**NATIONAL QUALITY FORUM**

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**MEASURE APPLICATIONS PARTNERSHIP**

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**HOSPITAL WORKGROUP**

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**THURSDAY**
**DECEMBER 14, 2017**

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**The Workgroup met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., Cristie Upshaw Travis and Ronald Walters, Workgroup Co-Chairs, presiding.**

**MEMBERS PRESENT:**
**CRISTIE UPSHAW TRAVIS, Co-Chair**
**RONALD WALTERS, Co-Chair**
**KEITH BELLOVICH, Kidney Care Partners**
**ANDREA BENIN, Children's Hospital Association**
**JOAN BRENNAN, Geisinger Health System ***
**ANNA DOPP, Pharmacy Quality Alliance**
**NANCY FOSTER, American Hospital Association**
**FRANK GHINASSI, National Association of Psychiatric Health Systems**
**KIMBERLY GLASSMAN, Nursing Alliance for Quality Care***
**MARYELLEN GUINAN, America's Essential Hospitals**
**HELEN HASKELL, Mothers Against Medical Error**
**MARTIN HATLIE, Project Patient Care**
**RICHARD KNIGHT, American Association of Kidney Patients**
**MARSHA MANNING, University of Michigan**
**SARAH NOLAN, Service Employees International Union**

JANIS ORLOWSKI, Association of American Medical Colleges
AISHA PITTMAN, Premier Healthcare Alliance
KAREN SHEHADE, Medtronic-Minimally Invasive Therapy Group
BROCK SLABACH, National Rural Health Association
MARISA VALDES, Baylor Scott & White Health
WEI YING, Blue Cross Blue Shield of Massachusetts

SUBJECT MATTER EXPERTS (VOTING):
GREGORY ALEXANDER
ELIZABETH EVANS
LEE FLEISHER
JACK JORDAN *
R. SEAN MORRISON
ANN MARIE SULLIVAN
LINDSEY WISHAM

FEDERAL GOVERNMENT MEMBERS (NON-VOTING):
PAM OWENS, Agency for Healthcare Research and Quality *
DAN POLLOCK, Centers for Disease Control and Prevention
PIERRE YONG, MD, MPH, MS, Centers for Medicare & Medicaid Services

MAP MEDICAID LIAISONS:

RICHARD ANTONELLI, MD *

MARISSA SCHLAIFER, RPh, MS *

**NQF STAFF:**
**ELISA MUNTHALI, MPH, Acting Senior Vice President**
**KAREN JOHNSON, Senior Director**
**MELISSA MARINELARENA, Senior Director**
**ERIN O'ROURKE, Senior Director**
**TAROON AMIN, NQF Contractor**
**KATE MCQUESTON, Project Manager**
**DESMIRRA QUINNONEZ, Project Analyst**

**ALSO PRESENT:**
**SUSANNAH BERNHEIM, MD, MHS, Yale School of Medicine**
**JOSEPH CLIFT, Centers for Medicare and Medicaid Services**
**ELIZABETH DRYE, MD, MS, Yale Center for Outcomes Research and Evaluation**
**REENA DUSEJA, Centers for Medicare and Medicaid Services**
**JESSE ROACH, MD, Centers for Medicare and Medicaid Services**
**JOSEPH MESSANA, MD, University of Michigan**
**COLLEEN MCKERNAN, The Lewin Group**
**LISA SUTER, MD, Yale University**

*** present by teleconference**

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

(9:01 a.m.)

MS. MARINELARENA: Good morning, everyone. I think we're going to go ahead and get started. We have a long day to review these measures and have these great conversations.

Hi. My name is Melissa Marinelarena. I am the senior director on the MAP Hospital Group.

I'd like to welcome everyone back for those of you that are back with us again this year. And for those of you that are new, which we will have introductions, welcome to MAP Hospital Group. This is an exciting time for everyone.

Right now I'm going to -- and I'd also like to welcome our CMS colleagues, the measure developer colleagues in the back, and anyone who's listening on the phone to the meeting today. Welcome.

Right now I'm going to turn it over to Elisa Munthali to do the disclosures of interest.

MS. MUNTHALI: Good morning and welcome, everyone. My name is Elisa Munthali. I'm the acting Senior Vice President for the Quality Measurement Department.

I am going to ask you to combine disclosures of interest with your introductions and it's going to be done in two parts.

There are two types of members on this workgroup; the organizational representatives and subject matter experts.

We're going to start with the organizational representatives. And for you, as you remember, we asked you a very simple question about you as an individual because you are a representative. We've asked you to participate on this workgroup because of your affiliation with your employer.

So we asked you if you had anything to disclose in excess of $10,000. And so we'll go around the room, and I think on the phone we have a couple of organizational reps. So I think we'll start with Marisa.

And, Marisa, sorry, a couple of housekeeping things. You have to press speak and just say your name, tell us if you have anything to disclose.

MEMBER VALDES: Hi. Marisa Valdes from Baylor Scott & White Health. Nothing to disclose.

MEMBER GLASSMAN: Kim Glassman. I'm representing the Nursing Alliance for Quality Care. Nothing to disclose.

MEMBER EVANS: I'm Beth Evans. I'm actually a subject matter expert for the American Nephrology Nursing Association and I have nothing to disclose.

MS. MUNTHALI: And just before we continue, we're just doing the organizational reps right now and then we'll go through the subject matter experts. Thank you.

MEMBER YING: I'm Wei, Blue Cross Blue Shield of Mass. Nothing to disclose.

MEMBER GHINASSI: Frank Ghinassi from Rutgers representing National Association of

Psychiatric Health Systems. Nothing to disclose.

MEMBER SHEHADE: And I'm Karen Shehade with Medtronic's Minimally Invasive Therapy Group and I do have disclosures of stock.

MS. MUNTHALI: Thank you.

MEMBER BRENNAN: This is Joan Brennan from Geisinger and I have no disclosures.

MS. MUNTHALI: Thank you. And we'll get to everyone else on the phone after we've gone around the room. Thank you so much.

MEMBER KNIGHT: Richard Knight, the American Association of Kidney Patients and I have nothing to disclose.

MEMBER BELLOVICH: Keith Bellovich representing Kidney Care Partners, rookie on the group, apparently. I am the medical director with the DaVita Corporation and also a joint venture partner.

MEMBER BENIN: I'm Andrea Benin. I'm at Connecticut Children's Medical Center, but I am the organizational representative for the Children's Hospital Association.

MEMBER HASKELL: I'm Helen Haskell representing Mothers Against Medical Error and I have nothing to disclose.

MEMBER SLABACH: Good morning. I'm Brock Slabach with the National World Health Association and I have nothing to disclose.

MEMBER GUINAN: Good morning, everyone. Maryellen Guinan for America's Essential Hospitals. Nothing to disclose.

MEMBER FOSTER: Good morning. I'm Nancy Foster with the American Hospital Association. Nothing to disclose.

MEMBER POLLOCK: Dan Pollock, the Centers for Disease Control and Prevention, Atlanta. Nothing to disclose.

MEMBER ORLOWSKI: Good morning. I'm Janis Orlowski. I'm with the Association of American Medical Colleges. Nothing to disclose.

MEMBER HATLIE: I'm Marty Hatlie, Project Patient Care. I have nothing to disclose.

MEMBER PITTMAN: Aisha Pittman with

the Premier Healthcare Alliance. Nothing to disclose.

MEMBER NOLAN: Sarah Nolan, Service Employees International Union. Nothing to disclose.

MEMBER MANNING: I'm Marsha Manning representing the University of Michigan Benefits Office. I have nothing to disclose.

MEMBER DOPP: Good morning. Anna Legreid Dopp. I work for the American Society of Health-System Pharmacists, but I'm representing the Pharmacy Quality Alliance this morning. Nothing to disclose.

MS. MUNTHALI: Great. Thank you. And so now we'll go to the phone for our organizational representatives.

And, Joan, if you could just give us your disclosure again, sorry about that.

MEMBER BRENNAN: I'm Joan Brennan. I'm representing Geisinger and I have nothing to disclose.

MS. MUNTHALI: Thank you.

Is Jeff Jacobs on from STS?

(No response.)

MS. MUNTHALI: Okay. Doesn't sound like he is on yet, and so we'll go back to the phone if he does join.

And so now we'll start with our subject matter experts. And for those of you who are subject matter experts, you know your form was a lot longer.

We asked you to disclose activities that were relevant to the work that's in front of you, whether it was, you know, disclosures related to consulting or any speaking arrangements or engagements that you've had, whether they were paid or not.

And so just as a reminder for those of you that are SMEs, you sit here as an individual. So you're not representing your employer or anyone who may have nominated you.

And just a couple of other reminders that are really important for you to remember is just because you disclose does not mean you have

a conflict.

And so we'll go around the room and I think we'll start with Kim. Kim, did you -- okay. So we'll go around the room to see if there are any subject matter experts that didn't go around the first time when we did the organizations. Thank you.

MEMBER SULLIVAN: Ann Sullivan, subject matter expert, mental health, and the Commissioner, New York State Office of Mental Health. No disclosures.

MEMBER ALEXANDER: Greg Alexander, subject matter expert, nursing informatics. Only disclosures I have, I have research funding through the Centers for Medicare and Medicaid. I also have research funding through the Agency for Healthcare Research and Quality.

MEMBER FLEISHER: Lee Fleisher, subject matter expert for method, methodology. I have funding through NIA and NIH for developing novel methodology to assess quality.

The first measure on the ambulatory

surgery is based upon some of my own research from about a decade ago, and I currently have some work with Yale around an all-cause mortality measure.

I can't tell if that's what's submitted here. But if that is the Yale core measure, they can tell whether I was one of the consultants who helped develop it.

MEMBER WISHAM: Good morning. Lindsey Wisham. I serve as a subject matter expert for health informatics and electronic clinical quality measures. No disclosures.

MS. MUNTHALI: Okay. Great. I think that's all in the room -- oh.

MEMBER MORRISON: Sean Morrison, Chair of Geriatrics and Palliative Medicine at Mount Sinai. So obviously older adults and those with serious illness.

MS. MUNTHALI: Thanks, Sean. And wanted to see if Jack Jordan has joined us.

MEMBER JORDAN: Yes, I'm here.

MS. MUNTHALI: Oh, hi, Jack. Could

you let us know if you have anything to disclose?

MEMBER JORDAN: I'm employed by Henry Ford Health System and I consult with IMPAQ International on the -- in CMS contracts. But otherwise, I have nothing to disclose.

MS. MUNTHALI: Thank you very much.

And so now I'll turn it over to our federal liaisons for an introduction.

Oh, our co-chairs. Sorry about that.

CO-CHAIR TRAVIS: I'm Cristie Travis. I'm with the Memphis Business Group on Health and I'm going to ask you, Elisa, I'm not sure under which disclosure I should make my disclosures.

MS. MUNTHALI: You are a subject matter expert, yes.

CO-CHAIR TRAVIS: Okay. The only thing I have to disclose and it really doesn't address any of the specific issues that we're talking about today, but I do serve on a health policy intensive faculty where I am reimbursed to lead a course at Johnson & Johnson on CMS payment programs and the inclusion of quality, but it's

just a factual presentation.

CO-CHAIR WALTERS: Ron Walters. I'm a subject matter expert, I guess. I work at MD Anderson. I'm on the board of NCCN, which is the National Comprehensive Cancer Network, and the board of TMF QIN-QIO. Neither of those are paying positions, unfortunately.

And I'm very disappointed that under the Sunshine Act I was originally at $11 and I don't know where that $11 came from, and it jumped to $110 this year and I don't know where that came from either. That's everything.

CO-CHAIR TRAVIS: Although not related to any specific measures today, I am the acting chair of the Leapfrog Group and serve on their board of directors.

MS. MUNTHALI: Great. Thank you and sorry for that. And so now to our federal liaisons. We have some in the room and some on the phone. We'll start with the room.

MEMBER YONG: Hi. Pierre Yong, CMS.

MS. DUSEJA: Reena Duseja, CMS.

MS. MUNTHALI: Pam from AHRQ, are you on the phone?

MEMBER OWENS: I am. This is Pam Owens from the Agency for Healthcare Research and Quality.

MS. MUNTHALI: Thank you. And I just wanted to remind you -- okay. Great. So our federal liaisons are on here for the discussion. They are nonvoting members.

Now that you've heard all of the disclosures from your colleagues, I just want to know if you have any questions of each other.

(No response.)

MS. MUNTHALI: Doesn't look like it. At any time if you remember or if something pops up like Lee was just saying, he wasn't sure if he has a conflict on a measure, please speak up. You can do so in realtime, you can approach your co-chairs or any one of us on the NQF team.

You can also just pull us aside and that's fine as well. So I just want to, before I conclude today, just see if there are any other

questions about disclosures.

(No response.)

MS. MUNTHALI: Okay. Thank you.

CO-CHAIR TRAVIS: Okay. Well, I'll just add Ron's and my welcome to everybody. Good to see you again, those of you who have served on this workgroup for a number of years, and we welcome our new participants as well.

It is a large group and so thank you for the time and commitment that you have made for this.

As you see on the agenda today, we do have, I think, nine measures that we will be going through related to specific federal programs, but we also do have a couple of special presentations that we will have after we have gone through the measures themselves, and they're listed on your agenda.

We will be hearing about the -- I want to be sure I get it right -- the Hospital-Acquired Condition Reduction Program.

And, really, we don't have any

measures under that today, but this is our opportunity to kind of hear about what the thoughts are moving forward with this program and for us to share our insights.

We also will be hearing later in the day from the MAP Rural Health Initiative and Karen will be giving us a presentation at the end of the day about that new group and how we will be interacting with that group and NQF's focus on rural health.

It is a very important piece. So I know it's at the end of the day. Hopefully we'll all still be here to listen to that.

And then the other piece is some input on the measure removal criteria. And, you know, as we will hear from Pierre when he kind of goes over some introductory remarks, being sure that the measure sets actually reflect the priorities and where there are opportunities is really important.

So thinking about the measure set as a whole, not just adding new measures, but at

some point when measures are ready to come out, that's going to be some of the conversation that we have later today.

So thank you all so much for all the prep that you have done to get ready for today, and also to help us think through some of these strategic issues at the end of the day.

So with that, I think that it is about time -- oh, we haven't introduced staff. Well, thank you. That's why there is a co-chair because as you're talking, you forget. So thank you, Ron, for that.

I would want to be sure to recognize the staff and have them introduce themselves. For those of us who have been on the workgroup for a number of years, you know what a vital role the staff plays in helping us prepare adequately to be able to actually take action on our responsibilities during the workgroup meeting.

So and all I can say is that we couldn't be here without their leadership and their assistance.

So you've already met Elisa. So I think we'll start over here and introduce ourselves.

MS. QUINNONEZ: Good morning. My name is Desmirra Quinnonez and I am the project analyst on this workgroup.

MS. MCQUESTON: Hi, everyone. I'm Kate McQueston. I'm project manager at NQF.

MS. MARINELARENA: Hi, again. Melissa Marinelarena, senior director.

MR. AMIN: Hi, everyone. Good to see everyone. Taroon Amin, consultant to the NQF supporting the MAP Coordinating Committee with my colleague Erin O'Rourke in the back.

MS. QUINNONEZ: Erin says hi.

(Laughter.)

MS. QUINNONEZ: Before we move on, I'd also like to recognize we have our Medicaid liaisons on the phone.

We have Marisa Schlaifer representing the MAP Adult Workgroup, and Richard Antonelli representing the MAP Child Workgroup liaison.

And they'll be available over the phone and be able to comment on any Medicaid-related measures.

CO-CHAIR TRAVIS: Okay. Well, thank you for that -- oh, and Karen -- Karen Johnson is in the back here as well. So thank you for that.

All right. Well, I think we will go on and get started. And we're going to turn it over to Pierre Yong from CMS to give us some opening remarks and also to review for us the meaningful measures framework that we should be keeping in mind as we take our action today.

MEMBER YONG: Well, thanks so much, Cristie. Good morning, everybody. And for folks who don't know me, I'm Pierre Yong, the director of the Quality Measurement and Value-Based Incentives Group at CMS where I and my team work on all the Medicare quality reporting and accountability programs that are a discussion at the MAP these past three days this week.

And so wanted to take the time and really thank all of you for taking time out of your really busy schedules and lending us your

expertise across, you know, the past couple of months for this particular effort. It's really nice to see a lot of familiar faces around the table and also nice to see some new faces as well.

So we hope that today we'll be able to -- and we always value the opportunity to hear your input and your recommendations. It's always a fantastic discussion. I expect nothing less today, but wanted to offer some framing comments.

And I see Erin sitting in the back over there, but Erin has heard this presentation so many times I think she can give it for me. I thought she was today, but -- and I would gladly let her, but you have probably heard this presentation also a number of times.

So I apologize I'm going to go fairly quickly in order to save some time for questions and discussion, but you probably have heard our Administrator Seema Verma as she launched an initiative called Patients Over Paperwork.

And the goal, I think, there, is

really to look critically at our regulations and our requirements and really think about what is really essential to help support, you know, and safeguard safety and quality and -- but really sort of try to support the work that -- the clinical care that's happening across the country. And really trying to minimize the burden and try to get out of the way so that you, as clinicians and providers and facilities, can really focus on what's important to the care that's being delivered and the patient.

So as part of that, we have been thinking about the quality measures as that's a big part of the CMS programs, is the quality reporting programs.

And so as part of that, we have also launched a framework called Meaningful Measures. And so that's what I was going to talk about today.

So if you move to the next slide, and if you move to the next slide, the framework itself is really drawn from a lot of the feedback

we have received over the past couple of years from conversations we've had in this very room and with this very workgroup, but also a lot of conversations that have happened elsewhere, including at the National Academy of Medicine as well as at the LAN, the Learning and Action Network, about sort of the measures that we're using in our programs.

Over the years, people have noted that we've had an increasing number of measures in our programs and that as that sort of measure -- the measure sets increase, there are a couple of issues that sort of arise.

One, that, you know, it becomes harder and harder to sort of decipher, when you look at the measure set, what is the overall measure set trying to accomplish? What are we really trying to focus on in terms of quality measurement as well as quality improvement?

Two, as we increase the number of measures, there's also an increasing burden, right, placed on providers for reporting measures

and as well as sort of reviewing, you know, the data, reviewing the preview reports, reviewing what's publicly reported.

So as a part of that, a way to address that, we have been thinking internally about, you know, how do we then get to the most parsimonious, but sort of meaningful measures for each of our programs that imposes the least burden possible?

And so we -- this framework that I'm going to go over has multiple components. The meaningful measure areas themselves really focus on the sort of topical areas that we think are of the highest importance to really drive quality and quality improvement really for -- to improve quality for the patient, but underlying that there are also other considerations that I think we -- are just as equally important. And they're listed on the slide and I'll review them really quickly.

So not only is the first point addressing sort of the measures, but we really

want to make sure that the measures themselves are meaningful to patients and to providers that -- and we've had many discussions around not just on the MAP side, but also on the endorsement side about sort of why you should eventually move to an increasing number of outcome measures over process measures.

This does not mean that there's no role for process measures. But I think when there's a choice, oftentimes we will prefer the outcome measure if possible.

That burden is a critical consideration, as I mentioned before. For measures that we use, we want to see that there's opportunity for improvement.

I think this is particularly critical as we have an increasing suite of accountability programs where we then try and decide payments based on performance of measures.

So if there's a significant opportunity in variation of the measure performance, I think that allows for more

meaningful distribution and assessment of facility and clinician performance.

We want to eventually sort of move to and support payment through alternative payment models and so think about measures in that context.

And we also want to make sure we align not only within CMS in terms of our measure work, but also across payers as we've often heard from clinicians and institutions that they're reporting not just to Medicare, right, we're not the only payer, but they're reporting to other payers, private payers, they're reporting to states. And so having some alignment between the reporting will help ease the burden there.

So if you move to the next slide, I'm not going to review this in detail, but it draws -- just illustrates that we've drawn on a couple of existing resources that have been really focusing on similar sort of efforts, including at the NQF.

If you move to the next slide, for

those familiar with the Learning and Action Network white paper on population health measures, I thought this particular graphic was really useful in sort of demonstrating at least conceptually what we're trying to do.

So if you look on the right side if you look on the bottom, you'll see these little circle -- blue circles. And what they've called Level 3, or atomistic performance measures, are little dots you can think of as an individual measure.

But what they encourage us -- or encourage the field, really, to do is move towards these Level 1 and Level 2 measures, these larger sort of more big dots, if you will.

And so the framework itself aren't measures, they are meaningful measurement areas, but we thought that was a good step forward in helping us focus our work.

So if you move to the next slide, these are the initial 18 that we identified of meaningful measurement areas.

They are grouped in six domains and are surrounded in the center with the patient at the center and then surrounded by several crosscutting principles.

And so if you move to the next slide, I'm going to quickly review each of the 18 just before we open this up for discussion.

The first domain is making care safer and here we have healthcare-associated infections as well as preventable healthcare harm.

If you look on the right side of the slide, you can see that you have these little circles. That's just to demonstrate that we've started to think about how to apply these meaningful measure areas to our programs and see what measures we have existing in our programs that address this particular meaningful measure area.

So under healthcare-associated infections, you'll see, for example, that we have the CLABSI measure, which is the central line-associated bloodstream infection measure, which

is present in several of our programs.

If we move to the next slide, we have strengthening person and family engagement. And here we have care that is personalized to and aligned with patient's goals, end-of-life care and patient -- I'm sorry, I can't see because of the reflection. Sorry. I apologize. I'm sorry, I can't see as well from this angle because of the reflection. Apologize.

If you move to the next slide, here we have promotion of effective communication and care coordination.

And here we have medication management, we have management -- sorry -- and we have seamless transfer of health information.

If you move to the next slide, here we have promotion of effective at prevention and treatment of chronic illnesses. And if you'll excuse me, I won't read all of them through, but we have a number of meaningful measurement areas here.

If you move to the next slide, working

with communities to promote best practices and healthy living. And here we have two meaningful measurement areas, including community engagement and equity of care. I do want to pause for a second on equity of care.

I think you can think of equity of care in a variety of ways. You can think of particular measures that might address equity of care, but you can also think about other ways. And certainly at CMS, we have other levers, really, to address equity of care. So we think about this a bit broader than particularly just measures, for example.

So those, you know, familiar with the Hospital Readmissions Reduction Program realize that we, this year, have shifted the direction of the program in terms of how we assess hospitals by stratification approach where we have stratified hospitals -- assessment of hospitals based on the percentage of dual eligibles. So that's sort of a more payment-side approach, if you will, to sort of address equity.

We also have several initiatives happening on the quality-improvement side. So it is broader than measurement, I think. And the framework itself, I think, encompasses more than just measurement, per se. It includes quality improvement work as well.

So if you move to the next slide, making care affordable is in this last sort of domain. And so I won't -- again, won't read through the specific domain -- specific mission meaningful measurement areas.

If you move to the next slide, we've had the opportunity to do this presentation a number of times. And I apologize, I should have all these memorized at this point, right?

So but a couple of questions that have come up that we just thought would be helpful to address up front; one is that the meaningful measure framework is really an overarching way for us to think about the measures and the quality improvement efforts that we have at CMS.

It, by itself, is not a new quality

reporting program. It doesn't impose any new requirements or impose any new measures on any particular provider or institution.

I think the other common question we get is, well, how is this going to be applied? How will we see it manifest? How will it impact burden that I feel as a provider? And I think those are fantastic questions.

So, one, we have started to think about how this applies, you know, to the MUC list, for example.

And as you may have noted, and for those who have been following this and sat around the table, you know, the MUC list is fairly succinct this year.

And that's a reflection of, I think, the critical sort of thinking that we're doing as we apply this framework to, you know, our measurement work, you know.

This year we actually had almost 200 measures submitted across the programs. And we actually put forward on the MUC list less than a

quarter of them, but it doesn't stop there.

I think we are also starting to think about how this applies to the existing measure sets and looking closely at each of the measures in each of our programs to see whether it makes sense to keep those measures, potentially remove those measures, you know, and so that's an internal discussion that's happening.

As noted earlier, we will have a discussion later on in the day about potential measure-removal criteria. We are having this discussion or have had this discussion across the other two MAP workgroups, and really has been great feedback to us about things that we should be thinking about as we do this review.

Certainly any decisions that get made will be put forward through our regular process in terms of notice and comment and rulemaking. So you can look forward to that in the coming months.

But as we also apply and look at our framework and at the measure sets, we are also

starting to think about gaps, right? And I think that's a common discussion that we have across all the workgroups, but I think there's opportunity to also think about how this applies to the measure development work. And so how do we fill those gaps and what kind of measures are we going to be developing?

And that's, obviously, a multi-year process, but we think ultimately hopefully this will lead us to our goal, which is really trying to get to these concise and less burdensome measure sets that really target the really critical quality areas that we want to -- are going to drive quality and quality improvement for the country.

So I'm going to stop there if you -- there's one last slide, but see -- and open this up for questions. This is an initial sort of 18 set of meaningful measure areas. We'd love to hear your feedback.

Are these the right 18? Is there something that's missing? Are there ways to make

this clearer? But welcome any and all feedback.

CO-CHAIR TRAVIS: Thank you, Pierre.

Any thoughts or comments from the workgroup?

Nancy.

MEMBER FOSTER: Thank you, Cristie. And thank you, Pierre, and to your entire team. Really delighted to see you embarking on this effort. Happy to provide some additional thoughts.

I know you know we've sent some information in, probably two dozen comment letters that you've had to read. So, really excited about this.

The thing I want to say and ask for your thoughts about is that, from a provider perspective, you don't experience measures as just those that CMS selects. There are other -- dozens of other organizations asking hospitals for quality metrics.

And to really make the kind of progress that I think you're striving to make

here, and I'm hoping we can all make together, CMS really needs to be in alignment with other organizations and with the public and with the providers who really need to weigh in and help understand what's going to matter.

So could you say a word about are these kinds of public discussions just the only way you're going to be soliciting comments? Are you looking at ways to work collaboratively with other organizations? What's that look like?

MEMBER YONG: So thanks, Nancy. Always count on you to ask really thought-provoking and great questions. No, but I think you bring up a great point, right?

And you might remember that one of the points that was on one of the earlier slides was about alignment, right? Not just within CMS, but with other payers and provider requirements.

And so -- and I recently was at Henry Ford and had a chance to visit there and they showed me a slide of all the different sort of initiatives and reporting requirements that they

have. And that filled two pages of slides and really sort of hit home that point that you're making exactly.

But, yes, no, I think we are trying to work and understand that there are ways that -- and opportunities to sort of promote that alignment.

I mean, I think they're -- one, we have for the past three years been involved with the Core Quality Measures Collaborative, which released eight sort of core measure sets, if you will, focused on different -- a variety of clinical topic areas so that -- on which CMS and those payers have agreed to align. And so we have implemented those measures into the MIPS program, for example.

But we also when our Administrator launched and announced this initiative, brought it to the LAN and that wasn't an accident, right, the Learning and Action Network, which is really about sort of driving payment reform, but has participation from a lot of payers as well as

provider groups as well as patient and consumer groups.

But so and we did the presentation not only at the open general session, but then also to the guiding committee and have been continuing to talk to them about opportunities to sort of leverage their existing sort of interests in sort of promoting alignment of measures as well as our interest in trying to get to the goals of this work.

So I think there are ongoing conversations that we're having and we know it's an active area for a lot of opportunity.

CO-CHAIR TRAVIS: Anna.

MEMBER DOPP: Pierre, this is the third time I've heard you give the presentation and I appreciate it. Your team has done a really thoughtful job of explaining it and depicting it on the slides.

My question, and maybe you've addressed it in one of those three times that I've heard it, so I'm sorry if you have, but when

you talk about those individual measures that then roll up into the meaningful measurement areas, is there a resource that's available to look at to see how those are rolling in?

It's clear to see where the areas link into the domains, but as far as those individual measures, you depict some examples on the slides, but is there a more comprehensive that has everything to see how they roll into each other?

MEMBER YONG: So I think that's a great question. And so maybe next time you want to give the presentation for me since you've heard it a couple times, but -- I'm looking for volunteers, actually.

(Laughter.)

MEMBER YONG: So but, yes, I think that would be -- I hear the need for that. We don't have that existing. I think right now we're trying to get comments about the meaningful measure areas themselves.

We've gotten some great feedback about, you know, potentially missing areas, so we

haven't quite -- like, this is an initial sort of set.

And even if we tweak them, I think it's going to be a living sort of process, right? There may be tweaks in the future.

So we have launched recently the CMS Measure Inventory Tool, which is a public tool of all the measures that we have across the CMS programs.

We have been actively talking about including in there like a column or field around, you know, linking each measure to a respective meaningful measure area.

So we're talking about that internally. It's not done yet, but that is something we want to make progress on and want to release in the future.

I think one particular issue that's come up is, you know, any particular measure may track to multiple meaningful measure areas which is not necessarily a bad thing. It's just that happens even, you know, regardless of what

framework you do. They're not mutually exclusive, but it is something that we have heard requests for and think there is value in doing, but it's not quite there yet.

CO-CHAIR TRAVIS: Dan.

MEMBER POLLOCK: Thanks, Pierre. And just to say out loud how grateful we are at CDC for the opportunity to work with CMS on the meaningful measures program and provide input on the decisions that are underway with regard to these measures. We're very grateful.

My question really relates more to data validation and how data validation figures into the whole movement towards more meaningful measures because certainly one of the ways to make measures more meaningful and credible to the end users is to assure that there is indeed validity to the data.

And that aspect of measure use actually becomes even more important when measures are aggregated into overarching measures where they could obscure some of the tails

regarding the components.

So just, if you would, just some thoughts about the way in which data validation figures into this process and one of the issues relates to the fact that the data validation and the inpatient quality reporting program is part of that program, but it doesn't necessarily extend to the HAC reduction or the value-based purchasing program.

So if a measure in IQR is effective, that could have implications for validation if it's -- the measure is used more exclusively in the other two programs.

MEMBER YONG: Yes. Thanks, Dan. And of course I certainly appreciate the collaborative relationship we have with CDC. So thank you for supporting that.

And I would also note that, like, you know, while all the measures that are in the, like, HAC, for example, are in IQR, they use the same data, right?

So any issues identified in IQR would

then carry over to the other programs that they're used in.

And so I think it's a great question about sort of validation. I mean, it's not explicitly mentioned and that's a good point. Maybe we should.

I sort of generally think of, you know, when we see meaningful measures or sort of measures that are, like, important to you, I think there are a couple ways to sort of slice and dice that.

I think it's not just sort of is the measure itself concept actually meaningful, but is it, you know, does it have the psychometric properties that, you know, that we all sort of look for like is it reliable and a valid measure? And is the data that we're collecting actually, you know, accurate?

So I think it's all part of my thinking in that, but it's a great point. Perhaps we should call that out more explicitly.

MEMBER JORDAN: Yeah. Pierre, this is

Jack Jordan. I'd like to, you know, tack onto that, that I think one of the ways it seems very unnatural for CMS to do this validation, but I think it's probably the most valuable and useful, and that's really to turn this on at scale with your QINs, HENs, TCPI and others to use this and tell you what's wrong with it at scale.

You know, if you turn this on and you have that large group kind of working through can we use it, what's wrong with it, how can we fix it, rather than kind of having a contractor in the background do this at three hospitals or whatever, I think you'll get much more robust and richer validation that's meaningful to the participants in the hospitals.

If you try to do that, though, I know that seems kind of counterintuitive to the way, you know, a lot of this kind of work gets contracted out and thought about.

MEMBER YONG: Thanks, Jack.

CO-CHAIR TRAVIS: Dan, did you have another follow-up?

MEMBER POLLOCK: I did, but why don't we go ahead on in the interest of time?

CO-CHAIR TRAVIS: Okay. All right. Thank you for that.

Ron?

CO-CHAIR WALTERS: This is a very good discussion and I would lump it into the category of maturation and evolution of the MAP.

We've always used the terms parsimony and harmonization. But as I look back, it's always been from the perspective of the -- of the MAP's charge to give input to the MUC list or the CMS proposal measures.

So, I mean, even starting today either during the meeting or as feedback to the measures or just plain commenting on proposed rules, start to put these thoughts together in what am I doing for other programs and how does that really harmonize or not with the kind of work I'm doing for other areas, and does it add value in that perspective?

We haven't taken -- we've been, I

would say, informally addressing that in the past. We can't get every group -- everyone from every group in this room, but as representatives of a lot of different areas, that's the kind of feedback that you are asking for. And I think it's becoming ever more relevant for all the issues you heard mentioned earlier.

CO-CHAIR TRAVIS: Thank you, Ron.

Marty?

MEMBER HATLIE: Pierre and colleagues, I just want to really commend CMS for its work on person-family engagement and integrating it officially into your quality strategy.

I think it's been consistent over a number of years. You see CMS pushing that forward and it's transformative. I really think it is.

As healthcare gets more complex as it gets less acute, more ambulatory, the ground truth is that patients and families are going to have to be more engaged if we're going to get the outcomes we want to get.

So, it's just -- my only concern is that most Americans don't know about this leadership that's coming here and I think that's partly our job.

So I have a kind of awkward request that you do as much as you can to really talk about this transformative move and we'll do our part as well to get the word out, too, to people about the opportunities that are being created. Not just the point of care, but in policy venues and in quality and improvement work at the provider level. I think it's really, really important.

MEMBER YONG: Thanks, Marty. We absolutely agree.

CO-CHAIR TRAVIS: Any other comments from people, workgroup members that are on the phone?

(No response.)

CO-CHAIR TRAVIS: Okay. Andrea.

MEMBER BENIN: I'll just say quickly I think this is a lovely framework. There may be

some value to just mapping it to the IOM domains, the six IOM domains as people, I think, still think about those as a way to organize the stuff in their mind. So there may be some value as you're communicating either layering or mapping or at least alluding to that because people do attach to that.

And then I guess I could benefit maybe from a little bit of a comment around the extent to which the metrics, the little dots are multi-select.

To what extent would a little dot be in multiple of these groups or, in your mind, is it one-to-one kind of mapping? I mean, maybe that's still work to be sorted out.

I'm looking at this and trying to think of examples of ones that might be in multiple ones. I'm not really thinking of any, but is the idea that a little dot is always in one group or would a little dot be in multiple groups potentially and that would be okay, but --

MEMBER YONG: Yeah, it has -- I mean,

there are examples, and I can't think of one off the top of my head, where a little dot does map to multiple domains, you know.

So it's something we're trying to think through. I mean, certainly we've encountered this problem before with other frameworks, right?

For example, we're mapping to National Quality Strategy domains. Like oftentimes they're so broad that, you know, a particular measure can go to multiple categories.

And I think how we handled it there is we had identified a primary sort of domain and then a secondary domain.

So that could be one approach. But if you have ideas, we'd like to hear feedback. But, yeah, there are examples where a single dot may match multiples.

MEMBER BENIN: But I don't know that -- to me it doesn't matter. I like things that count in multiple areas, but it may just be that part of the discussion will be to be over about

whether how you guys think about it, you know. I don't know that it matters, per se, but --

MEMBER YONG: Yeah. From my perspective, I think there are pluses and minuses either way, right?

I mean, as you mentioned, if it maps multiple dots, perhaps that actually is a very good thing, right, because we're getting multiple ways and it sort of signifies its importance, potentially, is one way to look at it.

CO-CHAIR TRAVIS: And Maryellen.

MEMBER GUINAN: Thank you. So thanks for your great work here. We, I think, certainly support the initiative itself.

I would just caution in terms of any initiative that the unintended consequences are looked at as well either prospectively or a year-end review in terms of as we narrow down the set of measures being, you know, the goal is ideal, but what measures are left then have great significance.

And so I think it's important to

particularly for our members, Henry Ford being one of them that deal with large, vulnerable populations, that we looked at the measures that are left and make sure that the risk adjustment is adequate and appropriate because, like I said, they're probably going to have more weight and value in the long run. Thank you.

MEMBER YONG: Yeah. Thanks, Maryellen. That's a great comment and you're right. You're absolutely right. It's something we do think about and we probably should call that out more clearly in the slides.

It is one of the things that we'll talk about when we talk about measure-removal criteria. We pulled together some draft criteria for just initial sort of conversation to stimulate the conversation, but on there is unintended consequences.

CO-CHAIR TRAVIS: All right. Well, thank you, Pierre, for the overview. And I think it is a good way for us to get started, and to Ron's point, thinking about these issues as we go

through the measures themselves.

And maybe thinking about not just how they fit within CMS, but how they're fitting in other payment models just for us to kind of consider some of those crosscutting initiatives so that we can start contributing to the meaningful measure framework in terms of our action.

So thank you all very much for that and I'm going to turn it over to Kate who is going to get us started with some overview on how we're going to do our work today.

MS. MCQUESTON: Great. Thank you. So we'll begin with just an overview of the approach and the voting process. It should be a refresher from information that you guys have seen before.

Overall, the approach is a three-step process. First, we're going to provide a very brief overview of the program. Also an overview of the current measures in the programs.

You should also have this information in a handout. We know that it's a lot of

information for a slide, so it might be a little bit easier to see in your handouts, the information on the measures currently in the program.

Then we will be reviewing the measures under consideration for what they would add to the program measure sets.

When the workgroup evaluates the measures under consideration, you'll be reaching a decision about every measure.

The decision categories are standardized for consistency and each decision should be accompanied by one or more statement of rationale that explains why the decision was ultimately reached.

To facilitate the consent calendar voting process, the NQF staff have conducted a preliminary analysis of each measure under consideration.

The algorithm asks a series of questions about each measure under consideration. The measure was developed from the MAP measure

selection criteria, which were approved by the MAP Coordinating Committee.

And the preliminary analysis are intended to provide MAP members with a small profile of each measure to serve as a starting point for the MAP discussions today.

Here's an overview of the measure selection criteria. These are intended to assist MAP with identifying characteristics that are associated with the ideal measure sets used for public reporting and payment programs.

These aren't absolute rules. Rather, they're meant to provide general guidance on measure-selection decisions, and to complement program-specific statutory and regulatory requirements.

The central focus should be on the selection of high-quality measures that optimally address the NQF's three aims, fill critical quality measurement gaps and increase alignment.

There are four decision categories today. These are support for rulemaking,

conditional support for rulemaking, refine and resubmit prior to rulemaking, and do not support for rulemaking.

The MAP may support a measure for rulemaking for a number of reasons. For example, if it addresses a previously identified gap in a program or to help promote alignment, MAP may conditionally support a measure if the group thinks it's ready for rulemaking, but needs NQF endorsement or should need another criteria or condition.

Refine and resubmit, we have -- we're going to discuss this in the following slide, so we'll get more to it later about what exactly the category is. And then MAP may also decide not to support a measure for rulemaking.

So in terms of the refine and resubmit category, we wanted to note that concerns were raised about the category during the fall web meetings.

Originally the Coordinating Committee created this category with the thought that

measures under consideration receiving the designation would be brought back to MAP before implementation, but we do note that the HHS Secretary has the statutory authority to propose measures after considering MAP's recommendations.

In addition, there is a feedback loop that was implemented to provide MAP members with updates on measures on prior MUC lists.

And so we're going to discuss it a little bit more today and the Coordinating Committee will review the decision categories before their January meeting.

So as said, the Coordinating Committee already discussed this a little at their meeting last month and reiterated the intent of the decision was to support the concept of a measure, but recognize a potentially significant issue that should be addressed before implementation.

So as a result, the Committee suggested when moving into these meetings, that the category should be used judiciously.

The Coordinating Committee recommended

that the workgroups use this decision when a measure needs a substantive change, but also noted that there's a need for workgroups to clarify the suggested refinement to the measure.

So I'll pass this to Erin to provide some additional comments.

MS. O'ROURKE: Thank you, Kate. Good morning, everyone. So just to give a little bit of history of how we ended up here and some of the concerns that we heard from this workgroup, as well as the others, and what we brought to the Coordinating Committee.

So if you've been on MAP from the beginning, you may remember we used to have three categories. The middle was what we called support direction.

The Coordinating Committee changed that to conditional support to be a little more clear about what MAPs were saying and to echo what changes they may want to a measure.

We did receive some feedback that that was making it challenging for measures that were

still early in development to be supported, so we started reviewing those through a separate pathway.

We ultimately collapsed that when there were some process concerns, but created this refine and resubmit -- last year, I believe, was the first year we operationalized it -- to preserve what people liked about that, that you could echo your support for the concept of a measure, but, as Kate was saying, with the hope that it would come back to MAP with the full specifications prior to implementation.

However, that doesn't necessarily track with the statutory authority that the HHS Secretary has to consider MAP's input and move forward on the measure.

So I think what we heard this fall was some concerns that there's some discordance between the intent of the category and the limits of when MAP actually does review things. So we brought that to the Coordinating Committee to get some input.

We couldn't change the categories prior to these meetings, since this was only about two weeks ago. So we wanted to see if they had guidance for you all on how to operationalize it, anything they wanted to share about their intent.

As Kate was saying, they recommended this category should really only be used when a measure has a significant change that would require it to come back on the MUC list anyway so that MAP could see it again.

They recommended for other issues you may consider attaching conditions to a measure under the conditional support or not supporting the measure, but to use this when you thought there was a major issue with how the measure was specified and send it more back to the drawing board rather than minor changes or something that was more in the domain of the NQF Endorsement Committee.

This didn't come up at PAC/LTC since we had only one measure, but the Clinician

Workgroup used conditions to really specify what they would like the standing committees to look at, if it was something within the specs of the measure that are outside of what the MAP criteria addressed.

They tended to put some very specific things they wanted NQF to send to the standing committees when the measures came in for endorsement, a please-look-here type of flag, if you will.

So I think I just wanted to bring that to your attention to let you know that if you vote refine, there's no guarantee it will come back to you. You may see it just in an update in the feedback loop as you did in the fall.

So we just wanted to pause here and make sure everyone knew what their votes meant and that you could have the full set of information in front of you to consider when you do this and that we're being clear with anyone.

I know, Pierre, is there anything you wanted to share about how CMS operationalizes

these?

MEMBER YONG: Yeah. Thanks, Erin. So realize this has been an issue that came up actually across the workgroups. So glad we are having a chance to discuss it certainly from our perspective.

We really do value MAP's input. That's why we're here all day. We've had multiple staff on the phone and in person at all of these meetings taking copious notes and, you know, these are sort of hard choices that we make.

I mean, we are not opposed to bringing measures back to the MAP after considering MAP's input. However, there are certain times when, you know, as Erin noted, you know, the Secretary has the discretion to really, after considering the MAP's recommendations, proceed with, you know, proposing a measure for a particular program.

And, for example, sometimes, you know, there may be pressing sort of policy priorities

that, you know, we think that are really pressing that really drive those decisions.

So I do think, you know, having sat here for the past two days, I think the clinician workgroup really found a nice balance in terms of how they applied the different categories.

And it really was, as Erin was saying, thinking a little bit differently about sort of conditional support, including more explicit conditions in there so that the refine and resubmit category was used fairly sparingly.

I mean, of all the measures we had on the Clinician Workgroup, I think only two measures actually got refine and resubmit and the others were on the other three categories.

So I'll stop there, but certainly welcome any questions or discussions.

MS. O'ROURKE: Yes. And Ron, Cristie, could we pause for if people have questions or comments or anything to bring to the Coordinating Committee when we review these categories in January? We'd welcome any input from the

workgroup to take forward.

CO-CHAIR TRAVIS: Sure.

Nancy.

MEMBER FOSTER: Thanks again. And I really appreciate the explanation and the clarity around what refine and resubmit would mean.

I think my concern is it does not go to the measures for which I actually can see the specifications and can make a judgment or make a decision for myself about how to vote as to whether or not there's a big-deal change that I think needs to be made in the measure, in which case refine and resubmit might be appropriate, and those measures for which we don't yet have enough information.

And it's been more prevalent in the past, and I certainly recognize CMS for making sure they're bringing forward measures that have more meat to their bones than in some of the early phases, but I think at least in the past we've used refine and resubmit to mean nice concept, but we don't really see a measure yet

here.

So I would submit that the MAP is at a maturity level now, to your point, Ron, where we could actually articulate -- not today, but in some workgroup -- articulate what it is we expect to see in order for the MAP to actually opine on a measure.

And I suggest that because, for me, that line between did we get a measure to offer an opinion on, or did we get a concept and not enough detail to actually offer an opinion, is a big difference because I think the legislative language suggests, you know, we're giving you advice on a measure.

If we can't do that for CMS, then I think it would be right to say "Nice concept, bring me a measure," instead of trying to offer it up as opinion.

MEMBER YONG: Thanks, Nancy. And I think you bring up some really valid points. And my hope is, you know, based on those prior experiences, and I think we have brought you

measures --- or put measures on the MUC list for feedback which perhaps haven't been as developed as some other measures, but I think hopefully, you know, as we move forward and especially as thinking about the meaningful measures framework, have really tried to be much more sort of selective about which measures we put forward on the MUC list.

Hopefully you will see that reflected in this year's MUC list in terms of not only the number, but really the stage of development so that they have more meat on the bones, as you say, so that you have the sufficient information you need in order to make, you know, critical recommendations.

MEMBER JORDAN: Yeah, this is Jack Jordan. I think that Nancy's things were spot on. I think the example last year of the measure of multiple opioids at discharges or opioids and benzodiazepine really fit that, that it hadn't really been field-tested at the time it got all the way through the process to here.

And, you know, then in the intervening year being one of the three health systems it was tested in, I think a lot more insight kind of came into that measure and it was probably not really ready to get all the way to MAP before, at a minimum, having its kind of field-testing of its definition.

I think that's kind of a minimal requirement that should be there before it gets to this point.

CO-CHAIR TRAVIS: Thank you.

Lee.

MEMBER FLEISHER: Yeah. Following up, also the absence of NQF endorsement in some of these measures, that's where some of the issues of unintended consequences and really the way they're analyzed make so much of a difference.

So revise and resubmit for some without NQF endorsement may mean something different than for other measures.

And I think that --- I don't know if we can add that in, that something really needs a

more rigorous analysis because of the nature of the measure.

MEMBER YONG: Yeah. Thanks, Lee. And I believe --- and I think it was on the slides, but NQF endorsement was part of the criteria, I think, for full support, but --- and maybe Erin is going to comment on that.

I would just flag, I mean, I think we hear you. We certainly value NQF endorsement. We submit all our measures for endorsement processes.

I think just so folks understand the time lines, sometimes don't --- if you want to proceed sequentially through, like, development and then endorsement, then the MAP and then rulemaking, that could be like a five-year sort of time frame for a particular measure.

And so sometimes we think it's too important a measure to wait for that five years, really complete that sort of process in a linear fashion.

That doesn't mean we won't submit the

measure to NQF endorsement, but we understand its importance. And so that's why we continue to submit, but there are those sort of time line considerations because of, you know, just the sequencing of availability of endorsement proceedings, et cetera.

MS. O'ROURKE: And just to clarify, NQF endorsement is certainly a condition you could put on a measure and a conditional support that it should be reviewed and receive endorsement and that the workgroup recommends these are the areas the standing committee pay specific attention to during that endorsement review.

CO-CHAIR TRAVIS: Okay. Well, thank you for that overview. And I imagine that as we go through the measures, we might come upon some practical reasons to pause for a moment and be sure that we understand, you know, how to use this category.

But, also, I think it is helpful that the Clinician Workgroup has already gone through

this process and once again trying to share with us, you know, maybe some ways they found them -- found ways to kind of give the kind of guidance that we want if there are other categories to which that might work. So feel free as we go through this to --- we can come back to this conversation.

So, Kate, you have some more things to tell us?

MS. MCQUESTON: Yes. So now we'll do a quick review of the voting instructions. So we have a few key principles.

The first is that there is a threshold of more than 60 percent of participants to reach consensus. This threshold was decided on because it was a good benchmark for allowing multiple stakeholder groups to agree to reach the threshold and just to note that those who abstain from voting do not count in the denominator.

Today every measure under consideration will need to receive a decision either individually or as part of a slate of the

measures. All measures will be voted on or accepted as part of the consent calendar.

Workgroups are expected to reach a decision on every measure. There is not a category of split decisions, which would mean that the Coordinating Committee decides on the measure.

However, the Coordinating Committee may decide to continue the discussion on a measure if it's deemed to be a particularly important matter of program policy or strategy.

So the way the voting will go, after introductory presentations from staff and the chair to give context to each program, the voting will begin.

And you can use the in-meeting -- in-person meeting discussion guide as a reference. And essentially the content is organized into a series of consent calendars where measures are grouped for the purposes of discussion and voting.

For our measures, these are organized

around programs. Each measure under consideration will have been subject to preliminary analysis based on a decision algorithm approved by the Coordinating Committee. And the discussion guide will note the end result of the preliminary analysis, one of the four decision categories, and provide rationale to support how that conclusion was reached.

So the first step of voting is that staff will present a group of measures as a consent calendar reflecting the result of the preliminary analysis using the MAP selection criteria and programmatic objectives.

Next, measures under consideration can be pulled from the consent calendar and become regular agenda items.

Co-chairs will ask the workgroup members to identify any measures under consideration they would like to pull off the consent calendar.

Any workgroup member can ask that one or more measures under consideration be pulled

off the consent calendar and removed for individual discussion.

Many of the measures we're looking at today have already been pulled from the consent calendar in advance, but we -- you can also remove a measure at any time during the meeting for discussion.

The workgroup members should clarify if they are pulling a measure for discussion only or if they disagree with the preliminary analysis result and would like to vote on a new motion.

Measures pulled for discussion will focus on resolving clarity questions, for example, if during the course of discussion a workgroup member determines the discussion has shown the need for a new vote, a workgroup member can put forward a new motion also during that discussion period.

There are many reasons members can pull measures, including disagreement with the preliminary analysis or the fact that new information is available that would change the

results of the algorithm.

Once all measures that the workgroup would like to discuss are removed from the consent calendar, the co-chair will ask if there's any objection to accepting the preliminary analysis and recommendation for the MUCs remaining on the consent calendar.

If a measure is not removed from the consent calendar, the associated recommendations will be accepted without discussion.

So for discussion and voting on measures, workgroup members who identify the need for discussion will describe their perspective on the use of the measure and how it differs from the preliminary recommendation in the discussion guide.

If a motion for conditional support or refine and resubmit is suggested, the member making the motion should clarify and announce the conditions or suggested refinements.

Workgroup members assigned as lead discussants for the relevant group of measures

will be asked to respond to the individual who requested the discussion.

Lead discussants should state their own point of view and note whether or not it's in agreement with the preliminary recommendation or the divergent opinion.

The co-chairs will then open the discussion among the workgroup. Other workgroup members should participate in the discussion and be ready to make their opinions known.

However, one should refrain from repeating points already made or presented by others just in the interest of time.

After the discussion, the workgroup member who made the motion has the option to withdraw the motion, if they would like. Otherwise, the workgroup will be asked to vote on the motion.

If the motion for conditional support or refine and resubmit --- if the motion is for conditional support or refine and resubmit, the chair can accept the additional conditions or

suggested refinement based on the workgroup's discussion.

If these conditions or refinements are contradictory to each other, the chair should ask for a separate motion after the original no motion has been subject to a vote.

The final step is the tallying of the votes. If the motion put forward by the workgroup member receives greater than 60 percent of the votes, the motion will pass and the measure will receive that decision.

If the motion does not receive greater than 60 percent of the votes, the co-chairs will resume discussion and develop another motion. To start discussion, the co-chairs will ask for another motion.

If the motion receives greater than 60 percent of the votes, the motion will pass. And if not, the discussion will resume.

If no motion is put forward by the --- if no motion put forward by the workgroup achieves greater than 60 percent, the preliminary

analysis decision will stand.

And then, again, those who abstain are discouraged, but will not count in the denominator.

And then before we begin, you've seen this slide before with our time line of events. So currently we're in our in-person meeting stage.

After our in-person meeting, the decisions will go out for public comment. And then in January, the MAP Coordinating Committee will meet again to finalize the MAP's input. The guidance for hospital programs will be finalized February 15th.

Okay. So I think we can go ahead and begin with pre-rulemaking input. We'll be looking at five programs today. Sorry, this looks like an error. There are no measures for in-patient psych.

Okay. So the first program that we are looking at today is the End-Stage Renal Disease Quality Incentive Program.

This is a review of information that was provided during our web meeting, but this is a pay-for-performance and public reporting program.

The program is designed to provide payments to dialysis facilities that are reduced to facilities do not meet or exceed the total required performance score.

Payment reductions are on a sliding scale up to a maximum of two percent per year. And the program goals are to improve the quality of dialysis care and produce better outcomes for beneficiaries.

These are the measures currently in the program and also included in your handouts. It's a little bit easier on the eyes.

There are two new measures for 2021. And these two measures are replacing the current vascular access measures that are included in the program.

CMS has identified several high-priority domains for future measure

consideration. The first of these is care coordination.

They note that ESRD patients are a vulnerable population that depend on a large quantity and variety of medication and frequent utilization of multiple providers. And they note that medication reconciliation is a critical issue.

They also note that dialysis facilities pay a substantial role in preparing dialysis patients for kidney transplants and coordination of dialysis-related services among transient patients has consequences for a nontrivial population of ESRD patients.

The next area that they've noted is safety as ESRD patients are frequently immune-compromised and experience high rates of bloodstream infections, vascular access-related infections and mortality.

The next area is patient and caregiver-centered experience of care, which is one of the main goals of the program. And this

includes issues such as physical function, independence in cognition.

They note that quality of life measures should also consider the life goals of a particular patient where feasible.

And then, finally, access to transplantation noting that obtaining a transplant is an extended process for dialysis patients, including education, referral, waitlisting, transplantation, and follow-up care.

CO-CHAIR WALTERS: So for each measure group, the first thing we'll ask for is for public comments.

And then we'll start the process, as outlined further earlier, as far as reviewing the ones that have been pulled, whether there's any others to be pulled, and then go through the discussion, where again the puller talks first, the lead discussants talk second, and then anybody else provides input, and then we proceed to a vote.

So at this time, I'd like to ask for

public comment on the ESRD measure set.

THE OPERATOR: Okay. At this time if you would like to make a comment, please press star and the number one.

(Pause.)

THE OPERATOR: And there are no public comments from the phone lines.

CO-CHAIR WALTERS: Thank you. Is there any public comment from people attending within the room?

(Pause.)

CO-CHAIR WALTERS: Okay. I see none. So there are three measures. Again MUC17-176 med rec, MUC17-241 the waitlist, and MUC17-245 the waitlist ratio.

So, two of those, the last two, have already been asked to be pulled for discussion by Nancy.

The first one has not been pulled yet and remains on the consent calendar. So I will -- we will put that up for auction right now. Going once. Okay. I see that Andrea and Anna

and -- anybody else? Okay.

MEMBER BENIN: Could I just ask for clarification about how this program works? Would this be for measurement --- what measurement year and what payment year? I'm just trying to understand this, the details of this program.

We would be adding these metrics to measurement year '19 and payment year '21? Is that what ---

CO-CHAIR WALTERS: '20-21.

MEMBER BENIN: '20 and '22? Do we know?

CO-CHAIR WALTERS: Not '18. That's for sure.

(Laughter.)

MS. DUSEJA: So the earliest we can actually propose would be for next year, but it would be not for two years after the fact, if that makes sense.

So it would be 2018 we would propose it in the rule and then --- if we propose it

based on the feedback, and then it would be 2020 in terms of it being taking effect.

CO-CHAIR WALTERS: Okay. Let's go to the people who ask that it be pulled first.

Anna.

MEMBER DOPP: It will be for discussion only. Is that -- so related to this when this measure went through the patient safety project last fall, we indicated our support overall for the measure.

We recognize that medication reconciliation meets those high-quality domains that were just outlined.

We also appreciate that the measure addresses a gap that was identified by this group last year where there needed to be further identification of and better management of the comorbid conditions of this patient population.

And so we recognize that medication reconciliation might also help with that, too. So we appreciate the need for the measure and support it being in there, but we do want to

point out that this is one of three med rec measures that have been endorsed from NQF.

There's four total, and then there's other from commercial payers or other groups that are looking at it.

And just thinking about the experience of care of the patient if there's different processes and expectations for med rec throughout the course of care, it just doesn't allow for a consistent establishment of baseline.

And so we'd like to see in the future more consistency in how med rec is defined and measured.

And so I realize that this group doesn't necessarily address it, but I just felt like it was important to make that comment and hopefully see some consolidation, harmonization, so that there's not this different measurement in these different areas whether it's inpatient or dialysis centers, et cetera.

CO-CHAIR WALTERS: Very pertinent to our earlier discussion. You're right. It can be

med rec measure for each location or there can be med rec.

Yes. All right. We have two lead discussants. Helen is next.

MEMBER HASKELL: I just wanted to ask a question of Anna.

What is the variation in med rec in these different areas? I thought that these measures were harmonized.

MS. MCQUESTON: There is variation in terms of whether it's just a checkbox whether it was done, or whether or not it meets certain criteria. So one of them meets three different levels of criteria for how the med rec was conducted.

And then there's just some differences between who can do it and what's collected overall.

CO-CHAIR WALTERS: Yeah. We all know --- everybody that does med rec knows there's med rec and then there's med rec.

Helen, did you have any input as a

lead discussant?

MEMBER HASKELL: Well, that was one of my concerns that, you know, I know that there are issues with med rec and having it done well.

And is there --- is there any way to --- for the measure to actually enforce that? And if not, is it worth doing?

But at the same time I can see that in this, you know, in this setting it seems important to have that for people who might not be traversing these other settings.

So all in all I, you know, I support the measure, but, you know, I'd like to hear more discussion of it.

CO-CHAIR WALTERS: Okay. I think you might get your wish very shortly.

DR. ROACH: So this measure is, like you said, just medication reconciliation and doesn't include management.

We have --- this has --- was a measure that got the support of CMS and of the community. We're working on developing the measures further

to work on management as well as medication reconciliation.

But given the safety issues, the thought that getting one that dealt with medication reconciliation only to start was important.

CO-CHAIR WALTERS: Okay. I might also mention that currently on the consent calendar it is support. I have not heard any motions yet to change that. We'll proceed now with any other input anybody else wants to give.

Rich.

MEMBER KNIGHT: Yes. My name is Richard Knight, and my colleague Paul Conway couldn't attend today. But from a patient perspective, I support this very critical issue.

When you really look at --- I always go right to the end. How does this impact the patient? How does it impact the quality of life?

And when you have a patient taking this number of medications as articulated here and then you have it from different providers, it

can get to be very confusing.

And one of the things that I want to emphasize is that a number of patients are just given pills and they take them. And I've been in a hospital and been given the wrong dose of medication and had some pretty serious arguments about I can't take that, it will harm my kidney.

So I think that it's important that the medical -- that the reconciliation is done and it needs to be done in the context of the overall care.

Many things that are done at a dialysis facility, they have so many things to do, are done in a checklist fashion, but this was something that really goes to the heart of the health of the patient because it's not just your kidneys. We're talking about heart, the impact on the heart. We're talking about eyes, eye stroke and things of that nature.

So I think that it does need to be more emphasis put on this, and we need to understand how important that it is.

**CO-CHAIR WALTERS: Thank you and I apologize. I forgot you were filling in for Paul.**

**Greg.**

**MEMBER ALEXANDER: I just --- I know this is the MAP Hospital Working Group, but I do a fair amount of work in long-term care facilities. And I just want to say that we address med reconciliation pretty heavily in long-term care facilities as well. And a lot of dialysis patients live in those facilities and transition out and go to the dialysis clinic and then come back.**

**And so med reconciliation really stretches across these different settings, like we said.**

**But don't forget long-term care because it's such an important -- a critical area for people who live in those residences who have dialysis.**

**Make sure that those reconciliation procedures are really well vetted across**

different systems so they're the same, you know, so you're measuring the same thing.

CO-CHAIR WALTERS: Keith.

MEMBER BELLOVICH: Along the lines of representing the kidney community at large, both the large, small, and medium-sized dialysis providers, as well as the entire kidney community, we're in full support mainly because of the NQF endorsement that exists.

It is a highly reliable measure that has been proven and, therefore, we have a very strong support for this measure.

CO-CHAIR WALTERS: Marty.

MEMBER HATLIE: Two people so far have raised the potential conflict between metrics from CMS and metrics from commercial payers.

And I operate under an assumption -- I'm just wanting to test it a little bit with the wisdom in this room -- that when CMS comes out with a measure set, the market moves.

I mean, is there some --- is that a valid sort of general assumption that when we do

this, there is adjustment in the field?

(Pause.)

MEMBER HATLIE: Okay. I guess I'm getting wisdom in the room because I do think that the med rec issue is important to patients and I want to support this very much, but I also am, you know, I'm sensitive to the burden issue.

MEMBER EVANS: So as an active clinician in this field, I just attended a meeting last month on one of the largest for-profit dialysis clinics and they initiated that prior to this because of that. So, yes, it does make a difference and I think it's a very important measure.

And I do like the fact that CMS outlined who were the professionals to actually do that reconciliation because that's very important.

CO-CHAIR WALTERS: Janis.

MEMBER ORLOWSKI: So good morning. First of all, just hello to everyone. I'm new to -- not new to NQF, but new to this committee. So

hopefully I will provide positive information.

I'm the chief healthcare officer at the AAMC, but I'm also a nephrologist. And so I have a particular personal and professional experience with this.

Pierre, you're going to be very surprised. I strongly support this.

(Laughter.)

MEMBER ORLOWSKI: I don't think I've ever said that with a measure. So that's --- and I think that there's two comments that I would make and it would just echo.

I have to say having just made rounds yesterday, that the number of medications and the complicated medication schedule is so different -- is so difficult and has to be monitored so carefully that this is really something.

And we all know that dialysis patients have a couple of providers, they actually touch many different aspects of the care system and so I really think that this is important for quality of care.

I don't believe that when CMS says something, that the other insurers move. I think what they do is they say, "What a good idea, let's develop our own."

And I think that --- and so making a comment, I think that there does have to be harmonization of measures. And if CMS developed something and someone else developed something that's better, then we should harmonize those measures.

But I will tell you from being in practice for a very long time, that a harmonization does not occur, there's differences in timing and reporting, you know, whether they report monthly or quarterly or whatever, and it really does cause a tremendous regulatory burden for us.

So I am absolutely in favor of this because it is high-quality care, and what people should do is then harmonize this requirement.

CO-CHAIR WALTERS: Okay. Thank you for the lively discussion. I have not heard any

other alternative proposal.

This --- going once, going twice, going three times. This remains on the consent calendar as support.

Okay. Now let's move on to MUC17-241, which is the percentage of prevalent patients waitlisted. That has already been asked to -- that was conditional support. The conditional support was for endorsement.

That has been pulled from the consent calendar by Nancy. So Nancy goes first.

MEMBER FOSTER: Thank you, Ron. And I'm looking forward to an education on this one. First of all, agree with the condition that was put on here that this really needs to be reviewed and endorsed by the National Quality Forum before it should be moved forward into a program, but the reason I'm going to suggest that we do not support it is around some of the comments that were made prior to our meeting.

And questions were raised around whose responsibility is this, why are we proposing to

measure the dialysis unit around who's on a waiting list for the transplant surgeons.

Help me understand what the relationship is here and what responsibility the dialysis center would have for this.

And then the second issue I want to raise is around the risk adjustment factors for this measure, you know.

It seems to me that there are a number of factors that would influence whether or not the patient is on a waiting list and want to really understand how robust this set of risk adjustments would be here because it would not be just -- I believe not just clinical conditions that would need to be risk adjusted for, but other factors, social risk factors may come in to play here.

And then on this measure as we looked at the C-stat, it was not impressive. I know that will be a discussion item for the steering committee when they come up, but would certainly want to either put a condition on it or urge the

steering committee, if this does go forward for NQF endorsement, that they really pay careful attention to whether or not this has the scientific properties it needs to assess the issue that it's intending to measure.

And then finally, I guess I don't fully understand here what's the right percentage of people being on the waiting list? So what are we measuring and how are we trying to influence this?

So lots of questions, but my recommendation to put on the table is do not support.

CO-CHAIR WALTERS: Okay. We'll now go to the lead discussants --- yes, Pierre, you can respond.

MEMBER YONG: If we can, and I think we do want to respond to Nancy's comments, but I thought it may be helpful since there are two --- we think of these as paired measures, the two transplant measures. Thought it may be helpful for the committee if we just address why we have

two measures even though we're discussing one of them first.

So I'm going to turn to --- Jesse, I think you were going to do this.

DR. ROACH: My name is Jesse Roach. I am a nephrologist that works at CMS. So the rationale why we have two of these measures, so we have the SWR, which is the waitlist measure, which is an incident measure.

So what it measures is the number of patients that are in the first year of dialysis put on the waiting list.

And then the other measure, which is the PPPW, which is a prevalent patient measure, is how many patients after the first year you have on the waitlist.

And there's a couple of reasons why we have two measures. The first reason is we have the incident measure, the SWR measure, because we believe that getting someone on the waitlist is a different activity than maintaining someone on the waitlist.

So there's survival and patient morbidity and mortality advantages to getting the transplant in the first year.

We also think that when someone gets on dialysis, there's a significant amount of coordination of care that has to go on and education of the patient to give them their options for transplant.

So we think getting someone plugged in, in that first year is especially advantageous, which is why we have that measure.

Maintaining someone on the waitlist is a different activity which is more of a maintenance of health to keep them healthy enough to keep on the transplant list and we think that patients that are after the first year deserve that benefit.

Furthermore, if we only had the incident measure, there wouldn't be incentive to -- there wouldn't be the incentive to work with patients that are after that first year, so patients that have been on dialysis for years.

And if we only had the prevalent patient measure, there wouldn't be the incentives to work with patients --- or there wouldn't be as much incentive to work with patients in the beginning when it's so crucial to get them set up for transplant.

CO-CHAIR WALTERS: Okay. Keith, I missed the fact that not only were you a lead discussant, but you also asked that we pull some measure.

MEMBER BELLOVICH: That is correct. So I appreciate Nancy's comments and I wish --- I'm very appreciative of all that you've proposed because basically those are the same rationale behind Kidney Care Partners' assessment of the same measure.

And they do apply to both of these proposals. And the main thing, indeed, that it does not meet NQF endorsement criteria is the first and foremost, but also holding dialysis units accountable for performance or the decision-making of transplant centers is ---

there's very little interrelationship.

Yes, there's an important part of education, guidance, and assistance in getting to that end point. But, unfortunately, because of access to a variety of transplant centers depending on where these patients are located or being dialyzed, they may be dependent on only one center who has the subjective criteria that they apply in their own domain that doesn't necessarily give them an opportunity to go across to other facilities or they may not have the resources.

Health is not the only factor related to maintaining your stability and eligibility for transplant either. We know that there's a lot of insurance purposes that the transplant centers will apply.

Sometimes there's patient choice, which is one thing that we strongly are proponents of and that patients make the decision of whether they truly want to be eligible, not just the fact that their age is less than 75

years of age.

We think there's a lot more sociodemographic factors that go into that decision-making about being eligible for transplantation.

And what we've seen in other measures in the past, is that not all measures apply equally based on dialysis facility size.

Smaller facilities in a location where they're near a transplant center that's turning over patients reliably may actually be reflected poorly merely by getting their patients transplanted quicker versus waitlist times which do vary across the country, thereby impacting and reflecting in the dialysis unit the fact of whether they're transplanting aggressively or not as aggressively or based on the transplant center's size.

So for these reasons Kidney Care Partners does not support either of these measures, 241 or 245.

CO-CHAIR WALTERS: Okay. Greg.

MEMBER ALEXANDER: I'm a subject matter expert, so I don't have anything to do with KCP or the American Hospital Association, but I came to those same conclusions on my own.

Just looking at some of the comments that they made, they made sense to me, you know, why these --- why this waitlist -- why there may be problems with this waitlist measure.

One of the things that I didn't really hear mentioned completely, or at least it wasn't clear to me, is that -- the way that some of the --- the reasons why some waitlist times may vary, one of those being there was some discussion about the evidence of the absence of chronic conditions or presence of chronic conditions and how those are documented. And it could be different among different transplant centers or dialysis centers.

And so the reasons that somebody might or might not be put on the waitlist could be dependent on the decisions made for that.

And so it seemed to me like that

criteria needs to be applied consistently and it's not very well explained how it's applied or if it's consistently applied in this measure.

I also noted the C-statistics that they talk about, they recommended 0.8. And this would range from 0.67 to 0.72, which is below customarily what is expected with this sort of variation.

And then I know you spoke about the redundancy between 241 and 245, but I wasn't really --- or why they're needed, but I didn't really understand what the redundancy was.

And if there is redundancy, then that's not really --- I need some clarification on what that redundancy is.

I think it's an important measure. I don't know that I would necessarily go to the point of not supporting it.

This may be one of those that needs one of the refine and resubmits which has a substantial change to the methodology and the measure itself to clarify some of the issues that

were brought up.

CO-CHAIR WALTERS: Marty.

MEMBER HATLIE: I, at this point, I support the recommendation to conditional support pending endorsement.

The thing about this measure that speaks to me is the incentive to really educate patients. I do worry that whether it is profit motive, that incentive is important.

Richard, I don't mean to put you on the spot. I'm glad you're raising your hand because I'd love your point of view on this. The patient's voice, I think, would be really important here, but it is that incentivization of education of potential candidates that really is behind my supporting recommendation.

CO-CHAIR WALTERS: Okay. Good. The day is started. Now we got us a conditional support, a refine and resubmit, and a do not support. All right.

(Laughter.)

CO-CHAIR WALTERS: First one up was

Janis.

MEMBER ORLOWSKI: I am going to recommend not supporting both measures. The reason for doing this is that I believe that referral for transplantation is very important and is the job of the nephrologist and the renal team as they look at renal replacement.

So whether you do dialysis in a unit, whether you do home dialysis, whether you do peritoneal dialysis, whether they are considered for a transplant, these are all decisions that need to be explained.

The patient needs to be educated, and it's the responsibility of the nephrologist and the renal team, and often should be done before dialysis is initiated, if possible, depending upon when the patient presents and what their illness is. These are all things that should be done.

What we have done in the nephrology world before is we've made sort of the dialysis unit the checkbox, you know. It sort of stops

and says, okay, you know, did all these things happen? Were there educations or whatever?

And I do believe that they can play a role in helping with that checkbox, but I don't believe, for the reasons that have been stated, that this is an appropriate measure for the dialysis unit.

Secondly, I think the measure is not how many folks you have on a transplant list, but whether the education occurred and whether the referral occurred. And so I believe we're measuring the wrong thing here.

And finally, this is a measurement that is more appropriate on the nephrologist and the transplant group, but the dialysis unit has in many, many areas, has helped to make sure that that patient education and social services and dietary, they play a very important role in providing additional education and being sort of a stopgap when all the appropriate education and referrals have not occurred, but it's not their principal responsibility.

CO-CHAIR WALTERS: Okay. Ann Marie, I think you're up.

MEMBER SULLIVAN: I understand the question about the ultimate responsibility being the transplant center, but I think the goal of this is to make sure, in some way, that the dialysis centers are doing absolutely everything possible to move that client to a waitlist and to get them into the transplant center.

That doesn't mean that everything is within their control. It reminds me a little bit of the readmission measure, 30-day readmissions, you know.

We do it, but everything isn't in our control when someone leaves the hospital, but we've been able to make gains over time in that readmission rate.

So I think the goal here is to push and do everything possible not necessarily to have 100 percent on the waitlist. So I'm not as concerned that there are exogenous factors that maybe can influence, I think it's just to keep

the dialysis centers right on in terms of pushing as much as they can to get clients on a waitlist.

And if you just use referral or others, those are kind of process measures. Actually sitting on the waitlist, to me, seems a little bit more like an outcome measure.

So I would go for conditional support maybe with modifying it, but I think that there's value overall in the measure.

CO-CHAIR WALTERS: Lee.

MEMBER FLEISHER: So I think Janis used the right word of "appropriateness," and it's almost an appropriateness criteria.

We're trying to get whether or not both the nephrologist appropriately refers, but the transplant surgeons in the center appropriately accepts.

And, therefore, whether this is not endorsed or revise and resubmit to try to get closer to whether or not the appropriate number of patients are on it, because I don't think this measure achieves that because of the pitchers and

the catchers as we talked about.

And I think that both need to be involved in the --- and the transplant centers are not appropriately integrated into this in a robust way from a risk adjustment.

It's only a patient risk adjustment, it's not how the center says, "Yes, we'll accept them."

CO-CHAIR WALTERS: Sean.

MEMBER MORRISON: Yeah. I'm going to speak as, actually, a subject matter expert in disparities, which is my other hat, and I just wanted to reiterate the NQF staff's conditional support.

And the reason behind that are several-fold. And I think it is about not making the perfect the enemy of the good here.

We know right now that close to 80 percent of the dialysis centers are now a for-profit business, 70 percent are controlled by two companies, and one of those companies reported a 350 percent profit margin.

We also know that there are very good data that demonstrate you are much less likely to be referred to transplant if you're in a for-profit rather than a non-for-profit transplant center.

And so right now, all the financial incentives and whether you agree with tax status or not, all the financial incentives now support continuing somebody on dialysis rather than referring to transplant.

And right now there are no measures, at least when I reviewed before this committee, that actually protect patients from unnecessarily long dialysis.

And we also have substantial data over the years that people do --- they live longer, they live better following transplant than on longstanding dialysis. Those are the data.

And, yes, there is the individual patient or the individual nephrologist who may make a different decision. But if we're looking at this from a policy perspective across a

population, then I think that we do need measures to be able to protect patients.

Is this the perfect measure? No. Then why is it a conditional? Because it hasn't gone through NQF endorsement yet, but I certainly would urge this group not to either reject it or to send it back for whatever revise and revision is under this year's measure, but think about the fact that does this measure protect patients who are very vulnerable in a system that all of the data right now, every single study, demonstrates that patients are not referred to transplant early enough. So I would just make that comment.

CO-CHAIR WALTERS: Thank you. By the way, the method to my madness is to let people who have not spoken yet, speak. And then we'll circle our way back kind of for any rebuttals that are necessary, so to speak, right before we vote.

All right. So, Beth.

MEMBER EVANS: So I want to bring up about the SWR measure first. And my concern

about that is they are excluding patients who are already waitlisted in --- being in that ratio and of course other people are institutionalized, et cetera.

But, to me, when you've selected that exclusion out, you're pretty much saying that the people who are coming in are the ones who haven't had --- or have had limited or no pre-ESRD care from a nephrologist.

Most of those people will already be started on the transplant list work-up and achieve it within that year if they're already in that process, and the dialysis clinic won't make a difference in that. That's part of their plan, the patient's plan.

The other patients who come in who have not had or very limited nephrology care, have so many issues that first year that need to be, to me, placed at a higher priority, we need an access that's a functional access. Not needing transplant is not important, but there's many issues.

I would rather have us not consider and not vote for that SWR measure because if they're truly already on that path, they will be in it, but I do feel that prevalent patient waitlist is an important measure.

The point that hasn't been brought out is the relationship between the dialysis staff and that patient is very strong, and patients listen to them very much.

And that tech who's placing that needle, they're the important provider to them. And if they don't know anything about transplant, have no idea of what these outcomes are, that may sway the patient to not pursue transplant.

And so I do feel if we put in some type of measure that transplant is the goal that we need to be at least attempting on these patients, is very important.

CO-CHAIR WALTERS: And I do realize from the first discussant, that it's very difficult to not talk about these in the same sentence, so just process that in your mind. It

will pay off in a little bit that we've actually talked about both of them.

Sarah.

MEMBER NOLAN: So Sean said some of what I was going to say, and I will just add that it is not only the profits or for-profit or not-for-profit status of the dialysis center that's at play here, I mean, it's also the fact that there is a big differential in reimbursement by private and public payers.

And that as CMS has laid out in the role that they released last year, there's clear evidence of steering of patients going on, which is supported indirectly by the two dialysis providers that you referenced.

And that that, in turn, has a very clear impact on whether people are placed on waitlists because people who are receiving premium support, lose that premium support when they have a transplant.

And if they have no evidence of care following the transplant or the ability to get

care following the transplant, are less likely to be placed on the transplant list.

So we think that some sort of measure, whether these are exactly the right measures or need some tweaks, but some sort of waitlist measure that holds dialysis centers accountable for people being --- receiving transplants is important. So support this.

CO-CHAIR WALTERS: It's important to state what you're recommending. So as you've heard so far, we've had support, do not support, and conditional support, and refine and resubmit.

Helen.

MEMBER HASKELL: Well, I just really am sort of echoing some of the earlier ones. I'm concerned about this that it's really a blunt instrument that we are sort of measuring the wrong thing and attributing it to the wrong people. That it needs to be more a decision between patient and doctor and not something that anyone's really putting pressure on the patient to do.

So I feel as though this is a measure that is just sort of unnecessary in terms of what the patient is doing.

CO-CHAIR WALTERS: Rich.

MEMBER KNIGHT: Thank you. First of all, I support both measures and I am a patient, but I also want to put on my hat as --- I teach graduate/undergraduate courses in business policy, which looks at industry structure.

And the very business model that is set up to which the gentleman referred to down here, you have 70 percent of the market control by two businesses, which is an oligopoly, there's certain behavior that takes place that is not necessarily intentional, but it just turns out that it may not be the best interest of the patients.

What Janis referred to earlier I agree with, but the fact is, is that 62 percent of the patients enter dialysis from the emergency room. So the counseling and education that we talk about, that doesn't happen, so we have to deal

with the situation as it currently exists.

Patients need to be educated, the incentive needs to be there so that they can get waitlisted.

The reality is, is that patients die on dialysis. And if they're not in the sooner, the better. If it occurs, if it does not occur and they're on dialysis for a number of years, the body deteriorates, and then you may not qualify. So the wait is long enough as it is.

Fortunately, they have changed the rules so that you can go back and make up for time that you were not listed.

When I was on dialysis, that wasn't the case. I didn't believe in the list. I went out and found my own donor because I looked at the numbers. I understand the numbers, but I think that for the patients overall, that these measures will be of great help to them.

The whole notion of education is important, but it's a question of who is doing the educating and there's a big difference in

that.

So as the independent patient organization, our viewpoint is that it is important for patients to be educated, placed on the waitlist, so that that increases the chance of them having a transplant, which is the ultimate renal replacement therapy.

And I also want to note that it is true that the non-for-profits have a much higher referral rate generally because they deal with a much fuller spectrum of the renal continuum -- not just on dialysis, but they start early on with the thought of real identification, slow to progression pre-emptive transplant.

Again, a very, very different business model. So I think that the incentives are in place that in some times you look at a process and you don't necessarily look at the patient outcomes. That's a concept.

But when we really look at what's going on, the numbers say something else. So I support it, again, both measures.

CO-CHAIR WALTERS: Keith.

MEMBER BELLOVICH: I just want to reiterate our position, and I take offense as a nephrologist myself of painting a broad brush that this is all about for profit. I think that's the wrong --- the wrong position or wrong direction to take. It still becomes patients first.

And for those same reasons stated earlier, that is the main reason is that why the dialysis unit should not be held accountable to these outcomes, there's so many other variables that work.

And profit is not the driving force here, it is a multitude of variables both sociodemographic --- our lack of endorsement or our vote for nonsupport is not a vote in --- not in favor of transplantation. We strongly encourage transplantation, and agree with Sarah's comments about emphasizing education, other measures that these measures don't cover.

CO-CHAIR WALTERS: Before we vote, we

need to be moving. Last comment from the measure developer.

DR. ROACH: Thank you. So there's a lot of things that were brought up here. So I'm going to try and go point by point on them.

So in response to the concerns that this isn't the responsibility of the dialysis unit, we believe that this is a concept of shared accountability.

We have other measures such as the readmission measure, in which there has to be coordination of care between transplant or between other facilities and the dialysis units, so other facilities being the transplant centers and the dialysis unit.

The benefit of transplants is significant. Depending on the study, 40 to 80 percent mortality benefit over staying on chronic dialysis, which is why it's so important that we have this measure.

And when I was practicing dialysis when I had a patient that wasn't listed, I

coordinated with the transplant center, with the dialysis facility, and we --- and the --- I'm sorry -- with the transplant facility and worked to get that patient listed. So it's a common effort and it's shared accountability.

We realize that some transplant centers aren't going to list every patient, but this gets measured on a facility level and this can --- and this can be evaluated compared to benchmarks. The TEP had support for this measure and we plan on submitting it to NQF.

As in reference to the concern that we should adjust this for transplant center rate, so when we did do testing on this measure, we looked at that looking at transplant center rate adjustment and found it wasn't statistically significant. And it's unstable depending on how a small percent of machine values are handled.

The C Index for both the model with and without a transplant rate --- center rate adjustment is 0.72 suggesting no improvement.

The IUR decreases from 0.82 to 0.79

when you add the transplant center rate to the model suggesting a small decline in reliability.

And when we looked at it and we added an adjustment for transplant readjustment, very few facilities, 3 percent, were reclassified. And the majority of those were to the disadvantage of the facilities.

What's next? So the comorbidity and socioeconomic status adjustments, we decided to include comorbidities as an adjustment in the incident measure, in the SWR, because we did feel that comorbidities that affected a patient's survival for the first year would make them less likely to be listed.

And so patients that were sick and had comorbidities that were likely to cause mortality in the first year, we did not think those should be counted.

However, for the prevalent measure for patients that have survived after that one year, we thought that that was a cohort of patients that were generally healthier and -- because they

had survived that year and they deserve the benefit of being --- they deserve the benefit of having access to transplants.

For instance, a diabetic patient might have worse outcomes or be less likely to be listed, but we feel that that diabetic patient still could be a potentially good transplant candidate and shouldn't be excluded.

And the one thing that I can't talk about is the C-stat comment that someone brought up. We have our contractor on the line. I was wondering if we could open it up just so they could comment on that.

MS. O'ROURKE: Operator, can you open the line?

THE OPERATOR: Yes, ma'am. To make a comment, please press star one.

DR. ROACH: Jennifer Sardone.

MS. O'ROURKE: Can you open the line for Jennifer Sardone.

THE OPERATOR: The line is open.

MS. O'ROURKE: Okay. Thank you.

DR. MESSANA: Yes. Good morning. This is Dr. Joseph Messana from the University of Michigan Kidney Epidemiology and Cost Center. Good morning.

So the question about C-statistic that was raised suggesting that there is a standard of 0.8 for a C-statistic for a measure submitted to the National Quality Forum is a bit of a surprise to me.

I was not aware that that's an NQF requirement, and I would request clarification from the NQF staff as to whether that is, in fact, a criterion for acceptance for a measure.

If it is not, and if the C-statistic of any particular measure that's submitted is open to consideration and debate by the standing committee who evaluates measures for approval, then I would strongly recommend the C-statistic discussion be left to the NQF ESRD standing committee when these measures are discussed in the context of the overall evaluation on the measures.

However, I happen to have one of the leading senior biostatisticians at the University, Dr. Jack Kalbfleisch, in the room. And if he has any additional comments in general about C-statistic or about the C-statistics of these measures, I'd certainly offer him the opportunity to ---

CO-CHAIR WALTERS: This is Ron Walters, the chair. I'm going to cut this off at this point. This is not a standing committee.

I know there was a question raised, but this is not the committee to get into the statistical arguments and the statistical validity.

(Off mic comments.)

CO-CHAIR WALTERS: That's what I'm trying to go back and forth, you know. So what I'm going to do is I'm going to take the chair's prerogative.

We had a five-minute break scheduled for 10:55. We're going to do that now. And the reason we're going to do this now is because we

have had four recommendations for classification and for the MAP's recommendation to CMS. And so we have to talk about how we're going to handle that voting process.

We've done all kinds of it in the past where we just put all four up on a screen and then see what comes up.

It's very unlikely to get 60 percent for anything in that circumstance, and so we're going to talk about how we want to handle the voting before we move into the voting next when we return from the break. Okay?

I think everybody has heard the arguments for support, the original argument for conditional support, the argument for refine and resubmit, and the argument for do not support completely. Thank you.

MS. DUSEJA: Ron, just one more comment. We have one more comment, if we can.

CO-CHAIR WALTERS: No. I don't want to have any more comments.

MS. DUSEJA: No more comments.

CO-CHAIR WALTERS: No. We've got to get moving on. Again, I think everybody has heard all of the considerations. All right. Take a five-minute break.

(Whereupon, the above-entitled matter went off the record at 11:05 a.m. and resumed at 11:15 a.m.)

CO-CHAIR WALTERS: If you want your vote to count, please come back to the table. I have to admit, I think in six years I don't remember all four options being open at the same time and discussed on a measure. It might have happened one time. It certainly is very unusual.

So, again, what we wanted to avoid was what we've done in the past where all four options are up or on the board because the odds are that will lead to nothing, the odds are. And the whole point of the MAP is to give a recommendation to CMS.

So despite the fact that we went kind of back and forth between the prevalent measure and the incident measure, the plans are to vote

first on the prevalent measure and then to only have discussion that differentiates everything everybody that has said, and I think there's been one or two comments about that, that from the prevalent measure. And then we'll try to get to a vote on the prevalent measure quickly.

And I did want to remind everybody that the 176 measure, the med rec, was left on the consent calendar and that passed. Our recommendation to CMS was that that was support.

So there's a lot of ways this could have been done, could be done. We had a little huddle about what we thought the best way was, and then we are limited a little bit by some technology glitches that occurred the last couple of days.

So the first motion that was made was actually Nancy's, and it was a do not support. So that's the first motion we're going to tackle. And then, this will be interesting, after we've reconciled that one, I'll ask for another motion if it doesn't pass. And then we'll reconcile

that one, and we'll move our way on down. Remember that the preliminary assessment was conditional support.

So, Nancy, would you state your motion again, if it's still active?

MEMBER FOSTER: It is still active for me, and my motion was do not support.

CO-CHAIR WALTERS: Okay. And I only have one other thing. Because of the technical glitches and the fact that it's not easy to set up the voting machines as a binary function at this time, we are going to ask people to raise their hands. So please recognize that that is an extra intricacy to this.

So all those in favor of Nancy's motion of do not support measure MUC 17-241 raise your hand. All those opposed to the recommendation of do not support raise your hands. Okay, 13 to 9. Okay.

MS. MCQUESTON: For those on the phone, can you please indicate --

CO-CHAIR WALTERS: I'm sorry. Yes, I

forgot.

MS. MCQUESTON: -- your vote, either on the audio or over the chat function.

CO-CHAIR WALTERS: Probably audio at this point.

MS. MCQUESTON: Please just speak up and let us know your vote.

CO-CHAIR WALTERS: Everybody will raise their hands, you know, so --

MEMBER BRENNAN: Joan Brennan. I oppose the motion.

MEMBER JORDAN: Jack Jordan. I oppose the motion.

CO-CHAIR WALTERS: Okay. We've got them. So by my headcount, that's 15 to 9 in opposition to do not support. Okay. Here's where it's going to get interesting. Do I have another motion? Sean?

MEMBER MORRISON: Conditional support current --

CO-CHAIR WALTERS: It mentions what it is. So --

MS. MCQUESTON: So we're currently, I'm going to try my best to explain. Feel free to jump in. So we're currently voting to overturn the current recommendation, which is conditional support for rulemaking. So at this point, we're only making motions that are different than conditional support for rulemaking.

CO-CHAIR WALTERS: Greg?

MEMBER ALEXANDER: I have a question about process. So --

CO-CHAIR WALTERS: You're not the first.

MEMBER ALEXANDER: So if Nancy was the first to make a motion, shouldn't the second person that made the second motion be the next in line?

CO-CHAIR WALTERS: And who was that?

MEMBER ALEXANDER: That would be the lead discussant, which was me.

CO-CHAIR WALTERS: Okay.

MEMBER ALEXANDER: Right? Not that I

--

CO-CHAIR WALTERS: Make a motion.

MEMBER ALEXANDER: -- but I think it's important to follow protocol.

CO-CHAIR WALTERS: Feel free to make a motion.

MEMBER ALEXANDER: And I don't want to -- you know, I have a problem with the sort of conditional support because the recommendations, my motion is for the one that we have a problem with is the substantial one, and the reason I have that --

CO-CHAIR WALTERS: Wait, wait, wait.

MEMBER ALEXANDER: -- is the one, the third one down.

CO-CHAIR WALTERS: We're not taking that one right now.

MEMBER ALEXANDER: We're not.

CO-CHAIR WALTERS: Hold that right now. We're talking about 241.

MEMBER ALEXANDER: No, revise and resubmit. That is my motion. And the reason for

that is because I think that the recommendations that were made both by the commenters and also by a lot of people in this room in their discussion are very substantial issues. I don't think it's a conditional problem. I mean, I don't think it's a conditional level. To me, conditional support with minor revisions, these revisions are major, substantial. So I think that's why I raise this issue.

CO-CHAIR WALTERS: Okay. So a motion is on the table that will revise and resubmit. All those in favor -- can you be explicit about what you want to revise and resubmit?

MEMBER ALEXANDER: Okay. So there were issues that were raised around age being the only variable and that that's insufficient. There needs to be other variables considered, and there was discussion about exogenous variables, which I think the other exogenous variables that need to be filtered out in this that are important, size of facility matters. I think I've heard size. The absence of or the way that

chronic conditions criteria are applied across facilities hasn't been well vetted. And those would be my major ones. There may be others.

CO-CHAIR WALTERS: The motion on the table is revise and resubmit. All those in favor, raise your hand.

MEMBER BRENNAN: This is Joan Brennan on the phone, and I support that.

MEMBER ALEXANDER: Are we just doing the first one, 241?

CO-CHAIR WALTERS: We're only doing 241. All those opposed?

MEMBER JORDAN: I oppose the revise and resubmit. This is Jack Jordan.

CO-CHAIR WALTERS: So that motion passes.

MS. O'ROURKE: Just to let everyone know that, as part of the MAP process, we capture all this feedback. It goes into the reports. The binary votes are not the only thing that goes to CMS. So when you see the report, you'll see all of this discussion, all of the concerns laid

out on people who support, people who suggested refinements, people who had concerns. So just to, before Kate announces anything.

MEMBER YONG: Can you repeat the count?

CO-CHAIR WALTERS: Fourteen - ten.

MS. O'ROURKE: So it is actually, refine is at 60. Kate pointed out it is greater than, not greater than or equal to 60 percent, so we actually need a 61. So that motion fails. So I think that, to jump in here, I know the process that Kate presented did not require a vote on the preliminary analysis decision of conditional support. The clinician workgroup was voting that so that people had some more comfort with where they were, so, Ron, Cristie, do you want to take a vote on that?

CO-CHAIR WALTERS: Is there another motion?

MEMBER HATLIE: I'm confused about support versus conditional support from comments made earlier today. If we want it to go through

the NQF endorsement process, is that a vote for conditional support or is that a vote for support?

CO-CHAIR WALTERS: That was the condition on the conditional support.

MEMBER HATLIE: Okay.

CO-CHAIR WALTERS: Is there a motion for support? And believe me, when we did our huddle the last, that break, these were all the considerations. So because no alternative motion passed the 60 percent, it defaults to the preliminary assessment of conditional support. And those conditions were?

MS. MCQUESTON: That the measure be submitted to NQF and it receive endorsement. And I'd also like to remind you that all of the lists that you gave us of the issues that you have, we will present that to the standing committee for consideration as well, and they can have that discussion.

CO-CHAIR WALTERS: Thank you for working through this process. Yes?

MEMBER FOSTER: I have a question. We have not yet considered whether additional conditions might be offered up by the committee to the one that was --

CO-CHAIR WALTERS: You can propose other conditions.

MEMBER FOSTER: -- offered up by the staff.

CO-CHAIR WALTERS: You can provide input to other conditions to the conditional support, yes. What would you have?

MEMBER FOSTER: I would have, I would offer up as conditions that the measure be, that -- I don't even know. I mean, let me think about how to phrase this. But others have voiced a lot of concerns, and I just think that we ought to sort of capture some of that.

CO-CHAIR WALTERS: Well, they got the feedback, yes. I knew that's where we're headed. All right. Now, and that's why I was a little bit abrupt earlier on because I could see that, ultimately, we're going to have to do something

like this, and it has to head to a recommendation to CMS.

MEMBER FOSTER: One other question about process, because I am reminded that, in the past, when this kind of mixed vote has occurred, when there was not a 60-percent agreement on any particular recommendation, what went forward was consensus not reached, rather than a recommendation for --

CO-CHAIR WALTERS: And that has been discouraged. I mean, we --

MEMBER FOSTER: But that would be a --

CO-CHAIR WALTERS: -- some sort of consensus, even if it's -- well, the consensus we just reached in the voting process was not to overturn the conditional support assessment, preliminary assessment. You know, that could have turned out differently in the voting.

MEMBER FOSTER: So because only 60 percent of us agreed that it should be revised and resubmit, we're declaring that there was a consensus of 40 percent for conditional support?

CO-CHAIR WALTERS: Yes.

MEMBER FOSTER: That defies a logic that I'm struggling to understand.

CO-CHAIR WALTERS: I understand. There was not greater than 60-percent support for the motion on the table.

MS. O'ROURKE: So this is the first time that we broke right at the 60 percent, so we're in a little bit of unchartered territory. Everything the other groups were at least -- yes, we haven't hit exactly 60 --

CO-CHAIR WALTERS: But everything has been documented, so I think that's why the discussion is worth it. And I'm sure a lot of the same issues will come up in the appropriate time.

MR. AMIN: So, Ron, can I weigh in on this voting question? I know we're trying to move on. So as we were discussing the voting, as it was introduced, Nancy, at the beginning of the presentations, the intent was to have the Coordinating Committee put out, you know, the

preliminary analysis algorithm, which is essentially what staff used to make a preliminary recommendation to the workgroup.

As we proposed, that's the decision of the workgroup until somebody overturns it. And, therefore, the binary questions that we asked everyone is to put forward a motion to overturn the PA discussion.

So when we look at the results of that, I mean, it would be appropriate if you do want to vote on the PA recommendation and see if it reaches a 60-percent majority. That would be appropriate to do from the, you know, the rules that have been set out. The assumption is if you haven't overturned that by 60 percent, then you default back to the PA recommendation.

So when we, you know, the problem is when you're doing that binary decision is that you could be, your alternative when you're saying no could be three options. So it's, you know, I think the other 40 percent is basically saying it could be any one of the other three options. So

that's where we landed.

CO-CHAIR WALTERS: We knew we were getting into a fix here when the discussion started. That's right.

MEMBER FOSTER: Could I get clarification on what, on Taroon's clarification? So if I were to make a motion that we vote on conditional support, we could take that vote and if it did not achieve a 60 percent then we'd be in the no man's land that I think we actually are in?

CO-CHAIR TRAVIS: Well, and I'm going to ask staff to clarify, we are to make a decision. We need to make a decision. We don't have the, quote-unquote, luxury anymore of bouncing it up and saying consensus was not reached. So depending upon what we do and if we don't get over 60 percent for anything, we have to keep talking about it until we get over 60 percent. That's what I was under the impression, and if I'm wrong, staff can correct me on that.

So we don't have the consensus not

reached option anymore. We got rid of that last year because too many things were getting kicked up to the Coordinating Committee, and they are not to serve the same function we are to serve, which is to actually make a decision.

CO-CHAIR WALTERS: So, yes, you are correct. If you make a motion of conditional support, which is already the PA, we could vote on that. It could well lead to not getting off this measure for a while yet.

MEMBER FOSTER: That is such a heavy burden to bear. But I think, I think in this reality, I mean, we didn't do -- it didn't appear that we were doing a head-to-head comparison to vote, you know, you either conditionally support or you revise and resubmit or something else. I mean --

CO-CHAIR WALTERS: And that was discussed. It's just kind of like, again, what you put first because, again, when you pair two people off, you don't get the same result as if you put all four on the ballot at the same time.

MEMBER FOSTER: Right. I understand that.

CO-CHAIR WALTERS: It's guaranteed. And so --

MEMBER FOSTER: I get that. But I guess to look at a vote that was 40 percent for one thing and 60 percent for another and declare the consensus to be with the 40 percent seems to be an erroneous misperception that we ought to re-figure here.

CO-CHAIR WALTERS: So when we ask to pull a measure, that's why we point out what the preliminary analysis was, and a lot of the discussion that occurred was how strongly do I feel about something else to not accept the preliminary analysis. And, unfortunately, there was a lot of people who did not want to accept the preliminary assessment, but they were split across what their alternatives were, and that created a dilemma. So I understand. Yes?

MEMBER MORRISON: So I hear that there are a lot of people, Nancy particularly, who feel

very strongly about this, but what I'm hearing is that this is about how the process was established before this committee met. And we may not like the process, and I've certainly been on this committee long enough not to have liked the processes in the past. But what I'm hearing is an argument and a discussion about what the established process was. And I think that if we don't like that, the time is not at this meeting right now to address that. The time is either before or after.

But that's how it was set up, Nancy, and that's what we knew coming in. So I hear you. I mean, I'm not happy either, but that's where we are. And I just would -- otherwise, we're going to be here until tomorrow, and I have to get home tonight.

CO-CHAIR WALTERS: And following on that point, I'm sorry, but we need to now vote, we need to have any more discussion that differentiates, other than that already mentioned, the incident dialysis patient measure,

17-245, MUC17-245. We heard some discussion earlier about there could be a difference between those two populations for a number of reasons. And the preliminary assessment from staff was conditional support, and those conditions were?

MS. MCQUESTON: That it be submitted to NQF for review and endorsement.

CO-CHAIR WALTERS: All right. At some risk, is there another -- oh, I'm sorry. Elizabeth was the lead discussant for that one. Is there anything you have to add that hasn't been mentioned already?

MEMBER EVANS: I don't think so. Good answer, huh?

CO-CHAIR WALTERS: Well, anyway, Maryellen?

MEMBER GUINAN: Nothing more than has been said already.

CO-CHAIR WALTERS: Sarah?

MS. NOLAN: No.

CO-CHAIR WALTERS: And Nancy was the one that pulled it.

MEMBER FOSTER: I have nothing more to say.

CO-CHAIR WALTERS: Okay. Is there -- so the preliminary assessment is conditional support. Is there any other motion proposed?

MEMBER FOSTER: Ron, when I pulled it, my motion was do not support.

CO-CHAIR WALTERS: Okay. We will have a vote on that motion then. So Nancy has put forth a motion of do not support, thereby canceling out the conditional support. If you are in favor of do not support, please raise your hand. And those on the phone, please tell us your recommendations.

MEMBER BRENNAN: I support that. Joan.

CO-CHAIR WALTERS: You support the motion of do not support?

MEMBER BRENNAN: Yes.

CO-CHAIR WALTERS: Okay, got you.

MEMBER JORDAN: I do not support that.

CO-CHAIR WALTERS: Okay. So we'll

count you in just a second. So all those who do not support the motion raise your hand.

MEMBER JORDAN: I do not support that.

MS. MCQUESTON: So for MUC17-245, we have 12 votes in favor of the motion to not support and 13 votes against the motion to not not support or --

CO-CHAIR WALTERS: Yes, we always get in trouble every year how you word that, but the point is it certainly is not 60 percent. Okay. So that means that it is conditional support. Is there any other motion that's proposed? It doesn't mean everybody is voting the same on each one. Is there any other motion about that measure?

MEMBER GUINAN: Can I submit a motion to refine and resubmit or revise and resubmit?

CO-CHAIR WALTERS: You most certainly can. Would you like to state what you would refine and resubmit?

MEMBER GUINAN: I think, at this point, a comment on the, I guess, locus of

control in this measure and that we're not measuring the right people, persons, facilities, and that it should be reinvestigated in terms of whether this measure targets what we're wanting to be measured, that being the discrepancy between facility centers versus dialysis centers. Also, just the statistical issues that came up in terms of this is even less than the prior measure. Yes, I think that should be enough for a vote.

CO-CHAIR WALTERS: All right. The vote is open for the motion of refine and resubmit. All those in favor of refine and resubmit raise your hand.

MEMBER BRENNAN: This is Joan Brennan. I support that.

MS. MCQUESTON: We have 11 votes in favor of the motion.

CO-CHAIR WALTERS: And all those opposed to the refine and resubmit?

MEMBER JORDAN: This is Jack Jordan. I'm opposed to refine and resubmit.

MS. MCQUESTON: We have 13 votes against the motion. Has someone abstained from voting? Okay.

CO-CHAIR WALTERS: Two people abstained. That's 26. Okay. That motion did not pass. Again, we are back to the conditional support. Is there any other motions that anybody would like to make? It's only one left. Okay.

I think what I'm going -- thank you, everybody. I mean, again, I think the discussion and the voting in this circumstance gives a lot of feedback and it's important feedback, so I don't want anybody to feel discouraged with the result, however you voted, because the discussion that occurred and the feedback that occurred and exactly the kind of issues we talked about are well reflected and certainly will be considered.

And I think, with that, I'm going to turn it over to Cristie.

CO-CHAIR TRAVIS: I'll add my thank yous. We're going to move on to the next MUC, MUC17-178, 30-day unplanned readmission for

cancer patients. And I'm going to ask the staff to, when they're ready, to give us an overview of the cancer project in this measure.

MS. MCQUESTON: Thank you. So this is the PPS-Exempt Cancer Hospital Quality Reporting Program. It's a quality reporting program, and it's voluntary. The data are published on Hospital Compare. The program goals are to provide information about the quality of care in cancer hospitals, specifically the 11 cancer hospitals that are exempt from the Inpatient Prospective Payment System and the Inpatient Quality Reporting Program. And the main goal of the program is to encourage hospitals and clinicians to improve the quality of their care, to share information, and to learn from each other's experiences and best practices.

These are the measures included in the program and also included in your handouts. On the next slide are the changes of the program, including measures that have been recently removed and measures that are new for 2022.

CMS had identified three domains as high priority for future measure consideration. These include measures related to communication and care coordination, making care affordable, and person and family engagement. In addition, last year, the hospital group identified the following gaps as global harm and informed consent.

CO-CHAIR TRAVIS: Okay. Operator, could you please open the lines for any public comment on this measure?

OPERATOR: Yes, ma'am. Just tell me if you would like to make a comment, and please press star and then the number one. And there are no public comments at this time.

CO-CHAIR TRAVIS: Thank you, operator. Any public comments in the room? Okay. Seeing none, we will move on for this measure. And I'm looking at my notes to be sure. At this point, no one has pulled this measure, and there is, I think, a slide -- I'm really sorry. Okay. This is MUC17-178. The preliminary analysis result is

support for rulemaking. No one has pulled this measure so far. Does any workgroup member want to pull this measure? Okay. Well, not seeing any. Boy, I like where I'm sitting today. Not seeing anybody raising their hand to pull this measure, this measure will move forward as a support for rulemaking as part of our consent calendar. And thank you all so much. It's great. Thank you, Ron.

CO-CHAIR WALTERS: I thought I was just in this position. Okay. Let's move on to the ASCQR.

MS. QUINNONEZ: Thank you. So the Ambulatory Surgical Center for Quality Reporting Program is a pay for reporting and public reporting. And the incentive structure is aligned so that there's a 2 percent reduction in annual payment for acts that do not participate or fail to meet the program requirements.

The program goals include promoting higher quality, more efficient healthcare for Medicare beneficiaries throughout measurement,

and also allowing consumers to find and compare the quality of care given at X to inform decisions of where to get care.

On this slide, you'll notice this is the ambulatory surgical center measure set as it stands today. There's 18 in total. In totality there is one measure that you'll notice with the green stars. The different stars mean different things. There's one measure that you'll notice that will be delayed and now added in calendar year 2020. There is one measure that is proposed for calendar year 2021, and there are two measures that are proposed for calendar year 2022, and three measures will be removed in calendar year 2019.

So on this slide, you'll see the priority domains that were recognized by CMS's high-priority domains for future measure consideration. Under making care safer, you'll notice infection rates was added. Under person and family engagement, there was improved experience of care for patients, caregivers, and

families, and promoting patient self-management.

Under best practices of healthy living, there was the increase appropriate use of screening and prevention services and improving the quality of care for patients with multiple chronic conditions, as well as to improve behavior health, access, and quality of care. Under the effective prevention and treatment, you'll notice that was added surgical outcome measures. And communication, care, and care coordination embedded best practices to manage transitions across practical settings, enable effective healthcare system navigation, and reduce unexpected hospital emergency visits and admissions.

And at this time, we'll let Ronald stop for public comment.

CO-CHAIR WALTERS: Operator, could we open up the lines for external public comment?

OPERATOR: Yes, sir. At this time, if you'd like to make a comment, please press star and then the number one. And there are no public

comments at this time.

CO-CHAIR WALTERS: Is there public comment in the room? Okay. Hearing none, would the measure developer like to make any comments?

DR. DRYE: Hi. Sorry. I didn't know I was going to get a little chance to introduce the measure. This is Elizabeth Drye. I'm from the Yale Center for Outcomes Research and Evaluation, and we led the measure development for CMS for this measure.

It covers a broad range of surgeries at general, at ambulatory surgery centers. These are surgeries that are within the scope of general surgeons' training, and many of them are not done by general surgeons, so I want to just point that out up-front, because, as you know, many wound or skin procedures, plastic procedures could be done by sub-specialists or by general surgeons. But we pulled this group of procedures together to evaluate care at ambulatory surgery centers because we, in consultation with surgeons, anesthesiologists, and other experts,

there was a recognition that the kinds of quality improvement efforts that can improve outcomes cross these areas, and the kinds of outcomes patients experience that can be improved are very similar for this broader group of procedures.

The outcome is hospital visits within seven days, specifically unplanned hospital visits, so unplanned admissions. We pull out planned admissions, ED visits, and observation stays. About two-thirds are ED visits. And the rates are relatively low compared to a similar measure that's been approved by NQF for hospitals that is a broad measure of different types of surgeries. It's two percent, but there is good variation both before and after risk adjustment. So it fills a gap.

Just my last quick comment. For ASCs, CMS has one measure that is just entering public reporting that is measuring colonoscopy care with the same outcome. They finalized in rulemaking two very similar measures structured similarly to this for urology and orthopedic patients. And

this one really covers the remaining groups of procedures that hang together within this broad category of procedures that general surgeons are trying to do and is harmonized in its outcome and basic approach to risk adjustment.

So I won't go into the technical issues. We submitted the measure for NQF endorsement under the new process to this first round of rapid review committees to the Surgery Committee. They had their first meeting this week, but they haven't started substantively engaging on the measure review.

We're really excited to hear your comments. We did review your comments, and I could speak specifically to those, but I'll defer that. I think it's probably better to just let you get started.

CO-CHAIR WALTERS: This measure, the preliminary assessment was conditional support pending endorsement. And Nancy asked that this measure be pulled for discussion, so, Nancy, the reasons why you pulled it for discussion and your

recommendation -- your formal recommendation.

MEMBER FOSTER: Sure. I'm going to be very popular today, huh? My formal recommendation is do not support. I'm glad to hear it has now been submitted for NQF review, but I am puzzled. As you've mentioned, Elizabeth, a vast majority of the procedures here are skin procedures, not typically general surgery domain. Yes, I'm sure they can do them but not a typical general surgery domain.

One of the things that bothers me about this measure is that it may already be topped out. Once we looked at the adjusted rate, we saw only 30 of the 650 surgery centers that were being assessed were significant outliers. That doesn't seem like a lot of room for improvement. It's not adjusted for social risk factors that may come into play here. You know, there are some other issues that I'm sure the Steering Committee will dwell on, but this seems like a fairly puzzling entry, given the comments Pierre made at the beginning about seeking

meaningful measures if it's this close to being topped out and not addressing general surgery in ambulatory surgery centers.

That said, I'd love to see some good measures of ambulatory surgery centers. But this doesn't ring my bell.

CO-CHAIR WALTERS: Okay. I try to learn something every time I do this, so the preliminary assessment is conditional support, and Nancy has already made a motion for do not support. So we're going to be coming back to that in just a second.

The lead discussants get the next comments. Janis? And you can, you can come to any recommendation you want to, but we do have a motion of do not support on the table, so just keep that in mind.

MEMBER ORLOWSKI: Thank you. So as I took a look at this, a couple of things. First of all, I do believe that we need to have some 30-day look at individuals that are cared for in an ambulatory center. The concern that I have

with an ER visit is that there may or may not be a condition that is an issue or, you know, is a problem. And depending upon access and social demographic factors, some of these patients would go to the emergency room and some will call their doctor and go to the surgeon's office. And I think those are counting the same thing.

I think I would like to see this measure where it actually counts some morbidity associated with it. So there's an infection that needs treatment, there's pain that needs observation, there's something. And so I think that, if we are going to include all ER visits, then we really have to SDS-adjust this because there are variations in inability to access.

I do, I was just looking at Nancy's comment about it being mostly skin. And I have to say, honestly, I didn't pick that up before. But the question that I have then is: are we measuring -- is this a physician measurement, or are there other providers involved in that? And so I think that's another thing that we'll need

to take a look at.

So those are my two comments. But really the SDS adjustment, I would say, is my main concern.

CO-CHAIR WALTERS: So I need to ask you specifically: is that an additional condition, or are you in support, so to speak, of the do not support, or do you have another recommendation?

MEMBER ORLOWSKI: I would say that that's an additional condition that I'd recommend.

CO-CHAIR WALTERS: Jeff is on the line. Right? I don't think he was. Kimberly?

MEMBER GLASSMAN: Yes. I think that it is good to have measures for ambulatory surgery centers. I share some of the concerns mentioned. An additional concern is that there's really no exclusions here, and I think that when you're looking at certainly planned admissions, but there are other situations that may have nothing to do with problems with the surgery or

complications related to the surgery that might bring patients into an emergency room.

So I would stay with the recommendation of conditional support, but I would add an additional condition to look more at the exclusion criteria.

CO-CHAIR WALTERS: Thank you for being quite clear about your recommendation. Would the measure developer like to respond to that?

DR. DRYE: Sure, thanks. I'll just take these in sequence, if that's okay. So let me clarify it's a facility-level measure score, and so these are at ASC facility levels. It's not a facility-level measure.

We struggled with the name of the measure, to be honest, because there are a lot of skin procedures and many of them are done by dermatologists. But in assessing the quality of care at ASCs, we are deliberately trying to be neutral to which specialist type is performing the procedure that can be performed by more than one specialist type and also, you know, to the

procedure itself.

So the inclusion criteria are the set of procedures that are within the scope of general surgery practice. And, again, we took that approach because when we grouped them that way and when we went through those with general surgeons and with our expert panel, the kinds of quality improvement activities that lower risk with similar costs, all those procedure types and the types of really preventable admissions or ER visits are similar. It's, you know, abdominal pain, hemorrhage or bleeding, nausea, vomiting, hematoma, urinary retention. Those are things that are related to the procedure and that are lowered by better care, and there are comments submitted by four or five organizations supporting the measure for those reasons.

So it's a risk-adjusted measure. You know, it adds to the complexity. The expected rate is not zero of hospital visits because this is a Medicare population, so they are going to go to the ER or they are going to go to the hospital

for things in a seven-day window post-surgery unrelated, but their rate of use of the hospital is elevated in those first seven days, which is why we focused on that period and not the 30-day period.

In terms of the variation in performance or the limited number of outliers, we use and we submit the material to the MAP. A typical approach we use in other CMS risk-adjusted outcome measures of using a 95-percent interval, estimate, a very conservative approach to classified better or worse providers, and there were not very many in the better or worse category at many facilities. But there is a range of performance, as I mentioned. This measure, this score is reported as a ratio of essentially adjusted to what's expected, given the case mix and the procedure mix. And some facilities have half of the rate expected, and some have, you know, two or three the rate of expected visits.

So there is a real range of

performance that you see. Some of that is practice variation, so going to the point about, you know, some of the ED visits may not be for, they may be really for convenience, like can you give me a catheter because I can't urinate. That's part of the design of the measure.

There was a lot of discussion in our expert panel, and we did put the measure out in public comment also around that. And you will see surgical groups or groups in certain areas that just say, okay, go to the ED, and you'll see other types of surgeons or surgeons practicing in certain areas that have office hours and are accessible to deal with those things. So I actually like that aspect of the measure because your score is higher, which is worse if you're not trying to see your patients outside the ER setting for things that really can usually be anticipated. So that's a deliberate aspect of the measure's design and that scenario where people can bring down ER visit rates over time.

I'm just trying to see if there's --

oh, in terms of exclusions, it might help to know a little bit more about what you were thinking about. You know, the measure has been through expert review and public comment. We don't have a lot of exclusions because there's some selection to ambulatory surgery centers for patients who, you know, would be expected to be able to have the procedure and then go home same day. So we don't worry too much about, they don't have the same kind of, you know, clinical differences that we might focus on in a hospital setting.

MEMBER GLASSMAN: I guess I was thinking, because this is such a wide group of patients with many different procedures, and I guess I would ask for clarification about the planned aspect so the planned return would not count against someone. I'm thinking of someone who might have a breast biopsy and be lucky enough to get a quick turnaround on a path report and then be able to go and have their procedure, and maybe that would happen within this window.

So because this is a seven-day measure, I'm concerned about people saying, oh, wait until ten days so that I don't get dinged here. So I guess I think this may need a little more clarity from that perspective, so that was what was in my mind.

DR. DRYE: Okay. Thanks for that clarification. The way the measure is designed, it does count only unplanned admissions. So we adapted an algorithm that CMS developed earlier called, it's a planned readmission algorithm. It's really based on admission types, not readmissions. It's agnostic to whether you were recently in the hospital or never in the hospital.

And so it pulls out, for example, admissions for cancer are not part of that. They get automatically pulled out. So we pull out anything where there's a procedure and a non-acute diagnosis. So it's not an emergent thing, but it's something that, if it happens in the seven days and that's good care, it won't be

counted.

Sometimes we miss very, you know, like, things that are relatively rare in that adaptation, and we did in public comment hear about one of those, which was, I think, related to breast cancer diagnosis and follow-up care. So then we can just add these specific procedures into the algorithm to make sure they're planned. And if there are those kinds of specific procedures that are not on our planned procedure list as laid out in excruciating detail in the technical report, we can add those. That's what we want to do. We want to be as accurate as we can in identifying those planned procedures, so we welcome those specifics.

And then I just wanted to add, because I didn't address SES, and CMS can speak to this, as well, we did test three sociodemographic status variables, African-American race, dual eligibility for Medicaid, and then a composite AHRQ SES index, as individual patient-level risk adjusters, and they really did not change the

measure scores for the facilities at all. I mean, they're correlated to the 0.9 and are even 1.0 level.

And then we looked at, well, would facilities that care for more low SES patients, as defined by any of those two variables, have higher rates of return visits? Because you could hypothesize that maybe they don't have as much social support or there are other barriers to care, and there's really very little difference. It's in table seven of our technical report. There is some at the very high end. We put ambulatory surgery centers in quartiles of the proportion of their patients who were low SES, three separate analysis, you know, so for each variable the proportion that had few African-Americans versus the quartile with the most. And you do see the medians are the same for the median hospital return rates across all those quartiles, but if you look at the very highs, like 95th percentile, there are some centers, the very tip of the distribution, that had higher

proportions of low SES patients. That's not atypical of what we see, and there were some members who were like you would never adjust this risk, you shouldn't take patients into the ambulatory surgery center patient setting if they don't have adequate support. So we heard both arguments on both sides. We didn't risk adjust or stratify, but these are, as CMS indicated in its most recent rule for the Ambulatory Surgery Center Quality Reporting Program, this is an ongoing area of discussion and investigation, so I don't think that's the end of the story. But that's the current status of the measure.

CO-CHAIR WALTERS: Thank you. Okay. We'll now open it up to the rest of the workgroup for comments. And, please, again be explicit whether you are in support of the EA of conditional support, in support of the motion on the table which is do not support, or any other motion. Lee?

MEMBER FLEISHER: I'm in support of the initial recommendation of conditional

support. It's interesting. We started this work with Sean Tunis in, like, 1997, so it's good to see the measure finally developed. And the seven days was actually, Jerry Anderson and I had done work to show that does prevent some of the concerns. So it's not consistent with the 30 days, but it showed out.

And I am, of note, the co-chair of the Surgery Standing Committee, so we will review it. And I thank you for all the comments because they will be now incorporated into how the Surgery Standing Committee looks at this measure.

But just the definition is truly freestanding ambulatory surgery center because that makes the biggest difference is whether or not this, how you define an ASC because some ASCs are attached to hospitals and, therefore, have a different rate of direct admission, and some are truly freestanding. And the truly freestanding, this is a critical measure. The ones in which a hospital say, well, we'll just take them through a tunnel back to the main hospital, they may look

at admissions differently. So that's the key question I have.

CO-CHAIR WALTERS: I think they heard that. Are there any other comments?

MEMBER SHEHADE: This is just a question actually just from the conditional support. Is it still just the NQF endorsement as a condition, or was there a motion to add another condition to --

CO-CHAIR WALTERS: You can add any conditions you want to your --

MEMBER SHEHADE: I just want to, I thought somebody added another condition to --

CO-CHAIR WALTERS: Yes, there was an additional condition. Would you state that, please? I think it was Janis.

MEMBER ORLOWSKI: So what I had asked is that there be an SDS condition that we apply to this. And there is one comment that I'd like to make is that I believe and the studies have shown -- particularly in return to the emergency room -- it is a sub-segment of the population,

sort of the poorest of the poor. And for us to say, well, there was only a little bit of a difference that we noticed, but it wasn't very much, so we're not going to, what does that does is, I think, adversely affect access for the poorest of the poor and that is the reason to do SDS adjustment.

CO-CHAIR WALTERS: Nancy?

MEMBER FOSTER: In light of the discussion, I'm going to withdraw my motion for do not support but ask that another condition be added, and that is -- due respect to my colleague to my left -- the research, I believe, he said was about 20 years ago. Was that correct? And I would suggest that that which we do in ambulatory surgery centers has changed enormously in that time frame, particularly over the last five years. And so I would ask the Steering Committee, that the Steering Committee be asked to really, really assess whether that's the right time frame or whether it's creating some of the unintended consequences that Kim and others have

discussed.

CO-CHAIR WALTERS: That's a nice peaceful way to do it. Is there any other comments that anyone on the Committee -- oh, Helen?

MEMBER HASKELL: Yes. I would just say that I support this measure, and I would be really wary of including SES. I think return to the emergency room is an indication of a serious complication, and it can be anybody. I think that that could really be muddied by including SES, which I, in general, oppose because I think it creates a dual standard of care. Anyway, I just wanted that on the record that I would oppose that condition.

CO-CHAIR WALTERS: So I believe you just said you were opposed to the conditional support, and you want to oppose full support?

MEMBER HASKELL: No, no, I said I do support it. That particular condition is not one that I would support. Conditional support is fine.

MR. AMIN: Maybe the condition should be an evaluation of the SDS factors by the Surgery Committee, rather than a yes or no on --

CO-CHAIR WALTERS: Is that acceptable to both of you?

MEMBER HASKELL: Yes.

MEMBER FLEISHER: Yes. And just the definition of the ASC to make sure it's really clear. It has to be distinct from -- do you have that --

MS. DUSEJA: Yes, I do have that information. It's freestanding, if that's your --

CO-CHAIR WALTERS: Andrea?

MEMBER BENIN: I guess I would just like to add another condition regarding the discussion about a biopsy that then needed immediate attention would be just to make sure that is part of the consideration. I think, Elizabeth, it sounded as though you have some sense of those things but maybe not a comprehensive listing, but that those are

evaluated more comprehensively as part of that, just to make sure that there aren't things that get included.

DR. DRYE: If I can just clarify, we think we have the comprehensive list because we put it together through research and through expert consultation and around a public comment. But occasionally we'll miss something, so we're very open to just expanding those planned procedures, as people bring them to our attention, as they may, during the Surgery Committee review and the public comment associated with that.

CO-CHAIR WALTERS: I appreciate everybody pointing these things out. I've learned to believe so much in the endorsement process that the Steering Committee and, of course, I think the Steering Committee's ears is listening. But certainly they will hear and support many of the things that were said or certainly discuss them.

Is there any other comments? Okay.

We're in the situation now that there is no competing motion, so, if the Committee agrees, these are all taken as additional conditions or suggestions for conditions. But the preliminary assessment of conditional support as recommended in the PA stands.

CO-CHAIR TRAVIS: Don't prove this a foolish decision, but I told Ron I would take the next one, even though it was technically supposed to be his. But you all have been so kind to me, I'm hoping that you will be again.

We're going to move on to the next measure, and it falls within the Hospital Outpatient Quality Reporting Program. And we are going to get a description of that program from staff.

MS. MCQUESTON: Thank you, Cristie. Again, this is a review of a slide that you have seen at least a couple of times. The Hospital Outpatient Quality Reporting Program is pay for reporting and public reporting. The incentive structure includes hospitals that do not report

data on required measures that they receive a two-percent reduction in annual payment update. And the program goals are to provide consumers with quality of care information to be able to make informed decisions and establish a system for collecting and providing quality data to hospitals providing these services.

Here's an overview of the current measures. Again, as previously, it's probably easier to see in your handout. And you received this information last year, as well.

So CMS's high-priority domains for hospital outpatient include making care safer, best practices of healthy living, patient and family engagement, and communication in care coordination. And to the right, you see examples of how they define those domains.

That's it. I'll turn it back over to you.

CO-CHAIR TRAVIS: Okay. Operator, can you open the lines and see if we have any public comments on this measure?

**OPERATOR: Okay. At this time, if you would like to make a comment, please push star then the number one. And there are no public comments at this time.**

**CO-CHAIR TRAVIS: Okay. Are there any public comments in the room? Okay. Seeing none, we'll go on to looking at the particular measure that's up for consideration. It's MUC17-223, lumbar spine imaging for low back pain. The preliminary analysis and the one that's on our consent calendar is do not support for rulemaking, and the rationale behind that is that this measure lost its NQF endorsement in 2017 due to the lack of validity.**

**Given the situation and the concept around this measure, I wanted to see if the developers would like to make any comments.**

**MS. MCKERNAN: Absolutely. Thank you. So my name is Colleen McKernan. I'm a senior consultant at the Lewin Group. Lewin and the Yale Center for Outcomes Research and Evaluation are the developers on behalf of CMS.**

So this measure, lumbar spine imaging for low back pain, was formerly known as MRI lumbar spine imaging for low back pain, and that version of the measure has been in the HOQR program since 2011. It calculates the percentage of CT or MRI studies of the lumbar spine with a diagnosis of low back pain on the imaging claim and for which the patient did not have prior claims-based evidence of antecedent conservative therapy. Antecedent conservative therapy can include claims for physical therapy or chiropractic evaluation in the 60 days preceding the study, or claims for evaluation and management in the 28 to 60 days preceding the study.

This measure is not age restricted but, rather, it includes Medicare beneficiaries who are enrolled in fee for service who are treated as outpatients in hospital facilities reimbursed through the OPPS.

So the reason we're bringing it up to you all today is because we believe that the

addition of CT lumbar spine imaging would improve the measure. We've come to this recommendation over a number of years, actually. The initial reason we wanted to add CT was to align with another measure, which is actually also last endorsement. So we've reviewed the literature. We've discussed this with our expert panel. We've done quantitative, some preliminary quantitative evaluation of the change. And, again, it would harmonize with another measure. Even though it's not NQF endorsed, it's still is in use in the public setting.

And when we look at descriptive data of this change, we see about a 20 percent increase in the size of the denominator and the numerator, but the scores remained relatively the same. So there's not a huge impact in either at the facility level or nationally on the rate of overuse. Thank you.

CO-CHAIR TRAVIS: All right. Thank you. This measure has not been pulled for discussion, but the opportunity is there if any

of the workgroup members would like to pull this measure.

MEMBER PITTMAN: I have a question. So I agree with the recommendation in terms of not supporting it, but -- so this is the new version. There's still an existing version in the program. Can we make a recommendation of removing that one, as well?

CO-CHAIR TRAVIS: You just made a statement on the record. That's not technically within our purview, but your comment will certainly be on the record relative to that.

Okay. Well, seeing that there are no workgroup members that would like to pull this measure for discussion, it does remain on the consent calendar as a do not support for rulemaking, and that is what we'll move forward as our action as a committee. Thank you.

Okay. We will take a five-minute break, but we're going to come back. Some people just may need a five-minute break. So we're going to take a five-minute break, and we will

come back, and we'll probably go on and get started. If lunch is not here by then, we'll probably go on and get started on this measure but trying to find a good place to stop or we may just work through lunch. So we'll think about all that. We will eat. Don't worry about that part. But if you'll just take a five-minute break. That puts us back here at 12:25. Thank you.

(Whereupon, the above-entitled matter went off the record at 12:20 p.m. and resumed at 1:14 p.m.)

MS. O'ROURKE: Okay. If we could all come back down. So I think we want to start the afternoon by letting you know that we've heard some of the concerns about the conversation this morning and want to just clear the air with you, if you will. We don't want people to come away from these meetings feeling unheard or that something went through on some sort of a technicality. We want you to know how much we value the time you all spend with us and

volunteer to be here, and we want everyone to feel like -- whether you agree with the decision or not -- at least your voice was heard and your opinion was valued.

So I think we want to revisit the ESRD measures from this morning --- not the med rec, the two transplant ratio ones. We want to allow you to take the vote that I think people want to vote on the conditional support, perhaps attaching some additional conditions, just taking no real prerogative in the staff but some suggestions, maybe conditions around some extra review of this measure as it comes in for NQF endorsement.

We were suggesting, Ann Marie, you mentioned this being closer to an outcome measure. We could have this reviewed by our new scientific methods panel who can take an especially deep dive on the methods, can provide people more comfort with things like the risk adjustment model, what the C statistic was, some of those issues that Matt may have imperfect

information to judge and are really not necessarily what we're asking you to do today.

We also think this is an important issue to take to our Disparities Standing Committee. If you may not know, NQF has a special committee that looks across all of our work on issues around equity and the reduction of disparities. And from some of the points we've heard, this is a crucial issue and fascinating measure that I think is something that they should take a look at.

We can also bring this issue to our attribution expert panel. We heard a lot of concerns about the locus of control of this measure and what can a facility reasonably influence how is the attribution set up, and I think we do want to let you know that we have experts who can also weigh in on that issue for you.

So nothing has to be fully finished today. You can take a look at this measure, attach some very specific conditions, charge CMS

and NQF with specific areas to look at, as this measure moves forward either through endorsement or other processes. But most of all, I think we want to make sure that the MAP process works for everyone. I don't necessarily think we have time for a thorough vetting of all the concerns, but please catch me offline or you can reach out via phone or email, because we will be bringing this to the Coordinating Committee in January some of the concerns about how we have the voting process, as well as the decision categories, so that every year we do try to fix the problems and refine it and make this a better process for everyone. So in the spirit of continuous improvement, we will be taking these issues to them and I'll let you know that the problems were noted and we will adjust them.

So I think, Ron, Cristie, I just want to kick it off to you for any reflections.

CO-CHAIR WALTERS: So Erin said much of what I was going to say. And, again, this is your workgroup, and I really would like to echo

that one of my goals is that everybody in this room feels heard and valued. We were in a situation earlier this morning we hadn't been in previously and ended up in a place that some were not happy with. So I'm going to have Sean say a few words, and then we're going to go back to what was proposed by Nancy and see where that gets us.

I will reiterate we do need to give advice and feedback to CMS. That's the job of the group. And it has to be a consensus of some sort, but we'll see where that takes us. So we purposely are using kind of like the 30 minutes we thought we had extra to revisit the ESRD 241 and 245.

So Sean?

MEMBER MORRISON: So, Ron, like many in this room, I have been on this panel from the beginning, and one of the things that has continuously impressed me is NQF and particularly the staff's work to make this a better process. And when this committee started, many of you know

we actually were into the weeds debating things that we actually had no idea or many of us had no idea what they were. And what I think I wanted to say is that we really need to trust the process, no matter how difficult we think that is, that all of these measures come to us with a recommendation not by, you know, sort of everybody around this table but by staff who are steeped in measurement, are experts in measurement, have reviewed the evidence very, very carefully, and made a recommendation. And I think that, based upon that process, and remember all of these measures that are NQF endorsed have had their scientific validity and reliability assessed again by people who are expert in the field.

So one of the things that I heard this morning was concern about the fact that, oh, is it 40 percent, is it 60 percent? My bias is that, given all the work that has gone into presenting the measures to this group by a relatively independent group of individuals, it

should take a majority, more than a majority to overrule it, that if the staff has come together with a very strong opinion, then I think 60-percent overrule? That's not unreasonable. We certainly used to see that a little bit across the way where it wasn't a 50-50 vote to overrule something.

And I do think that, yes, it's not perfect and many of us are going to be unhappy. And, certainly, in the past I've been unhappy with how the decision has played out. But what Helen Burstin used to tell me was trust the process and we'll make it better. And I think that part of our role here is to trust that process.

We all have opportunities to weigh in beforehand as to whether we disagreed with how the votes were going to happen or how we were going to initiate that. None of us, I don't think, did. There wasn't a lot of disagreement before we came to this meeting, and that may be because we didn't read it, but I would say that

we all came to this meeting agreeing that this was how it was going to be run.

So I am concerned about trying to go back and revisit things, re-do things, change the process in the midst of it. I think that's the goal for the next meeting. And I did feel very strongly about that this morning, given what we had been hearing.

**CO-CHAIR WALTERS:** So right now it was, again, the assessment made by staff was conditional support. There were those conditions outlined this morning, and Nancy pulled the measure -- and I'm talking about 241 now, not bundled together -- for do not support.

We're going to entertain any motion and any discussion about the conditional support staff assessment for 241 and feel free to make motions that then we will vote on, and we'll try to get to a consensus of whether or not we can support that. Okay? That's our job is to get to a consensus.

**MEMBER JORDAN:** This is Jack Jordan.

I would like to make a proposal to actually pass this as it's sent here with the recommendations that it has, and here's why. What I've heard in all the concerns from people around this and about the direct coupling of, you know, ownership of it from the center versus the transplant community I think are all things that become issues after the low-hanging fruit that this shakes out. I think, as it goes into the field, you'll see wide variation, and that will be a provocation that will really get a lot of the good low-hanging fruit fixed as far as places that aren't paying any attention at all to trying to get patients, you know, in the transplant. It will reinforce the importance of that.

And after that kind of shakes out, then all those concerns start to pop up that, you know, that there are other issues. And I think that's okay. I think delaying this for a couple more years because you're worried about what happens in year three or four it's in the field is really not what's in the best interest of

patients across the country. And I think kind of seeing this, getting that provocation, and then refining it once it's in the field, because those things can, I think, be done after this is in use and you fix some of those things is why I've been supportive of move them exactly as you have them, that they do have to kind of get their rulemaking conditional support. But I think we should move along with it just as it is.

CO-CHAIR WALTERS: Jack, this is Ron. I'm not clear. You support conditional support but with only one condition of endorsement or --

MEMBER JORDAN: Yes.

CO-CHAIR WALTERS: -- if there are other conditions?

MEMBER JORDAN: No, with just the condition of endorsement and get it into the field. I think we'll do more harm than good by delaying and worrying about secondary and tertiary issues with it.

CO-CHAIR WALTERS: Okay. Nancy?

MEMBER FOSTER: So, actually, Ron, I

think you just answered my question. The only condition that the current record shows we have on this is NQF endorsement. And in order for me, and I won't speak for others but I heard many other conditions voiced during the discussion that need to be really given some careful attention.

I'm also struggling because I'm not sure I have clarity on what the differentiation is between conditional support and revise and resubmit or refine and resubmit. To me, the difference is do I think, if I think substantive changes need to be made in the measure that I could identify now, that's a refine and resubmit. If I think it needs to go through further processing, it needs to have some things carefully looked at to see if they're unintended consequences or other things, that would be more of a conditional support. But that's my impression, not one universally held, and, you know, I appreciate the fact that staff tried to articulate what the difference is between the two

at the start of this conversation, but I'm not sure it really, I really understood exactly what they were trying to tell me as the distinction.

So if we can articulate the additional conditions that I heard around the room, I think I could leave it at conditional support at this point. If others believe my interpretation is correct and that refine and resubmit is for when we think there should be substantive changes to the measure, then I would propose that might be the better category, and I'm not sure there would be a different articulation of the reasons why or the things that need to be addressed.

But all of that aside, I appreciate the fact that you all have provided an additional opportunity to think about what advice we are articulating to CMS around this measure and how we capture that in the formal record of this body. And, Sean, with due respect, I think the legislative intent for creation of this body is that this group's recommendation and not staff recommendation is what's supposed to be the heavy

weight here. Informed by the work of the staff, which has been stellar, to really do the deep dive on some of these measures but not that alone because, otherwise, it would just be the staff recommending things and we didn't need to show up here.

So I think this group needs to weigh in and the plurality of this group's recommendations ought to be what we are voicing, even if it is not at the level of 60 percent is the consensus. But that's my opinion.

CO-CHAIR WALTERS: So do we have a formal list of all the conditions? And then we'll come back to Jack. Jack's motion was condition only on the endorsement.

MS. O'ROURKE: So Jack suggested endorsement only. I offered, obviously not a Committee member so this is my just unofficial advice, some things that we heard that might help were review by the NQF Disparities Standing Committee, consideration by NQF's attribution expert panel, and that this measure, as part of

its endorsement review, would go to NQF's scientific methods panel to take a deep dive on it since, as Ann Marie noted, it's getting close to an outcome measure, even if it is technically a process, so that they can weigh in on that. And just some extra considerations that the Committee could highlight for the NQF endorsement review.

MR. AMIN: Yes. Erin, I would just add, from my notes, there was significant conversation around the risk adjustment model, which will be looked at as part of validity, and then, secondarily, there's a question about attribution which can go to the attribution group but also could be evaluated as part of the validity.

So I think, you know, I think some of the challenges that I'm hearing, Ron, is that, you know, we want to just make sure that these conditions are clear and follow the workgroup's recommendation on conditional support. So there are five sort of major issues that have been

raised that we'll make sure sort of are looked at in particular by the relevant NQF standing committee.

CO-CHAIR TRAVIS: I have kind of a question of clarification. When we put conditions, and let's say we added a lot of those conditions to that if that's what the workgroup decides to do, I assume if some of those things weren't done then what's the implication of that? So what if it doesn't go to the attribution panel or the Disparities Standing Committee? I'm just trying to understand what would happen if those are formal conditions that we put on and, for some reason, they don't happen.

MS. O'ROURKE: Sure. So, obviously, for those things to happen, the measure would need to be submitted to NQF for endorsement, so that would kind of trigger these things happening. We have built out a feedback process where we take everything from MAP to the standing committees, and staff is cognizant that we do need to service that conduit and carry these

messages forward.

Obviously, as far as the formal MAP process, the conditions wouldn't necessarily negate the Secretary's authority to consider MAP's recommendation and move forward. But from an NQF perspective, we would make sure these things happen if the measure is submitted for endorsement.

CO-CHAIR WALTERS: Okay. I realize, I realize -- yes?

MEMBER YONG: Sorry. I was also going to say, as part of people understand these, we propose these, if we're going to propose a measure we put it through rulemaking. And as part of that discussion for measures, we specifically address the MAP's recommendations. And so it's conditional support. It's, in a simple case, pending NQF endorsement we do say whether it's been submitted or not or, you know, that we will submit it at the next opening.

Some of these conditions are not, we don't have, like, if the recommendation is, like,

conditional support but pending review of or involvement of the Methodology Committee, I don't know that we would address that particularly. That's part of the endorsement process.

MS. O'ROURKE: I think endorsement may be the main condition, and then we can put these caveats on it so that, once the endorsement process is initiated, NQF would make sure this special attention is paid and that your feedback is carried forward.

CO-CHAIR WALTERS: So, Jack, we have your motion on the table, and then we have some proposed amendments to it. So for those of you who like Robert's rule of orders, we'll come back to that. Lee?

MEMBER FLEISHER: For clarity, Pierre, my understanding is you can put something into your value-based purchasing without endorsement if you feel strongly.

MEMBER YONG: Right. I mean, generally, we have a preference for NQF-endorsed measures, but there's not a specific requirement

for an NQF-endorsed measure.

MEMBER FLEISHER: So as I vote, and this is what I'm struggling with, the revise versus the conditional, if I feel strongly that the NQF process is critical because I have significant concerns about some of the methodology and vetting that methodology, it's better to send a signal from my standpoint, and I'd like clarity, to say revise so that that actually gets worked out than just say conditional report because there's not a strength to the condition in my mind to say it really needs NQF vetting.

So I just wanted to make that clear in the way that I think about it because conditional support, well, if we get NQF review, great, because that's what we prefer. But it's not necessary. Well, in some things, I think it really is critical.

MEMBER YONG: Thank you, Lee. I will say our intention is to submit these for NQF endorsement.

CO-CHAIR WALTERS: Keith?

MEMBER BELLOVICH: I just have a simple question. Maybe it's my rookie-ness, but how many conditions do we need to apply before you reach that revision stage? How many amendments, how many additional committees can it visit before we say I think it's time to revise or reform and resubmit rather than -- is there a formal definition on what defines conditional versus revise and resubmit?

MS. O'ROURKE: Sure. So this is actually something that I think all the committees have been struggling with this year because there's perhaps some fuzziness between the refine and resubmit and the conditional support. We have no limit to how many conditions you could attach to something. The Coordinating Committee, when we brought them this back in their November meeting, suggested that you perhaps draw the line at a major change versus something that the measure, as structured may work, and you want an extra review paid attention

or an extra review or the Standing Committee should focus on certain areas but deferring to the scientific merits -- sorry, apologize -- deferring the review of the scientific merits to the NQF endorsement process, whereas refine is you see a very large change that would require basically going back to the development process.

CO-CHAIR WALTERS: Brock, is that you? Or Greg? Greg?

MEMBER ALEXANDER: So I just have a couple of questions. One, conceptually, the conceptualization of this measure, I didn't hear anybody mention that on the conditions before, maybe I missed it, whether this is conceptually the right measure because you're talking about centers versus the dialysis facilities, transplant centers versus dialysis facilities. So I was curious which of those committees addresses that conceptual issue because I appreciate all the list of the committees you gave, but I don't know what all the functions of those committees are and I'm not a rookie. I've

been here, and I still am trying to figure it out. So that would help me make sure that all of the things are going to be addressed and which were going to be addressed by what committee. And then so that's my first question.

And then the other question I have relates to, again, the substantial issue of revise and resubmit versus conditional. If it's conditional with approval, does that mean that it doesn't come back here? Does that mean that it's just with NQF committee above us, and it doesn't come back here? And the other one, the lower one, does that mean it comes back here so that we talk about the changes again? At what point do we stop talking about it or continue talking about it?

MS. O'ROURKE: So let me take those process concerns. To your first of who would look at the specifications of the measure, that is what we do during the NQF endorsement process. The standing committee, say for this one the Renal Standing Committee would look at how the

measure is specified. This question that you raised of transplant center versus dialysis facility, I think this would actually come out as a theme throughout the review, I think, in both importance to measure, as well as the reliability and validity of the measure. So that would be thoroughly vetted by the standing committee.

As far as your second question, that's a little bit trickier. To be honest, for either conditional or refine and resubmit, there is no guarantee it would come back before this committee for a formal MAP vote. Obviously, we do have the feedback loop process to update you on how development continues and what's happened in the endorsement process and the rulemaking process, but neither category would negate the Secretary's ability to propose a measure.

CO-CHAIR WALTERS: Ann Marie?

MEMBER SULLIVAN: Just in thinking about what's substantial, you know, issues like disparities, risk adjustment, who's really in control, I mean, whether it's the transplant or

the nephrologist, I think these will come up with other measures which have gone out, as well. I don't think that they rise to the level of significance that would say that you should re-do the entire thing. I agree with -- and I'm sorry, I forgot his name -- who made the original motion that these will fall out, I think, and be looked at over time as the measure is out there and being looked at for consideration.

So I just don't think that those issues have come up on multiple measures that have been passed, in my experience, including the readmission measure. I keep going to that one because that was one of my favorites. But those things were there, disparities, the same kinds of issues, the readmission measure went out.

So I don't think necessarily it's big enough to say it has to be -- go into that other category. I think you should go in with conditions.

CO-CHAIR WALTERS: Maryellen, is your card up?

MEMBER HATLIE: I want to say that I do trust the process. I mean, I am very unclear also about the difference between conditional support and revise and resubmit or refine and resubmit. But the discussion that was engendered here today was very rich, and I think I trust that the staff is going to capture those things. I kept looking at Helen because it might have been the first time that Helen and I have ever disagreed on a vote in this group.

But you got a lot of great feedback. And in terms of the voting processes in the four years that I've been here, they've always been a little awkward. So it's like we're PDSAing it for you guys to come back and look at it again and come back with something new next year. I kind of look forward to what the next version is going to be.

But I have no doubt that you're taking all of our comments. And I thought the discussion today was richer than in previous years. So there is a maturation happening here

while we continue to PDSA the voting process I think.

CO-CHAIR WALTERS: I agree. It's been learning for all of us. Janis?

MEMBER ORLOWSKI: With all due respect to CMS, to NQF, to the Committee, I would have to say that this is what drives the medical community absolutely wild that what we do is we come forward and we say this is what we want to do, we want to measure this, we want to make sure that there's particular requirements in it. And what happens is is that we actually are talking about why aren't we having metrics that matter, why don't we have attribution appropriately, why don't we have SDS?

And the medical community wants to and holds themselves to a high standard of quality of care. And for us to say, well, it's not perfect, but, you know, when people have said it's attributed to the wrong person, it's measuring the wrong thing, you know, there's not support. And, yes, we do believe that the patients have to

be protected in this and that there may be financial interest that will lead people astray that we have to be careful with.

But I have to say that it's, it has to be more precise. They have to be metrics that matter. They have to be metrics that the medical community believes are something that is valuable and that will provide value to the patients. And I would say anything less and holding ourselves in this committee to anything else and letting things wash out is not the right thing to do.

CO-CHAIR TRAVIS: Well, thank you for that. I think when I'm listening what I am not really struggling with because I've been on both the endorsement side and the MAP side. We are not structured in here to really do the in-depth deep dive into measures. That is what the endorsement side is all about. These measures have not yet gone through the endorsement side.

I think that that process is also something that I think I know I trust, and I hope others in the room do. I think with the guidance

that we can give that side of the equation with a rich discussion and the concerns that have been raised here, I mean, everything that Erin just pointed out, quite honestly, is what would be looked at and is part of the process of the endorsement process. I mean, the scientific methods panel is now there. There is a Disparities Standing Committee and an attribution panel, that these are things that can and I think would happen, as she indicated, because we have had this discussion.

We can't presuppose every decision they will make, but they have time and expertise to be able to dig deeper than we could do today. And so that's why, you know, taking my co-chair hat off and speaking kind of as a member, you know, that's why I feel comfortable with the NQF endorsement condition because this is what they would do. And I'm also comfortable if we want to call out these particular things to be sure that the endorsement process because we have had such a good conversation about it here.

So we just can't, we don't have the preparation, the background, the expertise. That's not how we were developed to do the deep dive that these measures do need to have. And I respect that, you know, very much, and that's what that process is for.

CO-CHAIR WALTERS: Helen?

MEMBER HASKELL: So I have a question. If this is not, doesn't come back to us and it hasn't yet been endorsed, who is it being resubmitted to?

MS. O'ROURKE: I think that's another one for me. So this is what we were trying to highlight when we introduced the categories. The intent behind this was that, in an ideal world, the measures would be resubmitted to MAP before implementation. However, for the reasons Pierre noted, that doesn't always work with time lines. And the MAP is an advisory board, and the Secretary can move forward with any measure after considering your input.

So the intent of the category perhaps

does not track with the language, the statutory language. So I think this is something we are going to bring to the Coordinating Committee and ask them to reconsider. But you raise a good point that the resubmit is a bit of a misnomer and it's perhaps a challenge between what was the intent when the Coordinating Committee created this and the practical matters of how this process works.

MEMBER HASKELL: Well, could I put a motion to maybe take that vote again after all this discussion and see where it ends up, if there's any --

CO-CHAIR WALTERS: We have a motion -- after a couple more comments, we have a motion and an amended motion on the table. So we're circling back to those. Is that Brock?

MEMBER ALEXANDER: I apologize I have so many questions, but I'm just trying to understand. So when I read the discussion guide, it talks about this measure being fully developed and tested, but fully developed and tested

doesn't mean that it's gone through all of those appropriations committees or whatever those committees are, even though they do further development and test the measure, correct? I mean, I think the issues that we brought up here are issues of development and testing and we're questioning whether it has been fully developed or tested. So I wonder if our definitions are getting -- I'm confused by that, so I'm curious about what fully developed and tested means if it doesn't go through all that vetting.

CO-CHAIR WALTERS: So they do not develop and they do not test, okay? That's what the measure developer does. They assess that process, like we're talking about, and then either support the endorsement or don't support the endorsement. And that's what you heard everybody saying is it hasn't even started that process yet to get all the feedback that probably is going to mirror much of what you've heard, and that's what we're recommending. Nancy?

MEMBER ALEXANDER: When you say

something is fully developed and tested, that leads me down a road of making some decisions about that when really there's been a lot of questions, to me, in my mind, about the development and testing and whether it has been fully done.

CO-CHAIR WALTERS: So it's not a measure concept. I mean, it's a little bit past that stage. But that testing and development has not been put through the process of evaluation.

I don't want to imply in any way it's not a good measure, it's not a good concept, or there hasn't been measurement and testing. All of that's true. Now, is it going to get through the rigor of the process? Don't know yet.

MEMBER FOSTER: So, Ron, I think you just started down this path but I was going to ask for clarification on the process here. What I understood you to say is we're going to take a vote on the original motion, which was NQF endorsement only without any of the further specifications that were just re-articulated

here.

CO-CHAIR WALTERS: Actually, first, I was planning on asking Jack if he would accept the amendments to his motion because that makes it a heck of a lot simpler.

MEMBER FOSTER: I appreciate that. I'll wait for his answer.

CO-CHAIR WALTERS: So, Jack --

MEMBER JORDAN: Yes, I would accept the amendments.

CO-CHAIR WALTERS: There you go. So the new motion, the amended motion is Jack's support for conditional support with a whole host of things attached that we have a list of here and have been documented.

MR. AMIN: Ron, let's just, just for the sake of, just so everyone is clear on what it is that is included in that motion, just so that we're all on the same page.

So it's the motion for NQF endorsement to specifically look at certain elements that have been of concern to the committee, starting

with SDS adjustment, accountability to be looked at as part of the validity assessment of the measure, risk adjustments, those are the risk adjustments which includes a specific discussion on the C statistic that was raised several times. And, obviously, SDS was related to risk adjustment, as well, but we'll put that in the same category. Did I miss anything?

MS. O'ROURKE: I think a special attention to the care setting, this dialysis facility versus transplant center, and also that we'll take this to our Disparities Standing Committee to weigh on any potential issues of disparities in care.

MR. AMIN: Okay. So all those are specific considerations as part of the endorsement process.

CO-CHAIR WALTERS: In the past, again, this is a little bit of maturation, I guess, we would have just said conditional on endorsement, and all of that presumably would have happened. So there's nothing wrong with being more explicit

in what the expectations are. It's fine.

MR. AMIN: Encourage so that we could make sure that, as these go to the standing committee, that they are, you know, looked at specifically.

CO-CHAIR WALTERS: I really would like to get to a vote pretty soon. Any new comments? Janis?

MEMBER ORLOWSKI: I just want to have a clarification. So if we're talking about conditional support, isn't that the terminology that led to all the discussion over the last couple of months that conditional support did not go through these processes and were taken up by CMS? So I thought that, even though they could, this is the category that there's been quite a bit of concern raised over because they have moved forward.

CO-CHAIR WALTERS: So one of the first lessons I had to learn about six years ago about this whole process is that key phrase that the Secretary can choose to adopt measures, and

there's nothing you can do about it.

MEMBER ORLOWSKI: But that's not what I'm asking. Of course. My question is is has there been concerns raised in the last couple of months regarding those measures that were conditionally supported where it was thought that it was coming back to Committee and, in fact, it did not?

CO-CHAIR WALTERS: That was the revise and resubmit category that Nancy brought up, not the conditional support.

MR. AMIN: Either one of them. Let's just be clear about the categories. Neither one of them require -- the feedback loop process is intended to update the Committee on the feedback that was provided, but there's no requirement of that.

And, again, I'd just reiterate -- let's talk about the categories for a second, just so that we're all on the same page. So a support is full support of what you're seeing in front of you. The conditional support is if

there are elements that you want specifically looked at for this measure concept.

The revise and resubmit is a problematic category. Even the Coordinating Committee that developed it recognized it as a problematic category because the intent was for it to be re-looked at. There is no process for that to occur so should be used sparingly. I just want to be clear about that.

And then do not support is intended to be if you do not agree with the measure concept even, if you do not agree with the measure concepts, I mean, you can't have a conditional support to change the measure. I mean, let's be clear about that. If the measure focus is completely different than what you intend, then that's where you should build in that category.

I just want to make sure everyone is clear about these categories. That's how they've been used in the other workgroups going forward. And, again, the revise and resubmit, given the problematic distinction between conditional

support and revise and resubmit, again, the Coordinating Committee's guidance going into this to the workgroups was to use that category sparingly.

CO-CHAIR WALTERS: So there is a motion on the table. I think we all know all the details of it now. I'm going to ask for a vote. All those in favor of the motion on the table, which is conditional support of MUC17-241, dot, dot, dot I'll just say, raise their hands.

MS. MCQUESTON: Actually, can we ask that everyone stand up? It's a little easier --

CO-CHAIR WALTERS: And the people on the phone, how do you vote? Is there anybody on the phone for?

MEMBER BRENNAN: Joan Brennan. I support.

MEMBER JORDAN: Jack Jordan. I support.

CO-CHAIR WALTERS: Thank you. Okay. All those opposed --

MS. MCQUESTON: So 25.

CO-CHAIR WALTERS: Twenty-five.

MS. MCQUESTON: Okay.

CO-CHAIR WALTERS: All those opposed? Okay. Thank you very much for your -- abstentions? Okay.

MS. O'ROURKE: We're missing two votes on the phone. Apologies. We just want to make sure we get this math right, so bear with us while we tally the phone votes.

MEMBER JORDAN: This is Jack Jordan. I voted yes.

MS. O'ROURKE: Thank you, Jack.

MEMBER BRENNAN: Joan Brennan, yes.

CO-CHAIR WALTERS: Okay. Now, kind of like I did this morning, now flip your thoughts to MUC17-245, which was also conditional support. Do we have a list of the conditions that were suggested attached to that measure? I know the first one was NQF endorsement. I know that. Or let me do this -- would anybody in the room, and this is the incident weightless measure, would anybody in the room like to add any conditions to

the, well, staff assessment -- we don't have a motion yet -- of the conditions required for endorsement?

MEMBER FOSTER: I'd like to say ditto to the previous measure. Could we add the same, I would propose that we add the same conditions, the same calling of attention of the Steering Committee and other related committees to the same aspects of this measure.

CO-CHAIR WALTERS: Would you make a motion, please?

MEMBER FOSTER: I move that -- I'm not sure I can articulate them all, but I move that we add the same conditions that are articulated for the previous measure to this measure to call the Steering Committee's particular attention to those aspects that need to be reviewed and support conditional endorsement.

CO-CHAIR WALTERS: Is there any other discussion about that? Okay. Hearing none, let's call for a vote on Nancy's motion. All those in support, raise their hand or stand.

Stand? Okay.

MEMBER BRENNAN: Joan Brennan. I support.

MEMBER JORDAN: Jack Jordan. I support.

MS. MCQUESTON: Thank you. So that's 21 votes yes, plus two on the phone, so for a total of 23 votes.

CO-CHAIR WALTERS: All those opposed, please stand. Abstentions?

MS. MCQUESTON: Is that three standing? Okay.

CO-CHAIR WALTERS: Yes, there's three. Okay. Thank you very much, and I hope --

MS. MCQUESTON: So we had 23 votes yes, 3 no. Were there abstentions?

CO-CHAIR WALTERS: Thank you again very much, and I hope everybody in the room acknowledges everything that was said was that we're trying to make sure we get the process right, and it was just an unusual event this morning.

Now I turn it over to you. Payback.

CO-CHAIR TRAVIS: Well, thank you. And I do want to thank Ron for helping us work through that process. As you all can imagine, it's not easy to kind of try to chair that, so thank you, Ron. I really appreciate it, and I'm glad that you were able to be the one to do that. So thank you for that, as well.

We're now going to move on to the next program, which is our Hospital Inpatient Quality Reporting Program. And I'm going to turn it over to staff to brief us on the program itself.

MS. MCQUESTON: Okay. Again, this is information that you have seen before. The IQR/EHR incentive program is a pay for reporting and public reporting program and hopefully less painful than the ESRD.

The incentive structure includes hospitals that do not participate or meet program requirements, they receive a quarter reduction of the annual payment update. And the program goals are similar to the other programs. They are

progressed towards paying providers based on the quality, rather than the quantity, of care that they provide. Still working on interoperability between EHRs and CMS data collection and to provide consumers information about hospital quality so they can make informed decisions about their care.

We'll not go through all of the measures because there are pages and pages of measures in IQR, but you have them in front of you and you have seen them in the past. And we have categorized them based on claims-based, the ECQMs, the cost and research use measures, so you can see them that way.

The high priority domains identified by CMS for IQR include patient and family engagement, best practices of healthy living, and making care affordable. I turn it back to Cristie.

CO-CHAIR TRAVIS: Okay. Before we start looking at the particular measures, we'll go to quality and make public comment.

**OPERATOR: At this time, if you would like to make a comment, please press star then the number one. Okay. At this time, there are no public comments from the phone line.**

**CO-CHAIR TRAVIS: Thank you. Any in the room? Okay. Well, thank you. Before we get started going through the measures themselves, I'm going to ask Pierre or his team to make some opening remarks.**

**MEMBER YONG: So can we just ask, I mean, we would want to offer context in all three of them, so I don't know which one you want to start with because there are two mortality measures that we want to discuss. That's why we have both on there.**

**CO-CHAIR TRAVIS: Yes. We were actually going to go in this order that's on the screen.**

**MEMBER YONG: So should we just address the opioid one first and then --**

**CO-CHAIR TRAVIS: Opioid is last.**

**MEMBER YONG: Oh, so you do want to do**

the mortality measures first. Okay.

CO-CHAIR TRAVIS: Yes.

MS. DUSEJA: All right. So we just wanted, at CMS, to just make a couple of remarks on why we brought these both to the Committee this year. So as you know, there's two versions that are submitting for the MAP to look at. One is a claims-only version, and one is a hybrid version of the hospital live mortality measure.

And so each version actually has distinct advantages, as you can imagine. The claims-only measure is obviously immediately feasible in the sense that we can get this through existing claims that hospitals submit, and we recognize it's also, like, least burdensome in terms of being able to get that information.

On the other hand, we're also very cognizant that we've heard from stakeholders in particular with this measure that the face validity of it could be better if we could do better or more adequate risk adjustment and so,

hence, why we're bringing also the hybrid version to you. And the hybrid version allows us to actually combine elements from the electronic health record, which allows us to further refine the measure itself. So that includes core clinical data elements that have also been recently specified.

So we're bringing both of these versions for feedback from you, one with hope that we have an immediate need and being able to look at the claims-only version and then the longer-term strategy with the hybrid version. So we really welcome feedback on both these individual measures, as well as any comparative feedback between both of those.

So that's all I have for now.

CO-CHAIR TRAVIS: Would you like a brief description of the measures together? I think what might be best would be to have a brief description of 195, which is the claims measure. And then we know just from your opening remarks that the next measure would also include some

additional access to additional refinements that we could do because of it being a hybrid measure.

So let's try to keep it straight. I think we're going to try to vote and talk about these measures. I know we'll have some bleed over like we did earlier, but let's try to go with 195 first and we'll try to focus on that one.

DR. SUTER: Sounds great. Thank you. My name is Lisa Suter. I'm coming from Yale University. Can you hear me now? Okay, great. So this is a measure that evaluates hospital-level 30-day hospital-wide risk standard mortality defined as death from any cause within 30 days after the index admission date for Medicare fee-for-service patients between the ages of 65 and 95. And death is defined as death from any cause.

It only uses administrative claims data. The cohort excludes patients for whom we believe and technical experts and patients agreed that mortality does not represent a quality

signal. I think that is probably the greatest concern with this measure of an unintended consequence that it would capture mortality for patients that is clinically and socially and emotionally appropriate outcome for that group of patients.

Patients in this category include patients for whom we cannot address survival, such as brain death patients; patients for whom mortality is not the goal of the admission, such as patients enrolled in hospice either prior to or within two days of admission to the hospital; patients with cancer who have enrollment to hospice at any time during the admission; or patients with metastatic cancer.

There are a few other exclusions that are detailed in the methodology report, which I'm happy to describe if there are questions about them.

As noted, the risk model uses risk variables drawn from administrative claims in the prior 12 months prior to the admission, including

the admission. Patients are divided into 13 service line divisions, and each of those 13 service line divisions, eight non-surgical and five surgical divisions, are risk adjusted individually. And then those standardized mortality ratios are combined using the weighted inverse variants.

The measure describes fairly remarkable range in mortality across the United States. The median is 7.6 percent mortality rate with a range of 5 to nearly 10 percent. I believe you have in your results that the C statistic for the service line divisions ranges from 0.75 to 0.84. The reliability for the overall measure results when performed as a random split sample, so half of the patients in the hospital are put into one group and the other half are put into another group, and those results are compared. The reliability from that comparison is 0.83, the interclass correlation coefficient.

These results were compared both to

the star ratings mortality domain, as well as to hybrid, the hybrid data. And those correlations are also high. The correlation to the hybrid data measure is 0.97, and the correlation to the star ratings mortality measure group score is 0.61. I'll stop there.

CO-CHAIR TRAVIS: Thank you for that. As you will see for MUC17-195, the preliminary analysis was conditional support for rulemaking, primarily based on not currently being NQF endorsed. This measure has been pulled, as have the others, but this measure has been pulled for deliberation and actual vote from the consent calendar. And I believe, let me just check to be sure I got this right, that Nancy Foster was the one that pulled it. So I will turn to Nancy and have her give us her thoughts around this measure and why she pulled it.

MEMBER FOSTER: Thanks, Cristie. I'd be glad to, and I would encourage my colleagues on the Committee to think about pulling some of these measures in advance next year just so I'm

not the only one talking, unless you really love to hear my dulcet tone.

So this particular measure I have some significant concerns about, and I would recommend a do not support. I believe, as we have seen with some of the other mortality measures, the ability to do appropriate risk adjustment without the clinical information that is necessary to really help you understand whether the patient is, by virtue of their health, their condition that brought them into the hospital, likely to die or not is significant. And we've seen that around congestive heart failure. We've seen it around the heart attack mortality measures. It is important to really know the clinical status of the patient in order to appropriately risk adjust this, any mortality measure.

For that reason and because this is earlier in the development. I believe the testing data has not yet been completed, at least that was the assessment that I saw. It has not yet gone through NQF endorsement. There are a

host of issues around this that really need to be attended to; so, hence my recommendation for do not support.

CO-CHAIR TRAVIS: Thank you, Nancy. So I'm going to take that as a motion on your part; is that correct?

MEMBER FOSTER: Yes, thank you.

CO-CHAIR TRAVIS: Okay. Thank you for that. Okay. We have some lead discussants that we will turn now to. Andrea?

MEMBER BENIN: So, Cristie, what I would like to do is give a summary of the pros and cons of the metrics, rather than sort of my interpretation. I can get to my interpretation at the end, but I think it's helpful. That way, everybody can make their judgment based on sort of hearing. And Karen and I had a brief conversation about the potential list of pros and cons, so we can add to that.

So I think that, if we start with the pros of this metric, it certainly seems as though it should be informative and should address those

big dot items that were on the original slides that were presented by Pierre. And that seems as though the direction that we would want to be going, and so I think that ability to potentially be a broad-based type of evaluation is a pro for this metric. I think it is certainly very thoughtfully developed and has had innumerable, it seems like, stakeholder groups involved.

Another pro is that it is suggested for use in the hospital IQR, which, if there were to be a program for it, that's the program that is pay for reporting, not pay for performance, and so that, if anything, seems like a potentially reasonable place to try this metric.

I think some of, another pro is that some of the key exclusions which I was concerned about when I started reading about this, for example patients with cancer and that kind of thing, those patients do seem to be excluded from the metric. I think another potential pro is that it may have the ability to drive improvements in coding of comorbidities as people

are working with their own data. I think those, to me, were the pros.

Then in the con category, I think I can re-express Nancy's concern about not having clinical status adjustments. For me, there is a concern that the development using the ICD-10 is still underway, and that is, for me and for how I think about metrics, this makes this not the same metric as what would ultimately be used, so this isn't the metric. So for me, there's a mismatch there. That's a technical thing in how I think about metrics that is hard for me to overcome.

I think that some of the other cons that have been listed, and these are in the comments also, is that this is potentially duplicative with the condition-specific metrics which are, to some extent, felt to be more actionable, that if you have a population of patients with AMI or heart failure or whatever you know where to go, as opposed to getting a list of all of your patients who died and chunking through them to try to figure out what

your action items are.

There were some concerns expressed in the comments regarding the need for some testing that specifically addresses the end-of-life interventions and that having a metric that is this global and overarching around end-of-life activity may promote extra end-of-life activities. And I know that we've certainly had conversations in this room about that issue, but some of the things that people may do to try to prolong life that may not really be warranted.

One of the comments was also indicated a lack of support by the National Coalition for Hospice and Palliative Care, and I'm not super familiar with that organization. Karen may actually know a little bit more about it. But it did concern me that that group was expressing concerns that this could inhibit referrals to palliative care, and I don't know their background or their biases, per se. But that did seem to be a potential con that was listable.

I think that the, again, the con goes

both in the pro category and the con category is the comorbidities are coded comorbidities. And then I think the range, and Lisa could probably express this more eloquently if folks are interested, but the range of performance was between five percent and nine percent, and two percent of hospitals are outliers. So I think in the technical report you guys had listed that there was some extent to which there's not a ton of discrimination in which hospitals are outliers.

So to me, those were the pros and cons. I think there's things on both sides of this. I think everybody in this room has a stakeholder group that they may or may not weigh these things differently. Personally, for me, the ICD-10 thing is a real hangup, and so that is sort of the overriding consideration for me. But I think that's what this metric -- and I know Karen had some other things to add, too.

CO-CHAIR TRAVIS: So, I don't want to characterize it for you so I'm going to ask you

to say, I know you've had that concern around the ICD-10, to what level does that, which decision category would you put your thoughts in at the moment, as to where you would want to be?

MEMBER BENIN: I would put that as a do not support. Because to me that it's a different metric with the ICD-10. So it requires a different set.

But then I realize there was some inconsistency in my thinking because I didn't, as we are voting on one of the earlier ones, I forgot that that was based on claims. And I didn't realize till later that it was probably based on ICD-9's also.

So I think to me having used ICD-10's it's a whole, it's really, really different how you interact with that set of codes when you're coding. So it's a very different beast.

So to me it requires pretty extensive redevelopment. And I think Lisa could probably speak to the extent of the redevelopment that you guys are working on. I know that there's some

underway.

Maybe that would put other people in a different category, but I do think that it's a different mapping. So I think maybe if we hear more about that we'll feel differently.

CO-CHAIR TRAVIS: All right, thank you for that. And then we have Karen.

MEMBER SHEHADE: Yes, the only thing I'd really like to stress, really in favor of this, speaks to two things. It is meaningful, I think, to patients and their families. And I think that's an important piece.

And it does put, when you read through it, you can see that it would push hospital facilities to work more closely with their other provider groups, like SNFs, like Home Health, other community resources for patients and families. And it really pushes the envelope, I think, to get that continuity of care, front and center, for any facility.

So, Andrea and I had gone through the pros and cons, but that was just one other point

I wanted to bring up.

And I think we had also talked about there would be better coding. Because people would definitely be making sure that they code better with this. So I think that was it.

CO-CHAIR TRAVIS: So, do you have a decision category that at the moment you would suggest?

MEMBER SHEHADE: Well, I would go with the recommendation of conditional.

CO-CHAIR TRAVIS: Okay, thank you. And --

(Off mic comment)

MEMBER VALDES: Right over here. Thank you. I would echo a number of the comments that Andrea made. And I believe that this has, this particular measure has more things against it than for it.

A couple that I would like to specifically call out would be that we have measures for mortality under condition specifics that really, based on the comments that I read

and based on my experience in our own hospital system, allow us to really aim improvement activity a lot in a much more targeted way.

We have been in the midst of developing a palliative care program for a number of years, and we actually are collaborating with Dr. Gawande on one of his national initiatives. And we have seen how difficult the decision and the communication between the physicians and their families have to be to reach end-of-life decisions in a crisis type of thing.

And I would be concerned and echo some of the commentary around either pushing folks out of the hospital a little too early or making hasty decisions around palliative care and hospice care.

The ICD-10 worries me as well a great deal. I'm assuming the measure was tested to the extent that it has been tested on ICD-9 primarily, given that we have a lot less time with ICD-10.

We have done a fair amount of internal

analysis with some of our readmission and mortality measures, comparing both sets. And I would be greatly concerned about using ICD-10 yet for this measure and our, the fact that it is a claim space measure only.

So, my inclination would be to not support the measure.

CO-CHAIR TRAVIS: Thank you very much. Just a couple of things I'd like to ask NQF Staff to help us maybe understand, because I saw some similarities in some of the issues that have been raised here.

What is the thinking about moving from ICD-9 to ICD-10 and how that impacts the work that NQF does both either in endorsement or in MAP? Does anybody know?

MS. MUNTHALI: I'll take that one. We've been thinking about this issue for the last five years and we knew when it came into existence, I mean, everyone in the whole world has been thinking about how we would convert.

So we've been giving developers some

time, especially on the endorsement side, to really get to be able to have the test beds, to do the testing in ICD-10. And so while this went into effect, I think 2016, we have extended and given a grace period of three years, to 2019.

So by then any measure that's submitted to NQF for endorsement must have ICD-10 testing.

Right now, they must MAP out. Do the cross walk between ICD-9 to ICD-10. But we're going to require everything that comes through NQF for endorsement. And as an extension, MAP, in 2019. I hope that helps.

CO-CHAIR TRAVIS: For that particular issue.

MEMBER JORDAN: This is Jack Jordan. And I feel a need to chime in here because this is something that just infuriates the hospitals.

We get a report, and we keep getting reports, that are still ICD-9 based. And of course your leadership thing, what are you going to do about it, and I can tell you the answer,

nothing.

Get the ICD-10 stuff out fast. We do not want things put on websites that's already older than two years old and they continue with it. Those should all be abandoned. And if you can't do it in an ICD-10, you can't do it.

CO-CHAIR TRAVIS: Well, thank you for that clear statement.

(Laughter)

CO-CHAIR TRAVIS: I do have one other question. Things that have already been endorsed, measures that have already been endorsed, what kind of timeline are we thinking about for them to be converted to ICD-10?

MS. MUNTHALI: So they're next maintenance review date.

CO-CHAIR TRAVIS: Okay. So next maintenance --

MS. MUNTHALI: So it's every three years.

CO-CHAIR TRAVIS: Right.

MS. MUNTHALI: We re-look at the

measure, we apply it against our evaluation criteria and we're going to expect that they're updated with ICD-10.

CO-CHAIR TRAVIS: Does that begin now or does that begin --

MS. MUNTHALI: Yes.

CO-CHAIR TRAVIS: Okay, so that's going now.

MS. MUNTHALI: Yes.

CO-CHAIR TRAVIS: Okay. All right. That was helpful to me. And then just one other, I'm going to turn it over to the developers for a couple of comments.

But I do have a question, ultimately, about when would this measure, if it moved forward, when would it be put into a program potentially?

And I know there's lots of if's around that, but I think that would be helpful to us. Understanding kind of where we're going with the ICD-9 and the ICD-10.

So you can address that whenever you

want to, but if you all want to do. Do we have a feel for when it would go? Or maybe the earliest --

MS. DUSEJA: So, the earliest that we can propose would be for next year. And then obviously that it would go into effect two years after.

CO-CHAIR TRAVIS: Okay, so the 2020 thing again --

MS. DUSEJA: Yes, that's right.

CO-CHAIR TRAVIS: -- would be the earliest --

MS. DUSEJA: That's right.

CO-CHAIR TRAVIS: -- that it could show up. Okay.

So those were just some clarifying questions that I had relative to some of the themes that I heard. And thank you all so much from the lead discussants for taking the time to help us understand this measure better.

I am going to give a very brief opportunity to the measure developers to respond

and to give us some information. The one thing that I do though want to remind myself of, is that this is not yet gone through NQF endorsement.

And so although I think that there may be some concerns about the results of the testing and the results, going back to our earlier conversation, we can't adjudicate all of that here. So, when you're giving your comments, if we can keep them a little broader.

And I'm going to ask if we can also do that here. Except for when, if we get to the point of putting conditions or review and revise on something, we can get more specific. But if you all want to take just a moment or two.

MS. BERNHEIM: Great. Hi, this is Susannah Bernheim. I'm going to let Lisa respond to a couple of the things that came up, but I just want to talk briefly about ICD-10.

As most of you know, we have the advantage of having a currently reported hospital-wide measure that's already in use in

CMS programs. The hospital-wide readmission measure.

So we have had to, to keep that measure in use, do a very extensive mapping of our ICD-9 codes to ICD-10 codes, using a lot of the same groupers and clinical categories and risk adjustment factors with a lot of success. Those results are available, they'll come back to the NQF.

But we have a lot of experience in doing that mapping, and we're in the process of doing it for this measure. This measure had to be developed in older data because we started a little while ago. It was a hard measure to build and we just didn't have the data at that point.

And the one thing I will say is that it will go to NQF this year, with the ICD-10 specifications. So that's underway.

So when it comes to NQF, it will come as an ICD-10 measure. Just to reassure people about that piece of the process. I'll let Lisa respond, high level, as per request, to some of

the other key issues.

DR. SUTER: Great, thank you, Susannah. So, just touching up on a couple of the other issues.

So, reinforcing that this measure was developed over a two year period, with a tremendous amount of stakeholder input, including a workgroup made up entirely of patients and care givers, with whom we spoke extensively about the end-of-life issues, there is no clear consensus broadly or with our technical expert panel.

But all of the stakeholder groups that we engaged with felt that this, the way that we defined the specifications and the hospice exclusions that we landed on, felt comfortable to them as a way to balance the challenge of measuring mortality while still understanding the potential impact on end-of-life discussions.

There were, although we are awaiting for formal TEP validity, and so I can't speak to the final TEP validity vote, just to clarify that.

This measure, in terms of the risk adjustment concerns, and I will try not to get into details, it has been compared to detailed risk adjustment with detailed laboratory and vital sign data available on your entrance into the hospital or into the emergency room and found to be highly correlated, which is reassuring to us.

In terms of the low number of outliers, although there aren't as many outliers as some of CMS's other claims, based mortality measures, there are similar numbers to several of the mortality condition and procedures, specific mortality measures, in use. Including CABG procedure mortality or AMI mortality.

And again, just reinforcing that this is currently under evaluation to update to ICD-10, with a plan to bring that information back to the TEP and then to the NQF.

CO-CHAIR TRAVIS: Okay, thank you very much for that. I see some cards that have gone up and since I was listening and looking over

here I don't know the order with which they did, so I'm going to kind of start with Helen and come around this way. So, Helen.

MEMBER HASKELL: I got lucky because I was indeed the last one to go up. So, but I'll take my opportunity.

I just wanted to say that as a patient advocate I strongly support this measure. If anything, my concerns would be that there are more exclusions then I would like. I think people with metastatic cancer should be referred to palliative care and hospice and you should not necessarily be dying in a hospital, that this would be an incentive rather than a disincentive, so I'm not sure --

(Off mic comment)

MEMBER HASKELL: Thirty day post-discharge, right?

MEMBER BENIN: Thirty day post-admission.

MEMBER HASKELL: Post-admission, yes.

MEMBER BENIN: So, 30 day post-

admission date. Right, Lisa?

(Off mic comment)

MEMBER BENIN: Yes. So if you die, you die. So, I mean --

CO-CHAIR TRAVIS: Can you put your -- yes.

MEMBER BENIN: Sorry, I must have dropped it. But this is, if you die any time after the day you're admitted to the hospital.

So if I think of friends who have died in the past couple of years they died either at home or in the hospital, but it was within 30 days of being admitted. Right.

MEMBER HASKELL: So, my understanding of mortality data now, and maybe I am wrong, is that if people are on palliative care, if they are in hospice, they are not included in those statistics?

CO-CHAIR TRAVIS: Why don't we get that from the measure developers --

MEMBER HASKELL: Yes.

CO-CHAIR TRAVIS: -- so we can do the

same page.

DR. SUTER: So patients who have a principle discharge diagnosis of cancer and who are enrolled in hospice at any time prior to or during the admission or upon discharge, they are excluded. If they have any diagnosis of metastatic cancer they are excluded.

Patients who have, who are enrolled in hospice, either prior to, on or within two days of admission, are all excluded from measurement.

CO-CHAIR TRAVIS: Thank you for that. Does that help clarify it, Helen, for you?

MEMBER HASKELL: Well, I think that's what I was assuming. So I think that this would actually encourage that, which is what, in general, we would like to see.

So, I think this is -- and the other comment I would make is that the condition, specific mortality measures, are not that useful to most people unless you happen to have condition.

So, the hospital-wide measure is

really much more useful for most patients in terms of looking at hospitals.

CO-CHAIR TRAVIS: Thank you. Andrea. Is your card still up? Oh, that wasn't even yours, that's Ann Marie's. Sorry about that.

MEMBER SULLIVAN: This question is for the developer. You said you looked at laboratory data, et cetera, did you ever compare by looking at a clinical record versus the claim stage and did you find out if there are any discrepancies?

In other words, did you ever test it to see, by looking at the clinical record, you got better data?

DR. SUTER: So we have not validated this with a chart review. We validated it with electronically pulled data elements that have previously been extensively studied and validated through a chart review. And that was what it was compared to.

So we know that the laboratory data and the vital signs that we were looking at, those have been validated through a chart review,

but we have not validated the claims based risk adjustment in a chart review.

MEMBER SULLIVAN: Yes. Because I would just like to add that I think, I absolutely agree that, when I have talked to people, patients, friends, family, what do you look at as a measure, mortality is the theme that jumps out. That's what seems to be important to people.

So I think this is when you have to be very careful about therefore, in terms of how you do it. Because I think it, a lot of our other measures, I think, they don't look at all that carefully, but this one they do.

And I think that's why I would tend to lean towards something that had a little more clinical information maybe added to it, as Nancy said.

CO-CHAIR TRAVIS: Thank you, Ann Marie. Sean.

MEMBER MORRISON: So let me just begin by saying that I support this measure based upon conditions of NQF endorsement for a couple of

reasons. The first is that hospital mortality is a key issue.

Hospital errors, if you believe Johns Hopkins, Johns Hopkins and the BMJ account for it are the third leading cause of death in the United States. And we need to do something about that and we need to do something about it now.

The concerns that I had, which I think will be addressed by NQF endorsement, was, one, I heard, and I agreed was, can claims do this? The answer is probably yes. If people document correctly.

Nancy is looking at me. But the reality is that under the other mortality ratios, hospitals have learned to document very, very well so they're observed to expected ratio changes. That's about behavior.

And I think that given the problem facing us and the fact that we will never have a perfect measure, this is probably going to be pretty reasonable.

The issue about palliative care comes

up. And just for those, to be clear, I direct an organization called the National Palliative Care Research Center. It is a member of the Hospice and Palliative Care Coalition.

That coalition represents the National Hospice and Palliative Care Organization which represents hospice in the United States. It represents both the physicians, nursing and social work chaplains and now pharmacists' organizations focused on palliative care, the Center of Advance Palliative Care and my organization.

I actually disagree with the letter that came in. I think that quite honestly this is a major issue.

I think that could it potentially prevent early referral to hospice or palliative care, perhaps. But I think when you weigh the issues around the number of people who are dying for medical errors, versus those who might have early hospice and palliative care referral, I think the public policy issue favors looking at a

standardized all-cause mortality ratio.

And again, I trust that when this goes through the endorsement process, that people will look very specifically at the issue around ICD-10's, which Lisa has raised. They'll look at the measures, they'll look at statistics, and that will be appropriately done.

CO-CHAIR TRAVIS: Thank you, Sean. Brock. Surprise.

MEMBER SLABACH: Thank you. Well, I would say that there's nothing that gets rural and small volume hospitals more excited than mortality measures.

And because I think it disproportionately impacts them, and we can go into a long discussion about that, and I think that it is a poor reflection of quality in an institution that's providing healthcare.

And the other main concern that we had, and was expressed to me in the conversations leading up to this, is the exclusions and how those exclusions of the 100 classification could

potentially reduce the population of patients being included. And then how does that impact the, so if you exclude a number of patients from your exclusions list, then how does that lead the statistic then in terms of its calibration to the rest of the population.

So, anyway, I'll just stop there. I am curious about the exclusions and how that impacts if there's a testing or any information on that.

DR. SUTER: I'm not sure I fully understand your question. I will say that this measure has been tested both with and without some of the exclusions.

Obviously the hospice based, most of the hospice based exclusions were made very early in development and we have not looked at putting those patients back in the measure.

We did exclude some groups of patients later in measure development based on challenges around risk adjustment, heterogeneity in the risk variables that led to model convergence issues.

We're revisiting those groups of patients during ICD-10 reevaluation with the hope that we can include them.

But we have tried to build the measure in a conservative way to make sure that the quality statement about the hospitals performance is a cautious one. And therefore, if we felt like we could not adequately risk adjust groups of patients, those patients were excluded.

The testing of the measure, in terms of the, you know, internal consistency among the service line division results and the overall results really haven't, did not change with the exclusion of those groups, which I think gets at your question. But I think this is certainly something that we could address with scientific methods committee with the NQF endorsement process.

MEMBER SLABACH: I want to be clear, Nancy, perhaps I was a little bit unclear. The mortality statistic is not a reflection, I don't feel, and I do not support the measure.

Because it's not a metric of quality, and I think that's what we're trying to measure within the programs that we're trying to yield improvement on. So I just wanted to be clear.

CO-CHAIR TRAVIS: Thank you, Brock. Lee.

MEMBER FLEISHER: So I will disclose, I was on the workgroup and I will not be voting, as Elisa will remind me.

But I did want to say, so the development of the measure was excellent. And the thought process, and they took all the input around the issue, from my perspective in the workgroup, a lot of the issues we presented.

The question is, and the developer knows this but it was requested by CMS, is whether this measure should exist at all. And the issue is, and I have to echo the question, we believe that, there is another colleague and I that service line specific measures are excellent, cardiovascular mortality, GI mortality, et cetera, but when you get to an all

hospital mortality the question is, there are great hospitals, which will be great overall, there are very poor hospitals, which will perform very poorly overall.

And everywhere in the middle the question is, that they're average but they may be excellent in one area and poor in another. They may be excellent at taking care of multi-morbidity or they may be excellent in taking care of the rural population.

So the question is, does, I recognize that patients believe they want this measure, but our question was, will this actually help patients to decide if they have a condition, like an acute MI, do they go to Hospital A or B, if in the middle it's all the same and it doesn't give you any discriminatory power.

So, again, if this measure is felt to be important, then I think that the measure developer took a lot of the concerns into consideration.

But the question is, would be better,

and I know they subdivided this, an all-cause hospital mortality measure may not be the most useful thing to actually drive quality, given the local issues of where best to go, for a given condition.

CO-CHAIR TRAVIS: So, just taking one moment out, I want to be sure that we do get through our work today, and we've got two more measures after this one. I think that there's probably, some of the things we're talking about here may be applicable, although it is a different measure setup differently that might address some of the concerns.

So what I'm going to ask is that as we go around, please kind of keep in mind if someone has already kind of stated what you think. Just do that with your vote.

And bring up, let's bring up the new things that we want to be sure, get on the table, so that they are heard. And I'm a little concerned about taking out, every time someone brings up an issue and having you all respond.

It would be helpful to me maybe though if you can kind of keep track of the issues and then maybe we can have, at the end, a time for you to address the significant issues.

And that will give us, I think, a way to still have your information but still to kind of move through the process.

So, we want to get everybody's comments online here. That's not the intent of this, but let's just be sure that we do it in a meaningful way.

So, Janis, are you next?

MEMBER ORLOWSKI: So, we do have extensive comments that are online, and so I won't repeat those. I just have two issues.

One is, I am concerned that the risk adjustment, first of all, obviously the issue of SDS adjustment, but also I think the issue of complexity.

I'm concerned that ICD codes, whether they're nine or they move to ten, that we have issues of frailty. And I think this is a measure

that would be better to have some EHR data that is associated with it.

The other specific question that I'd like to point out and ask and see if we can get an answer at some point, is that the description for the denominator is a little bit confusing. Or I found it a little bit confusing.

What it says is that the description of hospice enrollment is if the individual dies within two days of hospital admissions, are excluded from the denominator, I believe. If they're there for three or more they're included.

And I would say that there are conditions of rescue where it would be appropriate that you include the first 24 to 48 hours. And so I'm not sure as to the reasoning for this exclusion, for the denominator. Thanks.

(Off mic comment)

CO-CHAIR TRAVIS: I'm sorry, I couldn't hear you?

PARTICIPANT: To your point, I don't know how much you want us to get into technical

pieces, but I'm happy to give you my email address instead of spending time now going over it.

CO-CHAIR TRAVIS: I think that we will keep going at this point because I'm sure there are lots of specifications that we could try to get to, but we do want to be sure that Janis' point is being captured.

And when we get to deciding what to do with this measure, let's be sure that the question relative to the denominator and exclusions are there. Okay, Lindsey.

MEMBER WISHAM: So, I understand we'll be voting on these separately, but I wonder if there's value in the discussion in coupling the hybrid measure with the claims based measure, because I think in reading through some of the specifications, the hybrid measure does address some of the risk adjustment through clinic data and the robustness of it.

I guess I would like to hear, I think that may help inform the differences between the

specifications and how potentially implementing both in the same program could inform or complement each other.

CO-CHAIR TRAVIS: So that's a good question. I guess, kind of going back though to the original, when we had your original opening comments on this, would the intent be to offer them, to have both of them in the same program at the same time, or would the intent be, as I thought I heard it, to put the claims based in probably earlier because you could, and then the hybrid measure would come in later.

So my question would be, do you intend to have them both in the same program, at the same time?

MS. DUSEJA: Thanks for that question. So, due to operational issues we would be implementing the claims measure first. It will take time, as you can imagine, to being able to get the hybrid measure in and getting the required data collected from hospitals. We see that as a longer time frame in terms of that

being implemented into the program.

The goal would be, if it does get implemented into the program, just depending on the data collection or our ability that if we get enough data collected, that we would transition to the hybrid measure.

CO-CHAIR TRAVIS: So, in a perfect world, you --

MS. DUSEJA: In a perfect world, yes.

CO-CHAIR TRAVIS: -- probably wouldn't have both these measures in the program --

MS. DUSEJA: That's right.

CO-CHAIR TRAVIS: -- at the same time?

MS. DUSEJA: That's right.

CO-CHAIR TRAVIS: I don't know, Lindsey, if that reflects any difference for you or not?

MEMBER WISHAM: Yes, I'll save my questions until we talk about the hybrid measure though.

CO-CHAIR TRAVIS: Okay.

MEMBER WISHAM: Just knowing that they

will be handled neutrally exclusively as answers my question.

CO-CHAIR TRAVIS: In an ideal world.

MEMBER WISHAM: Yes, in an ideal world.

CO-CHAIR TRAVIS: Okay. I don't see any more over here. Oh, sorry, Dan, I didn't see yours.

MEMBER POLLOCK: I don't get to vote so I'll just be very brief in the comment about the application of standardized mortality ratios, which is a tool long used in epidemiology, to quality measures in general. Because I think the group, if you're not familiar with the history of this particular tool in epidemiology and you trace it, there is increasing concern about applying a standardized mortality ratios, in epidemiology, to understand the etiology of disease.

These are ecological measures that have to be used as hypothesis generating tools that require further study. In the analogy, in

the health care quality realm, is that, yes, the mortality ratio is going to capture a lot of attention, but to use it as a guide to a patient choice or to use it only as a starting place, is really what's necessary and calls out for further analysis.

So if this measure is indeed to be publicly reported, it will, no doubt, capture a tremendous amount of attention. But then there is going to be the rest of the story.

And the rest of the story is really where the action is in terms of getting at the quality issues that can be improved. So there is something to be learned from the history of this particular tool, which has value, but not really for the quality measure purposes that are being described today.

CO-CHAIR TRAVIS: Thank you. Is this Rich or Keith that has their card up? Okay.

MEMBER KNIGHT: Yes, I just want to say that I actually agree with what you said. I think that it's a starting point, as all the

ratios are.

And in many cases, people don't really understand them. But it's a starting point that can be an indication.

And I think when you start looking at smaller hospitals and other instances, you have to, certainly have to take that into consideration.

Quite frankly, from my community, when my friend went into the hospital, good friend of mine who has a degree in medical sociology, looks at the numbers and said, your mother's not going to do very well in the hospital, period. So you need to be ever vigilant.

And with respect to patients, I think that that's something that one does need to be aware of. There are disparate issues and there are issues.

So, getting a good framework from what a facility might offer, I think is very important. And I think that this is the measure that can at least give you a feel.

And then you're going to have to obviously go with more detailed information. So I certainly support the use of the measure.

And besides, we're talking about, what, 2020 implementation? So the future is based on decisions that we make today.

So that's pretty far down in the pipeline in terms of technology and everything, being able to help you better assess this. Just a thought.

MEMBER POLLOCK: I sense, if I could, that we're in fundamental agreement. This is a starting point.

But I think the question is, do we want to start with publicly reporting and use, as a basis for pay for reporting, a starting place or do we want to enable measures. And there's a tremendous call for more targeted measures to service the starting point.

I think that's the fundamental decision that this measure can serve certain purposes. And perhaps hospitals that aren't

already looking at their mortality data should be looking at their mortality data and using a standardized approach.

But do we want to publicly report these statistics and have that guide, consumer choice? I think that there are some misguided pre-steps there. And think of it, just to use an approximate analogy.

If you're a consumer and you want to make a decision about where, what city you want to move to and you look at homicide statistics, all-cause homicide statistics, and you make a decision on that basis, that says nothing about individual neighborhoods.

And cities are composed of neighborhoods, hospitals are composed of services. And there are differences. And to obscure them with a single measure as though it stands for the quality of care, takes away from where the action is.

CO-CHAIR TRAVIS: Thank you. Thank you, Dan. I appreciate that perspective.

Helen, is your card up?

(Off mic comment)

CO-CHAIR TRAVIS: Please use your mic.

MEMBER HASKELL: So, I would, yes, I would -- I really disagree with the epidemiological perspective on this. I think that these measures were very valuable in the U.K. for sort of pinpointing problems, or many pinpointing is not the right word, but flagging problems. And I think they would be here.

I think the hospital has to be responsible for all its programs. And if you've got failing programs, people need a little bit of a fire underneath them to improve those programs. And not just try to coast on their good programs. So that's one thing.

I think this is a really useful measure for consumers. And it's a really useful measure for improvement.

If it gets hospitals looking at every death, which I think it does when people start examining immortality data, then it's a good

thing.

And the other thing I would just say is about the exclusions. I am concerned about those, the first 48 hours and cardiac arrest. There's some things that I think look to me and said they would easily include errors and failure to rescue that are among the exclusions.

CO-CHAIR TRAVIS: Thank you. Wei.

MEMBER YING: I would say this conversation, this discussion is a little bit like what we discussed a couple years ago when the all-cause readmission measure came out then their service line readmission measure, it was a heated discussion at the time.

And I think the similar rationale would apply here to, that when there is a systemic issue we want to look at it globally. If there is a facility the mortality rate is truly an outlier, it doesn't matter which service line that is any more.

Of course, now clinic improvement point of view, again, the clinical line either

readmission or mortality measure will be more actionable, but just from a system level of measurement. These type of outliers, at the global level, is still very meaningful.

CO-CHAIR TRAVIS: Thank you. Jack, did you have another comment or have you made your comment?

MEMBER JORDAN: No, I do have one. I think there's a balancing measure with this that I think is important for interpretation.

You know, when we saw papers coming out around readmissions of CHF are negatively correlated with mortality, COPD and all-cause all have this potential issue that if you inflate your denominator because you're really bad about keeping people out of the hospital and they cycle in and out numerous times in their last year of life, that that inflation of the denominator actually makes your mortality look better when it's not.

And none of these measures ever seem to talk about or have any balancing measure of

kind of final year of life utilization to kind of give any idea about that inflation that can, or maybe in theory, happening.

And I think that's kind of an important thing to be considering that as we're trying to do better and better at population management, you may rightfully see mortality go up because you're not sending someone to the hospital four or five times in their last year of life, which they survive. But better care would have been keeping them out of the hospital altogether.

And I do think all these comments that people have talked about, the frailty and the things in the population are truly important as well. They're very hard to really interpret kind of a global mortality.

That said, I'm not against being transparent with it, I think things would be learned from it. But I think for fuller understanding, you need to have some of that utilization kind of things there to help tease

that out.

CO-CHAIR TRAVIS: Thank you. I see one more card up, Sean. And then after Sean, oh, you've already done it?

MEMBER MORRISON: Yes, I have.

CO-CHAIR TRAVIS: You're not going to do it again?

MEMBER MORRISON: I'm not going to do it.

CO-CHAIR TRAVIS: Okay.

(Laughter)

CO-CHAIR TRAVIS: All right. Well, I don't see any other cards up from the workgroup, so I will turn it back to the measurer developer for some final comments, if you like.

If you need to respond, because you just have to, to something that was kind of in the weeds, you may. But I would prefer for us to kind of think about the big implications that people have brought up and focus in that area, if you can.

DR. SUTER: So, the three sort of big

issues I heard were scientific acceptability, which I think will predominately be dealt with by the NQF community, flagging two things that just came up. One, this measure randomly selects a single admission.

So while a patient may have multiple admissions in a year, only a single admission is captured because of that particular issue with mortality and that your last admission, obviously, has the highest risk of mortality and your other admissions don't. So just, I think that addresses that more recent.

And the issue about the epidemiological use of SMRs, this is actually, it's not a traditional epi-SMR, it's a ratio of adjusted actuals to expected use using a hierarchical modeling. So it is a slightly different approach and allows us to compare to a nationally, a national average performing hospital who had your hospital's patients.

In terms of sort of usability and meaningfulness, again, we heard from a number of

patients, and patient stakeholder groups during development, the value of this measure.

We also heard the value of service line information. So, this measure does use 13 service lines. If we can include additional service lines during ICD-10 update we will.

And we have asked for public comment in the past and we will continue to ask for comments on how to present the information to be most meaningful to patients and stakeholders, in addition to an overall hospital-wide mortality rate. Thank you.

CO-CHAIR TRAVIS: Just one clarifying question. When hospitals get feedback on their performance on this measure, will they get feedback down at the 13 service lines as well, similarly to the readmission measure, I believe?

DR. SUTER: They'll get patient level hospital specific reports that include every single patient and where they sit.

CO-CHAIR TRAVIS: But they would be able to see, in each of those service lines where

their performance is?

DR. SUTER: Yes.

CO-CHAIR TRAVIS: So from a quality improvement standpoint, it could show them which of those service lines --

DR. SUTER: Yes.

CO-CHAIR TRAVIS: -- would be most important to take a deep dive into?

DR. SUTER: That's correct.

CO-CHAIR TRAVIS: Okay. Okay, thank you for that.

MEMBER JORDAN: One question though. You talked about a randomization, this means that a hospital could not recreate this measure at a local level because they wouldn't be able to recreate your sampling?

DR. SUTER: So, none of CMS's claims based measures can necessarily be duplicated because of the centralization needed for risk adjustment. And this measure is similar in that.

However, as you just described, CMS has in the past, and I anticipate would continue

to do so, would supply hospitals with every single patient in the measure for quality improvement purposes.

MEMBER BRENNAN: This is Joan Brennan. Related to the index. So, the index case would the mortality go to that in that, to the organization of the index case?

DR. SUTER: Yes.

CO-CHAIR TRAVIS: Yes.

MEMBER BRENNAN: Okay.

CO-CHAIR TRAVIS: Okay. Well, seeing no more cards up, and we do have a motion on the floor for do not support, so we will deal with that motion at this time.

And are you all going to want us to stand up again, is that the easiest way?

(Off mic comment)

CO-CHAIR TRAVIS: Okay. So, if you are in favor of do not support, please stand.

MS. MCQUESTON: Ten.

CO-CHAIR TRAVIS: And anybody on the phone want to vote for do not support?

MEMBER BRENNAN: Joan Brennan, do not support.

MS. MCQUESTON: We have 11 for do not support.

CO-CHAIR TRAVIS: Okay. So on those, all of those that oppose this motion, please stand. Anybody on the phone oppose this motion?

MEMBER JORDAN: I oppose the motion.

MS. MCQUESTON: Fourteen votes against the motion.

CO-CHAIR TRAVIS: Okay. So --

MS. MCQUESTON: So, the motion has not --

CO-CHAIR TRAVIS: The motion failed.

MS. MCQUESTON: Failed, yes.

CO-CHAIR TRAVIS: Okay. The motion failed. I'm trying to think through the next step, because we want to take our learning's from the earlier process that we went through and not recreate the issues, so I'm going to turn it to Erin since she seems to want to say something.

MS. O'ROURKE: We were going to

suggest, from a Staff perspective, that we not use the default part of the process and that the Chairs entertain additional motions until we can find consensus.

CO-CHAIR TRAVIS: Okay. All right, so do I hear another motion from the workgroup, on how to move forward with this measure?

PARTICIPANT: Can you repeat what the conditions are?

MEMBER MANNING: So right now the Staff conditions were submitted to NQF for endorsement. But you're welcome to add additional conditions.

MEMBER SHEHADE: I would move to support with conditional, under conditions of NQF endorsement.

CO-CHAIR TRAVIS: Okay, thank you. All right, so we have a motion for conditional support with the condition being NQF endorsement. Did I get that right? Okay.

All right, we can have discussion. Yes, you can go.

**MEMBER GHINASSI: You know, I've been listening to this, I've been experiencing a combination of amnesia and deja vu, which is a disconcerting sense I've forgotten all this before.**

**And what's been difficult for me with this measure is, I came into this wanting to support this. From a default position, it's very hard not to say this is a great thing. Until you open the hood up and you start to look at what's under the hood.**

**And I've worked in large systems my whole career, not-for-profit academic systems, and I've worked places that have very large academic centers. And they also have rural and outlying community hospitals, and I can tell you that the numbers, we looked at all the numbers, and I can tell you the numbers were always darker in the larger academic facilities. As was the selection of which patients went to which one. Not just by the organizations but the communities.**

And so, the concern I always have with this is, it's so hard to get the measurement right, and yet it's critical to get it right. Because while the obvious concern is that people are going to think a particular hospital is bad, I'm more worried about the other one.

Which is that a good number on this is going to lead consumers to think that a place is good, when in fact that may be completely inaccurate.

And I think that because I don't know what's under the hood in this, I haven't seen the exact algorithms that are involved in case mix analysis and whether there is an actual belief that the current state of the art in electronic case mix analysis is going to, even in the hybrid version, is going to allow us to accurately depict not only the conditions that got the person in the hospital and their physical conditions, but the other thing that people haven't brought up, although it was mentioned in the comments, I would want that analysis to also

include the capacity of that community to handle those conditions. Even if they're properly handed off, once they're left.

And I don't see that in the algorithm. There's no way for me to evaluate that. So what I'm left with is this sort of concern that it's a wonderfully compelling measure until you actually look at it.

And we're going to push data out that will have people either, they will make judgments that I am grossly concerned will be inaccurate. And I don't know exactly how else to say that.

So what I'm asking is, I would like the motion to include, but in addition to NQF endorsement, that there be substantive, published, evidence based empirically validated information on the algorithm, a demonstration that that algorithm is tied to actual mortality issues, that it's transparent so that it can be judged and looked at. And right now, we don't have any of that.

So when you ask me to make a decision

about whether I'm in favor or not in favor of this, what I have to offer is, how would I know.

CO-CHAIR TRAVIS: Thank you. Thank you for that.

MEMBER GHINASSI: You're welcome.

CO-CHAIR TRAVIS: And I'm hoping somebody other than just me wrote down that condition.

PARTICIPANT: I got it.

CO-CHAIR TRAVIS: Thank you. Thank you very much. Nancy.

MEMBER FOSTER: Thanks, Cristie. So, just for clarity, I thought the condition that staff imposed on this was that there would be demonstrated validity at the facility level. Because this measure has not yet been tested at the facility level, I believe.

So, it may be good at the national level, it may not be so great at the facility level is the question that was being put forward.

CO-CHAIR TRAVIS: So, thank you for raising that issue. I look to Staff. I mean,

this has not been NQF endorsed at the facility level.

MEMBER FOSTER: It has not.

CO-CHAIR TRAVIS: Or any level.

DR. SUTER: Sorry to interrupt. So it has been validity tested at the facility level, so hospital level testing has been compared to hospital level, mortality group score, domain group score for the star ratings domain. It's also been tested against electronic health record data.

MEMBER FOSTER: I'm sorry, that's a validity test?

DR. SUTER: It is --

MEMBER FOSTER: You and I have different definitions of a validity test then --

DR. SUTER: Agreed. And I'm sure that NQF --

MEMBER FOSTER: But I'm only asking for clarity around the staff recommendation.

DR. SUTER: Okay.

CO-CHAIR TRAVIS: Yes.

MEMBER FOSTER: To know what we're voting on. And then I have a comment.

CO-CHAIR TRAVIS: And my additional question, I would like Nancy's question answered, but I would also like to know if this is NQF endorsed at the level to which it is being asked for us to be putting it into a program.

(Off mic comment)

CO-CHAIR TRAVIS: Right. Okay, I mean, I didn't think so. And I guess I was interpreting the Staff's condition that it had not been endorsed at this level. That's how I was interpreting it. But please, the Staff knows what they said, so whatever you said, let's go to you.

MEMBER MANNING: So the language just refers to, the measures, when they're specified, they have to be tested at that specification. So it has been tested at the facility level. It will be submitted at the facility level.

And that's the level of analysis that it will be reviewed. It's just the language.

But it's not a provider level, a provider physician level measure.

MEMBER FOSTER: So, to be clear, the condition that exists right now, in addition to the one Frank just articulated, is that the NQF endorsed, which would include testing a validity at the facility level?

CO-CHAIR TRAVIS: That's correct, because you can't endorse a measure that has not been tested at the level to which it's being proposed for.

MEMBER FOSTER: And I would propose additional conditions that ask the steering committee to be very explicit around assessing what my colleagues here, Lee and Dan were articulating, around the importance of this measure, the worthiness of it, and the potential unattended consequences of sending the wrong signal, based on this measure of hospital-wide mortality.

MEMBER MANNING: And I can assure you all of those issues are part of our criteria and

part of our evaluation.

MEMBER FOSTER: Yes, I know they are, but I'm saying --

CO-CHAIR TRAVIS: It's okay, we're going to put them on the list.

MEMBER FOSTER: -- this measure has particular relevance.

CO-CHAIR TRAVIS: We will put them on the list, assuming that the original motion can be amended to include these additional conditions, which I'm pretty sure it will be. So, Marty.

MEMBER HATLIE: There is no perfect measure. The potential of unintended consequences I think is often used as a way to delay progress. I think this is a really meaningful piece of information for consumers to use.

I don't, frankly I respectfully don't think that people are going to make a decision based only on this measure. I think they'll factor it in.

Richard has spoken to that, Helen's spoken to that. So I'm going to support this motion just because I want to, I don't want to slow this process down.

I think this is years and years of work that will really move the discussion a field forward. Is it a perfect measure, no, but it's, it represents, again, a transformative approach to looking at something that consumers want, and that is an overall picture of a safe hospital.

CO-CHAIR TRAVIS: Dan.

MEMBER POLLOCK: I think it's also years of work going backwards. Because the call from the clinical communities of practice in the healthcare, which certainly are part of what we should be incorporating in healthcare quality measurement, are for more targeted measures. Not more broad measures, more targeted measures.

This moves us in the other direction. This moves us in the direction where the targets are submerged under a very difficult to interpret, for consumer purposes or healthcare

quality purposes, summary statistic.

So I think it will confuse a lot of people. Particularly when it's publicly reported and described as an indicator of overall hospital quality.

Yes, five years ago we had this same conversation, why are we having it again today. Yes, we have to look under the hood. But I would say we also need to kick the tires before we take the car off the lot.

CO-CHAIR TRAVIS: Let me go to Maryellen and then to you. Maryellen.

MEMBER GUINAN: Hi, thanks. I know, understanding that we're doing conditions that are getting pretty specific today that isn't usually the case, but also understanding that we did that for ESRD so I would like to add another condition.

That it certainly go to the disparities committee, specifically, and to look specifically at SDS and those factors that come into play. And just addressing, in terms of the

consumer role here and the confusion, I know that we've seen a lot of that with the star ratings itself that have come out with overall ratings.

Likewise, just as a quality improvement on the provider level, we do have condition specific measures that I think are valuable at the provider level in terms of designing quality improvement initiatives at a facility that drive then patient improvement or quality improvement.

So, at the provider level the condition specifics are working and are probably what facilities look to first in terms of driving their quality improvement. And likewise, consumers, when they have a condition and are going into a facility, they're looking at condition specific.

And if they're looking at a hospital-wide, then there really needs to be additional education at the consumer level that I don't think is very robust right now to clarify what that measure actually means.

And to Nancy's point, that is where the unintended consequences come from in terms of the measure not being understood or not being a valid indication of quality. That it's more factors that are beyond the control of the hospital in many cases. And so that needs to be made clear.

CO-CHAIR TRAVIS: Thank you, Maryellen. Sean.

MEMBER MORRISON: Yes, and I'm going to respectfully disagree with you. Because I think there are two audiences for this measure.

There is certainly patients, but the other major audience is hospitals. And hospitals look at this and they make changes very quickly.

Now, I think we can argue and we can go back and forth about whether the most appropriate manner is to make individual disease specific, condition specific adaptations or whether quality and the culture of quality really is an institutional-wide issue.

And I would argue actually it's the

latter not the former. And that we can narrowly focus on narrow conditions, but that ignores the entire system.

And is this measure perfect, no. And as you pointed out, I mean, is there a risk of using observed to expected ratios, yes. But is it, does it actually measure something different across different hospitals, I would argue that it does.

And if I'm a hospital looking at my rankings and looking at my score, I'm damn sure going to be focusing on trying to figure out how I'm going to improve it, even if it's a global measure. And so I don't think that it's just consumers that this targets. And so that is why I would, again, vote for the conditional.

And with NQF endorsement who will look at all of the conditions that have been raised already. That's all part of the NQF endorsement process.

CO-CHAIR TRAVIS: Okay. I don't see any other cards here. Anybody on the phone

raising their hands? Okay.

Okay, one question. Turn your mic on though.

MEMBER HASKELL: So, my question is, why it could not be made possible to drill down on a measure like this as part of the measure?

So, if we already have the condition specific measures that they could not somehow be correlated so that you could do both.

And then I'm going to slip in another question, which is, if this is fee for service, what about Medicare advantage data? I'm concerned that we're losing a lot of the population.

CO-CHAIR TRAVIS: Okay. Well, we will make a note of that last question. It is my understanding, and I'm just going to ask for one final clarification, that the hospitals are given this information at the 13 service lines, and they are also given the individual patients that are going into the numbers.

So the ability for the hospital, at

least by service line to be able to kind of dig a little deeper, would be there. Is that correct?

DR. SUTER: That's correct.

CO-CHAIR TRAVIS: And this also is not replacing the condition specific measures in the program either, correct?

DR. SUTER: That's correct.

CO-CHAIR TRAVIS: Okay. And this is taking off my Chair hat, I mean, I think we need the blend of both, because unfortunately we can't have condition specific measures for every single possible reason that somebody would go in.

And I also tend to agree with Sean relative to the cross cutting and the global nature of the culture and the approach within the hospitals. So, just a couple of other added thoughts.

So I think it's time for us to vote. The motion on the floor is conditional support for rural making.

The conditions that I was able to write down were for NQF endorsement, the steering

committee to be explicit at the worthiness and the unintended consequence, which are both part of the endorsement process but we will call that out.

There was a condition around the published evidence and empirically validated nature of the algorithm and to be transparent. And then the involvement or the, whatever is the appropriate way to engage the disparities committee.

So, those are the conditions. Do you accept those as amended to your motion? Okay, thank you, I appreciate that. Nancy?

MEMBER FOSTER: We had discussion around the ICD-9, ICD-10 issue, I don't know if that was to result in a condition, as in --

CO-CHAIR TRAVIS: It's going to come in as an ICD-10 measure, correct?

MEMBER FOSTER: Okay, so we don't need a condition.

CO-CHAIR TRAVIS: That's what I was thinking. But thank you for bringing that back

up.

Okay, so all those in favor of the conditional support with the conditions that have been outlined, please stand. Anybody on the phone?

MEMBER BRENNAN: Joan Brennan and I support it. Sorry.

CO-CHAIR TRAVIS: Okay, Joan supports.

MEMBER JORDAN: Jack supports.

CO-CHAIR TRAVIS: Jack supports. So two on the phone support. Okay, all those that --

MS. MCQUESTON: Sixteen votes supporting the motion.

CO-CHAIR TRAVIS: Okay. Sixteen. I talked over, 16 support. All those who oppose the motion please stand.

MS. MCQUESTON: Nine votes against the motion.

CO-CHAIR TRAVIS: And I don't have a way to calculate and I can't do it in my head, so at what percentage are we?

(Off mic comments)

CO-CHAIR TRAVIS: It's higher than 60?

(Off mic comment)

CO-CHAIR TRAVIS: Okay, thank you. I'm glad you're so good, I don't know how you do that in your head.

PARTICIPANT: Twenty-five people times --

CO-CHAIR TRAVIS: Well, that doesn't mean anything to me.

(Laughter)

CO-CHAIR TRAVIS: Okay. So it appears this measure has, this motion has passed. Because we're above 60, so we've reached a consensus. So, congratulations to everybody in the room.

MS. QUINNONEZ: Just to make a quick announcement so everyone is not wondering who else is on the phone, we had two phone participants to drop off, so we're only looking for two votes on the phone.

CO-CHAIR TRAVIS: Okay, thank you for

that. Okay, well, let's move to the second one. It's MUC17-196, which is the hybrid hospital-wide all-cause risk standardized mortality measure. The preliminary analysis result is conditional support for rulemaking.

This measure has also been pulled by Nancy, and so I'm turning it over to you, Nancy.

(Off mic comment)

(Laughter)

MEMBER FOSTER: Okay.

CO-CHAIR TRAVIS: Well, let me ask you this, does anybody else want to pull this measure and relieve Nancy of her --

(Off mic comment)

CO-CHAIR TRAVIS: We're not looking askance, we just appreciate that you --

MEMBER FOSTER: No, no, no, I didn't feel the anger yet.

(Laughter)

CO-CHAIR TRAVIS: No. We appreciate your preparation for this meeting.

MEMBER FOSTER: Right. Right. My

recommendation here is for conditional support. But the issue I want to raise in addition to the one that the Staff has already outlined, has to do with the fact that we have, in existence, a variety of electronic EHR measures.

Our ability to generate accurate valid data from those EHRs has been less than acceptable. In part because of the way the measures were designed, in part because of the way the EHRs are designed, and the marriage has not been perfect. By any stretch of the imagination.

And therefore I am concerned that we pay particular attention to the ability to accurately and consistently collect that data that is necessary to do risk adjustment, across various EHR platforms and hospitals. Before this measure is put into action.

CO-CHAIR TRAVIS: Okay, thank you for that. So two conditions, the NQF endorsement plus the concern that you just raised.

I am going to ask the measure

developer, before we even get into the lead discussant, to give us a very brief, a very brief description of this measure, so that we can all be on the same page about it.

DR. SUTER: Absolutely. So, the brief description is, you take the claim spaced measure and you add an additional set of clinical variables into the risk adjustment model. That is the difference of the specifications.

Those clinical variables are, they're all in a voluntary reporting for the current hybrid hospital-wide readmission measure. They've all been clinically adjudicated through formal testing in multiple EHR systems for their feasibility and reliability of extraction.

The other difference for this measure is because it uses electronic health record data, it was developed not on a national sample but on a limited number of hospitals. Twenty-two hospitals.

And the testing data essentially show a very similar result to the claim space measure,

similar reliability. We have not done validity testing at the facility level at this point, and it has not been submitted to NQF. I think those are the salient differences.

CO-CHAIR TRAVIS: Okay, thank you for that. So, we have some lead discussants who we will go to first, and then we will open it up for the rest of the workgroup. So, Frank.

MEMBER GHINASSI: So, I'm not going to repeat any of the issues that were raised last time, everybody has heard them already. Just a couple of additional thoughts about this.

This one comports to be a more informed measure. That's the presentation. And so, just some issues to have the group at least consider.

There is, at best, a patchwork of electronic medical record systems across the country. They are driven by a totally separate industry. They are not yet speaking a single voice.

And it's concerning, I think, at least

at this juncture, that we're predicating the current data on an n of 22.

So I would recommend that there be a systematic stratified look at a reasonable set of electronic medical record systems, across the country, that look at different systems, systems that are integrated with FIN, systems that aren't integrated with FINs, ones that are in standalone facilities versus ones that are in large systems. That we really look at the industry.

And you can't do that with an n of 22. And that's got to be systematic. And I think that's got to be very transparent.

And then I, I lied, I'm going to reiterate one thing. I really think that the devil is in the detail on this.

And my hats off to people that are going to try to tackle the algorithm that's going to look at acuity. And I'm saying that because we have not done a good job at that in this country. We say we have but we haven't.

And this measure is predicated on

doing a good job at that. It will be among the first to do that, if it pulls this off, in a broad system.

So I think the weight of responsibility sits on us who are saying we are going to do that.

And then the final piece on this was lost in the previous recommendations. This is taking one segment of an issue, which is mortality.

Which is an issue that spans an arc of an illness and multiple institutions that happen before the hospital, during the hospital and after the hospital. And it's predicating the measurement on one link in that arc.

Which makes me question the 30 day mark. I noticed in one of the other measures seven was chosen. I'm guessing because of the proximity to the surgical procedure.

So it strikes me that having chose 30 is taking into account a bigger swath of the arc, which then, I believe, loads responsibility back

on the measure development. That it includes risk adjustment, that includes those other segments.

Including the ability of the community to provide post-hospital services, the ability of that community to use appropriate methods. And just the plain availability of that in an urban area versus a frontier state.

And all of that has to be transparent if this is going to have any validity. I'll stop with that.

CO-CHAIR TRAVIS: Thank you, Frank. Marsha Manning.

MEMBER MANNING: Well, like Frank, I don't want to repeat some of the comments that were made on the prior measure. But related to a couple of issues that Frank brought up.

I recognize that some of the EHR fragmentation issues are real. I think that the hospital purchasers of those systems need to drive alignment across those EHR systems in order for the entire system to be able to support these

types of measures.

So, that's something that the hospital community needs to call for from their vendors, to drive that alignment.

And in the same way, that sort of arc of care issue that you mentioned. You know, I think that that is a reality.

And like many other measures that are part of these programs, this should drive the hospitals that are being measured for mortality, to work more closely with the other members of that arc of care, to improve care across the continuum.

CO-CHAIR TRAVIS: Thank you, Marsha. Nancy, you're also one of our lead discussants, did you have anything else you wanted to add?

MEMBER FOSTER: So, in addition to the condition I added at the beginning in my motion, include the conditions that were added to the last measure. Around relevance of the measure, importance of looking at unintended consequences and so forth.

CO-CHAIR TRAVIS: Okay. Okay, thank you for that. Okay, Lindsey.

MEMBER WISHAM: So first I think, I'd like to say, I don't think we should be scared away because it's an eCQM. I will acknowledge that there have been a lot of challenges.

I think most of us in this room would probably have a personal anecdote about one or two measures out there. But I think that what I'm hearing, the way that the eCQM is modeled in this measure, is that it's just for the risk adjustment variables.

Which is an interesting concept that's not a complete end-to-end eCQM. There's no definition of the populations or any of the logic criteria. It's just identification of variables only, correct?

Which, if it gives anyone a little bit more of a sigh of relief is that that adjustment is happening. Just using the, basically the data coming out of those variables and not the actual calculation at the hospital level.

Even though we know a lot of hospital measures happen. You know, the calc here, all the patient data is provided for submission.

I do think though, and I don't know if this is another condition to add, but with the recent transition to the clinical quality language, I do think that, just as a measure developer, it will be good to look at how CQL does support some enhanced risk adjustment functionality and the potential for maybe adding clarity within the measure and the specification.

CO-CHAIR TRAVIS: Thank you, Lindsey. Aisha.

MEMBER PITTMAN: I just wanted to go a step further in Nancy's recommendations. So not only looking at that you can feasibly collect the data, but recommending that if it's in the program that there's a period of voluntary reporting, noting that there's so many challenges with pulling EHR data.

And currently in the program there's about 15 eCQMs and you're only required to report

four, so there's already a history of volunteering reporting, so I think we should suggest that as a condition. That there is an initial volunteering reporting period, so that those leading systems can help test it out and workout all of those kinks before it's mandatory.

CO-CHAIR TRAVIS: Wei.

MEMBER YING: A question for the developer actually. When you said that when you looked at, compared to this EHR related measure and to the claim based measure, you see consistent result, I just want to make sure, what do you mean by consistent?

That, when you look at these 22 hospitals the story doesn't change, do you mean that?

Basically, the relative position, I mean, the absolute number of course would change, but in terms of relative performance among these 22 hospitals, the good performers do good performer, bad performers do bad performer.

DR. SUTER: So, my meaning was both

that the qualitative results of testing were similar. So a high reliability seen across both measures.

And also that the quantitative information of hospital rank, hospital-wide mortality rate, when you calculate it with just claims data or with enhanced risk variable data, you're seeing almost identical results.

CO-CHAIR TRAVIS: And, just as a follow-up, if I may, Karen, before I turn it to you, and I apologize because they may just be a really naive question. But then, why are we looking at a different measure if the results are the same?

I mean, why don't we just use the claims measure, why are we going to go to the hybrid measure if doesn't change the results?

MEMBER YONG: We pursued both versions. I mean, there was a lot of discussion earlier around sort of the feeling that the clinical factors really were important to include, as part of the measure.

So that's why when we looked at the options available to us we had claims only. Which doesn't have the clinical factors. But then we also saw this option to have the hybrid version as well. So that's why you see two versions.

CO-CHAIR TRAVIS: So the preferred version, from your standpoint, is probably the hybrid? Because we're able to look at the clinical, more clinical measures in the risk adjustment?

DR. SUTER: Yes. You do see slightly better risk model performance. It's marginal, but it is improved.

And when we asked the stakeholders, the technical expert panel, the patients, the clinical technical workgroup, they all preferred the face validity that was gained by including clinical data in the model.

CO-CHAIR TRAVIS: Lee.

MEMBER FLEISHER: Just to back up. In the ability to get frailty measures, we discussed

albumin on the call, would make the clinical people and the technical expert panel feel much more comfortable.

CO-CHAIR TRAVIS: Okay.

MEMBER FLEISHER: We just weren't there yet.

CO-CHAIR TRAVIS: Okay. And I'm sorry, Karen, I skipped over you, Karen.

MEMBER SHEHADE: Yes. Just to clarify the timing for this measure, I know that the claims based, earliest it could go out would be in 2020, but I thought I heard at the beginning that this hybrid measure would be further out. Could someone just clarify? You may have said it and I'm sorry if I missed it.

MS. DUSEJA: So to answer your question for the hybrid, it could be voluntarily reported in 2020 as well.

CO-CHAIR TRAVIS: And with the term, could be voluntary reported, does that mean that you are open to the discussion that we had a moment ago about voluntary reporting?

MS. DUSEJA: Yes.

CO-CHAIR TRAVIS: Okay. Okay, Lindsey.

MEMBER WISHAM: Based off of the discussion on the previous measure and the ability to provide hospitals with kind of that drilled down stratified data, I'm interested to know if you think that this will provide any additional stratified data because it includes clinical, additional clinical concepts having been reported? Or would that not change?

DR. SUTER: So, the clinical data would be included in the information going back to the hospitals, although the hospitals would be the one who had supplied it. But we would be presenting it to them in a more useable format. Does that address your question?

MEMBER WISHAM: Correct. So would it, again, would the clinical information, having been included in the risk adjustment, didn't affect the results that go back in the stratified results to the hospital?

DR. SUTER: Yes.

MEMBER WISHAM: Yes?

DR. SUTER: Yes.

CO-CHAIR TRAVIS: Frank.

MEMBER GHINASSI: Just a point of clarification, I may have misheard. Did you say that the clinical data that's currently part of the model, the risk adjustment model, was included in the 22 hospitals that you already did? That you've already included?

DR. SUTER: Yes.

MEMBER GHINASSI: It was? And did you also say that it was of minimal impact?

DR. SUTER: So, if you look at hospital performance in correlation as well as the C-statistics for models that use only claims data versus using claims data plus clinical variables, and we looked at a number of different combinations, for example, we looked at not using 12 months of data prior to the hospitalization for additional comorbidity risk adjustment, all of those models perform very similarly.

I think there are, we are able to capture enough of a risk signal that we see a lot of consistency when we pull in and out, sort of components of the risk adjustment model.

And I think, to Lee's point, we would be eager to include additional risk variables that were clinical, electronic health risk, risk variables. But we are also trying to create a measure that's feasible.

And right now, EHR data has a limited amount of feasibility for extracting reliably extracted data. And so as EHR is advanced, I think this measure could advance as well.

MEMBER GHINASSI: But it's currently minimal impact? Or added information.

DR. SUTER: It has, .1 or .08 changes to C-statistics.

MEMBER GHINASSI: I would just want it on the record that that is of grave concern to me. Because if the point of the measure is to have a hybrid that allows for enlightenment and a better understanding of the variables that could

impact this and the current model in the 22 facilities has produced minimal input, I would have grave concerns about moving that forward. It's just a comment.

CO-CHAIR TRAVIS: No, I appreciate that. And that was really the reason that I asked my prior question.

I guess what I took away from the answer from my prior question was that in the face validity, when this question was put out, there was a greater acceptance, now this is my language, not yours, but there appear to be a greater acceptance of the results because the clinical measures had been added.

From a statistical standpoint, it doesn't seem to have really made a difference. But there seem to be more acceptance. And they favored, or liked better, the measure with the clinical information.

So I don't know if I'm paraphrasing that correctly. People are nodding their heads that I am.

So, I think there is something, at least this is just my thinking, and I'm taking off my Chair hat, is that there is something to, there's some value, I would think, to better acceptance, if clinical measures, additional clinical information has been added. Because then maybe there will be more action that would be taken from that.

But, that's just my personal opinion. So I appreciate you, your points on that Frank. Nancy.

MEMBER FOSTER: So, just one point of clarification. If I understand the information that was presented correctly.

This was tested in Kaiser Permanente in Northern California, and I would say that that system has spent a lot of time trying to drive a standardization into their processes across their hospitals, in which case I would have expected to see very little variation in and of itself.

I don't know that that would be true as we look across all of the hospitals of the

United States.

(Off mic comment)

MEMBER FOSTER: You're right, I do know. They will not be true.

CO-CHAIR TRAVIS: Okay, thank you for that, Nancy. Any comments from anybody on the phone?

MEMBER BRENNAN: No, I'm fine. Thank you.

MEMBER JORDAN: No, I'm fine as well.

CO-CHAIR TRAVIS: Thank you. Okay. Well, I think that we are ready to move to vote.

The motion on the floor is for conditional support for rulemaking. The conditions include NQF endorsement.

The other issues include the same. Conditions that we put on the prior measure. And I want to try to re-look at my notes on Nancy's initial condition that she added here.

That given the variability and data and EHR systems, pay special attention to the accurate collection and risk adjustment across

different types of EHR systems, as well as hospitals. Does that capture it okay, Nancy? Okay.

So that's the motion that is on the floor. All those in favor of the motion please stand.

MS. MCQUESTON: We had a condition about voluntary --

CO-CHAIR TRAVIS: Sorry.

MS. MCQUESTON: -- period.

CO-CHAIR TRAVIS: I didn't know if that was a formal condition, but Aisha's point about the voluntary reporting. And it appears that that will be fine anyway, so let's add that, the voluntary reporting, first.

Okay, now, those in favor please stand.

(Off mic comment)

CO-CHAIR TRAVIS: Yes, conditionally support. I'm sorry, with all those conditions. On the phone?

MEMBER BRENNAN: I support, Joan

Brennan.

MEMBER JORDAN: I support, Jack Jordan.

CO-CHAIR TRAVIS: Thank you both.

MS. MCQUESTON: There were 23 votes in favor of the motion.

CO-CHAIR TRAVIS: Okay. All those opposed to the motion please stand. I'm, oh.

(Laughter)

CO-CHAIR TRAVIS: Well actually, just stand if you all don't mind for more than just a passing. I don't want to call it, but if you'll stand. Both of you all just stand.

MS. MCQUESTON: Two.

CO-CHAIR TRAVIS: Okay, thank you. Not everybody up here was looking. All right, so that motion carries.

Okay, we have one last motion.

(Off mic comment)

CO-CHAIR TRAVIS: Yes?

MS. MCQUESTON: The final votes were 23 votes for the motion and two against.

CO-CHAIR TRAVIS: Thank you. Okay, we have one last measure that we're going to be looking at. It is MUC17-210, hospital harm performance measure opioid related adverse respiratory events.

This measure has also been pulled by our favorite puller, Nancy Foster.

(Laughter)

CO-CHAIR TRAVIS: Maybe our only puller. But, Nancy, you're doing it on behalf of a lot of people, I can tell already today. So, Nancy, any comments as to why you pulled it, and then we'll go to the measure developer?

MEMBER FOSTER: Sure. This measure has not yet been submitted for NQF endorsement so it's hard to make some judgments about its properties.

It was proposed as part of the EHR incentive program, as I understand it. And is in field testing right now.

It's unclear to us that there is true variation across hospitals and would like some

better clarity around whether there is enough variation to really expect that this could drive improvement.

I know the appeal of this measure is going to be because it has the word opioid in there and that opioids are an incredibly important issue right now, but I'd like us to make sure that we focus on making sure this is the right thing to be measuring about opioids as opposed to just reacting to that word.

And I say that as someone who's done a lot of reacting and spent a lot of time working on things related to improving the opioid addiction crisis in this country.

Because it's a measure that looks at the administration of naloxone, we worry that it might inhibit people's willingness to administer naloxone and in favor of taking other measures to try and address the respiratory problems, like intubating a patient. And that may not be the right strategy, that may not be in the patients best interest.

And there was an issue raised during the comment period around not having a risk adjustment or exclusion around opioid sensitivity, so I'd like to hear more about why that was not dealt with.

And let me just leave it at that. And my recommendation would be revise and resubmit. As judicious as I want to be around MAP.

CO-CHAIR TRAVIS: And I failed to comment at that beginning that that is the recommendation from the preliminary analysis. So I think Nancy has done a good job for us in outlining, from her perspective, why that is the appropriate category for this.

Before we move into lead discussants and workgroup, I'd like to give the developers a brief moment to give us a description of this measure so that we're all working from the same platform.

MS. DUSEJA: Okay. So I'd just like to make a couple of comments from CMS's perspective and then I'll hand it over to

Susanna, the measure development team.

So, in terms of this measure concept that we're developing and presenting to the MAP today with the measure that we've specified to this point, we see this measure really meeting one of the meaningful measurement areas that we talked about earlier in the beginning of the day, under preventable healthcare harm.

You know, opioids are a frequent medication that are given and associated with adverse drug events. We know, as most of you probably know, that respiratory depression comes from these opioids that lead to brain damage and death.

And we also have seen that there is demonstrated variation among hospitals in terms of this issue. And patients with opioid related adverse drug events have been noted to have 55 percent longer lengths of stay, 47 percent higher costs, 36 percent higher risk of 30 re-admissions and almost three and a half times higher payments then patients without them.

So I wanted to give you some context behind the reason behind moving forward in this direction of this measure development.

We also understand that we got from preliminary analysis, a refine and resubmit to two issues. One, that it did not receive NQG endorsement.

I just wanted to let you know that we do have plans to submit it for endorsement for next year. And then there was some issues around testing that I'm going to defer to Susanna to talk about.

MS. BERNHEIM: And, Cristie, I hear you loud and clear, I'll be quick. I'll just say two words.

So our aim is fully in eCQM, right, it's just a electronically specified data elements and our aim was to really focus on feasibility so we kept the specifications as much as possible, have structured fields.

What this measure looks at is naloxone administration as a sign of an adverse event

related to opioids. It does not assess that during a time when a patient is in the operating room.

And to avoid counting it as a harm when the opioid use was community acquired, if you use naloxone in the first 24 hours of a hospital stay, we require evidence that there was also a prior hospital administration of opioids.

The thing I think is most important to clarify is the state of testing. And a note about the MUC list.

So the original version that was on the MUC list was earlier specifications. And a lot of the comments from the public.

Luckily we had come to the same conclusion and we changed some of the specifications that people were concerned around the two hour window around a procedure. So those specifications are not a part of what was tested.

I'm just going to say how the testing was done because it was presented as alpha testing, but it was substantially more robust

than the typical alpha testing. So this measure has been tested in five hospitals with multiple different EHRs.

We used an entire year of patients, a full sample of patients. The denominator is hospital admissions for patients over 18.

And for each instance we had clinical adjudication and showed a positive predicted value of 95 percent that the, using our specifications that the administration of naloxone was given for a probable over administration or adverse event related to hospital administered opioids.

So it does not meet full beta testing because we did not use a measure authoring tool. And that's the testing that's going on now.

But I just want the committee to be aware of how robust that first phase of testing was. And as you said, it will go to NQF this summer.

There was one other issue that came up from folks that I wanted to respond to that Nancy

had said and I'm, oh, I'll wait. That's the measure overview, I'll let you guys tell, tell me what else do you want to hear about.

CO-CHAIR TRAVIS: Okay, I'm sure we will. Thank you for that.

I would like, before we go to the lead discussants, I would like to ask staff if they could talk with us a moment as to why the specifics, why you put this in revised and resubmit. I think it would help us think about our comments.

MEMBER MANNING: Sure. So the difference is because of the level of testing. Because the beta testing has not been completed.

So the other measures that are not NQF endorsed are fully tested. That was the difference for us.

CO-CHAIR TRAVIS: Okay, thank you. That's extremely helpful. Okay, well, let's go to our lead discussants. And, Brock, I have you up first.

MEMBER SLABACH: Yes, and thank you.

I think this is, as everybody indicated, a huge problem. The opioid addiction and the use of this in the hospital setting is certainly something that's concerning because of the opioid related adverse respiratory events.

We, I mean, obviously I agreed with the recommendation of staff on this new category of revise and resubmit. And I now understand more about what that means, and for the staff to put that down as a recommendation since we're supposed to be sparing in its use. I thought that was very significant in the conversation this morning.

I am concerned, I mean, I think that the question that I have, and I'm not sure yet, is if this measure actually measures the problem that we're trying to solve, and I guess the testing and the validity will do that as we go forward, so I'll have to have, as Sean said, confidence in the process to see that that is going to in fact be the case as we go through this study. So I agree with revise and resubmit.

CO-CHAIR TRAVIS: Thank you. Jack, on the phone.

MEMBER JORDAN: Yes. This is, luckily, something I have a ton of experience with. I built four different versions of this in a five hospital system.

And also, there is a lot of exposure of the hospital engagement networks. You know, they struggle getting this from hospitals, but with this.

As of conceptually, I think this is a wonderful idea. I think in the writeup, them pointing out that there's real struggles with finding respiratory depression and it's much easier and then it works well to use the Narcan administration.

In order to improve this in the hospital, helping differentiate between the differences in how medicine and surgery and cancer and palliative all think fundamentally differently about pain treatment and helping get them on the same page. Also, clearly documenting

patients that are opioid-naive and making sure you're aware of that.

There are things people can do to make this better that we don't uniformly have across the country. I think this is an important measure to do. I agree with them, you know, getting it cleaned up a bit and getting it out there.

And then just a general eCQM thing I'd love to try to plant in people's head a different way of thinking about this. That, yes, I agree with having a value based purchasing website and putting it up there after it's been looked at cleaned up for months.

But data like this should be shared within 24 hours of when it's submitted. Even if it's dirty and has mistakes in it, with your contractors, the QINs, the HENs, they need this kind of stuff and they would love to be able to have this on a shorter cycle.

And by the same token, hospitals should submit this stuff weekly, not quarterly.

So that, again, you can have rapid cycle work with the money you're spending on contractors to work on this stuff.

So, I am a huge advocate of this exact measure because I've, like I said, I've looked at it four different ways in a system, and I do think it does take a little, a few iterations to clean up. But I think this is a great way to go.

CO-CHAIR TRAVIS: And just for clarification, Jack, is it still your feeling that it sits in the revised and resubmit with some of the specifics that we've been talking about?

MEMBER JORDAN: Yes. From what I read in the PDF that was sent out, it does look like they do need a little bit of firming this up.

I do think, one of other thing, just as a experience of working with these kinds of measures too, how you define them makes a huge difference on how easy they are to build.

So an example would be, I can write code in one minute to get a drug contained

component opioid. If I have to manage a list of the 6,600 codes for drugs in America that contain them and update it every year, it's an enormous amount of work.

Going through the work to define things properly so they're easy to pull is important, I think, as well in just conceptually how we build these kind of measures.

CO-CHAIR TRAVIS: Thank you for that. Okay, Lee.

MEMBER FLEISHER: So, for full disclosure, I don't think I have to recuse myself, but I did speak to Yale as an unpaid consultant. So, correct, I do not? Yes, no?

MS. MUNTHALI: So, this was just advice you gave them?

MEMBER FLEISHER: Just advice.

MS. MUNTHALI: Was it, sorry we're having this discussion with everyone here, was it on an ongoing basis or was it just --

MEMBER FLEISHER: A one time.

MS. MUNTHALI: One time. And was it

on the testing and specifications or anything like that?

MEMBER FLEISHER: No, it was just content expert.

MS. MUNTHALI: Okay, thanks. You're fine.

MEMBER FLEISHER: Okay, so there's the disclosure. So I am an anesthesiologist. So as an anesthesiologist who oversees both the chronic pain clinic and impatient pain service, I was queried.

So I agree with a lot of the comments, the issues of the changing drugs and the opportunity. I think those could be updated.

My biggest concern are two. One is what Nancy mentioned. And this is one of those measures, the unintended consequences of what people will do in response to the information that having the information out is fantastic. Putting it into value based purchasing quickly could have serious unintended consequences.

So, similar to your colonoscopy

measure in which you actually put it out for a year, I actually think this may take several years of reporting. Because I think it is a great measure for quality improvement as opposed to a great measure for value based purchasing initially.

So that, I don't know, that's advice to CMS, which they can take, as opposed to advice on the measure itself.

The second one is the issue, both as -- Janice pointed out the issue of obstructive sleep apnea, which will be difficult, versus any chronic opiate user, you should adjust things.

But for storytelling, I had a patient who called me, who was furious at my pain clinic for adjusting her medications down so that she would safely go through the perioperative period, because she wanted to be, as she said, slobbering at the bedside with no pain at all. So the chronic opiate user and ED physician should know this.

The chronic opiate user, again,

another reason of unintended consequences. I'm not sure it's risk adjusted as opposed to stratified by percentages or some other qualification would help make this a more useful, you know, places that have similar, whether or not they use Suboxone and have a history. I don't know, I didn't see whether that's built into, it's not built into the measure. Huge issue.

And our rural hospitals, in particular, have a real problem with Suboxone. So I think those are some of the things that could be added to the measure.

So I'm supportive of having a measure, not for value based purchasing, but a high quality reported even publicly, but importantly I think it needs some additional refinement.

**CO-CHAIR TRAVIS:** Okay, thank you, Lee, appreciate that. Now we'll go to the workgroup members for your comments. And I'll start with Anna.

**MEMBER DOPP:** Thank you. We agree

that it's a very important measure concept. We agree that it's a topic that needs to be addressed sooner rather than later.

Even hearing years down the road to have it moved forward as you take with it a grain of salt knowing that these need to be addressed now.

And also we hear from the HENs that this is the exact concept, is a part of their structure to try to reduce ADEs by 20 percent. This is one of the three areas they're trying to do that. And that there is difficulty in reporting that, as is right now. So, the concept is very important.

The feasibility is where we have questions. As a pharmacist, and in a former life conducting medication use evaluations in a health system, it's not as clean of a pull as you might expect. It's not exactly a binary yes or no this happened.

There could be other considerations from prominent use of benzodiazepines.

Additional indication of use of naloxone that could just muddy the waters a little bit.

So, agree with the idea to revise and resubmit to try to really refine, refine the measure. But agree that it is indeed important.

CO-CHAIR TRAVIS: Thank you. Maryellen.

MEMBER GUINAN: I just wanted to let the workgroup know that I served on, previously and currently I'm still on the technical advisory group for this measure so I will abstain, but look forward to continued work on the measure.

Specifically, I know risk adjustment came up and wasn't strongly supported in the technical group and so hoping that further iteration and work will kind of delve into that a little further. Thank you.

CO-CHAIR TRAVIS: Thank you, Maryellen. Karen.

MEMBER SHEHADE: Medtronic already submitted some public comments with some evidence on the measure. I just actually had some

questions about the timing of this. What is the difference between the timing with revise and resubmit versus something submitted with the condition of NQF endorsement?

Because it's going to go in 2018, so I was just curious if there is a difference at all and maybe there's no difference in the timing.

MS. MUNTHALI: So, you probably heard Pierre talk about the availability of a committee to review this, this and other measures that they'd like to go through the process. So we do have two opportunities a year now with our redesign consensus development process. That's a process by which we endorse measures.

So this will probably be slotted into our patient safety portfolio. And so they could look at this either in April of next year. Would that be ready by then?

MS. BERNHEIM: We plan to submit in the August cycle --

MS. MUNTHALI: Okay.

MS. BERNHEIM: -- so that we have the full Phase 2 testing.

MS. MUNTHALI: Exactly. And the committee would convene in October, although the testing would need to be submitted by August. Part of the intent to submit, which is a new process.

So, the committee would start reviewing, the scientific methods panel would look at this in October of next year.

MEMBER SHEHADE: So there's no real difference then whether it's conditional being submitted with NQF endorsement, because they're waiting till 2018 anyhow, right?

Until August of 2018 anyway, so whether it's a revise and resubmit or a, on the condition of a NQF endorsement, the submission date remains the same as August of 2018. And we know that by that time the testing will be completed. I just want to make sure that I'm understanding it.

MEMBER MANNING: Yes. And I want to

remind you, with the feedback loop, that's what CMS has brought back, was measures that were revised and resubmit.

MEMBER SHEHADE: Yes.

MEMBER MANNING: And so you would be able to hear input on the measure, how it's developed and tested.

MEMBER SHEHADE: Yes. Okay.

CO-CHAIR TRAVIS: I would think that there are some other layers that might have it being, being in this category versus in the conditional though. Since it's still in testing, what kinds of refinements would come out of testing that would change some of the specifications, plus some of the other issues that have been brought forth here.

So I think, at least from my perspective, thinking about this category a little bit different than conditional, it may not be so much a timing issue as the measure may change. In fact, we're hearing that there's some suggestions that it really should change.

And so we can't really make a conditional, wait. Well, one argument would be that we could not make a conditional decision because we don't have what the measure may really end up looking like in front of us today. That's just a proposed way of looking at the difference between the two categories.

MEMBER SHEHADE: No, I understand that. So --

CO-CHAIR TRAVIS: Okay, good.

MEMBER SHEHADE: -- it goes in, when would the earliest be that it goes into the program, as discussed, would it be 2019 to then 2021? So it would come -- would the earliest be 2021?

MS. DUSEJA: If we do propose this next year then it could go into 2020. So --

MEMBER SHEHADE: 2020, okay.

MS. DUSEJA: It just depends when we propose it.

MEMBER SHEHADE: Okay, thank you.

CO-CHAIR TRAVIS: Thank you, Karen.

MEMBER SHEHADE: Yes.

CO-CHAIR TRAVIS: We have a motion on the floor for a revise and resubmit. There have been a number of comments and I'm going to look for some guidance from the Staff as to how best to characterize the revise and resubmit.

Because we've had such a rich discussion here, I'm not really sure how to get specific about what we need to tell the coordinating committee, and CMS, about specifically what needs to be revised and resubmitted.

So I'm going to see if Staff can help me kind of walk that tight rope. And be sure that we do what we're supposed to do for you all.

MEMBER MANNING: So, I would suggest adding that, and we have it in here, that the reliability and validity testing does demonstrate reliability and validity in an acute care setting. Because all of those issues will come up as they continue the testing. And will be evaluated through the standing committee and the

methods panel.

CO-CHAIR TRAVIS: And do we need to say anything about NQF endorsement in all of that too?

MEMBER MANNING: I think that's part of our condition. It is --

CO-CHAIR TRAVIS: It's a revise and resubmit --

MEMBER MANNING: -- part of our condition.

CO-CHAIR TRAVIS: Okay.

MEMBER MANNING: And then we can add additional comments about the other medication.

MEMBER FLEISHER: I'm sure that the measure has the ability to change as people develop alternate drugs to treat this. And the unintended consequences it may need to be reviewed more frequently than every three years.

MEMBER MANNING: So there are annual updates that tend to be just small changes, but depending on the large change could trigger an ad hoc review, and then it would go through the

process again.

MEMBER HASKELL: I don't know if anyone has mentioned it, but in the underlying comments there were a number of organizations commenting that they disagreed with the two hour window after a procedure. They thought that should be eliminated. I would support that also.

MS. BERNHEIM: Yes. Sorry, I tried to clarify that in my earlier remarks. That was eliminated before testing, so that was a very early version of the measure and is included in the measure that was tested.

CO-CHAIR TRAVIS: Okay. Well, this was the recommendation in the preliminary analysis, but with our new approach to being sure that we take official votes on everything, Nancy essentially was making a motion that this be the category, revise and resubmit.

We have captured the specifics relative to what the revision should include. So I think we're ready to go to a vote.

Would all those in favor of revise and

resubmit with the information to be provided please stand. And on the phone? Is anybody left?

MEMBER JORDAN: Yes, this is Jack, I'm here. I support --

CO-CHAIR TRAVIS: Okay, thank you.

MEMBER JORDAN: -- revise and --

CO-CHAIR TRAVIS: Joan, are you on? Okay.

MS. MCQUESTON: All right, so it's 24 votes in support of the motion.

CO-CHAIR TRAVIS: All right. Well, thank you all very much for that. Yes?

MEMBER BRENNAN: Guys, did you get me? I had it on mute, but I do support it.

CO-CHAIR TRAVIS: Oh good, thank you.

MS. MCQUESTON: That's 25 votes for the motion.

CO-CHAIR TRAVIS: Okay, Andrea.

MEMBER BENIN: Can we just make sure, in the testing and this revise and resubmit that it gets noted, Nancy's original comment around

the concern that people will not use the Narcan?

Maybe they would just try to bag the patient up or, I mean, because I do know how these things play out in real life and you start saying we're not supposed to be using Narcan, and it doesn't get into the, like, the way it gets out in real life is they'll be like, oh. Because it's a bunch of residents in the room, oh, we're not supposed to use Narcan, we're going to bag him up.

Like, there's just the way these things play out it gets weird. So I would appreciate if we could just note that in the testing, as part of the revise and resubmit, that some of that, looking for those kinds of things, would be valuable piece of the further consideration. Thanks.

CO-CHAIR TRAVIS: Thank you for that.

MEMBER HASKELL: That's what you want an all-cause mortality measure.

(Laughter)

MEMBER FLEISHER: And actually, the

balancing measure should be the HCAHPS pain measurement, Pierre. You know, we really need a balancing measure.

(Off mic comment)

MEMBER FLEISHER: Yes, this should be one that when you look at it, you're not seeing those unintended consequences.

CO-CHAIR TRAVIS: I think we're fine. Don't you all think we're fine, we voted?

MS. O'ROURKE: Does anyone have an objection to, we'll add some language in the report around consideration for balancing measures and to monitor for any potential unintended consequences around the reduced use of Narcan?

CO-CHAIR TRAVIS: I don't think anybody has any objections. Which is also the reason we should probably move on so that we don't have to ask everybody.

MS. MCQUESTON: We haven't done an official vote for this that object against the motion.

CO-CHAIR TRAVIS: Oh, I'm sorry. She's telling me I never went to the second half. Does anybody not -- does anybody oppose the motion?

MS. MCQUESTON: No. Great.

CO-CHAIR TRAVIS: Thank you. I guess when I got to the 25 I figured nobody was opposing, but thank you for that. I now understand what you were trying to tell me.

Okay. Well, one, I think everybody in this room deserves a round of applause for getting through our measures.

(Applause)

CO-CHAIR TRAVIS: We do have a couple of other items that we are trying to get done. We do need to get out of here by 5 o'clock.

And so we do have on the agenda, overview of the HAC reduction program and discussion of future measures. Pierre, is that --

MS. MCQUESTON: So, if I can make a suggestion, given that we're quite a bit behind

on the agenda, what we had discussed is potentially skipping this agenda item and moving on to the input on measure removal criteria, as that's something that the coordinating committee is going to be looking across --

CO-CHAIR TRAVIS: Great.

MS. MCQUESTON: -- all of the work groups. And then moving to the HAC discussion if we have time and rural health. And if not, moving those into a conference call.

MEMBER YONG: Yes, that's fine.

CO-CHAIR TRAVIS: Sounds good. Thank you.

MEMBER YONG: We're fine with that.

CO-CHAIR TRAVIS: Okay.

MEMBER YONG: Should I start? Okay, great.

So, thank you everybody. So we, as Kate mentioned, having this particular discussion across the workgroups and then we'll be bringing that feedback from each individual workgroup up to the coordinating committee.

But sort of to close the circle from the discussion this morning, had been thinking internally as we look at our measure sets across our programs, the criteria we should be using to make those decisions. And again, any decisions we make would be made through notice and comment rulemaking.

But the broader question that we had, and we want to take advantage of the fact that we had all of you experts in the room was, what criteria should we be considering. And so we had drafted some initial criteria, but we would, this again is a starter set so it is really to spark conversation, and so welcome any feedback about them.

So if you move to the next slide please. And the criteria, I will say, echoed a lot of what I, we mentioned earlier, that you saw on the slide.

So, one, that the measures themselves are meaningful to patients and providers. That, also of note, sometimes there are particular

statutory requirements for particular measures in programs, so we do want to keep and meet our specific statutory requirements. That there are maybe particular reasons to keep measures for those reasons.

Measure types, again, we mentioned preference for outcome measures. Again, it's a preference. We understand there's often not outcome measures available that, and it's not to say that the certain process measures aren't valuable, it's just that there's a preference for outcome measures.

Variation for performance, again, as we are looking at how the measure performs and looking at the range of performance, that's come up several times today, I think you understand why we think that's important.

Performance trends, we haven't talked much about, but certainly some of the measures have been in the programs for several years. And so we've been looking at the overall trend and performance.

Some measures are improving or the rates are declining or, depending on the measure, whether it's an inverse measure or not. Other measures have been static and other measures the performance are getting worse.

And the question becomes why. And if there is other reasons that we need to think about, perhaps it's not a good measure, it's not really driving quality improvement.

Perhaps it means that there needs to be additional attention focused on quality and improvement efforts, so there may be a variety of sort of additional actions that may stem from that.

If you move to the next slide. Burden is something we've talked about.

Unintended consequences, again, I think it was Maryellen who sort of mentioned this the morning, but is certainly a particular aspect of the measures use that we want to consider.

Operational issues hasn't come up as much in this workgroup but came up in some of the

other workgroups, in the PAC workgroup for example, about the measure that was on the MUC list for that workgroup. But there are specific operational issues that may impact measure that we need to consider, that may impact whether or not to keep the measure.

And then alignment which is, again, something I think we raised earlier and want to consider in terms of whether or not to keep a measure or not.

So these are just initial sort of set of elements. I certainly welcome any feedback or reactions to it. Thank you.

MEMBER BRENNAN: This is Joan. I think it's a good starting set.

MEMBER YONG: Thank you. This was not the reaction I expected, but I'll take it. I'll take it.

MEMBER FOSTER: I don't know if we're waiting to be called on or what.

MEMBER YONG: Defer to the Chair.

CO-CHAIR WALTERS: Nancy.

MEMBER FOSTER: Thanks. I missed my place as the first commenter. So, Pierre, thank you.

I do think this is a good starting point. I would put an emphasis on a couple of things.

One is, to your first one. It has to be important to both providers and to the public, in some sense. And to that end I would suggest to you that maybe some of the things that are keenly important to providers are those where you not only have a way to measure an aspect of care, but you've also coupled it with some new knowledge, or even some known knowledge but not fully implemented knowledge, around how to actually improve care.

So, having a measure that holds people accountable to something they don't feel like they can actually change, is really not going to drive quality forward.

I would add to that this notion that I think it's critically important for you to take

a look at those trends. There are some measures, the last time I looked, the mortality measures among them, where performance has not varied enormously, and that ought to be something that you look at and maybe take a step back, rethink whether that's the right measure to include.

Maybe take a couple of years off and rethink whether that's the right way to go. And why it hasn't worked, to really kind of study it before you impose that.

And the third thing I think may be important is to really hone in on some of these unintended consequences and know what's happening in the field. We've seen some in some measures, but --

And I point, for instance, at the JAMA article, the recent JAMA article around the rise in mortality rates associated with a decrease in readmission rates. That's concerning to me. It's worth further look at least.

And there are others where we know, there's enough history there we should know

whether there's something of concern going forward. So thanks for really looking at this, and I think you're heading in the right direction. I would emphasize those three.

CO-CHAIR WALTERS: Wei.

MEMBER YING: I agree this is a great starting point. At least we have the framework online at this moment.

But one thing I do want to point out is, we joked earlier that when CMS acted not all the time, local market or the private payers will follow, but I think everyone agrees, when CMS acts, everyone take notice.

So, even though we're talking about the measure selection criteria, if CMS is truly going to sort of formalize it in some way, then I hope CMS will realize that each of these sometimes is a double-edged sword. Not all the time is always absolute.

Let's use sort of alignment as an example. We talked about it earlier a little bit. It's great that if everyone aligns, but if

it becomes amended, then everything has to be aligned and then there is no innovation left.

We all agree that today the current stage is not perfect. If we first ever want to say that's aligned on perfect stage, then just deal with it, then I don't think that's where your intention is.

And just for example, the outcome preferred rate, we already heard from the field that, okay, because the focus is outcome, so don't even talk about process measure. But sometimes process is the starting point.

We can't get to outcomes if we don't even start to measure something. So each one of these I totally agree, they all have, they're all great. It's just when, if you try to formalize it just be careful that sometimes it's not, it has its own unintended consequence.

CO-CHAIR WALTERS: Marty.

MEMBER HATLIE: I wanted to also speak to the alignment issue. I think if, the biggest, I think, problem for consumers is the confusion

that's caused by lack of alignment. Not by giving limited information that they can't get now.

I'm willing to take the risk of unintended consequences because we have a history of not giving patients enough information to make decisions, but the alignment piece I think is confusing. And we've heard from Janice and others that it's also just, it drives industry crazy. So, I'm glad to see it here and I want to speak in support of it.

CO-CHAIR WALTERS: Helen.

MEMBER HASKELL: So, I'm also very concerned about unintended consequences and balancing measures. I think we often put measures in place that promote things whose risk we don't necessary understand or there's risk a few people may understand very well but it's not getting out.

So I think the balancing measures are really critical. Not to keep one thing in place and not have another.

And the other concern I have is all the process measures around preventative medicine. I think that's the huge burden in primary care, both for doctors and patients.

And a lot of those things seem to me are either obvious or, again, there are risks that haven't been taken into account. So that's the place that I would look.

CO-CHAIR WALTERS: Maryellen.

MEMBER GUINAN: Hi, thanks. Speaking to the burden. And also, I think it touches upon operational.

I would, I'm assuming that this is a line of thinking that you've gone down in terms of burden and technology and the future, both being a facilitator of kind of reducing burden by moving towards EHRs and moving towards technology based innovation. But that can also be a burden for providers that are not as quick to adopt or are being faced with interoperability issues that are still pervasive right now.

So, I think that goes to both burden

and the operational issues that are of concern. And then I would just tag on, I would be remised having essential hospitals as our members and vulnerable populations to look at the fact that we're moving to a lot of outcome measures.

And outcome measures are, or should be properly risk adjusted for those social risk factors that are not currently in any of the programs. And so moving beyond just dual eligibility that we're seeing in the readmission's program.

But looking at those factors that are outside the control of the hospital and often influence outcomes. Thank you.

CO-CHAIR WALTERS: Andrea.

MEMBER BENIN: Pierre, I find this to be a good list and that it seems to me as though, in general, you guys have done a good job of removing metrics as they need to be removed.

But what I have found repeatedly kind of missing from this conversation over the handful of years is a real sort of surveillance

framework for each of these things.

So I think for me the thing that would take this to the next level would be a really concrete framework that says, and here's how we're going to know what each of these are and this is how we're defining it and this is what we want to, how we might think it could look. So that we might sit here and say, unintended consequences are important, but I don't know how you are doing surveillance for unintended consequences short of coming here or going to the different committees.

Those things may well be part of a valuable framework, but there may be some other things that would be relevant that you might commission work around unintended consequences. Or you know, I don't know, I'm sure you could think of a whole spectrum of activities around any of these things.

And so, to me the next step would be fleshing out a little bit more what the work is that really gets you to be able to use a criteria

in a way that is beyond the hit or miss. Maybe that exists and I am just not familiar with it, but that's what I would suggest.

CO-CHAIR TRAVIS: I was going to make some similar comments to Andrea. I think one of the advantages to having this framework is to begin to measure and have perhaps some answers to some of the questions that are available when measures are endorsed or when measures are put on the MUC list or recommended by the MAP and then put into programs.

So I do think that it would be helpful to have kind of a measurement strategy so that we would know.

The other thing, and I apologize, I missed the very beginning and so if this is not pertinent let me know later, but I think that it's the combination of some of these things. Measures don't necessarily just fall into categories very clearly.

So for instance, it may be meaningful to patients and providers but be burdensome. So,

how are you going to reconcile, and I don't know that, I'm not saying you should have all these answers in the front end, but it may be a very meaningful measure but burdensome, and then how will you address that?

Thinking through, is that something worth removing if it comes back to the fact that then we have a gap of something that is very meaningful.

And I could see that happening among a number of these measures. And so I think you're going to have to think through a process of understanding.

It's almost even a matrix for the ones you're thinking about removing as to which of these characteristics does it fit in. And then at the end of the day, which ones may be more important than others about a particular measure.

Not necessarily always that way, but about a particular measure. That means you leave it in or take it out.

CO-CHAIR WALTERS: That's kind of

where I was headed too is, I was envisioning a weighted average type score. Which would probably have to go through this Committee actually.

(Laughter)

CO-CHAIR WALTERS: But it would be very interesting to see if you conducted a survey of any group like this and said, which of these are more important to you. Then probably the first question you'd get asked is, yes, but what's the situation, what's the measure, what's the conditions on.

And so, yes, I think there has to be some sort of formalization that is adaptive to a particular program situation, whatever, and you're willing to make tradeoffs. Much of the kind Cristie alluded to. It may be high burden but it's really, really important.

And I don't know how to do that conceptually right now, I was kind thinking it through and it could get very complicated, but some at least start towards getting to that point

would probably be helpful.

MEMBER PITTMAN: So I have a question back, because I know there are already criteria for removing measures in most of the programs, so how is this different and what is your vision for how these criteria are going to be, have a different process than what you've already used for removing measures?

MEMBER YONG: Yes, thanks, Aisha, that's a very good question. As you noted, we do have, in our programs, existing measure MUC criteria.

I think we are trying to think, particularly in the context of meaningful measures, whether those are the right criteria. So this is sort of, we are looking at that at the same time we are looking at the measures within the sets, see whether or not those are the right criteria that are existing in the rules for each program or whether we need to adjust those.

MEMBER PITTMAN: And then sort of in process, so I learned earlier that it's not our

charge to weigh in on measures for removal, but with weighing in on the criteria, is it the thought that you'll eventually start bringing measures for removal to the MAP?

MEMBER YONG: So, I'm not sure that there has been decisions made about that, so that's an open question.

MEMBER FOSTER: So, Pierre, to be totally out of the box about this, if you scrap virtually every measure you have right now it wouldn't bother me if you replace them.

(Laughter)

MEMBER FOSTER: No, I mean, honestly, I think some of them are tired, some of them have been around, their ability to drive, change in performance, not great anymore. Some of them are process measures, not really great in terms of driving outcomes that are meaningful for patients or providers there.

But it's what you're going to replace them with. It's, can you get to ten really good patient reported outcomes.

I'd give up everything you have right now to get to ten really great patient reported outcomes. And they would drive change.

So, that's not on your criteria of what, how could we balance the burden of collecting or reporting all of this with the outcomes. But that, to me, is sort of where I'd go. If I got rid of all of these, who would miss any of them and why. And what --

CO-CHAIR TRAVIS: I would.

MEMBER FOSTER: -- do we really need instead.

(Laughter)

MEMBER FOSTER: But wouldn't you give it, if you could give up the 80 measures now and get to ten really great patient reported outcomes, wouldn't you feel good about it, Cristie?

CO-CHAIR TRAVIS: You know, since I'm in charge of trying to get us out of here by 5 o'clock I won't go into detail on that. However, I think that patient reported outcomes are a

critical need, but there are other measures that are also, need to be part of the equation in my mind.

So, I wouldn't give up all 80 for ten patient reported outcomes. I'd like to have ten, or some number of really good patient reported outcomes. So, no, I probably wouldn't do that. But we can have a discussion after 5 o'clock on that.

CO-CHAIR WALTERS: Rich.

MEMBER KNIGHT: I was thinking about the conversation earlier, so I'll be very brief. You mentioned to me about 5 o'clock talking.

But I certainly agree with you. And I do think, I think it's a question of how you view, and I'll say redefined value.

And for patients who tend to be baffled and just will be polite and not say anything, process measures drive them crazy when they really don't serve any meaningful patient related outcome. But we're used to doing them so we do them.

And so I think because you look at the tradeoff, the burden that's aligned with something, sometimes when you look at burden you have to look a little bit further than the cost of it right then.

Infections, hospital, re-admissions. A lot of people don't want to deal with bloodstream infections. It's not valid, but when you have them and you don't report them, the patients are going to be in the hospital, it's going to cost you money.

So I think when you look at, and as one person said to me, Rich, it's not that simple. I said, it's real simple for me because I look at it from the prism of patients.

Even patients and a reimbursement, if it makes sense, if that's the objective of what we're dealing with. If we're dealing with something else then I understand that because the institutions are institutions.

But I just think that, that the observation you made, and we all have to rethink

how we view value into what end of some of the things that we do. Particularly in light of changing technologies. And there are a lot of people who are really struggling with that.

CO-CHAIR WALTERS: Okay, Pierre, did you get your feedback?

MEMBER PITTMAN: We did, thank you.

CO-CHAIR WALTERS: Okay. Reena, you want to try to --

MEMBER JORDAN: This is Jack. I did have a comment as well.

CO-CHAIR TRAVIS: Yes.

MEMBER JORDAN: One, I think on alignment, and this is actually slightly asking for a new measure, but having a common method for social determinants that you could use across, even if it was just ten bad variables that was way better but then you could apply it everywhere, would be a dream come true. Because I think there is so many measures that that's a challenge.

I also think one thing that triggers

some of these off of, you have the topping out and then inadequate spread where if you look at the same measure three, four years in a row, it just looks like it's kind of random chance turning, that should be a criteria there.

And I think there should be a bias toward these measures being something that can be recreated locally. It does really concern me when it's going to be a, well, we're going to randomly select from you and you can't say to your board, here is exactly what's coming in three months because we've built the exact same thing here.

That I think is a problem that health systems really would like to be able to say, we know exactly what we're sending to you and we can show ourselves exactly what it is and it isn't a surprise six months later. So I think trying to retire measures so they can be replaced with ones that can be recreated locally is important to health systems.

CO-CHAIR WALTERS: That's very

important, thank you. Reena, why don't you tell us what's going on with HAC?

MEMBER YONG: So, we're just looking at the schedules. I mean, because there is still remaining the HAC and then the rural health discussions, so would ask which one, I guess, you or the Committee prefer to discuss. The HAC one are okay delaying, but it's up to you guys.

CO-CHAIR WALTERS: If you leave that the decision then we'll probably be doing both on the phone and we'll take off.

MS. O'ROURKE: I think, yes, we can do HACs now or perhaps if people are amenable, reconvene for a phone call in January to hear about HACs and rural health, is that okay?

CO-CHAIR WALTERS: I don't care.

MEMBER BRENNAN: I think that's wonderful.

(Laughter)

MS. O'ROURKE: Do you conditionally support that?

(Laughter)

MS. O'ROURKE: So, we'll look for time to get everyone back together in January and cover the presentations.

MS. MCQUESTON: So, I think Desi has some next steps for everyone. There is still a lot to happen in a short amount of time.

MS. QUINNONEZ: Yes, thank you. So as you just heard, we will be reaching out to you to discover a good time for everyone to schedule a follow-up phone call and web meeting.

We also have, we'll be posting our draft report by December the 21st. And so that public commenting period will be from December the 21st through January the 11th.

And also, we have our upcoming coordinating committee meeting, and that will be January the 25th and January the 26th.

MS. MCQUESTON: So, that's it. We just want to thank you all, and especially our Chairs, for all the great work and feedback today. It's been really, really interesting and helpful.

CO-CHAIR TRAVIS: And thank you all for your patience as we work through, once again, a different voting mechanism.

(Laughter)

CO-CHAIR TRAVIS: And if we're here next year, we'll probably have a different one.

CO-CHAIR WALTERS: They'll be another one.

CO-CHAIR TRAVIS: But thank you for your patience.

MS. MCQUESTON: So --

MEMBER PITTMAN: So -- oh.

MS. MCQUESTON: Oh, I was going to say, I feel obligated to thank Ron and Cristie for their patience with some of the process flaws and all of you as well. Please let the coordinating committee team or your Chairs know what worked, what didn't.

We're going to be bringing all of this to the coordinating committee to continue to refine the process. So please, I would welcome any input, feedback.

We want to work through these road bumps and continually make this a valuable process for all of you. And thank you very much for all the time you dedicated to today and your flexibility and doing this difficult work to come to consensus on these challenging topics.

MEMBER YONG: And just on behalf of CMS, I want to thank you again. It was, as I had anticipated, one of the most excited MAP meetings ever.

(Laughter)

MEMBER YONG: We crammed it all in one day this year, so thank you very much. I do want to, in particular, recognize Cristie and Ron for their excellent efforts as co-Chairs. Thank you very much.

(Applause)

MEMBER YONG: And of course want to recognize all the NQF Staff without whom this would not have been possible, with including, Erin, Elisa, Kate, Desi and Marisa. Thank you very much.

And then I know that, and if you'll have to just bear with me for a second, but there is a whole host of people, as staff, at CMS who put in many, many hours working through what you saw today. Including reevaluating all the measures that did not make it down to the MUC list, that I just want to recognize.

Many of whom were in the room or on the phone but did want to recognize all of them, so just bear with me, but Reena, Cindy, Robert, Joan, Benethea (phonetic), Jesse, Joel, Jo, Leanne, Jim, Timara (phonetic), Grace, Delia, Katlin, Anita, Lauren, Jeff, Elizabeth, Maria, Michelle, Helen, Brenden, Sophia and Nitty (phonetic).

But all of those people touched different pieces of this process, so just wanted to say thank you to all of them.

CO-CHAIR TRAVIS: Thank you.

(Whereupon, the above-entitled matter went off the record at 4:36 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Hospital Work Group
Measure Application Partnership

Before: NQF

Date: 12-14-17

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

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Court Reporter