NATIONAL QUALITY FORUM

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MEASURE APPLICATIONS PARTNERSHIP
HOSPITAL WORKGROUP

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TUESDAY
DECEMBER 11, 2018

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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 Ron Walters, Co-Chairs, presiding.

WORKGROUP CHAIRS
CRISTIE UPSHAW TRAVIS, MSHHA
RONALD S. WALTERS, MD, MBA, MHA, MS

ORGANIZATIONAL REPRESENTATIVES
KEITH BELLOVICH, MD, Kidney Care Partners
ANNA LEGREID DOPP, PharmD, Pharmacy Quality Alliance
NANCY FOSTER, American Hospital Association
FRANK GHINASSI, PhD, ABPP, National Association of Psychiatric Health Systems
KIMBERLY GLASSMAN, PhD, RN, Nursing Alliance for Quality Care
MARYELLEN GUINAN, America's Essential Hospitals
MARTIN HATLIE, JD, Project Patient Care
GAYLE LEE, Association of American Medical Colleges
MARSHA MANNING, MLIR, BSN, RN, University of Michigan*
LISA McGIFFERT, Mothers Against Medical Error
R. SEAN MORRISON, MD, National Coalition for Hospice and Palliative Care
SARAH NOLAN, Service Employees International Union

SHANNON PHILLIPS, MD, MPH, Intermountain Healthcare
AISHA PITTMAN, MPH, Premier, Inc.
KAREN SHEHADE, MBA, Medtronic-Minimally Invasive Therapy Group
SALLY TURBYVILLE, DrPH, MS, MA, Children's Hospital Association
MARISA VALDES, RN, MSN, Baylor Scott & White Health
DEBORAH WHEELER, Molina Healthcare

INDIVIDUAL SUBJECT MATTER EXPERTS
ANDREEA BALAN-COHEN, PhD
LEE FLEISHER, MD
JACK JORDAN
ANN MARIE SULLIVAN, MD
LINDSEY WISHAM, BA, MPA

FEDERAL GOVERNMENT LIAISONS
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PAM OWENS, PhD, Agency for Healthcare Research and Quality (AHRQ)*
DAN POLLOCK, MD, Centers for Disease Control and Prevention (CDC)

NQF STAFF:
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KAREN JOHNSON, MS, Senior Director, Performance Measures
MADISON JUNG, Project Manager
MELISSA MARINELARENA, RN, MPA, CPHQ, Senior Director, Quality Measurement
ELISA MUNTHALI, MPH, Senior Vice President, Quality Measurement
DESMIRRA (DESI) QUINNONEZ, Project Analyst
ERIN O'ROURKE, Senior Director

ALSO PRESENT:

CORINNA ANDIEL, Alliance of Dedicated Cancer Centers*

SUSANNAH BERNHEIM, MD, MHS, Yale CORE

KRISTEN McNIFF, MPH, Alliance of Dedicated Cancer Centers

ROBERT MORGAN, Hospital IQR and VBP Programs, CMS

IRA MOSCOVICE, PhD, MAP Rural Health Workgroup Co-Chair*

GIGI RANEY, LCSW, Health Insurance Specialist, CMS*

TOM ROSS, MS, PCHQR Program Lead, VIQR Outreach and Education Support Contractor*

MICHELLE SCHREIBER, MD, QMVIG Group Director, CMS

***Present via telephone**

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

9:01 a.m.

CHAIR WALTERS: Good morning. Thank you all for coming. I wanted to -- my name is Ron Walters. Cristie and I are the co-chairs. I'll let her speak in just a second. I wanted to say a couple of things first because we really do appreciate all of you coming to the meeting.

We know that the thought has probably crossed more than one mind around the room, why am I coming all this way, possibly through some bad weather, to talk about four measures? And for people who have been on this group for a while, we all remember the two-day marathons with, I don't remember where we peaked, but it was somewhere in the 40 measures.

This is, again, part of the patients over paperwork trend, part of trying to trim down to the ones that are most meaningful and worth the time and hassle to collect since many places cannot spit these out automatically, as automatically as they want to. It certainly

affects the hospital program tremendously, as Nancy has pointed out since the very first meeting. And we, of course, never really know until December 1st or within 24 hours of that day how many measures there are going to be, so when they book everybody's appointments and everything and travel and hotels, they're, at best, only a feeling of, well, it's not going to be two dozen measures or even one dozen measures and we never know the exact number.

So congratulations to staff. There was a lot of last -- the version you're seeing of the agenda is probably about the fifth or sixth one, as usual, and they have to also change the plan as it goes along and they get exactly what we're going to be doing on December 1st. So, again, a big congratulations to staff and to everyone for showing the dedication to come here in what could have been really nasty travel. I know for some of you it still was.

But we have to, we literally have to do this. We commit to doing it as our

responsibility to give feedback to CMS about the MUC list and about any other measure, actually, existing measures or ideas for measures. And I think, as Michelle will say later on, CMS really does appreciate that feedback and taking into consideration. This is an important meeting to try to go to all odds to get to, and there was a time where we thought those were going to be considerable odds over the last few days and still were for some people.

Cristie, do you want to say anything?

CO-CHAIR UPSHAW TRAVIS: Well, I will just say ditto to all of that. And in our efforts to be efficient, I won't repeat them. But just to give my personal thanks to all the work you have to do in advance, as well as the work that we will be doing here today, so thank you for being here. This is a big group of people. I don't remember actually it being this big in the past, so we're filling every seat. This is wonderful. But thank you for all of that, as well.

CHAIR WALTERS: Have we stalled long enough that you're ready, or would you like a few jokes or magic or something?

MS. MARINELARENA: We can do an icebreaker, okay? Good morning, everyone. My name is Melissa Marinelarena, and I'm the Senior Director -- they're working on my badge outside -- for those of you that don't me, but I think mostly everybody does. I'd like to welcome you to the MAP Hospital Workgroup, although we have a small number of measures compared to the number that we've had in the past. I think it will still be an exciting and productive day, so thank you very much.

CHAIR WALTERS: And I believe on the phone do we have Marsha and Pam yet?

MEMBER MANNING: Marsha Manning is here.

CHAIR WALTERS: Thank you for calling in. Pam?

MEMBER OWENS: This is Pam Owens from AHRQ.

CHAIR WALTERS: Good. So I think

that's, we'll see, I think that's everybody almost. Good. Remember that, as we work our way through this, we're going to go over that the process has changed just a little bit, but the underlying process hasn't. Raise your tent cards if you have something to say. Restrooms are in the hallway. Please mute your cell phones and speak directly into the microphone with it turned on and then try to remember to promptly turn your microphone off when you're done so that we don't look around the room and see 20 people talking when only one person does. And as we say every year, your input is very important. We want you to say what you need to say and give the input that you came here for, but the co-chairs tried to also make sure we get through the agenda and we don't get terribly duplicative in our conversations repeating what others have said.

So anything else? I think we're ready to roll on to disclosures.

MS. MUNTHALI: Thank you, Ron and Cristie and Melissa. Good morning, everyone. My

name is Elisa Munthali. I'm the Senior Vice President of Quality Measurement at NQF, so I would like to welcome you, as well, and to thank you so much for serving on the Committee.

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

We're going to start with the organizational representatives, and you'll remember you received a form. It was an abbreviated form. We just asked you about your financial interest if it exceeded, it was $10,000 or more. So what we're going to do is start with the organizational representatives in the room first. We're going to ask you to introduce yourself, tell us who you're with, and let us know if you have any disclosures. Once we do that, then we'll go to the organizational reps on the phone and then we'll go to our subject matter

experts in the room and those on the phone.

So I think we're starting with Frank, who is to my left. Yes.

MEMBER GHINASSI: So good morning. Frank Ghinassi. I'm at Rutgers University, and I'm representing the National Association for Behavioral Health. I have nothing to disclose.

MEMBER McGIFFERT: Good morning. I'm Lisa McGiffert. I am subbing for Helen Haskell today for Mothers Against Medical Errors. I'm also a patient advocate with the Patient Safety Action Network, and I directed the Consumer Reports Safe Patient Project for about 15 years, and I also serve on the Patient Safety Committee for NQF.

MEMBER GLASSMAN: Kim Glassman with the National Nursing Alliance for Quality Care. Nothing to disclose.

MEMBER McGIFFERT: I don't have anything to disclose. Sorry.

MEMBER VALDES: Good morning. Marisa Valdes from Baylor Scott & White Health. Nothing

to disclose.

MEMBER SHEHADE: Hi. Karen Shehade with Medtronic's Minimally Invasive Therapies group. I'm a physician assistant and work in our health economics and health policy and reimbursement, and I do have disclosure of more than $10,000 in stock.

MEMBER BELLOVICH: I'm Keith Bellovich representing Kidney Care Partners. I'm a nephrologist from Detroit, Michigan. And my disclosures, I'm a medical director with DaVita Corporation and a joint venture partner.

MS. MUNTHALI: Thank you, Keith. I'm just going to pause briefly. Just to remind those who are on the phone if you could please mute your lines if you're not speaking. Thank you.

MEMBER HATLIE: I'm Marty Hatlie. Good morning, everybody. I'm the CEO of Project Patient Care. We're an improvement coalition in Chicago, non-profit improvement coalition, and it's nice to be here. And I have nothing to

disclose.

MEMBER MORRISON: Sean Morrison. NQF has found me out. I am no longer a content matter expert, but I'm now representing the National Coalition of Hospice and Palliative Care.

MS. MUNTHALI: Sean?

MEMBER MORRISON: I have to disclose no disclosures.

MEMBER WHEELER: Debbie Wheeler. I'm representing Molina Healthcare, and I have no disclosures.

MEMBER GUINAN: Morning, everyone. Maryellen Guinan with America's Essential Hospitals, and I have nothing to disclose.

MS. MUNTHALI: So let me tell you who the subject matter experts. So right now everyone with the exception of Andreea, Lee, Jack, Ann Marie and Lindsey.

MEMBER PHILLIPS: Good morning. My name is Shannon Phillips. I am a pediatric hospitalist. I'm the Chief Patient Experience

Officer at Intermountain Healthcare and I lead safety, quality, and experience for our health system. Have no disclosures. However, as relevant to today's discussion, our organization has participated in the pressure ulcer work with Mathematica but, otherwise, nothing.

MEMBER LEE: I'm Gayle Lee. I'm with the Association of American Medical Colleges. I'm subbing today for Janis Orlowski, and I have no disclosures.

MEMBER DOPP: Morning. I'm Anna Legreid Dopp. I'm a pharmacist. I'm the Director of Clinical Guidelines and Quality Improvement with the American Society of Health System Pharmacists. However, today we're representing the Pharmacy Quality Alliance on the MAP, so I'm really thankful to be here. I have nothing to disclose.

MEMBER FOSTER: Good morning. I'm Nancy Foster. I'm the Vice President for Quality and Patient Safety Policy at the American Hospital Association, and I have nothing to disclose.

MEMBER BALAN-COHEN: I'm Andreea Balan-Cohen. I'm a research leader with the Center for Health Solutions. I'm also the chair of the Quality and Value Group at Academy Health, and I have nothing to disclose.

MEMBER NOLAN: I'm Sarah Nolan from the Service Employees International Union, SEIU. Nothing to disclose.

MS. MUNTHALI: So thank you to everyone in the room. Now we'll go to Marsha Manning from the University of Michigan.

MEMBER MANNING: Good morning.

MS. MUNTHALI: Hello.

MEMBER MANNING: Good morning. This is Marsha Manning, Manager of Medical Benefits from the University of Michigan, and I have nothing to disclose.

MS. MUNTHALI: Thank you very much. So thank you to all of our organizational representatives, and so now we'll do the disclosures for the subject matter experts. And for those of you that completed the form, you

know it was a lengthy form. We asked you about your activities as they're related to the work in front of us. A couple of reminders. We wanted you to know that you sit on this committee as an individual. You do not represent the interest of your employer or anyone who may have nominated you for the Committee. We're interested in hearing any relevant work, not just that that is paid but also unpaid. And I think this is a most important reminder. Just because you disclose it does not mean you have a conflict. We do this in the interest of openness and transparency.

And so I'll start with your co-chairs. Ron and Cristie are both subject matter experts. I'll start with Ron and then go to Cristie, and then we'll go to, I think Andreea, you did yours already, we'll go to Lee, Jack, Ann Marie, and Lindsey.

CHAIR WALTERS: Ron Walters. I'm a medical oncologist at MD Anderson. I have two affiliations. One is I'm on the board of NCCN, which is the National Comprehensive Cancer

Network. They are not a measure developer. I'm not sure what they're doing, but they're definitely not developing measures. They use the word endorse. They don't really know what that means. And I'm also on the board of the TMF, Texas Medical Foundation, QIN-QIO organization, and it has about six states that it oversees and numerous contacts with CMS. They are also not a developer, they are an implementer of a lot of things that go on.

When we get to later this afternoon, I'm going to kind of recuse myself from the cancer discussion, although I am not a part of that measure development. You'll hear from the measure developer for that. I was kind of the idea generator, I guess.

CO-CHAIR UPSHAW TRAVIS: Good morning. I'm Cristie Upshaw Travis, and I'm the CEO of the Memphis Business Group on Health. I have just a couple of disclosures. I do serve on the Board of Directors as Vice Chair of the Leapfrog Group which does put together measures related to

hospital quality and safety, and I do have stock ownership in healthcare-related stock of more than $10,000.

MEMBER FLEISHER: I'm Lee Fleisher. I'm the Chair of Anesthesiology at the University of Pennsylvania. I do have grant funding from the NIH with Jeff Silber on measure methodology. I also chair the Leapfrog's Ambulatory Surgery Group, as well as I am the affiliations with the American Society of Anesthesiologists in the AAMC. No other financial.

MEMBER JORDAN: I'm Jack Jordan. I'm the Director of Quality at Henry Ford Hospital in Detroit. I do also consult with Impact International as a provider with CMS on the HINN contract.

MS. MUNTHALI: Thank you.

MEMBER SULLIVAN: Hi. I'm Ann Sullivan. I'm the Commissioner of the New York State Office of Mental Health and on the faculty of the Mt. Sinai School of Medicine and a psychiatrist.

MEMBER WISHAM: Good morning. I'm

Lindsey Wisham. I here as a health informatics expert. I would like to disclose that my employer, Telligen, does have contracts with CMS. I'm also the patient representative for a macro measure development and some DoD reviews.

MS. MUNTHALI: Thank you.

MEMBER FLEISHER: And just to add, I'm a paid consultant to Yale CORE for the development of some of the hospital mortality measures.

MS. MUNTHALI: Thank you very much. So that concludes our disclosures for the subject matter experts. We also have federal liaisons that are on the workgroup. They're non-voting members of the workgroup, and I'd like them to introduce themselves. We have colleagues from CMS and Dan is here from CDC and I understand Pam Owens is here from AHRQ on the phone. So we'll start with Michelle and Reena and Dan and then go to the phone to Pam.

DR. SCHREIBER: So good morning. I'm Michelle Schreiber. I am one month into my new

role as the Director of QMVIG, the Quality Measures and Value-Based Incentives Group, and you'll hear a little bit more from me later. I have nothing to disclose.

MEMBER DUSEJA: Good morning. My name is Reena Duseja. I'm the Chief Medical Officer of QMVIG. Looking forward to the discussion today. Thanks. And nothing to disclose.

MEMBER POLLOCK: Dan Pollock. I'm a medical epidemiologist at Centers for Disease Control and Prevention. My day job there is to provide oversight to the National Healthcare Safety Network, which is a surveillance system that's used widely for quality measure purposes.

MS. MUNTHALI: Thank you. Pam?

MEMBER OWENS: Good morning. My name is Pam Owens. I'm an epidemiologist, and I co-lead the AHRQ quality indicators. I'm with the Agency for Healthcare, Research, and Quality, and I have nothing to disclose.

MS. MUNTHALI: Thank you very much. Now that you've heard all of the disclosures, I just

wanted to remind you if, at any time, you remember you have a conflict, we want you to speak up. You can do so in real-time, or you can approach any one of us in the front and on the side. These are our colleagues all over here and the co-chairs. Likewise, if you believe that anyone on the Committee is acting in a biased way, we want you to speak up.

If you have any questions of me, please do ask them. But thank you and have a good meeting.

CO-CHAIR UPSHAW TRAVIS: So we do want to be sure that we have an opportunity to introduce our team from NQF that is supporting our work. You've already met Melissa, and I'd like to introduce Madison. And you can, if you want to, say a few words and maybe introduce your colleagues.

MS. JUNG: Sure. My name is Madison Jung. I'm the Project Manager for this project. You've probably received a lot of emails from me, but thank you for joining us today.

MS. QUINNONEZ: And I'm Desmirra Quinnonez, Desi. And I'm the project analyst on this project, and I'm happy to work with this workgroup.

CO-CHAIR UPSHAW TRAVIS: Okay.

MS. O'ROURKE: I'm Erin O'Rourke. I'm one of the Senior Directors supporting the Coordinating Committee.

DR. AMIN: Taroon Amin. I'm a consultant to NQF supporting the MAP Coordinating Committee, as well.

CO-CHAIR UPSHAW TRAVIS: Hi. Well, this is the team behind the curtain, although they're not very much behind the curtain, so thank you all so much for all of your work today.

You see before you kind of an outline of what our agenda is. We do have a mixture of some updates and some reports, as well as working, obviously, on the measures under consideration. And so we are really respectful of the time that we have here and we want to be sure that we are using it to really further the work that we have

as a workgroup but also to provide CMS with some comments along the way and our thoughts for their use. So we do plan to be out of here no later than 3:00 and, hopefully, that will be good for all of your travel arrangements.

So if we want to go to the next. Obviously, our meeting objectives are to review and provide input on the measures under consideration for the applicable federal hospital quality programs that are under our purview and also, as we do every year, to help identify gaps in measures for these programs, really trying to take a systematic view, if you will, of the portfolio of the measures that are put together, and our recommendations or at least thoughts to CMS on what's missing and where we would like to see those portfolios go.

Next slide. So it is my pleasure, Michelle has already introduced herself, but I would like to turn it over to Michelle so that she could give us some opening remarks.

DR. SCHREIBER: Thank you, Cristie. I

appreciate it. As you heard, I'm Michelle Schreiber, a grand total of one month into this new job. But on behalf of CMS, I would truly like to welcome you to the Hospital MAP and sincerely thank you for your participation. Welcome to all the hospital types represented. It's actually very interesting. I've been on the hospital side for a long time, but we have rural hospitals, we have cancer hospitals, we have inpatient psych hospitals, and so thank you for that wide representation.

You know, your input really is extremely valuable, as Ron eluded to before. In the short time that I've been there, I have really witnessed how CMS takes these comments to heart and it does affect policy and it affects what goes forward into the federal programs. So your comments really are extremely appreciated and helpful. Thank you also to NQF for convening this work and as well as our CMS partners, our contractors, who are here today to help support us.

The Measure Application Partnership is an important annual process, you all know this, frankly probably better than I do, where NQF really convenes multiple stakeholders. And my computer doesn't want to work. That was not good. But it convenes multiple stakeholders to provide input on these measures that will go into federal rulemaking that starts really almost as soon as these meetings are over.

The Committee also helps provide guidance on future direction and helps us identify gaps in measure opportunities, as well. There's also the important opportunity for public comments, so we look forward to any comments from the public either in person here or on the phone.

The Quality Measures and Value-Based Incentives Group, QMVIG, that we're representing today is the group responsible for developing and stewarding measures and for those programs that I know you all love, including the hospital stars; the hospital value-based programs; MIPS; meaningful use, also known as promoting

interoperability; post-acute care programs; inpatient psyche; ESRD. And so this really is the whole host of programs, so that what you say can affect not just hospitals but really all of the programs that CMS has to offer.

By way of background introduction, actually it turns out I know you. I trained one of you, surprisingly enough. I'm a primary -- it's hard to believe. I'm a primary care general internist by background and training, and I've worked both inpatient and outpatient. I've been in the healthcare quality space really for many years both in quality and as a practitioner, mainly in Detroit but elsewhere. Most recently, I was the Chief Quality Officer at the Henry Ford Health Systems, so Jack and I do know each other well. And I was the lead clinician for their Epic implementation, so my particular interest is actually the intersection of quality and electronic medical records, and I have a tremendous amount of experience in implementing these systems.

I really chose to come to CMS to be on the other side, to see the policy side and the development of it, and it's been an amazing transition filled really with wonderful people at CMS who truly are committed to making it better, and we all look forward really to working with you today.

I know that you have heard presentations on Meaningful Measures. CMS is an important initiative around making sure that we have only the most essential Meaningful Measures and to reduce burden, as well. But let me just touch on a few things for you to keep in mind as you consider the measures before you today.

So Meaningful Measures was just launched last year, and it was to improve outcomes for patients and caregivers by empowering them with information that's meaningful to them to make decisions. But additionally, Meaningful Measures is also about reducing burden to clinicians because we recognize, and I've lived it, that clinicians in healthcare organizations sometimes

find some of this work difficult and onerous, and so CMS is actually committed to reducing that burden and to promote patients over paperwork.

With this in mind, actually, we narrowed down the initial 184 measures that were originally the MUC list to a very parsimonious list, so you're not seeing that many measures come to you today. Part of that was intentional.

We recognize that really quality measurements and reporting isn't a perfect science. It hasn't been. I don't know that it ever will be. But we're all trying to make it better and that the programs have opportunity for refinement.

As I said, I've lived for many years on the receiving end of these programs, but, being at CMS, there is ongoing and continued work for improvement around both the programs and the measures to provide better care for all patients. And I think that's what we all have to keep in mind that that's our primary goal.

As part of the effort to reduce burden,

last year Meaningful Measures removed 79 measures from the various programs and saved over $100 million in expense while continuing to align measures across multiple programs so that we're not duplicative. Meaningful Measures is a commitment to infusing the principles of value, innovation, and flexibility and following CMS's quality strategy goals to remind us all making care safer, strengthening the person and family engagement, promoting effective care communication and coordination, promoting effective prevention and treatment of chronic disease, working with communities to promote best practices of healthy living, and, of course, making care affordable.

Meaningful Measures is not just about burden removal, however. The work also calls for identifying and filling in gaps where there's a lack of important measures, and we know that there's many areas like that, and focusing more on outcomes measures, although process measures are still important, I want to be clear about

that, and patient-reported measures.

We'll also continue to align measures across all programs and payers, and I'm really particularly excited about the re-initiated work that NQF, AHIP, America's Health Insurance Plans, and CMS are jointly leading about the Core Quality Measures Collaborative, in other words trying to align measures not only across CMS but across all payers in the United States as much as we can so that we reduce burden with multiple programs having multiple measures. So this is really very exciting work, and we thank NQF for that, as well.

Finally, we recognize that we must lower the burden of measurement systems, including making quality measures more real-time so that they're more actionable. There's a great deal of work going on with ongoing and multiple registries and significant thought to electronic quality measures.

So please think about these areas as you make your recommendations today: One, are we

addressing high-impact areas? Do these make a difference? Are they meaningful? Are the measures meaningful to patients and caregivers and include the patient voice? Is this an outcome versus a process measure? Both have a role. What's the burden of the measure? Are there burdens or unintended consequences of including the measure into a value-based program? Is there a significant opportunity for improvement or are these measures really just topped out? And does the measure fit a population-based payment or alternative payment model and align with other programs and payers?

Finally, I would encourage everybody to think about equity and to think about advancing interoperability within electronic health records.

So thank you all again for your time, your dedication. And on behalf of CMS, thank you for your participation. We all look forward to working with you. Thank you.

CO-CHAIR UPSHAW TRAVIS: Thank you.

Thank you very much. I'm going to turn it over to Ron, but, before I do, I do think we have a couple of more disclosures that we probably need to make. And just in case this is a disclosure I should have made before, I do sit on the steering committee for the Core Quality Measure Collaborative, so thank you for bringing that up.

MS. MUNTHALI: Thanks, Cristie. And Aisha and Sally just walked in, and so if you can let us know, introduce yourself and let us know who you're with and let us know if you have any disclosures. Thanks.

MEMBER TURBYVILLE: Good morning. My name is Sally Turbyville. I'm here representing the Children's Hospital Association. I have no conflicts of interest to disclose.

MEMBER PITTMAN: Hi, good morning. Aisha Pittman with Premier. No conflicts or disclosures.

CO-CHAIR UPSHAW TRAVIS: Sorry. We want to just be sure we had all the disclosures out, but thank you so much, Michelle, for your opening

remarks. It was very helpful to me. I wrote them all down right at the end there about what you were encouraging us to kind of keep in mind as we go through our work.

We do have a few minutes if there are some questions or discussion with Michelle before we move on to our next agenda item. Well, it says here, it says ask if the workgroup has any questions.

CHAIR WALTERS: We're all friends here.

CO-CHAIR UPSHAW TRAVIS: And remember this is her first time and we want her back. So Nancy.

MEMBER FOSTER: Was that directed at me? I actually want to thank CMS for its focus on the Meaningful Measures initiative. The opportunity to really hone down the list of measures to those that are most meaningful to making a difference for patients is really going to help drive quality forward in ways that we all want to see happen and kudos to you for making that happen, to all of CMS for making that happen. It's

really an extraordinary opportunity because one of the things you didn't mention, Michelle, but I know you know from your previous experience is that what that does is free up the time of the quality improvement staff to really re-focus their attention on making improvement happen, rather than just measuring what's happening, and that's truly important.

I don't know if this is the appropriate time. Cristie, I'll leave that up to you. But I am curious as to why the one psychiatric measure that was initially listed has disappeared off the list and if we can understand because CMS in its rulemaking has said, has acknowledged that it needs more good psychiatric measures. So just curious about that.

DR. SCHREIBER: I actually am happy to take that one. I have tremendous interest, actually, in the psychiatric hospitals, having worked with them through Henry Ford and other places. We did a lot of deliberation around the psychiatric measures. One had actually already

been passed through, and that's why you're not seeing it, and the other one was on medication reconciliation, which we actually thought was too burdensome, had become much more of like a checkbox-y thing than a meaningful measure, and we pulled it.

CO-CHAIR UPSHAW TRAVIS: Thank you for that, and I actually did mean to mention that earlier. So thank you for bringing that up, Nancy.

Can you show us your card? Sorry. It's hard to tell. Shannon.

MEMBER PHILLIPS: In the spirit of if you remember something say something, I am a member, a senior fellow in the Society for Hospital Medicine and I sit on the Public Measures and Reporting Committee and we do regular feedback to measures that come up as it relates to hospitalists. So thank you for the opportunity to add.

CO-CHAIR UPSHAW TRAVIS: Thank you. I had my own opportunity, so thank you for that.

Are there other thoughts that we'd like to share with Michelle or questions? All right. Well, hearing none, we will move on to our next agenda item, which is an overview of the MAP Rural Health project. And Ameera, I'm going to let you say your last name, will be walking us through that. So thank you, Ameera.

MS. CHAUDRY: Thank you. Good morning, everyone. My name is Ameera Chaudry. I'm the project analyst on the MAP Rural Health project. I'm joined by Karen Johnson. She's the senior director on the project, as well as Ira Moscovice. I believe he is on the phone. So, Ira, if you're there, if you can just say hello.

DR. MOSCOVICE: Hello. I'm here.

MS. CHAUDRY: Hello. Good morning. Thank you. So next slide, please. So just a quick agenda here. I'm going to provide a brief overview of previous NQF work followed by a presentation by Dr. Moscovice on the 2018 recommendations made by the MAP Rural Health Workgroup. And then, last, we'll discuss some of

the current work, next steps, followed by a short discussion.

So in 2015, the Rural Health Project identified four key issues faced by rural providers and patients. Those four issues were geographic isolation, small practice size, heterogeneity, and low case volume. Based on these issues, an overarching recommendation was made to allow a phased approach towards mandatory participation of rural providers in CMS quality measurement and quality improvement programs.

Supporting recommendations addressed guiding the selection of quality measures relevant to rural providers, using a core set of measures, and creating a MAP workgroup, a rural workgroup, to advise CMS on the selection of rural measures.

Next slide, please. So in 2017, the MAP Rural Health Workgroup was assembled to ensure that the rural providers selected was represented on MAP. The workgroup is comprised -- clearly, I'm a little nervous -- of 18 organizational

members, seven subject matter experts, and three federal liaisons. Key activities of that workgroup included identifying a core set of rural relevant measures to address the needs of the rural population, identifying rural relevant gaps in measurement, and making recommendations on access to care.

So with that, I'll turn it over to Ira on the phone. He's the co-chair of the MAP Rural Workgroup and the Director of the University of Minnesota Rural Health Research Center.

DR. MOSCOVICE: Okay. Thank you. So what I've done with the other workgroups is spend about 15 minutes describing what we've been doing in the MAP Rural Health Workgroup and that means that I'll give an overview of the activities, but we won't go into a lot --

MS. CHAUDRY: Ira?

DR. MOSCOVICE: Yes?

MS. CHAUDRY: Would you mind talking either a little closer to the phone or a little louder? It's just difficult to hear you in the

room.

DR. MOSCOVICE: Okay. Can you hear me now?

MS. CHAUDRY: Better. Okay. Thank you.

DR. MOSCOVICE: Okay. So I have worked, made this presentation with the other NQF workgroups and it takes about 15 minutes, and we're going to give a broad overview of what we've done. I won't go into excruciating detail on any of the specific measures, but I'd feel free to answer any questions you might have about them.

But, basically, in 2017 through '18, the MAP Rural Health Workgroup had a couple of key activities. The first was to identify a core set with the best available rural relevant measures and, you know, the motivation here is that many of the measures that have been approved by NQF or by other groups really aren't relevant in the rural environment. It could be because of low case volume, etcetera. And so the workgroup really tried to figure out what kinds of measures

are particularly relevant for rural.

The second activity was to identify gaps in measurement and provide recommendations on the alignment and coordination of measurement efforts, and the third was to make recommendations regarding measuring and improving access to care for the rural population. So we'll talk a little bit about the work we did in identifying gaps in measures and why we focused on access to care.

And so if we look at the core set, we had 20 measures in the core set that we identified. Nine measures were for the hospital setting at the facility level of analysis, and 11 measures were for the ambulatory setting at the clinician level of analysis. And what we decided up-front was to use four criteria to help with identifying these measures.

The first is that they had to be endorsed by NQF. The second is that they would be cross-cutting measures ideally, i.e. not simply focused on a specific diagnosis, and that

would help with the third criteria which is being resistant to low case volume. So the notion was if we could look at cross-cutting measures, when possible, that would be helpful.

And then, finally, the fourth criteria was to address transitions in care. And the feeling here was that this whole issue of care coordination and transitions from rural environments to secondary and tertiary care environments was a really important activity for rural health professionals and something we should look at.

And so, just briefly, the nine measures for the hospital setting, two of them focused on infection-related measures, one related to CAUTI, and the other related to CDI. We had a measure from HCAHPS because we really wanted, we felt it was important to get the patient viewpoints here. Another measure related to falls with injury, and that was particularly relevant for the elderly population. The emergency transfer communication measure which tried to measure the

appropriateness of communication between patients who were in emergency rooms in rural hospitals and then get transferred out to secondary and tertiary hospitals. A measure related to VTE, prophylaxis, really felt it was very important across all environments.

And then we had an interesting discussion about including a measure, and this was on cesarean birth rate. And although the debate went, well, there are lots of smaller rural hospitals that don't have, don't do deliveries any longer, despite that, the overall committee voted that it would be important to include the cesarean birth rate in the measure set because it's such an important issue for the rural population.

A real interest in also including measures that are related to substance abuse. And for the hospital setting, the focus was on alcohol use screening. And then, finally, self-comparisons could be made with other hospitals directly. We introduced a measure on hospital-

wide all-cause unplanned readmission measure. So those are basically the nine measures for the hospital setting.

The 11 measures for the ambulatory care setting, once again, included a CAHPS clinician and group surveys for adults and kids, so it was getting input, once again, from patients. A whole set of prevention and screening measures, one related to tobacco use screening and cessation intervention, one was related to influenza immunization, and another is related to screening for clinical depression and follow-up plan. Another related to BMI screening follow-up. And then, finally, another preventive care screening measure related to unhealthy alcohol use for screening and brief counseling.

In addition, there was a focus on diabetes. Although we wanted cross-cutting measures, diabetes has become such an important issue, both in terms of obesity-related and other kinds of comorbidities. As a result, we included two measures. One was hemoglobin A1c poor

control and the other was optimal diabetes care.

Then a couple of the other measures in the ambulatory care setting. One was for medication reconciliation post discharge, which was a big issue out in the rural hospitals. The Committee felt strongly that we should include a measure on advanced care planning, and we had an interesting discussion on that. And then the last ambulatory care setting measure was on depression readmission six months and a strong belief that we needed to have mental health substance abuse measures in this overall set, and we tried to do our best on that.

And then, finally, seven additional measures were identified for the ambulatory setting, but they're currently endorsed with NQF for the health planning integrated delivery system level analysis. And we went back and forth on the committee and decided to identify these measures but to say we would really like to see them endorsed at the clinician level if we're going to use them.

And those measures, several were for cancer screening. There was a feeling we need some cancer screening measures here. One was cervical cancer screening. Another was colorectal cancer screening, and the last was breast cancer screening.

In addition to those measures of controlling high blood pressure, a measure related to weight assessment and counseling for nutrition and physical activity for children and adolescents, a measure on childhood immunization status, and, finally a measure on contraceptive care for the most and moderately effective methods.

And so those were the measures that were identified by the group. We believe they apply to a majority of rural patients and providers because of the criteria we used. They include both process and outcome measures. They include measures based on patient reporting, as we said, and the majority are already used at quality programs, which was important to us.

So that's a summary of the measure set. In addition, the committee was charged with looking at where are the measurement gaps for the rural environment, and there were five areas we discussed. One was access to care; the second was transitions in care; third was the whole cost arena; the fourth were specifically focused on substance use measures, particularly with a focus on alcohol and opioids; and then, finally, outcome measures and particularly patient-reported outcomes.

Because of the importance of access to care in the rural environment, that's the one area that we thought there was a gap in that we did some work on, and we identified the facets of access that are particularly relevant to rural residents, documented the key challenges to access to care measurement, identified ways to try to address those challenges.

And we looked at this from three perspectives in terms of access to care. The first was availability, the second was

accessibility, and the third was affordability. That really built on some of the previous NQF work in this arena.

On the availability area, you know, key items, we're focusing on specialty care, appointment availability in terms of timeliness, and we discussed strategies for addressing it in terms of workforce policy, team-based care and practicing the top of the license, use of telehealth, improving referral relationships.

On the accessibility side, a key issue that came up was the whole issue on accessibility, both transportation, which geography basically brings to the table key issues in terms of transportation and the lack of public transportation, etcetera, out in the rural environments, but also accessibility to health information, which relates to health literacy, accessibility to language interpretations, etcetera. And we discussed strategy to address this via tele-access to interpreters, building community partnerships, and use of remote

technology, and improving clinician-patient communication.

And then a final dimension on the access to care we looked at related to affordability. Out-of-pocket costs, which are an issue, clearly, for everybody but, clearly, play out in the rural environment population. And delaying care due to those out-of-pocket costs. And we talked here about strategies in terms of policy insurance expansion, strategies for protecting the safety net, and the issue got raised here also the notion of how important it is to appropriately risk adjust any measures we're looking at in this arena.

And key aspects of the discussion that we had at the workgroup on the access issue is, you know, we noted how difficult it is to separate or de-link access and quality. We had a vibrant discussion on this notion of what can we expect clinicians to be accountable for and what should we expect higher-level accountability for. And where we came down on that in the end was,

yes, there are some variables that are out of the individual clinician's control, but clinicians can have a major impact in terms of decisions their patients make and we felt it was important to include these kinds of measures even if clinicians don't have total control of all of the levers, so to speak, in terms of improving access to care.

And then, finally, you know, we mentioned that telehealth can address several of the barriers to access, but there still are limitations to its use. We know the majority of states now do have policies on reimbursing telehealth services, but there still are about a third of the states that don't. And so starting with payment but there are other issues also that need to be addressed if telehealth is going to be more fully used.

And so that, I guess, will conclude my comments on this end. I'll turn it back to my colleague at NQF and then we can open up for questions.

MS. CHAUDRY: All right. Thank you, Ira. So I think the next slide, I believe, yes. Go back. All right. So, yes, I guess the final recommendation from the MAP Rural Health Workgroup is listed here: that CMS should continue to fund the workgroup's work, view the current core set as a starter set, and, over time, you know, being open to the opportunity to refine that core set and involve the rural perspective in various topics moving forward.

Next slide, please. Oh, yes?

MEMBER PHILLIPS: Shannon Phillips, Intermountain. The use of the CAHPS survey in the ambulatory setting for children, I think that would be a first requirement, right? Is there another program that requires child CAHPS? I mean, I think that little piece is a big change potentially, so a lot of children centers are doing their own surveys. They have some flexibility. So I want to call that out. If this went in, that would be a major change, and is that the intent?

And the interested in what the discussion might have been around the fact that the end sizes are tiny, right? So I did hear the comment about risk adjustment, but in any rural hospital the numbers of patients that would fall into any one of these measures might be one or none or a handful. And was there discussion about how to approach that? Really important to measure and we need to be careful if there's transparency, if this is public, the end sizes will be very small. The other thing is if you set them up and say we're not going to show them if they're less than X patients, there's going to be a lot of blank slots around the country and so just if there was discussion with the group on that.

DR. MOSCOVICE: I'll take the first one and try to deal with the second one and see if my colleagues want to add to that. But, basically, we really felt it was important to have input both in terms of HCAHPS and CAHPS, and I'd be interested in, I'm not a child health expert, but

the group felt that we did want to get input both on the adult and the child side of things. And one thing about using these surveys is that they are cross-cutting, and so the experience has been that some hospitals, some rural hospitals, are able to provide enough surveys, others provide more limited surveys, but we felt it was important to include this and to try to, you know, build the work in that area. But I am interested, if there are child health experts in the group, if they felt it was, it would be useful and important from a policy perspective to include that.

In terms of the overall volume issue, we know some of the measures, we know we do have enough sample size. Some we know right now we don't. And the feeling was that we would include, you can't come up with a rural health core set of measures right now that have for sure enough sample size for every hospital, every rural hospital in the country. And what we tried to do was to balance ones that we know we have,

and there are some where it's close. We ruled out measures where we felt there wouldn't, you know, be any volume whatsoever. And we need to start some place, and the feeling is these measures can both be used for internal quality improvement, as well as external, for external comparisons. And we played that back and forth and got a variety of information in terms of the volume related to many of these measures and took some out, left some in, even though they're sort of on the cusp, so to speak.

So there's no easy answer to that. What's happening now is NQF has a working panel of statistical experts who are trying to address this issue and come up with some recommendations in terms of how the low volume issue can be handled in general, and that should be done over the next six months or so.

So no easy answer to that question, we recognize it and try to put together a set that would be as useful as possible.

MS. RANEY: This is Gigi Raney from the

Center for Medicare and Medicaid Services. I work on the child core sets, and I think one of your questions was about whether similar measures are used in other spaces. So I just wanted to let you know that we do have a CAHPS health plan survey child version on the child core sets. I know that if ours is collected at a state level, our end is obviously very different from what you're working at here, but we did have 40 states that said that they reported using the child CAHPS for FY17 reporting, just for a frame of reference for other states that are using those core sets.

CHAIR WALTERS: Who's actually chairing this now? But Lisa, go ahead.

MEMBER McGIFFERT: I'm wondering if you discussed the idea of combining years of care, looking at over time to address the small numbers. As consumers, we're looking at old information often, but if you, if you could stretch it out and take a couple of years, two or three years maybe at a time, did you have any

discussions about that? And I know there's, you know, issues about the hospital changing, but I think that there might be some way to address the historical care that the hospital might give or an ambulatory setting.

DR. MOSCOVICE: So the committee discussed that very little, I would say. I can say from my own work in this area previously combining years of care does tend to help improve obviously the volume consideration. But if you're really going to try to make it relevant from a policy perspective, particularly a payment perspective, we haven't gotten a lot of positive feedback in terms of let's use two or three years' worth of claims to try to deal with, you know, any kind of value-based payments or any other kinds of programs like that.

So it's tricky. I think you're right. On the one hand, we certainly can increase volume by using more than one year. I think we need to be considered from a policy, that's from a statistically perspective but from a policy

perspective would be able to use that in terms of payment updates for instance, etcetera, etcetera. And I haven't heard any good evidence that that would be helpful to CMS, to be honest.

CHAIR WALTERS: Nancy.

MEMBER FOSTER: Thanks, Ron. Hi, Ira. Nancy Foster. As I look at this list of measures and think about what the committee went through, it seems to me that there is sort of an interesting blend of measures that you've recommended here. There are some, in fact the ones that I'm looking at on the screen right now where I would say clearly the action is the hospitals and/or the hospital and its clinicians. There are others that I think are absolutely worth measuring in a rural setting but more likely to be good fodder for discussions among policymakers and others who care about rural health in general and the huge transitions that are going on in rural health right now, and so even if CMS or others who might pick up this rural health core set and try to implement it

decide that some of these aren't direct or appropriate for hospitals or other sets of providers, I guess I'm standing up in support of measuring some of these things and thinking about how they're best used, including holding communities and insurers and others accountable for making sure that we're working to achieve the goal here, which is health in that rural community.

So did your committee have discussions about other potential uses of these measures?

DR. MOSCOVICE: Not that much. I don't know if my NQF colleagues have anything to add on that. But I agree with what you're saying, Nancy, but we didn't really talk in detail about that. What we raised is, the biggest discussion we had is are we really going to hold clinicians responsible for all of the ambulatory care setting measures we laid out there, even though they don't control, as I said, all of the resources or levers to make sure that, you know, patients follow recommendations, etcetera,

etcetera. And there was certainly a discussion on both sides in terms of people who felt strongly shouldn't all the clinicians be accountable, but the majority felt that we should but make it clear in the report that makes it clear that we recognize they don't control, the individual clinicians don't control all the levers but they have such a potential for impacting these decisions that we really need to be involved.

So that was the discussion more so than holding a higher level responsible, although we did identify seven measures in the ambulatory care setting that have been approved at the health integrated delivery system level now, so it related to that for sure in terms of the cancer screening, controlling high blood pressure.

So there was some discussion in that vein, but not so much, I think, above and beyond what you're suggesting. But I think it's a relevant comment.

CHAIR WALTERS: Lee?

MEMBER FLEISHER: Thank you again. And you just mentioned the health system level, and I think about some of these measures and whether or not patients really are willing to go outside of the rural local community hospital and the transfer issues. That's a really interesting question about health systems. I wonder if there's, you know, looking at whether these large health systems, which have a tertiary care sort of center and how that is affected by some of these either readmission or emergency transfer because I would think, in some ways, I'd hold them to a higher standard because they're supposed to be integrated or at least look at it in that sort of manner than stratified by whether or not they are a system or they're not a system because that would give us information from a policy perspective of whether it's useful to allow some of these mergers or aggregations.

DR. MOSCOVICE: I definitely agree with the sentiment of your comments. And we have a

couple of measures, as you pointed out, the emergency transfer communication measure and the cause on planned re-admissions, but, to be honest, I was a little disappointed because up-front we had everybody acknowledge that this notion of transition through care and care coordination is really important, but, in the end, we came up with just one or two measures at this point. As it was mentioned earlier, this is going to be an ongoing effort that, you know, this isn't the one and only. Certainly, things change over time.

But I was a little bit disappointed that we didn't get more there, but the committee as a whole didn't come down to the final set to add additional care coordination transition measures. But I think the comments made are important ones.

CHAIR WALTERS: So this is a new program, and this is the opportunity for the members of this group to give feedback about what they've heard. I'll ask the team in just a little bit if they have felt they've gotten

enough feedback. I think common themes that we talk about in every session were brought up. Is there anybody else that would like to give the rural health team some feedback?

CO-CHAIR UPSHAW TRAVIS: I just want to echo what Lee was saying about, you know, about systems. I think it's important to measure at both the individual hospital where we can, but the at the system level, as well.

The other aspect, which I think was referred to but perhaps not said out loud is the number of facilities that are closing. And so although it certainly impacts access, geographic access, I think we do need to be sensitive to the fact that these systems, especially if they're operating in systems, the infrastructure may be there to actually get the telehealth and get the other pieces of some of the core work that was said here out into the different geographies.

And this is an impossible request, but I'm going to make it anyway. There are several other parts of the federal government that work

with rural health, and I think it is really important to think about how rural health is addressed across the federal continuum because there are even probably some places where it's not pushing for the same things and could be sending contradictory messages down into rural America. Tennessee is a major rural state. My other heart is in Mississippi, which is another rural state. So we're very sensitive to it, and I think that sometimes the federal government is not sending the same set of messages and wherever that could be aligned I think would be helpful, as well.

DR. MOSCOVICE: So I think that's an important comment, and the creation of a federal officer of rural health policy is a couple of decades almost now, I think it was an important step in that direction because I think different parts of government were really considering or not considering rural in many different ways. And I think the federal officer of rural health policy in its efforts have really helped improve

this whole issue of making sure that the notion of is what we're doing relevant in a rural environment, that that's really being considered more and more in a variety of CMS programs and CMS recently introduced, you know, their rural health strategy and we need some more details as time goes on now.

But I think more and more of governmental entities and bodies really are thinking, at least, as they develop new policies and measures and you name it that, you know, is this going to work out in the rural environment? And, you know, going back to just the implementation of DRGs many years ago, there really wasn't much thought up-front about how this was going to play out in a small volume environment, and it continues as we go through the pay-for-value environment and the comments that were raised today in terms of are we going to have enough sample size to look at things?

From my perspective, what's most important is we need to get out of the ball game

of having asterisks in lots of tables, whether it's measures or whatever else, and saying not applicable or just not enough volume here because when people see asterisks in the table related to rural environments, they take that as a negative, not just it wasn't applicable or they can't even do it. And I think the efforts of our group and the continuing efforts of CMS and other groups is to really try to see: can we make sure that the policies we're developing can really play out in all environments? You know, we have a little under 20 percent of the population living in rural areas now. We need to make sure that they are, whether it's through Medicare or other public programs, that they are getting access to as high quality of care as possible. And that's why I think this effort is a starting point, not an end point, and I think it's important because of that because we need to really try to pay attention, as has just been said, to make sure that, A, we're doing something in this arena and it's been coordinated across governmental

agencies and, hopefully, with the private sector also.

CHAIR WALTERS: Thank you. Michelle would like to respond and then Jack, and then we'll go to some of the questions that Madison has teed up on the screen.

DR. SCHREIBER: Thank you. I would like to just really echo what was said on the phone that the administrator, Seema Verma, this is of particular interest to her, and that she's done a tremendous amount of work and is bringing agencies across CMS for focusing together on rural health and I think is doing that for all government agencies. So I think this really is the beginning of a lot of new opportunities to consider rural health and the health of rural citizens together in a unified way.

MEMBER JORDAN: I think one comment to make, too, is that sometimes we overly focus on wanting to think about what we can do with the data drilled down to its deepest point, but I think, actually, with the rural health, just

filling in so many of the holes, you may get a lot of insight into kind of regional or group differences that may give you some actionable things to move forward on this. Even when you get down to a single hospital or a single physician, you know, it's just too sparse. But I think you'll see patterns in this, and I think there's great, you know, gains to be made by kind of filling in all the missing data spots so you can kind of get some of those insights with this and not get overly hung up on it has to be something you can drill down to the individual level to be your only actionables in place.

CHAIR WALTERS: Okay. Just hold a second. Madison teed up some questions for everybody just in case. You want to read them off just in case not everybody can see them?

MS. JUNG: Sure. So on the screen, we just have some questions addressing the topics that we discussed related to core set gaps and access to care. Specifically for core set, some questions for the workgroup from the macro health

team is: do you agree with the overall topic areas that were covered? Was there anything missing? Do you have any particular concerns or questions about any specific measures for gaps? What are your initial thoughts on the identified gaps for access to care? What did you think of the approach? Do the three domains seem like the right ones to focus on? Was there anything particularly surprising or intriguing? And was there anything missed?

So if there are any slides we want to toggle back to, just let me know.

CHAIR WALTERS: Andreea?

MEMBER BALAN-COHEN: So I just wanted to follow up on the comment about, like, the gaps in the data and also the asterisks. And I think that just to second that and say, like, how important that is because a little bit of a concern and, again, like, knowing the difficulties about, like, the low volume, but when I look at the sets of measures, like one of the things that strikes me is that in the attempt

to try to make sure that we have all the right information before we have all of these measures, there's likely to be a lot less variation in terms of, like, hospitals as a result of using this specific set of measures, so they get a little bit more diluted.

When I look at those measures, they are probably only like one or two for which they are likely to be, like, big meaningful differences in terms of hospitals. Like, for some of the other ones, they are likely to get, like, topped off, like, relatively early. So that's why I just wanted to second that it's important to try to maybe get some of this information, even if it's imperfect at first, and then, like, try to build up on it and then try to get some meaningful measures that can get to some of these, like, true differences, even if there are for a specific region, when you try to fill in some of the gaps.

CHAIR WALTERS: Thank you.

DR. MOSCOVICE: Let me just offer one

comment in response. I think it's an important issue. I'm never surprised at how much variation exists out in the rural environment, and, in general, if I had to generalize it, I'd say there's more variation within rural environments, across rural environments, as there is compared to looking overall at rural providers versus urban providers.

So there is substantial, in general there's substantial variation in a lot of these measures. That may be surprising, but that's the reality. And that points out that you can do well on many of these measures, and there's really no excuse not to be doing well. And this notion of best practices and finding out how people are achieving some of these results they're doing out in rural environments, that's really important. There's been a variety of technical assistance and health information resources. RHIhub is one that has a lot of information that is in this area. But it never ceases to amaze me how much variation there is

across rural hospitals and small rural hospitals in many of these measures.

CHAIR WALTERS: Okay. Lee.

MEMBER FLEISHER: Just a quick comment to CMS in that, yes, volume does matter and low volume we acknowledge in these hospitals, but there's low volume and there's very, very low volume. So I wonder if having more transparency to say this hospital only does two a year, should they be doing any, versus they do ten to twenty, acknowledging that they can't get to fifty for some procedures may be of some value to patients. So just something to think about.

CHAIR WALTERS: Thank you. Do -- sorry. Ira.

DR. MOSCOVICE: No, I was just going to say I really agree with that notion and, you know, one of the important decisions, I think, from a hospital's perspective is to say: should we be doing whatever the procedure is we're talking about, or should we not be doing something? And, you know, for some of the

measurers here in terms of screening, you know, I think we want all facilities to be doing screening for a variety of ambulatory care settings, but I think all these smaller facilities particularly need to really think should they be doing something? If it's not an emergency and they can't transport out quickly, should they be doing very low volume as was just pointed out. I think that's an excellent point.

CHAIR WALTERS: Frank.

MEMBER GHINASSI: There are three measures on alcohol screening and use and one on tobacco, and in the notes I think there's a mention of other substances, as well. Is that going to make it into this set, or will the focus solely be on alcohol? I think you're missing a large segment of the population who may be in jeopardy of either with prescription medication or illicit use of other substances, especially given events of the last couple of years.

DR. MOSCOVICE: I think it's a valid point. The set that we proposed is what you're

seeing and, as we said, in terms of the treatment gaps, the measure gaps that were identified, the use of opioids and other drugs is something that we need further work on. The committee shared your sentiment, but in the context of trying to have a manageable number of items, decided on the ones that are here right now.

CHAIR WALTERS: Nancy.

MEMBER FOSTER: So just a couple of quick points. One is I think that there might be use, it might be a good step forward in advancing these measures if there were what I will refer to as a collaborative organized where you collected the data for a period, you brought people together who were in those rural hospitals and said, okay, here's what we're seeing from the data, what does that mean to you? I've been impressed over the years where I look at some of the data we're publicly collecting and think, oh, there's something wrong with the practice here at that hospital, let me call them up and see, and I learn that there's just something unique abut

that hospital. And as we explore this territory where we haven't measured a lot and haven't played with the data a lot, there might be a real value in thinking about bringing together that kind of collaborative, either under Ira's direction or some other, but really just learning from the data first before deciding it's appropriate for public accountability as a sort of one-two phasing.

Secondly, Ira, I wanted to ask, I saw the admission, re-admissions measures on there. I know there was talk about the mortality measures and so forth. Those measures are, I would say, exquisitely sensitive to sample size by the way they are constructed, and I was curious as to whether the group thought about that. They're important things to measure. I'm sure the public would like to know about them, but not sure the way the measure is constructed will get people the information they actually think they're getting.

And then, third, there was sort of this

casual mention of telehealth in the things that you could look at in the set of measures that you thought were worth CMS looking at further. To me, telehealth is a great national experiment. There are lots and lots of things that are going on with telehealth, and lots and lots of plans for more to go on with telehealth, and it helps solve that access problem. But I think we don't really understand yet: how is telehealth as it is delivered comparable to the in-person, or what are the bonuses for telehealth, what are the deficits from telehealth in each kind of encounter?

So I think measuring telehealth itself and learning from that would be extremely helpful as we move the nation forward on telehealth, not just rural. But there you go.

DR. MOSCOVICE: Those are certainly good comments. The notion of, I'm trying to remember, you said the notion of the collaborative and what's learned from the data before we start using it publicly I think is a terrific comment,

and we'll see how NQF responds to that.

I can say, in terms of the last comment on the re-admission measure, I was just looking at our notes and it basically says, you know, commenters noted that the majority of critical access hospitals meet the threshold number of cases for this measure. So we need to check that if that's not the case.

And another part of this was that if a hospital didn't have enough volume to report the measure, then it would not be assessed with this measure or otherwise penalized with inability to report the measure.

So those are the two, just looking at our notes, we had related to your comments. And so there are some hospitals clearly that aren't going to have enough sample size, but it's not the numerator, remember, that we're concerned about; it's the denominator obviously. And maybe we can talk afterwards about this in terms of the data you have in terms of how many smaller hospitals would be involved.

Those are the two comments you had on that. You had one other point raised. Oh, the telehealth stuff. Hey, I agree with you. You know, the federal health policy is funding a telehealth research center down at the University of Iowa is the lead on it, and Marcia Ward is on that, and they are in right now developing new measures trying to see how telehealth is being used, trying to identify the pros and cons of it, etcetera, etcetera.

So I agree with you. We're sort of in an experimental stage, and we see new articles every day. I just saw one this morning about how, although it's much greater use of telehealth than we've ever had, there's still the majority of providers don't use telehealth at all or maybe very little. So we had a lot of ways to go. And they haven't been great measures in terms of quality of telehealth care. And that field is just starting really to be developed, so it's going to take a little while.

CHAIR WALTERS: Okay. Let's go to Ann

and then Sally. And then I'm going to give our members on the phone a chance if they want to say anything and then public comments. So Ann.

MEMBER SULLIVAN: Yes, hi. Just in terms of, you mentioned insurance coverage, and I'm not sure if you're really going to be looking into that or not. But if you should, I would just emphasize that you think about parity for mental health and substance abuse and to look at that kind of specifically because that tends to be a real access issue across the country. Despite a lot of the parity legislation, that the insurance is still not following on those rules. So if you are going to look into insurance, I would just keep parity on the list of what you look at.

DR. MOSCOVICE: Okay.

CHAIR WALTERS: Sally.

MEMBER TURBYVILLE: Good morning. This is Sally with the Children's Hospital Association. Really great and important work and lots of really great insights so far today.

You know, we share with Children's Hospital something in common with rural health, and that's real challenges with comparative performance measurement, whether that's comparative performance over time or to peer groups. And I just wondered from those who worked on this how much discussion was given to alternative approaches to measurement. It's become very clear in pediatrics that condition-by condition measurement for children, especially acute inpatient care but even ambulatory specialty care, is very problematic and so been pushing the envelope. At what point is the perfect, the enemy in this case, not having the perfect, you know, so looking at measures that have worked very well in the adult healthcare system condition by condition and any kind of emerging new ways to measure, whether it's through patient-reported outcomes, really focusing on what matters to them or otherwise. I'm just curious what you all learned in those deliberations.

DR. MOSCOVICE: Yes, I think that influenced the work of our group a lot. In fact, you really only see one or two measures that are diagnostic-specific just because of that. We didn't have enough time or resources honestly to start mapping out alternative strategies, so we did start with the notion that any measure we were going to look at had to be NQF endorsed, and we had a thousand measures or so just within that rubric. And so it was a pretty big framework to start.

We didn't really spend a lot of time on alternative strategies for measurement, and I don't know if NQF has any thoughts about the future work in that area. But I agree with your comment there. On the one hand, it's hard to compare, to make comparisons, as you said, just the relevant peer groups, sample size, etcetera. But if you use alternative strategies for measurement, then the issue is how are they going to get integrated into the existing measurement world that's out there now. And I think that

shouldn't stop work on alternative strategies for measurement, particularly low volume environments. But we didn't, at least, have the time in this workgroup to deal with that.

CHAIR WALTERS: Okay. Sometimes we do remember that there is committee members on the phone. Marsha, Pam, did you have anything you want to say?

MEMBER MANNING: I do not. Thank you. Other than I appreciate the comments about thinking across the federal government when we think about the rural issues. I think that's absolutely true.

CHAIR WALTERS: Thank you very much. And we didn't specifically have a time slot for public comment, but I would like to open up the lines if we can for any. Let's go to comments in the room first. I see none in the room. Any public comment?

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

CHAIR WALTERS: Okay. I'll turn it back over to Madison for some next steps, and then we'll move on to the next agenda item.

MS. JUNG: Great. Thank you. Just toggling back to our slides. So I'll be reviewing the pre-rulemaking approach, and then we'll be getting into some of the semantics and logistics regarding the new updated voting process.

CHAIR WALTERS: Oh, next steps on -- there's a slide there somewhere.

MS. JOHNSON: Go back two from the discussion, and I'll just, Ira already noticed or talked about these. Do one more. We have done quite a bit of work with the work that came out of the Rural Health Workgroup, including setting up a Capitol Hill briefing that went very, very well. Rural is very, it's a topic of interest to our leadership in Congress, so that went well. A couple of folks did a healthcare blog, so that was a nice way to kind of publicize the work.

In terms of what the Rural Health Group

is doing right now and in the future, again, sharing our recommendations to each of the three MAP workgroups so you know what we're doing and what we're thinking. Tomorrow, at the clinician MAP workgroup meeting, Ira is actually going to be here to give the rural perspective on the clinician MUC list. So we had a call yesterday and got some really interesting feedback from our rural group on those measures, so we weren't able to do that this time around with you guys to give you the rural perspective, but we think that might be coming, and it's a way to get the rural perspective into this pre-rulemaking process. So we're very excited about that.

And then, as Ira mentioned, we have convened a five-person technical expert panel, most of them Ph.D. statisticians, to help us think through this low-case volume problem and what do you do about it, and to go back to the question about, you know, even doing, adding over time. It's an idea, but there are very complex statistical ways that you could approach doing

even more than that, and they're talking about those things, but we're talking about future work in measurement because it's so complicated. But I think it's a really interesting little project, and we will have a report out, if you're interested, in mid-January going out for comment. So if you're interested in seeing what our statisticians think about this low-case volume problem and what might be some of the next steps, stay tuned for that. Thank you.

CHAIR WALTERS: Thank you all for your feedback. I think the group got some very good feedback. All right. Melissa and Madison, moving forward into the pre-rulemaking process.

MS. JUNG: Okay. Now we will be going over the rulemaking approach. So I'll just be giving an overview of our process and some of the updates and our approach for this meeting.

The approach for this meeting, as in other years, is to provide, we'll start off by providing a program overview, then reviewing the current measure, and then evaluating the MUC for

what they should add to the program set. So that's the lens through which we'll be looking through things.

So the MAP workgroups must reach a decision about every measure under consideration. The decision categories are standardized for consistency. We have had some updates to decision categories this year, and we'll be reviewing them on the next slides. But each decision should be accompanied by one or more statements of rationale that explains why each decision was reached.

To facilitate the voting process, we have conducted a preliminary analysis for you. That was included in your meeting materials in the discussion guide. The preliminary analysis follows an algorithm that was based on the MAP measure selection criteria. This measure selection criteria was approved by the MAP Coordinating Committee, and it's intended to provide MAP members with a synced profile of each measure and to serve as a starting point for MAP

discussions.

This is just a list of the MAP measure selection criteria. I won't read these in detail. And then these are the decision categories for 2018 and 2019. Of note, we have added the do not support for rulemaking with potential for mitigation. This was added to -- excuse me. I dropped my notes. This was added to preserve MAP's ability to show support for a measure concept but clarify that MAP does not think it's ready for implementation as it's currently specified.

So to reiterate, the four decision categories are support for rulemaking, conditional support for rulemaking, do not support for rulemaking with potential for mitigation, and do not support for rulemaking.

I'll turn it over to Erin and Melissa to add any maybe comments or coloring to that.

MS. O'ROURKE: Sure. I can start. Just to add a bit on the do not support with potential for mitigation, as Madison said, we used this to

replace the refine and resubmit because I think last year we heard from everyone there was some confusion about how to operationalize that and where the line was between conditional support and refine and resubmit, and the confusion that the MAP process only really requires MAP to review a measure once. So by having this resubmit language, we were making an ask that's not really within the scope of what MAP can control.

So based on input from you all and other MAP members, we are trying this new category this year. And, again, we'd always welcome feedback if this is an improvement, but hopefully this makes it a little bit clearer where the dividing line is with two categories essentially saying you think the measure is ready for implementation to saying it's not ready for implementation at this time.

MS. JUNG: Did we have any questions about the decision categories? Otherwise, we can review the voting instructions. Okay.

MEMBER HATLIE: I'll just make a comment that I think it is clearer. Having seen the process get reinvented every year since I've been on it, I think this is an improvement. We'll see. I'm with Cristie. We'll see as it plays out.

MS. MARINELARENA: So the voting process has changed as well. The text in red is what is different. They share from previous years. Quorum is defined as 66 percent of the voting members of the Committee that is present in person or on the phone, so we establish that before we actually start the voting.

And then we have also established a consensus threshold of greater than or equal to 60 percent of voting participants voting positively, and a minimum of 60 percent of the quorum figure voting positively. And abstentions do not count in the denominator.

And then different from other years, we've had the consent calendar in the past. We no longer have that. We also only have four

measures, so it's kind of a moot point. But every measure will receive a decision from the MAP, and, again, staff is going to, you know, we're going to go over this process. And then we'll provide some introductions from staff as to how we reached a decision and then the lead discussants will also provide their review of the measure, and then we'll open up the discussion to the group. And then you can provide clarifying questions, we can respond as to the NQF part of it, and then the lead discussants can provide the additional information about the measure or any clarifications before we move on.

And then, again, the preliminary staff analysis is based off of the algorithm that has been approved by the Coordinating Committee.

So the procedures are, so the staff, again, did the preliminary analysis for each MUC based off of the algorithm. We will present the measures. The co-chairs will ask if there are any clarifying questions, so, again, we've done away with any motions this year. Everybody will

just have the opportunity to ask for any clarifying questions, and then the developers will also be able to respond to any clarifying questions about the measure specification, so they're either here in person or on the phone. Staff will provide any clarifying questions about the preliminary analysis itself, how we reached it, or if there's any other information that may be confusing to you that NQF can clarify. And then the lead discussants will also dive into the measure.

The voting is going to be, the first vote will be based on the acceptance of the staff preliminary analysis. That will be a yes/no vote. If that doesn't pass, then the co-chairs will be taking down any questions or any clarifying issues. If the staff recommendation doesn't pass, then we can either start with each category or the co-chairs also have the discretion to see, you know, if the group is leaning towards one way or another. If we don't need to go through all four categories, then we

can start there. But if there is any dissenting opinion, then we can just go through all of them so that everybody's voice is heard.

And, again, we need 60 percent or greater for each of, for it to pass, for a decision to past. If none of them are reached, none of the categories reached 60 percent or greater, the default is the staff recommendation. Correct? Yes.

MS. O'ROURKE: Correct. But at that point, we would also like to pause and get some input on why people feel so split so that we can pass your reasoning, the results of the staff PA, and then any comments and flag this all for the Coordinating Committee to take a special look at as a place where the group was having trouble coming to a consensus.

MS. MARINELARENA: And, again, we'll be capturing everyone's comments because I know in the past CMS has really valued that, so we want to capture all of your comments and your concerns and recommendations as long as, in addition to

the votes.

So we talked about the discussion of voting on the MUC. Ron and Cristie will be leading that, and we've got it all ironed out, of course, as we always do. And I think I already went through all of this. You know, they'll determine what decision category we're going to start at, and they will put the vote forward. And I went through this, right? Yes. And then tally the vote.

Again, if no decision category archives greater than 60 percent to overturn the preliminary analysis, then the preliminary analysis will stand, unless we, you know, can come to another decision, but we can continue the discussion. Again, we have four measures, so feel free to discuss.

Commenting guidelines do not change. Comments from the early public comment period have been incorporated into the discussion, into the discussion guide, so they were there. I know that we updated the discussion guide so you've

had the opportunity to look at those. We will also ask the public to provide any comments here as well. We ask you to limit your comments to two minutes.

And then the public comment on your recommendations will run from the 21st through January 10th. And then your recommendations will go to the Coordinating Committee. And this is just, you've seen this before, but it is an overview of the time line.

And Desmirra is going to do a test vote. Since we have new voting software, rather than the clickers or the hands, so we're going to go through that.

MS. QUINNONEZ: So this is exciting. I just want to make sure that, at this time, I want to make sure that everyone is logged in and has had assistance or you've received your instructions that were on the table of how to log into Poll Everywhere. At this moment, if there's anyone who has not logged in, if you could raise your hand. Well, this should be great.

So we're going to read our first test slide, and, as we do, usually we'll read through the voting question just to make sure that we're clear about what you're voting on. And you will actually be able to enter your vote, and we will be able to calculate those votes real-time.

So at this time, we're going to open voting for our test voting, and please input yes to cast your vote. So if you'll notice on the right-hand side, you'll see the percentage. You'll see at the bottom where you can toggle to see the total results of how many people are actually voting at this time. Right now, we have a total of 25 results. Okay. And what I'll also do is give you -- so we have 100 percent, which is 25 people voting yes. So at this time, it looks like everything is working wonderfully.

What I will ask that you do is refrain from casting your vote until we open voting, so that I don't have to lock the slides on you. But we will vote after we finish the discussion. We'll announce voting and then voting will

commence. Thank you.

Yes, they are voting online. Marsha, Pam, have you all -- Pam is not voting. But Marsha, have you been able to enter your vote?

MEMBER MANNING: Yes.

MS. QUINNONEZ: Awesome. Thanks so much.

CHAIR WALTERS: It's going to be fine; I know. I would like to echo again the process which is, again, I agree that every year it's changed a little bit. I think, as I was reflecting on this, what becomes even more important for, because Cristie and I are listening for what to do with a second vote, okay? If both the lead discussants and any other people who enter in the discussion, we started this actually at the beginning, but it's had some improvements over the years, please state exactly which of the four categories that you are in support of. And what we can do is if, for any reason, the staff recommendation is not the consensus of the group, it gives us a numerical

way, I guess more than anything else, to try to move to the appropriate one that we think reflects the majority of the group, rather than leaving it up to us and rather than just leaving it up to our opinion of what we hear.

So that would help an awful lot, I think. The default is, of course, as you heard working our way right on down the list from support to conditional support to do not support, etcetera, the old refine and resubmit. We can do that. It will just take a little more time to do that.

But I hope, again, to try to give your rationales and then a very specific which one of the categories you support. I think that will help us out.

CO-CHAIR UPSHAW TRAVIS: I'll just add one other piece. Because we have four measures and lots of people sitting around this table, you'll notice that our lead discussant list is very long. So, you know, I think what would be helpful probably to the whole group is to build

on each other's comments versus feeling an obligation to repeat them. You know, certainly, if you have a differing opinion, please be sure and articulate that so that we can all, you know, understand. If it's consistent, you can certainly say that, too, but maybe not feel like you have to go into the same level of detail as others that may have gone before you.

But we do appreciate the additional time that each of you took on your measure that you are a lead discussant, so we want to be sure to capture what you wanted to say just as much as we can be kind of efficient and build on it. It will help us all, I think, be a little bit clearer in our own minds as to where you are. So thank you for that. Marty.

MEMBER HATLIE: I have a quick question. I'm looking at our voting system, and it's got my name on it, and I can't remember whether in the past we have tracked who has voted how and whether that becomes a part of the record. Was it an anonymous voting process in the past, and

is it this year, or are we being tracked and becoming part of the record.

CHAIR WALTERS: I think it's a fair statement. It is not anonymous, but it is not tracked. How is that?

MS. O'ROURKE: So it is tagged to your name. We can't see how you voted. It's just to make sure that the right people are voting and that only the workgroup members are voting. In the past, I know we just kind of assigned. In the past, you had a clicker, so we didn't know that Marty was clicker number 24. But when you -- Desi doesn't have that information of who voted yes, who voted no. It just, all we see is, like, 20 yes, 5 no.

MEMBER HATLIE: Right. Okay. Well, I wouldn't be opposed to actually going on record with our votes. So maybe we'll think about that in the future, but thank you for the clarification. I appreciate it.

CHAIR WALTERS: We're talking about -- yes?

MEMBER GUINAN: A quick question. Maryellen here. Given that I don't have a math background, so that's full disclosure, but I'm wondering, I do appreciate that it will have a further discussion because I could imagine that if staff recommendation is to support and we have 50/50 in the two do not support categories, then that's fairly meaningful. And so I think I hope that doesn't occur but would welcome the additional discussion.

CHAIR WALTERS: Oh, we all can remember 55 to 45. I wish I could promise you that wasn't going to occur. So I think we're going to shift the agenda up a little bit. Okay. And we talked about this ahead of time. Since we went over the voting process and the whole thing and then we took a break to talk about pain, and you kind of said why did they go through all that, we're going to switch those up and Michelle is fine with doing the pain management through quality measurement after we do the IQR. And we're going to take a ten-minute break first. So let's start

at 11. Is that okay?

CO-CHAIR UPSHAW TRAVIS: Great. Thank you all.

CHAIR WALTERS: 11:00, and you get to vote soon.

(Whereupon, the above-entitled matter went off the record at 10:48 a.m. and resumed at 11:02 a.m.)

CHAIR WALTERS: So for those of you that are here for the first time, the general order is we go through the details of the program, and then we see if there's any questions about that.

And then we work our way into the first measure and work our way through the measures for that program.

So who's going to do the over -- Melissa? Okay.

MS. JUNG: Just providing this slide as a reminder of the programs that are considered by the Hospital Work Group. We have nine programs in total.

But, as this table displays, only two of

the programs have measures under consideration today. It's the Hospital IQR Program, Inpatient Quality Reporting Program, and Medicare and Medicaid Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals.

So there are three measures in total being considered today. And then the other program is Prospective Payment System Exempt Cancer Hospital Quality Reporting Program. And we have one measure under consideration today.

MS. MARINELARENA: Okay. Before we get started, I just want to do a quick overview of the Hospital IQR Program.

Again, this is -- you've seen this before, we went over it during the web meeting. But this is a pay for reporting and public -- a pay for reporting and pubic reporting program. Hospitals that do not participate or meet the program requirements receive a one-fourth reduction in their Annual Payment Update.

And the goals of the Program are to progress toward paying providers based on quality

rather than quantity of care that they give patients, and interoperability between EHRs and CMS data collection, and, again, to provide consumers information about hospital quality so they can make informed choices about their care.

We presented this on the webinar as well. As Michelle discussed earlier about the meaningful measures incentive at CMS, the updates on the right include all of the measures that have -- that were finalized for removal. And we included the fiscal years.

So these are the updates that are going to -- these are all the measures that are going to be removed out of Hospital IQR.

We can -- you have that. And we're not going to go through all of these. There were a lot of them. Keep going, and there's more.

And then this is what is left after those measures are removed. So the IQR Program is quite smaller now. And then we have the NQF status to the right. And you have seen this before. And you have copies of this as well.

We talked about this on the webinar as well, the high priority domains for Hospital IQR that CMS identified, which included strengthening person and family engagement as partners in their care; promoting effective communication and coordination of care; promoting effective prevention and treatment of chronic disease; and making care safer.

CHAIR WALTERS: The first thing we do each -- kind of after we went through all the measures in the program, we'll do at the start now, is to open up the lines for public comment. Let's do the -- anybody on the telephone first. And then we'll do the people in the room.

So could we have the lines open for public comment?

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

There are no public comments from the phone lines at this time.

CHAIR WALTERS: Thank you very much.

We'll open it up to the people in the room for public -- for their comments about any of the measures in the IQR MUC list.

Okay. Seeing none, we'll move ahead with the -- these are the three measures that we'll talk about. Hopefully they're in the same order I have them. Yes, they are. That's always good.

C-section birth first. Then the hospital harm pressure injury. And then the hospital harm hypoglycemia.

Lead discussants, this is a good time to start getting ready. Okay. Starting with Cesarean birth.

MS. MARINELARENA: Yes. So since the staff is going to provide the introduction, I think since we have a small amount of measures and a lot of lead discussants, staff will initially just go over the preliminary analysis result and the summary of it.

And then we'll have the lead discussants go over. And then we --

CHAIR WALTERS: Hold on just a second. Nancy, do you want to say something?

MEMBER FOSTER: I just have a question. We talked about this as the IQR Program. But it's my impression at least, some of these measures are for the Electronic Clinical Quality Measures reporting program.

They do get publicly displayed or could get publicly displayed, but are not yet for eCQM, as I recall. But there's a penalty for not reporting them. So I'm just -- I'm trying to understand with clarity here, are these three being proposed for IQR? For eCQM? For both? What?

CHAIR WALTERS: Reena or Michelle? I know that came up in my mind, too.

MR. MORGAN: This is Robert Morgan. I'm the CMS measures lead for hospital -- oh, great. Okay. Sorry.

So I'm the CMS measures lead for the hospital inpatient quality reporting program and the hospital value-based purchasing program.

With respect to these eCQMs, yes, they're included in the hospital IQR program and the PI program.

Historically those two measure sets have been aligned. Particularly with this last one -- where we removed the ED-3 measure from the PI program hospital measure list.

And you are correct that for the hospital IQR program, facility is allowed to report one quarter of self-selected data for four eCQMs of their choosing among the broader eCQM measure set.

And that would be true for these measures as well if we maintain that requirement.

MS. MARINELARENA: Okay. The C-section measure. The staff analysis was -- preliminary analysis was do not support for rulemaking.

And the summary was -- this is because -- this is a fully developed outcome measure. It is the eCQM version of the existing chart-abstracted version.

The chart-abstracted version is NQF

0471. The 0471 was supported by MAP for inclusion in IQR back in 2014.

This is the first time you're seeing the eCQM version of the measure. The eCQM version of the measure was submitted to NQF in the fall of 2017 for endorsement.

It was reviewed by the new Scientific Methods Panel for the scientific acceptability of the measure, and they determined that it did not demonstrate sufficient reliability and validity.

Therefore, it did not move forward for the rest of the endorsement process. NQF, the preliminary analysis summary recommendation is that the eCQM should be resubmitted to NQF for evaluation and endorsement.

So then I will turn it over to the lead discussants.

CHAIR WALTERS: All right, Karen? Would you like to say anything about that process? Just briefly. Because this is going to come up.

This is the first time it has come up before this Committee. And, you know, Melissa

explained how it was arrived at a do not support rulemaking, but the Scientific Methods Panel process leading to that is the first time they've seen that.

MS. JOHNSON: Sure. I'd be happy to. And Ron is one of our Scientific Methods panelists. So I'm sure he could do a great job on this just as much as I can.

We implemented our Scientific Methods Panel just over a year ago. And the idea is that the statistical questions about reliability and validity is sometimes a little bit out of reach of many of our standing committee members.

So we wanted to have experts who really know what they're doing look at these measures. And we don't have them look at all of the measures, just a selected set of measures that we call complex measures, usually outcome measures, composite measures, measures based on instruments. Those kinds of things.

When we first started the process, we set it up in kind of like journal editors do,

where you have kind of blinded reviewers if you will. And that worked fair. But we have recently changed that. So now it's a little bit -- we still have them do things in subgroups.

But we allow some discussion. We allow more participation by the public and the developers in being able to listen to the conversations, that sort of thing. So that's one of the things that's a little bit different about this particular measure. This one was looked at by the Methods Panel.

I believe it was in the first cycle that we did. So that Panel was brand new then. And we have changed the process then.

So we don't really have details that we can share with you about what they saw with that particular measure. Going forward we might be able to provide those kinds of things.

I'm not sure if that got to what you were thinking, Ron.

CHAIR WALTERS: That's exactly what I wanted you to say, rather than me. That may

happen for -- as a measure comes up for maintenance. It can also happen, and you'll see a couple of examples again, where that happened when a new measure was coming up for initial endorsement.

And so the general theme is that if a group of people who are experts in the assessment of reliability and validity could not come to consensus agreement about a measure that it should not go to the panels. And I know that was the subject of a lot of discussion. That's why you'll see a do not support for rulemaking. I've said that now.

I'll move into the lead discussant list. And, again, please in a couple of minutes summarize your -- your recommendations, and with a specific opinion about which of the four categories it should be in.

Anna? Or sorry --

MEMBER DOPP: Lisa was ahead of me.

CHAIR WALTERS: Lisa?

MEMBER McGIFFERT: No, I had a question

about -- because I think I read that one of the reasons that the Panel didn't recommend it was that the data elements were not present in many of the test sites, or whatever.

That hospitals didn't use the data elements. That's what it sounded like, that it was something that was missing in a lot of the information.

Is that -- am I understanding that correctly? And if so, my experience, which is somewhat limited, but pretty broad in this area, is that kind of, you know, if you require a measure and put some validity to it, then the data elements will follow.

And we saw that clearly happening when infection reporting started. And unless, -- you know, hospitals have a lot of things to do, and unless they're required to submit certain data elements, they're not probably going to do it. So I want to clarify in my mind if that's the issue.

CHAIR WALTERS: Well, that was certainly

the discussion in the early meetings of the group, is that they had to go with the assessment of reliability and validity for the data elements that were built into the measure specs.

And if those data elements were not present for whatever reason or unclear for the group, they could not make an adequate determination of the reliability and validity for that measure.

Fair statement? Okay. Let's move on now to Anna.

MEMBER DOPP: So I'm listed first in the list of lead discussants. I'm a pharmacist. I mentioned that earlier. So this is -- the topic is a little out of scope, quite a bit out of scope for my background.

But our group did meet by email on Friday night. And we -- some of us were able to meet yesterday. And so I think we have a good understanding of what the thoughts are with this measure.

So I have a question, and then I'll

defer to the rest of the group. Because I -- it was very valuable discussion over email and over our meeting yesterday, brief meeting yesterday. So they have good information to share.

But under the voting procedures there was a step that was going to allow for the measure developer to respond. Is anyone from Joint Commission present to react to the staff analysis? Or -- or not.

MS. O'ROURKE: Correct me if I'm wrong, but I don't think we have anyone from the Joint Commission who was able to join us.

MR. MORGAN: Well, this is Robert. I can speak on their behalf as I have spoken with them about this measure. This is a Joint Commission measure. And -- CMS is no longer maintaining this under one of our contracts.

What I will say is that through their testing, they did find that, I believe, approximately 68 percent of the data elements currently are captured in discrete fields.

And in the near future, within two

years, approximately 90 percent. But with that said, you know, CMS we agree with the need to resubmit this measure for NQF endorsement.

And we have implored the agency to do so. So we're looking forward to that.

MEMBER DOPP: Thank you. I'll defer to the rest of the group.

CHAIR WALTERS: And I wasn't explicit, but, again, your recommendation can be any of the four categories that you want to recommend. And that is worthwhile information back to CMS also.

The Scientific Methods Panel process is a process related to this process, but this is a separate process, so please feel free to give your recommendations. Okay. Nancy?

MEMBER FOSTER: So thanks, Ron. In the spirit that you and Cristie outlined where we're going to build on each other's comments, I'm going to focus on the sort of a conceptual issue around the measure first. Which is -- and let my colleagues talk about some of the specifics of the measure, the specifications and so forth.

The conceptual issue I have right now is, as you would think about including this measure in a program, there are two main issues that I'm aware of that hospitals are working on very hard.

One is to eliminate early elective deliveries. And we've made great progress in that regard. But we're not where we need to be. And the second is more -- has come to attention more recently, and that's maternal mortality.

To the extent this measure would be related to maternal mortality, it might be important to include. But as I understand the issues around maternal mortality, this is not the first issue that would be addressed.

And so in my mind one of the issues that wouldn't have been addressed by the Scientific Methods Panel is that we really want to stay focused on those two critical issues right now as we move things forward.

And I worry that adding this measure any time soon, even if it were scientifically

superior, would distract from the need to focus on getting those two things right as we work towards better reliability in healthcare.

CHAIR WALTERS: And I think you -- yeah?

MEMBER FOSTER: I was just going to say, and I support the staff recommendation.

CHAIR WALTERS: I think you pointed out one of the -- many -- criteria. So there are other criteria other then reliability and validity, and your comment was very pertinent. Gail?

MEMBER LEE: Thanks. So I think that as well, I support the staff recommendation of do not support at this time for a couple reasons. I think -- I was hoping to find out a little bit more information about what the Scientific Methods Panel had discussed.

And so we tried to find that report. But we couldn't, I guess. But, looking at it, I think that there were a lot of questions that were raised about the variability of the rates of C-sections.

And that, I think, raised for me questions about risk adjustment and whether there's adequate -- it says there's no risk adjustment for this measure at this time.

And so I think that's something that NQF needs to really take a closer look at. Also questions about just the overlap that this measure has with the elective delivery measure that already exists in the denominator piece.

And also the last point is whether there are -- would be any unintended consequences associated with this measure due to some of the pressure that may occur in the delivery room to meet certain criteria or certain ratios.

And so, you know, there's a lot at risk when you're dealing with -- both the mother and the baby. And so that was also a concern and I think something that needs to be looked at more closely.

CHAIR WALTERS: Thank you. And I think, again, as this continues, it is helpful to hear some of the other criteria that fail. And you

brought redundancy into play. And you brought unintended consequences into play.

So -- the whole criteria set's important. Okay. All right. Sally?

MEMBER TURBYVILLE: Thank you. I agree with my fellow lead discussants. Only to add that I also am inclined, as Nancy is, to question whether this is the right focus at the right time.

I do -- I'm probably a little bit more open in thinking that the high performance variability found might actually be real.

But that maternal outcomes is a real issue we know. As well as the outcomes of the infant, being from the Children's Hospital Association, is of great importance.

And the impact of the delivery, care delivery. So not much else to add other then agreement.

CHAIR WALTERS: Okay. Thank you. Lisa?

MEMBER McGIFFERT: I do not agree with my fellow discussants. I think that this measure

should move forward.

C-sections are one of the most common procedures in the hospital, and there is substantial overuse in this procedure, and I personally, as a consumer advocate, have been involved in trying to get public reporting on this for decades, beginning in Texas.

It does create a significant risk for adverse outcomes for mothers like infections, blood clots, length of stay, and maternal mortality is probably one of those issues, and for babies, respiratory problems and the likelihood of some chronic childhood conditions.

The cost is about 50 percent higher to Medicaid and Medicare. It triggers subsequent C-sections nine and ten, despite best evidence that this is not appropriate way to provide care.

Professional societies support it. It is -- and I think that generally this population is highly attuned to getting information about quality.

This measure is, my understanding, is an

electronic medical record measure. Which I understand is the way we want to go.

The chart review measure has been endorsed. It's been out there. A lot of hospitals are using it. It is not publicly reported. I think there are some states that publicly report it. But it's spotty. You know, it's not all over the country.

And I -- as I expressed before, not knowing exact -- I understand the reliability could not be established. But I think this is one of those situations where you have to get out there and do it.

And I'm kind of, you know, if there are some states that have been publishing this information, then we could start with them and try to see what kind of electronic health records they have.

But I personally believe we have to really push hospitals to get on board with electronic measurements so that we can reduce the paperwork and focus on the patients. So I would

recommend that this go forward.

Another comment about risk adjustment, from my reading, it is my understanding that risk adjustment for age was removed from the chart review version of this.

And I don't exactly know why, but I'm assuming it's because this population is well defined as, you know, women who are giving their first birth, and so it's a -- and not high risk.

So it's a narrow enough population for us to look at on this measure. And I believe that this is an extremely important measure for us to move forward after so many decades of talking about it.

CHAIR WALTERS: So your recommendation would be support or conditional support?

MEMBER McGIFFERT: Support.

CHAIR WALTERS: Okay. Deborah?

MEMBER WHEELER: I agree with the majority of the lead discussants, where I do not support the measure due to the lack of validity and reliability.

Many of us -- we've had many comments so far related to the measure. But one that I want to bring up is related to the comparability of data collection processes, whether it's this measure or measures related to chart review.

Has there been, or can there be work to focus on, you know, if a hospital collects data in one system using the same specifications, is that process comparable to another hospital that looks at the measure?

So I think there should be more work in that area.

CHAIR WALTERS: Okay. As we continue to work with the new -- thank you very much. That gives us very explicit direction exactly how the lead discussants feel.

So now we're going to turn it over to the measure stewards and have them comment -- comment and/or reply to some of the consideration they heard from the lead discussants.

Then we'll go back to open it up to the entire committee. Then if we need to, we'll go

back to the lead discussants to respond to the entire committee points.

And then we'll have a vote. So, yes, sir?

MR. MORGAN: So this is Ronald Morgan again. I'll say one, with respect to risk adjustment that was brought up earlier, age was previously included in the chart version but was removed prior to -- submission of the measure for NQF endorsement. And it was subsequently endorsed, and that's because the correlation between age and body mass index cancelled out the defect, and BMI isn't regularly captured, so it couldn't be included.

And so therefore, the lack of risk adjustment in this electronically specified version of the measure is in fact to align with the chart version of the measure, which was NQF endorsed.

I also note that in terms of, you know, the PC-01 was brought up quite a bit. And early in the slides, you had listed the various

removals for the hospital IQR program.

Among them was the electronically specified version of PC-01, the early elective delivery measure. Which, to get at someone's earlier point, does capture a different population then PC-02.

That same measure is also moved from the hospital value-based purchasing program, but was retained in chart form in the hospital IQR program. And for those who rated close to the FY 2019 VS rule, you'll note that that reason was really because we recognize the importance of capturing maternal health in the program in some way or form.

And that was the only measure through which we can get at that at this point in time. However, that measure is of course -- the performance of the measure is topped out.

So that's a measure we're looking very closely at and monitoring in the future to see whether or not that topped out performance continues.

So in bringing this measure before the MAP, what we're really looking for, really trying to convey is our intent to look at more meaningful measures related to maternal health.

Although it may not directly get a maternal mortality, which we agree is an important issue. This is more related to surgical complications if you think about the ultimate outcome.

So to that end, that's really what we're looking at. But we do welcome, if you have any sort of feedback related to what risk adjustment variables we might need to incorporate for CMS consideration and for feedback to TJC since they support this measure.

And also where you see this measure and the IQR program relative to PC-01. Because this is a measure where you do see variation in performance, unlike the PC-01 measure, which is topped out.

CO-CHAIR UPSHAW TRAVIS: I'm going to ask you to tell -- remind me what PC-01 is.

MR. MORGAN: I believe it's early elective delivery prior to 37 weeks gestation, or 39 weeks. One of the two.

CO-CHAIR UPSHAW TRAVIS: Thank you. I just am probably not as familiar with the numbers and letters that get associated with things. So, thank you.

CHAIR WALTERS: I'll open it now to everybody else on the committee and their comments. And that was a hard thing to see. Lee?

MEMBER FLEISHER: With regard to risk adjustment, I'm just wondering in the way it's constructed, eclampsia or preeclampsia, which is one of the major risk factors for increased maternal mortality, is or is not included?

And if it's not, then we're -- and having a C-section addresses eclampsia. Then we have unintended consequences of this measure.

Do you know the answer?

MR. MORGAN: So in terms of measure exclusions, abnormal presentations are excluded.

But there is no risk adjustment for the measure.

MEMBER FLEISHER: So -- but you don't exclude patients with eclampsia or preeclampsia?

MR. MORGAN: I don't believe so, no.

MEMBER FLEISHER: So getting to Nancy's comment, you know, I can -- I understand from a consumer perspective, we want to do the right thing.

But this actually goes against potentially optimal treatment of a patient with -- who is at increased risk for maternal mortality.

So I think before I would be willing to endorse it, I'd have to see that adjustment.

CHAIR WALTERS: Lindsey?

MEMBER WISHAM: Yeah. I don't know at this point that I have an additional suggestion to the status.

However, I do have a question. I think it's interesting, this was the measure that we received additional information on.

And the testing results that we received

indicate May and June of 2018. Yet the Scientific Review Panel addressed this measure in 2017.

So I'm curious to know if this measure has been updated to address any of those concerns? Or if that was additional testing?

Because this current status still reads as in field testing.

MR. MORGAN: Yes. So this measure is now fully tested. And so that's why, you know, CMS is looking forward to TJC resubmitting the measure for NQF endorsement.

We feel pretty positively about with this additional data, its ability to obtain NQF endorsement.

MEMBER WISHAM: Thank you.

CHAIR WALTERS: Jack?

MEMBER JORDAN: I think one of the things to remember though is that CMS putting something out there can fix documentation. You know, we saw that when we first had, you know, beta blocker kind of issues.

And the documenting that there was a contraindication was terrible. And that was all the misses. And within a year or two, we got reliable at documenting the contraindications. And the same kind of thing here.

I don't think we should be held back on a measure because we have some, you know, missing documentation things. Because if you're missing BMI, and that's important in the severity adjustment here, you turn this on, that will get fixed incredibly quickly.

And that's one of the things that I think CMS can be a forcing function. And the other comment with this is I don't know how many states are like my own. But the private insurers are -- we're going to do this.

So in some sense it's not going to go away. I mean, does Medicaid, you know, care around this? But the private insurers do. It's going to be there. Hospitals are going to deal with it if CMS does or doesn't.

So, I think, you know, being on there to

help with it be as good as it can be, is probably better for us then to cause kind of the challenge of, you know, not endorsing it might.

CHAIR WALTERS: Marty?

MEMBER HATLIE: I looked at the comments for this measure, and there was a really striking comment from Lamaze International about how this fills a data gap.

And I think Lisa spoke to it. And I think Jack just spoke to it as well. If support for this would help -- and Lamaze's comment was it would fill a data gap for both consumers and for perinatal professionals, people who are working in this field. And it sounds like we do have a data gap and that this measure could perhaps help us close it.

I'm liking what I just heard Jack say in terms of using this as a way to drive better data reporting. And I'm also wondering, Lisa, you mentioned professional groups supporting it.

I don't know if there's anyone besides Lamaze. I was surprised that there were only

three comments on this measure.

Are there other groups, Lisa, that you know of that you could tell us about?

MEMBER McGIFFERT: Well, I think A -- I want to say ACOG has supported this measure for a long time.

I did hear back from several people who really weren't aware that this was coming up. There's a group in California that's been working on these issues.

And I've talked to some of those people. And they're very supportive. Let me see if I can find -- give me a second if there are other comments, and I'll find the list because I think I have it.

MEMBER HATLIE: Thank you.

CHAIR WALTERS: Are there other comments and feedback you'd like to give to the --- to CMS? Cristie, sorry.

CO-CHAIR UPSHAW TRAVIS: That's all right.

CHAIR WALTERS: It's hard to see

sideways.

CO-CHAIR UPSHAW TRAVIS: I know.

MEMBER McGIFFERT: Okay. I just found the list and, you know, it's -- like the Leapfrog Group has it as voluntary measure.

It's part of the Medicaid Child Core Set. It's the Joint Commission, of course the National Quality Forum, multiple state level perinatal quality collaborative use this.

Over 100 hospitals in California are participating. Healthy People 2020 included this as an indicator of a national goal.

And then mention of NQF measures. Which we already know.

CO-CHAIR UPSHAW TRAVIS: Well thank you. I probably don't have any way to really add to that long list.

You know --

MEMBER McGIFFERT: Oops, I found a few more.

CO-CHAIR UPSHAW TRAVIS: Oh. Go on.

MEMBER McGIFFERT: The Alliance for

Innovation of Maternal Health is a multi-professional group. ACOG and SMFM, which I'm not sure what that is. And the American College of Nurse Midwives.

The -- okay, I think that's it.

CO-CHAIR UPSHAW TRAVIS: Thank you. Just a couple of comments as -- I'm taking off my co-chair hat and putting on my other hat.

I certainly would agree with Nancy around maternal mortality being a significant issue. But this has been an issue, Caesarian birth has been an issue that we have been trying to address across the country in many ways.

And Lisa's list, I think, really shows it. Personally, if you're having surgery and you don't really -- shouldn't really be getting surgery that is a harm to a patient. To go through surgery when they really should not appropriately have been getting it.

I do think the cost is an important criteria as well because when we allocate money in that direction, we don't have it to allocate

in other pieces.

And I know just in looking at the Leapfrog data, which I'm glad you mentioned. And just to remind you, I serve on the Leapfrog board. There is -- there's significant variation in this across the country.

And trying to think about how we could make this part of maternal health, an important improvement I think is valid. All that said, I think we need to be really looking at maternal mortality and how we can advance it.

This is probably one piece of the solution. I think the elective early deliveries is another piece.

But I don't think that by putting this in it means that we're not going to continue to look at the bigger picture for maternal health.

CHAIR WALTERS: Okay. Andreea?

MEMBER BALAN-COHEN: Just adding to some of the comments to say that this is definitely an area where there's been some experimentation.

And there is definitely a lot of

evidence like coming from California and from Massachusetts that reporting on this issue can have significant and relatively rapid consequences in the sense that the declines like in C-sections have been rapid after some of this reporting has been implemented.

So that's something to keep in mind. So even though this might not be, and again, it's just like a smaller component of the larger issue regarding maternal mortality. But it could be one first important step. And we all probably have to start somewhere.

And the other point is that I like the fact that it has a little bit like the cost component like implicitly built up on it. And then there is also the relationship with some of the efforts potentially around like maternity bundles, and there are like some other considerations as well.

So I think it could be an important step like by filling the data gap from that point of view as well.

CHAIR WALTERS: Okay. Nancy?

MEMBER FOSTER: Thanks. I just wanted to provide a point of clarification, which is this measure is not NQF endorsed. This measure is not on the NQF list.

Its predecessor, the chart abstracted measure is. Or was. I don't know if it still is.

But part of what you're seeing here, part of what you're seeing in the Scientific Methods Panel comments is that people are struggling to find the data in an electronic capture. Right?

And it's -- I can tell you how vehemently our members have said we want to be able to measure most of this electronically and accurately.

And we've tried valiantly on a number of measures. We haven't gotten to accurate yet. So what you're seeing here is them saying this is -- you can get some information. It will not be accurate.

And they said the differences that they could see, as I understand it, were related to the patient population rather than to actual performance when they looked at the data.

So it's a struggle here. It's not -- please understand me, I'm not saying this a bad concept. I have prioritization issues. But it's not that the concept is bad. It is that the execution is not where you need it to be to provide useful information.

And to date, the history has been that wishing we could capture things electronically has not resulted in actual accuracy.

CHAIR WALTERS: I'm trying to get all of them to respond to. Marty?

MEMBER HATLIE: I want to mention one thing that hasn't been mentioned yet, and that is the importance of information like this.

So this is kind of conceptual, Nancy, but it's information like this to share decision-making.

I mean, this is an area where, I mean,

the core to the CMS policy on quality and the PFE component of it is this focus on shared decision-making. And this is the kind of information that I think really, really advances that dialog between potential mother and provider.

So conceptually I'm for it. And then, Nancy, where I always kind of feel like I part ways with you, even though I like you so very much and we go way back, is, you know, we have to drive data and to make it better. So I think I'm agreeing with Jack here.

Sometimes setting -- if the data is crappy and we've been waiting for a long time, how do we drive it to make it better?

And if -- and sometimes putting out a requirement that forces whoever is in charge to kind of make the data better, needs to be done.

And that's kind of where I fall here. It's not like I'm comfortable waiting for the data to get better. I want to drive something that makes the data get better.

And I'm not a measurement person. So I

know that was a pretty sloppy thing. But I am an advocate, and that's what I'm really looking for here is just ways to drive the -- I'm so tired of hearing about how we have systems full of bad data.

We've got to figure out a way to create the drivers and make that data better. Thank you.

CHAIR WALTERS: So I think I have Sean, and then Ann. And then I think it was Lindsey.

And then it was over here to Sarah and -- so anyway, Sean?

MEMBER MORRISON: Yeah. Thanks Ron. You know, I'm hearing this, and this happens almost every year, the tension between what we think needs to happen, and the way to make it happen.

And I completely agree that this is a very important issue. And yet lousy data, Marty, are lousy data.

And we shouldn't be putting people or trying to drive quality by saying well, we should

just go out and measure it. Because we don't know what we're measuring.

And we could easily be measuring rates from hospitals which bear no resemblance to reality. And that's not fair to our patients. It's not fair to our families. And it's not fair to our hospitals.

So yes, it is important, you're right, we should be driving data collection. But driving it through this particular process is -- is not the way to do it.

There are other ways of approaching this. And I'd like to see this come back when it's NQF endorsed and when I can see that what's being reported is truly, A, valid, which is we are reporting what's actually happening, and, B, reliable, that if we continue to report it, we're getting the same results every single time.

That is what we owe our patients and our families. We owe them that degree of responsibility in my opinion. And so I completely agree with the staff's recommendation

not to move this forward yet.

CHAIR WALTERS: Ann?

MEMBER SULLIVAN: Yes. I just need clarification. When we say this long list of groups that have endorsed it, have they endorsed this electronic measure or did they endorse the older measure?

MEMBER McGIFFERT: The other measure --

MEMBER SULLIVAN: The other measure.

MEMBER McGIFFERT: That this is based on.

MEMBER SULLIVAN: So I think that makes perfect sense that there's a kind of a consensus that this is an important thing to measure.

I think the question is kind of what we're here for, is how you measure it. And I tend to agree with the previous speaker that you have to be cautious about the data that you put out there from hospitals and from this.

And I'm not saying at all that it's not a good measure. And agreeing with all the people who endorsed the chart review.

I assume we want to go to electronic because it will make it easier. And we'll get more people to do it.

But, if we're not ready yet to really do it that way, then I would have serious concerns about going forward with this measure.

CHAIR WALTERS: Lindsey?

Turn on your mic.

MEMBER WISHAM: -- that the measure that the Scientific Panel probably reviewed in 2017 was not a measure that was specified using the clinical quality language.

The clinical quality language is the new expression model used for eCQMs. Which did allow for a -- for much more expressivity in the measures, including in the description of gestational age.

So knowing that that's an element in this measure, I know the Joint Commission is here to speak to the details of it, but the measure has changed.

The measure specifications that we were

provided is specified using the clinical quality language. Which would have been a different version than what the Scientific Panel had reviewed.

And so I do think it is, as stated before, that the measure would be coming back through NQF for additional review for endorsement.

But I do think it's worth note that again, the reliability of how that data is captured electronically, very much has changed as the expression model has been updated.

CHAIR WALTERS: Dan?

MEMBER POLLOCK: Yeah, another comment about the use of quality measures to drive changes in documentation. The flip side is, is that quality measures can have unintended consequences with respect to documentation.

Which actually can deteriorate the record keeping rather than improve it. And I think we all have to be very cognizant of that and not let data quality improvement be a

principal driver of quality measurement.

CHAIR WALTERS: Sally?

MEMBER TURBYVILLE: It's really more of a question, and it might not be answerable given that the Joint Commission is not here.

But given that it is a Joint Commission measure, which is a well-known measure steward who has their own products, do we know if they plan to continue to gain more experience with this measure and bring it back to NQF for endorsement?

And so that there's -- this is not the one and done kind of killing of the measure's prospect?

Did they --

CHAIR WALTERS: Sure.

MEMBER TURBYVILLE: Do we have any sense of --

MS. MUNTHALI: We haven't -- this is NQF, Elisa. We haven't heard anything from the Joint Commission directly. But perhaps from CMS?

MR. MORGAN: So this is Robert again.

From what I've heard, they are considering that. But they haven't made a decision yet on that point.

I'll also add that we agree that the industry is in a state of transition. Right, that's something we've heard. That's something we've seen in the data.

And that's really partly why we have the fairly lenient program requirements that we have. Where you can voluntarily report the data and that data will not be publicly reported.

And really the primary driving reason for that is, you know, one we're still -- we still have some improvement to go in terms of data quality for all of our extant measures.

But, two, we want to give hospitals and implementers an opportunity to become accustomed with submitting EHR-based data, and not be punished for that.

CHAIR WALTERS: Aisha and then Marsha on the phone. Aisha?

MEMBER PITTMAN: So my point is

following along that. In that we know that just adding a measure doesn't actually improve the data.

So there have been lots of eCQMs that have taken them out of the programs because they don't continue to work. So just adding it isn't going to help drive the data.

We know that's not the issues. There's far more far reaching issues with trying to get to the electronic capture. So just putting it in a program doesn't necessarily help.

CHAIR WALTERS: Okay. Marsha, you're on the phone.

MEMBER MANNING: Thank you. I just perhaps a question related to clarification after listening to this, you know, very robust discussion.

When I look at the decision definitions, I'm actually just a little bit confused as to how the preliminary analysis came to the do not support for rulemaking decision.

I believe this is a very important

concept for a measure. And I've heard that from several other committee members.

When I look at the criteria that's used for -- for the decision categories, I guess my point of confusion is Item Number Three, which is does the measure address a quality challenge?

The answer to this question from the preliminary analysis is no. But what I'm hearing is, is that it's -- that our -- that data issues are driving this analysis, and not the importance of the measure to address a quality challenge, perhaps conceptually.

So I'm just a little bit confused about that. And if anybody can provide some clarity, I would really appreciate it.

Because it does -- I'm hearing and my perspective on this is that addressing -- providing data related to Caesarian rates does address a quality challenge.

And there may be another decision category that's more appropriate if we're really looking at significant data issues. So if

there's any clarity that can be shared, I would appreciate that.

CHAIR WALTERS: I'll try to get that. Anna and then Lee, and then Shannon. And then Reena.

MEMBER DOPP: I'm thinking about how much this discussion reminds me of last year when we had the ORARE measure, the opioid-induced adverse respiratory event. And everyone in the room felt like it was compelling and met an important need.

And then -- and we went against our purview, I think, and said to refine and resubmit.

But that's -- that's how I view this. It's just not ready. And it seems to go against the real intention from CMS to -- with the meaningful measures and reducing burden to people to show they're not going to just put a measure out there that's not ready to be met.

CHAIR WALTERS: Okay. Lee?

MEMBER FLEISHER: Yeah. In listening

and trying to read the materials, and this is a common both for CMS and NQF, it's interesting that this is an endorsed measure in the old world.

Do we have data, and I don't have it in my packet and maybe I'm not finding it, on how that old measure had done?

Because -- both from unintended consequences and achieving its goal. Because we're actually arguing around conversion to an e-measure and the scientific acceptability or the methodology without actually asking the question of did the original measure achieve its goal?

Even if not nationally, we're looking at Utah where we're seeing that C-section rates came down. A few years later, maternal mortality is going up.

So my question is, give us more data to judge both issues, scientific acceptability and relevancy if you have a previous measure.

CHAIR WALTERS: Shannon?

MEMBER PHILLIPS: I'm not far off of

that. I guess I would say part of what would be compelling is to look at the, I think somebody said 40, but many states that are using this measure, ours included.

And let's see what that's shown. Right? So why wouldn't, you know, so really echoing what Lee said.

But that data would be impactful to understand if the burden of the measure is worth it. Or is it really an issue of risk adjustment? Right?

So to the point of eclampsia and other things, maybe it is completely a great measure. But not -- it would explain why infant -- or maternal mortality is going up.

And it's an interesting measure to potentially place next to an outcome measure of interest. So if this process measure may be risk adjusted, we do see helps.

Put it next to infant mortality or maternal mortality so that we can see the process and the outcome together. Because that speaks to

clinicians, and I would think would speak to patients powerfully as well.

CHAIR WALTERS: Reena?

MEMBER DUSEJA: So first I just want to thank everyone for their comments. I mean, as always it is so delightful to be here and to hear the variety of comments, particularly with this measure.

I just wanted to just have some framing comments from CMS's perspective as we think about this as it relates to meaningful measures. And I heard a comment, well this doesn't really translate to meaningful measures.

And I want to first point out is, we do believe -- we wouldn't bring this to the MAP if we didn't feel like it was meeting a gap. We do feel like this is addressing an area of variation in care.

We have data to at least point that there has been variation in rates in terms of C-sections from 20 to 50 percent. And so we do think that there is room to improve.

We also think there is a link if we measure this measure in terms of improving morbidity for mothers as well as for children. So I just wanted to specifically say that in terms of that link.

Now as far as this measure being put into a program, just to remind the work group, this is voluntary. So hospitals can report on this measure.

I think one of the advantages, especially with some of these concerns about the data science, and are we there in being able to report this?

Is if you allow it to be voluntary, perhaps we can actually get those hospitals that are at the forefront in being able to report on this. And other hospitals can learn from them. Right?

So, and how they're able to successfully capture this data. So we have to start somewhere. We -- I think that from our perspective, at least from our group, we believe

that you know, measures can drive some of this data collection.

So those are some of our thoughts from bringing this for the discussion today. But if there's anything else you would like to add, okay. That's it.

CHAIR WALTERS: Lisa and then Aisha. And then I think we'll be about ready.

MEMBER McGIFFERT: Just real quickly, kind of to follow up on those comments, is I don't know why the chart review has not been put through this process since it's endorsed by so many groups and has been around for so long, and lots of states are using it.

But set that aside, from the consumer perspective, we really need public reporting. We do not have public reporting on this measure.

And it, again, I mean, this was like the first thing I did on quality back in 1989 or '93, or somewhere around there. And we still weren't -- we still are not getting public reporting on this across the board.

And so I think that is a compelling argument to move this forward, that the public deserves to see these results.

And again, I don't know why the chart review has never been put forward to the IQR. Maybe that's a good question.

MS. MARINELARENA: This is Melissa. So just some clarification. The chart-abstracted version has been through MAP. MAP did recommend it, I believe, with some conditions back in 2014. Now I don't know if it was -- ever went through rule or not. But it did come through MAP.

CHAIR WALTERS: Aisha. And then I think we're going to move into voting.

MEMBER PITTMAN: I guess just to Reena's point about it being voluntary. So, yeah, while eCQMs are voluntary, CMS could change that policy at any time and say, all eCQMs are mandatory, which was the case.

And they've switched going back and forth with how many measures are voluntary. So I think that's just a point for the group to be

aware of.

If it goes into the program, it can be mandatory at any time, and that decision doesn't come back to the MAP.

CHAIR WALTERS: Okay. I'm going to have staff review the four categories again and make sure everybody's clear on the criteria. And to remind everybody that first we'll vote on the staff recommendation.

MS. MARINELARENA: Okay. So as a reminder, support for rulemaking, you absolutely support it with no conditions.

Conditional support for rulemaking, you would include any conditions that you want to add to this measure. Some common conditions are NQF endorsement.

Do not support for rulemaking with potential mitigation, it's kind of the opposite of that, you don't support it because there's some things that are wrong with it, usually the specifications so we would include that as well.

And then do not support for rulemaking,

which is the staff recommendation, was you just don't support it at all for inclusion in the program.

MEMBER McGIFFERT: So are we voting on the staff recommendation?

CHAIR WALTERS: That's the first thing we vote on. That's correct.

MS. MARINELARENA: The first thing. So it will be --

MEMBER McGIFFERT: And that's what we mean by the work group recommendation?

MS. O'ROURKE: So the first vote would be if you -- sorry. If you want the staff recommendation to become the work group recommendation.

If -- yes. And just a caveat. If you want to keep discussing, vote no here, even if you think you may eventually agree with the staff recommendation.

If you think there's a need for further discussion, vote no. Because that would be the end of voting if that reaches 60 percent.

CHAIR WALTERS: You want to tee up the voting? So the staff recommendation, again, was do not support for rulemaking.

MS. QUINNONEZ: Okay. We are now voting for MUC2018-52. And the question reads, do you vote to support the preliminary analysis as the work group recommendation.

So that's do you accept what the staff's recommendation is? Option one is yes. Option two is no.

Can you refresh your browser? It should be unlocked now. Sorry.

(Laughter.)

MS. QUINNONEZ: You're not in trouble. I promise.

(Laughter.)

CHAIR WALTERS: No, but showing the results while we're voting. But, none of the -- it's a different MAP.

So we talked about the days of when we could hit close votes. And -- we're waiting for one vote to come in, right?

MS. O'ROURKE: We -- yes, most of the numbers work out to a percentage point. So we rounded, I believe, always up to count for the next whole person.

MS. QUINNONEZ: I'll read it. You want me to read it out loud?

CHAIR WALTERS: Yes.

MS. QUINNONEZ: Okay. So the results of the voting were 14 individuals who voted yes, and that is 11 individuals who voted no.

Which that actually puts us, we do not move forward. So this goes down at this point. So we'll have to vote on the sections after this individually.

CHAIR WALTERS: Now this is where we kind of jot around, and Cristie and I have been talking.

We think we heard, if not the staff recommendation, the next category that got a lot of discussion was something in the realm of conditional support.

Is that correct? And that condition

almost certainly was NQF endorsement. Is that assessment correct or not?

Is there anybody in the room who would like to say that they do not believe conditional support was the next thing to vote for?

We certainly could vote for support if you wanted to although I think we're going to run into some problems there with endorsement.

So speak up. Yes, Lee?

MEMBER FLEISHER: I would propose do not support for rulemaking with potential for mitigation is the next thing if there was -- if we were very close to the -- I think there is uniform interest in this measure and getting it right.

And what I heard was that it may be a little further from getting it right. Or more data to get it right.

So I would propose we vote on that next.

CO-CHAIR UPSHAW TRAVIS: Could staff once again kind of give us your suggestion on how to differentiate between conditional support and

do not support with potential for mitigation?

MS. MARINELARENA: Sure. So the do not support with potential for mitigation would mean that the measure -- there needs to be changes to the specifications.

You know, and the Methods Panel, based on what they looked at, said there were issues with the measure. Right? There were issues with the data.

If that's the way you want to go, you could provide some recommendations as to what issues you have. Is it risk adjustments?

Are there other issues with the measure specifications? And then of course, you can include the NQF endorsement.

The difference with conditional support for rulemaking could be that the measure as specified is fine, it just has to go through NQF endorsement.

CO-CHAIR UPSHAW TRAVIS: But I hate to muddy up the waters, but you know, personally I don't know that I have enough information to say

whether the specifications are right or wrong.

So if I have to make a decision, which I do, between those two categories, if you're unclear about the need for it to be re-specified, what do you do? And I'm not telling -- I'm not asking you to tell me how to vote. I'll make that clear.

But I'm just trying to weigh it. Because I don't really know, you know, since it -- and I don't know whether, you know, I'm thinking of Lindsey's comments.

It may already have been done. But it hasn't been reviewed by the Methods Panel under its current, you know, specifications even if they have changed.

So, I'm just -- and does it really -- I mean, I hate to ask it this way, but, is -- tell us the implications of conditional.

Because in the past conditional meant that if the -- if the condition is met, it can automatically be put into the program. I mean, our recommendation is that it would

automatically.

Does that still work?

MS. O'ROURKE: Sure. Do you want me to try to take some of that?

CO-CHAIR UPSHAW TRAVIS: Yes. Please.

MS. O'ROURKE: So I think first to start with your last point. I would emphasize that MAP is an advisory body to CMS.

So nothing would automatically go into the program. That's --

CO-CHAIR UPSHAW TRAVIS: Right. Okay.

MS. O'ROURKE: Again, I think what we were trying to do with these changes, were say that the conditional support, you're ready for the measure to go forward with some changes.

The do not support is, as you see it currently specified, you're not comfortable with it being implemented.

And again, we know there's a lot of gray in between there. So it's probably, you know, to everyone to vote how they feel it's best.

We did use it yesterday in the PAC to

capture some concerns about coding, risk adjustment exclusion, those types of issues. But in the past we have also used conditional support to capture those.

And we do pass this feedback on to CMS, to the measure developers, to the Standing Committees that will review the measure for endorsement. We don't necessarily need to come up with the full list of change specifications today.

But I think just getting a broad flavor of the concerns. And just to make sure that people know we passed that all along and it goes in the report.

And we have channels to make sure that it's acted upon.

CHAIR WALTERS: So we have two choices for voting realistically. Conditional support for rulemaking, and do not support for rulemaking with potential for mitigation.

The steward is on the phone, but we're deep in the process now.

One way to handle this is to march down the list. You can decide which of the two categories you want.

If you're not in favor of conditional support for rulemaking, then I would certainly suggest a no for that. And then we'll vote for do not support for rulemaking with potential for mitigation after that.

If you are in support of conditional support for rulemaking, vote yes. And if 60 percent of the people support that, then we will not vote on do not support for rulemaking with potential for mitigation.

So just as we said, in your minds you have to decide which of those -- since we've eliminated two of the categories, there's only two.

Choose which one you like the most. And what we'll do first is vote for the conditional support for rulemaking, just because it's higher up in the list. No special reason on that.

MS. QUINNONEZ: Okay. We are going to

vote for MUC2018-52. The question reads, do you vote conditional support? And this is for MUC2018-52. Do you vote conditional support?

Option A is yes. Option B is no. Okay.

CHAIR WALTERS: Results?

MS. QUINNONEZ: So it looks like -- give me one second. So nine individuals voted yes, and 16 individuals voted no.

So for percentages, we are at 36 percent voted yes, and 64 percent voted no.

CHAIR WALTERS: So now we move on to the next on the list, which is do not support for rulemaking with potential for mitigation.

And please don't make me sorry we did this.

MS. QUINNONEZ: Okay. We're now voting for MUC2018-52. The question reads, do you vote -- is your vote do not support for rulemaking with potential for mitigation?

Option A is yes. Option B is no. I'll give you a couple more moments to enter your votes. Okay.

Ten seconds and I'm going to lock the vote so no one changes. Okay. It looks like all the votes are in. Voting is closed.

So for -- it looks like 88 percent voted yes, and 12 percent voted no, and those specific counts are we have 22 individuals who voted yes and three individuals who voted no.

CHAIR WALTERS: So for those of you that have been on the committee for a while, remember when we used to vote on all four measures at once? And we've been through all various permutations of this I think you can possibly have.

Let us know how you thought, not only for this, but for the rest of the day, how this process worked. But the sequential voting on category by category according to the feel of the group is we thought would simplify and shorten the process.

Break?

CO-CHAIR UPSHAW TRAVIS: Yeah. Oh --

MS. O'ROURKE: Before I just want to

make sure that we've captured the mitigating factors correctly.

So from what I was hearing, it sounds like first and foremost making sure the EHR measure can be operationalized and it's feasible. And then asking the measure to be resubmitted for NQF endorsement.

And passing along to the Standing Committee to pay close attention to the potential need for risk adjustment or additional exclusions to address some of the concerns that MAP raised.

MEMBER McGIFFERT: I'd add to that the issue of eclampsia and preeclampsia that was brought up.

MS. O'ROURKE: Yes. We can highlight with a particular attention to how to handle eclampsia and preeclampsia.

MEMBER McGIFFERT: And what about getting the Science Panel to review the current data?

CHAIR WALTERS: Sure.

MEMBER PHILLIPS: And I was going to

say, can we add looking at the data that exists today from all the states that are doing this?

CHAIR WALTERS: Sure.

MEMBER NOLAN: And I would say not only the states, but Medicaid as well. I mean, that's more than half the burden in the country. And they do have some kind of measure.

CHAIR WALTERS: Nancy?

MEMBER FOSTER: So just to expand on the preeclampsia. I mean, the data Lee was quoting were not about preeclampsia although his point was about preeclampsia.

But the unintended consequences, I'd never before heard that data. The unintended consequences of the increasing maternal mortality are concerning. I would like to make sure they look at that in the available data as well.

CHAIR WALTERS: Anna then --

MEMBER DOPP: One of the other comments, or it was from Shay, didn't believe that this fell under the healthcare associated infections. I don't know if that is a point of consideration

to make either.

MS. O'ROURKE: We can certainly highlight it that it might be closer related to other meaningful measure areas than infections.

CHAIR WALTERS: Okay. Let's take a lunch break. And thank you all for helping us pilot --

MS. MARINELARENA: Let me just confirm really quickly.

CHAIR WALTERS: -- the voting process.

MS. MARINELARENA: So you want -- you want the measure developer to provide data from the chart abstracted version of the measure? To compare?

MEMBER FOSTER: I'm sorry, I'm not sure that it's the measure developer. We were asking for organizations currently collecting the chart abstracted measure to be asked to provide that data.

Right? Because Joint Commission may or may not have that.

MEMBER PHILLIPS: So -- in Utah we're

required to report this to the state. There are other states that do that. Medicaid, great point.

We should look at that data to inform. And have a balancing measure of maternal mortality, infant mortality to make sure that we're assessing that there's not an unintended consequence to the measure.

MS. MARINELARENA: Okay. I know the chart-abstracted version is going to be up for review within a year or so. I'm looking at Kate.

So we can make that recommendation for that measure. And then we can make the recommendation from the MAP for both different measures as they go through the committee, that you have talked about balancing measures as well, including maternal mortality.

Does that satisfy?

MEMBER FLEISHER: Well, I think there's a lot of support for a measure that works correctly to reduce C-section rates. So to wait for a year for the review, I mean, it would be

great if CMS comes back within the next year with this data.

So that we can get a robust measure for public reporting that reduces C-section rates in the right population that doesn't increase maternal mortality. That's what I would like.

And I'm hearing at least people surrounding me say that would be an ideal thing. And if we can do it in an electronic measure that's fantastic.

CHAIR WALTERS: Okay. Okay, go --

MEMBER BALAN-COHEN: And just one quick comment about like the maternal mortality. So just making sure that the maternal mortality though is for the right population.

I mean, there are so many other drivers of maternal mortality. I mean, like maternal mortality has been increasing like independently.

So just like just putting the data side by side, like an increase in C-section and an increase in maternal mortality, I mean, just making sure that we're looking at the right data.

All right?

So if you're looking at like decreasing C-sections and then like maternal mortality for that specific population, where we've examined the C-section rates.

CHAIR WALTERS: Okay. We've got three more measures and lunch. I mean, and the presentation after lunch. So --

MS. O'ROURKE: Lunch is ready, yeah. Do you want to let people take a lunch? Would people maybe be okay with a working lunch?

CHAIR WALTERS: Okay.

MS. O'ROURKE: And with the -- you know, maybe we could take 15 minutes. Get our lunch. Take a little --

CHAIR WALTERS: Start a working lunch kind of at about 12:30?

MS. O'ROURKE: Stretch your legs and then take a little bit of a working lunch.

CHAIR WALTERS: Okay. Thank you.

(Whereupon, the above-entitled matter went off the record at 12:14 p.m. and resumed at

12:30 p.m.)

CHAIR WALTERS: So you now have experience with the new process and the new categories. The feedback was absolutely fabulous. And again, the job of the committee is to give appropriate feedback back to CMS. That's the job. And you know I'm not the judge of whether that occurs; the people sitting in this corner over here are. And we just try to make sure the process works.

So the next -- I lost all my staff.

Now that you've been through it once, again, there are two more measures in the IQR and there's one in the cancer program. So we'll go ahead and move along with the 2018-107 Hospital Harm for Pressure Injury.

MS. MARINELARENA: Just one moment, while we're queuing everything up.

CHAIR WALTERS: Yes, so I think what this first one did was to try to get you thinking in terms of what category you feel the strongest about relatively early on and then aligning your

vote, whether it's with a first vote or sequential votes to get to that category and yet, make all the points you want to in support of your recommendation.

Let's see who our lead discussants are okay. Want to go over pressure injury?

MS. MARINELARENA: Okay, the next measure up for discussion is the pressure injury electronic measure.

The staff's preliminary analysis result was conditional support for rulemaking. And the reason for that is this measure is not fully -- our recommendations are that this measure is not fully tested and it should be submitted to NQF for review and endorsement once testing is complete.

The difference between this one and the C-section measure in the recommendations is because NQF has not seen the testing results. We don't know if there's any issues with it at all. Again, just looking at how it fits in the program the recommendation was conditional report and,

again, that it gets submitted to NQF. So that's the difference between the two recommendations.

So I will turn it over to Ron.

CHAIR WALTERS: So we'll go through the lead discussants and then, as I did on the last measure, then we'll turn it over to the measure stewards to respond to -- public comment -- I'm sorry, we'll go to public comment, then we'll turn it over to the measure developers to respond to any concerns the lead discussants had, then we'll open it up to the committee to express their feedback, and then we'll go back to the stewards and/or CMS in this circumstance to kind of wrap everything up as best we can.

So the first thing -- we did public comment for the IQR at the beginning of the IQR session for all measures.

Kimberly.

MEMBER GLASSMAN: Okay, I'm very excited that after three years I finally get a measure I know something about.

(Laughter.)

MEMBER GLASSMAN: So that's exciting. So this measure for hospital-acquired pressure injury is being proposed for an eMeasure. The reporting of a hospital-acquired pressure injury currently exists, I believe, in the HAC program. So these are already being reported stage 3, stage 4, primarily.

This now adds stage 2, along with deep tissue pressure injury and unstageable. So, it has the full range of the five descriptors of how we would note someone with a pressure injury.

It continues the theme that we would need to note this for all patients who are admitted to the hospital and we have a 24-hour period to identify a pressure injury for a patient that is coming from another setting, so either being admitted from home or a nursing home. We have to do careful assessment and note if the patient is coming in with something and if we don't do that, then we own it.

It's an outcome measure. It's an important measure for patients and the staff

recommendation was, as Melissa said, conditional support.

I am inclined to support the staff's recommendation with a comment and that is, deep tissue pressure injury sometimes can take longer than 24 hours to develop. It can appear as a bruise. The bruise could be small visually and have potentially injury to the tissue down below. So many of the comments on this measure noted that the ability to have a wider window of time with which to see if this deep tissue injury is, in fact, real and is going to progress or if it's going to go away might be something to be considered.

So because this has not gone through testing, as was noted, I guess I have a question, if I'm allowed to ask a question, which is can the testing also include the ability to look more closely at that one particular stage. Two, three, four, and unstageable are quite clear in the definitions. This is the one that there is just a little bit of question around.

CHAIR WALTERS: So as I understand it, the question your asking is is that a substantive change.

MEMBER GLASSMAN: Yes, I'm asking if under conditional approval, where the condition is this has to go through more testing, can we also add something to be looked at in testing.

CHAIR WALTERS: Got it. Okay, well-understood.

Marty.

MEMBER HATLIE: I support the staff recommendation for many of the comments that were just made. The only thing I guess I would add is that there were several comments made. I think there were nine in total and there was just broad support from a wide variety of organizations for this measure.

CHAIR WALTERS: Jack.

MEMBER JORDAN: I also have a fair amount of experience with this in building an internal ECQM on it. So I have three things, actually, to add to the list for them to be

looking at as well.

One of the things we found in validating our measure was that you could not rely on the nurse checking the box present on admission and we actually used did they start documenting on the injury within 24 hours was a much more reliable thing when we were validating it. And at least in the definition you gave us, we couldn't really see that level of discernment in detail.

The other one is I have mixed feelings on the stage 2 in that should it actually be separated as a separate measure. I think there's wide variation across the country about incontinence-associated dermatitis being documented versus stage 2 and I think you get into some issues with inter rater reliability kind of challenges there that go away if you either carve out stage 2 as its own thing or exclude it from the measure altogether. And I think looking at that topic is important.

And then the other one that happened

with the billing measure that they have now in the HAC penalty is guidance was given to billers, I don't know about 18 months ago, that if a patient came in with an unstageable, there was debridement, and then it's a three or a four, their guidance in the billing was to put that as a three or a four not present on admission when, in reality, it was present on admission in different from and that actually caused a huge jump in the HAC kind of thing.

I think it's important here that, and I know I'm thinking in my own electronic record, these are a flowsheet row that that injury should probably be defined as the final stage in its course for the thing versus having that whole issue of it changed.

And I know at one time they had a measure, it's been dropped now, that was looking at pressure ulcers that did progress and that is extremely difficult to do with an ECQM and I see it's dropped. And the reason is if you put the staging as a flowsheet row, then the nurses have

variability in what they document and that drives you nuts. And if you put it as a header row, then it's very difficult to find that change in staging because you don't have kind of a time stamp of it changing. So I know there's some real challenges with this.

But that said, I'm wholeheartedly in agreement we need an ECQM on this. I think it's an important thing to do. And so I want to endorse that we move forward with it but make sure that we're really trying to fix some of these things and you may have some tweaks in the definition that really can do that. But with that said, I wholly support going about it.

CHAIR WALTERS: The developers will get to respond in just a little bit.

Sean.

MEMBER MORRISON: Just I support the staff and nothing to add that hasn't already been said, Ron.

CHAIR WALTERS: Thank you.

And Lindsey.

MEMBER WISHAM: So I also agree with staff's recommendation and obviously have wise lead discussants -- or fellow lead discussants. So I won't cover what they've covered. I do agree that this is best suited for ECQM due to the large population.

CHAIR WALTERS: Okay, I'm going to turn this over to either CMS or the Yale people in the room to respond to some of the measure spec changes that might be considered.

DR. BERNHEIM: Hi, this is Susannah Bernheim from the Yale CORE. I see some future TEP members in our room.

(Laughter.)

DR. BERNHEIM: So thank you for the good comments. I'm going to be very brief.

I just want to actually update this committee to let you know that we are now just completing two rounds of testing of these measures. So I'm going to consult my notes so I get it right.

We do enhanced alpha testing, which is

to say that we do an early stage testing, where we have a clinical adjudication to ensure that the harms that are identified are confirmed by clinicians looking at the chart and then we do second round of that. For this pressure injury measure, we've now done that in three health systems with different EHRs at a total of 25 hospitals and we are finding, as we'd hoped, that they are quite feasible, that people are finding them, except for the issue exactly as you identified, of being sure that we could track from one location, the same location, the worsening issue, which as you know that we dropped because the testing confirmed exactly what we noted, but that, otherwise, we're finding high degree of positive predictive value for what we're finding in the EHR compared to a chart.

And we did look at some high-risk patients to ensure that we weren't missing and also found that that was extremely rare.

So the measure testing is supporting what you're saying and there's some great things

for us to go back and look in a little more detail at here.

CHAIR WALTERS: Okay, other committee comments? Time to raise your cards.

MEMBER PHILLIPS: So I had disclosed at the beginning that we are one of the participating organizations in this and when I asked our team about that, just a couple of comments had come up.

One, patients can have multiple skin issues, each with varying stages, which I think makes a flowsheet pull or an eMeasure quite challenging.

And the measure, I guess some of the technical specification is difficult because the documentation requirements or the specs say every time something is charted by nursing about the ulcer that matters and it is, they thought very cumbersome.

So an incredibly important topic in hospital care and their sense was technically not ready for prime time yet for entirely the reason

we're all doing this but thought it was very hard to do.

CHAIR WALTERS: What is your recommendation for a category?

MEMBER PHILLIPS: Oh, sorry. I would support the staff recommendation.

CHAIR WALTERS: And did you have your card up?

MEMBER GUINAN: Thanks. So a couple of comments just on the risk adjustment aspect of the measure. I fully support this being an important issue to track. I think speaking from the essential hospitals or safety-net providers in terms of the complexity of the patients that they see, both clinically and socially, just things to consider in terms of a lot of our members are academic medical centers and have a lot of folks in the ICU. There is a lot of complex clinical issues that they're dealing with that may want to look at whether this measure, when you're looking between teaching status/non-teaching status has any unintended consequences,

just based on the number of patients that are in that condition.

The social aspect may be not as direct but frailty comes into play when talking about pressure injury. Also nutrition comes into play, so very aware of food and security being an issue for a lot of our members in terms of how the patient comes to the hospital.

And so I just wanted to put that out there in terms of the risk adjustment conversation.

So my vote would be to not support with potential for mitigating.

CHAIR WALTERS: Nancy.

MEMBER FOSTER: I'd actually like to ask Jack a question, since you've built your own electronic version of this. It's not the exact same measure, I assume, but very close.

One of the benefits that has been supposed about the capture of this information in that rapid format is that it will foster greater opportunities for quality improvement and I would

like to know if that's been your experience sort of really addressing issues that appear in the moment.

MEMBER JORDAN: Yes, it has been. You know we did have kind of an unreliable process, as you know, filling out an incident report you know when you had a thing. And yes, we find them all now. There's never a miss from that.

A number of us in our hospital, we get an email every day with any of these 22 -- they're running you know. So you know yesterday someone documented in a flowsheet a new pressure ulcer and so our wound ostomy nurses can use that every day so that they're on it very quickly. They actually have a report they can run inside the record as well for that but they tend to much prefer having the ding, go look at these kind of process.

So it has been very helpful in tying up the -- in making things very fast. And then also, you never have any issues of oh, well that was two weeks ago. This got billed and I don't

remember the patient. You know they are there right then and there so you know they're still present. So it has been I think very helpful to really close the loop on those things.

CHAIR WALTERS: Is there anybody else that would like to comment? Maybe we should have all the measures after lunch.

Gayle.

MEMBER LEE: I just wanted to ask a question for clarification between the categories. So we have the same concerns about the time frame, the 24-hour window and the fact that a pressure ulcer might not immediately show up.

So if we were to vote conditional support, would that be something that would be addressed or does it have to be the do not support with the -- you know the other category, I guess.

CHAIR WALTERS: Yes and that's why I brought up the substantive change things. It depends on what data they submit and how it's

analyzed.

So if the measure is rewritten and then analytics is supported to substantiate those changes, it could fall in either category but it might be possible to get by as conditional support.

I can't tell you because those are decisions made actually at a sub-regulatory level.

MS. O'ROURKE: And I obviously can't speak for CMS but when we were designing this category, we tried to align with the CDP around the language for substantive change. But again, the categories aren't meant to be binding and the group has the freedom to vote the way you think it is if you think it's a significant change or if it's something that you'd be okay having it addressed and the measure move forward.

Again, it's not always clear and it's to your discretion of what you like the better.

DR. BERNHEIM: -- the way the measure is set up -- this is just a brief clarification so

that I'm sure people are understanding the way the measure is designed.

Because we're not using claims, we're using the electronic record, we are not counting something as a new pressure injury unless the first time that it's documented is after 24 hours. So I wasn't sure if there -- I mean there was a lot of discussion with our TEP and in public comment about what the window should be but the general sense was that any pressure injury that is present on admission should be documented within the first 24 hours and so that then it will only kind of be things that show up for the first time after that, you should be largely capturing things that are new.

MEMBER FOSTER: So just for clarification, and since you're here, Susannah, did you think about the issues of the academic medical centers that may have more patients who either can't be moved or there is an extreme danger in moving them, those kind of patients who would be perhaps more susceptible to pressure

ulcers but reasonably so?

DR. BERNHEIM: Yes, this was a discussion with our technical expert panel as well, and a thoughtful discussion. We spent some time thinking about it. The general sense was that most pressure injuries can and should be avoided and that the measure was simpler to implement, which is part of what we're trying to balance here bringing forth these measures and would be supporting the right kind of improvements to not complicate it with trying to risk adjust, given the sense from our Technical Expert Panel that these greater stage pressure injuries should be avoided in inpatient hospitals.

CHAIR WALTERS: Jack.

MEMBER JORDAN: You did bring up a recommended exclusion that made me think of this, Nancy, and that would be ECMO patients are an order of magnitude at more risk. And if you do want to compare hospitals that have some penalty program on it, it would be an unfair disadvantage

to hospitals if you didn't have an exclusion for ECMO.

If you're just looking for improvement, it's one thing. If you're going to actually do comparison, the ECMO is a whole other animal.

CO-CHAIR UPSHAW TRAUS: I hate to ask this but what is ECMO?

MEMBER JORDAN: Extracorporeal membrane oxygenation.

CO-CHAIR UPSHAW TRAUS: I knew I would regret that.

(Laughter.)

CHAIR WALTERS: Nancy.

MEMBER JORDAN: Yes, it's expanding more and more the uses for it but it's essentially getting oxygen to put back into your blood, other than your lungs. Is that an okay --

CHAIR WALTERS: TEP is never big enough, is it?

Maryellen.

MEMBER GUINAN: I have question more on process in terms of the mitigating category.

Last year I know we spoke about sending a measure back through the Disparities Committee for review as part of kind of the risk adjustment conversation. Would that then come under the purview of do not support with potential mitigating factors?

MS. O'ROURKE: I think that's one you could make that a condition or you could make it a mitigating factor, depending on your comfort with what's in front of you. Yes, it's another one that you could use that type of a caveat either way.

MEMBER GUINAN: Okay. I'm sorry, follow-up.

So, in that case, then if I made it a condition, then it would be a support with the condition of going back to the Disparities Committee but then that could be taken up by CMS as-is, regardless of the decision. Whereas, if it's a do not support with the mitigating component of going through the Disparities Committee, then it's not to CMS.

MS. O'ROURKE: That's a good way to put it, yes.

You know, at least what we're trying to say from the MAP point of view is that you would not want CMS to use the measure as-is without doing that. Again, just to emphasize that the input is advisory and not binding in any way but that is the -- you know it's to try to clarify what the recommendations are saying from the MAP perspective.

CHAIR WALTERS: Nancy.

MEMBER FOSTER: Thank you, Maryellen, because you reminded me of my question, which was if we were to recommend that it be conditional support -- if we recommended a condition that was CMS look at whether there is an unfair and an inappropriate kind of publication to the public about performance for hospitals that have a lot of ECMO or other patients of that nature, do we -- is that a mitigate? Is that -- where are we on that?

MS. O'ROURKE: Again, I think you could

probably do it either way. Again, this came up in PAC a little bit, so just to give you the history of yesterday, so it's not a great sample but they -- when they looked at some of the transfer of health information to the patient, the group had some input for CMS which was a little bit maybe broader than a strict condition of how that list would look, and what information would be useful to patients, how you would communicate it. And it was some guidance on being very clear about how information gets reported out that I think would be in the domain of what MAP could talk about under the conditional support.

CHAIR WALTERS: Shannon.

MEMBER PHILLIPS: Really questions for nursing colleagues. I think of two things and I think it was touched on a little bit but the expertise for trying to stage pressure ulcers is significant and I wonder about bias in that against hospitals who are not part of large health systems or don't physically have on-the-

ground people who really have certification and expertise in this and was there any look at that.

And then the second is the opportunity, which I, again, have learned about over time, that one notices skin issues and it ends up ultimately being maybe a vascular issue rather than a deep tissue injury. And does this measure take into account the fact that this -- what you see from one day to the next or one week to the next may give you a better sense of what the underlying cause was and to have that, again, not get in the way.

But my nursing colleagues probably could speak to this better but curious about that as it relates to measuring performance in hospitals.

CHAIR WALTERS: Yes. So reliability comes up in every Scientific Methods Panel discussion about exactly issues like that and it would be noticed.

When humans report things, how do you know that humans are reporting things consistently?

Okay, I'm going to turn it over to measure developer to see if there's any other comments they want to make in response to this.

Lee, did you flip yours up?

MEMBER FLEISHER: I'm just wondering as we talk about it, because in working with the Yale CORE, one of the nice things is they were able to get albumin in some of the data sets. Kaisers were working on some of the measures. And some of the future risk adjustments, and that's really the robustness of ECQMs is how do we sort of give advice, which may be by me stating this now, that it would be great for you to start looking in subsets of data, where we could even more robustly risk adjust these and, therefore, it would be an even better measure.

MS. O'ROURKE: Ron, could I make one process concern that --

CHAIR WALTERS: Yes.

MS. O'ROURKE: Or, not concern, but that Lee's question just triggered. I did want to highlight to everyone that the spreadsheet of

decisions is only one deliverable we report out from the MAP conversations. There is also a whole written report that has all of -- a summary of this whole conversation and all of the context that goes along with the group's discussion and how they came to that decision.

So to highlight that you have the opportunity to make comments like that that might go outside of the strict recommendation categories, and that we capture that, and we pass it along to CMS and to the field broadly.

CHAIR WALTERS: Yes. Any last comments?

In one form or fashion, then, whether it be with conditions that we're not sure whether they'll go through or not but at least listen to, or through conditions that should be added, the staff recommendation, the preliminary analysis recommendation was conditional support for rulemaking. Cristie and I heard that that was generally there were some questions about what conditions could and could not be but, generally, the discussion flavor that we had with outside

chance that if that -- or I shouldn't say that -- with the chance that if that does not go through, it might be the category below that, the do not support with potential for mitigation.

So I believe we'll take a vote on the preliminary analysis of conditional support first.

MS. QUINNONEZ: Yes, thank you.

Voting is now open for MUC2018-107 and the question reads: Do you vote support the preliminary analysis as the workgroup recommendation?

And this is for conditional support for rulemaking for MUC2018-107. Option A is yes; option B is no.

It looks like a couple more votes are coming through. Do you need to reconnect to the WI-FI?

Just waiting for one more vote.

CHAIR WALTERS: Okay, Marty votes yes.

MS. QUINNONEZ: Okay, we're going to close the vote.

On the screen you'll see 87 percent of individuals voted yes so this will be a little higher, and 13 percent of individuals voted no but we will add Marty's vote in there and get our total count.

And our count for this measure is 20 individuals -- actually 21 individuals, with Marty's vote, voted yes and three individuals voted no.

CHAIR WALTERS: Thank you very much. That was very good feedback given to the measure developer and thank you for your participation.

All right, having tested the process, now I'm going to turn it over to Cristie for hypoglycemia.

DR. SCHREIBER: Do we have clarity on what the conditions are?

CHAIR WALTERS: Tabulate the list there.

MS. O'ROURKE: So the one that staff put forward was NQF endorsement. Also hearing some particular concerns that perhaps the Disparities Committee could take a look at this measure.

CHAIR WALTERS: ECMO patients.

MS. O'ROURKE: ECMO patients.

CHAIR WALTERS: The timing of the sequential assessments.

MS. O'ROURKE: Sequential assessments. For the record, that's multiple ulcers at the same time and how that's handled.

MEMBER GLASSMAN: I thought this was tissue injury.

MS. O'ROURKE: And a focus on deep tissue injury.

CHAIR WALTERS: There was something in there also about competence assessment but I think that might be a whole different measure, actually. I don't know. It's going to come up in our other committee, I know that.

Michelle.

DR. SCHREIBER: May I just ask the group another point of clarity because Jack raised this as an issue? Is everybody comfortable with it including stage 2 pressure ulcers? It's a big change from prior pressure ulcer measures.

CHAIR WALTERS: That was the first thing that was brought up.

Sally.

MEMBER TURBYVILLE: I just wanted to -- I voted no because I was going to go for the mitigation but mainly because there were so many conditions that were uncovered that some of them may imply specification changes and further field testing and that regardless, supporting the group's decision and deferring to the majority, that it's not just about NQF endorsement, that it's actually looking at these conditions and whether or not the measure currently meets them and if not, what changes would have to happen regardless of that kind of committee's decision that reviews it for endorsement? They're just too important, the conditions being listed by my colleagues.

CHAIR WALTERS: Keith.

MEMBER BELLOVICH: I just wanted to offer another additional diagnostic group, being the ESRD with calciphylaxis as another group with

horrible skin conditions that sometimes are misinterpreted as decubitus ulceration and is not.

CHAIR WALTERS: I believe you could stratify this by a whole bunch of things. Have fun.

CO-CHAIR UPSHAW TRAUS: Okay, well thank you all.

Our next measure is MUC2018-109, Hospital Harm for Hypoglycemia.

MS. JUNG: This is Madison, for those on the phone. I will be giving the overview.

So for this measure, the staff's preliminary analysis result was conditional support for rulemaking with the rationale that while this measure addresses a gap, it does not address the concerns of the previous MAP Workgroup. This measure was submitted to the MAP Workgroup back in 2013. The previous workgroup had expressed concerns that electronically-specified measures -- that this measure is only electronically specified. The concern was

because many hospitals still face significant barriers in reporting eCQMs and using them to drive quality improvement.

Of note, this measure is based on NQF 2363, which is endorsed but this measure here has been re-specified. The re-specified measure is not fully tested and should be submitted to NQF for review and endorsement once testing is completed. And I believe it is due for maintenance in 2019.

CO-CHAIR UPSHAW TRAUS: Okay, just one clarification because I know it may impact our thinking on this. I assume the eMeasure with its re-specifications would go through separately from the other measure that is up for maintenance. Is that correct? Okay, so it gets its own independent review. Okay, wonderful.

All right, well let's go to our lead discussants and we can start with Keith.

MEMBER BELLOVICH: Thank you for pulling this fish out of dialysate waters and putting me into hypoglycemia. I'm not sure how that

happened but my sympathies to those that have been in the same situation before.

With regard to our initial analysis, it certainly is an important issue about helping patients and avoiding harm to patients that are hospitalized with hypoglycemia. They certainly do happen frequently. It's the most common drug event in the hospital in the range of 2.3 percent to 5 percent among hospitalized patients is a real consideration and almost 2 percent of these patient in the ICU.

But there's three steps in this process that give us cause for concern. One is the patient must receive a hypoglycemic agent within a 24-hour period to be considered as part of the numerator, a low blood glucose of less than 40, and then a second lab measurement within five minutes of the discovery of that low blood sugar. There seems to be some disparities in terms of that previous presentation back in 2014 as part of the endocrine project in that basically a difference between including hypoglycemic

episodes versus one patient over that entire hospitalization.

So it seems to be that there is a little disparity between what was initially approved by NQF and what is now in this MAP measure. We just need clarification as to making sure that it is one patient per hospitalization but out of concern would be the concept that one patient could have multiple episodes and, in fact, they are at higher risk of having adverse events mainly by having one hypoglycemic episode.

Secondly, the actual value of less than 40 is a concern. In fact, the American Diabetes Association has even made recommendations that hypoglycemia as low as 50 or even less than 70 is concerning. So even the 40 we're curious as to why we went so low and there's probably some adverse events that are happening that aren't being discovered as well.

And then lastly, this second lab measurement within five minutes, I don't know about you around the table, but that seems to be

a very complicated process to identify a second measurement while you're supposed to be first addressing the needs of your patient initially.

So for these reasons that overall our impressions were to not support this measure.

CO-CHAIR UPSHAW TRAUS: Thank you.

Richard Knight. He's not here. I didn't think so.

Maryellen.

MEMBER GUINAN: Great. Full disclosure, I'm an attorney by trade so I'm really out of water here but we'll just go with this.

A few things in terms of the measure. One just general comment in terms of eCQMs and resource allocation I think is a concern for a lot of our members because they do operate on low margins. And so kind of where we're signaling to the medical community where to dedicate those resources in terms of having that kind of boost in infrastructure that's really needed for eCQMs is something to kind of take into consideration in terms of this measure specifically.

Also just the range of folks' adoption of eCQMs and their ability to work with vendors and being varied nationally.

The other issue was, to your point, Keith, in terms of the kind of multi-step, it was interesting to see the glucometer is usually the point of care kind of diagnostic use. And so the switch to then include lab testing seemed to go or run counter to what is currently probably the more cost-effective avenue and actually at the point of care and not adding that what could be burdensome or more complicated in terms of the measure itself.

So and I do also caution in terms of -- and again, out of my wheelhouse here, but the standard of care being that there could be an unintended consequence that we're causing hyperglycemia by trying to control for hypoglycemia. So just those kind of adverse effects I think we should think more carefully in terms of the mitigating side.

And so ultimately, that led me to a not

support with potential for mitigation for those conditions.

CO-CHAIR UPSHAW TRAUS: Thank you very much.

Shannon.

MEMBER PHILLIPS: I absolutely won't repeat but it clinically happens to me regularly. So I guess different from my colleagues, I do see this. You know narcotics, anticoagulants, and antihyperglycemics are the most risky drugs we prescribe in hospitals and so I appreciate the fact that there is attention to figuring this out.

Forty feels comfortable to me because 70 would have a lot of noise. Maybe 50 would be different but what we have to be careful about is if we measure people on something we need to be really sure it's abnormal. And so I appreciate that.

As was stated, five minutes after identifying it, you should be tending to a patient and repeat tests might be done to verify

that it is low but you're not stopping to do that. You're actually taking care of the patient and so the timing on this measure feels very off.

And in fact, if we really want to understand the burden of this risk in healthcare, simply saying one event and one admission per patient completely misses the boat on looking at safety around these drugs in healthcare.

So all that said, I would not support it and I think there are mitigating factors. I think it's important to do this. It's just not ready yet.

CO-CHAIR UPSHAW TRAUS: So just to be sure I write it down right, do not support with potential for mitigation. Okay, thank you.

Aisha.

MEMBER PITTMAN: I'll be quick. I think I'm aligned with the other lead discussants of not supporting it with mitigating factors.

It just wasn't clear to me if it was intended to just solely be lab tests or was including glucometer readings. It says lab tests

but not seeing the full specifications. So can the measure developers comment on that?

CO-CHAIR UPSHAW TRAUS: Let's finish up with our last lead discussant and then we'll go to the developers.

Ann Marie.

MEMBER SULLIVAN: I basically agree with everything that's been said. And I think what was most troublesome was the five minutes I think that even timing that becomes a little bit crazy. So I think that that kind of requirement on staff, when you have that, that's particularly difficult. And I agree with everything else that's been said.

So basically with the mitigation.

CO-CHAIR UPSHAW TRAUS: Thank you.

Okay, we'll kind of look to the developers to maybe address some of these issues and I wrote down a few but if you don't address them I'll remind you what they were. So you can go.

DR. BERNHEIM: Prefect, thank you. I

wrote them down but I appreciate you keeping me online.

Thank you for the comments. I will say just two -- a few brief things about the status of this measure and some of the concerns. I hope that in better explaining the measure we may be mitigating some of your concerns already.

So again, this measure was selected because our Technical Expert Panel and patient group felt that it was both important and meaningful for patients and that it would be feasible. And our aim is always not to add anything to clinical workflow. So I'm going to start with that five-minute piece because I think it was misinterpreted and I want to be really clear.

What this measure does is it looks at among patients who have been given antihyperglycemic medications, or dealing with a group of patients who are risk of hypoglycemia based on our actions in the hospital, it identifies whether a patient's blood sugar goes

below 40.

And you're exactly right, the reason we choose a lower number than some of the guidelines is to make sure that we're really identifying serious hypoglycemia and not spurious events.

And the issue of spurious events is where that five minutes come in. This measure does not require you to recheck blood sugar. It simply says if we see in your lab values that you rechecked it in five minutes and it was over 80, then we believe that 40 was spurious. So it's just to prevent us from counting something as serious hypoglycemia when it was not but there's no requirement of a recheck at all.

It does bring in both lab values and point of care values. Many of these are done at point of care. So both of those are read.

And what we're learning is that this is -- these labs -- I mean now I'm using the term lab value which I think is confusing you -- these blood test results, whether they are done at the point of care or from the lab are the things that

are among the most feasible for hospitals to extract, including timestamps. The timestamps seem to be pretty good.

So it is not -- there is no work for that five minutes. There is only an opportunity to prevent us from counting something as having been hypoglycemic when it wasn't. So I think those are the most important clarifications.

Stay tuned on the concern of a balancing measure. We'll see you next year.

(Laughter.)

DR. BERNHEIM: And then the one other thing is that this is, at this point, specified as a one event per patient, either the event occurred or not. And I hear -- and we thought about it and we tried to balance the question of sort of do you look for multiple events. The advantage of a single event, if you think that this something that we should try to avoid in all cases, is that there's less data to be extracted once you see that there has been a severe hypoglycemic event and there was not an immediate

improvement based on suggesting a spurious lab value, you found that event. In some of these measures, we look for numbers of events and I think you could argue either way but we did that to keep it as simple as possible.

Did I get them all, Cristie?

CO-CHAIR UPSHAW TRAUS: You got the ones I wrote down.

DR. BERNHEIM: I will say, like the other measure, this is now done with two rounds of testing with very high positive predicted value and good reliability in those results and it will be going to NQF in January.

CO-CHAIR UPSHAW TRAUS: So just to remind everybody, the staff's recommendation was conditional support for rulemaking.

What we heard from the vast majority of our lead discussants was to not support with mitigating factors and a couple of do not support at all.

So hopefully this clarification at least gets us on a common foundation in terms of what

this measure is and what it is not.

Are there any additional questions or clarifications? And I probably should have started looking earlier but I'm just going to start with Jack and then go around the room this way. So, Jack.

MEMBER JORDAN: Thank you.

A couple things. Opposite of the others here, I think the five minutes is actually too short. Well one, I know my hospital policy is ten but also if you think the glucometer something is wrong with it so you're going to go find another one and come back, you'll flag over the five. Though I can tell you looking at over three million glucose readings in my lifetime kind of things with that, that rarely really happens where you get the false positive there.

But that said, the other thing with this that can make this a lot easier to build, and anytime you are using drug class kind of things, to avoid making the definition be a list of a bazillion RxNorm codes and instead to say

contains drug class or sub-drug glass. That's ten times easier for someone to build the rule and it doesn't have to be maintained every year that you build a new list every year for your definition of the new list of RxNorm codes.

So that's just something whenever you're doing one of these eCQMs with drugs, it makes the world a lot easier to implement for that.

And then I agree on kind of switching to the multiple incidents kind of thing. Our rule, we use 15 minutes and if you have a second one, more than 15 minutes apart, then we count it as a second event.

And I think we have actually done some things where we've had resident kind of studies and such where they look at the recidivist patients and see are there things different there and such. So I think they are kind of something interesting to look at multiples.

CO-CHAIR UPSHAW TRAUS: So do you mind sharing with us what you're leaning towards in terms of the decision categories?

MEMBER JORDAN: I guess the challenge is always you know what is kind of agree with it and these kind of things or tweaks that don't count, which I would be fine with saying that or saying go back and kind of fix the things.

To me, if you changed it from five to ten minutes, I don't think that's a substantive change that's like saying you have to go back.

The drug class kind of thing, again, that's probably a big deal in one way but, in reality, it's kind of a trivial change to it. So I would say I would agree to move forward with it but I think those things could be done but I think of them as minor changes.

CO-CHAIR UPSHAW TRAUS: Okay, so conditional support?

MEMBER JORDAN: Conditional support.

CO-CHAIR UPSHAW TRAUS: Okay, that sounds great. Thank you, Jack.

Keith.

MEMBER BELLOVICH: I just wanted a point of clarification. Was there any thought -- I

don't want to step on the toes of future MAPs -- but the concept of unintentional hyperglycemia as a result of erring on the side of no therapy?

CO-CHAIR UPSHAW TRAUS: Was that your balancing measure or --

DR. BERNHEIM: I can't speak to CMS' future intentions but yes, a lot of thought about that. We felt like hypoglycemia was -- a single instance of hypoglycemia is a much more serious event for patients associated with all kinds of morbidity. And so that was our first focus but there is a lot of thought about the importance of balancing measures.

CO-CHAIR UPSHAW TRAUS: And I'm sure our comments can incorporate that as well, Keith.

Lee.

MEMBER FLEISHER: I guess I'll take up my role from the methodology standpoint. So we actually did get funded by the NIH to do a study of the SCIP measures and glucose levels. Unfortunately, it's never been published because CMS did not renew our data use agreement.

(Laughter.)

MEMBER FLEISHER: Yes and we called Patrick.

CO-CHAIR UPSHAW TRAUS: So noted.

MEMBER FLEISHER: So we went all the way to the top.

But the important interesting question is risk adjustment, which we never thought on process measures that you would need it, but what we found in a national sample was that the incidence of CABG at your local hospital and CABG in diabetics at your local hospital. So while I think this is a fabulous and important measure, that that particular subset of how many CABGs you do and how many CABGs with diabetics change whether or not a hospital is great or really quite poor because essentially in that subset of population, you had wilder swings in their glucose levels from the measurement.

So I'm just saying that something -- this is a conditional with -- do not but mitigating. So I think if you -- whether you

subset out that population or look at it, if they are doing less CABGs, they may look better because of the attempt to control glucose tighter in that subpopulation.

CO-CHAIR UPSHAW TRAUS: Thank you, Lee.

We're just going to continue to go down, if that's okay with you all.

Nancy.

MEMBER FOSTER: So just one note related to the measure but not about the specifications in the measure, per se, and that is recently the FDA put out guidance to blood glucose meter developers, which may mean some of the things we currently use in hospitals will no longer be available to us. If that comes to pass in a time frame when you would launch this measure, it would cause strange results to occur, perhaps.

So I just offer that up not as a deterrent to doing the measure, per se, but as a timing issue around implementation and to watch what the FDA is doing.

CO-CHAIR UPSHAW TRAUS: Andreea.

MEMBER BALAN-COHEN: And just building up on the comment about risk adjustments, just a suggestion. I like the point that was brought up about how there hasn't really been made a differentiation between whether this is an episode like for a patient or like multiple or like repeated episodes for a given patient. And it seemed to me that underlying reasons for those would be very different.

And then maybe one of the suggestions you try to see if you need additional risk adjustment is like maybe comparing you know like how would the data change when you do this like separately. Like if you only look at like one incident versus if you look at like the population or have like multiple incidents and that would give you like some additional information on that.

CO-CHAIR UPSHAW TRAUS: Great. Thank you.

Okay, any final comments, Susannah? Okay.

All right. Well why don't we tee this up the way that our process says, which is to first vote on whether or not we support the preliminary analysis as the workgroup recommendation. And the preliminary analysis was for conditional support on the condition that in the staff analysis is NQF endorsement, correct? It's hard for me to look at million things at once. I apologize. Yes, for conditional support but that was the condition that was attached to it.

So we can start with voting for whether or not we approve the preliminary analysis as our formal recommendation.

MS. QUINNONEZ: Thank you.

Voting is now open for MUC2018-109. Do you vote to support the preliminary analysis as the workgroup recommendation and that was the recommendation of conditional support for rulemaking? Option 1, yes; Option 2, no.

Votes are coming in. I'm just looking for a couple more votes. We're at 23 votes now

so I'll give you five more seconds.

All right. Okay, voting is now closed.

So right at this time, we have 63 percent voted yes and 38 percent voted no. I will give you the count so you'll have a specific count for that.

For the record, 15 individuals voted yes and 9 individuals voted no.

CHAIR WALTERS: Yes, so I think -- I was saying Cristie, I heard an awful lot of do not support with mitigation possible.

So I think that the vote reflects exactly some of the discussion that occurred was there's got to be some conditions. And we talked a lot about some of those risk adjustment ones and about there were some things in the specs.

MS. O'ROURKE: Yes, I can start and please feel free to chime in if I missed anything.

Some guidance for the developer and the Standing Committee that would eventually be looking at this measure for endorsement, take a

look at that threshold of 40, as well as the five-minute time frame. Also some guidance that it would make this measure more feasible if it focused on drug glass, rather than a list of RxNorms.

Also perhaps some bigger picture implementation events -- or as some bigger picture illumination, it would be a balancing measure for hyperglycemia, to keep track of what the FDA is doing around blood glucose meter development and to not put this measure into effect at the same time that goes into effect to avoid some unintended consequences.

And Maryellen's point about EHR vendor issues and national variability and to make sure CMS is working closely with the EHR vendors to minimize the burden, especially on facilities that may not have as many resources as others.

MEMBER McGIFFERT: And then there in the multiple events.

MS. O'ROURKE: And the multiple events oh, and also the risk adjustment model.

CO-CHAIR UPSHAW TRAUS: Okay, that seems to have captured for the record. Okay, that sounds great.

All right, well thank you all for that. Let's go on and move into our next measure, which gets out of IQR and into the Prospective Payment System for PPS -- I'm sorry -- PPS - Exempt Cancer Hospital Quality Reporting Program.

We're going to have an overview of that program, and then we will go to public comment, and then we will start with our lead discussant on the one measure that we have in this program.

MS. JUNG: Great, thank you.

So this slide is just giving an overview of the PPS - Exempt Cancer Hospital Quality Reporting Program. Again, this was reviewed at the web meeting but just to reiterate, the program type is a quality reporting program. The incentive structure is a PCHQR. It's a voluntary quality reporting program. Data is published on Hospital Compare.

The program goals are to provide

information about quality of care in cancer hospitals, in particular to the 11 cancer hospitals that are exempt from the Inpatient Prospective Payment System and the Inpatient Quality Reporting Program.

The other goal is to encourage hospitals and clinicians to improve the quality of their care, to share information, and to learn from other's experiences and best practices.

This slide displays the recent updates, the most recent federal rule to the PCHQR programs.

MS. O'ROURKE: Sorry, Madison, to interrupt you. Just to note on the public SharePoint site we do have a spreadsheet that has all of the measures in the programs. We know this is not the easiest thing to read.

MS. JUNG: Yes, and then there's a version of the slides on the public SharePoint as well for reference. But these measures that had recent updates to the program.

And this slide just lists the measure

that are currently still existing or had no changes in the last rule.

The high priority domains that were noted: communication and care coordination, making care affordable, person and family engagement.

CO-CHAIR UPSHAW TRAUS: Okay, we would like to open it up for public comment on this program. And we can start with people in the room.

Anybody in the room want to make a comment? Okay, I don't see any.

Operator, could you see if anybody on the phone would like to make a comment, please?

OPERATOR: Yes, ma'am.

At this time, if you would like to make a comment, please press * then the number 1.

And there are no public comments at this time.

CO-CHAIR UPSHAW TRAUS: Okay, thank you.

So we want to go into the measure that we have before us, which just went away on the

screen but I can probably find it over here. There are so many things we have to flip between, the screen is helpful.

Surgical Treatment Complications for Localized Prostate Cancer and it's MUC2018-150. And if the staff will, give us a summary of the preliminary analysis.

MS. JUNG: So the result of the preliminary analysis was we do not support for rulemaking with potential for mitigation, the reason being that this measure should be revised as recommended by the methods panel and resubmitted to NQF for evaluation and endorsement.

CO-CHAIR UPSHAW TRAUS: Can you just point out to us or remind us the MAP -- the Methods Panel discussion that was around this so we have that walking in as to understanding where the preliminary analysis landed?

MS. MARINELARENA: Sure, this is Melissa for those of you on the phone.

So this measure was submitted to NQF for

review in the fall of this year, fall of 2018. It went to the Methods Panel because it is an outcome measure. And the Methods Panel did not recommend it because there were some issues not with the concept of the measure but with the actual testing that was provided to them at the time.

In your preliminary analysis we did provide the Methods Panel's very specific recommendations. As Karen explained this morning, the MAP -- or the Methods Panel has evolved over the past year. So this measure was discussed over a public telephone call and then the measure developer was provided recommendations. There are recommendations that the Methods Panel, overall, would like to see but then very specific recommendations that they provided that would meet NQF criteria.

So it was around their reliability and their validity testing. They have provided some face validity testing, some data element validity testing that just did not meet NQF criteria, just

giving them some more specifics about if you're going to do face validity, this is what we are going to need if you're going to do data element. And I believe they are on the phone as well and can provide you some more specifics on what we require for data element validity testing.

So we did include their very specific recommendations. So that's why this one received the mitigation because they have to tighten up their specs a little tighter. They have received those recommendations and then they can tell you themselves what they plan to do with the measure. So that's why this received the do not support as it is with mitigation.

CO-CHAIR UPSHAW TRAUS: Thank you very much.

Well, let's go to our lead discussants first and then we'll give opportunities for the developers and others to answer questions and concerns that may have arisen.

So we'll start with Andreea.

MEMBER BALAN-COHEN: Thank you. So to

begin with, I do -- we do think that this is a very important measure. There are many things to like about it. This surgical treatment complications for localized prostate cancer are certainly very frequent and something that really matters to patients. So something very important from a patient perspective.

I had some concerns about in addition to some of the ones from the Method Panel in terms of like both a little bit conceptually and also in terms of the measurement. And I think that's why I would go with the current staff recommendation, which was not supported with potential for mitigation.

And the concerns that I had were around -- one was around like the measurement. So it wasn't very clear whether this is something that is going to be separately reported for different types of surgeries. It seems that minimally invasive versus open surgeries would have very different types of complications. So accounting for that would be important.

The other issue was around like the time interval, like the one-year time interval and also the types of complications. Again, not my main area of expertise, per se, but I did do some literature review and it seems that a lot of these complications tend to occur over like a longer time frame, so like between two to four years.

And also some of these complications tend to sometimes happen in opposite directions. So you have like a higher prevalence of one like might mean that you won't have the other one. And there might be some other complications that weren't necessarily captured in the measure.

So this seems to me like it would be like more maybe better suited as a kind of like almost like index of like complications. So that's something that I think would be interesting to address.

And also like a little bit in terms of like the risk adjustment, again, there are different patients that have like different risk

and there are certainly like high-risk like prostate cancer patients. And then accounting for that, like there didn't seem to be like a way to risk adjust. It seems like that would be important as well.

And then finally, this is a very specific set of hospitals. There aren't that many. They are in very specific geographies and it would be interesting to see if like some kind of adjustment was made when the data and then like in terms of the validity of the data to make sure that it pertains like specifically for these specific geographies.

And I will turn it over to my fellow discussants.

CO-CHAIR UPSHAW TRAUS: Thank you.

Frank.

MEMBER GHINASSI: Well that was a very thorough set of recommendations. I agree with all of them.

Just a couple of small points. I think the concerns around reliability and validity were

really well laid out in the comments and they are of concern to me. A lot of this is not clearly specified and it looks like a lot of questions were left in the minds of the individuals who looked at it. I'm assuming that a rigorous NQF process would ferret out that on the basis of scientific acceptability. So I think that's critical for this.

The second thing is I was curious. I was curious about the age of 66 and I wondered why that was chosen as the cutoff. And so then I went to the American Cancer Society page and it does turn out that that is the arithmetic mean for onset but that only accounts for, according to the Cancer Society page, at least, it only accounts for six out of ten cases, which means four out of ten happen between 40 and 65. And I'm wondering why the measure would leave out those four out of ten cases by choosing 66.

So those were the questions I had. And I agree with the recommendation of the counsel.

CO-CHAIR UPSHAW TRAUS: Thank you.

Lee.

MEMBER FLEISHER: I'll start big picture. I'm totally confused by it's in this program, as opposed to the physician program. So for full disclosure, I am an anesthesiologist to many for many of these cases, more in the past than in the current.

But as watching these cases, this is entire -- this is so much more operator-dependent than system-dependent except for two factors. One is did they buy a robot and what generation robot may or may not influence that. And number two, is how young are their surgeons in both extremes. In other words, do they allow a surgeon who is newer at this? They may be better or an older surgeon may be worse. Do they allow them to operate?

So there's technology issues which may be something they are talking about and there are surgeon issues.

Complications after prostate surgery that are not incontinence and erectile

dysfunction I'd say are the systems issues. This is the operator issues. So that's why I got confused.

So if you wanted to say in-hospital complication, I, my hospital, the surgeon can take credit. So that's I think an overarching -- so good measure; different program. Put it for the surgeons.

The second is the number of days. And I find the use of calculating the days out of the year in which somebody experienced this based -- did I get it right -- based upon the claims, is a really surveillance-biased assessment. I mean a yes/no of somebody who is having these problems I could be more comfortable with but because they talked about it with one physician who may or may not -- if you have Epic, it's going to carry over to every single encounter, so you're going to get more days than if you are the private doc in the office who is the PMD who might see him one time and mark it down and put it on a code but they might not the next time. So I think that's a

very contrived way of assessing.

I love days at home. Please change your readmission measures to days at home within 30 days so you've got it right conceptually. I've been pushing for that. Yes, methodology but this is, I think, the wrong way.

It's a great measure. Change it. Put it in a different program. So I do not support at all for this program. I don't know if there's a way -- it's a different sort of answer.

MS. O'ROURKE: I think that that's -- we can capture that all in the report and say that conceptually, the measure is on point and should potentially be put forward for a different program after re-specification to the clinician level of analysis.

CO-CHAIR UPSHAW TRAUS: Yes and just as a reminder, that is what our job is today is to say whether or not these measures actually work within these programs. So you know they may be good measures and may have value but should it be in this program?

So thank you very much for actually bringing this up, Lee.

Sarah had to leave early. She let me know. She apologizes.

Karen.

MEMBER SHEHADE: Yes, the only other point to add I think around refinement would be to look at the open versus MIS versus robotic as three very separate and distinct procedures with different rates of complications. And being able to cull that out I think is important. To cluster all non-open procedures under one header in the old days may have worked but with almost 90 percent now being robotic, it may not make sense. So it would be very interesting to see how those pan out.

And I agree with the other comments from the lead discussants.

CO-CHAIR UPSHAW TRAUS: Which way would lean on the four voting categories?

MEMBER SHEHADE: As recommended by NQF.

CO-CHAIR UPSHAW TRAUS: Okay, thank you.

Okay, Marisa.

MEMBER VALDES: Thank you. So totally out of my element. I never worked in oncology but I haven't read as much about prostate cancer as I did in the last five days.

I agree with the NQF assessment. I'm not a statistician. One of the things I like about the methodology is that it works in some scaling that I think it is easier for hospitals to look at. If this were to remain a hospital measure, that is a nice way to look at the methodology, though I'm not a statistician.

I don't think this measure, while it's a good measure and obviously this is a very prevalent form of cancer, it doesn't seem to address the gaps in this particular program, as they were on a prior slide.

The other thing that I think -- I agree with all the other comments and the only thing I would add is that in this particular type of complication, maybe patient-reported outcomes would be a better way to get at this particular

result. So I think the measure developer probably should consider. In a lot of the literature reviews that I did to be ready for today, talk about that particular method of gathering information about these two complications for patients who have partial prostatectomies. So maybe the measure developer can consider that.

And I would agree with the NQF recommendations.

CO-CHAIR UPSHAW TRAUS: Thank you very much.

So we do have with us this afternoon Kristen McNiff, who is in the room. And is Tom going to join us by phone? Tom, are you on the line?

MS. O'ROURKE: Operator, could you make sure Tom Ross has an open line?

OPERATOR: His line is open.

MR. ROSS: Good afternoon.

CO-CHAIR UPSHAW TRAUS: Oh, hi, Tom.

MR. ROSS: I'm on the line and also

Corinna Andiel from Memorial Sloan Kettering, Chair of the Quality Committee has also joined us.

CO-CHAIR UPSHAW TRAUS: Okay, wonderful.

So, thank you. I'm going to give you all a few minutes, if you'd like, to kind of give an overall response to some of the issues that you've heard. And if for some reason some of them aren't covered, we'll try to bring them back up again.

So, thank you.

MS. McNIFF: Perfect. Thank you. Again, I'm Kristin McNiff. I'm here today representing the Alliance of Dedicated Cancer Centers, which is a group of the 11 freestanding cancer hospitals that are part of PCHQR. So all of the hospitals that report in are part of the Alliance of Dedicated Cancer Centers and that group sponsored development of this measure.

And I will get into more of the details but I want to clarify that this measure was developed not specifically only for use within

PCHQR and as such, we used national Medicare data as the data source for this with SEER, which is based on the Federal Cancer Registry Program which is implemented through the states as a testing source and I'll describe why, as we get further into addressing some of your questions.

So while we are recommending this for use in PCHQR because we think it's important for discriminating outcomes within our own hospitals, there is nothing that would prevent the use of this measure in any other setting, except that we tested it at the hospital level. So, I'll put that out there.

So we think it's important for us but we do not think by extension that it's not important for other providers.

So I wish I could go in a logical order but I think I'm going to have to just kind of go backwards from the order of the discussants. And yes, please, keep me honest if I miss anything.

So first there was a comment about PRO-based measurement maybe being the ideal source

for this measure. We could not agree more. In fact, we are in the midst of a measure-testing project trying to collect this information using PRO-based performance measures. Needless to say, there are two barriers to collecting this via PRO. One is obviously, the workflow and implementation challenges of a PRO-based performance measure we all know well. And then the second -- which are working to address.

The second for this measure specifically is that there is a year between the recommended pre-post assessment. So it's a long testing cycle when you have to wait a year even to get your testing data but that is seven, I believe, of our centers currently are working on that measure testing projects. We agree that that is ultimately the best way to do this.

In the interim, however, using claims in a novel way to try to look at some of these outcomes we think is the way to get us nearer-term data that are very useful, we think, and bring no burden associated with its collection.

So I'll go backward here. Again, there were questions about specifically using the measure for this program and I reiterate that we think it's important for our program but we also have tested it in a way that it should be appropriate for any use in any hospital. Again, we use the Medicare claims as the data source. That's also the reason why age 66 is the cutoff is because Medicare claims is the data source.

So there are, obviously, some individuals who are under age 65 who are included in Medicare claims but because they tend to come in because they have ESRD or some other condition that would influence our outcome, we wanted to limit to those who are in Medicare due to age. So that's why we have that cutoff.

Absolutely, this could be useful to look at in private payer claims as well but that's not the -- you know obviously that's a different specification and testing project.

All right, I think I'll keep going and hope I hit them here.

There have been several questions about risk adjustment. In this testing, to be clear, one of the things that was really important to us is that we were able to really validate using claims as a data source. Without going into too many details, for oncology it's very challenging to use claims as a data source because there is such limited information in claims related to the cancer itself, the clinical factors that are important for both the prognosis and treatment.

So, in claims, there is no information for prostate cancer, for instance, about the stage of disease. There's no information about the grade. All of these things that really are critical for not only the treatment and prognosis but also related to some of these patient-sensitive outcomes as well.

So that's why we used a combined SEER-Medicare data set for the testing. SEER, again, comes from the federally mandated and funded Cancer Registry Program, which is implemented through the states. The SEER program collects a

very rich data set of clinical information and the federal government provides SEER-Medicare as a linked data set. It's not very identified, which may get to some of the questions that you have, but allows you really to look at those combined claims and clinical data at the patient level. And as such, we were able to see whether we needed to have clinical richness in order to have a valid measure.

So that's why when we were testing we were able to look at things in risk adjustment that really are clinical that aren't usually in claims. If in fact we needed those for risk adjustment, then we would have questioned whether this was a measure that could come from claims alone.

It turns out that when we looked at lots of clinically important information for risk adjustment that, actually at the patient level, there were a variety of patient-level factors, covariate, and there were a variety of hospital-level covariates that were -- that did

significantly impact outcome but when we tested that at the hospital level, it did not impact. We were very surprised. There actually was no need to risk adjust this measure because the correlation coefficient was 0.96.

And that information was all provided. I know it's hard to believe we couldn't -- you know we found it a little challenging but, in fact, that is true that in our data set we did not find the need to risk adjust. So it's not that we didn't test those clinical factors. We did but we didn't need it.

I also would like to just make sure that it's clear that we were able, and as part of our validation, we were able to validate that using our claims algorithm alone, that we were able to remove almost of all of the advanced prostate cancer patients which we don't want in this measure but that again you can't identify, just based on one ICD-9 or ICD-10 code. So that's included in the testing documentation that 96 or 98 percent of our patients included did in fact

have localized prostate cancer. So we didn't have those advanced stage cancer population included at all.

And then again, beyond that, we did not find that we needed to include stage, grade, or other clinical factors for risk adjustment.

Okay, then we had questions about the types of complications. So in the submission materials we included the whole list of the different complications that we tested. We used the report ICHOM Localized Prostate Report for the basis for most of the source documentation for this measure. And one of the things that we looked at there is the list of all of the patient outcomes that they included as meaningful.

We tested all of them that we could capture in claims. Again, there's quite a long list and the vast majority of the claims that we found were for erectile dysfunction and urinary incontinence. So that really was -- including the rest of them got you a very tiny benefit for a lot of codes that needed to be maintained and

that's why we limited it to ED and UI.

We also looked at claims days and I'm not sure -- I want to just make sure that this is clear. You may like or not like this methodology but we looked at the number of claims days that were billed in that time frame prior to the diagnosis and then we looked at the number of claims days that were billed after. So that's the comparison for the numerator so that a patient is really being compared to him or herself.

All right. We did not have information about the age of the surgeon. So that is not something that we were able to look at.

And then there were a whole variety of questions about the different types of surgery and then I know it came up in our discussion about a recommendation for stratification. So we did look at open versus non-open. I hear the feedback that we may need to refine that further.

The data set that we were looking at was 2009 to 2013 because that was the most recent

data that was available via using SEER-Medicare as a combined data set. And as this measure moves forward into contemporaneous claims sets, then you could -- I think that's a very good point that we may need to consider breaking it out further.

For this measure, again, at the patient level we did see a significant difference between type of surgery. When we looked at the hospital level, that difference went away. But we still think for both face validity and for future kind of acceptance and meaningfulness of this measure, that it would be useful information for the hospitals who are receiving the data to see their data stratified by surgery type.

And so we propose that the measure score that would be used for accountability is the overall score so it's not a true stratification both for the purposes of understanding and being able to find meaning in the measure that actually would be reported broken out by open versus not. So it's not true stratification but it is broken

up for the reason of meaningfulness, ultimately, at the point of reporting.

Did I miss anything?

CO-CHAIR UPSHAW TRAUS: I think you did a pretty good job.

MS. McNIFF: Thank you.

CO-CHAIR UPSHAW TRAUS: Thank you. It's always difficult to listen and take notes at the same time. So thank you for doing such a good job.

Before we move into voting, are there other questions, especially after hearing her response in terms of from the developer's perspective?

Dan?

MEMBER POLLOCK: Yes, thank you for that great response.

I may have missed it but how many patients were included in the sample in which you evaluated potential clinical risk factors?

MS. McNIFF: So we started out, again, looking at Medicare claims from 2009 to 2013. At

the highest level, our patient population were those with at least two ICD-9 diagnosis codes for prostate cancer and they need to be separated by at least 30 days. And we had 347 to 128,000.

MEMBER POLLOCK: So those were all the prostate cancer patients that fit the criteria?

MS. McNIFF: Yes and once we -- so then we added -- and there's -- I don't know what documentation you all have but there's the flow diagram. Then we looked at those who had prostate surgery. That did bring the overall population down to 25,422. And once we applied, they needed to be 66 and above, survive at least a year, and be continually enrolled in Medicare Fee-for-Service because, of course, we didn't have Medicare Advantage in here. We have 15,545 patients included.

MEMBER POLLOCK: Thank you.

CO-CHAIR UPSHAW TRAUS: Shannon.

MEMBER PHILLIPS: Thanks. Can I just ask you to clarify again? I appreciated Lee's comment about the difference between is this

really about -- is this a hospital measure or is this a measure at the surgeon level?

Can you reflect again on why we think these complications, which are technical in nature, should be accountable at the hospital level?

MS. McNIFF: I think one reason is because you are going to have real problems with small ends once you get down to the surgeon level. I mean, we didn't look at the surgeon level. We looked at the hospital level but even so, once you get -- despite me talking about looking at Medicare claims, once you are attributing patients to an individual hospital, we set a minimum threshold in order to calculate the measure. And at that point, there were -- and don't hold me to this number and I can get it for you if you'd like to, but maybe 30 percent of the hospitals dropped off because they didn't even have that number of patients. So then if you imagine applying that to a physician instead --

We did look, by the way, at -- I don't want to go into it too much but we looked at was there a difference between higher and lower volume hospitals. And actually, there weren't, which again, was surprising we didn't see a difference based on volumes, though we felt okay about making that distinction of it but I think that's the first challenge is that you wouldn't have sufficient and that for any except the highest volume surgeons.

And then the second is we wanted to -- we just wanted to recognize the importance of the team. I mean there may be a whole team involved in providing the support and intervention that prevents these from occurring or minimizes their impact.

So since we're counting claims days, if you had one of these -- if you had the issue show up but then it's addressed quickly, that is going to count differently in your numerator than if you have it and it extends and it extends. And we feel that's a reflection of that team. You

know it's really a team-based approach.

CO-CHAIR UPSHAW TRAUS: Frank.

MR. ROSS: Yes, I would like to add from somebody who was a cancer quality director for 24 years. Lee had asked the same question. And I'm thinking the hospital investment in the technology, the training, the peer review, you know the medical staff review, the cases all feed into creating the environment, providing the equipment, and the feedback that I do think influences to lend itself as a hospital measure.

CO-CHAIR UPSHAW TRAUS: Thank you for that and I'm sorry I didn't hear you earlier.

Frank.

MEMBER GHINASSI: Just a clarification point. And if you've already answered this, don't feel like you have to answer it again. I'm sure they wrote it down.

But since it appears there are a number of different procedures that are being looked at, it mentioned open and closed, it mentions robotic, there is generations of robotic devices,

et cetera, et cetera, is this measure going to be looking at those separately or are those all going to be lumped into one measure?

MS. McNIFF: So we looked at them as one and then we looked at it as open versus closed. And yes, there are a variety of different surgical types that encodes that MAP up to each one of those.

Again, since we didn't see hospital-level difference in the data set we were looking at, which is not last year's data set, we recommended that overall measure be reported as one score but then that for informational purposes that you are able to see open versus closed.

I again the feedback that there may need to be additional categories there to be maximally meaningful is important.

MEMBER GHINASSI: Yes, the reason I am asking is the purpose of these measures is to increase the likelihood of -- or reduce the likelihood of negative. And so you're wanting

this to be actionable.

MS. McNIFF: Yes.

MEMBER GHINASSI: And if I look at a number that has four, or five, or six procedures in it, I'm not sure I know what to fix.

CO-CHAIR UPSHAW TRAUS: Lee.

MEMBER FLEISHER: I appreciate it, Michelle, and the CMS team so that I can get some clarity.

So if I were to say whether or not Sloan is a good place to go versus I should go to Texas, et cetera, part of that is going to be end up follow-up is how far I'm going to travel. So that's an interesting question about follow-up, which is a further complicating.

And I agree that it's the group and it may not be the physician but it's the physician group but if I want to see if Sloan is a good hospital and there is a great surgeon who moved from one hospital to another, that's what's driving this. And maybe it's you have more money to recruit, maybe you don't, but I'm still -- I

agree with the N and the value of a group of surgeons. I'm still not sure, if CMS is looking to measure cancer hospitals, if this is the right measure to assess whether cancer hospitals are doing a good job.

So what are your goals from the CMS to put it into this program? Yes, I don't know if I'm totally clear but I'm fine with rolling it up as a group.

DR. SCHREIBER: So I'll give you an opinion. First, as we've heard, it was developed by the cancer hospitals because this was something that they felt was important. And my personal answer to your question is it's bull.

So I think to use it within the cancer hospitals, frankly, to perhaps use it in all hospitals is not unrealistic because hospitals do have some responsibility for this, for their OR staff, for their training, for their training around the da Vinci robots, for their training around their house officers, quite honestly who are doing this. I think there are hospital

elements that are very real that play into supporting this being a hospital measure.

Do I also think that something like this could be a physician-based measure? Yes, I do but I don't think that necessarily negates it being a hospital measure.

CO-CHAIR UPSHAW TRAUS: Thank you for that.

Andreea.

MEMBER BALAN-COHEN: I was also going to make a plug for having this like perhaps even like in both programs. So certainly I see the appeal of having this like at a physician group level but from the hospital point of view, I think there are like two arguments that have been made. So one is the one that you just mentioned like even for the specific cancer hospitals provide transportation. Maybe not everybody has like specific access to certain types of hospitals. That's one. And also maybe they don't have access to specific physicians and, therefore, having the choice be made at the

hospital level would be a little bit easier.

There is also a lot of evidence there is more visibility patients than to choose like hospitals first and sometimes like physicians like afterwards, especially for some types of group of patients. Where again, like having some accountability at the hospital level I think would be very helpful.

The other point there I was going to make is that also making hospitals accountable might drive some of these investments. Like I'm sensitive to the point that was made earlier about how maybe it's all moving towards let's like say toward robotic surgery. So maybe all hospitals should be investing in certain types of surgeries and maybe if there is enough evidence that the results really are better for certain types of procedures, then if you see hospitals that are doing better, you are going to try to find out why and make this specific investment. So I think that's an argument in favor of having this at the hospital level.

The other comment I was going to make is about risk adjustment. So one thing that I noted in your comments was about there is a difference at the patient level like in terms of the risk adjustment but not at the hospital level.

One thought I had about that one is that it might be driven by selection within hospitals. Maybe certain types of patients are going to specific hospitals and maybe that's why you see some of those effects wash away. It doesn't mean it's not important. Just something to look into.

CO-CHAIR UPSHAW TRAUS: Thank you.

Lisa.

MEMBER McGIFFERT: I just want to reiterate what an important measure this is and to pick up, I can't remember who said it, but the importance of having a patient-reported outcome measure on this and would encourage the developers to create one of those measures to go along with this one. It is probably the number one thing that is feared and experienced by people going through these procedures that really

changes their lives.

So I think that it's really important. I agree that it does have something to do with the hospital and how the hospital does it business but I also would support a physician-level measure, too. Thanks.

CO-CHAIR UPSHAW TRAUS: Anne Marie.

MEMBER SULLIVAN: Just to add to that, I think it's so important as a patient outcome but also as gone over time. And I think that that's very interesting. I think a lot of our measure don't go out that far. Maybe people say it should be more than a year but I think by going to a year, you're getting information you wouldn't get like at two months, or just infection rates, or just initial impressions of what's happening post-surgery.

So I think that's something important to keep in mind in measures generally that if you're looking -- even if the surgery occurred or the incident, or the hospitalization occurred at a point in time, what are the long-lasting effects

of that? And I think this measure really begins to get into that world of functionality post, not just a few months but actually a year, which I think is really valuable.

And then just to say on the issue of hospital versus I think that's a tough one. You know I could say the same thing about caesarians. I could say you know that the doctors -- there are doctors who do lots of caesarians and there's doctors who do very few. You know I think almost every procedure, when you're talking about that with surgeons, there's a differential to what surgeons do. And then there's things that happen in the hospital that contribute to the bad effects.

So I think it's good to measure the hospital system, too, because I think that that's where the quality sits and that's where people make their choices about -- you know systems make their choices about what procedures they are going to kind of really have happen or not and who they are going to hire to do things. So I

think it's an important hospital measure.

But I really like the fact that this one went out over time. I think that that's really good.

CO-CHAIR UPSHAW TRAUS: Okay. I think everybody with a card up has already spoken. So trying to bring this, I think, to a point now where it's probably time to vote.

We'll start where we did before, which was the staff recommendation, which was do not support for rulemaking with potential for mitigation.

We certainly heard a lot from our lead discussants as supporting the staff recommendation. I think we had one that felt like perhaps this wasn't the right program for that but I think we have had a discussion around that. So clearly thinking about how you want to vote personally, hopefully you found that helpful.

So if we want to start with the vote, that would be great.

MS. QUINNONEZ: Thank you.

So we will now be voting for MUC2018-150. And the questions reads: Do you vote to support the preliminary analysis as the workgroup recommendation, and that is the recommendation of do not support for rulemaking with potential for mitigation?

Option A is yes and option B is no. You may enter your votes.

Okay, so I will close voting at this time.

And the results are 87 percent of individuals agreed yes and 13 percent of individuals voted no. And I will give you a specific count for that. So that is 20 individuals who voted yes and three individuals who voted no.

CO-CHAIR UPSHAW TRAUS: Okay, that concludes our individual measure work. I want to thank everybody. I think it was very thoughtful. We do owe back after this meeting some feedback on the process that was used. Personally, I

thought it was great and much easier than what we tried to navigate last year, in terms of our voting.

So I want to thank the team, and the coordinating committee, and whoever else was part of that.

MEMBER McGIFFERT: Cristie, before we move on, on this measure, there was a lot of discussion --

CO-CHAIR UPSHAW TRAUS: Oh, I'm sorry. Thank you for that.

MEMBER McGIFFERT: -- of the major issues and I think while I won't repeat all of them for today, I think there was a robust response from the developer and CMS on this. So we'll make sure to include both the committee discussion and the developer responses to this and make sure that that's relayed to the Coordinating Committee.

Because it wasn't, interestingly in this discussion, which was very rich, it wasn't that these were issues that weren't considered. They

were considered and there may be a difference of opinion among how the workgroup considered them vis-a-vis the developer.

CO-CHAIR UPSHAW TRAUS: Thank you. Thank you for that. I appreciate your support in getting that documented as we move forward.

So I think what we want to do at this point is we've got two things left to do. We do have a public -- actually three -- a public comment period, summarizing what the next steps are relative to our work on the measures here, and then we want to circle back on the opioid discussion that we delayed until the end of the meeting. I think it's probably best to do it in that order so that we can kind of close out the measure consideration.

So I am going to open this up for public comment and would like to see if there's any public comment in the room. None? We used to actually, every now and then, have a little bit.

So, Operator, could you see if there's any public comment on the phone, please?

OPERATOR: Yes, ma'am.

At this time, if you would like to make a comment, please press * then the number 1.

And there are no public comments at this time.

CO-CHAIR UPSHAW TRAUS: Thank you.

I'm going to ask Desi to kind of go through the next steps. We will have one last final opportunity at the end, after our opioid, to be sure we get our thanks in and everything but if you could go through the next steps, at least in terms of the measures.

MS. QUINNONEZ: Thank you, Cristie.

So the slide that you see before you is just a high-level update of what's going to be to come. So it's not only for hospital but also for PAC/LTC, as well as the Clinician Workgroup. So you'll be able to see things that you can look forward to as we move on.

And just to keep this impressed in your mind, PAC had their workgroup meeting yesterday. It was successful. We have almost concluded our

Hospital Workgroup meeting. And tomorrow the Clinician Workgroup will be meeting.

And just to give you a heads up, in January, so that you can keep this on your calendar, the 22nd and 23rd will be the Coordinating Committee meeting.

And we will also have to look forward to our public commenting period, the second one, and that's going to be, again, on December 21st and it will end on January the 10th.

All right, so at this time, I just want to say thank you to Cristie and Ron, our wonderful co-chairs. Thank you for all of our workgroup members, and CMS, and all of the developers that have come out and joined us today.

And do you want to pause here now to see if you all have anything else to say or do you want to wait for public comment?

CO-CHAIR UPSHAW TRAUS: Yes, we're going to go back to the pain but --

CHAIR WALTERS: Just feel free to let us

know or maybe next year we won't have to make any more process changes. Next year might be the first year where we keep the prior year.

CO-CHAIR UPSHAW TRAUS: Since we're usually the one that finds the fault with the process, I think that maybe this is true.

CHAIR WALTERS: No, let us know if there is anything that you didn't like or want to see improved upon.

CO-CHAIR UPSHAW TRAUS: And of course I would be remiss if I didn't thank the staff for all their hard work on the measures, themselves, and getting us to a place where we have the resources we need at our fingertips to actually be ready and prepared for our meetings. So thank you all for that.

Okay, I'm going to turn it back over to Michelle for our final presentation.

MEMBER WISHAM: So thank you. I know that we've completed the work of looking at the measures and people may have flights and escape early but we did want to take the opportunity to

seek feedback from this committee on what we think is now a gap measure, quite honestly, and that's around pain and pain assessment.

So there's a slide here, if we can pull it up, please.

All of you, obviously, know that we've removed the pain questions from HCAPHS because of the concern of the unintended consequences with giving patients opioids and, frankly, leading to an opioid epidemic. And we are considering alternative questions regarding pain to replace these, recognizing absolute importance of pain control to patients.

But the question really is before the group components under consideration include addressing sort of a multifaceted approach to pain management because it's obviously not just giving opioids for pain but there are multiple modalities for pain management and a focus on the overall pain management.

We'd like to know what other areas CMS should consider or what suggestions and ideas you

have. And I do recognize this probably could go on for days and so we'll ask you know to keep us honest with time but we would like feedback really from the group here.

CO-CHAIR UPSHAW TRAUS: Okay, are you doing this or me?

CHAIR WALTERS: Lee.

MEMBER FLEISHER: I'm the anesthesiologist in the room.

So it's been very interesting watching what's been happening and, again, we've actually been interviewing patients, a kidney donor and what has happened is they actually are stopping using pain management until post-op day number one because of the opioid crisis. And then when they finally get their relief, they're saying I was really stupid or something to that effect. But they recognize that we're in a difficult situation here.

So trying to figure out a balancing measure is going to be really important.

The other issue because of my interest

of why I'm coming down next month is the delirium issue in hospitalized patients. So what we're doing is we're using multimodal analgesia, things like gabapentin, ketamine, all kinds of other drugs which, in the elderly is actually increasing the risk of delirium. In particular ketamine, so that's in my space, increases hallucinations and nightmares, in a large-scale randomized trial.

So I think as you go into this space for the hospital, since we are the Hospital Workgroup, I think you should look at delirium and you should look at -- and the hard thing is getting to patient-reported outcomes. The patients are getting -- are not understanding. In fact, we are selling opiate-free care and that may actually be worse than opiate-sparing care.

So I think the right question is did we meet your expectations, which really gets to are hospitals correctly setting their expectations for pain management, not was your pain well-managed. So I think that's a huge differentiator

that is really getting to all of Lisa's comments about if you want a prom, it's about expectations and then you get both sides of the equation.

CHAIR WALTERS: Sean.

MEMBER MORRISON: So three quick comments. The first is the importance of language. And there are absolutely no data that hospital prescribing of opioids for pain have been associated with quote, unquote, the opioid epidemic in this country. And it's very important that that language be A) corrected; and B) CMS does not continue to propagate that because there are absolutely no data on that.

And in fact, there are very few data but what we're seeing is you know the unintended consequences of that. So that's number one.

Number two is the original CMS pain measures actually did not have anything to do with opioids. There was no recommendation in those measures that the appropriate treatment of pain was opioids. That was an interpretation by physicians but there was absolutely nothing --

it's the same as the CDC guidelines that everybody is criticizing. The CDC guidelines say that there is absolutely no reason not to prescribe opioids for people with serious illness, cancer, pain, or who need it.

So I think, again, with language in terms of new measures to treat pain, we should be focusing on pain. And linking that to saying oh, these measures led to inappropriate opioid prescribing was a response to hysteria, and a reason to make policy changes, and a quick fix.

So again, the second piece around that is language.

And the third piece, again, is what is the problem you are trying to fix? If the problem is untreated pain in hospitalized patients, which is what our workgroup is, and we know that untreated pain in hospitalized patients leads to, particularly post-surgery, the development of chronic pain syndromes, it leads to increased sympathetic stress, then A) we should be measuring pain; B) we should be

focusing on how it is treated appropriately, rather than simply on the number that it goes down to.

So I would encourage CMS not only to begin to reassess pain because it is an important quality measure but with doing that focusing are appropriate treatments being implemented.

And certainly, as Lee said, what we're seeing now is we're seeing the unintended consequences of that, in terms of high incidence of delirium, which has adverse consequences, certainly the high probability of chronic pain syndromes in the setting of absolutely no data that hospital prescribing has led to the problems we're seeing with opioids in this country.

CHAIR WALTERS: Shannon.

MEMBER PHILLIPS: The comments of both were wonderful.

I reflect on yes, we need to treat pain and I think Sean's described the unintended consequences of that. I also wonder -- I think the discussions that have happened with the

removal of the measure and the focus on the opioid crisis has been really good at our institution. And I wonder if we ought to be focused with patients on did we set good expectations. We need to manage the pain when it's there but maybe getting a little upstream. And were you offered, whether in addition to or singularly, other ways to manage and control your pain in the hospital so that that is encouraging the wave of there's -- you know it's multimodal. It's not simply the drug or the right choice of category of drug but did we present you with what might work for you in your value system and meet you where you are?

So those sorts of things come to mind in the discussion but I appreciate the other comments so far.

CHAIR WALTERS: Jack.

MEMBER JORDAN: I think there's another group that all of us across the country I think really tried to change our practice with the opioid-naive person coming for a procedure and

such and have made see change, things that are kind of -- but there are the people who already have addiction problems that are there and I think there is a lot of room for us on a large scale to kind of think through doing that better, you know to have more people that are effectively know how to wean patients.

So I think there are room -- well, that goes kind of outside the hospital to more of an outpatient setting but I think that's the next wave of opportunity for us to improve in this. So you know I really want to encourage CMS to really thinking about how they can support that effort because I don't think we have the right people out there. You know the poor primary care docs kind of getting this thrown on their back and in many cases there really aren't adequate kind of addiction specialists to help out with this.

So I mean it's going to be suboptimal but I think we can do better than what we're doing and I think CMS helping with that would be

really important.

CHAIR WALTERS: Nancy.

MEMBER FOSTER: So I want to second what everybody has said and particularly, Jack, picking up on your point, this is obviously a very complex problem with a lot of different steps that need to resolve it -- need to happen to resolve it.

Maybe the part of the problem is when CMS incorporates a measure into a program, particularly a payment program. It suddenly takes on more emphasis than maybe you intended. And so it may not be the ideal time to be thinking in terms of a measure yet, other than I think the patient expectation measure that Lee and others have been talking about makes sense so we all know are we getting it right. And once we know we're getting it right, then the question of well what did we do to get it right and how do we measure that becomes natural.

And otherwise, I think there's a -- because we're a walking a thin line here between

managing pain and creating an ugly problem. And hospitals, other settings of care, docs are all struggling with that right now.

And Sean, I will disagree with you somewhat here. Hospitals today are not just the inpatient setting by far and we have a lot of opportunity to be better stewards of opioids and many, many are working on that. Jack shared some information with me a little while ago. There are just some great things going on to be better stewards and we need to learn from all of that and make that happen at the same time we're managing pain. Good luck.

CHAIR WALTERS: Marty.

MEMBER HATLIE: I want to just pile on to the comments already made to say this, to make this point. I mean whether it's monotonic consequences, language, different kinds of patients, I mean I'm involved in the Transforming Clinical Practice Initiative, which is ambulatory and we find patients there who are not prone to addiction or don't have substance use issues but

are having a hard time getting off of really powerful pain killers that they needed for a reason.

So there are different kinds of patients and it underscores for me the importance of bringing patient and family engagement into the measurement development process, just to make sure that those inputs are there, especially on an issue like this, which is really complex and really would benefit from that.

And one of the exciting things about the Meaningful Measures Project is that they are doing that. I mean there is just much more emphasis on PFE across CMS programs but I think especially the measurement area. It's exciting to see.

And I have a suggestion, actually, that might be our last 15 minutes but I'd like to see more in the analysis that we get as MAP members of the level of person and family engagement that went into the measurement development that we consider. I don't ever see that really reflected

in the analysis. CMS has mentioned it several times today. The panels they have taken this to and the input they've gotten is a valuable input but it would help me I think give me another dimension on the measurement development process that we're seeing.

So thank you.

CHAIR WALTERS: Maryellen -- oh, is that Ann Marie?

MEMBER SULLIVAN: I'd just like to say that I agree a lot with what Marty just said.

I think that you know if you're going to do some personalized care, this is probably the area where you really need to pay attention to that. We need to talk to patients about what pain means to them, what they're afraid of when they leave the hospital.

I agree by and large I don't think the use of it after an acute episode in the hospital has caused the opioid epidemic but at discharge, when you're sending people home with prescriptions, and you're telling them how to use

the medication, and why to use the medication, that's where you really have -- and it takes time to talk to people about this. You just don't hand them a bottle of pills and say when you have pain, try this.

So I think you've really got to talk to the individual what it means to them. Do they have an addiction history of any sort? It makes them probably more likely, even if they are not addicted right now to get addicted if you give them the wrong thing.

You have to have these discussions I think in detail. Think about the ramifications of what is happening and then be very cautious about what you give at discharge, while recognizing that people can be in a lot of pain.

You know and I think there is still an ease with which it is given at discharge. I just know from personal experience and friends who have been in the hospital that if they think you're not likely, you get kind of a pretty big prescription for these pain meds without a lot of

discussion about what -- how else maybe you can deal with it.

So I'm just saying real personalized care around this, talking with people, offering them other options if they're reluctant or scared. But if they have a low threshold for pain, maybe they do need them but they need to know how to use them. And maybe you need to check in on them, not say here's something for a month but maybe in a week you call and say how many of these have you been taking and that kind of thing. Give them the smaller prescription but then give it to them if they need it.

So I think the devil is in the detail of this and I think we just have to pay a lot more attention to how we're prescribing than we have in the past.

CHAIR WALTERS: Lisa.

MEMBER McGIFFERT: Well, I support a lot of what has been said and I do think bringing in people -- patients into the discussion is really important. And I would suggest you know

narrowing that even further with people with chronic pain.

A lot of the people I have worked with who have chronic pain have it due to a medical implant, for example, that is in their bodies and they can't get out. So I think that it's important to bring them in.

The other things that the group of patients that I talk to regularly have talked about is that some people are being given more invasive treatments as an alternative that can be more damaging. And also just generally, that there needs to be more exploration of other ways to manage pain, that the drug is a quick fix, and our system is pretty keen on quick fixes and it takes care of the problem.

So I think exploring other ways to handle pain is a really important issue and I think it would be a really interesting measure about discharge instructions and things like that. And boy, we need to include dentists. I just I had a couple teeth pulled and I was sent

home with enough opioids to last me for months and that should never happen.

CHAIR WALTERS: Lindsey.

DR. SCHREIBER: Obviously, all of the comments about patient-centered care ring true and I think just for future consideration I want to bring up that I word, which is interoperability and the fact that pain does not know a specific care setting. And if we're truly looking at person and patient-centered measures around pain, it carries from setting to setting.

So again, as we're looking at development of new measures, I think this would be a perfect opportunity to truly try to develop a measure that, again, maybe it has to be tested across all care settings, but something that can be transferrable because that pain travels with the patient, as they go along their journey.

CHAIR WALTERS: Dan.

MEMBER POLLOCK: Clearly, this is a very complex problem. No single measure really is going to capture all of it so I think it's better

to try to conceptualize this from a number of different perspectives.

And it may be helpful to just perhaps place it in context and refer to overuse of antibiotics, where there's some real comparability here, and in fact there is some suggestive data geographically that in many of the locations around the country where antibiotics are seemingly overused, there is also overuse of opioids.

To that effect, stewardship, to use the word Nancy used, is really important and underdeveloped. And measuring stewardship I think is another dimension to all of this. Measuring and providing metrics for opioid prescriptions, including at the point of discharges Ann mentioned. In fact that is one of the major stewardship targets in antimicrobial use now is patients leaving the hospital with extended courses of antibiotics for which there isn't a compelling use.

So I would say both the antimicrobial

overuse problem and the opioid overuse problem in the therapeutic context, or the multifaceted attention that includes measures of the indication for use, includes measure of the infectious disease burden, or the pain burden, but also these other dimensions of what's being done to marshal resources more successfully, what's being done to measure and provide feedback on the extent to which those resources are being deployed, particularly at critical milestones in episodes of care.

CHAIR WALTERS: Andreea.

MEMBER BALAN-COHEN: So piling on the comment it seems to me that this is one situation where like maybe an outcome measure might not be ideal. Like here's where the goal, per se, although it's important as we all recognize, it's more like the unintended consequences of all of the affecting factors and that's why you need like a series of like process measures.

So not reducing the level of pain but how do you get there? And you know like are you

doing it for specific patients, in which context, and for how long. And you know like how many measures were taken? And I would say like that in particular, like maybe with a goal to incentivize like other different types of measure for reducing pain, again, like for certain specific types of patients was like physical therapy or whatever is appropriate tried first, or maybe a couple of other of these other options as well.

And certainly also the importance of care coordination and like extending it like beyond the acute setting.

CHAIR WALTERS: Frank.

MEMBER McGIFFERT: Just echoing some of this but just a small additional point. If you do in fact move forward with this, I would recommend you consider involving behavioral specialists in this as well.

I think a great example is when you're working with somebody who has a severe anxiety disorder. If as part of your treatment

anxiolytics are involved and that's not cast as one step in a very different treatment plan, and that the anxiolytics are put in the context of the eventual goal, which is a behavioral management of the cognitions and behaviors, but feed that anxiety, there is an enormous difference between patients who are given anxiolytics without that as opposed to ones who are. It's more work but I think the output is much better.

And I think that if you're going to be looking at something, I would recommend technologies around motivational enhancement, MI work, and stages of change models that are part of a conversation and measure that, it's labor but I think it's labor that bears the kind of fruit that you're looking at there.

CHAIR WALTERS: Sean.

MEMBER MORRISON: I'm sorry but I didn't want to let this go because I have been deeply involved in this multiple times and actually was at a National Academy of Medicine workshop last -

- two weeks ago. But Dan's comment about equating this to antibiotic overuse is one that I actually hadn't heard before and is one that I would very strongly encourage us to think about. I mean at least the data that about 15,000 people die of prescription opioid-related deaths in this country every year, about 25,000 die of resistant antimicrobial infections.

And somehow, you know the opioid quote unquote epidemic has sort of eclipsed that but I think these are two issues that we should be thinking about very similarly because they are both around probably inappropriate prescribing in the setting of serious medical issues. And I don't think any of us would say that we shouldn't be drawing blood cultures or checking urine cultures because we wouldn't want to be prescribing antibiotics if we found those. And if you take the analogy to control of pain, what we're saying is we shouldn't be assessing or measuring pain because we might prescribe an opioid if we found it.

And they are both, you know when you look at the mortality rates, they are both about the same.

CHAIR WALTERS: More blood pressure, anything else?

Maryellen, close us out.

MEMBER GUINAN: Oh, no, I didn't want you to make me have the last word. So someone else say something eloquent afterwards.

I think coming from the Essential Hospitals or the Safety Net, and I tip my hat to Michelle at Henry Ford and whatnot, but we very much deal with a patient population and the opioid epidemic is one that we're facing day-to-day in our hospitals and in various amount of ways.

And so I think kind of what I have heard here and what we've heard consistently is there is somewhat of a misalignment of incentives. And I know Nancy touched on it briefly in terms of tying payment to patient experience, tying payment to pain management, insofar as measures

being put into payment programs, puts physicians in a somewhat difficult position in terms of where they're focus lies or kind of redirecting where their focus should be. And really what we want to do is incent the use of proper prescribing guidelines and that's very much along the lines of the AMR world and kind of where stewardship has gone. And so I definitely fully support that.

And I think the general kind of takeaway that I at least gain from this is flexibility being key in terms of allowing the provider to kind of meet the patient population where they are in terms of in the hospital who they treat in the best way possible.

So for folks in our membership that have offices of opioid safety, they do things in various ways in terms of prescribing patterns or having dashboards for their physicians to see how they prescribe. Others offer up the non-opioid treatment alternatives and that's a whole separate conversation in terms of cost that needs

to be kind of directed towards those non-opioid treatments.

But I think the key takeaway there is just the flexibility to not box people in to directing their program or their improvement activities towards a specific measure and allowing flexibility to kind of develop programs where they see is going to have the most meaningful impact on their patient population.

So, thank you.

CHAIR WALTERS: Thank you. I agree. This might be the biggest issue diagram you've ever seen in your life but people need to be -- we need to relieve pain. We need to relieve it appropriately. Don't back down from making people not suffer.

And all the points that are made are very appropriate. It's a huge system thing.

CO-CHAIR UPSHAW TRAUS: There's been a lot of discussion about having measure sets and measuring systems and you know not thinking about this, as someone mentioned earlier, about a

particular setting of care. This may be -- well, actually somebody -- and I'm really just repeating what somebody else said now that I realize it. This really maybe the opportunity to look at that you know where we can look at the issue, regardless of where the patient is and think about it as a measure set and we're measuring a system, which is pain management, that goes across all settings.

I know that NQF has done some work around opioid stewardship. So I'm not an expert on that document but I would certainly anticipate that there could be value in there. It was really done right after the antibiotic stewardship document and some work around that.

But the other thing is there is a lot, as you all know, there is so much work being done at the state level that is around this and a lot of it regulatory, a lot of it still struggling to figure out what to do within those states that have particular issues relative to opioid abuse.

And I think thinking through how CMS

could potentially amplify some of the work that is being done at the state level to think about what are some of the best practices that states are identifying that you could bring into your programs so that there could be alignment because the states are addressing this. Whether or not it is effective, I don't know but they are having to deal with it.

CHAIR WALTERS: Well, thank you, everyone, for showing up and providing input. And we got 15 minutes back.

DR. SCHREIBER: Ron, can I second the thanks?

I'd just like to thank everybody, also, first of all for the feedback on all of the pain discussion that we had and for the really very important feedback that you provided us on all of the measures. It really is taken seriously. It does impact rulemaking and we really appreciate kind of the struggles that everybody went through trying to decide what are the right votes, what are the right categories but it's really the

discussion that is so meaningful.

So thank you to each and every one of you and certainly to our co-chairs and, again, to NQF. Thank you.

MS. O'ROURKE: I just want to jump in on the thank you. Thank you to all of the workgroup members for your very insightful conversation today. We really appreciate you making the time. Also to our CMS colleagues for all your help in planning and support, to the measure developers for joining and providing such essential input, and especially to our co-chairs, Ron and Cristie, for all your guidance and leadership. We appreciate you getting us through this very packed agenda, even though we only had four measures --

CO-CHAIR UPSHAW TRAUS: It was painless.

MS. O'ROURKE: -- and all of your leadership and prep with us ahead of time.

Especially, thank you to the Hospital Workgroup Team for all of their hard work.

So we can let everyone go and please

keep your eye out for the draft recommendations that will be out for public comment. And the Coordinating Committee will meet to finalize everything January 22nd and 23rd.

(Whereupon, the above-entitled matter went off the record at 2:44 p.m.)

C

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Measure Applications Partnership
Hospital Work Group

Before: NQF

Date: 12-11-18

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter