -- to change that -- the measure developer comments.

DR. SANGHAVI: Hopefully you can hear me. Hi, I'm Darshak Sanghavi. I'm Chief Medical Officer at OptumLabs, which is the collaborative research and development organization that sits within Optum as part of United Health Group.

I am formerly the Director of Prevention and Population Health at CMS. I developed the Accountable Health Communities model diabetes program certification, a Million Hearts model, and other projects as well.

I'm here just because I wanted to briefly talk about the initial opioid prescribing measure for CDC compliance, which is the measure that our organization has put forth for endorsement here and just to address some of the

comments that were made both in the written comments, as well as some of the ones we spoke about here.

We, as an organization, feel very strongly about this measure and believe it has the potential to markedly improve the health of America. Just by way of baseline, today the opioid crisis kills more individuals than almost any other cause in young people. We have no measures that have yet addressed the crisis on a federal level in the SSP program. So I think that there is some need to actually take action here.

In the absence of that, there have been guidelines before. As many of you are aware, CDC 2016 put out guidelines relating to daily -- the reasons this is a composite measure is because opioid prescribing is complex. There are many components, MME, total duration, co-prescriptions with benzodiazepines. And if any of you had a chance to look at the slides that we distributed ahead of time, looking at the

national variations measures -- by the way, these are claims-based -- our enterprise, the largest payer in the country right now, runs these on a quarterly basis across all lines of business. These are the measures we used to track our plan performance at both the ACO plan and plan level in Medicare, Medicaid, and in commercial health insurance. This measure has also been adapted for the all-payer claims data set in Massachusetts, as well as in North Carolina, as well as in Ohio, and in California. So this measure is widely used right now.

We presented the information at the county level, principally just so people here could get a sense of why -- the theoretical underpinnings of this measure. The variation in opioid prescribing problems is widespread. Some parts of the country have problems with dosage, some parts have with duration, some parts have with benzodiazepines combined. So, putting it altogether was our solution to the problem.

The measure has been fully specified.

Those specifications also noncommercial. We published them in Health Affairs last December so they are widely available. Again, I want to emphasize they are claims-based.

I also want to say one other thing, which is what the public comments I believe were not accurate about, which is that the CDC intended these only for chronic pain, not for acute pain. In other words, you have a child who has had a wisdom tooth removal, our contention would be that child should not be given 30 days of 100 milligrams of oxycodone. That is acute pain. There is a problem with that. We think we should be doing something about it. This measure actually addresses that.

And this measure by the way was developed by an advisory board that was co-led by Tom McLellan, the Deputy Drug Czar under President Obama, as well as Mark Wallace, Chair of Pain at UCSD; he was a member of the CDC writing committee. I emailed him last night and said that some members of the committee have said

this measure is only for chronic pain. He wrote back and said this was extensively discussed by CDC. It is not just for chronic pain. It is for new opioid prescriptions.

The final thing I will say is two pieces of information. I'll draw your information to the last two slides in the deck we distributed, which is why do we care about this particular measure. Why is this one the one we focused on?

The reason CDC put this together is that each of these are correlated with a high risk of long-term opioid use. In other words, you get a seven-day prescription of opioids. That's very different from getting a 10-, 15-, or 30-day in terms of the risk of becoming a long-term opioid user. The same goes for MME and others.

If we enforce compliance, we reduce the risk of creating new long-term opioid use that should not have happened.

I want to point out the second to the

last slide shows a pseudorandomized experiment. In 2017, the summer, all of OptumRx, our PDM, one of the top three, rolled out hard edits, meaning if prescriptions are out of compliance at the point of care, they are automatically edited at the pharmacy down to a compliant prescription. That actually rolled out in sort of a step-wedge manner across all of America. So we have tens of millions of pieces of data here.

Looking at those that were exposed to the intervention versus not, the risk of becoming a long-term opioid user in those individuals fell by 50 percent. That is a massive public health benefit and that is what was in the slides here as well. That's now been adapted across all lines of business at United Health Care earlier this year and we're seeing the same thing now occurring in Medicare, Medicaid, and our commercial markets.

Finally, the last slide shows that yes, we have not yet run this on the Medicare ACO data, only because getting ahold of that data is

really hard. It takes years.

However, I want to emphasize two things. The first is this measure is run on the One PI platform at CPI and CMS currently. They can run this at the ACO level, if they're asked to do so and that can be shown to the committee here at some point soon.

Secondly, we actually do run this measure at the Medicare ACO level in our Medicare Advantage markets. That's what the last slide shows. And that also shows that in four major markets -- I'm sorry, in the three major markets where we did intensive QI efforts, we saw improvement in the measure, as opposed to the five market ACOs where we did not do QI measures so we did not see improvement.

So in summary what I would like to say is that this measure, we believe, has substantial public health benefit, addresses an urgent problem here, also has been used widely in tens of millions of Americans already and we are sort of pushing this forward only because we think

that there is an important public health argument to made for putting this ahead.

So we would argue that this measure should be put forth for rulemaking, at least for additional comment to give CMS the opportunity to do the additional work and put this out to help Americans.

Thank you.

MEMBER FIELDS: What slides are you referring to? Because I have no idea what slides they are.

DR. SANGHAVI: Sorry. Reena, were these distributed to the committee?

MS. KUWAHARA: That's correct, they were distributed on December 5th.

DR. SANGHAVI: I have them right here, so I can send them to anybody who needs them. We're under the gun, I guess.

MS. KUWAHARA: And they are on the public SharePoint site. Anyone following along with this meeting can go to public.qualityforum.org to access those

materials.

A link was emailed to you on December 5th.

CO-CHAIR MOYER: So we're going to go to Rob for a comment but I also have a question.

So I mean we've heard from more than one provider organization, including National Association of ACOs that there is a challenge getting the data on this. I appreciate that Optum has large data resources and the ability to do this but we're not necessarily looking at is this a good measure, is it feasible in general. What we're looking at is it feasible within the context of MSSP, I believe.

So could you talk specifically to that and does that help with what you were going to raise?

MEMBER FIELDS: Yes. No, that's exactly it. I mean just going on record that the argument. I don't think anyone argues with the public health implications of this and the need for something, to take some action in regards to

opioid use. The issue for us is exactly what you pointed out, that it is completely untested in the ACO model, in terms of how we get that data. It is relatively invisible or fractionated at best in the ACO world. So I can completely appreciate and it helps that it's purely a claims-based measure. That absolutely helps and I can understand in the health plan how that would work really well.

It's just there are a thousand reasons why the MSSP doesn't work like any other shared savings arrangement with MA and information is one of those reasons.

So that's our issue with it. It's not the public health implications or the importance of it. We actually for sure want to go on record as saying we very much support it.

DR. SANGHAVI: I'll just say that that's a really valid point. I think the pain of sort of trying to get data that you can't get is one that many people feel.

Our thinking would be two-fold. The

first is that it can be run -- as I said it's being run at CPI, which has a consolidated Part B and other sort of -- it's all put together and so it is run now. It can be run at the ACO level and reported back.

The second is that there's a chicken and -- or cart and the horse issue here, which is that until we say this is what we need to do, nobody actually does it. And until somebody does it, then -- do you see what I'm saying? We just need to sort of take a stand that this is the right thing to do and then rulemaking, other stuff, there is a process to make that happen. That's when resources are dedicated to actually make this easier on everybody. But if we say it's just hard to do, it's challenging to do so let's not even get involved, that sort of seems to cut against the fundamental goal of this entire measures process.

CO-CHAIR MOYER: Helen and then we'll go on to Peter.

MEMBER BURSTIN: Oh, no, I was

actually just going to ask if Peter can weigh in.

MEMBER BRISS: I'm not going to weigh in extensively. What I am going to say is that as I listen to the conversation, it's pretty clear that nobody disputes the public health importance of the issues and nobody seems to be pushing back much on the need for measures. So we also want to commend CMS for trying to move some of this forward. As we're talking about -- there are also clearly feasibility concerns around the table.

So one of the things that happens frequently around these tables is that when people have concerns, we're not necessarily very specific about what would need to happen next to actually mitigate concerns. So to the extent that there are people around the table that are going to have concerns today, it would be most helpful for CMS and others that are trying to move the fields forward to be as specific as you can about what it would -- if you feel like it's not getting over some bar, being as specific as

you can about what it would take would be really helpful.

MEMBER FIELDS: Again, just responding to the comments earlier. I mean I can also understand the chicken and the egg or the horse and the cart analogy to this. But having measures that have not been tested and, therefore, have the potential for pretty significant flaws when it gets people that actually have to operate ACOs and get and show data to providers, it actually does damage, I believe. You end up going backwards if you show providers, even if it's reporting only.

I mean I would gather that if this actually ended up in the MSSP program, it would be reporting only until it was tested. But I guarantee you that if it's fundamentally flawed and it hasn't been tested, I get that we can do it somewhere, that the data exists and we can do it. But I think at least taking the minimal step of proving that it can be done and visualizing that at the ACO level is an important one because

if it somehow ends up that we can't do it completely or accurately, providers not only ignore it but I think actually revert backwards a little bit. It causes a lot of tension among the actual providers who are having to execute on the outcomes of that data. I mean the data by itself is meaningless if the providers don't take action. And if you're actually discrediting the measure and the initiative by showing data that is potentially flawed, it is counterproductive to the goal.

So I would just argue that at least one step or one round of testing, whether or not it can actually be done at the ACO level at scale is an important one and at least a minimal requirement of due diligence before we actually put this out in some sort of MSSP program.

MS. SPALDING BUSH: Thank you for that. This is Kim Spalding Bush from CMS. Could I just respond on that concern? And I think we do hear you. Certainly, we don't want to cause any confusion or have people drawing conclusions

based on data that we put out there that might not be accurate ones.

I just wanted to note that for the three PQA measures, so 077, 078, and 079 that we do currently have the data that's produced by our Part B plan staff and is provided to our Part D plan themselves. In an effort to help them have someone to coordinate with, we wanted to share the same data with our ACOs so that they can do something about it.

So the plan is actually being held to a different standard here. You are completely correct. We are talking about providing for information only, certainly as a start, until we learn a lot more about these measures. And we would have to go through a long process before we could add them to our measure set.

And but we have worked closely with the Part D plan folks at CMS around messaging, what should the ACOs be taking away from this in order to make sure that if they get the measure data in a report they kind of know what it means

and what they can do. And we've run the data. We've seen it's a pretty low instance that the ACOs have beneficiaries hitting these marks, only because they are a pretty high bar for potential overuse and there is a lot of interest in being careful not to share what some people call a false positive with the ACOs, if it is in fact someone who legitimately just had multiple providers for some kind of legitimate reason.

So we've been pretty cautious in working closely with the Part D plan staff and making sure that the data that we put out there are consistent with what the plans are seeing and so that we are helping the ACOs with interpretation as well.

So I don't know if that helps you assuage some of those concerns. We do have that data ran at the ACO level and we have reliability information around that as well so for the PQAs.

CO-CHAIR MOYER: Okay, thank you for your comments.

MS. SPALDING BUSH: Thank you.

CO-CHAIR MOYER: I see in the room I have Bruce, Amy, and Ann.

CO-CHAIR BAGLEY: Yes, I'd like to speak as a physician for a minute. And I want to talk about the first three measures first and they are to identify people who might be at risk of opioid overdose. Isn't that the purpose?

So what clinician or organization in this room wouldn't want to get a list of all the people that need some attention like we get a list of all the people that need a mammography and you do something about it? Why wouldn't you want to get a list from anywhere you can get it and do something about it?

Now I don't know that everybody can get that list but the PBM should be able to do this. Your own internal EMR probably can do this better than you think.

Why wouldn't you want to have a list if you could have a list?

So my only comment about one, two, and three is that there is absolutely no advantage of

the third one, I mean to do both, because you've already got all those people identified on the first two lists? So I would suggest that you just use the first two because the real purpose is I want a list of people who need some attention. So that's how I see it as a physician.

The fourth one is very different and it really is to get at the root cause of getting people addicted in the first place. It has nothing to do with high dose, or long-term, or anything. It's that first prescription. And for people, for instance, who walk into a doctor's office for low back pain and get an extended prescription for opioids, there is one in five chance that they will become addicted, or an opioid-naive person.

If anybody has other -- is that about right?

So this is a big deal. And to say it's hard when you can have flags in your EMR for all kinds of crazy stuff, to say it's hard to do

this is just, in my mind as a clinician, not right. So if we put this in place -- first of all, CMS wouldn't put it in place without actually offering the data, right? There you go. So I mean how could they do that? Well, they've got the data. They've got to give it away to make the measure work I think.

So I mean I agree with if you don't put it in, nothing's going to happen. If you put it in, it's going to be a little inconvenient for some people. But to identify, you know get at the root cause of the problem, they have all kinds of problems with how to deal with people who are already addicted. We're not talking about -- you know it's more important to not get them addicted in the first place. So why wouldn't you want to do this?

CO-CHAIR MOYER: Do have a quick response to that?

MEMBER SHALLER: Can I ask a question? Because I appreciate your comment. I just want to

understand the logic from your perspective as a clinician in favoring the two first separate measures as opposed to the combined measure.

It seems to me the combined measure is a higher threshold.

CO-CHAIR BAGLEY: Yes, the combined measure could miss people on the first two lists because it has to be an and.

MEMBER SHALLER: Right.

CO-CHAIR BAGLEY: So I think if you have the first and the second, you've covered the third easily. There's nobody going to be missed on the first two lists that will show up on the third list.

MEMBER SHALLER: Got you.

CO-CHAIR MOYER: Amy.

MEMBER NGUYEN HOWELL: Good morning, everyone. So Amy Nguyen from the America's Physician Groups. So I appreciate the comments from NAACOS and Premier. And we have ACOs in our physician organization so I appreciate the sensitivity around that.

My question is really more for CMS. So as you move along the risk continuum for risk-bearing organizations and as we step back and look at Meaningful Measures Initiatives and the burdensome for physicians, I want to ask, looking at the bigger picture for CMS, are you looking at these measures to be cross-cutting in the other Quality Measurement Programs, especially Stars, and given that this is potentially measured at the plan level for Part D and also for other measurement programs for CMS. Just so we -- if you can answer that because I think it will give us an idea, a general overall idea as you look at SSP, ACOs, but then also as you move along the continuum, how are other programs going to be measured?

MEMBER DUSEJA: I think that's a really great question. I'm glad you brought it up.

I think from the agency perspective we really are looking at alignment internally as well as externally. So there is a Core Measure

Collaborative that you might be aware of that we are trying to externally align with other payers as well and internally, the same. I think we're having a hard look in our next space of Meaningful Measures. We looked at each of the programs. We look at this burden reduction effort in our first case.

The second really is looking at how do we align across settings with the metrics that we're using. With opiates in particular, I think this is a high priority area. So I think we're going to have, depending on the setting, and the right setting, making sure that is specified at the right place. So we want to be mindful of that as well.

MEMBER NGUYEN HOWELL: Yes. Yes, so we see it on the strengthening on the Core Measures Collaborative so that's why I bring it up because we talk about alignment a lot. And as we look at these measures I know we're talking just about SSP but I just ask that everyone in the room look at it generally and more broadly as

we move forward with our measurement development and quality assessment.

CO-CHAIR MOYER: All right, we're going to go to Ann next. Trudy's on the phone and she will be the next commenter, and then we will be going to David.

MEMBER GREINER: Thank you. Point of clarification for the gentleman from Optum. I'm sorry I'm forgetting your first name.

DR. SANGHAVI: Darshak.

MEMBER GREINER: Thank you. Did you say that you have successfully implemented -- I know you said in Medicare Advantage plans but have you also done it in private sector ACO plans?

DR. SANGHAVI: We don't --

MEMBER NGUYEN HOWELL: The last measure.

DR. SANGHAVI: Yes, the last measure. So it's being run principally at the plan level. And we run it more at the employer level, rather than the private ACO level but it can be done at

that measure. It's reported but we don't necessarily use that for anything just yet.

MEMBER GREINER: You know it seems to me that we've kind of done this swing in terms of you know our taste for measures. I've been around measurement for a while, not always at this table, but back in the day so many measures were approved and we moved quickly to put measures into programs and now we're completely swung in the other direction.

However, this is one of the biggest health issues that our country faces. And I think that to walk away from an effort that is going to be multi-year to get to actual public reporting would be a mistake. And so I really think that this committee should take seriously the public issues that we're facing and get CMS going on whatever it needs to do to get this measure in place that we can get the proper data and we cannot have this be very burdensome but move this issue along.

And I appreciate all of your comments.

CO-CHAIR MOYER: Thank you. Trudy, on the phone.

MEMBER MALLINSON: Thanks. There is somebody, Chris, who had their hand up before me. I don't know if --

DR. BEADLES: Hi, can you guys hear me?

CO-CHAIR MOYER: Yes, we can.

DR. BEADLES: So I just wanted to -- I'm Chris Beadles. I work for RTI International on behalf of the SSP ACO operations contract. And I just want to kind of echo some of things that have already been said this morning with respect to these three measures, as Kim Spalding Bush already alluded to.

We have looked at these measures, the three PQA measures, the first three, and ACO performance during the performance year for 2017 in terms of testing purposes in preparation for sharing these measures with ACOs on an informational basis. So we do have a pretty good idea of what the spread across ACOs looks like.

And there is a sizeable spread there, some ACOs that appear to be doing a lot in the opioid space to improve opioid safety and then there are others that I think there are opportunity for improvement.

So we can say that this as a claims measure is operationally feasible and is readily adaptable to the Medicare Part B claims data. We can also say with pretty high confidence that the reliability that is listed in the NQF forms for these measures I believe was tested on Medicaid data in eight plans. We've tested reliability and have similar reliability looking at the ACO of a plan.

So with the exception of the OHD/OMP measure, which is that combined measure of the first two, where the reliability is lower as you would expect, it's a smaller subset of individuals that meet both of the first two measures, the reliability is similar to what is published in the NQF on the Medicaid data and at the ACO plan during performance year 2017.

I think I would also just echo the same comments that I think the other clinician previously mentioned. As someone that is prescribing opioids in that space, I would want to know if I am one of five or six other prescribers that are prescribing opioids to a patient, to a beneficiary. And I think that one in particular, being able to give ACOs this information, being able to help them know the full space of the patient -- of the providers that their patients are seeing is really where we need to move. I think based on what we've seen, this is a -- these first three measures sort of aim at the highest risk of non-beneficial opioid uses, probably how I would characterize it, opioid use that is at least, both in the Medicare Part D plans, which is part of the reason they use it there, but also in ACOs when you have beneficiaries that have those dosages and that number of different providers, prescribers providing the medication, it's worth further review.

MS. SPALDING BUSH: And this is Kim. Since Chris didn't mention it, I will offer that he is an anesthesiologist. And I'm sorry I'm forgetting if that was in your bio but yes, thanks.

DR. BEADLES: Right, yes. So having gone through chronic pain and acute pain rotations and being in those situations where we think through a comprehensive approach to managing chronic, I can say that with some experience that yes.

CO-CHAIR MOYER: Okay, thank you.

Trudy, go ahead.

MEMBER MALLINSON: Thanks. I just had a question for the clinicians. One of the public comments asked about exclusion for palliative care. And I just wanted -- are there situations where there might be exclusions for I guess palliative reasons for people who do not have cancer but are receiving some kind of palliative care. Is that a reasonable question?

CO-CHAIR MOYER: Okay, I am going to

start accumulating questions for the developer. We have quite a few cards up in the room and I want to make sure we get to everyone.

David, did you have a comment?

MEMBER SEIDENWURM: Yes, I just wanted to say that maybe I'm coming at this from a different direction. I'm not sure these go far enough.

I mean I think this is a great first step and you know the end gates swing out a lot of people. If we approve 79, that would be a smaller sample.

I think this is a circumstance in which we would want to try to cast a wider net, rather than a narrower net. So I'm going to advocate going forward with these as they are and hopefully as we get this population under control, perhaps we could move further.

CO-CHAIR MOYER: Thank you.

Helen.

MEMBER BURSTIN: Just two brief comments. Again, I think these measures are

incredibly important. We need to get some measures here so I applaud CMS for picking up some measures that are out there that could be used.

Just again, some of the comments that emphasize the importance of getting these feedback reports, it's not clear this measure includes feedback reports. It includes the rate.

So I would love the feedback reports and I would love to see if CMS in fact puts this forward it isn't just going to give a rate to an individual MSSP but, in fact, provide that information in a timely manner. Because otherwise, it's just not very helpful to get the rate.

And so again, I would love the feedback reports, Bruce. I don't think that's what this measure is about. So if CMS could give us that, I think that would be really important.

And then lastly, I do think there is a lot of action happening currently in this guideline space. There's a lot happening and

just there's real potential for unintended consequences. So I think as these measures go into place, if they move forward, really important to get continuous feedback from both patients and clinicians as these measures are out in the field.

CO-CHAIR MOYER: Bob?

MEMBER FIELDS: Yes, similar to that because it seems like we're still having the conversation, I'm a family doctor. I'm a clinician also. No one is arguing. Of course, I would love a list of patients that have multiple providers but I don't think that's actually the issue here.

I would like to separate, kind of extending what Helen said. It's one thing to have data and it's one thing to have a measure. And you can have one without the other. And if the goal here is actually to improve patient care, we would love the data. It's just right now we don't get it.

As I mentioned earlier, the most

actionable data that is close to real-time is our controlled substance database is they tend to be state run. It's when the patient fills the prescription, I can look him up and you can tell. It's very actionable at the point of care in that context but it completely misses anyone that prescribes out of state and those are invisible to us.

Claims, when I get it 90 days later and hope that I have an analyst that can actually piece it together and give me the feedback that I need to actually take action on it, there are so many dependencies and it's so delayed by the time I actually see it, it is not actionable in the same way.

So if we're going to apply pressure, I would love to see CMS or other -- it's probably not in their purview but certainly on a federal level in some way relax the interstate data sharing guidelines so we can have a national controlled substance database. That would actually be much more helpful than having a

measure that is, at this point, the data has been invisible.

I hear what everyone is saying that it's been tested, and reliable, and all those things. We haven't seen it. And so that's all we're saying is that to put it as a measure has real consequences and actually doesn't deliver by itself, at least in the current format on the things that we actually want to get done on opioids. It's important to make that distinction between the data and actually creating a measure around it.

MS. SPALDING BUSH: Yes, I think we certainly appreciate that. This is Kim and we always are interested in hearing the ACOs' feedback on what we give, what's useful and what isn't, or could be more helpful to you. So thank you for sharing that.

I don't know, Chris, I hate to put you on the spot but do you know -- so we are planning to provide feedback reports on these.

DR. BEADLES: Yes.

MS. SPALDING BUSH: And they would have a breakdown so that they can be more actionable. As I mentioned earlier, the Part D plans will be getting the same information so that it would be an easier thing to coordinate between the plans and the ACOs because even though as we mentioned it's just for information purposes, for ACOs at this point in time, the plans are actually -- and I don't work on the plans, so I don't know really what their metrics are, but they are held accountable for performance on the rates currently.

So sorry, Chris, I didn't mean to cut you off.

DR. BEADLES: Yes. No, I think the prior comment is exactly right. I think it's one thing to get a performance rate to know that at an ACO level something is high, but what are we doing from the CMS SSP side to really encourage closer to real-time actionability?

I don't want to provide any false expectations that these reports would be of the

same kind of point of service where you could type in a prescription and instantly see in your EHR that seven other providers have prescribed this real-time. But I think what the reports will contain and what we're planning to do is send those reports and say this list of beneficiaries has greater than four providers in the last -- well, cumulative to date. So doing it quarterly in every quarter, saying okay, in the last three months, these prescribers -- this list of beneficiaries had more than four prescribers or four pharmacies. And here are the MBIs. Here are the provider names of the prescribers of the top six prescribers for this beneficiary.

And I think yes, it would be great if it was instantaneous. I think that's a limitation that there's not an easy way around but the idea is to get that information so you're not having to sift through the claims yourself but you're getting a beneficiary MBI, and name, and date of birth, and the number of prescribers,

and who those prescribers are as close as we reasonably can get it to you that goes beyond just what's in your state and your prescription drug board.

And yes, I think the suggestion about relaxing the rules so that there's a single national Prescription Data Monitoring Board is also a great idea. So I completely agree with that.

In the interim, I think there are things that we can continue to do to move this forward.

CO-CHAIR MOYER: Okay, Dale.

MEMBER SHALLER: Well, the last two comments have really addressed the question that I think Helen raised for me, which was kind of almost startling. If there isn't a plan in place implicit for all of these measures to include periodic feedback, which I'm kind of interpreting now that to be on a quarterly basis -- is that correct through the standardized --

MS. SPALDING BUSH: That's correct,

yes.

MEMBER SHALLER: Okay. Yes, I just want to -- you know I've done some work in the prior feedback reporting space lately and I mean I think that's why we want to do these measures, it's to feed them back to the organizations, the clinicians involved so that Bruce can know who these patients are.

So I just think it's important to know that that's actually part of all of the measures that we're looking at and deciding whether to move forward or not.

CO-CHAIR MOYER: Thank you. Amy.

MEMBER NGUYEN HOWELL: Just one last comment. This is Amy again from America's Physician Groups.

I just wanted to recommend that if CMS decides to move forward with these measures to consider eCQM for the measures, given promoting interoperability.

Thank you.

CO-CHAIR MOYER: All right, seeing no

other cards in the room, I did have an outstanding question on palliative care patients and their inclusion or not inclusion in the measure.

Do we have a measure developer who could speak briefly to that?

DR. SANGHAVI: Yes.

DR. PEZZULLO: Yes, thank you. This is Lynn Pezzullo from PQA.

So for 077, 078, and 079, currently the measures exclude individuals with cancer and those in hospice care. We certainly can explore exclusion of palliative care, given the recommendations from the group.

CO-CHAIR MOYER: Thank you.

Darshak.

DR. SANGHAVI: Yes, so I was just confirming with my colleague, Stephan Dunning, who is working us on this measure.

So our initial opioid CDC compliance measure does in fact, I think as pointed out, exclude individuals that are in institutions,

those with cancer, palliative care.

CO-CHAIR MOYER: Thank you.

Bruce.

CO-CHAIR BAGLEY: I would think that although hospice care is coded, palliative care probably is not. So that's a problem that would have to be worked out.

CO-CHAIR MOYER: All right.

Girma.

MEMBER ALEMU: Just a quick question. Unintended consequences were mentioned during the discussion and I know and I understand that NQF looks into such issues during the endorsement process. Is there anything which was explained about the unintended consequences during the endorsement process for any individuals?

It may be difficult to answer the question but we don't have the details but I just want to make sure to the group that it is one of really the criteria or the main points that needs to be discussed in that.

CO-CHAIR MOYER: I do know that as a

discussion point during the CDP process for endorsement and these are, I believe, all NQF-endorsed. So they have all gone through that process and had a committee that took a look at that. I don't know what was discussed during that committee but it is a point that would have been raised.

DR. BERNOT: Yes, 077, 078, and 079 are NQF-endorsed; 106 is not.

DR. PEZZULLO: And this is Lynn again from PQA. You know so our measures are also used -- I know there was in the interest of aligning across various programs, all three of our PQA opioid measures are used in the Medicare Part D program.

The high dose, so 078 measure is also used in the Medicaid adult core set and 077 for multiple providers has been recommended for use within that program.

So you know through that use as part of our feedback loop, as with all of our measures, we assessed for unintended

consequences. So we do work closely with those programs to understand their use and their impact.

CO-CHAIR MOYER: Okay. I am not seeing any committee cards up. I think we are at the point we're ready to start moving toward a vote.

Before we do that, we do want to open it up to public comments. So we'll start with anyone in the room who wants to make a public comment on the measures. All right, I don't see anyone in the room.

Operator, would you check for public comment on the phone?

OPERATOR: Yes, ma'am. At this time, if you would like to make a comment, please press star-1.

And you do have a comment from Sandy Pogones with the American Academy of Physicians.

MS. POGONES: I'm sorry, you can take me off that. I'm in for the next round.

CO-CHAIR MOYER: All right, thank you

very much.

So I am not hearing in the room that we're going to be moving forward en masse with the recommendation. So I don't want -- I don't think we have to do that vote.

So we're going to go ahead and vote on these individually. We're going to start with the first measure and just work through in order.

I want to check with the committee. I am not hearing like yes, this is perfect, we're all going to be voting for that first category. I mean is there anyone who feels the need to start the vote at full support for this? I'm just trying to narrow down what we're going to be working on.

MS. MUNTHALI: So yes, I think that would be a cleaner vote and then go through the rest of the categories.

CO-CHAIR MOYER: Okay. So first we will vote to accept en masse the preliminary analysis results. As a reminder for 077, that is conditional support for rulemaking with the

condition of considering not duplicating measures. For 078, conditional support for rulemaking with the condition of considering duplication; 079 conditional support with, again, consideration -- okay.

MS. KOSURI: I'm unlocking the vote. Voting is now open for MUC2018-077. Do you vote to support the preliminary analysis as the workgroup recommendation?

DR. BERNOT: I had a comment, just before people put the vote in and you can't change. If this goes through as a yes, 60 percent or higher, it locks in on the preliminary analysis. If you want to add different conditions or go to the other categories, you would vote no here; you do not want the staff recommendation to become yours. And then we will continue vote in process.

I just wanted to make sure it's clear, since it's the first vote on this one.

So not over 60 percent continues the vote; yes, we lock in the staff preliminary

analysis as the workgroup's recommendation and we would move to the next measure. For this measure only, correct.

MEMBER DUSEJA: John, can I ask for clarification?

If the workgroup decides to go with the preliminary recommendation, they can also add conditions on the conditional support. Like that's how it was operating in the last two workgroup meetings.

DR. BERNOT: It will be captured in there.

MEMBER BURSTIN: It will be summarized.

MEMBER DUSEJA: Yes, it's just to summarize what the concerns are.

DR. BERNOT: Yes.

MS. KOSURI: And just to clarify that the preliminary analysis recommendation would be conditional support for rulemaking, with the condition that duplication is considered between the measurement for MUC-079.

Perfect. Okay, voting is now closed. The committee recommendation based on 95 percent of the vote is to support the preliminary analysis of the workgroup recommendation with 18 supporting yes and one supporting no.

CO-CHAIR MOYER: All right, we'll move on to voting on the next measure.

MS. KOSURI: Okay, so we're going to vote on MUC2018-078. Do you vote to support the preliminary analysis of the workgroup recommendation? And once more, the workgroup recommendation is conditional support for rulemaking with the condition that duplication is considered between the measure and MUC-079.

I'm going to unlock.

And voting is now closed.

The committee's recommendation, based on 95 percent of the vote, is yes to support the preliminary analysis as the workgroup recommendation with 18 people voting yes and one person voting no.

Now we'll move on to MUC-079. And so

voting is now open for MUC2018-079. Do you vote to support the preliminary analysis as the workgroup recommendation, which is conditional support for rulemaking with the condition of potential duplication between this measure and Measure 077 and 078?

We're still waiting for one more vote.

Voting is now closed.

And the committee's recommendation, based on -- there is 63 percent of the vote is no for MUC-079 to support the preliminary analysis as the workgroup recommendation, with -- let me go back to the count -- seven supporting yes and 12 supporting no.

CO-CHAIR MOYER: Okay, I believe since we voted on that measure to not support the preliminary analysis, we are going to move on, stay with that measure and move on to voting on the next category down, which I believe is do not support with potential for mitigation.

And so what we'll do is vote if we believe that is what the measure should be. If

it does not receive support for that category, the final category we would vote on is do not support.

MS. KOSURI: So voting is now open for MUC-079. Do you vote to do not support with the potential for mitigation?

We're still waiting on a few more votes. One more.

Okay, the committee's recommendation, based on 72 percent of the vote is no for MUC-079, do you vote do not support with potential for mitigation, with 15 people on no and three people on yes.

Voting is now open for MUC-079. Do you vote do not support?

MS. O'ROURKE: So we did a little bit of clarification with the other workgroup after these votes and I just want to make sure that we're tracking and that we're going to convey your input correctly.

So this landed on a do not support and my interpretation of the committee's discussion

was that you -- and of the voting was that you think CMS should move forward with the first two measures. To Dr. Bagley's point, this measure may redundant with the others and would create, perhaps a parsimony issue. So the group's recommendation is the first two would be the ones you'd like to see added to the program, this one duplicative.

MS. KOSURI: Okay, voting is now closed. The committee's recommendation, based on 67 percent of the vote, is yes for do not support for MUC2018-079 with 12 people voting yes and six people voting no.

MS. O'ROURKE: And apologies for jumping in again but I do want to make sure that everyone is aware that we do pass on all of your comments, not just about the voting, but all the questions and concerns the committee had about the feasibility of the measures and the availability of data. We provide that to CMS as implementation guidance for the measures. It goes into not only the spreadsheet of decisions.

We also produce a report that has all of the summary of your conversation, that type of more cross-cutting input, minority opinions. So that all gets packaged up and goes to CMS out for public comment and to the Coordinating Committee for their consideration.

CO-CHAIR MOYER: All right, we're moving on to vote on accepting the preliminary analysis on the final measure, 106, the initial opioid prescriptions.

MS. KOSURI: So voting is now open for MUC2018-106. Do you vote to support the preliminary analysis as the workgroup recommendation, which is do not support for rulemaking with the potential for mitigation? Mitigation would include specifying the measure at the health plan level.

MEMBER SHALLER: Is it possible to just change the wording at the end of the recommendation to ACO level and not plan level because we just I think had that conversation?

DR. SANGHAVI: So just as a developer,

just understanding the feedback, so if it's a do not support with condition, it meant that we'd have to come back to the MUC with that information or is it -- or is what would ideally be requested is a support with condition of the same thing with the obligation that we do this at the ACO level and Fee-for-Service.

MS. O'ROURKE: Sure, I can clarify on at least what the distinctions the decision categories were intended to convey.

What the Coordinating Committee was trying to say here with conditional support is along the line of what Helen was saying. You see this as a fairly minor update to the measure but you're comfortable with it going forward for a program at this time.

Do not support is a larger scale change to the measure. We've use some of the language from the CDP about substantive change, something that the PAC and Hospital Workgroups were using this for were to convey issues that may require respecification and retesting might

change the score of a measure, things like changes to the numerator, denominator, level of analysis, exclusions, risk adjustment model, that type of a wholesale change, if you will, to the measure that would require some additional testing and rework.

The point of how that gets operationalized, that's really to CMS as to whether things would need to go back on the MUC list. That's out of MAP's control but that's the degree of change where we've been operationalizing the two categories.

CO-CHAIR MOYER: David.

MEMBER SEIDENWURM: So it's a question on the order that you could have people wanting to approve the measure completely and people wanting to reject the measure completely are voting the same way, the way this question is framed. And is that intended? Is that a feature of this system or a bug?

MS. O'ROURKE: That's a good question. I would just -- whether it's a feature or a bug,

I'm still thinking through. But I would say if you want to vote differently than the staff preliminary analysis, vote here, even if you -- or vote no, even if you think you might eventually end up in the same spot as the staff decision.

It's really just putting forward something for the workgroup to start voting on, maintaining some of the spirit of the old process, where we could just match with measures that have broad agreement quickly.

So even if you think you might ultimately go with the do not support with mitigation for this measure but you want to keep talking about it or you want to work through different scenarios as a committee, vote no. That opens us up to a full voting and any additional discussion and then we'll just work through the categories.

CO-CHAIR BAGLEY: Maybe I can clarify that. As a procedural matter, you have a motion on the floor which is the recommendation of the

preliminary analysis. And that's what we're voting on.

If you after this vote, if we don't get 60 percent approval, then you can offer an alternative motion to approve.

MS. KOSURI: We're still waiting for two more votes. Oh, perfect.

Voting is now closed.

The committee's recommendation, based on 68 percent of the vote is yes for MUC2018-106, do you vote to support the preliminary analysis of the workgroup recommendation with 13 people voting yes and six people voting no.

DR. SANGHAVI: So I guess -- I was just talking to our CMS colleagues. I was just trying to -- that's a confusing outcome for me because I don't know what to do with that feedback.

If the idea -- in other words, if people here could specify what they want to see that's different, it would be very helpful for us to understand the nature of the objection here.

I will point out, by the way, that we are not paid for this at all. This is all volunteer time for us. So it's a fairly big lift for us to keep coming back like this.

So the option for us is just to let this go, CDC compliance just will not happen here. Or if we understand specifically what the issues are, then there's a chance I guess we can go back to CMS to push this forward against this committee's recommendations, potentially, to just kind of not support it at all.

MEMBER BURSTIN: But nothing in this recommendation means this has to come back to us again.

DR. SANGHAVI: Oh, it doesn't? So that is what's confusing to us. What does do not support mean, then?

Maybe that -- I'm confused by what this outcome means.

MEMBER BURSTIN: I think what the committee had said was that it should be appropriately tested and CMS, I think, has heard

that. So that's all for the right level.

CO-CHAIR MOYER: Yes, that was what I heard and what my understanding of the vote of the vote and the recommendation, that there was concerns about the existing specification, or the existing definition or testing of the measure versus the population to which it might be applied.

And so we want to make sure -- we want to strongly recommend that that get reconciled or addressed before use in the CMS program. That's our recommendation.

We don't have the authority to make that happen or to say how that happens. It's just our feeling as a group. So that's my --

DR. SCHREIBER: First of all, thank you for all of the input. In the other meetings, it has been useful for us to kind of summarize some of the comments. And I wrote them down or you wrote them down. I would really appreciate making sure that we captured everything, if I could for a moment.

So on the first three, thank you, but I've heard that there is some conditional support that people would like to see improvements around the following: 1) to ensure that there's feedback on a reasonable basis in confidential reporting; 2) making sure that there's no redundancy with other measures, which I think you did by taking out the third one; 3) trying to exclude palliative care, if that's at all possible; 4) ensuring that we are excluding Suboxone and I can't pronounce -- sorry -- Suboxone but just to verify that; 5) obviously, long-term following for unintended consequences, considering this ultimately as an eCQM; 6) including post-acute care settings in this measure; 7) in the future, casting a wider net and ensuring that we are aligning this across all programs.

Did I miss anything, any major points?

And then in addition to the last measure, looking at the CDC requirements for initial opioids, those issues plus perhaps

seeking NQF endorsement, so testing, that there were too many variables. There was some concern about that. And there was some concern that the CDC recommendations may be changing and it would be hard to capture a measure wants the CDC criteria if they are changing.

So that's what I heard.

DR. BERNOT: I apologize if I misheard. The other thing I had down was to ensure that that Part D data is readily available for the --

DR. SCHREIBER: I assumed that under feedback but yes, thank you.

CO-CHAIR MOYER: And again, we really thank you. Having an opioid measure, quite honestly, is important I think to all of us. So, thank you.

CO-CHAIR BAGLEY: Okay, we're going to move on to immunization. And John, do you want to introduce that one measure?

DR. BERNOT: Yes, and for this measure, the one thing that is a little unique to

it, this measure has been put for consideration on both the Shared Savings Program as well as MIPS.

So what we would propose to do is to introduce it, because it is the exact same measure, give our preliminary analysis, what it would be for both programs. In this case, it is actually different between the two programs. Have one discussion and then two votes on it, just for the efficiency.

So this will be the only MIPS measure that we're moving forward at this point because it's the same exact measure.

So if I can begin, the measure is the Adult Immunization Status Measure. This is MUC2018-062. It is the percentage of members 19 years of age or older who are up to date on the recommended routine vaccines for influenza, tetanus and diphtheria, or tetanus, diphtheria, and acellular pertussis, zoster, and pneumococcal.

For the Shared Savings Program we had

a conditional support for this with the condition of NQF endorsement, which subsumes the test for reliability, validity, feasibility, all of which are part of the endorsement process. So for the Shared Savings Program it is the conditional support with the condition of NQF endorsement.

The same measure also, this is MUC2018-062 Adult Immunization for MIPS. Everything else is the same however, the preliminary analysis for this is do not support with the potential for mitigation and the mitigation would be that it would have to be tested at the clinician level with the program differences between MIPS and the Shared Savings Program.

Any clarifying questions on what I said?

MEMBER BURSTIN: So what was the preliminary recommendation for the MSSP program? I just want to make sure I got that because it says clinician level, which doesn't make sense.

DR. BERNOT: Yes, there is a version

of the discussion guide, I apologize, where it is flipping one of the sections. I'm sorry. I very much apologize.

For the Shared Savings, conditional support with NQF endorsement. And MIPS is do not support with potential for mitigation, with that mitigation being demonstrating testing at the patient level -- or excuse me -- clinician level.

CO-CHAIR BAGLEY: Okay, our lead discussants, Rob, you're up.

MEMBER FIELDS: Yes, I actually had a comment but actually first had a question from CMS' point of view.

So recently some of the immunization measures were removed from the measure set. And I just wanted clarification on the logic of this past year removing PNEUMOVAX off the measure set and then now potentially reintroducing it in the composite format.

I do have an additional comment on this actual measure but I'm not going to say that now. I guess we can respond to that.

But I think from our perspective, the issue with this one is that two of those vaccines are not a covered benefit under Medicare. So it seems sort of illogical to create a financial barrier for seniors by not covering the benefit and then holding providers accountable for completion of the measure. It just seems like there's a discordance there that's a fundamental flaw in this.

I mean it's obviously good health care. Nobody's going to argue that. And tetanus is actually not a covered benefit either.

So it's a little confusing and illogical and, for that reason, we couldn't possibly support it as written.

CO-CHAIR BAGLEY: Helen, do you have comments on this one?

MEMBER BURSTIN: I'm not sure if CMS heard the question.

CO-CHAIR BAGLEY: You're also a lead reviewer.

MEMBER BURSTIN: Yes. Okay, I'll just

do mine, then.

So I thought this was a very interesting measure, obviously really important. Nobody would argue with the importance of doing an adult measure of immunizations. It was very difficult to look at this measure without actually having the detailed specifications and if I missed them, I apologize. But for example, I don't know if it's an all or none composite, you only get credit if you do all of them. I don't know if it is a weighted composite. I don't know how the composite is actually structured.

And so my concerns actually relate somewhat to what was said because in fact if it is very difficult to get zoster, the zoster vaccine, as an example, covered, then in fact the overall composite may, if it is an all or none composite, just reflects what is difficult to get, as opposed to what the true immunization is.

So I would like some clarification as to what the specifications actually look like.

And I think several people raised a concern in comments about how the specifications don't align with some of the other immunization measures, in terms of time frame or in terms of time frame for a flu vaccination or time frame in terms of the pneumococcal vaccination. So I guess whatever moves forward, hopefully that can be harmonized going forward so we don't have different measures going back and forth.

Again, this is currently tested at the health plan level. I think the question is how would this perform in an ACO.

I also have some concerns about the ability to see so far retrospectively for patients 19 and up to really be able to see vaccines ten years previously or be able to keep track across time and place. If people churn through Medicaid to private to back, what does that actually look like? And again, this is an MSSP measure so the age issues were an interesting question to me overall.

CO-CHAIR BAGLEY: And before we open

up to the general comments, do either Reena or Michelle have comments from the CMS standpoint?

MEMBER DUSEJA: I'm sorry, I think we did miss a question earlier.

MEMBER FIELDS: Yes, so my initial question was just trying to understand the rationale for removing PNEUMOVAX off the MSSP program this past year but now reintroducing it. There must have been a rationale for removing is what I'm trying to understand so reintroducing was confusing to me, in particular in this format.

And then of course the comment I made earlier about coverage benefits.

MEMBER DUSEJA: That's a good question. So I think at least for this particular program is for harmonization. So the reason why that they just had to bring it back to the committee was because of the updated guidelines and to do an all or none measure to reflect that, based on what we've been hearing from stakeholders.

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

MEMBER PADDEN: I guess I would also raise similar concerns if it's all or none. If we think about where some of our patients get immunizations, in terms of influenza, they're not always at a clinician's office. It might be at a health fair. It might be at a pharmacist. So then how are we going to capture that as all or none?

CO-CHAIR BAGLEY: Other comments or questions? This is quite a group.

This is all okay, huh? Any other comments? Yes, go ahead, Dale.

MEMBER SHALLER: Confirmation that this is not a covered benefit under Medicare. The question was raised. It is not a covered benefit? That's an important question.

CO-CHAIR BAGLEY: Are you guys --

MEMBER FIELDS: It is not. I mean Zostavax is absolutely not. You have to write a prescription and there aren't on a Part D plan. Some Part D plans with an NA covered as a

pharmacy benefit, for instance, but for a straight Fee-for-Service Medicare, it's not a covered benefit for many plans. And it's certainly not within Fee-for-Service plans and Tdap as well.

MEMBER SHALLER: Another question is is zoster the one that is in short supply? So that's an issue, too.

MEMBER GREINER: Can you repeat your last question?

MEMBER SHALLER: Zoster is the one, the newer one in short supply. It's very hard to get, at least depending on where you live.

CO-CHAIR BAGLEY: Other comments? It looks like we must be ready to vote.

Okay, let's move ahead. Now, should we vote on the different programs separately?

Okay, I think the first thing we need to do before we vote is to have a public comment opportunity.

So is there anybody in the room who would like to comment?

Anybody on the phone? Operator, can you open up the line?

OPERATOR: Yes. At this time, if you would like to make a comment, please press star, then the number 1.

You do have a comment from Sandy Pogones for the American Academy of Family Physicians.

CO-CHAIR BAGLEY: Okay, Sandy.

MS. POGONES: Hi, this is Sandy Pogones speaking on behalf of the American Academy of Family Physicians.

In general, the American Academy of Family Physicians opposes the use of all or none composite measures in accountability programs. The all or none measures don't award partial credit. So as was mentioned earlier, they only reflect what's the most difficult to get. That is, a physician or a group that does very well in six of the seven measures but poorly in one will be scored the same as a physician or group that does poorly in all measures. And we don't feel

that that offers equitable quality. We think the difference in quality between the two groups would be very different.

And at minimum, you know there are other ways of scoring composite measures. As was mentioned you might sum the numerators, sum the denominators, and then calculate a composite by dividing the numerator by the denominator. But the all or none really does give a very harsh penalty for doing poorly in one measure.

We feel that composite measures of this type may be very useful for internal quality improvement because they are quite sensitive to differences in variations but we don't feel that they're appropriate for accountability for the reasons that I just mentioned.

In addition, when you look at these vaccination composites, the numerators, denominators, and exclusions for the influenza and pneumococcal vaccine measures within this measure are not consistent with those in the annual wellness visit composite. And we have to

be absolutely certain that measures are aligned to the extent possible prior to NQF endorsement and prior to CMS using them in a quality payment program.

When you look at errors in measurement, they are amplified by composite measures. And since five of the seven -- I'm sorry -- since two of the seven vaccines are often given outside of the physician office, in fact in many office they aren't given in the office at all but are given in the community as was mentioned before, it can be extremely difficult to which the lack of data sharing and interoperability for a physician or group to get that data. The lack of access to claims data, the lack of access to interoperable information is probably going to lead to very poor data and very low scores for these measures. And so the scores are more likely to reflect the extent of the EHR documentation than they are actual performance of the action.

And as we mentioned in the past,

insurance coverage may in fact impact patient willingness to be vaccinated.

Thank you.

CO-CHAIR BAGLEY: Rob, go ahead.

MEMBER FIELDS: Yes, just for confirmation on the Medicare.gov, I just confirmed that both those are it is dependent on your Part D plan. It's a pharmacy benefit, which is different than flu and PNEUMOVAX. So that's Tdap and Zostavax are covered via Part D. So it's dependent if you have a Part D plan, and if that plan covers it, you know what copays. It's just fundamentally different than the way flu and PNEUMOVAX are administered.

CO-CHAIR BAGLEY: And anybody else on the phone for public comment?

OPERATOR: No, no public comments at this time.

CO-CHAIR MOYER: So I was trying to see if I could figure this out from the specifications.

In terms of data source for the

measure, so I always get my flu vaccine someplace other than my primary care office. And then when I show up back at the health system, they say hey, have you had your flu vaccine? And they put the date in the system.

So I mean that feels like a fairly low barrier and I realize patients don't always know but if you don't know if your patient has had the vaccine, then you don't know if the patient needs the vaccine. I mean it feels like that is information you would need to have for clinical care.

And I guess just to provide a slightly different perspective on the composite, I do agree that an all or none, and especially with the fractioned data from Medicare can be challenging but I mean from a patient perspective, if a patient were looking at this and using this from a public reporting, get all your vaccines is really easy to understand. Several different vaccination rates is really a lot more challenging.

And I do believe that achieving a high rate on an all or none composite measure really shows a mastery of a process and a very consistent level of care in place. So I just wanted to raise these points.

CO-CHAIR BAGLEY: Thank you. And if I might, I'd like to correct something I think is a misperception. I heard it said twice and that is that if you have five components to a composite all or none measure, that the lowest rate is what is the determining factor.

If you have five components, I don't care what measure it is, and you are doing 75 percent on every last one of them, the composite rate is .75 times .75 times .75 five times and it comes up to like 28 percent. So it's not just the lowest measure. It's the rate of each one multiplied together for all five components.

And I heard twice people to say that that's not the case.

MEMBER BURSTIN: Except we don't actually have the specifications of how the

composite is done.

CO-CHAIR BAGLEY: I mean I'm not talking about this measure at all. I'm just talking about the idea of an all or none composite measure. That's how you end up with a rate.

So the diabetes composite measure in Minnesota started out with people getting rates of like 15 percent, even though they were doing fine on some other things. So and that caused them to systematize, as Amy mentioned, to get a systematic approach to getting all that stuff done.

This one doesn't lend itself to that kind of systematic approach very well but I just wanted to get the math straight. It's about math.

I'm getting a -- go ahead, Scott, before we summarize.

MEMBER FURNEY: So I really enjoy math and trying to figure out composites. Without the measure specs, there are two different versions

of composites one could calculate. So one would be considered perfect care. How often do you achieve all of the measures so that that patient goes from a zero to a one?

And then there's the composite that you're describing and, again, I may have missed it as well but there is not the level of details or specificity in the linked materials that I could find to figure out which version of either perfect care or a rated composite awaited composite, as you are saying this is.

DR. SCHREIBER: So let me just read you what I have in the measure specs right now. That it's the percentage of members who are up to date on -- and it lists them one by one -- and says all of them. So I think that this is trying to capture all of them.

And it goes one by one, member in denominator 1 who received influenza; member of category 2 who received Tdap; and so forth and so on. And it is all.

Does that help?

MEMBER FURNEY: Yes, so that sounds like what we determined -- what we call perfect care, which is a binary zero-one-one. You either have all of them or you have one, two, three, four, five of them but just shy. And those are -- that does run the risk, especially with two of the immunizations being either a non-covered benefit or a co-pay eligible benefit of disenfranchising providers or practices that have a higher proportion of underserved patients. And that's a concern.

I'm foreshadowing the conversation a little bit about risk adjustment but if you have a demographically challenged population versus an affluent population, the ability to get perfect care and afford the copays or the -- pretty pricey, having recently sent patients for the new shingles vaccination, the two-shot series, which is SHINGRIX, it is very expensive. So I think we run the risk with perfect care measure of having pretty significant variation, just based on demographics.

CO-CHAIR BAGLEY: Ira.

MEMBER MOSCOVICE: Yes, just seconding that the Rural MAP Workgroup really raised that point in terms of the population they're serving often is underserved and has lower economic status. And the lack of coverage for Medicare would really disadvantage rural providers.

CO-CHAIR BAGLEY: I want to know if anybody from NCQA is on the phone or in the room to comment for the developer?

MS. WILLIAMS-BADER: Hi, this is Jenna Williams-Bader from NCQA. Are you able to hear me?

CO-CHAIR BAGLEY: We can hear you fine, Jenna. Go ahead.

MS. WILLIAMS-BADER: Okay, so I am with NCQA. I am not the actual measure developer. I have her on a chat. She's been trying to speak and hasn't been able to get through, unfortunately. So I will have to try and relay what she has told me.

Lindsey Roth is our measure lead here

and she actually said that the measure is not an all or none composite. So we did want to make that clear.

Let me see if I can get any more information from her and see if she is able to --

MS. ROTH: Great, hi.

MS. WILLIAMS-BADER: -- join the line maybe using a different number. Oh, there you are Lindsey. I can hear you.

MS. ROTH: Yes, thank you. Sorry about that. I apologize for not being able to get through earlier.

So yes, I did want to clarify about the composite rate. This has been a really interesting discussion and I'm sorry I wasn't able to chime in earlier but I did want to clarify that the composite rate in this measure is not an all or nothing rate. It actually assesses each patient's opportunity for a vaccine based on their age.

So for instance, adults 66 and older would be eligible for four vaccines, the pneumo,

zoster, Td or Tdap, and flu versus a 19-year-old adult who only has the opportunity for flu, or Td, or Tdap.

So then the composite was calculated by then adding up all the patient vaccine opportunities as the denominator and then the numerator is based on the total number of those vaccines that were received or that they're up to date on.

So essentially, you are summing up the denominators across the individual vaccinations and summing up the numerators and dividing. So that would give you an overall snapshot of the vaccination. And then there are individual vaccine rates so you can understand what is perhaps driving that composite rate.

And then I did want to also mention that in our field testing of this measure we did calculate the composite as an all or nothing in addition to the way that it's currently specified. And the all or nothing composite rates were extremely low across the plans that we

tested them.

CO-CHAIR BAGLEY: Lindsey, thank you for that clarification.

Anybody have questions of Lindsey about that?

Scott.

MEMBER FURNEY: Sorry, I'm obsessed about this but the way I understood the comment, Lindsey, is it's not an all or none on all of the vaccines but for each age group, if a younger person is eligible for two or three, it is still considered perfect care for that age appropriate set of vaccinations. Same thing for someone who is 65 or older.

So I think there's a difference between a weighted composite with a percentage of achievement on each of the immunizations versus all immunizations for each age range.

PARTICIPANT: Actually, I think it wasn't either of those. I think it sounded like she was counting the number of vaccines eligible as the denominator. So if you're 19, you only

get two. If you only got one of those, you get a one in the numerator and you've got 50 percent. If you're due for five, you only got three of them, then you've got three out of five so that's 60 percent.

CO-CHAIR BAGLEY: Lindsey, did you hear that?

MS. ROTH: Yes, and that's correct. Exactly.

MEMBER FIELDS: It's not weighted or perfect care. It's a raw percentage based on opportunity.

CO-CHAIR BAGLEY: Any other comments from around the table?

Okay, I think we're ready to vote. And what I'd like to do is ask John to summarize. And we're going to vote on the same measure for two different programs. So we're going to vote first for one program and then the other program.

So it is the same measure with the same specifications but we're going to vote on the different programs because we're charged with

determining the appropriateness of any particular measure for a program. So we're going to do it that way.

Any questions about that?

DR. BERNOT: Okay, so the preliminary analysis, again, was the conditional support with NQF endorsement. And now again, that endorsement is a very broad process. Let me capture some of -- or demonstrate some of the things I've captured. And if there's anything that I'm missing that we need to highlight, please let me know.

Again, I think most of these would be covered under that process but I want to make sure that they are explicitly listed. In testing at the ACO level, what was mentioned what I'll consider the variability of benefits; that is, the reimbursement of vaccines, the shortage of vaccines issue which would have to go through that process also, I can scratch the part about the all or none, data availability, again with pharmacy giving vaccinations versus them coming

through the clinical offices.

So I have all of those components. Again, I do believe they would be largely subsumed under endorsement but I wanted to highlight those. And if there's anything else I am missing as specific --

MEMBER BURSTIN: The issue that the individual measures may have different time frames or different specifications so there should be -- I think they're all NCQA measures, I think. So just some internal harmonization or updating of the existing individual measures that they're still in the program, depending on the MSSP would be helpful.

DR. BERNOT: Okay.

CO-CHAIR MOYER: I apologize. I just have one quick thought that is rattling around. We were talking about the covered benefit of this and the reason for that not to be care.

I don't know what flexibility there is but we are seeing a lot of organizations who are ACOs or Shared Savings type programs take on

things they wouldn't normally take on because there is a cost benefit to it, I mean giving people rides, housing, all kinds of things. It would feel like if there is a cost benefit to these vaccines, perhaps measuring on it would help drive a shared savings because your patients get the vaccine. And whether it's covered or not or whether they can afford it, making sure that happens might result in shared savings and benefit from the program.

So I'm not sure if that is actually the case. This is not really my core group or vaccines but I was just curious about that and how that might fit in the program.

CO-CHAIR BAGLEY: Lindsey, do you have any comments on that? Any comments around -- oh, go ahead.

MS. ROTH: I have no comments.

CO-CHAIR BAGLEY: Okay. Anybody around the table want to comment on that? I guess that's up to ACO to decide. Okay.

All right, John, you want to set up

the vote here? Let's just make sure we know which program we're voting on first. SSP first.

MS. KOSURI: SSP first, yes.

CO-CHAIR BAGLEY: And the recommendation is?

DR. BERNOT: Is a conditional support with NQF endorsement and, again, highlighting the items that I mentioned, including the addition from Helen about the time frames.

MS. KOSURI: So voting is open for SSP MUC2018-062. Do you vote to support the preliminary analysis as the workgroup recommendation?

Okay, I think we have our vote. I think we have our 19 votes. So voting is closed.

The committee's recommendation based on 68 percent of the vote is yes for support for the preliminary analysis as the workgroup recommendation with 13 people voting yes and six people voting no.

CO-CHAIR BAGLEY: Okay, let's go on the MIPS measure.

DR. BERNOT: Same measures as for the MIPS program. Again, we'll start at the preliminary analysis and, if you recall, this is a different preliminary analysis. This was a do not support with the potential for mitigation and that would include testing at the clinician level for the mitigation. And of course, all of the other items I listed would carry over, unless we hear otherwise, as points to note.

MS. KOSURI: Okay, voting is now open for MIPS MUC2018-062. Do you vote to support the preliminary analysis as the workgroup recommendation?

Okay, I think we have our 19 votes so voting is closed.

The committee's recommendation based on 89 percent of the vote is yes to support the preliminary analysis as the workgroup recommendation with 17 people voting yes and two people voting no.

MEMBER FIELDS: Can I make a quick comment? Are there any -- I'm curious if there

are any consumer folks that could -- either nonprofits or other advocacy groups either in the room or on the phone.

CO-CHAIR BAGLEY: Robert is basically a consumer person, as well.

MEMBER FIELDS: Okay. Again, it just seems like a fundamental discordance, based on what we just -- the vote's done and that's fine but to not -- to raise the level of accountability for vaccines that are not covered under Medicare Fee-for-Service seems like you know injustice might be overstating it but it certainly seems fundamentally flawed as a strategy for taking care of patients.

So from the consumer angle, just someone who sees patients, and tries to prescribe these, and tries to figure out how they are going to get them paid for because they see all sorts of commercials about they need to get this vaccine or that vaccine and it's not a covered benefit and they are having to shell out sometimes over $100 for ZOSTAVAX, that's the

reality out there in the world. So if no one is going to raise that from the consumer angle, as I just put it on record while there are CMS folks in the room, I would hope that that is a consideration that is taken back for those that are able to act on them.

CO-CHAIR BAGLEY: Well said. Other comments?

You know CMS has asked us also to entertain a conversation about where there might be gaps in the MSSP program in terms of measurement.

MEMBER BURSTIN: Do you have the list of the current MSSP measures? That might be helpful.

MS. KUWAHARA: They are included in the link in the email I just sent out. It's under measure frameworks. We have the 2018 SSP measure set as well as 2019.

CO-CHAIR MOYER: David.

MEMBER SEIDENWURM: Well, I've said this every year since the first MAP and we're not

there yet so I'll say it again because I guess this is my cue.

I think that one of the things that is missing is when we have a performance metric in the Shared Savings Programs for some clinical activity, such as breast cancer screening, colorectal cancer screening. We don't require the underlying process to be monitored for quality. And so I would advocate employing in those two examples mammography quality metrics and cohorts of cancer screening quality metrics as components of the Shared Savings Programs.

So since we're essentially compelling people to have these procedures done, we ought to I think also ensure that they are done well.

CO-CHAIR MOYER: I'm going to go ahead and echo that as well. Full disclosure, David and I have done some work on this together.

One of our huge spend areas as a purchaser is around colonoscopies because they frequently start before people come on to Medicare. And the level of quality information

that we can make available to our people because if you're going to go through that, you want it to be effective, to accomplish what it is supposed to accomplish and you want it to be safe.

And we do have you know the seven-day hospital visit but in terms of consistent availability of the quality of the procedure, the adenoma detection rates, bringing people back at appropriate guidelines for follow-up, that is something that is really very scattered and inconsistent.

And I have actually tried to help family members who are on Medicare trying to figure out where they should go and it's really hard but if they needed smoking cessation, we could go to the gastroenterologist. So I don't expect you to magically fix that but it is -- you know if we put a lot of effort into it to make sure that we get that full benefit would be terrific.

CO-CHAIR MOYER: Helen.

MEMBER BURSTIN: It's great to be asked. I think it's a really important question. I think you obviously want to try to get to the measures that meet your Measures that Matter piece.

You have many measures that are sort of related to various settings of readmissions, which I assume are intended to be proxies for care coordination. They are really precious few measures that actually get at coordination.

And I know we've talked about this forever. A friend of mine notoriously said care coordination is the Bermuda Triangle of measurement. Many of gone in and few have emerged with a measure. Credit to Eric Schneider for that. I've always loved that and unfortunately, it is true.

But I think the whole purpose of ACOs is really intended to in fact be able to see more of that direct clinician-clinician coordination. And it just always make me sad when I look at this list and it doesn't actually have anything -

- it doesn't have very much. I mean it does have some in the CAHPS realm, of course, and readmissions may be a proxy for that but the way to really begin looking at that and maybe some of that is getting back to Dave and Amy's point, maybe even things like time to.

Some of the timeliness measures are on patients with a new diagnosis. So they are getting coordinated care. They are getting their biopsy done. They are getting it done quickly. Those kinds of measures may be more reflective of what you intent is of having a truly coordinated patient-centered system of care and these are really just proxies for that and I recognize how difficult that is to do.

CO-CHAIR MOYER: Amy.

MEMBER NGUYEN HOWELL: Yes, so I echo that comment from Helen absolutely and I thank CMS for asking the important question.

So I'd like to see more patient-reported outcome measures for this program. And along those lines, as we look at, especially the

LAN outline of how value-based care and value-based payment should be made within this country in the next few years, looking at risk and how that follows with organizations, also trying to align measures better, as we look at how these organizations assume risk and then take care of patients.

And so with that cost and resource use, utilization measures are appreciated because -- but in looking at that, we should hopefully refine the attribution answer -- not question but answer better to help define the attribution for the intendees.

CO-CHAIR MOYER: All right, I am not seeing additional cards in the room. And I apologize because I haven't been able to find the list. I'm just going to guess, though, that we could use measures around perhaps the shared decisionmaking process and making sure that we're not just giving appropriate care to patients but that they are involved partners in the discussion around treatment, and that they understand what

they are getting into, and that it is in line with their values, and what they expect to obtain, and their goals for life, as well.

Ann.

MEMBER GREINER: This summer we, in conjunction with The Graham Center, put out a report that looked at the contribution of advanced primary care to ACO performance. And there's actually not a lot of research in this area, which I was surprised at. And what we found is that the ACOs that were most successful had a strong foundation of patients under Medical Homes.

So one suggestion, and this is a structural measure, I believe, would be just to find out from the ACOs what proportion of their physicians are in a PCMH because that does appear to provide the sort of infrastructure and the foundation for the ACOs to manage patient care so that they can get to the population health outcomes that we all seek. So that's a suggestion for consideration.

CO-CHAIR MOYER: I see no other cards. I feel like I have this long list of demands.

This is suggestions, very, very true, well and especially because I personally don't know of any current existing measures but a lot of what we do here is pinned on the idea that the diagnosis the patient has received is correct. And so getting at diagnostic error and that would be -- I think it is an important frontier in measurement that we haven't addressed or really gotten our arms around yet at this time.

Dae and then David.

MEMBER CHOI: Yes, I just wanted to echo those comments. We have a lot of measures that are doing the screening, and they have the eye exams et cetera. I think that's really kind of the next frontier in terms of how we can evolve these process measures is to look at what are the things being done in those next steps that are insured, and the appropriate care, and timely care.

MEMBER SEIDENWURM: So with respect to

diagnostic quality and safety as opposed to diagnostic error, I think the frame is really important. So I think if we can look at the NQF report and the NAACO report and try to develop measures around that, that would be great.

It turns out to be enormously challenging to do that. As a radiologist, we've worked on that and we haven't really made a lot of headway. I mean we'll take all the help we can get.

CO-CHAIR BAGLEY: If I were running an ACO, I would want a conversation started in my ACO about diagnostic and therapeutic efficiency. How do we get to the right answer? And how do we get it treated as efficiently as possible?

You know, again, it's a proxy for the clinical integration maybe but it really, instead of talking about errors or where we fell down, what is your diagnostic and therapeutic efficiency in your organization? And I don't have a measure to recommend but maybe we should start calling it that instead of something else.

It really is what they should be about, I would think.

MEMBER FIELDS: Sorry, I couldn't resist.

You know it's interesting. I'm a part of other committees that are thinking about measure development around diagnostic accuracy and it supposes or it assumes that it is a somewhat black or white sort of outcome. And I think all of us that are in the room that are clinicians know that it's far from that. And it is highly subjective and it evolves. And you know there are varying opinions on if any one set of symptoms and categories -- and safety I totally get. You can get your head around safety much easier. But the whole concept of diagnostic accuracy, it implies that there's a single outcome that we're looking for and it is much more subtle than that, depending on the complexity of the patient, which I think then sort of says why everyone has struggled with it is that having one measure, or even two, or

three, four measures probably doesn't get us there.

I don't have an answer for it but I think, to me just clinically, that's why we struggle with it because it's hard to get it down to something that is measurable either as a numerator or a denominator really.

MEMBER BURSTIN: I agree it's a tough area. And certainly when we did the work here at NQF, and if you haven't seen it, we did a report literally laying out what were the low-hanging fruit of things you could at least begin to do. They're not going to be the measures that look at was there a diagnostic error but there are some potential issues like timeliness of test result follow-up that to me seem like they might be a really nice one for this kind of program that is supposed to, again, be about does the right hand know what the left hand is doing, patient access to information, handoffs, again goes back to care coordination.

Those are the kind of things that I

think really reflect what we hope is the spirit. What we hope ACOs do and you would know this better than me, but those are the kind of measures I think are ready.

The other thing is the Moore Foundation is going to be putting out a massive grant program to develop some of these measures. We've had lots of conversations with them. So I think this is a great time as well for CMS to talk to -- you know see if there is a public-private partnership there to get you something quickly.

MEMBER SEIDENWURM: The Moore Foundation is what, a $75 million project that they're putting forward on this exact topic. Is that what you were referring to?

MEMBER BURSTIN: Yes.

MEMBER SEIDENWURM: Okay.

CO-CHAIR MOYER: All right, any -- please do.

DR. SCHREIBER: Are there any measures around equity that you think are important?

MEMBER FIELDS: At the provider level? That's where it gets a little tricky.

At the community level, I could totally see that happening and I think the really important one is from a public health standpoint.

It's a little trickier to do at the provider level. You know when you think about perinatal mortality, or pre-term labor, C-section rates. I mean I see it in OB a lot because at least in my prior community, that's where we see the most disparity is actually in prenatal, and OB, and perinatal care.

So that's my concern with it is that at the provider level that gets tricky but perhaps through other contexts, if that makes sense.

MEMBER BURSTIN: Again, this is a place where the work we did with CMS at NQF on looking at measures that would get at the five domains of equity I think are really important.

A big piece of this is also just saying you may have existing measures that should

always be stratified or at least look to see which one of them. So you want to begin to see is that overall number really belying the fact that underneath that is in fact some significant differences. So that would be one thing.

I think a lot of the questions as well around access to timely interpreter services I think are particularly things that might be something you want to take a look at. And again, I think that those initial recommendations showed there are some things you can kind of take now that may not be the perfect ones but I would love to see CMS try to move into getting more measures that reflect the differential -- the differences across populations.

And while I have the floor, I also do think there are some interesting shared decisionmaking measures that I think might be sort of ready for prime time. NQF has endorsed several in the last year, the last couple of years. And again, fairly simple, getting back to Amy's point about PROs. There are some very

simple tools that have been put together like collaborate a very simple three-item measure developed out of Dartmouth that is intended to be done on a cell phone, as a patient leaves an office.

So being able to think about maybe not big, hairy difficult measures but maybe just something simple that you could start to think about incorporating in.

But I think you know the beauty I think of many of those measures is they don't just resonate with patients. They really resonate with clinicians as well. And so I think that might be a sweet spot.

CO-CHAIR BAGLEY: Okay, I think we're going to move on to a presentation from the Rural Health folks. Ira, are you prepared to do that?

Ira, do you mind if I have them do a quick stand up, sit down break? Just stand up and stretch in place. No conversation. Just get moving.

Okay, we're going to let you break for

lunch pretty shortly. So let's keep going.

As I was just reminded, we did actually have a presentation on our conference call. Could I have your attention please? Hello.

We did actually have a conversation on our conference call about this presentation. And this was supposed to be the follow-up discussion, which we didn't actually have on our conference call. So I apologize for misrepresenting that.

And what we thought we would do is start with sort of a quick summary of the presentation, the ideas that were presented at that time and then open it up for conversation, if that's okay with everybody.

So introduce yourself and take it away.

MS. CHAUDHRY: Thank you.

Hi, everyone. My name is Ameera Chaudhry. I am the Project Analyst on the MAP Rural Health Project. I am here with Karen Johnson, who is our Senior Director, and we also

have Ira Moscovice, who is our co-chair.

So we already had this presentation over the phone. I'm sure everyone remembers. Just as a quick reminder, there are 20 measures in the core set that was developed in this last phase of work; 11 of those are in the ambulatory setting. And again the criteria I guess that we used was that they would be NQF-endorsed, cross-cutting, and resistant to low case volume.

Next slide. And again, here's just a list of the measurement gaps that were addressed. We did go over this in our last call. So we can just keep moving.

And this slide, again, is going over the access to care issue that was addressed through this iteration of work.

So if we can just move on, again, to the discussion. We have a few questions up on the screen, if you would like to go off of those or, Ira, if you have any comments that you would like to start with, feel free.

MEMBER MOSCOVICE: The only thing I

would add to the discussion we had, which I'm sure is just fresh in your mind, is the point Helen raised about how challenging it is to get care coordination measures.

And actually the fourth criteria that wasn't on the chart, we wanted to have cross-cutting. We wanted to look at the low volume issue. We wanted to have the measures NQF-endorsed but also care coordination measures were a high priority.

And what was disappointing to me was after a long deliberation with the committee, we came up with one of all these measures related to care coordination. So I just highlight and it's a particularly important issue in the rural environment, where you don't have specialists and other kinds of providers necessarily available so it even takes on a new dimension.

So I think that's an important area and any feedback you have on that would be greatly appreciated.

CO-CHAIR BAGLEY: Go ahead, Girma.

MEMBER ALEMU: I would like here to mention some things that needs to be mentioned. I would like to thank Ira's group for their painstaking efforts to come up with the recommendations of need.

So I was work on CMS for tasking indicate to establish some workgroup, which is really relevant and the federal office of Rural Health Policy for serving as a government task for the project. Really that was an important step in considering there were issues that are relevant to the rural providers and the rural health in general.

Having said that, I want to point out two issues from what I heard that may need to be addressed by CMS, NQF, and measure developers. And the first one is the issue of the level of analysis. You know we have heard how controversial and how important it is just today. And there were many measures which they considered that they would like to include in the core set, you know where we saw 20 measures. I

don't know how many of you are inclined to use that one. They came up with 20 measures in the core set.

And there were other measures which needed to be included, which are very important in the core set but the issues was the level of analysis. So the measures were mostly involved and specified at the health plan level, so they couldn't include those measures in the core set.

Just to give you an example, you know controlling high blood pressure, which is an important one, which is in MIPS and it's widely used but they couldn't put that measure in the core set because of just the level of analysis that the measure was endorsed to that. So that is one of the issues and CMS and measure developers need to look into that.

The second issue is the gap they mentioned, access to care. We know that access for all your patients and providers is an important issue. And we also know that telehealth is getting more support from

policymakers, payers like CMS, and health plans. So the group also discussed that in order to solve that problem, one of the ways to get it done is by expanding telehealth.

So what I wanted to say now about telehealth is there is a lack of measures about telehealth. You know we have to make sure that the services we provide. So telehealth is relevant for quality improvement and, at the same time, it assures the quality actually is provided by telehealth.

So I would like to mention that point here, you know that CMS, measure developers, and the like also are interested should look into that.

A few years back, NQF has written a report about the framework of measurement for telehealth and I think measure developers need to look into that and CMS -- with CMS help I think something can be done.

So I just want to highlight those two points and the level of analysis issue is also an

important issue for our group here.

So again, I thank the group for doing that.

CO-CHAIR BAGLEY: Go ahead, Ira.

MEMBER MOSCOVICE: Yes, just one last observation on the morning's discussion here. You know my take on it is a lot of people here are in the mindset of large ACOs serving urban populations. You represent organizations that are heavily oriented in that direction. I understand that. We have 20 percent of the population just about in rural environments.

And I'll just take us back to the implementation of the PPS system and what we went through for over a decade to try to finally recognize that you know what, you can't do it the exact same way in a rural environment with solo or small group practices as in larger urban environments. And I just hope as we move forward in this whole discussion about relevant quality measures and the pay for value orientation, that we really do think about how is this going to

play out for that 20 percent of the population living out there in rural areas. And that's what was underlying really the formation of Rural Health Workgroup.

CO-CHAIR BAGLEY: Other comments, questions, concerns?

Michelle or Reena, any observations? What has CMS done thus far?

MEMBER DUSEJA: So I think you know from our perspective we believe the work that NQF has done on this is really going to help us in our next steps in thinking about how we apply the Rural Health Core Measure Set across our programs.

We find this work really incredibly important. And you know the comments that were made today with regard to care coordination, telehealth, trying to think about how to incorporate those concepts, we hear loud and clear, particularly with the programs that we're going to be discussing this afternoon because that is actually part of our policymaking as

well.

DR. SCHREIBER: Just a couple of points. So I think that most of us know that the Administrator is really particularly interested in the issues of rural health. It is an area that is definitely different than it is to be in the bigger cities or even in the communities that have care that is easily accessible or the bigger care that is available right down the road, as opposed to 100 or 200 miles away.

And so the work that has been done for the committee, both even in defining issues of rural health, not just measurement development, but issues of rural health and how this can be translated into programs I think has been very exciting. And we are very pleased, actually, with the recommendations that are coming forward, again, not just for measures but how we look at and think of rural health in a holistic approach.

They are somewhat different and have their own unique challenges.

CO-CHAIR BAGLEY: We are seeing more

and more ACOs in rural areas. Does anybody have experience with that as part of your organization and you could talk about that?

Yes.

MEMBER FIELDS: Not at Sinai or Upstate but at my previous organization, Mission Health in western North Carolina. Sort of the largest proportion of our physicians were in actually more of a suburban environment but it gets very rural very quickly, leaving the central county.

And yes, it's certainly an issue for lots of reasons in little ways. Certainly, the economic disparities are significant and cause significant barriers to access, not just in lower dollar amounts like vaccines, but in the significant things like OB care, and even just quality medical care.

It's definitely an issue and the rates are higher. We'll call it the noncompliant -- I hate that word -- but sort of those kind of, anything that measures adherence to either

medications or care plans just become proportionately more difficult in those environments.

We also have a shrinking workforce in those areas as well. So we may have attributed lives by you know because they utilize somewhere in our system some access point in the system but when you look at ongoing real primary care or ongoing care anywhere closer to home, we find that they have none because their workforce is shrinking.

So there are pretty dramatic challenges and you have to get somewhat creative. We would establish things like community paramedic programs and all those things to try to increase the access points but it's still in telehealth and all those things. But it's certainly challenging.

You know I always struggle should there be -- sometimes I think -- this wasn't my idea but somebody said should there be some sort of risk adjustment based on that. I'm trying to

get my head around that.

You know I always struggle with having disparate targets for those populations. We shouldn't accept less quality. It just feels like we should try to problem solve around it and actually getting there just becomes really difficult.

So I don't know if I have answers but it is different and it is difficult.

CO-CHAIR BAGLEY: Michelle.

DR. SCHREIBER: I just wanted to say one other thing, thank you.

When it comes to rural health, I think one of the other challenges that we have, and I say this now as we think of developing measures, is that the N for them is frequently so small that they fall off sometimes the measures. And then it appears that you're not doing the care at all, for example, or it's just kind of a blank. And I don't know that that even sends the right message.

And so I think one of the challenges

that we all have is even what is the statistical modeling that we can come up with when the N is really generally pretty small.

MEMBER FIELDS: Yes, it almost feels like you need to take even more of a public health approach in hyper urban, and hyper rural environments, and somewhere in the middle. Because urban environments, I'm finding, have their own struggles. It's interesting the similarities of -- you know Sinai is interesting. The main hospital sits on some of the highest per capita income demographic literally on one side of the hospital and some of the lowest on the other side of the hospital, with straddling Harlem on one side and the Upper East Side $20 million townhouses on the other side.

And it's just interesting to see the similarities actually when it comes to access even. And some if you know you are homebound in a large high-rise in Harlem, it's actually still an equally challenging thing to get you in for your dialysis as it is in rural environments.

But it does feel like it requires like bigger or wide-reaching public health approaches to things and maybe the measurement should follow that, as opposed to more operational clinical process kinds of things. It's a vague thought but that's sort of where I end up coming to because when you do it at the patient level, you end up with those tiny Ns and then it becomes less relevant, when what you're really looking for is how do you serve on those basic needs across the entire population?

CO-CHAIR BAGLEY: Go ahead, Ann.

MEMBER GREINER: This is more granular than what Robert and Michelle were just talking about but I am curious this movement towards e-consults and now that being recognized for payment purposes. And it seems to me an exciting development that really could help rural health.

I wanted to know if you wanted to comment on that and I don't know if there is a measurement implication here but it really does help with the coordination, obviously, between

primary care and specialty care.

DR. SCHREIBER: Thank you for the question. It's interesting it came up at yesterday's Hospital MAP also about the e-consults and telehealth.

I think this is an area that ripe for exploration and opportunity. And I actually think it may be that rural health leads the way because they are the ones who have frankly had to bring forward some of that care earlier because of the distances involved. And I think this is a great opportunity to study it, perhaps even starting there.

So thank you.

CO-CHAIR BAGLEY: Michael.

MEMBER HASSETT: Thank you. I just want to follow-up on that comment because I think the telehealth question is a very interesting question and very helpful but from a specialty perspective, I think there are also unique challenges.

So for example, radiation oncology, as

a treatment, is a cognitive decision to be made but there are definitely access issues that aren't solved by the telehealth question. And how we deal with those two things I think the concept of availability is an important concept to have on a framework. How you measure availability of services for something like radiation oncology or really who is the targetable audience for that sort of a measure I think is very challenging.

CO-CHAIR BAGLEY: Go ahead, Chad.

MEMBER TEETERS: So speaking from an ACO in western New York, we have seven hospital affiliates of which four of them were actually in rural areas across upstate New York, which gets very rural very fast. And one of the things that we found with MIPS and some of the other ACO models is that there is so little money to be made for successful practice and adherence to metrics but there is significant money to be lost. And for these hospitals that are operating on the margin or worse, they're expending

significant financial resources to have the services to provide in their communities that actually cost them more than what they could gain by providing those services to the patients in their area.

And so if they are not a part of a large ACO conglomerate, many of them were going out of business. But by being a part of an ACO conglomerate, they are either siphoning funds from the larger system or the ACO is having to send resources down to these rural communities, where they're getting, especially when we're talking about the subspecialty realms, and even primary care, we have an aging provider population, sending a limited resource into a community, where it will be reduced as far as utility to maybe 30 percent where it would in its normal environment, obviously, is diluting the resource pool even farther for the entire population.

So, obviously good care and things that we all care about but it makes it even more

difficult when it's to the financial detriment of facilities.

CO-CHAIR BAGLEY: Other comments?

Okay, we're going to take a low tech straw poll here. How many would like to break for lunch now and come back at 12:30? And then the next vote will be for 12:45.

So how many vote for 12:30, raise your hand; 12:45? Get at it. You know we have a real exciting conversation after lunch about cost of care measures. So get tanked up.

(Whereupon, the above-entitled matter went off the record at 11:53 a.m. and resumed at 12:34 p.m.)

CO-CHAIR BAGLEY: Okay, I'd like to get started because the sooner we get started, the sooner we'll be done, right? No, no, maybe not, but let's start anyway.

We have a fascinating discussion this afternoon about cost and care measures. I think before we start that, I'd like Reena to do an overview of the MIPS program and give us sort of

what are you looking for and what do you need from us conversation.

MEMBER DUSEJA: Absolutely, yes. Well, thanks, Bruce.

Good afternoon, everyone. It's a pleasure to be here for this afternoon's session.

Again, my name is Reena Duseja. I'm the Chief Quality Officer for the Quality Measurement Value-Based Incentives Group.

What I wanted to do today before we delve into the afternoon session with the quality measures and the cost metrics was really to provide the Workgroup some framing thoughts on the Merit-Based Incentives Program, as you consider the measures that we're putting forth for your consideration for rulemaking.

Could you go to the next slide, please?

All right. So, just as a reminder, the Merit-Based Incentives Program sits under the Quality Payment Program, and MIPS is just one of the two tracks that clinicians can choose to

participate with in QPP. So, if a clinician is MIPS-eligible, than he or she is subject to a performance-based performance adjustment through MIPS. And the other track is the Advanced Alternative Payment Models, where a clinician can earn an incentive payment if they participate in a particular model.

Next slide.

Again, there are four performance categories for MIPS in year three. Here, we actually have the weight, so you can see what we finalized for year three of the MIPS program. So, there's the Quality Performance Category, the Cost Performance Category, Improvement Activities, and then, the newly-renamed Promoting Interoperability Performance Category.

In the calendar year Physician Fee Schedule this year, we finalized the weights, such that the Quality Performance Category now is 45 points of a total of 100, and the Cost Category is 15 points.

Next slide.

So, in the Quality Performance Category, the clinicians have the choice to select six measures, one of which must be an outcome measure or what we define as a high-priority measure. And we applied in our rule the Meaningful Measures Framework to what was the existing MIPS quality measures to identify what was the high-priority areas for quality measurement and quality improvement to assess the core quality-of-care issues that we believe was the most vital to advancing our work.

So, this year we actually finalized removing 26 quality measures. Many of those were process, duplicative, or what we defined as topped-out. We also added eight measures, which are four patient-reported outcome measures, and six of those eight were actually high-priority measures. So, we have a total of 257 quality measures for 2019 that clinicians can choose to report on.

Next slide, please.

Then, I also want to just focus on the

fact that we also have, similar to what we do with our other programs, the topped-out analysis. So, we apply that also for the MIPS program. Of note, in this year's rule we also finalized what we define as extremely topped-out, and that's a measure that attains an average mean performance within the 98 to the 100th percentile range.

And the next slide actually shows the measures that we're going to put forth for the Committee to discuss shortly after we talk about the Cost Category. So, I would like to actually spend a few minutes talking about the Cost Performance Category.

Next slide.

So, we're required by statute to develop the episode-based cost measures to meet the mandate of the MACRA Section 101(f). These measures really address the Meaningful Measure areas of patient-focused episode of care and risk-adjusted total cost of care. I want to note these measures are claim-based. They do not require any additional clinician burden and

calculations. And these measures that we're putting forth for you today, just like we did last year, really had extensive clinical input through our clinician subcommittees.

Next slide.

So, as you can see in this slide, we've utilized a broad range of stakeholders that have provided input into each component of the class measures throughout its development. Input has been gathered through Technical Expert Panels, through clinical committees, as well as the subcommittees, measure-specific workgroups, the Person and Family Committee, public comment, and field testing.

And it's with all this input that we are bringing you today 11 episode-based cost measures that were selected by the clinical subcommittees to develop, as well as two measures that are currently in the MIPS program, the Medicare Spending Per Beneficiary Measure as well as the Total Per Capital Cost Measure, and they were reevaluated as per our routine and

maintenance, as well as incorporating stakeholder feedback for discussion today.

The next slide actually gives you a sense of the input that we've had in this process. So, our Technical Expert Panel includes representatives from specialty societies, academia, healthcare administration, person and family organizations.

The TEP has met since 2016 to really provide high-level advisory roles and providing guidance on the overall direction of the measure development and reevaluation. We also have had the Clinical Committee meet. They convened back in the fall of 2016, and it included over 70 clinical experts from 50 professional societies, to provide us the experts to draft this initial list of episode groups and trigger codes to define these episode-based cost measures.

And the real work and the real meat is really in these clinical subcommittees. I cannot stress the smile factor I have in terms of the engagement that we have had with clinicians and

specialty societies in helping us develop these cost measures.

In Wave 1, we had seven clinician subcommittees, approximately 150 clinicians, representing nearly 100 societies. And in Wave 2, which is this year -- and this is actually what we're going to be presenting, the 11 episode-based cost measures -- we had 10 clinician subcommittees meet and it comprised over 265 clinicians affiliated with more than 120 societies.

The next slide, please.

So, I thought I would briefly, just for the Workgroup, talk about what is an episode-based cost measure, just for some level-setting in how we are defining it. It represents the cost to Medicare for the items and services furnished to a patient during an episode of care. And unlike TPCC and MSPB, they only include items and services related to the episode for a clinical condition or procedure, as opposed to all of the services to a patient given in a

timeframe.

The episode-based measures have five components, as you see here. It's defining the episode group, then attributing the episode group to the clinician, and then, assigning cost to the episode group. Risk adjustment is a piece with this as well in terms of risk-adjusting the episode groups, and then, adjusting or aligning the cost with quality as the fifth dimension.

As I mentioned last year, we submitted to this Workgroup eight episode-based measures, and we received conditional support for rulemaking. We finalized those measures in the rule for this year, and our intent is to submit those for NQF endorsement in the spring of 2019. And they will continue to be updated based on our regular measure maintenance.

And in this year, we have 11 episode-based cost measures that were developed in a continuation of the same process for the Workgroup to consider. And again, this really was developed with extensive stakeholder input to

meet the mandate of MACRA.

Next slide, please.

So, the other two measures that we're bringing forth today are a version of the MSPB and the TPCC measures. These are currently used in the MIPS Cost Performance Category and we're also using the Value Modifier Program. What we have done is reevaluated those measures as part of our regular measure maintenance for the blueprint for the CMS Measure Management System.

And the refinement process included getting clinical input again from the Technical Expert Panel through in-person meetings from 2017 to the end of this year. And we've also used a MSPB Service Refinement Workgroup that was convened during the summer of this year to help us think through the MSPB revisions.

Slide 12, please, the next slide.

What we have done, after getting all this input that I described to you, is actually also go an additional step beyond by doing field testing. We did this for our Wave 1 episode-

based measures. We did that again for our Wave 2 measures.

And so, we had actually, for this wave, had over 700,000 field test reports that were produced, and we got key areas of feedback based on that field testing. I've listed here some of the key areas for the MAP Group to see what we received.

In addition, we got a lot of stakeholder appreciation for the Clinician Subcommittee process in developing these measures and detailed suggestions regarding specific trigger and assigned service codes that were employed for the episode-based cost measures, which our team has incorporated for consideration for today.

Also, general support for the reevaluation of the MSPB clinician measure refinements, and there were also some questions regarding changes to the service category conclusions that we can discuss for the TPCC measure.

Next slide.

So, this lists, again, the measures that we're going to have for discussion. The first 11 up there are the episode-based ones, and the other ones are the reevaluated cost measures for MSPB and TPCC.

So, I'll hand it back to Bruce to start the discussion.

CO-CHAIR BAGLEY: I have just a quick question. On the Wave 1 measures, can you tell us a little bit about what your experience has been with them? What do you know about them? And do you have any feedback for how that's working? As a corollary to that question, are the ones we're looking at today similarly constructed and specified? In other words, is it kind of more of the same thing, and how is it going so far?

MEMBER DUSEJA: Yes, I think it's even getting better. I think these clinician subcommittees are learning from that first wave, and like getting comfortable with this concept of

cost and how do we actually measure it. And I think there's been a lot of learnings from the second group, especially the ones that have met again from Wave 2.

And I'm looking over to our contractors here. Acumen is here, so Sri and Joel, who manage the contract with CMS. Feel free to add as well.

DR. NAGAVARAPU: Yes, I think that's exactly right. I think people who have been involved in the first wave have become used to the process. And so, that's led to the sorts of improvements that Reena mentioned.

We've also been able to take into account some feedback from Wave 1 about aspects of the process people didn't like or wanted to change, to refine. And we're able to take into account some of that feedback.

So, one of the points that I'll bring up just very quickly is that people asked for a smaller group of people to work on the very detailed aspects of measure specifications. And

so, we moved to an aspect of the process where the broader Clinical Subcommittee, after providing initial guidance as to which measure should be developed, provided some input as to a composition of what a smaller group would look like, and we operationalized the smaller, more targeted Workgroup, composed especially of societies, partly from the clinical subcommittees and partly recruited new expertise based on what the Subcommittee told us, in order to do some targeted refinement.

But the measures you'll see today are all based on the same framework that people seemed like in Wave 1 and that went through the proposed rule process.

CO-CHAIR BAGLEY: To what extent were the Wave 1 implemented and what's your experience, I guess is what I really wanted to know.

MEMBER DUSEJA: So, we finalized it for this year's rule, and we are planning to go through NQF endorsement. So, that will happen in

the spring of this year.

CO-CHAIR BAGLEY: For Wave 1?

MEMBER DUSEJA: For Wave 1, that's right.

CO-CHAIR BAGLEY: Okay. Can you introduce this?

DR. BERNOT: In a very minor deviation to the way we had it laid out on the agenda, we'll do the 11 cost measures as one group, and then, talk about the total cost ones after that. So, instead of introducing 13, as it looks on the agenda, I'll just introduce the first 11. And they are on the screen. But, for the record, I'll just read the titles, not the description. I know we've had a lot of time to look over this material. And then, I will give the preliminary analysis, which will be the same for all, and I'll explain that. So, I'll just introduce the measures first.

The first is MUC2018-115. That is Inpatient Chronic Obstructive Pulmonary Disease, COPD, Exacerbation.

Next is MUC2018-116. It's Femoral or Inguinal Hernia Repair.

Next, MUC2018-117, Lumbar Spine Fusion for Degenerative Disease. It's one to three levels.

The next is MUC2018-119, Psychoses and Related Conditions.

Next, MUC2018-120, Lumpectomy, Partial Mastectomy, Simple Mastectomy.

The next one is MUC2018-121, Acute Kidney Injury Requiring New Inpatient Dialysis.

Next, MUC2018-122, Lower Gastrointestinal Hemorrhage.

MUC2018-123, Renal or Ureteral Stone Surgical Treatment.

MUC2018-126 is Hemodialysis Access Creation.

MUC2108-137 is Elective Primary Hip Arthroplasty.

And finally, the 11th is MUC2018-140, which is Non-Emergent Coronary Artery Bypass Graph, CABG.

And so, I know that was a long list, but, for the preliminary analysis for this, I wanted to point out a couple of things. One, if you noticed in the Discussion Guide, there is a link to updated materials. The material that came out of JIRA did not have test data in it.

Between the meeting and the JIRA release, we were able to get some of the field test data, and we did the PAs based on that field test data, rather than having such a large proportion of the measures say, well, we need to update; we need to update in the meeting. So, that's the PAs that we have done on this.

And the preliminary analysis from staff for all 11 measures is a conditional support with a condition of NQF endorsement. And again, that is after analyzing that newer supplement of the field test data that you can see referenced either on the website or through the link on the Discussion Guide.

Any questions, clarifying questions, from what we did?

MEMBER SHALLER: Well, I don't know. It's a big-picture kind of context question that I think might help before we dive into the details.

So, we moved forward eight measures last year. There are 11 on the table. That's 19 episode-based measures. Any idea what sort of percentage of total spending in the inventory sector that represents? And kind of a related question is, did you pick these off based on their feasibility technically or because of their cost burden, or some other combination? That's the other question.

MEMBER DUSEJA: It's both. It's both in terms of the decisionmaking and the pleasures of the committees on what they wanted to actually measure and focus on. But we do have the percentage, I believe, of how much it covers in terms of Medicare-based spending for the 19.

MEMBER SHALLER: The total?

MEMBER DUSEJA: Yes, the total.

DR. ANDRESS: Thank you.

So, our current estimate has the total coverage for the 19 measures at about 7.8 percent of total cost for Part A and B. Now I will note that that does not account for clinicians who aren't included within that center because they're part of the APMs or for other reasons.

So, we've been talking a little bit about how we might do an analysis in the future that accounts for these factors as well and give a percentage of coverage for what's actually within the potential MIPS pool.

The reason we did the analysis as we did is because that's a part of the statute that underlies MIPS, that we're seeking to cover a total of these measures and approximately 50 percent of Part A and B spending.

So, I think the kind of takeaway from that is we developed the 19 measures. We're clearly going to have a fair bit of work ahead of us in identifying not only episodes that address cost, but also the clinical needs of the patients and aligned with quality measures that are

included in MIPS.

We're currently beginning Wave 3 development. We actually have a TEP meeting on Friday to start that process. We'll be looking at chronic care, and our anticipation is that we're going to start taking some larger chunks out of the overall cost, as a consequence of that, moving forward.

DR. NAGAVARAPU: And one thing I'll just quickly add on the measure selection is this, to me, is a really unique aspect of this whole process. The way that we went about this is using NQF criteria as well as criteria suggested by our TEP, including beneficiary coverage, opportunity for improvement, the potential for alignment with quality measures, the feasibility of measures, the feasibility of defining coherent clinician cohorts.

We took those sorts of criteria to the clinical subcommittees in each of these clinical areas, presented a bunch of data on what the coverage looks like in terms of cost, clinician

coverage, beneficiary coverage, presented information on the overlap with existing quality measures, and then, went through a selection process with the clinical subcommittees, where they were able to vote for which measures they wanted to start with in Wave 1 and in Wave 2.

So, that's how the measures that you see here came about, is the clinical subcommittees, with representation from the professional societies, went through a voting process, trying to weigh the tradeoffs of those various factors, including quality alignment, and so on.

CO-CHAIR BAGLEY: Okay. Before we start the discussion, I want to just outline -- I have you on my list, David -- I want to kind of outline how I intend to try to get this done.

As noted, the first 11 are pretty much the same; you know, plug in this diagnosis or that diagnosis or that procedure. But, other than that, they're similarly constructed, and similarly constructed to the ones we dealt with

last year. As such, they all have the same problems. So, I'll outline what I think the problems are and the same kind of things that we discussed last year, so you won't think we're missing anything.

All of the measures have a concern by clinicians of what do I do if I only have two procedures. You know, small numbers in terms of making it valid and reliable. Attribution is always a concern.

The materials that we saw really didn't specify the episode itself. In other words, an episode has to have a trigger code and a certain duration, and what's excluded from that or included, whichever way you want to do it. But it's actually pretty complex, depending on the episode. But we didn't see any of that information last year. We just trusted you. So, we'll probably do that again.

But the other thing that's always a concern for the clinicians, and that is risk adjustment. A new twist on that is, does the

risk adjustment include social determinants of health, access to insurance, and some of those things that have become highlighted, more so at least than it was when we had this conversation a year ago.

So, to me, those are the big issues that relate to all of these. I think what we'll do is we'll start out with some of our lead discussants and sort of talk about at least those issues, and see if there are other particular issues that kind of go through the whole set.

Before we vote, what I'm going to suggest is that anybody can have the opportunity to pull one off the list to be voted on separately. In other words, as we have the discussion, it will be about all of them because of their construction, if you will. And then, if somebody really needs to talk about one particular disease or procedure category, then you're welcome to pull of them off the list, so that we can kind of talk about what the specifics about that particular disease might be.

So, a general discussion about construction and problems and how you guys have decided to deal with that, and how people would like to see you deal with that, is what we'll start with. And then, we'll go on to talk about particularly voting.

Is everybody okay with that? In other words, we're going to have the same conversation over and over again.

The other thing that I would like to do is ask for public comment before we start, because in the past there has been some feedback from the public that, if we ask for public comment after we're finished voting, then it's really not input. So, we're going to give that a try. And I think that we have some people anxious to give us some public comment.

So, we'll start with people in the room.

Do we have a microphone that's set up and working?

I see some people moving to the

microphone. All right.

MS. McLAUGHLIN: Hello.

MEMBER WHITACRE: Is this public comment on the overall group or on individual measures within the group?

MS. McLAUGHLIN: These are overall comments on the episode-based measures.

Good afternoon. My name is Jennifer McLaughlin. I'm staff with the American Medical Association. Thank you for this opportunity to offer public comments.

Overall, the AMA supports the episode-based cost measure development process and the movement.

Are you having difficult hearing me? Can you hear me?

CO-CHAIR BAGLEY: Yes.

MS. McLAUGHLIN: Excellent.

Okay. So, I'll just start over then real briefly.

My name is Jennifer McLaughlin. I'm staff with the American Medical Association. And

thank you for the opportunity to announce our public comments today.

Overall, the AMA does support the episode-based cost measure development process and, also, the movement to episode-based measures over broad cost measures. We do, however, have some concerns that the rush to count as many physicians as possible on cost measures may be compromising the process.

And to the MIPS program in some context, I do think it is important to remember that, when the program is fully implemented in 2022, and the threshold is set at the mean or median, about half of physicians will be required -- or will likely fail. And the cost measures will be a large contributor to those failures. So, we think it is extremely vital that these cost measures get it right before they do move forward.

One area, in particular, where we think there is room for improvement in the episode-based cost measure development is the

timeline for developing and testing the episode-based measures, which we think in this process with the Wave 2 measures was rushed, and that the ability of practicing physicians to engage was limited. Stakeholder input was also hamstrung by the complexity of the field testing reports and challenges accessing the reports.

And for these reasons, we urge the MAP to carefully consider feedback from the specialty societies regarding the 11 episode-based measures in front of you, and we recommend that the highest level of endorsement from the MAP be conditional support.

Thank you.

MS. BOSSLEY: Hi. Heidi Bossley, on behalf of the American College of Gastroenterology. We submitted comments, but also just wanted to reinforce what the AMA said.

The feedback timeline was very short, and members had a very challenging time getting access to the reports. So, I'm not sure that you have as much information, CMS, as would be

desirable.

The second thing is, ACG did provide very substantive comments on the triggers, the codes, all of that information. And we would ask that those be looked at very carefully before these measures go out.

Thank you.

CO-CHAIR BAGLEY: Is there anybody on the phone? Operator, can you ask for comments? Hello. Is the operator there?

OPERATOR: Yes. If you would like to make a comment, please star, then the number 1.

There are no public comments at this time.

CO-CHAIR BAGLEY: Thank you.

Normally, we would go to the lead discussants next, but virtually everybody around the table is a lead discussant on one of these, right? So, we're going to skip that step on the general conversation, if that's okay.

So, David, you've had your card up for a while. You might as well lead us off.

Scott, I've got you on the list, too,.

MEMBER SEIDENWURM: Okay. So, I have a question for our CMS colleagues. That is, how do the episode cost metrics interact with the more global cost metrics?

And I think that a question, and perhaps a source of some confusion and angst among the specialty societies, has to do with the tradeoffs of either submitting, as it were, to an episode measure or be subject, as it were, to one of the more global metrics. My bias is I would rather be measured on something in my own field of interest, especially since there's been severity adjustment and further refinements. But could you clarify what would happen if the specialty societies did not have these or what happens to clinicians who are subject to an episode metric or not?

DR. ANDRESS: Thank you.

So, the question you're asking about is less a matter of the measures themselves and more a matter of implementation of the measures

within the program. So, of course, we're a little bit limited in terms of what we can say, due to the rulemaking rules. That's not a good way to say that.

So, I think the thing to keep in mind is that we're aware of the potential, for instance, for overlap, and we're also very much aware of the preference within the community to be as specific as possible rather than focusing on the generalized to a broad overall population-based cost measure.

I think the way that they interact right now is that we have 19 measures that represent a small subset of all episodes of care, a relatively small subset of all costs of care to be captured by episodes. And so, what we've done up until now is to use those population-based measures as a stop gap, essentially, to say we have the capacity to look at cost with what we have available.

Our focus has been twofold in terms of the development of these cost measures. The

first has been development of episode-based cost measures with as much rapidity as we can. And I can vouch for, first of all, the development has been very rapid and, also, that there are some unintended consequences that go along with this, which you have heard with some of the public comments we just heard. And so, we're trying to balance those needs.

On the other hand, we've also been working to refine the two existing population measures to address some of the overarching concerns that we've heard about from stakeholders regarding their implementation within the program. I can't say for a certainty even now exactly how they're going to interact, but I can say that, as we're putting the measure set together, our emphasis is on being as specific as we can possibly can to the cost as it's being assessed, and being mindful of the potential consequences of, for instance, duplicating attribution across multiple measures, episode-based and population-based measures. And so, I

think our intention is to reflect that in the policymaking that follows from, any policymaking that follows from these measures going forward.

MEMBER SEIDENWURM: Is the unit of analysis going to be the clinician or the episode? And maybe you can't say this because the rules haven't been promulgated yet. But let's say you're a surgeon of some sort, and there's an episode in your field and you might have 30 of those, but you might have done 300 other operations during the year. Would those 30 be your cost component or would they only be, in my example, 9 or 10 percent of your cost component?

DR. ANDRESS: I think that's the kind of decision that we have to put through policymaking. But I can say that it's exactly the kind of question we've been asking ourselves as we're moving forward to the development of measures and thinking about how they'll fit within our programs potentially, yes.

MEMBER SEIDENWURM: Thank you.

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

MEMBER FURNEY: So, my question -- first, a couple of comments. I understand that my requirement, where the MACRA requires us to come up with episode-based measures under a very, very tight timeline. As I read through the materials, which are a bit limited compared to the workload, it's clear there was a lot of stakeholder involvement. I have a couple of specific questions.

One is, in last year's meeting, we asked about the risk adjustment methodology and didn't get a great deal of transparency around that. So, the question of social determinants of health, socioeconomic status, which is incredibly important to do that risk adjustment, how confident are we that we have an adequate risk adjustment for that? The first question. I have more.

(Laughter.)

CO-CHAIR BAGLEY: We'll take them one at a time. It would be easier.

DR. NAGAVARAPU: Should I just go ahead? Okay, great.

So, we have been aware of the interest in looking at socioeconomic factors. We've done testing with various socioeconomic factors. The way we did this in risk adjustment is that we linked the Medicare claims and enrollment information and the measure information to the American Community Survey, and at a very granular level. So, the most granular level that the ACS will allow for five-year averages, and we're going to get estimates of socioeconomic status in particular neighborhoods.

We, then, included variables based on income, unemployment status, and education, in addition to, for people's Census Block groups from the ACS, linked that to our data, and, also, had information on dual status, for instance, and ran risk adjustment models to try to understand the impact of including those variables that CMS traditionally hasn't included in these sorts of measures because of concerns about masking

disparities, and so on. Because we wanted to get at exactly what you're saying of like whether we're missing anything.

What you see across the measures this year, as well as what we saw last year, was almost no movement in R-squareds and invested R-squareds. And so, I think, going forward, it's something that routinely now we're keeping track of because we realize that, if we ever do see a change in predictive power, it's important to flag. But, for the 19 measures so far, we haven't seen that, but that's something we'll definitely keep in mind.

MEMBER FURNEY: The follow-up comment, that's, I think, more transparency and certainly much more robust risk adjustment than I would have expected. So, thank you for that.

The follow-up question is regarding the tight timeline and the data. Many of the comments that were registered for these 11 measures was about the limited access to data, challenges in getting the data. Do you feel

there's adequate feedback on the data to say that the risk adjustment is not inducing disparities? I understand that the statistics look great. Do we have feedback at the level of analysis to know that the stakeholders who are seeing that data are comfortable that they are being judged equitably?

DR. NAGAVARAPU: Yes, and I think the answer to that question really goes hand-in-hand with the answer to some of the questions that people have had about timeline so far. Maybe what I can do is walk very quickly through what the processes look like, and I think it will help answer the question about risk adjustment.

Really, I think what you're asking is, you know, we've done all the statistical analysis for validity testing and risk adjustment. We've looked at predictive ratios, tried to make sure that those don't vary in unexpected ways across the deciles of risk scores and all the standard statistical analyses. I think what you're asking is, what is the extent to which clinically what

we have makes sense, and that the measures aren't going to leave unintended consequences.

I think the jumping-off point that I'd like to start with -- and I think it will address some of the public comments as well as some of the points that Bruce made -- is about the timeline and the way that the episode specifications are done. This is a process that started for this wave back in April with the Clinical Subcommittee choosing which measures to develop based on where there is alignment with quality, what kind of cost coverage you could get, what kind of beneficiary coverage, where is there opportunity for improvement.

Then, they gave us guidance on how to compose the Workgroups that actually built the measure specifications. The Workgroups were comprised of members from the clinical subcommittees as well as additional types of specialty expertise that the clinical subcommittees told us would be important to have at the table.

The Workgroups met in person in June in order to go through in detail every single aspect of how to build the measure. That includes what sorts of risk adjusters should be there, but really that meeting focused especially on how to define the patient cohort, making sure this is clinically homogeneous, making sure this has the potential for being a clinically-valid measure in terms of the types of treatment tradeoffs that are available.

But they did talk about risk adjustment, provided guidance on the service assignment for what costs should be included in the measure, as well as talked about how we should think about making sure that the patient cohort definitions are aligned with any quality measures that are up there.

And so, that was an in-person meeting. The Workgroup, then, followed up with a webinar that we did where we presented information to them, and they provided detailed additional input on what types of costs should be included, so

what types of post-acute care, for instance, are clinically-related to the treatment that's done for the initial patient cohort -- that's starts the episode -- in order to make sure that we're only holding clinicians responsible for the types of items that they have influence over.

That webinar also covered input into risk adjustment. And so, what we did is we took the standard CMS ACC model that's used in other measures as a starting point. We realized that people have felt that there's limitations of those models for the purpose of these episode-based measures. And so, starting with that webinar as well as the in-person meeting before it, we started collecting detailed input from each Workgroup on risk adjusters that are specific to a given measure.

So, particularly, there's certain types of surgery you'll see here where people felt very strongly in the Workgroup that frailty measures should be there. And so, those were included.

After that webinar, we went through the field testing that people talked about. That was a month-long field testing period. We do appreciate the comments that we've heard on problems accessing the EIDM portal in order to get those field testing reports. Luckily, there's sort of tens of thousands of reports that were downloaded. We received public comments, on the order of 70 public comments in that process from specialty societies, and so forth.

We had a chance to summarize all of those public comments after the month-long field testing, take it back to the Workgroups, and say, "This is what we've heard. These are the concerns people are bringing up."

We had a webinar with the Workgroups, walking through each of those concerns. For the ones that got through all the concerns and through their voting process -- and all the Workgroups use a voting process with a 60 percent threshold -- for the ones that got through the concerns in the first webinar, we were able to

finalize the measure at that point. Some wanted to keep going and do some additional discussions in the second webinar. So, we held a second webinar on the post-field-testing in order to go through that feedback.

And so, I do recognize the timeline is very tight. A lot of that is dictated by statute. At the same time, I've never seen a process like this in terms of amount of touchpoints that we've had with the Workgroup over that stretch.

And as Bruce mentioned, the cost measures in general are very complex. And so, from my perspective at least, the only way a cost measure like this could be built is sort of the way we did it, in the sense of having the Workgroups that were immersed in the details of the specific measures and could go through and make those sorts of fine-grain decisions that are hard for anyone to look at for an hour or two hours and make decisions on.

So, I'll stop there, and I'm happy to

address some of the other points that you made, Bruce, about small numbers and attribution down the road at some point.

CO-CHAIR BAGLEY: I'm sure we'll get to it, yes.

Patti, you've been very patient.

MEMBER WAHL: I had a comment. I represent large purchasers.

I want to compliment CMS for all your work on these cost measures. Cost measures are very important to employers who are very concerned about the rising cost of health care at such an unsustainable rate and the impact on our employees. So, we appreciate your work on not only developing both procedure-based bundles, but also condition-specific.

We're very interested, as employers, working with providers and partnering with them to continue to evolve this, and really, to continue to push forward value-based purchasing and all the different types of models along the whole APM perspective.

Thanks.

CO-CHAIR BAGLEY: Mike?

MEMBER HASSETT: Thank you.

I have two questions. The first relates to the risk adjustment, which I'm sure will be a common source of questions. I assume that your risk adjustment is looking at factors for people who are in the measure, who are in the denominator of the measure. My question is, how do you deal with the situation where, let's assume a large group of patients across all measured entities become less likely to get a specific treatment because everybody knows that they're a higher-cost risk. So, the denominator is actually changing over time as a result of the measure, but you're not actually picking it up because the risk adjustment is confined within the denominator itself. Does that make sense?

I'll hold my second question.

DR. NAGAVARAPU: So, I think this is one of the unique aspects of the episode-based cost measures. It is that I do think that the

risk adjustment models have benefitted a lot from the input that we've gotten from the Workgroups as to very specific items. And so, to the extent that the specific items that are closely clinically-related that really belong in any given measure are taken into account, we can avoid the sorts of access-to-care issues that you're talking about that would shift around what's actually counted in the denominator.

And the other point that I think is unique in the episode-based cost measures is in a lot of ways the risk adjustment has to do less than it has to do in a lot of other measures. And the reason I say that is that there may be patients who are particularly unique, for instance, because they have very high-cost needs. It could be the use of clotting factors. It be the use of the especially high chemotherapy, and so on.

And what the episode-based cost measures do is only count costs related to services that are clinically-related to the

beginning of the episode. That affects a specific patient cohort. And so, I think that helps a lot with the sorts of concerns about especially complex, high-risk patients, because the costs that are associated with those patients that are unrelated that could show up otherwise are not counted in those cost measures.

MEMBER HASSETT: I think I'm asking a different question, though, and maybe I'm not understanding your response. What I'm trying to understand is, let's just assume I'm a surgeon and I'm treating patients, and I know that higher-cost patients -- or higher comorbid patients are going to have higher costs. So, I stop offering that surgery to that patient.

If that systematically happens across the country, and patients who are at risk for higher costs aren't getting treatments, is there an unintended consequence of a cost measure when we stop providing services to patients because we know that they're higher cost in general?

DR. NAGAVARAPU: Yes, and I think to

the extent that the risk adjustment and sort of the counting of cost ensures that people aren't penalized for taking into the account those high-risk patients.

MEMBER HASSETT: But I'm not talking about penalizing the person who's being evaluated. I'm talking about the impact on the patients and the clinical care. Are we creating an incentive to undertreat people who would have otherwise benefitted from this therapy because every physician knows that we don't want to touch these patients because we know that they're going to be higher cost and they're going to affect their measures?

DR. ANDRESS: So, to Sri's point, I think the issue that Sri is getting at is that the more robust the risk adjustment, and the more effective and appropriate it is for a particular patient population, the less of a mathematical incentive there is to not provide treatment to those patients because that additional risk for cost will be adjusted for within the measure. I

think that's what Sri is trying to --

MEMBER HASSETT: But that works in a comparative way for surgeon one versus surgeon two. I'm saying, what if every surgeon in the country stops treating these high-risk patients?

DR. ANDRESS: So, the measure itself can't address that directly.

MEMBER HASSETT: Okay.

DR. ANDRESS: That has to be a programmatic thing on the part of CMS. What CMS has to do is be proactive in monitoring shifts in data trends, particularly in the kinds of patients who are receiving certain kinds of treatments, whether or not the treatments themselves are becoming more or less frequently used. And then, also, take into consideration the extent to which a particular treatment may be simply targeted toward a particular population, one that is considered low risk as opposed to patients who would be considered high risk.

I think the role that CMS plays in that is to be cognizant of what the unintended

consequences of a measure limitation may be, and then, to take appropriate steps to either remediate the measure, address the issue through additional policy, or consider withdrawing the measure if it simply can't be addressed through those other forums.

So, I think you're not going to address the question you have through the specifications of the measures, but the infrastructure you put into place to monitor its continued appropriateness in the program.

MEMBER HASSETT: And trying to figure it out, and I guess I'm trying to just kind of make that point, that with these sorts of measures, trying to be sure that there are parallel efforts to make sure that we're not creating undesirable incentives as a result of the measures I think is a critical component of the whole program in general. I'm not saying that it's going to be a problem, but I anticipate that it is a potential risk.

DR. ANDRESS: So, consider the last

two measures we're going to be talking about for cost measures, the MSPB and the TPCC. Those measures are already in existence. What we're currently undertaking is a part of our ongoing maintenance of the measures. And that's going to be true of all of the episode-based measures going forward was well.

And a big part of that is understanding the trends that we're seeing and the utility of those measures when we're undertaking maintenance, as well as taking into account the feedback we get from the clinical subcommittees, you know, physicians who tell us this is an issue, but we also would be looking at the data. And then, as we're maintaining the measures, that's the process we already have in place to, I think, do what you're talking about.

So, that system is certainly in place. It's reinforced through the endorsement process with NQF, but also the ongoing need to undertake rulemaking in a program like MIPS on an annual basis. If there's a problem, we tend to hear

about it not just once and, then, no more; we hear about it consistently until we've been able to take steps to address it.

CO-CHAIR BAGLEY: If I might just jump in with sort of an add-on question to the same topic, have you considered some kind of truncation or stop-loss calculation that comes from the aggregate data to use on individuals? So that you kind of mitigate that at least a little bit? It doesn't make it all go away in their heads, but it does mitigate that problem a little bit.

DR. NAGAVARAPU: Yes. We have an exclusion for outlier cost. So, to the extent that the risk adjustment model now is not able to predict the cost very well for certain types of especially complex patients, if you have a high unpredicted variation for those patients, those outliers are excluded from the measures, in order to sort of protect the integrity of the measure, as you're noting.

And this is something we could

definitely track over time. To the extent that there's 10, 20 of these complex patients that are in the sample, our risk adjustment model can pick that up and reflect the increased cost for those patients. But, if it is the case that the number of those type of patients goes to zero, that's something we can track over time.

CO-CHAIR BAGLEY: I have a long list of Helen, Dae, Rob, Chad, Michelle. Anybody else need to be on the list?

Helen, you're up.

MEMBER BURSTIN: Great. Thank you.

And thanks to CMS and Acumen for obviously being very inclusive, bringing the specialty societies to the table. I've heard from many that they appreciated being asked, although it was incredibly rushed. And this stuff, even for those of us who have spent a lot of time looking at it, is really complex, and I think it was very difficult to really wrap their head around it in the timeframe in which it was presented.

So, I hope it won't be a "thank you for your initial input," but I think, ideally, you would actually keep these groups going. Actually, I think the key thing here is going to be the continuous input as the measures are out in the field. Because, again, echoing a lot of the concerns that have already been raised, particularly for cost measures, particularly going back to the issue that Scott raised about social risk, we have not seen the analyses that you're pointing out are small. There may be differences at the margin for those who take care of the folks who are certainly the most at risk, where some of those differences might be apparent.

The report by ASPE on social risks, we did the work, the National Medicine did, all really pointed to the fact that, particularly for cost measures, this issue of social risk adjustment is even more important potentially than for quality measures.

And the concern, and going back to

Michael's point, is also not just that there may be high costs, but, in fact, the concern is the flip side of that. You may, in fact, see lower cost because you're stinting, because you don't want to provide care that patients really need. So, it's a double-edged sword.

I think anything that CMS can do as these measures going forward, first of all, get them into NQF. We have been waiting a while, actually now for these measures to come to this process. We talked about some of them a year ago. So, I think the more we can get these measures in, get a really detailed look at those very comfortable looking at cost measures with the time to do it, I think that's going to be key. I think really being able to look at those social risk factors you've been able to look at, potentially exploring what other risk factors could be looked at if you took a more expansive view, I think are all going to be really important.

The issue of attribution is still --

I mean, I've read these measures several times -- it's still very complex to understand how it goes across different clinicians and providers. So, I think anything you can do to really be very mindful of the potential of social risk here, which I think is real, particularly on the cost side; thinking about the unintended consequences; really looking at whether some of these are truly ready for implementation in a cost-based environment, are really ready for additional -- put it out there; get additional feedback.

And I hope CMS will also consider a set of balancing measures, I think particularly on the cost side. This is where looking at cost in isolation is terrifying because you can do some things that look really low cost and they're really low quality. I would really encourage you to think about how these come together, and think about is there a set of balancing measures, and consider the outliers, both in terms of high cost and also those for a low cost. Because I really do worry a lot about how you can look good by, in

fact, doing bad for patients.

And again, try to keep that clinician input all the way through the processes. These will allow us to begin to see what the feedback is. These are really important measures and really complicated measures. And we all know we need to get our arms around reducing cost, but we can't do it at the expense of patients.

So, thank you.

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

MEMBER CHOI: Yes. I just share the same concerns with these cost measures in general. What kind of effect do they have on quality and patient outcomes? I would just be interested to hear, during your field testing, if you had observed any decline in quality or patient outcomes with the implementation of these cost measures. But, even so, I think you referred to testing care as one month. I think that's not a sufficient period to really understand the kind of long-term impact it might have. So, again, I think just something to be

mindful of while we address these cost measures.

DR. NAGAVARAPU: And I'm happy to respond. I think one thing that, Reena and Joel, you should speak to more, if it would be helpful -- but the balancing of quality has been sort of an important aspect of the process from the beginning in terms of how the measures were selected. We're very cognizant of the fact that the cost measure category is one category in MIPS, and that there's a quality category as well that these measures will be balanced against.

Something we wanted to make sure that went into the decision process of which of these measures are built is that people consider whether there's quality measures out there that they feel good about that could be balanced with the measures. And that's something we'll definitely keep taking into account going forward.

Another aspect of this that I thought was very useful in the Workgroup process, and the sorts of decisions that the Workgroups made, is

that all of these measures include not only the cost of initial treatment, but also the cost of complications. That could be the admissions and patient readmissions, the cost of the emergency department visits, and so on.

And so, I think the costs of those sorts of complications do help pick up some aspects of quality that the Workgroups have found important to include in the measures, to try to balance that against the initial cost. So, I think both the balancing with the quality category as well as the design of the measures has helped to kind of address this, and it's something we'll certainly be keeping in mind going forward.

CO-CHAIR BAGLEY: Thanks.

Rob, you're next.

MEMBER FIELDS: Yes, I'm not sure if my comments will appear they're a comment or a question. But it seems to me like these sort of measures, I get the concern of potentially, then, cherrypicking lower-cost patients. It's a real

concern.

However, like I think on the medical side, in a world of risk, it actually changes that completely, right, because that's where your entire margin is actually in your more complex patients. So, people that know how to manage risk flow actually look, do you want to manage the more complex folks? And I am curious about, looking at these measures as a standalone, if you run into these sorts of problems. But it seems like in the context of a risk environment, then it makes a ton of -- you have to do this. Like you have to actually measure risk-adjusted total cost in order to figure out what your performance is.

And the reality is that your operating margin actually comes in your ability to manage those most complex folks, because it's normally a high-cost environment, can reduce the cost by all the different wraparound services you might provide, right? So, I don't know if we're supposed to look at them in the context of moving

towards risk. Would that be helpful or less helpful, or is that irrelevant? We should just look at the measures in and of themselves? I don't know exactly.

MEMBER DUSEJA: I think we have to think about the context of this program on the overall quality payment program. So, we're trying to get clinicians who participate within MIPS to really get comfortable with this concept of performance-based payment. And with that, it's really about value.

So, there's a lot of thought, I think, within CMS in making sure we align, for example, to Helen's point, in making sure quality and cost are aligned with what measures we are going to continue with in the program, to try to make sure that we are moving toward not having unintended consequences.

But the other part of this in terms of the policy perspective is to try to get clinicians to take on more risk and go through that glide path, getting into more APMs. So,

that would be the goal. It is a glide path. And I think what we're trying to do in terms of internal work is trying to make sure we also try to align our measures across that continuum, if that helps.

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

MEMBER TEETERS: I've got several points. And I apologize, some of this is going to get into the weeds of the individual measures, but I think it will good for illustrative purposes.

So, getting back to Michael's point, aside from risk, one of the other concerns I have, especially around the procedural measures, is the potential to actually stifle technological development in advance. So, CABG is a perfect example. As we move into robotic or thoracoscopic procedures, which are inherently more costly but have less morbidity and mortality to the patient, there's the potential that you will stifle the development of those service lines within institutions, which may actually

have a longer-term decrease in value to the patient that would be unintended.

No. 2 -- and again, I'll use CABG as an example -- the concern, and this is going to cross since we get into total cost-of-care measures, but the double jeopardy alignment. So, you could be in a CABG bundle, but also be adherent to the CABG MIPS metric. And that would be potentially crossing over into two separate spheres where you could either lose big or win big potentially.

The final piece -- and I think this is probably a little bit less of a concern in the Medicare space because I think this is probably more of a factor in commercial -- but we're seeing more and more, especially with these larger conglomerate ACOs that were developing Centers of Excellence, patients are being referred sometimes hundreds of miles from home to get specialty surgeries, procedures, joint replacement being a perfect example. And those patients, you know, if we have an elderly patient

who goes 300 miles from home to get a joint replacement, it's much more difficult to send that patient home the day after surgery. So, they may inherently need a couple of days' rehab before they're suitable for discharge home, but that encompasses a higher cost for that travel from afar, so that patient can get higher-quality surgical intervention.

So, again, these are kind of minor points, but they do have factors when we talk about quality and access for patients.

CO-CHAIR BAGLEY: Michelle, I have you next on my list. I wasn't sure whether you were going to comment on something that was said. You guys have a special place at the table. So if you need to jump in somewhere and give a CMS perspective, it's okay to jump the queue. Just flag me down, you know.

DR. SCHREIBER: I was really just going to say thank you to Michael for bringing this up.

I've been sitting here thinking

through all of these issues. I'm particularly sensitive to them. As a general internist, I was actually an HIV provider. So, you can imagine, when you looked at me as a general internist, I looked terrible as a provider. And so, what would be the answer for me? Well, just don't take care of those patients. That wasn't the right answer for the patients.

The other thing that has happened -- and Helen knows this because I've share my story -- is, when I wanted to look like a good provider, all I did was move to the rich suburbs, quite honestly, and I looked like a better provider.

And so, I think what we put in for balancing is really important, and I thank you for bringing that up. Because if we start seeing trends that nobody is taking care of some of these patients, I think that's probably the biggest disservice we can do.

So, thank you.

CO-CHAIR BAGLEY: Amy?

MEMBER NGUYEN HOWELL: Thank you, Bruce.

I had a question and also a comment. So, along the lines of what is an episode, and how is that defined. I appreciate all of the specialty comments, and I concur. As a family physician, primary care, and from a risk-bearing organization, I concur with Rob's statement. We love all of this.

And so, what is an episode? Are we going to be included in this, in MIPS? Because, for us, when you look at an episode for, let's just say, any of that, COPD, are you going to evaluate and assess the quality in the delivery of care of the provider as they have the conversations on palliative care, as they have the advanced illness management conversations, as they have the obesity prevention conversations? Because that is what needs to be a part of this episode, looking at total cost of care, really for all providers, specialty and primary care.

So, I didn't know, because in the

exclusion criteria it says that if it's not in an outpatient -- or if it's in outpatient or ASC, then it's excluded from the denominator, from that episode.

DR. NAGAVARAPU: Yes, I could answer a couple of the recent questions.

So, on that more recent question, actually, on Friday we're meeting with our TEP to discuss the development of chronic condition episode-based measures. There are unique challenges and opportunities for chronic conditions, exactly what you're getting at. And we have thoughts based on what we've heard from the clinical subcommittees and Workgroups about the acute and procedural measures that apply to some extent to the chronic episode-based measures. And so, we'll be talking with the Technical Expert Panel about that on Friday, and are hoping to move into the development of these sorts of measures in Wave 3 coming up in the new year. And so, that's an area we're really excited about.

The point about technological development, this is a point that we've been very sensitive to during the measure development process. In fact, some of our clinicians work with CMS on thinking through those sorts of issues.

Specifically, what we tried to do is, if there are cases where there's new technology that's developed, we try and talk to the Workgroups about it and potentially deal with that in two ways. One way is, if the new technology is itself part of the procedure that starts off the episode. And the Workgroup felt that that new technology or the use of that technology is not something within their influence or should not be something within their influence if it's best for patients.

Then, we have the option of subgrouping the episodes in order to make sure that only like episodes are compared to like episodes. So, only episodes using new technology compared with others using a new technology.

The other approach in cases where the worry is about new technology that may count as a cost in the episode, but not necessarily as part of the initial procedure, is something, if this ever came up, we talked with the clinical subcommittees and Workgroups over the past couple of years about, then, having the option to not count it as a cost in the measure. And I think there are tradeoffs to doing that. A lot depends on exactly how you feel about how much discretion there is to use this new technology and what are the challenges with unintended consequences. But they had the opportunity to kind of make that decision.

And then, the last thing I was going to note about especially complex patients, and it's related to this point, is that, in the case of the Workgroups, another point, another dimension of trying to address this sort of concern is we talked in detail with the Workgroups about doing measure-specific exclusions. So, if there were particular patient

populations that just seemed extremely complex, they're extremely worried about the notion that, if they were included in the measure, that there would be access-to-care issues, the Workgroups had an option to exclude those populations from the measure.

And down the road, that's something that Workgroups could revisit, but a conscious decision was made by the Workgroups where, if they're very concerned about access to care, delineate those subpopulations very clearly in the data and not include them in the measures at this time.

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

MEMBER WHITCARE: I just had a question about how to analyze reports with limited data, specifically two to three patients.

CO-CHAIR BAGLEY: So, it's a low-numbers question. Help us here.

MEMBER DUSEJA: Yes. For each of these measures that we're bringing forth to the Workgroup today, they do have case minimums in

order the meet the reliability and validity. And so, if you want -- do you have a particular one that you are concerned about? Was it included in the materials to the Workgroup? Was it an attachment?

MEMBER WHITCARE: Yes.

MEMBER DUSEJA: You should have it in your attachments. While I speak, can we send it to the Workgroup now? That would be great.

MEMBER WHITCARE: Yes, to me, that would be great. Thank you.

MEMBER DUSEJA: Yes. But they have to meet a threshold in order for us to feel confident to be able to report on the measure, at the TIN level or at the TIN/NPI level.

CO-CHAIR BAGLEY: Do you have a sense what is the magnitude of that number? I mean, is it 2, is it 10, is it 30?

MEMBER DUSEJA: Sri, keep me honest, but I think it's NF 20, correct, for at the TIN/NPI, and then, depending on the acute versus the procedural, right?

DR. NAGAVARAPU: That's exactly right, yes. No, that's exactly right. For the acutes in the previous, in the Wave 1 measures, the case bin was typically 20, and then, for procedurals, it was 10. And that decision was made based on reliability numbers, because the reliability numbers of procedural episodes were particularly high even at 10.

CO-CHAIR BAGLEY: Trudy, on the phone, you're next.

MEMBER MALLINSON: Great. Thank you.

And I'm new to this Workgroup. So, you may have discussed a lot of these things before.

One of the risk adjustment, and I know other people have expressed concerns about or additional things that might need to be considered in the risk adjustment. And I would just sort of echo that in terms of thinking about social demographics and social determinants of health.

I had a question at least what I could

find online about the amount of variance and cost that was explained by the current model, which I think is about 13 percent. That, to me, seems low. At least it seems that there's a lot else going on in producing variance of cost that's not explained by the model.

And I wasn't clear how much of that additional variance does clinician behavior actually explain. So, we've got these models. Great. But how much does physician behavior or clinician behavior actually change or explain, you know, affect. So, we can implement these, but, in fact, there's a lot of other things going on that are influencing cost, and we're not going to make a lot of dent in that. And yet, there are these potential risks in terms of particularly thinking on access to care that could affect people. So, I'm just wondering if someone could sort of talk about what impact we think provider behavior really has and what other things could be explaining sort of the -- what? -- 87 percent variance that we haven't explained.

And the other question was about, if these were implemented, the idea is they would drive down costs, right? But they're not associated with outcomes right now. And so, what's the break on decreasing cost and, therefore, potentially decreasing access to care, and how do we stop that in a very timely fashion if we think it's resulting in bad outcomes?

I heard someone say, well, we hear about these on sort of a yearly ongoing basis. But there could be potentially hundreds or thousands of people who don't have access to care before we get a break in place. So, I'm just wondering if people have thought about sort of the long -- like two or three years down the line, how you would look at this reduction in cost is actually affecting patient access to care or outcomes.

CO-CHAIR BAGLEY: Do you want to take that?

Thank you, Trudy.

DR. ANDRESS: Yes, I think this is a

really important point, because there's no inherent link because these measures and quality. It's all in how you combine them with quality measures within the context of the program itself and with other quality improvement efforts, I think.

As Sri indicated earlier, one of the criteria we use to choose the episodes that we develop measures for includes consideration of where we thought we had relatively solid quality measures available for use in the program along with them. And that continues to be a major consideration.

In fact, CMS has been working internally to think about how we can continue to strengthen the alignment between quality measures and cost measures, because they really do have to function in tandem in order to, one, drive for better value, but, also, to ensure that we're not simply reducing costs by providing less care, which flatly is one avenue that can be taken if these measures are addressed in a vacuum, I

think.

That's one of the reasons that the cost component within the MIPS program, even when fully ramped-up, are a smaller consideration than the quality components and the quality improvement efforts incorporated with it. And I think that's been built into the design of the program as a whole.

I think we're certainly cognizant of the risk, and that kind of helps us make decisions about where we're going to target our development of future episode-based cost measures; and, also, to get a finer understanding of what exactly it means to be aligned with quality measures. Does that mean you just have measures in the same specialty? Do you have measures with the same denominator? Do you have measures addressing the exact same episodes or procedures? And then, think about how we can move toward development of measures, both on the quality and cost side, that meet those kinds of alignment parameters. Because you're right, if

we don't, then that's a very serious risk that we'll be facing as a healthcare system and as a whole.

DR. NAGAVARAPU: And just to get at the first question about risk adjustment, I think this is a very important aspect of the measures actually. Because the costs included in the measures are costs that the Workgroups have specifically said are clinically-related to the procedure that's being done or the condition that's being managed. And it could be clinically-related as part of treatment costs, but it also could be clinically-related as downstream outcomes, so in patient readmissions, in terms of department visits, and so on. And so, a lot of the variation that is not explained by the risk adjustment models is variation that's really driven by costs that the Workgroups have said are clinically-related to the procedure that's being done or the condition that's being done.

And so, to get specifically at the

question, because the Workgroup had this opportunity to not include any costs that were unrelated to the treatment, and include only costs that were related to the treatment in the measure calculations, a lot of the variation that's not explained by the risk adjustment models are picking up real differences in provider behavior for services and costs that happen to patients that the Workgroup itself has said are related to that.

MEMBER MALLINSON: Right, but you haven't modeled that, right? I mean, that's an important question that's still hanging out there?

DR. NAGAVARAPU: So, that's a question that is -- empirically, I would say that that question is more difficult to get at, to distinguish what goes to a provider versus not. And so, because of that, we really relied on the clinical validity aspect of the measures and trying to make sure that the Workgroups are comfortable with the costs that are being

calculated, so that they know the costs that are actually entering the measure. And if there's costs that are outside of providers' influence, that they can remove those costs from the measure, and so, they won't show up in these sorts of risk adjustment specifications.

DR. ANDRESS: I would also point out that, in my experience in developing quality measures in other settings, frequently when a new quality measure gets into a payment program, it tends to cause something of a flurry of research into interventions and analyzing what potential there is for different kinds of interventions to affect the quality outcome. I think anticipating that kind of information is also going to be flying around with the new episode-based measures, if and when they go into effect, will also give us more information to link specific activities by clinicians and what their impact on the cost is.

I mean, admittedly, when you're looking at claims, there are certain things that

you can look at fairly easily, but there are other activities by clinicians that you can't measure as readily. And so, I think one of the things that we'll be looking for as we're doing the measure maintenance and watching the measure's performance is considering the literature that is generated by the community around the measures and clinicians' experience in trying to respond to the measure-driven mandates in the MIPS program.

CO-CHAIR BAGLEY: David, you've been patient. Do you remember what your question was?

(Laughter.)

MEMBER SEIDENWURM: So, it had to do with the other side of the risk adjustment coin. Having participated in the spine surgery episode development cost measure, we adjusted away the patient selection part of the equation. And so, I think that something that we risk, if we go too far in risk adjustment, is that we allow people a free pass at selecting patients who are unlikely to benefit from the service or more likely to

have complications, and, therefore, are less likely to behave like the patients in the studies that justify those procedures themselves.

So, I think that we have to strike a balance that, on the one hand, you know, we want to be fair to people who have difficult populations to care for; yet, at the other side of the coin, we don't want everyone within the ejection fraction of 10 to get cardiac surgery or something -- that's hypothetical, of course -- if we risk adjust for that.

So, I think that it's very important that we not just look at the one side of the risk adjustment coin. We absolutely have to look at both sides.

DR. ANDRESS: I think you're driving at a fundamental tension in the concept of measure development, quality measure and cost measure. You're never going to get an exact assessment of attribution. What you're going to get is either an overestimation or an underestimation, and you can pick either one.

There are going to be consequences either way you go.

I think one of the things that sort of hasn't been done, as a broader measure development and quality community, is the decision about which one is preferable, if it's always the same answer in the same context. But I think you're hitting on the exact point. It's like going all in one direction is not inherently better, either for the clinicians or for the patients in terms of the measure. It's frequently something that has to be determined within the context of the measure itself, and with an understanding that there are potential unintended consequences either way.

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

MEMBER SEIDENWURM: Yes, and I would just like to follow up just to say that I think that we've gone far enough in the direction of protecting against avoiding risk, and we need to maybe start being a little more cognizant in the other direction.

MEMBER BURSTIN: I just want to go back to Eric's other point about volume and reliability and the small numbers issue, and Reena's comment about procedural-based ones. So, I actually went back through and looked through it.

So, the differences in reliability are dramatically different for the same end. For the TIN/NPIs at 20, you can go from .8 for a spine to .5 for COPD and GI bleed. So, I hope that CMS will also consider the fact that these sample sizes are going to need to be logically tied to the underlying condition. I mean, I assume -- we talked a lot about social risk -- there's also a lot of unmeasured clinical complexity, particularly probably for some of those patients coming in with kidneys, COPD, GI bleed, that are probably not accounted for. There's no way to get at frailty, for example. That might be driving a lot of costs, a lot of post-acute care admissions as well.

So, I just hope it won't be a one-

size-fits-all and you'll consider both social risk, but also unmeasured clinical complexity, and then, adjust your thinking around the reliability based on the given episode. Because, I mean, clinically, as another fellow general internists, I could easily see a totally different trajectory for some patients coming in for a more chronic-level issue, rather than somebody healthy enough to come in for spine fusion.

So, I think really being able to balance that, and, also, understanding what's going into those lower reliability estimates. What other costs are going into those factors? Why are we not able to get reliable estimates? I think just a deeper dive into understanding those differences between the procedural-based reliability versus the non-procedural-based, I think it will be an important learning that might help us going forward.

CO-CHAIR BAGLEY: Amy?

CO-CHAIR MOYER: I had wanted to echo

a little bit what David had said. In the absence of a good understanding of the appropriateness or usefulness of the procedure, cost is one thing, but there's no value if it wasn't needed in the first place. So, it's really only the downside of risk from the patient's perspective.

And the other thing I wanted to throw out there, because I get concerned sometimes that we who sit here in this room don't have front of mind -- I don't know if you saw the Board of Governors of the Federal Reserve Report of Economic Well-Being that came out this year, but, 4 in 10 adults, if they're faced with an unexpected expense of $400, they literally have no idea how they would pay for that.

We're not even talking high deductible there. There's no limit on out-of-pocket on Medicare for inpatient, and one-fourth of adults are skipping necessary medical care in 2017. We're already there with the access problem due to cost.

Let's not just say people should have

access to technology; they should have access to this, but, I mean, I want to make sure that we remember why this important and what the impact is to the average person who I am not always sure is sitting here in this room.

CO-CHAIR BAGLEY: Okay. I'd like to make a couple of observations, having looked at episode-based care and reimbursement over a long period of time, and especially with your meeting coming up on Friday about chronic illness.

Episodes in the past have been most useful, most effective, and have the highest utility when there is a high cost-episode trigger that's usually a hospital procedure, so some kind of big deal in a hospital. It's got a pretty defined beginning and a fairly defined end, and you know what's associated with it and what's not. That's way up there in terms of its usefulness and utility and what you're trying to accomplish.

Way down at the other end, the marginal utility of using the episode technique

for chronic illness, when Mable has six different things going on, becomes so complex that what you're going to get back from it is not worth it. That's my observation.

And I, as a family physician, would rather be measured on the total cost of care than I would on some kind of hocus-pocus thing about a very complex set of things that go on in old folks who have three or four things. So, just for that.

The other thing, there was a high expectation early on in the episode-of-care movement that, just by having episode payment, that would cause clinicians to talk to each other, and they might actually do some clinical integration. Well, that hasn't really panned out.

If you have people that are already talking to each other, okay, so they're in some kind of a clinically-integrated system or a highly-developed ACO, plugging them in there makes a lot of sense. But to think that it's

going to make the people in the general kind of population out there all of a sudden start talking to the other people that would be involved in the episode has just not panned out.

So, two observations as you're going to move forward with this from somebody who has been trying to see how it works for a long time.

I think that we've reached a point that we're kind of finished talking about the generalities. I guess at this point the next thing I would like to do -- I don't think we're ready to vote because I want to give you the opportunity. Are there any of these measures that have some specific commentary that you have a commentary on because of its specific disease or procedural content? So that, if you want to kind of pull it off the list for at least some casual discussion here, that would be helpful.

Eric?

MEMBER WHITCARE: Sure. First, a disclosure. I'm sorry I didn't mention it earlier. I'm a full-time breast surgeon. So,

the breast measure is interesting to me. For that reason, obviously. I will abstain from voting. But there are some things I would like to say.

I hinted at the beginning in the initial disclosures that I had some email exchanges with some members of the different Workgroups. This is not a criticism on reporting information that's not available in the materials, but it didn't go well. The breast surgeons felt they were disenfranchised. They felt this cookie-cutter-fits-all-type approach that might work for hernia was not appropriate for a disease such as breast cancer. Granted, both surgeries, but very, very different in the treatment path.

They weren't able to make many of the meetings. They didn't feel the testing was adequate. They didn't feel they had adequate input. You have access to their comments, which are really a very limited version of a 70-page letter that was sent to CMS in late October.

So, the process -- I'm sure it worked very well many times -- did not work well in breast surgery. To me, one reflection of that is the title of the measure. Can I ask about the title for three operations?

Well, lumpectomy and partial mastectomy are the same operation. They're the same CPT code. Clinicians who do breast surgery don't talk that way. And anyone participating in a functioning committee -- Bruce, if that were to happen here, I would raise my card. You'd say fix it. If I felt it was more difficult, I would come around with my computer and say, look, here's a copy of the 2019 CPT Manual; they're the same operation. And you would to turn to staff and they would fix it.

So, that speaks to a level of dysfunction that makes me worry of the measure. Now could have found this under a rock. It may have fell like manna from heaven. Maybe it's still a good measure. Just because people had trouble in the development process doesn't make

it bad.

The testing, although brief, may be accurate and may be reinforced and validated in subsequent testing. But I still have two very, very critical issues.

One actually involves my own understanding of the measure. I couldn't tell on reading the measure -- and I think we have a pretty well-defined group, right, or episode? Thirty days before. You have specific breast surgical CPT codes. Ninety days after. Is that correct?

I couldn't discern from the measure whether or not reconstruction or radiation therapy was included. When I emailed the Chair of the Committee, the Clinical Chair, he said he didn't know.

Now, in terms of cost, that's huge. Here's where I'm going to share some of the cost information I have. In the picture of treating breast cancer -- and if you look at the supplementary materials, they talk about the cost

of treatment breast cancer in this country -- 30 percent of all new cancers in women are breast cancer, but surgery is a small part of that. In terms of cost, especially in the non-Medicare population, it's chemotherapy. Then, it's radiation. Then, it's surgery.

To put the numbers in perspective, Medicare allowable for a mastectomy in Arizona, which is where I practice, is about $1100, a little less. A lumpectomy, called in the Coding Manuals "a partial lumpectomy," is about $680.

The most important feature in the surgery in the cost of the care is site of service. Did you do it in a hospital or did you do it in an outpatient center? The most important component in the totality of care is chemotherapy, but in deciding surgery, it's about radiation. The cost of a course of radiation therapy is about $8,000.

The last thing I would want to happen is to have clinicians not understand the measure well. They need to know if these other measures

are included, radiation and chemotherapy. They need to understand the site of service. None of that is clear from the measure, as I read it.

But the last thing I want is to have those cost differences impact the shared decisionmaking process. Because I'm sitting there -- you can fix my hernia with a scope or you can do it through traditional mesh, and maybe you can fix my hip with this or that prosthesis. But most people care a lot about how we address their breast cancer in terms of surgical management of the breast.

So, if radiation therapy is included, slam dunk, everybody gets a total mastectomy with no reconstruction. Perfectly valid cost-efficient care. Would I do that? I hope not. But with people who misunderstand the measure, or perhaps have less good understanding of the situation, that could happen, and that will influence the discussion.

Alternatively, if reconstruction is included, it's delayed. I can get that off

because the plastic surgeons and I can make a perfectly valid medical argument in terms of reducing complications by delaying the reconstruction. So, this is all good medicine where I have equivalent outcomes, but huge differences in costs and bigger differences in individual patient care.

This is metric-specific. I won't be voting on it. But I think it's important you know the background of the breast surgeons' participation and how it would impact someone who sees this measure, and even reviewing it, can't fully understand it, and could then make poor decisions based on what I see.

DR. NAGAVARAPU: I could respond to that. Fortunately, the Workgroup has discussed the issues that you've brought up, actually. So, in discussing the measures over the course of the webinars, including the post-field-testing webinars, the Workgroup decided not to include reconstruction or chemotherapy or radiation as costs due to concerns about being able to

influence those costs.

The Workgroup also was concerned about site of service, what this might do to access to care if it was the case that certain patients particularly needed to be treated in an inpatient setting. And so, the Workgroup decided to eliminate the inpatient cases from the measure, according to a vote.

And the discussion of sort of the trigger codes, as well as the title of the measure, is something that originally came from the Clinical Subcommittee, but was discussed during the Workgroup process to make sure that the trigger codes were appropriate.

I definitely understand the time pressure involved in the measure development process. It was a rapid process in order to meet the sorts of statutory timelines that CMS is working under. And so, I definitely have appreciation for the time that people put in, as well as the challenges that are involved with the speed of that process.

At the same time, we had a long sequence of meetings with the particular Workgroup. There is a Clinical Subcommittee in-person meeting. There is a Workgroup in-person meeting to start off. There is a Workgroup webinar focused on service assignment of costs and risk adjustment.

After the field-testing period, in which the full measure specifications were laid out for public comment, there were post-field-testing webinars, two of those. We've also offered the opportunity to talk with any of the societies that had additional questions about the measure, either the field-testing reports that they received or not.

And so, I think in terms of the opportunity to contribute to the process, the Workgroup has had input at each step of the process. And the Workgroup, in terms of composition, had a full range of specialty societies that were related to the episode of care under consideration. So, beyond the

American Society of Breast Surgeons, it also includes the Society of Surgical Oncology, the American Society of Clinical Oncology, the National Association of Clinical Nurse Specialists, Anesthesiologists, the American College of Surgeons, and so on.

So, I do appreciate that the process is a challenging one, but I think that the results of the measure have been very good. The public comments that we received from the society that you've mentioned didn't express concerns about the process, but, notably, didn't express specific concerns about aspects of the measures, that they didn't have a chance to talk about and change after field testing. And I think that, as well as the fact of the reliability of the measures, is high, anywhere ranging from .69 to .75 for TINs at 20 or 30 episodes and .65 to .71 for TIN/NPIs at 20 and 30 episodes, really speaks to the fact that, despite all the challenges that I think are inherent to the speed of the process, that we did end up in a good place with the

measure.

And I'll just end on a comment that was submitted late on the measures by the American Society of Clinical Oncology, where it was a general comment in support of the EBCM development process, sort of talking about the usefulness of the EBCMs and appreciating the opportunity to be involved in measure development and looking forward to additional oncological surgical measures.

And I think that the fact that we've had a lot of re-engagement from specialty societies that engaged in the first wave of the process in the second wave, as well as re-engagement from specific people, speaks to how people felt about the process overall.

I think for any process like this, there are definitely going to be challenges, especially with timelines. And what we've tried to do is, at the end of each wave, try to talk with the societies, the participants as much as possible and incorporate their input into the

next wave, and we'll continue to do that going forward.

CO-CHAIR BAGLEY: Dave, is your card up from your last comment or do you have a new comment?

MEMBER SEIDENWURM: I would just like to comment a little bit about the process as I experienced it. And the first thing I want to say is I've been in measure development circumstances with various organizations and specialty societies, and I thought that the degree of both intellectual rigor and engagement by the consultant was superior to that that I've seen elsewhere or at least as good as the best.

I also think that the concerns of the clinicians were answered in each case using the most conservative decisionmaking process. In other word, the process erred on the side of allaying the concerns, even though in many cases there were very strong arguments to be made against adjusting away those risks or against excluding certain categories of patients.

I also think that, despite this, I think that a lot of the concerns seemed to come from an overall skepticism with the whole concept of cost measurement rather than from the specific sort of technical aspects of the measure development process that we're kind of discussing now.

So, I think that the challenge going forward is not so much in terms of the technical specifications and the analytical rigor that was brought to the problem. I think that we really have to either explain to people that the law says what the law says, and if they have a problem, they should talk to their Congressman, or we need to do a better job of educating the clinical community now about the value and the goals of cost measurement in the system.

So, I don't think that the difficulties that we're experiencing in understanding these measures have to do with the process through which they were developed or through any lack of intellectual rigor. I really

do think it's somewhere else.

CO-CHAIR BAGLEY: Robert and Chad, I didn't see who put up first.

MEMBER FIELDS: Mine's just a quick procedural question. It seems to me that you shouldn't recuse yourself just because -- but we all have conflicts on a lot of the different measures by virtue of what we do. I think your opinion is actually exceedingly valuable. So, just a procedural question that probably the Chairs need to comment on, but I would imagine that you would not need to recuse yourself from the vote.

CO-CHAIR BAGLEY: We've already discussed that. We told him he didn't need to recuse himself, but that's his decision. I mean, he's a content expert, and that's his role on this Committee, and he wasn't directly involved in developing the measure. So, we know he's opinionated.

(Laughter.)

CO-CHAIR BAGLEY: You know, he's

bringing his biases like I am, you know, but, hey.

Chad?

MEMBER TEETERS: I have two separate points. The first one is going to lump three measures together. I guess this is really going to be a question of -- and either I missed it or I didn't see it in the measures -- what defines the duration of the episode? So, I'm going to lump COPD, lumbar spine fusion, and CABG for the moment.

So, one of the biggest things that determines outcome/readmission rates is access to rehab. Right now, across the country only about 20 percent of CABG patients have access to cardiac rehab. Only about 2 percent of patients have access to pulmonary rehab, and only about 30 to 40 percent of patients complete PT rehab after spine fusion.

So, those that do will have an increased cost of care in the short term. If it's 30 days post-procedure or post-inpatient

admission, there will actually be a higher cost. And cardiac rehab is an example. It's about $3,000 a month. However, if looked at for a six-month term, that group may have a lower cost of care because they'll be less apt to be readmitted after their procedure or incipient hospitalization.

So, that's one and that's one of those unintended consequences of the scope of the procedure and, you know, kind of what Bruce alluded to before. Looking at these things as too finite of an iterative entity rather than a duration of care of an individual makes it difficult, and perhaps total cost of care is more apt when what we're talking about, especially complex care of elderly patients.

The next thing -- and I don't know if this gets factored in, and again, I'm going to use CABG as an example. I'm a cardiologist, so I have a built-in bias to this. I'll admit that. So, I can take two patients. They may be on paper the same risk, but the difference in

whether I do two bypass grafts or one, whether they have sufficient mammary artery to do the bypass or I'm using GORE-TEX graft, that will affect the cost. That will affect the type of surgery that is done. And I don't know that that would actually be factored into the risk of the patient per se. That's almost a separate risk calculation that I don't know if it will get reflected.

And I could say the same thing about hemodialysis access creation. It's a difference between a branchial fistula versus a fistula anywhere else in the body, for that matter. So, those kind of nuances of the procedure or the complexity of the patient may not get reflected in their actual medical risk, but more so just the technical difficulty of that particular procedure.

CO-CHAIR BAGLEY: Okay. Yes, do you have a comment on that?

DR. NAGAVARAPU: Sure. Yes, I can make a quick comment just on the episode window

question you had. That's something that varies by episode group just because, clinically, because of the sort of tradeoffs that you're talking about, that's going to be different for each episode group. For COPD, the episode starts at admission and continues for 60 days. For spine fusion, there's a 30-day pre-trigger period to help account for a small number of pre-op services that happen, and then, 90 days post. And then, for CABG, it's 30 days pre and 90 days post.

The types of tradeoffs you're talking about are the types that the Workgroup discussions kind of went through, and there were cases where, after the field testing, the Workgroup looked at what they saw in field testing and made a change based on that. So, I think the psychoses measure, for instance, went down from a post period of 120 days to 90 days after what they saw in the field-testing results.

MEMBER TEETERS: I understand there has to be a decision made. For each one of

those, I would almost say, for those patients who get access to the superior quality with the rehab service, they will be a higher cost of care in that window, but actually will be a better longer-term outcome for what CMS wants to achieve. And that, unfortunately, won't get reflected in those measures.

CO-CHAIR BAGLEY: Okay. I would like to try to move to a vote on these measures. I am going to propose that we vote on all 11 together. Any member can ask for a division of the question. So, if anyone wants to pull any measure off of that list, now is the time to speak up.

Okay. So, we will be voting on the first 11 measures, and we'll be detailing the numbers, and all that stuff, along with the recommendations of the preliminary review and a preliminary assessment. And then, we'll vote on them en masse. All right.

DR. BERNOT: Sounds good. I will be as brief as possible, but I do want to get it on

the record. We will do those 11. I will not read the names, just the numbers.

So, MUC2018-115, 116, 117, 119, 120, 121, 122, 123, 126, 137, and 140.

So, to remind you, this was a conditional support with a condition of NQF endorsement. We have over 90 minutes of recording and transcripts that we will be pooling through looking for themes, dissenting opinions, other relevant information. I will highlight a couple right now, just to make sure there's nothing I'm missing.

On the really, really high level, we have risk adjustment, so social risk adjustment, a lot about balancing measures. That's quality, efficiency, access, appropriate use measures that could balance the cost measures. Unintended consequence, we have another theme of that. Attribution, we've heard much about attribution. Feedback and continued testing, this is an iterative process. This is not a one-and-done process.

The understanding and the transparency of the measure for the clinician to know what are the components. We've heard different parts about the components. And then, making sure we are always cognizant of that linking of the clinician behavior to that cost, that it is something that they can change. Again, I know that's somewhat within the range of the attribution. Again, much, much more, but I wanted to at least highlight those are the types of things that we would be passing along for endorsement, that we expect these things would be analyzed during an endorsement process.

Any questions or other points?

CO-CHAIR BAGLEY: Yes, and as part of that special seat that you have here, do you have any comments you wanted to make before we go ahead and vote, Michelle? Did John cover most of them? Okay, good.

All right. Without objection, we'll proceed to a vote, and it should be on your voting machine, if you still have that available.

They're called Group 4. They're on the screen, if you need to see the numbers.

And by the way, on the screen, the last two are not included in this, right? Okay. Just to be clear about what we're voting on. Okay.

MS. KOSURI: So, voting is now open for the episode-based cost measures of Measure Group 4. As we said, it's the first 11.

Do you vote to support the preliminary analysis as the Workgroup recommendation, as John stated earlier?

(Voting.)

MS. KOSURI: Okay. I think we have our total 19. So, the voting has now closed.

The Committee's recommendation, based on 79 percent of the vote, is yes, to support the preliminary analyses as the Workgroup recommendation.

Fourteen members have voted yes and four have voted no.

CO-CHAIR BAGLEY: Okay. Thank you for

your patience with that. That was a good discussion. Hopefully, that's helpful to all of you going forward. You know, this is not simple stuff, and to a great degree we're going to have to see how it works.

We are going to talk about the last two individually, if that's okay. First, we'll talk about 18-148.

John, do you have some comments?

DR. BERNOT: Sure. Just to put on the record, this is MUC2018-148, Medicare Spending Per Beneficiary, a clinician measure.

The preliminary analysis from staff was a conditional support for rulemaking with a condition of NQF endorsement.

CO-CHAIR BAGLEY: Is there any discussion from our lead reviewers? I'll have to look up and see who that is. See who finds it first. Oh, Amy and Diane. Okay.

Any comments from either of you?

MEMBER NGUYEN HOWELL: I'll be brief because I think you alluded to my comment

earlier.

When we talk about the risk-adjusted cost across all episodes, my comment relates to the social determinants of health. So, how are we accounting for these determinants in all episodes as we look at these cost measures, the MSPB and the Total Per Capita, TPCC?

Because I think if we're not evaluating it, if we're not measuring this, then how are we truly moving the dial on total cost of care as it pertains and it is relevant to a patient's outcome, total health outcome, as we know it; and also, as it aligns to CMS's Meaningful Measures Initiative with population-based payment, with APMs, with patient-centered care, outcome-based care, and high-impact conditions?

CO-CHAIR BAGLEY: Diane?

MEMBER PADDEN: Nothing to add. I also made note of the same thing. Thank you.

CO-CHAIR BAGLEY: Okay. Any comment from CMS about this and about its current use?

Is it in use anywhere?

DR. ANDRESS: Sure. Thank you.

So, this measure is currently -- well, I should say, the original form of this measure is currently in use in the MIPS program as one of the two cost measures, the other being the TPCC. The version that we've brought to you today is a modified form of this. It's undergone the maintenance process, as we mentioned earlier.

The purpose of the maintenance process was to take into account a lot of the feedback we had gotten, particularly after we had taken these measures into the arena for MIPS. They had previously been used elsewhere, and we received feedback there as well. We thought it was important to think about how we could modify the measures in a way to address some of the concerns that were raised.

I think kind of the biggest overall critique that we've seen of them is the fact that they are not as specific as episode-based measures. I think there are arguments to be made

for using generalized measures. Part of the problem with episodes is that some of the cost is not going to be directly attributable to an episode, no matter how you define the episodes. And so, of course, that's a potential opportunity lost for controlling cost of care.

I think that in a program environment where we have a relatively small percentage of coverage, both in terms of total cost and in terms of clinical episodes with our current measure set, these kinds of measures play an important role in helping us get started in paying attention to the cost of care. We're obviously going to be working on developing the cost measures, but if you look at the coverage numbers that we quoted earlier, I mean, you're potentially looking at we've developed something on the order of 100 measures in order to cover the 50 percent mandated by statute. Not only will that take time, but resources as well.

And even after we've completed that, there will still be costs that are not covered

under those. There will be clinicians will not be contained within the denominators for any of those measures. And so, these are the kinds of measures that I think play a role in potentially filling that gap.

And so, that's one of the reasons that we felt it was (a) important to bring them into the program in the first place and (b) to expend the resources to address some of the methodological concerns that have been raised with regard to the measures to ensure that, while they're playing their role within the program now and into the future, they are also as methodologically robust as we can possibly make them.

And so, I think that's what we've had in mind with presenting these modified measures for your consideration. I'd certainly suggest that, as you're talking about them, you want to take that into account, the fact that we have already have these forms of measures in the program. So, a big part of the question I think

should be, is the improvement to the measures worth considering taking them forward into the program or are we happy with the measures as they currently are within MIPS?

CO-CHAIR BAGLEY: This may be my problem, but what was changed and why?

DR. NAGAVARAPU: Sure. I could give you a quick summary for each measure.

Starting with MSPB, the current version of MSPB in MIPS is an all-cost measure that's surrounded around inpatient episodes. The measure currently counts all costs from three days prior to an admission to 30 days after the discharge, and then, risk adjusts those costs using an adaptation of the CMS HCC model.

The measure is attributed to the clinician or clinician groups that bill for the plurality of Part B physician supplier costs during the inpatient hospitalization. So, that's the current version of the measure.

In terms of stakeholder comments that we've heard over time, that CMS has wanted to try

and address with the reevaluated measure, the comments centered around two things. One was the inclusion of all costs in these measures. And two was the method of attribution, because of a concern that the plurality of Part B physicians' supplier costs, like who's billing the most cost in the inpatient hospitalization, may not pinpoint the clinician or clinician groups responsible for the costs that follow the hospitalization.

And so, we went through the reevaluation process. We discussed the attribution methodology in detail with the TEP. The TEP also suggested that we convene an expert Workgroup in order to figure out what costs should be excluded from being counted in the measure. And so, we convened an expert Workgroup with representatives from over 20 specialty societies with focus on specialty societies likely to have clinicians that would be attributed in an MSPB measure. So, we met with that Workgroup multiple times over webinars in

order to think about which specific costs should be excluded.

The reevaluated MSPB measure on those two dimensions has the following basic changes: the first is in terms of including all costs. Certain costs that the expert Workgroup determined were unlikely to be clinically-related to the care provided in the hospital have been removed. Some of those costs are common across all the different types of hospitalizations you can get. For instance, most of the costs that happen three days prior to the hospitalization have now been removed because of a concern that, regardless of inpatient hospitalization, many of those costs are not in the control or under the influence of the clinicians who are performing the management during the hospitalization.

It's also the case that certain clinical distinctions have been made. So, the inpatient stays, after discussion with the Workgroup, were divided up into different types of categories, based on major diagnostic

categories, and some major diagnostic category-specific exclusions were provided. We can go into more detail on that, if people are interested.

So, those were the costs that were removed. The hope is to ensure that costs that are very directly outside the influence of those in the hospital would not be included in the measure.

The attribution changes that we discussed with the TEP and, then, looked through public comments, and discussed with CMS, is the program priorities. What we have in the reevaluated measure is a distinction in attribution depending on whether we're talking about surgical hospitalizations, so surgical DRGs, or medical DRGs in terms of medical management of cases.

In surgical DRGs, the TEP felt strongly that surgical DRGs, those episodes should be attributed to those performing the core surgical procedure in that hospitalization. And

so, what we did was go through/identify the core surgical procedure that is billed in Part B physician supplier claims that is tied to each DRG for a Part A hospital stay, and attribute based on who's doing those actual surgical procedures. So, that's for surgical DRGs.

That's both for TIN reporting and TIN/NPI reporting. And so, in MIPS there's a distinction in that clinician groups can choose to report as TINs, in which case they would get a TIN-level cost measure, or they can choose to report as individual TIN/NPIs, in which case they would get individual TIN/NPI cost measures.

For surgical DRGs, whoever is performing the surgery would be attributed the episode. For TINs, that would be anyone in the TIN performing the procedure. Each episode is only counted once for each TIN. For TIN/NPIs, that would be whichever TIN/NPI is performing the procedure, and that's what would go into the measure. So, that's for surgical DRGs.

For medical DRGs, the discussion that

we've had over the past year in terms of attribution has to do with how to move away from just the plurality of Part B physician supplier claims. People have felt on the TEP, and other sources, that using evaluation and management claims is a potential solution, pending the wider introduction of patient relationship codes.

And so, for the TIN-level reporting, an episode for a medical DRG is attributed to the TIN that bills at least 30 percent of those evaluation/management claim lines during the hospital stay. That's for TIN-level reporting.

For TIN/NPI-level reporting, the episode is attributed to the TIN/NPI who is part of the TIN that bills at least 30 percent of the evaluation and management claim. So, that's important. They're part of the TIN that's helping to manage the case, and they bill at least one evaluation/management claim in that specific hospital stay, to indicate that they are part of the episode.

This is something that over time we've

had a chance to look at in order to see how this attribution rules compares to other possibilities. And recently, we've been able to do some comparisons of reliability and other metrics between those using that rule for TIN/NPIs versus using a narrower rule, such as using the plurality of E&M claims for a TIN/NPI during a hospital stay or just identifying one TIN/NPI for every TIN during the hospital stay.

Both of those, conceptually, have problems in the sense that they may not incentive care coordination between the various TIN/NPIs in a given TIN. But we did want to take seriously that these are alternative possibilities that people have brought up. And when looking at reliability, the distinctions in the reliability metrics are extremely small, less than .01 on average.

So, given the conceptual advantage in terms of identifying clinicians that are part of a TIN managing the case and ensuring that there's care coordination between all of them, we've

moved in the direction of the TIN/NPI attribution rule that I just walked through. So, that's the way that attribution works.

So, really, the reevaluation is focused on those two items: removing certain costs that are outside the influence of the attributed clinician and reconfiguring the attribution to be more in line with what clinicians may expect for surgical DRGs and medical DRGs.

CO-CHAIR BAGLEY: A long answer, but good.

Kevin, you're next. Oh, I thought you were trying to get my -- okay.

Any other comments before we vote? Yes, go ahead, Dale.

MEMBER SHALLER: And we're going to just vote on the MSPB measure first?

CO-CHAIR BAGLEY: Yes, we are, one at a time, yes.

MEMBER SHALLER: But my question is, we've talked a lot about the duplication or

potential duplication between the global measures and the individual episodes. What I don't quite understand is the overlap or tension between the TPCC and the MSPB. Who gets counted? If you're a clinician, do you get kind of once for one? Or, potentially, twice for being in the MIPS program? I don't understand how that works. It's like an implementation question really. It's not a measurement question.

DR. ANDRESS: Thank you. So we've been talking a little bit about this. There is potentially a policy decision to be made where you attribute both to a clinician and the idea that it's especially important. I don't think that's how we approach development of the episode-based measures with the idea that they're just taking out the most important episodes on top of the MSPB or the TPCC.

I think from a policy perspective we've talked about a number of options for how you can do this. You can potentially, for instance, you know, only use the population-based

measures for people who don't have episode-based measure attributed to them or you can set a minimum threshold for the cost that's covered for the denominator under the episode-based measure for those clinicians. There are a number of different ways you could do that.

(Off-microphone comment.)

DR. ANDRESS: The TPCC versus the MSPB, okay, right. I'm sorry, I must have misheard the question.

So I think in terms of having two measures, they really focus on two different areas as Sri has pointed out.

The MSPB deals with costs associated with acute hospitalization, whereas the TPCC is dealing primarily with primary physician care. And so the expectation is that the individual measures, while there is some overlap, they're really focusing on different considerations.

Different aspects of the care, there is some overlap, but not -- but it's not a focus of the measures. And we haven't taken steps

within the measures themselves to separate them out from one another, so there is the potential, for instance, that a particular set of billing could be captured in both measures at the current time.

I think is your question is how are we planning on implementing the measures?

MEMBER SHALLER: If you're following both, do you -- how do you reconcile them in a kind of a payment-based program setting?

MEMBER DUSEJA: Well, as of now, if you're counted in terms of attribution, then you will be measured on both as it stands for the cost category.

Now moving forward, as these measures go in and we do more analysis based on this reevaluation period, I think we need to consider like the overlap. I don't think we have the data at this point to be able to determine that because we're still trying to get the input from yourselves, as well through public comment, on these measures, as well as going the NQF

endorsement process.

But there will be some overlap. I think you're right to point out that there could be some clinicians that will be measured on TPCC over that one year length time frame, versus those that are practicing in the in-patient setting and might be attributed to the MSPB depending on the episode.

DR. NAGAVARAPU: And then just speaking to the details of the measure specification and to the extent that they feed into that implementation issue, there is an effort as Joe and Reena are saying to ensure that the measures are trying to measure different things. And so, for instance, one very clear way in which this is operationalized is that evaluation and management claims that are billed in the in-patient setting do not count for the attribution of a TPCC. The TPCC is really focused on management in an office setting and so on.

And so the notion is to try and create

the TPCC measure as something that's focused on care outside of the in-patient setting and focus on MSPB as care that's triggered by the treatment episode and to the extent that there's overlap, there's significant benefits to that in the sense that a measure that looks at management in the out-patient setting can speak to whether or not someone is doing things that can keep a patient out of the hospital, but once a patient is in the hospital, then the MSPB measure is able to speak to whether that care that's happening in the hospital is happening in an appropriate way.

CO-CHAIR BAGLEY: Okay, let's have a few more comments. I have Helen, Eric, Ira, and Peter.

MEMBER BURSTIN: Just a brief question. It was helpful to hear the changes that were in the attribution model. I have to say it's really hard to just hear them. This is something, it's really complex. I can't fully wrap my head around whether the changes had a positive impact or not. We haven't seen the

changes in reliability. So again, to me this just screams for why this measure needs to come for NQF endorsement.

And unlike what you said earlier about the episode-based measures, you haven't stated that's the case, but I certainly hope this measure will come forward as it did from the hospital level because again, I think the attribution methodology is really critical here and even if you look at the reliability and the supplemental materials you put forward, I don't know how often clinicians get to 20 episodes as a minimum, but even that is only a reliability of .6.

So again, there's a lot of opportunity here that needs a much deeper dive with a lot of folks around the table who feel very comfortable looking at what this all means and whether the changes have, in fact, improved the attribution approach, but again, hearing this verbally without a lot of this, you know, to really review and see the differences and a table that explains

what's in, what's out, compared to the prior measure is really difficult to process. I just have to be honest. So for me, it just would really need to come forward for a full review again.

DR. ANDRESS: And to clarify on the point about NQF, our intention is certainly to bring these measures to NQF for endorsement. Unfortunately, we took away one measure. We actually had to bump one of our sister programs back to the second set of submissions in the year, so we're going to need to talk about things with NQF staff about capacity for taking measures and when the timing will be appropriate for that. But we're planning on having those conversations.

MEMBER BURSTIN: Just one more comment on that. These measures are already out there. So again, anything you can do to look at unintended consequences, feedback from the community, even if it gets in in the spring, it's still awhile until you actually get a decision or at least deliberations out of NQF. As fast as

they have become, it's still not an easy process, especially for these kind of measures.

CO-CHAIR BAGLEY: Eric.

MEMBER WHITACRE: I, too, was getting lost a little bit in the verbal discussion and I had a question again about risk adjustment. Is it still independent of socio-economic status?

DR. NAGAVARAPU: So for MSPB, there is no socio-economic status that's included in the risk-adjustment model right now. We did perform the same testing that we did for EBCMs using the American Community Survey as well as enrollment information on dual status. And also see similar conclusions that there is very little impact on that. It's just negligible. So that's helpful, but it's something that we'll continue tracking for MSPB.

For Total Per Capita Cost, what we wanted to do, and I can walk through if there's time in a moment, I can walk through the improvements for TPCC relative to the current measure, but what we wanted to do was really

focus on the items that stakeholders brought up as detailed concerns and keep other aspects of the measure as similar as possible.

And so the risk-adjustment model we're using is the same approach for risk adjustment that's used in the current TPCC measure which uses the Medicare Advantage risk-adjustment model and coefficients and dual status is included in that in the Medicare Advantage model.

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

MEMBER MOSCOVICE: First, I do want to commend CMS in terms of trying to do sensitivity analyses in these kinds of issues. They're really important.

The only thing I would -- just two things. First, if the people around this table are having a hard time understanding what's going on, you can imagine what primary care providers who are out there who think they're totally being taken advantage of in any attribution method. So I think when we do get to a final state on all of this, it really lends itself to -- it's going to

be very important to have a dissemination process that really embraces primary care providers and gets them to at least try to hopefully understand what's going on. Depending what you're doing, your work is really important.

The second part is it's hard for me to believe that risk adjustment for socio-economic, socio-demographic variables doesn't have any impact. It's hard to believe.

DR. ANDRESS: So I think one of the things to keep in mind with this, I have had this come up with, for instance, readmission measures in the post-acute and ESRD settings a lot which is that frequently you'll find the factors will be predictive at the end of the dual patient level. A lot of that variation tends to be explained away, something like a third to half when you take into account the comorbidities and other conditions of the patient's age, and so forth.

And then it becomes a question for the measure, what is the impact for the setting or

clinician when you wrap it into the model and that's where the impact tends to dissipate in most of the measures where I've done those kinds of analyses.

I think it's important to keep in mind it's not that those -- the analyses don't demonstrate that those factors aren't relevant. I think that would be incorrect to say and it's certainly counter-intuitive. I think it's more to say that once you have taken into account the other factors of the models and you've aggregated the assessment to the provider level, the impact of these factors is negligible in terms of how they affect the assessment and then the payment determinations associated with it. And that's been our experience in looking up these measures.

So it's not a statement that social-risk factors don't matter. We would absolutely disagree with that statement. It's just that a lot of the stuff is baked into what we think of as patient risk, patient condition when we're risk -- and the more robust the risk adjustment,

the more that you're going to be accounting for in the model.

MEMBER NGUYEN HOWELL: So is that data -- does that change at the organizational level? Have you looked at that, versus the provider level?

DR. NAGAVARAPU: Could you clarify, actually, what you mean by organizational level?

MEMBER NGUYEN HOWELL: So let's just take the TIN. You know, you were talking specifically provider level, so the actual NPI level, so at an organization at an ACO, at a medical group level, at an IPA level.

DR. NAGAVARAPU: So the data that we've looked at in estimating these risk-adjustment models using the base model for their re-evaluated measure, as well as alternately adding dual status and other socio-economics status variables, those are all risk-adjustment models at the episode level and so it doesn't distinguish between sort of levels of characteristics that let's say a TIN model versus

an NCI. I think that's an area we have experienced with in thinking about an MSPB measure in a hospital context.

Here, we really wanted to focus on the question that Joel was getting at which is that we know that these factors can be significant predictors of spending, but how much do they add in our ability to capture expected cost above and beyond what we're already including. And so absolutely, as Joel mentioned, these factors are important to track over time, as well as to analyze in this way. And what we're seeing is that while they may individually explain episode costs, later we're talking about TIN or TIN/NPI that the predictive power models in terms of the standard measure people use like R-squareds and just R-squareds are not changing very much like on the order of less than .001.

CO-CHAIR BAGLEY: Okay. I think we need to wind this conversation down so we can have a vote.

Peter and Raj, any new material you

want to bring? I'm going to stop looking for cards here pretty soon.

MEMBER BRISS: I can be quick.

CO-CHAIR BAGLEY: I hope so.

MEMBER BRISS: All right, I had three reactions to the conversation. One of them is I think I heard you say that you're thinking about for these measures that have been in play for a while whether you use the improvements and so my gut reaction is you those don't need to go back to NQF, but you've done a lot of work to do to do stakeholder process and technical process. And if you've tried to make improvements, you should use them as point one.

Point two is it strikes me that both these more global measures and the more specific episode measure, both have strengths and weaknesses. And if I were CMS, I might try to pair them up to take advantage of both. So the episode things are more specific, but more reliable for gaming, for example. The more global measures might include a lot of costs, and

a lot of providers that aren't otherwise included in it. And including both might not make any one measure a little bit lower stakes. And so if I were CMS, I would be trying to pair them up.

And then on this last point about risk adjustment, even if it doesn't matter as a technical matter, in epidemiology we used to talk about political confounders. Sometimes you've got to -- sometimes you've got to include a confounder in your model to help people believe the results you're getting. And you guys might have political confounders here. I might try to risk adjust even if it doesn't matter, so you can tell people you did.

CO-CHAIR BAGLEY: Rob.

MEMBER FIELDS: Two super quick comments. One is on the -- I noticed on 13, it's measure 149 on the Part B costs, traditionally you try to risk adjust by chronic condition management, right, and get your RAF score up. But increasing what we're seeing is Part B drug spend doesn't carry as significant ACC weight.

So things like macular degeneration, for instance, don't carry a kind of weight you can't risk adjust away its pretty intense cost. We're seeing macular degeneration treatment beyond par with SNF costs in many cases in parts of our network. So it's no joke, and it's getting worse. So just be cautious that it's going to screw up the Part B cost methodology and benchmarking because you can't risk adjust away some of that Part B cost.

The second piece just supportive on the statistics, we're doing some work with artificial intelligence and social determinants using purchase data like credit agency and consumer data to predict the risk of a new admission in the next 30 days. It's kind of fun to be able to predict it, but it turns that we can do using AI just as well as just claims and social determinants just to support what you're saying, didn't add a ton of predictive value on top of that. It was a helpful operation, but didn't add a ton of predictive value to your

claims.

CO-CHAIR BAGLEY: Okay. John pointed out to me that when we ask for public comment initially, there may have been some confusion about whether we were asking for public comment on the entire list or just the 11. So I guess I would invite at this time any public comment on the last two in case you thought we were going to let you do that later.

Okay. I guess we guessed right. Good job, John.

MS. McLAUGHLIN: Hi. Is this on? Jennifer McLaughlin with AMA again. And thank you for offering us a second opportunity to make public comments. I appreciate it. And again, I want to say that we appreciate the efforts of CMS and Acumen to bring forward these measures that were originally used in the value modifier and revised them according to a number of concerns that have been heard. It varies in the modifier and often now under MIPS.

And in particular, I want to spend

some time talking about the total per capita cost measure which I know you have it in speaking about a lot yet, but I'm sure you.

So we have a number of concerns with the revisions and first, I want to say we do have a concern that the proposed revision is extremely complex in tracking patients. Under the new attribution methodology, in particular, we think it's going to be nearly impossible because the new attribution is based on a combination of specialty and also a series of services or costs. And the new episodes are based on month-long periods. My understanding is that those month-long periods can extend through a full year, but there may be TPCC episodes that run concurrently during the next performance year and also TPCC measures that leak over from one MIPS performance year into another MIPS performance year and so those costs will be prorated, I believe. That's my understanding for different MIPS scoring systems.

We also have concerns about the equity

of the revised measures. We question the elimination of the specialty adjustment and also question the exclusion based on specialty or service threshold. And it's not entirely clear because we have received some information since the field testing, solicitation of comment and through this meeting today it seems to indicate that some of the attribution discussion is in flux, but what seems to potentially raise an equity issue for your consideration is that eliminating the specialties, that may be the ones who are routinely performing services such as chemotherapy or radiation therapy and not excluding those costs or those services from the measure means that a primary care physician, as opposed to the physician who is routinely performing those services, will be held accountable for those costs.

Another issue that we do want to raise is our understanding is that the attribution change from the original TPCC measure to the revised measure would increase the number of

physicians who are attributed the measure and based on information provided throughout this process, it appears that the number of physicians who would be attributed TPCC would be more than double and so this gets to a point raised by this workgroup earlier today about the "double jeopardy" or "double counting" issue. We think not only does it raise that issue again here when talking about the TPCC measure, but also again gets to this issue of complexity and tracking patients because you are attributing the same patient, the same episode to multiple physicians in the same TIN, but also in different TINs and then it just becomes more challenging to sort out who is responsible for the costs and the measure.

For these reasons, we do recommend that the MAP, the highest level of endorsement for the Total Per Capital Cost we do not support, but it's essential for mitigation. And then again due to concerns about the double counting of the MSPB and the Total Per Capital Cost along with the more precise Episode-Based Cost

Measures, we would recommend that the MAP also consider urging CMS to evaluate whether there would be a possibility to use the more precise Episode-Based Cost Measure when two points raised today, when that Episode-Based Cost Measure is reliable, is valid, it is understandable and actionable, when that measure does exist and can be applied, whether it does make sense to continue using the MSPB and TPCC measures. Thank you.

CO-CHAIR BAGLEY: Thank you, Jennifer. Heidi.

MS. BOSSLEY: I have comments on behalf of two groups and I'm going to kind of do it together for sake of time.

So for the American College of Gastroenterology and then also the American Society of Clinical Oncology, just want to confirm our support for the AMA comment. We think it's very important for you all to weigh in and provide this information to CMS on the concern of double counting.

I do think it could really send mixed messages, both to providers, as well as to ultimately those who may see this information, if you're double counting and applying different cost methodologies to the same item that triggers an episode.

Also, agree that the recommendation for the TPCC measure should be the do not support with potential for mitigation. We are having a hard time explaining this measure to our members. We cannot actually tell them what triggers an episode, how all the costs get attributed. So we think this needs more work and a lot of more education. So thank you.

CO-CHAIR BAGLEY: Okay. We'd like to go to a vote on 18-148. That's the Medicare Spending Per Beneficiary.

DR. NAGAVARAPU: Bruce and John, I'm happy to walk through the TPCC improvements and answer some of the comments that have been made after that as well.

CO-CHAIR BAGLEY: Thank you.

DR. BERNOT: Okay, so this is for just the one measure. This MUC 2018-148. Remember, this is the vote to accept the staff preliminary analysis which was conditional support with the condition of NQF endorsement. The highlights, just for summary, were really to evaluate this change in these costs that are unlikely related to the clinician and the attribution. So with that, we can move to the vote.

MS. KOSURI: Voting is now open for MUC 18-148. Do you vote to support the preliminary analysis as the workgroup recommendation?

(Pause.)

MS. KOSURI: Okay, I think we have our total. Okay. Voting is now closed. The Committee's recommendation, based on 79 percent of the vote, is yes to support the preliminary analysis of the workgroup recommendation for MUC 18-148. We had 15 who voted yes and 3 who voted no. Oh, four, sorry.

CO-CHAIR BAGLEY: Okay. Let's move on

to the last one 18-149, Total Per Capital Cost. And you guys are all out of ideas here, right?

(Laughter.)

CO-CHAIR BAGLEY: Are there comments about the total cost of care measure that might be specific to that as opposed to very similar kind of comments that we had for the last measure? I'm not trying to stifle debate. I'm just trying -- if you've got something new, bring it on, you know?

I don't see anybody jumping up. I guess you guys needs a break.

(Laughter.)

CO-CHAIR BAGLEY: In order to get a break, you're going to have to vote.

(Laughter.)

CO-CHAIR BAGLEY: Did you have something? It's okay. No punishment.

CO-CHAIR MOYER: The only thing that I was going through on here because we're doing work in this area for self-insured commercial groups is we feel like if there's an expectation

of holding that primary care clinician accountable for that cost, then it's on us to give them some information about the cost implications of choices they make, whether that's facility A, facility B.

In our case, that's a little complicated because it varies a lot more, I suspect, Medicare's costs. But you and Pat are going back to that feedback, I feel like if there is this expectation of information in that area could be helpful.

CO-CHAIR BAGLEY: I certainly would concur with that. Whenever we in the past have been able to give primary care physicians the information about both cost and quality to the extent we could do that, they would respond to that very nicely.

Okay, any other comments on this? Helen.

MEMBER BURSTIN: Again, I think because this measure previously failed NQF endorsement as opposed to not been submitted, I

think it very important we need a closer look, particularly since again it's very difficult to track the changes that have been made.

Many of the same issues that have already been raised, but I think certainly the issues you've heard about risk adjustment, social risk, double counting are probably even more so with this measure. So again, I don't think it's a simple "just submit it" issue.

DR. NAGAVARAPU: If it would be helpful, I could walk through the changes, kind of analogously to MSPB.

Sure, yes. Or people can just use this as a break.

(Laughter.)

CO-CHAIR BAGLEY: So there are basically four dimensions of TPCC that we have improvements on. The current TPCC measure, the way it works is that there's a list of E&M codes that are often associated with primary care, but aren't billed only by primary care practitioners. What they do is the current measure looks for the

clinician that bills the maximum number or value of those E&M codes over the course of a calendar year and then attributes the entire year of a patient's Part A and B costs to that clinician, that billed the plurality.

The stakeholder concern that we've heard about in this regard is that if a clinician sees a patient, for instance, for the first time, later in the year such as in October or November, they would still get all of the costs for the ten months before they saw the patient attributed to them. So that's one core problem that the reevaluating measure fixes. The way it fixes it is by looking for the evaluation management claims that a TIN is billing or appearing in evaluation management equipment with a primary care service, like a diagnostic test. And then initiating the one-year period from that point forward, rather than looking backward before a clinician may have ever seen the patient.

But the second dimension is on risk adjustment. The current measure looks at risk

adjustment based on comorbidities that are found in Medicare claims data in the previous year. This measure looks on a month-by-month basis and looks at the comorbidities that are found in the year prior to each month under consideration. What this allows for is the evolution of comorbidities over the course of time so that a general practitioner, for instance, isn't penalized for items that may have been outside of the general practitioner's control that changed over the course of the year.

The third point is about the specialty list. The way the current measure works is that there's a two-step process. They first look for a primary care practitioner that satisfies one of those criteria about the E&M claims I mentioned. If they can't find one, they move to specialists. So it's possible for specialists to get attributed the measure, even if the specialist is unrelated to primary care management.

The way that we've -- originally, we in the field testing excluded specialties based

on the performance of global surgery claims, anesthesia, therapeutic radiation, and chemotherapy. We had a post-field testing webinar with a test. We got comments from the AMA and others that emphasize that the specialty coverage was still too broad in the measure and so since then we've worked with CMS to pare back the specialty list dramatically and that was the change that was being referred to in the public comments because we took seriously that too many -- a broader set of specialties were getting attributed than preferred, and so the updated empirical analyses that went to the MAP on December 1st incorporated those changes.

And finally, for care coordination, and multiple attribution, a concern with the current measure is that by identifying only one person over the whole course of the year, it doesn't recognize the fact that there may be handoffs of care between primary care practitioners over the course of the year or that there may be multiple physicians that are

managing a patient in different aspects of comorbidities in coordinating with each other and this measure is an effort to take that into account and attribute months of care to both types of people.

And the last thing I'll say is for the risk windows, the way this works in terms of which months are counted for the measure --

CO-CHAIR BAGLEY: You're running out of time.

DR. NAGAVARAPU: Okay, well, you take one year from the point at which the initial attribution happens and then you look only at those months that are in the performance period and we're counting average monthly costs risk adjusted just for those months that are in the performance period.

CO-CHAIR BAGLEY: Thank you. Okay, additional comments before we vote?

All right, let's go to the vote.

DR. BERNOT: So I can summarize for this, this is for MUC 2018-149, the Total Per

Capital Cost. Again, the preliminary analysis was conditional support with the condition of NQF endorsement and we would be voting for the workgroup to accept that recommendation as the workgroup's recommendation.

MEMBER GREINER: Can I speak. I just want to clarify. So basically, we have an existing measure in the program which has a lot of the flaws that we just described, so this would be voting for an updated measure that has these improvements. But the measure that's existing in the program is not NQF endorsed.

CO-CHAIR BAGLEY: All right.

MS. KOSURI: Okay. Voting is now open for MUC 2018-149. Do you vote to support the preliminary analysis for the workgroup's recommendation? And I think we had a member step out, so.

(Pause.)

MS. KOSURI: So I think I'll close the voting. So based on the results of the Committee's recommendation, based on 67 percent

of the vote is yes to support the preliminary analysis as the workgroup recommendation. We had 12 votes for yes and 6 votes for no.

CO-CHAIR BAGLEY: So let's try a ten-minute break, if that could ever happen. And then we'll head for the final, the home stretch, if you will. So let's have you back at 20 after. How about that?

(Whereupon, the above-entitled matter went off the record at 3:09 p.m. and resumed at 3:21 p.m.)

CO-CHAIR MOYER: All right. We're in the home stretch and I know we all want to get through this before people have to leave and we lose the quorum. So we're going to get started. So last set of measures we have are quality measures under consideration for MIPS.

And I'm going to turn it over to John to quickly introduce these. We are going to go through these measures individually because they really lump together in any easy sort of way. But we'll be efficient.

DR. BERNOT: I apologize for the delay. So for the first measure here again, we're going to do these one by one for the sake of the discussion is MUC 2018-063. That's Functional Status Change for Patients with Neck Impairments.

So this is -- the preliminary analysis for this was a conditional support for rulemaking with a condition of NQF endorsement. So I'll turn it back to you, Amy.

CO-CHAIR MOYER: All right. Lead discussants on this were Rob and Diane. Any additional thoughts on this that you want to add?

MEMBER FIELDS: I don't have a lot to add. I plead ignorance on this one other than the specs have no contest. It seemed reasonable.

(Laughter.)

CO-CHAIR MOYER: Diane, anything.

MEMBER PADDEN: No. I didn't have anything on that one.

CO-CHAIR MOYER: No. Okay. Dare we just go to a vote?

MEMBER BURSTIN: Again, this is a FOTO measure. I know the FOTO measures haven't been in NQF. This is a proprietary functional status measure. It's an incorporated instrument that I don't believe is open and available. It's just a question if somebody chooses to use this, what are the arrangements with FOTO?

MS. HAYES: Hi. This is Deanna Hayes from FOTO. I'd be happy to answer that.

CO-CHAIR MOYER: Go ahead.

MS. HAYES: There is a free public access version. It's posted on our website and the link to that site is in the measure specifications.

MEMBER BURSTIN: Is that a pen and paper survey or has that been updated?

MS. HAYES: I beg your pardon?

MEMBER BURSTIN: Is the free version literally pen and paper?

MS. HAYES: Yes. There is a pen and paper. It can be used as pen and paper. Is that what you're asking?

CO-CHAIR MOYER: Can it be used through other methods than pen and paper, for instance, is there an electronic version or are there any limitations on how it's given to patients?

MS. HAYES: There is a Computer-Adaptive Testing version on the website, so that's -- not only electronic, but that's the CAT item response series version.

I'd like to define the word proprietary. You know, it just means the measure is owned and stewarded. It doesn't necessarily mean inaccessible. And it's important in today's healthcare environment that high-quality measures have an owner and a steward or they cease to be high-quality measures. This is the same for the FOTO system. The PROMIS measure is out of Northwestern University, the AM-PAC out of Boston. Every measure that's going to be high quality and good for healthcare today needs to be taken care of and I think that's an important point to keep in mind.

MEMBER BURSTIN: I stand corrected. Proprietary is fine. I guess the question is is there an associated cost for using the CAT version of the survey. Sorry for my imprecision.

MS. HAYES: Not at all. Thanks for the chance to address it. There is not a cost for using the CAT version on the website.

CO-CHAIR MOYER: Robert.

MEMBER KRUGHOFF: Who in the government is using this now? Is the government getting any data out of this system now? I mean out of this measurement type now? I asked that question too late, didn't I?

DR. GREEN: So we are not using this particular -- we are not using this particular measure. I don't recall off hand if it's a QCDR measure. It is not. So we have not -- we have some testing data that was supplied to us by the measures steward, but we don't have any official use data that was submitted to us.

MS. HAYES: This is Deanna from FOTO again. This will be the first time that it would

be directly entered into CMS' handpicking data. We offered data to CMS and we're told that they preferred to gather their own. It was just endorsed as the 2019 QCDR measure and additionally we are working in the NQF endorsement pathway at the same time.

CO-CHAIR MOYER: Any additional comments or questions or discussions on the measure?

DR. BERNOT: Okay, it sounds like we can move to a vote then. I'll just do the summary again so we know what we're voting on. This is MUC 2018-063. That's the Functional Status Change for Patients with Neck Impairments. Again, the staff recommendation through the preliminary analysis was a conditional support with the condition of -- in this case the completion of NQF endorsement.

CO-CHAIR MOYER: My apologies. Just to make it be a little more efficient, do we have anyone in the room who'd like to make public comment on these measures before we vote? I

don't see anyone in the room.

Operator, can you check if there's anyone on the phone who would like to make public comments on this measure?

OPERATOR: Yes. Ladies and gentlemen, if you would like to make a public comment, please press star-1 on your telephone keypad. Again, that's star-1 to make a public comment.

(Pause.)

CO-CHAIR MOYER: So I don't think you have any?

OPERATOR: And at this time we have no public comments.

MS. KOSURI: Perfect. I will be opening the vote for MUC 18-063. Do you vote to support the preliminary analysis that is the workgroup recommendation?

So we're waiting on one more vote. I think we have 17. We lost two. So we should get 17. So anyone else? Perfect. Okay. We have our total of 17.

So voting is now closed. The

Committee's recommendation based on all of the votes, so 100 percent of the votes is to support the preliminary analysis of the workgroup recommendation for MUC 2018-063 with 17 members voting yes, and zero voting no. Thank you.

MS. HAYES: This is Deanna. Could I ask for some clarification?

CO-CHAIR MOYER: Sure, go ahead.

MS. HAYES: First, I'd like to thank you for your review of the measure and for this opportunity to share it with you and for the support. We appreciate that very much. I wanted to ask about the conditional support, pending NQF's endorsement.

Is that a standard that other measures, similar measures, are being held to? I'd also like to mention that the science of this measure follows the exact sophisticated, high rigor science that the other seven NQF-endorsed FOTO MIPS become followed. Does it need to wait for NQF endorsement and experience that delay in light of that?

MS. O'ROURKE: Sure. This is Erin from the -- one of the staff supports for the Coordinating Committee. And I can try to clarify this.

To your second point, it's really CMS' decision on whether the measure would need to wait to be proposed for rulemaking or not. As far as if this is a standard that other measures are held to, yes, it's been MAP's precedence that conditional support is often the highest category that the workgroup feels comfortable giving a measure that hasn't had NQF endorsement. It's almost always one of the most common conditions for the conditional support category and it's been exceptionally rare that a measure has gotten a full support without NQF endorsement. That's felt pretty strongly about the need for multi-stakeholder review of the evidence and the scientific accessibility behind the measure that this process doesn't allow adequate time to fully address.

MS. HAYES: Oh, very good. Well, thank

you for that clarification then and telling me that it's being held to the same standard. We are very supportive of NQF endorsement being the gold standard for all measures. We think it's the highest level of scientific rigor and it's best for everyone. That's why we continue to support it. Thanks for the clarification and your time today.

CO-CHAIR MOYER: All right. Thank you. We will move on to the next measure on the list, the Time to Surgery for Elderly Hip Fracture Patients.

DR. BERNOT: All right. So this is MUC 2018-031 which is the Time to Surgery for Elderly Hip Fracture Patients. The preliminary analysis done by staff gave this a rating of a conditional support for rulemaking, again, with the condition of NQF endorsement.

I'll turn it back to you, Amy, for public comment.

CO-CHAIR MOYER: All right, lead discussants on this measure are Trudy and Chad.

Chad, do you have anything?

MEMBER TEETERS: Yes, I'll jump in, why not? So first clarification, I don't think this really is a conflict, but I was on the Pre-Surgical Evaluation Committee, pre-approval, whatever they called it, for the American Academy of Orthopaedic Surgery which was referenced in the guideline, but I don't think that would impair.

Overall, I think it's perfectly -- it's strong, scientific evidence. I think it's a great measure. Two minor details that I wanted to point out. Number one, we're talking about taking elderly hip fracture patients to surgery within 48 hours. We do have to be mindful in our rural community hospitals if someone comes in on a Friday night, what's the availability of an orthopedic surgeon within 48 hours to do the case? So that's one consideration.

Two, I didn't see any stipulation. A lot of these patients are frail and elderly and sometimes there's a decision to move toward

palliative care or hospice with the fracture being the incipient issue. And that patient would not go to surgery because they would transition to that palliative care realm, but that would be a failure of the metric that would not be excluded. So those were two concerns that I had.

CO-CHAIR MOYER: All right. Trudy, anything to add to that?

MEMBER MALLINSON: No, actually, that last comment about frail, elder adult to potentially might make the decision to move them to palliative was also my question for should that be included in the exclusion criteria.

CO-CHAIR MOYER: All right. Do we have a measure developer available to speak to that?

MR. PEZOLD: Hi. This is Ryan Pezold with the American Academy of Orthopaedic Surgeons. I'm not sure. I may have one or two of the surgeons who was included on this as chairs on the line. Are either of you guys here,

Dr. Olson or Dr. Brox? That's fine if they're not.

I think as far as this measure goes, it's a reasonable concern and it's something that I think that we would be interested and willing to address in future updates and iterations in making sure that we're not counting that against patient providers who would report on this measure for those frail patients.

CO-CHAIR MOYER: All right. I would expect that as well and see if there a recommendation of condition as NQF endorsement for this and I would expect that would be something the CDP process would bring up.

Any other discussion in the room from the Committee on this?

Any public comments in the room? I'm sorry, Ira.

MEMBER MOSCOVICE: Just following up on Chad's comment. The Rural Network Group really wanted to know more about are transfers included in this measure or not? For instance,

if you had an emergency department clinician who saw a patient who needed this and had to transfer a patient out, when would the time actually start?

CO-CHAIR MOYER: That's an excellent question. Go ahead.

MR. PEZOLD: Sorry, again, I think this is something that will probably be addressed when we're going through the NQF endorsement process, but I'm happy to touch on it now. I don't believe transfers are covered in this explicitly and I believe the time starts, if I'm not incorrect, at the time of admission.

CO-CHAIR MOYER: Okay. Robert, I see you have your card up. Do you have a comment on this? No? Okay.

Any public comments on the phone on this one?

OPERATOR: Ladies and gentlemen, if you would like to make a public comment, please press star-1 on your telephone keypad. Again, *1 to make a public comment.

And no public comments at this time.

CO-CHAIR MOYER: All right. Putting on my committee member hat, not speaking as a chair at the moment, I could see making the case further being substantial changes needed on this. I know we usually say hey, it needs to be NQF endorsed and I trust that consensus development process, but I'm wondering about dealing with the transfers and dealing with some of the potential valid exclusions that aren't currently in place in this.

You all, of course, will vote however you feel, but I wanted to make that comment as a committee member, not as a chair instructing you. I think we can move forward with the vote now.

DR. BERNOT: Okay, just to introduce this, so this is MUC 2018-031, the Time to Surgery for Elderly Hip Fracture Patients. Just to remind the preliminary analysis recommendation was a conditional support and that condition being NQF endorsement and did flag here the exclusion concerns, as well as the definition of

that to the start time in the episode as concerns here.

MS. KOSURI: Voting is now open for MUC 2018-031. Do you vote to support the preliminary analysis as a workgroup recommendation?

(Pause.)

MS. KOSURI: We're waiting for one more. If there is anyone who hasn't voted yet -- oh, perfect.

Okay, voting is now closed. The Committee's recommendation based on 94 percent of the vote is yes for MUC 2018-031. Do you vote to support the preliminary analysis of the workgroup recommendation? And that is with 16 voting yes, and 1 voting no.

DR. BERNOT: Okay, the next measure is MUC 2018-032. This is Discouraging the routine Use of Occupational and/or Physical Therapy after Carpal Tunnel Release.

This particular measure has a preliminary analysis result of do not support for

rulemaking with the potential for mitigation. And that mitigation would include specifying the measure at the clinician level.

I can give a couple of sentences of background to this. This is a measure that was brought forth into the CDP process that testing, those intended uses for the clinician, the testing at this point is at a metropolitan and statistical area so it's actually testing it comparing essentially cities to each other rather than the individual clinicians.

We have talked to the developer. They were responsive, but the preliminary analysis is based on the information that was presented to us for this process. Again, that was a do not support for rulemaking with potential for mitigation and that would include specifying and testing the measure at the clinician level.

CO-CHAIR MOYER: So our lead discussants on this are Patti and Dale.

MEMBER WAHL: So I agree with the preliminary analysis of do not support. In

addition, to the concern I have about the comparisons be done at the MSA level and not at the Commission level. The other concern I have is that there are currently no exclusions and so basically any patient who would have any physical therapy or occupational therapy within six weeks for non-related reason would be included in this measure.

CO-CHAIR MOYER: Dale, do you have anything to add? All right.

Any other comments, discussion, concerns from the Committee?

MEMBER MALLINSON: This is Trudy.

CO-CHAIR MOYER: Go ahead, Trudy.

MEMBER MALLINSON: I would also echo the concern about there not being exclusions and so essentially any patient having a carpal tunnel release who got OT or PT in that six-week period would be included even if there were legitimate reasons for that.

And so for a number of patients with co-occurring conditions like fracture or

arthritis is that all who are having issues with scar tissue or any unresolved -- you know, if there was continued numbness or tingling might actually be a legitimate and reasonable approach to refer them to OT or PT.

And so while certainly we would agree that perhaps every patient doesn't need OT or PT, there certainly are legitimate and valid reasons why individuals might need those services in that six-week time frame.

CO-CHAIR MOYER: Helen.

MEMBER BURSTIN: Just one brief comment. There are two approaches to measure development, one of which is to load them up with exclusions and expect 100 percent and one of which is not to load it up with exclusions particularly around appropriateness and just expect that the rate won't be 100 percent. So just to counterbalance that comment, because I'm not sure everything needs to be an exclusion.

CO-CHAIR MOYER: And Chad -- okay. Any other comments or discussion among the

Committee? Any public comments in the room? And any public comments on the phone?

OPERATOR: And ladies and gentlemen, if you'd like to make a public comment press star, then 1 on your telephone keypad. Again, that's star-1 to make a public comment.

We do have a public comment from the line of Heather Smith.

MS. SMITH: Hi, good afternoon. Thank you. This is Heather Smith. I'm the Director of Quality at the American Physical Therapy Association and I just wanted to thank the Committee for allowing public comments on this measure.

And I would echo a lot of the comments that have already been made in the room. We actually did outreach to the measure developer and we would be happy to work with them further in trying to refine the measure so that it appropriately targets this patient population. Thank you.

OPERATOR: And at this time we have no

further public comments.

DR. McCOLLAM: Wait, wait, wait. We do. We do. We have some more. Can you hear me? Hello?

OPERATOR: Yes, sir. I was referring to no further public comments on the phone.

DR. McCOLLAM: I'm sorry, we do have more public comments.

CO-CHAIR MOYER: Is this a measure developer?

MR. PEZOLD: That's Dr. McCollam who is one of our -- on the -- one of the chairs for the measure developers.

CO-CHAIR MOYER: Okay, go ahead.

DR. McCOLLAM: I'm sorry. And I'm going to ask Ryan Pezold who was with the Academy to talk about the MSA versus the clinician data. We ran the data yesterday.

Ryan, are you on the phone?

MR. PEZOLD: Yes, yes. I was just going to speak about that in a moment here. So again, this is Ryan Pezold with AOS. We do have

an update on this measure. We have had the opportunity to test this measure at the clinician level now and I do feel that that's been shared too recently to have been included in materials for the preliminary analysis for this measure.

As indicated in the introduction for this, the measure was always designed for limitation at the clinician level. So the decision to test the measure at the regional level was based on that being the most readily available clinical data at the time. Again, we did retest this at the clinician level using the five percent TMS outpatient sample data set and sent that to the mailbox literally just yesterday afternoon.

I'll try to stay away from the statistical aspect of the analysis, but in the data set that we looked at the signal-to-noise analysis statistic was .99, looking at 1683 clinicians who'd be included in the denominator, so we would certainly interpret that as being reliable. We also used face validity for this

and the interdisciplinary panel evaluating the measure determined that it did have face validity when used as the intended clinician level analysis.

As far as the exclusions go, I appreciate Heather Smith speaking out on behalf of the APTA and the other comments that we've received. And I think the comment that was made previously about throwing in inclusions versus expecting that there's not going to be 100 percent rate is something that is reflective of our approach to this. And we appreciate that there would not be 100 percent compliance with this because you would end up with some of those odd timing issues where someone happened to have something that required physical therapy within that same window.

The workgroup from looking at this measure felt that the chance that that was going to happen was going to be such an uncommon situation that they deemed not to include it in the exclusion criteria, although again, we

certainly would be open to working with the APTA or other comments and seeing how the rates played out to identify areas that we would want to exclude going forward.

DR. McCOLLAM: Can you all hear me? This is Dr. Steve McCollam who is the chair of the workgroup on this. Can I say a word or two of follow up?

CO-CHAIR MOYER: Go ahead.

DR. McCOLLAM: So thanks for being able to speak up here. So we had a 16 member multi-stakeholder workgroup, including therapy, and we did discuss this exact issue. And based on our -- there are a number of hand surgeons on this committee as well as therapy, and we felt like the risk, if you want to use that word, of prescribing therapy in the first six weeks was so small that it wasn't worth listing a whole series of exclusions knowing that we wrote the measure so that we would not be expecting 100 percent compliance. So that's why we wrote it that way. Although we're open to listing several

exclusions, we didn't feel like it was necessary and it might clutter the measure a little bit more than needed.

CO-CHAIR MOYER: Okay.

DR. McCOLLAM: And as far as -- one more thing. As far as ordering therapy for a different condition during that 42 days, the work flow that physicians usually perform is to if you order a therapy for a given condition, you have to attend that or attach it to a certain ICD-9 or ICD-10 diagnosis. So if for some reason within that 42 days, you order therapy for a different condition, I physically cannot order therapy with my EMR unless I append it to the current diagnosis and for the reason for therapy.

So if somebody, for example, had shoulder arthritis and needed therapy within that 42 days, I would be appending the therapy prescription to the shoulder arthritis ICD-10 code, not to a carpal tunnel code which limits the likelihood there would be any confusion or conflation with the therapy for carpal tunnel.

Again, we don't expect 100 percent of patients not needing therapy. We specifically didn't write it that way. We just don't expect every person who has carpal tunnel surgery to need therapy and that's supported in the literature.

CO-CHAIR MOYER: Thank you, that was a helpful clarification. Any other discussion or questions from the workgroup?

MEMBER BURSTIN: So is the only reason it was not given conditional because it wasn't yet tested? And if so, just to be consistent, should that then be conditional rather than do not support with --

DR. BERNOT: That is the reason why it was given conditional was because of the testing. It sounds like -- Susan, is it okay if we point to you? Susan does have the document that was sent yesterday, if there's anything that you can glean from it at this point.

MS. ARDAY: Yes, this came into us around five o'clock yesterday Eastern Time. What

I'm looking at here is your data. This is Susan Arday. I'm directing this to the measure developer.

The table that says discouraging routine use of occupational and physical therapy after carpal tunnel release initial analysis. 2017, your N for number of physicians was 1,683. Your reliability statistic from general to signal noise, you said was .99 with a variation of .99 to .99. Pretty tight.

CO-CHAIR BAGLEY: There's no gap in care?

MS. ARDAY: That's what I would preliminarily --

MR. PEZOLD: I wanted to make a clarification on that. That's not a performance rate. That's not the calculated compliance to the measure. That's using a signal-to-noise reliability statistic to identify how well back in -- successfully the measure as specified can identity the signal from the noise.

MS. ARDAY: Okay.

MR. PEZOLD: As part of the reliability analysis.

MS. ARDAY: Okay, this is Susan Arday again. I'm an epidemiologist. Could you then give me what your performance rate is?

MR. PEZOLD: So I don't have the rate in front of me for the CMS data that we looked at yesterday as we were focused on the reliability analysis. But when we were looking at the MSAs, and the variation there, this was all somewhere between about 80 and 95 percent, depending on how you look at the data, different data sets.

CO-CHAIR MOYER: So this is Amy. I'm going to recommend that we move forward and vote on the measure. It sounds like the mitigation is already under way, so if we were to put that out there as a condition it's in process. But I do want to make sure that we get through all the measures again before we lose quorum because I know people have flights to catch.

DR. BERNOT: I can introduce it for everybody. Just for procedure sake, we do need

to vote on the staff preliminary analysis which is the mitigation. So if you think that this new information from a procedural point of view will change your mind and potentially, as Amy said, could be a condition of NQF endorsement, rather than do not support for mitigation, you would vote no.

If you vote yes here, you would be saying the workgroup's recommendation is do not support with the potential for mitigation. If you want to continue both, you would vote no in this instance.

I'll turn it over to you, Vaishnavi.

MS. KOSURI: Okay, voting is now open for MUC 2018-032. Do you vote to support the preliminary analysis that the workgroup recommended?

Perfect. I think we have our 17. Voting is now closed.

DR. BERNOT: Okay, because we went to under 60 percent, we'll continue moving and you can decide if you want to do a straight support

vote.

(Pause.)

CO-CHAIR MOYER: All right, I'm going to suggest that we start the vote at conditional support with a condition of NQF endorsement unless there's an objection from the workgroup.

MS. KOSURI: Okay. Voting is now open for MUC 2018-032. Do you vote conditional support?

(Pause.)

MS. KOSURI: We are waiting on one more vote. Perfect. We have the 17 that we need. So voting is now closed.

So the Committee's recommendation, based on 88 percent of the vote, is yes for conditional support for MUC 2018-032 with 15 members voting yes, and 2 voting no. Thank you.

DR. BERNOT: I'll try to keep this moving because I do know I am sensitive to making sure we maintain a quorum if anyone has to leave early. But this next measure is MUC 2018-038. That is the International Prostate Symptom Score

or the American Urological Association Symptom Index.

The change in 6 to 12 months after diagnosis with benign prosthetic hyperplasia. This is preliminary analysis from the staff is a conditional support for rulemaking with the condition of NQF endorsement and also as background knowledge, this measure is in the process of NQF endorsement.

CO-CHAIR MOYER: Terrific. Our discussants are Patti and Diane.

MEMBER PADDEN: Okay, I just had two things. As it notes that it is a quality measure that not all electronic health records would have this measure available to them. And the second was clarifying for me not being a special -- in this specialty area, but in primary care, is the 6 to 12 months adequate time in terms of seeing the score change 3 points? And what difference? I mean is it three points, four points, five points in that six months? I guess I was just wanting a little more information there.

MS. PARKER: This is Colleen Parker. I'm representing the Large Urology Group Practice Association and Oregon Urology Institute. And I can address both of your questions.

The first one on the electronic medical record, this was tested in two electronic medical records that do have the ability to register the information for the urinary symptom scores. They are numbers. They have appropriate SNOWMED codes associated with both the IPSF, also the AUA score and there's another code for a bother score that would combine with the AUA score, but also equals the IPSF.

So an HL7 qualified EMR should be able to register those SNOMED codes. It might require some programming by that EMR vendor, but this was tested in two EMRs that did have that capability.

Your second question, will you repeat that second question for me?

MEMBER PADDEN: It states that there would be a change of three points in the symptom score from the time of diagnosis and start of

treatment within a remeasure of 6 months to 12 months.

MS. PARKER: Right. Okay. This was discussed by the technical expert panel. There is literature to support that a three point difference is significant. So a three point change is significant. And that in 6 to 12 months there should be the ability to determine whether there was improvement or whether was actual additional, you know, intervention, medication, procedures, in order to show improvement for that patient. So those were determinations by the technical expert panel.

CO-CHAIR MOYER: Patti, did you have anything you want to add?

MEMBER WAHL: The only thing I want to add is I'm pleased to see this was a patient reported outcome measure.

CO-CHAIR MOYER: Any other committee member discussion, questions, comments?

Any public comments in the room? Any public comments on the phone?

OPERATOR: Ladies and gentlemen, if you'd like to make a public comment over the telephone, please press star-1. And no public comments on the telephones lines.

DR. BERNOT: Okay, I'll just introduce this measure for voting. This is measure MUC 2018-038 again. It's the International Prostate Symptom Score or American Urological Association Symptom Index having a change within 6 to 12 months after diagnosis of benign prosthetic hyperplasia.

The preliminary analysis for this was conditional support with the condition of NQF endorsement.

MS. KOSURI: Okay, voting is now open for MUC 2018-038. Do you vote to support the preliminary analysis of the workgroup's recommendation?

(Pause.)

MS. KOSURI: Okay, I think that's our total. We just have lost one more member. Voting is now closed and the Committee's

recommendation based on 100 percent of the vote is to support the preliminary analysis of the workgroup's recommendation for MUC 2018-038 with 16 people voting yes, and zero voting no.

DR. BERNOT: All right, there's been a request for this to be divided into two, so I will just introduce the first one which is MUC 2018-047. That is Multimodal Pain Management. The preliminary analysis for this is also conditional support for rulemaking with the condition of NQF endorsement. So we'll talk about this measure first, do the vote, and then talk about 048 separately.

CO-CHAIR MOYER: So the lead discussants for this measure, David had to leave early, but Patti do you have anything?

MEMBER WAHL: I talked with David before he left and we were both in agreement with the preliminary analysis of conditional support. And we noted that the steward is the American Society of Anesthesiologists and this is an anesthesiology-type measure.

CO-CHAIR MOYER: Is there any other discussion, comments, or questions among the committee members? Okay. Any public comments in the room?

And any public comments on the phone?

OPERATOR: Ladies and gentlemen, if you'd like to make a public comment over the phone, press star-1. And currently no public comments on the phone lines.

DR. BERNOT: Okay, I can introduce this for voting. Again, MUC 2018-047, that's the Multimodal Pain Management. Right now, we would be voting for the workgroup to accept the preliminary analysis result which is condition support for rulemaking with the condition of NQF endorsement.

MS. KOSURI: Okay, voting is now open for MUC 2018-047. Do you vote to support the preliminary analysis of the workgroup recommendation?

(Pause.)

MS. KOSURI: I think we're waiting for

one more vote. There we go. Voting is now closed. The Committee's recommendation based on 100 percent of the vote is yes in support of the preliminary analysis of the workgroup recommendation from MUC 2018-047 with 16 people voting yes and zero voting no. Thank you.

DR. BERNOT: Okay. Next is the measure MUC 2018-048. That's the Potential Opioid Overuse measure. The preliminary analysis for this is conditional support for rulemaking with the condition of NQF endorsement.

CO-CHAIR MOYER: Michael and Dale are the lead discussants on this.

MEMBER HASSETT: I closed my notes, but I don't have any major comments and agree with the recommendation of the NQF.

MEMBER SHALLER: There were quite a few pushback comments on this and I guess to summarize what I gleaned, there would be broad exclusions for this particular measure. But some sort of philosophical arguments that it's addressing the wrong issue and that the focus

should be on pain management, sort of the flip side of what we just said as opposed to prescription or prescribing behavior. So I'm not quite sure where the truth lies because there's very significant stakeholder concerns on this one.

CO-CHAIR MOYER: I will throw out there that I found myself looking at this against the measures that we just put into MSSP and particularly the kind of individual that initial prescription one, and noticing that they weren't necessarily really harmonized and so I have a concern with putting differing measures into the two different programs, would be my comments on that.

MEMBER BURSTIN: I just put my card down, but I was going to say the exact thing. Amy, thank you. I just think it would be really confusing for clinicians to have measures that are -- were at the MSSP level and at the MIPS level that are different.

CO-CHAIR MOYER: Any other workgroup

comments, questions, or discussion? I don't know if we have a developer on the line who cares to address that?

MEMBER TEETERS: I mean would we go so far as to say we would not approve this measure just because we don't want to -- I mean I realize that's -- but from my take, I would even say we're adding complication that we're approving a measure that is distinctly different from another measure that we're putting on the list.

CO-CHAIR MOYER: I would be concerned about that. I mean ideally if they both go through that NQF endorsement process there would be like a measure harmonization discussion if everything plays out the way it's supposed to. I thought the initial prescription one --- okay. But I do have concerns about that and we've seen that happen with measures and then it's been very difficult to change what type of --

MEMBER FIELDS: It's happening right now, formerly known as MU thing, we have two different roles in MSSP versus MIPS. So as much

as we could say that CMS would have to negotiate that between MIPS and MSSP, history would tell us if that doesn't happen smoothly. And so to be perfectly transparent, I don't trust that process well enough yet to leave it to the two parts of CMS to talk to each other and do that well. So I would actually vote against it for that reason.

CO-CHAIR MOYER: Do we have someone from Mathematica on the line that would like to comment on that?

MS. BANDYOPADHYAY: Hi, this is Jay from Mathematica. Can you all hear me?

CO-CHAIR MOYER: Yes, we can hear you.

MS. BANDYOPADHYAY: Okay, wonderful. Yes, so I just wanted to say that we have undertaken efforts to harmonize the measure to the extent possible to the Pharmacy Quality Alliance measure around high dose opioids.

Can you restate the title of the -- this measure and the other program that you're talking about?

CO-CHAIR MOYER: So the one I was

thinking of was Initial Opioid Prescription Compliant with CDC Recommendations. And that had been MUC-106 in case you happen to have the MUC list. It was Afton Labs was the steward.

MS. BANDYOPADHYAY: Okay. We can look into what -- how we can all harmonize on that or with that measure further. But the efforts that we have undertaken so far, we've -- across the claims-based measures and the other eCQMs that have this -- have a similar concept area and focus, we've tried to align to the extent possible to ensure that we're both harmonizing, but there aren't any kind of redundancies or conflicting specifications. So we can look into that further.

MEMBER BURSTIN: It would also be the high-dose ones from PQA. That's actually what I thought you were referring to, so actually both of them are related. It would be good to see them harmonized before they get put in the program.

MS. BANDYOPADHYAY: Yes, and with the

high dose one that you're referring to, we have been in conversations with the PQA and we have aligned, for example, the opioids within the scope of the measure to the extent possible.

One of the differences between the measures are that you've aligned with the CDC guidelines threshold and you've got as the strengths of the evidence base for this measure whereas I believe the other PQM measurement gets 120 MME. Our expert workgroup did confirm that aligning with the CDC guideline would be appropriate for this measure which is an electronic health record-based provider level measure.

CO-CHAIR MOYER: All right. Thank you for that. Any other workgroup comments or discussion? Any public comments in the room? Any public comments on the phone?

OPERATOR: Again, to ask a public comment on the phone line press star-1.

DR. GREEN: Sorry, I just want to double check to make sure I'm following along.

The measure that we're talking about in MSSP was an initial -- was that initial prescription? I think this is directed toward chronic, so a little bit different. Thanks, Helen. Thank you.

OPERATOR: And currently no questions on the phone lines or excuse me, public comments on the phone lines.

DR. BERNOT: Okay, I think everybody has got this by now, but we're going to be voting on MUC 2018-048. This is Potential Opioid Overuse. The first vote would be to accept the staff preliminary analysis which is conditional support with a condition of NQF endorsement. Voting yes would accept that as the workgroup. If you would wish to continue voting for other categories, you would vote no at this point.

MS. KOSURI: Voting is now open for MUC 2018-048. Do you vote to support the preliminary analysis as the workgroup recommendation?

(Pause.)

MS. KOSURI: Okay. We have our 16, so

voting is now closed. The Committee's recommendation based on 69 percent of the vote is no to not support the preliminary analysis as the workgroup recommendation for MUC 2018-048. Sorry, with 5 voting yes, and 11 voting no.

CO-CHAIR MOYER: Okay. Based on the discussion in the room, it sounded like the next vote we would most likely want you to consider is a do not support with potential for mitigation. Are there any objections to that of the workgroup if someone would like to start with a different vote? Seeing none, we will move to that vote.

DR. BERNOT: For the record also, just the mitigation would include what the discussion that occurred here which was largely around the harmonization of the measure with other measures specifically the ones we've talked about for the shared savings program.

MS. KOSURI: Okay, voting is now open for MUC 2018-048. Do you vote do not support with the potential for mitigation?

(Pause.)

MS. KOSURI: Voting is now closed. The Committee's recommendation based on 88 percent of the vote is yes for MUC 2018-048, do you vote do not support for the potential for mitigation, with 14 voting yes and 2 voting no. Thank you.

DR. BERNOT: Okay, looks like one more and this is MUC 2018-057, this is the Annual Wellness Assessment. I will read the description on this because it is a composite measure and that's the percentage of patients 65 years of age and older with an annual wellness visit who received age and sex appropriate preventive services, the measure's composite of seven component measures that are based on recommendations for preventive care by the USPSTF, ACIP, and AGS. And the preliminary analysis was the conditional support for rulemaking with the condition for NQF endorsement, but also for the harmonization of this measure as some of the seven noted components are already in the program.

CO-CHAIR MOYER: All right. The lead discussants on this are Helen and Eric.

MEMBER BURSTIN: I'm happy to start. I had a couple of questions, again, the detail of what kind of composite it is was still not clear. I can't tell. It sounds like it's also an all or none. We had a very long discussion about all or none composites this morning. So some further detail there would be very helpful.

I guess I have one question since we did have that very long discussion about the composite measure this morning and immunizations about whether it makes sense to have immunizations in this measure as well. We're going to talk shortly about having the composite measure immunizations in this program as well as we talked about for MSSP. And it might just be cleaner to have a screening measure and immunization measure rather than having them in there twice. And I was very pleased to see that it was e-specified. Thank you. I think those are my only concerns.

MEMBER WHITACRE: I agree completely. Initially, I had a question about how this would be documented, but obviously with existing measures for fall risk and depression, there must be a way to do that readily in the EMR. So that was the only other question I had.

CO-CHAIR MOYER: All right.

MS. WILLIAMS-BADER: Hi, this is Jenna from NCQA, could I speak to the type of composite this measure is before we get much further?

CO-CHAIR MOYER: Go ahead.

MS. WILLIAMS-BADER: Great. So this is actually called a patient -- wait -- patient level linear combination, sorry. So basically, what we're doing is we're averaging -- we're averaging for each patient how many of the screenings and immunizations they get that they're eligible for. So it's not an all or none composite. It basically averages across all the patients the percentage of screenings and immunizations they're getting that they're eligible for. Does that make sense?

CO-CHAIR MOYER: Yes. Thank you, Jenna.

MS. WILLIAMS-BADER: Sure.

CO-CHAIR MOYER: All right, any other questions or discussion on the Committee?

MEMBER CHOI: Just sort of a real quick comment. I really support this measure, but I think it would be also great to see a component of brain health in terms of establishing baseline for kind of detecting cognitive impairment moving forward. Just a suggestion.

CO-CHAIR MOYER: Michael?

MEMBER HASSETT: I may not have seen it, this is more of a question for the measure, but based on the cancer space, we have a lot of patients who are not necessarily on hospice, but have a relatively limited life expectancy and have been first time screen program such as mammography and colonoscopy, but trying to avoid these procedures in these patients. So I'm wondering if the measure addresses those

particular issues that actually become part of our choosing measures to recommend against treatment and again, if these two things are happening at the same time it may be confusing.

But my point is besides excluding hospice, I have a lot of patients who may have an 18-month life expectancy who are not on hospice, but I don't want to send them for a colonoscopy.

CO-CHAIR MOYER: Jenna, are there any components to this measure around palliative care and limited life expectancy?

MS. WILLIAMS-BADER: So as I said we've -- or as has been pointed out, we have aligned exactly or as much as we can with the existing measures that are already in the program. The only changes we've made is that our measure is limited to those patients 65 and older and we obviously have an annual wellness visit requirement in ours.

NCQA is the parent -- is the steward of several of the parent measures including colorectal cancer and breast cancer screening on

which the annual wellness component measures have been based. And we are actually working through the annual update process this year with our eCQM to include some -- or to have some exclusions to the measure that are addressing like some of the things that have been brought up.

We've actually at NCQA been developing some exclusions that try to take out patients who are frailer or might not benefit from screening such as breast cancer and colorectal cancer screening. So they're not in the annual wellness assessment yet, because we are letting the parent measure stewards lead, but once those things are incorporated into the parent measure and those follow that we would be able to incorporate those exclusions into the annual wellness assessment measure.

CO-CHAIR MOYER: Terrific. Thank you. Any other Committee comments or discussion?

Any public comment in the room? Any public comment on the phone?

OPERATOR: And again to make a public

comment on the phone line press star-1. And we do have a public comment. Go ahead, caller.

MS. POGONES: Hi. This is Sandy Pogones calling from the American Academy of Family Physicians. We have concerns with this composite measure that are similar to what our concerns were for the other. It did help to have it explained that this is not an all or none composite measure. So that certainly does help.

Our main concerns now are with the exclusions. They don't seem to be consistent across the seven measures. For instance, there are exclusions for patient refusal for the influenza immunization, but not for the pneumococcal immunization. And there are no -- well, you can refuse measure number two, the screening for depression and you can refuse influenza. You can't refuse a mammogram or a colonoscopy.

And we think that patient refusal is an important exclusion in all of these measures. We know that patients do not follow through on

recommendations and orders from their primary care physician to get mammograms, colonoscopies, particularly because these are done outside the primary care office. So we do have a concern with that.

I think those are the main concerns that we have. Thank you.

MEMBER FIELDS: I may be disagreeing with my own specialty society on this, so as a family doc, but we get this complaint from docs constantly. I just had this argument with a physician in our network in the last week about the ability to count patient refusal as an exclusion which I completely disagree with.

Our job as primary care physicians in a huge way is behavior change, and so you know, we often have two or three ways of presenting a needed service to patients and sometimes it works and sometimes it doesn't. It really depends on the mood of the patient that day. We catch them the next day and we readdress it or use different words. It seems to -- did the patient really

grasp on to that and actually changes her mind?

We're not going to get everybody, you know, not everyone is going to be adherent to our recommendations. That's absolutely true. But it is absolutely our job to find new ways of approaching patients that get them from Point A to Point B for necessary services. So I am intensely against anything that just says any sort of flippant patient refusal is proprietary for exclusion.

MEMBER FURNEY: I'll just add that internal medicine perspective that I agree wholeheartedly. If the expectation would be that the measure would be at 100 percent and topped out in two years, then having refusals count, I think would be appropriate. For most of these measures, if you take colorectal cancer screening, the top decile gets to about 80 percent of your eligible population.

So I think as long as we understand the goal is not 100 percent and that is often what I'm talking about with our docs is you won't

get all of these measures to 100 percent, but your job is to get as many patients as far along the pathway as is feasible. So I agree.

CO-CHAIR MOYER: All right. Any other discussion among members of the Committee? Okay.

One last vote.

DR. BERNOT: All right, so this is MUC 2018-057. That is the Annual Wellness Assessment for Preventive Care. Just to remind you, the preliminary analysis that you would be voting to accept is conditional support for rulemaking with a condition for NQF endorsement and making CMS aware for the harmonization necessary of this measure with existing subcomponent measures already in the MIPS program.

MS. KOSURI: Voting is now open for MUC 2018-057. Do you vote to support the preliminary analysis of the workgroup recommendation?

(Pause.)

MS. KOSURI: We have 16 votes. So I will -- voting is now closed. The Committee's

recommendation based on 88 percent of the vote is yes for MUC 2018-057 to support the preliminary analysis of the workgroup recommendation with 14 voting yes and 2 voting no.

CO-CHAIR BAGLEY: Well, we're going to wrap it up -- pardon? Oh, we did that earlier. We did both. Yes, we did. It zipped right by, Helen. You don't usually miss much.

It's customary to have a quick meeting evaluation and just any comments? What did you like about the meeting or what could we have done better? And it goes everything from the room temperature to food to meeting time back to preparation materials and stuff like that. Anything that you want to call out as a great job or things that you think we should work on for the next meeting? Go ahead, Diane.

MEMBER PADDEN: I would just like to commend you on the new voting software, very quick, easy to see, easy to use. Excellent.

CO-CHAIR BAGLEY: Other comments?

DR. GREEN: I'd like to say thank you

for having us last because this is the most painless MAP meeting. Thank you, guys.

CO-CHAIR BAGLEY: We can fix that next time.

(Laughter.)

DR. BERNOT: I want to make one comment about -- something to think about and we'd love the feedback is the use of the measure developers, their ability to answer questions beyond the phone. We apologize. We had a little bit of a hiccup getting the first NCQA person on line, but other than that, it's just something that it does not have to be right now, but after on your way home on the airplane, let us know what you think how much of a stage influence would we like that to be part of the MAP meeting so we can really address that as a concrete item going forward, one of the NQF takeaways that we have.

MEMBER PADDEN: Of course, I have to thank the staff who did a fabulous job and really I think the discussion guide was really, really

well done. A couple of thoughts, I thinks perhaps as a measurement geek, things shouldn't be called measure specifications unless I can really click through the actual specs I need to see.

A lot of the questions we had today were, in fact, about things that would have actually been in something labeled measure spec. Those are really just measure detail descriptions and it's hard to make a lot of decisions.

And also just back to the discussion of the very complex cost measures. You know there are times when we've gotten slides and sort of descriptions of things that would have just made that discussion so much easier. It's a very hard conversation to listen to without anything on paper. So a couple slides here and there would have just made the world of difference instead of trying to process and I was not tired then, Dan, process the fact that very complex, what changed, what didn't change. So just anything you can do to make the information

easier to see, particularly when it's new. We literally just got that information the last couple of days on these incredibly complex measures. So again, visuals help.

CO-CHAIR BAGLEY: I actually made that recommendation to them before they left about picking, we had a whole long list, pick one and do a detailed analysis to show the detail level that they get to. And then we could assume they're doing the same thing on the other end. So yes, exactly. Other comments? Ann.

MEMBER GREINER: I think we didn't have time for this, given the number of measures that we had to review, but I am cognizant of such a large number of measures and how did the ones that we vote on today sort of fit into it and at the end of the day, what does it mean for either the ACOs or really more of the clinicians that are reporting those measures.

I don't have a good sense of that and I know that generally you like to provide that, but we just had a lot of issues to review. So I

think it's a challenge.

CO-CHAIR BAGLEY: It is a challenge. I think it's a good idea and we probably should include that in sort of the opening remarks, now here's the big picture, here's the program and that sort of thing, so we probably should do that in the future.

MEMBER BRISS: You could actually do that efficiently in the pre-meeting webinar actually. That might save a lot of discussion time.

CO-CHAIR BAGLEY: Okay, any other comments or recommendations for improvement? Opportunities for improvement?

MEMBER KRUGHOFF: Well, I came late enough that I thought all the things you're suggesting had been done, so I gave you 100 percent credit.

CO-CHAIR BAGLEY: We're supposed to summarize the day a little bit so I'll give it a whack at it. It will be brief.

I think this is very important work

that we're doing and CMS is generally interested in hearing this conversation, you know, probably even more than the letter of the actual measure. It's helpful to them as they try to refine them and rework them or get them in the right program or get them working properly.

So Michelle and Reena, thank you for listening and your staff, I mean you had a number of your staff here as well, either here in the room or on the phone so thanks for that.

The issues we dealt with, the opioids is a critical issue for our country as a public health issue. This year we heard the news that because of the number of overdose deaths that the life expectancy in our country is actually dropping and it's attributed to so many young people dying of this problem. So it's serious business and I think we made some tiny bit of progress.

The cost of care is another critical issue for our country and although we talk about it all the time, if we're not willing to measure

it and promote transparency, it will not change, so once again, we're taking a step in that direction.

It was nice to see some -- the last set of measures, I'll call it sort of patient-centered and patient-reported outcome. I think we need to see more of that and start to see some of the feedback that we get from that and see how they're working out. So with those comments, thank you for your time. Thank you for your commitment and thank you for your contribution. We hope you had so much fun this year that you might consider coming back next year.

(Laughter.)

(Applause.)

(Whereupon, the above-entitled matter went off the record at 4:35 p.m.)

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: 12-12-18

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